CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR PROGRAM INTEGRITY

OMB Control No: 0938-1237
Expiration Date: 07/31/2026

User Guide for Reporting Entities

OPEN PAYMENTS

CREATING PUBLIC TRANSPARENCY INTO INDUSTRY-PHYSICIAN FINANCIAL RELATIONSHIPS

January 2025

Disclaimer: The Centers for Medicare & Medicaid Services (CMS) is providing this guidance document as informational material on Open Payments. Although every reasonable effort has been made to assure the accuracy of the information, it is the responsibility of the user to ensure adherence to the requirements of the Open Payments implementing regulations, the Medicare, Medicaid, Children's

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Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests Final Rule codified at 42 C.F.R. Parts 402 and 403 [CMS-5060-F].
This User Guide is not intended as a supplement or replacement of the Final Rule

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INTRODUCTION

Purpose of the Open Payments Reporting Entity User Guide

This Open Payments User Guide includes definitions, descriptions, screenshots, tools, and tips designed to help applicable manufacturers and applicable group purchasing organizations, 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
20.0	January 2021	Update	Updated to reflect system updates
21.0	February 2021	Update	Updated to reflect EIDM to IDM Migration changes
22.0	July 2021	Update	Updated to reflect system updates
23.0	January 2022	Update	Updated to reflect system updates
23.1	January 2022	Update	Updated to reflect system updates
24.0	September 2022	Update	Updated to reflect system updates
25.0	January 2023	Update	Updated to reflect system updates
25.1	April 2023	Update	Updated to reflect new IDM password requirements
25.2	August 2023	Update	Updated to reflect new IDM updates
25.3	December 2023	Update	Updated to reflect 24.2 system updates
26.0	July 2024	Update	Updated to reflect OPS 1.0 to OPS 2.0 features
27.0	January 2025	Update	Updated to reflect system changes

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, non-physician practitioners (NPP) 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 GPO as well as reporting payments or other transfers of value made by these applicable manufacturers and applicable GPOs to these physicians.

As of January, 2022, the Open Payments System is updated per section 403.902 of the Affordable Care Act to include the NPPs as covered recipients in the Open Payments System. Per the final rule, the updated definition of covered recipient means— (1) Any physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, anesthesiologist assistant, or certified nurse-midwife who is not a bona fide employee of the applicable manufacturer that is reporting the payment; or (2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.

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, NPPs and teaching hospitals) on a publicly accessible website. The health care providers that are included in open payments are: physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, certified nurse midwives and teaching hospitals

This publicly available website is designed to increase access to, and knowledge about, these relationships and provide the public with information to enable them to make informed healthcare decisions. The public can search, download, and evaluate the reported data at https://openpaymentsdata.cms.gov/. This data is available on a public website. The goal is to increase transparency and allow people to access information about these financial relationships. The public can search, download, and analyze the reported data on the website to make informed decisions.

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, NPPs 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, NPPs, and teaching hospitals.

Certain ownership or investment interests held by physicians or their physicians' immediate family members.

Applicable GPOs are required to annually report to CMS:

- Payments or other transfers of value made to physician owners or investors.
- Certain ownership or investment interests held by physicians or their immediate family members.

Certain manufactures of the covered products are required to report the following information to the Centers for Medicare & Medicaid Services (CMS) annually:

1. Applicable manufacturers of covered products, and entities under common ownership with these manufacturers who provide assistance and support, must report:

   a. Payments or other transfers of value made to physicians, NPPs, and teaching hospitals.

   b. Certain ownership or investment interests held by physicians or their immediate family members.

2. Applicable group purchasing organizations (GPOs) must report:

   a. Payments or other transfers of value made to physician owners or investors.

b. Certain ownership or investment interests held by physicians or their immediate family members.

While not required to participate, Open Payments encourages physicians, NPPs, and teaching hospitals to participate by reviewing data reported about them in the Open Payments system to ensure the accuracy of the information.

Open Payments also encourages the 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

Open Payments operates on a yearly cycle of four key activities: (1) Data Collection, (2) Data Submission, (3) Pre-Publication Review, Dispute and Correction, and (4) Data Publication.

1. **Data Collection**: Reporting entities are required to collect data documenting their financial relationships with covered recipients for the period of January 1 to December 31 of each year.

2. **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 2023 took place February 1, 2024, through March 30, 2024. During this time reporting entities submit their data to CMS through the Open Payments System. Reporting entities must be registered in the Open Payments System in order to complete data submission. Registration for the Open Payments System is available year round (see Chapter 3 for registration details).

3. **The pre-publication review and dispute period** occurs immediately after the submission period ends and extends for at least 45 days. During this period, covered recipients review, affirm and, if necessary, dispute data submitted by reporting entities. Reporting entities can then correct the data to resolve any disputes for an additional fifteen-day correction period. Review, dispute, and correction activities can continue 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/Resources.

4. **Data publication** occurs twice per year, with a June publication and an early year data refresh.
   - **June Publication - Initial Publication**
     - The first publication of the eligible records submitted and attested on or before the submission closing date of the latest program year.
     - The republication of eligible records from prior program years, including updates to previously published records made since the previous publication.

    - The data published is the latest attested version of the payment records at the end of the correction period of the latest program year.

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

For example, the June 2024, data publication included the initial publication of Program Year 2023 data and republication of prior program years.

The 2024 data refresh included updates to Program Year 2023 data and republication of prior program years.

Registration for the Open Payments system is available year-round.

The table below outlines the annual Open Payments Program Timeline.

Figure 1: Open Payments Program Year Timeline

Program Activities	Program Timeline
Data Collection: Reporting entities collects data	January 1 – December 31 of program year
Data Submission: Reporting entities submit and attests to data in the Open Payments system	February – March of the calendar year after the program year
Pre-publication Review Dispute and correction: Physicians, NPPs, 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
Annual Data Publication: Initial program year initial data publication Prior program year data refresh publication	On or by June 30
Physicians, NPPs, and teaching hospitals continue to review and dispute data; industry continues to make corrections to the data (reflected in the data refresh publication)	May 15th - December 31
Data Refresh: Open Payments data refresh	January

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 covered recipients 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 operates in the United States (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 activities 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 covered products. 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.

The below figure provides a reference guide for determining if a drug, device, biological, or medical supply manufacturer is an applicable manufacturer in accordance with Open Payments and outlines the characteristics of two types of applicable manufacturers.

Figure 2: Determining if an Entity Is an Applicable Manufacturer

Characteristic	Type 1 Manufacturer IF	Type 2 Manufacturer IF
Operate in US?	• Entity's physical location is within the United States and/or it conducts activities within the United States. This includes any territory, possession, or commonwealth of the United States, either directly or through a legally authorized agent.	• 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.

Characteristic	Type 1 Manufacturer IF	Type 2 Manufacturer IF
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 3 provides a reference guide for determining if a drug, device, biological, or medical supply purchasing entity is an applicable GPO in accordance with Open Payments. Figure 3 also outlines the characteristics of applicable GPOs.

Figure 3: Determining if an Entity Is an Applicable GPO

Characteristic	Group Purchasing Organization IF
Operate in US?	• Entity's physical location is within the United States and/or it conducts activities within the United States. This includes any territory, possession, or commonwealth of the United States, either directly or through a legally authorized agent.
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

Reporting entities are required to report payments or other transfers of value to covered recipients and physician owners/investors. Covered recipients in Open Payments include any physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, or certified nurse-midwife who is not a bona fide employee of the applicable manufacturer that is reporting the payment 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

For the purposes of Open Payments, "NPPs" are defined as legally authorized to practice by their state as follows:

- Physician assistant
- Nurse practitioner
- Clinical nurse specialist
- Certified registered nurse anesthetist or anesthesiologist assistant
- Certified nurse-midwife

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.

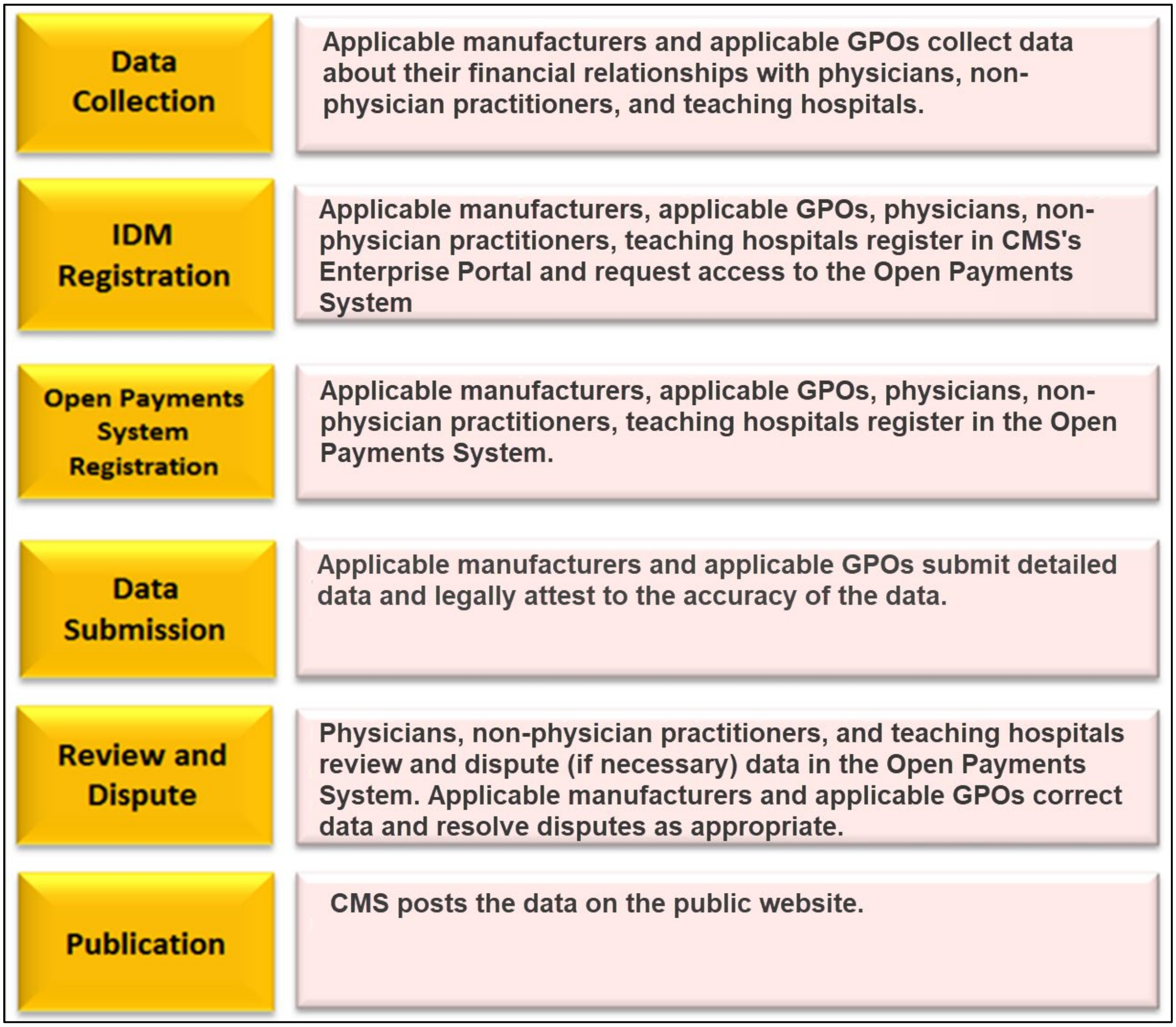
Additionally, reporting entities are required to report ownership or investment interests in the entity held by a physician (referred to as a physician owner or investor) or the physician's immediate family members, and report payments or other transfers of value to these physicians holding ownership or investment interests. A physician's immediate family member is the physician's (1) spouse; (2) natural or adoptive parent, child, or sibling; (3) stepparent, 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 the Open Payments Program. Users will interact with the system to perform several functions based on their role.

Reporting entities and covered recipients who participate in the Open Payments program must register in the Open Payments system. **Figure 4** provides a high-level process flow.

Figure 4: High-Level Process Flow for Open Payments



1.4a: Open Payments System Browser Requirements

The Open Payments system is a web-based application which operates through one of the listed browsers below.

- Google Chrome (Version 89 or higher),
- Microsoft Edge (Version 89 or higher),
- Safari (Version 13.1.2), and
- Mozilla Firefox (Version 83 or higher) browsers.

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: Create an entity profile in the system, submit data into the system, verify the data, and attest to the accuracy of the data.

For physicians/NPPs/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 the 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 or your mouse. 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 with users. Take precautions to ensure that these emails are not directed into your junk mail or spam folders. Open Payments notification emails will come from the address openpaymentsnotifications@cms.hhs.gov.

1.4d: Accessibility Guidance

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

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

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

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

1.4d (2): Useful JAWS Keystrokes

The keystrokes given in **Figure 5** find the next occurrence of a particular element on a page. Using the Shift key at the same time will find the previous occurrence. These shortcuts allow a screen reader user to quickly jump their screen reader between the form fields on each page or explore the overall structure of the page by jumping between the different headings on the page that denote the start of different content areas on the page.

Figure 5: Useful JAWS Keystrokes

Key	What it finds	Why this is useful
F	Form field	The F key allows users to move from form field to form field. Most pages on 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 several 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.

Published Open Payments data can be viewed on the Open Payments data website.

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, NPPs, 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/Resources.

Reporting entities who are required to report can find helpful resources within the Open Payments system. These resources include user guides, reporting templates, error and warning code explanations, frequently asked questions (FAQs), and other useful materials. All these resources are available under the "Resources" tab in the Open Payments system.

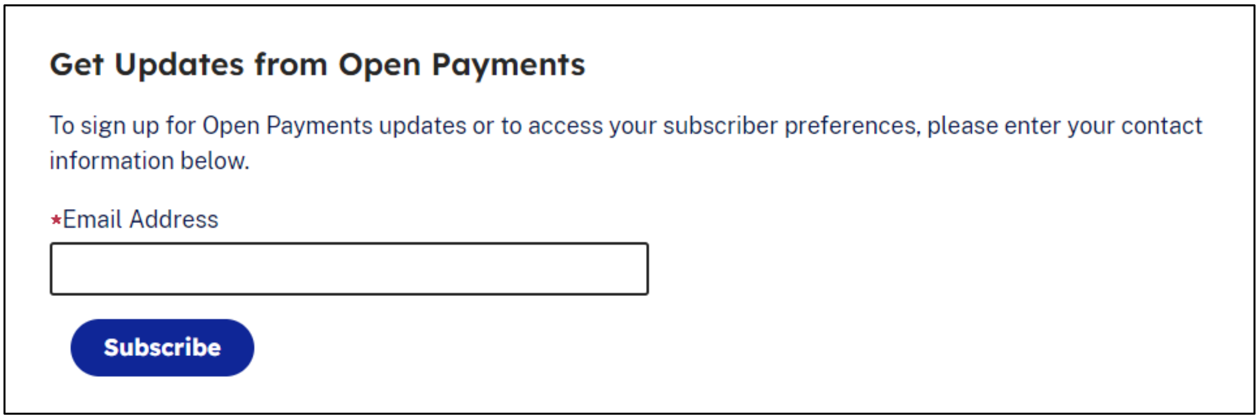
1.5c: Open Payments Help Desk

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 Email List

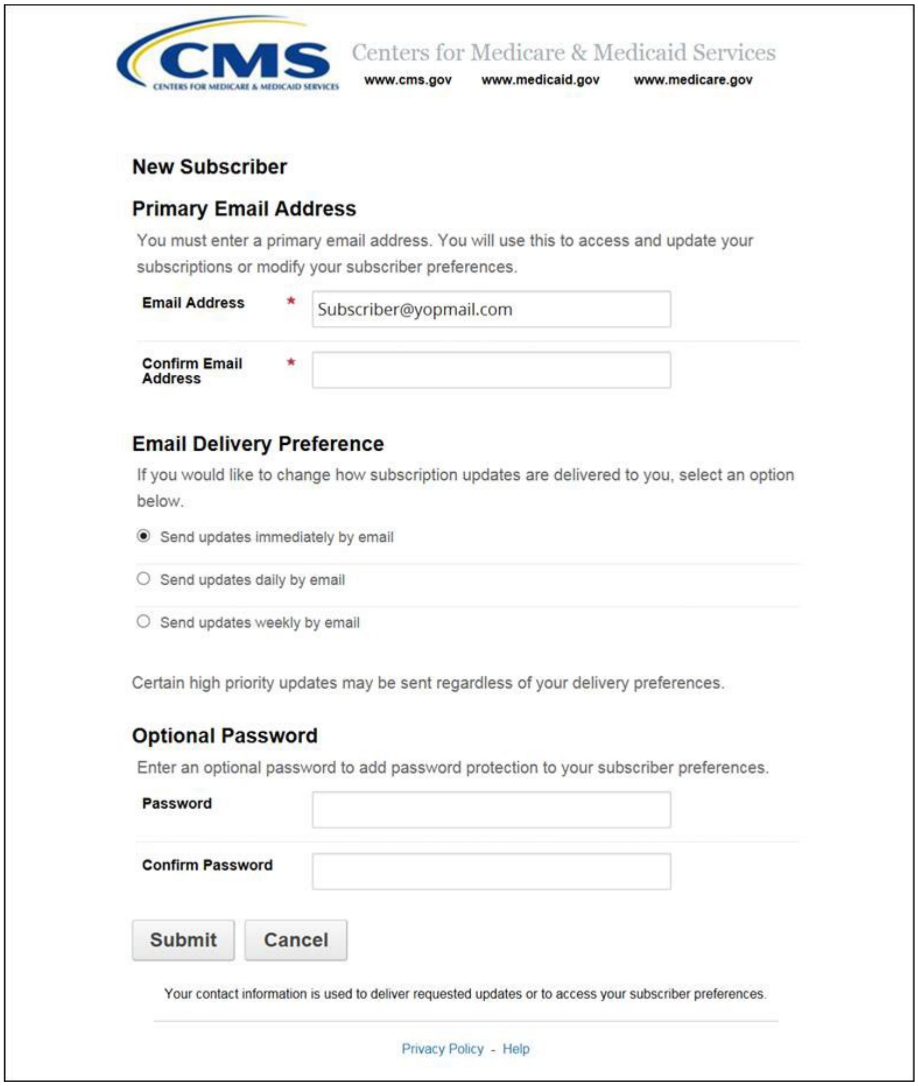
By registering for the Open Payments email list, you will be signed up to receive periodic email notifications regarding program, system, and resource updates. This is a good way to keep informed on any updates, changes, or important messages from CMS. To sign up for the Open Payments mailing list, visit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

Figure 6: Receive Email Updates



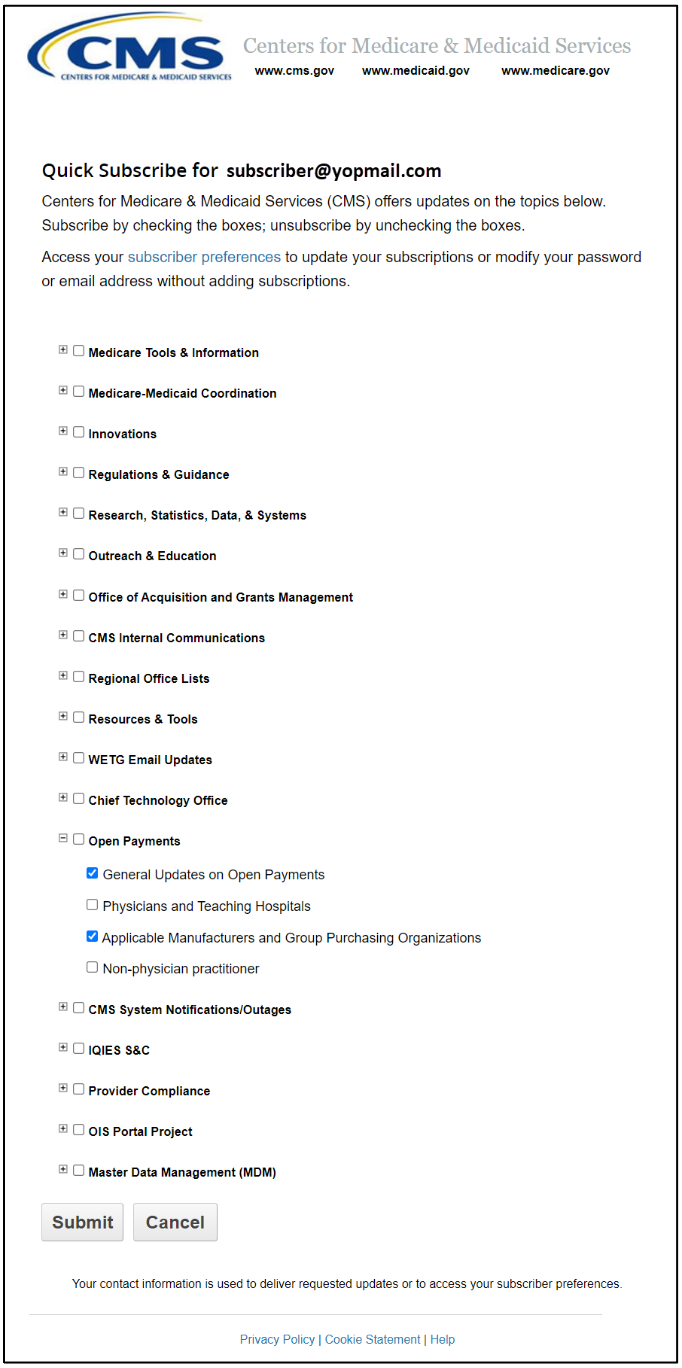
Entering your email address will take you to a page where you can select which mailing list you want to subscribe to.

Figure 7: New Subscriber Screen on the CMS Website



Under the Section “Open Payments,” 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 the boxes that apply to your OP user type, such as “Physicians and Teaching Hospitals”, “Non-Physician Practitioner” or “Applicable Manufacturers and Group Purchasing Organizations”.

Figure 8: Checkboxes for Selecting Email Updates on the 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.

As described in detail in Chapter 4 of this document, data is reported to the Open Payments system through bulk file uploads using templates that are character-separated values (CSV) files and through manual data entry through a graphic user interface (GUI).

A listing of helpful documents used by entities for payment data input into the Open Payments system can be found at https://www.cms.gov/OpenPayments/Resources. 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

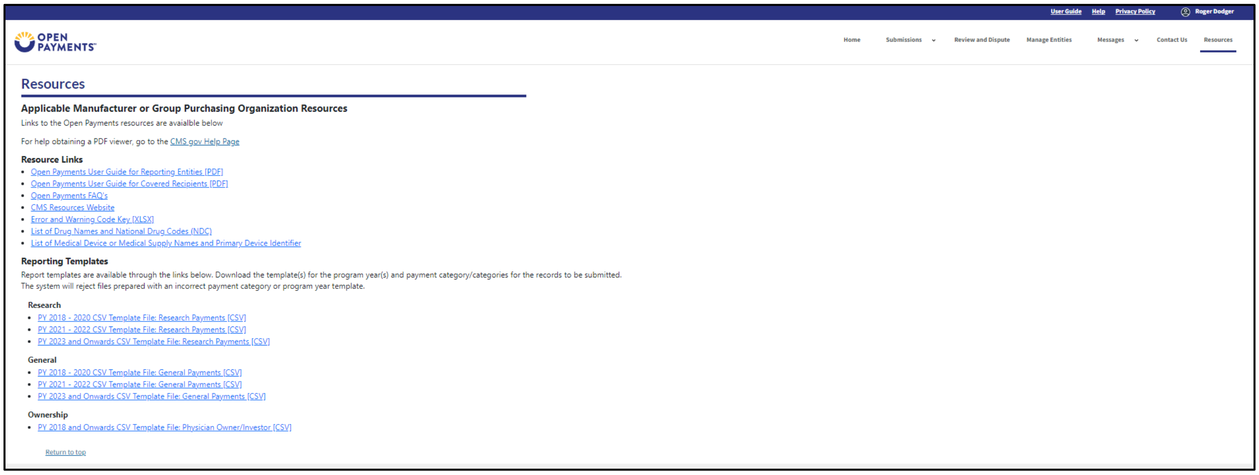
This section on general payments reporting and data collection provides information about data collection for entities required to report certain general payments and other transfers of value in the Open Payments system. Five categories of information related to general payments made by applicable manufacturers and applicable GPOs to recipient physicians, NPPs, 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/Resources), 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 in the “Resources” tab of the Open Payments system.

Figure 9: Open Payments System "Resources" Tab for Submitters Displaying Available Reporting Templates



Due to changes in record formats, there are three general payments sample files for “Program Years (PY) 2016 -2020”, “PY 2021-2022”, and “PY 2023 and onwards”.

Section 2.2: Research Payments Reporting and Data Collection

This section on research payments data collection and reporting 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, NPPs and teaching hospitals should be captured during data collection; these categories are shown in the 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/Resources), 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 three research payments sample files, one for PY 2016-2020, one for PY 2021 to 2022, and one for 2023 and onwards.

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/Resources) , 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 are two physician ownership/investment sample files: One for PY 2016 to 2022, and one for PY 2023 and onwards.

Registration

Chapter 3: Applicable Manufacturer and Applicable GPO Registration

This chapter provides information on registering in CMS's Identity Management system (IDM) and registering an entity profile in 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 (IDM and Open Payments) prior to reporting payments or other transfers of value made to physicians, NPPs, and teaching hospitals. Each individual user is required to create their own account.

This chapter is divided into the following sections:

3.1**: Two-Step Registration Process Overview:** provides information about the registration process. Registration includes user registration in IDM, requesting access to the Open Payments system, as well as creating an entity profile in the Open Payments system.

3.2**: IDM Registration**: provides details on registering for IDM and requesting access to the Open Payments system.

3.3**: Open Payments Users and User Roles:** 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.

3.4**: Registering Applicable Manufacturers and Applicable GPOs for the Open Payments System:** instructions for registering, logging in to the system, and managing the reporting entity and user roles.

3.5**: Entity Recertification:** instructions for recertifying reporting entity information in the Open Payments system for entities that registered for the prior calendar year.

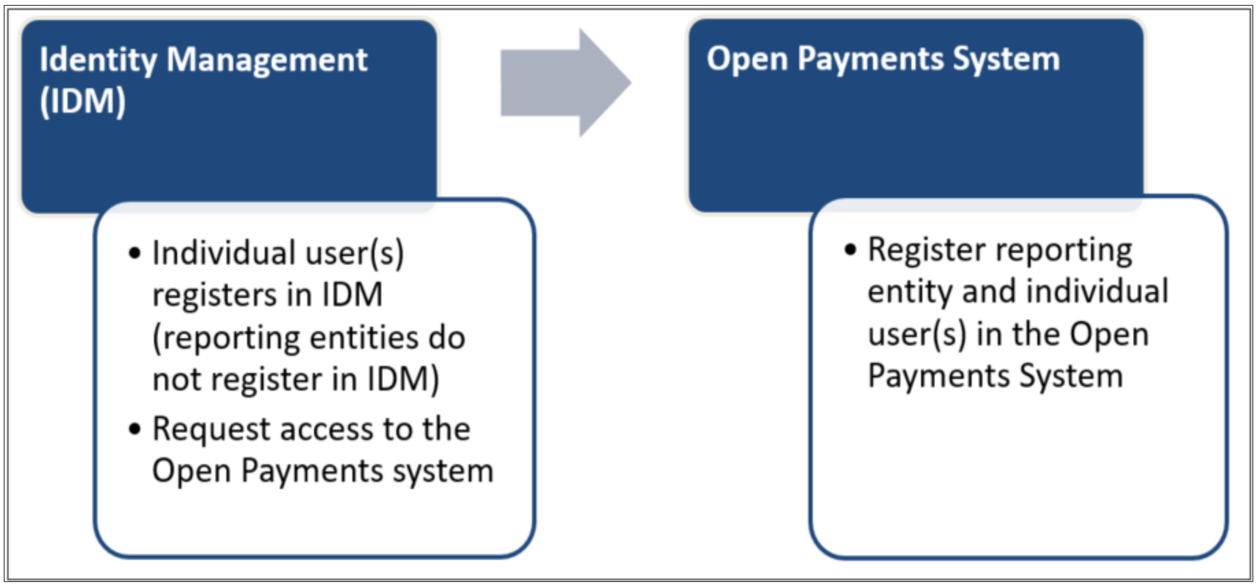
3.6: **Nominations:** contain information on how to nominate other individuals for roles associated with physicians, NPPs, and teaching hospitals.

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

Section 3.1: Two-Step Registration Process

Open Payments registration is completed in two steps, illustrated in **Figure 10**. First, you must obtain IDM credentials and obtain access to the Open Payments system. Second, you must register your reporting entity profile in the Open Payments system. If your reporting entity is already registered, you can register as an individual and affiliate with the reporting entity.
Reporting entities must register a profile in the Open Payments system to submit, attest, correct, and view data. The person completing the registration process in the Open Payments system must be highly placed in the organization.

Figure 10: Applicable Manufacturer and Applicable GPO Registration



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

Identity Management (IDM) 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 IDM provides you with login credentials **required** for access to the Open Payments system. You will be able to set up your own login credentials in the form of a user ID and password during the IDM registration process.

To begin the registration process, access IDM by going to https://openpayments.system.cms.gov .

If you already have IDM credentials, you can move to

3.2c: Requesting Access to Open Payments with IDM Credentials for instructions on how to request access to the Open Payments application.

- IDM 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 the challenge question. 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.

- IDM will automatically deprovision your account if you have not logged in for two years or more. Once deprovisioned, the account cannot be reactivated again and you will be required to set up a new account, by completing the full registration process by going through the entire registration process by setting up a new account using steps in Section 3.2b through 3.2d, followed by steps in Section 3.4.

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 Open Payments system:

Disable pop-up blockers prior to accessing The Open Payments system.

Use one of the following browsers with JavaScript enabled:

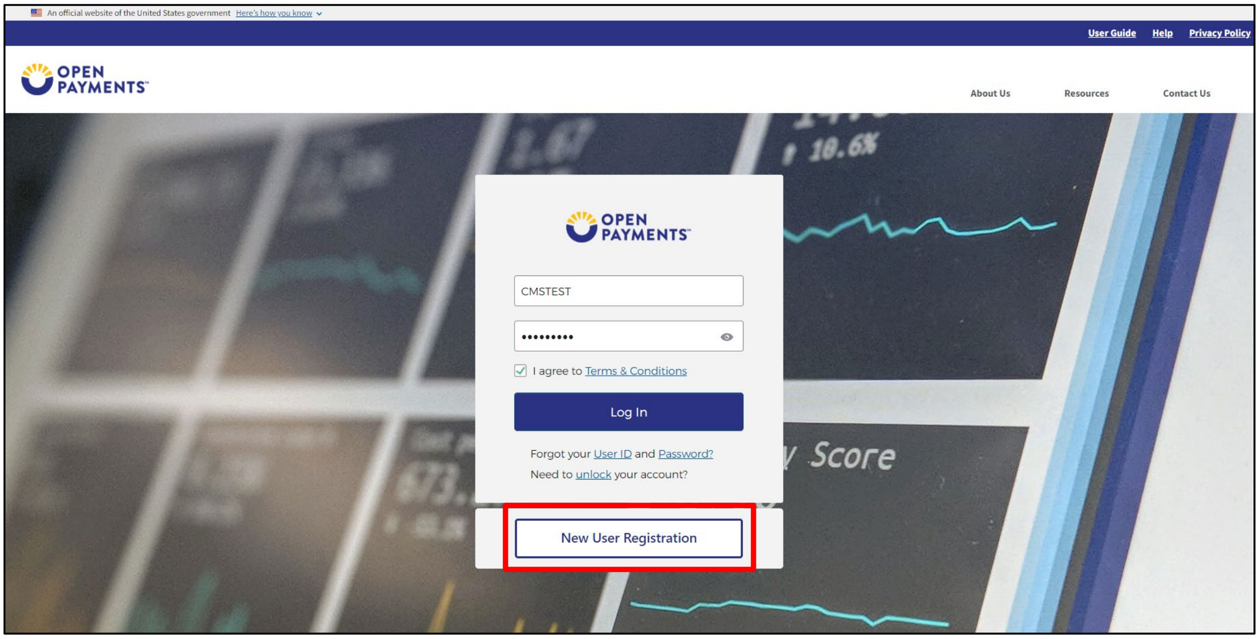
- Google Chrome (Version 89 or higher)
- Microsoft Edge (Version 89 or higher)
- Safari (Version 13.1.2)
- Mozilla Firefox (Version 83 or higher)

3.2b: IDM New User Registration

Go to the Open Payments login page at https://openpayments.system.cms.gov.

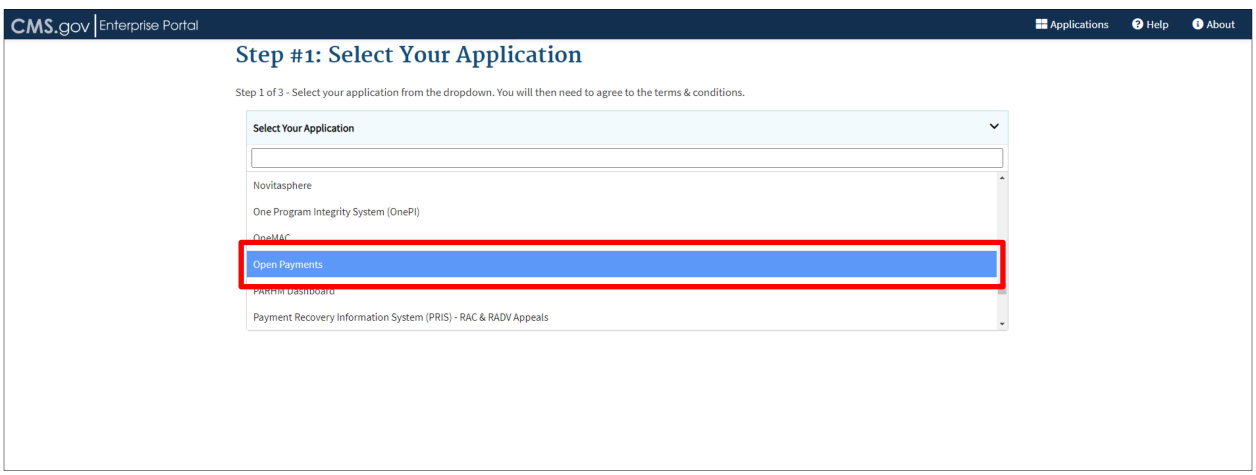
Step 1: On the Open Payments system landing page, select **New User Registration** to continue. You will be automatically brought to the IDM Portal website (portal.cms.gov) for IDM account registration.

Figure 11: Open Payments System Public Landing Page



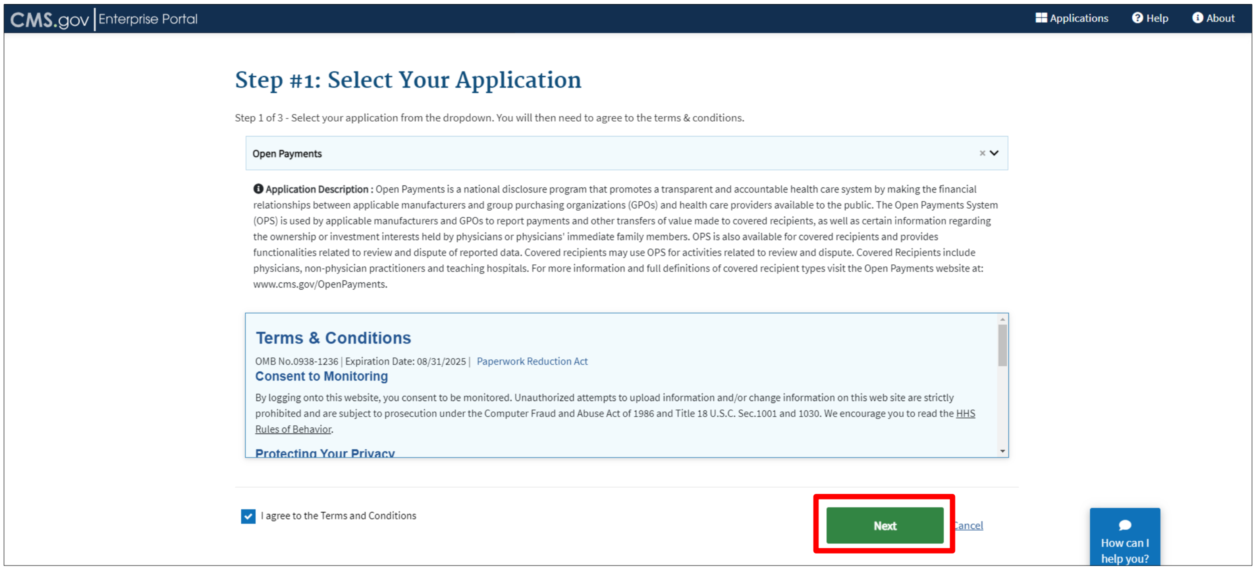
Step 2: On the “Select Your Application” page, select “Open Payments” from the drop-down list and agree to the Terms and Conditions of the Open Payments system, then select the **Next** button to continue.

Figure 12: Select Your Application



Step 3: Review and accept the Terms and Conditions of the Open Payments system page and then select **Next** to continue.

Figure 13: Terms and Conditions



Two Terms and Conditions sections of particular importance to read are:

- Consent to monitoring; and
- Collection of Personal Identifiable Information (PII).

"Consent to monitoring" means that you agree to allow CMS to monitor your activity and actions performed through CMS applications while logged into the CMS Enterprise Portal and accessed through IDM.

"PII" is information that can be used to uniquely identify, contact, or locate a single person, or can be used with other sources to uniquely identify a single individual. Personal information collected will be used for the purpose of verifying your identity only.

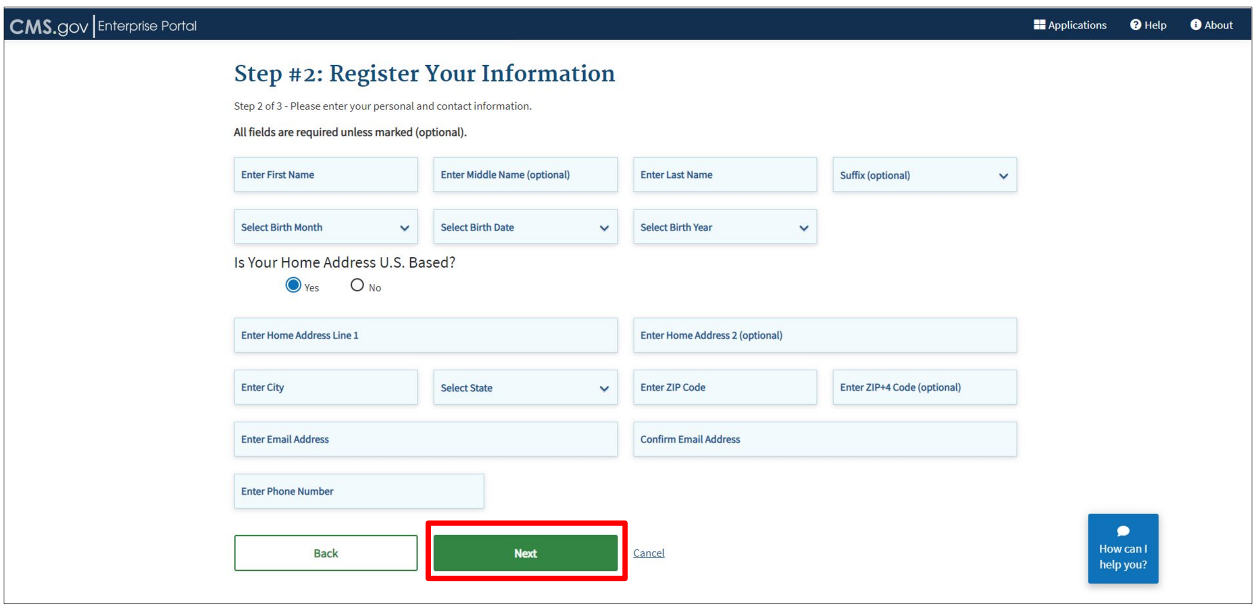
Step 4: On the "Register Your Information" page enter your personal user information. Be sure to enter all information in all required fields. **Note: Selecting the "Cancel" button will cause you to lose all data entered.** Select the **Next** button when all information has been entered.

Data fields to be completed are the following:

- Name (First, Middle, Last, Suffix)
- Date of Birth (Month, Date, Year)
- Is Your Address US Based (Yes/No)
- Home Address, City, State, Zip Code
- Personal Email Address
- Confirm Email Address
- Personal Phone Number

Enter your legal name, current home address, primary personal phone number, and personal email address correctly.

Figure 14: Register Your Information Page



NOTE FOR INDIVIDUALS WITH FOREIGN ADDRESSES: Individuals with addresses outside of the United States can register in IDM, but further identity proofing may be conducted manually when you request access to the Open payments system.

Step 5: On the "Create User ID, Password & Security Question/Answer" page, create an IDM user ID and password in accordance with the guidance provided below. This User ID and password will be used to log in to the Open Payments system. You will be asked to select a security question and provide a security answer. Select **Next** when finished.

User IDs cannot be changed once your account is created. Passwords never expire, as long as you log in at least every 60 days. If your password expires after 60-days, use the self-service kiosk on the login page by selecting "Need to unlock your account?".

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

Figure 15: Create User ID, Password & Security Question/Answer Page

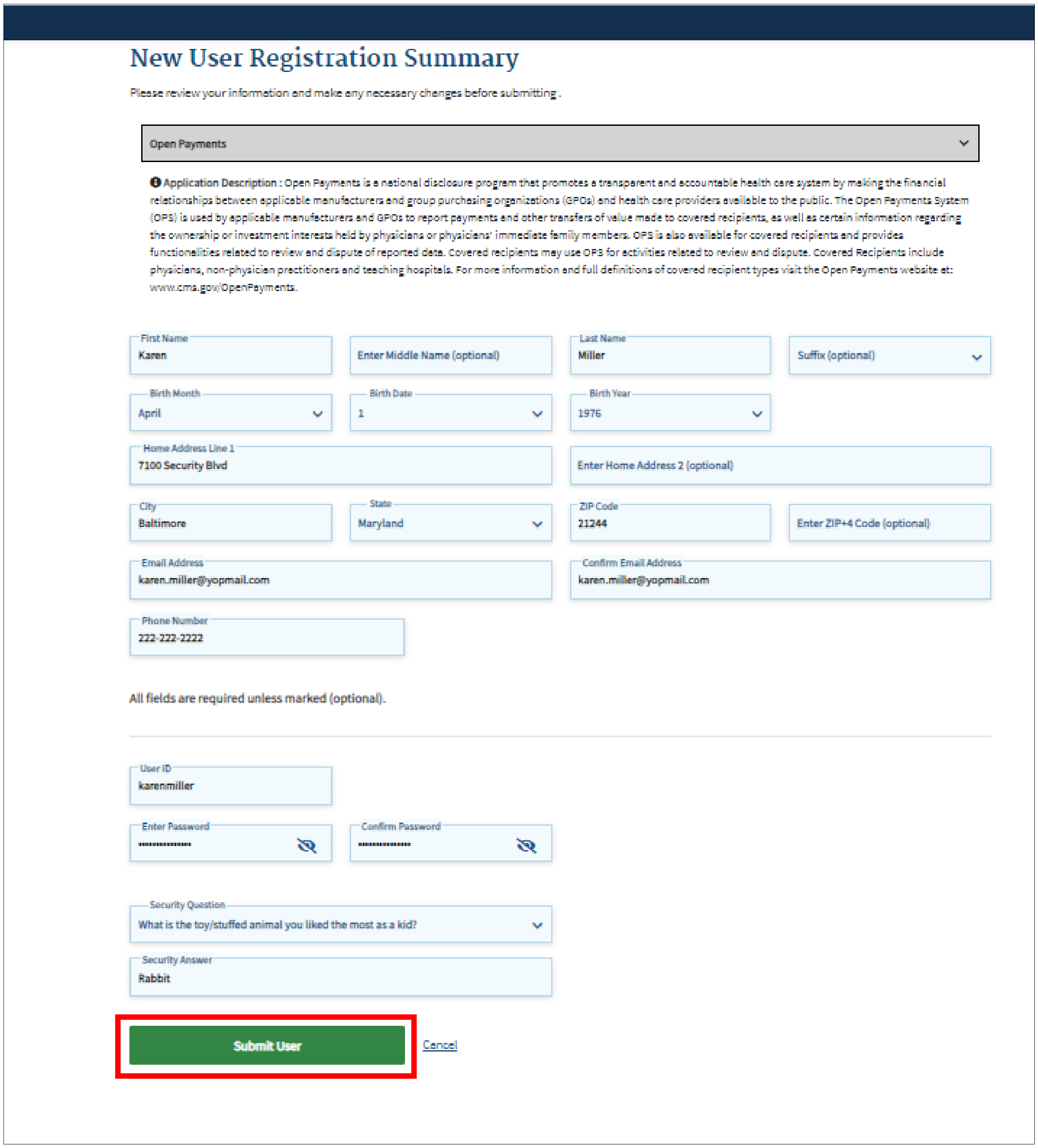
- The IDM/Open Payments system User ID must:
  - Must be between 6 - 74 characters and contain at least one letter;
  - Can contain alphanumeric characters;
  - Allowed special characters are limited to hyphens (-), underscores (_), apostrophes ('), and periods (.)
  - The @ symbol is allowed only if the User ID is in a valid email address format (j.doe@abc.edu or 123@abc.com)
  - Cannot contain 8 consecutive numbers;
  - Cannot begin or end with special characters;
  - Cannot contain more than 1 consecutive special character;

- User IDs are not case-sensitive.

- Password Requirements:
  - Password must be a minimum of 15 characters;
  - Password must contain: 1 upper case and 1 lower case letter, and 1 number;
  - The following special characters may be used: " ! # $ % & ’ ( ) * + , - . / \ : ; < = > ? @ [ ] ^ _ ` { | } ~
  - Password cannot contain: Parts of User ID, First Name, Last Name, common passwords;
  - Password can only be changed once every 24 hours;
  - Password must be different from the last 6 passwords;
  - Password must not exceed 60 chars.;
- Confirm password:
  - Confirm password;
  - Enter the same password;
- Select your security question:
  - Select a question from the dropdown list of questions;
- Security answer:
  - Can contain alphanumeric characters;
  - Can contain spaces;
  - Must be at least 4 characters;
  - Cannot contain part of the security question;
  - Your security answer will be required in order for you to reset your password or unlock your account;

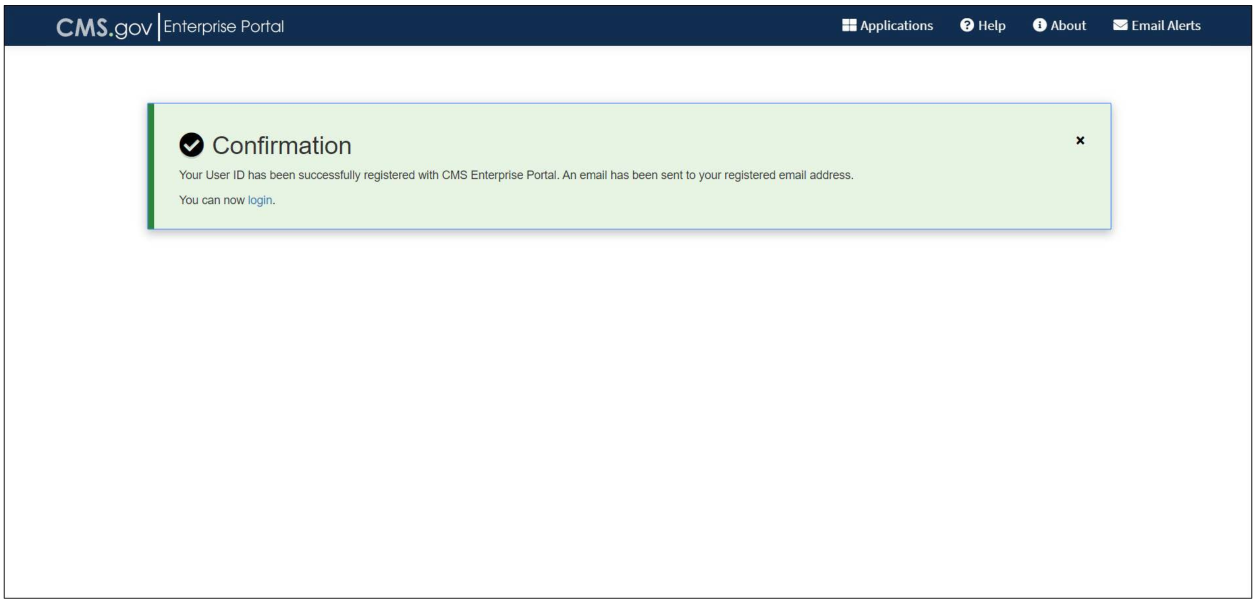
Step 6: On the "New User Registration Summary" page, review the information and make any necessary changes before submitting. Select the **Submit User** button to submit the information.

Figure 16: New User Registration Summary Page



Step 7: A "Confirmation" page is displayed acknowledging successful registration in IDM. Select the "CMS.gov Enterprise Portal" link (top left) or the **Login** link in the green window to take you to the CMS Enterprise Portal login page. The profile configuration can take up to 24 hours but is usually instant. If you are unable to log in after 24 hours, call the Open Payments Help Desk.

Figure 17: Confirmation Page



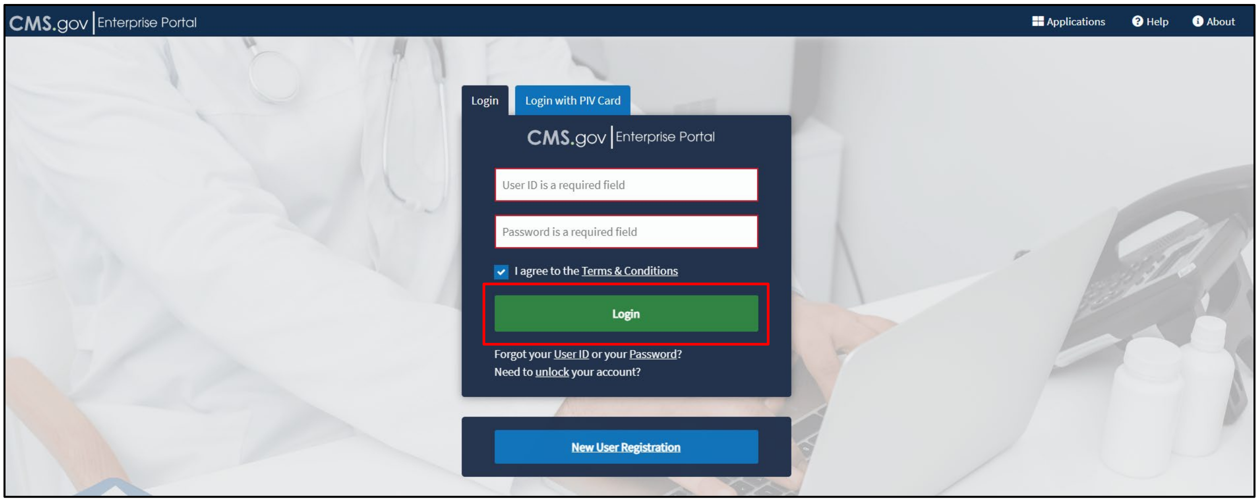
Step 8: Request access to the Open Payments system.

3.2c: Requesting Access to Open Payments with IDM Credentials

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

Step 1: On the Enterprise Portal login page, enter your IDM 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 log in.

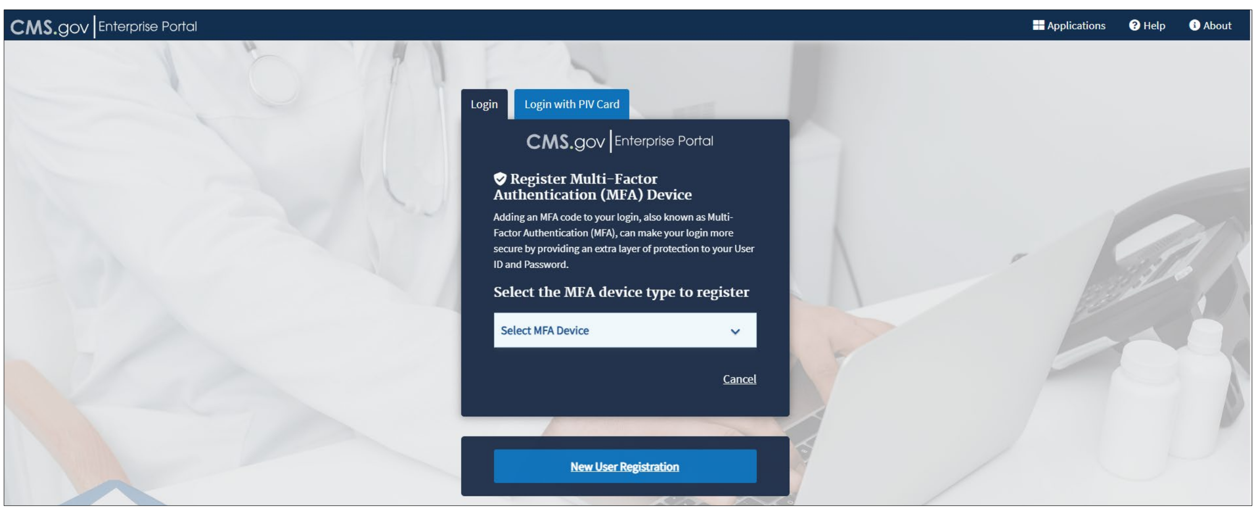
Figure 18: CMS.gov Enterprise Portal Landing Page



You will be prompted to register a Multi-Factor Authentication (MFA) device. Select the MFA you would like to register by using the drop-down arrow.

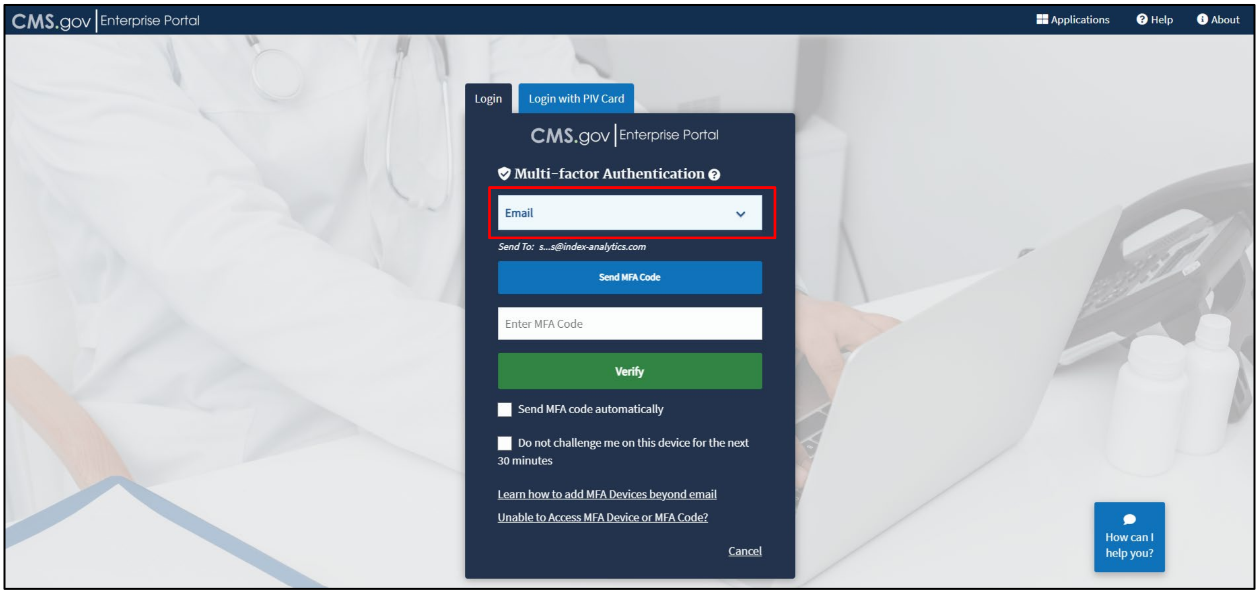
The email address you entered during registration will become the initial MFA device by default. The email MFA is required and cannot be deleted. You may, however, change the email for the MFA, as well as assign additional MFA devices after your first login.

Figure 19: Registering a Multi-Factor Authentication (MFA) Device



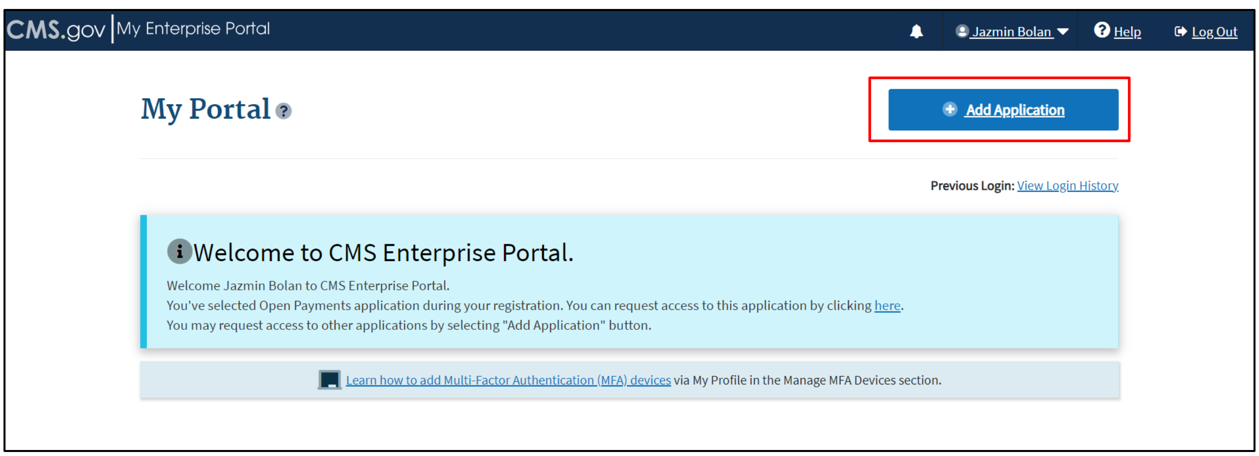
Next, enter the information for your MFA. See 3.2d for registering additional MFA devices.

Figure 20: Entering Device MFA Information



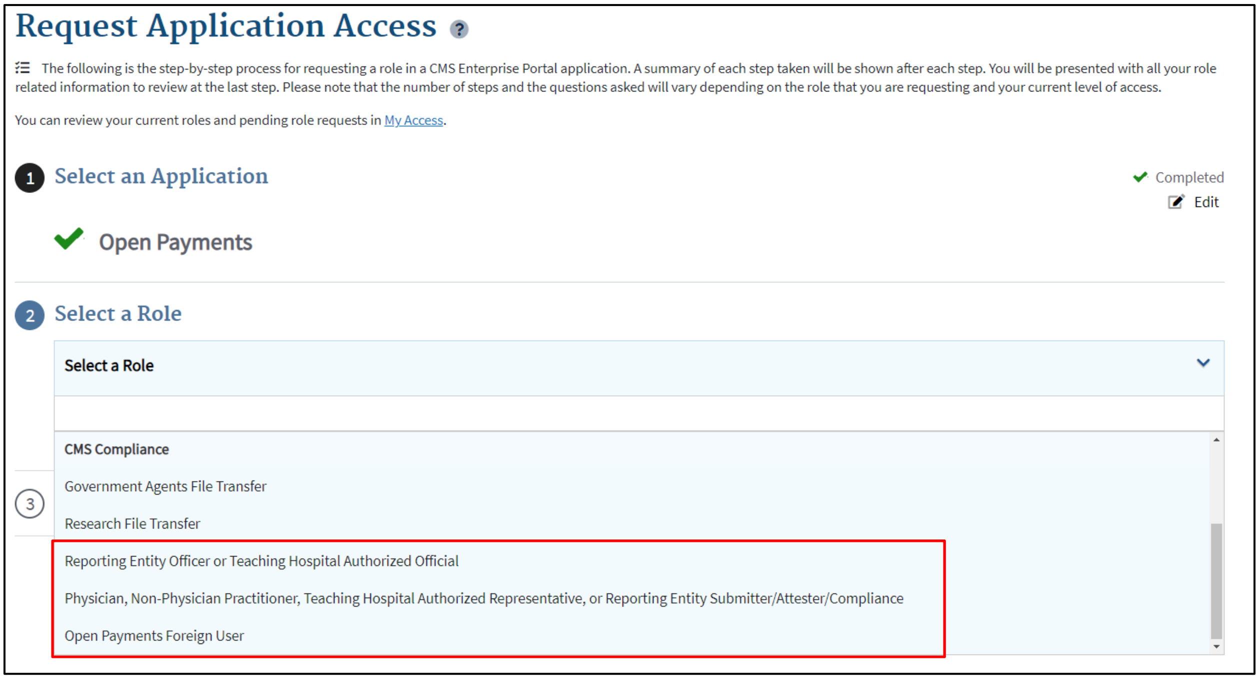
Step 2: You will land on the "My Portal" page. Select the **Add Application** button.

Figure 21: "My Portal" Page



Step 3: Select "Open Payments" from the drop-down list and select **Next.** You will then be asked to select a role. The role you select will determine how you create your Open Payments system profile. There are many roles to choose from, however only three may be selected by Open Payments reporting entities and covered recipients, as shown below.

Figure 22: "Request Application Access" Page



Reporting Entity Officer or Teaching Hospital Authorized Official Role:

You should select this role if you are a US user that would like to register a NEW reporting entity (applicable manufacturer or applicable group purchasing organization) or a teaching hospital that is not currently in the Open Payments system.

If you would like to request this role, go to Step 3a (below).

Physician, Non-Physician Practitioner, Teaching Hospital Authorized Representative, or Reporting Entity Submitter/Attester/Compliance Role:

You should select this role if you fall into one of the following scenarios:

- US and foreign (those users that do not have a US-based address and/or a US Social Security number) physicians, non-physician practitioners, and users nominated for a role by a covered recipient/registered entity.
- US and foreign (those users that do not have a US-based address and/or a US Social Security number) that have been nominated to associate with a teaching hospital that already exists in the Open Payments system.

- US and foreign (those users that do not have a US-based address and/or a US Social Security number) that have been nominated (or are self-nominating) to a role in a reporting entity that already exists in the Open Payments system.

If you would like to request this role, go to Step 3b (below).

Open Payments Foreign User Role:

You should select this role if you are a foreign user (those users that do not have a US-based address and/or a US Social Security number) that falls into one of the following scenarios:

- You would like to create a NEW reporting entity profile (applicable manufacturer or applicable group purchasing organization) not already registered in the Open Payments system.
- You would like to create a NEW teaching hospital profile.

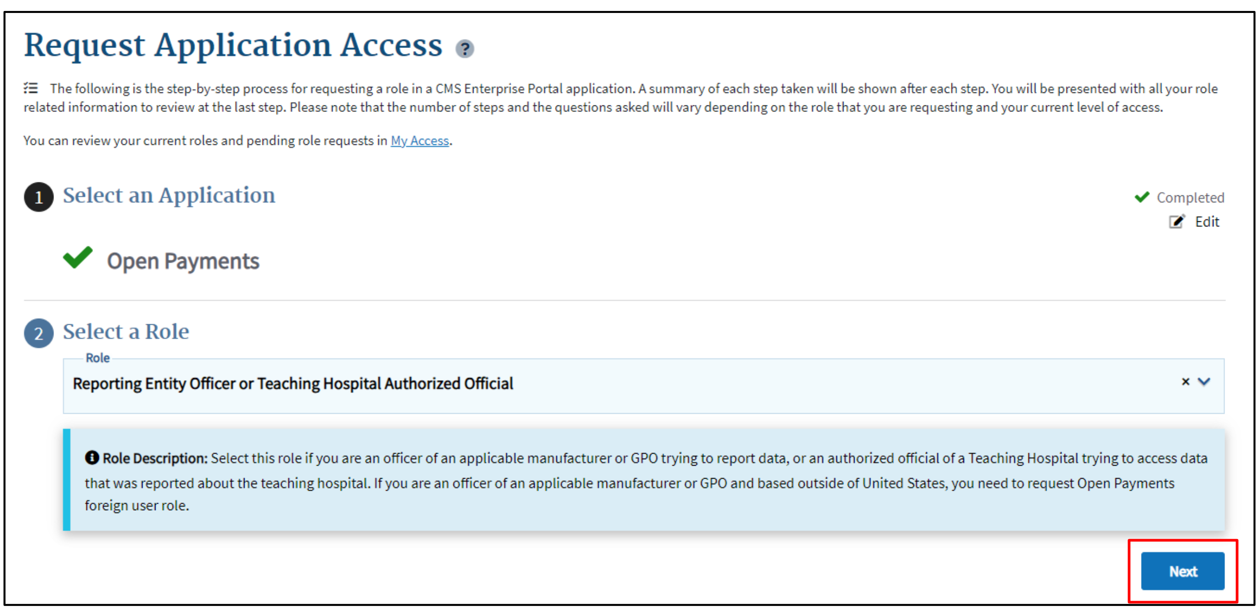
Note: After selecting this role, users should wait for an email from the Open Payments Help Desk that will provide additional information that must be provided before you have access to create your Open Payments profile.

If you would like to request this role, go to Step 3c (below).

Step 3a: Choosing the Reporting Entity Officer or Teaching Hospital Authorized Official Role:

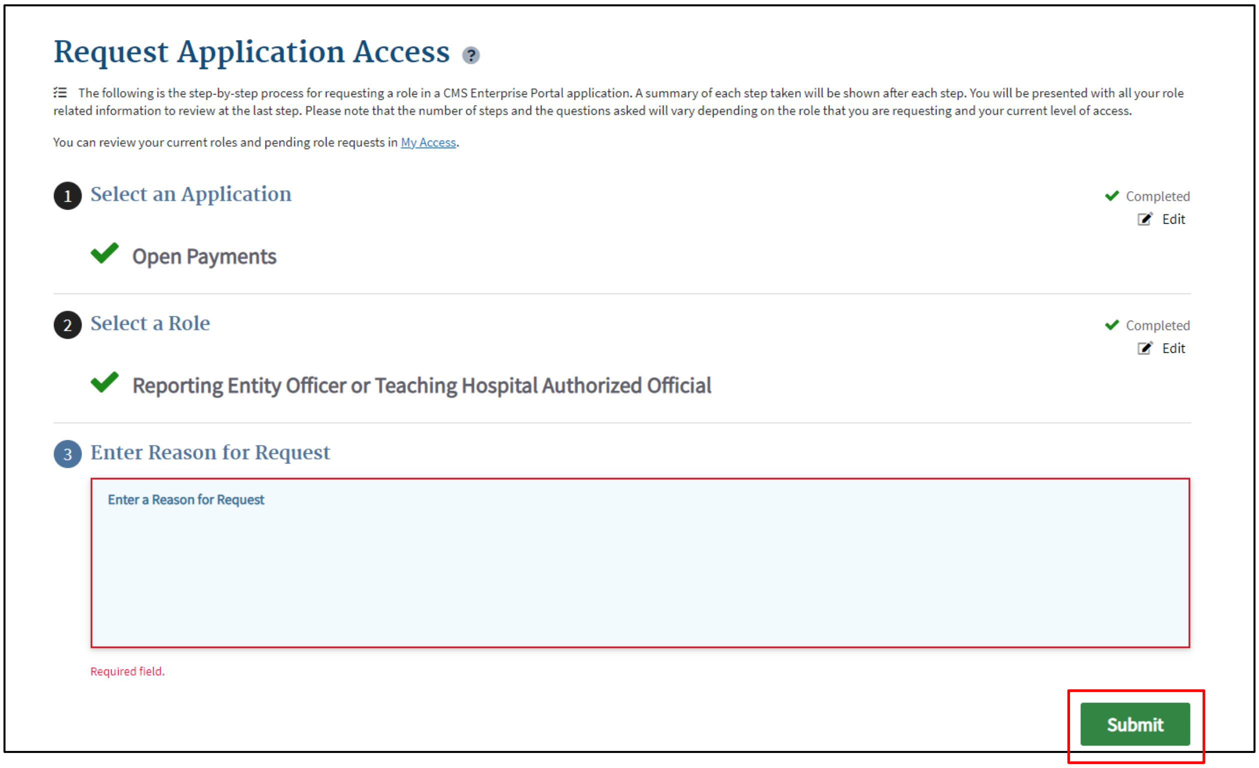
__Step 1:__ Select the Reporting Entity Officer or Teaching Hospital Authorized Official Role, and then select **Next**.

Figure 23: Request Application Access



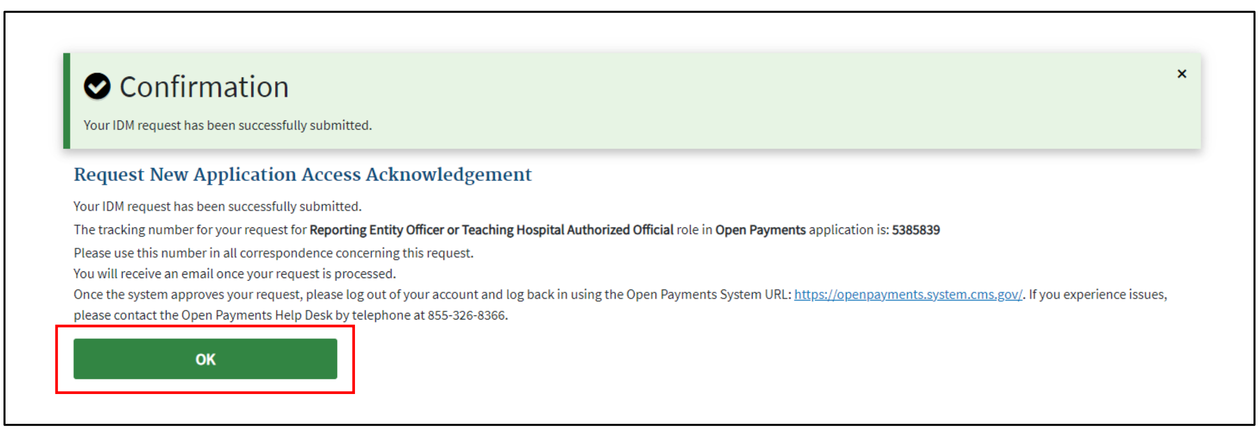
<u>Step 2:</u> Enter a brief statement about why you are requesting the role, then select **Submit**.

Figure 24: Reason for Request



Step 3: You will be shown a confirmation screen. Select **OK**.

Figure 25: Confirmation



Step 4: After selecting **OK**, see Section 3.3 to proceed with creating your Open Payments system profile.

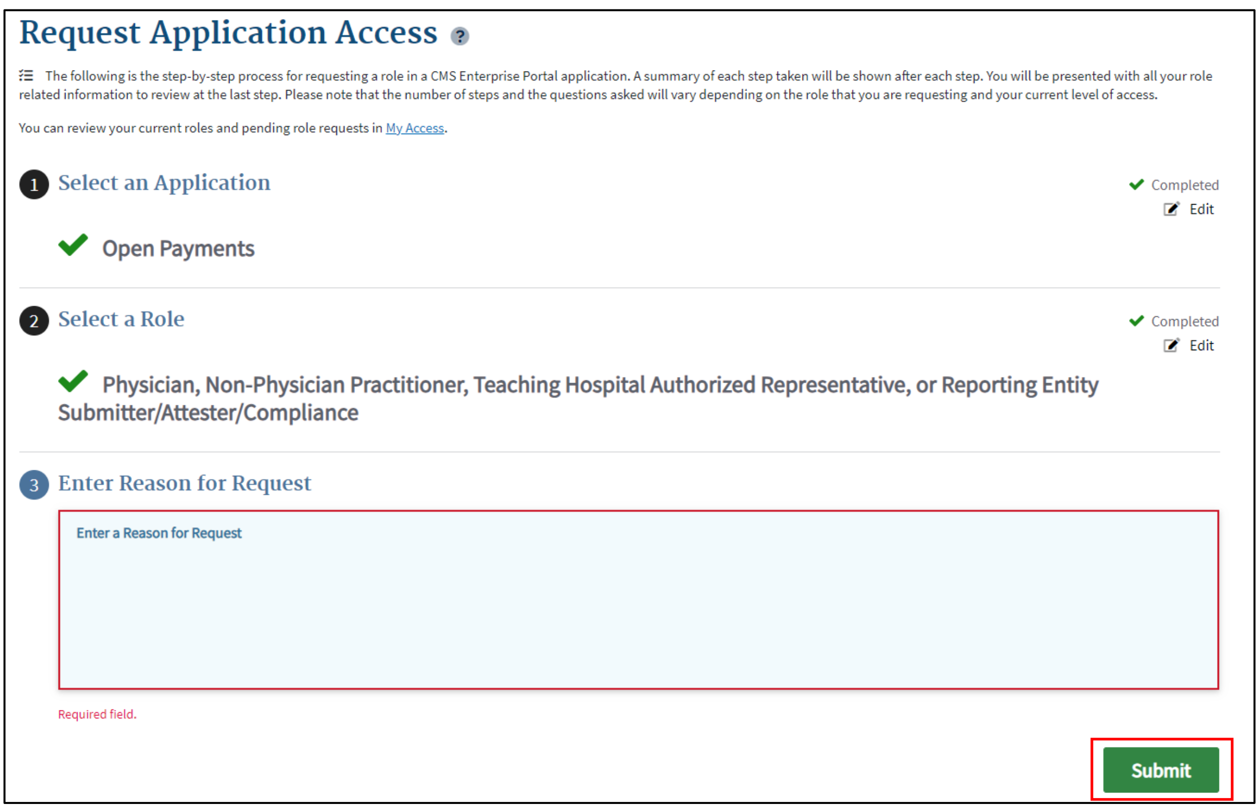
Step 3b: Choosing the Physician, Non-Physician Practitioner, Teaching Hospital Authorized Representative, or Reporting Entity Submitter/Attester/Compliance Role:

1) Select the Physician, Non-Physician Practitioner, Teaching Hospital Authorized Representative, or Reporting Entity Submitter/Attester/Compliance role, and then select **Next**.

Figure 26: Select a Role

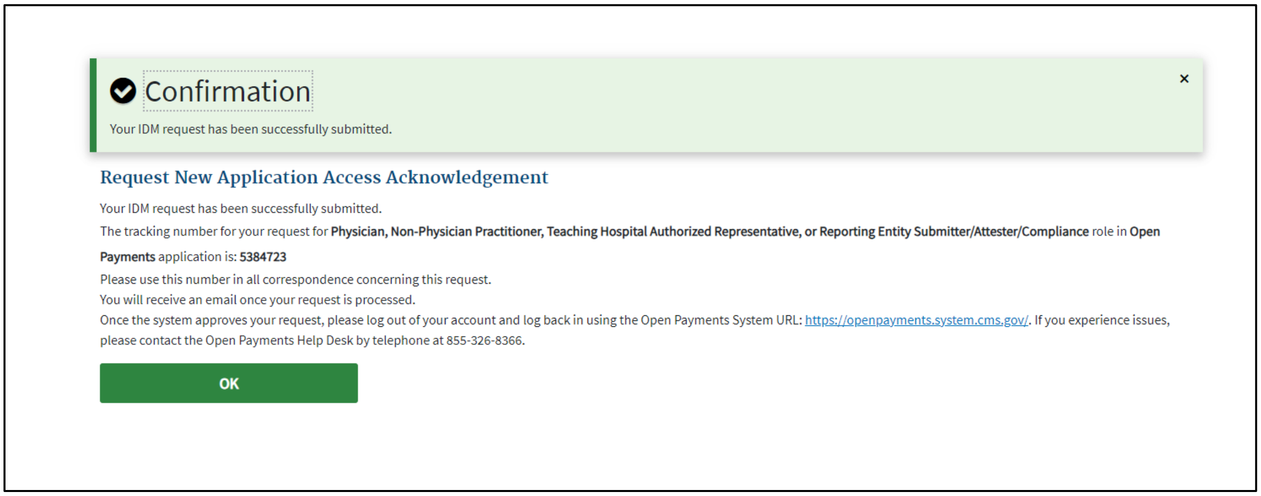
2) Enter a brief reason for requesting the role and then select **Submit**.

Figure 27: Reason for Request



3) You will be shown a confirmation screen. Select **OK**. Selecting OK will NOT bring you to the Open Payments system website. Go to https://openpayments.system.cms.gov to register a profile in the Open Payments system.

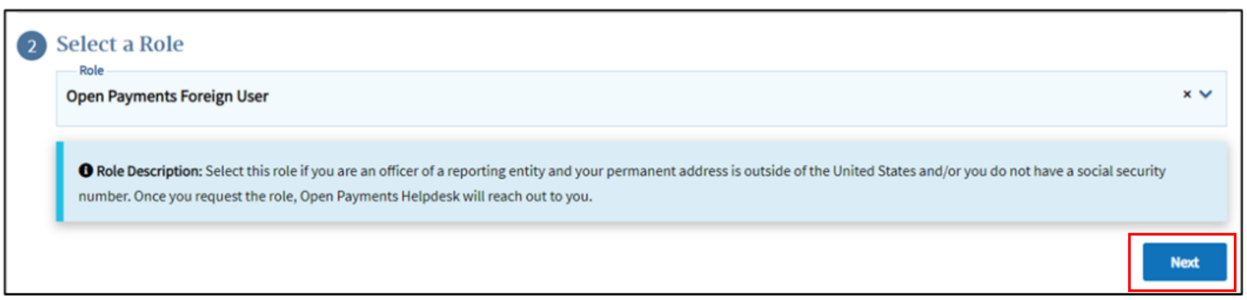
Figure 28: Confirmation



Step 3c: Choosing the Open Payments Foreign User Role:

1) Select the Open Payments Foreign User Role and then select **Next**.

Figure 29: Select a Role

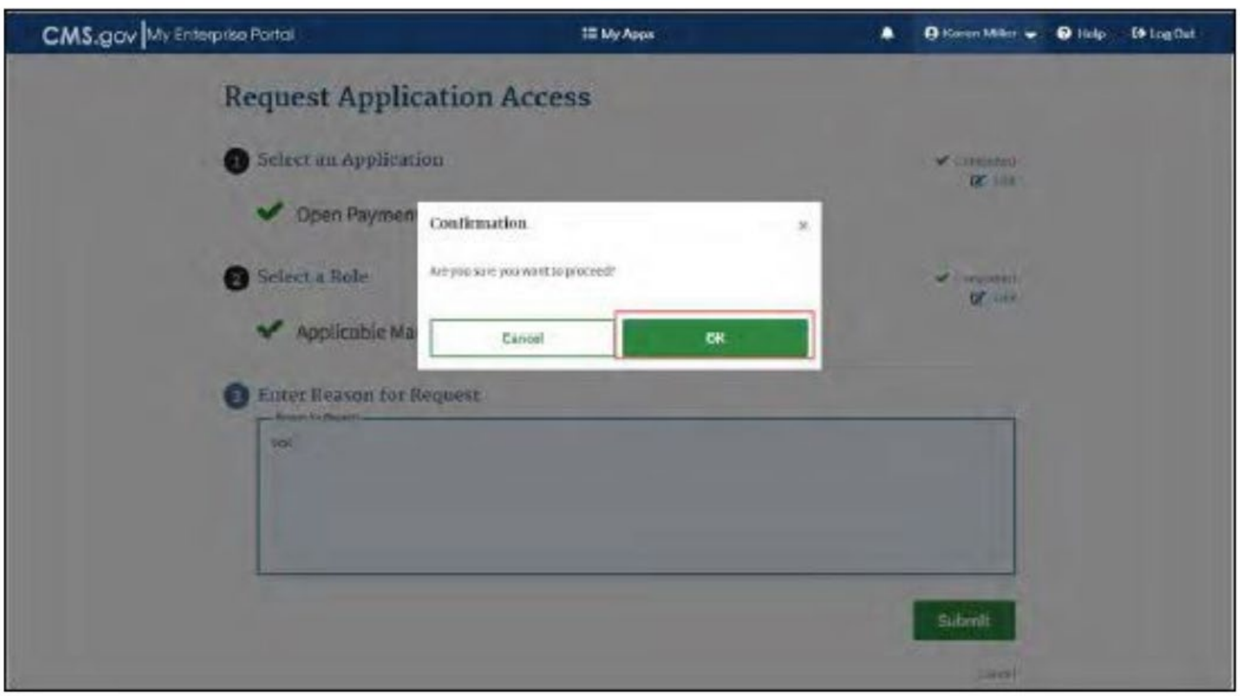


2) Enter a brief justification for requesting this role, and then select **Submit**.

Figure 30: Reason for Request

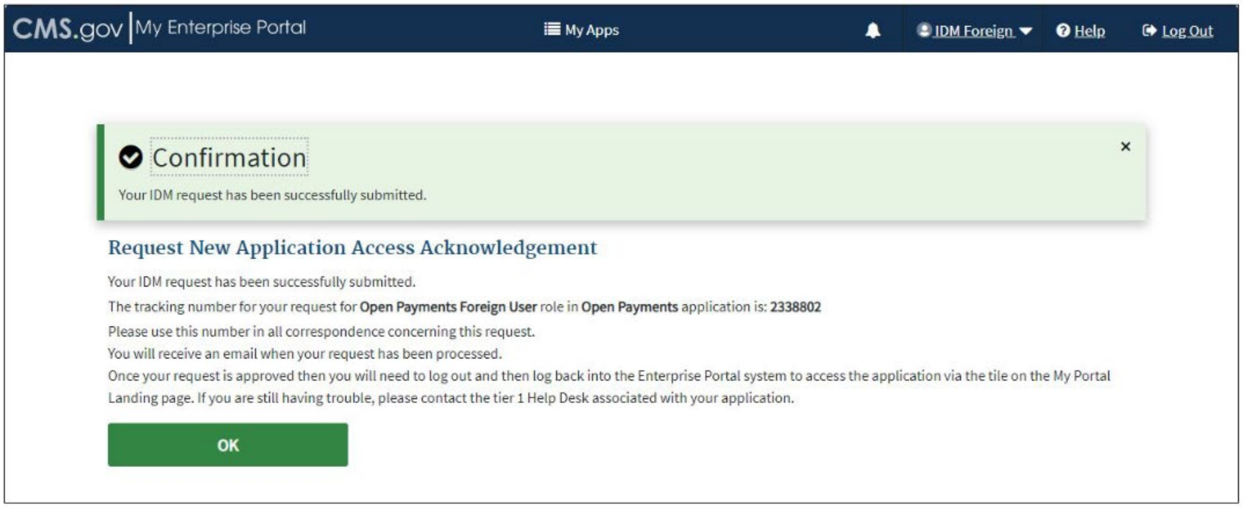
3) You will be shown a confirmation screen. Select **OK**.

Figure 31: Confirmation



4) You will see confirmation that you requested this role. You will receive an email from the Open Payments Help Desk in one to two business days providing you with your next steps.

Figure 32: Second Confirmation



3.2d: Adding Multi-Factor Authentication (MFA)

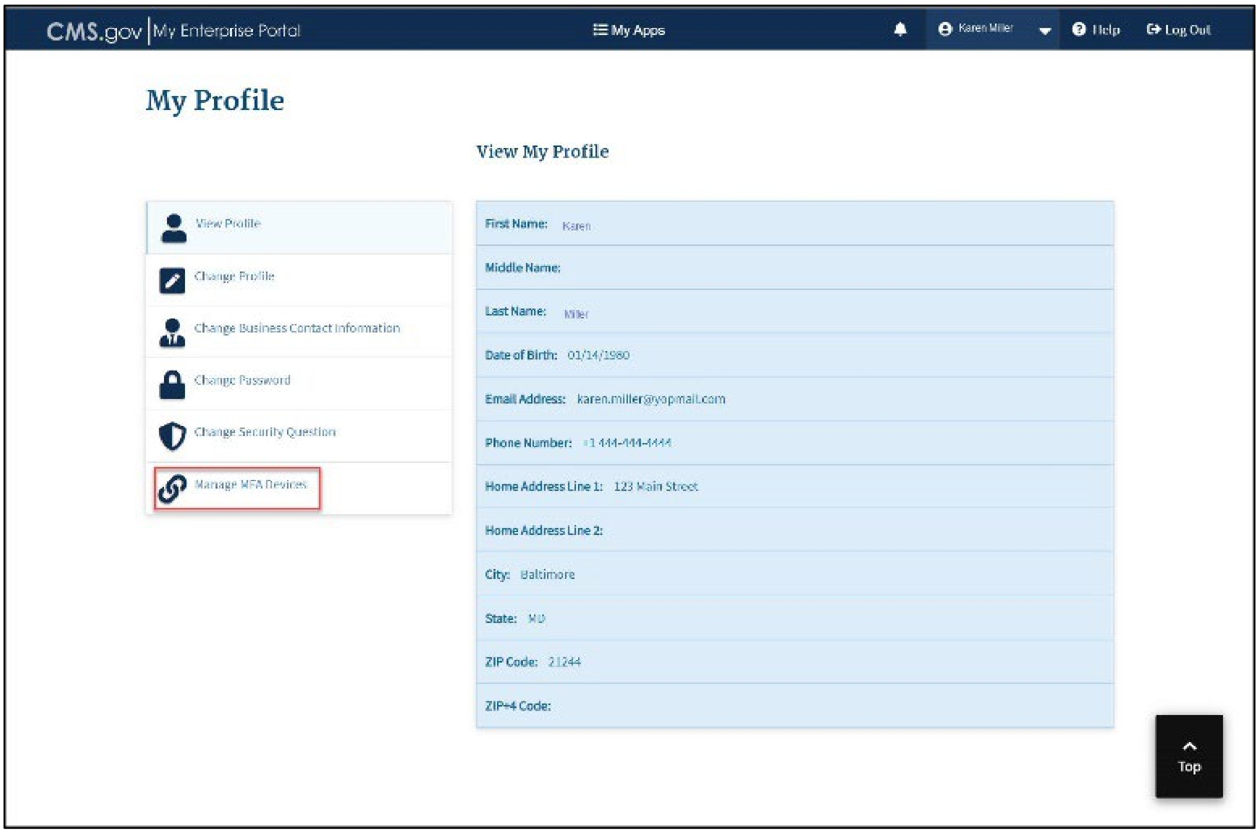
Multi-Factor Authentication (MFA) provides an extra layer of security to your account. You should already have Email as your first MFA. Again, Email is a required MFA and cannot be removed.

IDM suggests having more than one MFA registered to your account as a backup option.

To add additional MFAs:

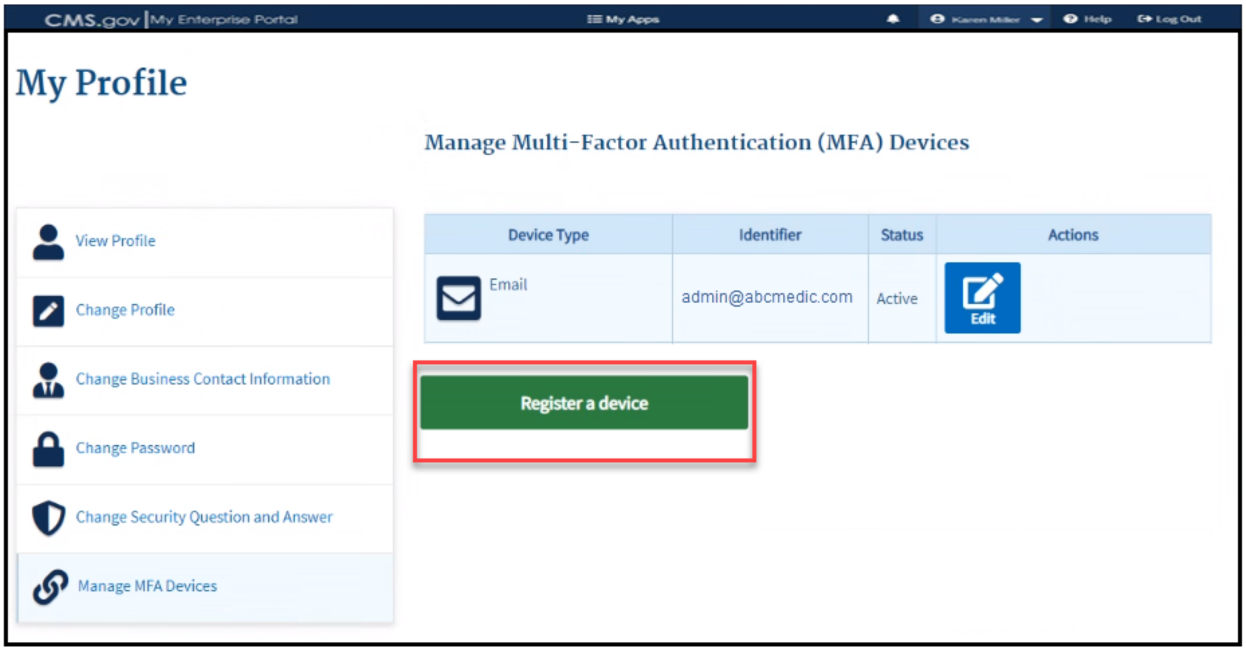
Step 1: Go to portal.cms.gov, and use your credentials to sign in. Navigate to My Profile and select **Manage MFA Devices**.

Figure 33: My Profile



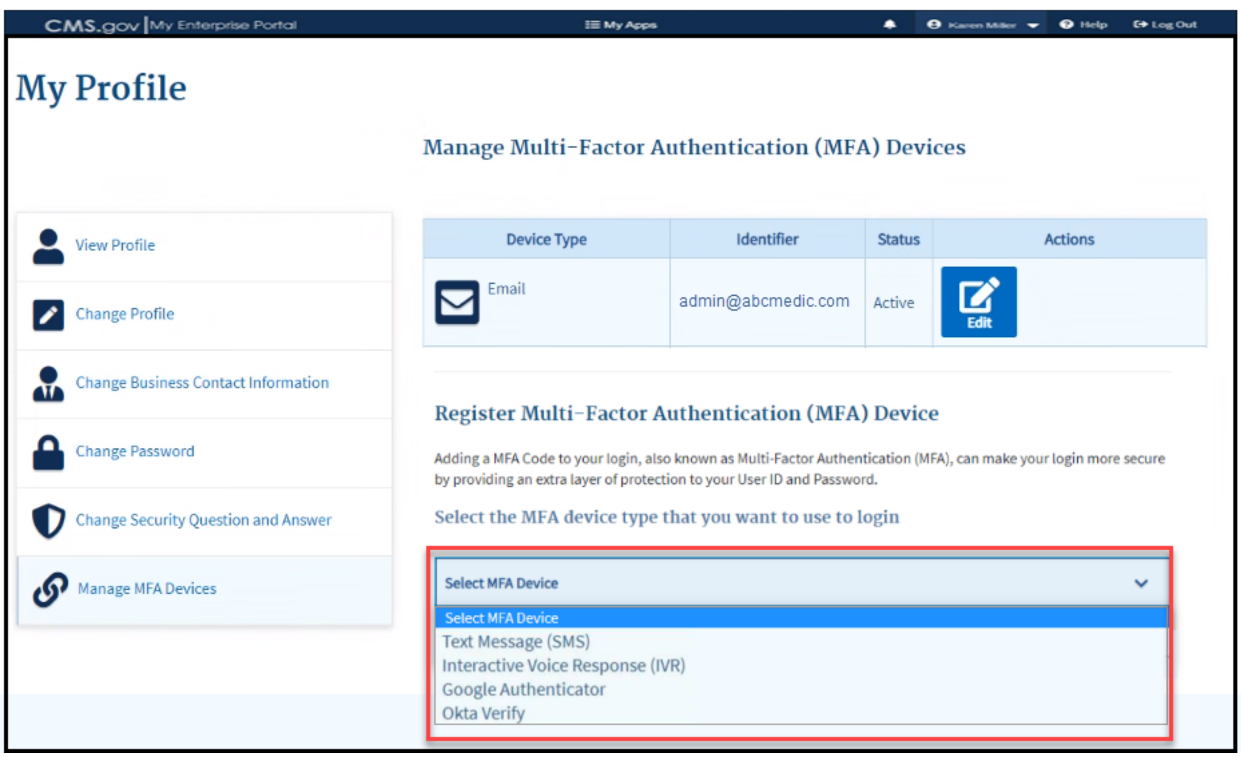
Step 2: Select **Register a Device**.

Figure 34: Manage MFA Device Register a Device Page



Step 3: Select the device you wish to register.

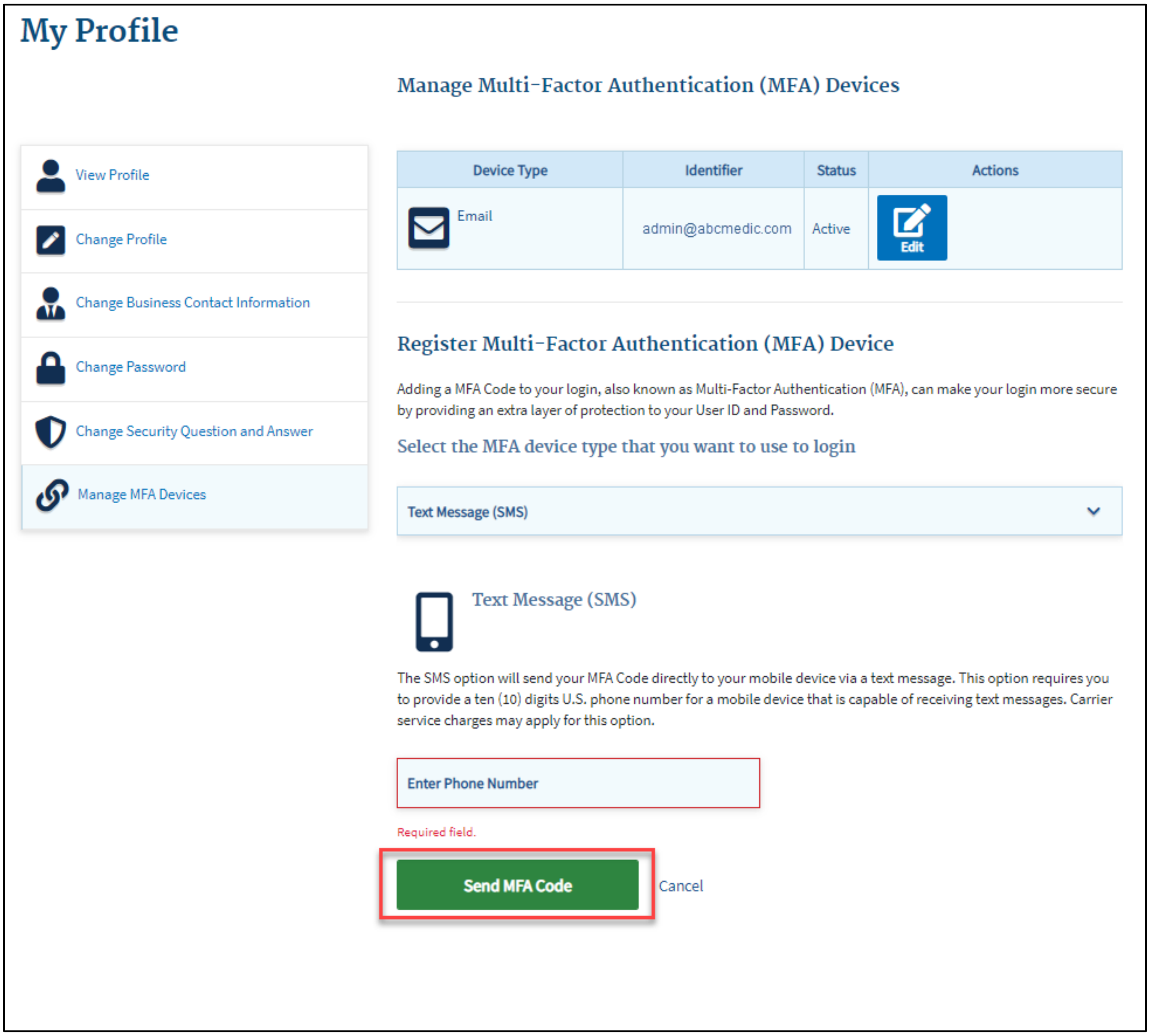
Figure 35: Register MFA Devices



Step 4: Depending on the device you choose to register, you will be asked to provide information about that device. For example, if you choose "Text Message", you will be asked to provide a phone number.

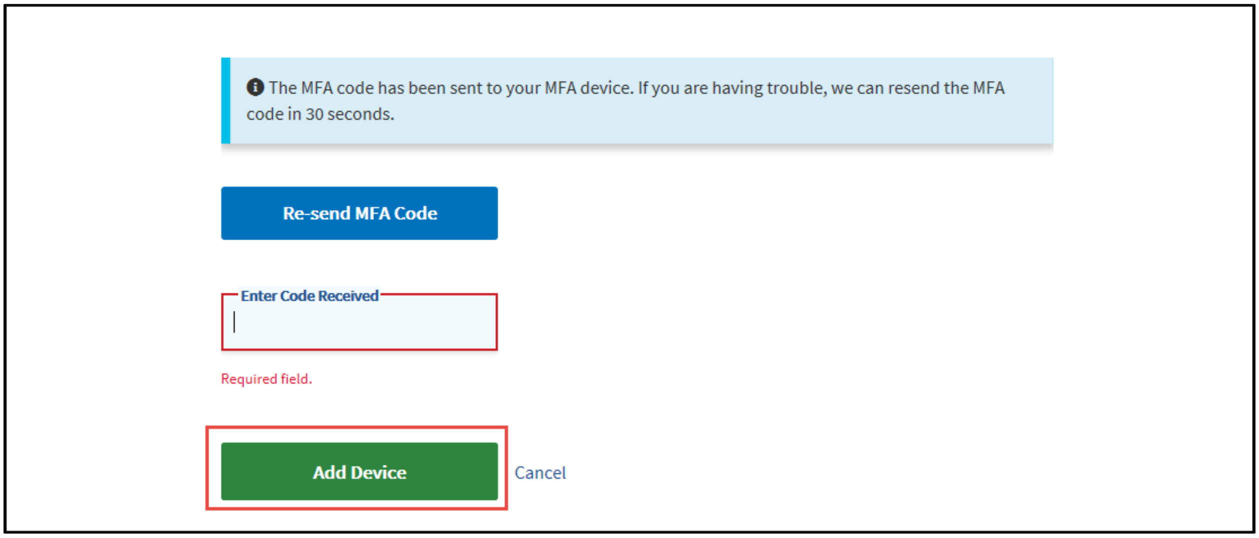
Enter the required information for the device you are registering and select **Send MFA Code**.

Figure 36: Send MFA Code



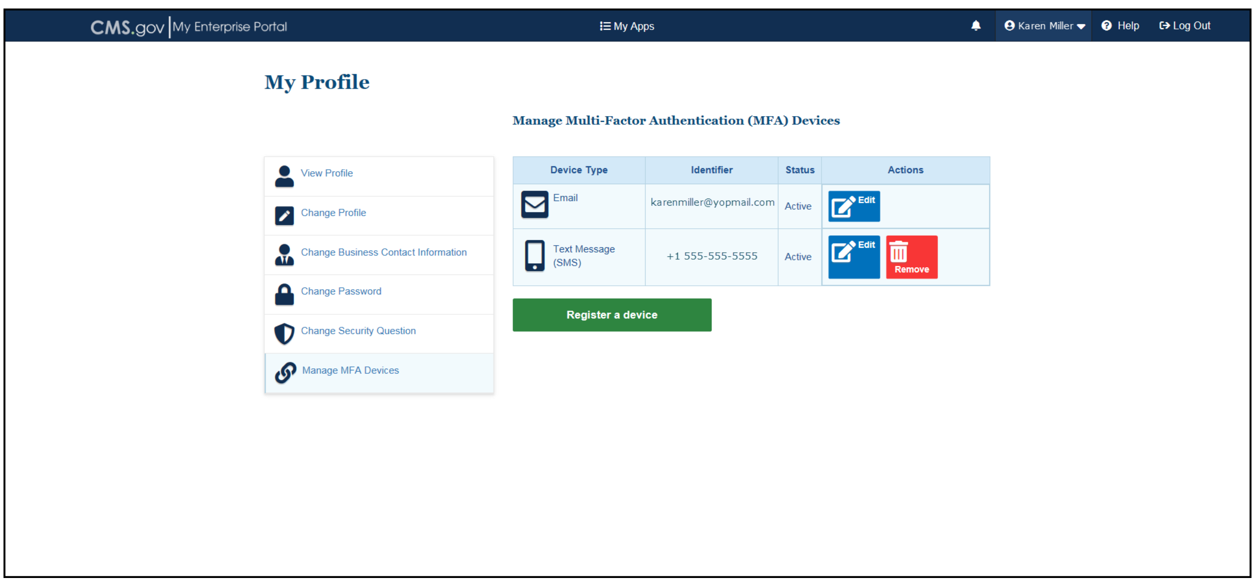
Step 5: Enter the code sent to your device and select **Add Device** to add your MFA Device.

Figure 37: Enter MFA Device Code



Step 6: You have successfully added an MFA device to your IDM account.

Figure 38: Manage MFA Devices Page



Section 3.3: Open Payments System Users and User Roles for Entities

When you have successfully created an IDM account, and requested access to the Open Payments System, you are ready to create a profile for your entity in the Open Payments system.

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.

- **Officer**: Manages the reporting entity in the Open Payments system, manages user roles, and is permitted to view and download any compliance communications associated with the reporting entity.
- **Submitter**: Submits data on payments, other transfers of value, and/or ownership and investment interests for the reporting entity. The submitter also receives all notifications of disputes initiated by covered recipients against the reporting entity's submitted data.
- **Attester**: Attests to the accuracy of the data that has been submitted for the applicable manufacturer or applicable GPO.
- **Compliance**: Views and downloads compliance communications uploaded and sent by the CMS Compliance Team to the applicable manufacturer or applicable GPO.

Each reporting entity must maintain at least one officer in the entity profile. The officer must be highly placed within the entity, such as 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).

The person registering the entity in the Open Payments system will automatically hold an officer role, and must meet the requirements of that role, as explained above.

There can be a total of twelve unique users per entity, with no more than five of those users holding an officer role, and 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.

Entities must have at least one officer, submitter, and attester identified or nominated in the system at the time the entity is registered. You are not required to have a person in the compliance role.

Note: Many entities have found it helpful to have more than one person in the officer, submitter, and attester roles, as a backup.

The roles, responsibilities, and requirements for the roles are shown in **Figure 39** below.

Figure 39: 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 • 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	• Must be an officer as designated by the applicable manufacturer or applicable GPO • If nominated, must either accept or reject the nomination
Submitter	• Submit data in the Open Payments system on behalf of the applicable manufacturer or applicable GPO • May 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, NPPs and teaching hospitals	• Not required to be an officer of the applicable manufacturer or applicable GPO • Not required to be an employee 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 • Respond to any compliance communications sent by CMS	• 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.

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 40.** Details on these steps are included later in this section.

Figure 40: Entity Registration

An authorized official of the entity enters all required information to create the entity's profile. The authorized official must 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 later. You will be able to edit, manage, or update a profile once it is created. The system does not have an auto-save feature and will time out after 30-minutes of inactivity. A popup will appear as you get close to the 30-minute timeout.

Figure 41 and **Figure 42** detail which fields are required, and which fields are optional when creating an entity and user profile. This will help you have the required information on-hand prior to creating your entity profile.

Figure 41: 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

Fields	Required or Optional?
Taxpayer Identifier Number (TIN)/ Employer Identification Number (EIN)	Required
Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS)	Optional, but entering the information will assist in vetting your entity
Food and Drug Administrator (FDA) Establishment Identifier (FEI)	Optional, but entering the information will assist in vetting your entity
Uniform Resource Locator (URL) of Parent Company*	Required
Consolidated Report Indicator (Y/N) (default N)	Required
Primary Point of Contact Name	Required
Primary Point of Contact Business Phone Number	Required
Primary Point of Contact Title at the Entity	Required
Primary Point of Contact Email Address	Required
Backup Point of Contact Name	Required
Backup Point of Contact Business Phone Number	Required
Backup Point of Contact Title at the Entity	Required
Backup Point of Contact Email Address	Required
Contact Information for Review and Dispute. A primary is required, and you will have the option of entering in a backup contact.	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 42: 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

After submitting both the entity and user profiles, the Open Payments system will confirm the information you entered matches industry records. This is also known as "vetting". 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.

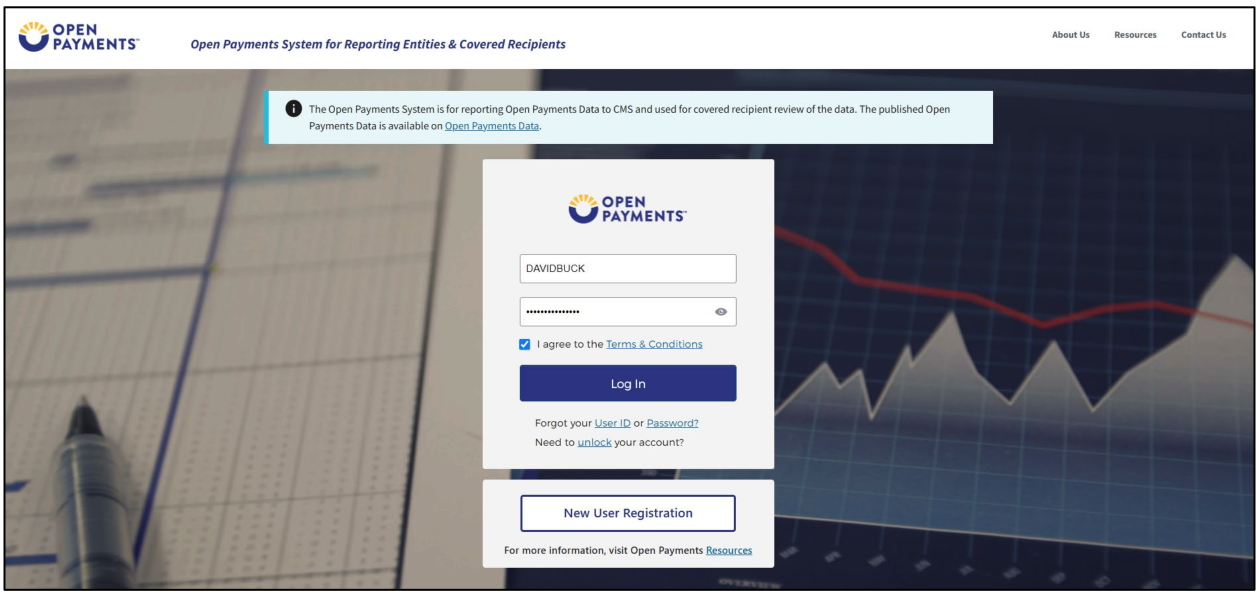
Important Notes:

- Reporting entity profile registration must be completed in one session.
- The Open Payments system will log out all users after 30 minutes of inactivity.

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

Step 1: Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials and agree to the Terms and Conditions.

Figure 43: Open Payments Home Screen

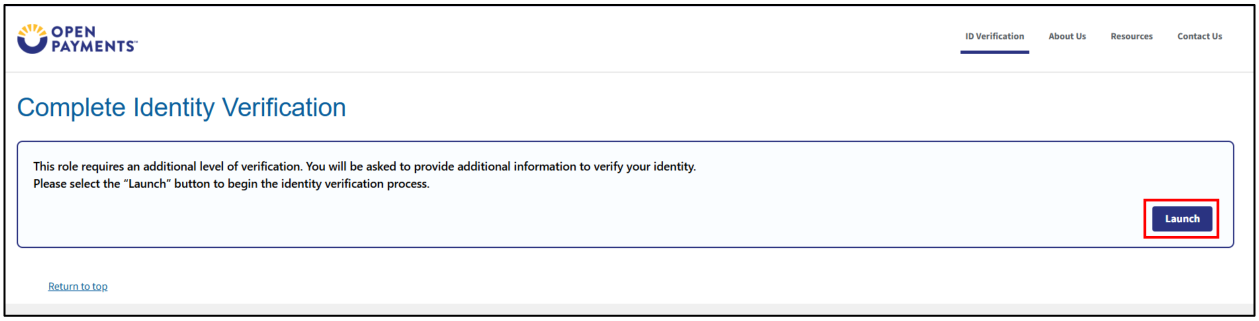


Step 2: Experian will perform a soft credit inquiry to verify your identity. Identity proofing does not affect your credit score. Soft credit inquiries are visible only to the user and only appear on credit reports produced by Experian. Credit inquiries are not visible to lenders. If you order a credit report from Experian, you will see an entry of inquiry by the Centers for Medicare & Medicaid Services with CMS's address and the date of request.

If you have questions about Experian's verification process, please refer to Experian Customer Assistance at http://www.experian.com/help/.

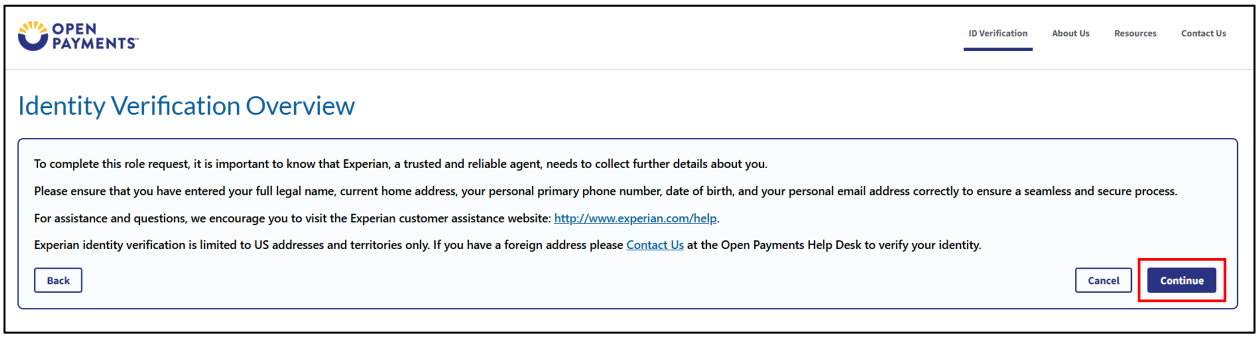
Select **Launch** to continue.

Figure 44: Identity Verification Notice



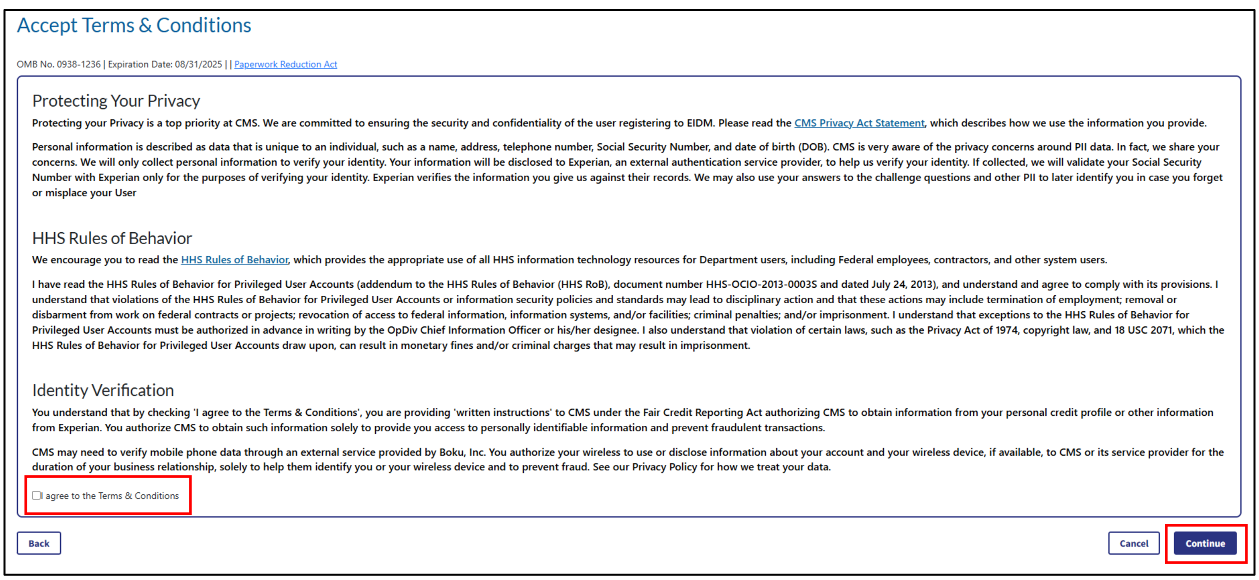
Step 3: View the identity verification overview and select **Continue**.

Figure 45: Identity Verification Overview



Step 4: After reading the Terms and Conditions and selecting **agree**, select **Continue**.

Figure 46: Accept Terms and Conditions



Step 5: When entering your information into the Experian Identity Verification screen, ensure you enter only your personal information.

You will only have three attempts to enter information that matches the Experian database.

Tips for successfully completing Experian Identity Verification:

Full Legal Name:

- You must use your full legal name as listed on your Driver's License or financial account information.
- Your surname must match the surname Experian has for you on file.
- Do not use nicknames.
- If you have a two-part name, enter the second part in the middle name field.

Social Security Number:

- If you elect to add your Social Security Number, ensure that the fields are filled in correctly. Users can review and edit these fields prior to sending the information to Experian.

Date of Birth:

- Ensure that the Date of Birth field is entered accurately. Users can review and edit this field prior to sending the information to Experian.

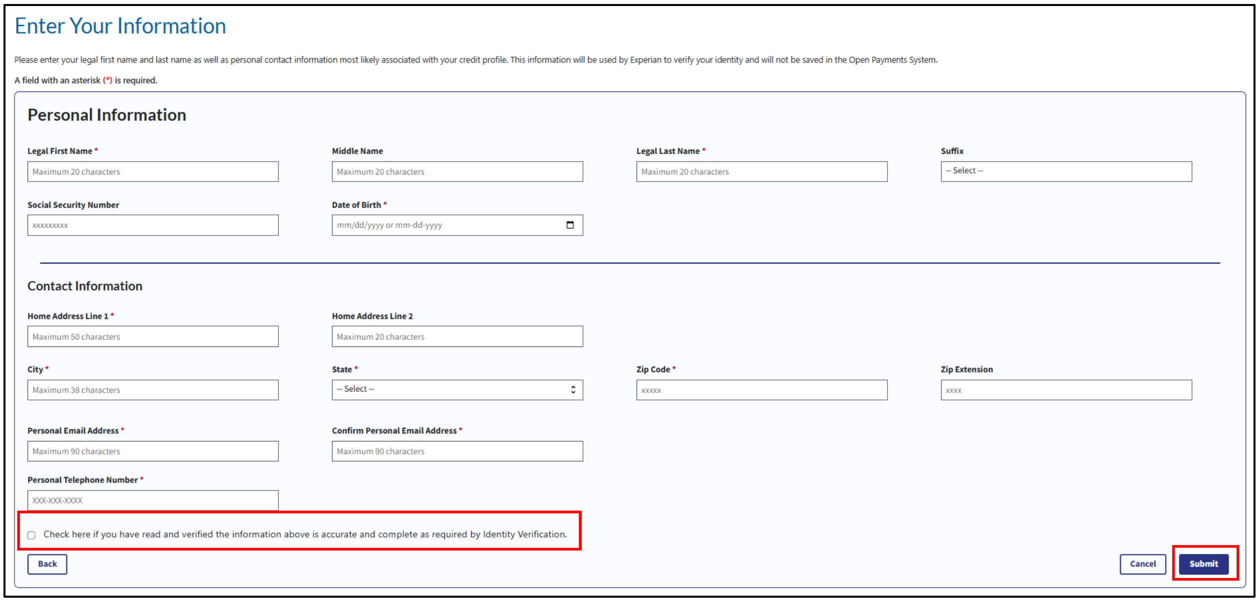
Current Residential Address:

- Ensure your personal/residential/home address is used:
- Where you receive Credit card, utility bill statements.
- Associated with your credit report.
- Do NOT use your business address.
- If you have a recent change in address, try to identity proof with a prior address.
- Do not enter any extraneous symbols in the address field.

Personal Phone Number

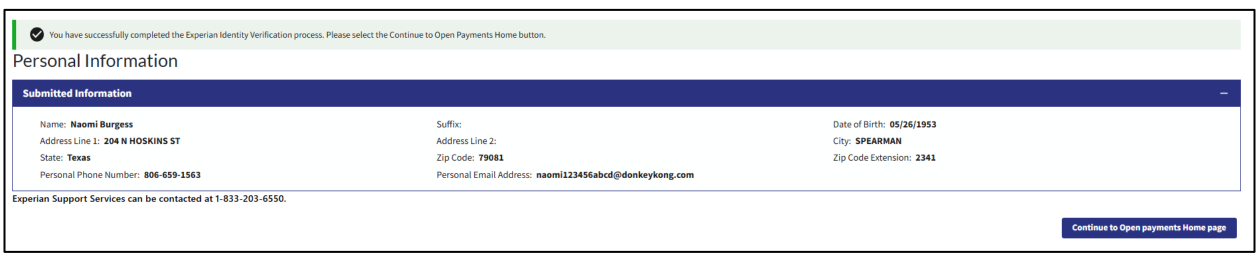
- Enter a personal landline phone number (if you have one).
- A cell phone can be used, but a residential landline is preferred.

After reviewing the above information enter your information in the spaces provided, and then select **Submit**.



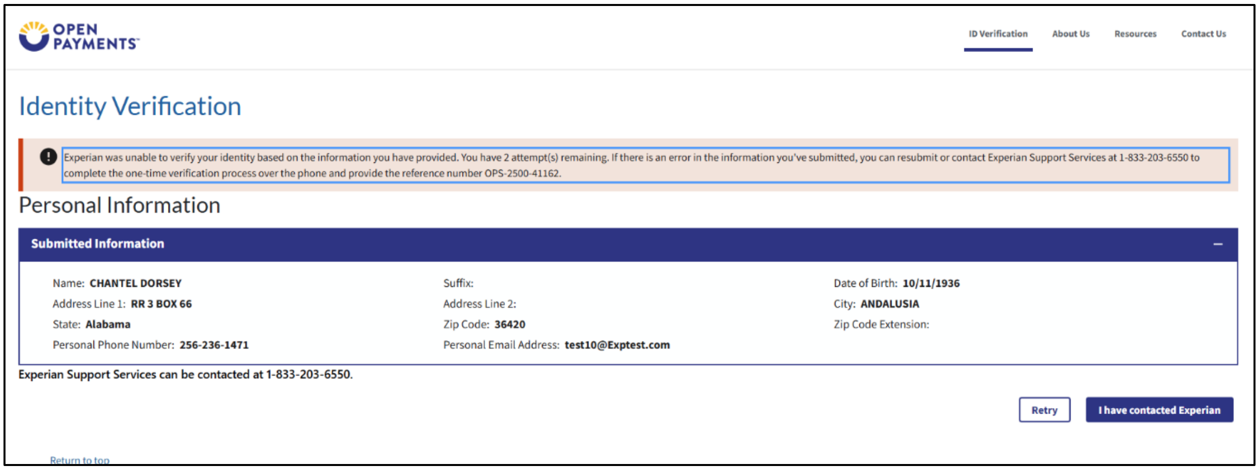
Step 6: If Experian Identity Verification is successful, you will receive the confirmation notice. Select **Next** to continue.

Figure 47: Successful Identity Verification



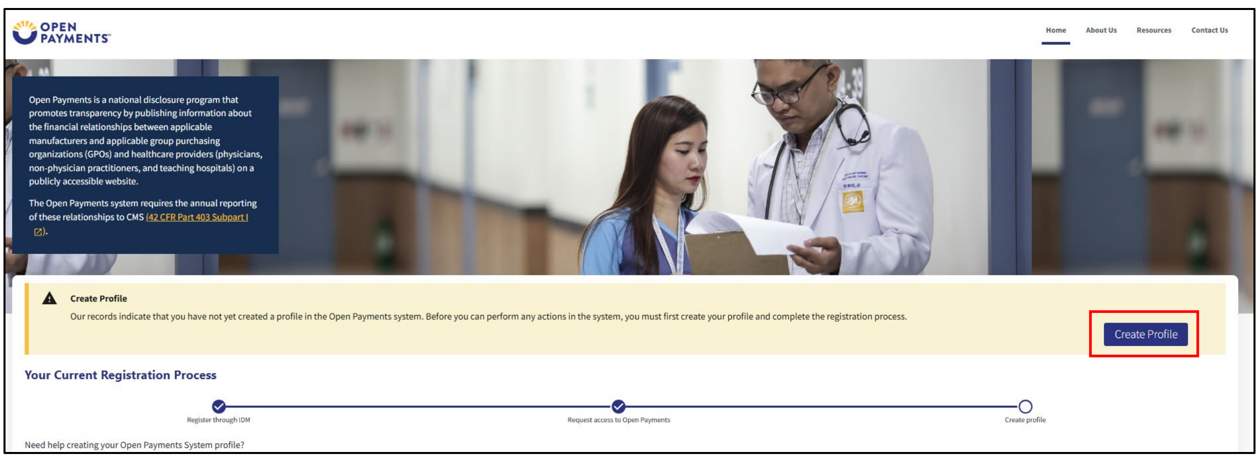
Step 7: If Experian Identity Verification is unsuccessful, note the reference number, and follow the directions in the error message.

Figure 48: Could Not Verify Personal Information



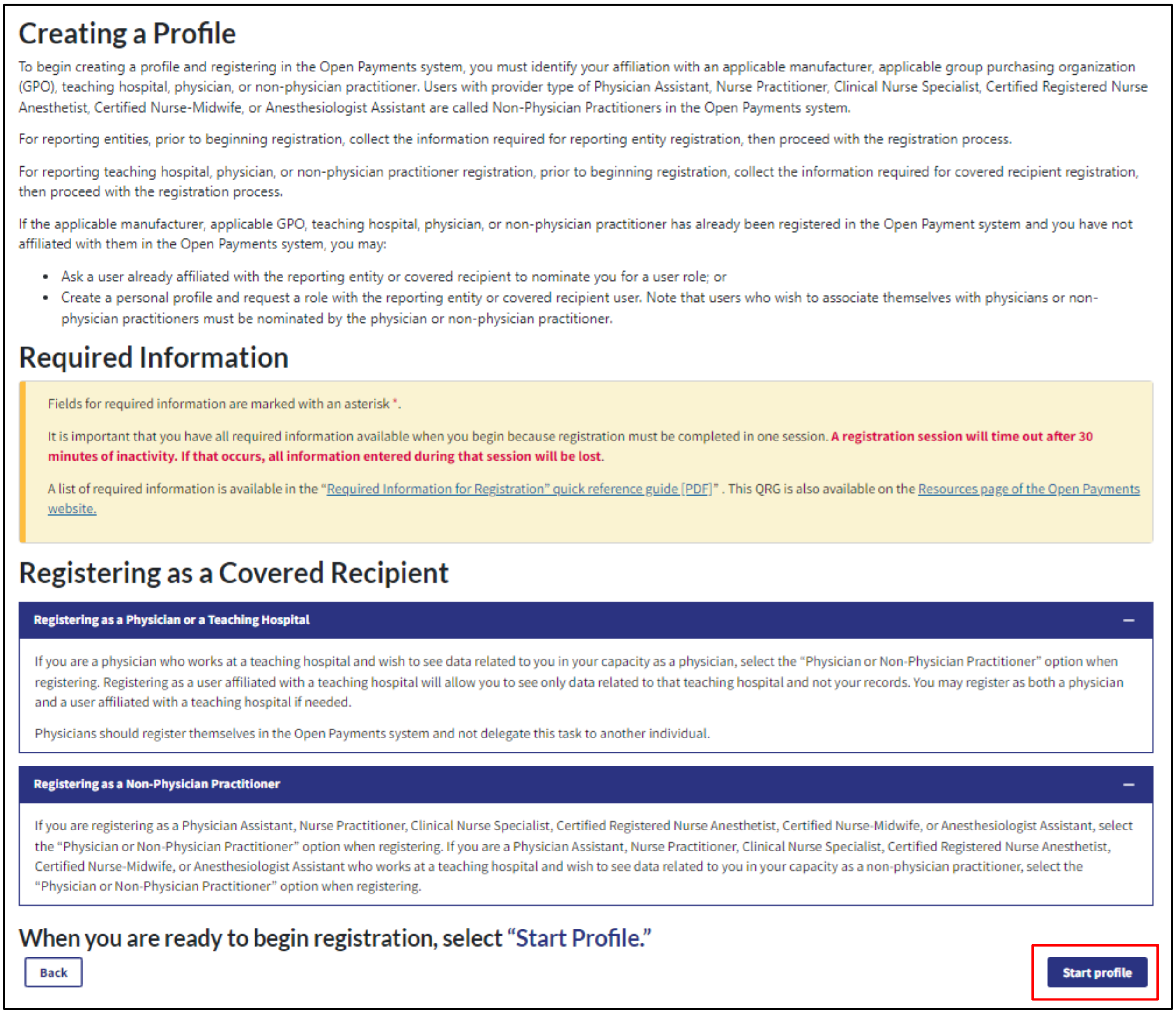
Step 8: After successfully completing Experian Identity Verification, you may now create your entity profile in the Open payments system. The on-screen text contains important information regarding the registration process. Read the on-screen text and select **Create Profile** when you are ready to begin the registration process.

Figure 49: 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 **Start Profile** at the bottom of the page when you are ready to continue.

Figure 50: Create Profile Page



Creating a Profile

To begin creating a profile and registering in the Open Payments system, you must identify your affiliation with an applicable manufacturer, applicable group purchasing organization (GPO), teaching hospital, physician, or non-physician practitioner. Users with provider type of Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist, Certified Nurse-Midwife, or Anesthesiologist Assistant are called Non-Physician Practitioners in the Open Payments system.

For reporting entities, prior to beginning registration, collect the information required for reporting entity registration, then proceed with the registration process.

For reporting teaching hospital, physician, or non-physician practitioner registration, prior to beginning registration, collect the information required for covered recipient registration, then proceed with the registration process.

If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has already been registered in the Open Payment system and you have not affiliated with them in the Open Payments system, you may:

- Ask a user already affiliated with the reporting entity or covered recipient to nominate you for a user role; or
- Create a personal profile and request a role with the reporting entity or covered recipient user. Note that users who wish to associate themselves with physicians or non-physician practitioners must be nominated by the physician or non-physician practitioner.

Required Information

Fields for required information are marked with an asterisk *.

It is important that you have all required information available when you begin because registration must be completed in one session. **A registration session will time out after 30 minutes of inactivity. If that occurs, all information entered during that session will be lost**.

A list of required information is available in the "Required Information for Registration" quick reference guide [PDF]" . This QRG is also available on the Resources page of the Open Payments website.

Registering as a Covered Recipient

Registering as a Physician or a Teaching Hospital –

If you are a physician who works at a teaching hospital and wish to see data related to you in your capacity as a physician, select the "Physician or Non-Physician Practitioner" option when registering. Registering as a user affiliated with a teaching hospital will allow you to see only data related to that teaching hospital and not your records. You may register as both a physician and a user affiliated with a teaching hospital if needed.

Physicians should register themselves in the Open Payments system and not delegate this task to another individual.

Registering as a Non-Physician Practitioner –

If you are registering as a Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist, Certified Nurse-Midwife, or Anesthesiologist Assistant, select the "Physician or Non-Physician Practitioner" option when registering. If you are a Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist, Certified Nurse-Midwife, or Anesthesiologist Assistant who works at a teaching hospital and wish to see data related to you in your capacity as a non-physician practitioner, select the "Physician or Non-Physician Practitioner" option when registering.

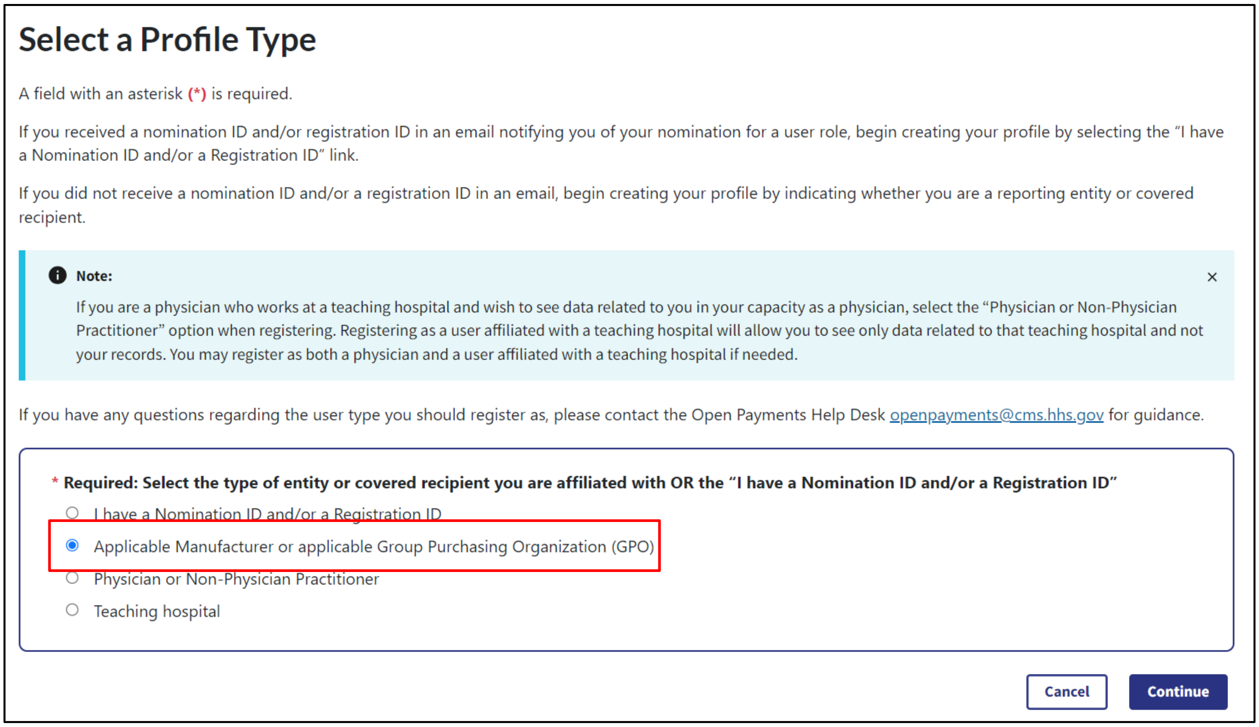
When you are ready to begin registration, select "Start Profile."

Back

Start profile

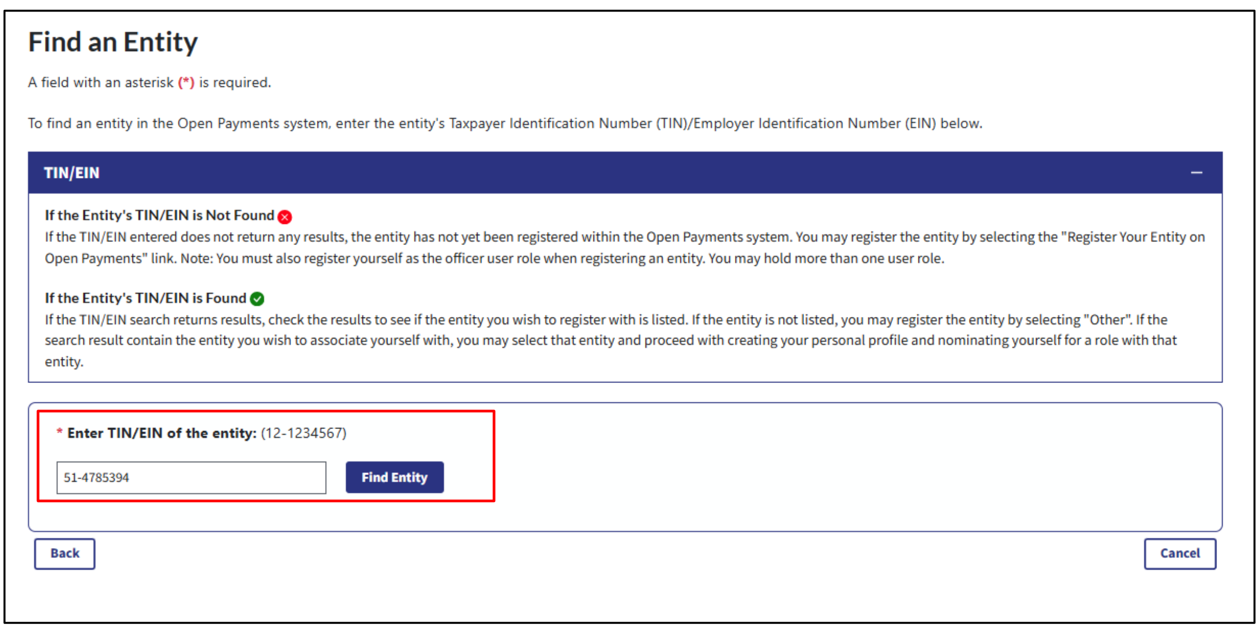
<u>Step 4:</u> Select the profile type **Applicable manufacturer or applicable group purchasing organization (GPO)** and then select **Continue**.

Figure 51: Select Profile Type Page



Step 5: Once your entity type is selected, provide the reporting entity's 9-digit Taxpayer Identification Number/Employer Identification Number (TIN/EIN) and select **Find Entity**.

Figure 52: Find and Entity Page

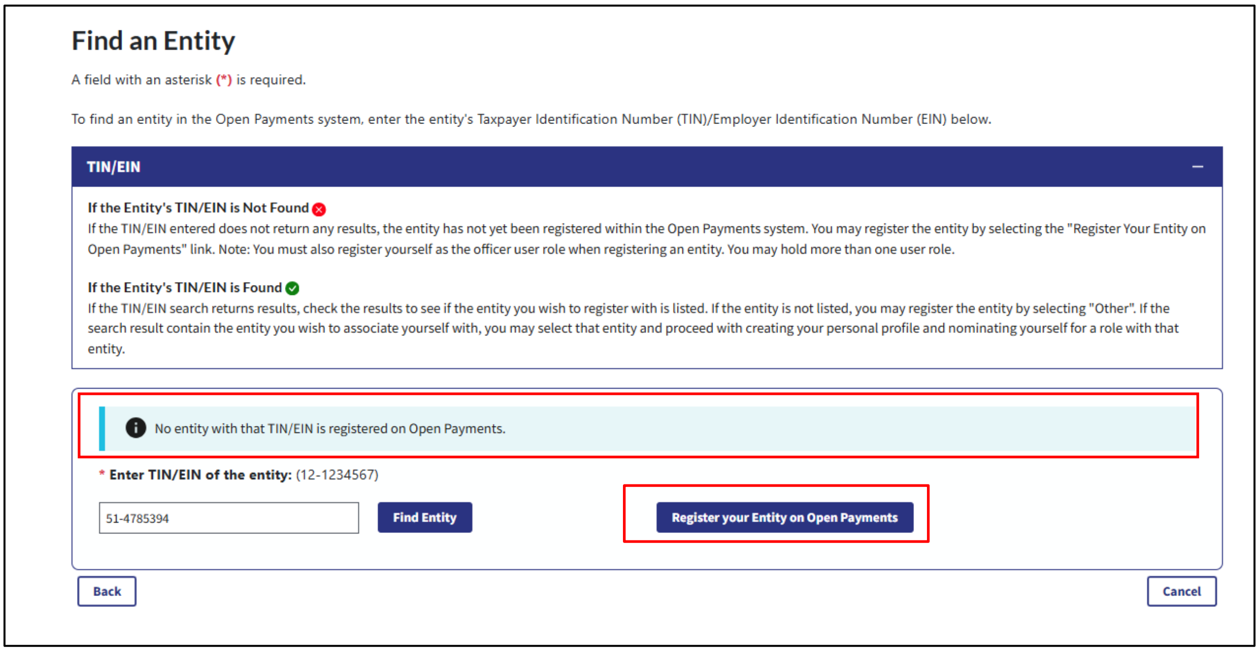


Step 6: The system will perform a search for the TIN/EIN you entered to determine if it has already been registered in the Open Payments system.

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** button to continue with entity registration.

Figure 53: Find an Entity Page



Step 7: 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 the required fields have been entered.

Additional Information on the fields for entity registration:

- The **Consolidated Report Indicator** indicates whether 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 under the same ownership.

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, or not 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:
  - **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 distributorship

    – applicable manufacturer-hospital-owned distributor

    – applicable manufacturer-distributor/supplier (non-hospital, non-physician-owned)
  - **Applicable GPO**

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

    – GPO-drugs/biologicals

    – GPO-devices/medical supplies

    – GPO- drugs/biologicals and devices/medical supplies

    – GPO-physician-owned distributorship

    – 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 **Review and Dispute Primary and Backup Points of Contact** fields are 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. The contents of the “Review and Dispute Primary Point of Contact” and “Review and Dispute Backup Point of Contact” fields will be visible to the covered recipients associated with the records during the review process. The contents will be displayed exactly as entered in these fields.

- The FDA and D.U.N.S. fields are not required to be filled. However, if you have an FDA and/or a D.U.N.S. number, entering them will assist in successful vetting once your entity profile is submitted.

Figure 54: Register Entity Pages

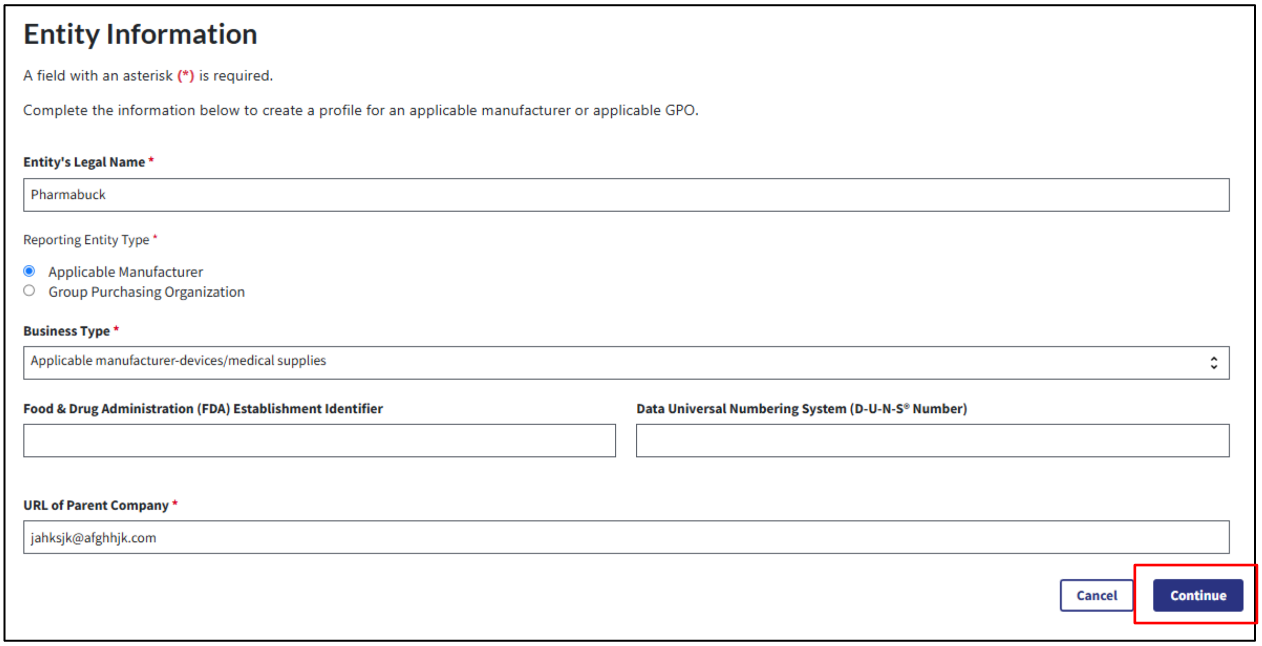


Figure 55: Business Information Page

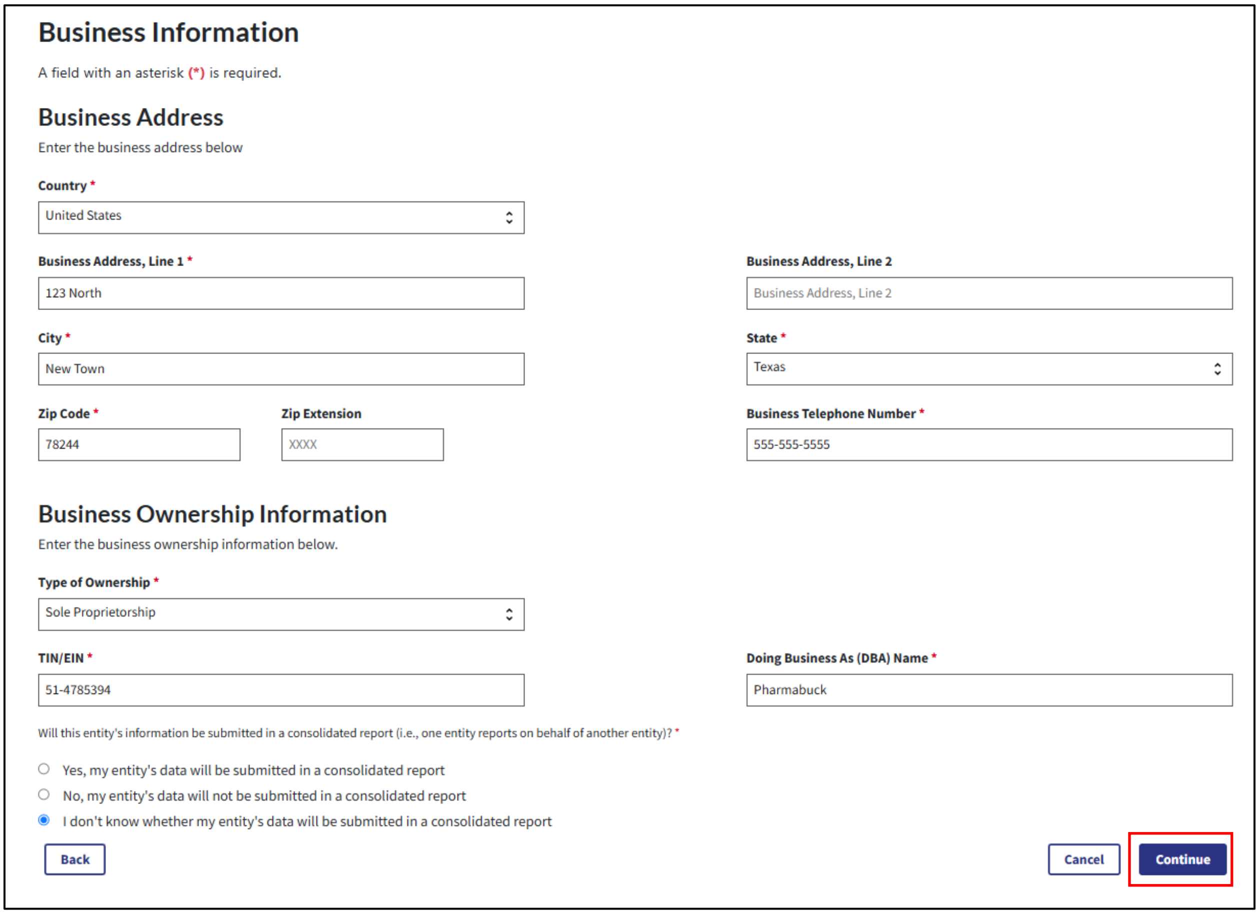


Figure 56: Points of Contact Page

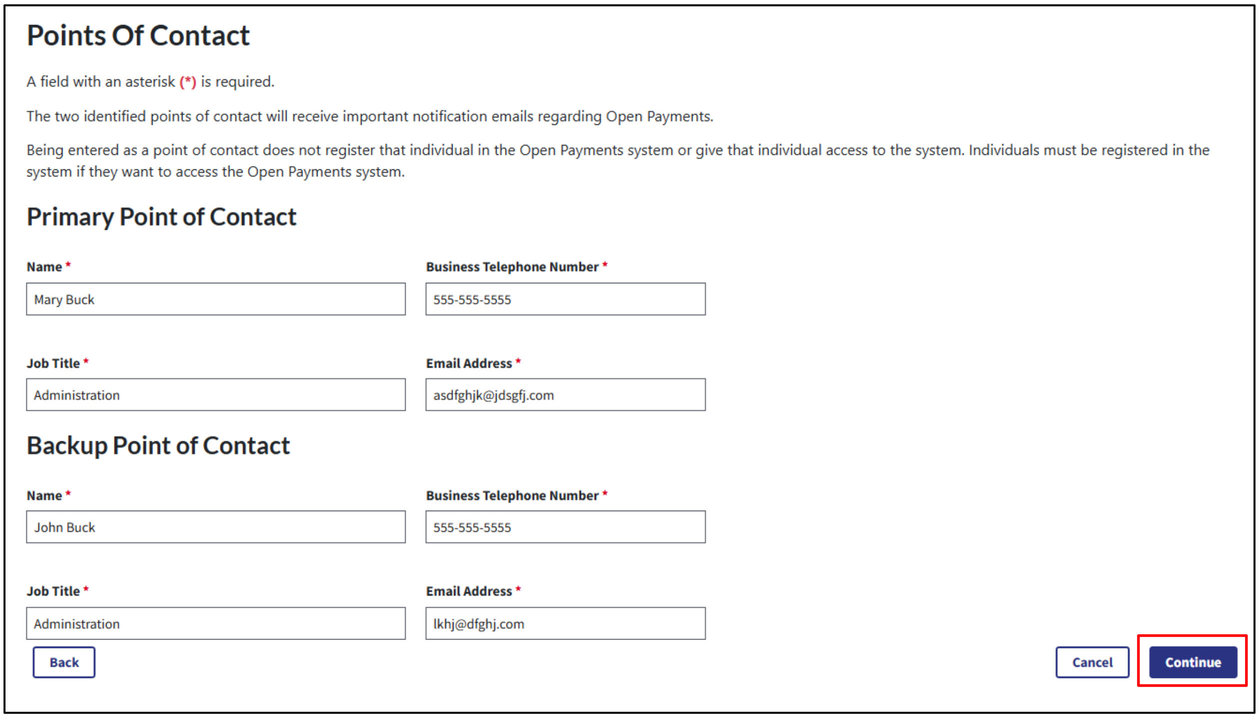
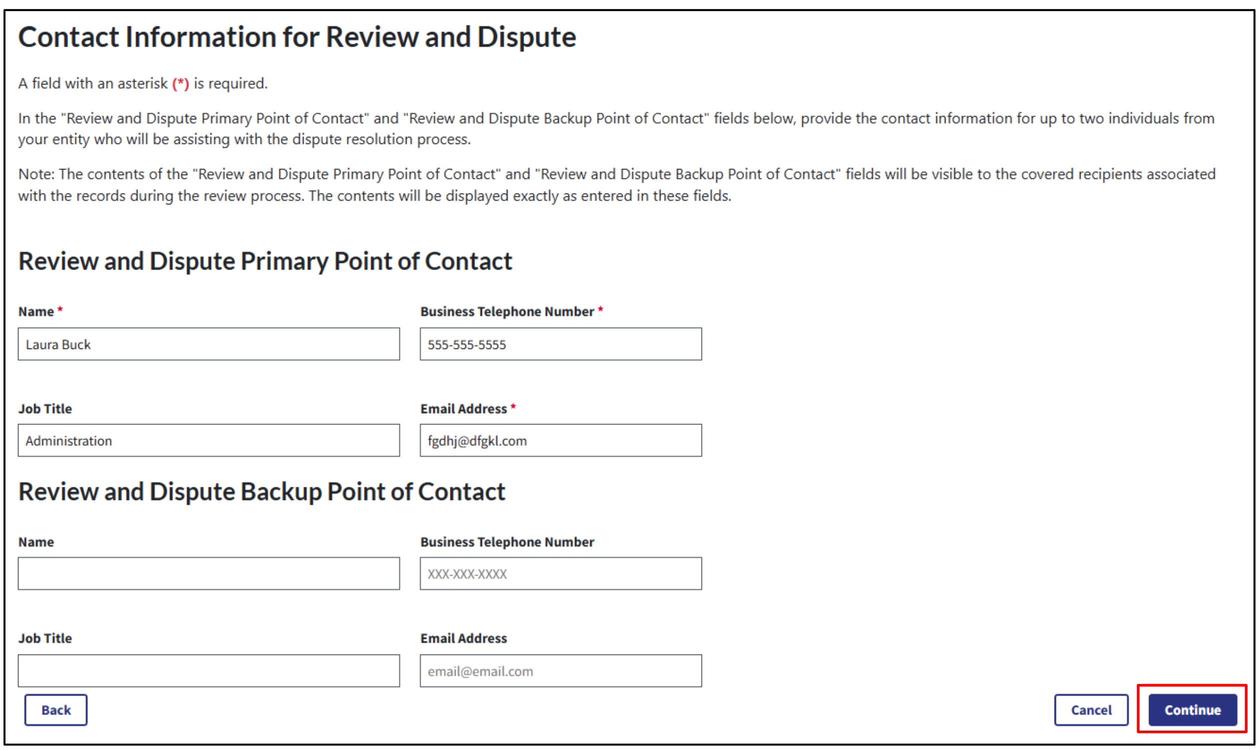


Figure 57: Contact Information for Review and Dispute Page

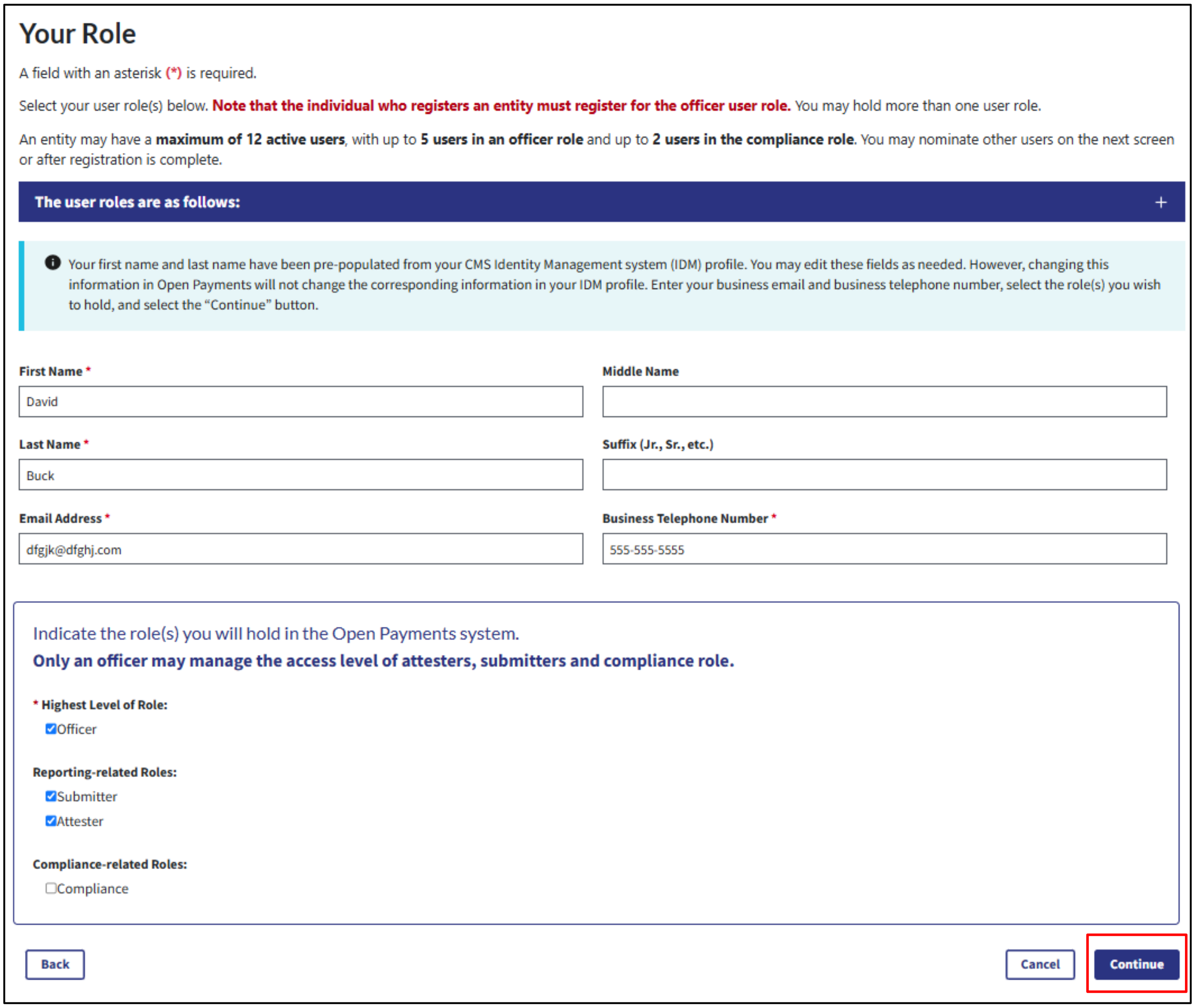


Step 8: Enter the required information and select the entity user roles **you** will be holding. For a description of user roles, see Section 3.5.

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, 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 58: Your Role Page



Your Role

A field with an asterisk (*) is required.

Select your user role(s) below. **Note that the individual who registers an entity must register for the officer user role.** You may hold more than one user role.

An entity may have a **maximum of 12 active users**, with up to **5 users in an officer role** and up to **2 users in the compliance role**. You may nominate other users on the next screen or after registration is complete.

The user roles are as follows: +

Your first name and last name have been pre-populated from your CMS Identity Management system (IDM) profile. You may edit these fields as needed. However, changing this information in Open Payments will not change the corresponding information in your IDM profile. Enter your business email and business telephone number, select the role(s) you wish to hold, and select the "Continue" button.

First Name * David

Middle Name

Last Name * Buck

Suffix (Jr., Sr., etc.)

Email Address * dfgjk@dfghj.com

Business Telephone Number * 555-555-5555

Indicate the role(s) you will hold in the Open Payments system.
Only an officer may manage the access level of attesters, submitters and compliance role.

*** Highest Level of Role:**
- [x] Officer

Reporting-related Roles:
- [x] Submitter
- [x] Attester

Compliance-related Roles:
- [ ] Compliance

Back | Cancel | Continue

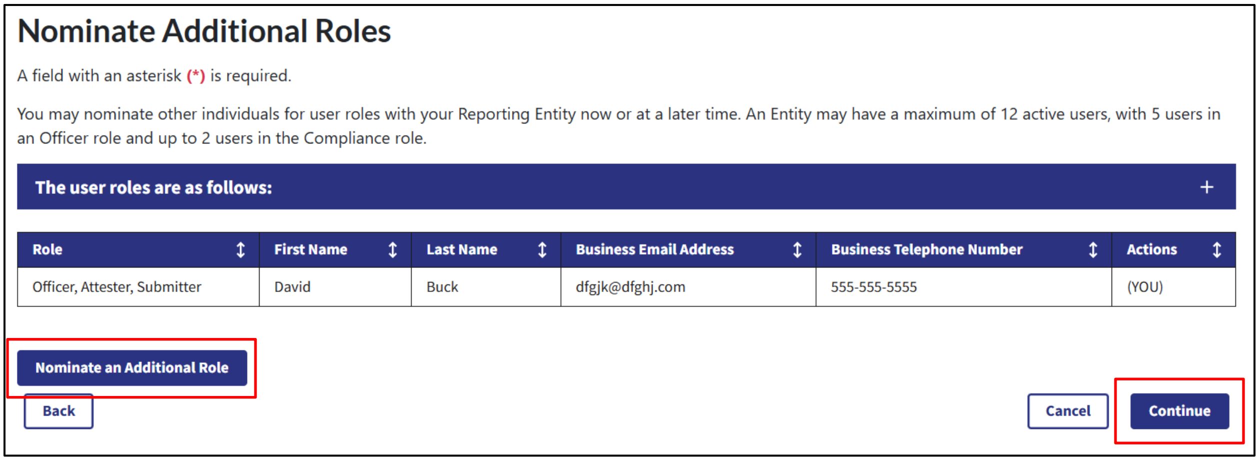
__Step 9:__ **At least one individual must be identified for officer, submitter, and attester roles in the Open Payments system during initial entity registration.** The system will not allow you to proceed without at least one individual associated with each user role except compliance. The system will allow registering an entity without assigning a user for the compliance role.

In the scenario shown, the user has selected officer, submitter, and attester, so it would not be required to nominate additional roles, though the user could, at this time.

You may now nominate additional individuals for the officer, submitter, attester, and compliance roles at this step. To add a nomination, select the **Nominate an Additional Role** button and proceed to Step 10. If you do not wish to nominate additional individuals, select the **Continue** button and proceed to Step 11.

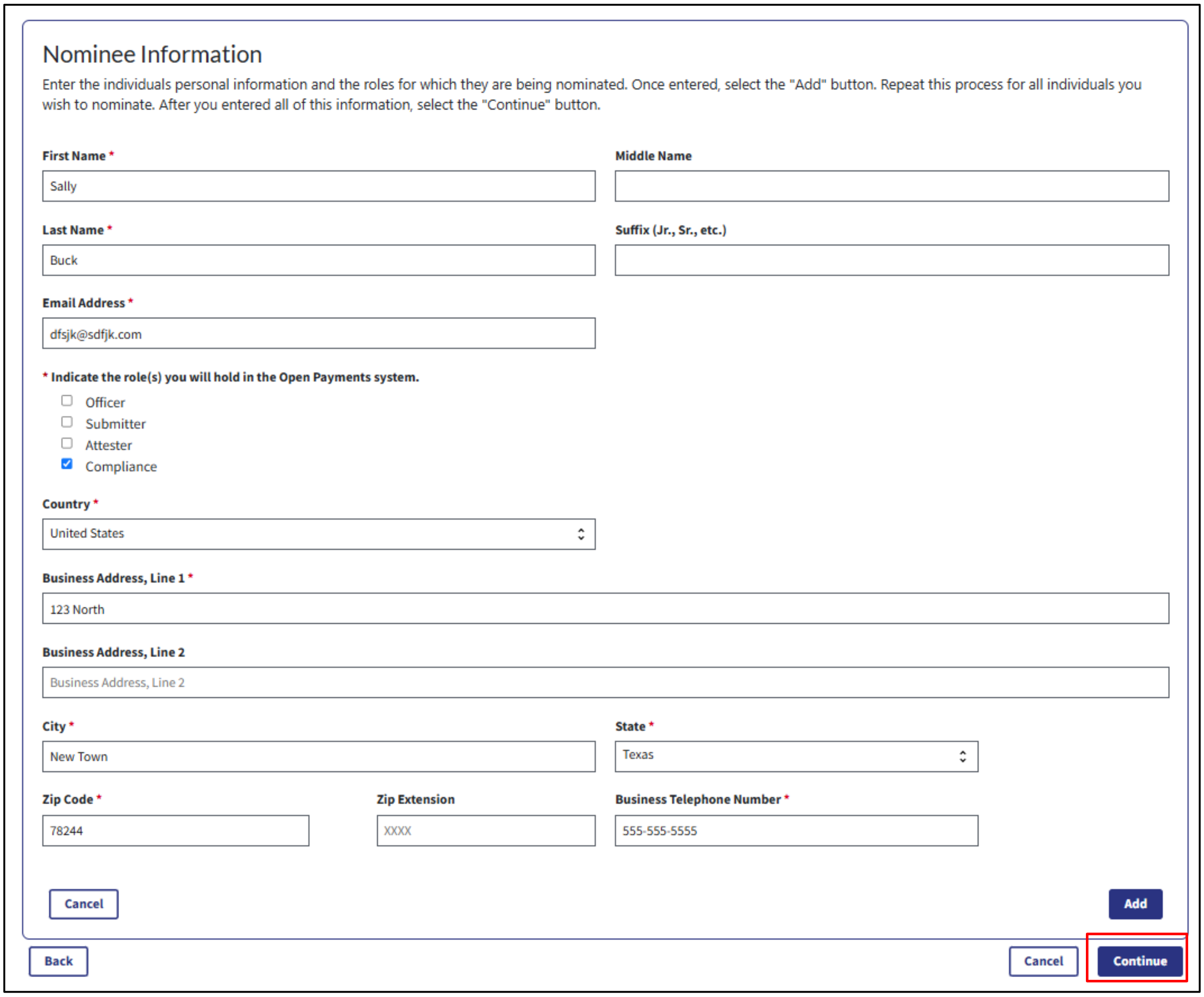
Refer to Section 3.3: Open Payments System Users and User Roles for more information on user roles.

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



Step 10: If you select **Nominate an Additional Role**, the page will expand to show nominee information fields that you will need to complete. 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.

Figure 60: 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.

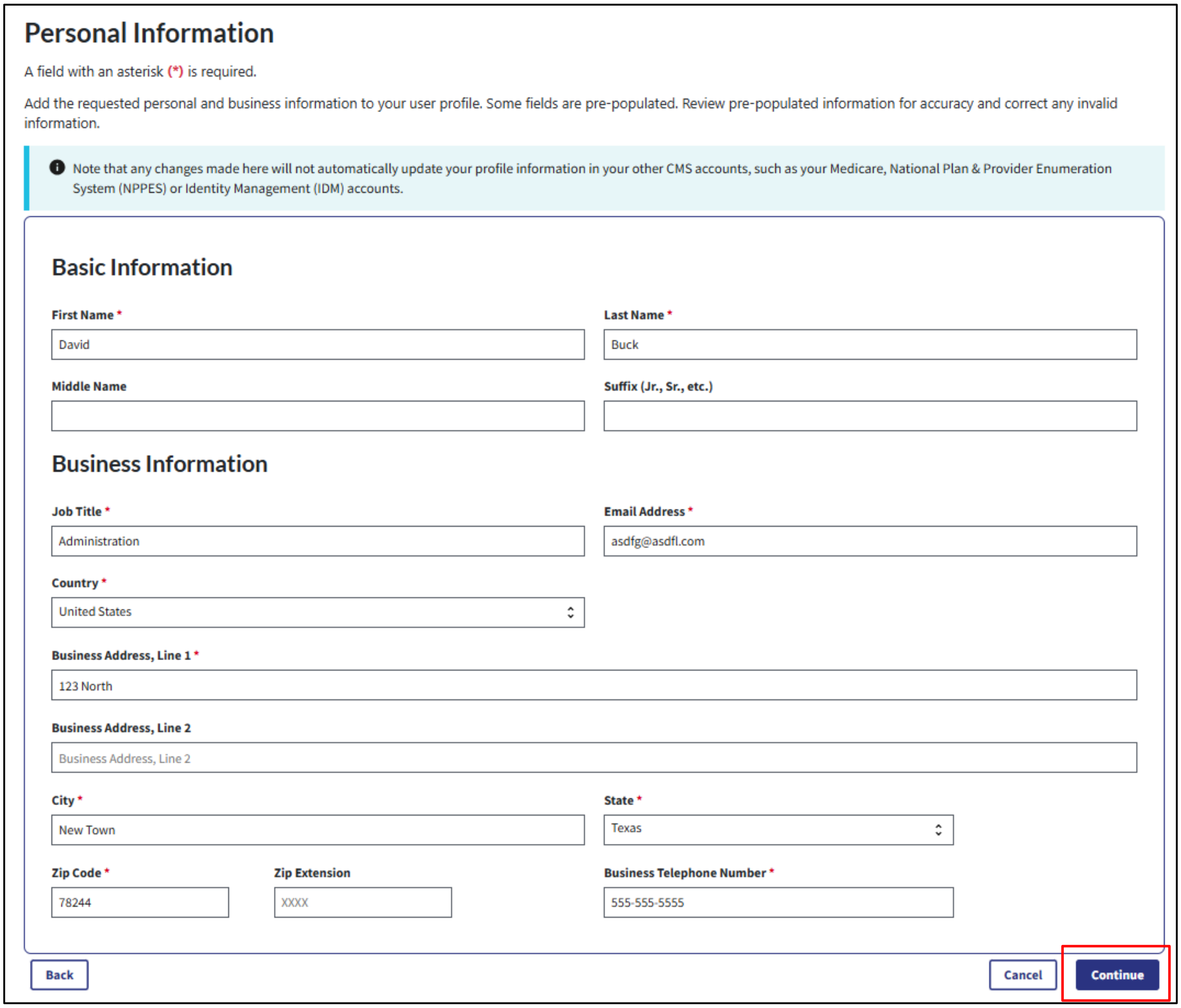
Individuals can be nominated for user roles after entity registration is complete and your entity is vetted.

The page will display a summary of all the individuals being nominated for user roles for this reporting entity. If you want to nominate additional users, select **Nominate an Additional Role**. Once you have entered all nominations you wish to include at this time, select the **Continue** button.

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 the required fields have been completed. Once your personal information has been entered, select **Continue**.

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

Figure 61: 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 62: Review and Submit Profile Page

Review and Submit Profile

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

Entity Information

Entity's Legal Name: Pharmabuck
Reporting Entity Type: Applicable Manufacturer
Business Type: Applicable manufacturer devices/medical supplies
Food & Drug Administration (FDA) Establishment Number:
Data Universal Number System (D-U-N-S Number):
URL of Parent Company: jahksjk@afghhjk.com

Business Address

Country: United States
Business Address, Line 1: 123 North
Business Address, Line 2:
City Name: New Town
State: Texas
Zip Code: 78244
Business Telephone Number: 555 555 5555

Business Ownership Information

Type of Ownership: Sole Proprietorship
Taxpayer Identification Number (TIN)/Employer Identification Number (EIN): 51 4785394
Doing Business As (DBA) Name: Pharmabuck

Will this entity's information be submitted in a consolidated report (i.e. one entity reports on behalf of another entity)?

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

Points of Contact

The two identified points of contact will receive important notification emails regarding Open Payments.

Being entered as a point of contact does not register that individual in the Open Payments System or give that individual access to the system. Individuals must be registered in the system if they want to access the Open Payments System.

Primary Point of Contact
Name: Mary Buck
Job Title: Administration
Business Telephone Number: 555 555 5555
Business Email Address: asdfghjk@jdsgfj.com

Backup Point of Contact
Name: John Buck
Job Title: Administration
Business Telephone Number: 555 555 5555
Business Email Address: lkhj@dfghj.com

Contact Information for Review and Dispute

The content of the Contact Information for Review and Dispute fields will be visible to the covered recipients associated with the records during the review process. The content will be displayed exactly as entered in this field.

Review and Dispute Primary Point of Contact
Name: Laura Buck
Job Title: Administration
Business Telephone Number: 555 555 5555
Business Email Address: fgdhj@dfgkl.com

Review and Dispute Backup Point of Contact
Name:
Job Title:
Business Telephone Number:
Business Email Address:

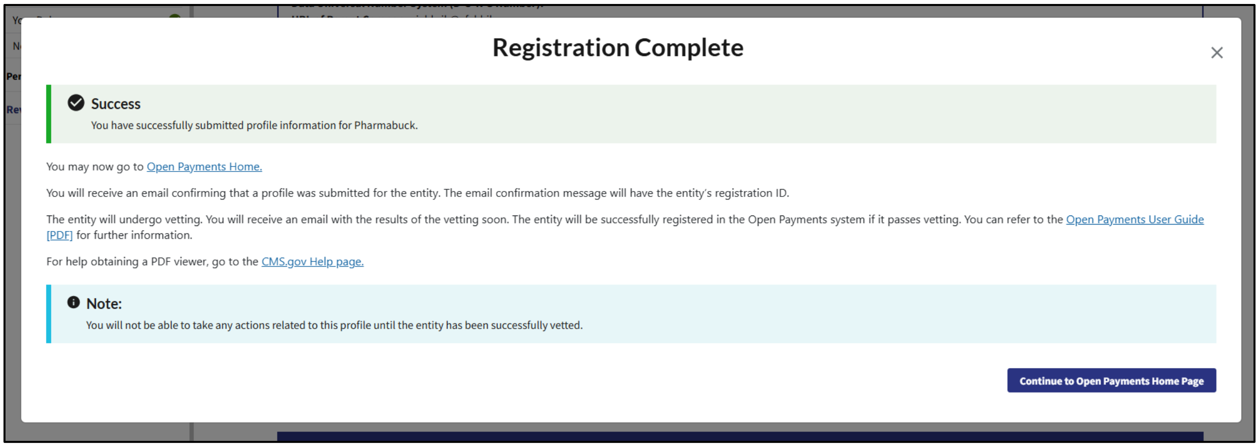
Nominations

Role:	First Name:	Last Name:	Business Email Address:
Officer, Attester, Submitter	David	Buck	asdfg@asdfl.com

Back | Cancel | Submit

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

Figure 63: Success Confirmed Page



An email notification with the entity's registration ID will be sent to you, the individuals you nominated for user roles during registration, and the individuals listed as points of contact for the reporting entity.

After both the reporting entity profile and officer profile are created, the Open Payments system vets the reporting entity based on the information you 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**.**

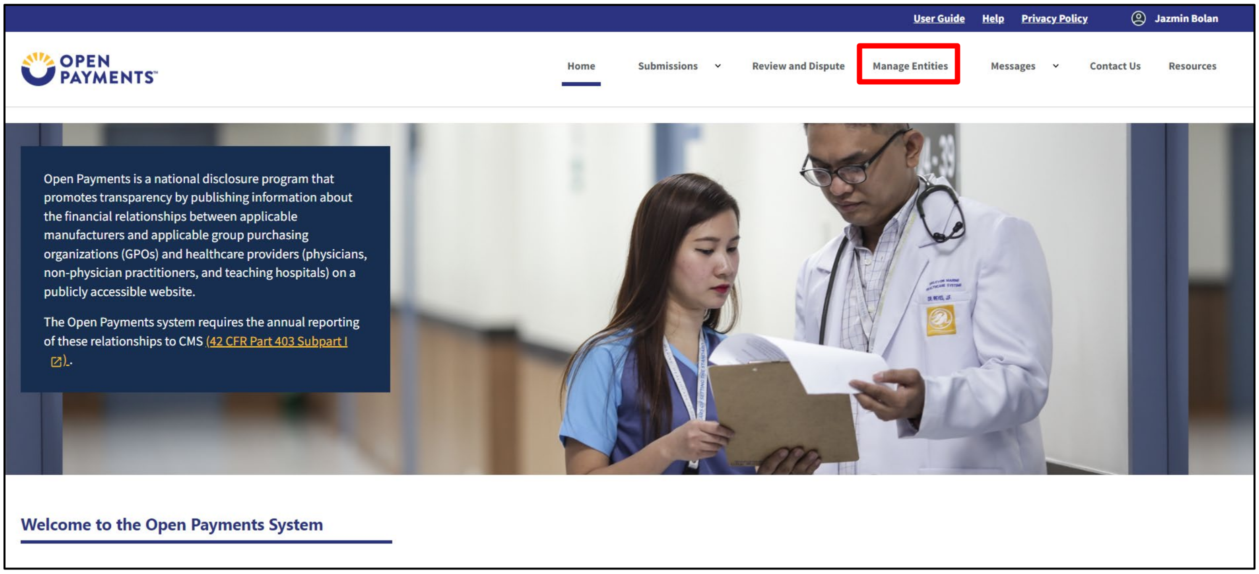
3.4b: Registering an Entity as a Returning System User

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

Step 1: Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials and navigate to the Open Payments home page.

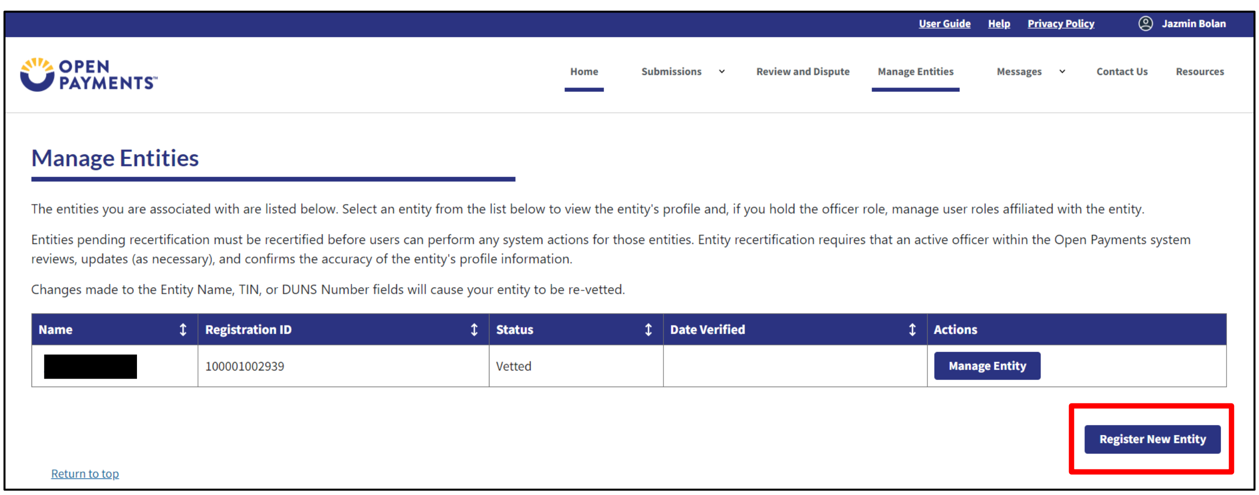
Select the **Manage Entities** tab from the header menu on the Open Payments home page.

Figure 64: Open Payments System Landing Page for Returning System Users



Step 2: Select **Register New Entity**.

Figure 65: Manage Entities Page



Step 3: The remaining steps are the same as when you registered a profile for your first entity. If you require a walkthrough for those steps, go to step 4 in Section 3.4a.

Section 3.5: Entity Recertification

Reporting entities who registered for Open Payments in a previous calendar year are required to recertify themselves each calendar year.

"Recertified" means you have reviewed the information in the entity profile for accuracy and have made any needed updates.

Only officers in the entity can complete recertification.

Entities may recertify beginning January 1st of each calendar year.

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.

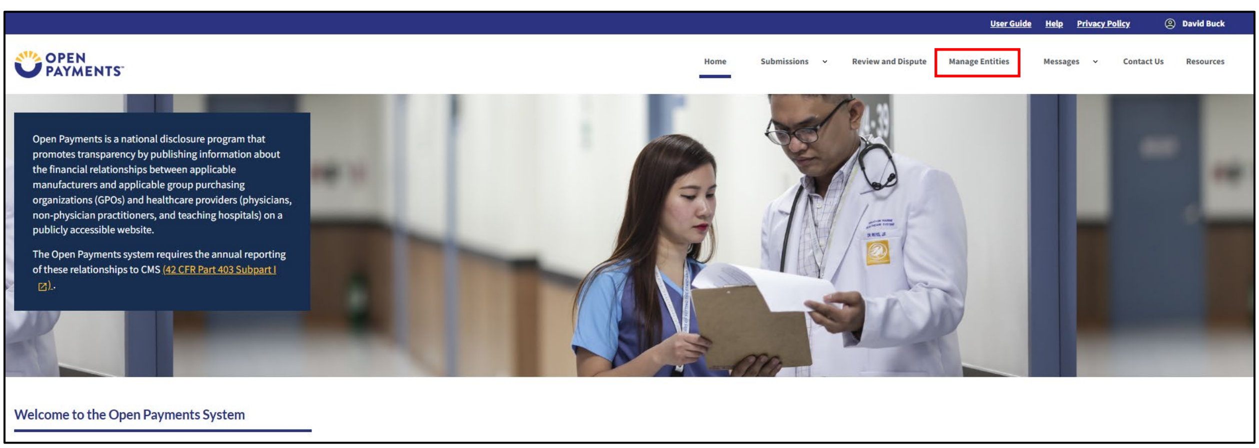
If you do not have an active officer for your entity, you will need to *call* the CMS Open Payments Help Desk at 1-855-326-8366 for assistance. For the TTY line, call 1-844-649-2766.

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.

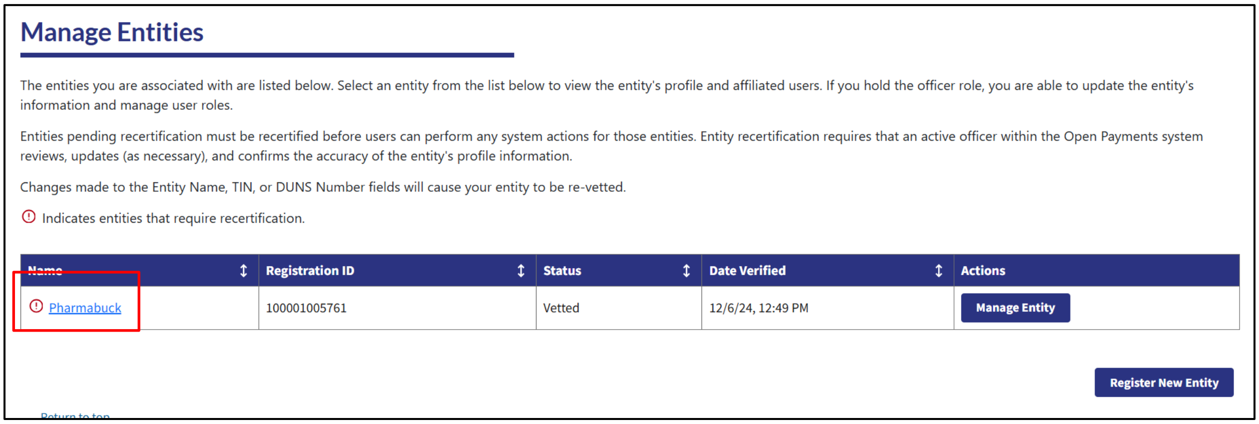
Step 1: Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials and select the **Manage Entities** tab from the header menu on the Open Payments home page.

Figure 66: Open Payments System Landing Page for Returning System Users



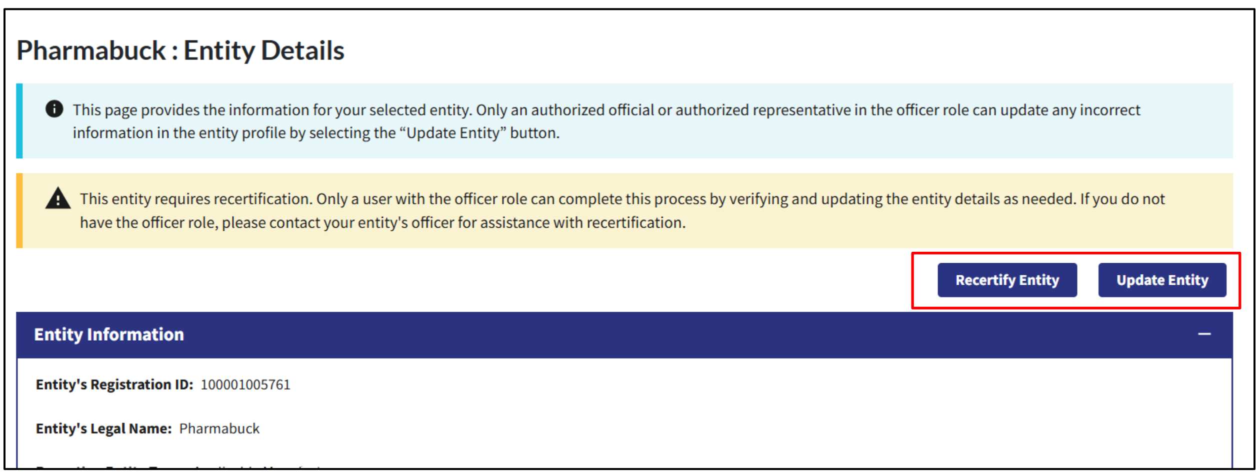
Step 2: Each entity with the red ! symbol requires recertification. Select the hyperlink for the entity you wish to recertify.

Figure 67: Manage Entities Page



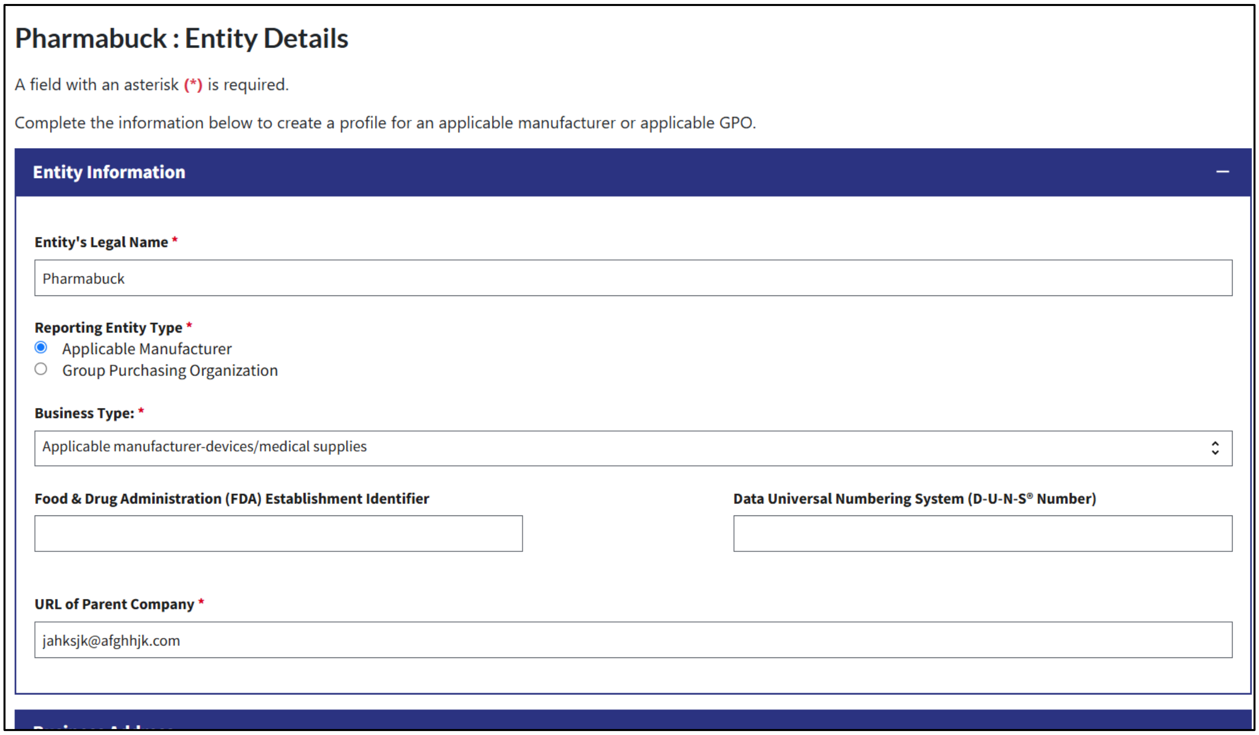
Step 3: Review the information on the Entity Details Page. You can select **Update Entity** without recertifying, or you may select **Recertify Entity** to move forward with recertifying your entity. When selecting **Recertify Entity**, you will have the opportunity to edit your entity's information. In this scenario, select the **Recertify Entity** button.

Figure 68: Entity Information Page



Step 4: Review the entity information and edit the fields as needed. 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.

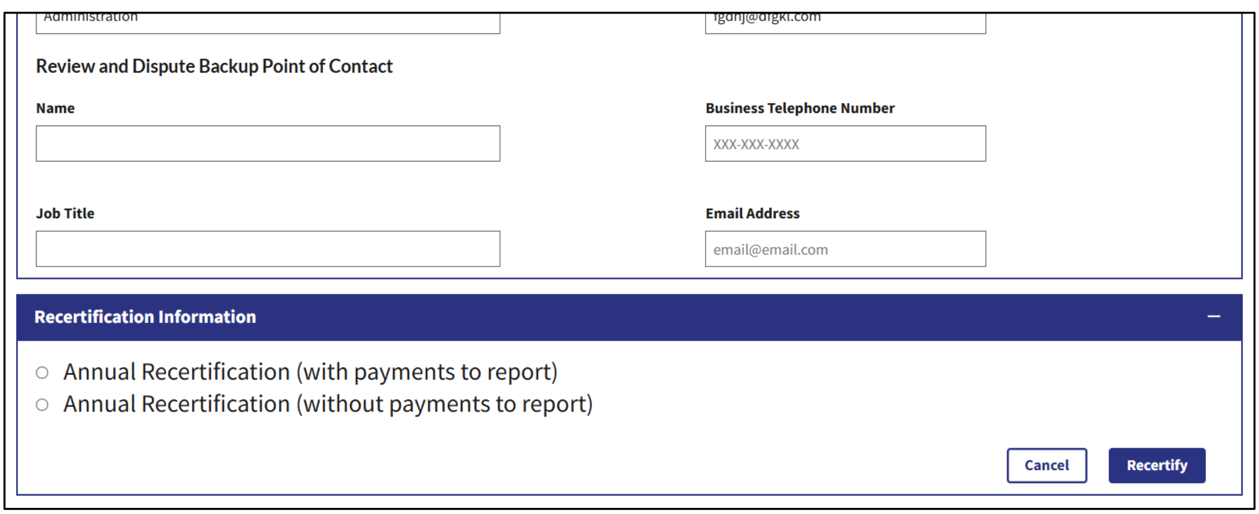
Figure 69: Top Portion of the Recertify Page



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

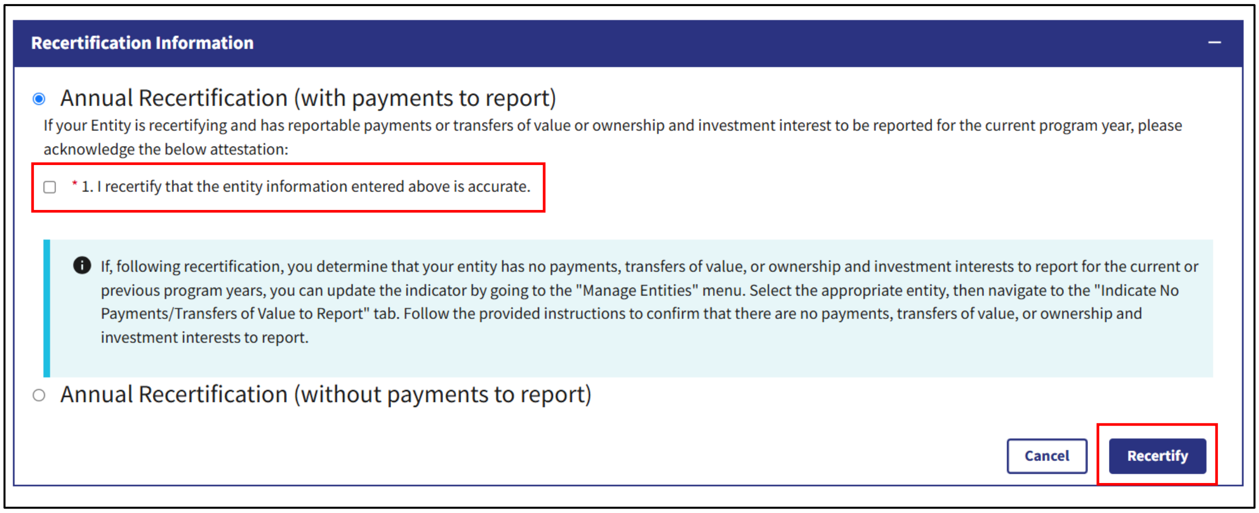
Once you have updated all the entity profile information, you can choose to recertify and attest that you have payments to report, or you have no payments to report. Select the box that applies to you and view the expanded page.

Figure 70: Bottom of Recertification Page



Step 5: If you selected the **Annual Recertification (with payments to report)** button, check the box that states your entity information is correct, then select **Recertify**. This completes your recertification.

Figure 71: Recertifying with Payments to Report



Step 6: If you are recertifying and wish to attest that you have no payments to report for this program year, select **Annual Recertification (without payments to report)**, and view the expanded screen.

If there are no payments to report, an officer may attest that there are no payments.

Attesting to no payments at this time does not prohibit your entity from reporting any payments that you may later find.

To attest to no payments for the current program year, check the four boxes, and select **Recertify**.

This will complete your recertification for the current year, and you attest that you have no payments to report.

Figure 72: Recertification with No Payments to Report

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 can 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").

The system will generate an email notification to the nominee once their nomination has been approved by an officer.

Any user 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.

If you have been nominated for a role in an entity, you will receive an email with instructions describing the process to accept the role. Once you receive the nomination notification, you must access the Open Payments system and either accept or reject the nomination. You have 10 calendar days to accept or reject the nomination. If you do not act 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 create an IDM registration, request access to Open Payments, complete a user profile, and, finally, gain access to the entity's profile. You may then 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 you have accepted the nomination.

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.

Reporting entities may have third parties serve in the submitter role. Third-party submitters may submit payments or other transfers of value on behalf of the entity. 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. If you self-nominate, you will receive an email once the officer has approved your request. The following figure depicts the self-nomination process.

Figure 73: Self-Nomination Process

To self-nominate for a role in an entity registered in the Open Payments system, you must access the Open Payments system and use the reporting entity's TIN/EIN to find the reporting entity in the Open Payments 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.

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 by an entity officer. 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 74: 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)

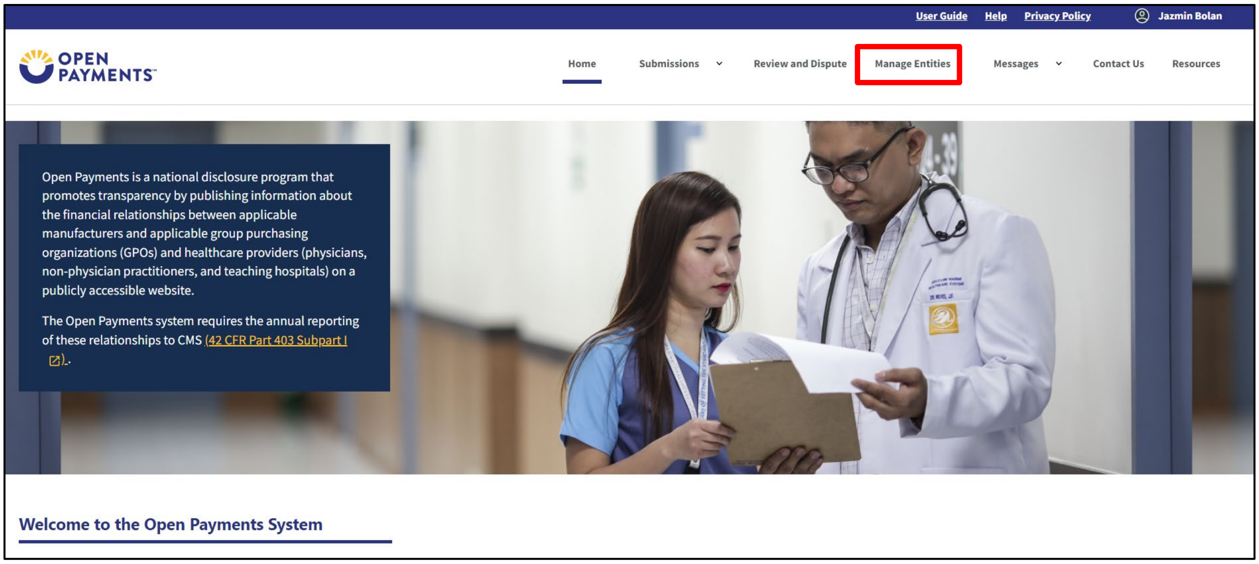
3.6a: Nominating Individuals for a Role with an Existing Reporting Entity

Nominations can be made when registering a new reporting entity or after the entity has been successfully registered. Anyone holding any role in the entity may nominate someone for a role in that entity. If someone other than an entity officer nominates someone, an entity officer must approve the nomination prior to the nomination being sent to the nominee.

To nominate individuals after an entity has been successfully registered, follow the process detailed below:

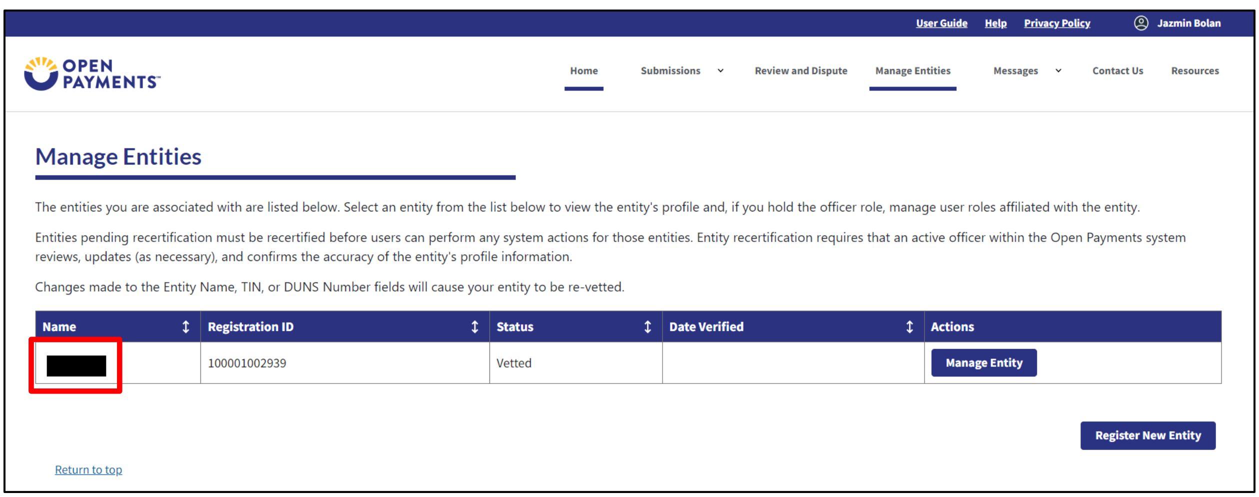
Step 1: Log in to Open Payments at https://openpayments.system.cms.gov using your IDM credentials, navigate to the Open Payments home page, and select the **Manage Entities** tab from the header menu on the Open Payments home page.

Figure 75: Open Payments System Landing Page for Returning System Users



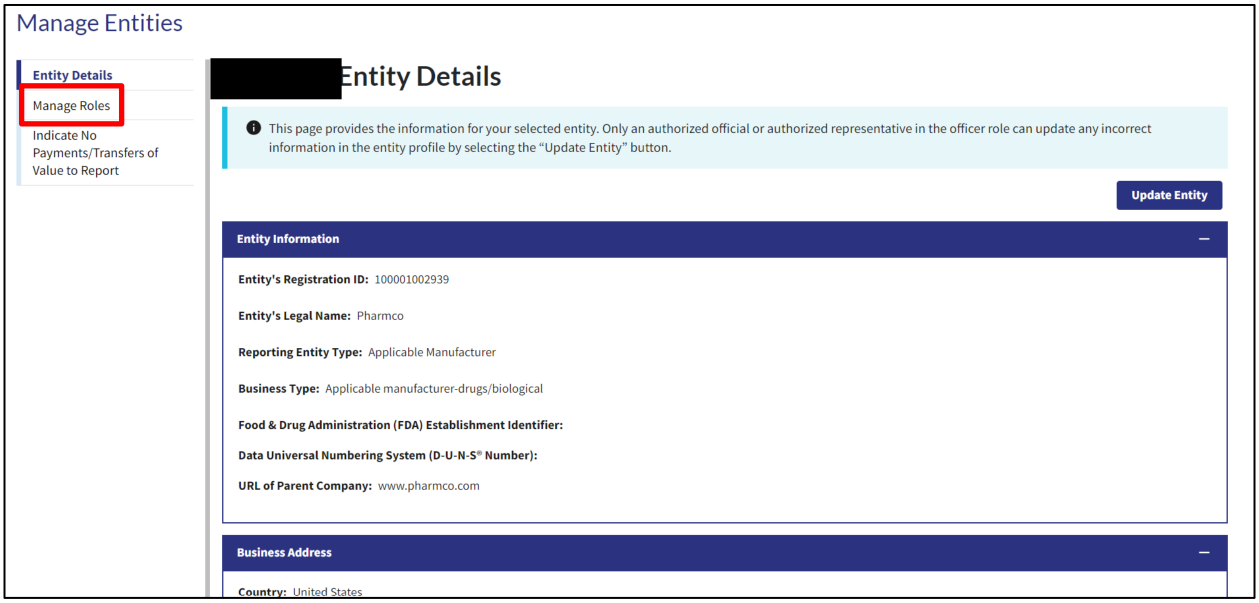
Step 2: On the "Manage Entities" page, indicate the reporting entity for which you will nominate an individual for a user role by selecting the reporting entity's hyperlinked name.

Figure 76: Manage Entities Page



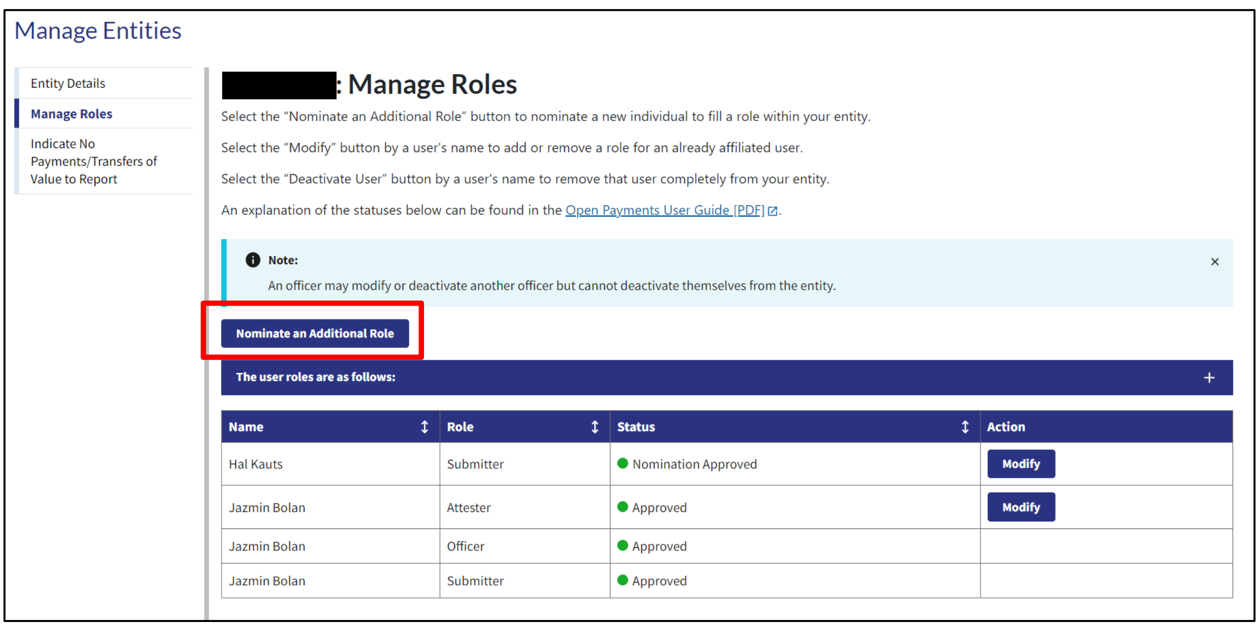
Step 3: Select the **Manage Roles** link on the left side of the screen.

Figure 77: Manage Entities Page



Step 4: Select **Nominate an Additional Role**.

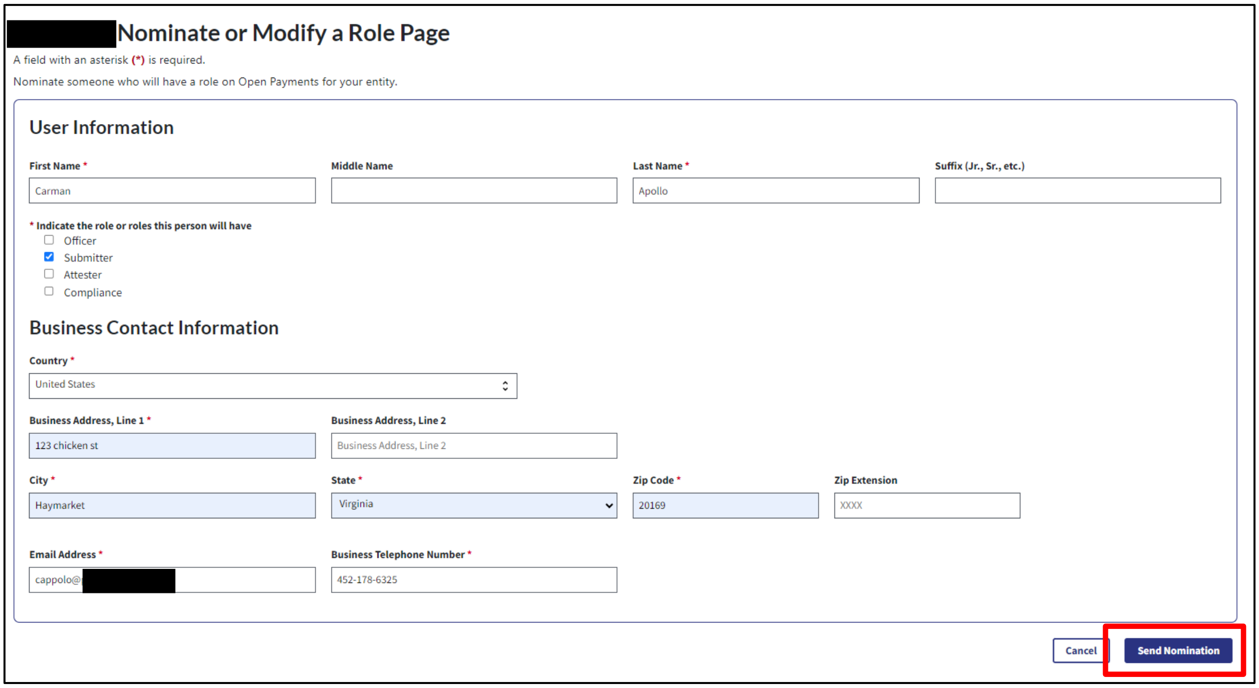
Figure 78: Entities Manage Roles Tab



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

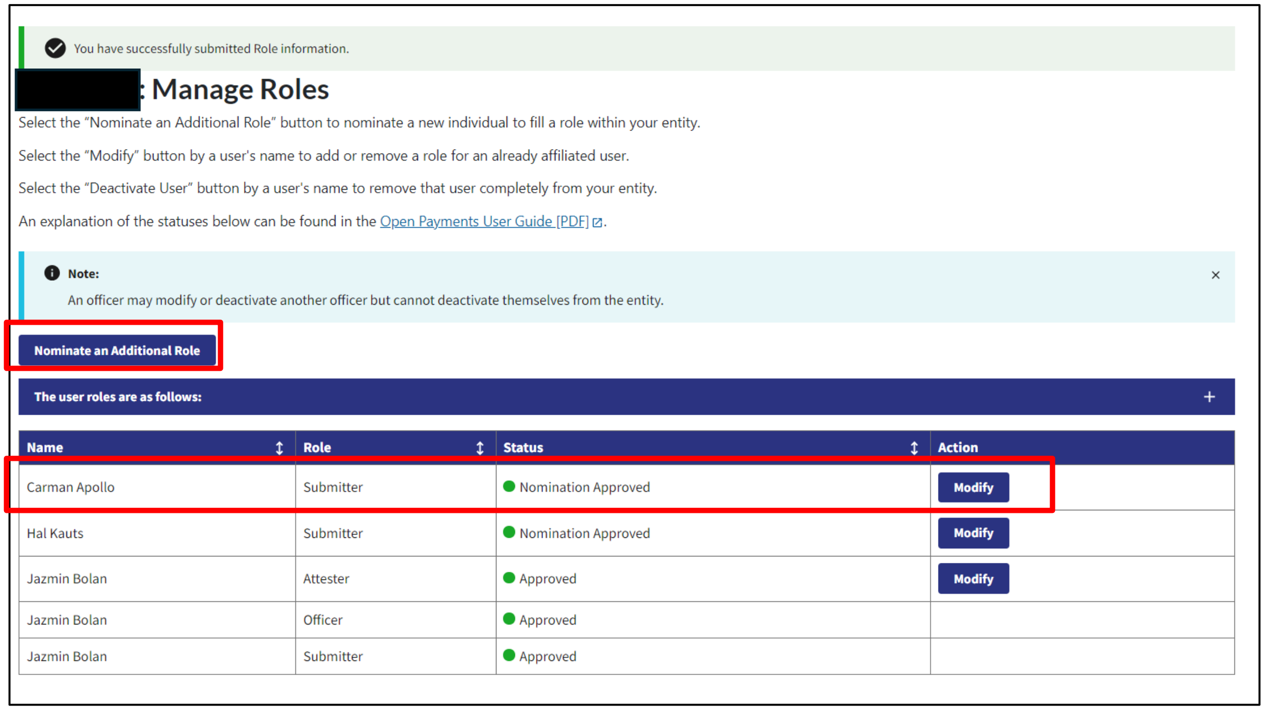
Note: Selecting the "Cancel" button will cause you to lose all data entered.

Figure 79: Nominate New Role Page



The on-screen message below will appear once you have completed the nomination. Note the addition of the nominee in the list.

Figure 80: Entities 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 and 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 acted 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), or request that you be nominated again.

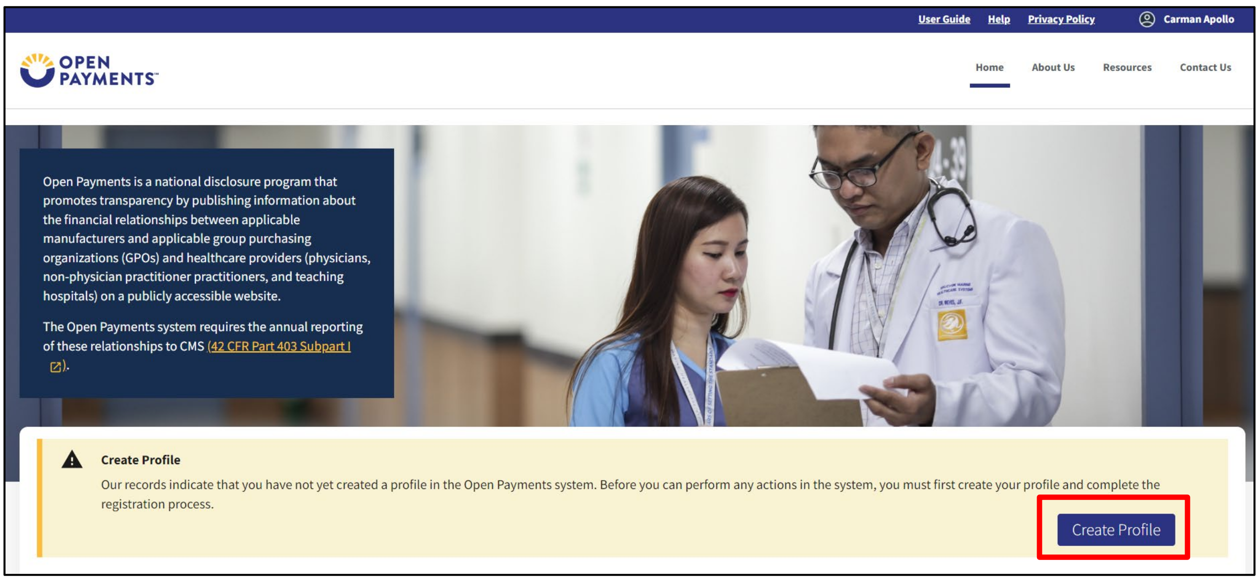
The process for accepting nominations is outlined in **Figure 82**, below.

Figure 81: Accepting Nominations

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

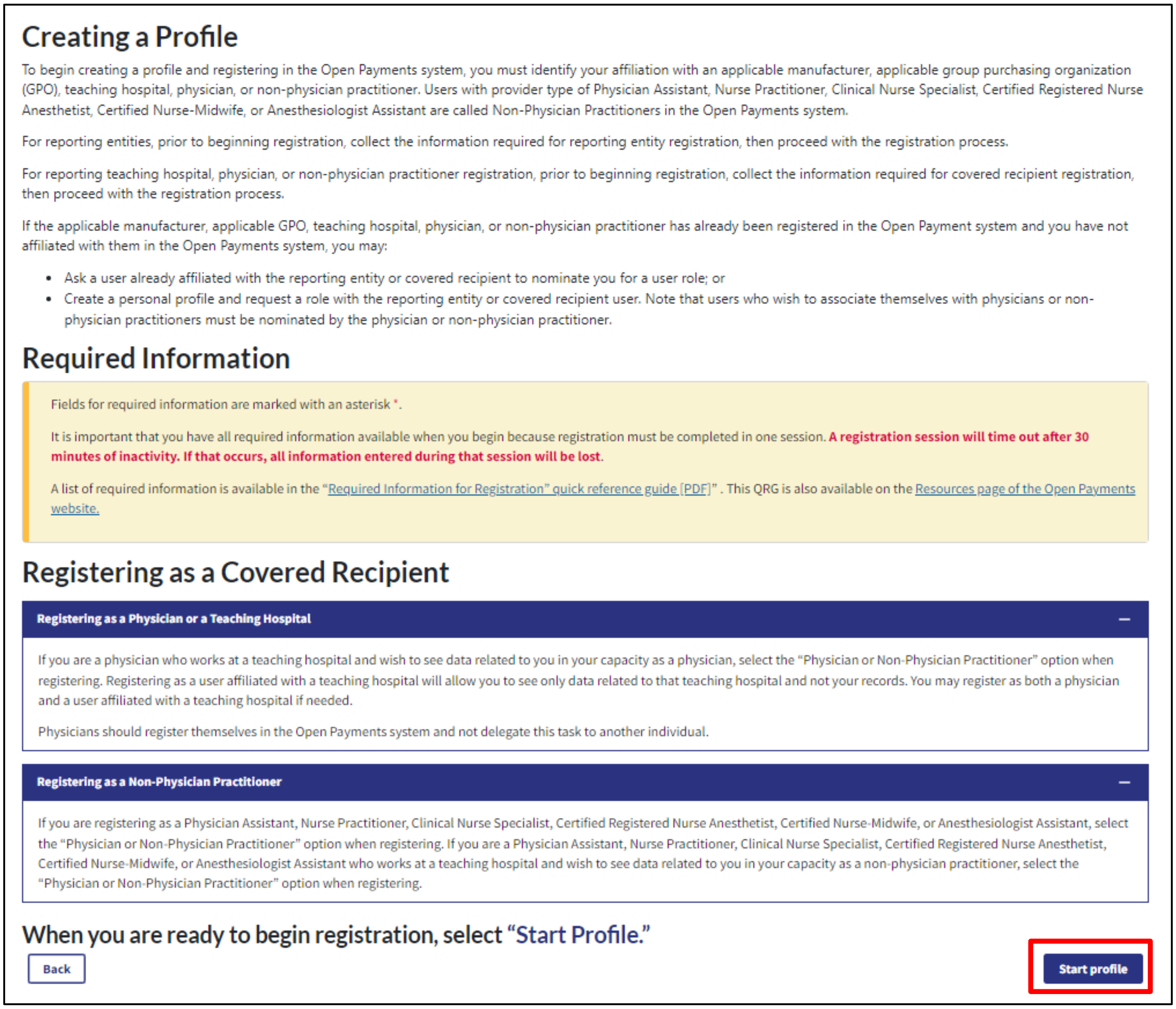
__Step 1:__ First, you will need to create an account in the CMS Identity Management (IDM) system (see section 3.1 and 3.2b, above), and request access to Open Payments. Once you have done that, log in at https://openpayments.system.cms.gov using your IDM credentials and select **Create Profile**.

Figure 82: Open Payments System Landing Page for First-Time System Users



__Step 2:__ Read the instructions on the "Creating a Profile" page. Once done, select **Start Profile** at the bottom of the page.

Figure 83: Create Profile Page



Creating a Profile

To begin creating a profile and registering in the Open Payments system, you must identify your affiliation with an applicable manufacturer, applicable group purchasing organization (GPO), teaching hospital, physician, or non-physician practitioner. Users with provider type of Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist, Certified Nurse-Midwife, or Anesthesiologist Assistant are called Non-Physician Practitioners in the Open Payments system.

For reporting entities, prior to beginning registration, collect the information required for reporting entity registration, then proceed with the registration process.

For reporting teaching hospital, physician, or non-physician practitioner registration, prior to beginning registration, collect the information required for covered recipient registration, then proceed with the registration process.

If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has already been registered in the Open Payment system and you have not affiliated with them in the Open Payments system, you may:

- Ask a user already affiliated with the reporting entity or covered recipient to nominate you for a user role; or
- Create a personal profile and request a role with the reporting entity or covered recipient user. Note that users who wish to associate themselves with physicians or non-physician practitioners must be nominated by the physician or non-physician practitioner.

Required Information

Fields for required information are marked with an asterisk *.

It is important that you have all required information available when you begin because registration must be completed in one session. **A registration session will time out after 30 minutes of inactivity. If that occurs, all information entered during that session will be lost.**

A list of required information is available in the "Required Information for Registration" quick reference guide [PDF]" . This QRG is also available on the Resources page of the Open Payments website.

Registering as a Covered Recipient

Registering as a Physician or a Teaching Hospital –

If you are a physician who works at a teaching hospital and wish to see data related to you in your capacity as a physician, select the "Physician or Non-Physician Practitioner" option when registering. Registering as a user affiliated with a teaching hospital will allow you to see only data related to that teaching hospital and not your records. You may register as both a physician and a user affiliated with a teaching hospital if needed.

Physicians should register themselves in the Open Payments system and not delegate this task to another individual.

Registering as a Non-Physician Practitioner –

If you are registering as a Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist, Certified Nurse-Midwife, or Anesthesiologist Assistant, select the "Physician or Non-Physician Practitioner" option when registering. If you are a Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist, Certified Nurse-Midwife, or Anesthesiologist Assistant who works at a teaching hospital and wish to see data related to you in your capacity as a non-physician practitioner, select the "Physician or Non-Physician Practitioner" option when registering.

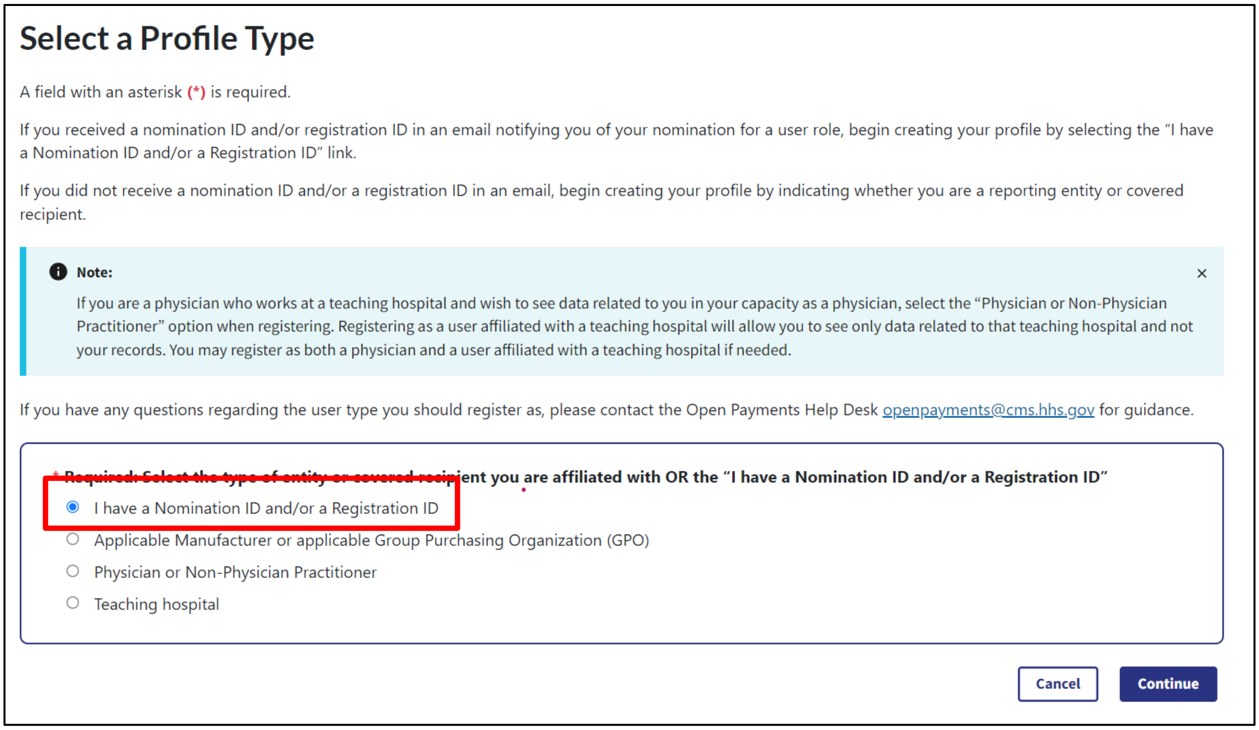
When you are ready to begin registration, select "Start Profile."

Back

Start profile

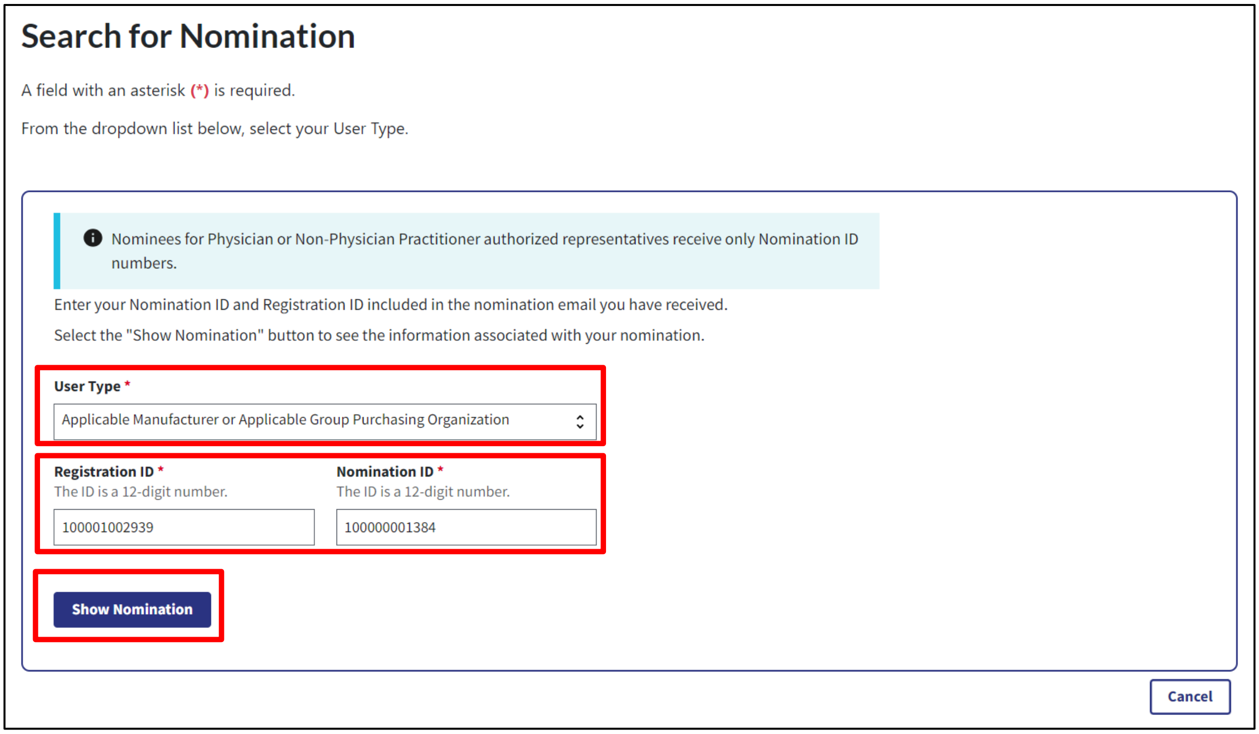
Step 3: Select the **I have a Nomination ID and/or a Registration ID** link on the "Select Profile Type" page.

Figure 84: Select Profile Type Page



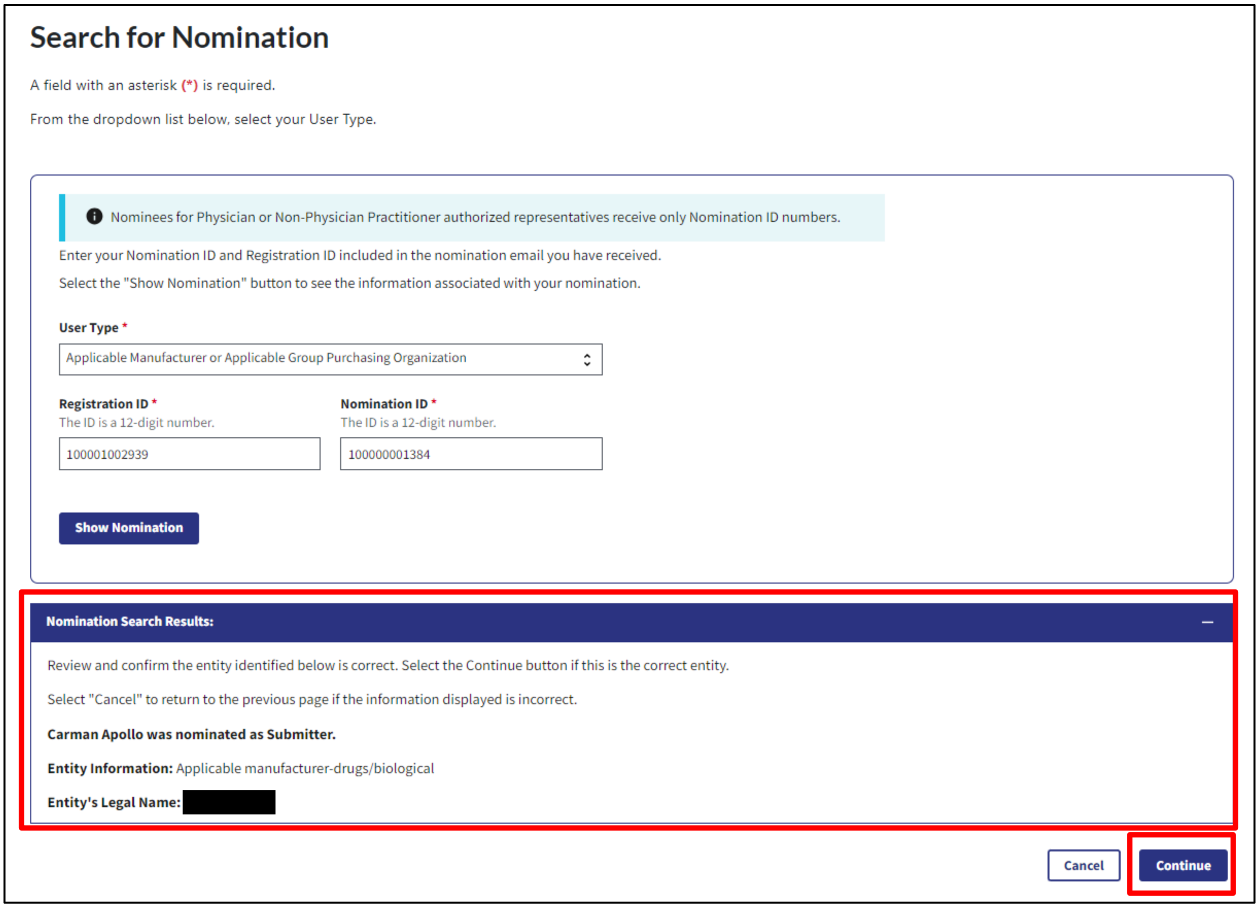
Step 4: Select the User Type "Applicable Manufacturer or Applicable GPO." Enter the registration ID and nomination ID that you received in the nomination notification email and then select **Show Nomination**.

Figure 85: 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 86: Search for Nomination Page

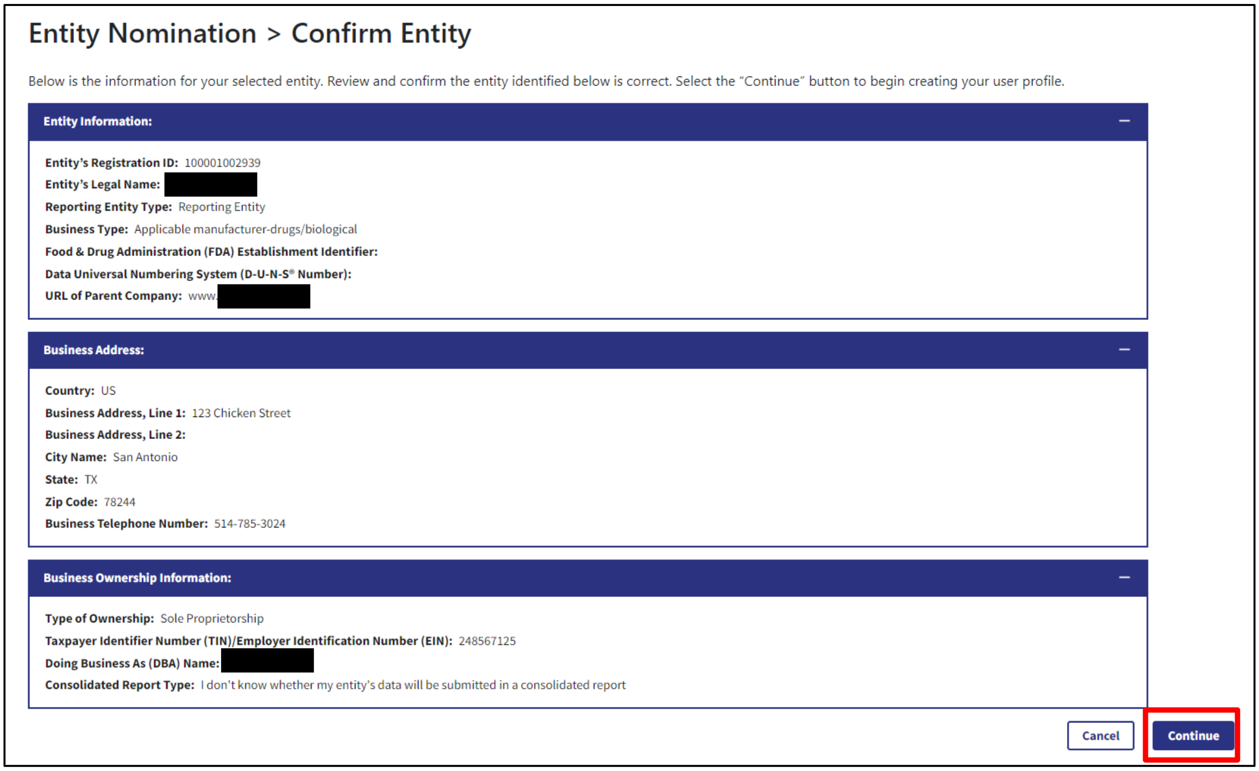


<u>Step 6:</u> Review and confirm the reporting entity information displayed on the page.

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 87: Confirm Entity Page

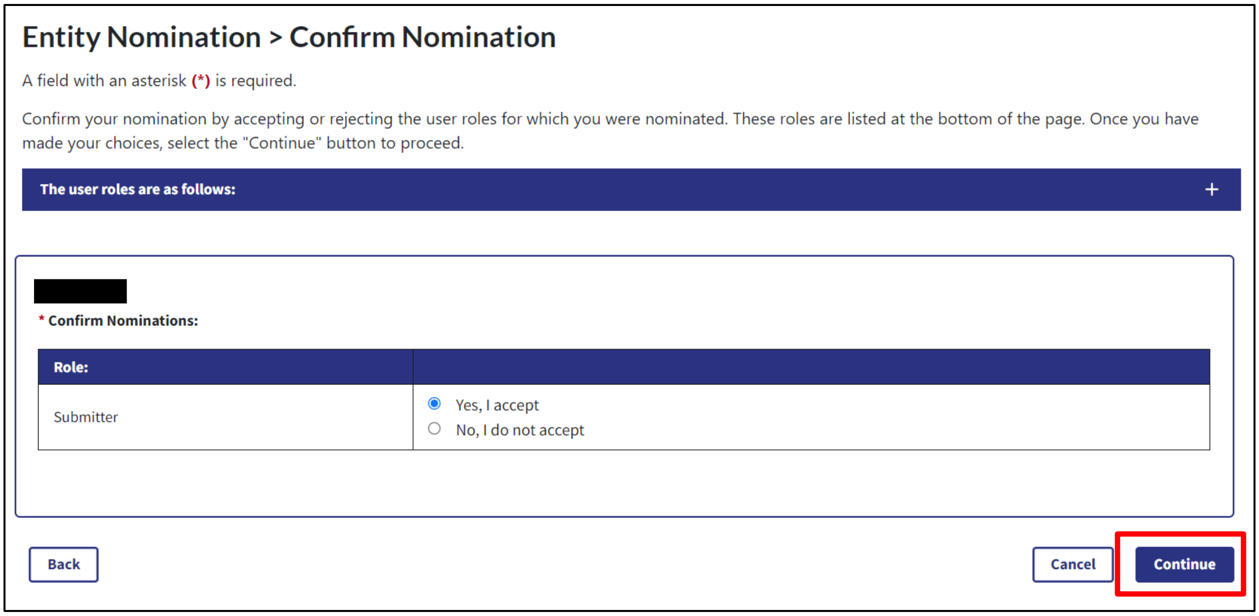


Step 7: Select "Yes, I accept" for roles you accept and "No, I do not accept" for roles you do not accept.

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.

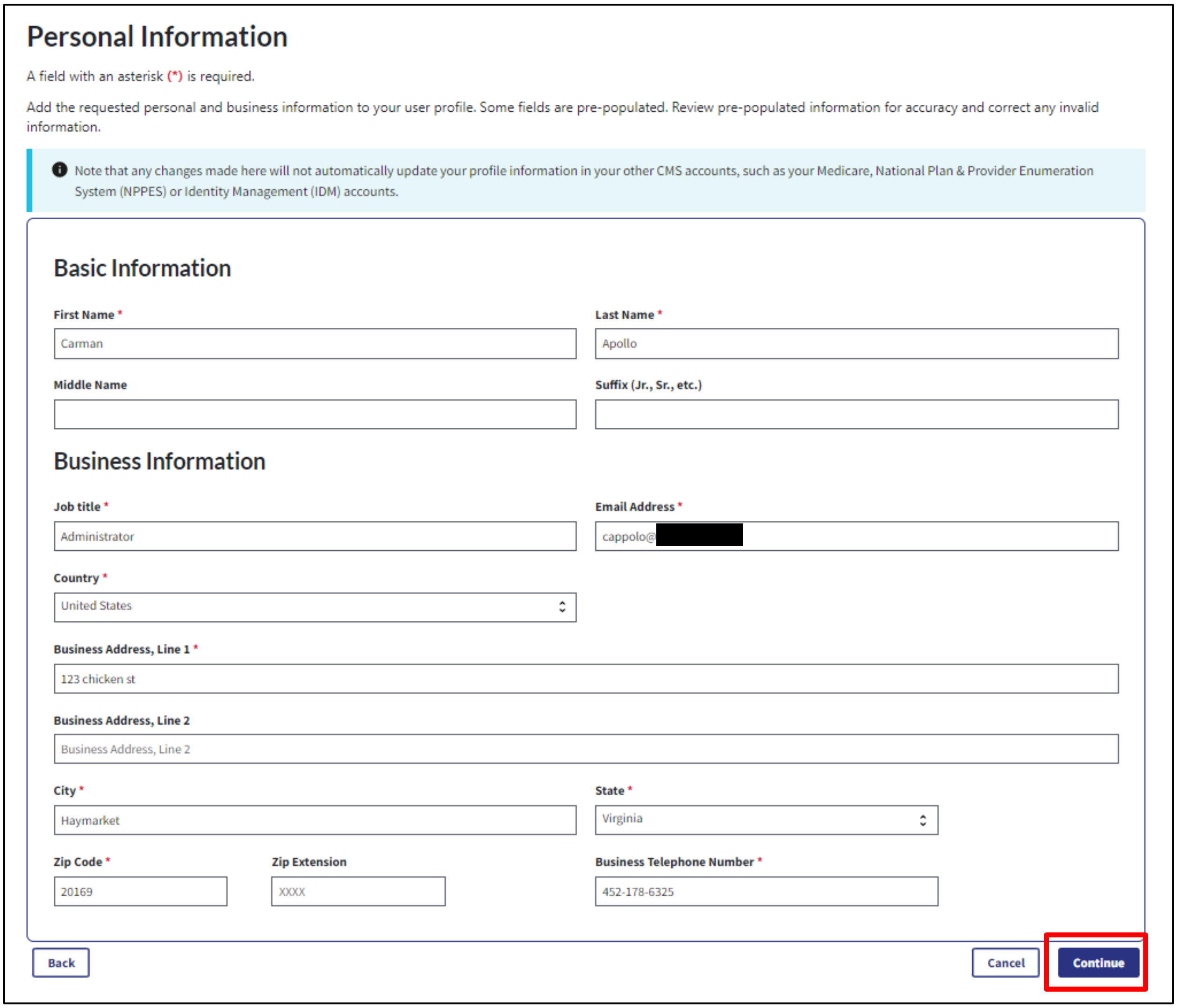
If you accept one or all roles and select **Continue**, you will continue the nomination confirmation process.

Figure 88: Confirm Nomination Page



Step 8: Enter the requested information and select **Continue**.

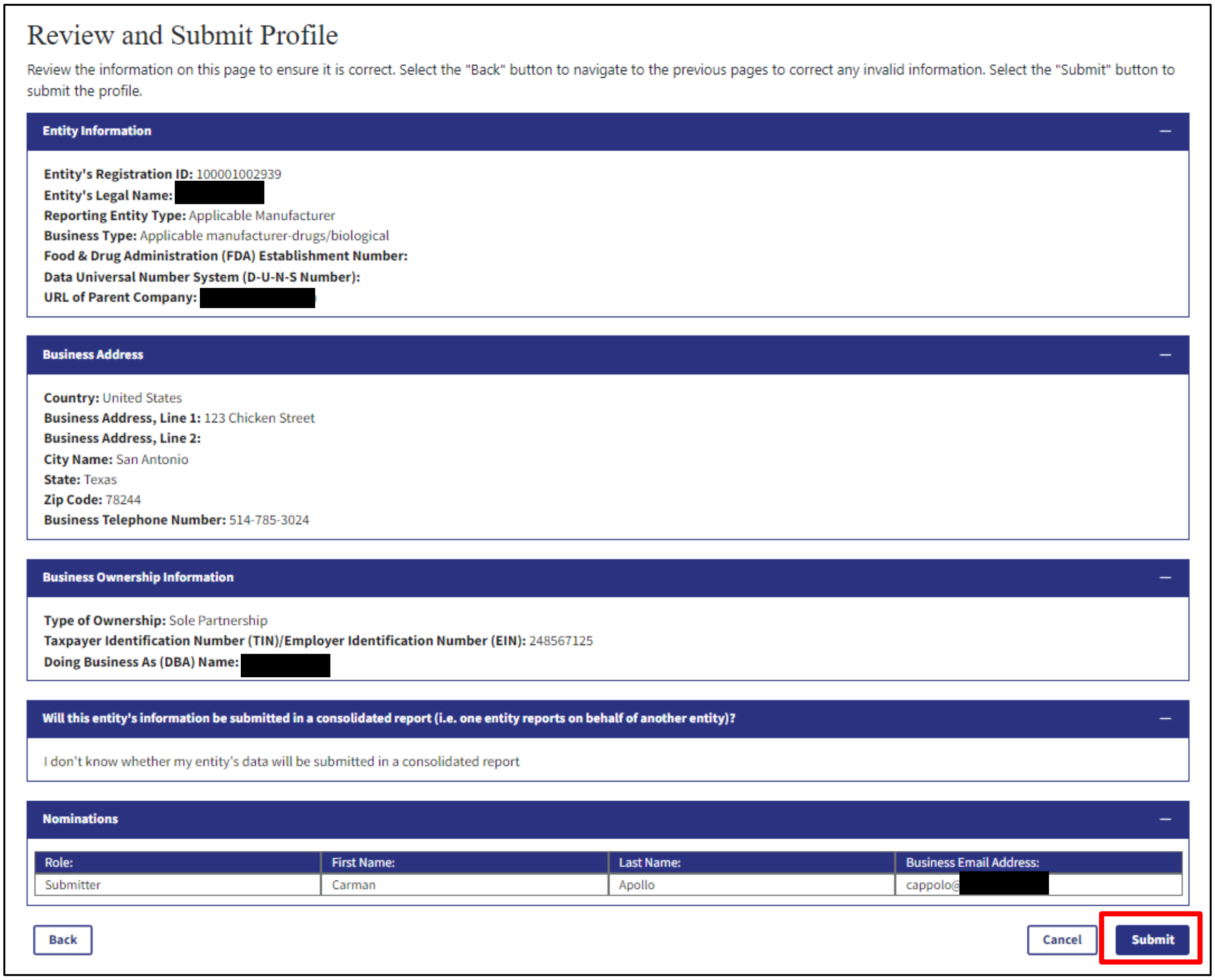
Figure 89: Enter Personal Information Page



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**. You will receive confirmation after selecting **Continue**.

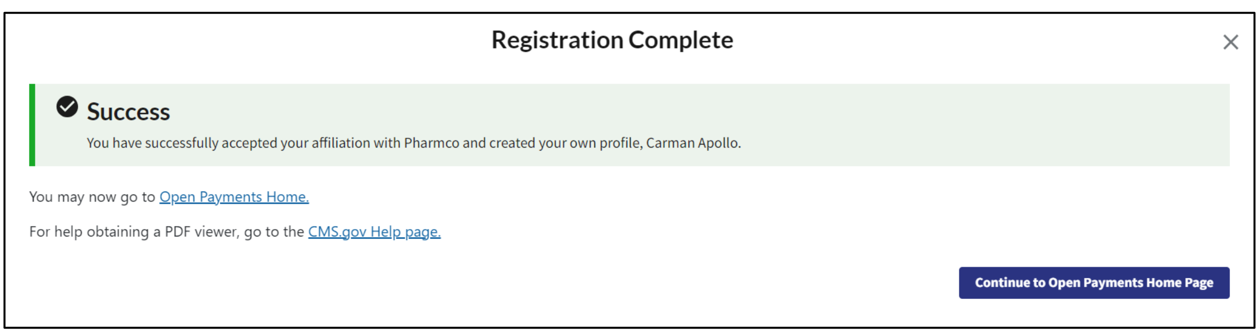
Figure 90: Review and Submit Profile Page.



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

Notification emails will be sent to all users who hold the role of officer with that entity that you have accepted your nomination.

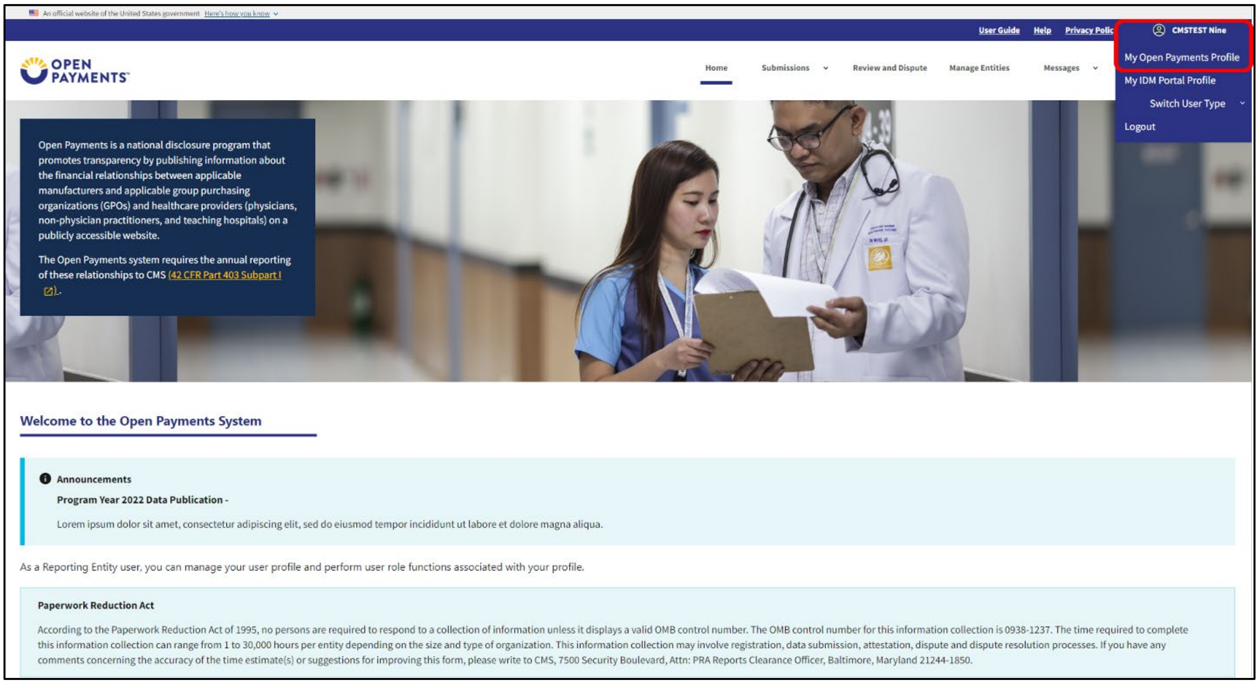
Figure 91: Registration Success



3.6c: Accepting a Nomination: Returning System Users

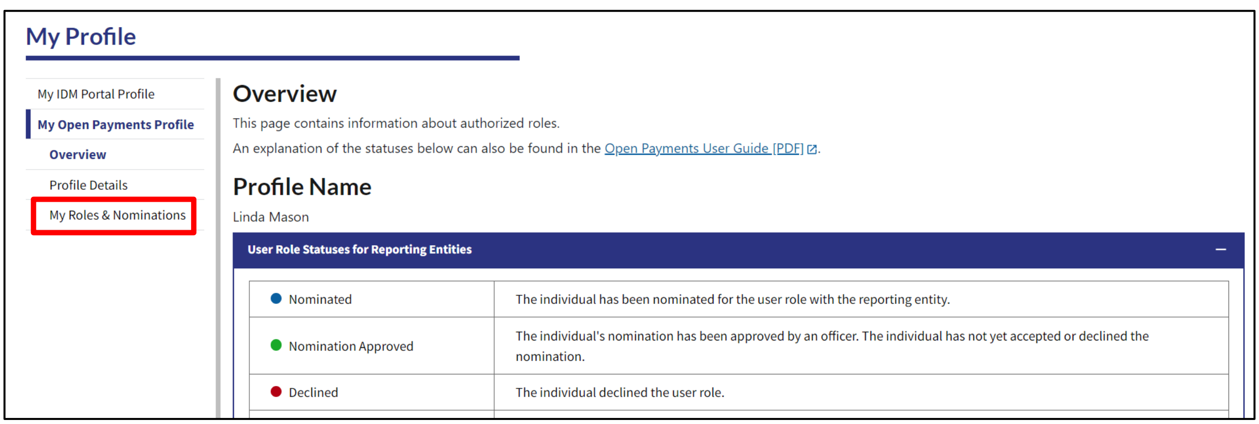
Step 1: Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials and select **My Open Payments Profile** from the header menu on the Open Payments home page.

Figure 92: Open Payments System Landing Page for Returning System Users



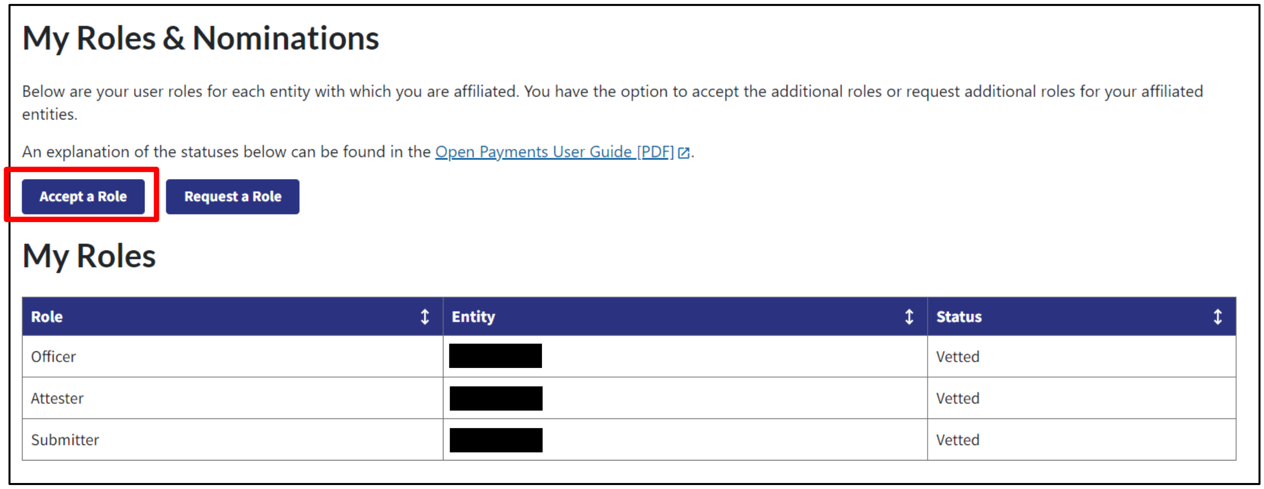
Step 2: Select the My Roles and Nominations link.

Figure 93: My Profile Page



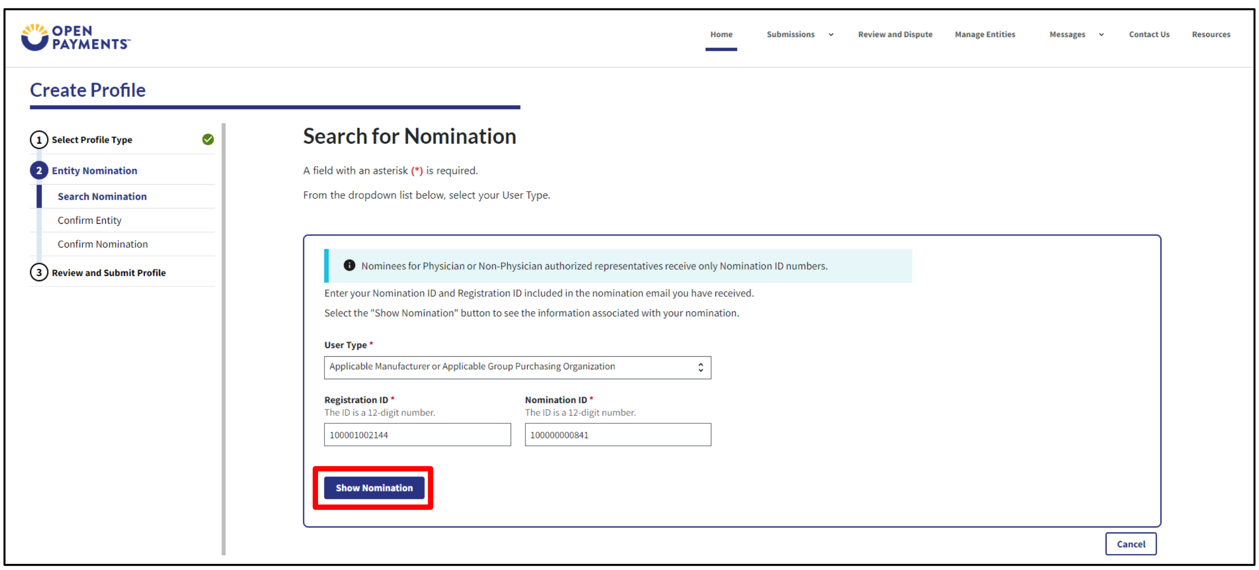
<u>Step 3:</u> On the "My Roles and Nominations" page, select **Accept a Role**.

Figure 94: My Roles and Nominations Page



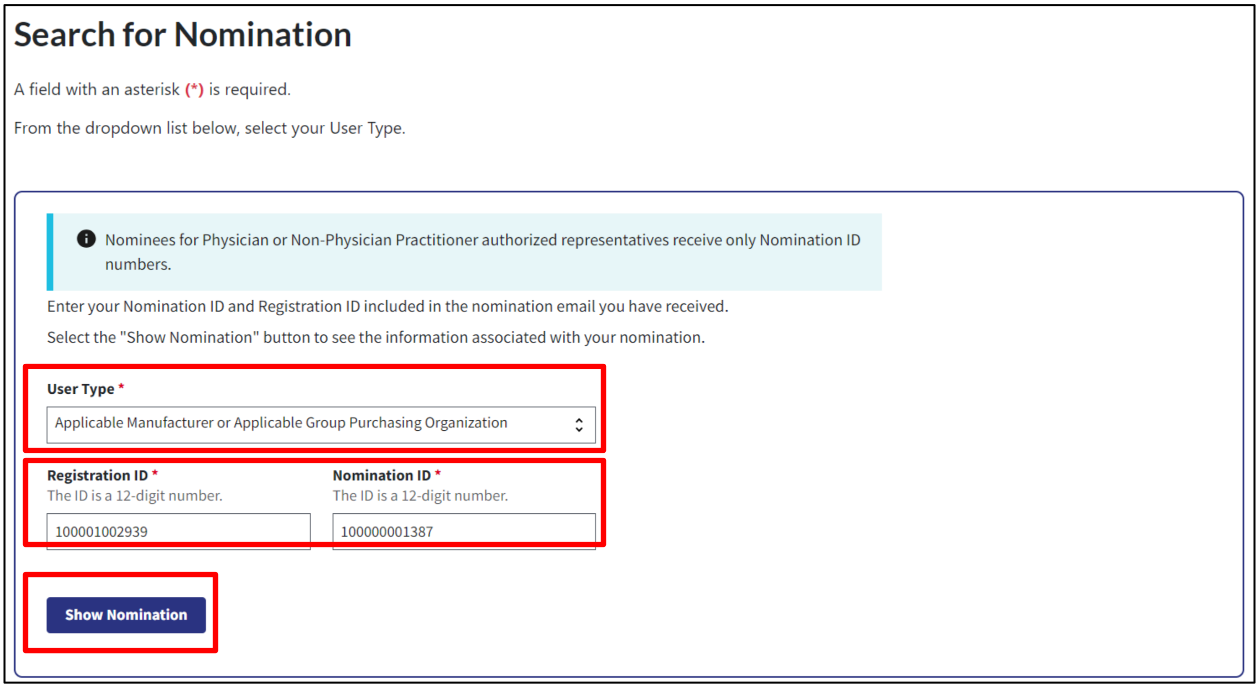
<u>Step 4:</u> Enter the registration ID and nomination ID provided in the email notification and select Show Nomination.

Figure 95: 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.

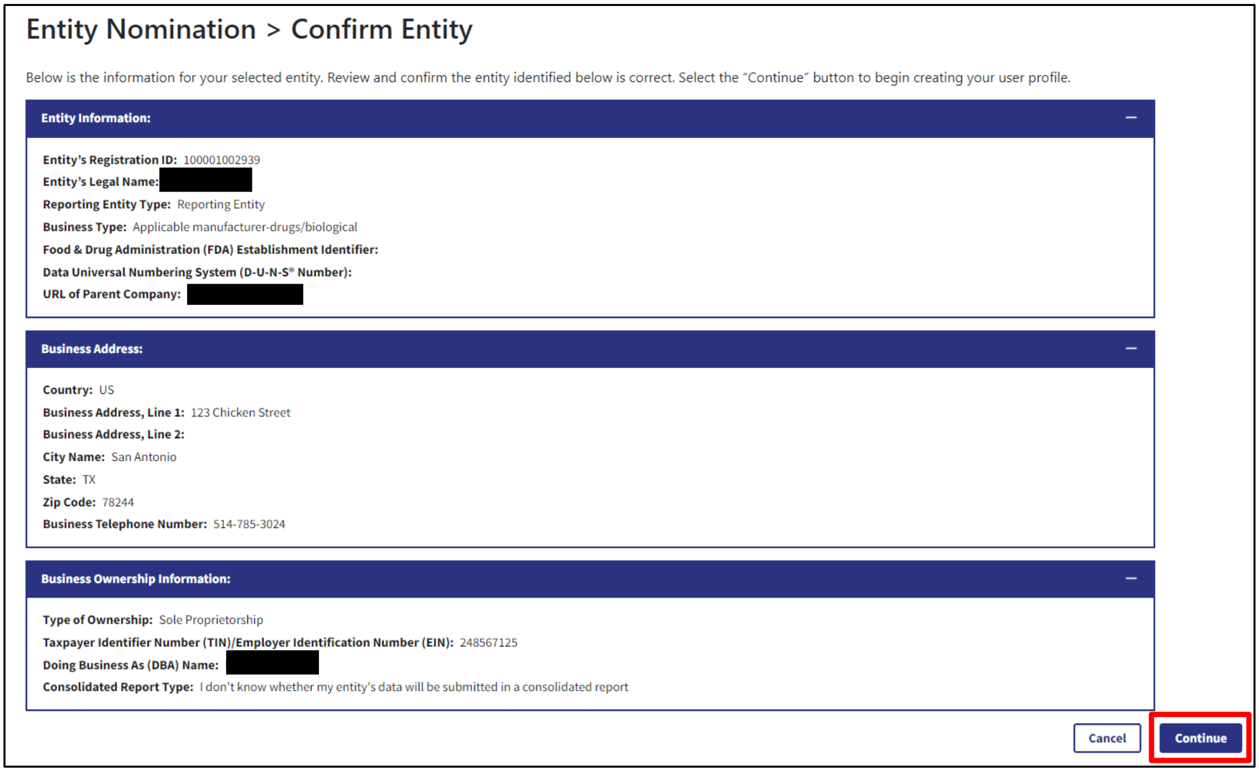
Figure 96: Search for Nomination Page



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, but you may continue this process.

Figure 97: Confirm Entity Page

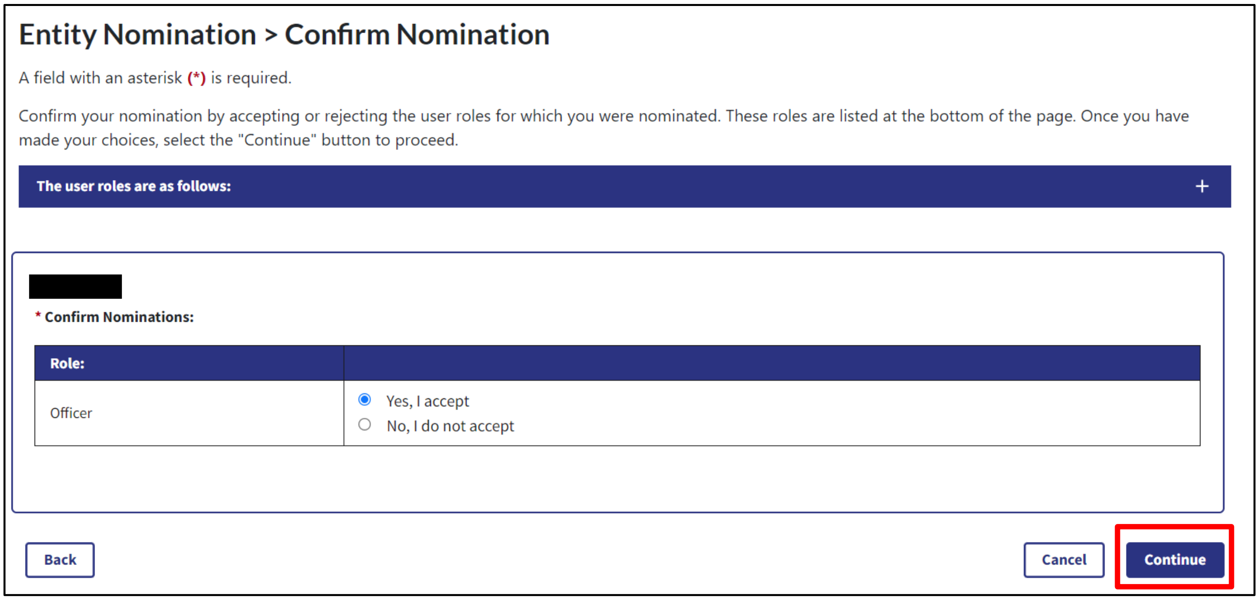


<u>Step 7:</u> Select "Yes, I accept" for roles you accept and "No, I do not accept" for roles you do not accept.

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.

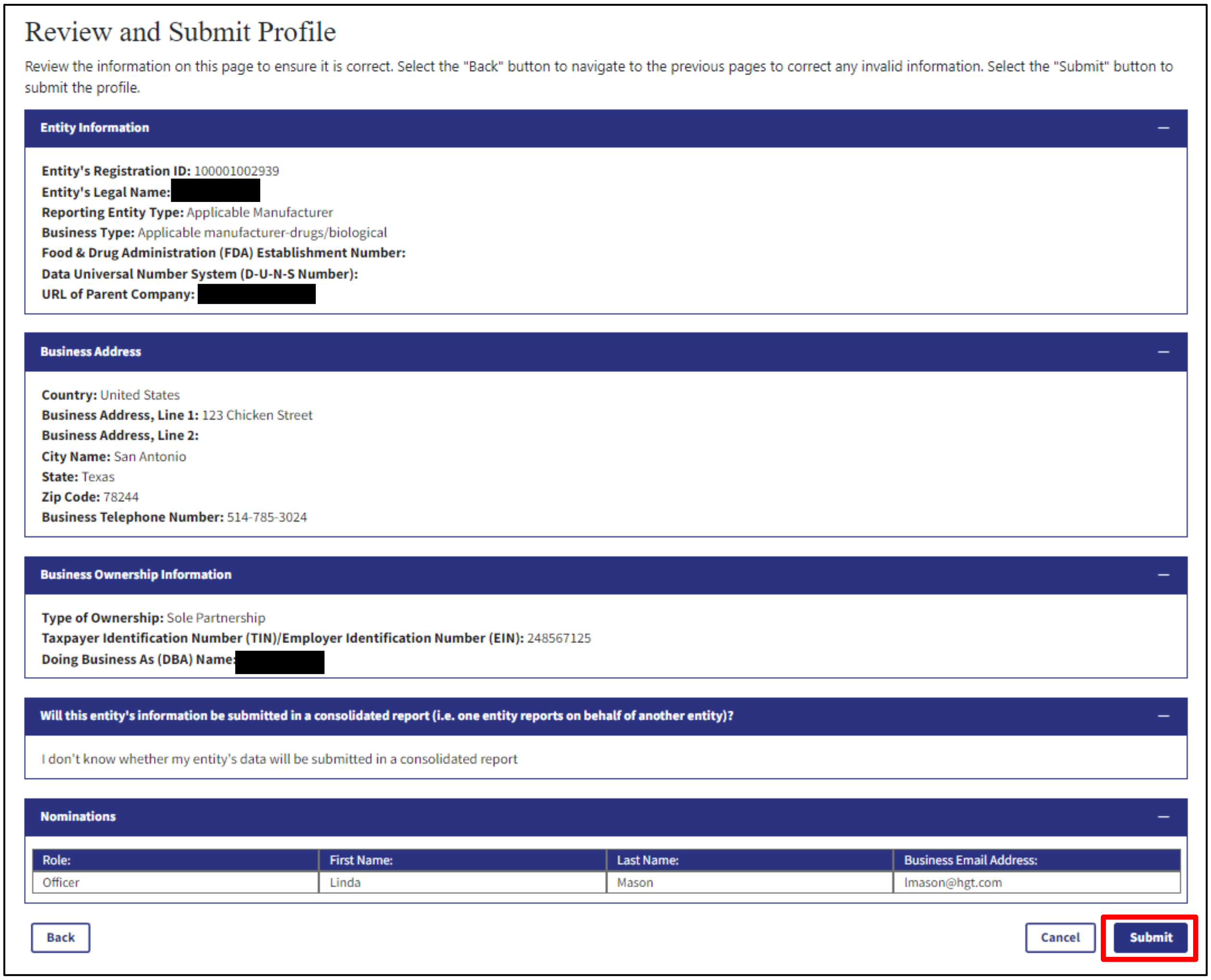
If you accept one or all roles and select **Continue**, you will proceed to the nomination confirmation process.

Figure 98: Confirm Nomination Page



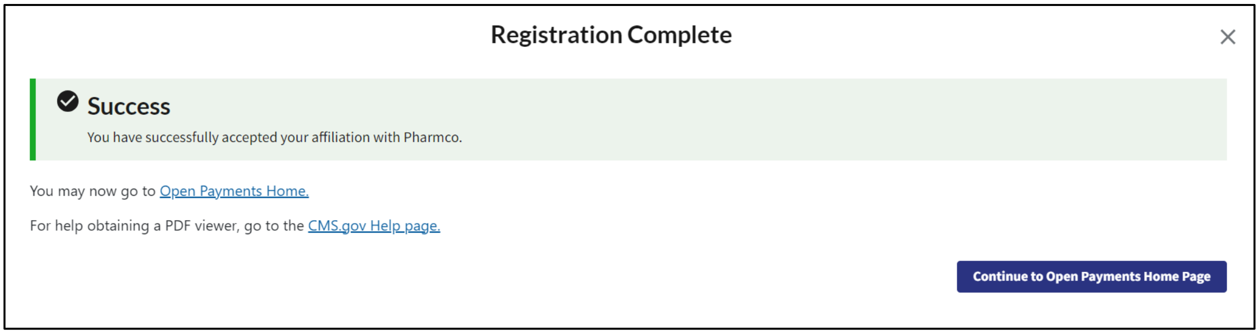
<u>Step 8:</u> Review the reporting entity information and personal profile. Select the **Back** button at the bottom of the page to go back and edit any personal information. If the entity information is not correct, select **Cancel** and contact your reporting entity's authorized official. If the information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

Figure 99: Review and Submit Profile Page



The following message in **Figure 100** will appear on-screen to confirm your successful acceptance of one or more user roles. Notification emails will be sent to all users who hold the role of officer with that entity that you have accepted your nomination.

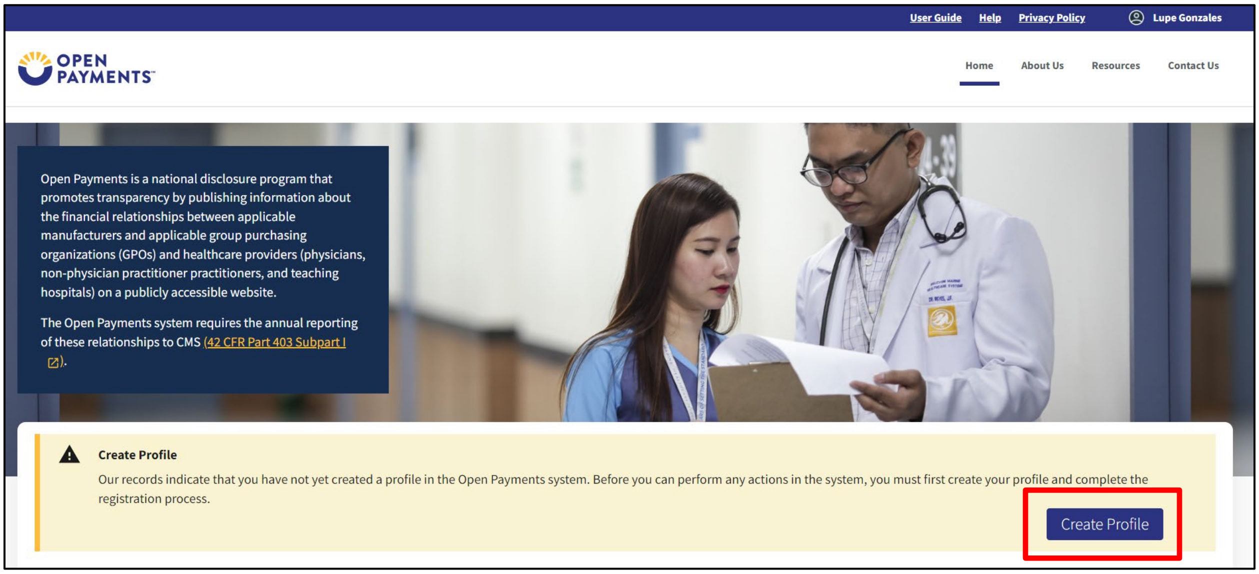
Figure 100: Success Confirmed Page



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

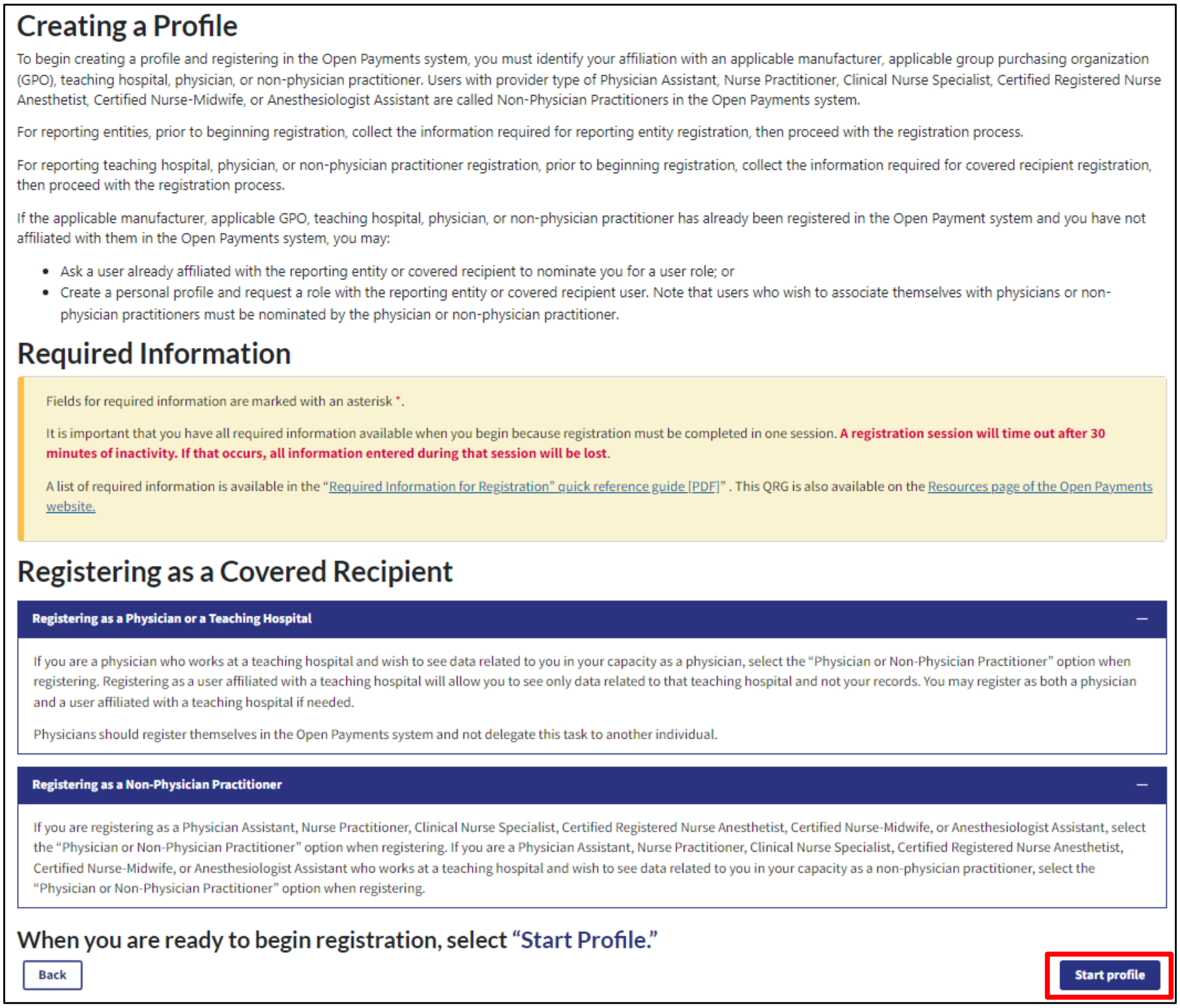
Step 1: You will need to create an account in the CMS Identity Management portal, then request access to the Open payments system (see section 3.1, above) Next, log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials. The on-screen text contains important information regarding the registration process. Read the on-screen text and select **Create My Profile** to begin the registration process.

Figure 101: Open Payments System Landing Page for First-Time System Users



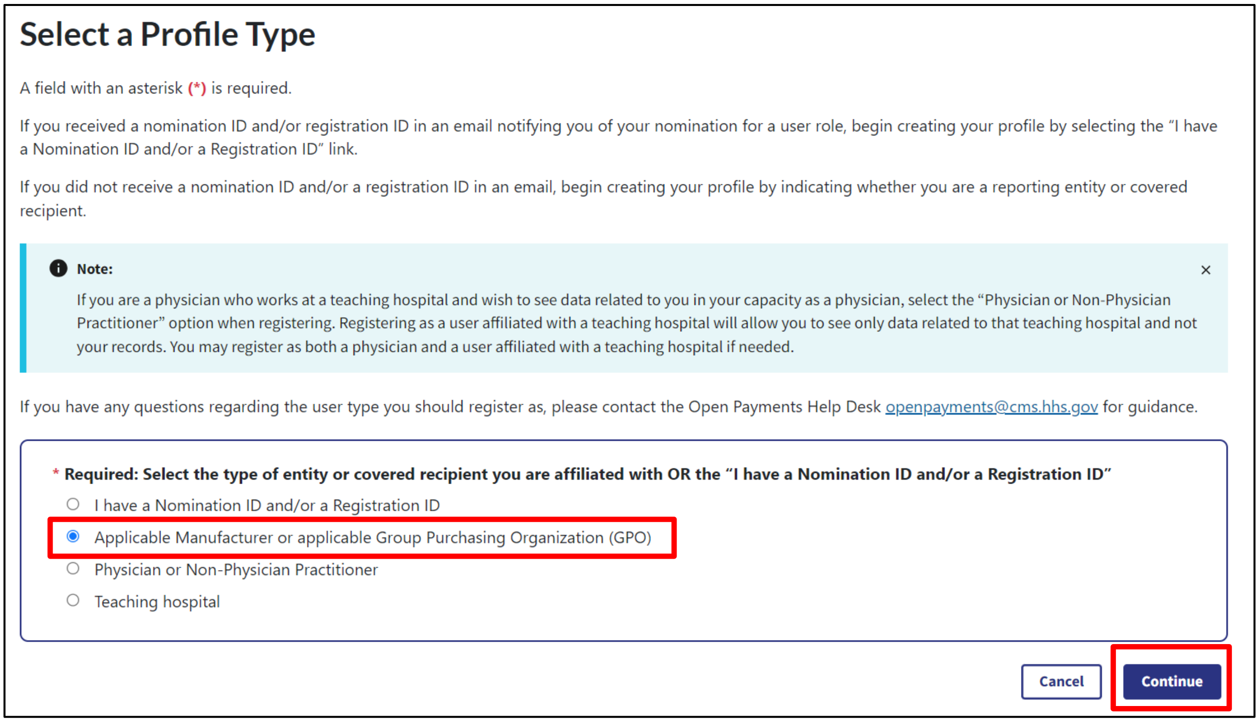
Step 2: The on-screen text contains important information regarding creating the reporting entity and individual profile. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start Profile"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

Figure 102: Create Profile Page



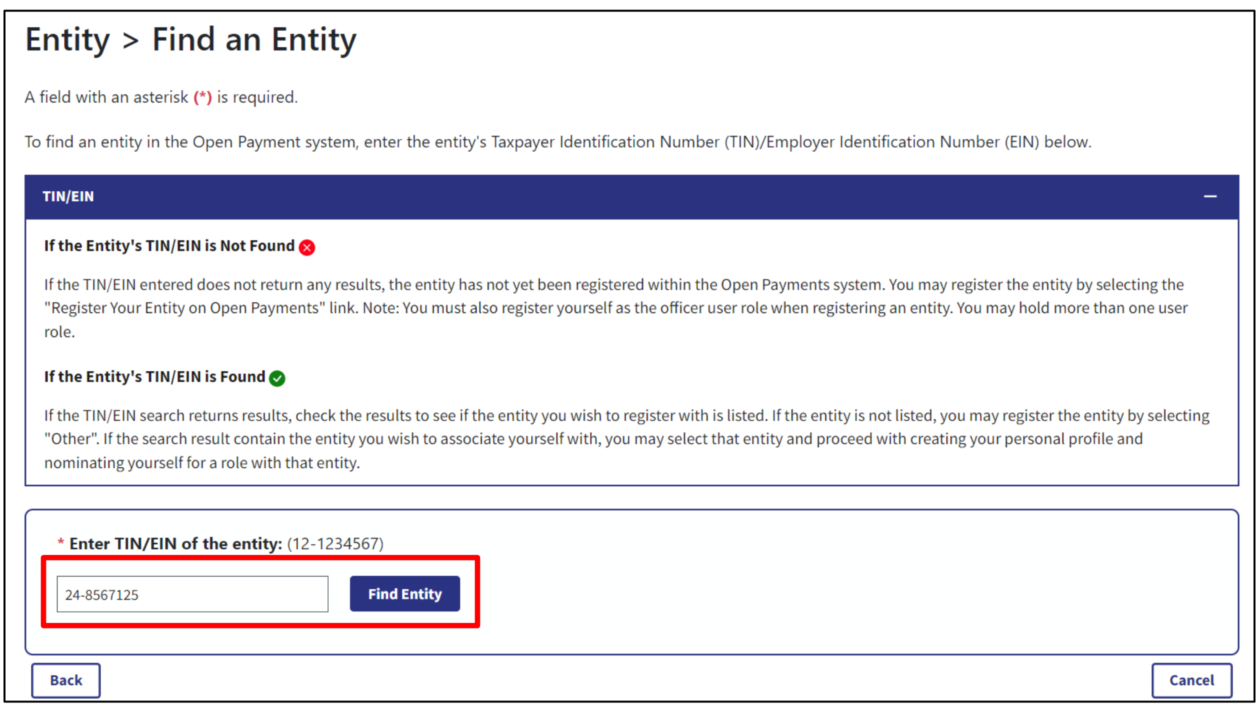
Step 3: Select the profile type "Applicable manufacturer or applicable group purchasing organization (GPO)" and select **Continue**.

Figure 103: 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. Select Find.

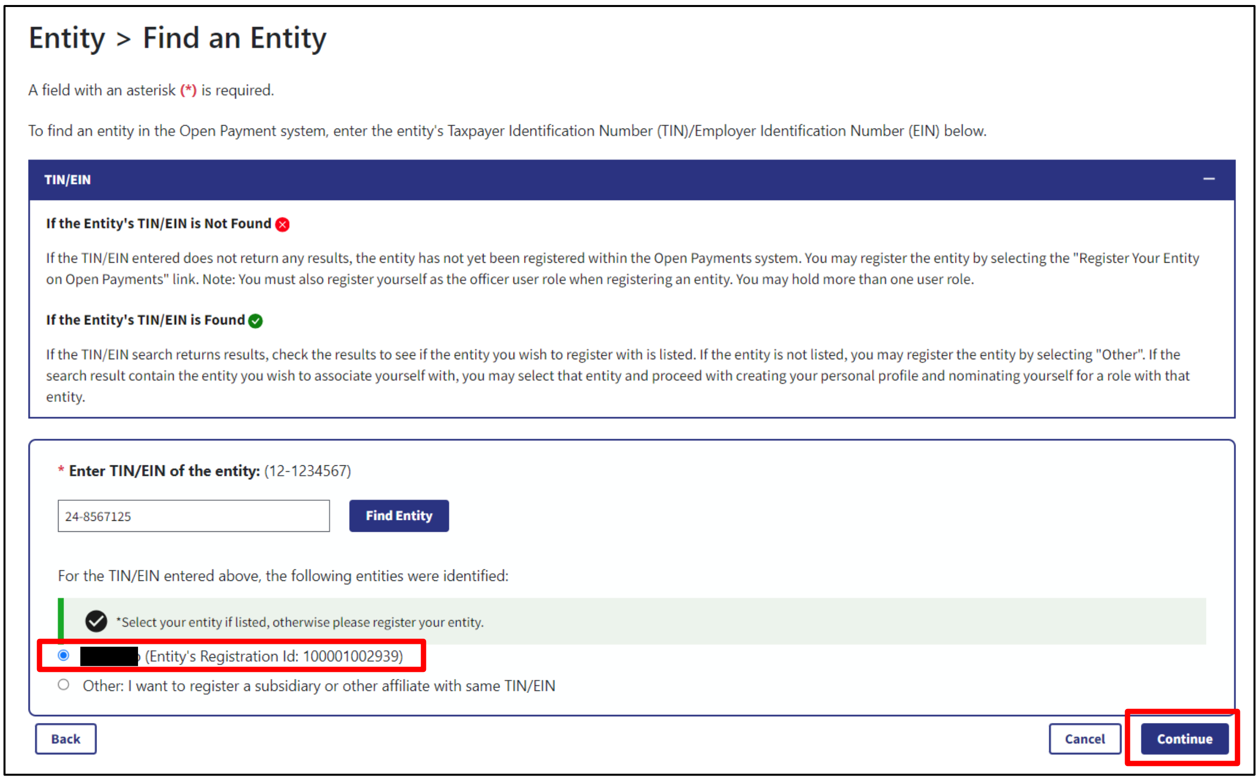
Figure 104: Find an Entity Page



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

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 highly placed in the company. If you are not, or do not wish to register the entity yourself, you may contact someone highly placed in the company. within the entity to request that he or she register the entity in the Open Payments system.

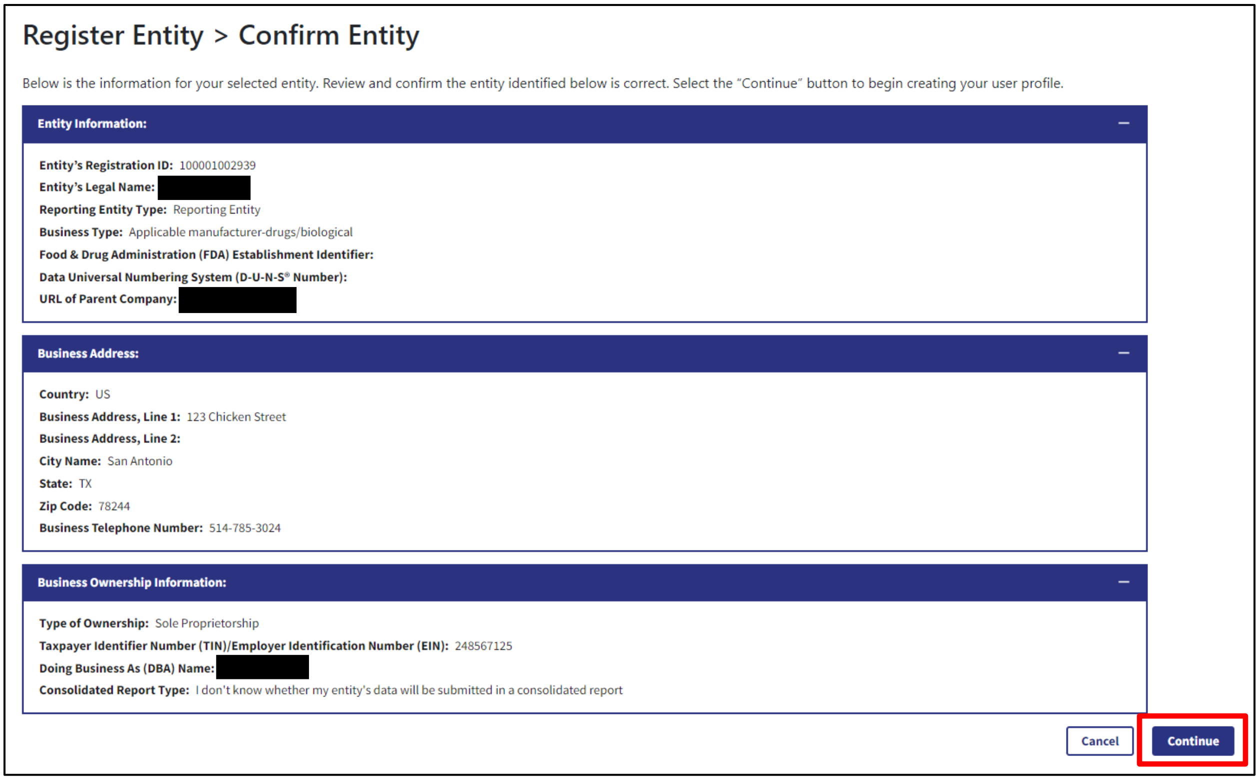
Figure 105: Find an Entity Page



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

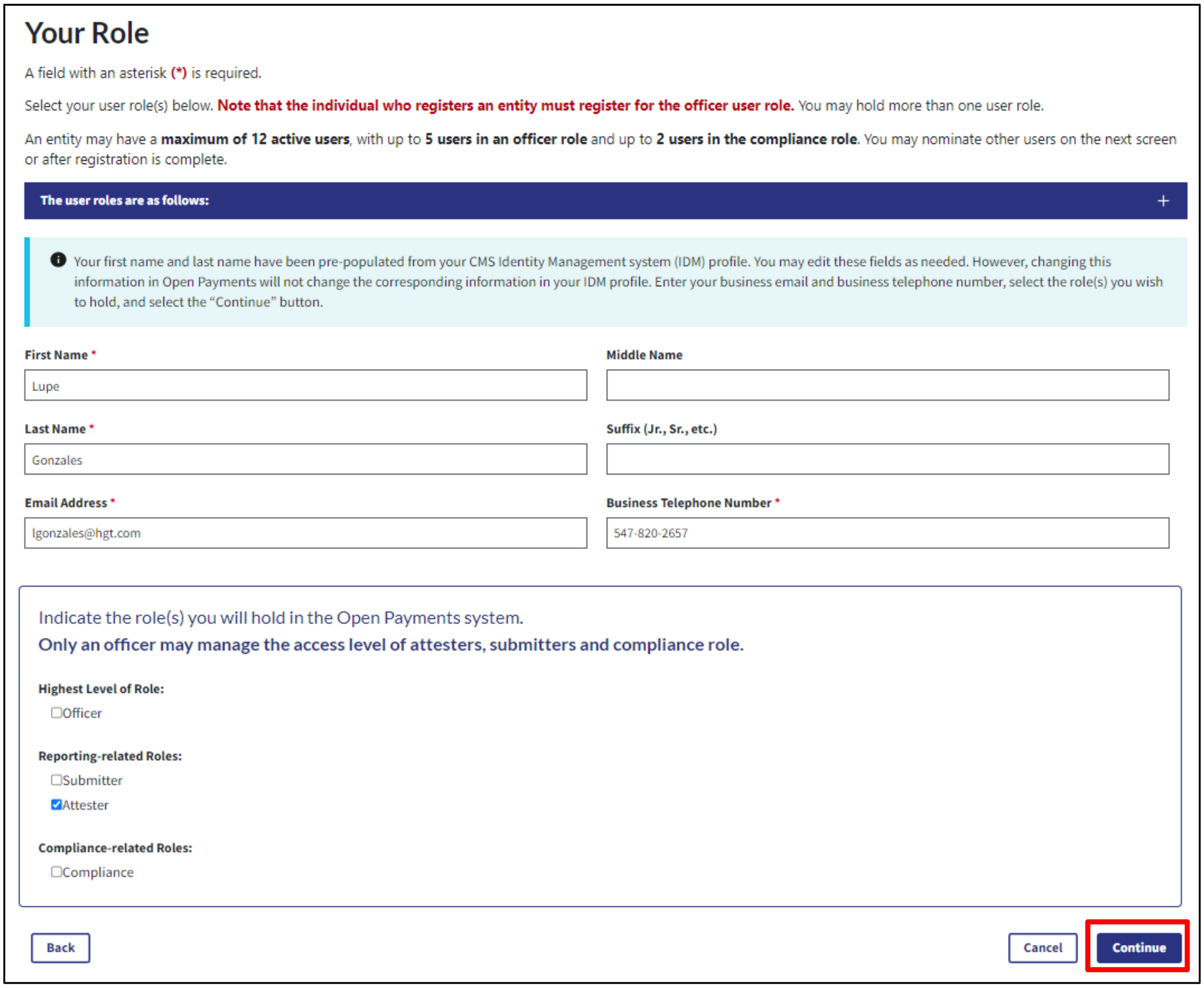
If the information is correct, select the Continue button to proceed. If this information is not correct, you may still proceed with registration. After registration is complete, contact an individual who holds the user role of an officer for the reporting entity in the Open Payments system to notify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

Figure 106: Confirm Entity Page



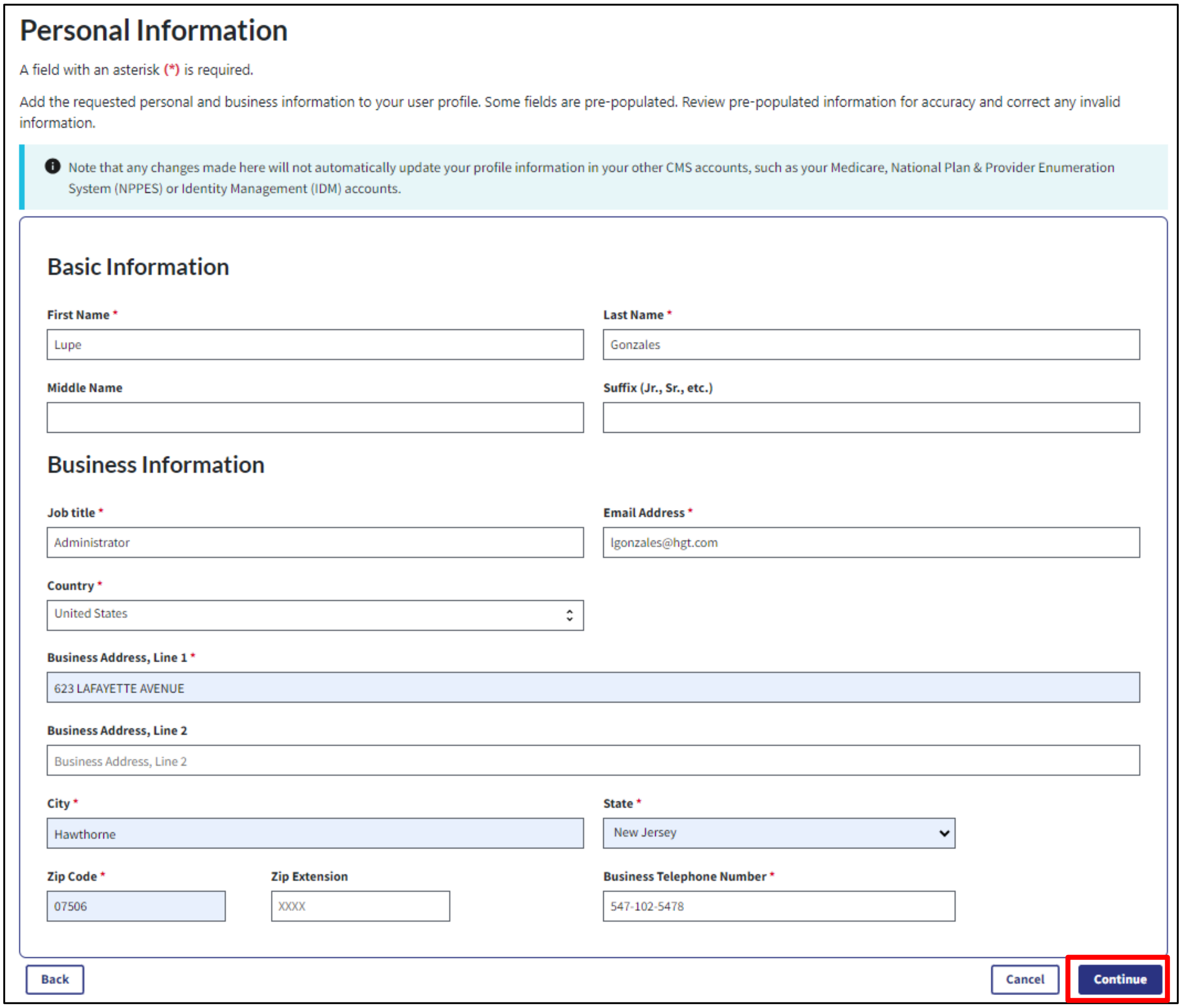
<u>Step 7:</u> Enter your personal information and select the roles for which you want to nominate yourself. Select the **Continue** button to proceed.

Figure 107: Your Role Page



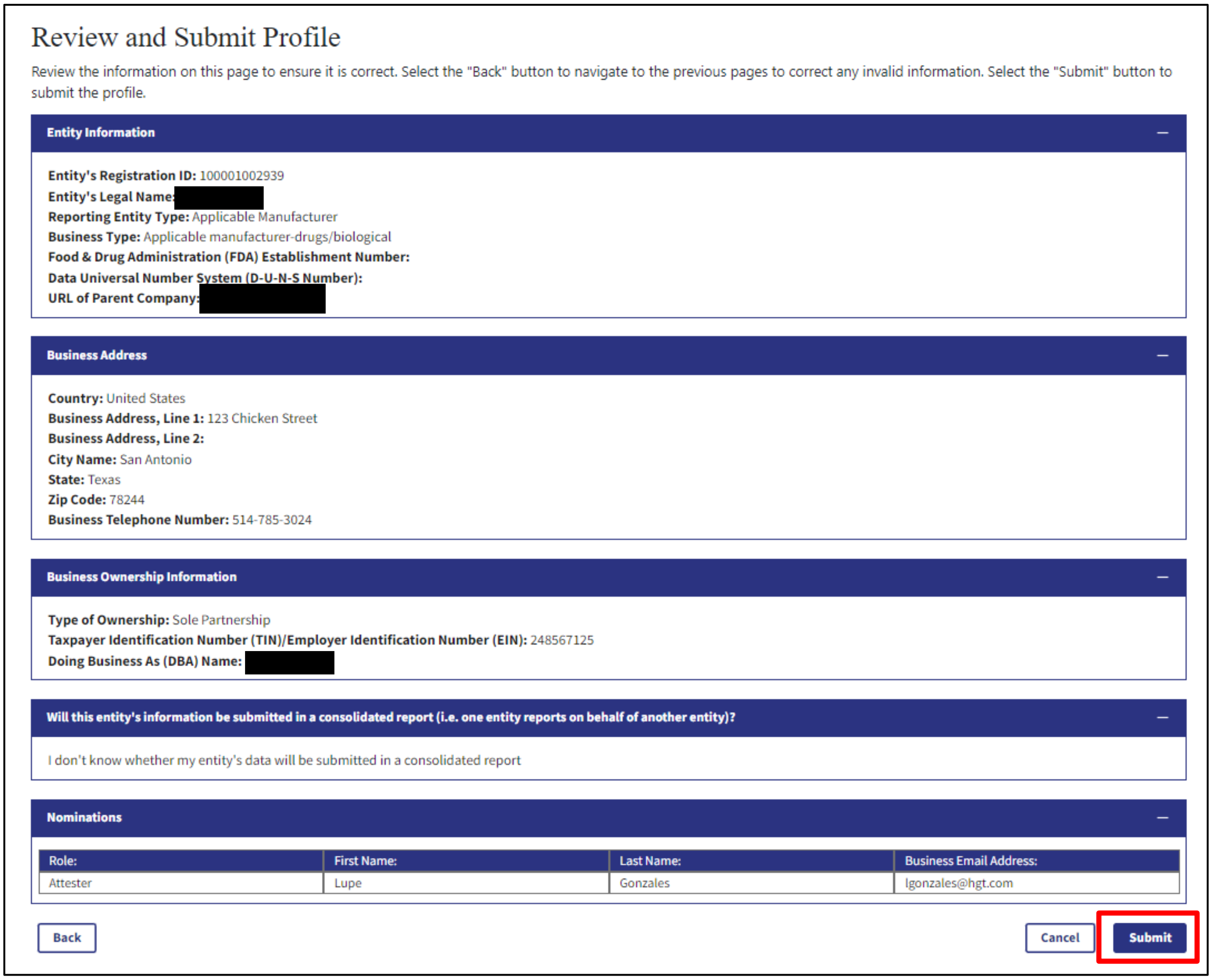
Step 8: On the "Personal Information" page, enter your personal information and business contact information. Required fields are marked with an asterisk (*). Once you have entered all the information, select the **Continue** button.

Figure 108: Enter Personal Information Page



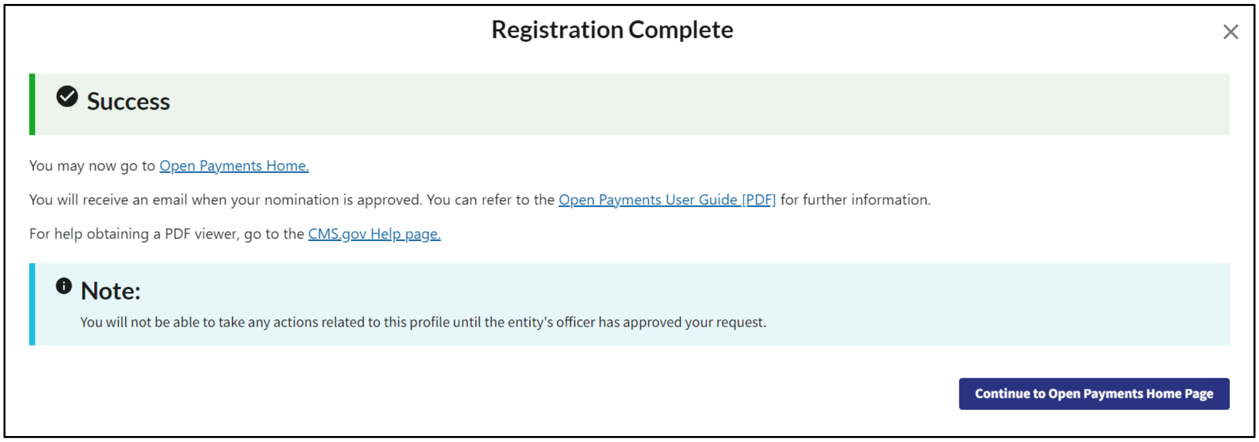
Step 9: Review the information entered in your profile. Select the **Back** button at the bottom of the page to go back and edit any incorrect information. When the information is correct, select the **Continue** button.

Figure 109: 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.

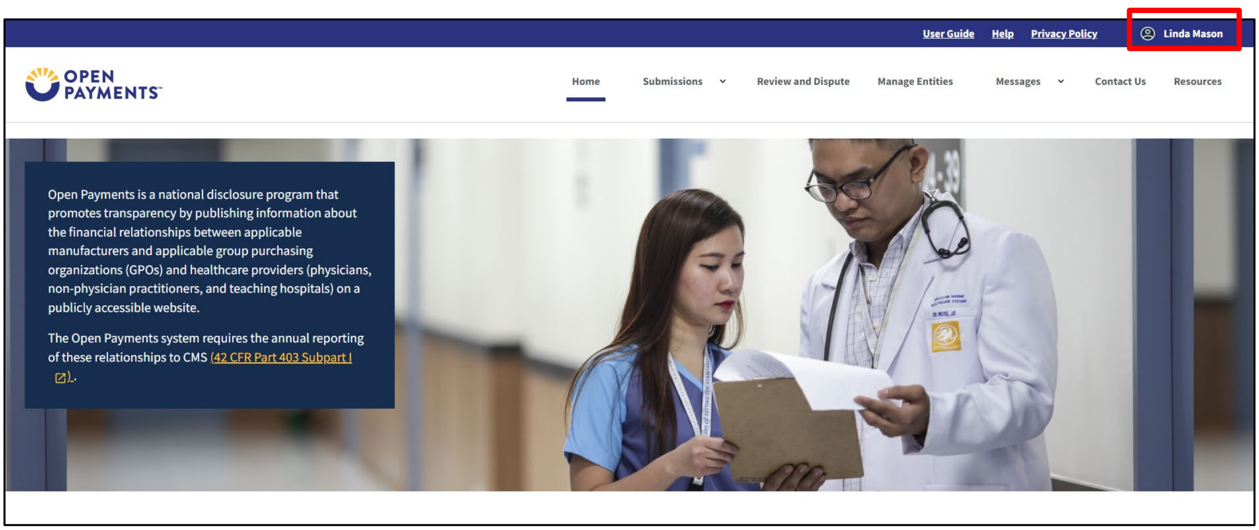
Figure 110: Success Confirmed Page



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

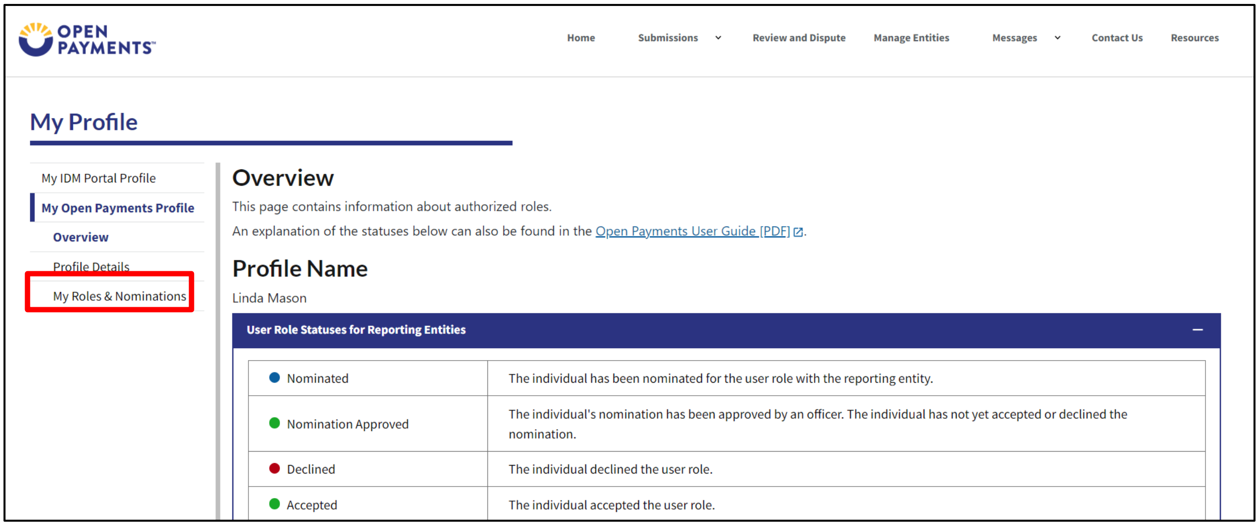
<u>Step 1:</u> Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials, select the My Open Payments Profile link under your name the header menu on the Open Payments home page.

Figure 111: Open Payments System Landing Page for Returning System Users



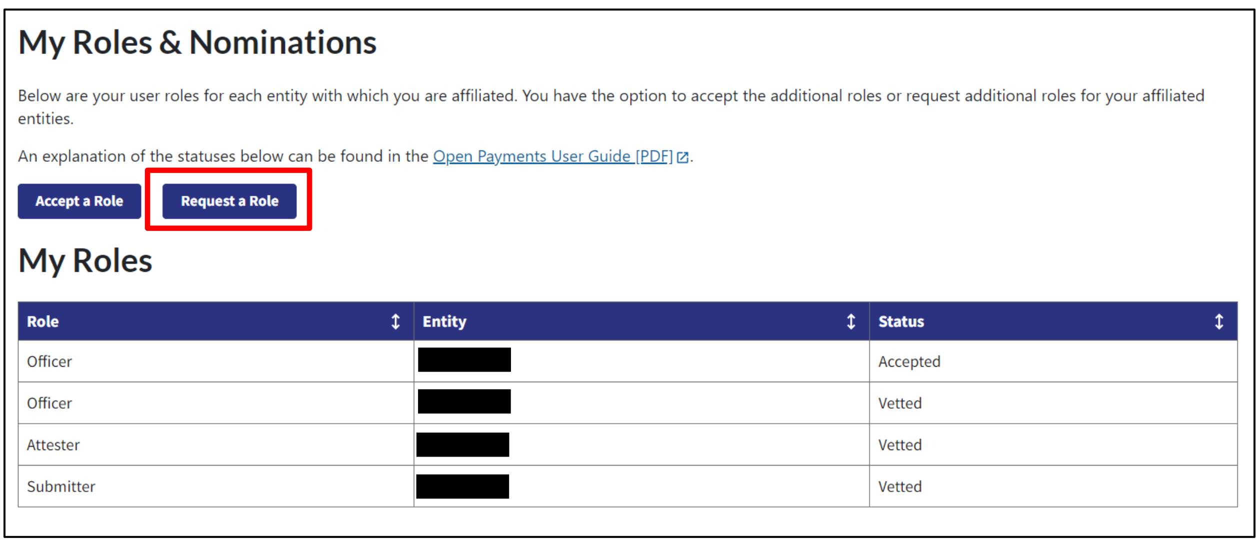
Step 2: From the "My Open Payments Profile" page, select the **My Roles and Nominations**.

Figure 112: My Profile Page



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

Figure 113: My Roles and Nominations Tab

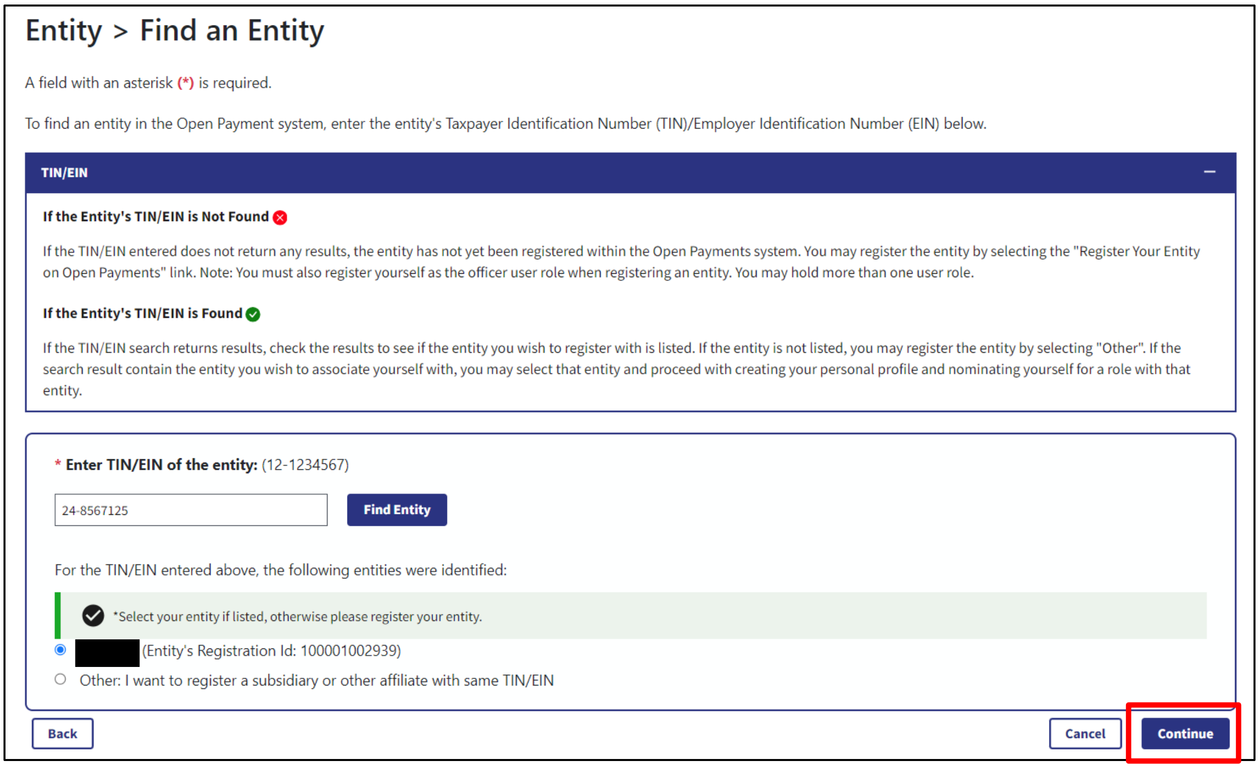


Step 4: Enter the Taxpayer Identification Number/Employer Identification Number (TIN/EIN) of the reporting entity that you want to associate yourself with. The TIN must be nine digits, with a dash after the second digit. Select **Find Entity**.

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

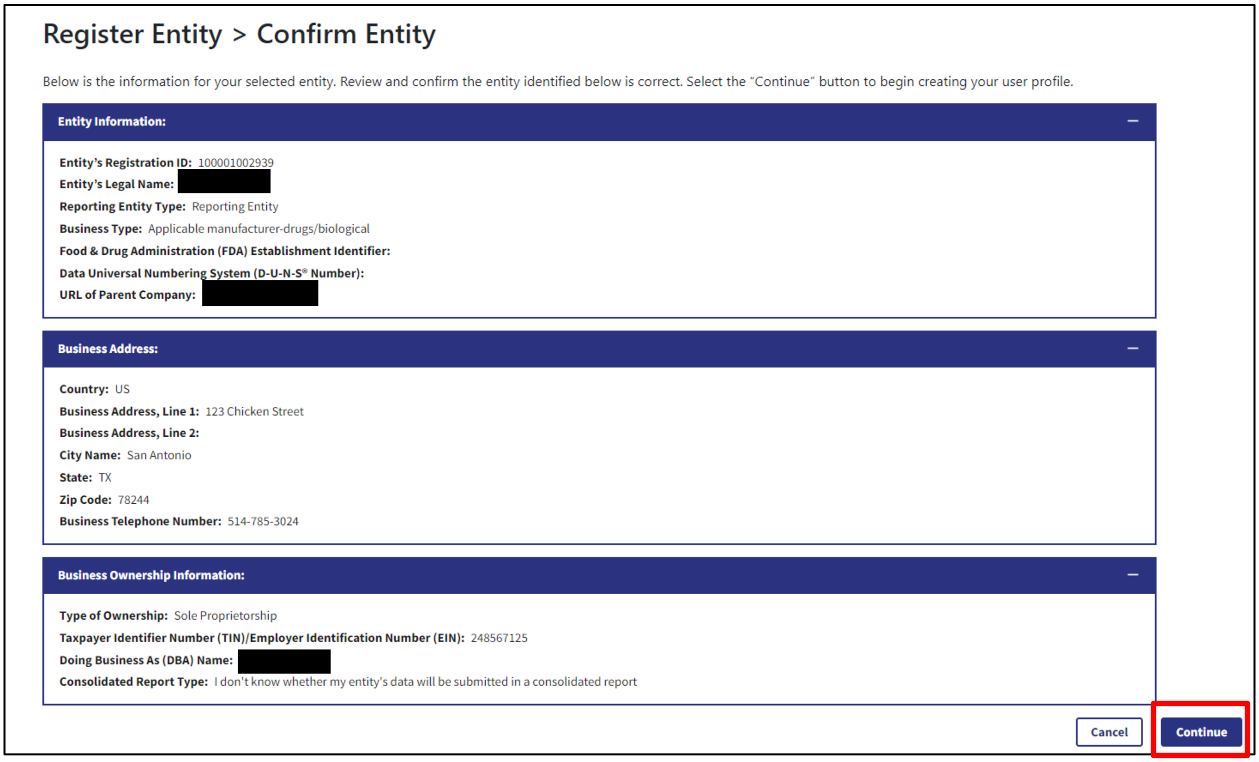
If no reporting entity is found for the TIN/EIN you supplied, the entity has not yet been registered in the Open Payments system. You may register the entity in Open Payments yourself if you are highly placed in your company. If you are not, or do not wish to register the entity yourself, you may contact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

Figure 114: Find an Entity Page



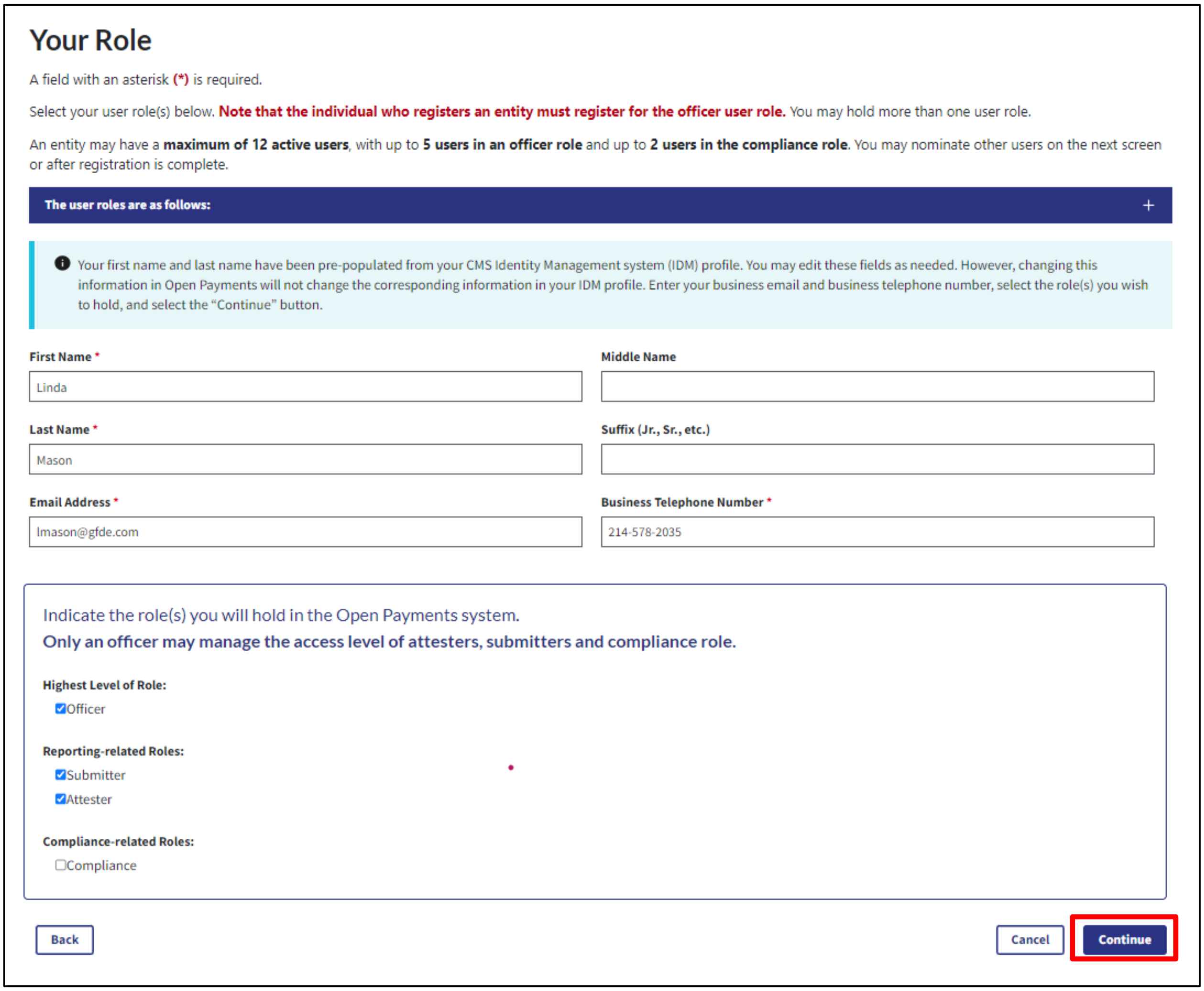
Step 5: Review and confirm the reporting entity information displayed on the page. If any of the entity information is incorrect, inform a user holding the role of officer for that entity of the incorrect information. You may still proceed with this process, or, if the information is correct, select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

Figure 115: Confirm Entity Page



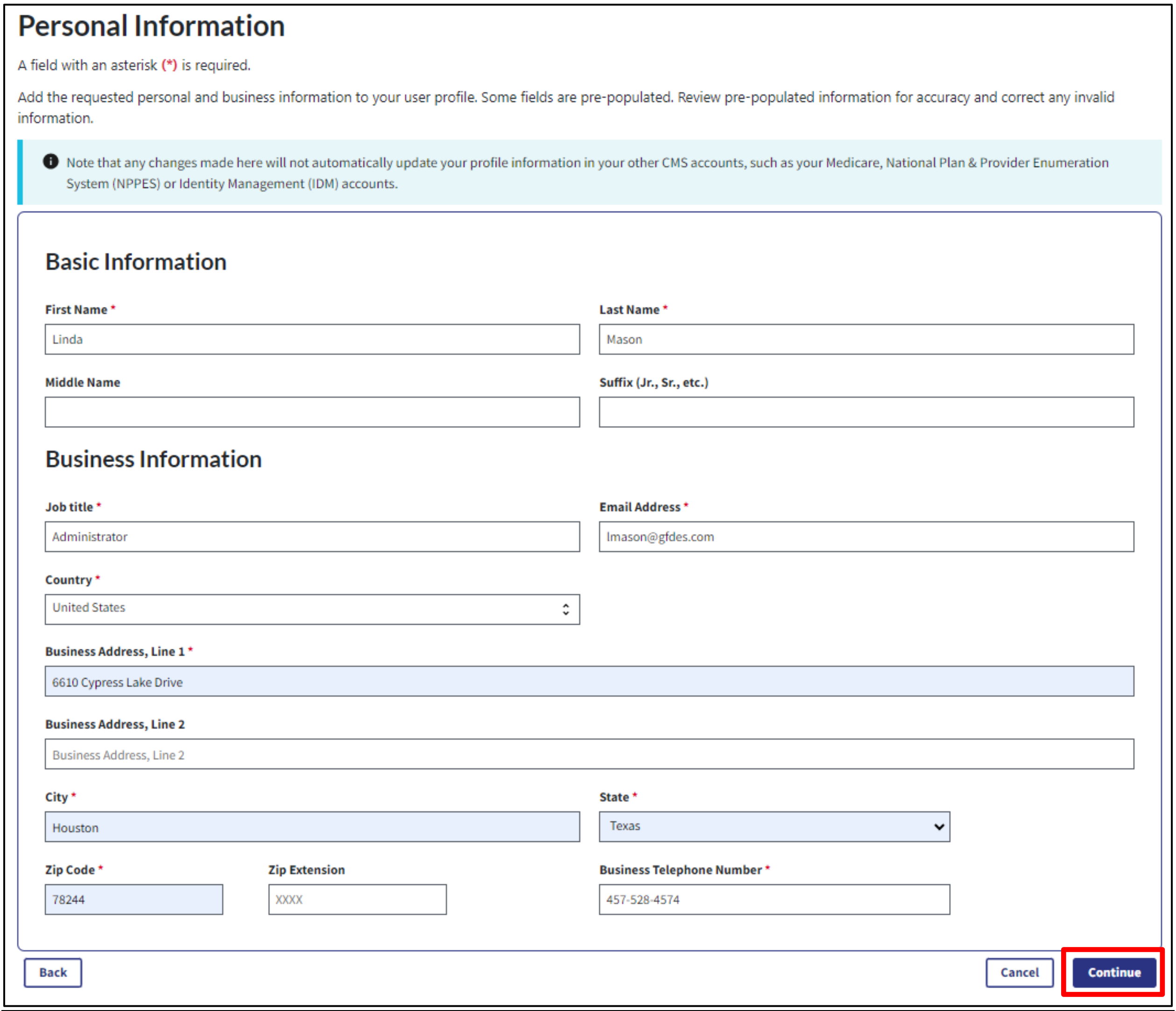
Step 6: Enter your personal information and select the roles for which you want to self-nominate. Select the **Continue** button to proceed.

Figure 116: Your Role Page



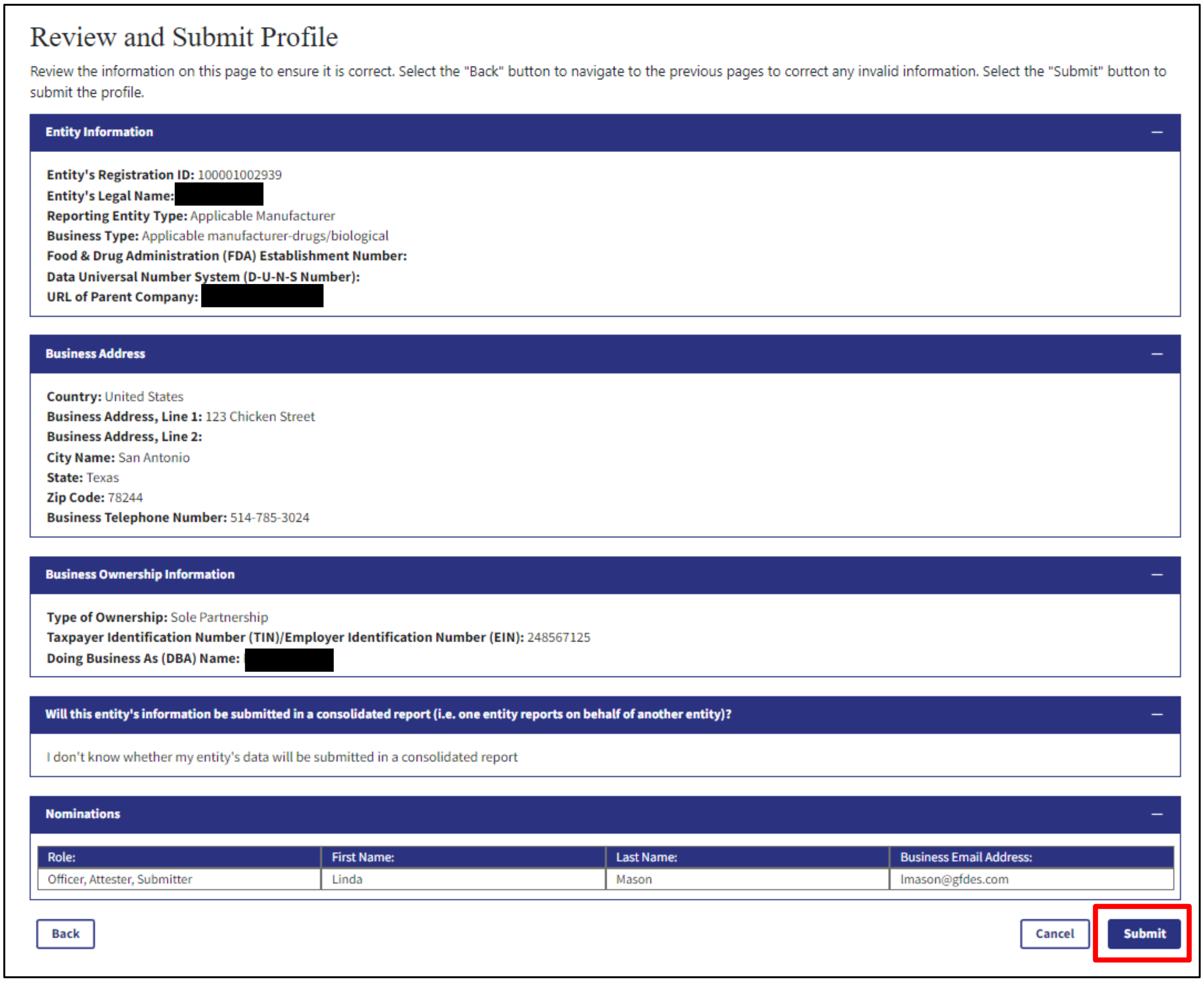
Step 7: Enter the information requested, then select **Continue**.

Figure 117: Enter Personal Information



Step 8: 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 118: Review and Submit Profile Page



Review and Submit Profile

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

Entity Information

Entity's Registration ID: 100001002939
Entity's Legal Name: [redacted]
Reporting Entity Type: Applicable Manufacturer
Business Type: Applicable manufacturer-drugs/biological
Food & Drug Administration (FDA) Establishment Number:
Data Universal Number System (D-U-N-S Number):
URL of Parent Company: [redacted]

Business Address

Country: United States
Business Address, Line 1: 123 Chicken Street
Business Address, Line 2:
City Name: San Antonio
State: Texas
Zip Code: 78244
Business Telephone Number: 514-785-3024

Business Ownership Information

Type of Ownership: Sole Partnership
Taxpayer Identification Number (TIN)/Employer Identification Number (EIN): 248567125
Doing Business As (DBA) Name: [redacted]

Will this entity's information be submitted in a consolidated report (i.e. one entity reports on behalf of another entity)?

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

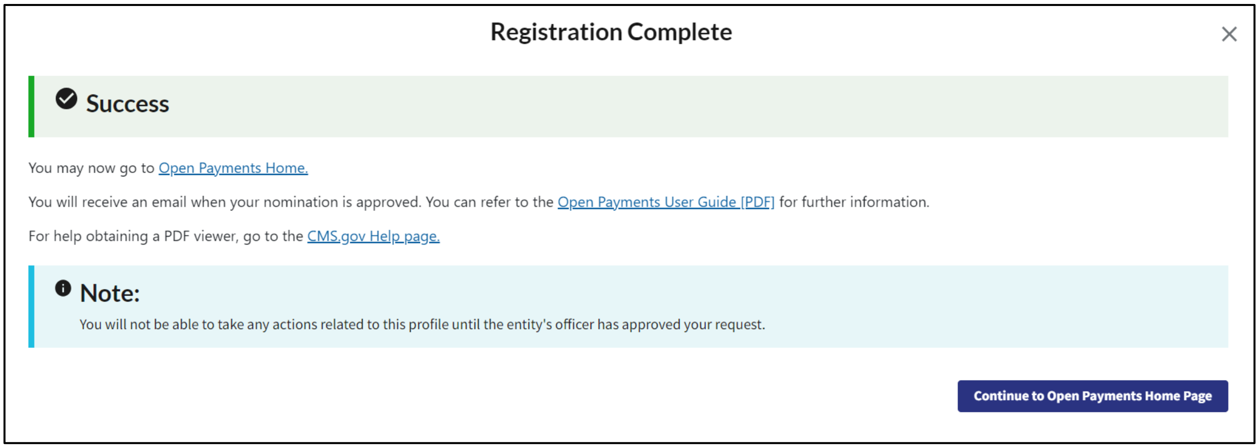
Nominations

Role:	First Name:	Last Name:	Business Email Address:
Officer, Attester, Submitter	Linda	Mason	lmason@gfdes.com

Back Cancel Submit

You will receive the on-screen “Registration Complete” message, and a notification email will be sent to officers of the entity, informing them of your self-nomination request.

Figure 119: Registration Complete Message



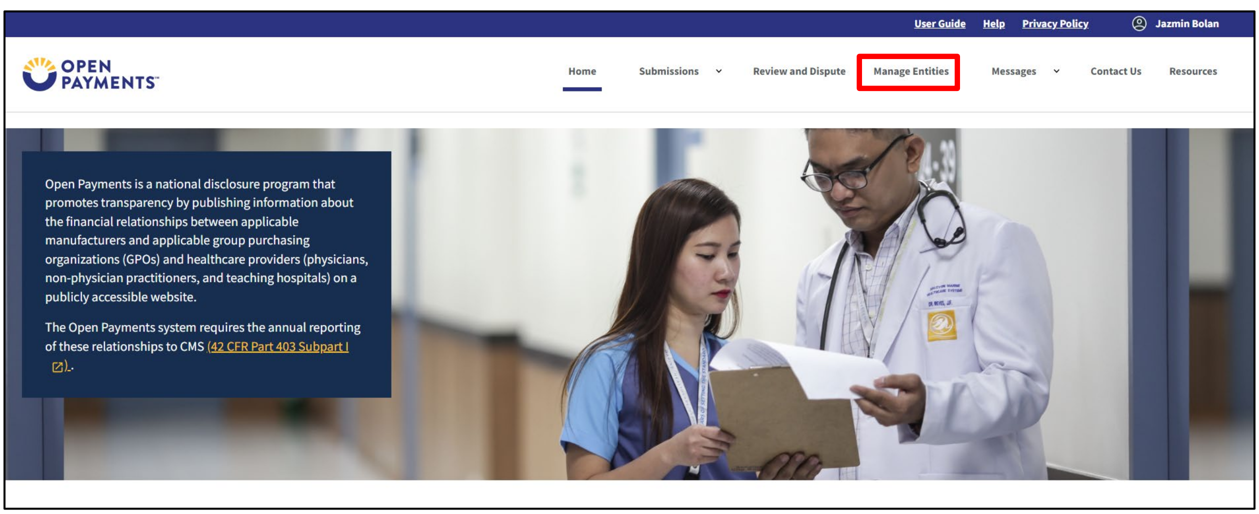
3.6f: Approving or Modifying Nominations: Returning Officers Only

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 has 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.

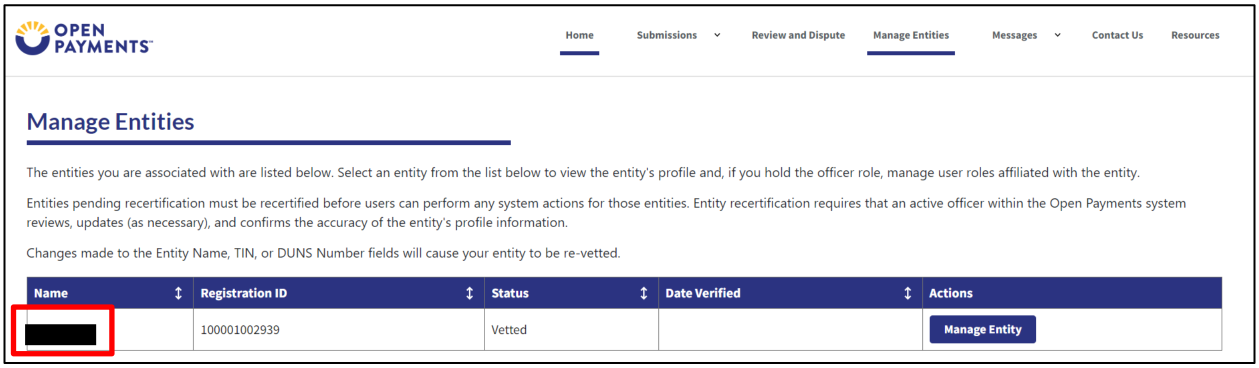
__Step 1:__ Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials and select the **Manage Entities** tab from the header menu on the Open Payments home page.

Figure 120: Open Payments System Landing Page for Returning System Users



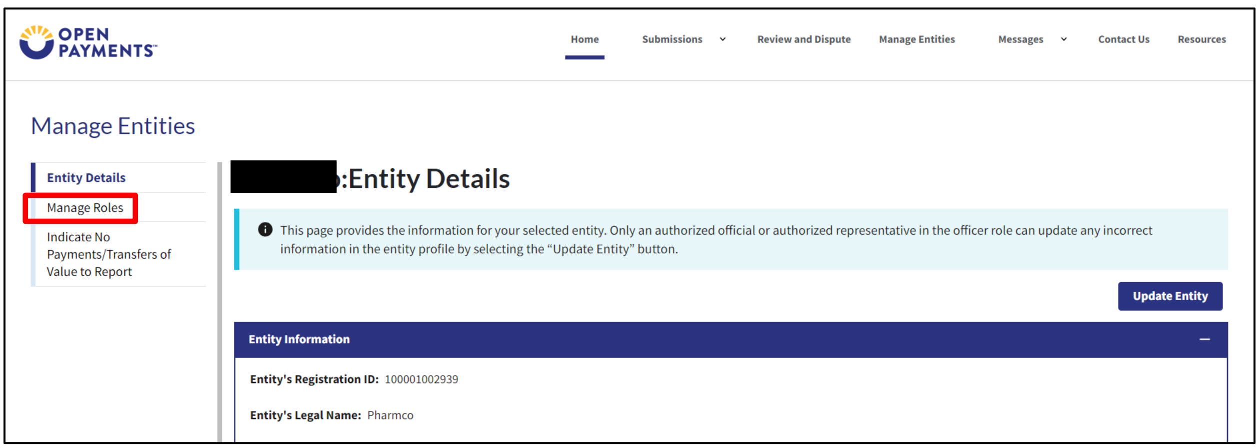
Step 2: You will see a list of all the reporting entities you are associated with. Select the hyperlink for the entity for which you will be confirming nominations.

Figure 121: Manage Entities Page



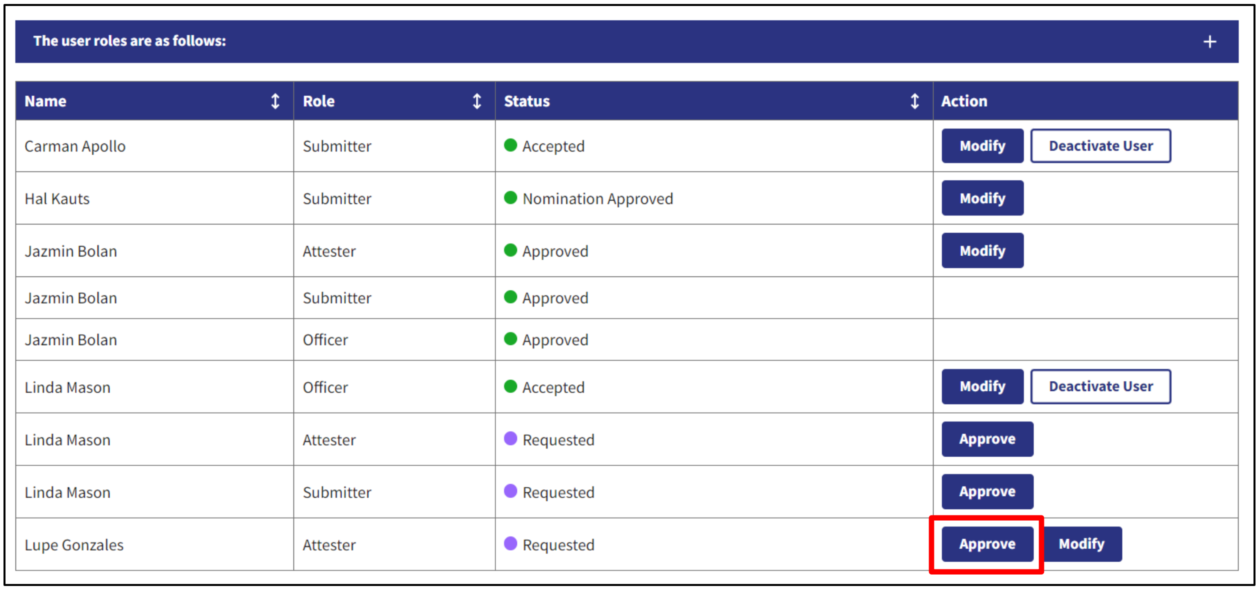
Step 3: You will be taken to the "Entity Details page, which displays the profile details for the reporting entity selected. Select the Manage Roles link to continue with the process.

Figure 122: 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 123: Manage Roles Page

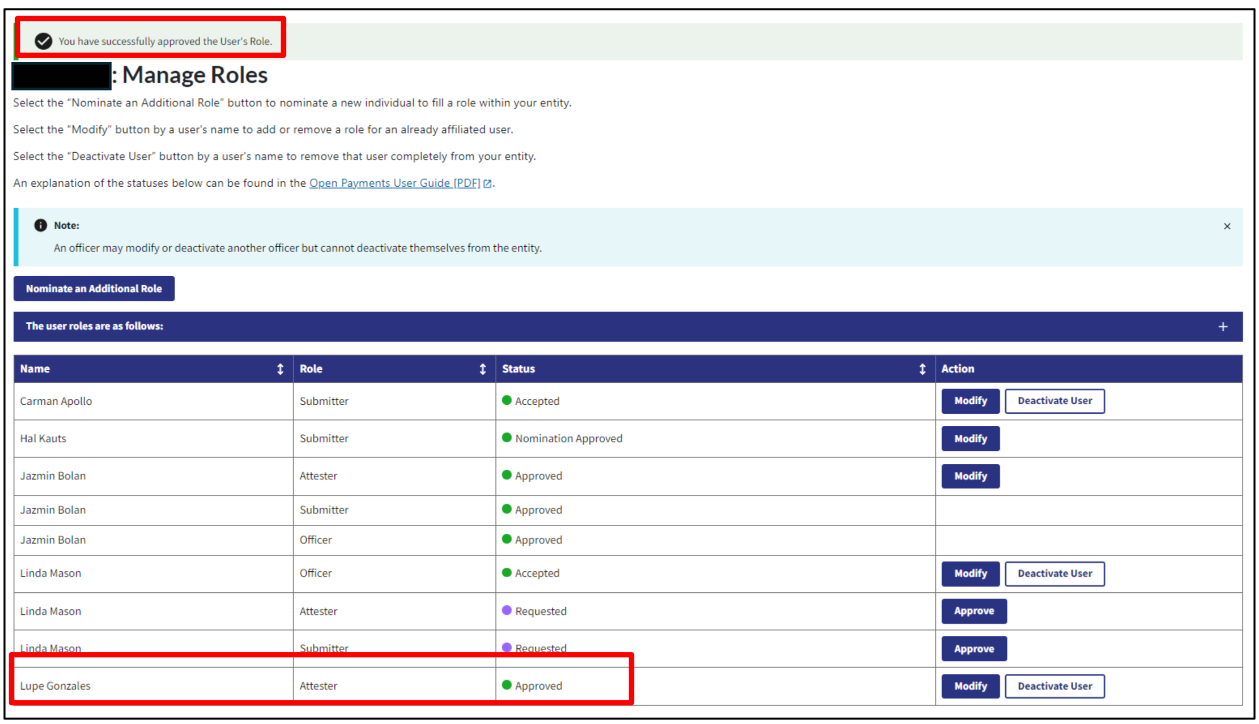


The user roles are as follows:

Name	Role	Status	Action
Carman Apollo	Submitter	Accepted	Modify Deactivate User
Hal Kauts	Submitter	Nomination Approved	Modify
Jazmin Bolan	Attester	Approved	Modify
Jazmin Bolan	Submitter	Approved	
Jazmin Bolan	Officer	Approved	
Linda Mason	Officer	Accepted	Modify Deactivate User
Linda Mason	Attester	Requested	Approve
Linda Mason	Submitter	Requested	Approve
Lupe Gonzales	Attester	Requested	Approve Modify

The status will change directly on the page from "Requested" to "Approved" and a confirmation message will be displayed.

Figure 124: Red Box Circles Confirmation Message



You have successfully approved the User's Role.

[redacted]: Manage Roles

Select the "Nominate an Additional Role" button to nominate a new individual to fill a role within your entity.

Select the "Modify" button by a user's name to add or remove a role for an already affiliated user.

Select the "Deactivate User" button by a user's name to remove that user completely from your entity.

An explanation of the statuses below can be found in the Open Payments User Guide [PDF].

Note:
An officer may modify or deactivate another officer but cannot deactivate themselves from the entity.

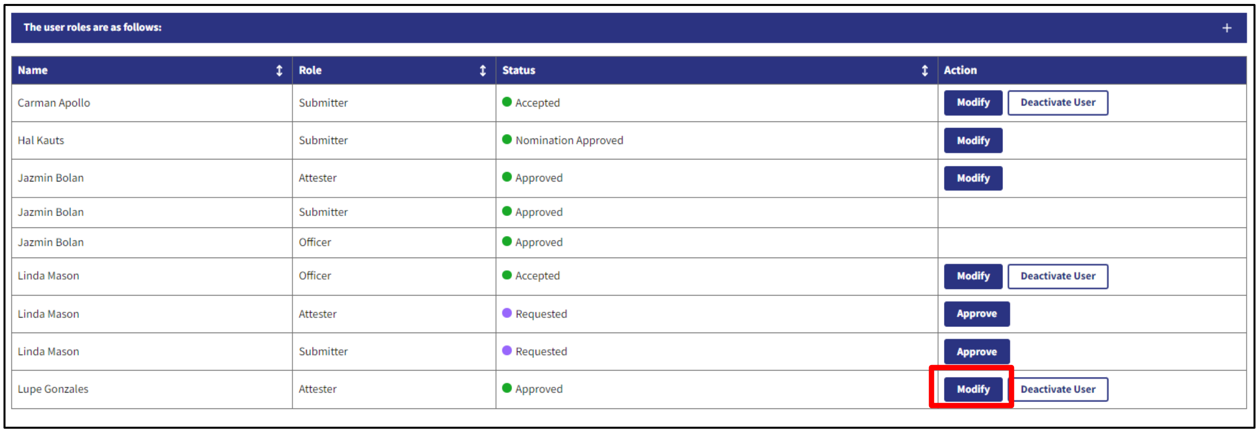
Nominate an Additional Role

The user roles are as follows:

Name	Role	Status	Action
Carman Apollo	Submitter	Accepted	Modify Deactivate User
Hal Kauts	Submitter	Nomination Approved	Modify
Jazmin Bolan	Attester	Approved	Modify
Jazmin Bolan	Submitter	Approved	
Jazmin Bolan	Officer	Approved	
Linda Mason	Officer	Accepted	Modify Deactivate User
Linda Mason	Attester	Requested	Approve
Linda Mason	Submitter	Requested	Approve
Lupe Gonzales	Attester	Approved	Modify Deactivate User

To modify the nomination, select “Modify.”

Figure 125: Manage Roles Tab



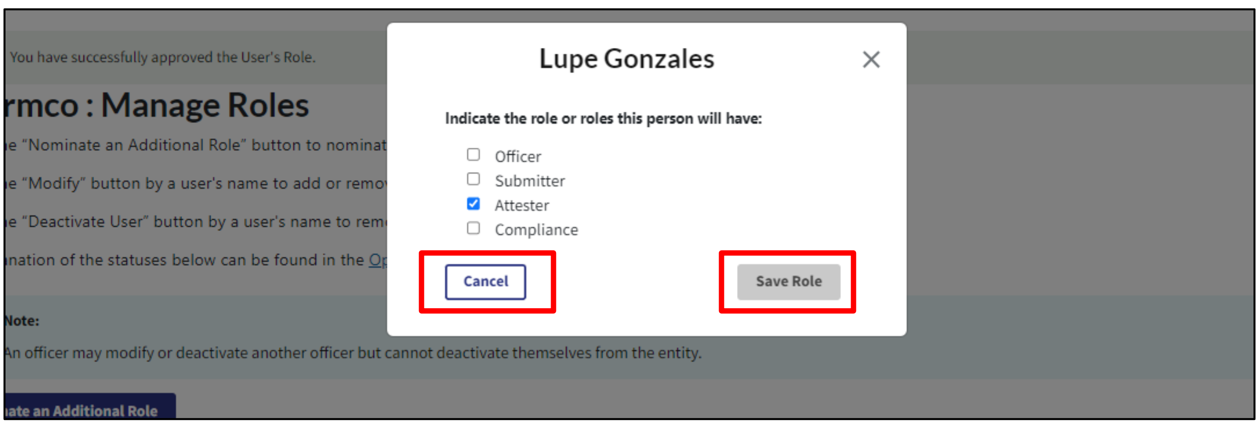
The user roles are as follows:

Name	Role	Status	Action
Carman Apollo	Submitter	Accepted	Modify Deactivate User
Hal Kauts	Submitter	Nomination Approved	Modify
Jazmin Bolan	Attester	Approved	Modify
Jazmin Bolan	Submitter	Approved	
Jazmin Bolan	Officer	Approved	
Linda Mason	Officer	Accepted	Modify Deactivate User
Linda Mason	Attester	Requested	Approve
Linda Mason	Submitter	Requested	Approve
Lupe Gonzales	Attester	Approved	Modify Deactivate User

To modify the nomination, change the information on the popup. You can add or remove roles the user has.

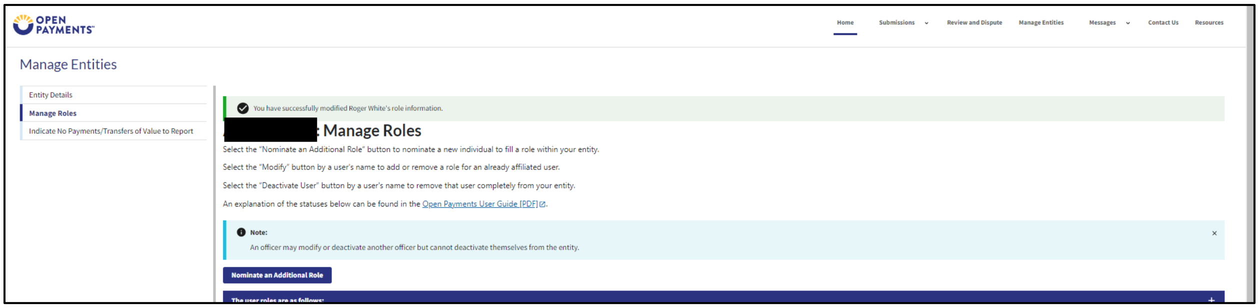
When you are finished, select **Cancel** or **Save Role**. You cannot remove all an individual’s roles via the “Modify” function.

Figure 126: Manage Roles Tab



You will receive an onscreen confirmation of the information submission.

Figure 127: 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 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.

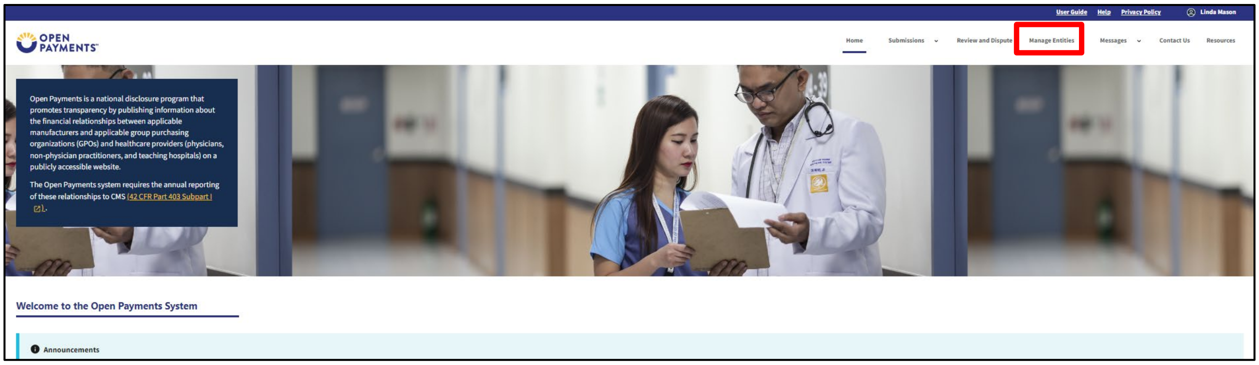
Officers cannot deactivate themselves, though an officer can deactivate another officer. If you wish to be deactivated, contact the Open Payments Help Desk or another individual who holds the user role of officer in your reporting entity. A reporting entity must have at least one active user who holds 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.

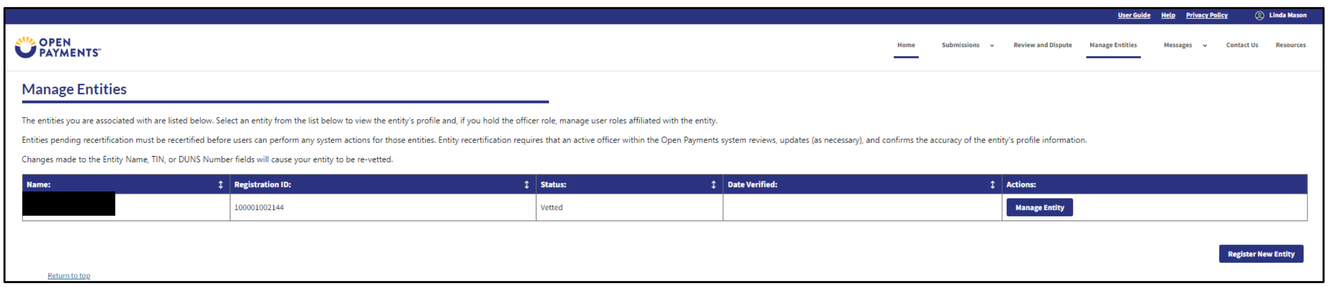
Step 1: Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials and select the **Manage Entities** tab from the header menu on the Open Payments home page.

Figure 128: Open Payments System Landing Page for Returning System Users



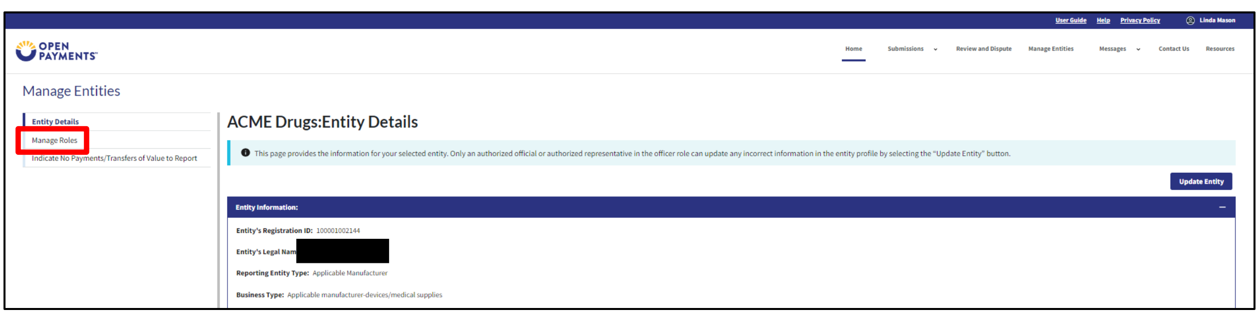
Step 2: You will see a list of all the reporting entities you are associated with. Select the hyperlink for the entity for which you will be deactivating a user.

Figure 129: Manage Entities Page



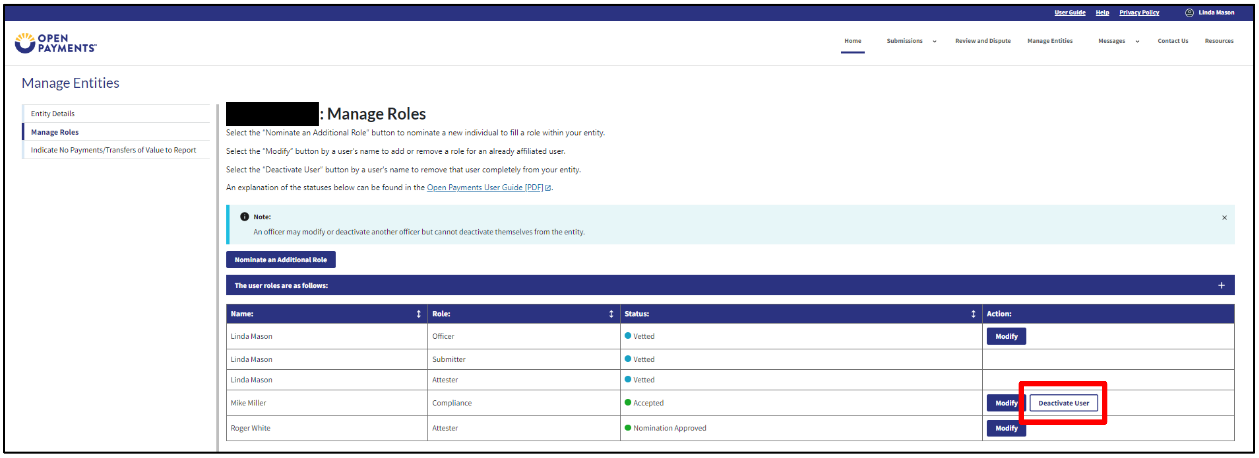
Step 3: On the "Entity Details" page, select the Manage Roles tab.

Figure 130: Manage Roles Tab



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

Figure 131: 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.

Section 3.7: Vetting

Vetting is the process of verifying a reporting entities' 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. **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, and the officer will receive an email stating the status. 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 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 is not able to 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.

If the vetting status remains "Vetting in Progress" for 48 hours, contact the Open Payments Help Desk for assistance at openpayments@cms.hhs.gov or 1-855-326-8366. For the TTY line, call 1-844-649-2766.

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 also called "Reporting Entities", 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, and manual data entry via a Graphic User Interface (GUI).

This chapter is divided into the following sections:

4.1: **Overview of Data Submission and Attestation**

4.2**: Data Submission:** information on data submission for the Open Payments system.

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

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

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

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

4.7: **Identifying Errors:** information on errors in bulk file and manual record data.

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

4.9: **Copy/Duplicate Records:** information about how to copy or duplicate record data.

4.10**: Deleting Records:** information about how to delete individual records and entire CSV files.

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

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

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

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

4.15: **Attestation and Assumptions:** 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 (collectively referred to as “Reporting Entities") to submit detailed information regarding payments or other transfers of value made to physicians, NPPs, and teaching hospitals (collectively referred to as “Covered Recipients”). To complete data submission, reporting entities must upload their data to the Open Payments system and legally attest to the accuracy of the data. After attestation, the data will be made available for covered recipients to review and dispute any discrepancies.

The figure below provides an overview of the data submission and attestation process.

Figure 132: The Four Steps of Data Submission and Attestation

Reporting entities 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 at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

Data submission is complete only after electronic attestation is received by CMS for the program year.

To assist with the preparation of data for submission, CMS has made resources available to help reporting entities confirm covered recipient identifying information. Physician identifying information can be found in the Validated Physician List (VPL). Non-Physician Practitioner identifying information can be found in the Validated Non-Physician Practitioner List (VNPPL). 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/Resources.

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.

If the NPP license information is not active (beginning with Program Year 2021 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 enables reporting entities to submit detailed information regarding payments or other transfers of value made to covered recipients, and attest to the accuracy of the data. Reporting entities can 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 via Bulk File upload that contain multiple payments to validate the file structure and payment record information; and/or individual payments via Manual Data Entry using the Open Payments system GUI.

- Use the error report generated by the Open Payments system to fix any data errors in submitted files; and/or any validation/matching errors affecting the manual data entries.

- Perform final data submission for records that do not contain any errors.

Then, the attester can attest to the accuracy of the submitted data. All submission/attestation 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/Resources.

Section 4.3: Preparing Your Data

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), NPP (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), the Validated Non-Physician Practitioners List (VNPPL) and the CMS Teaching Hospital List.

- The Validated Physicians List (VPL) contains two files, one listing physicians who have a National Provider Identifier (NPI), and an additional Validated Physician Supplemental List Without NPI that identifies physicians who do not have an NPI and have been reported on in the Open Payments system. Both the VPL and the Validated Physician Supplemental Lists are provided for reference only. If a physician does not appear on either list, it does not mean he/she is not reportable. Physicians that are not on the VPL may still be successfully matched; users may consult the National Plan and Provider Enumeration System (NPPES) or other data sources for information on reportable physicians not listed on the VPL. The VPL and supplemental files are downloadable CSV files that are **only accessible within the Open Payments system** on the "Bulk File Upload" page.

  - The VPL is a very large file and, depending on your network characteristics and software, may take a long time to download or fail to download. Additionally, the number of rows in the VPL file may be larger than the maximum rows your Microsoft Excel version supports. If you can't download the file, we recommend engaging your IT support staff. If you can download the file but are unable to open it in MS Excel or get a message that the data has been truncated, we recommend trying alternative programs such as MS Access, Universal Viewer, Editpad, Notepad++, or any other software your organization has available for large datasets.

- The Validated Non-Physician Practitioners List (VNPPL) is a reference data file that lists information about Physician Assistants (PA), Nurse Practitioners (NP), Clinical Nurse Specialists (CNS), Certified Registered Nurse Anesthetists, Anesthesiologist Assistants (CRNA/AA), and Certified Nurse-Midwives (CNM), collectively called "NPPs". The VNPPL contains two separate files, one listing NPPs who have an NPI, and the second listing NPPs without NPI and have been reported on in the Open Payments system. The VNPPL is **not** an exhaustive list of all NPPs who should be reported in the Open Payments program. It can only be accessed on the "Bulk File Upload" page by those with a role within the entity.

- The Teaching Hospital Lists include all teaching hospitals that should be included in Open Payments reporting, for a specified program year. They can be accessed via the Resources page on the Open Payments website (https://www.cms.gov/OpenPayments/Resources).

  - 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."

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

  - There is a separate Teaching Hospital list for each program year. Only teaching hospitals on the list may be reported.

Another key resource is the "Submission Data Mapping Document," which maps each data element in Open Payments records to the appropriate CSV field names. (Due to slight changes to reporting requirements in different years, there are different versions of this document for PY 2018-2020 data, PY 2021-2022 data, and 2023 and Onwards 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 for Reporting Entities page on the Open Payments website: https://www.cms.gov/priorities/key-initiatives/open-payments/resources/reporting-entitities.

4.3b: Validation Utility for Covered Recipients: Physicians and NPPs

If you hold a submitter role for a reporting entity, you can access the covered recipient validation tool to validate information prior to reporting payments made to a particular physician and/or NPP. When you upload the physician and/or NPP information to the system, the information is matched using the CMS-validated resources, which can reduce matching errors when reporting.

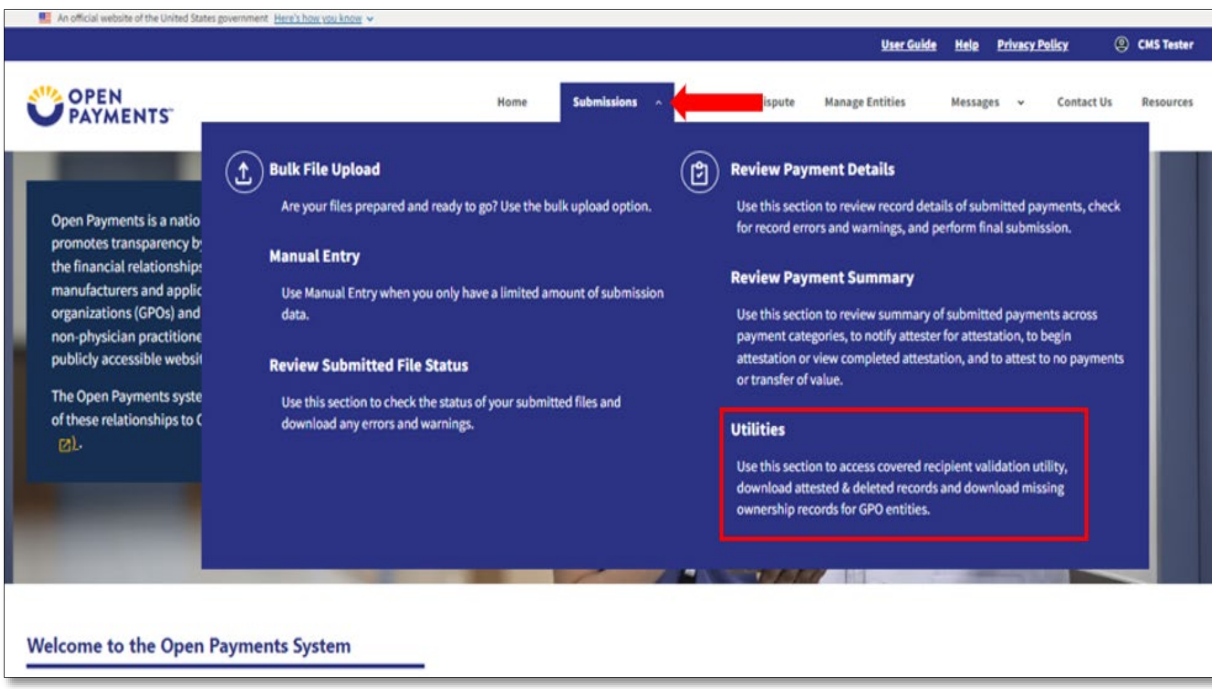
You must use the specific Covered Recipient validation template provided on the Open payments “Validate Covered Recipient” page to upload physician and/or NPP profile information for validation. Once the validation process is completed, you can download the results file for any physician and/or NPP that were not successfully matched.

Character-separated value (CSV) is the only file format accepted by the Open Payments system to validate physicians and/or NPPs. Submitted validation utility 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.

4.3b (1): Validating physician and/or NPP Instructions

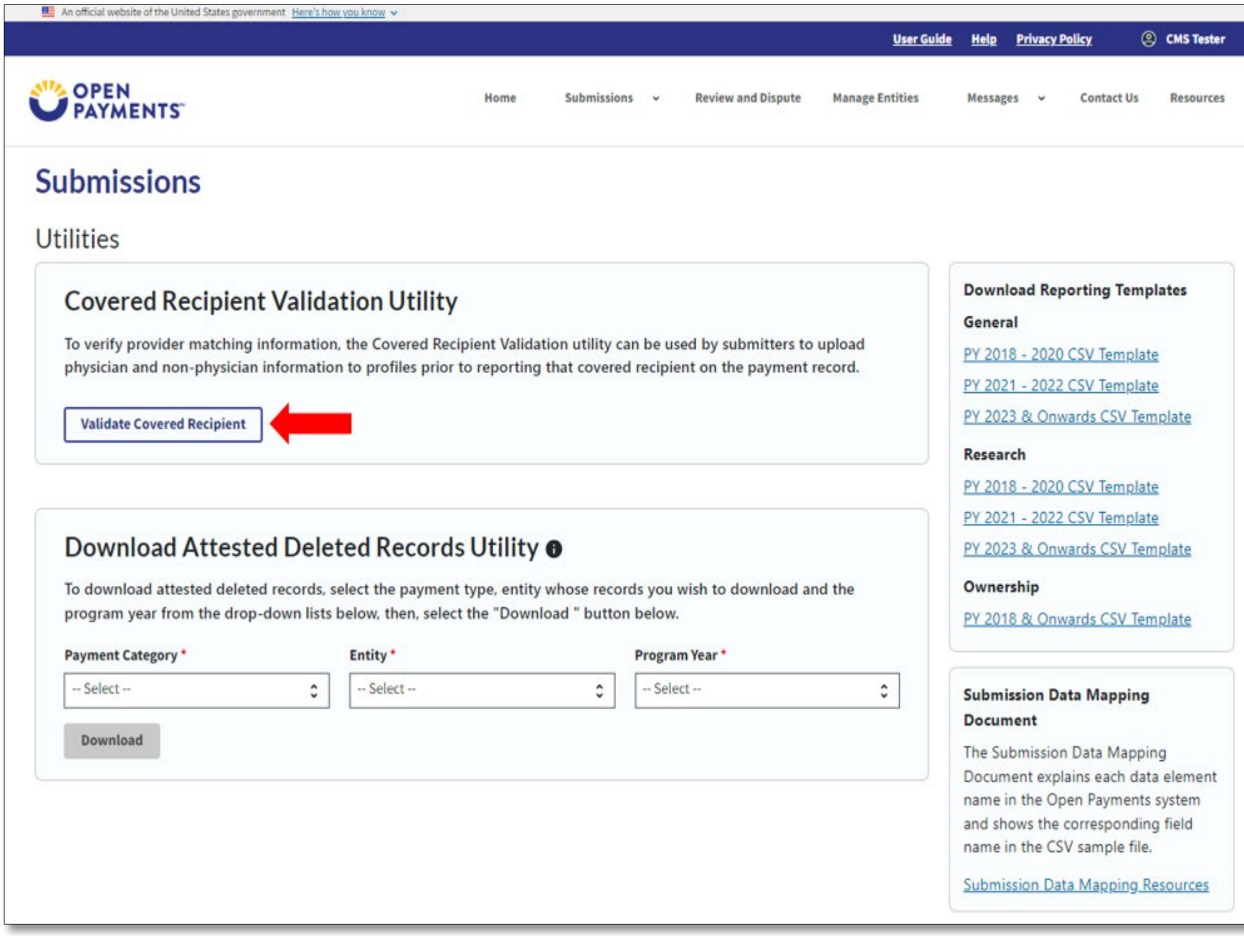
Step 1: Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials, select the **Submissions** tab and then select **Utilities** in the drop-down menu.

Figure 133: Submissions Tab



Step 2: You will be brought to the "Utilities” page. Select the **Validate Covered Recipient** button to begin the physician and/or NPP validation process.

Figure 134: Validate Covered Recipient Button



Step 3: Download and use the "Covered Recipient Validation Template" available on the right pane of the "Covered Recipient Validation" page to validate **physician and/or NPP** information using this tool. An example of the "Covered Recipient Validation Template" data fields are shown below.

Figure 135: Covered Recipient Validation Data Fields Table

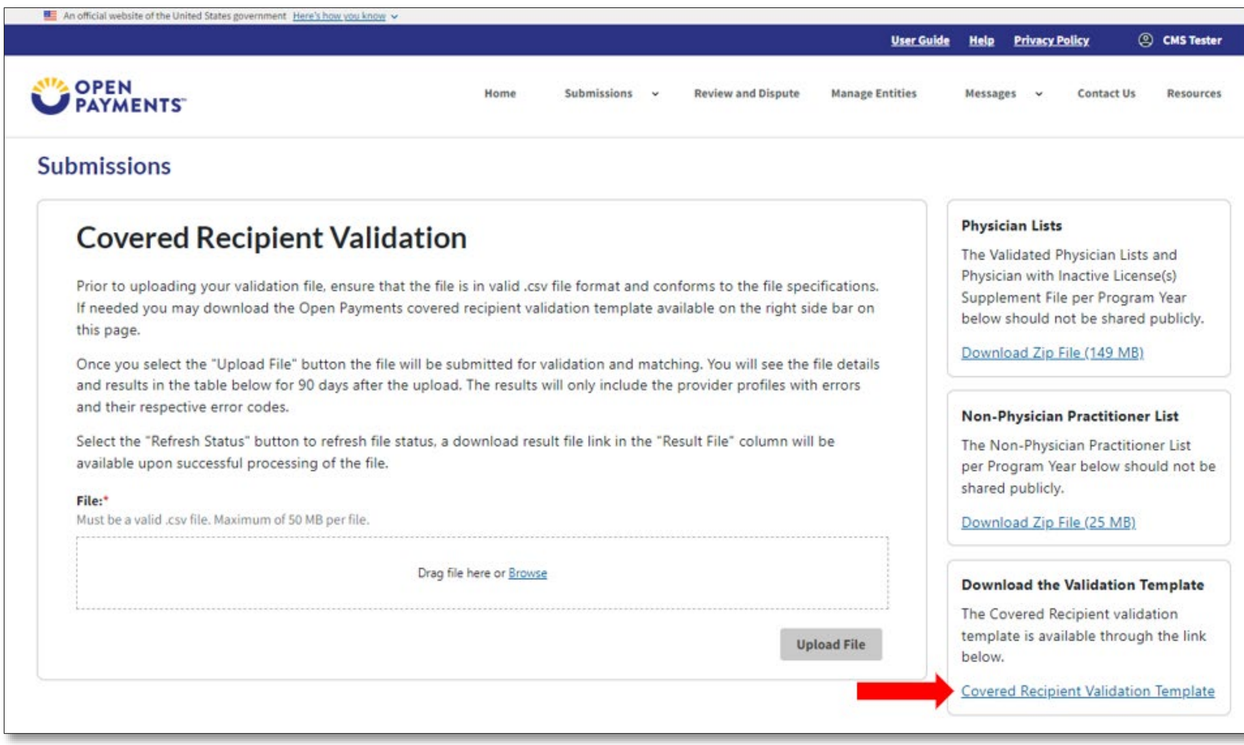
Element	Description	Format
APPLICABLE_MANUFACTURER_OR_APPLICABLE_GPO_ID	Enter the Applicable Manufacturer's/Applicable GPO's Registration ID in this data field	Free form text
COVERED_RECIPIENT_TYPE	Enter the covered recipient type either physician or NPP. Allowed values include "1" = Physician "10" = Non-Physician Practitioner	Less than or equal to 20 digits

Element	Description	Format
COVERED_RECIPIENT_FIRST_NAME	Enter the textual first name of the physician or NPP receiving the payment or other transfer of value.	Free form text
COVERED_RECIPIENT_LAST_NAME	Enter the textual last name of the physician or NPP receiving the payment or other transfer of value	Free form text
COVERED_RECIPIENT_NPI	Physician or NPP NPI (not the NPI of any group the physician or NPP belongs to)	Numeric digits only
COVERED_RECIPIENT_PRIMARY_TYPE	Enter Primary type of medicine practiced by the covered recipient Physician or NPP. Allowed values include "1" = Medical Doctor; "2" = Doctor of Osteopathy; "3" = Doctor of Dentistry; "4" = Doctor of Podiatric Medicine; "5" = Doctor of Optometry; "6" = Chiropractor "101" = Physician assistant "102" = Nurse practitioner "103" = Clinical nurse specialist "104" = Certified Registered Nurse Anesthetist "105" = Certified nurse-midwife “106” = Anesthesiologist Assistant	If Covered Recipient Type = "1" (Physician) then enter only one value between Covered Recipient Primary Type= "1" and Covered Recipient Primary Type= "6" as applicable OR "10" (NPP) then enter up to 6 comma separated values between Covered Recipient Primary Type= "101" and Covered Recipient Primary Type= "106" as applicable

Element	Description	Format
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_1	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA-9999999999999999999999999
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_2	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA-9999999999999999999999999
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_3	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA-9999999999999999999999999
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_4	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA-9999999999999999999999999

Element	Description	Format
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_5	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA-999999999999999999999999

Figure 136: Covered Recipient 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 the 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.

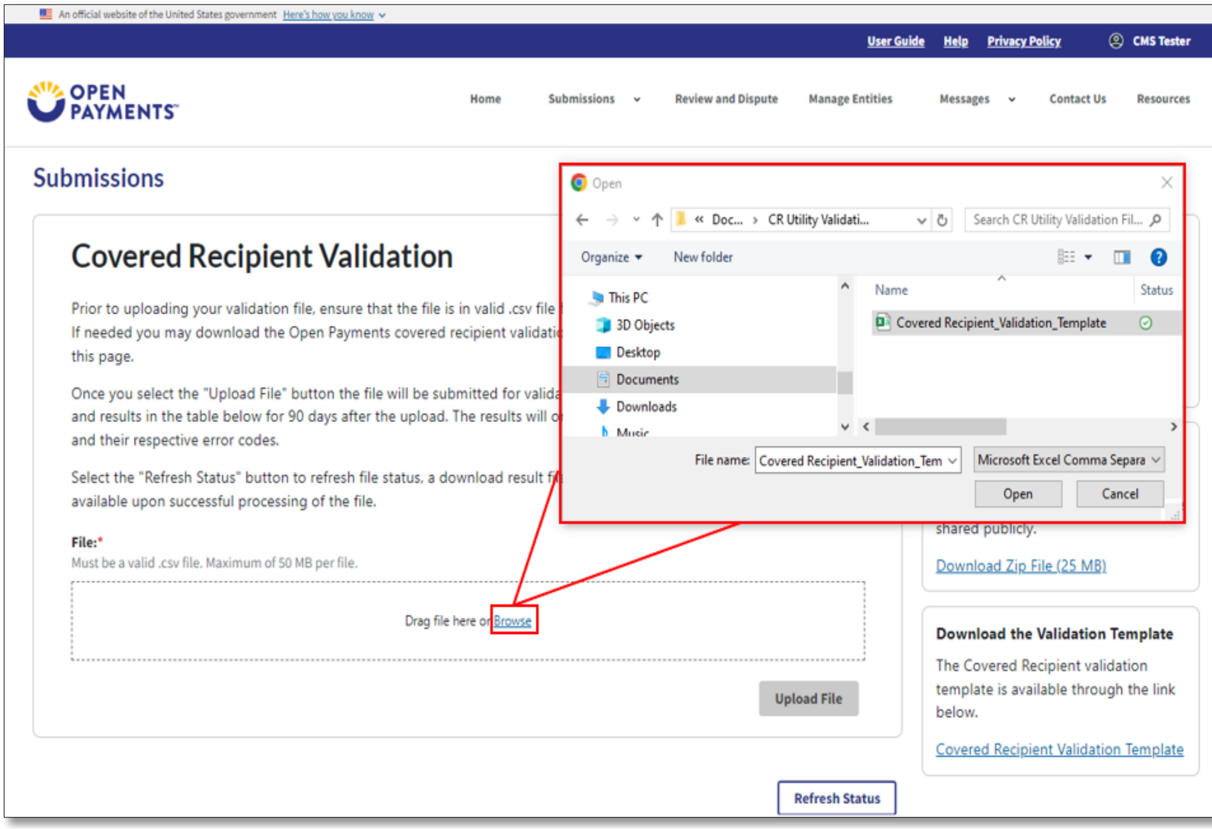
Note: Operating system companies are known to change their workflow methods at different times of the year, and the methods shown in the User Guide may not be current. If these methods are not applicable, please see your IT Department for updated instructions.

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 **Browse** button to choose a file to be uploaded.

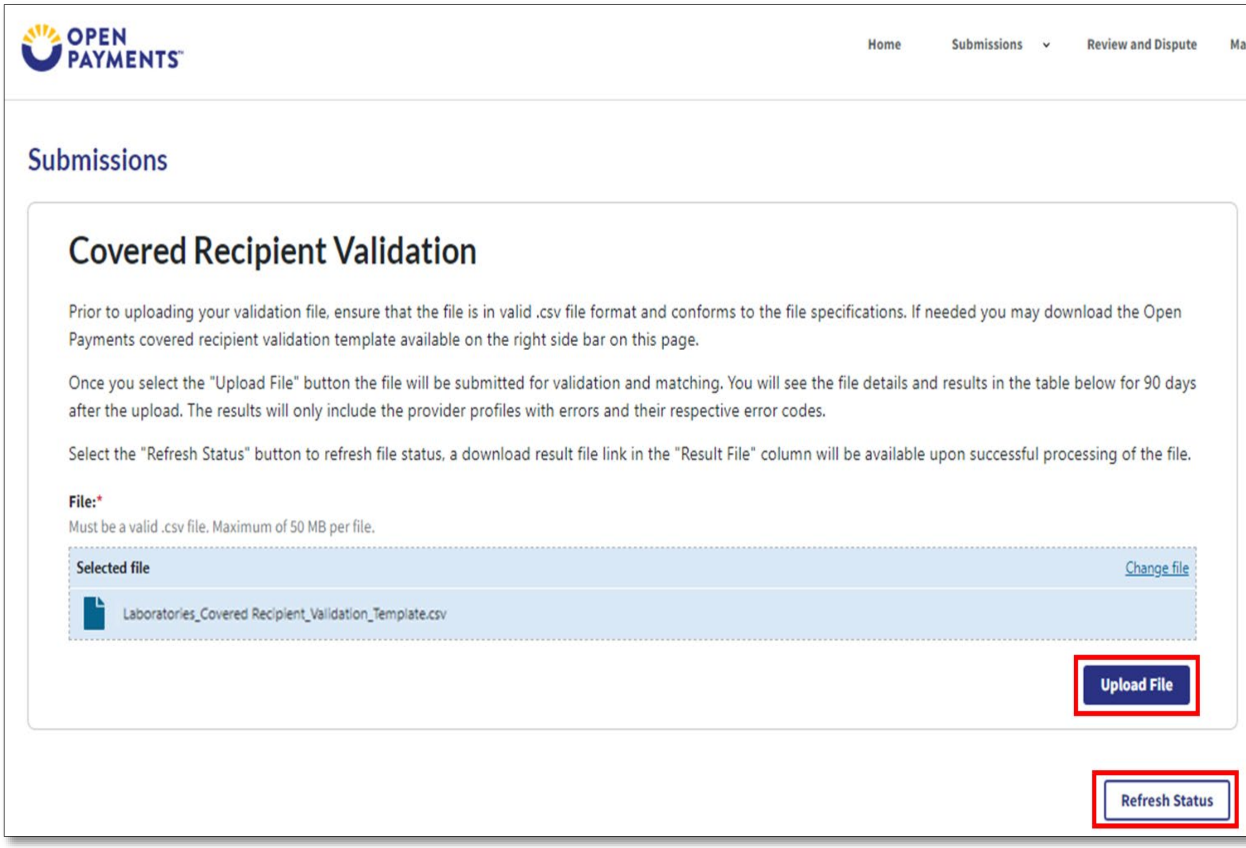
Figure 137: Browse Pop-Up Window



Step 5: Select the **Upload File** button to upload the chosen file to the Open Payments system. Select the **Refresh Status** button to refresh the "Covered Recipient Validation" page.

You will receive a confirmation message stating, "You have successfully refreshed the page" and you will be able to download a results file. **Selecting the "Cancel" button will cause you to lose all data entered.**

Figure 138: Upload File and Refresh Status Buttons



<u>Step 6:</u> Select the **Download Results File** button to download the results file. The results file, which is a pipe delimited .csv file inside of a .zip file and will include only the profiles with errors. If the system found a successful match on the entered physician and/or NPP profile then the results file will not include that NPP profile. The system will display the results file for 90 days after the upload within the Open Payments system.

Figure 139: Covered Recipient Validation with Download Option

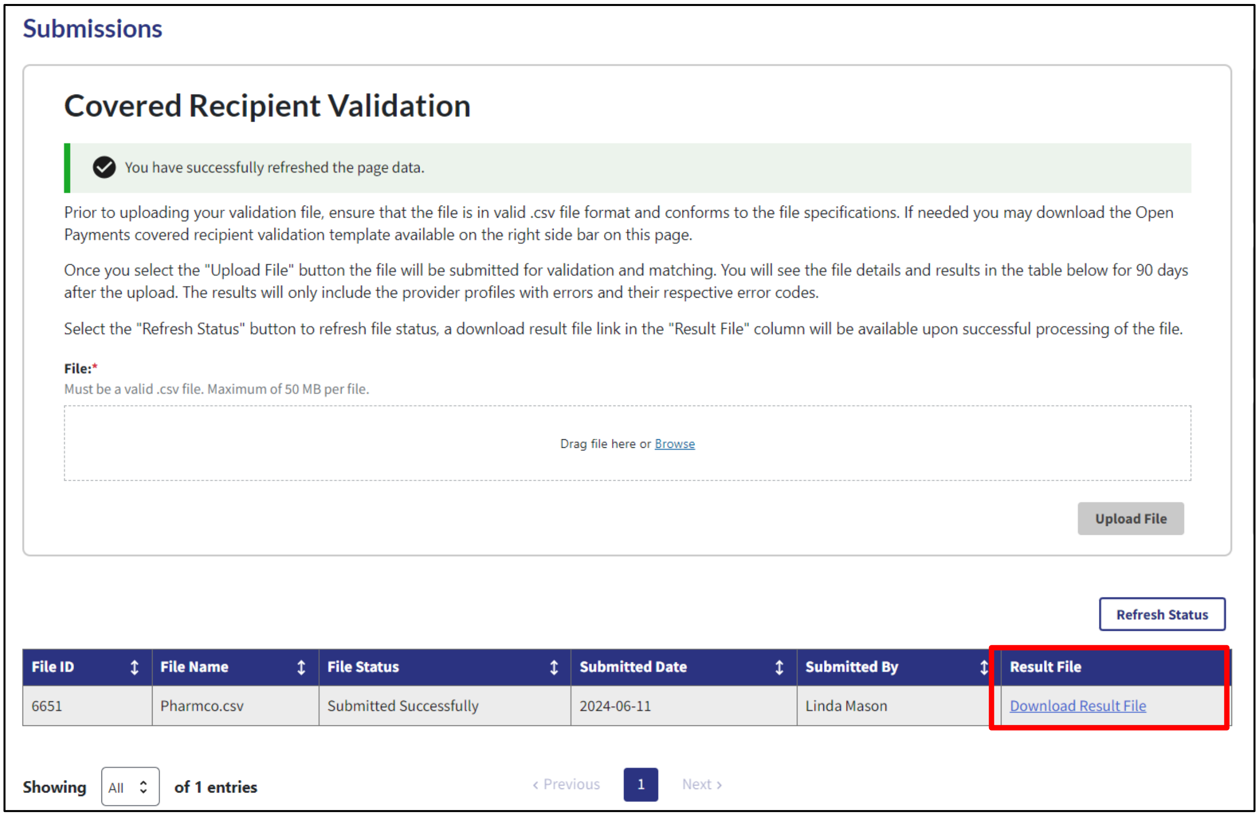


Figure 140: Results File Data Elements

Element	Information Displayed
APPLICABLE_MANUFACTURER_OR_APPLICABLE_GPO_ID	Input from user
COVERED_RECIPIENT_TYPE	Value-based on Input from the user
COVERED_RECIPIENT_FIRST_NAME	Input from user
COVERED_RECIPIENT_LAST_NAME	Input from user
COVERED_RECIPIENT_NPI	Input from user
COVERED_RECIPIENT_PRIMARY_TYPE	Input from user
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_1	Input from user
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_2	Input from user
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_3	Input from user
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_4	Input from user
COVERED_RECIPIENT_LICENSE_STATE_AND_LICENSE_NUMBER_5	Input from user
ERROR_MESSAGE_ID	Error codes (separated by comma)
DATA_ELEMENT_VALUE	Element(s) that causes the error(s) (separated by comma)

When all profiles in the file are successfully matched, the results file download link will still be available. Inside the downloaded file, only the following message will be displayed:

All Covered Recipient profiles you uploaded were successfully matched. Hence, there are no errors in this file.

Section 4.4: Bulk File Upload

The Open Payments system allows reporting entities 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 4.13 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);
- Correct or modify existing records in the Open Payments system (refer to Section 4.8a);
- Delete existing records (refer to Section 4.10b); and
- Update the delay in publication status of existing records (refer to Section 4.12).

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. Refer to the Submission Data Mapping documents for details. Data supplied in fields identified as optional for these file templates will not be validated but saved in the Open Payments system.

Character-separated value (CSV) is the only MS Excel 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 if 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.

According to the Open Payments Final Rule, Group Purchasing Organizations (GPOs) are only required to report payments or other transfers of value made to physician owners/investors.

The GPOs **cannot report any general, research payment, or ownership/ investment record for NPPs; however, they can report NPPs as a principal investigator on the research payment.**

The Open Payments system will prevent GPOs from submitting general and research payment records for teaching hospitals or non-physician practitioner covered recipients.

4.4a: Delay Limit Reached

Per the Final Rule, research records can only be delayed from publication for four years from the year of payment (i.e., the record's program year). As such, records attributed to Program Years 2014-2019 are no longer eligible for a delay in publication and will be included in the June 2024 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 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 of 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 for Reporting Entities” page of the Open Payments website (https://www.cms.gov/OpenPayments/Resources). 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.

Figure 141: CMS Open Payments Website "Resources for Reporting Entities" Page

SUBMISSION SAMPLE FILES

Use the sample files below to format your data correctly for upload into the Open Payments system.

Program Year 2023
ONLY use these files for records dated from January 1, 2023 and onward:

- CSV Sample File: General Payments (CSV)
- CSV Sample File: Research Payments (CSV)

Program Years 2021 to 2022
ONLY use these files for records dated from January 1, 2021-December 31, 2022:

- CSV Sample File: General Payments (CSV)
- CSV Sample File: Research Payments (CSV)

Program Years 2018 to 2020
ONLY use these files for records dated from January 1, 2018 -December 31, 2020:

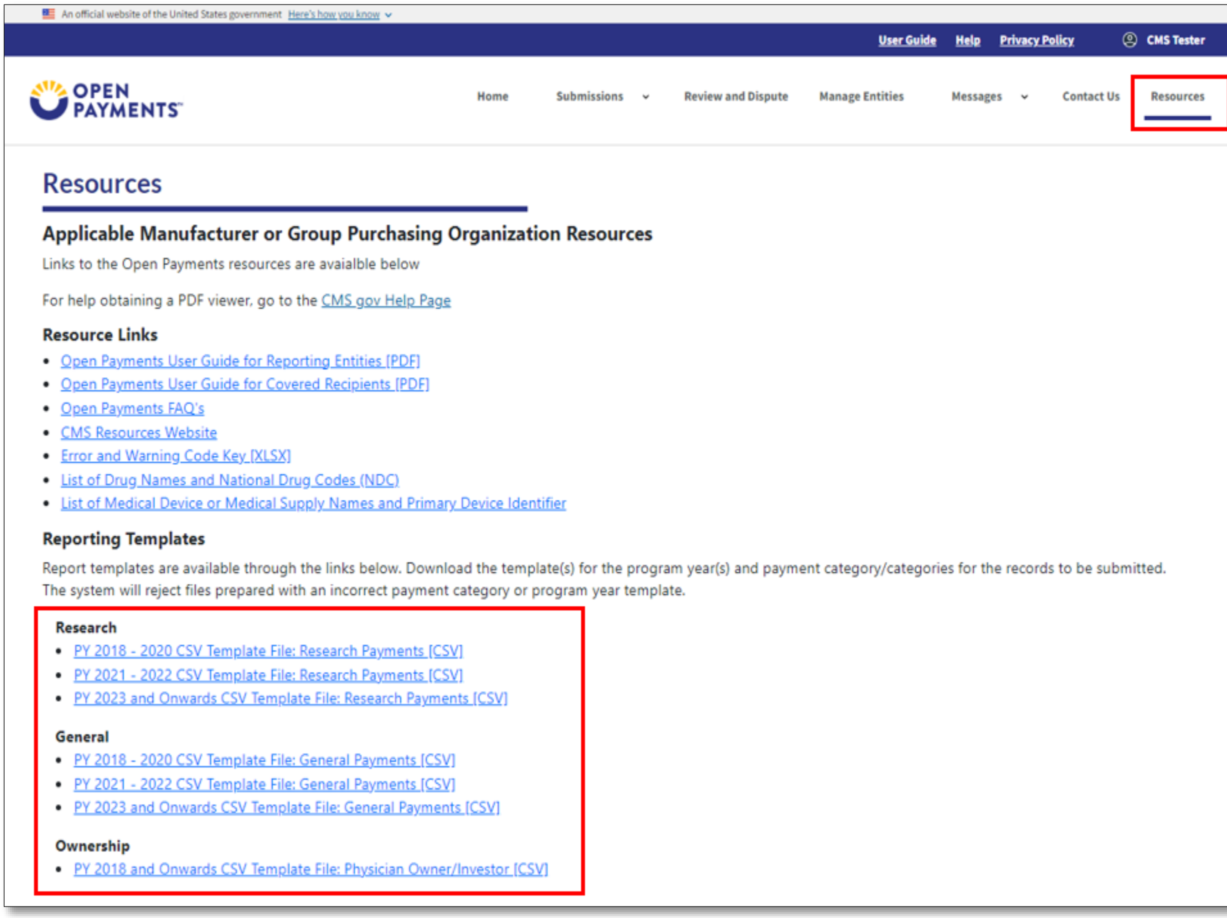
- CSV Sample File: General Payments (CSV)
- CSV Sample File: Research Payments (CSV)

Program Years 2018 and Onwards: Physician Owner/Investor
This sample file should be used for submitting ownership/investment interests for all program years.

- CSV Sample File: Physician Owner/Investor (CSV)

Reporting templates are also available within the Open Payments system and can be accessed on the **Resources** tab by users with an entity role. The templates define the exact format and layout of the files accepted in the Open Payments system.

Figure 142: Open Payments System "Resources" tab -> 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. “Program Year” is defined as the year the payment was made to the covered recipient.

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 for Reporting Entities’ 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.

The list below explains which guidance documents to use, with active hyperlinks to download documents:

Figure 143: Submission Mapping Document and Reporting Template Links

Submission Mapping Document	CSV Reporting Template
Program Year 2023 and Onwards (XLSX)	CSV Sample File: General Payments (PY2023 and Onwards) CSV Sample File: Research Payments (PY2023 and Onwards) CSV Sample File: Physician Owner/Investor (All Years)
Program Years 2021-2022(XLSX)	CSV Sample File: General Payments (PY2021-2022) CSV Sample File: Research Payments (PY2021-2022)
Program Years 2018-2020 (XLSX)	CSV Sample File: General Payments (PY2018-2020) CSV Sample File: Research Payments (PY2018-2020)

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 *Clock and Region -> Region: Change date, time, or number formats -> 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 the 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:

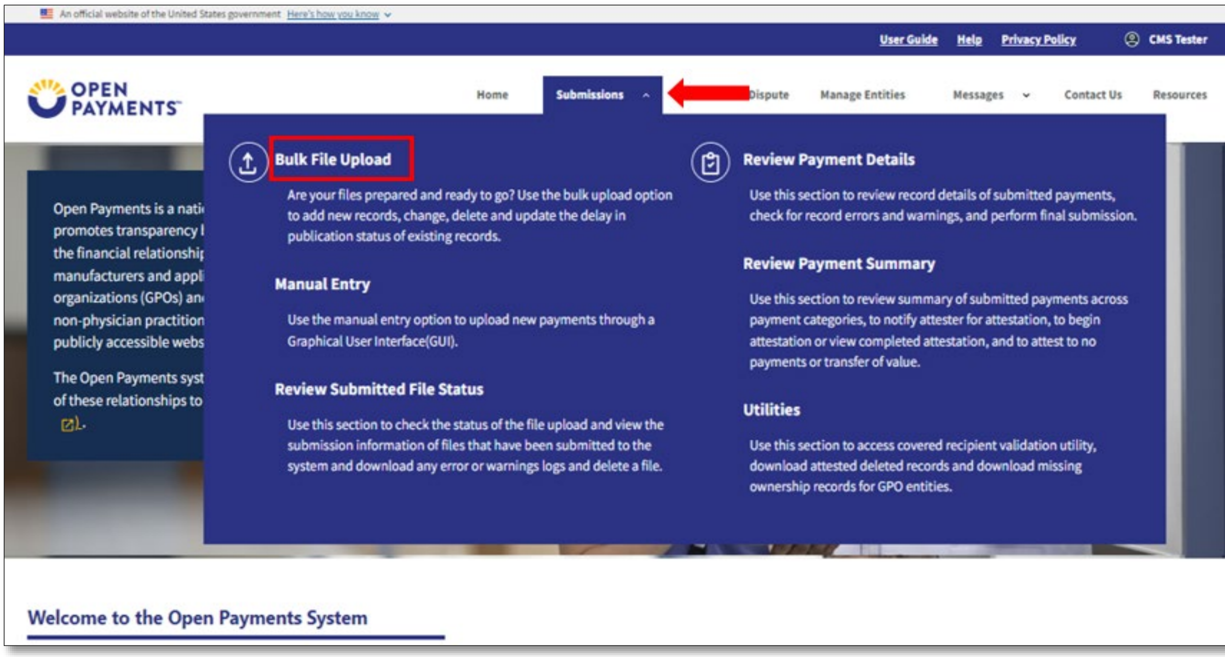
- Open the CSV file in a text editor (Notepad for Windows, Text Editor for Macintosh) and confirm that the rows are delimited with pipes; and
- Ensure that rows of data are not contained within quotation marks to avoid the data being rejected by the system.

4.4c: Bulk File Upload Instructions

Step 1: Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials, select the **Submissions** tab on the toolbar and then select **Bulk File Upload**.

Note: Only those in a submitter role have access to the submission menu.

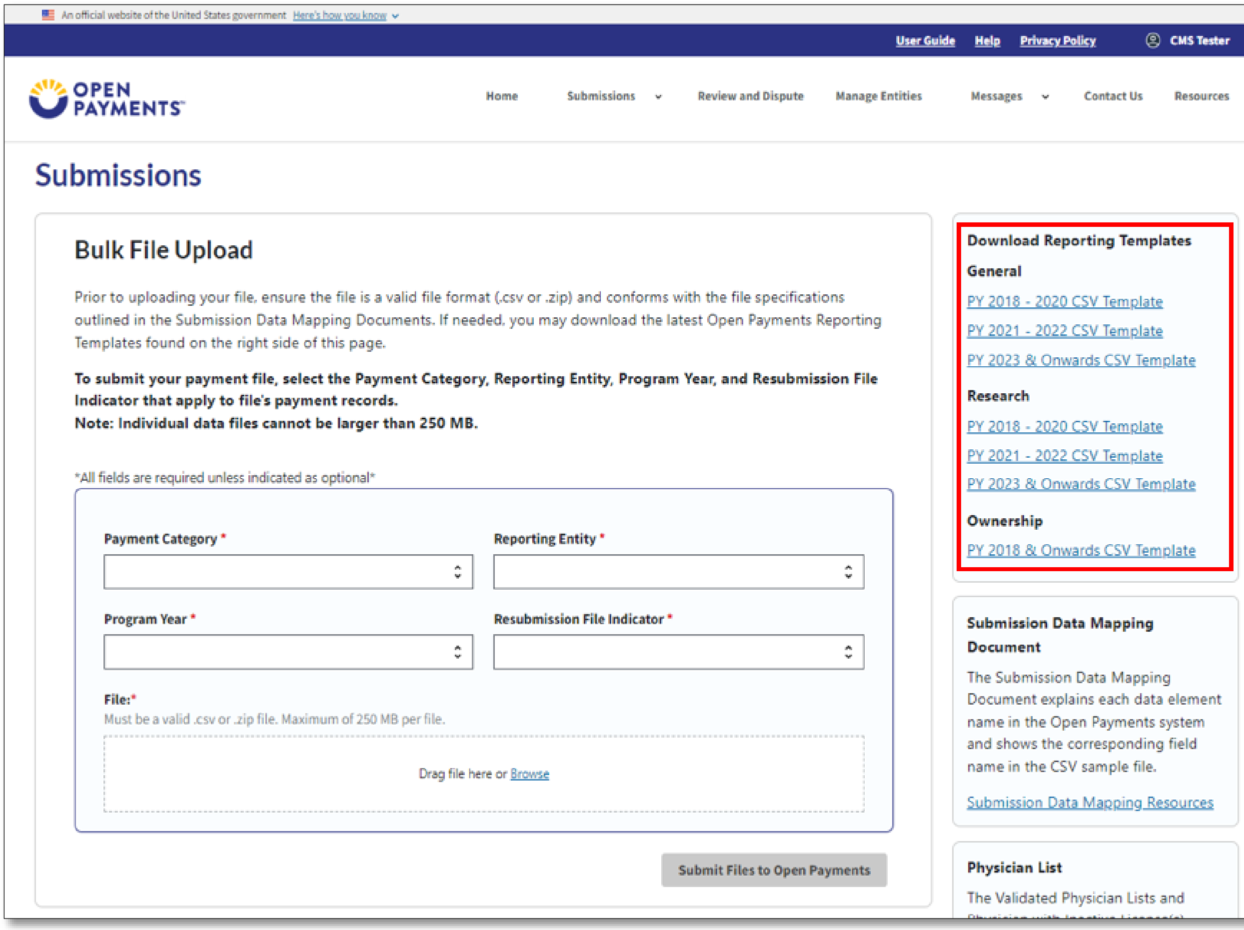
Figure 144: Submissions Tab -> Bulk File Upload



Step 2: Prior to submitting your file:

- Ensure the file you are uploading is in the correct file format (.csv or .zip).
- Ensure your entries in the file are as outlined in the Submission Data Mapping Document.
- Ensure your file is pipe delimited.
- Ensure your file is built using the Sample File. If needed, you may download the latest Open Payments Reporting Templates found on the right side of this page.

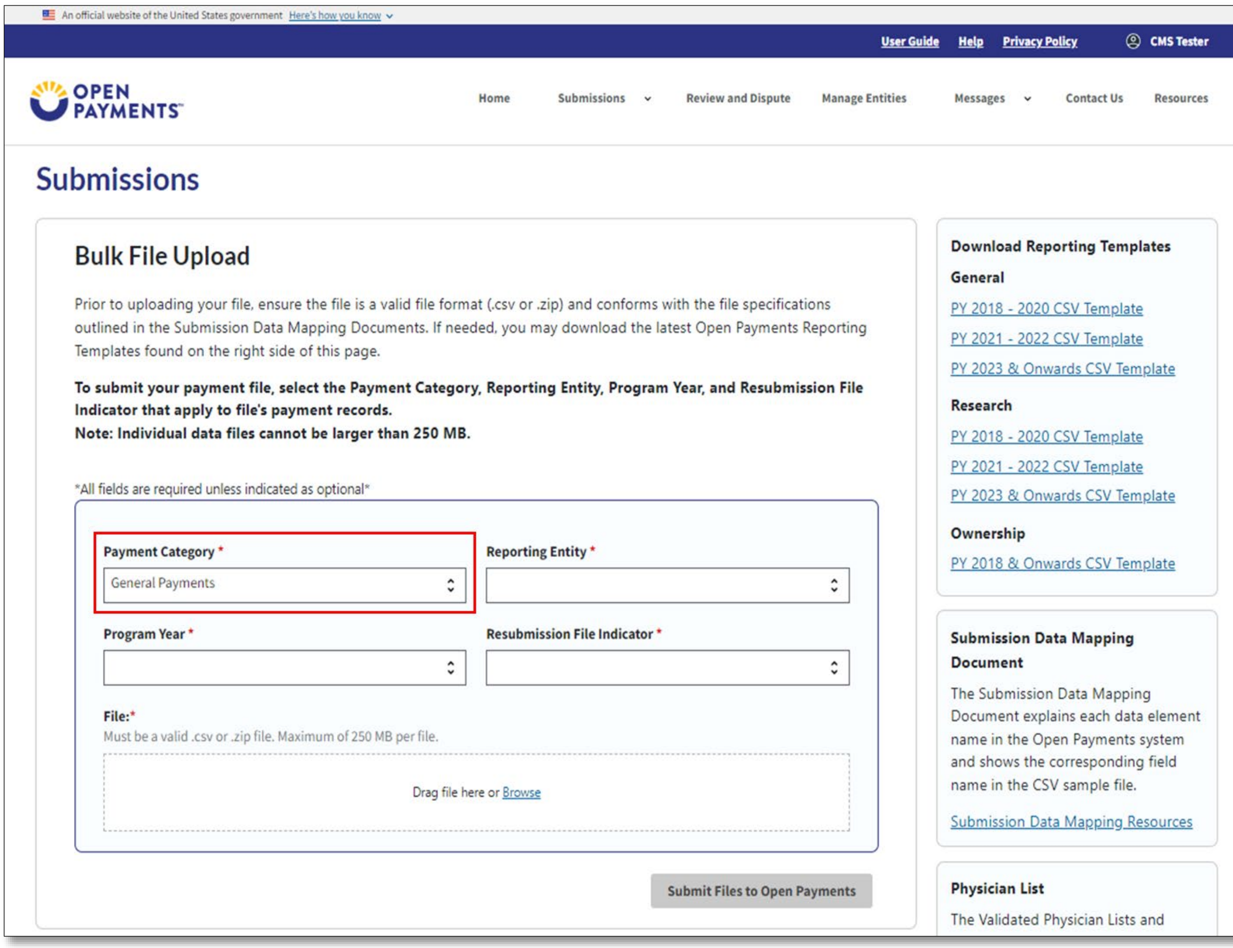
Figure 145: Bulk File Upload Page -> Download Reporting Templates Section



Step 3: Select the **Payment Category** for the type of file being submitted:

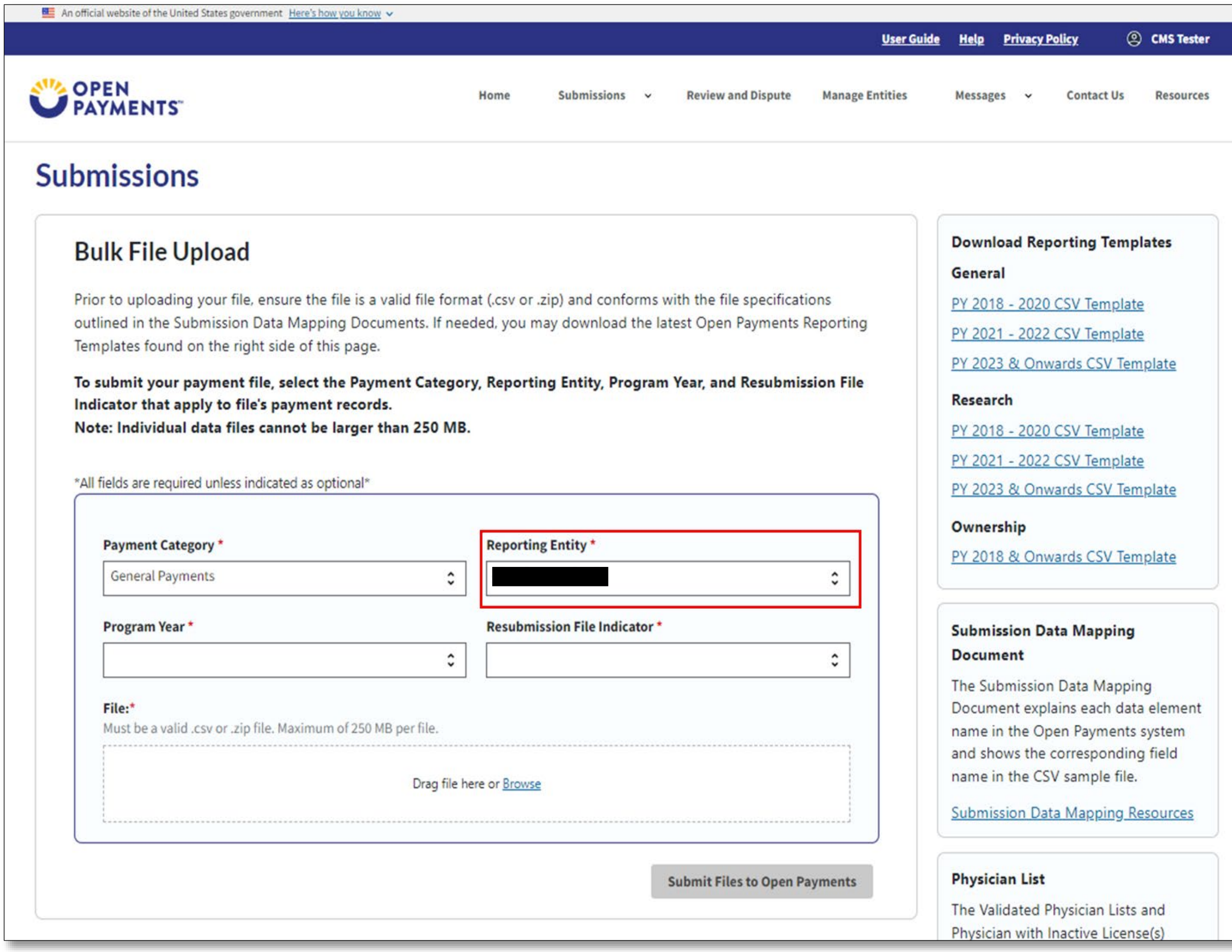
- General Payments
- Research Payments or
- Ownership/Investment interests.

Figure 146: Bulk File Upload Page -> Payment Category



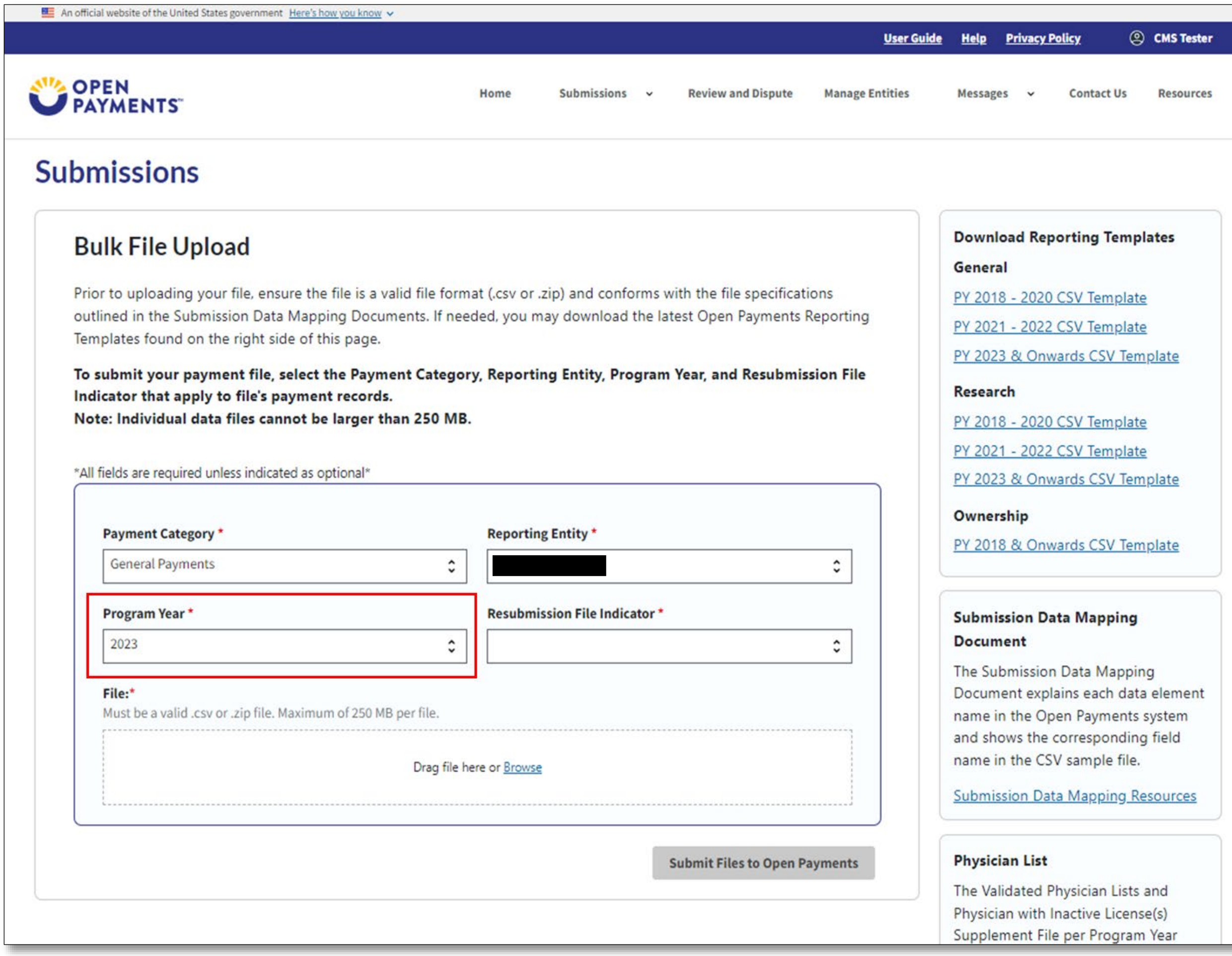
Step 4: Select the **Reporting Entity** for which you will be uploading the files.

Figure 147: Bulk File Upload Page -> Reporting Entity



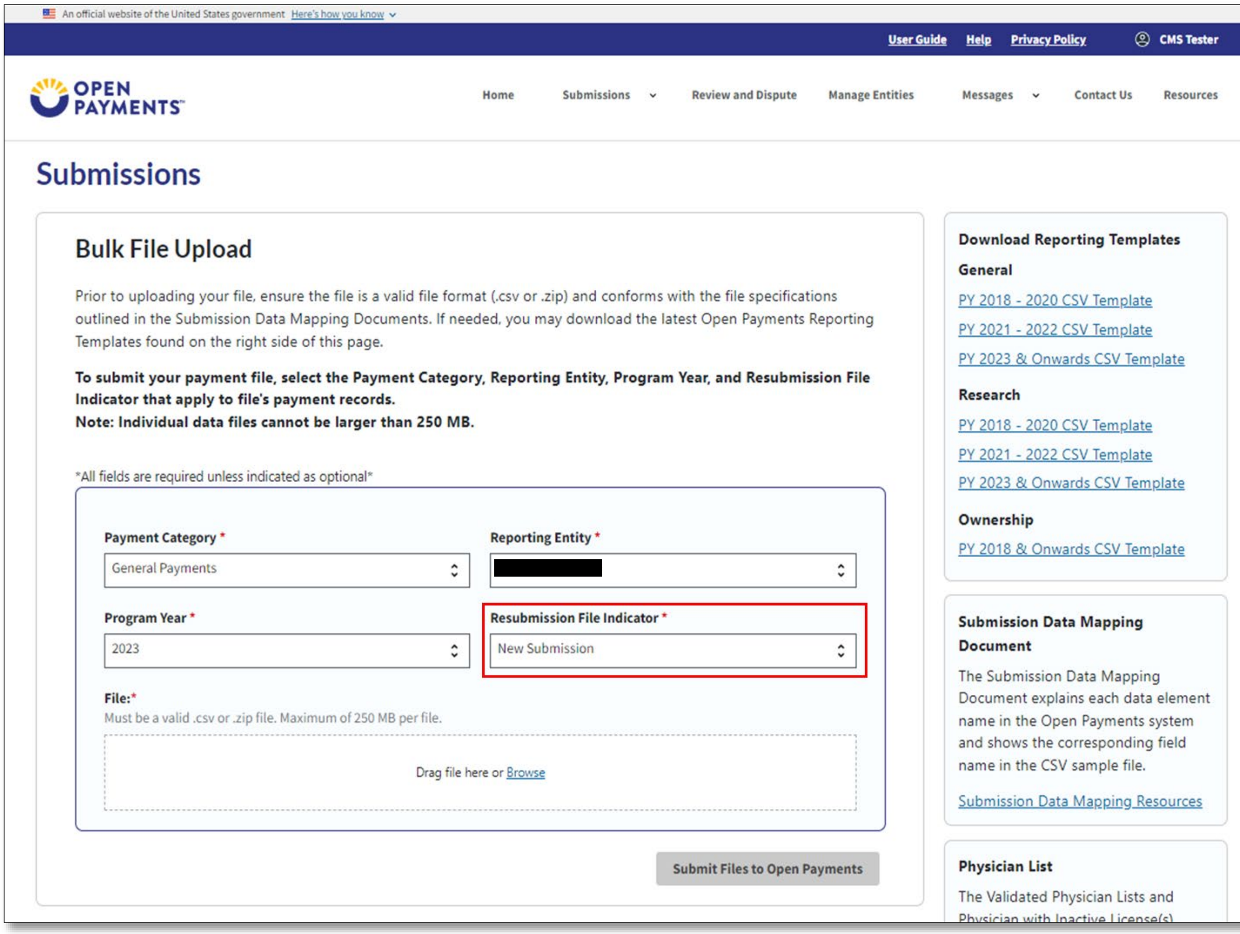
Step 5: Select the **Program Year** of the data from the dropdown.

Figure 148: Bulk File Upload Page -> Program Year



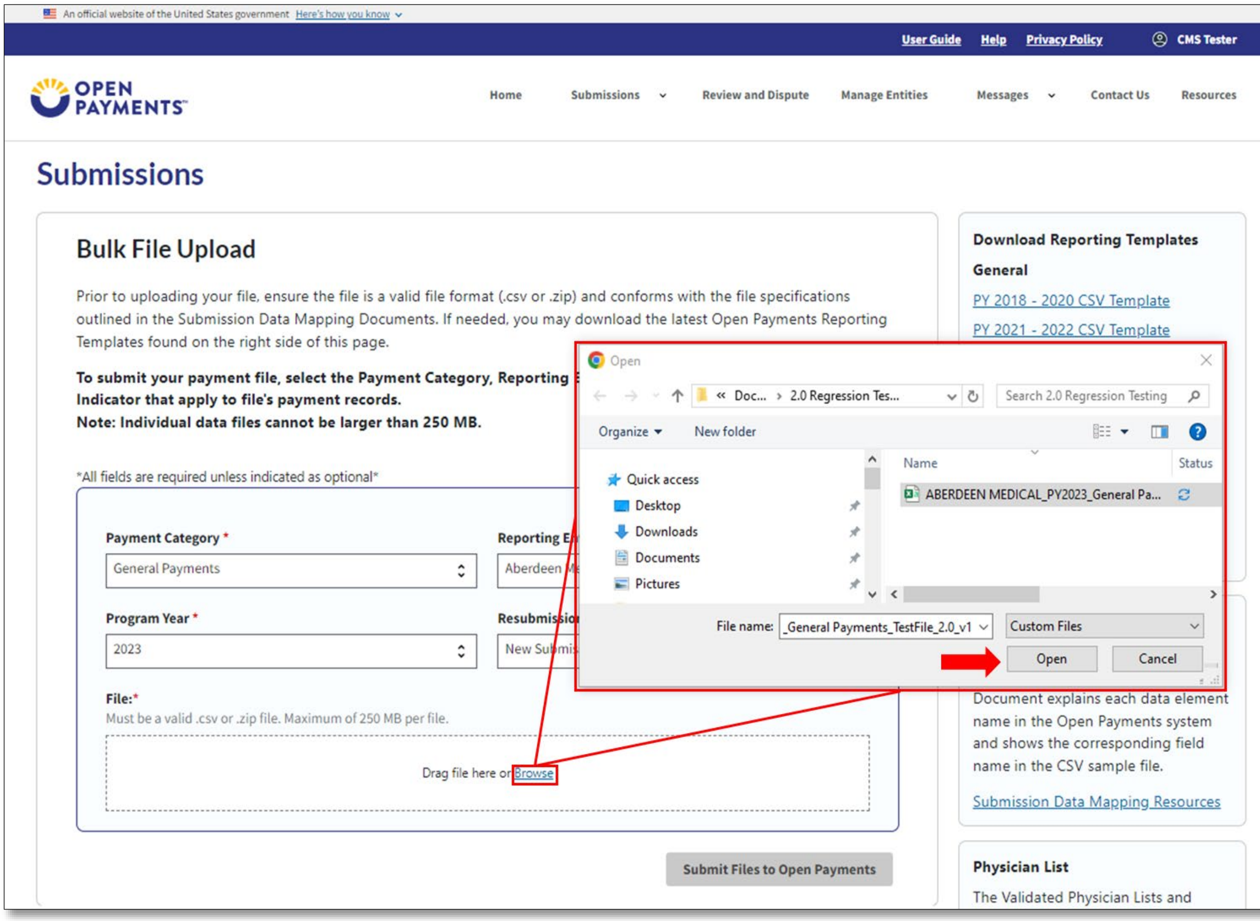
Step 6: For the Resubmission File Indicator drop-down, select the value that matches the value given in the "Resubmission File Indicator" in the file's records (e.g., If this is a new file, select "New Submission").

Figure 149: Bulk File Upload Page -> Resubmission File Indicator



Step 7: Select the **Browse** button to find and select the file to be uploaded or drag the file from your file's location into the box provided.

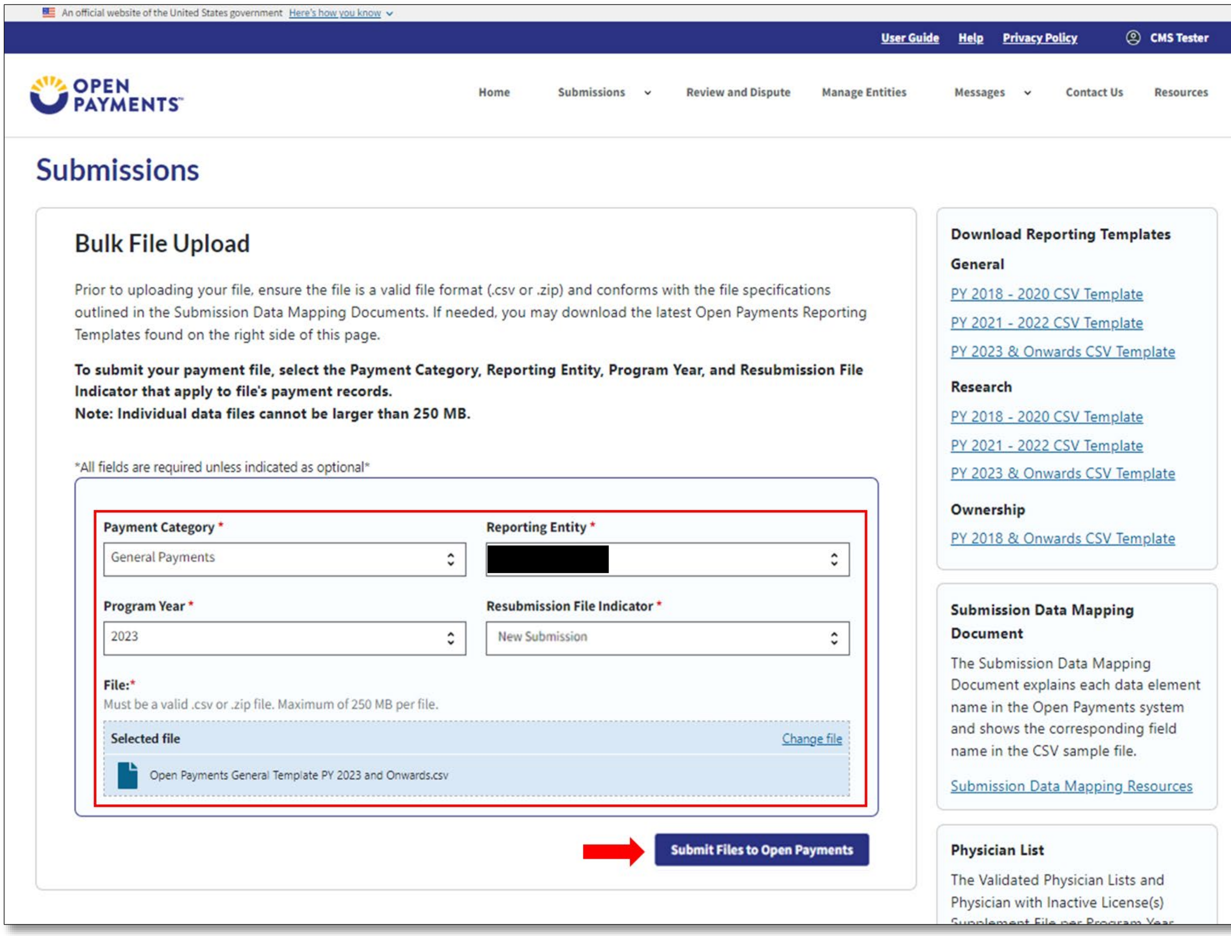
Figure 150: Bulk File Upload -> Browse File Example



Step 8: Select the **Submit Files to Open Payments** button when all required fields are completed.

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

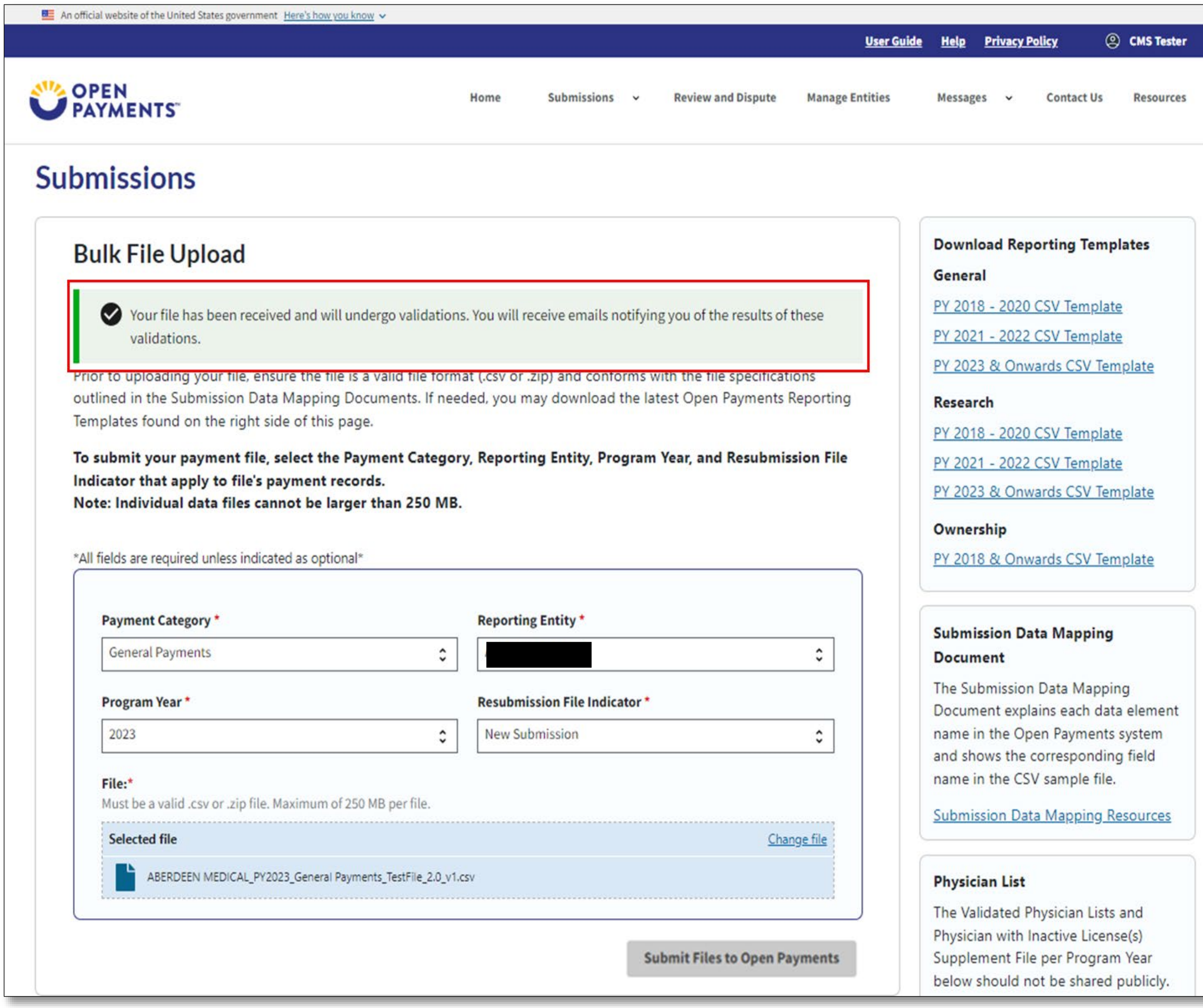
Figure 151: Bulk File Upload Page -> Submit Files to Open Payments Button



<u>Step 9:</u> Ensure you receive the green confirmation message on top of the page, which indicates the file was received, and will progress through additional validations.

If you receive a red notification message, you will need to correct the file you are trying to upload. Contact the Open Payments Help Desk for live assistance if you are unable to successfully upload your file after uploading the file after making the necessary corrections and ensuring that all requirements are met.

Figure 152: Bulk File Upload Page -> File Confirmation Message



After a file upload is confirmed and successful, 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 and/or NPP licenses or late submissions. Such records should be reviewed for accuracy from the warning log but can proceed to final submission without correction.

See Section 4.8 for details on record correction and resubmission.

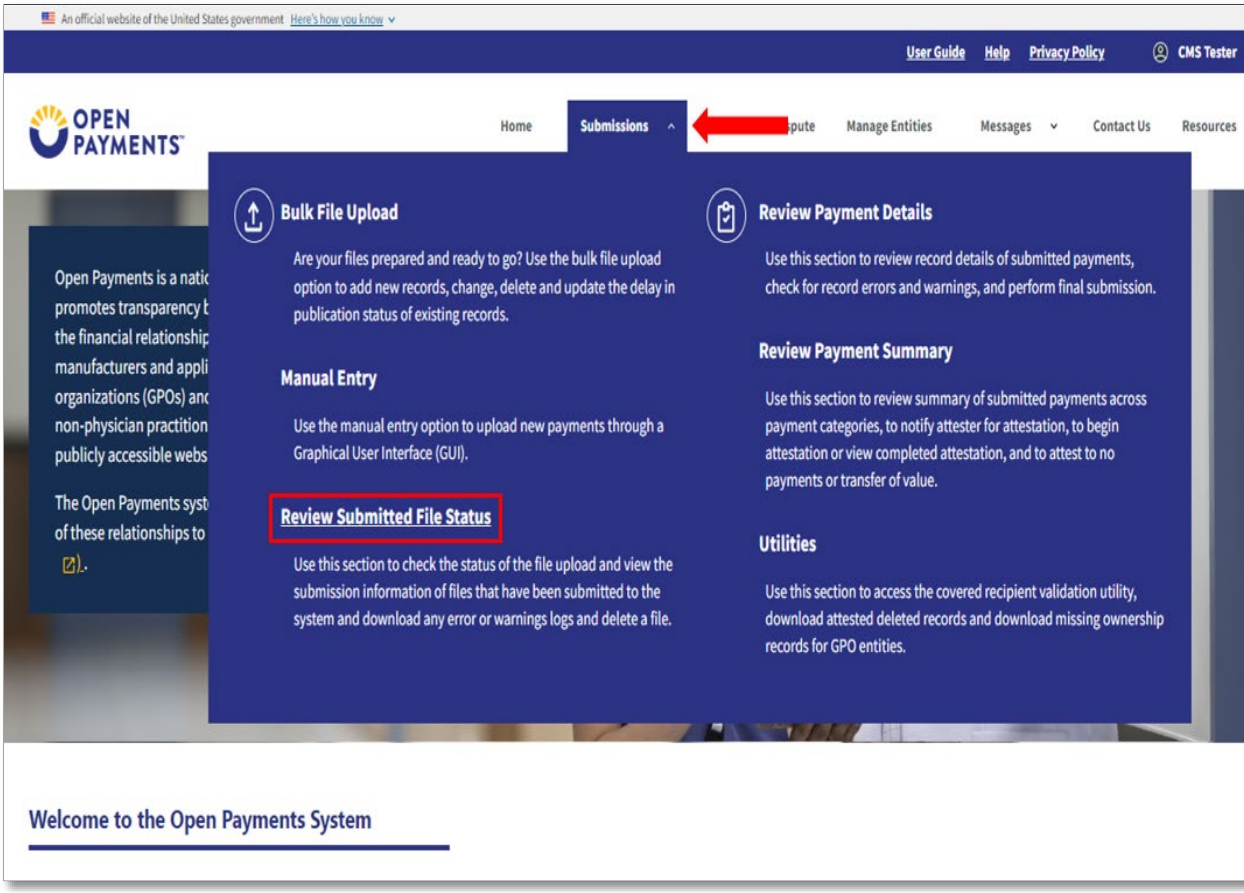
4.4d: Review File Status page

Reporting entity users with a submitter role may check the status of their file upload from the "Review Submitted 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.

To access the "Review Submitted File Status" page, follow the steps below:

Step 1: Log in to the CMS Open Payments system at https://openpayments.system.cms.gov using your IDM credentials, select the **Submissions** tab and then select **Review Submitted File Status**.

Figure 153: Submissions Tab -> Review Submitted File Status



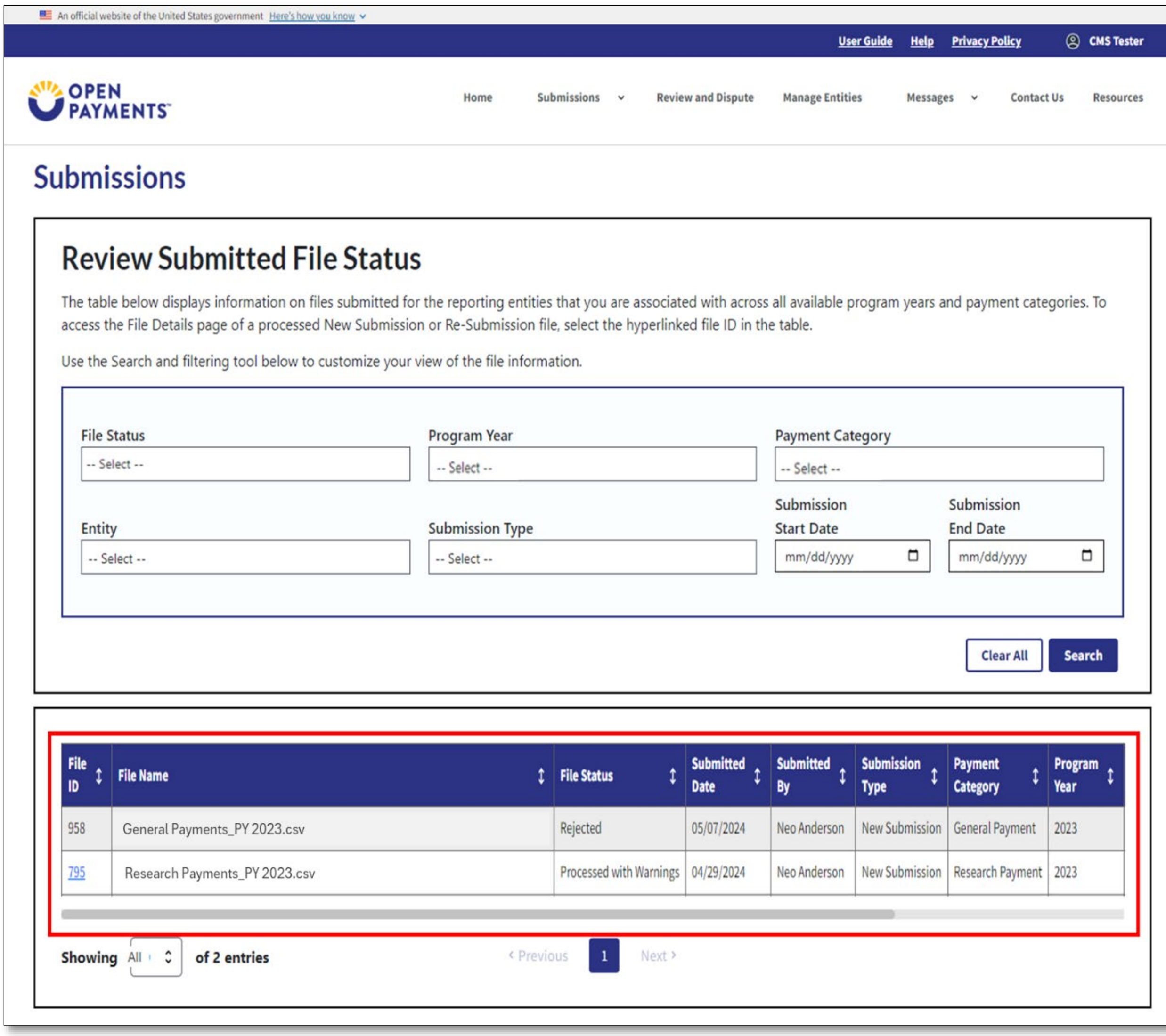
Step 2: Scroll down to the table at the bottom of the page displaying information about files submitted for the reporting entities you are associated with across all available program years and payment categories.

The file table provides the following information for each file:

- File ID
- File Name
- File Status
- Submitted Date
- Submitted By (i.e. User First Name and Last Name Corresponding to IDM ID)
- Submission Type

- Payment Category
- Program Year
- Entity
- Deleted By (i.e. User First Name and Last Name Corresponding to IDM ID)
- Deleted Date

Figure 154: Review Submitted File Status Page -> Files Submitted Data Table



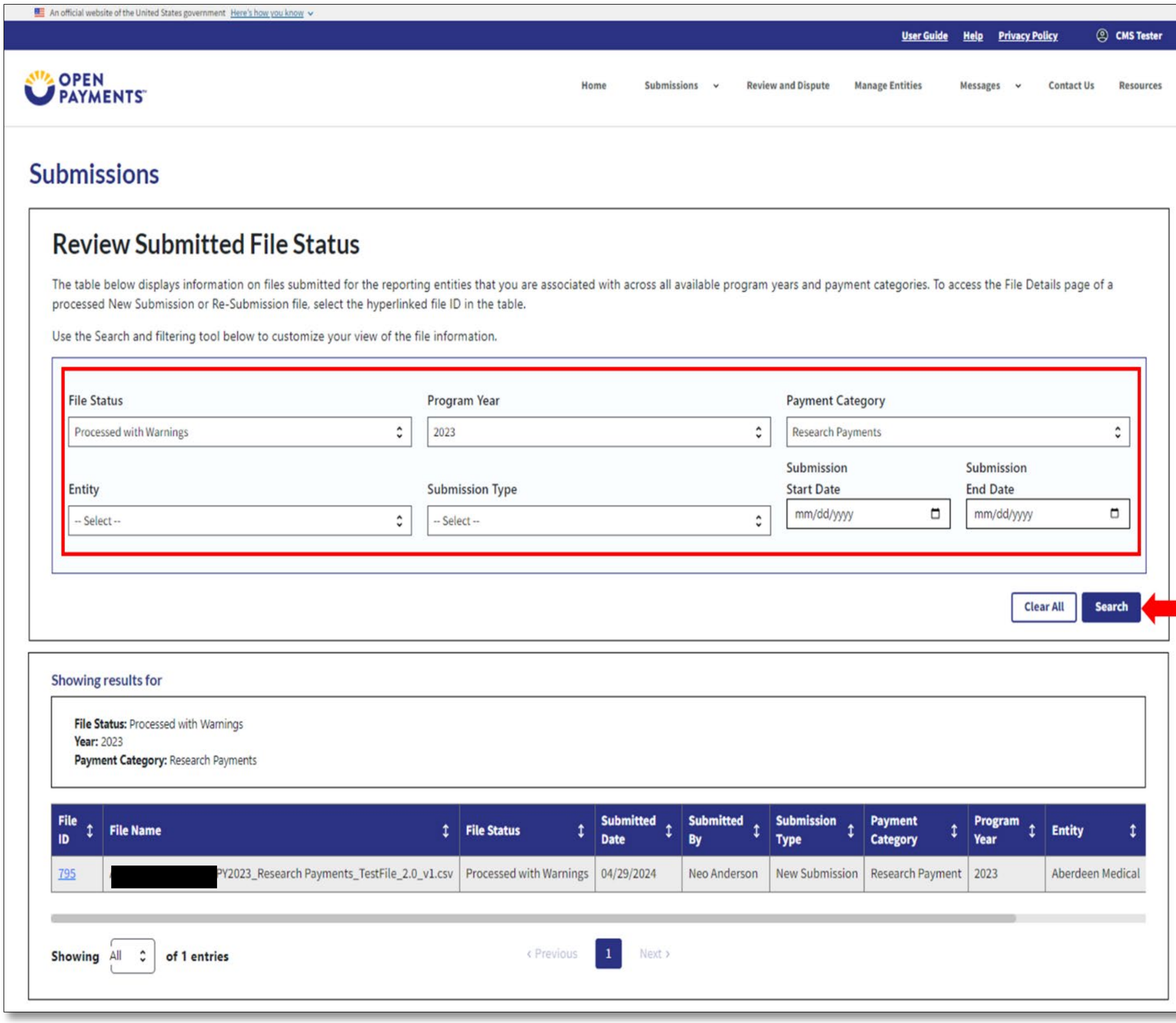
<u>Step 3:</u> Search for specific files by choosing the file-level search criteria and selecting **Search**. The file table will be updated with your search results.

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 155: Review Submitted File Status Page -> File Level Search

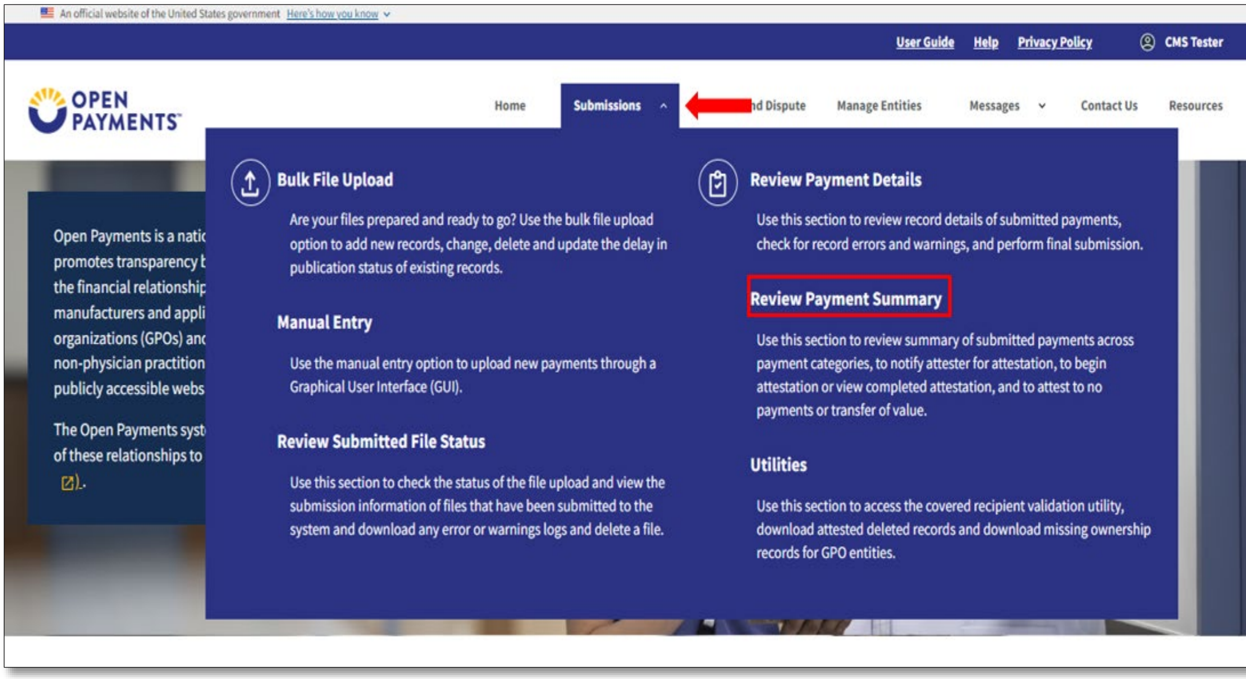


4.4e: Review Records

You may check the status of records that were successfully uploaded at any time via the "Review Payment Summary" and/or "Review Payment Details" pages: *Review Payment Summary* page instructions:

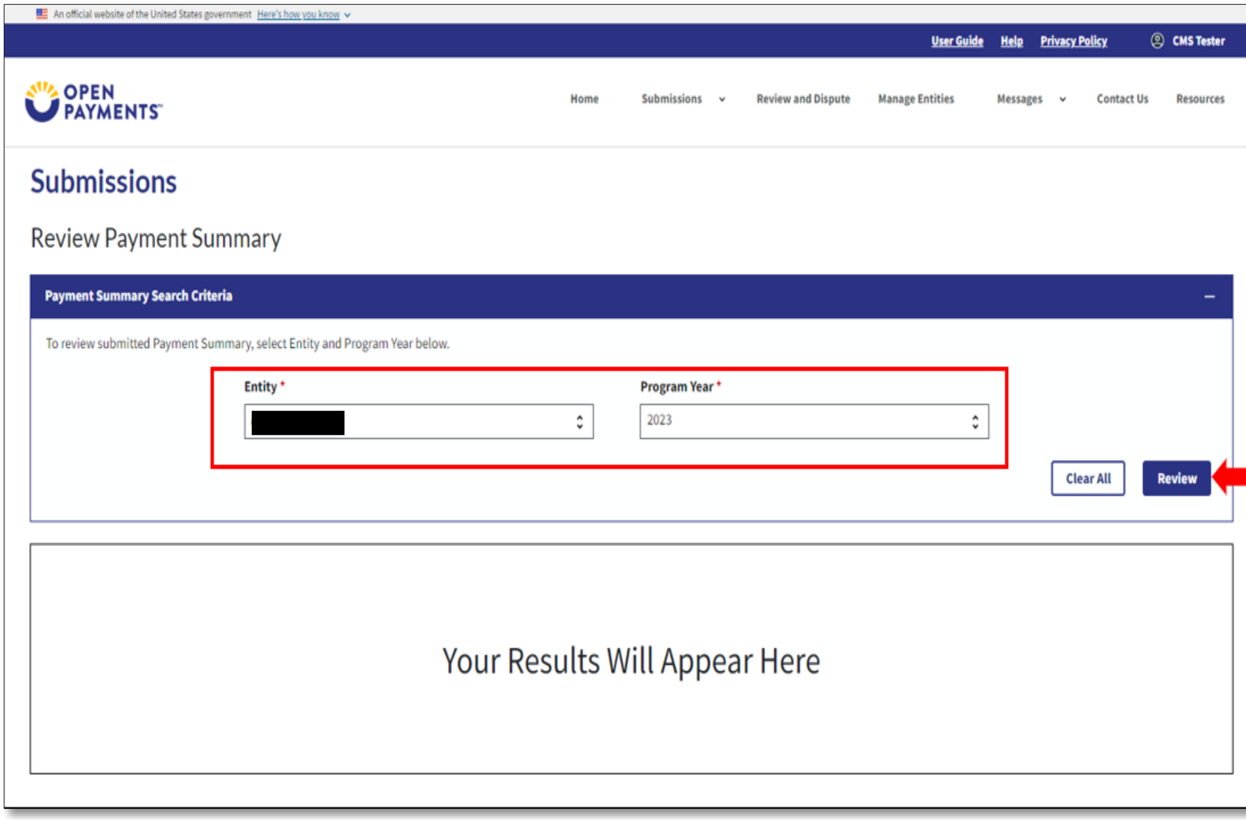
Step 1: Log in to the CMS Open Payments system at https://openpayments.system.cms.gov using your IDM credentials. Select the **Submissions** tab and then select **Review Payment Summary.**

Figure 156: Submissions Tab -> Review Payment Summary



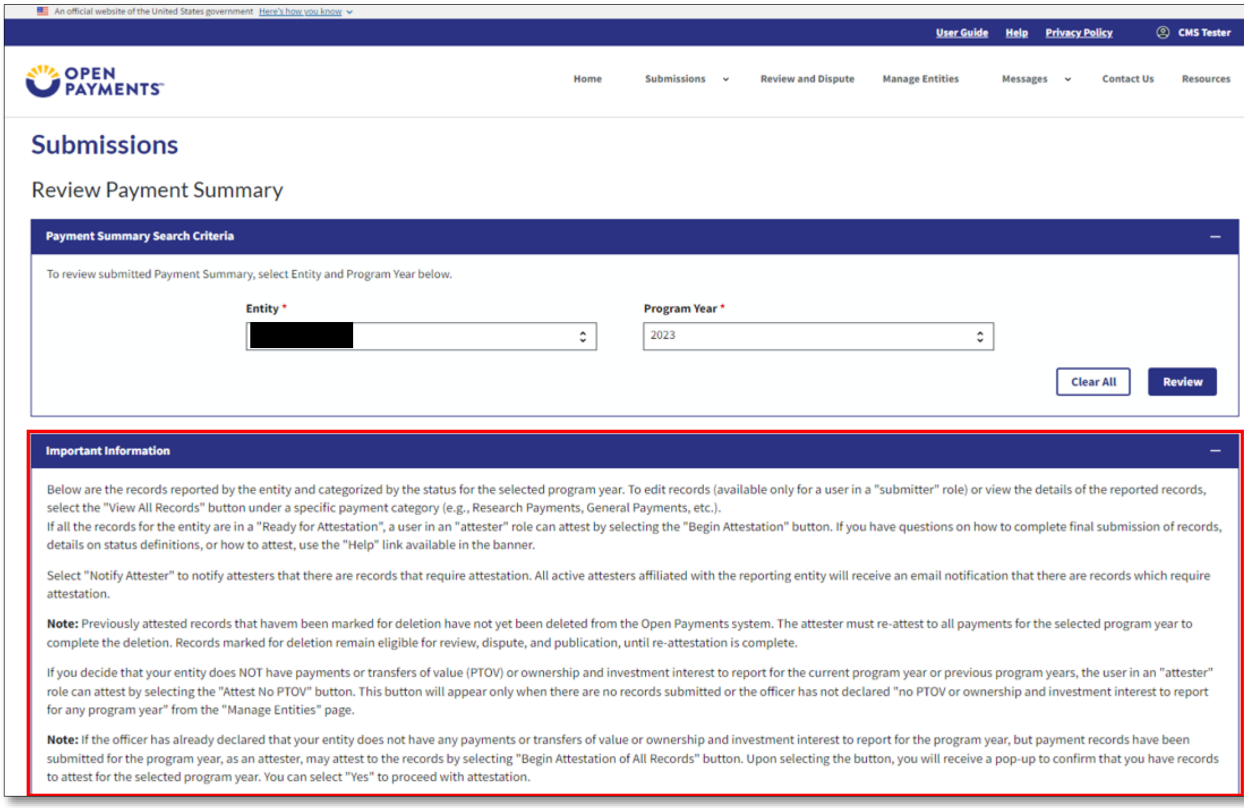
<u>Step 2:</u> Select **Entity** and **Program Year** of the records to be reviewed and then select **Review**.

Figure 157: Review Payment Summary Page -> Payment Summary Search Criteria



Step 3: Read the **Important Information** before proceeding to the **Payments Summary** Section.

Figure 158: Review Payment Summary Page -> Important Information



__Step 4:__ Review the total number of records in each record status for the program year, sorted by payment category. Records 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 prior to Final Submission:

1. **__System Processing__** – Records which the Open Payments system is still processing and validating.
2. **__Failed Validation__** – Records in a bulk CSV file uploaded did not pass field validation checks.
3. **__Failed Matching__** – Records that were not successfully matched to a valid covered recipient.
4. **__Ready for Submission__** – Records which are successfully validated and matched and are ready for Final Submission.

Figure 159: Review Payment Summary Page -> Payment Record Statuses

Entity: [redacted] **Program Year: 2023** Refresh Status

General Payments Summary

Status	Record Count	Action Required
System Processing	1	No Action
Failed Validation	1	Correction
Failed Matching	0	Correction
Ready for Submission	3	Final Submission
Ready for Attestation	0	Attest
Returned to Submitter	0	Correction
Attested †	0	No Action
Total Payments	5	N/A

Records counted as "Marked for Deletion" are also included in the "Attested" (†) record count

Marked for Deletion	Record Count	Action Required
† Attester to confirm deletion	0	Attester to Attest deletion action or Reject Deletion

View All Records

Research Payments Summary

Status	Record Count	Action Required
System Processing	1	No Action
Failed Validation	1	Correction
Failed Matching	0	Correction
Ready for Submission	3	Final Submission
Ready for Attestation	0	Attest
Returned to Submitter	0	Correction
Attested †	0	No Action
Total Payments	5	N/A

Records counted as "Marked for Deletion" are also included in the "Attested" (†) record count

Marked for Deletion	Record Count	Action Required
† Attester to confirm deletion	0	Attester to Attest deletion action or Reject Deletion

View All Records

Ownership or Investment Interest Payments Summary

Status	Record Count	Action Required
System Processing	1	No Action
Failed Validation	1	Correction
Failed Matching	0	Correction
Ready for Submission	3	Final Submission
Ready for Attestation	0	Attest
Returned to Submitter	0	Correction
Attested †	0	No Action
Total Payments	5	N/A

Records counted as "Marked for Deletion" are also included in the "Attested" (†) record count

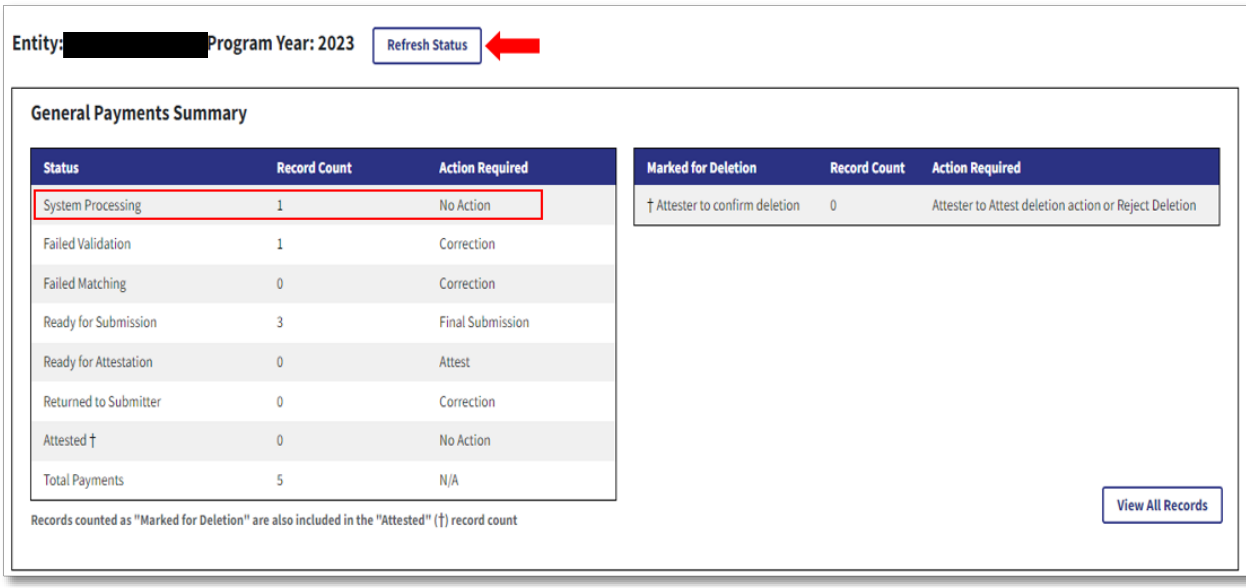
Marked for Deletion	Record Count	Action Required
† Attester to confirm deletion	0	Attester to Attest deletion action or Reject Deletion

View All Records

Step 5: Select the **Refresh** button if any records are in "System Processing" status to refresh record statuses; skip to Step 6 if there are no records still processing.

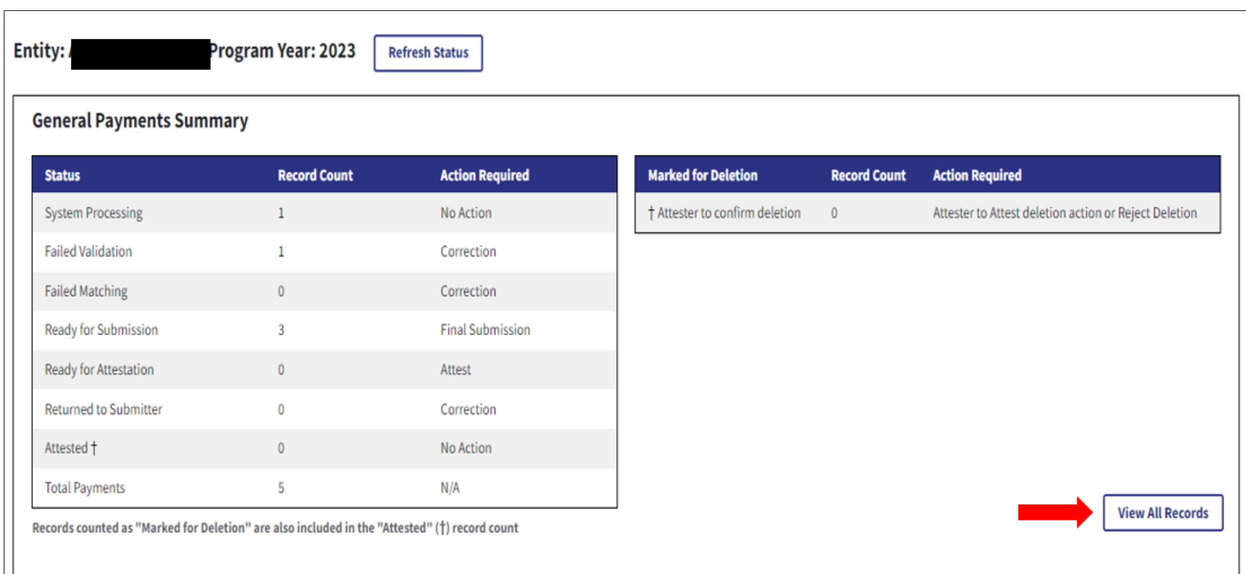
If records are stuck in "System Processing" status for more than 3 hours, contact the Open Payments Help Desk for live assistance at 1-855-326-8366 or send an email to openpayments@cms.hhs.gov.

Figure 160: Review Payment Summary Page -> Refresh Status Button



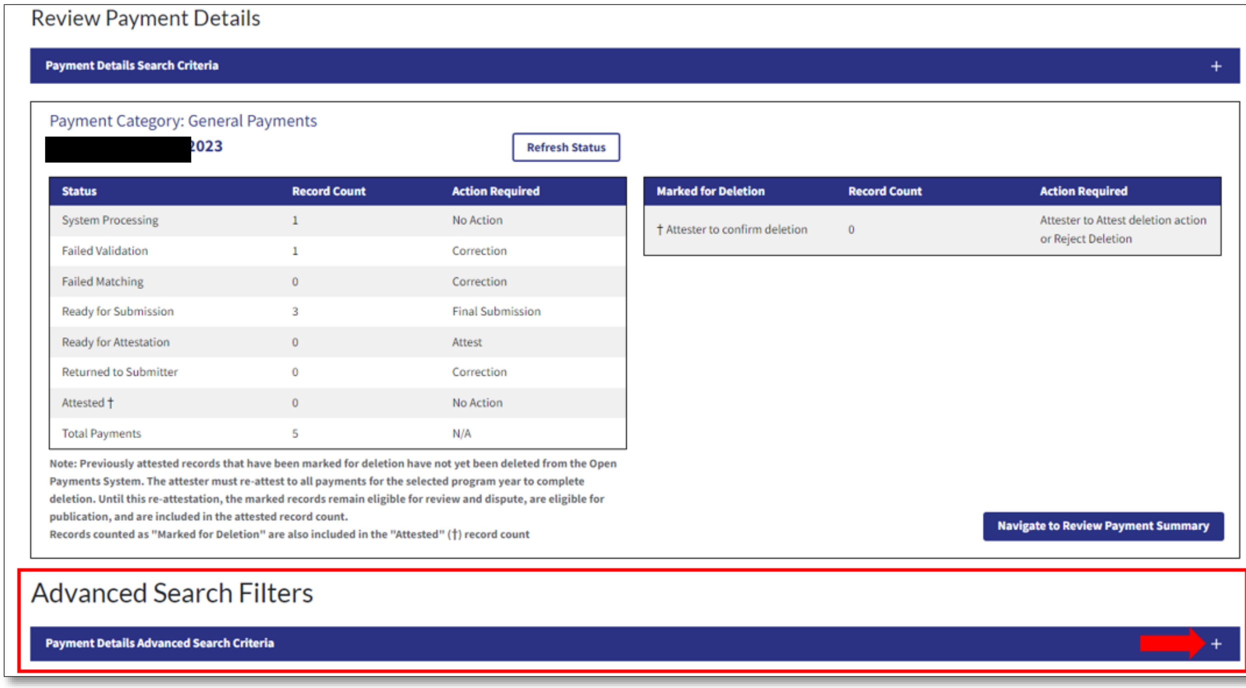
Step 6: Select the **View All Records** button next to a payment category to go to the "Review Payments Detail" page and view the individual records for that category.

Figure 161: Review Payment Summary Page -> View All Records



Step 6b: Expand the **Advanced Search Filters** tool to search for records by choosing the record-level search criteria to filter records by: Records Status, File ID, Record ID, Home System Payment ID, etc.

Figure 162: Review Payment Details Page -> Advanced Search Filters Tool

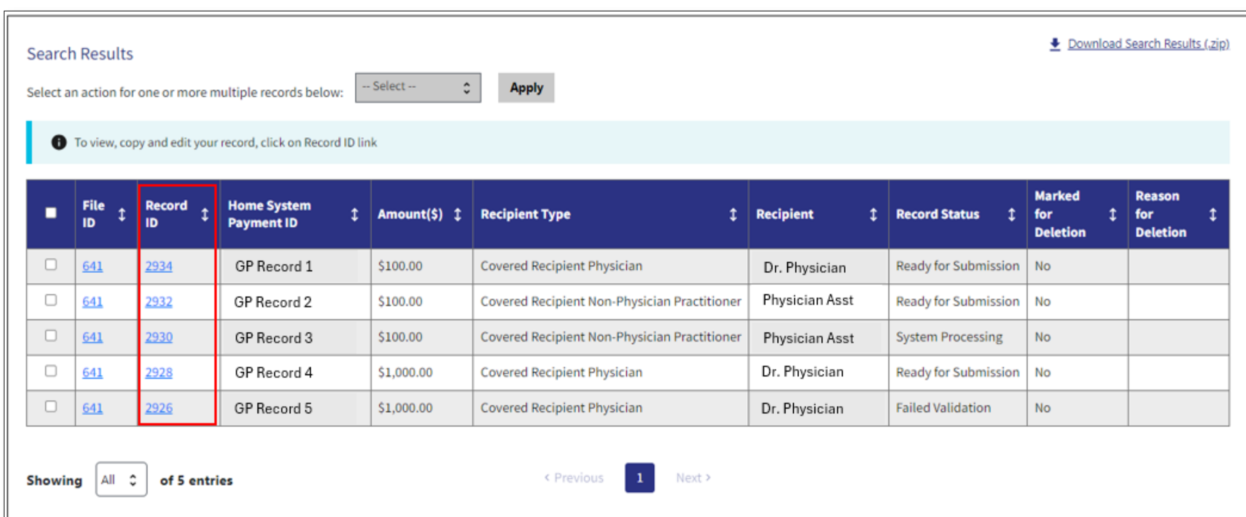


Status	Record Count	Action Required
System Processing	1	No Action
Failed Validation	1	Correction
Failed Matching	0	Correction
Ready for Submission	3	Final Submission
Ready for Attestation	0	Attest
Returned to Submitter	0	Correction
Attested †	0	No Action
Total Payments	5	N/A

Marked for Deletion	Record Count	Action Required
† Attester to confirm deletion	0	Attester to Attest deletion action or Reject Deletion

Step 7: Select the **Record ID** link for an individual record on the "Review Payment Details" page to view the record's details. The "Record ID" page displays the record's error messages, if applicable.

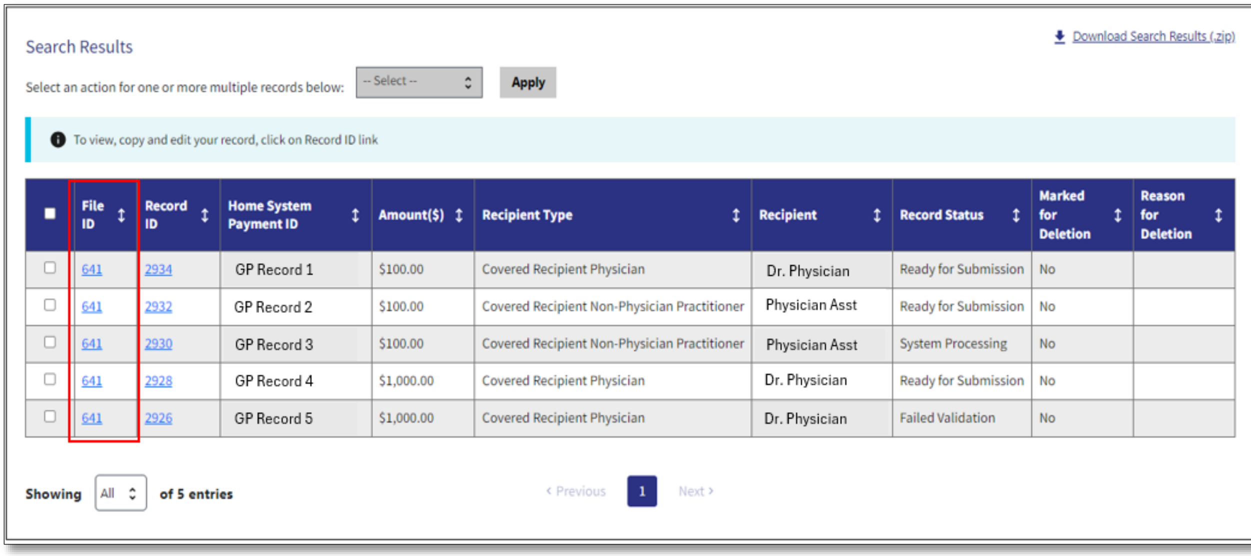
Figure 163: Review Payment Details Page-> Record ID Link



	File ID	Record ID	Home System Payment ID	Amount($)	Recipient Type	Recipient	Record Status	Marked for Deletion	Reason for Deletion
☐	641	2934	GP Record 1	$100.00	Covered Recipient Physician	Dr. Physician	Ready for Submission	No	
☐	641	2932	GP Record 2	$100.00	Covered Recipient Non-Physician Practitioner	Physician Asst	Ready for Submission	No	
☐	641	2930	GP Record 3	$100.00	Covered Recipient Non-Physician Practitioner	Physician Asst	System Processing	No	
☐	641	2928	GP Record 4	$1,000.00	Covered Recipient Physician	Dr. Physician	Ready for Submission	No	
☐	641	2926	GP Record 5	$1,000.00	Covered Recipient Physician	Dr. Physician	Failed Validation	No	

Step 8: Select the **File ID** to view details about the submitted file. File Upload Statuses are displayed on the File ID page and on the File pop-up window. Refer to the File Status definitions in Section 4.4d for more details.

Figure 164: Review Payment Details Page -> File ID Link

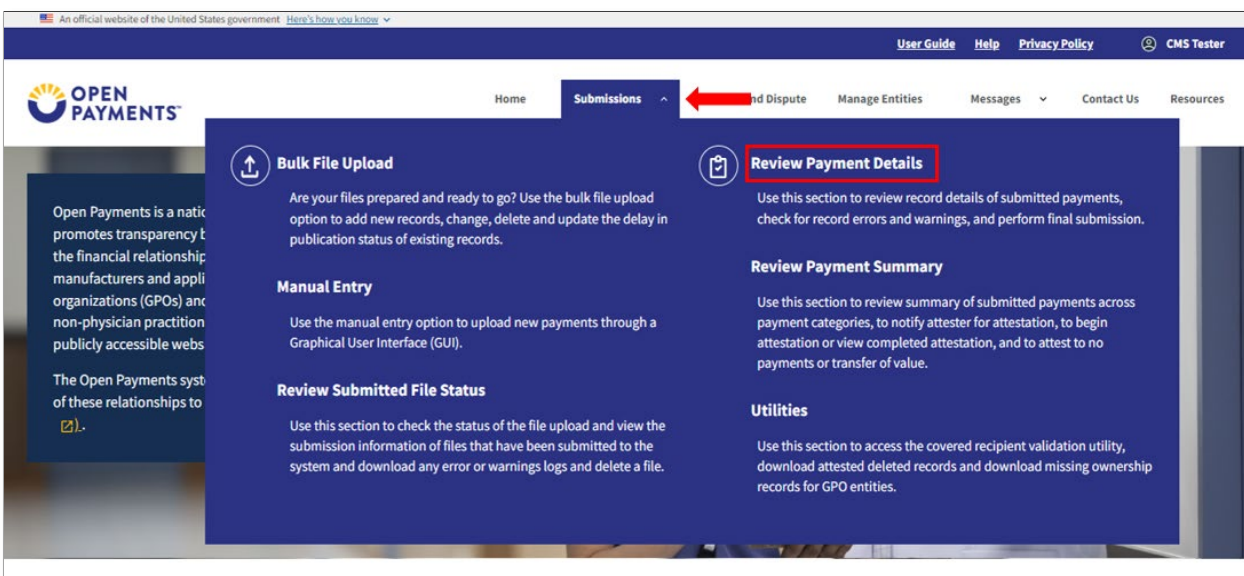


	File ID	Record ID	Home System Payment ID	Amount($)	Recipient Type	Recipient	Record Status	Marked for Deletion	Reason for Deletion
☐	641	2934	GP Record 1	$100.00	Covered Recipient Physician	Dr. Physician	Ready for Submission	No	
☐	641	2932	GP Record 2	$100.00	Covered Recipient Non-Physician Practitioner	Physician Asst	Ready for Submission	No	
☐	641	2930	GP Record 3	$100.00	Covered Recipient Non-Physician Practitioner	Physician Asst	System Processing	No	
☐	641	2928	GP Record 4	$1,000.00	Covered Recipient Physician	Dr. Physician	Ready for Submission	No	
☐	641	2926	GP Record 5	$1,000.00	Covered Recipient Physician	Dr. Physician	Failed Validation	No	

Review Payment Details page instructions:

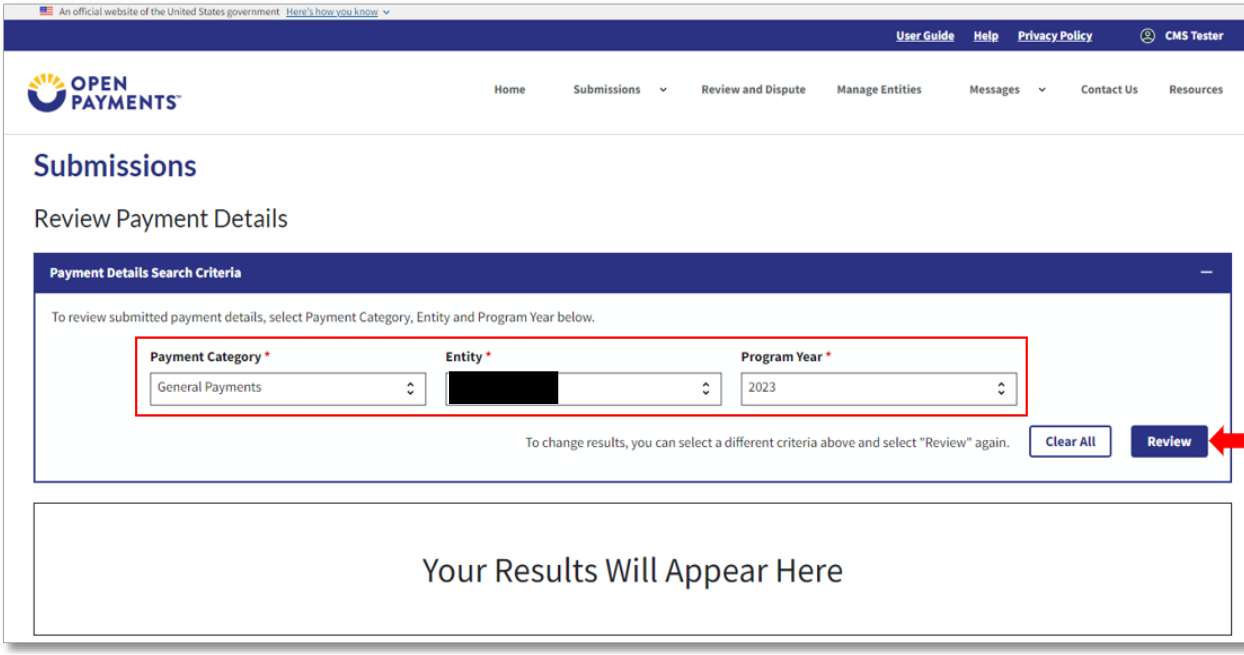
Step 1: Log in to the CMS Open Payments system at https://openpayments.system.cms.gov using your IDM credentials, select the **Submissions** tab and then select the **Review Payment Details** menu option.

Figure 165: Submissions Tab -> Review Payment Details



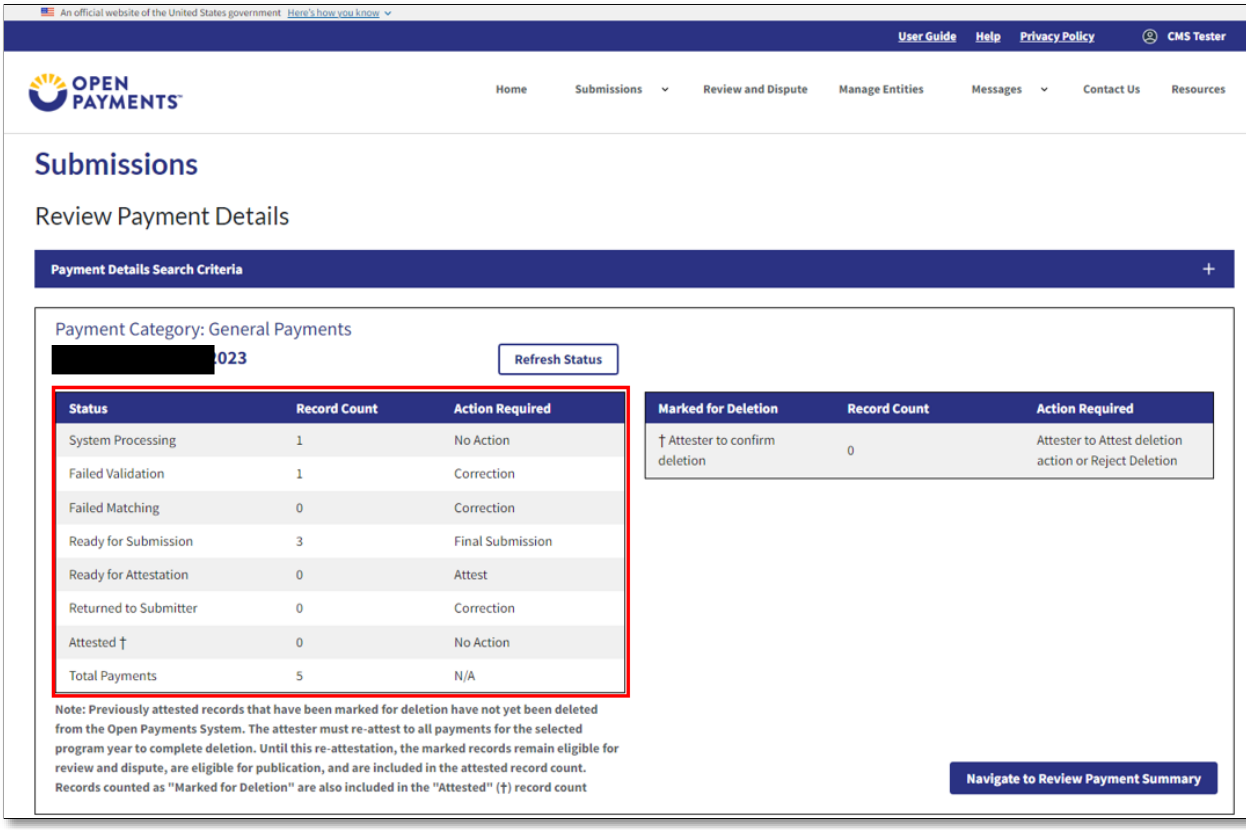
<u>Step 2:</u> Select required payment details for **Payment Category**, **Entity**, and **Program Year** to be reviewed and then select the **Review** button.

Figure 166: Payment Details Search Criteria -> Review Button



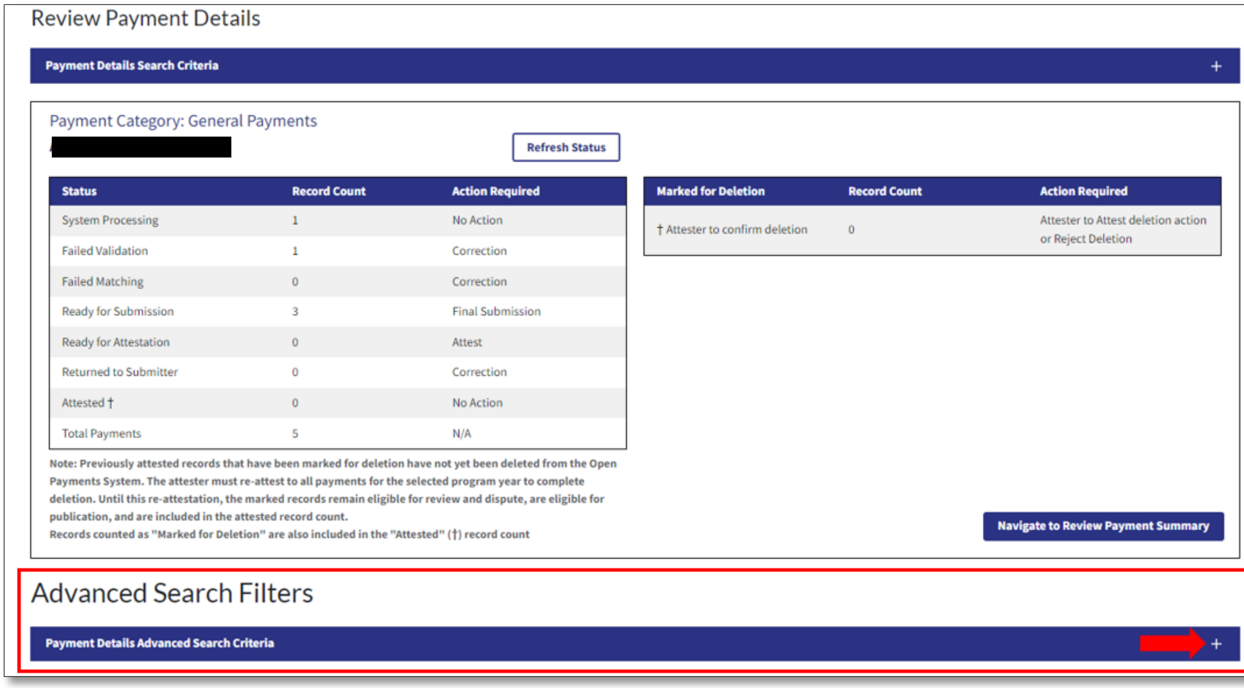
<u>Step 3:</u> Review the total number of records in each record status for the program year, sorted by payment category selected.

Figure 167: Payment Record Statuses



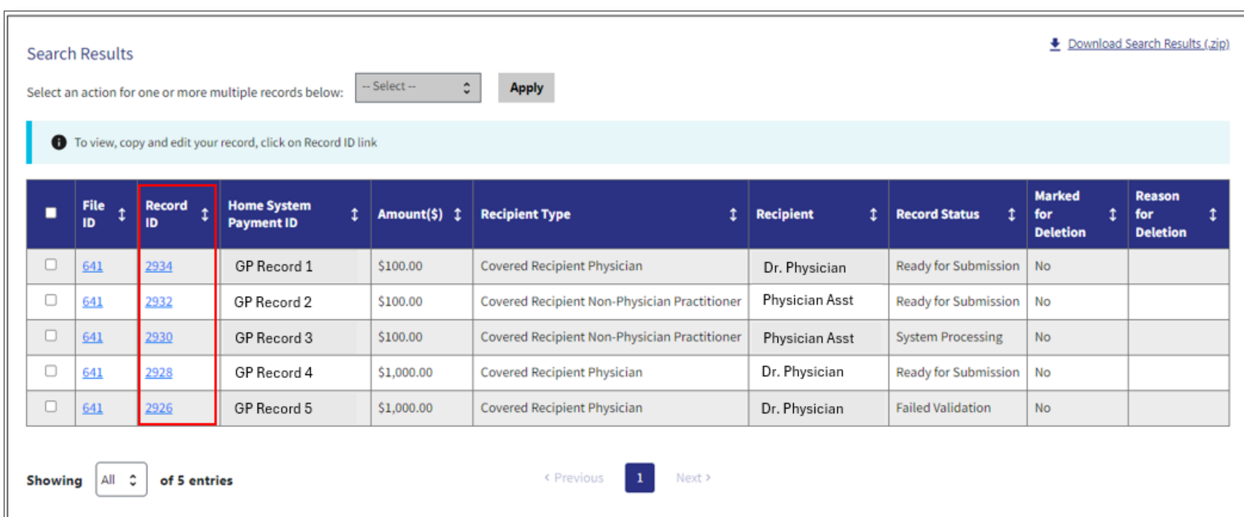
Step 3a: Expand the **Advanced Search Filters** to search for records by choosing the record-level search criteria to filter records by: Records Status, File ID, Record ID, Home System Payment ID, etc.

Figure 168: Advanced Search Filters Tool



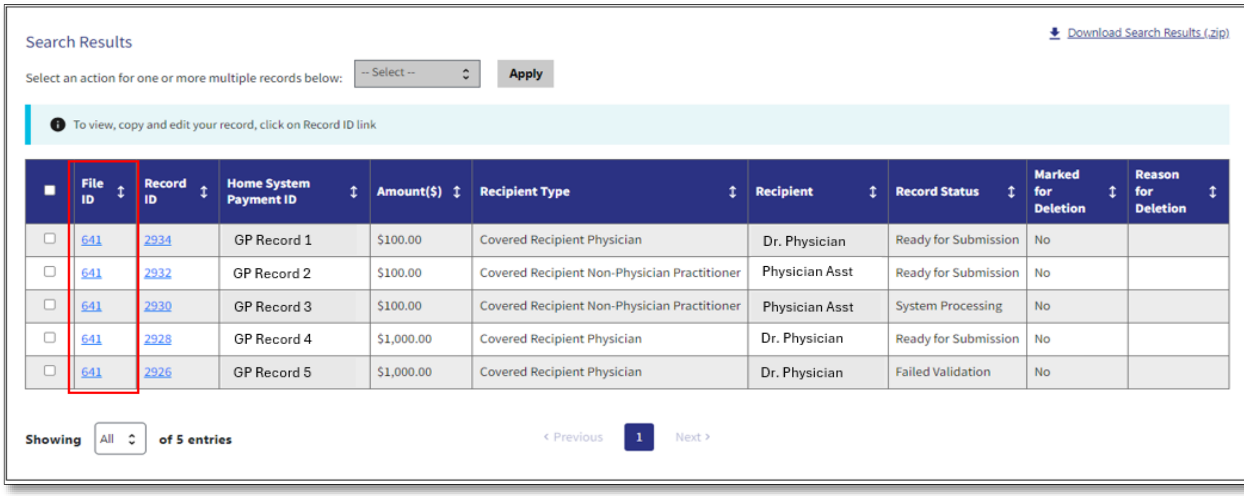
Step 4: Select the **Record ID** link for an individual record on the "Review Payment Details" page to view the record's details. The "Record ID" page displays the record's error messages, if applicable.

Figure 169: Review Payment Details Page -> Record ID Link



Step 5: Select the **File ID** to view details about the submitted file. File Upload Statuses are displayed on the File ID page and on the File Modal.

Figure 170: Review Payment Details Page -> File ID Link



	File ID	Record ID	Home System Payment ID	Amount($)	Recipient Type	Recipient	Record Status	Marked for Deletion	Reason for Deletion
☐	641	2934	GP Record 1	$100.00	Covered Recipient Physician	Dr. Physician	Ready for Submission	No	
☐	641	2932	GP Record 2	$100.00	Covered Recipient Non-Physician Practitioner	Physician Asst	Ready for Submission	No	
☐	641	2930	GP Record 3	$100.00	Covered Recipient Non-Physician Practitioner	Physician Asst	System Processing	No	
☐	641	2928	GP Record 4	$1,000.00	Covered Recipient Physician	Dr. Physician	Ready for Submission	No	
☐	641	2926	GP Record 5	$1,000.00	Covered Recipient Physician	Dr. Physician	Failed Validation	No	

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 4.11 for details on final submission and Section 4.15 for details on attestation.

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 Payment Detail" page. See Sections 4.6 and 4.7 for more information.

Section 4.5: Manual Entry Using the Graphical 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. Many reporting entities have found this method to be useful when there are smaller numbers of payment records to report.

According to the Open Payments Final Rule, Group Purchasing Organizations (GPOs) ***are only required to report payments or other transfers of value made to physician owners/investors.***

The GPOs cannot report any general, research payment, or ownership/ investment record for NPPs; however, they can report NPPs as a principal investigator on the research payment.

The Open Payments system prevents GPOs from submitting general and research payment records for teaching hospitals or non-physician practitioner covered recipients.

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.

An **Add** button is available in many 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.

Manual data entry does not complete the submission process. Once a record is manually entered, it will be subject to the matching process for 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.

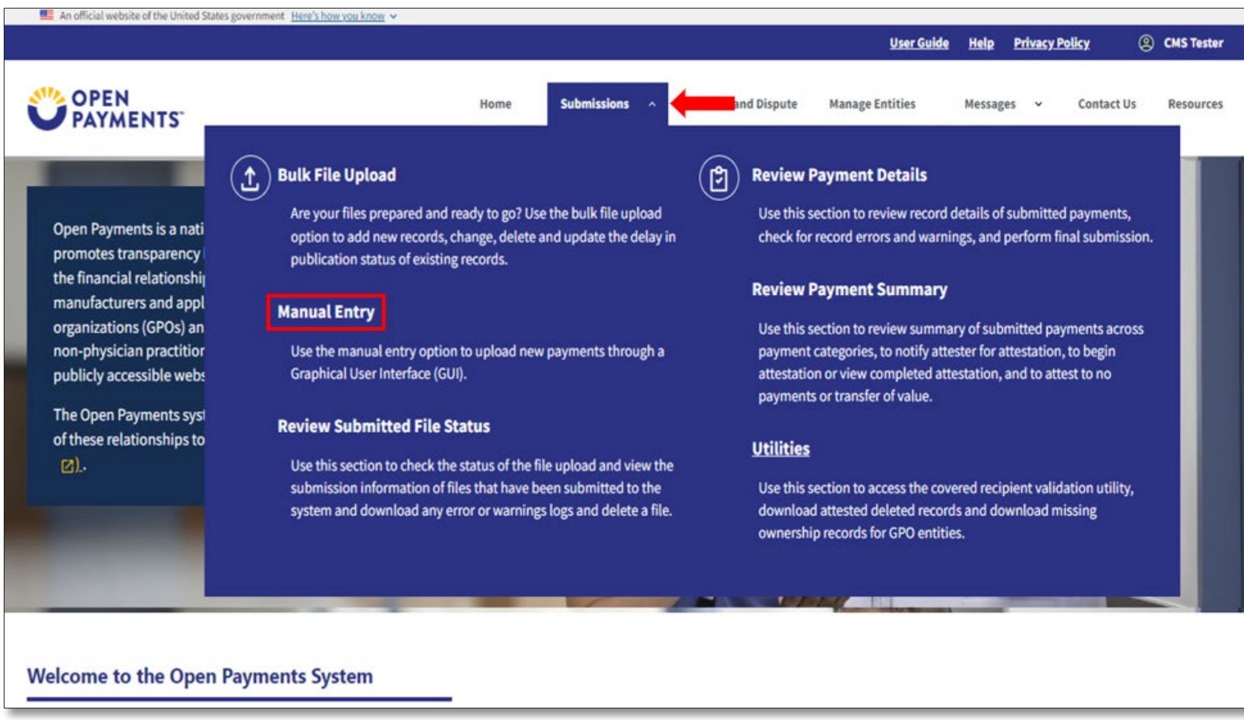
The steps provided below assume that a user is entering the data in a consecutive manner, however, users can utilize the "Payment Navigation Bar", located on top of the record, to go directly to a specific page, assuming there are no errors on the page they are currently on.

4.5a: Manual Entry of General Payments Data

To enter general payments data manually, follow these steps:

Step 1: Log in to the CMS Open Payments system at https://openpayments.system.cms.gov select the **Submissions** tab and then select **Manual Entry**.

Figure 171: Submissions Tab -> Manual Entry

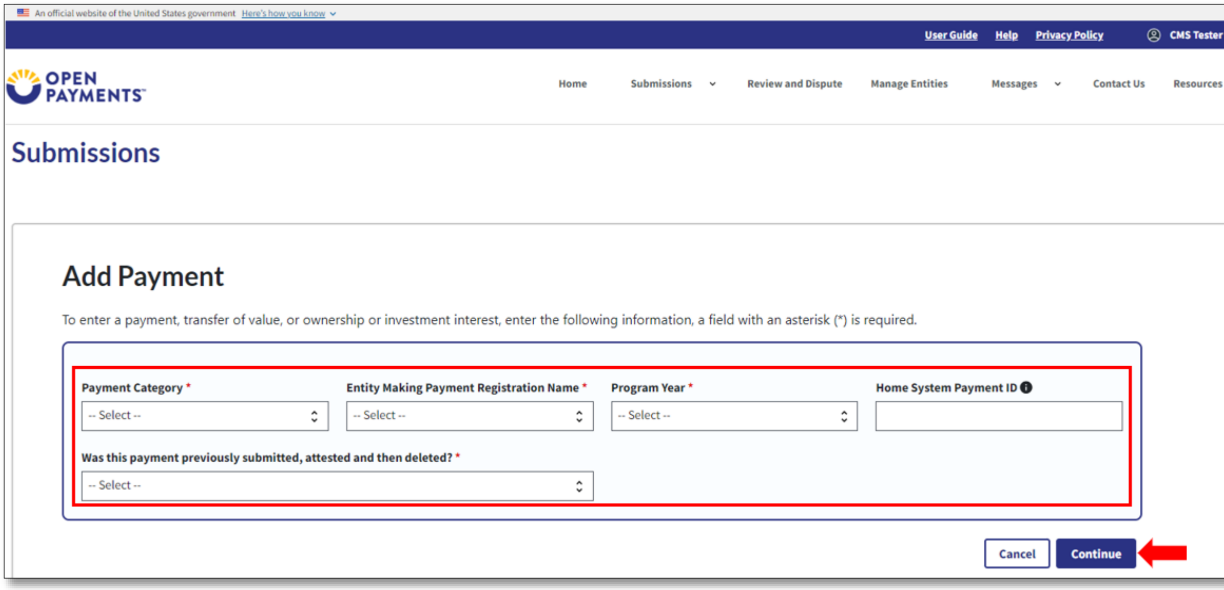


Step 2: On the "Add payment" page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year for the record to be entered.

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

If the payment is being entered because of a payment that was previously submitted, attested and then deleted, you must select **Yes** in the drop-down box and enter the record id of the previously deleted record. Select the **Continue** button to proceed to the "Covered Recipient Demographic Information" page.

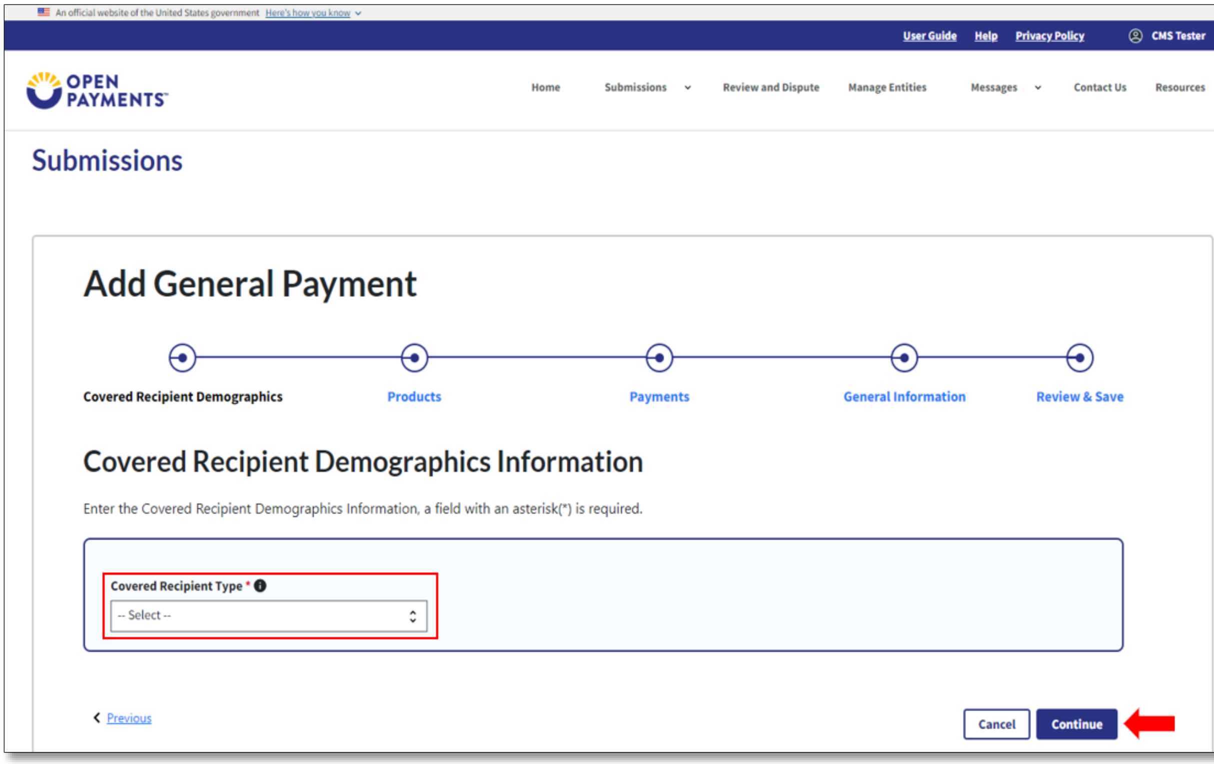
Figure 172: Add Payment Page -> Required Fields



Step 3: On the "Covered Recipient Demographic Information" page, select the Covered Recipient Type: Physician, Non-Physician Practitioner, or Teaching Hospital.

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

Figure 173: Covered Recipient Demographics Page -> Covered Recipient Type Required Field



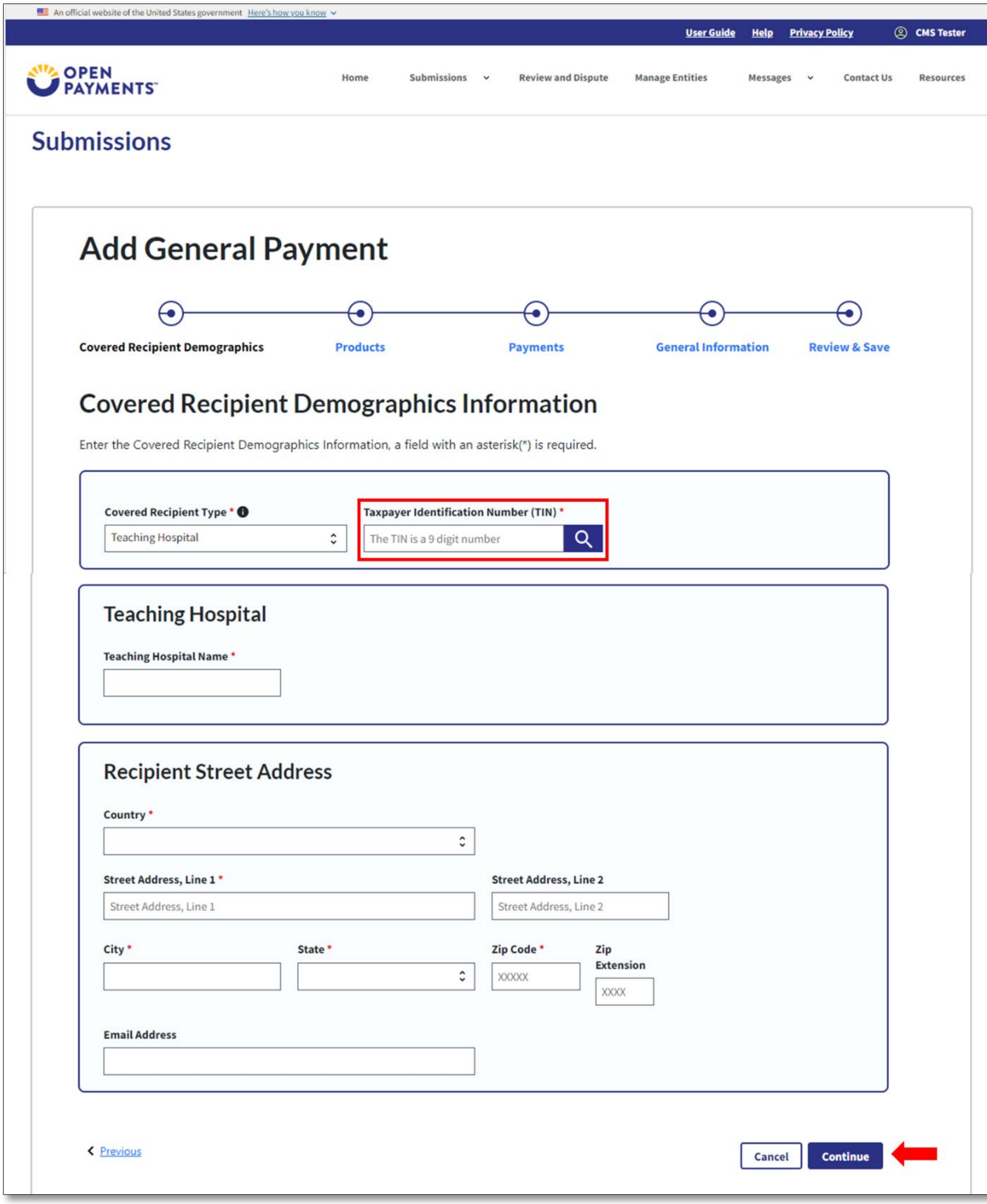
Step 3a: For Teaching Hospitals: Enter information as requested on the page. Required fields are marked with asterisks.

The Taxpayer Identification (TIN) search field will auto-populate Teaching Hospital information associated with the TIN entered. Refer to the CMS Teaching Hospital Lists to confirm any populated teaching hospital information, for which the download link is in section 4.3a.

If the teaching hospital information does not populate, double check the TIN. If the TIN was entered correctly, check the Teaching Hospital List for that program year in case there is conflicting information. If there is conflicting information, check with the teaching hospital to clarify.

When you have validated all teaching hospital information on this page, select the **Continue** button.

Figure 174: Covered Recipient Demographic Information Page: Teaching Hospital

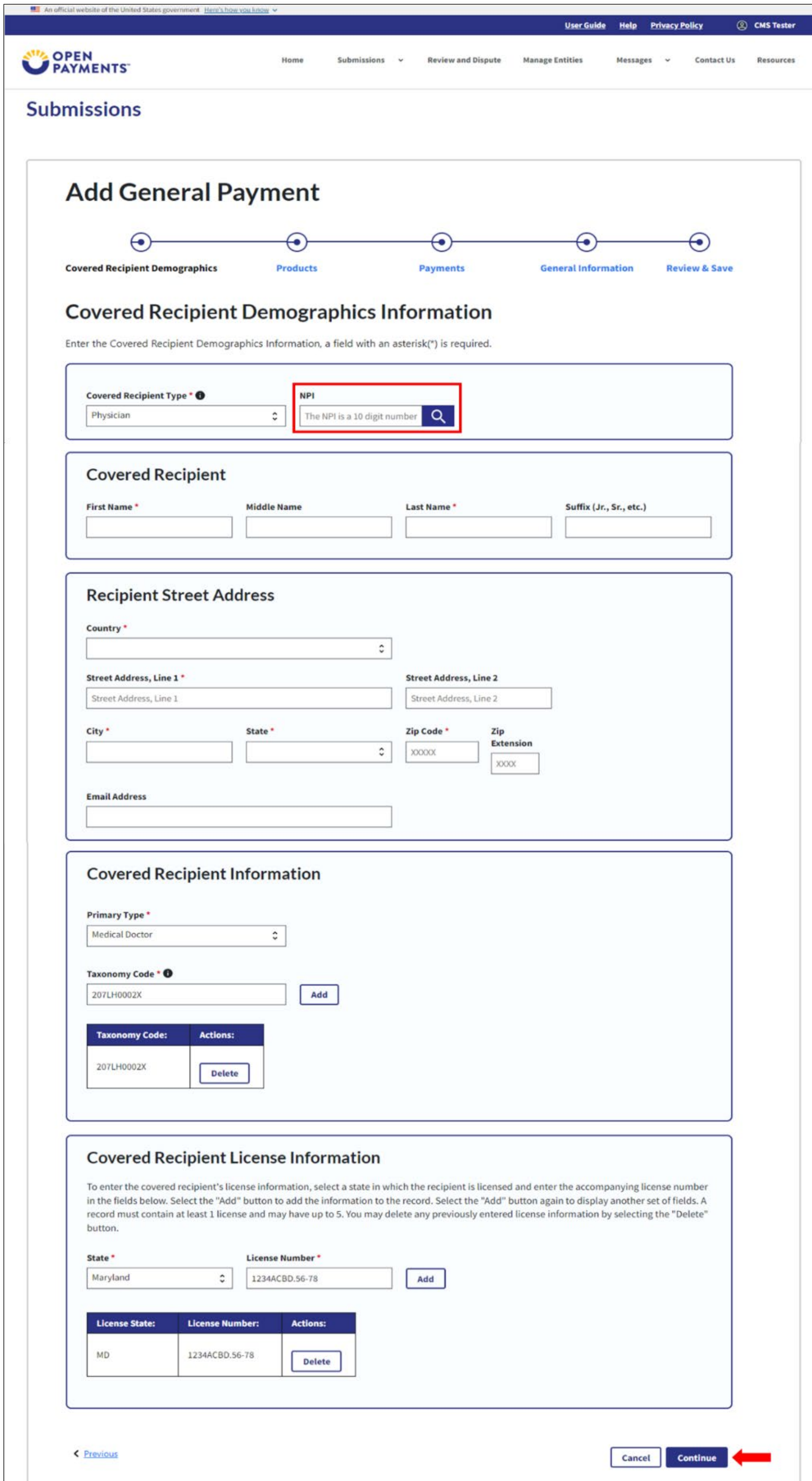


Step 3b: For Physicians: Enter information as requested on the page below. Required fields are marked with asterisks. Consult the Validated Physician List (VPL), downloadable from the **Submissions** tab, to confirm the identifying information for the physician.

The NPI search field will auto-populate Covered Recipient information, (i.e., First Name, Last Name, Taxonomy Code, and State License(s)) for an NPI entered. Refer to a CMS provided resource (VPL) to confirm any populated provider information, if necessary.

When you have validated all your information, select the **Continue** button.

Figure 175: Covered Recipient Demographic Information Page: Physician

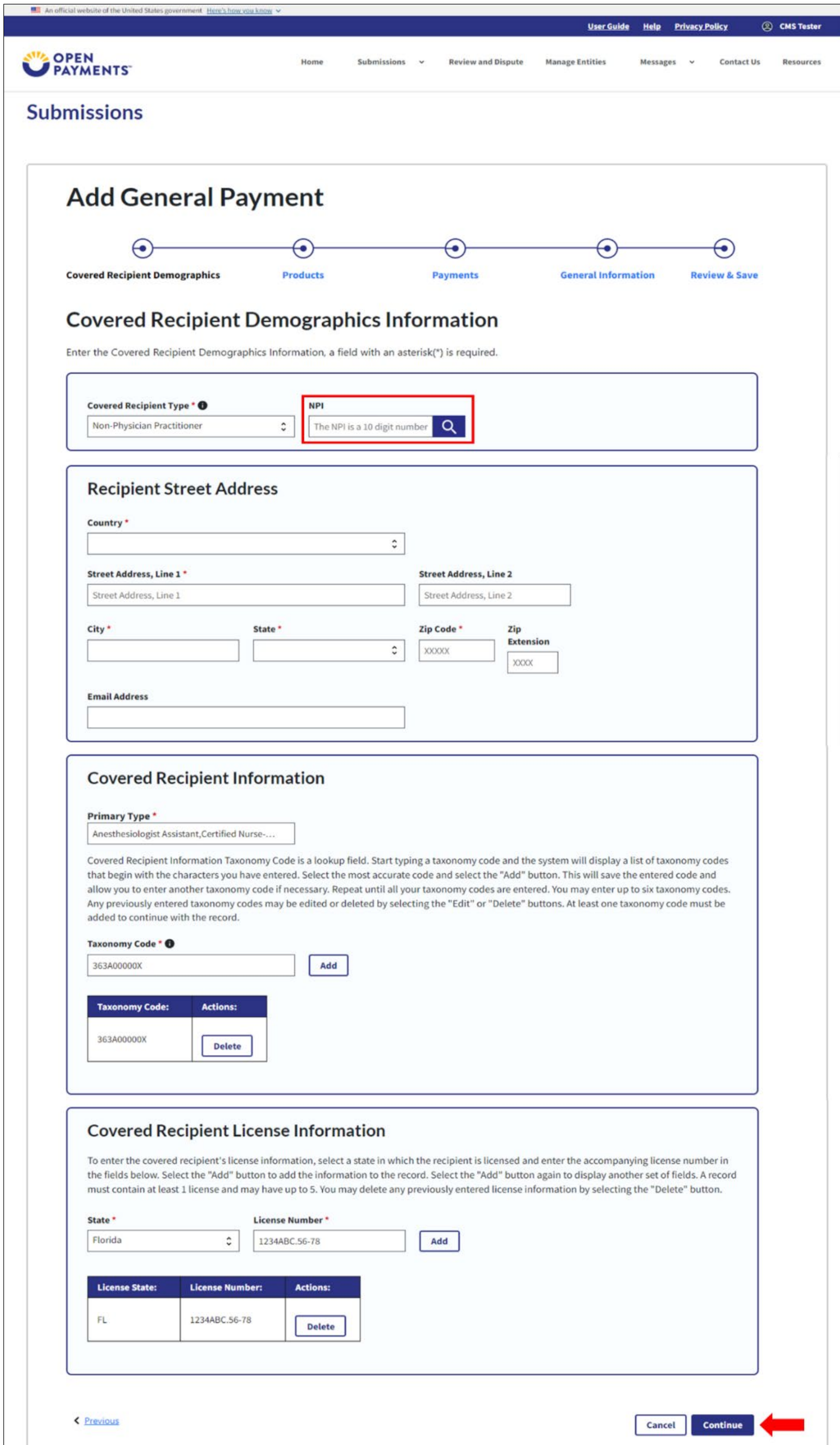


Step 3c: For NPPs: Enter information as requested on the page below. Required fields are marked with asterisks. Consult the Validated Non-Physician Practitioner List (VNPPL), downloadable from the **Submissions** tab, to confirm the identifying information for the NPP.

The NPI search field that will auto-populate Covered Recipient information, (i.e., First Name, Last Name, Taxonomy Code, and State License(s)) for an NPI entered. Refer to a CMS provided resource (VNPPL) to confirm any populated provider information, if necessary. To add the NPP's primary type, multi-select up to six valid values as per reference data list.

When you have validated all your information, select the **Continue** button.

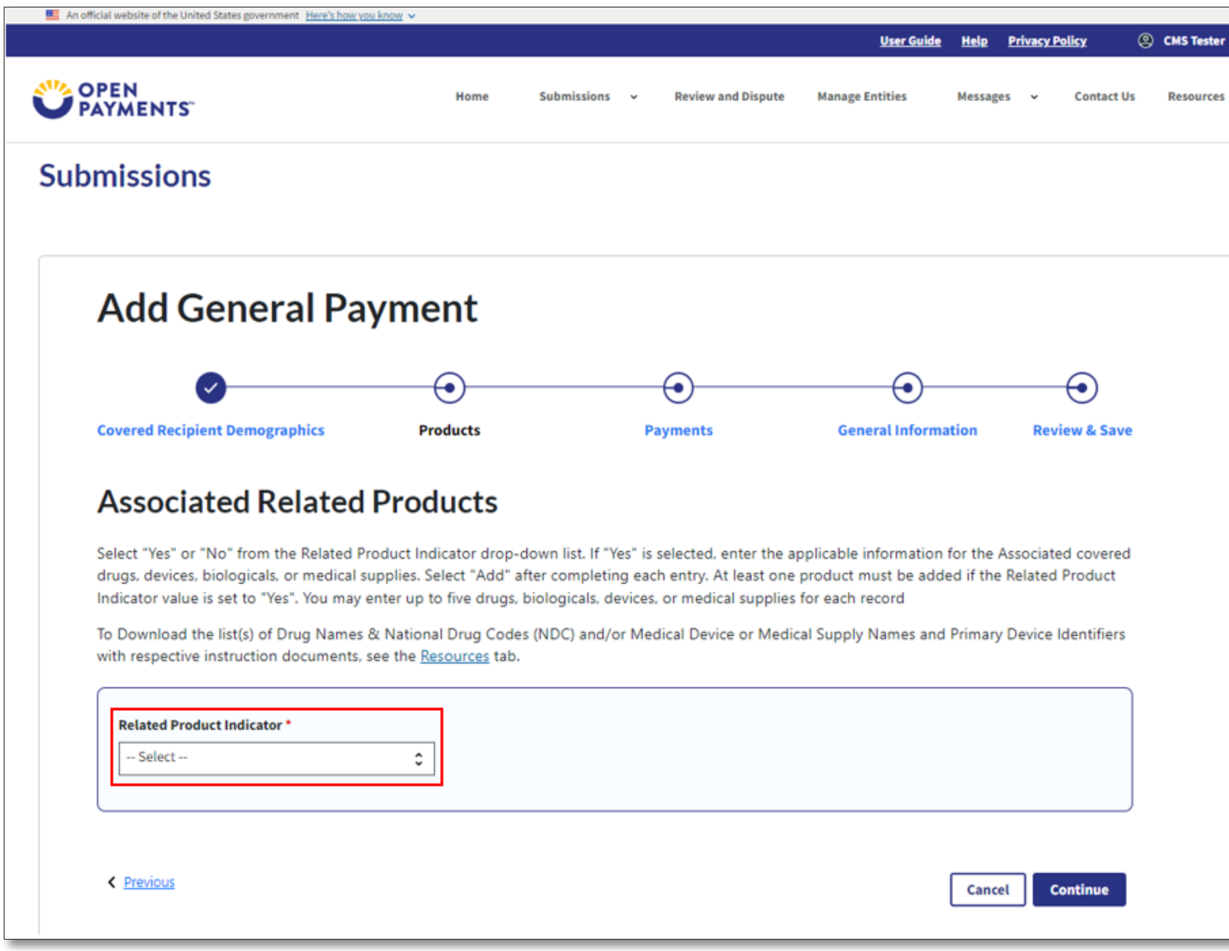
Figure 176: Covered Recipient Demographic Information Page: Non-Physician Practitioner



Step 4: On the "Associated Related Products" page, enter the associated drugs, biologicals, devices, or medical supplies, choose the option applicable to the record.

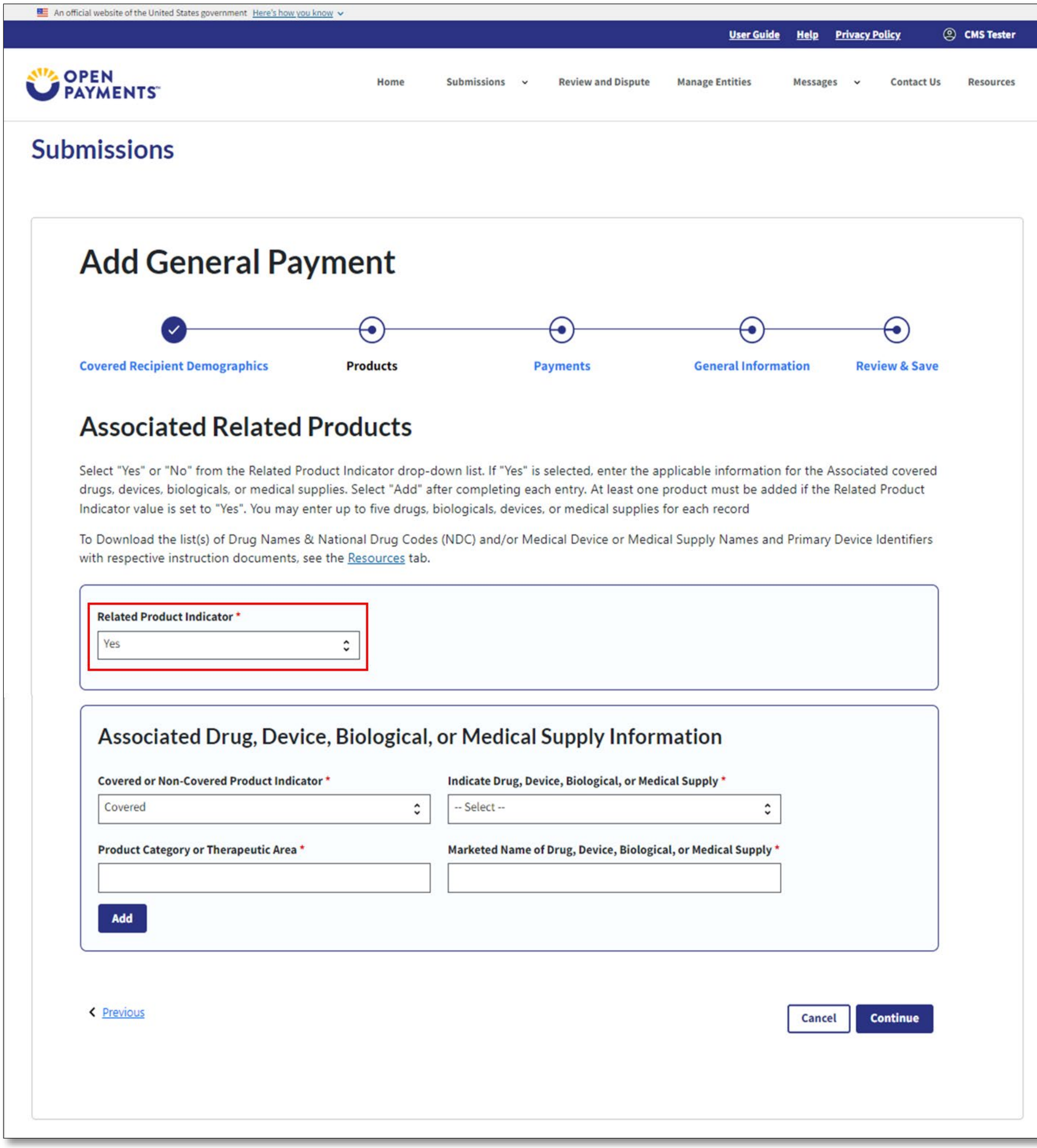
- **Select "Yes"** if the payment record needs to include a drug, biological, device, or medical supply and follow the instructions for the rest of step 4 below. You can enter up to five drugs, biologicals, devices, or medical supplies per record. Begin by selecting the appropriate value in the "Related Product Indicator" drop-down list.
- **Select "No"** if the payment did not include a drug, biological, device, or medical supply and proceed to step 5.

Figure 177: Associated Related Products Page: Related Product Indicator



Step 4a: If you selected "Yes," multiple fields will appear that will allow the entry of one drug, biological, device, or medical supply. Required fields marked with an asterisk will dynamically display based on the type of covered product selected.

Figure 178: Input Fields for Related Product Indicator



Step 4b: 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 text fields and select "Add" as a table will populate under the form containing the product(s) you added.

Drug or Biologicals and National Drug Codes (NDC):

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 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.

The following validations are performed for the Drug or Biological Name and NDC fields:

- 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.

The submitter receives an error message if any of these validations fail. You cannot continue with record submission without fixing the error. To address the error, please refer to the Drug Name and NDC dataset reference file on the CMS Resources Page to identify the correct NDC and Drug or Biological Name combination for submissions.

Device or Medical Supply and Primary Device Identifier (PDI):

For PY2021 and onwards, if the product is a device or medical supply, enter the Primary Device Identifier (PDI) for the device or medical supply in the "Primary Device Identifier" field. PDIs are unique identifiers for the medical devices and supplies, as listed in the Food and Drug Administration's Global Unique Device Identification Database Directory (GUDID).

PDIs entered that contain any of the following are not accepted.

- All zeroes
- Any leading or trailing spaces
- Consecutive spaces
- Special characters not permitted in the Open Payments System

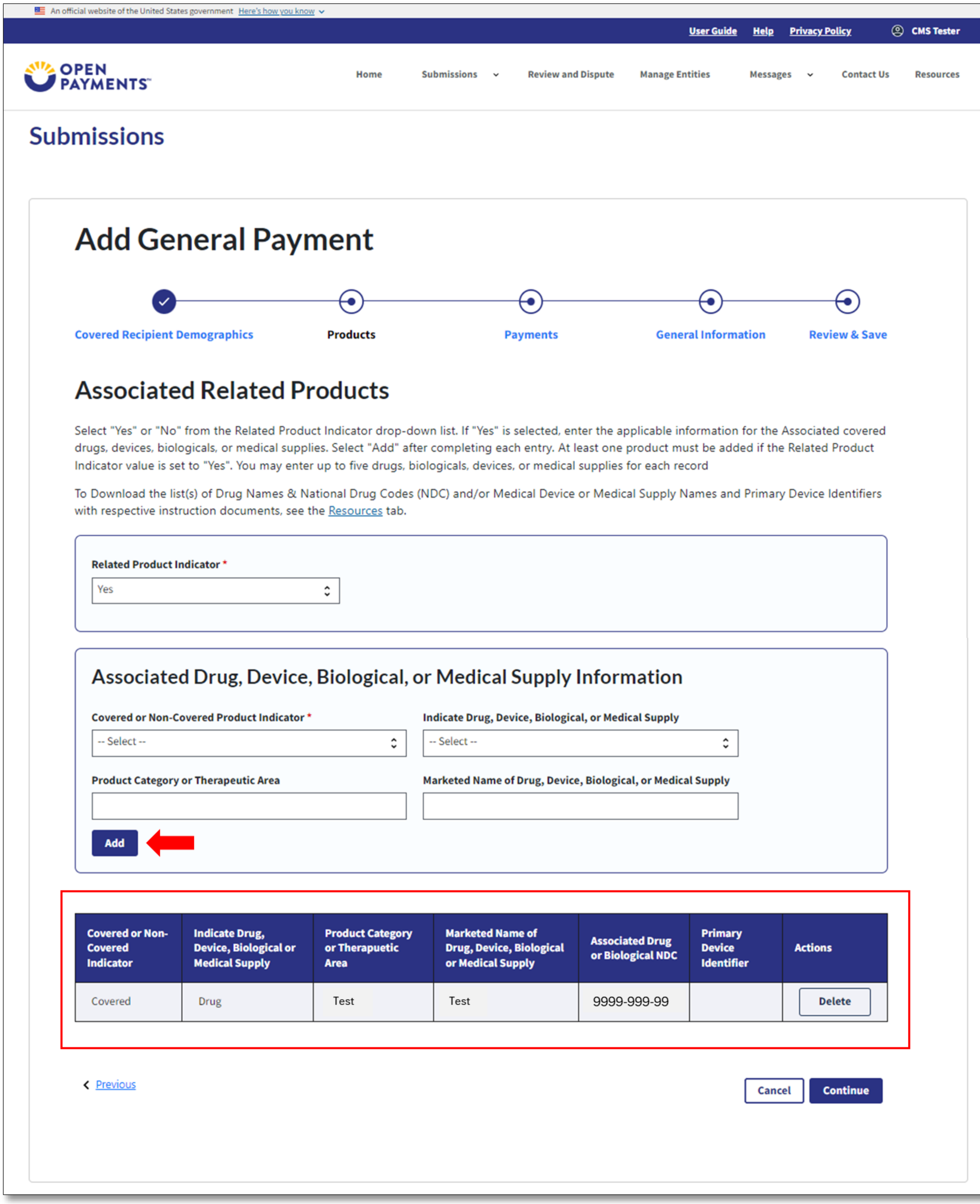
PDIs can be found on the website https://accessgudid.nlm.nih.gov/download/delimited. The Device and Medical Supply Name and PDI reference file and PDF Instructions document are zipped together and are available within the Open Payments system Resources tab.

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

The following validations are performed for the PDI field:

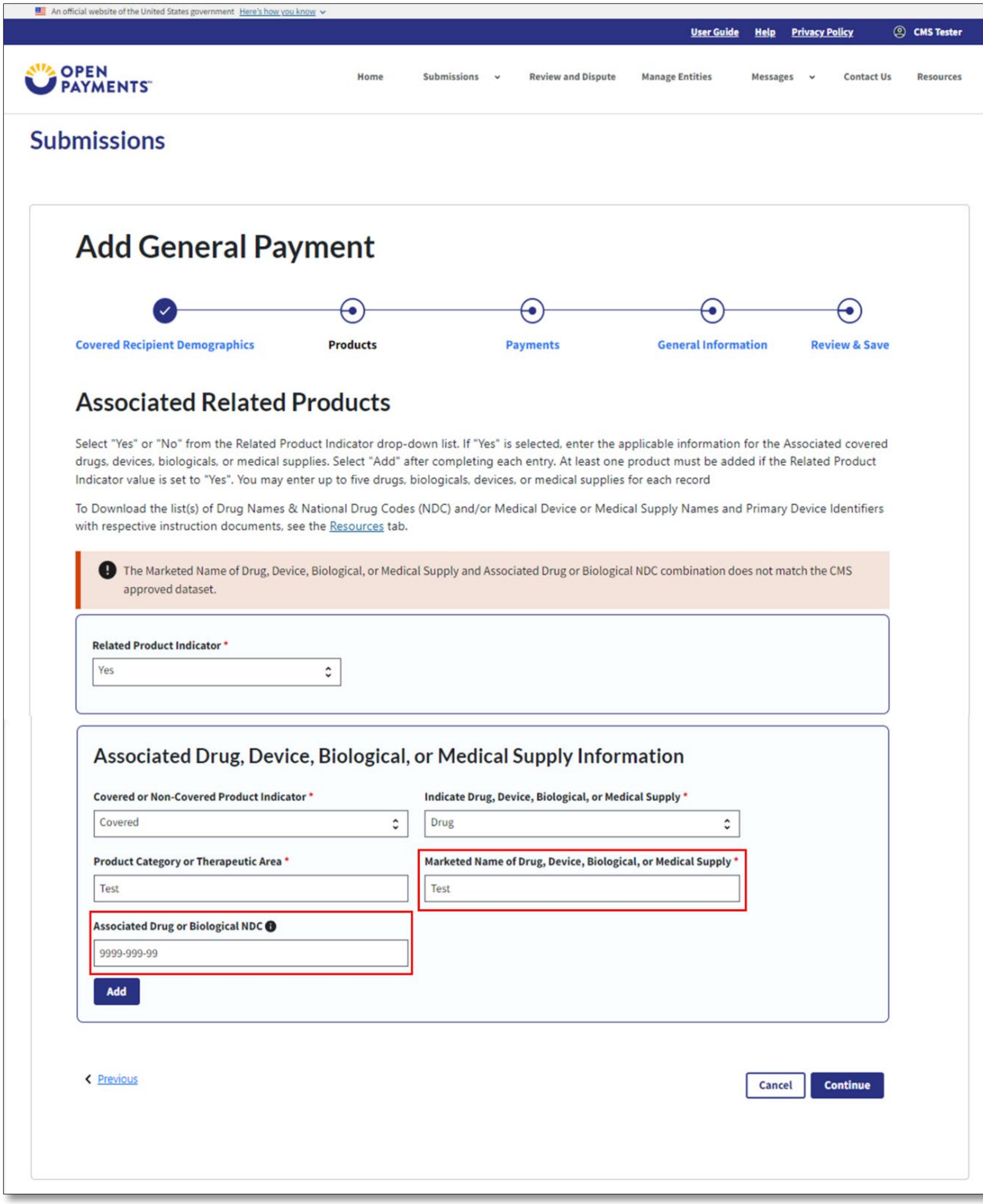
- The PDI entered by the user is valid against the FDA GUDID dataset.
- The Device or Medical Supply name and PDI combination is valid (if PDI provided) against the CMS approved dataset.

Figure 179: Associated Related Products: Add Button and Products Table



The submitter will receive an error message if a product does not match the associated CMS approved dataset. You cannot continue with record submission without fixing the error. To address the error, please refer to the Medical Device and Medical Supply Name and Primary Device Identifier dataset reference file on the CMS Resources Page to identify the correct PDI and Device Name combination to use for submissions.

Figure 180: Drug Information Validation Error Message

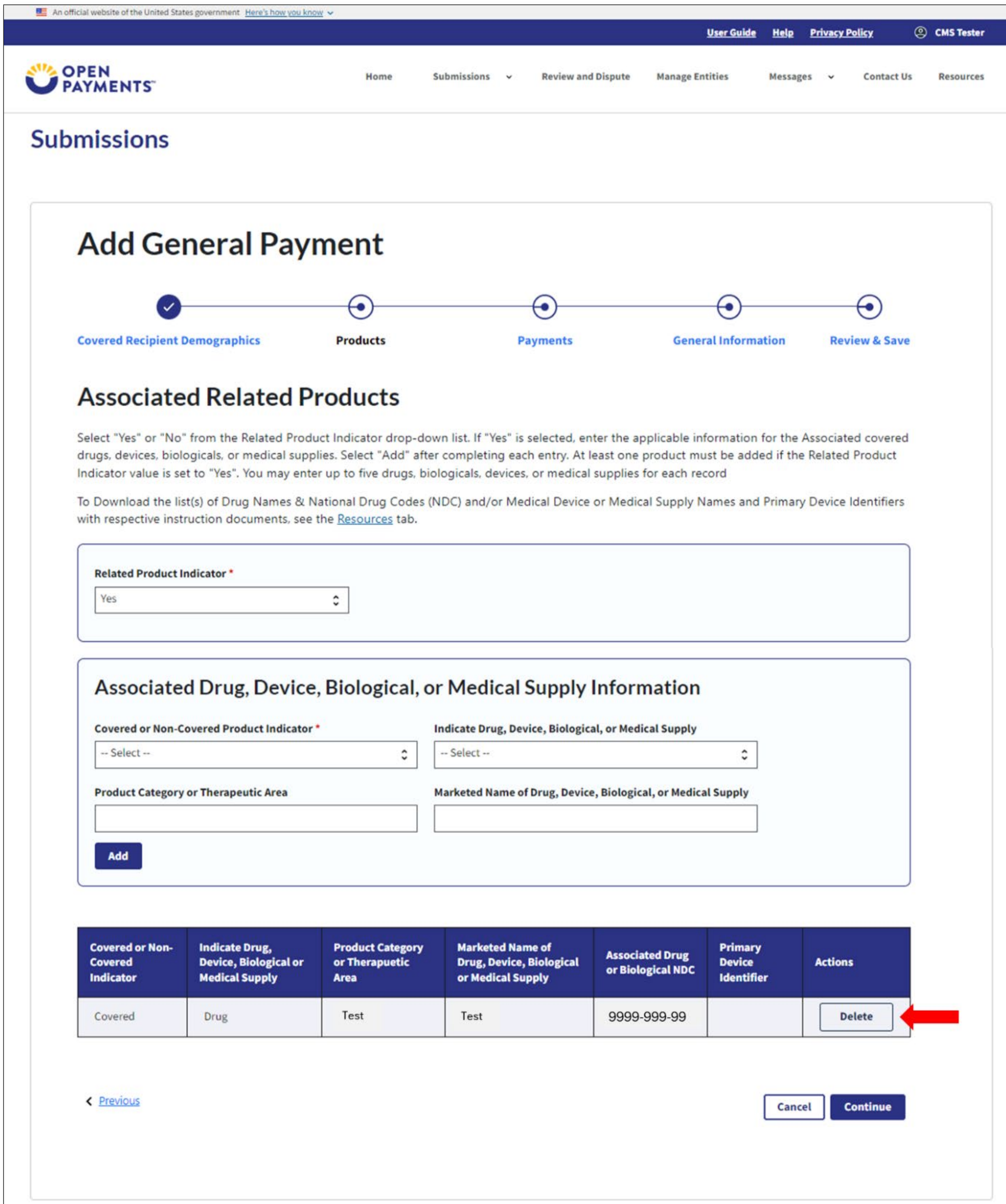


If you do not need to add another product and there are no other errors upon selecting the **Continue** button, you can proceed to the “General Payment or Other Transfer of Value Information” page.

If you have another product to add to the record, follow the same process at the beginning of this step and enter the appropriate information in the text fields and select "Add". A single payment record may contain up to five products.

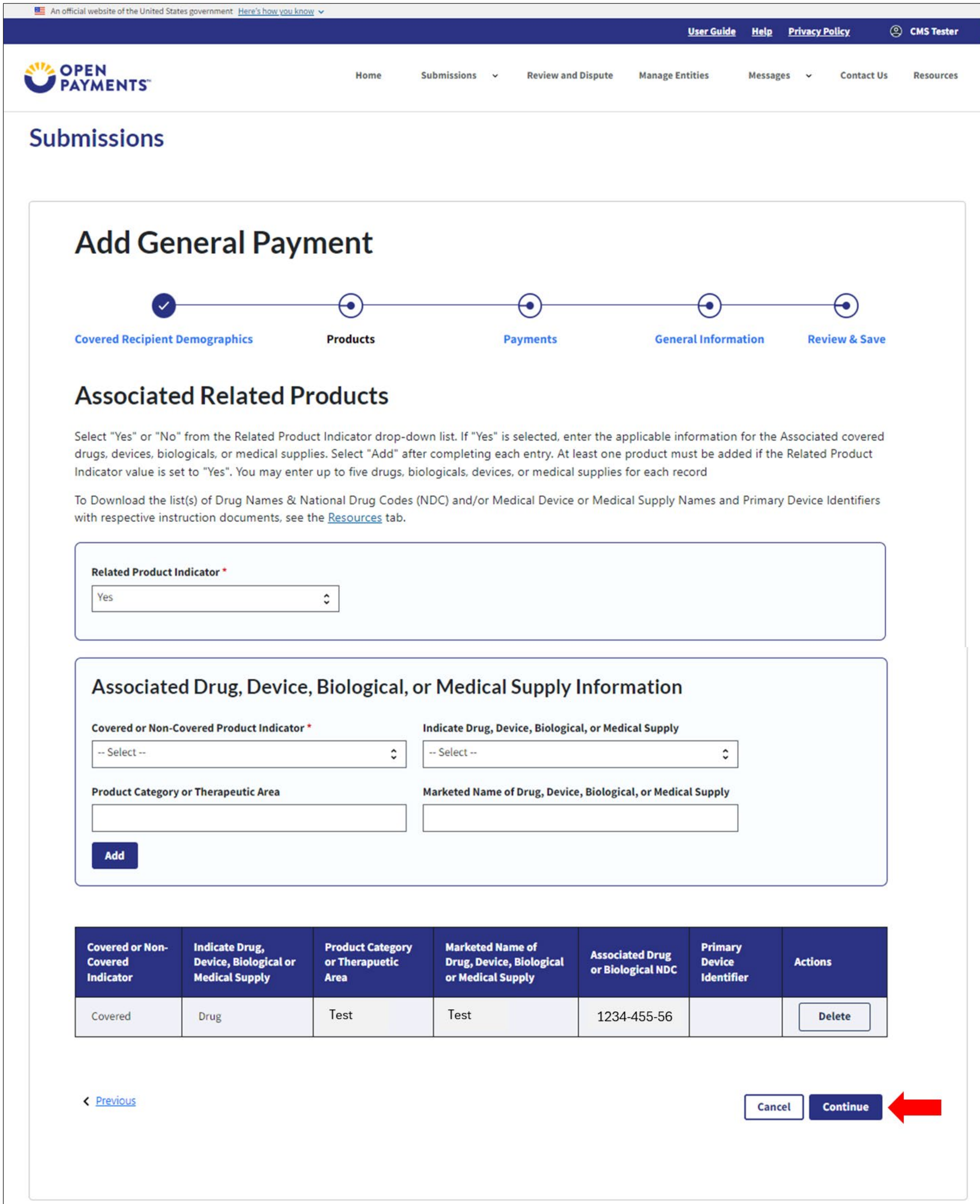
Step 4c: If you need to delete the product information after adding it, select the **Delete** button in the table of saved products, enter the product information again, and select **Add.** There is no edit option.

Figure 181: Delete Button for Associated Related Product Information



Step 4d: Select the **Continue** button if you are done entering related products and there are no validation errors to proceed to the "General Payment or Other Transfer of Value Information" page.

Figure 182: Associated Related Products



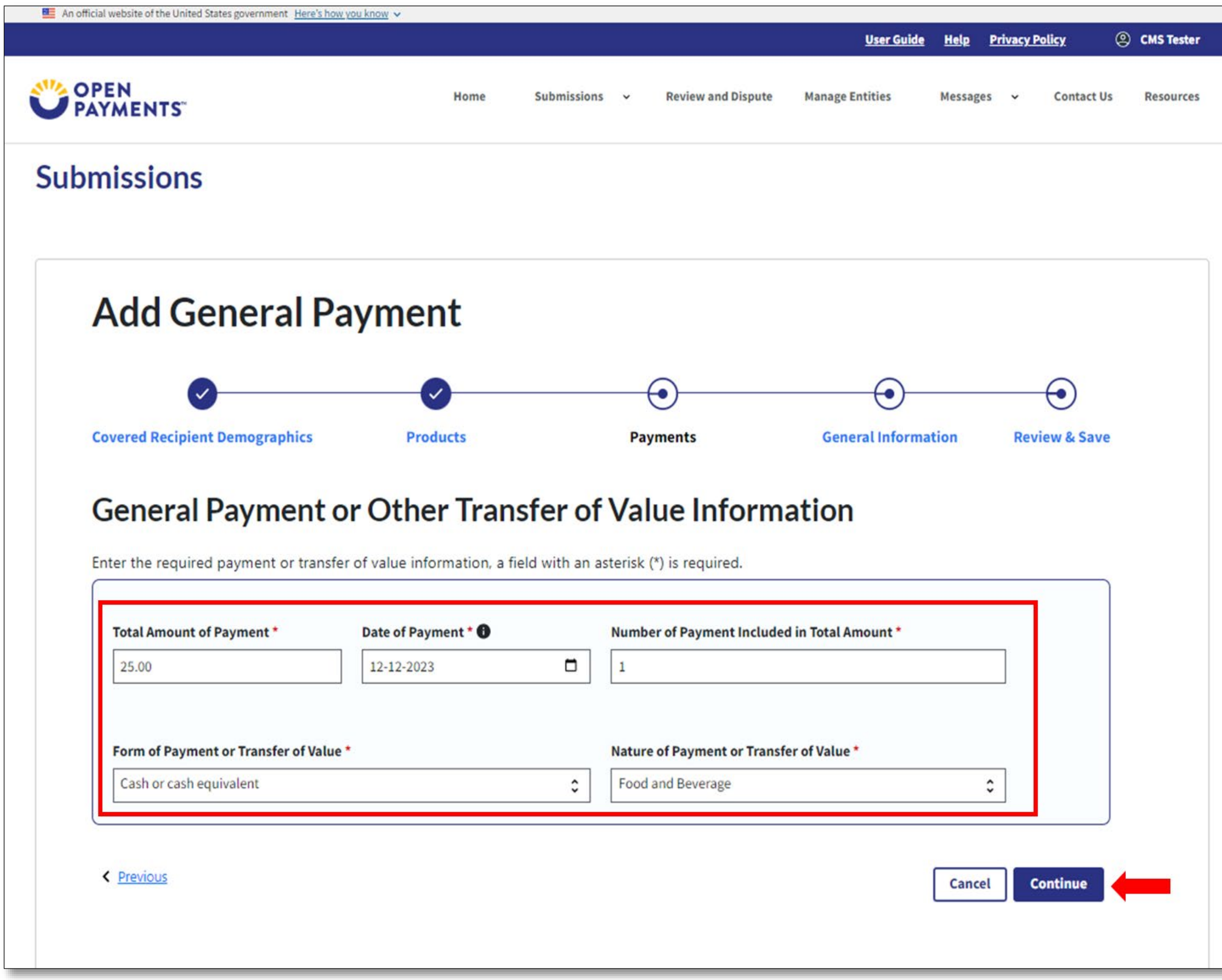
Step 5: Enter payment information in the required fields on the General Payment or Other Transfer of Value Information page.

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

It is the responsibility of the submission team to select the most-appropriate Nature of Payment.

Once all information is entered, select the **Continue** button to proceed to the “General Record Information” page.

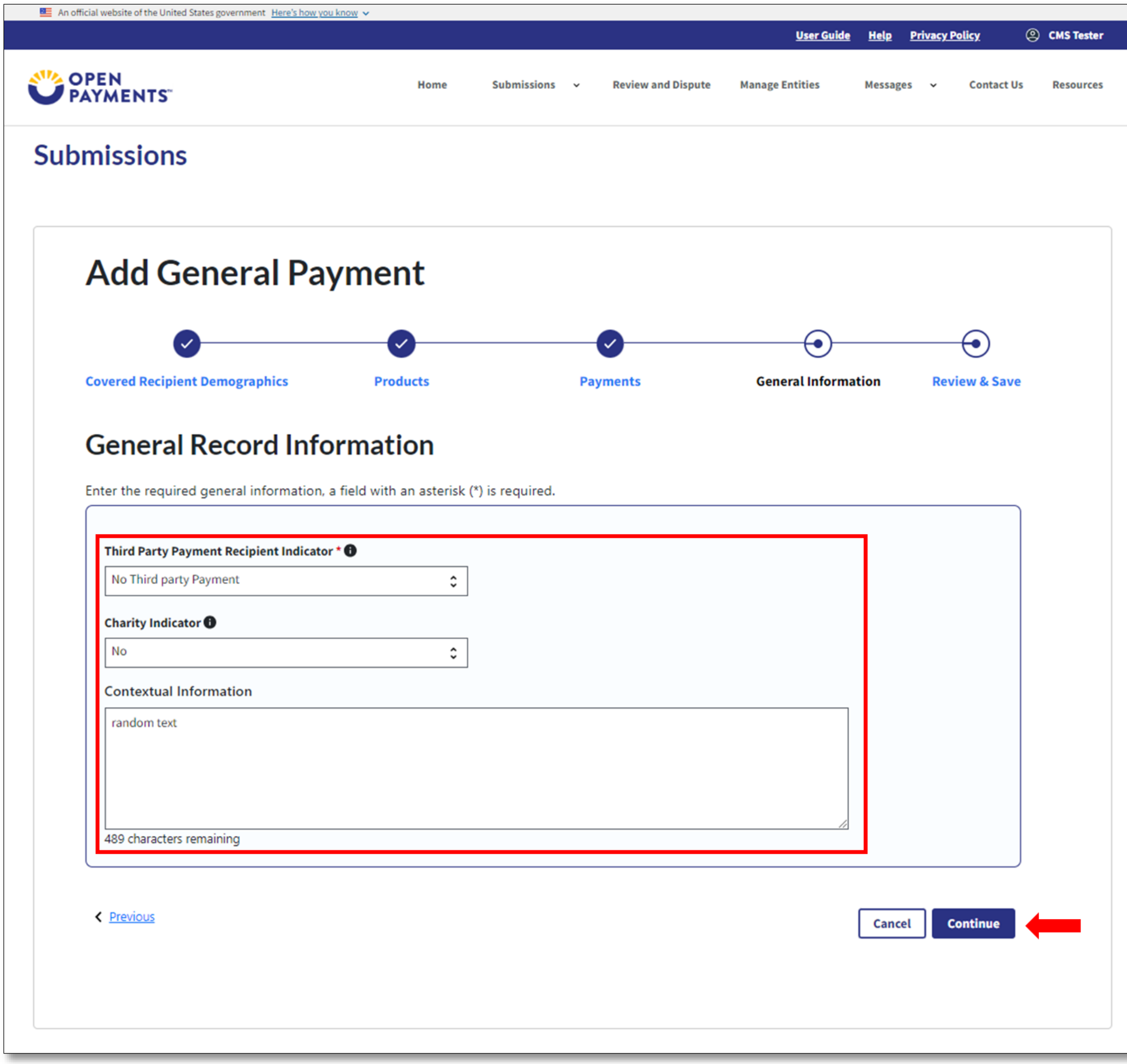
Figure 183: General Payment or Other Transfer of Value Information Page



Step 6: Enter all required information on the “General Record Information” page.

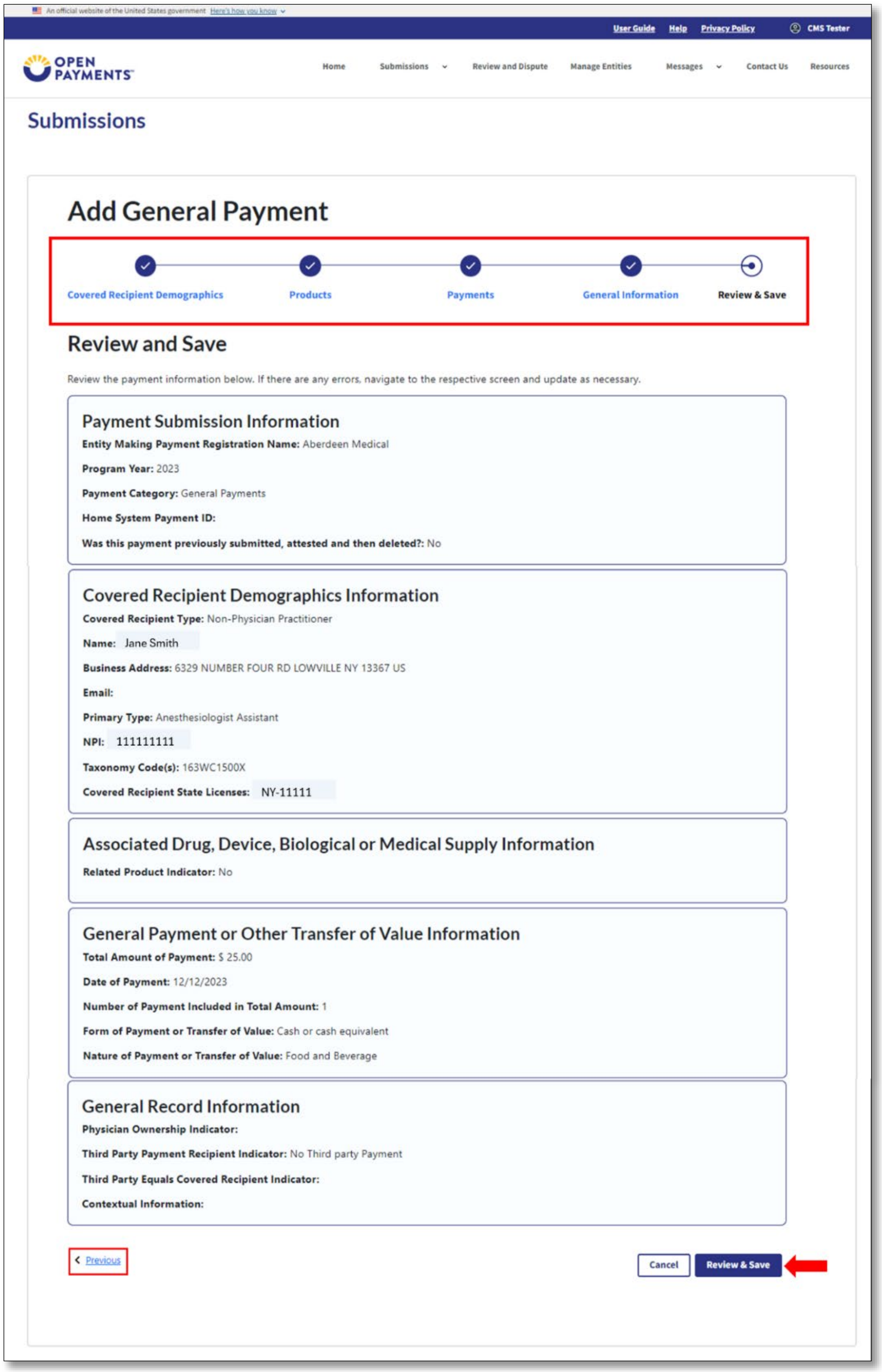
Select the **Continue** button to proceed to the “Review and Save” page.

Figure 184: Continue to Review Button on General Records Information Page



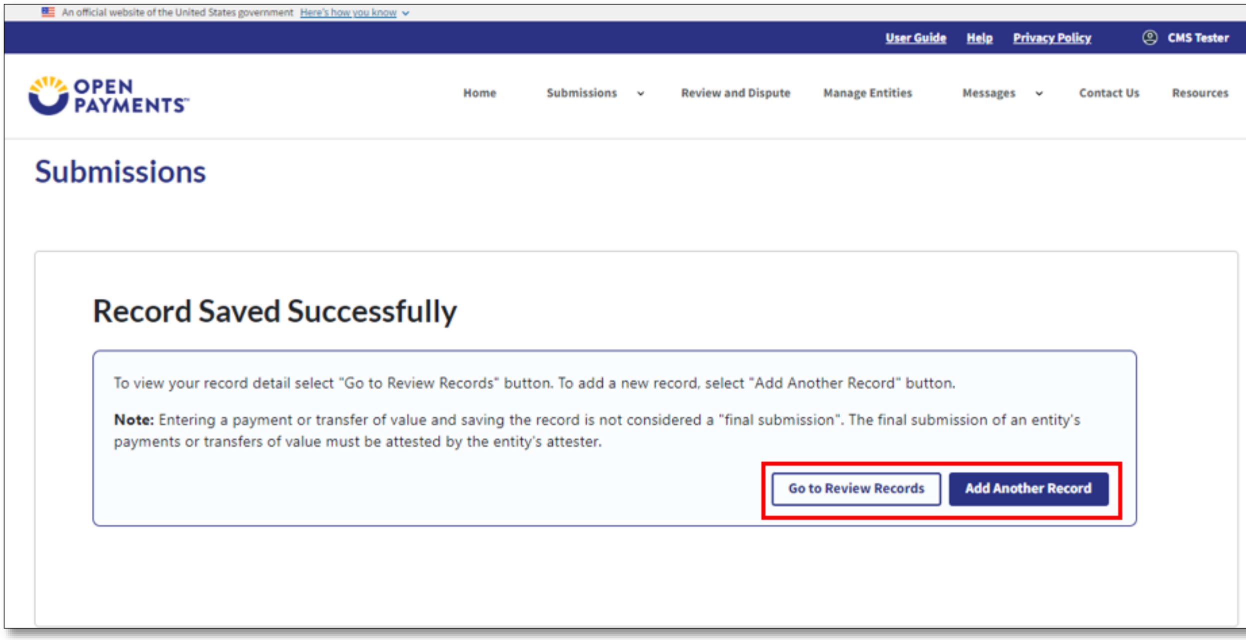
<u>Step 7:</u> Review the payment information entered in the previous pages on the "Review and Save" page. If necessary, select the "Previous" button at the bottom of the page to go back and edit information. Users can also select an icon from Payment Navigation Bar, located on top of the page, to go directly to the desired page. Once the record is accurate, select the **Review & Save** button to continue.

Figure 185: 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. Select either **Add Another Record** to add another General Payment record or select **Go to Review Records** to review details about the record(s) you entered.

Figure 186: Record Saved Successfully Page



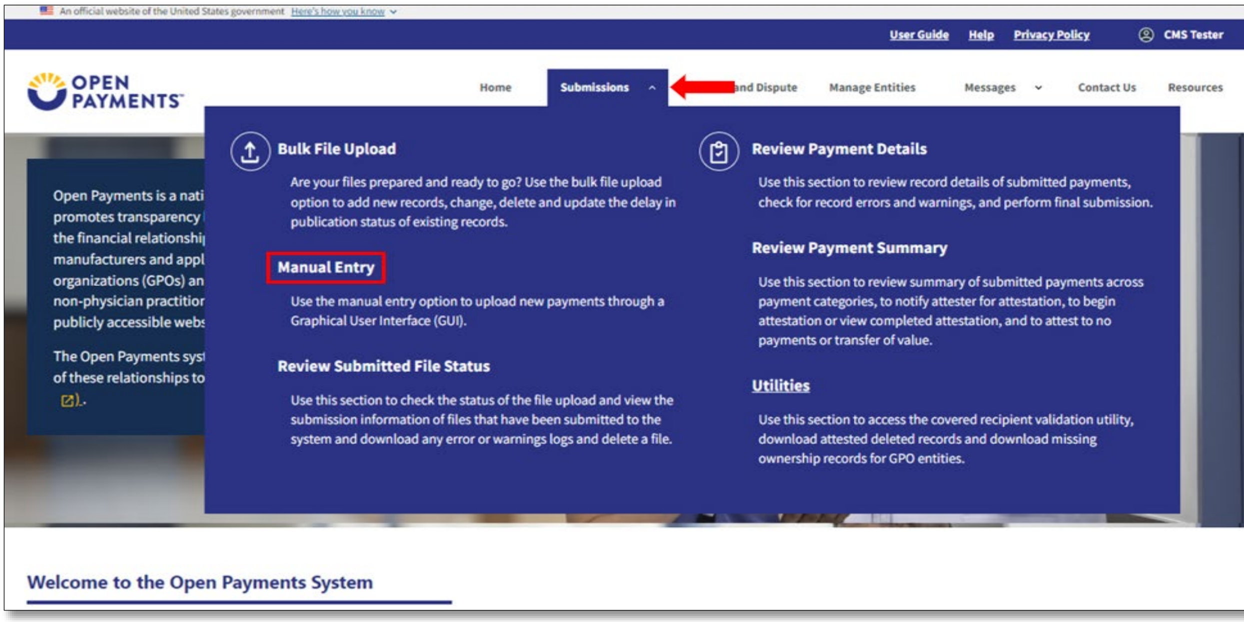
You must complete the final submission and attestation process for the data to be considered reported. See Section 4.11 for details on final submission and Section 4.15 for details on attestation.

4.5b: Manual Entry of Research Payments

To enter research payment data manually, follow these steps:

Step 1: Log in to the CMS Open Payments system, select the **Submissions** tab, and then select **Manual Entry**.

Figure 187: Submissions Tab: Manual Entry



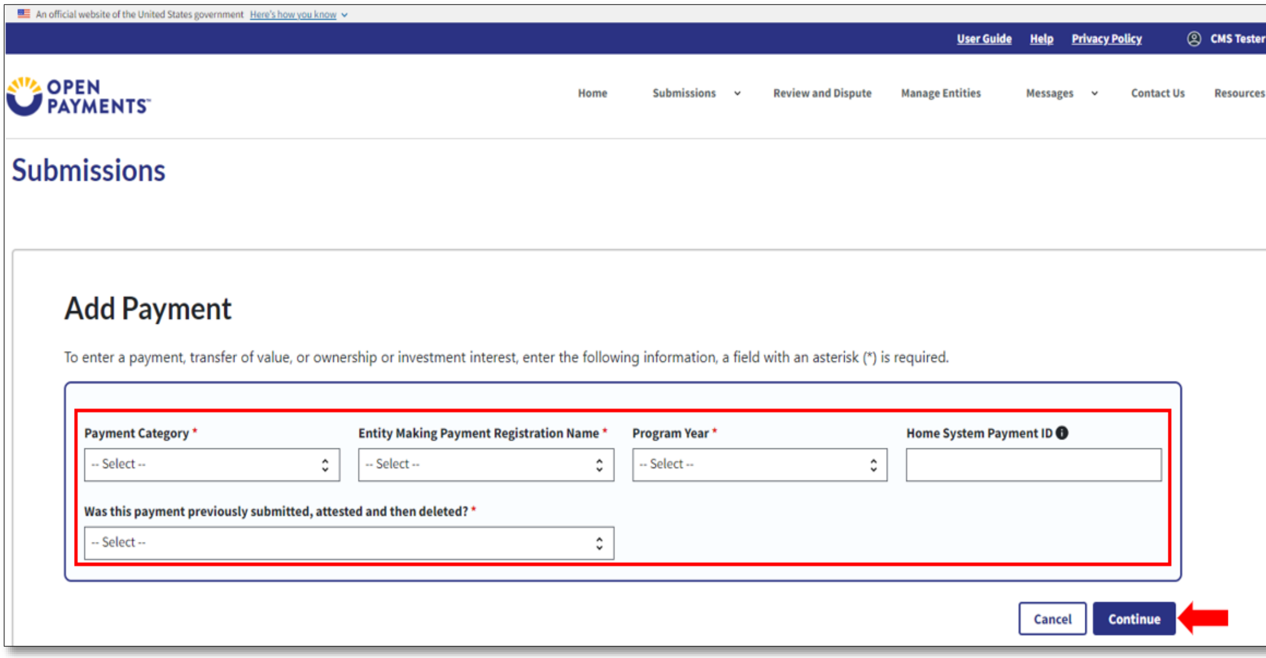
Step 2: On the “Add Payment” page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year.

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.

If the payment is being entered because of a payment that was previously submitted, attested and then deleted, you must select “Yes” in the drop-down box and enter the record id of the previously deleted record id.

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

Figure 188: Add Payment Page



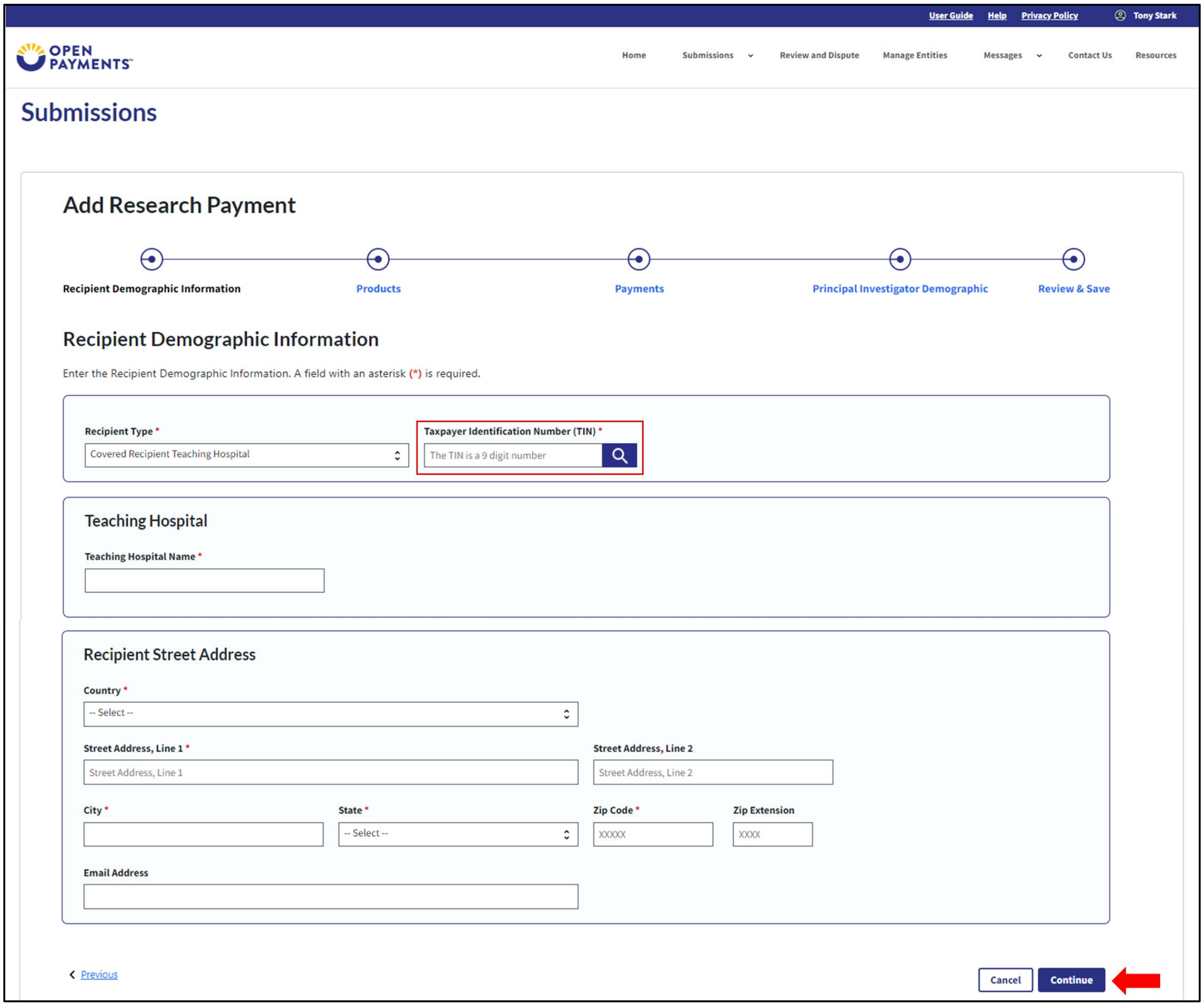
Step 3: On the "Covered Recipient Demographic Information" page, select the Recipient Type: Covered Recipient Physician, Covered Recipient Non-Physician Practitioner, Covered Recipient Teaching Hospital, Non-Covered Recipient Entity, or Non-Covered Recipient Individual. The next steps will differ depending on the Recipient Type selected.

Step 3a: For Teaching Hospitals: Enter information as requested on the page. Required fields are marked with asterisks.

The Taxpayer Identification (TIN) search field that will auto-populate Teaching Hospital information associated with the TIN entered. Refer to the CMS Teaching Hospital Lists to confirm any populated teaching hospital information, for which the download link is on in section 4.3a.

When you have validated all your teaching hospital information, select the **Continue** button.

Figure 189: Teaching Hospital Information

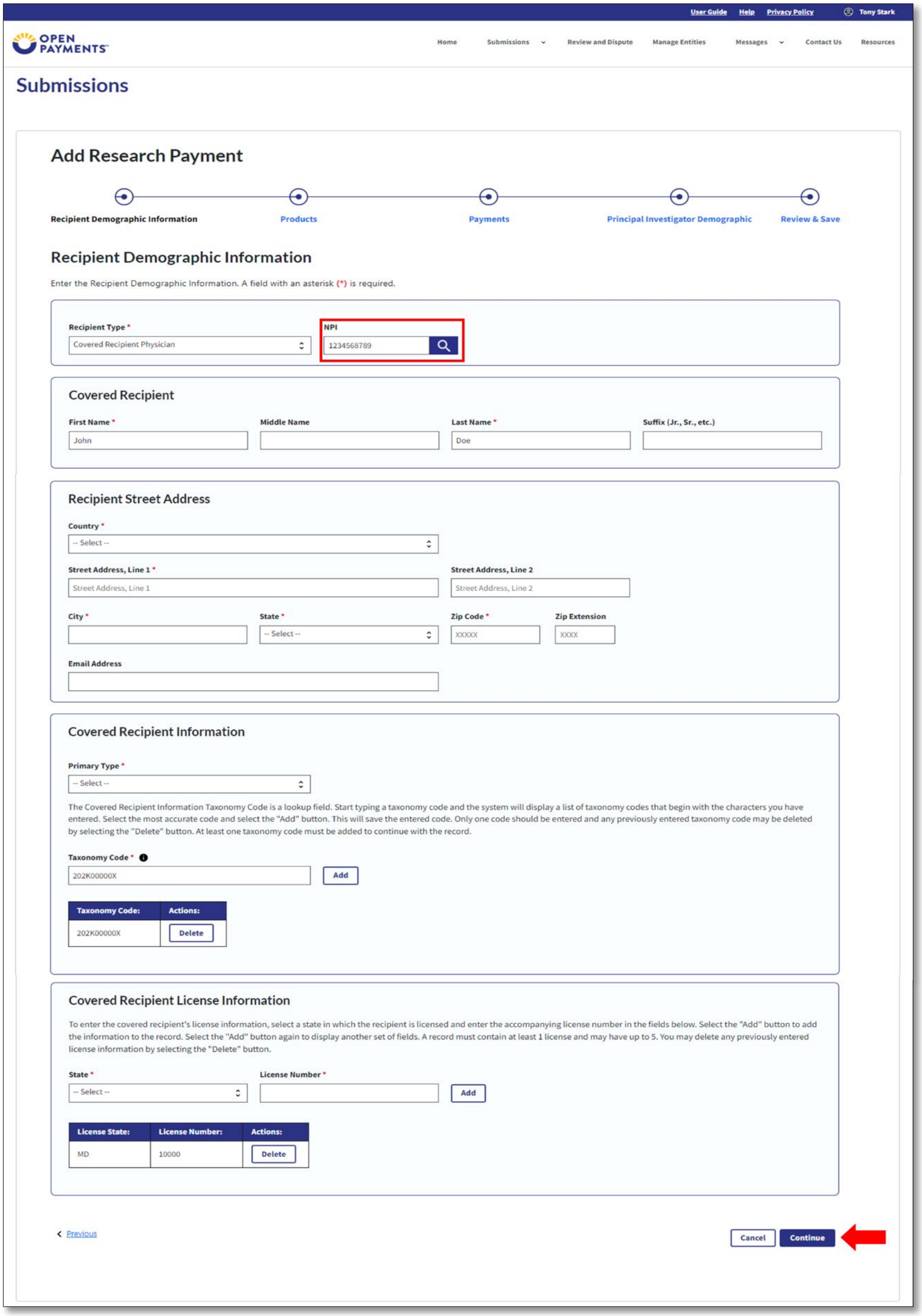


<u>Step 3b:</u> For Covered Recipient Physicians: Enter information as requested on the page below. Required fields are marked with asterisks.

The NPI search field will auto-populate Covered Recipient information, (i.e., First Name, Last Name, Taxonomy Code, and State License(s)) for an NPI entered. Refer to a CMS provided resource (VPL) to confirm any populated provider information, if necessary.

When you have validated all your information, select the **Continue** button.

Figure 190: Covered Recipient Demographic Information Page: Physician

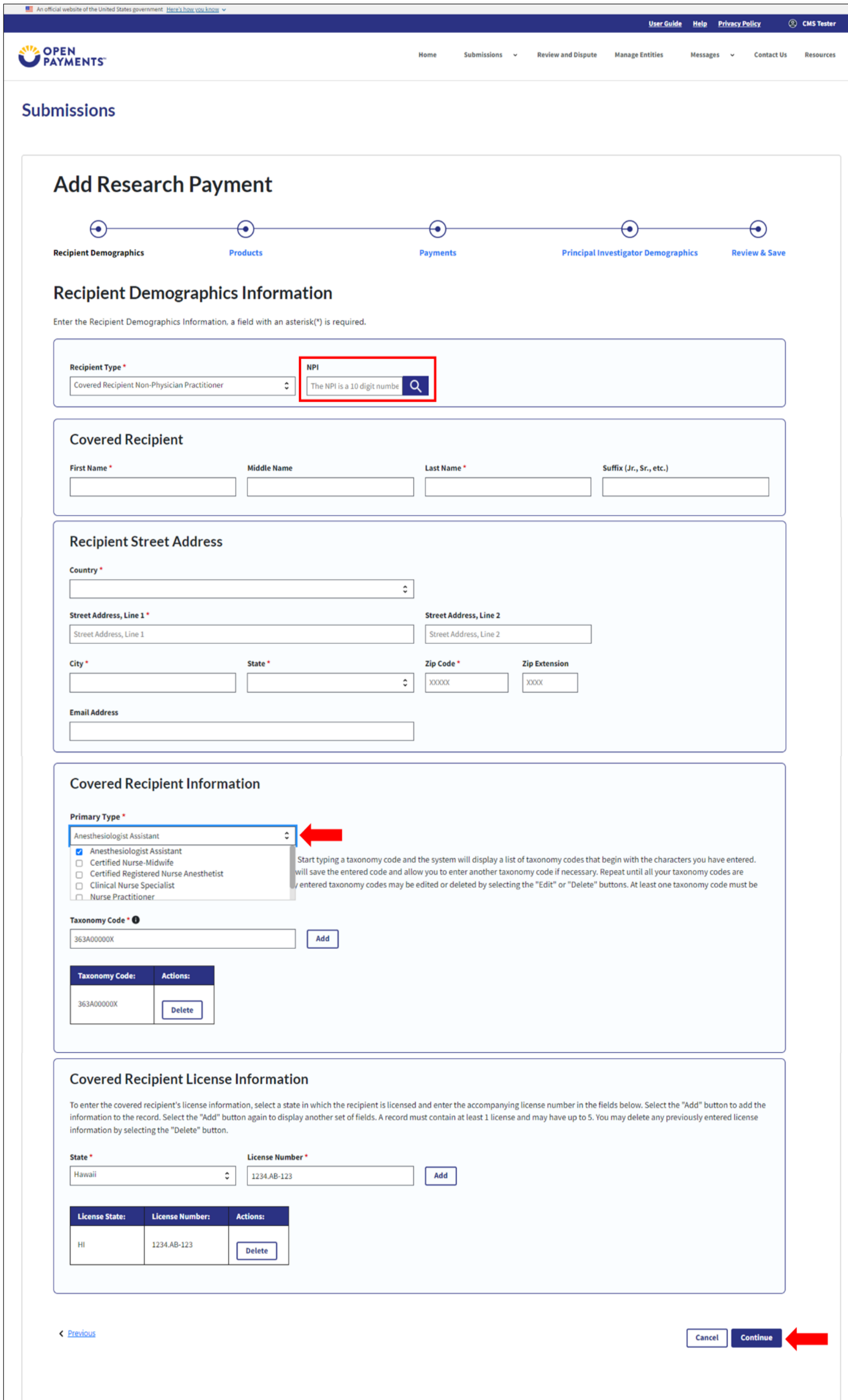


<u>Step 3c:</u> For NPPs: Enter information as requested on the page below. Required fields are marked with asterisks.

The NPI search field will auto-populate Covered Recipient information, (i.e., First Name, Last Name, Taxonomy Code, and State License(s)) for an NPI entered. Refer to a CMS provided resource (VNPPL) to confirm any populated provider information, if necessary.

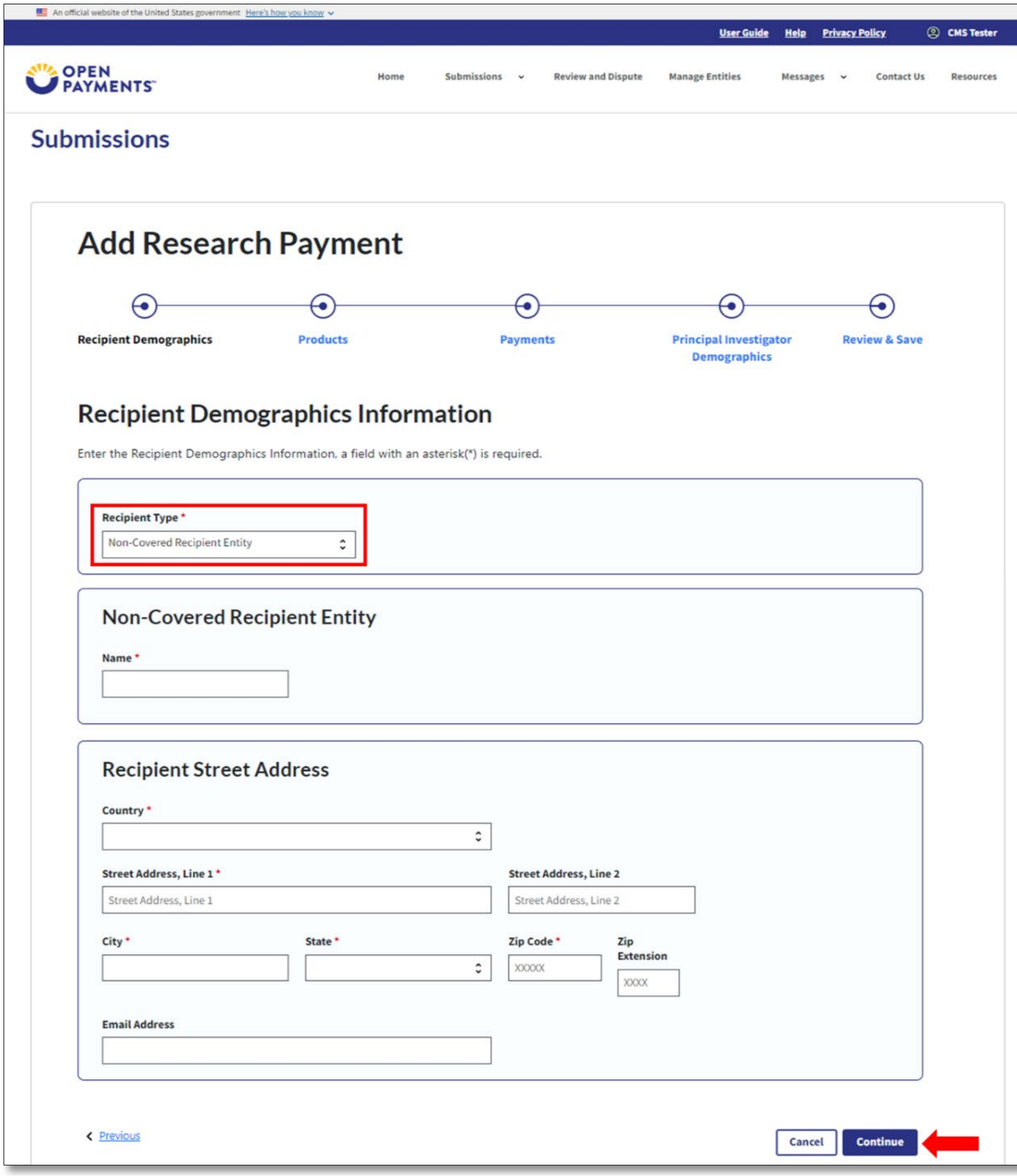
To add the NPP's primary type, multi-select up to six valid values as per reference data list.

Figure 191: Covered Recipient Demographic Information Page: Non-Physician Practitioner



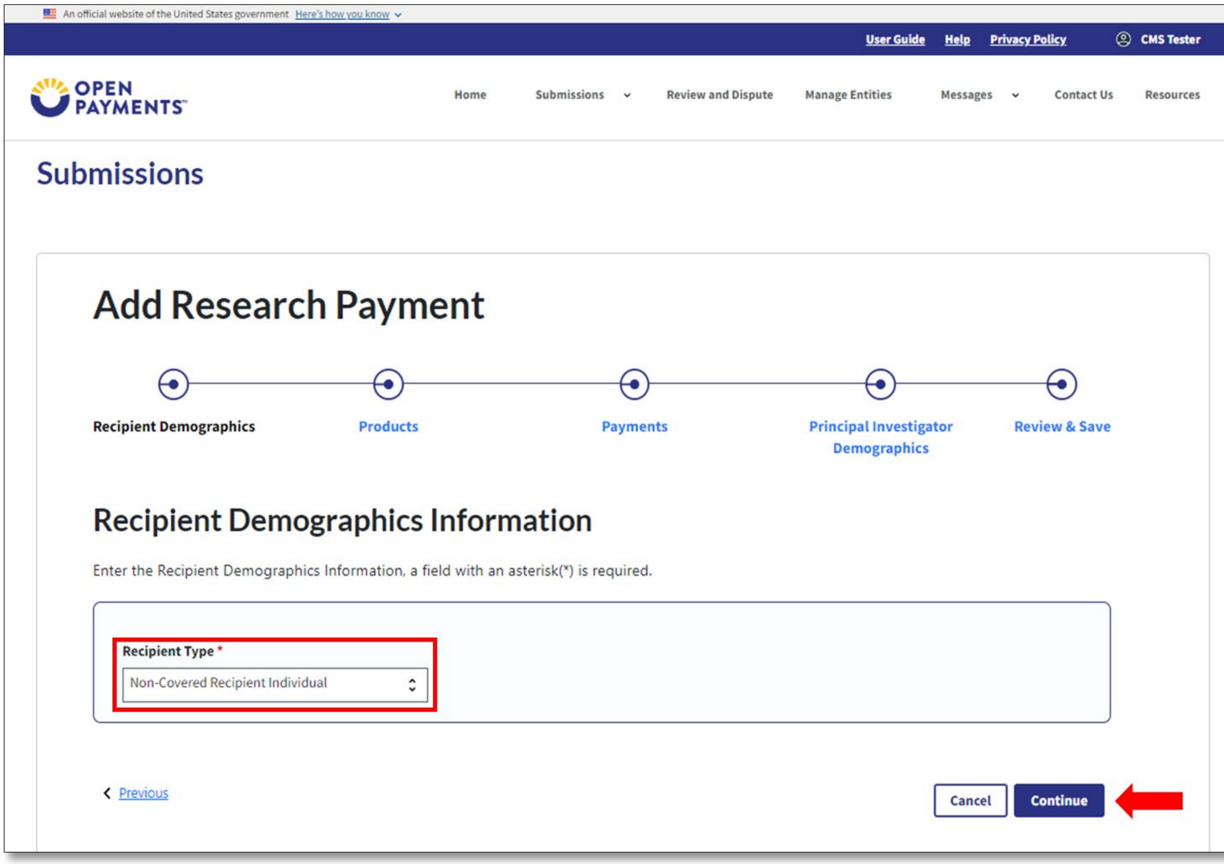
Step 3d: For **Non-Covered Recipient Entity**: Enter information as requested on the page below. Required fields are marked with asterisks. Select the **Continue** button when you are ready.

Figure 192: Drop-Down for Non-Covered Recipient Entity



Step 3e: For **Non-Covered Recipient Individual**: Make the appropriate selection from the drop-down on the “Recipient Demographic Information” page and select the **Continue** button.

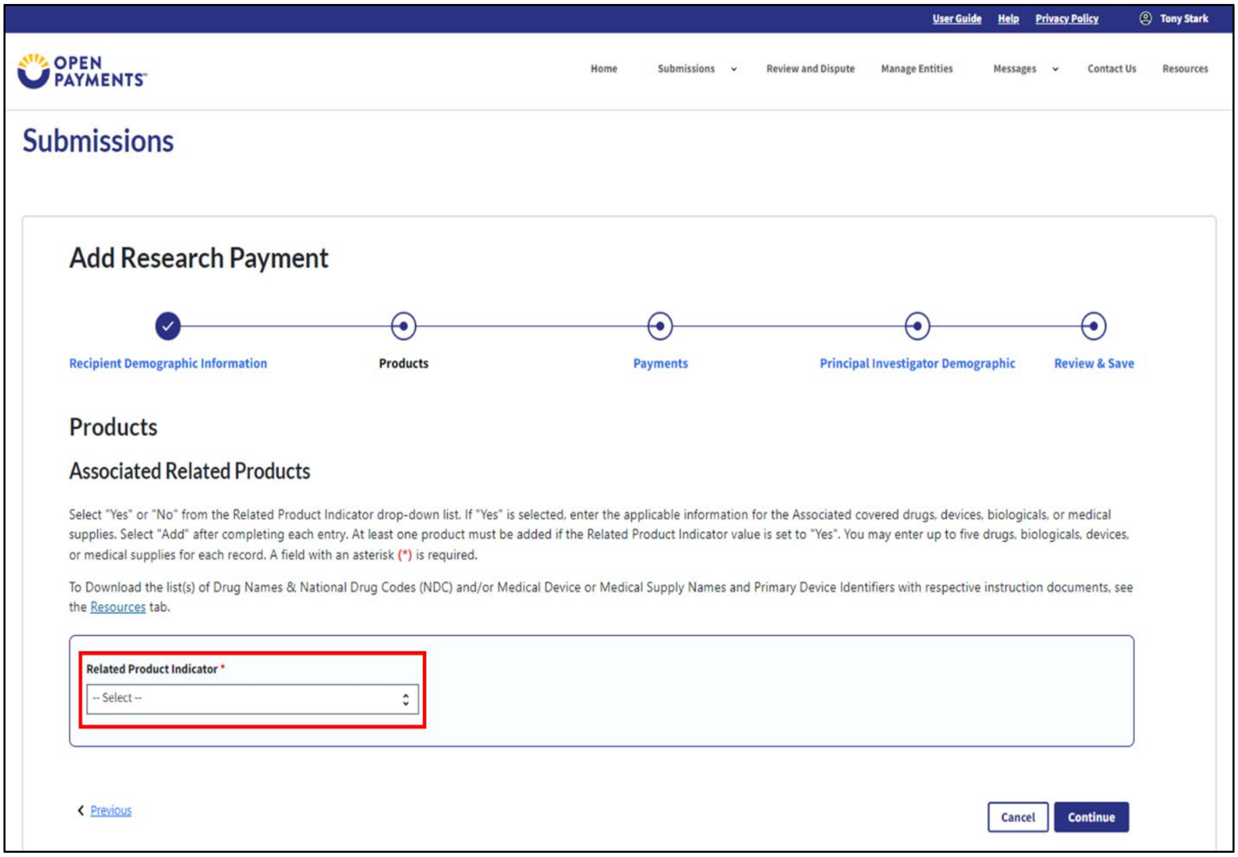
Figure 193: Drop Down for Non-Covered Recipient Individual Type



Step 4: On the "Associated Related Products" page, enter the associated drugs, biologicals, devices, or medical supplies, choose the option applicable to the record.

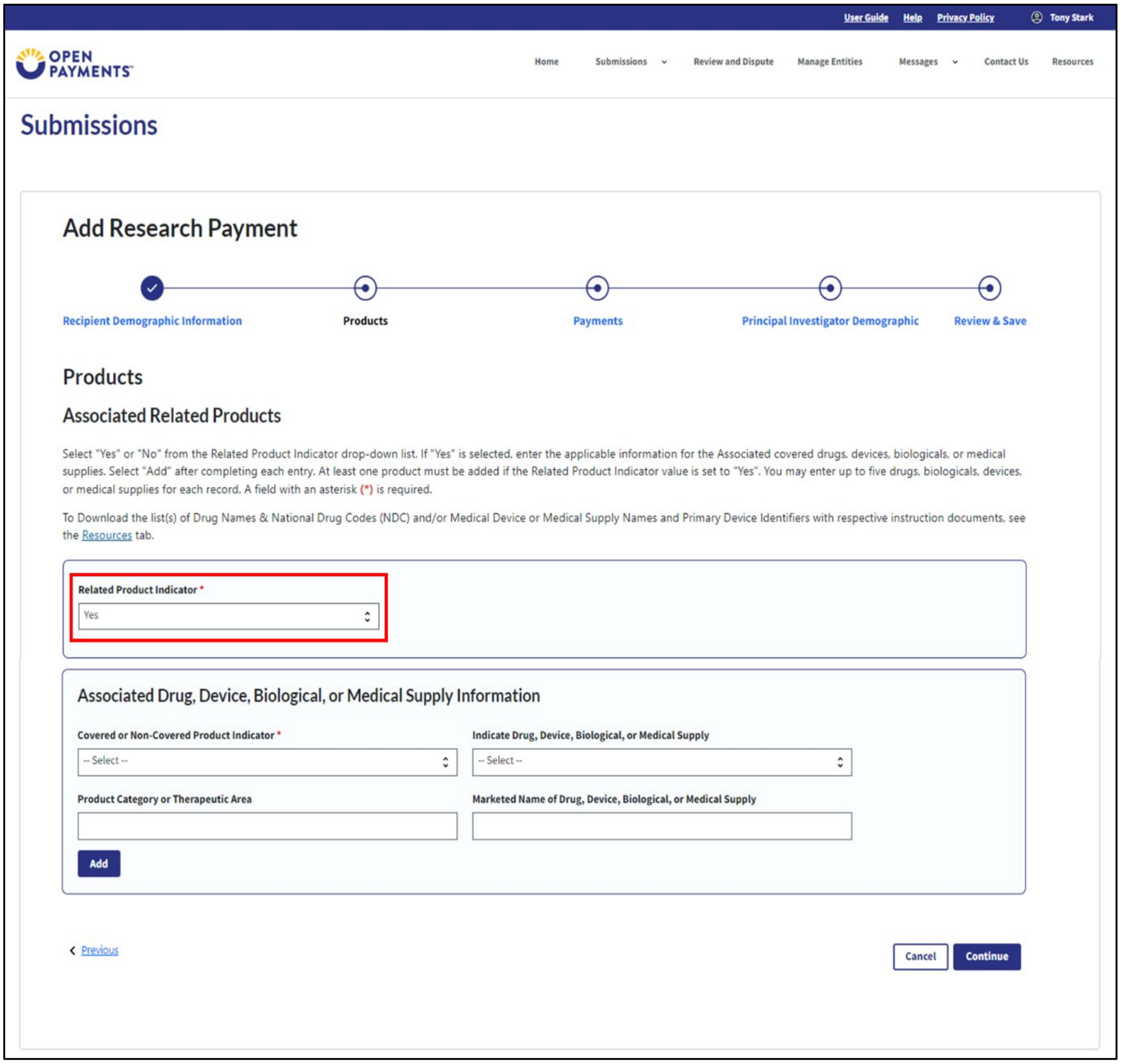
- **Select "Yes"** if the payment record needs to include a drug, biological, device, or medical supply and follow the instructions for the rest of step 4 below. You can enter up to five drugs, biologicals, devices, or medical supplies per record. Begin by selecting the appropriate value in the "Related Product Indicator" drop-down list.
- **Select "No"** if the payment did not include a drug, biological, device, or medical supply, and proceed to step 5.

Figure 194: Associated Related Products Page -> Related Product Indicator



Step 4a: If you selected "Yes," multiple fields will appear that will allow the entry of one drug, biological, device, or medical supply. Required fields marked with an asterisk will dynamically display based on the type of covered product selected.

Figure 195: Input Fields for Related Product Indicator



Step 4b: 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 text fields and select **Add**. A table will populate under the form containing the product(s) you added.

Drug or Biologicals and National Drug Codes (NDC):

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 an error 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 for the Drug or Biological Name and NDC fields:

- 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.

The submitter receives an error message if any of these validations fail. You cannot continue with record submission without fixing the error. To address the error, please refer to the Drug Name and NDC dataset reference file on the CMS Resources Page to identify the correct NDC and Drug or Biological Name combination for submissions.

Device or Medical Supply and Primary Device Identifier (PDI):

For PY2021 and onwards, if the product is a device or medical supply, enter the Primary Device Identifier (PDI) for the device or medical supply in the "Primary Device Identifier" field. PDIs are unique identifiers for the medical devices and supplies, as listed in the Food and Drug Administration's Global Unique Device Identification Database Directory (GUDID).

PDIs entered that contain any of the following are not accepted.

- All zeroes
- Any leading or trailing spaces
- Consecutive spaces
- Special characters not permitted in the Open Payments System

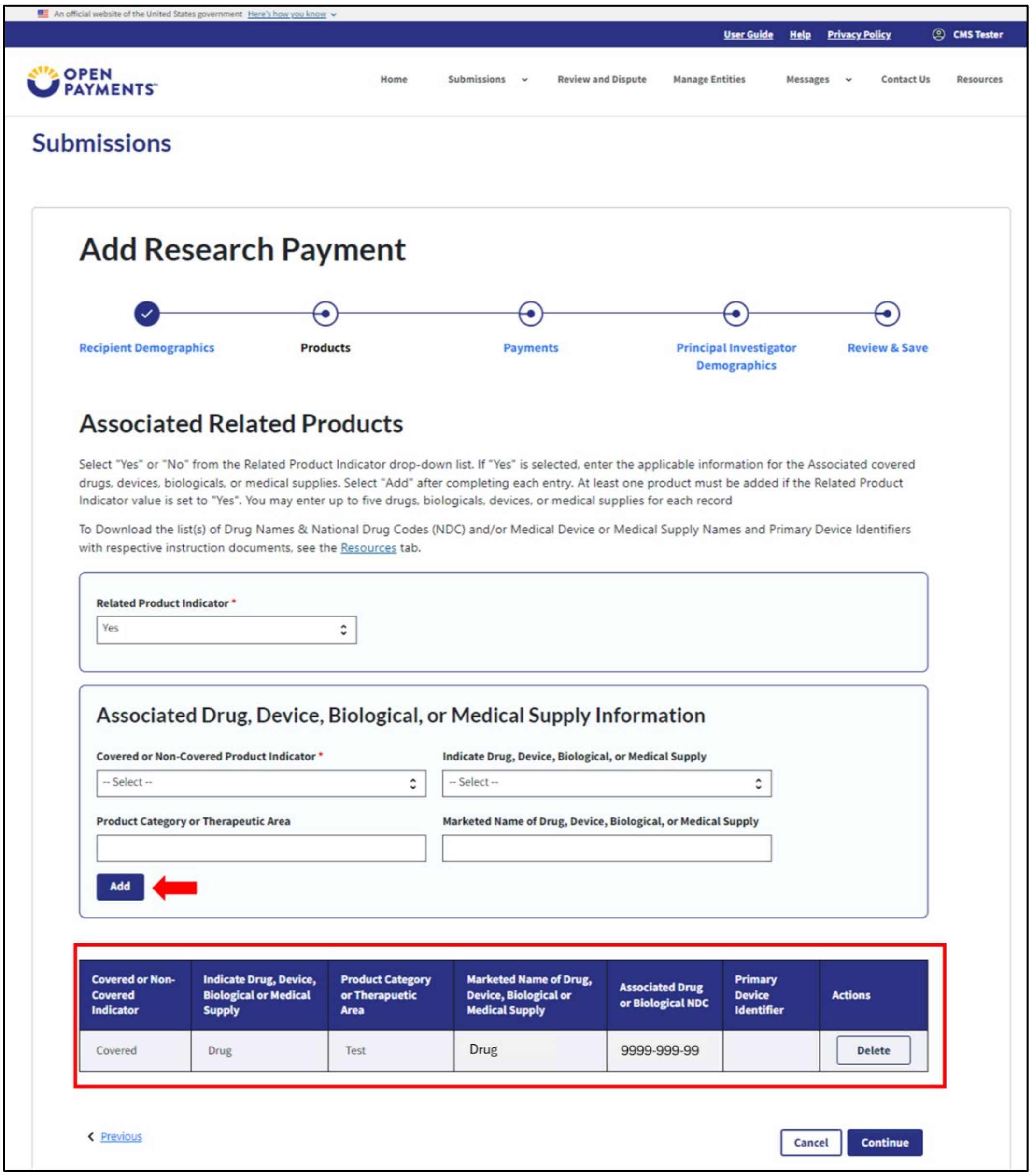
PDIs can be found on the website https://accessgudid.nlm.nih.gov/download/delimited. The Device and Medical Supply Name and PDI reference file and PDF Instructions document are zipped together and are available within the Open Payments system Resources tab.

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

The following validations are performed for the PDI field:

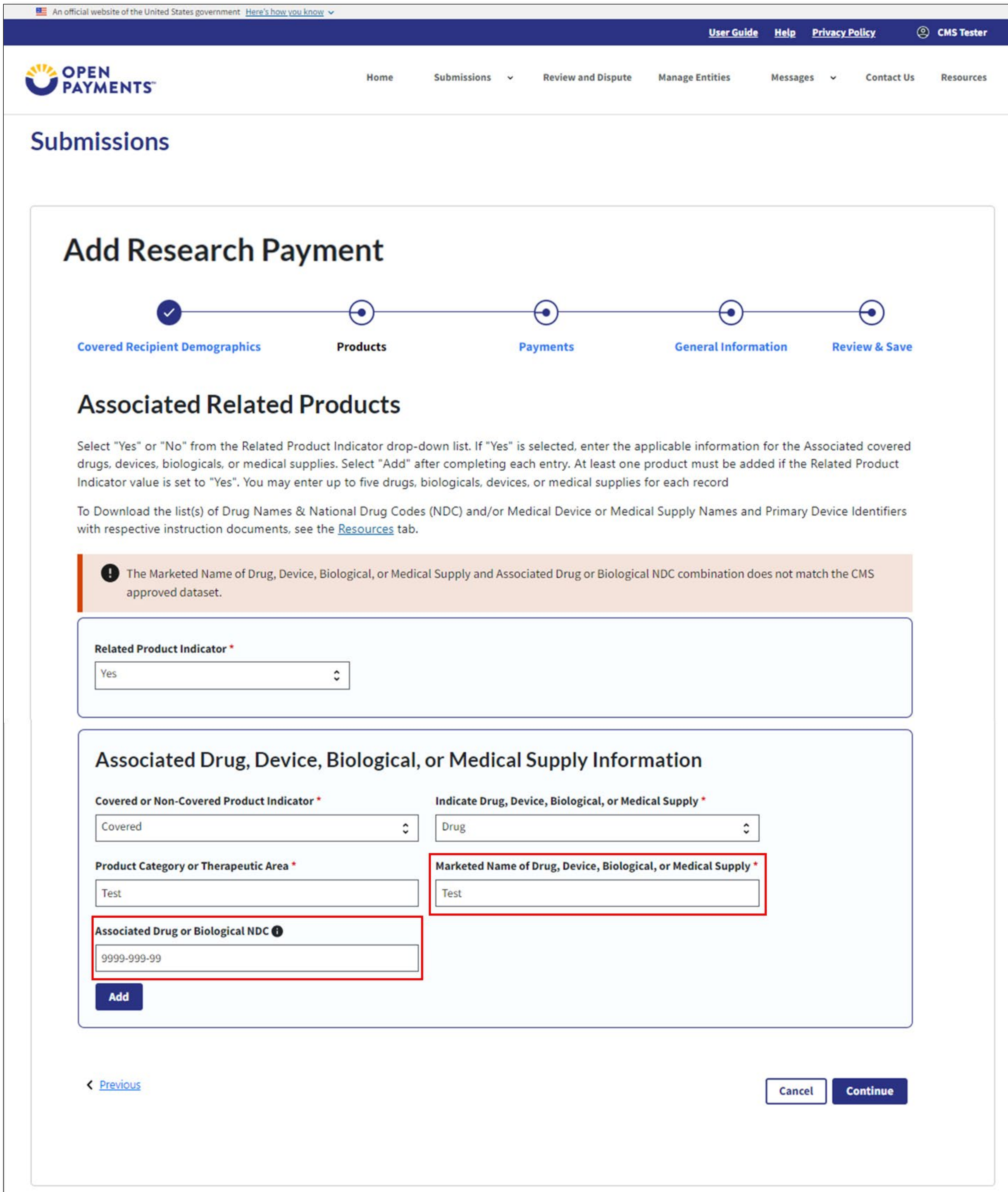
- The PDI entered by the user is valid against the FDA GUDID dataset.
- The Device or Medical Supply name and PDI combination is valid (if PDI provided) against the CMS approved dataset.

Figure 196: Associated Related Products: Add Button and Products Table



You will receive an error message if a product does match the CMS approved dataset. You cannot continue with record submission without fixing the error. To address the error, please refer to the Medical Device and Medical Supply Name and Primary Device Identifier dataset reference file on the CMS Resources Page to identify the correct PDI and Device Name combination to use for submissions.

Figure 197: Product Information Validation Error Message



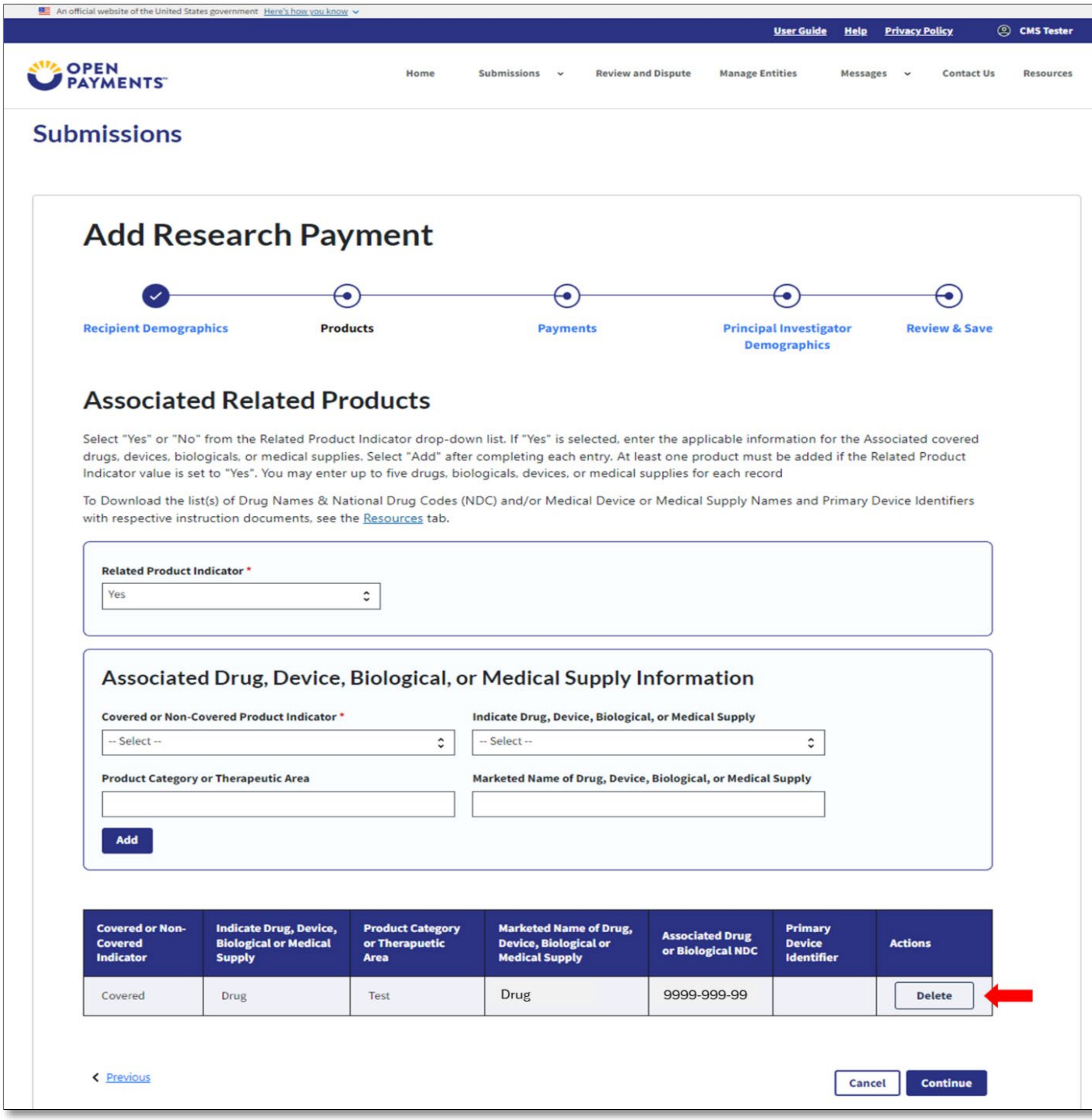
Step 4c: If you do not need to add another product and there are no other errors upon selecting the "Continue" button, you can skip to step 5 and proceed to the "General Payment or Other Transfer of Value Information" page.

If you have another product to add to the record, follow the same process at the beginning of this step and enter the appropriate information in the text fields and select **Add**. A single payment record may contain up to five products.

Step 4d: If you need to delete the product information after adding it, select the **Delete** button in the table of saved products, enter the product information again and select "Add". There is no edit option.

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

Figure 198: Delete Button for Associated Related Product Information



Step 5: Enter all required information on the "Research Payment or Other Transfer of Value Information" page.

To request a delay in public reporting of that payment, select one of the following from the drop-down values in the "Delay in Publication of Research Payment Indicator":

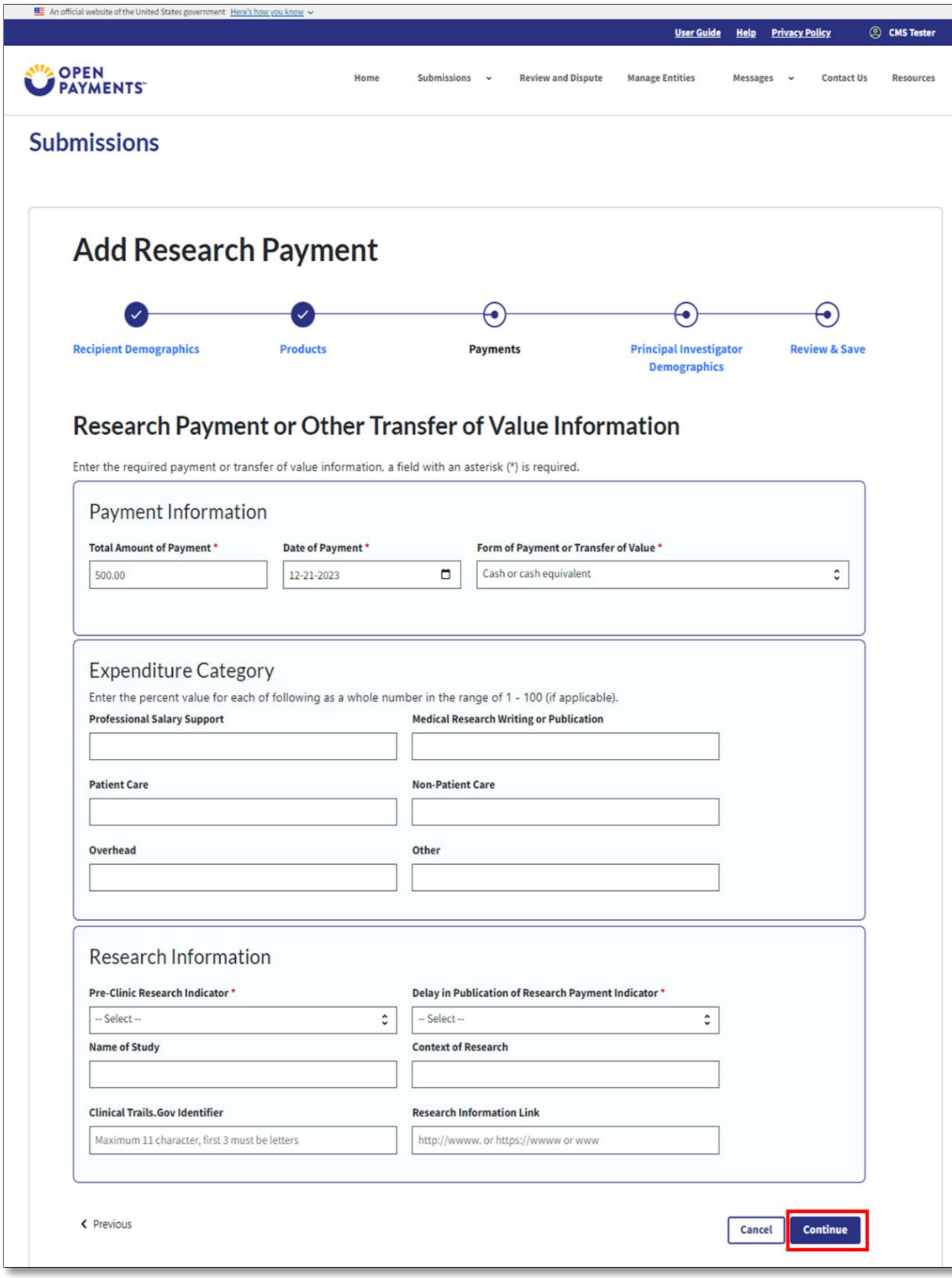
- R&D on New Product
- Clinical Investigation on New Product

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 Years 2014, 2015, 2016, 2017, 2018, and 2019, are no longer eligible for a delay in publication in calendar year 2024.

Please see section 4.12 for more information about requesting a Delay in Publication.

Select the **Continue** button to proceed to "Principal Investigator Demographic" page.

Figure 199: Add Research Payment Page: Research Payment or Other PTOV



Step 6: If the record has a principal investigator associated with it, select **Yes** from the “Principal Investigator Covered Recipient Indicator” drop-down box on the “Principal Investigator Demographics” page.

To add the Principal Investigator physician's primary type, select single valid values as per reference data list. To add the Principal Investigator NPP's primary type, multi-select up to six valid values as per reference data list. Use ctrl button to choose multiple values from the list.

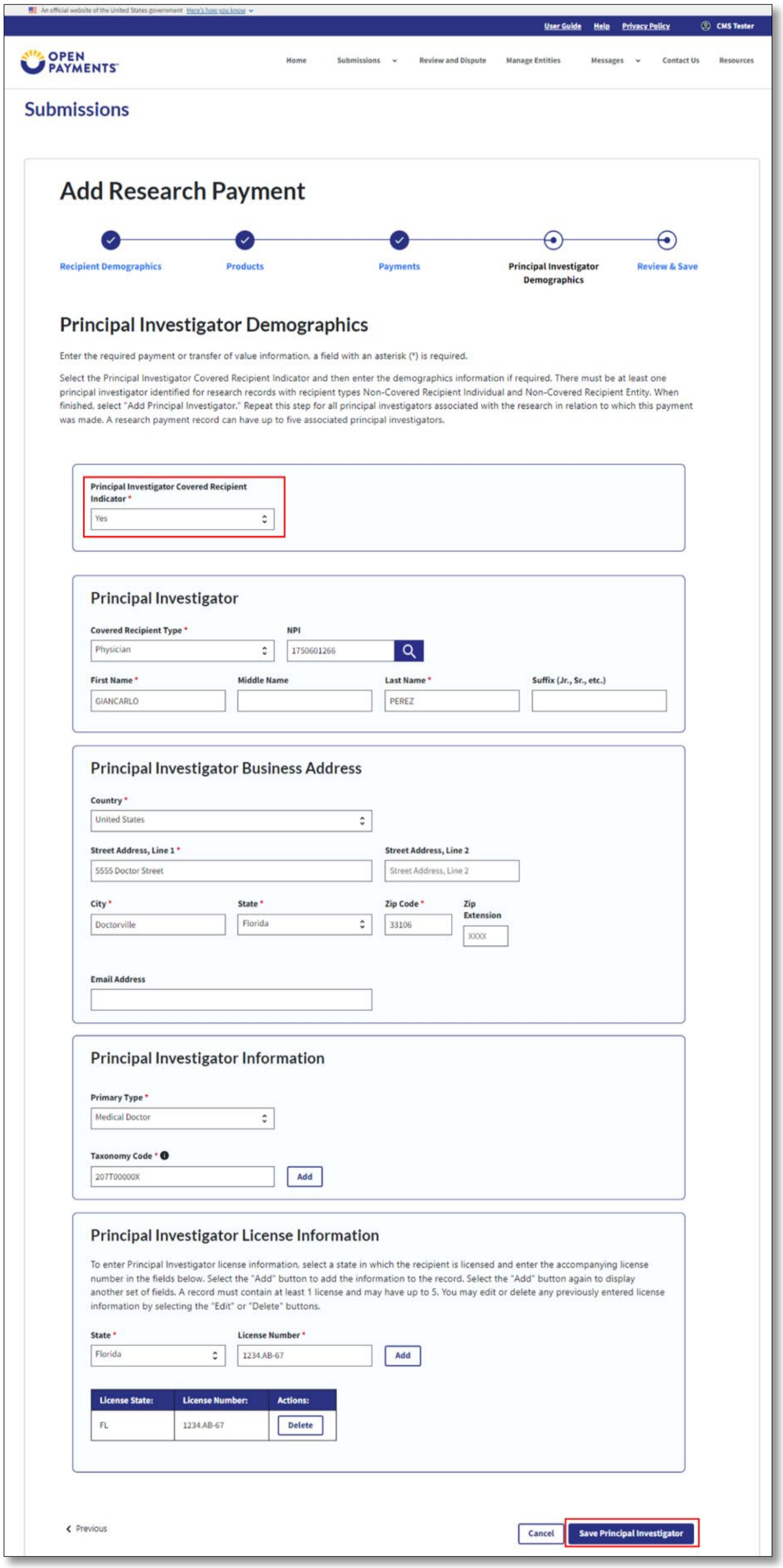
After providing all required information for one covered recipient, select "Save Principal Investigator" to add that individual to the record.

Repeat this step if you have more than one principal investigator to report in this payment, as you can add up to a total of five.

A principal investigator's identifying information cannot be the same as the covered recipient physician or NPP's identifying information (i.e., the physician and principal investigator in a record cannot be the same individual), when the "Principal Investigator Covered Recipient Indicator" is set to "Yes".

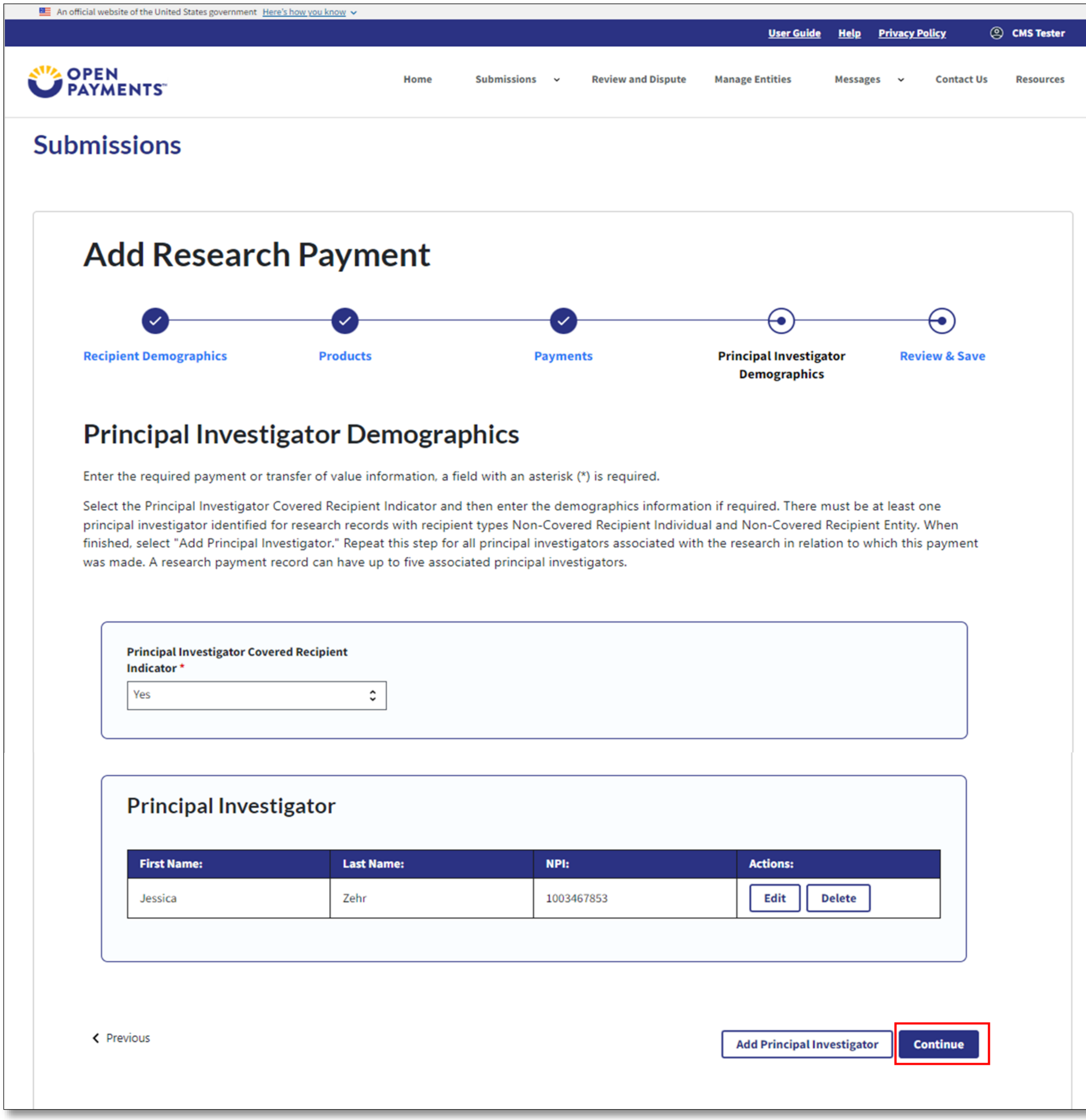
The "Non-Physician Practitioner" covered recipient type for a Principal Investigator will not be listed for any payment records prior to Program Year 2021.

Figure 200: Principal Investigator Demographics Page: Save Principal Investigator



Step 7: Select the **Continue** button if you are done adding associated principal investigators to proceed to the “Review and Save” page.

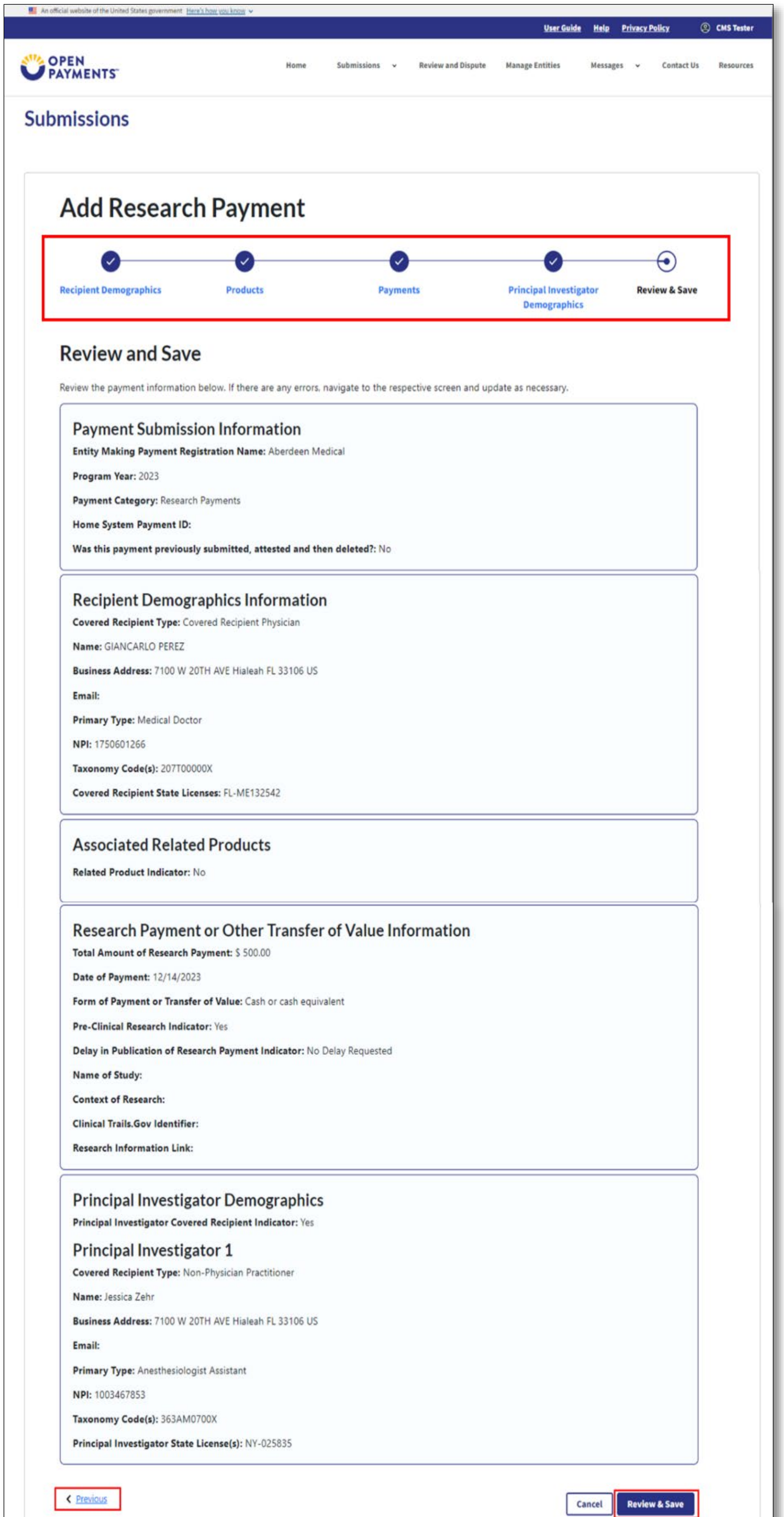
Figure 201: Principal Investigator Information



Step 8: Review the payment information entered on the “Review and Save” page. If necessary select the **Previous** 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.

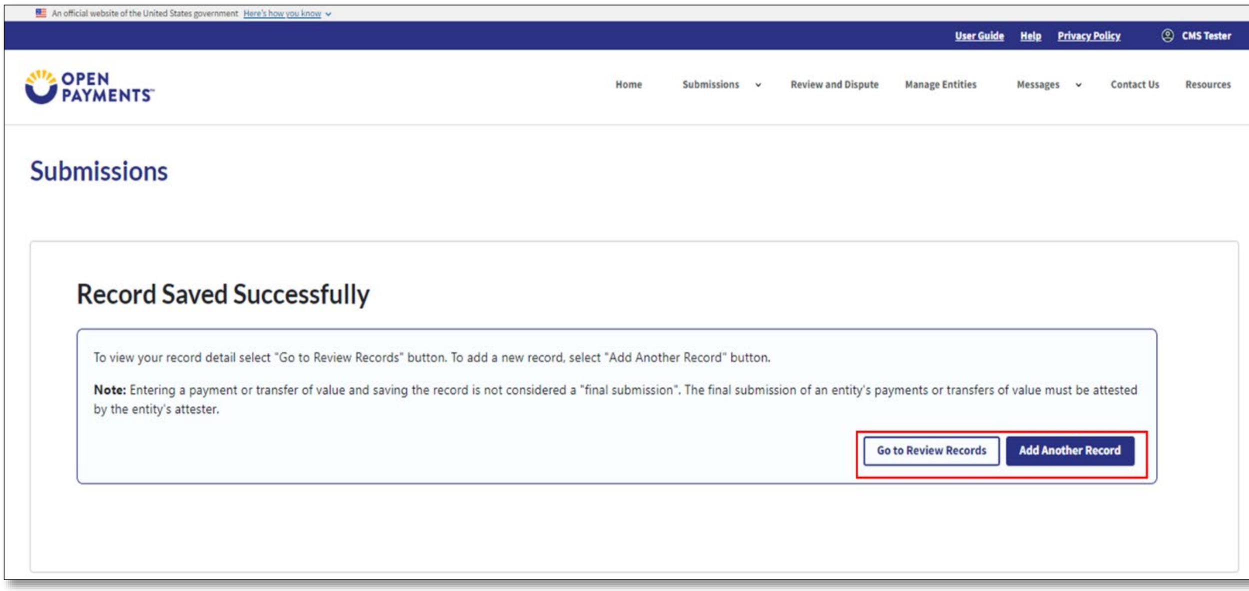
Once the record is accurate, select the **Review and Save** button to continue.

Figure 202: 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. Select either **Add Another Record** to add another Research Payment record or select **Go to Review Records** to review details about the record(s) you entered.

Figure 203: Manual Submissions: Record Saved Successfully Page



You must complete the final submission and attestation process for the data to be considered reported. See Section 4.11 for details on final submission and Section 4.15 for details on attestation.

4.5c: Manual Entry of Ownership/Investment Interests Payments

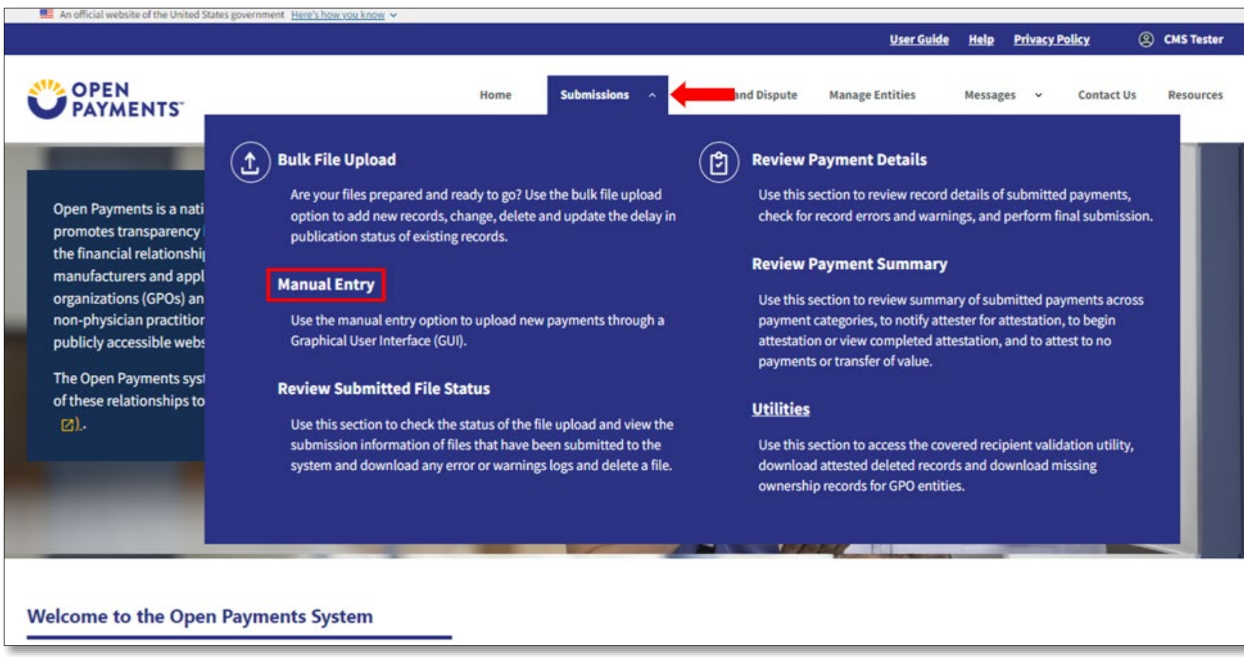
To enter ownership/investment interest payments manually, follow these steps:

Note:

1) **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.**
2) **Reporting Entities cannot report Ownership/Investment Interest Payments for Non-Physician Practitioner**

Step 1: Log in to the CMS Open Payments system at https://openpayments.system.cms.gov using your IDM credentials, select the **Submissions** tab and then select **Manual Entry** menu option.

Figure 204: Submissions Tab -> Manual Entry



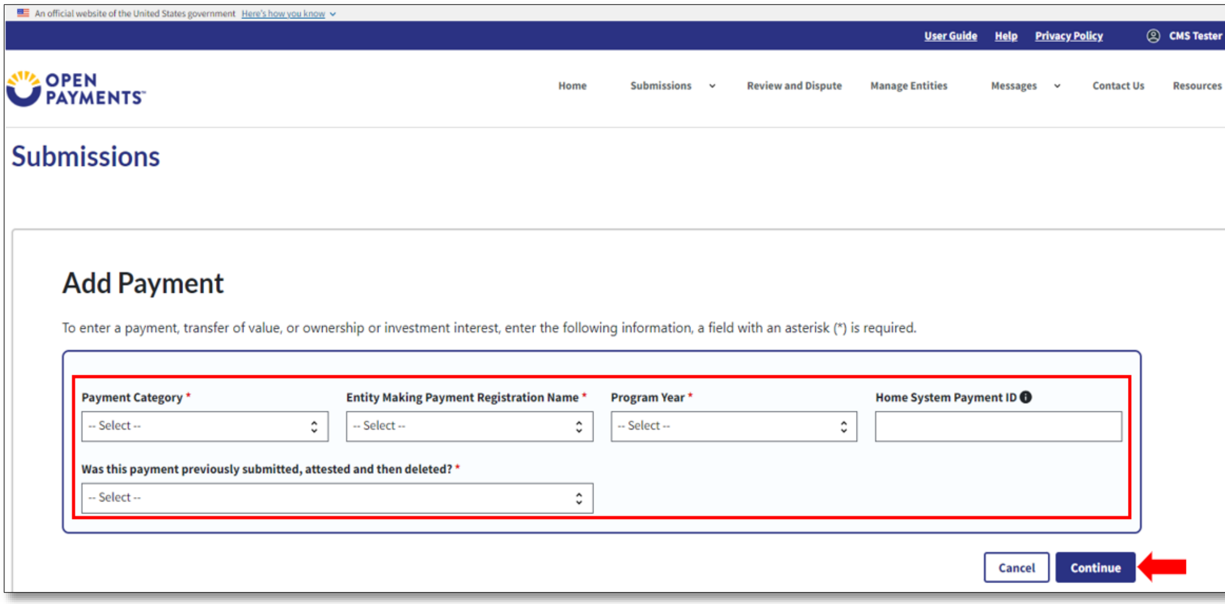
Step 2: On the "Add Payment" page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year.

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.

If the payment is being entered because of a payment that was previously submitted, attested and then deleted, you must select "Yes" in the drop-down box and enter the record id of the previously deleted record.

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

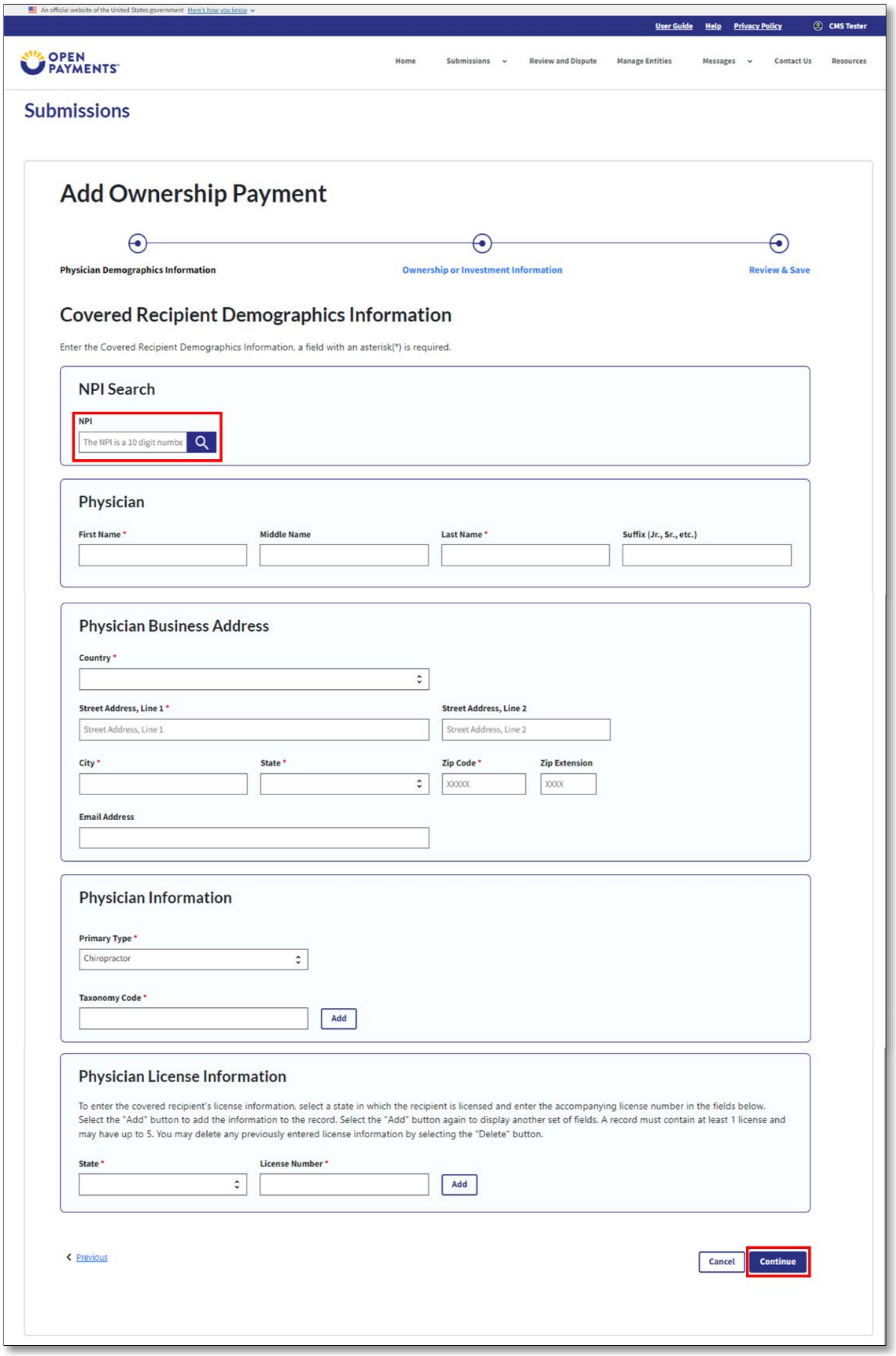
Figure 205: Add Payment Required Fields



Step 3: Enter the Covered Recipient Demographic Information seen on the page below. Required fields are marked with asterisks. Select the **Continue** button to proceed to the "Ownership or Investment Information" page.

The NPI search field will auto-populate Covered Recipient information, (i.e., First Name, Last Name, Taxonomy Code, and State License(s)) for an NPI entered. Refer to a CMS provided resource to confirm any populated provider information, if necessary.

Figure 206: Add Ownership Payment: Physician Demographic Page

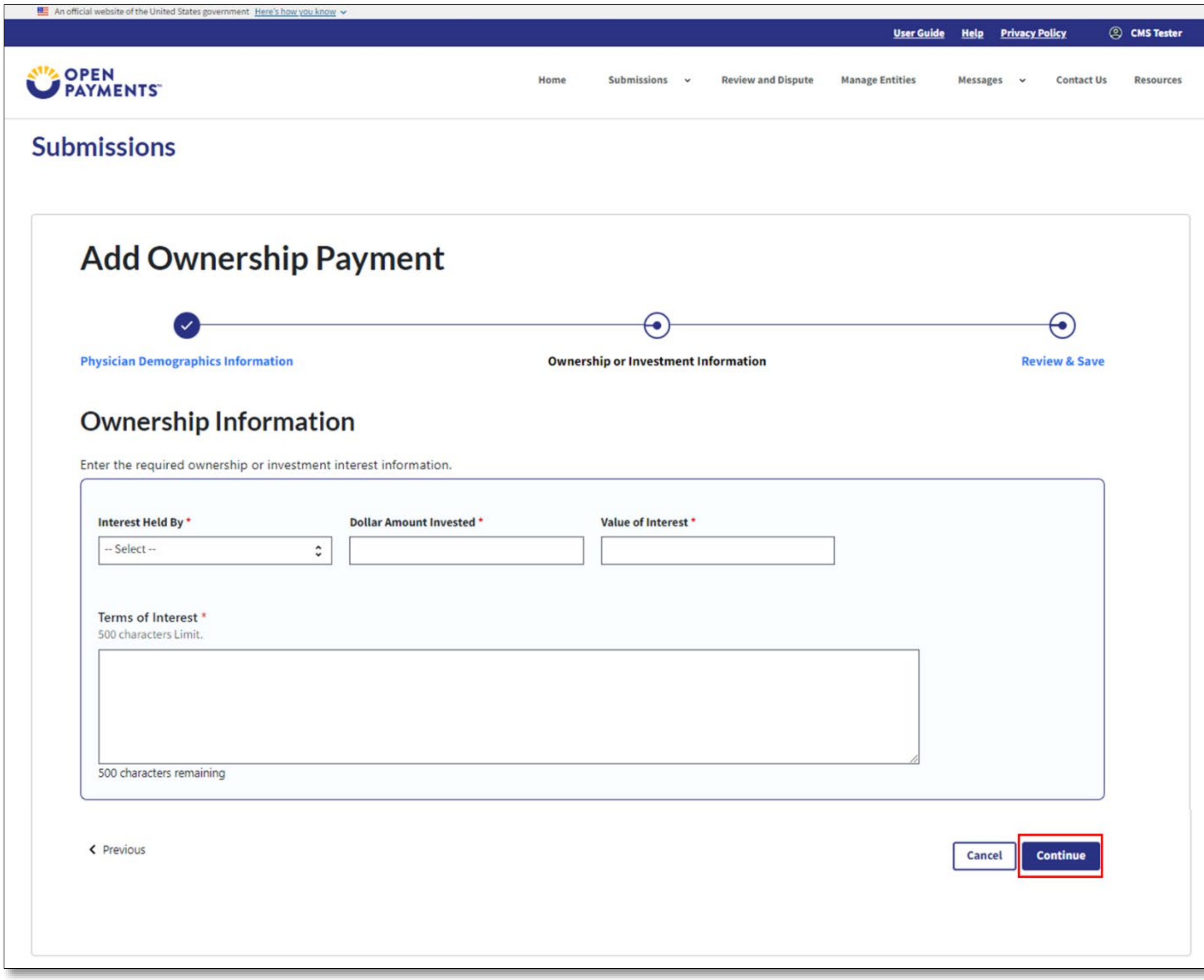


Step 4: Enter the ownership or investment interest information. Required fields are marked with asterisks. Select the **Continue** button to proceed to the "Review and Save" page.

The "Terms of Interest" field must contain a description of any applicable terms of the ownership or investment interests.

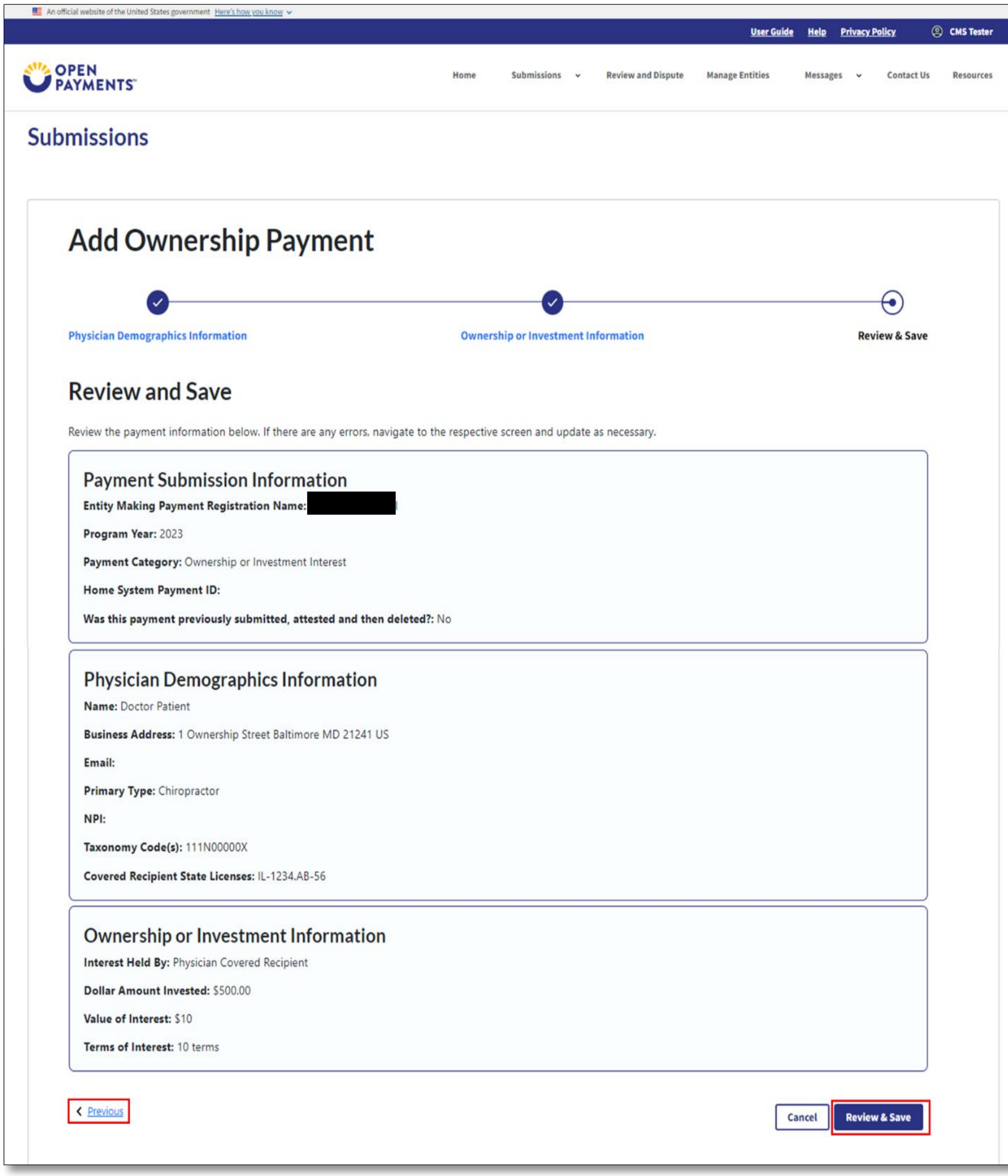
When reporting the terms of any ownership or investment interests, provide the type of ownership or investment interests, including but not limited to stock, stock options, partnership shares, loans, bonds, or other financial instruments that are secured with an entity's property or revenue, or a portion of that property or revenue.

Figure 207: Add Ownership Payment: Ownership Information Page



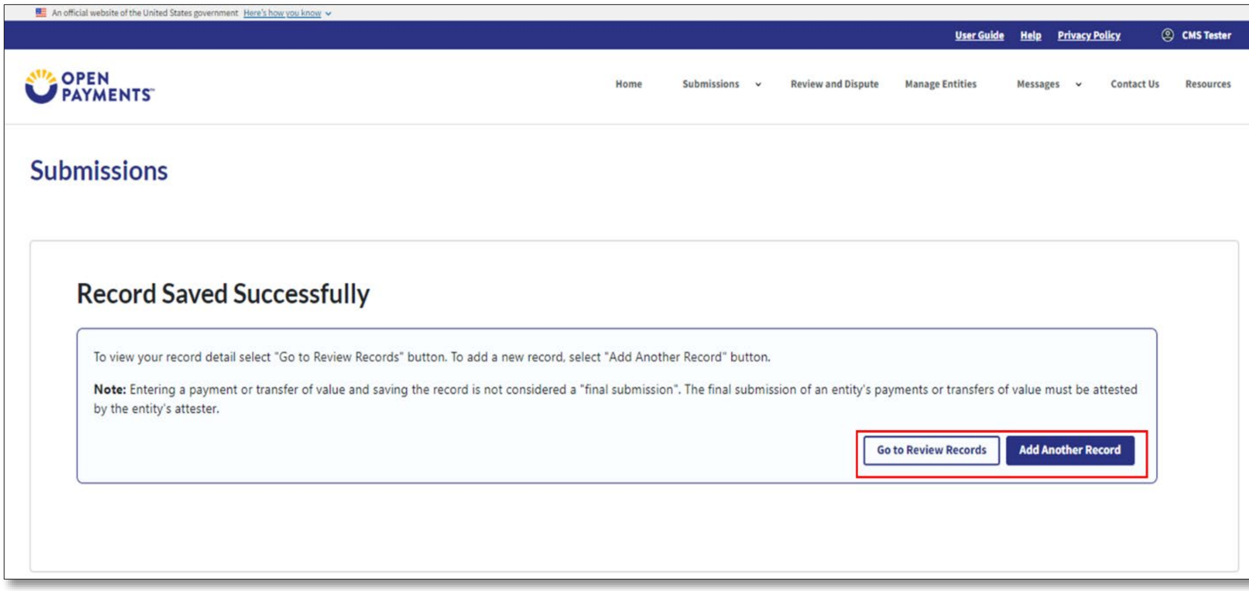
Step 5: Review the ownership or investment interest information entered in the previous pages on the "Review and Save" page. If necessary, select the **Previous** button at the bottom of the page to go back and edit information. Users can also select an icon from the Payment Navigation Bar, located on top of the page, to go directly to the desired page. Once the record is accurate, select the "**Review & Save** button to continue.

Figure 208: Add Ownership Payment: 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. Select either Add Another Record to add another Ownership Payment record or select “Go to Review Records” to review details about the record(s) you entered.

Figure 209: Manual Submissions: Record Saved Successfully Page



You must complete the final submission and attestation process for the data to be considered reported. See Section 4.11 for details on final submission and Section 4.15 for details on attestation.

Section 4.6: Record Validation and Matching

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

Figure 210: Validation Steps

Details on these types of validation are given below.

4.6a: Validation Step 1: File-Level Validation

Once you submit your file, bulk files undergo automated validations before the records within the file are uploaded into the Open Payments system. 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.

Files that receive no file-level validation errors are then automatically uploaded to the Open Payments system and moved to Record-Level Validations.

Most Common Bulk File-Level Errors:

- 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 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/Resources). 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., Covered Recipient First Name, Covered Recipient Last Name, NPI number (if entered), State License(s), 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.

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.

Records containing NPP licenses that were valid after January 1, 2023, 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 by multiple 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.

If you did not receive an email notification, you can locate all emails by going to the **Messages** tab on your home screen.

Figure 211: Validation Step Failures

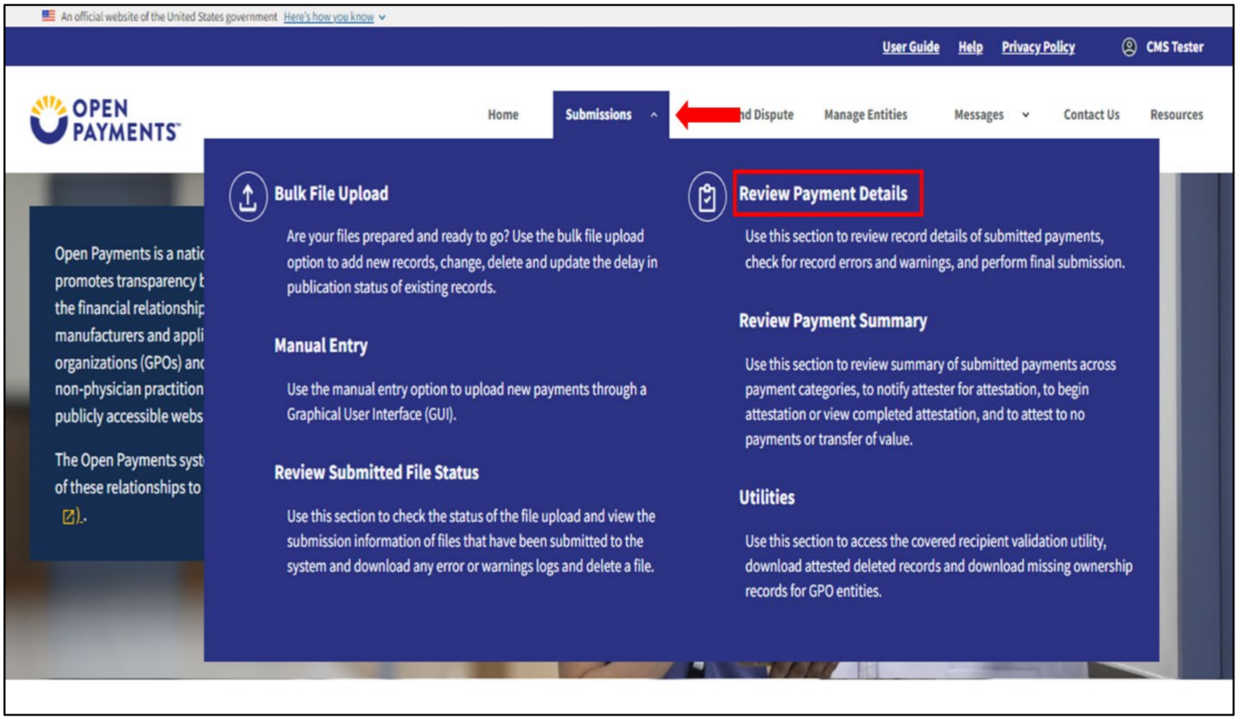
Validation Step	System Generated Email	Submitter Action
Step 1 – File Level Validation Failure	This failure email describes a file validation failure, the reason for the failure, and, if applicable, the line number of the submitted data file where the failure occurred. Files that fail at this step will have a status of "Rejected" on the "Review Files Status" page. Note: step 1 validations stop upon finding an error	Submitter will need to correct the error and re-upload the file to continue with processing. Refer to Section 4.8, "Correcting Records," for more information and further instructions.
Step 2 - Pre-Upload Record Validation Failure	This failure email lists the reasons for record rejections, the number of records in the file that failed for each reason and identifies up to a set number of records for each rejection reason. Files with records that meet these criteria will have a status of "Submitted with Errors" on the "Review File Status" page.	Submitter will need to correct record errors and resubmit the records. Refer to Section 4.8, "Correcting Records," for more information and further instructions. Note: these records will NOT appear in the error log. Please refer to the file you are uploading.

Validation Step	System Generated Email	Submitter Action
Step 3: Record Validation Failure	This failure 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 these criteria will have a status of “Submitted with Errors” on the “Review File Status” page.	Submitter will need to review the saved records in the Open Payments system that failed validation correct them either by manual edit process or bulk file resubmission.
Step 4: Matching Validation Failure	This failure 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 these criteria will have a status of “Submitted Successfully” or “Processed with Warnings” on the “Review File Status” page.	Submitter will need to review the saved records in the Open Payments system that failed validation correct them either by manual edit process or bulk file resubmission.

4.7a (2): Search within the Open Payments system for records with errors. To do so, follow the steps below:

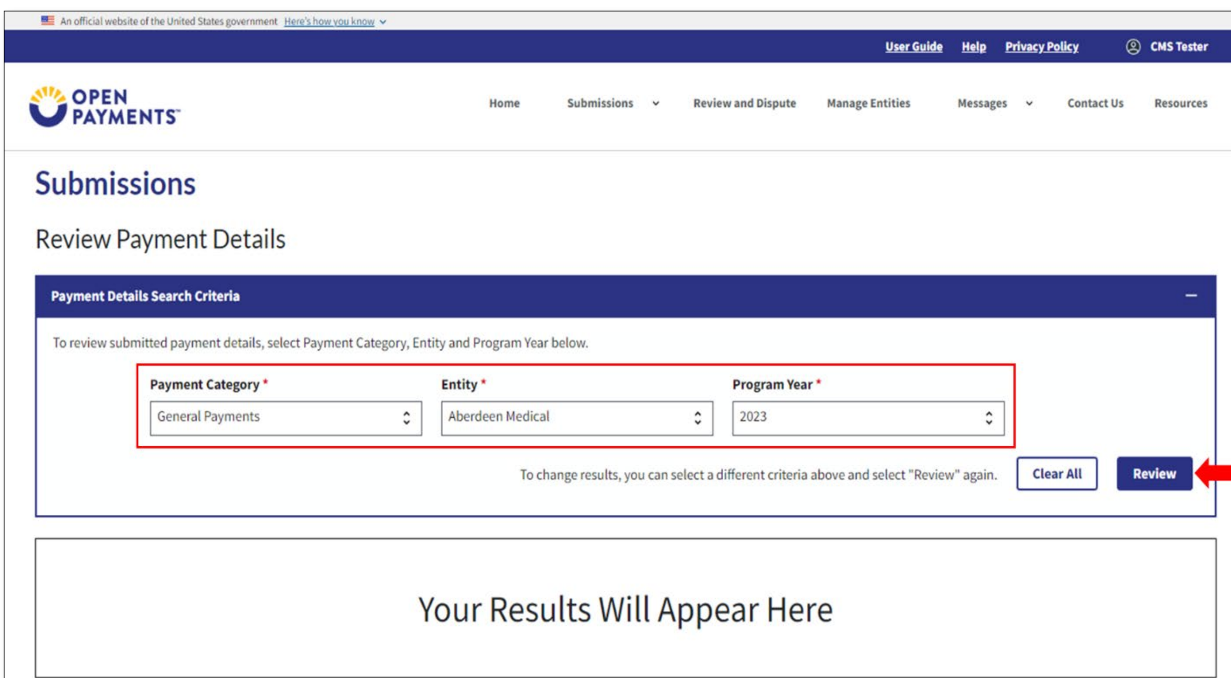
Step 1: Log in to the Open Payments system select the “Submissions” tab in the toolbar and then select “Record Payment Details”

Figure 212: Submissions Tab: Record Payment Details



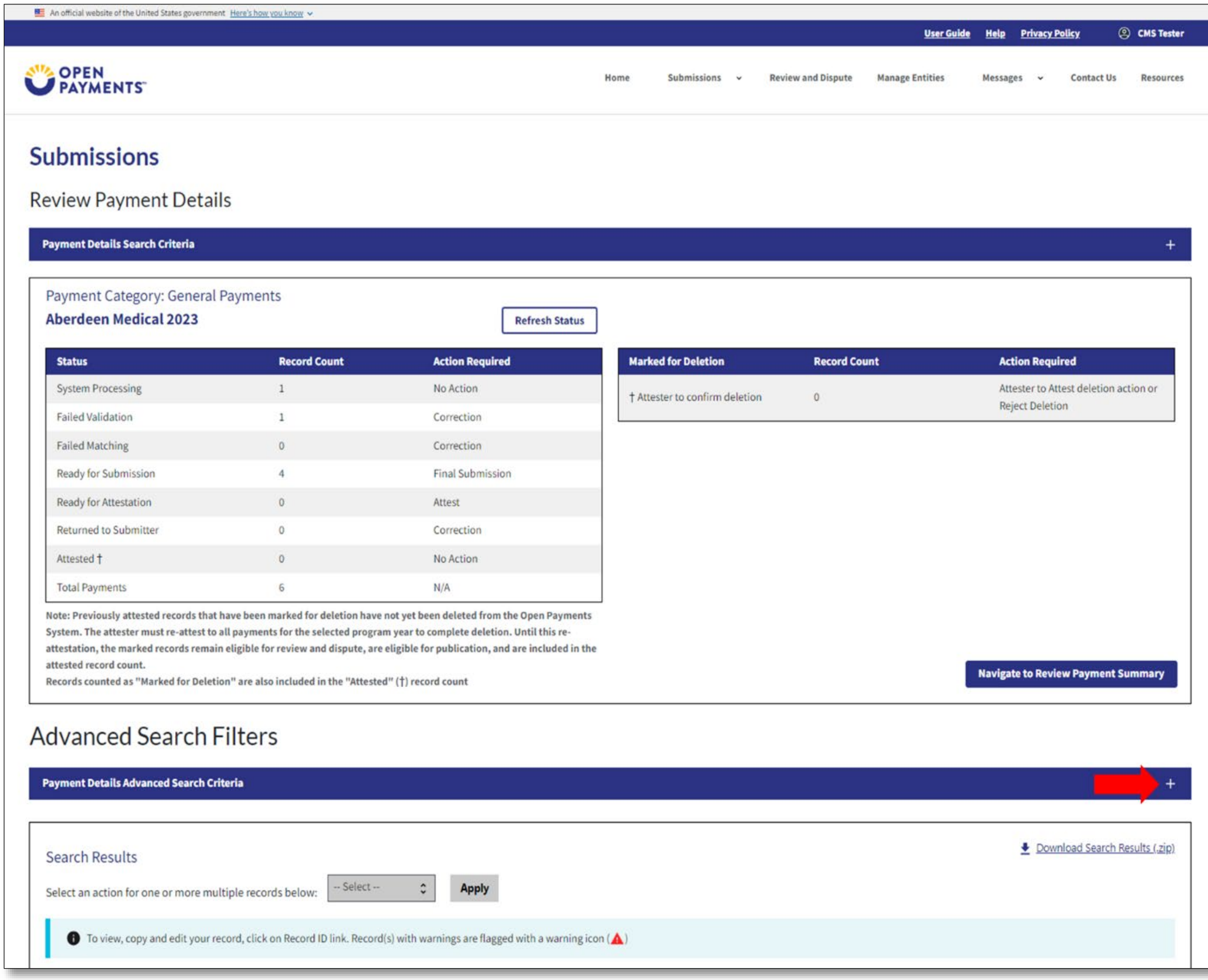
Step 2: Select the payment category, entity, and program year for the records you wish to review, then select the Review button.

Figure 213: Payment Details Search Criteria



Step 3: Expand the "Advanced Search Filters" search criteria fields on the "Record Payment Details" page.

Figure 214: Advanced Search Filters Expand/Collapse Box

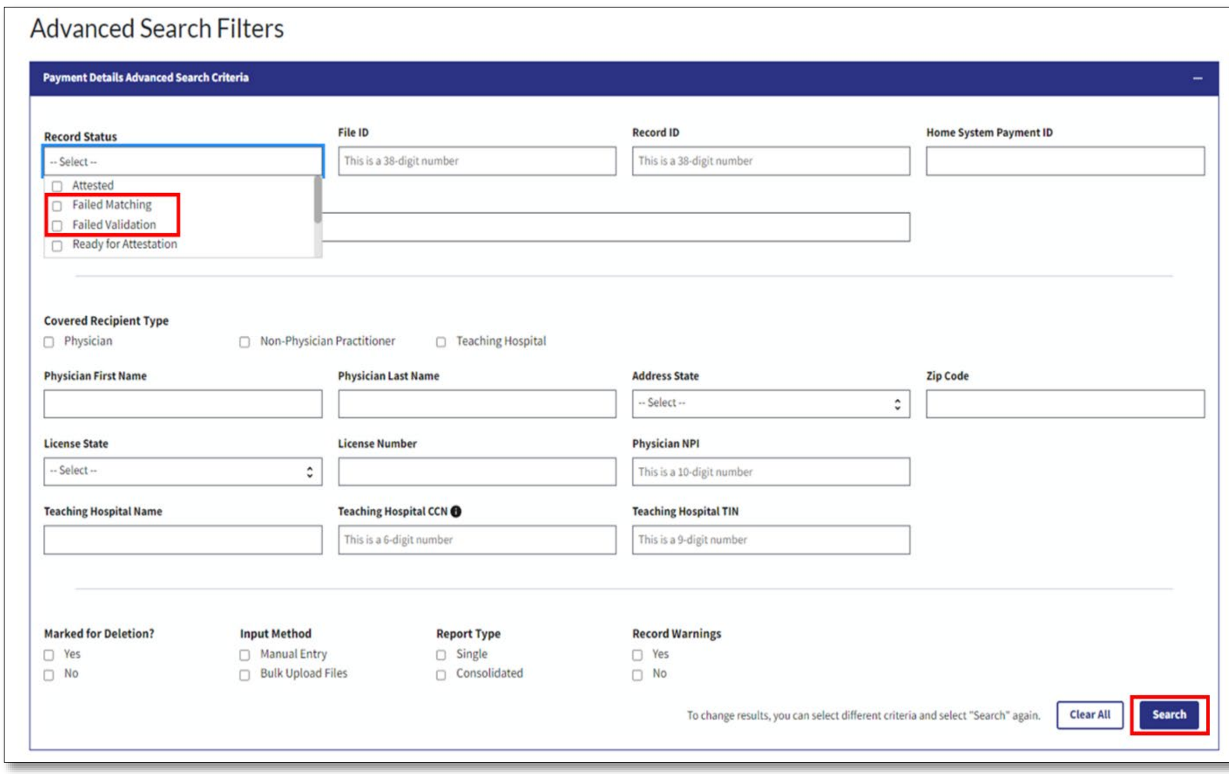


Step 4: Use the filters for "Record Status" to search for records in a "Failed Validation" and/or "Failed Matching" statuses.

- "**Failed Validation**" means that a required field was left empty, or the field was not formatted according to the Submission Data Mapping Document. Also, ensure the correct Submission Data Mapping Document was used.
- "**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 covered recipient NPP or teaching hospital in CMS resources. To successfully "match" a physician or NPP to CMS resources:

1. If the covered recipient is a physician, consult the CMS Validated Physician List (VPL); If the covered recipient is a non-physician practitioner, consult the CMS Validated Non-Physician Practitioner List (NPPL). Both lists are located under the **Submissions** tab.
2. If using the information in #1, above, does not resolve the matching error, or if the covered recipient is not in the VPL or NPPL, attempt to use the covered recipient information in the NPPES lookup tool: https://npiregistry.cms.hhs.gov/search
3. If using the information in #1 or #2, above, results in a matching error, proceed to look up the provider information in the state licensing board where the covered recipient is licensed.
4. If using steps #1-#3, above, still results in a matching error, attempt to contact the physician or NPP directly.
5. If you have exhausted the efforts in #1-#4, above, please contact the Open Payments Help Desk.

Figure 215: Advanced Search Filters Record Statuses Search



__**Note:**__ To download the record information returned by your search into a CSV file by selecting the "Download Search Results" link in the "Search Results" section. The filters applied on the page will be applied to the download.

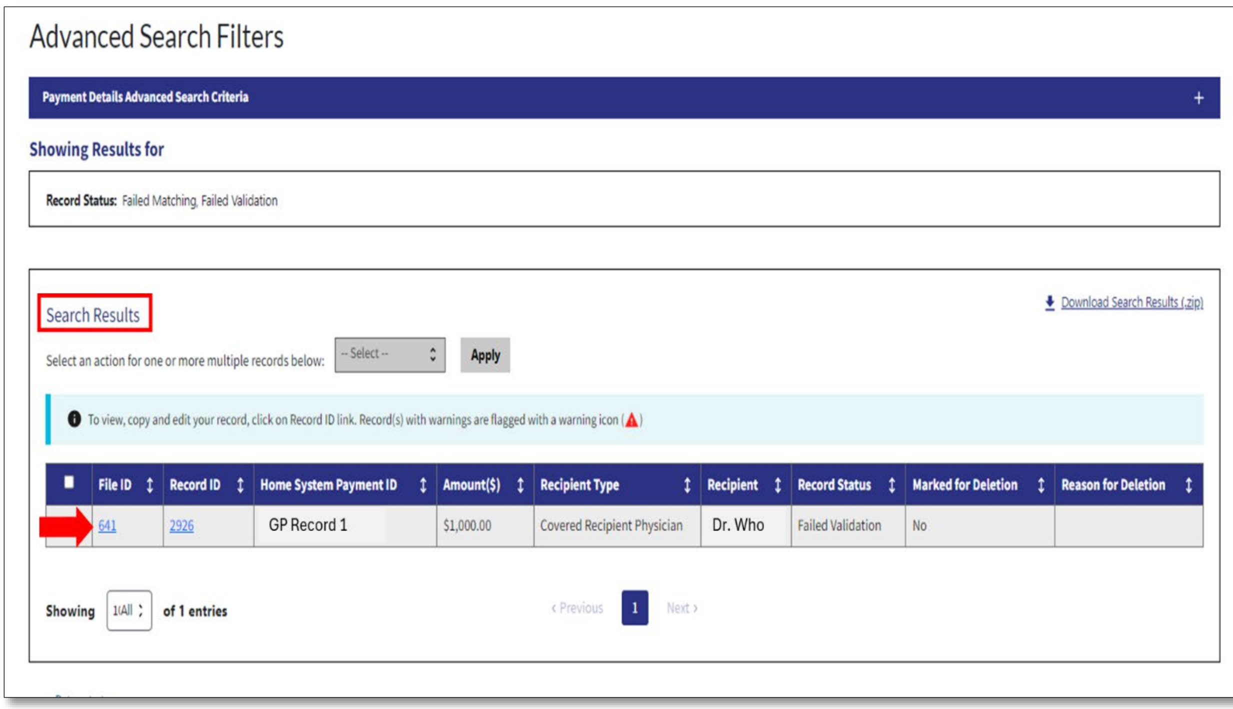
Downloaded data files cannot exceed the acceptable limit of 400,000 records. If your record volume exceeds the record limit, you will not be able to see some data. Filter your search results by File ID to create smaller subsets of records and download them in multiple files.

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.”

4.7a (3): 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 2 or 3 and interpret the error codes it contains:

Step 1: Go to the table at the bottom of the Record Payment Details 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.

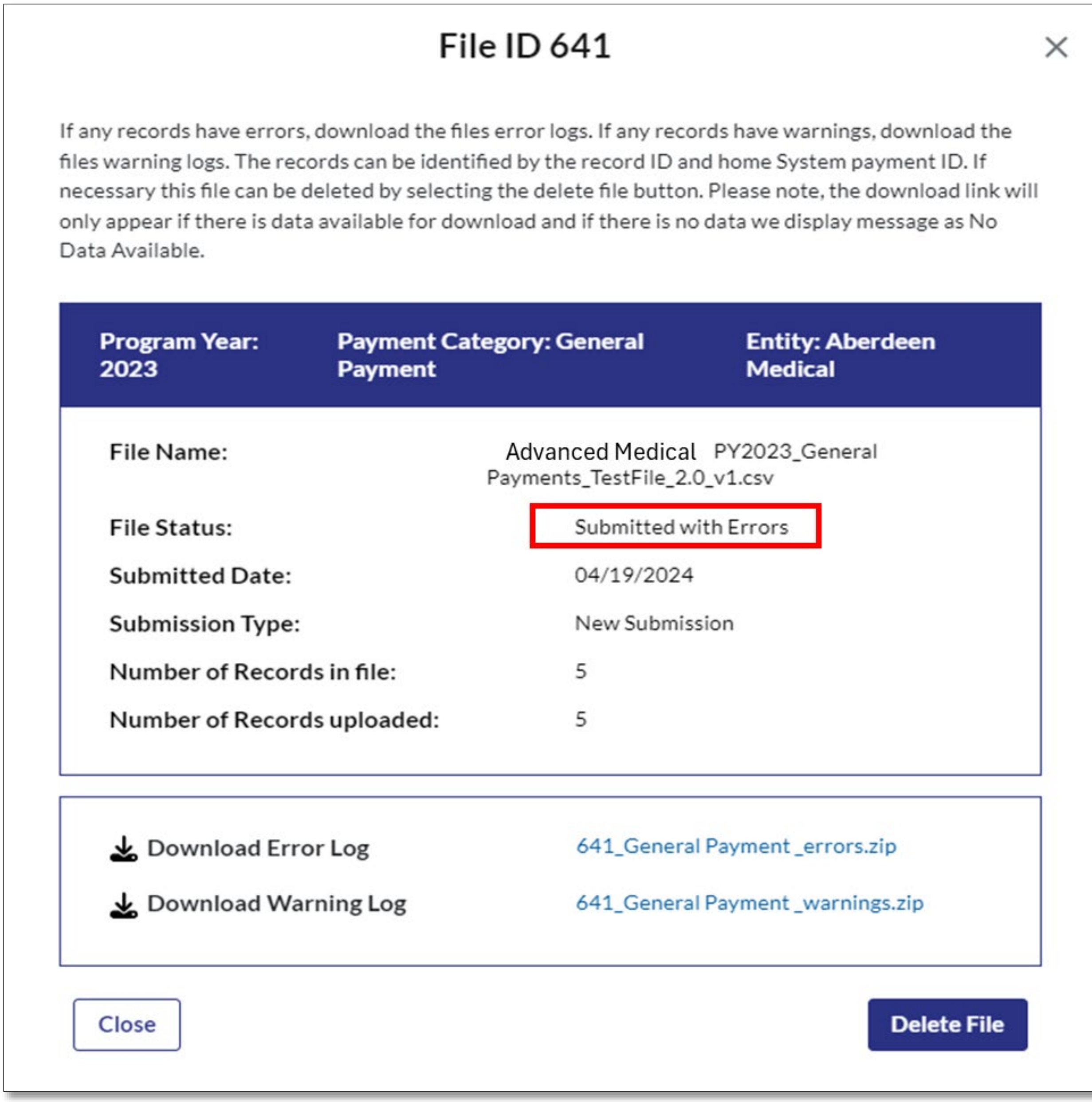
Figure 216: Search Results Table File ID



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

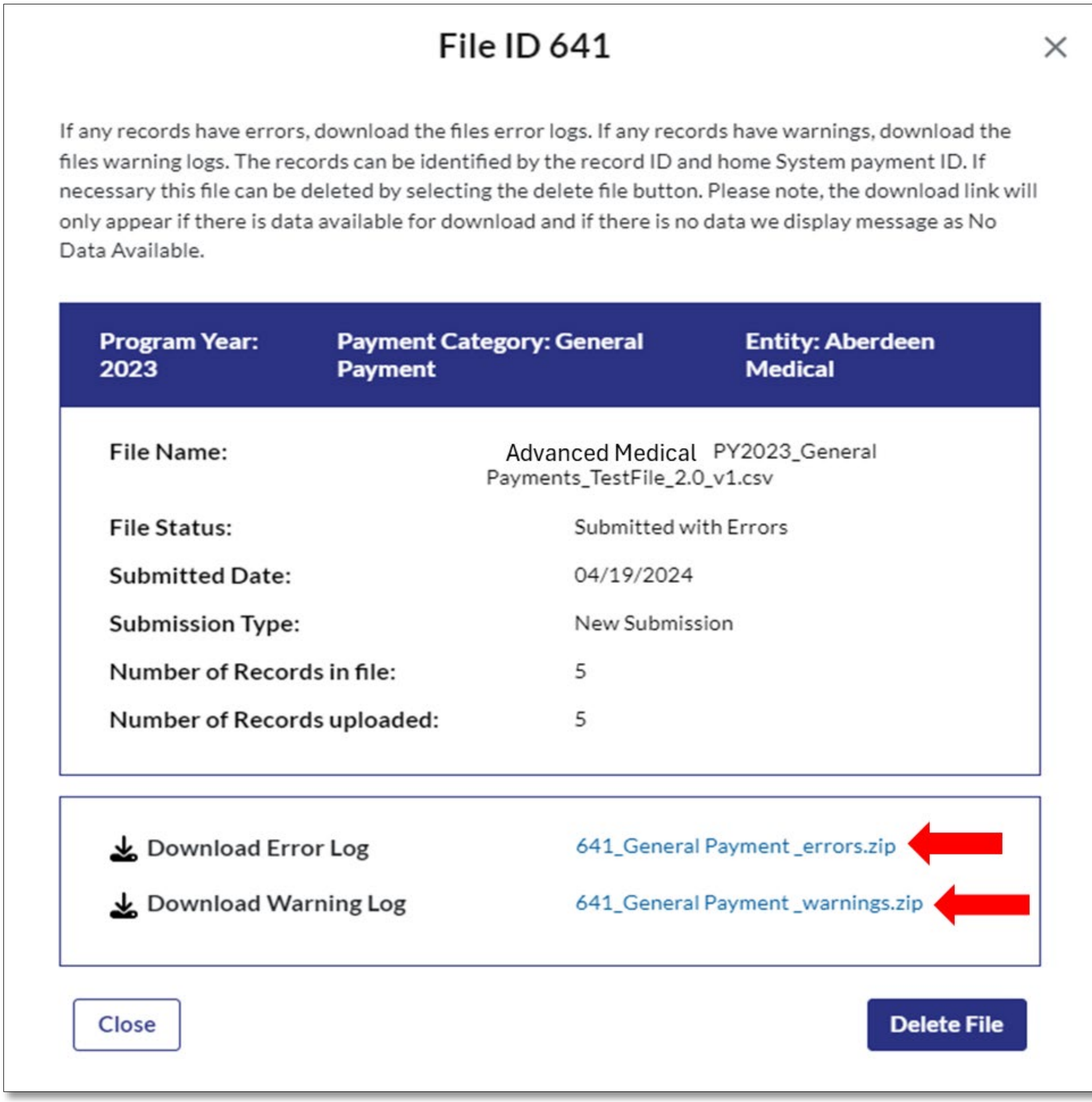
- **Submitted with Errors**- The file is uploaded successfully but one or more of the records in the file are in “Failed Validation” or “Failed Matching” status. An error log will be generated for a file that contains records that generated errors for failed validation or matching.
- **Processed With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

Figure 217: File ID Page: File Status Indicator



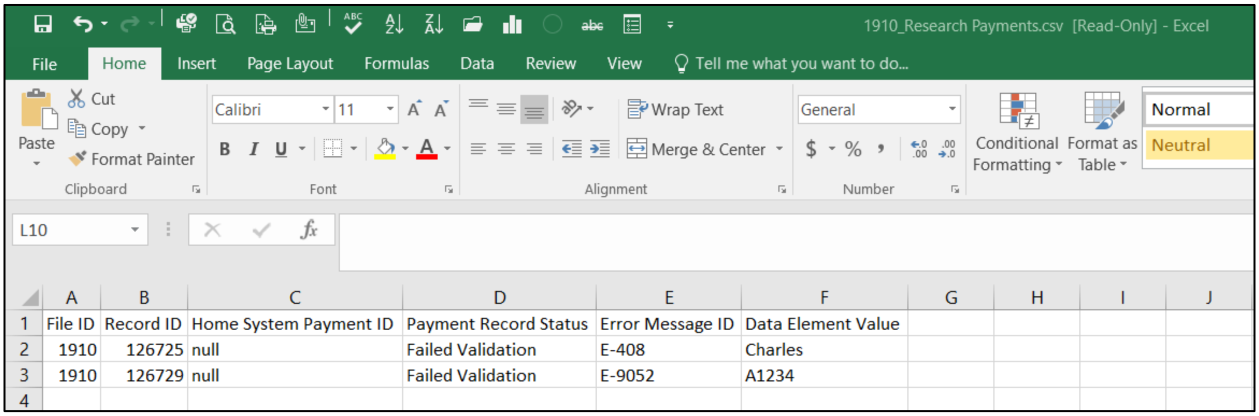
<u>Step 3:</u> On the “File ID” page, select the “Error Log” hyperlink at the bottom of the page to download the error log (or) and/or select the “Warning Log” hyperlink at the bottom of the page to download the warning log.

Figure 218: File ID Page: Error and Warning Logs Hyperlinks



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 219: Sample Error report in Excel Showing Error Message IDs and Data Element Values

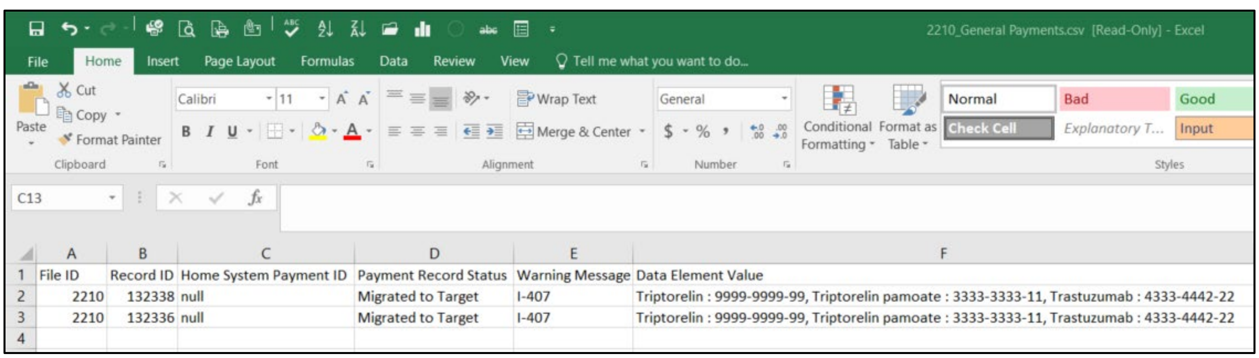


File ID	Record ID	Home System Payment ID	Payment Record Status	Error Message ID	Data Element Value
1910	126725	null	Failed Validation	E-408	Charles
1910	126729	null	Failed Validation	E-9052	A1234

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

Remember, you should correct “Warnings” whenever possible, however, records may still be pushed through Final Submission with warnings.

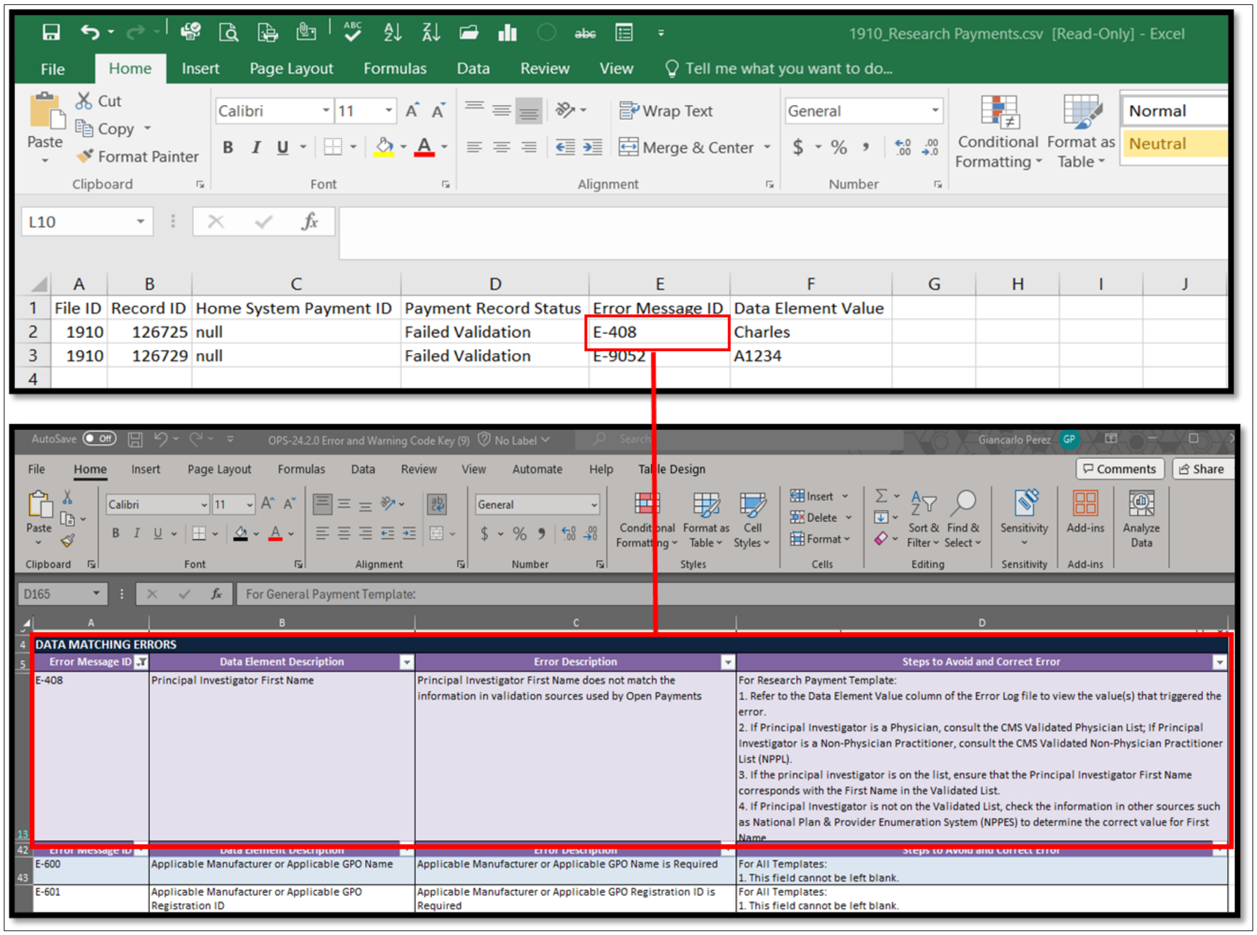
Figure 220: Sample Warning report in Excel Showing Warning Message IDs and Data Element Values



File ID	Record ID	Home System Payment ID	Payment Record Status	Warning Message	Data Element Value
2210	132338	null	Migrated to Target	I-407	Triptorelin : 9999-9999-99, Triptorelin pamoate : 3333-3333-11, Trastuzumab : 4333-4442-22
2210	132336	null	Migrated to Target	I-407	Triptorelin : 9999-9999-99, Triptorelin pamoate : 3333-3333-11, Trastuzumab : 4333-4442-22

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

Figure 221: Error and Warning Code Key Search Sample

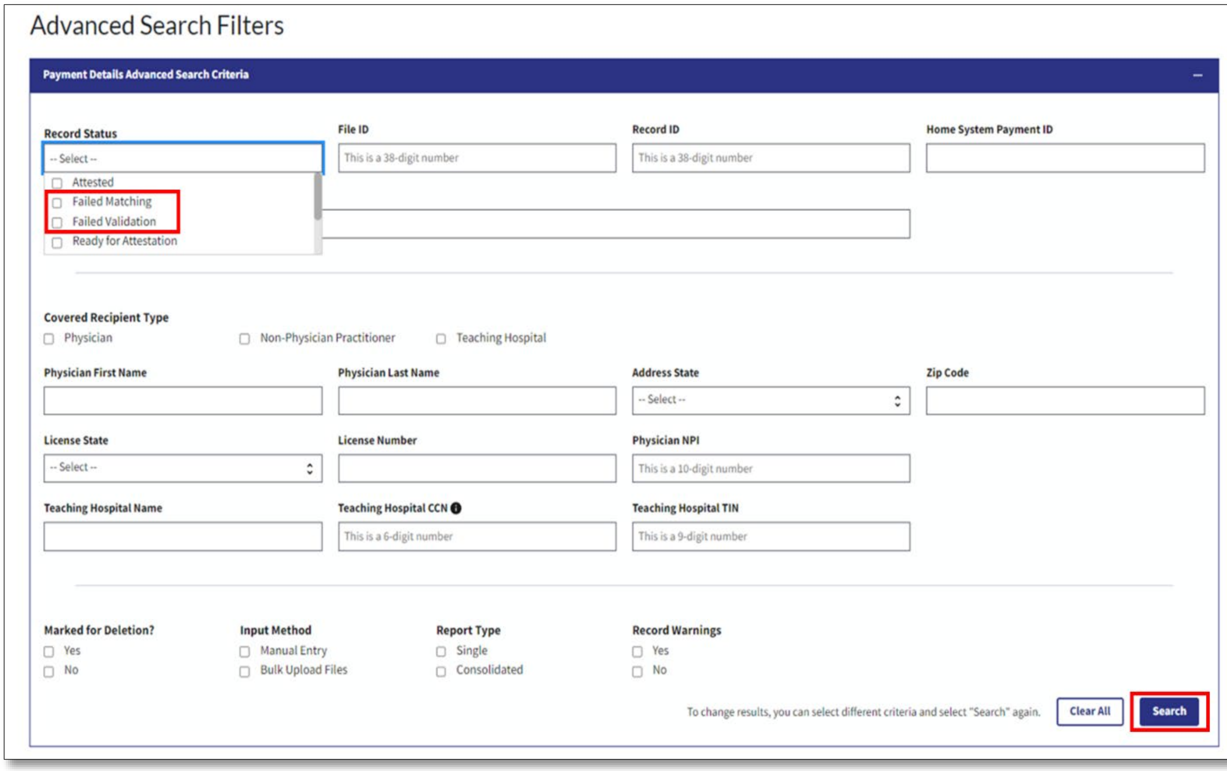


4.7a (4) Errors on individual records in the Open Payments System

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

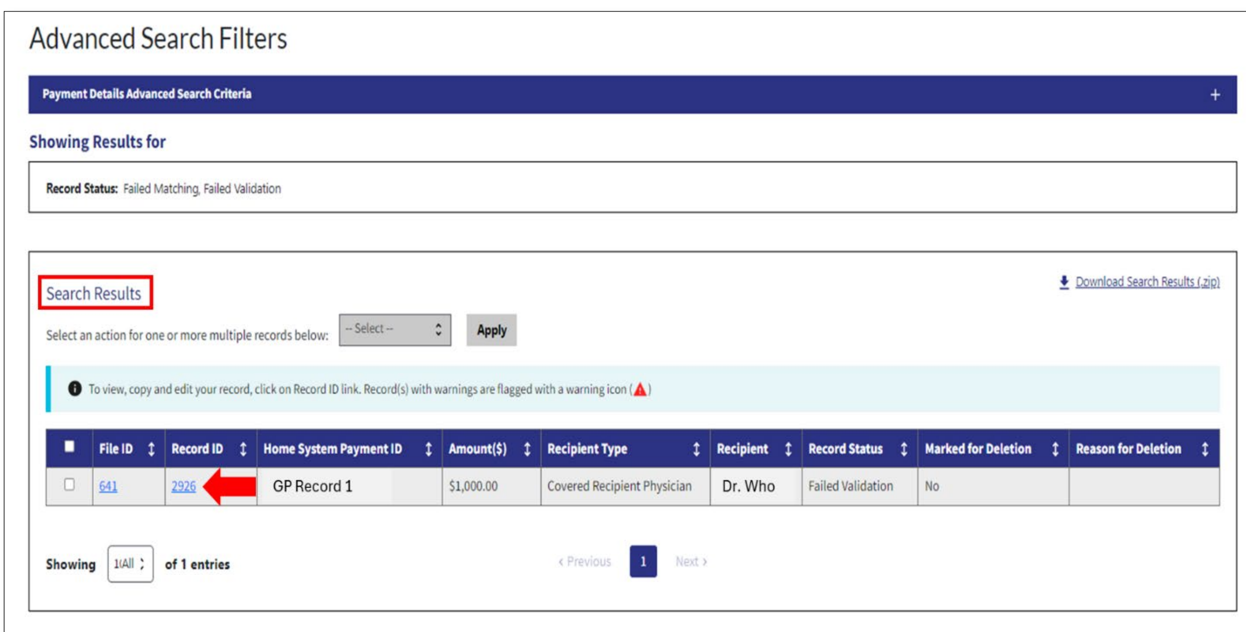
Step 1: Go to the table at the bottom of the Record Payment Details page. Filter the records as needed in the Advanced Search Filters section to locate the failed record to be examined.

Figure 222: Advanced Search Filters Record Statuses Search



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

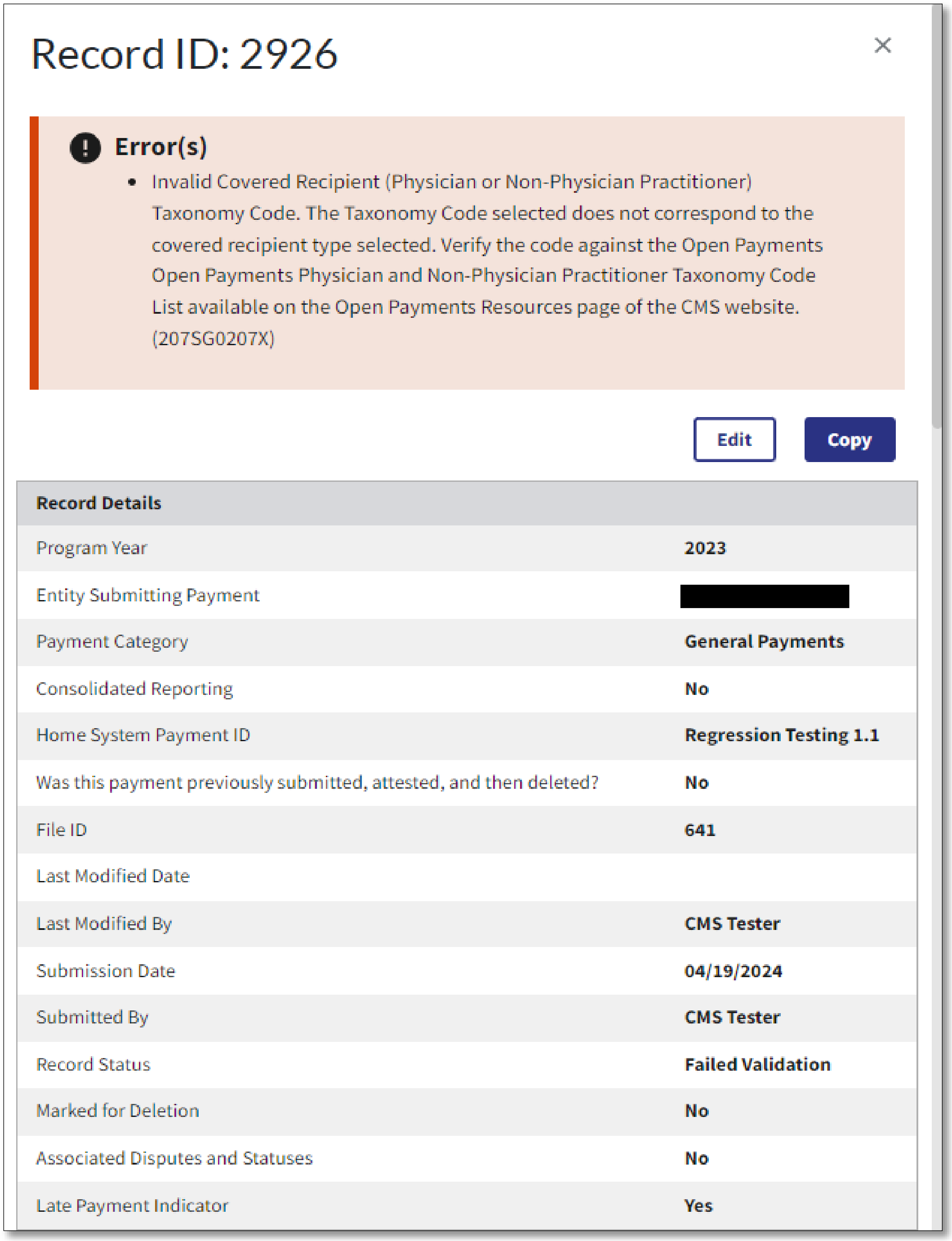
Figure 223: Search Results Table Record ID



<u>Step 3:</u> On the "Record ID" window, error messages for the record will be displayed at the top of the page.

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

Figure 224: Record ID Window Error Message



4.7b: Identifying Manual Entry Errors

Record validations are applied during the manual data entry process, and any failures 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 on-screen 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, follow steps outlined in section 4.7a (4) to search in the Open Payments system for records that failed matching validation.

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

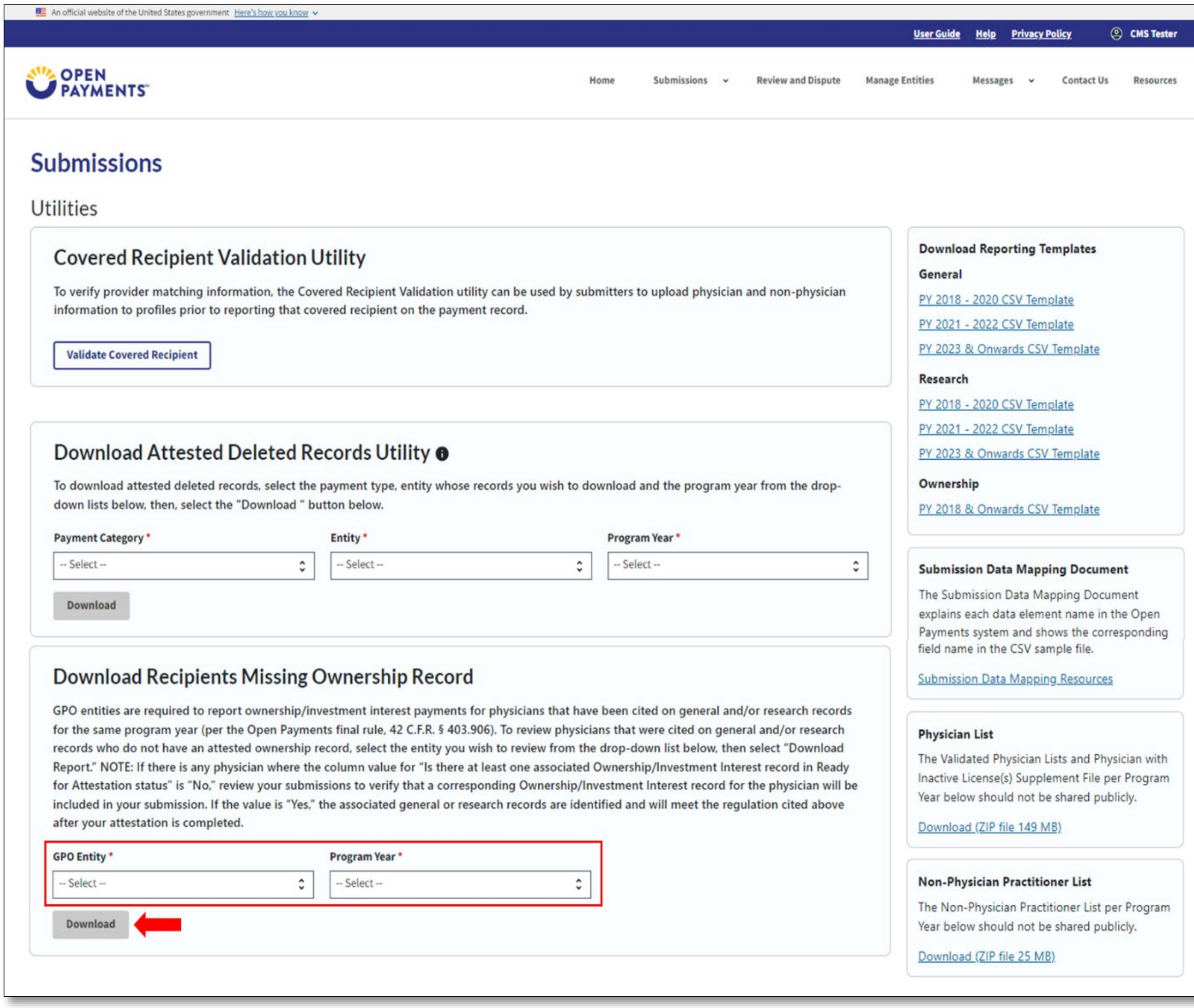
This section is for applicable group purchasing organizations (GPOs) users only.

According to the Open Payments Final Rule, GPOs are only required to report payments or other transfers of value made to physician owners/investors. The Open Payments system prevents GPOs from submitting general and research payment records for teaching hospitals or non-physician practitioner covered recipients.

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 in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials, select the **Submissions** tab on the toolbar, and then select **Utilities**.
2. GPO users have access to the “Download Recipients Missing Ownership Record” section. Under the section, select the **Entity** and **Program Year** that you wish to review, then select the **Download Report** button.

Figure 225: Utilities Page -> Download Recipients Missing Ownership Record Utility



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/NPP. 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/NPP. 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. If 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 no validation or matching errors do not need to be corrected before proceeding but checked for accuracy.

Records can be corrected via bulk file upload or manual editing in the Open Payments system.

Once free from errors, you can complete final submission and attestation processes for these records.

Note: Covered recipient or principal investigator identifier fields (e.g., First Name, Last name, NPI, etc.) cannot be changed once a record is in a “Ready for Attestation” or “Attested” status.

- If the original payment record is in “Ready for Submission” status, then the submitter may choose to change any information or delete the record freely.

- If the original record is in "Ready for Attestation" status, this record must be deleted and then re-submitted. The record with this status does NOT need to be attested before it gets permanently deleted from the system.

- If the original record is in "Attested" status, this record must be deleted and then re-submitted. The submitter can only mark this record for deletion. The attester must re-attest to the record before it gets permanently deleted from the system. The attestor will need to provide a "reason for deletion" for each record that is deleted. This is because the original attestation was to the record's timeliness, completeness, and accuracy, which is no longer applicable. The attester is also encouraged to use the assumptions text statement, a document that communicates reasonable assumptions around reporting methodology to CMS, to denote records that have been deleted and then resubmitted. This includes, but is not limited to, providing the circumstances around records that were resubmitted after the submission deadline. Also note that if the record is being resubmitted, the “new” record will need to be linked to the “old” record using the record’s ID.

The relevant fields that identify the record's covered recipient or principal investigators are as follows:

- For physicians and NPPs (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/Resources.

Submission Tip: at least one state license is required for covered recipient and principal investigator system matching.

4.8a: Correcting Records via Bulk File Upload

To correct records via bulk file upload, the file must undergo the "Resubmission" process:

Step 1: Consolidate all identified records with failed validation and/or failed matching errors of the same payment category, into a new, separate CSV file template of that payment category and program year.

Step 2: Correct the record details using the "error log" and "error and warning code key" document accordingly.

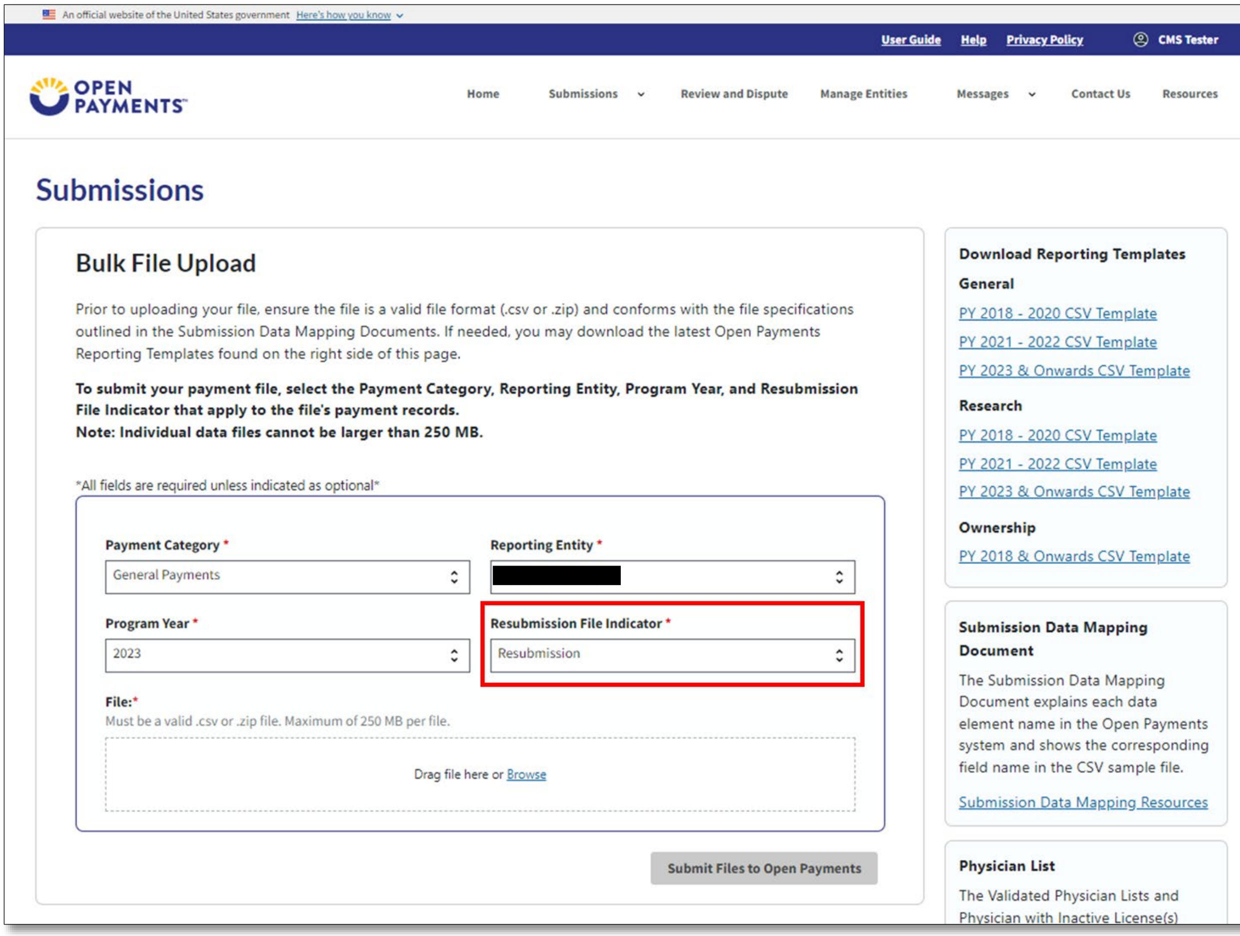
Step 3: Set the Resubmission File Indicator as explained below, in each corrected record's row. All records in a bulk file must meet the following conditions:

- Each corrected record must have its "Resubmission File Indicator" value set to "Y".
- The original record's Record ID must be provided in the updated record's "Resubmitted Payment Record ID" field. This Record ID for each record can be obtained either from the "Review Payment Details" page or the error log file.

Step 4: Submit the file through the bulk file upload process with the "Resubmission File Indicator" set to "R" for Resubmission 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 4.11, Final Submission and Section 4.15, Attestation and Assumptions.

Figure 226: Bulk File Upload Page: Resubmission Indicator



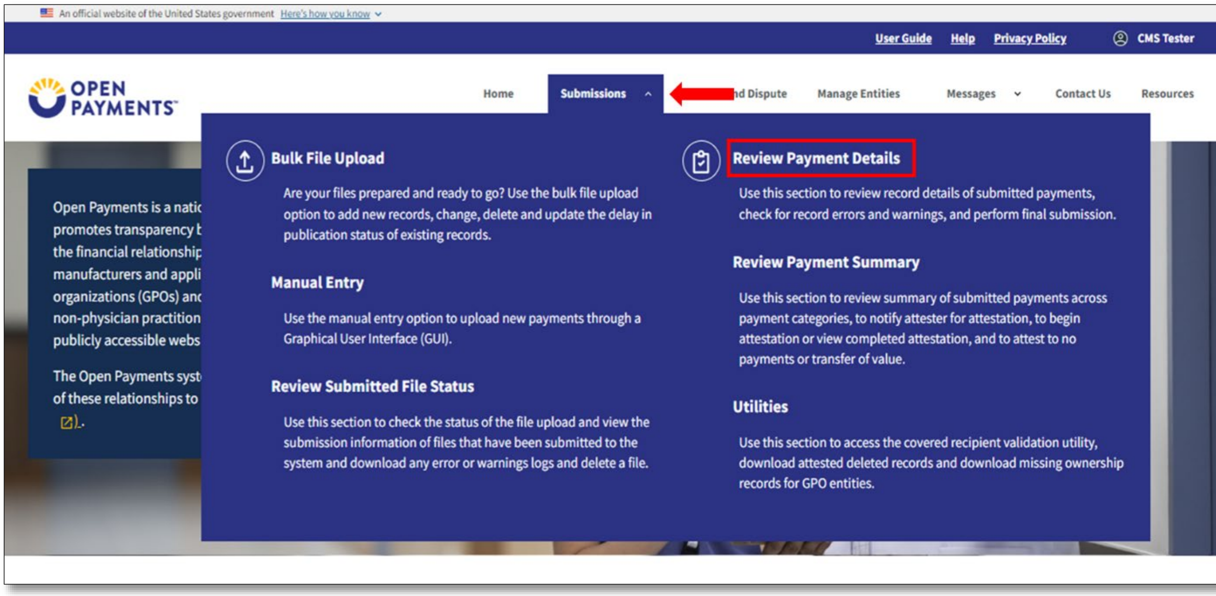
If a failed record must be deleted and replaced due to changes in identifying information (per the boldfaced text in the “Correcting Records” section above), consult the Deleting Records section 4.9. Replacement records will be new submissions and should have a “Resubmission File Indicator” value of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

4.8b: Correcting Records Manually

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

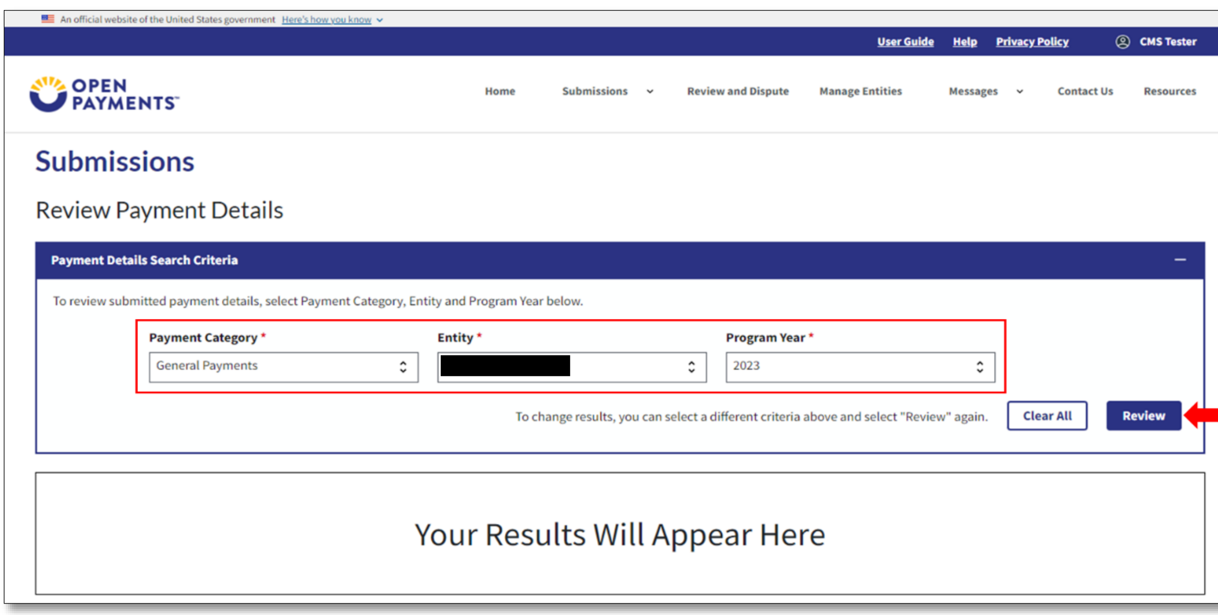
Step 1: Log in to the Open Payments system select the **Submissions** tab on the toolbar, and then select **Review Payment Details**.

Figure 227: Submissions Tool Bar: Review Payment Details



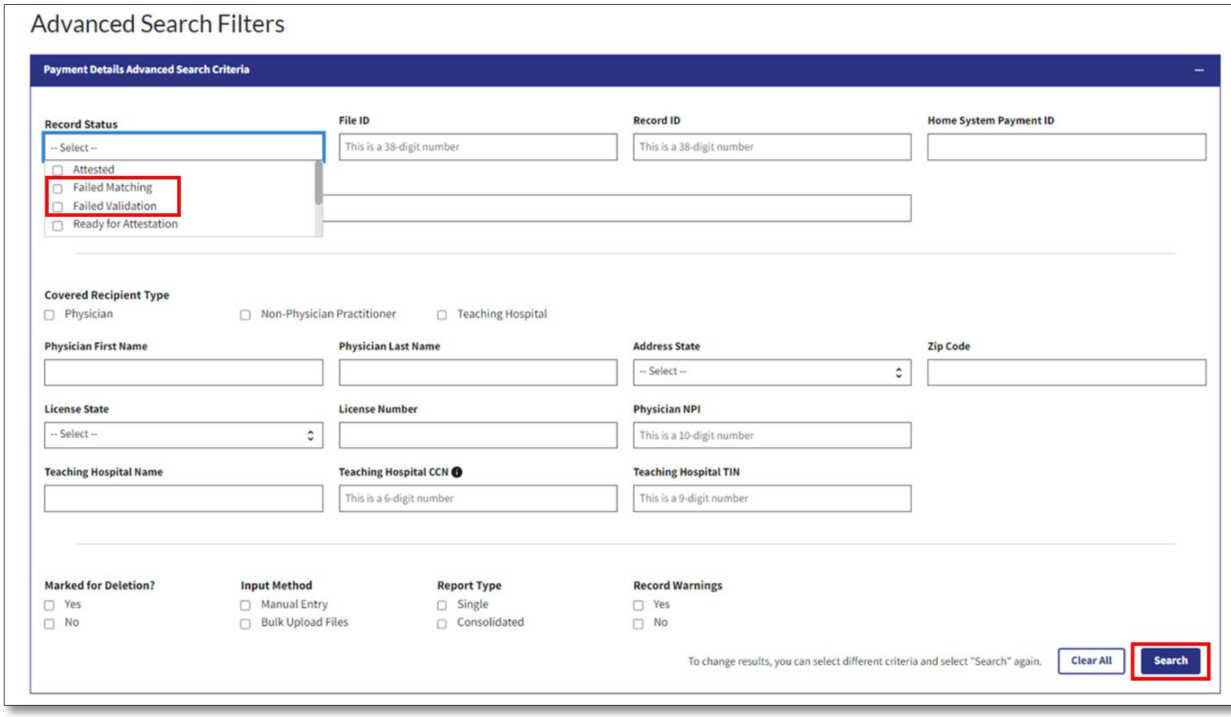
Step 2: Select the payment category, reporting entity whose record you wish to view and the program year for that record, and then select the **Review** button.

Figure 228: Payment Details Search Criteria: Review Button



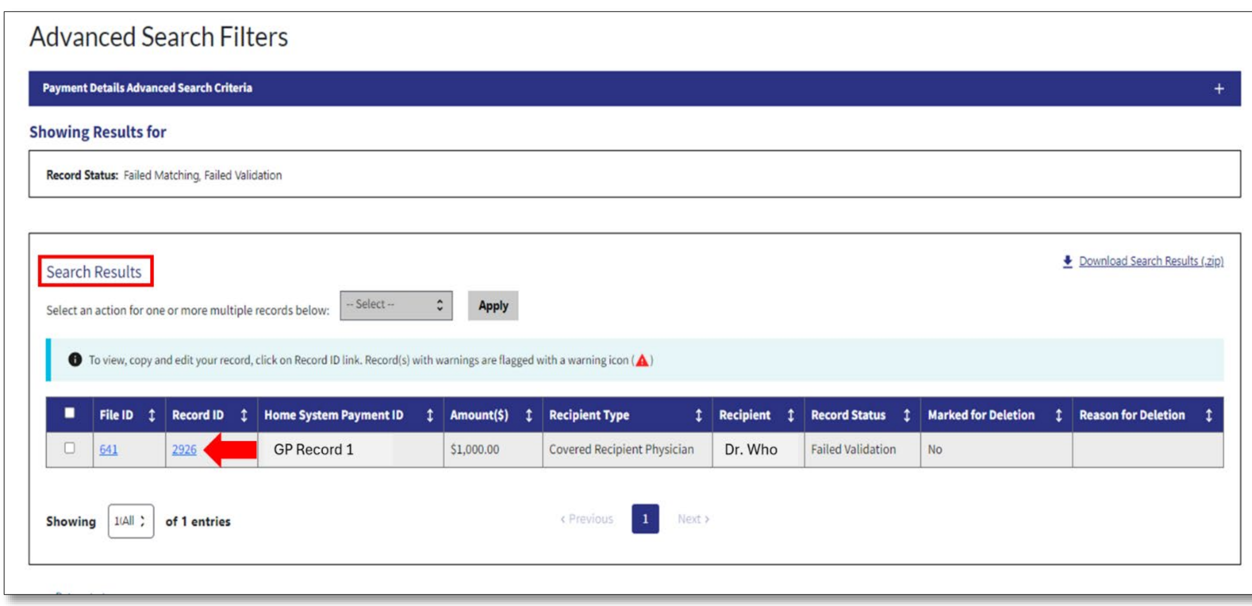
Step 3: Locate the record with the Failed Validation or Failed Matching status in the data table at the bottom of the "Review Payment Details" page. You can use the "Advanced Search Filters" tool on the page to help find a relevant record.

Figure 229: Advanced Search Filters: Record Status Menu



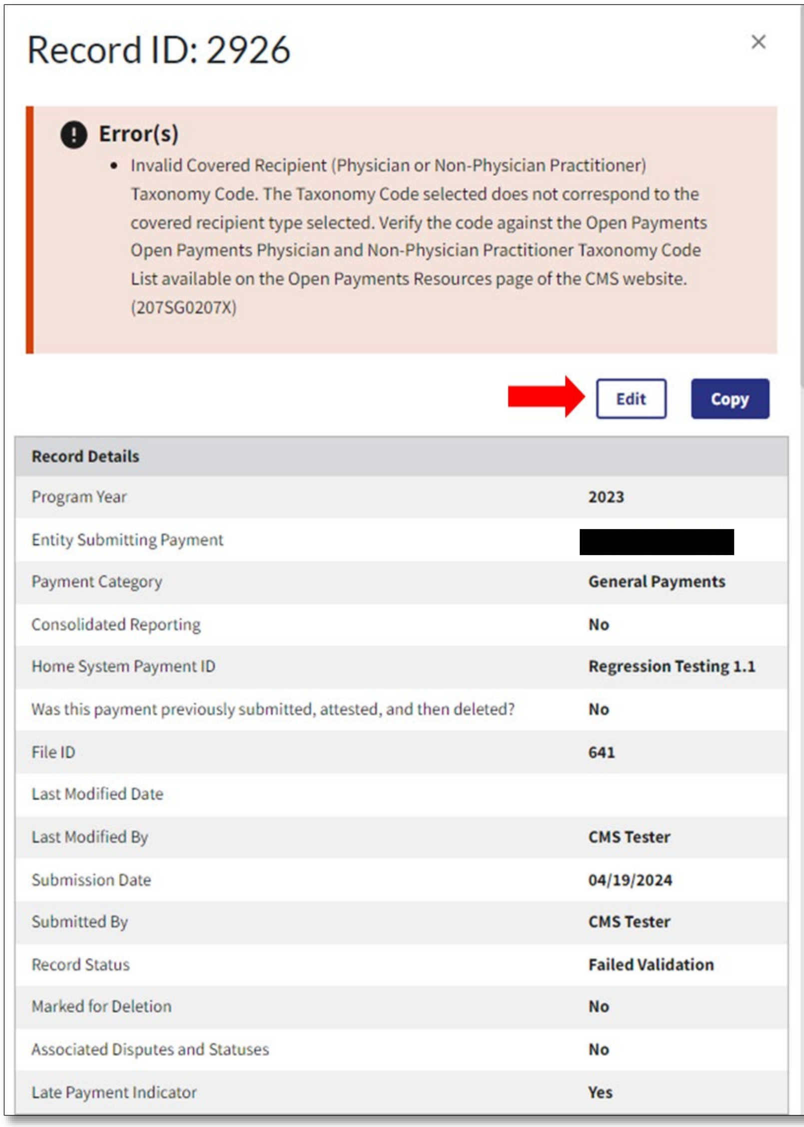
Step 4: Select the **Record ID** hyperlink.

Figure 230: Search Results Table: Record ID Hyperlink



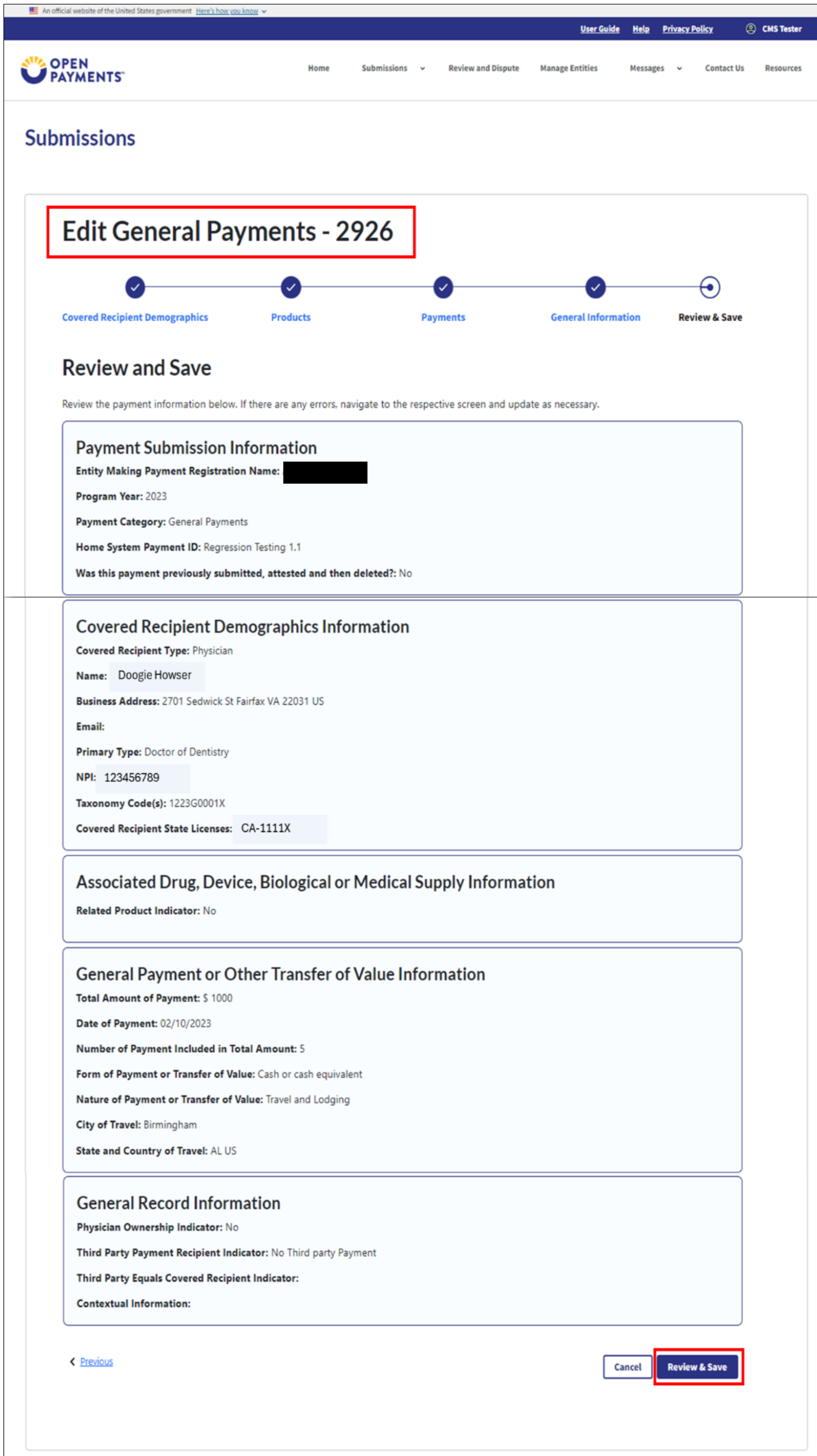
Step 5: Select the **Edit** button.

Figure 231: Record ID Window: Edit Button



<u>Step 6:</u> Update the record information as needed to resolve the failed validation and/or failed matching error(s). Once all the errors have been fixed, navigate to the “Review & Save” page and select the **Review & Save** button.

Figure 232: Review and Save Page: Review and Save Button



Note: Edited records must undergo final submission and attestation. Instructions are available in Section 4.11, Final Submission and in Section 4.15, Attestation.

Section 4.9: Copy/Duplicate Records

Records submitted to the Open Payments system 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 can 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.

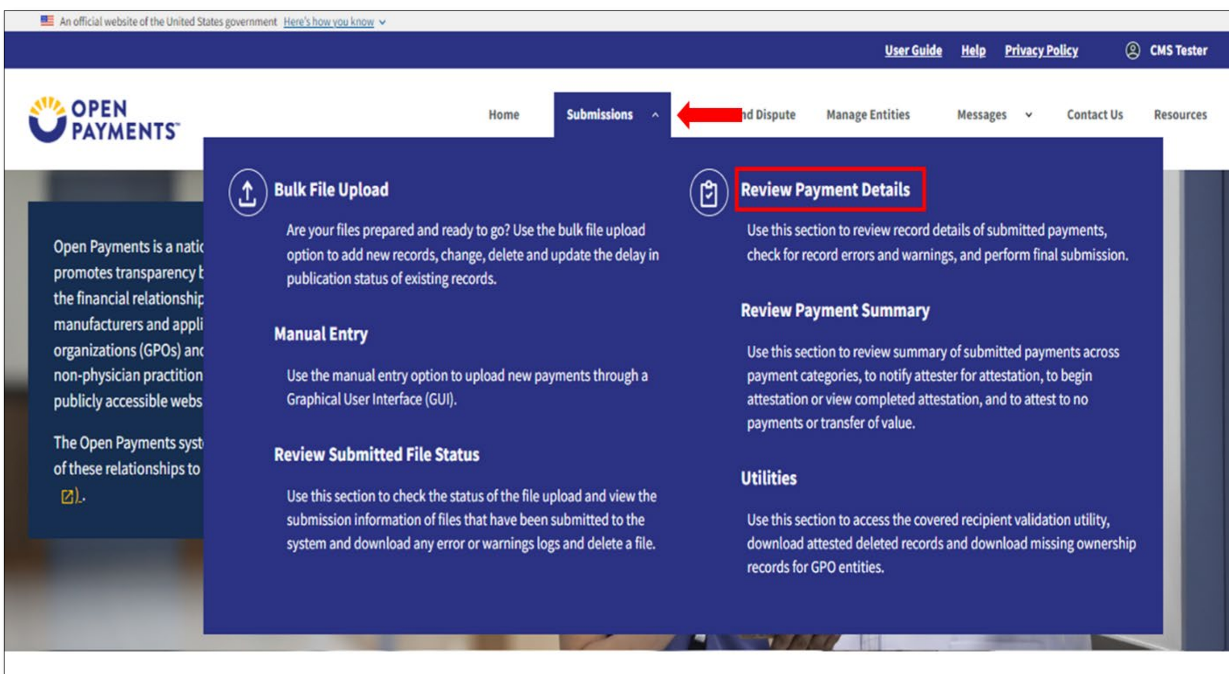
Validation of fields are performed when you select **Continue** on each page or save the new record and not at the time of copy action. NOTE: Payment Category field is read only on copied record.

4.9a: Copying a Record

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

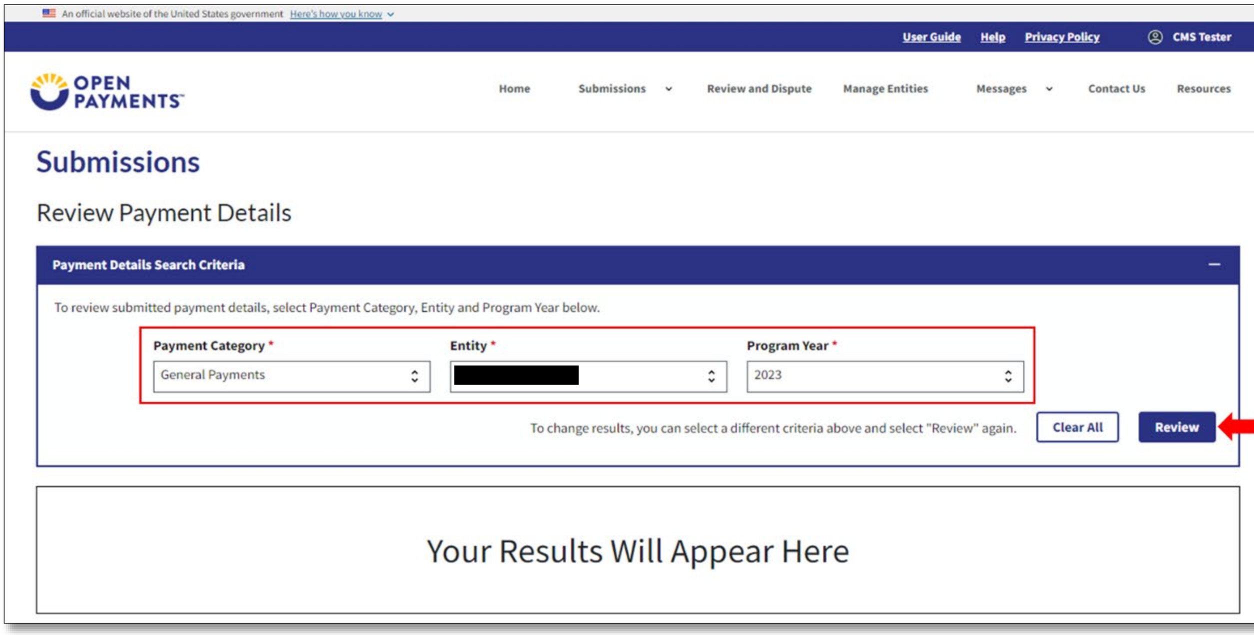
<u>**Step 1:**</u> Log in to the Open Payments, select the **Submissions** tab on the toolbar, and then select **Review Payment Details**.

Figure 233: Submissions Tool Bar: Review Payment Details



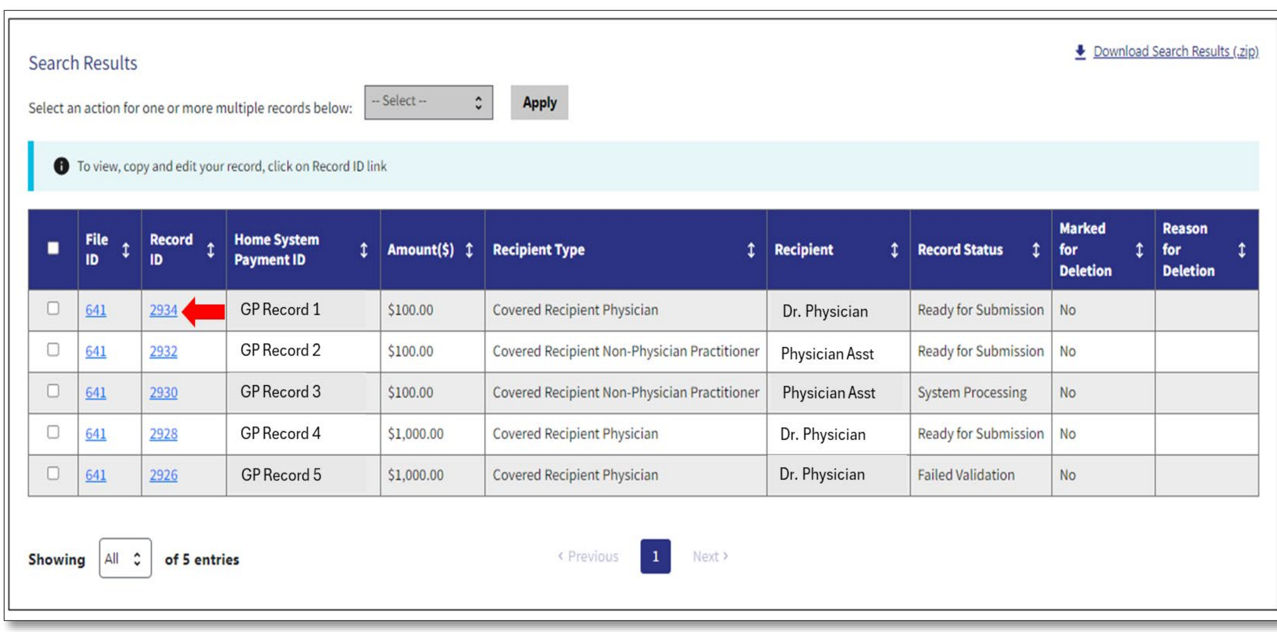
<u>**Step 2:**</u> Select the payment category, entity, and the program year for the records you want to copy. Select the **Review** button.

Figure 234: Payment Details Search Criteria: Review Button



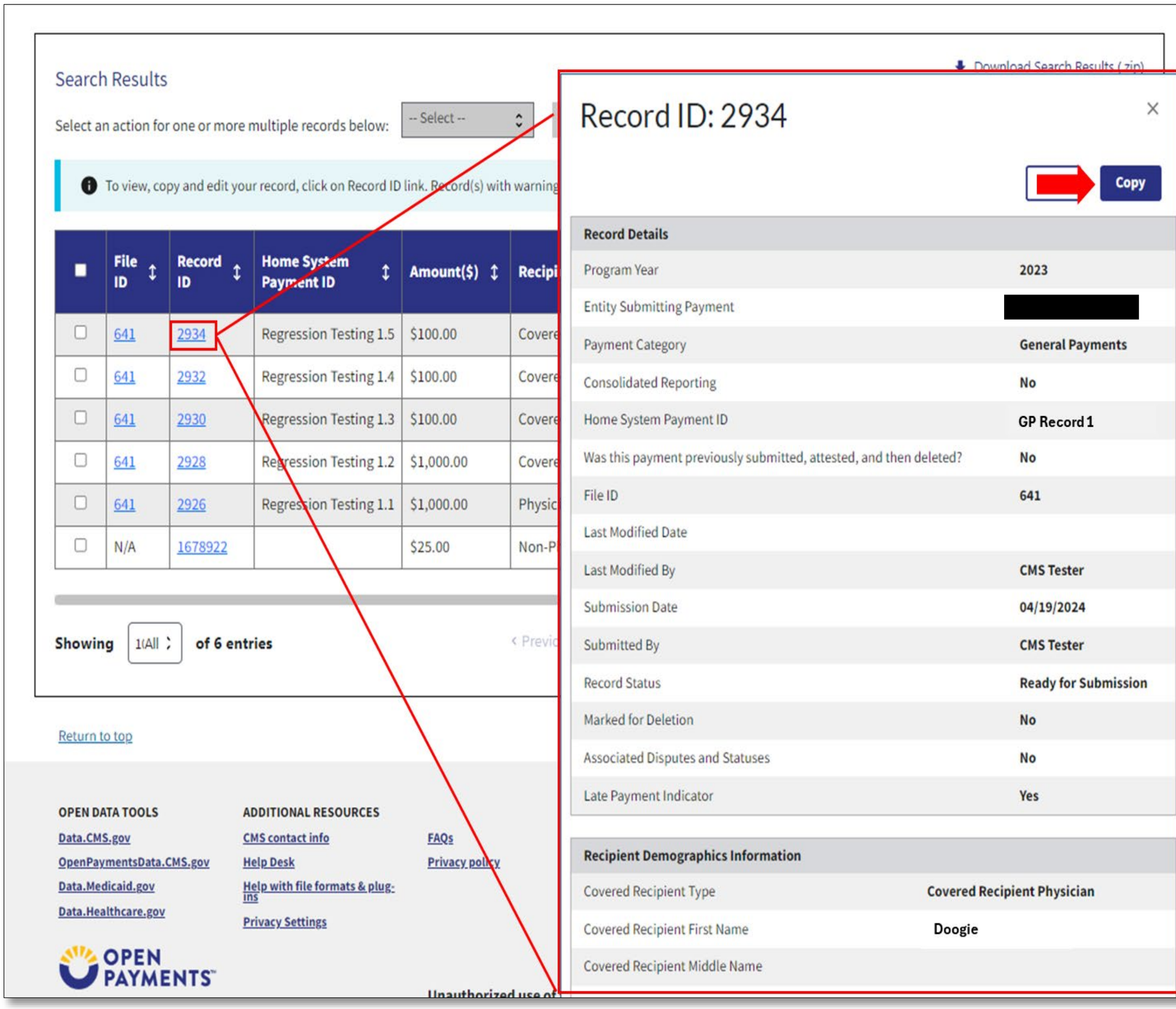
Step 3: At the bottom of the "Review Payment Details" page is a data table. Find one record from the file you wish to copy. Select the **Record ID** hyperlink.

Figure 235: Record ID Hyperlink



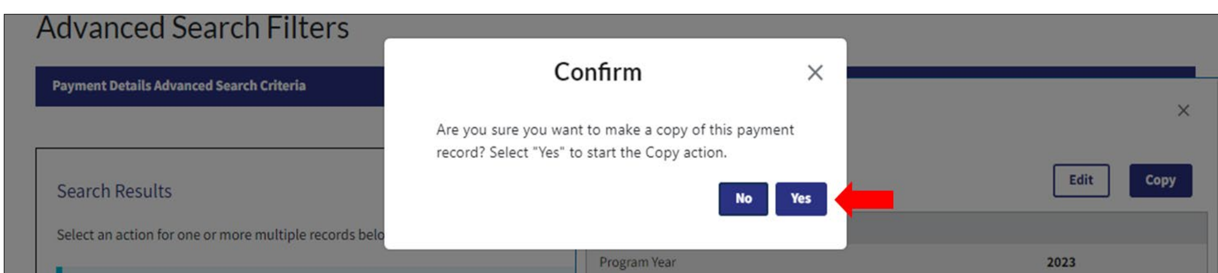
Step 4: Select the Copy button from the top of the "Record ID" window.

Figure 236: Record ID Window: Copy Button



Step 5: A confirmation pop-up box appears. Select the **Yes** button.

Figure 237: Confirmation Pop-up Window

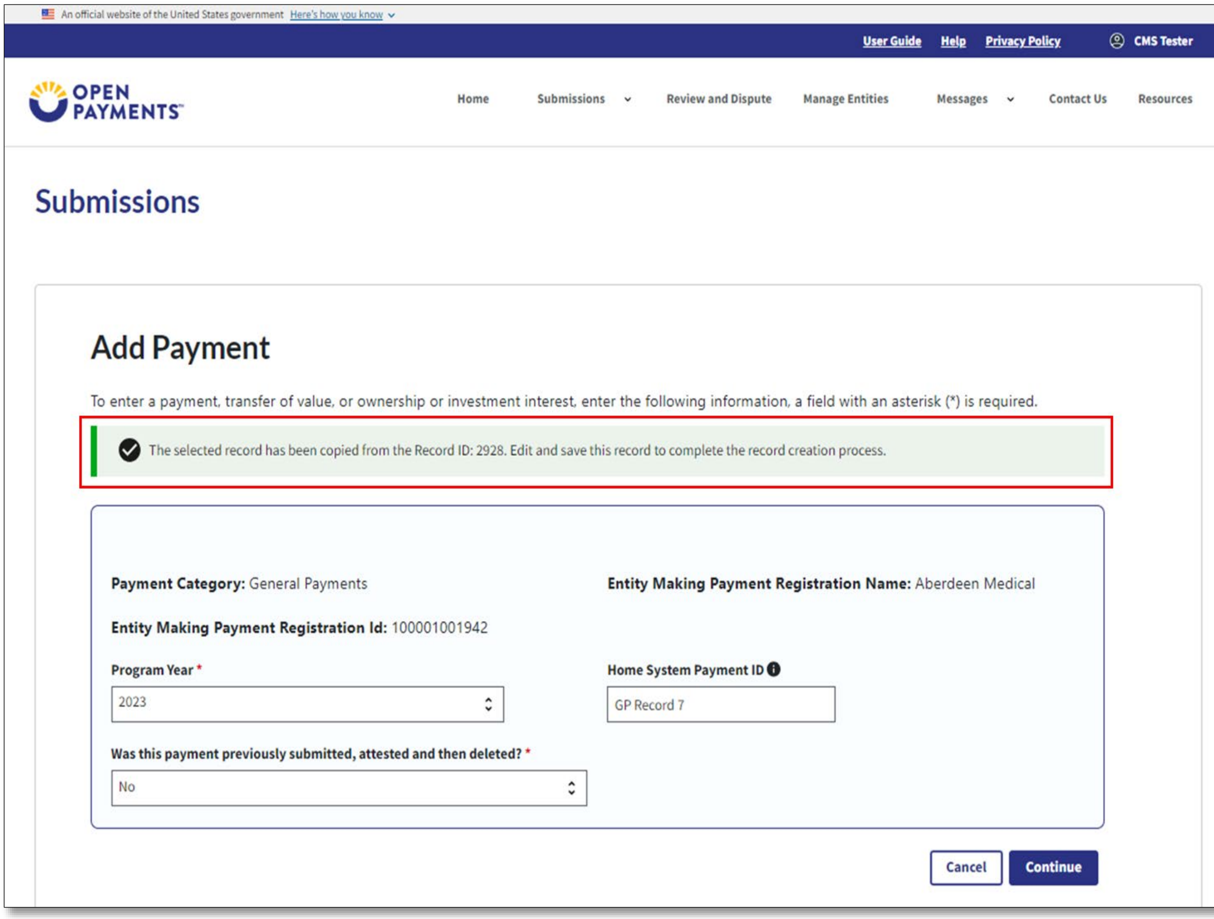


Upon selecting the **Yes** button, you will be redirected to the "Add General Payment" page. A confirmation message will be present on the "Add General Payment" page confirming the payment has been copied. You will be able to add data to the payment record that has been copied. You may update the record data as needed and the copied record will be successfully created only upon the **Review and Save** action.

Note that, while copying records,

- The fields may differ based on the Program Year selected. E.g., Covered Recipient NPP is available only from PY 2021 and onwards.
- The fields may differ based on the Covered Recipient type selected. E.g., you can select a single primary type for Covered Recipient Physician whereas multi-select up to six primary types for Covered Recipient NPP
- If you change the Covered Recipient type fields including "Country", "Primary Type" and "Taxonomy code", will switch to blank and will allow you to select those values.
- When you copy the record and click on **Continue** button at the bottom of the "Products" page, an error message will be displayed indicating the incorrect values of Drug or Biological Name or Drug/Biological Name and NDC combination.
- When you copy the record and select the **Continue** button at the bottom of the "Products" page, an error message will be displayed indicating the incorrect values of Device or Medical Supply or Device/Medical Supply and PDI combination.

Figure 238: Confirmation Message on Add 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 via bulk file. You may also delete a previously submitted bulk file, thereby deleting all records that had been submitted in that file.

Records that have not yet been attested to will be immediately removed from the Open Payments system.

When you are trying to delete records that have not been attested, the system will not require a reason for deletion. In other words, only records that have been attested will require a reason for deletion. These records can only be marked for deletion by the submitter.

In order for the records to be deleted, the attester will need to re-attest before these records permanently deleted from the Open Payments system. CMS encourages the use of the assumptions statement to explain circumstances around deleted records, though this is not required.

Figure 239: Record Status and Actions

Record Status	Submitter Actions	Attestor Actions
Failed Validation Failed Matching Ready for Submission	Update or delete the record(s) as needed.	None
Ready for Attestation	Mark the record for deletion.	None
Attested	Mark the record for deletion. Document the record ID in order to link it to the corrected version of the record. Note why the record is being deleted so that you can provide a reason for deletion.	Re-attest to the records that are marked for deletion in order to have them permanently removed from the system.
System Processing	None.	None
Returned to Submitter	Update or delete the record(s) as needed.	None

You must provide one of the following reasons below for deleting attested records:

- Correction to Covered Recipient Information (But to Same Covered Recipient)
- Different Covered Recipient
- Record Should Have Been Reported by a Different Applicable Manufacturer or Applicable GPO
- Payment Had Not Been Furnished to the Covered Recipient
- Disputed by Covered Recipient
- Correction at CMS's Request
- Duplicate Record(s)
- Incorrect Record Classification
- Check was Voided or Not Cashed
- De Minimis was Not Met
- Record Meets Reporting Exception
- Other

The 'attested' record(s) which are deleted will be placed in a "Marked for Deletion" status rather than immediately deleted.

To complete the deletion of attested records, the attester for the reporting entity must attest to those payments marked for deletion for that program year, until they are attested and removed from the system. Attested records in "Marked for Deletion" status will remain visible to covered recipients and are eligible for publication.

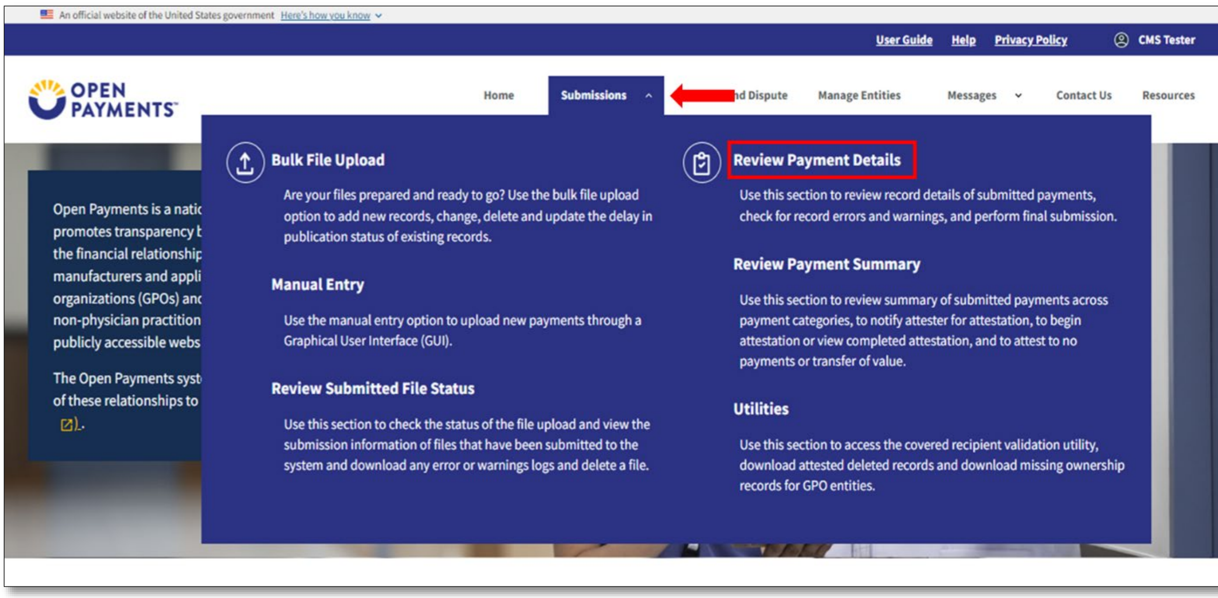
Note: Records that are deleted through any of the methods described below cannot be recovered or viewed.

4.10a: Deleting a Bulk File

The process outlined below will delete all unattested records in a previously submitted bulk file immediately and all attested records contained in the file, will be marked for deletion but will not be permanently deleted from the system unless attester re-attest those records which are marked for deletion.

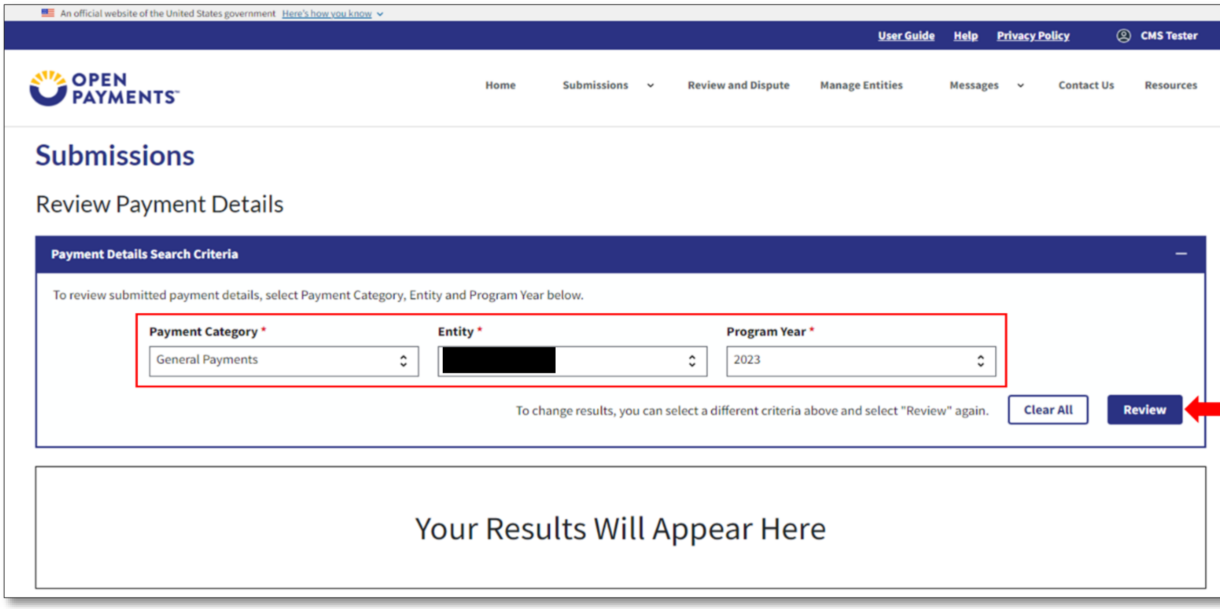
Step 1: Log in to the Open Payments system select the **Submissions** tab on the toolbar, and then select **Review Payment Details.**

Figure 240: Submissions Tool Bar: Review Payment Details



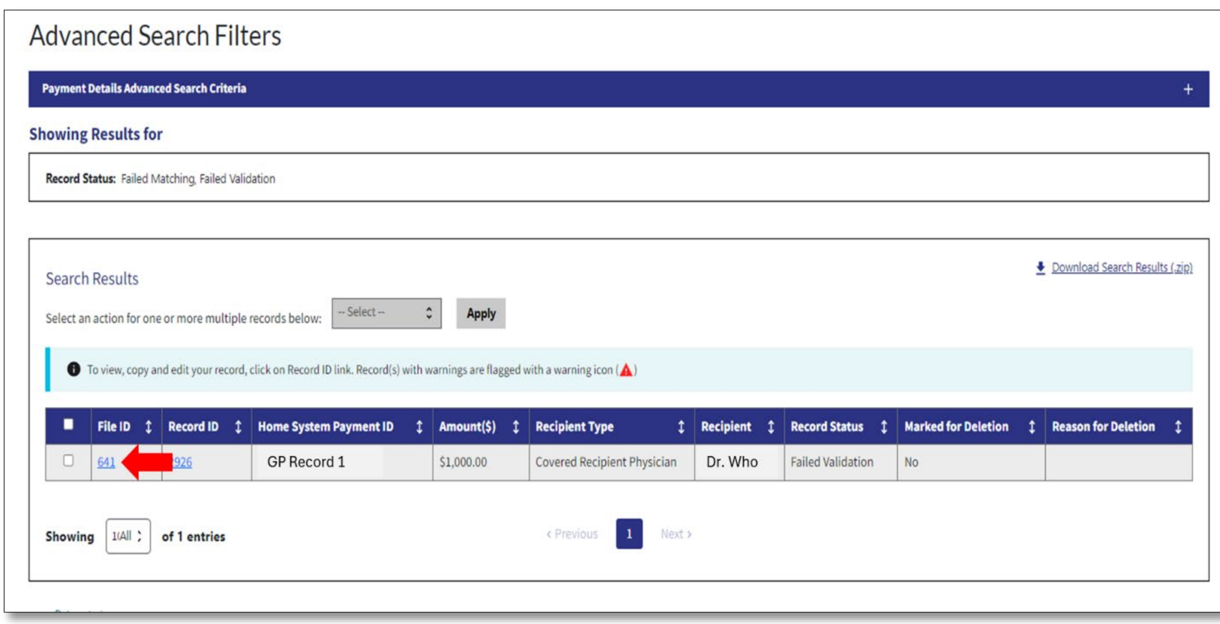
Step 2: Select the payment category, reporting entity whose record you wish to view and the program year for that record, and then select the **Review** button.

Figure 241: Payment Details Search Criteria: Review Button



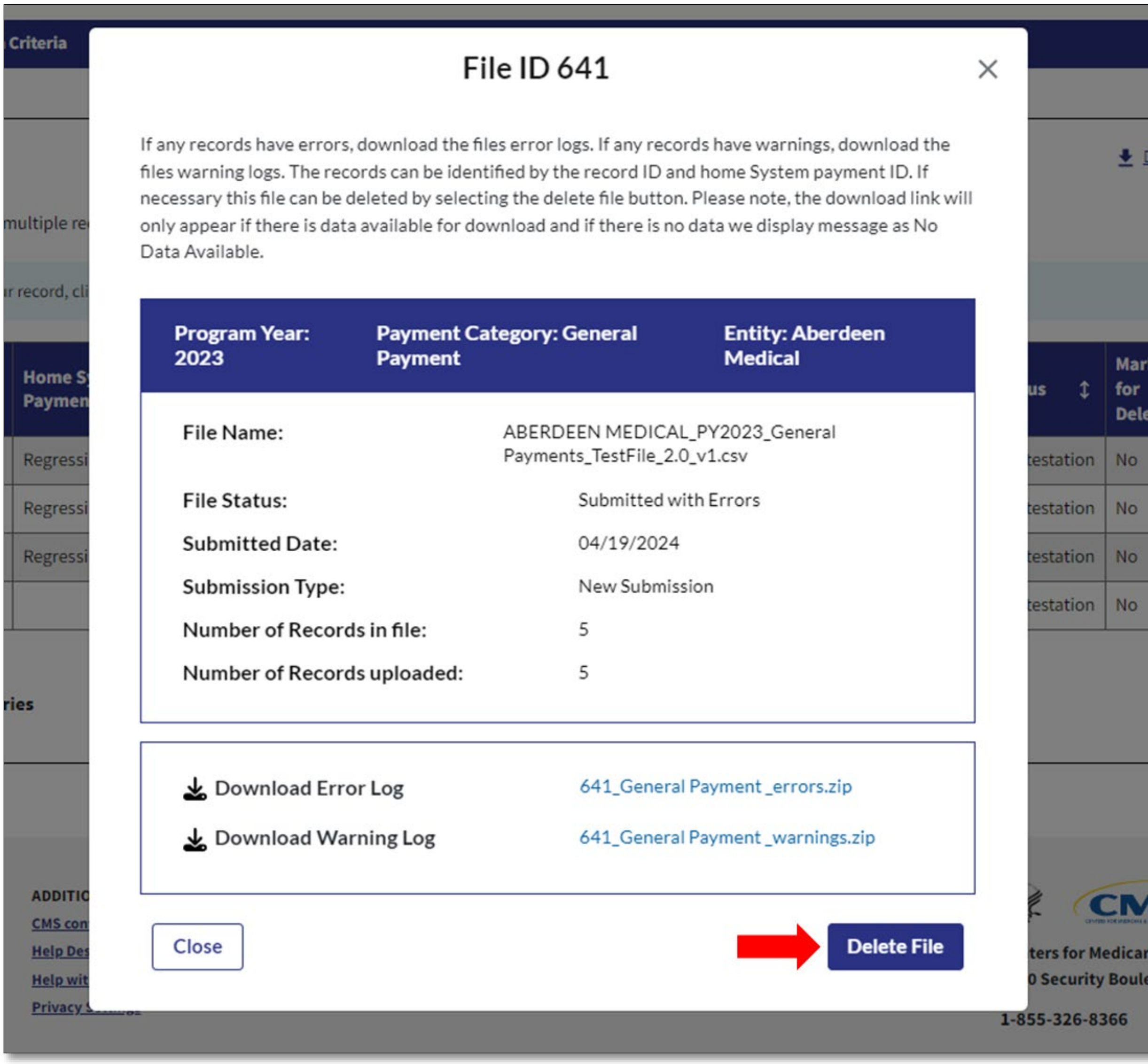
Step 3: Scroll to the bottom of the "Review Payment Details" page to find the "Search Results" data table. Find one record from the file you wish to delete. Select the hyperlink in that record's "File ID" column.

Figure 242: Review Payment Details Data Table: File ID Hyperlink



Step 4: On the "File ID" window, select the **Delete File** button.

Figure 243: Delete File Button on File ID Window



Step 5: An on-screen message will appear to confirm you want to delete the file. To proceed with deletion, select the reason for deletion and select the **Delete** button. One or more reasons for deleting the file can be selected. If **Other** is selected, an alternate reason for deleting the file must be entered in the field “Other Reason for Deletion.” To cancel the deletion, select the **Close** button.

Figure 244: Delete File Window: Reason for Deletion and Delete Button

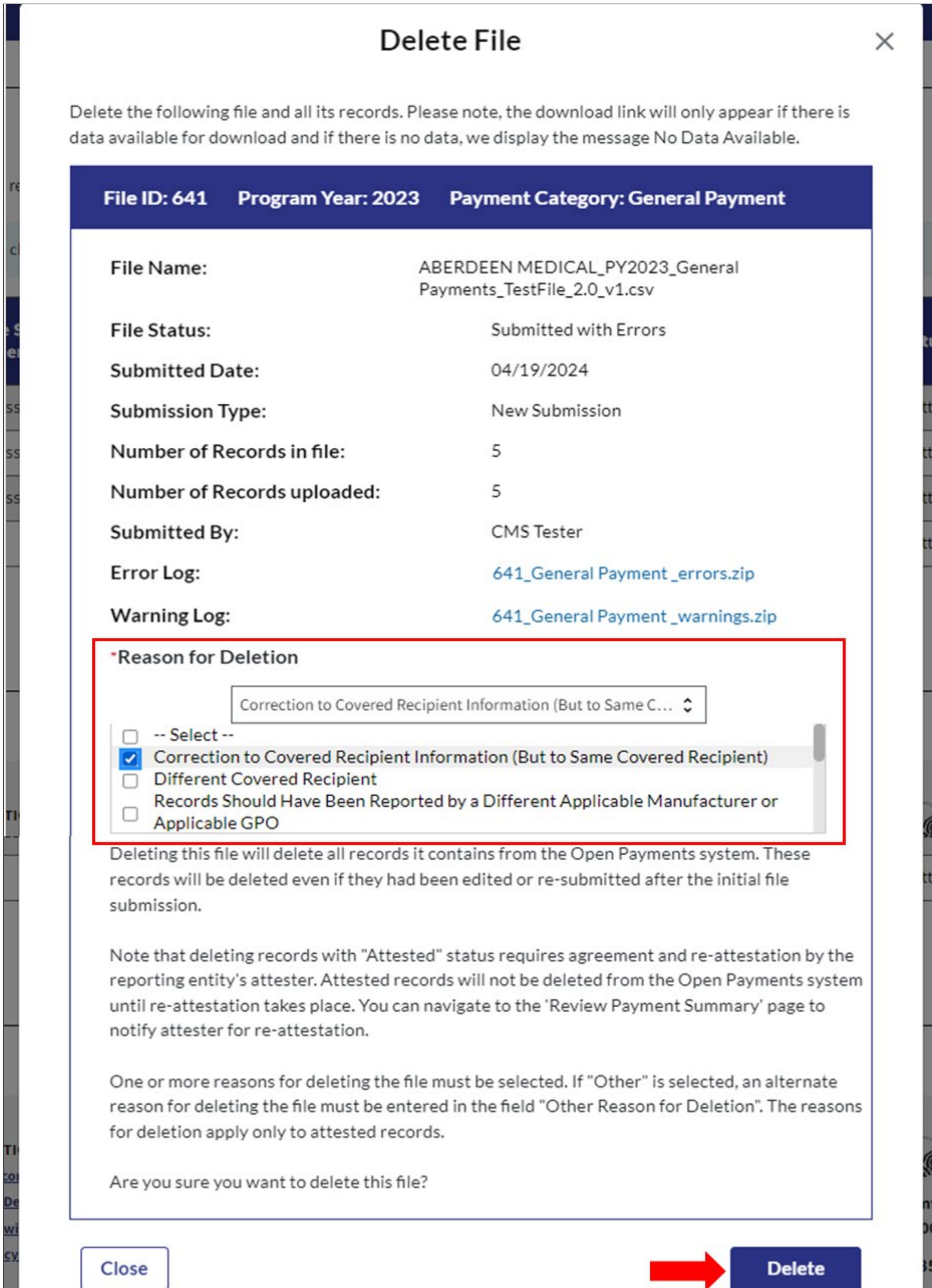
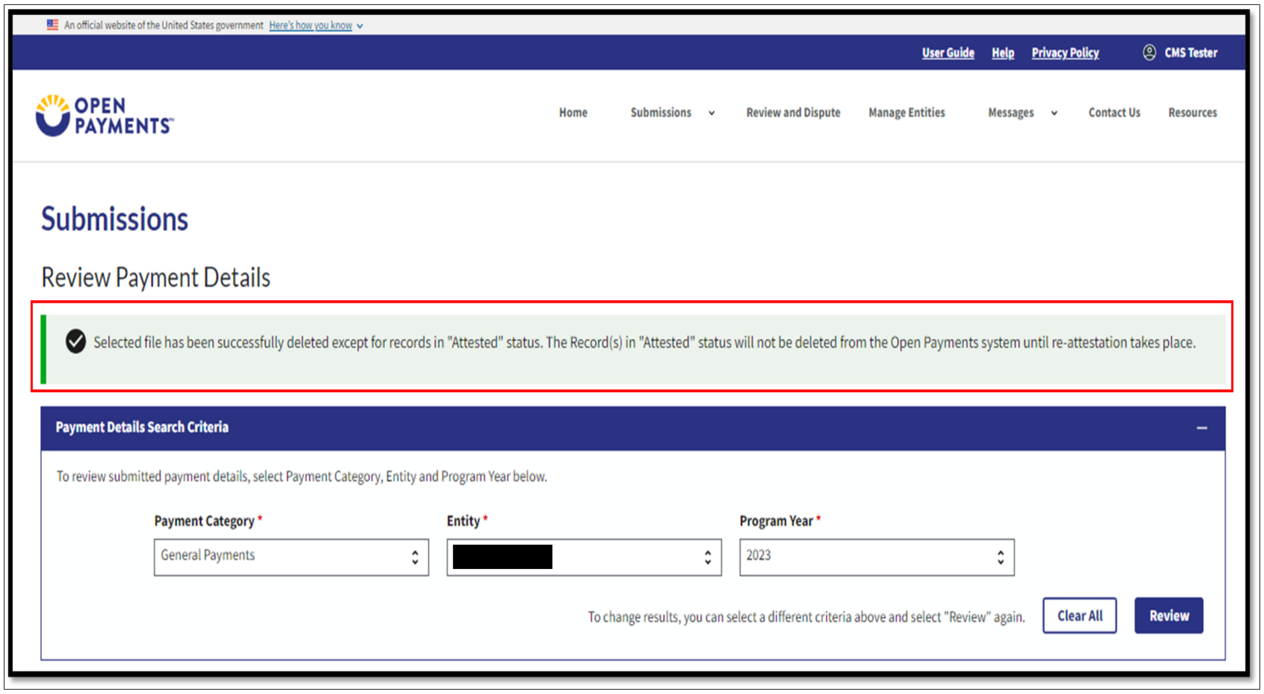


Figure 245: On Screen Message File Deletion Successful: Attested Records Not Deleted from System



Step 6: Notify the Attester if any records from this bulk file had been previously attested to, the previously attested records will not be immediately deleted but placed in "Marked for Deletion" status. The attester for the reporting entity must attest to these payments marked for deletion for that program year, which will completely remove them from the system.

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 the required fields. Note that only the following fields are required for bulk file records intended for deletions:

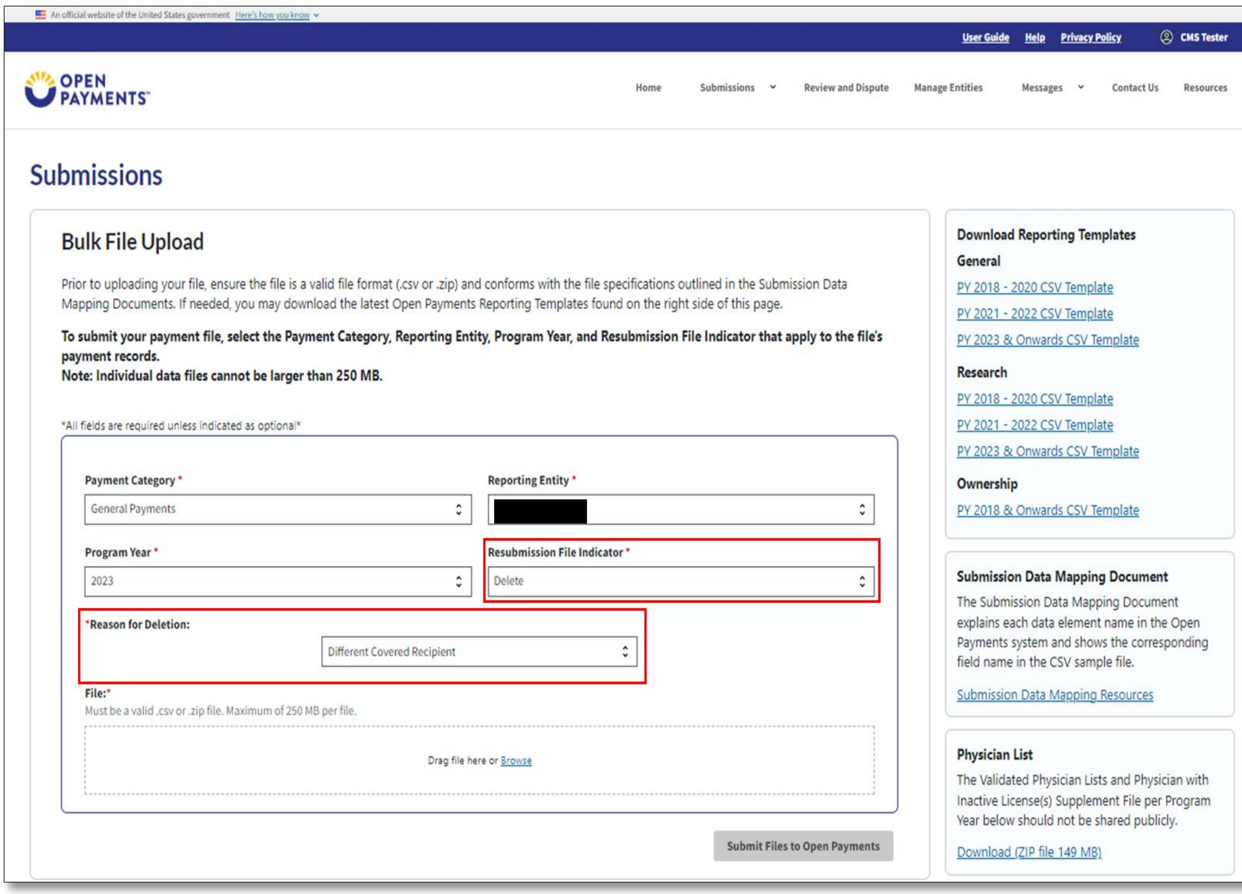
- Applicable Manufacturer or Applicable GPO Registration ID;
- Consolidated Report Indicator;
- Resubmission File Indicator (must be "D" to delete records);
- Applicable Manufacturer or Applicable GPO Making Payment Registration ID;
- Resubmitted Payment Record ID; and
- Date of Payment (General and Research payment records only).
- Information included in other fields will be ignored by the system.

Step 2: Log in to the Open Payments system, select the "Submissions" tab on the toolbar and then select "Bulk File Upload".

Step 3: From the drop-down menus, select the appropriate Payment Category, Reporting Entity, and Program Year.

Step 4: For the Resubmission File Indicator value, select **Delete** and select a reason for deletion from the dropdown options. One or more reasons for deleting the file can be selected. If **Other** is selected, an alternate reason for deleting the file must be entered in the field "Other Reason for Deletion."

Figure 246: Resubmission File Indicator and Reason for Deletion



Step 5: Choose the file and select the **Submit Files to Open Payments** button.

If the file is rejected, you will receive an email with an explanation of 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 immediately. Records included in this bulk file that had been previously attested to will be marked for deletion but remain undeleted 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.

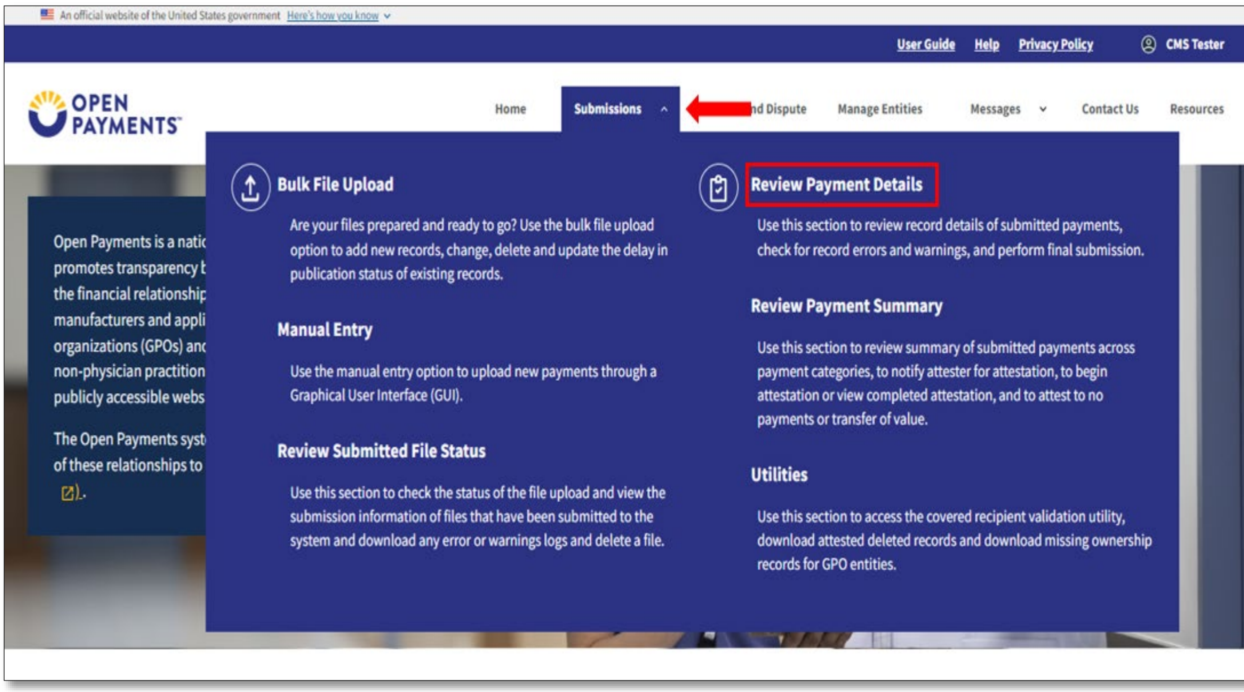
4.10c: Deleting a Record Manually

4.10c (1) Deleting a Record from the "Submissions" tab

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

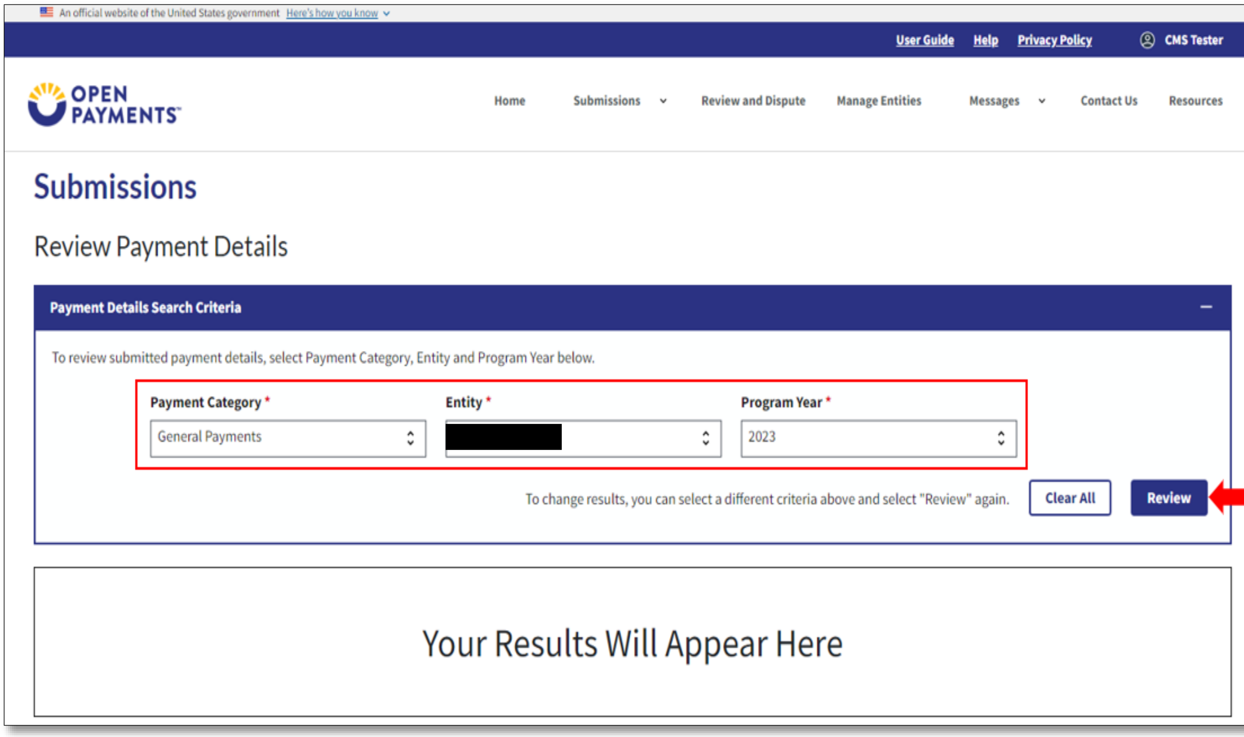
Step 1: Log in to the Open Payments system, select the **Submissions** tab on the toolbar, and then select **Review Payment Details**.

Figure 247: Submissions Tab: Review Payment Details



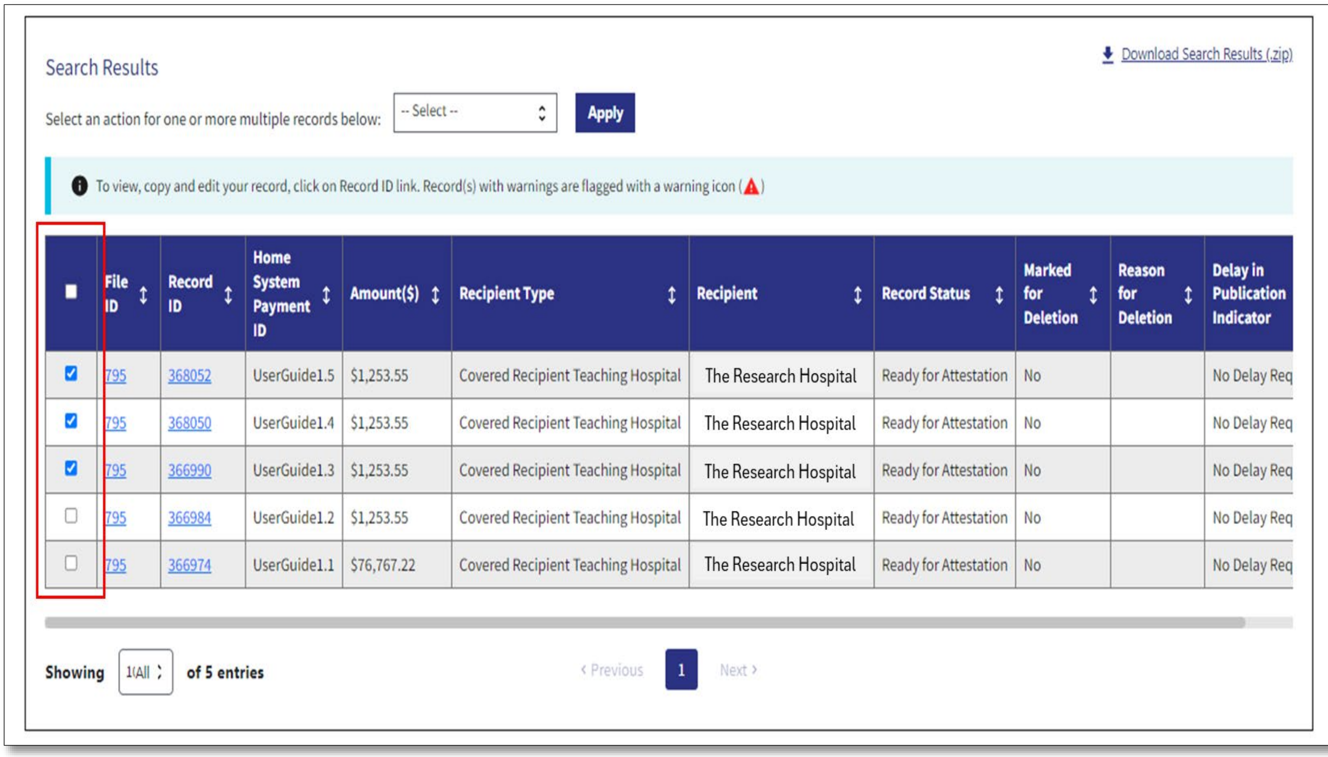
Step 2: Select the payment category, entity whose records you want to delete, and the program year for those records. Select the Review button.

Figure 248: Payment Details Search Criteria: Review Button



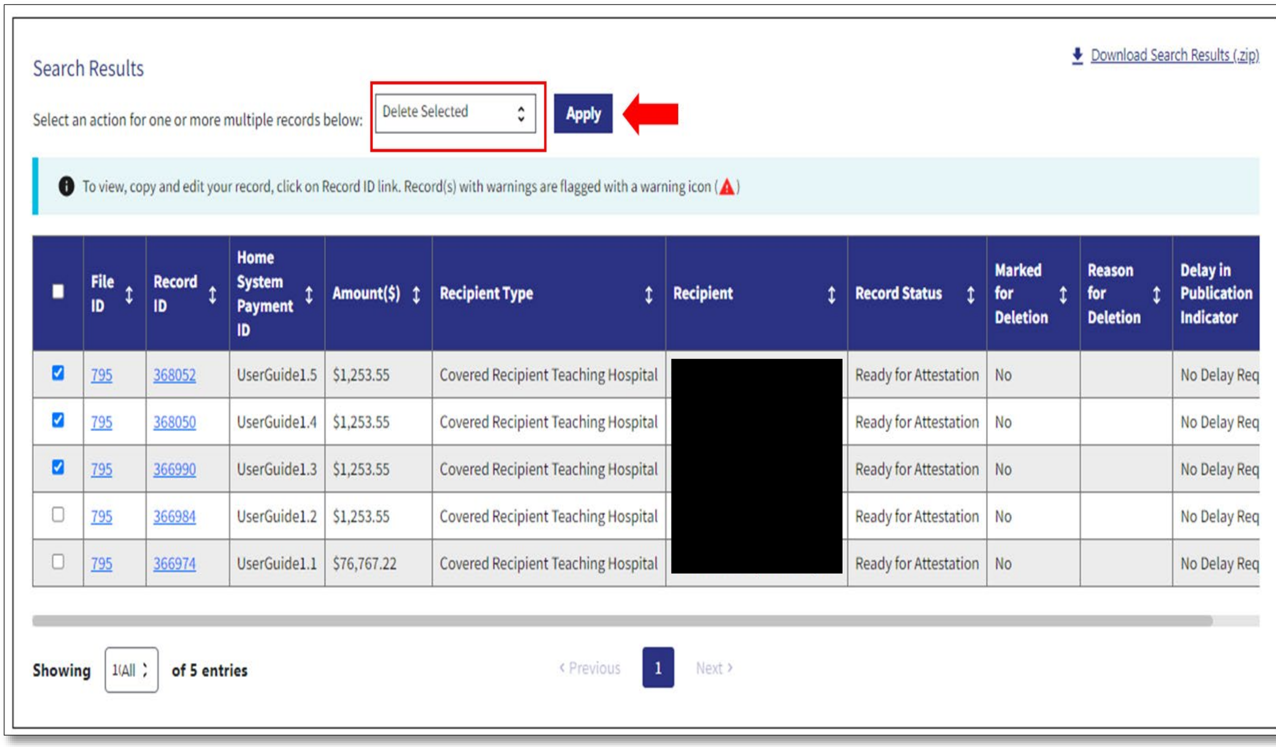
<u>Step 3:</u> Scroll to the bottom of the "Review Payment Details" page to the data table. To delete an unattested record, select the checkbox next to the corresponding record(s).

Figure 249: Data Table Checkbox Column to Select Records



<u>Step 4:</u> Select the “Delete Selected” action in the drop-down menu above the table, and then select **Apply**. This will delete the records.

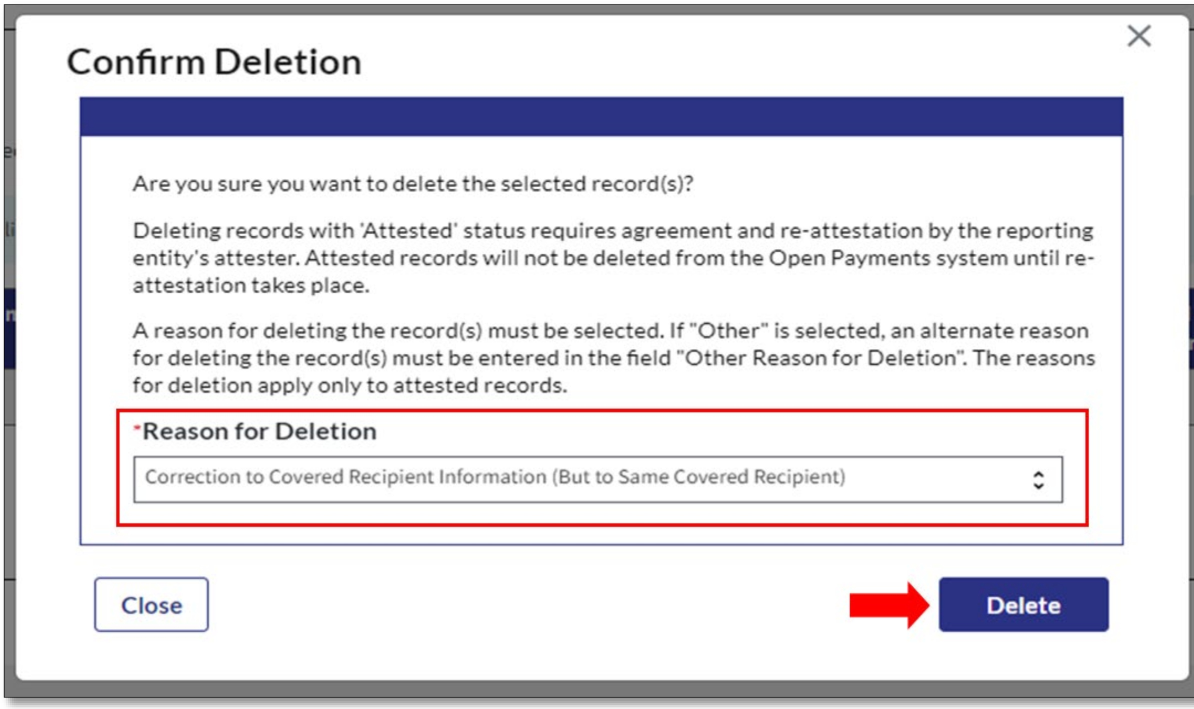
Figure 250: Delete Selected Action: Apply Button



<u>Step 5a:</u> For Attested records: An on-screen message will appear to confirm you want to delete the selected record(s). To proceed with the deletion of an "Attested" record, select a reason for deletion and select the **Delete** button.

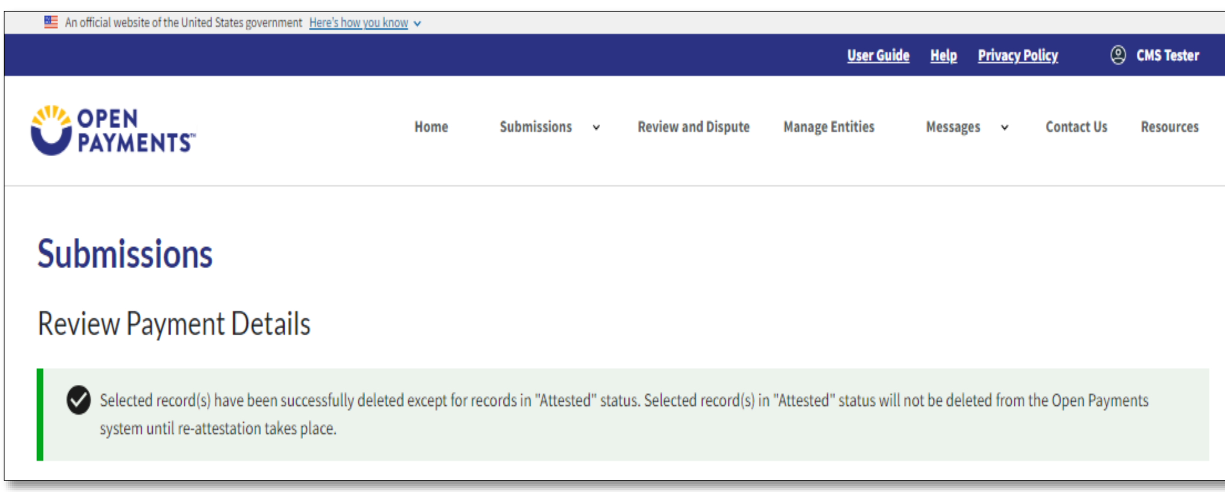
One or more reasons for deleting the record can be selected. If **Other** is selected, an alternate reason for deleting the record must be entered in the field "Other Reason for Deletion." To proceed with deletion, select the **Delete** button. To cancel, select **Close**.

Figure 251: Confirm Deletion Notification for Attested Record(s)



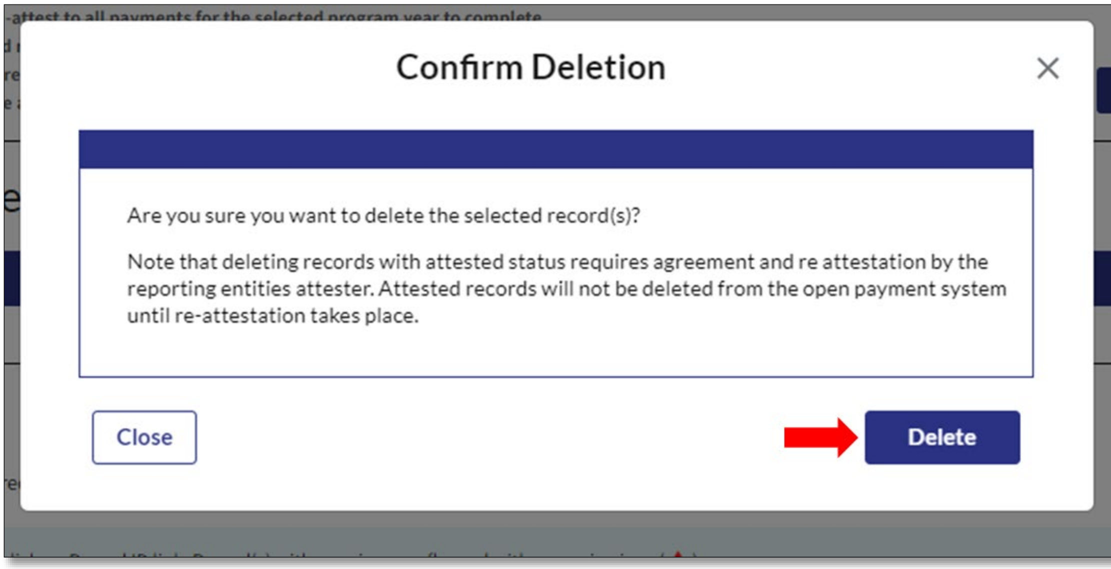
You will receive an onscreen notification of the deletion.

Figure 252: Deletion Confirmation Message



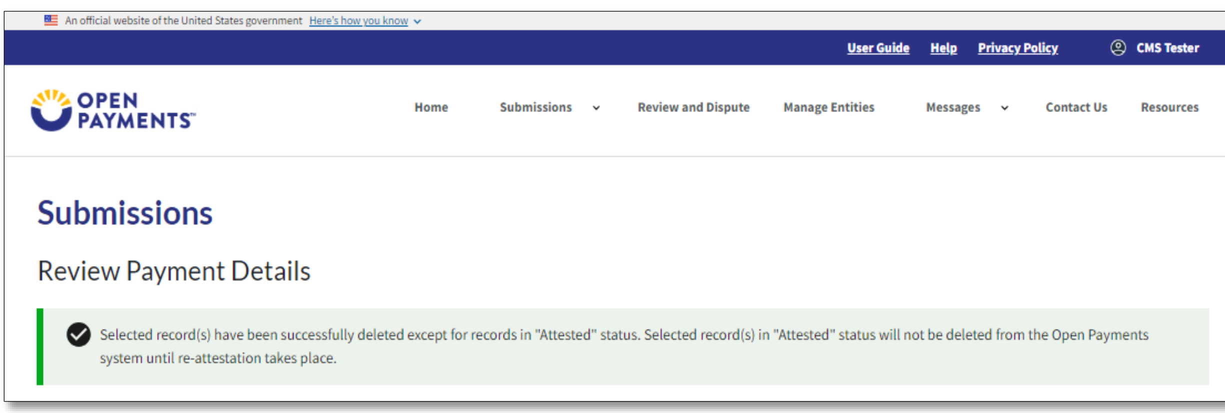
__Step 5b for non-Attested Record(s):__ An on-screen message will appear to confirm you want to delete the selected record(s). To proceed with the deletion, select the **Delete** button. To cancel, select **Close**.

Figure 253: Confirm Deletion Notification for Non-Attested Record(s)



You will receive an onscreen notification of the deletion.

Figure 254: Deletion Confirmation Message



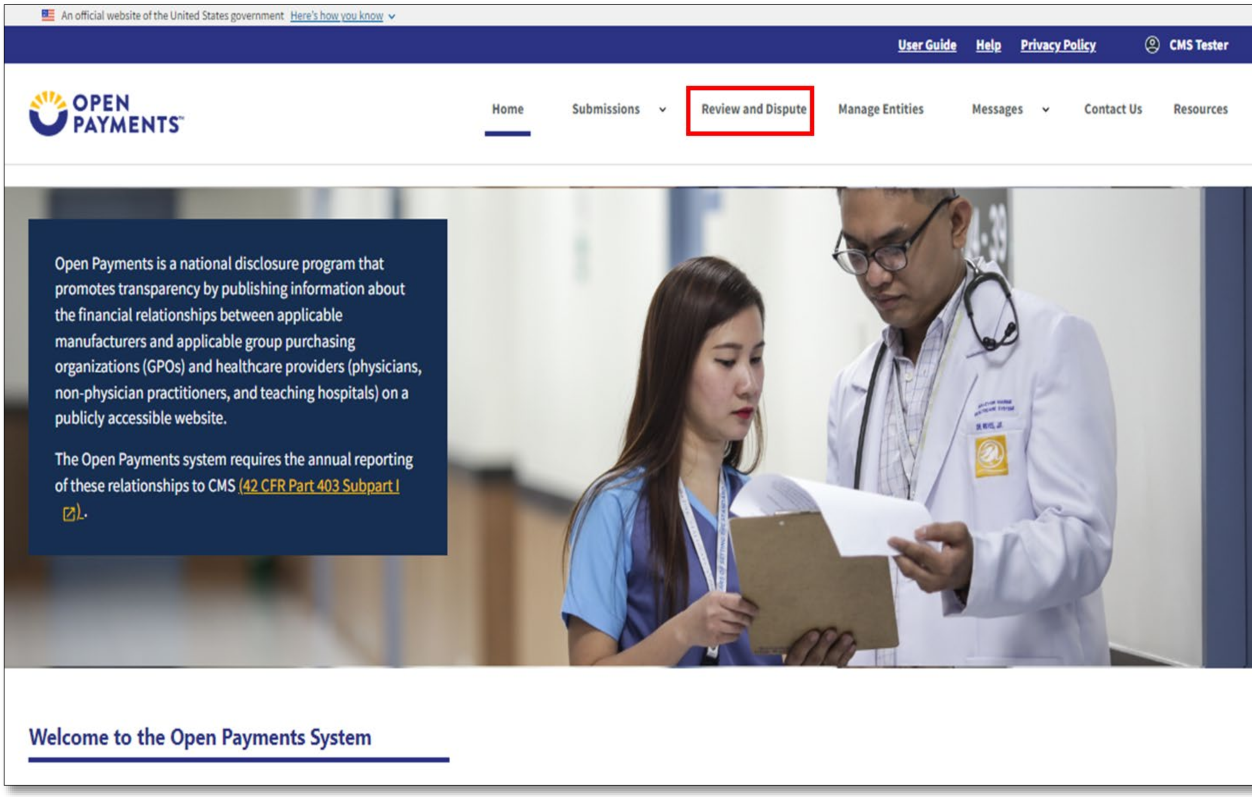
<u>Step 6:</u> Notify the Attester if any records from this record deletion process had been previously attested to, as these records will not be immediately deleted from the system but marked for deletion. The attester for the reporting entity must attest to the payments marked for deletion for that 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.

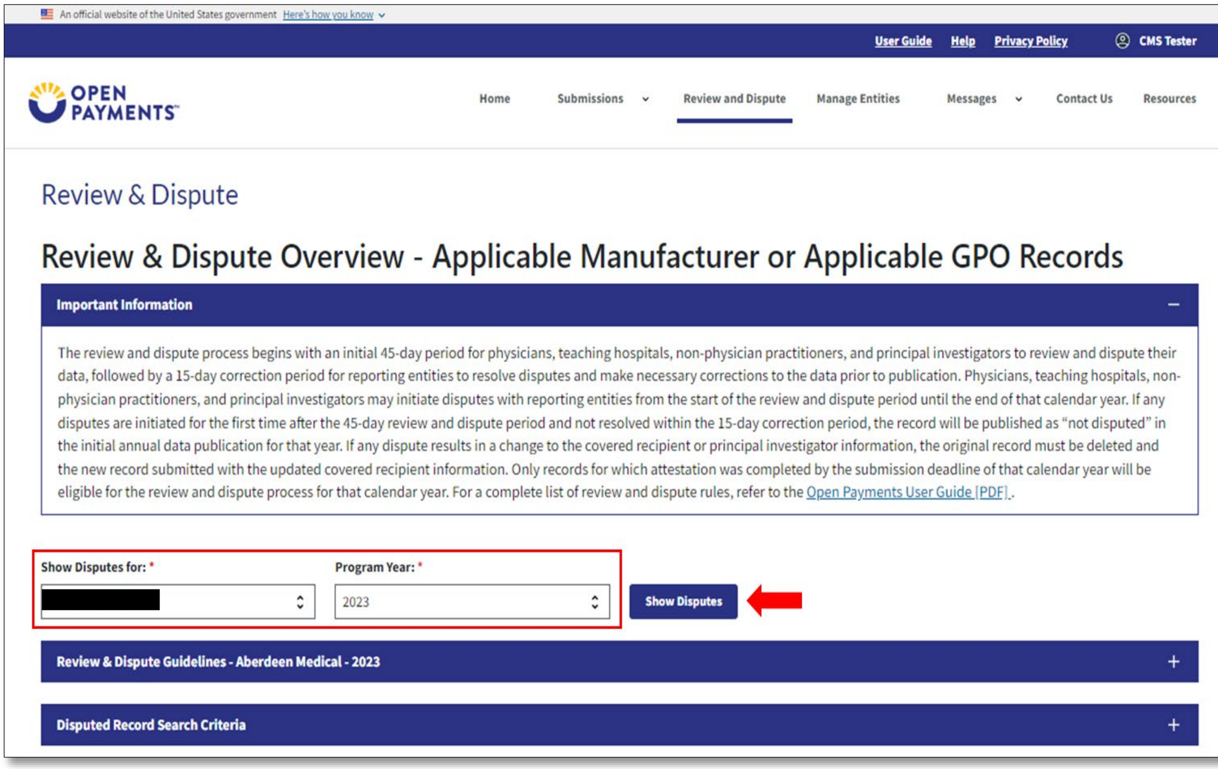
<u>Step 1:</u> Log in to the Open Payments system and select the **Review and Dispute** tab on the tool bar.

Figure 255: Review and Dispute Tab



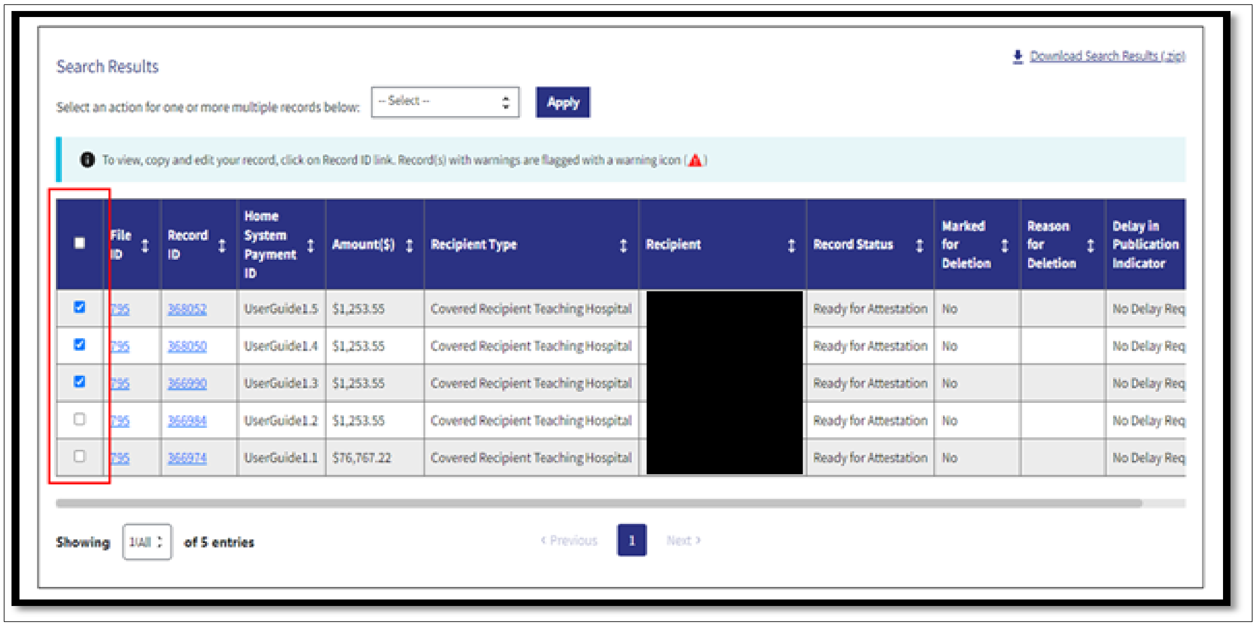
Step 2: Select a reporting entity and appropriate program year from the "Show Disputes for" and "Program Year" drop-down fields. Select the **Show Disputes** button.

Figure 256: Show Disputes Button



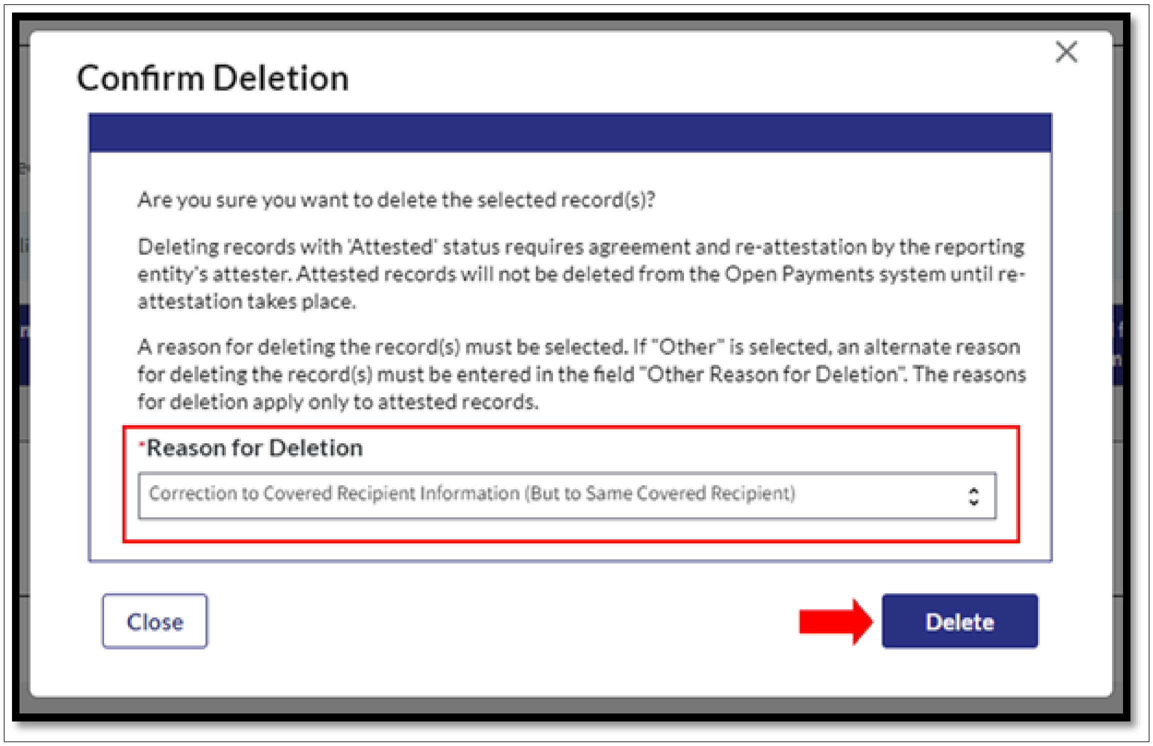
Step 3: At the bottom of the "Review and Dispute" page, there is a data table. To delete a record, select that record in the data table by selecting the corresponding checkbox and select the **Delete Selected** button.

Figure 257: Record ID Links



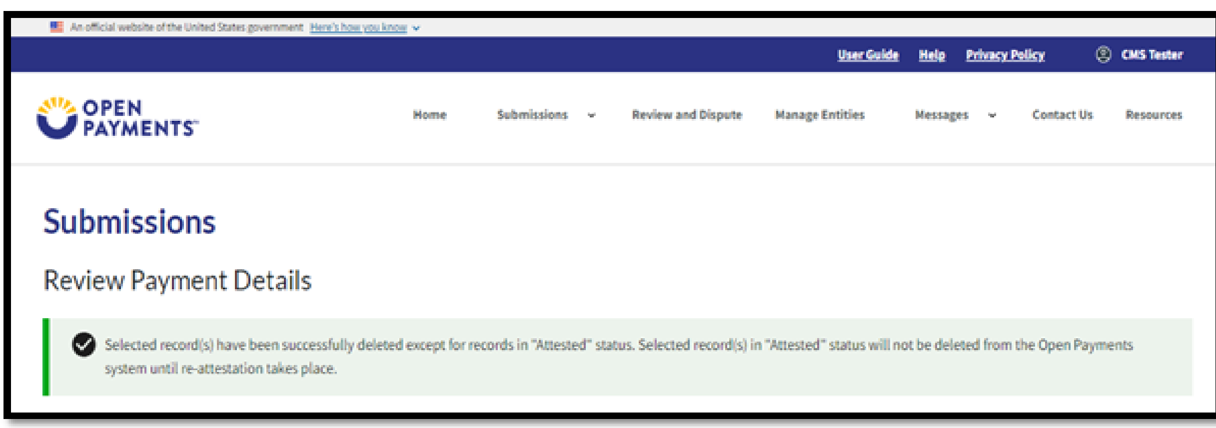
<u>Step 4:</u> An on-screen message will appear to confirm you want to delete the selected record (s). To proceed with the deletion of an "Attested" record, select a reason for deletion and select the **Delete** button. One or more reasons for deleting the record must be selected. If **Other** is selected, an alternate reason for deleting the record must be entered in the field "Other Reason for Deletion." An on-screen message will appear to confirm the user wants to delete the selected record. Select **Delete** to delete the selected record. Select **Cancel** to cancel.

Figure 258: Confirmation of Deletion



Step 5: An on-screen message is displayed to confirm the deletion of the selected record.

Figure 259: Deletion Confirmation



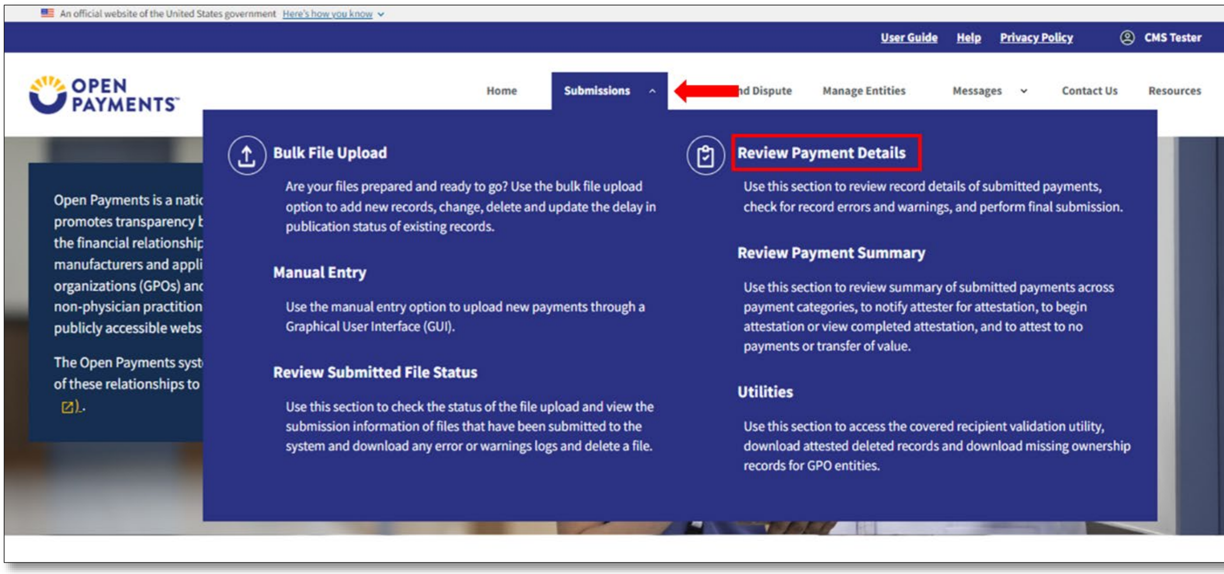
If the record had been previously attested to, it will not be immediately deleted but marked for deletion. To delete records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year. If the record is in "Attested" status, the record is "Marked for 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 immediately 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: Viewing Records Marked for Deletion

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

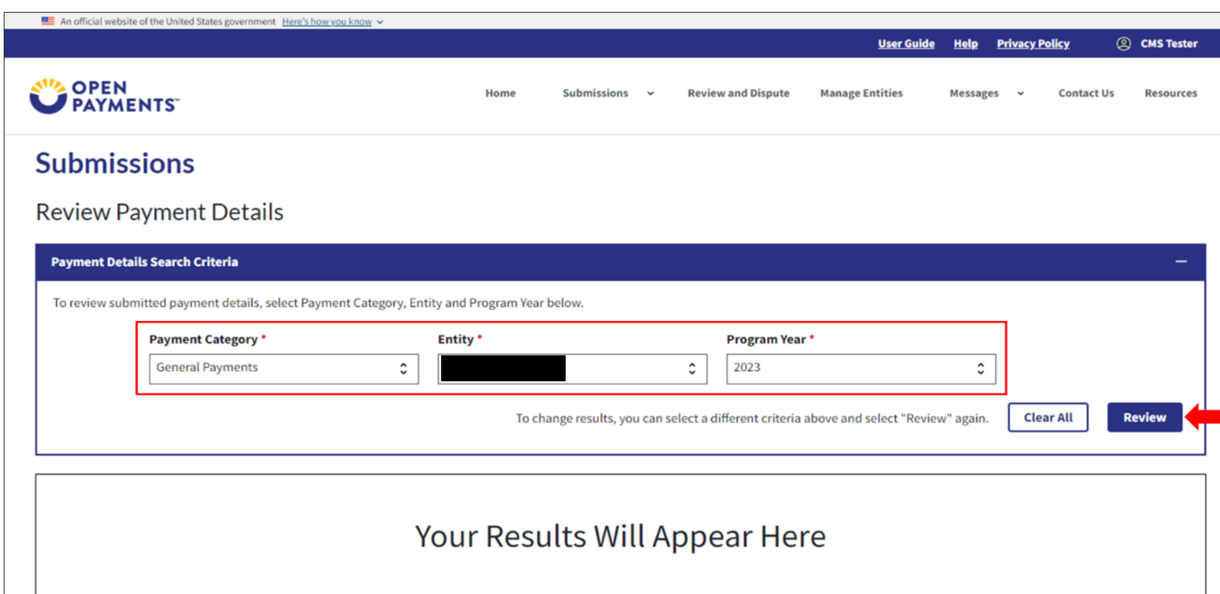
Step 1: Log in to the Open Payments system, select the **Submissions** tab on the toolbar and select **Review Payment Details**.

Figure 260: Submissions Tab: Review Payment Details



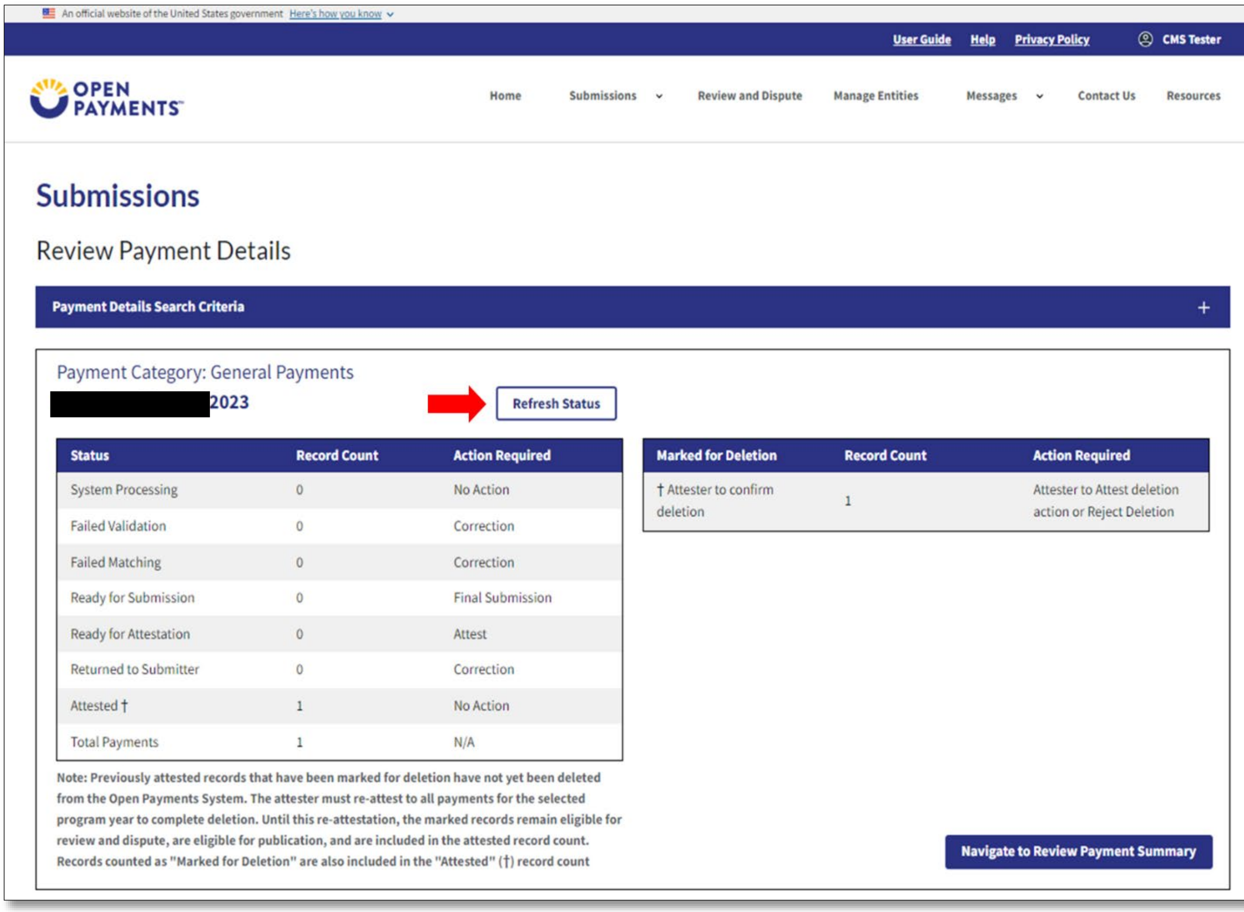
Step 2: Select the payment category, entity, and the program year for the records you want to delete. Select the **Review** button.

Figure 261: Payment Details Search Criteria: Review Button



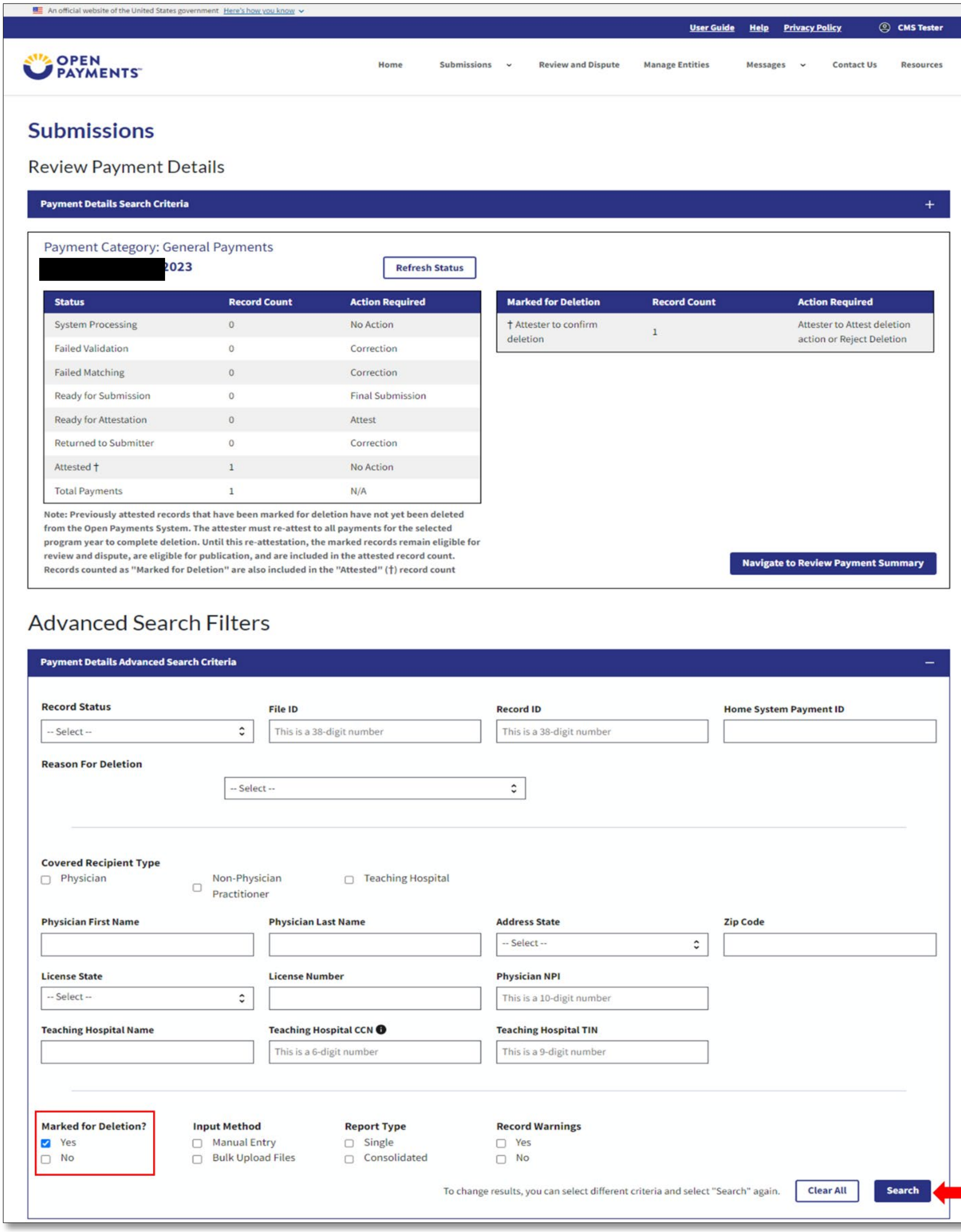
Step 3: If records are still processing select the **Refresh Status** button to refresh the status of the records as they are processed. Note that once the "Refresh Status" button is selected, all other buttons on the "Review Payment Details" page will be disabled until the page has been refreshed. A confirmation message is displayed when the refresh action is completed as described above and displayed in the figure below.

Figure 262: Review Payment Details Page: Refresh Status Button



Step 4: Expand the "Advanced Search Filters" tool, check the box for **Yes** under the heading "Marked for Deletion" and select the **Search** button. This will display all the records "Marked for Deletion."

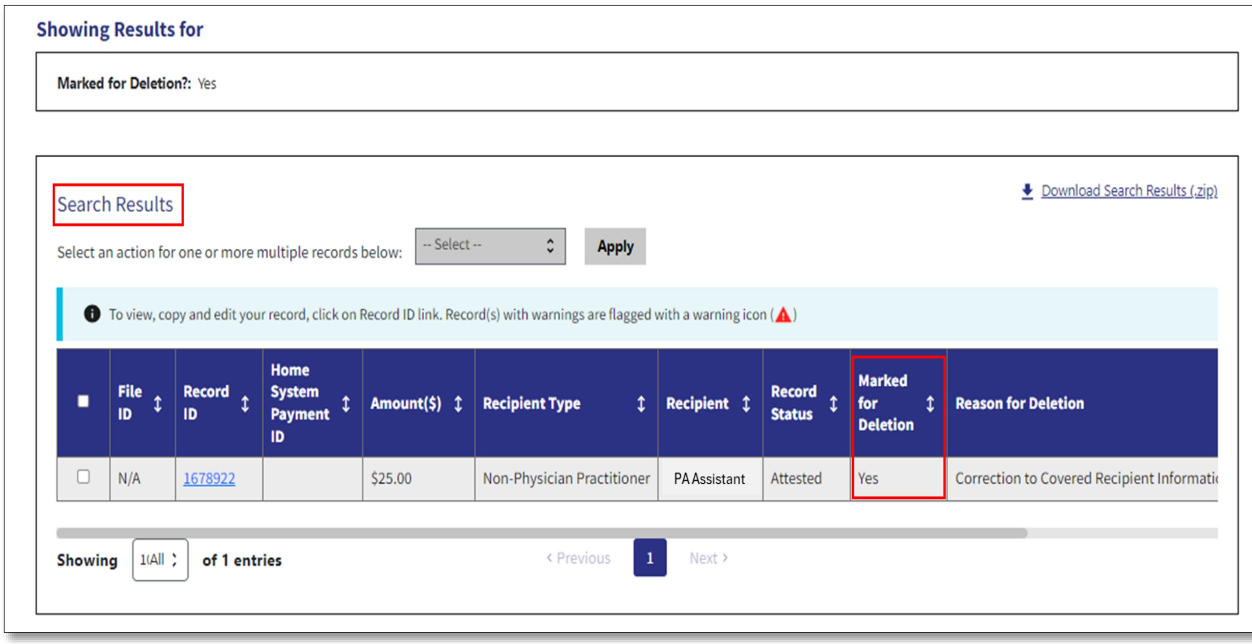
Figure 263: Advanced Search Filters: Marked for Deletion Checkbox



Step 5: Review the filtered records in the "Search Results" table and determine your next steps per role below:

- For Submitters, notify the attester to attest the marked for deletion records and remove them from the system.
- For Attesters, perform attestation on the marked for deletion records to remove them from the system; refer to section 4.15b Attesting to Data in the Open Payments System.

Figure 264: Search Results Table: Records Marked for Deletion

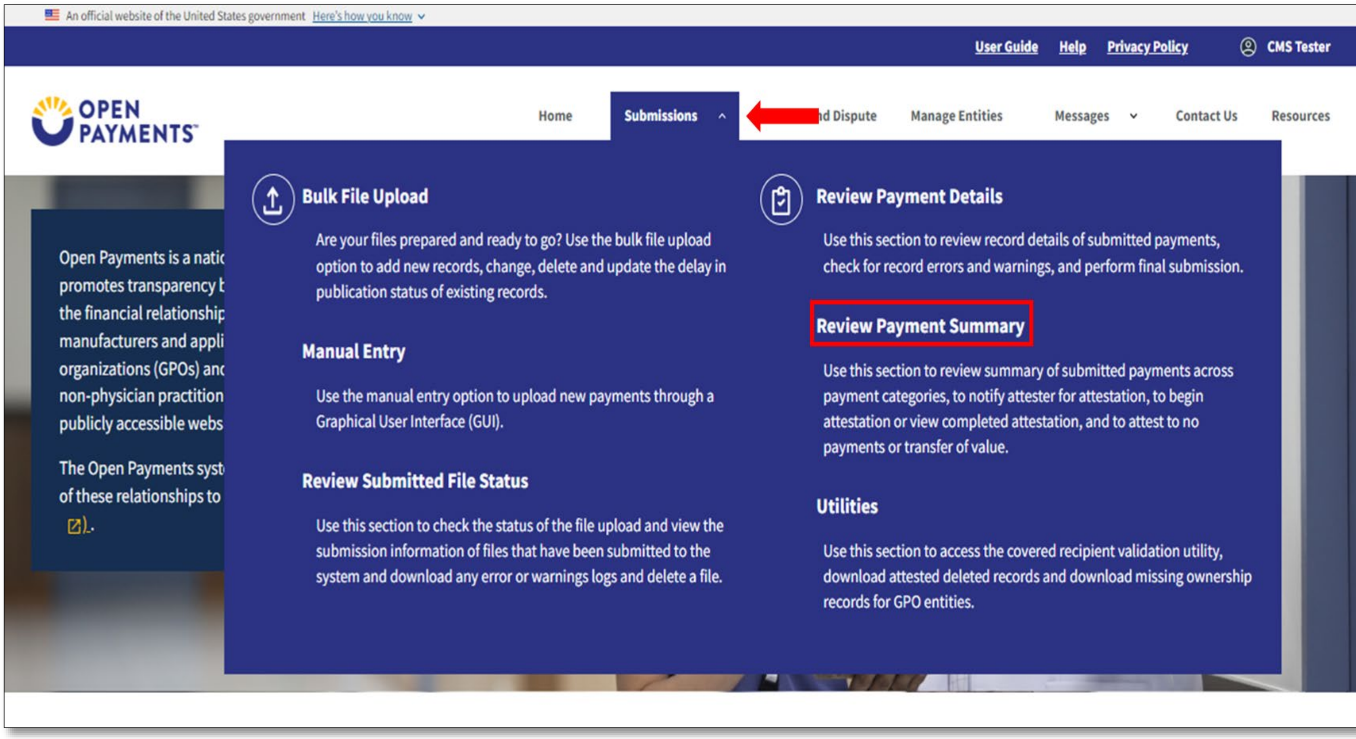


Section 4.11: Final Submission of Data

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.

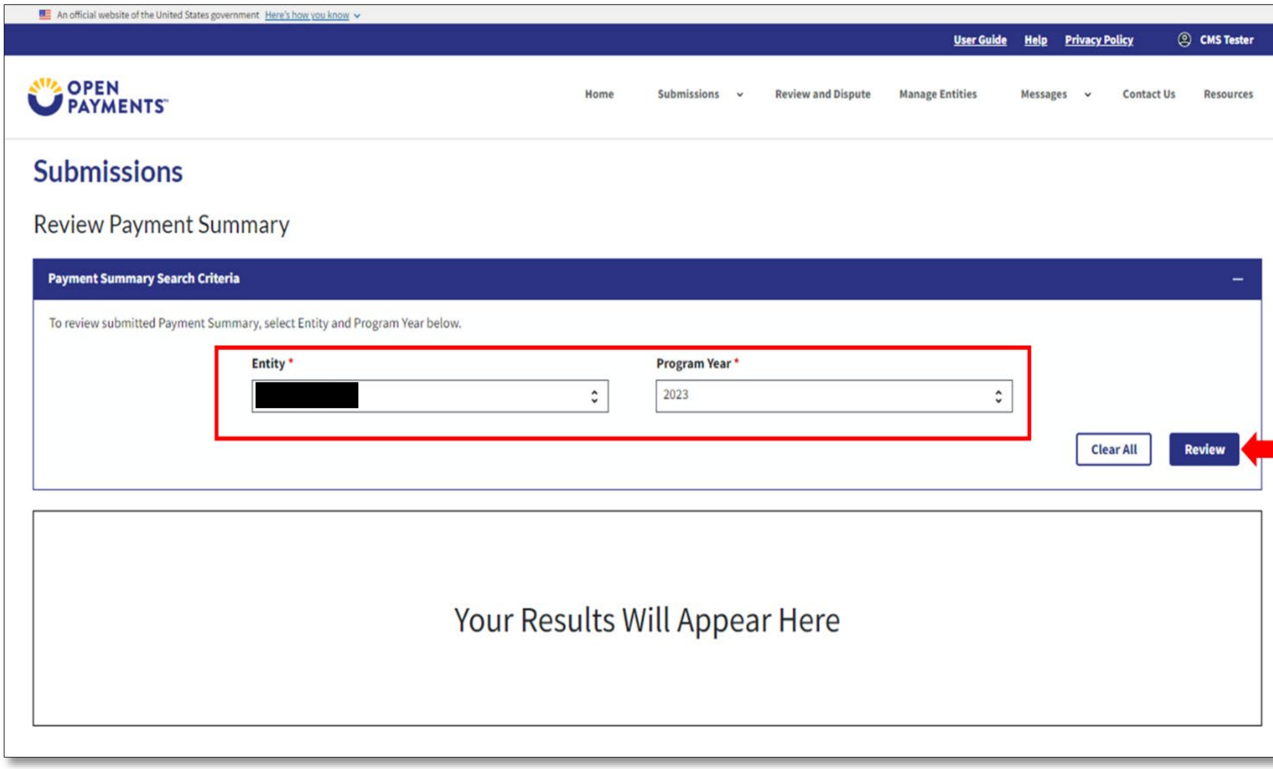
Step 1: Log in to the Open Payments system, select the **Submissions** tab on the toolbar, and then select **Review Payment Summary**.

Figure 265: Submissions Tab: Review Payment Summary



Step 2: Select the entity and program year from the drop-down list for which the payments were uploaded and select the **Review** button.

Figure 266: Payment Summary Search Criteria: Review Button



Step 3: Review the summary of all records that have been submitted for that entity. The three payment categories will be in separate sections. In each section is a series of statuses, number of records currently in that status for the entity, and the next action required.

The numbers displayed are for all records submitted for the entity to date for that program year. The statuses are the following:

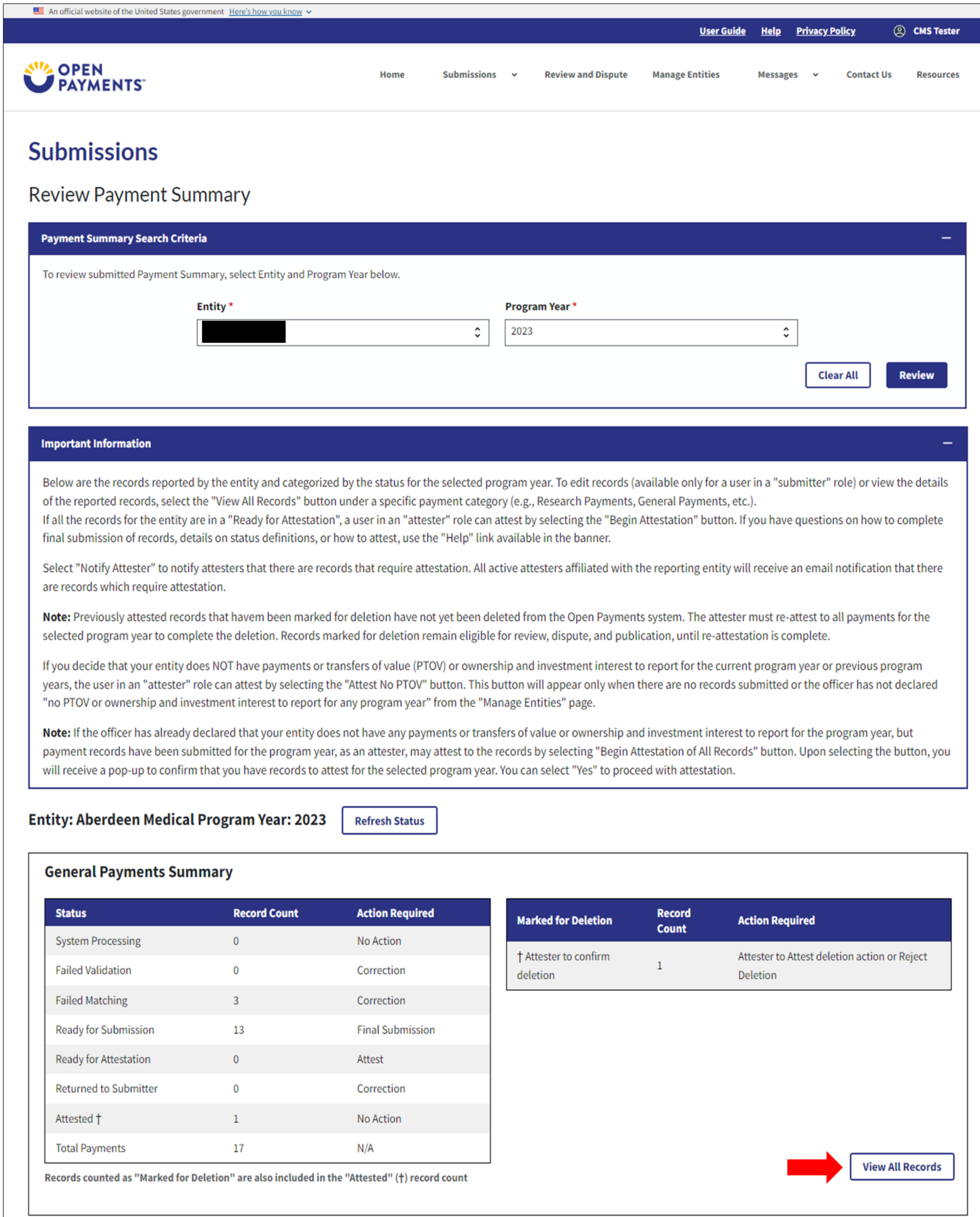
Figure 267: Record Statuses

Record Status	Definition
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 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.

Record Status	Definition
Total Payments	Total number of records in the Open Payments system for that reporting entity and payment type.
Marked for Deletion	Records that have been previously attested to and have been selected for deletion.

Step 4: Select the payment category for which you wish to perform final submission and select the **View All Records** button to proceed.

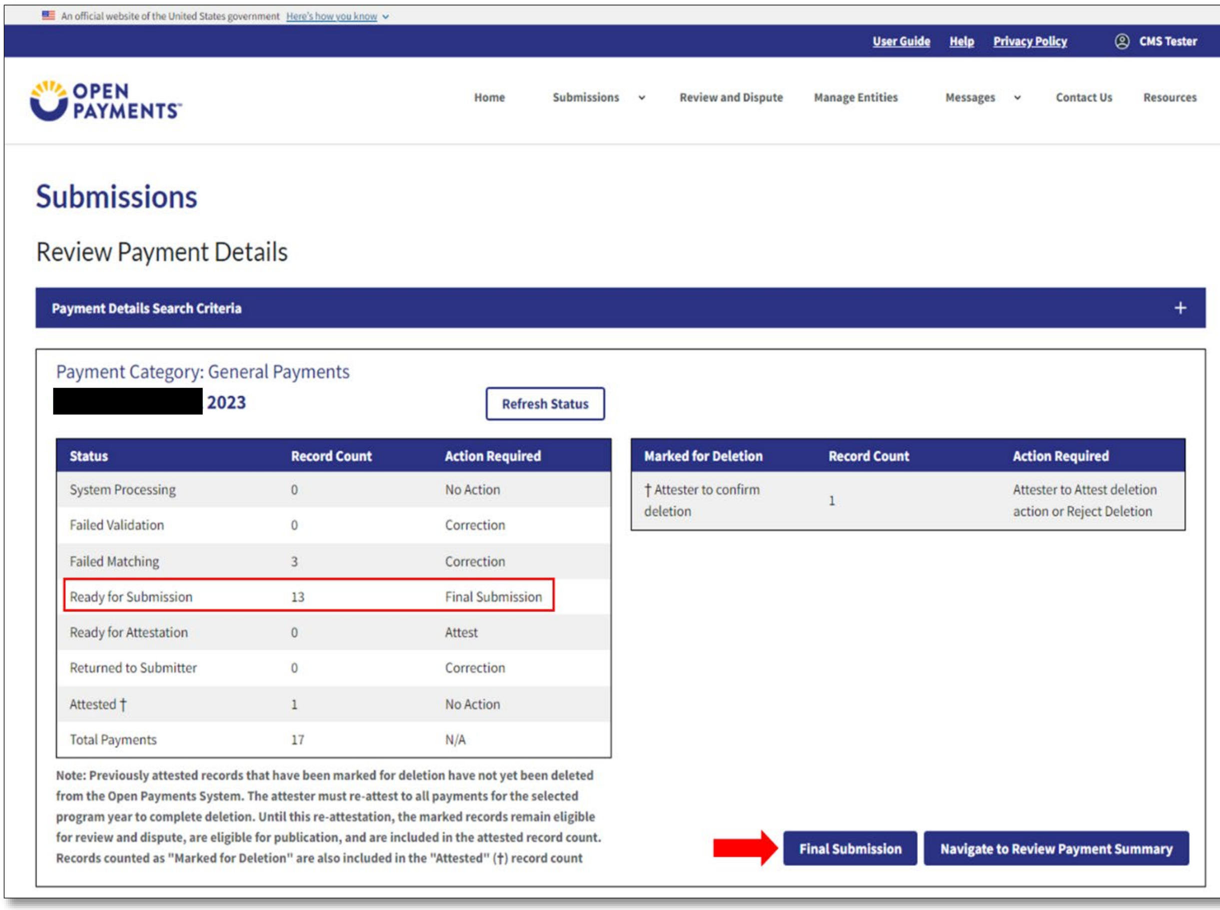
Figure 268: General Payments Summary Example: View All Records Button



Step 5: Select the **Final Submission** button.

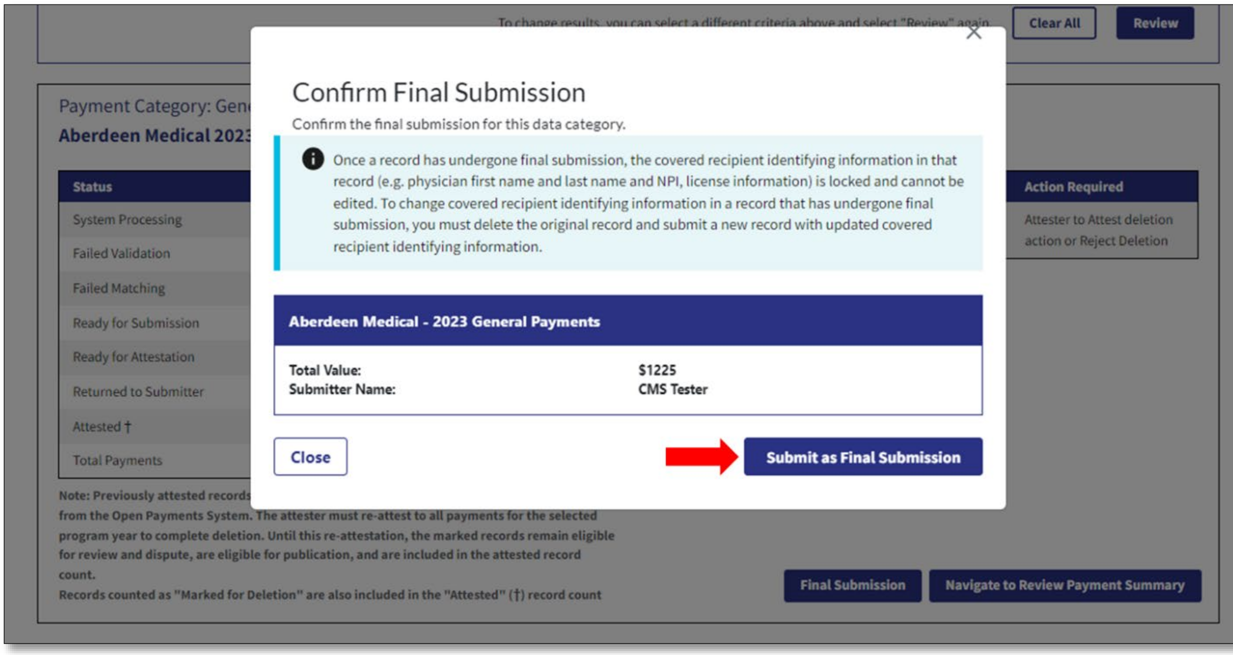
Note the **Final Submission** button will only be visible if at least one record is in "Ready for Submission" status and no record for the same payment category is in "System Processing" status. If this button is not visible, review the record's status in the "Status" column and make sure that at least one record is in "Ready for Submission" status.

Figure 269: General Payments Sample: Final Submission Button



Step 6: Review the summary details of your final submission in the confirmation pop-up window. If those details are correct, select the **Submit as Final Submission** button.

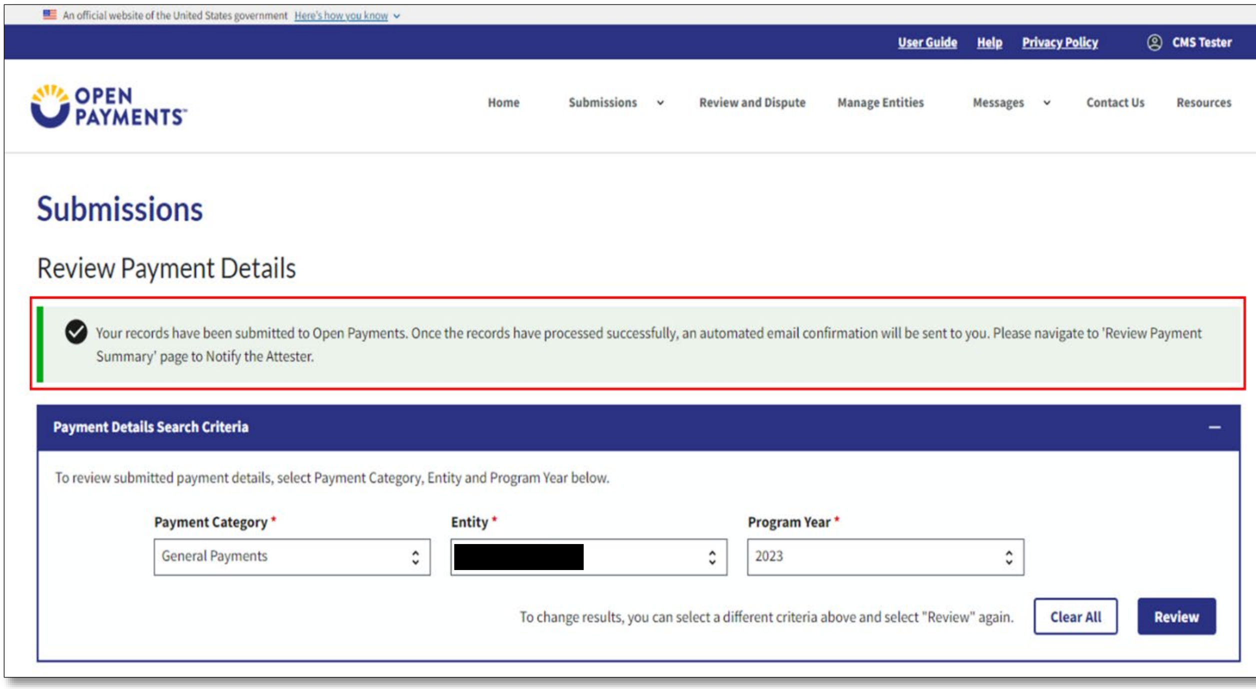
Figure 270: Confirm Final Submission Window



The Final Submission process can take several hours to complete, especially during peak submission times.

Step 7: Confirm you received the green confirmation message on top of the "Record Payment Details" page stating the records were successfully submitted. You will also receive an automated email notifying you that the final submission was successfully processed.

Figure 271: Review Payment Details Page: Final Submission Successful Confirmation Message



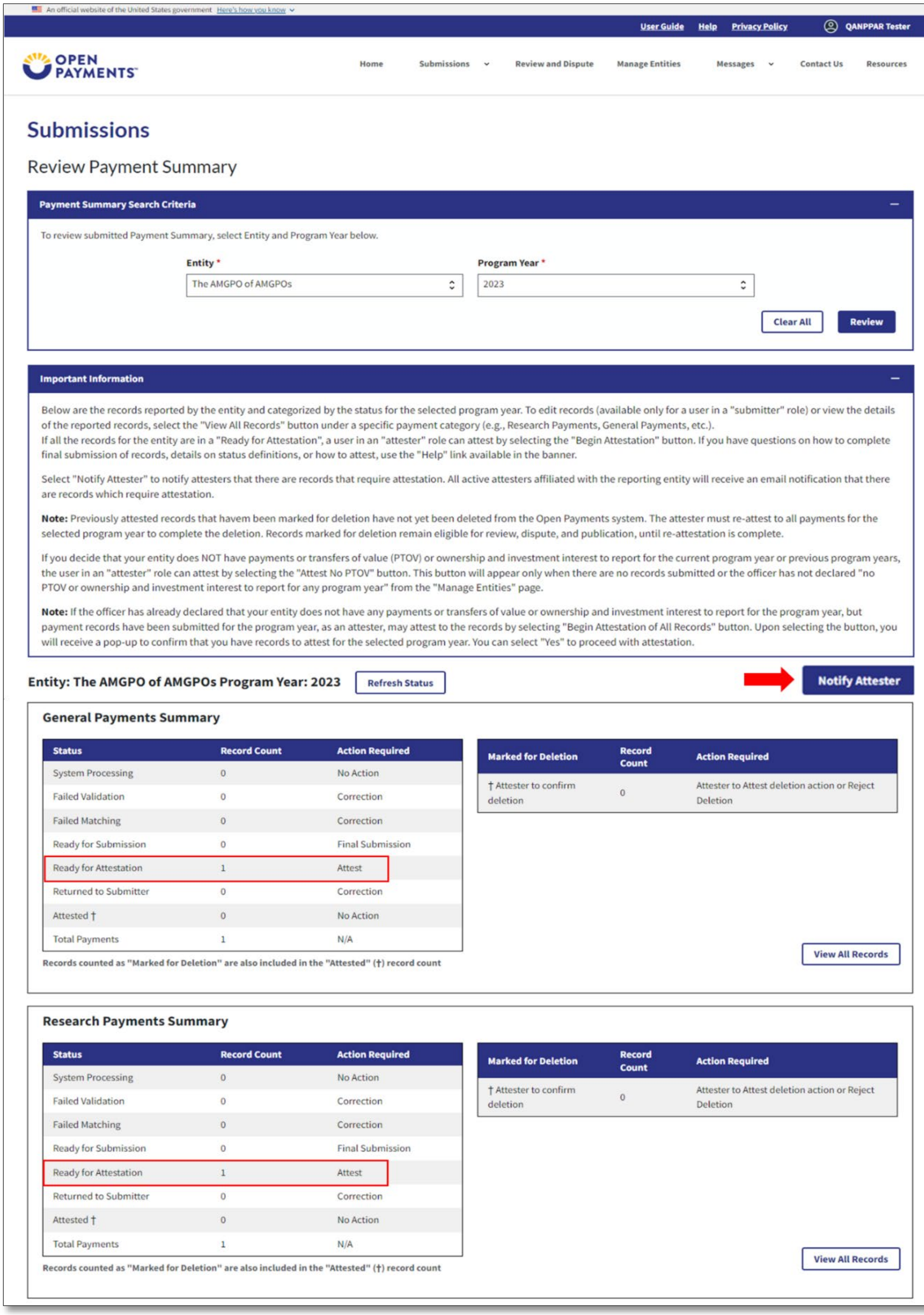
Step 8: Repeat the final submission process for all three payment categories. Once all records are in "Ready for Attestation" status, proceed to Step 9.

If you hold the Attester role, please follow the instructions in Section 4.15 to complete attestation.

Step 9 (if applicable): Navigate to the "Review Payment Summary" page and select the **Notify Attester** button once ALL submitted records from the same program year are ready for the attester to review (e.g., all records are in "Ready for Attestation" status), to send an email notification to the attester informing them there are records ready for attestation.

The **Notify Attester** button will only be enabled if there are records in "Attested" or "Ready for Attestation" status.

Figure 272: Review Payment Summary: Notify Attester Button



Section 4.12: Delay in Publication

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 for 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 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 of 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.

The delay in publication indicator is found on the "Research Payment or Other Transfer of Value Information" page.

Ownership/investment and General records cannot be delayed.

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 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 of 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 4.11 for guidance on final submission and Section 4.15 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 Open Payments system at https://openpayments.system.cms.gov. Select the **Submissions** tab on the header menu.

Step 2: Click the "Review Payment Details" hyperlink on the "Submissions" header menu, and select the payment type, entity whose records you wish to review and the program year for those records. Select "Review" button.

Step 3: Search for the records eligible for renewal on the Research payment category page by using the "Delay in Publication Indicator" filter above the data table to search for records with a Delay in Publication status of either "Pending Renewal - R&D on New Product" or "Pending Renewal - C.I. on New Product." You may also select any other search filter(s) as appropriate.

4.12c (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.

- This process can only be performed on records in "Ready for Submission", "Ready for Attestation," or "Attested" record status.
- 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").
- 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.

- 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.
    - To renew a delay in publication: Set the indicator to '1' if you are requesting a delay because the record relates to research and development on a new product, or '2' if you are requesting a delay because the record relates to clinical investigation on a new product.
    - To indicate a delay is no longer requested: Set the indicator to '3,' which indicates no delay is requested.

Step 2: Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials, select the "Submissions" tab on the toolbar and select "Bulk File Upload".

Step 3: 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 Files 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 attestation of the records for that program year. Refer to Section 4.11 for instructions on final submission and Section 4.15 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.

Step 2: Log in to the Open Payments system, select the "Submissions" tab on the toolbar and select "Bulk File Upload".

Step 3: 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 Files 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 attestation of the records for that program year. Refer to Section 4.11 for instructions on final submission and Section 4.15 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, select the "Submissions" tab on the toolbar and select "Review Payment Details".

Step 2: Select the payment category, entity, and the program year for those records you want to update delay in publication indicator. Select the "Review" button.

Step 3: Locate the record you wish to update in the data table; use the Advanced Search Filters tool, if necessary. Select "Record ID" from the "Record ID" column for that record.

Step 4: Select the "Edit" button.

Step 5: Navigate to the "Research Payment or Other Transfer of Value Information" page; use the navigation bar and select "Payments" to go directly to this page.

Step 6: Update the Delay in Publication of Research Payment Indicator, with one of the two options below:

- 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."
- 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 7: Select "Continue" until you reach the "Review and Save" page, and then "Review & Save" button to save the changes.

Step 8: Complete the submission process by putting the record through final submission and attesting to the records for that program year. Refer to Section 4.11 for instructions on the final submission and Section 4.15 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 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 4.12c (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 Section 4.12c (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, select the “Submissions” tab on the toolbar and select “Review Payment Details”.

Step 2: Select the payment category, entity, and the program year for those records you want to update delay in publication indicator. Select the “Review” button.

Step 3: Locate the record you wish to update in the data table; use the Advanced Search Filters tool, if necessary.

Step 4: Select the checkbox in the first column of the data table for the record you need update delay in publication and select “Apply".

Step 5: Select the “Update Delay Indicator” option in the “Select an action for one or more multiple records below” drop down box.

Step 6: 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 7: Complete the submission process by putting the file through final submission and attesting to the records for that program year. Refer to Section 4.11 for instructions on the final submission and Section 4.15 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.

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.

Within the Open Payments system, consolidated report payment records are affiliated with the individual entities that made the payment and published as though the information had been submitted by them, not the entities that submitted the records

The “Record ID” hyperlink, on the “Review Payment Details” page provides 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, follow the steps below. The entity names and registration IDs in the records must match exactly those provided during Open Payments registration.

Step 1: Create a CSV bulk file(s) for the type of payment category (general, research, or ownership/investment) that will contain payment data from all the reporting entities in the consolidated report.

Step 2: Provide the submitting entity's name and registration ID in the fields "Applicable Manufacturer or Applicable GPO Name" and "Applicable Manufacturer or Applicable GPO Registration ID."

Figure 273: General Payments File Example: AMGPO Name and Registration ID

	A	B	C	D
1	APPLICABLE_MANUFACTURER_OR_APPLICABLE_GPO_NAME	APPLICABLE_MANUFACTURER_OR_APPLICABLE_GPO_ID	CONSOLIDATED_REPORT_INDICATOR	RESUBMISSION_FILE_INDICATOR
2	Entity A	111111111111	Y	
3	Entity A	111111111111	Y	
4	Entity A	111111111111	Y	
5	Entity A	111111111111	Y	
6	Entity A	111111111111	Y	
7	Entity A	111111111111	Y	
8	Entity A	111111111111	Y	
9	Entity A	111111111111	Y	
10	Entity A	111111111111	Y	
11	Entity A	111111111111	Y	

Step 3: Set the "Consolidated Indicator" field, under column C, to "Y" for each record. Note the "Consolidated Indicator" will be the same column for all three of the payment category CSV file templates.

Figure 274: General Payments File Example: Consolidated Indicator Field

	A	B	C	D
1	APPLICABLE_MANUFACTURER_OR_APPLICABLE_GPO_NAME	APPLICABLE_MANUFACTURER_OR_APPLICABLE_GPO_ID	CONSOLIDATED_REPORT_INDICATOR	RESUBMISSION_FILE_INDICATOR
2	Entity A	111111111111	Y	
3	Entity A	111111111111	Y	
4	Entity A	111111111111	Y	
5	Entity A	111111111111	Y	
6	Entity A	111111111111	Y	
7	Entity A	111111111111	Y	
8	Entity A	111111111111	Y	
9	Entity A	111111111111	Y	
10	Entity A	111111111111	Y	
11	Entity A	111111111111	Y	

Step 4: Provide the making payment entity's name and registration ID 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.

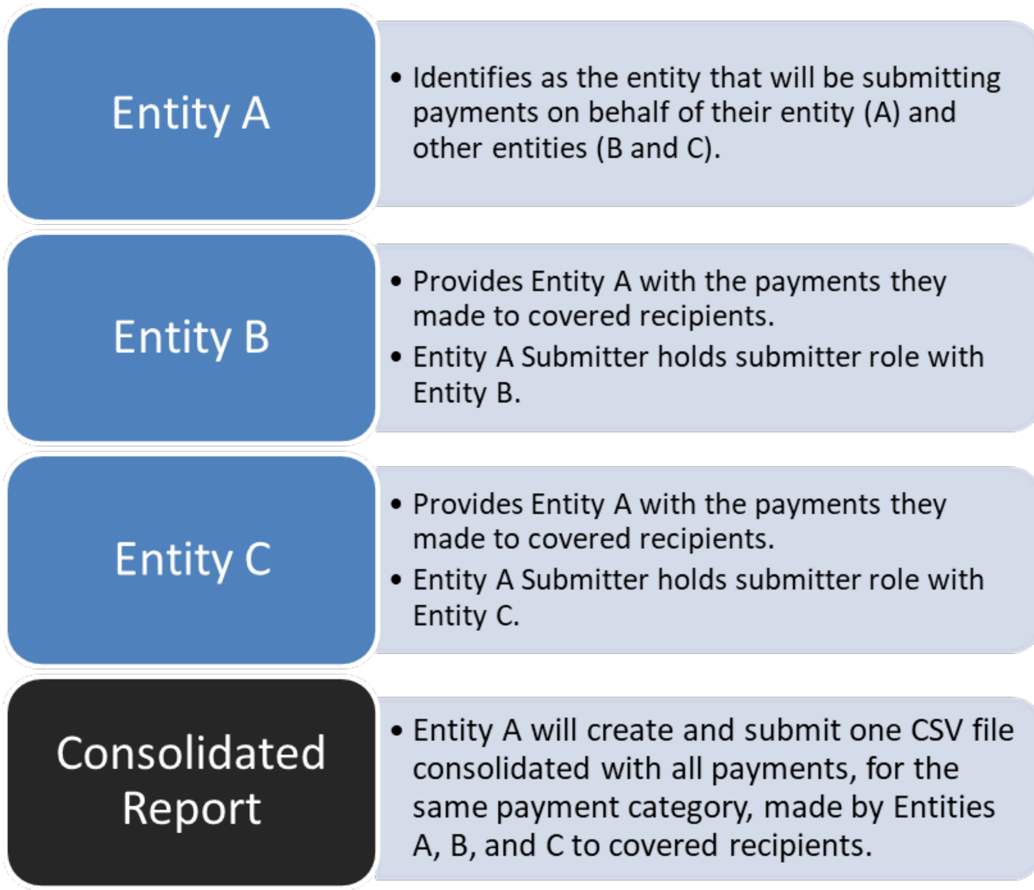
Figure 275: General Payments File Example: AMGPO Making Payment Name and Registration ID

BH	BI	BJ
APPLICABLE_MANUFACTURER_OR_APPLICABLE_GPO_MAKING_PAYMENT_NAME	APPLICABLE_MANUFACTURER_OR_APPLICABLE_GPO_MAKING_PAYMENT_REGISTRATION_ID	HOME_SYSTEM_PAYMENT_ID
Entity A	111111111111	Consolidated Reporting A Record 1
Entity A	111111111111	Consolidated Reporting A Record 2
Entity A	111111111111	Consolidated Reporting A Record 3
Entity A	111111111111	Consolidated Reporting A Record 4
Entity B	122222222222	Consolidated Reporting B Record 1
Entity B	122222222222	Consolidated Reporting B Record 2
Entity B	122222222222	Consolidated Reporting B Record 3
Entity C	133333333333	Consolidated Reporting C Record 1
Entity C	133333333333	Consolidated Reporting C Record 2
Entity C	133333333333	Consolidated Reporting C Record 3

<u>Step 6:</u> Once the records are complete, submit the bulk file(s) normally. Note that each entity's records must go through Final Submission and Attestation 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:

Figure 276: Consolidated Report Example



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; no third-party officers, attesters, or compliance users. **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, completeness, and timeliness of the data in the Open Payments system. This applies to all data resubmissions and for the deletion of previously attested records as well.

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

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

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.

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.

Therefore, entities 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 monetary 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 attest the deletion of these 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.

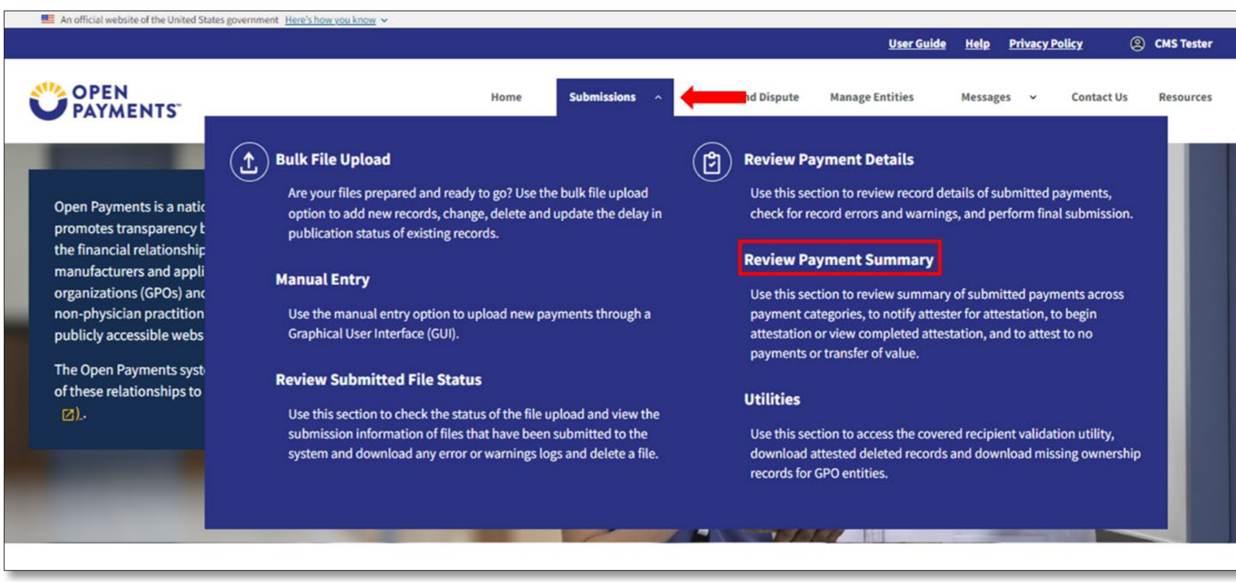
4.15b: Attesting to Data in the Open Payments System

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.

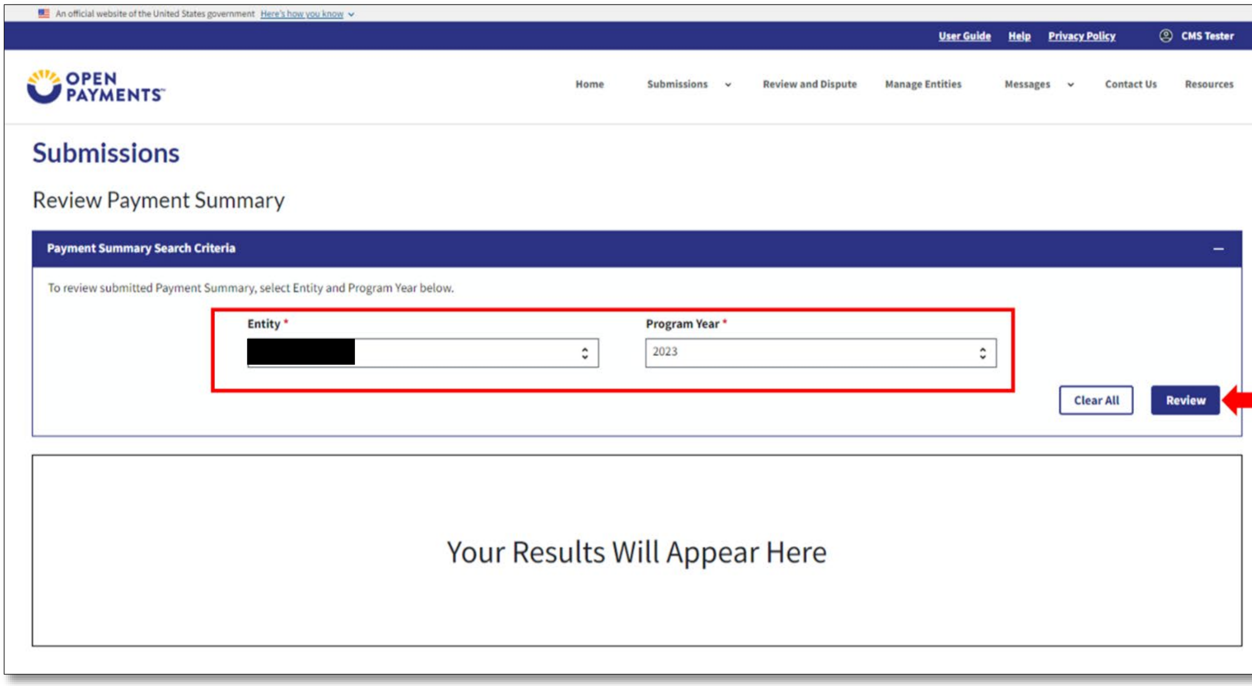
Step 1: Log in to the Open Payments system, select the **Submissions** tab on the toolbar, and then select **Review Payment Summary.**

Figure 277: Submission Tab: Review Payment Summary



Step 2: Select the entity and program year from the drop-down lists and select the **Review** button.

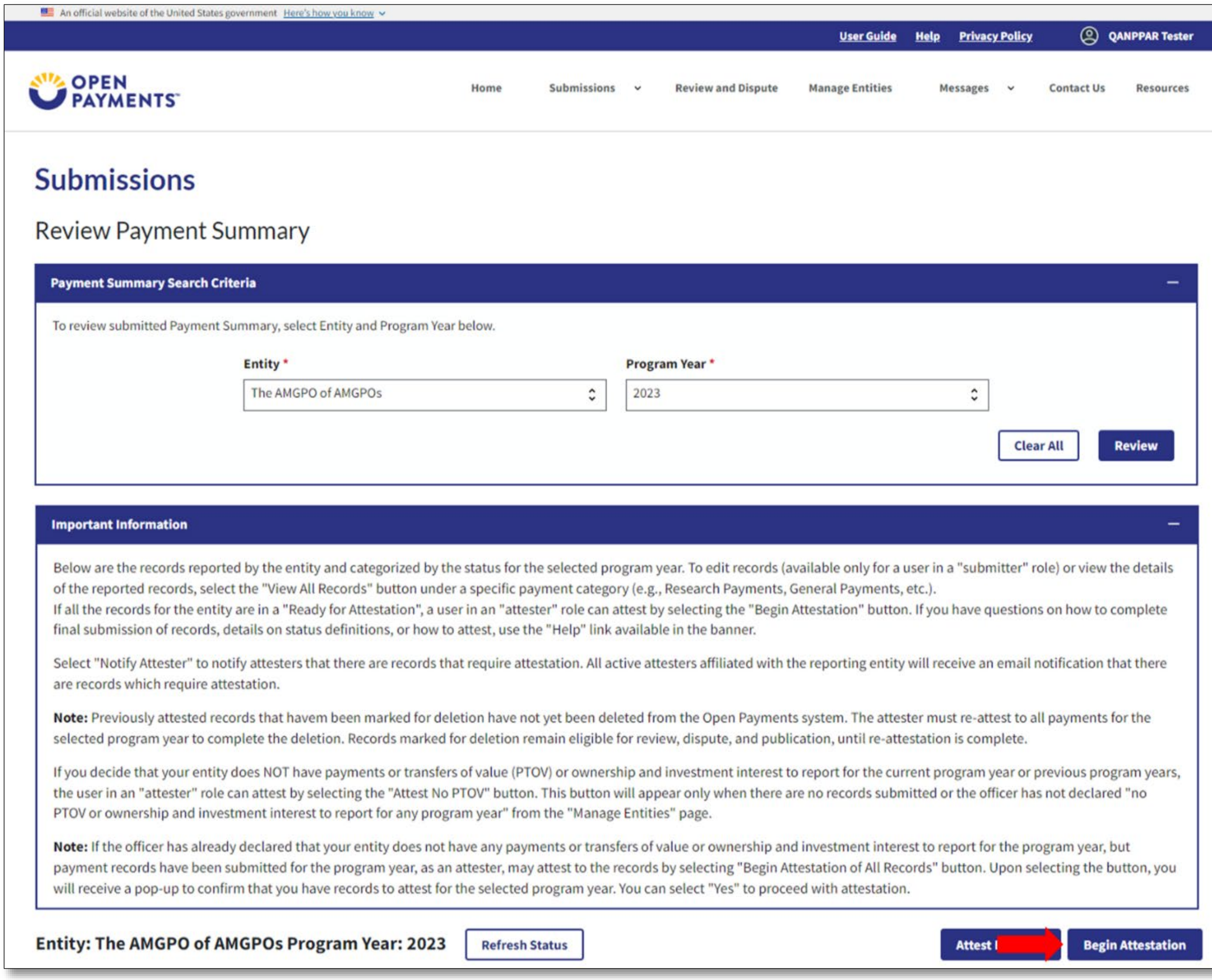
Figure 278: Review Payment Summary



<u>Step 3:</u> Select the **Begin Attestation** button under the "Important Information" section.

If the **Begin Attestation** button is not visible, check that all records for the program year are in "Ready for Attestation" 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).

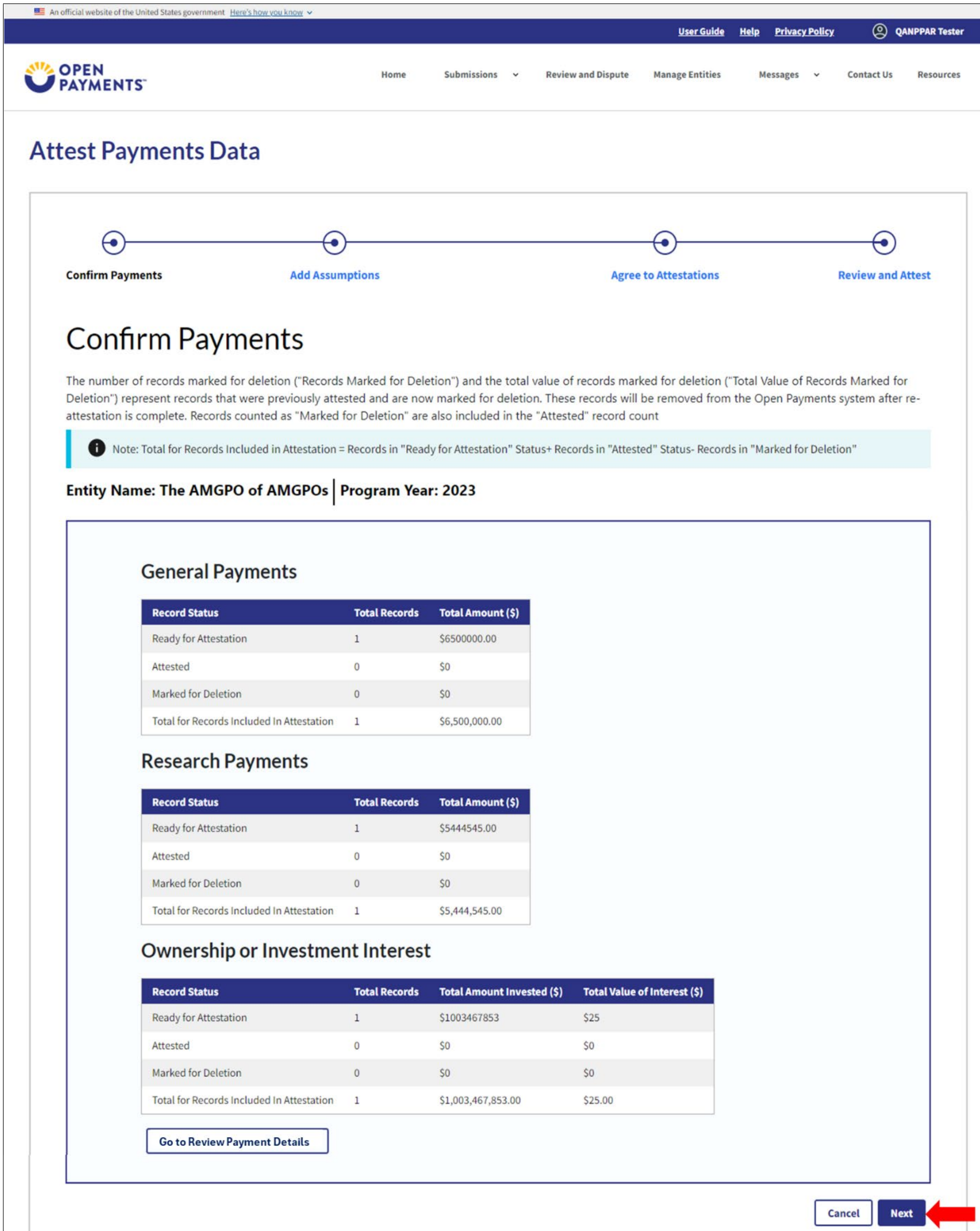
Figure 279: Review Payment Summary: Begin Attestation Button



Step 4: Review the detailed summary of records being attested to for the program year, displayed per payment category and select the **Next** button when you are ready to continue with the attestation process.

If you need to view details on the records being attested, select the **Go to Review Payment Details** button.

Figure 280: Confirm Payments: Next Button



Step 5: Next, the option to add assumptions associated with these records is presented. Select **No** if you will not provide assumptions or select **Yes** if you will provide assumptions.

If you select **Yes**, a free-form text field will appear for you to type your assumptions. If assumptions have previously been entered for these records, those assumptions will be in the text box and can be edited.

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

Figure 281: Add Assumptions: No Radio Button

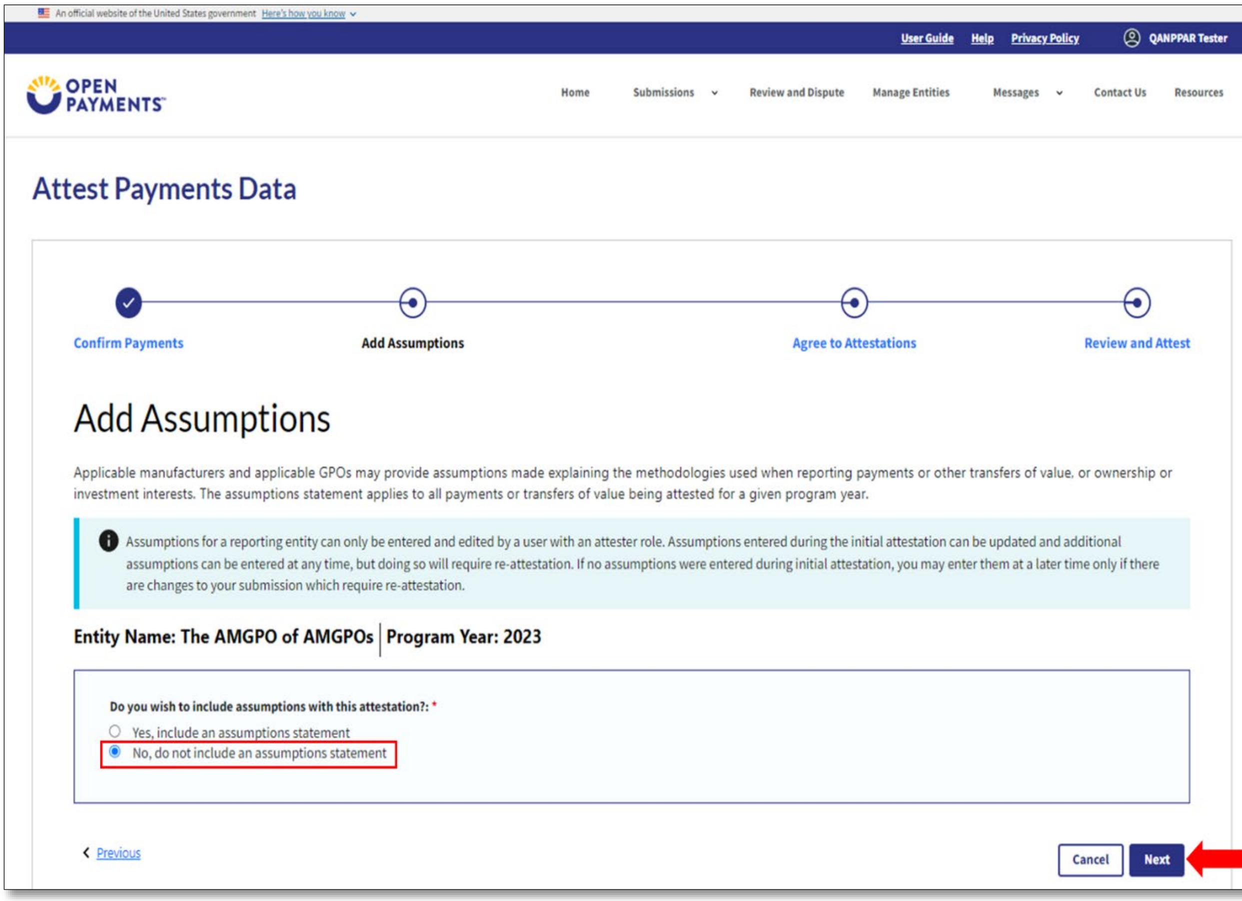
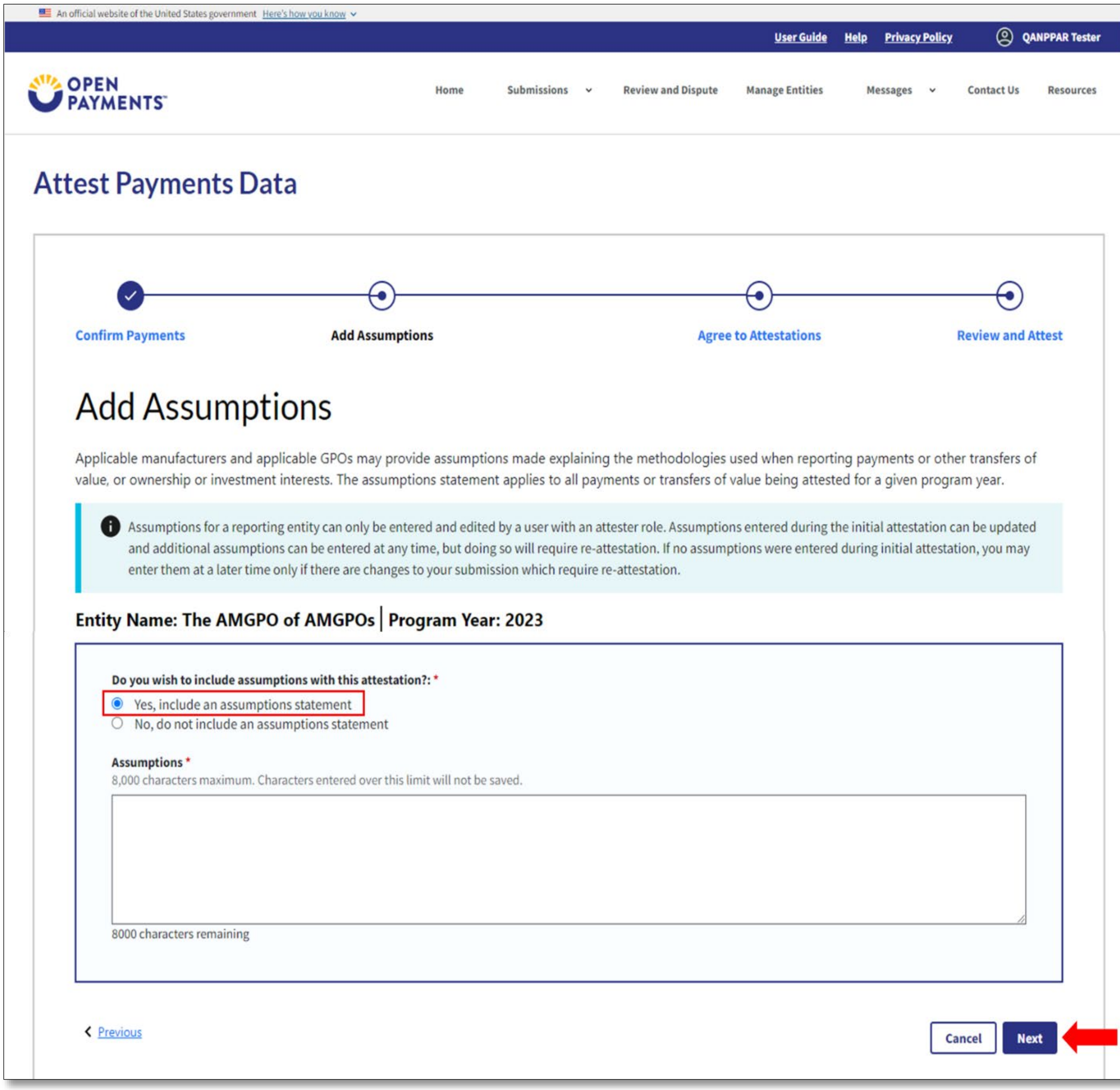


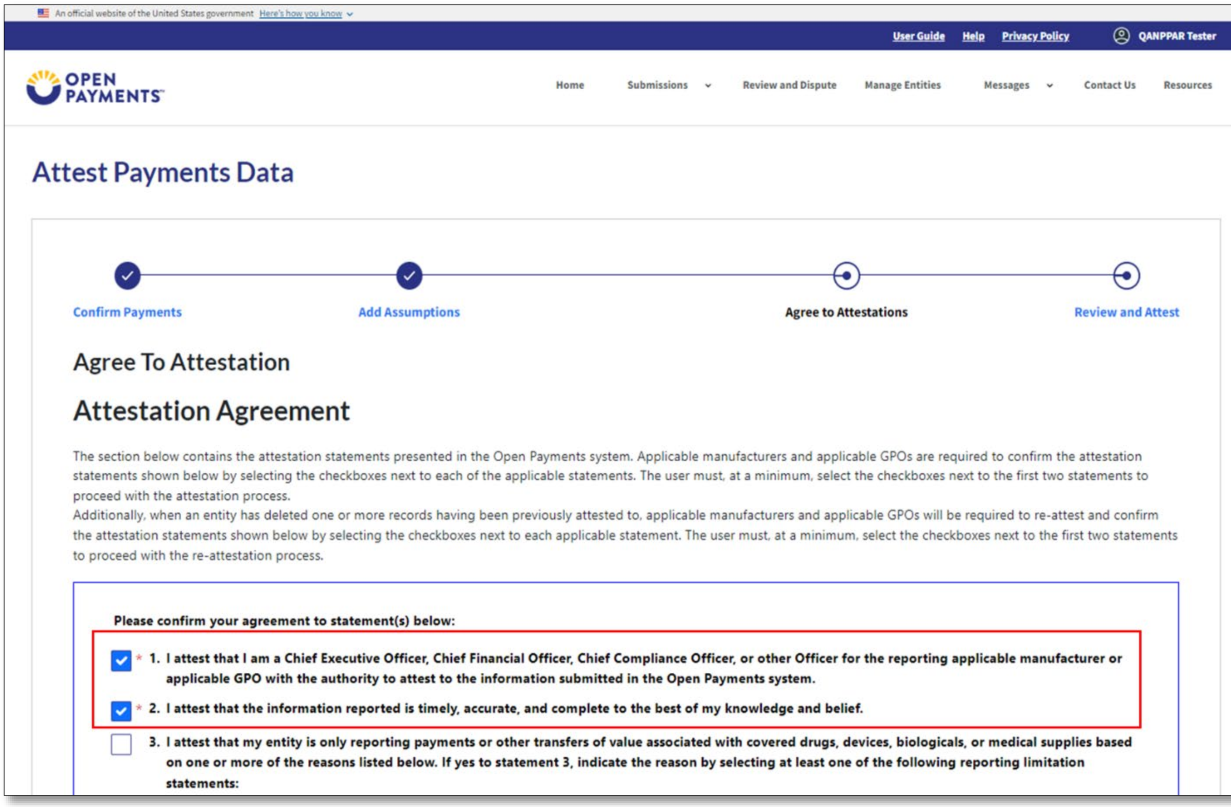
Figure 282: Add Assumptions: Yes Radio Button



<u>Step 6:</u> Read and agree to the attestations shown below. The text of these statements is provided earlier in this section.

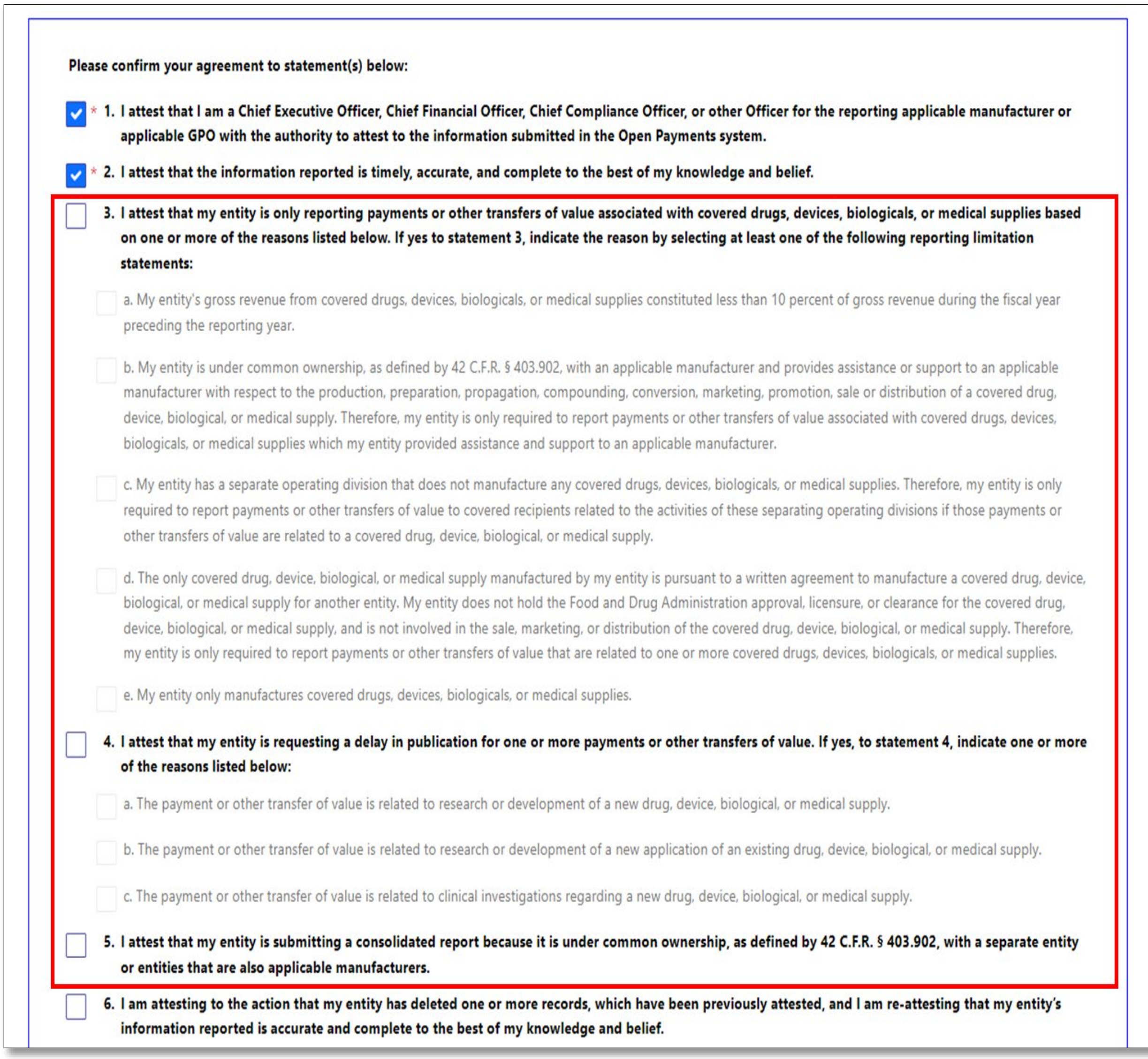
<u>Step 6a:</u> You **must** agree to attestation statements 1 and 2 to complete the attestation process.

Figure 283: Agree to Attestation: Statements 1 and 2



<u>Step 6b:</u> Select attestation statements 3 through 5, only if they apply to your reporting entity and the payments being attested to.

Figure 284: Agree to Attestation: Statements 3 through 5

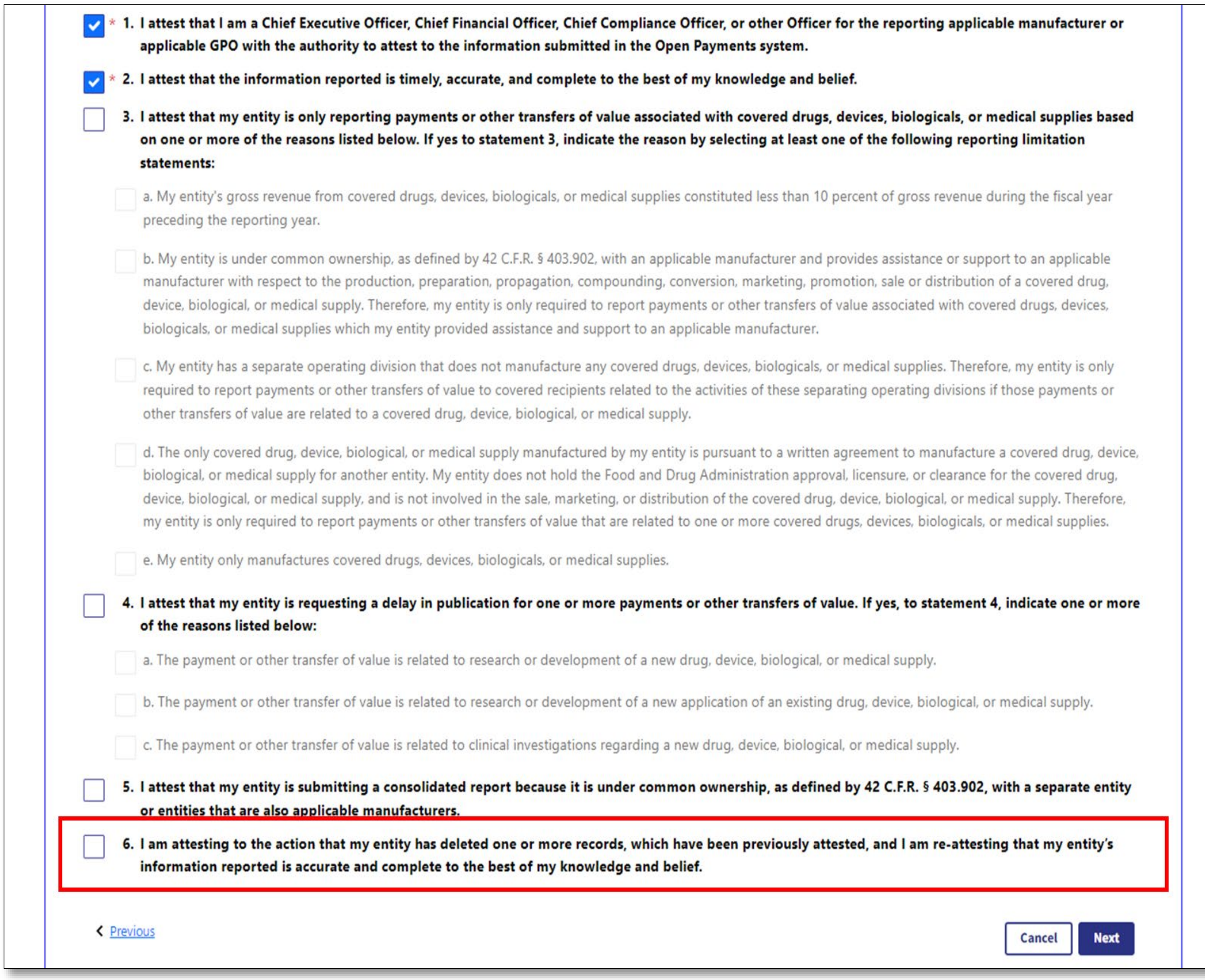


Please confirm your agreement to statement(s) below:

- [x] * 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.
- [x] * 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, 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, indicate one or more of the reasons listed below:
  - [ ] a. The payment or other transfer of value is related to research or development of a new drug, device, biological, or medical supply.
  - [ ] b. The payment or other transfer of value is related to research or development of a new application of an existing drug, device, biological, or medical supply.
  - [ ] c. The payment or other transfer of value is related to clinical investigations regarding a new drug, device, biological, or medical supply.
- [ ] 5. I 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 been previously attested, and I am re-attesting that my entity's information reported is accurate and complete to the best of my knowledge and belief.

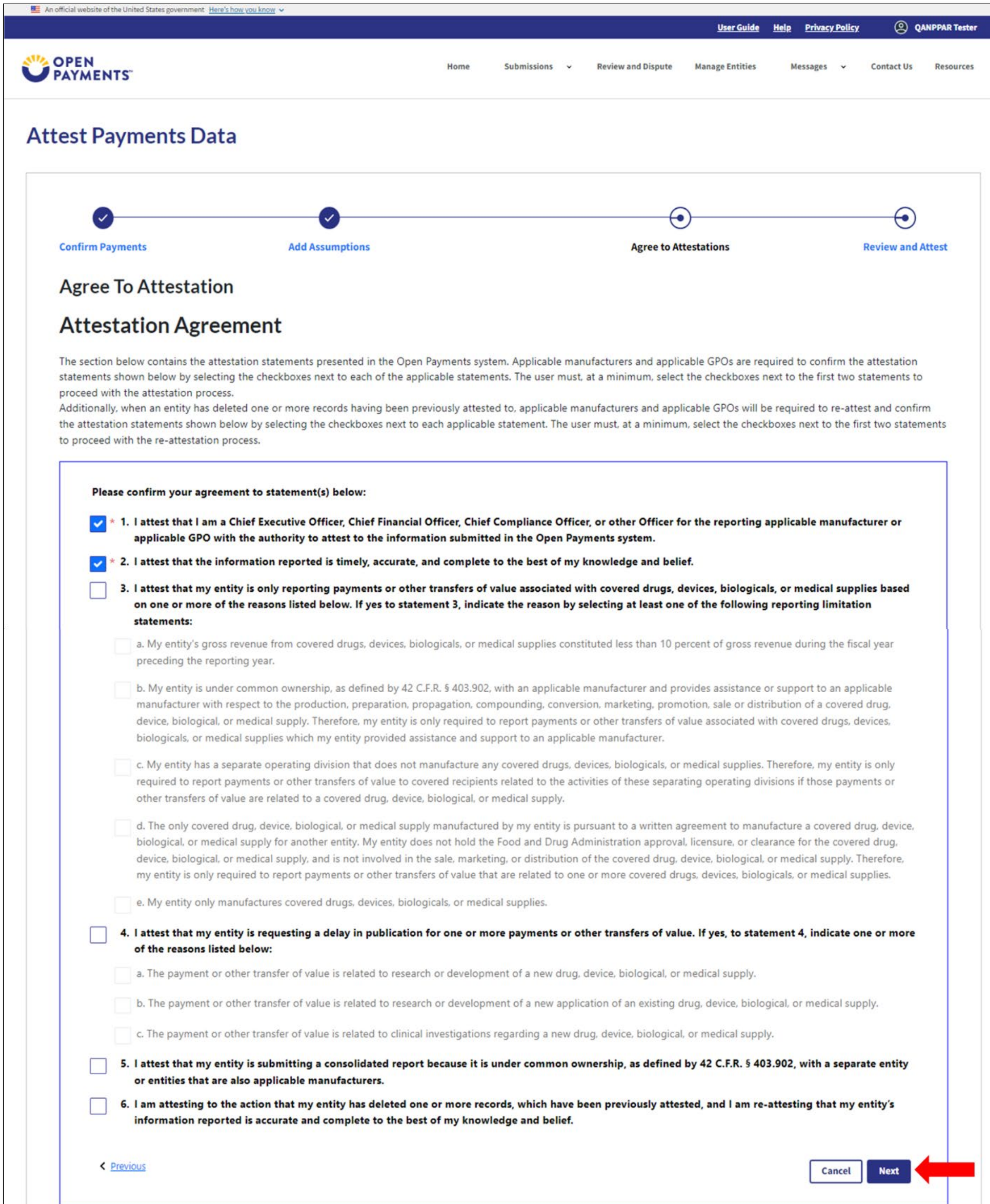
Step 6c: Select attestation statement 6, if you are attesting to the deletion of records, as it is strongly encouraged for this action.

Figure 285: Agree to Attestation: Statement 6



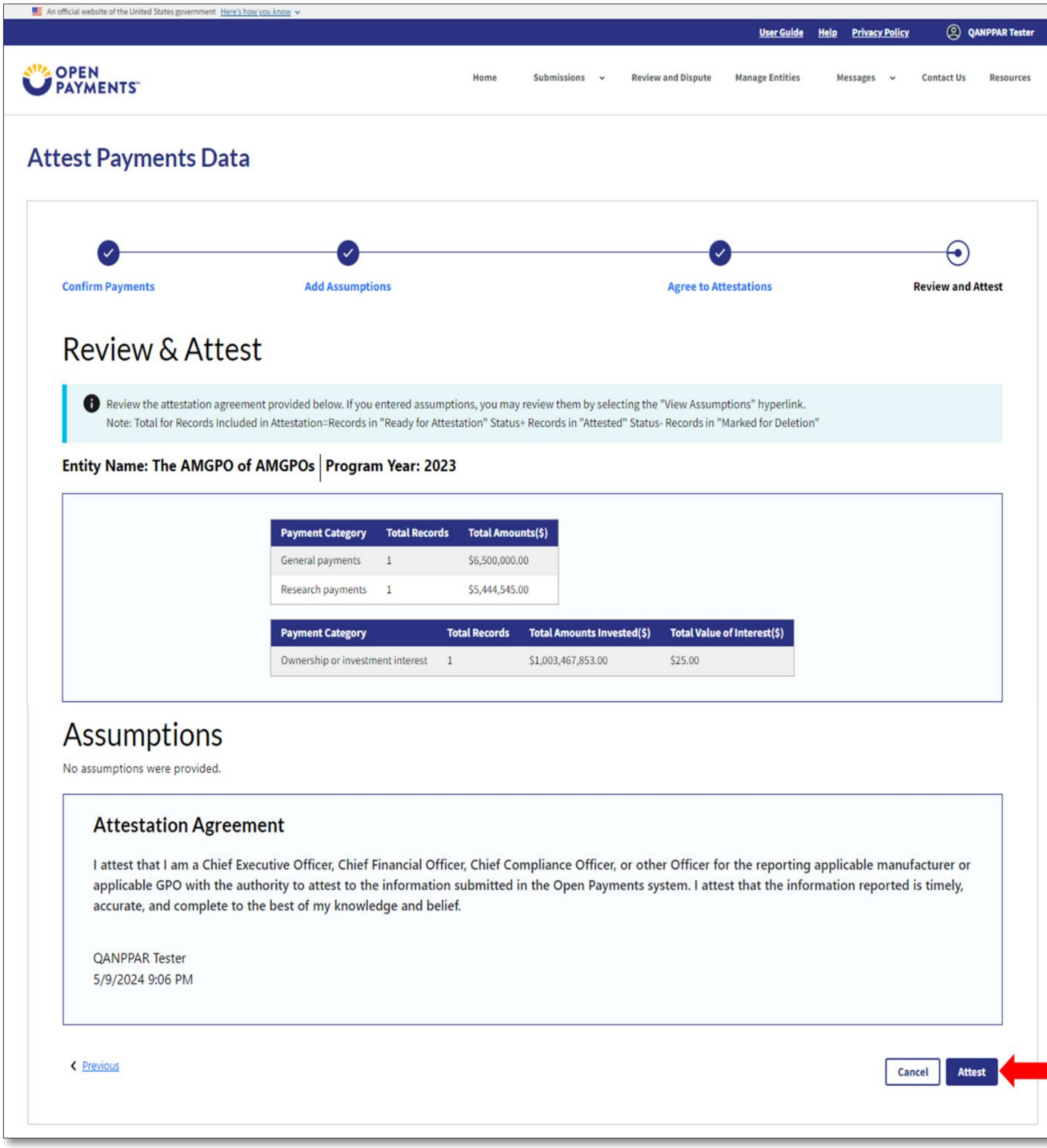
Step 7: Select **Next** button once the appropriate attestation statements have been chosen.

Figure 286: Agree to Attestation: Next Button



Step 8: Review the information entered on the previous pages. If the information is correct, select **Attest** to complete attestation.

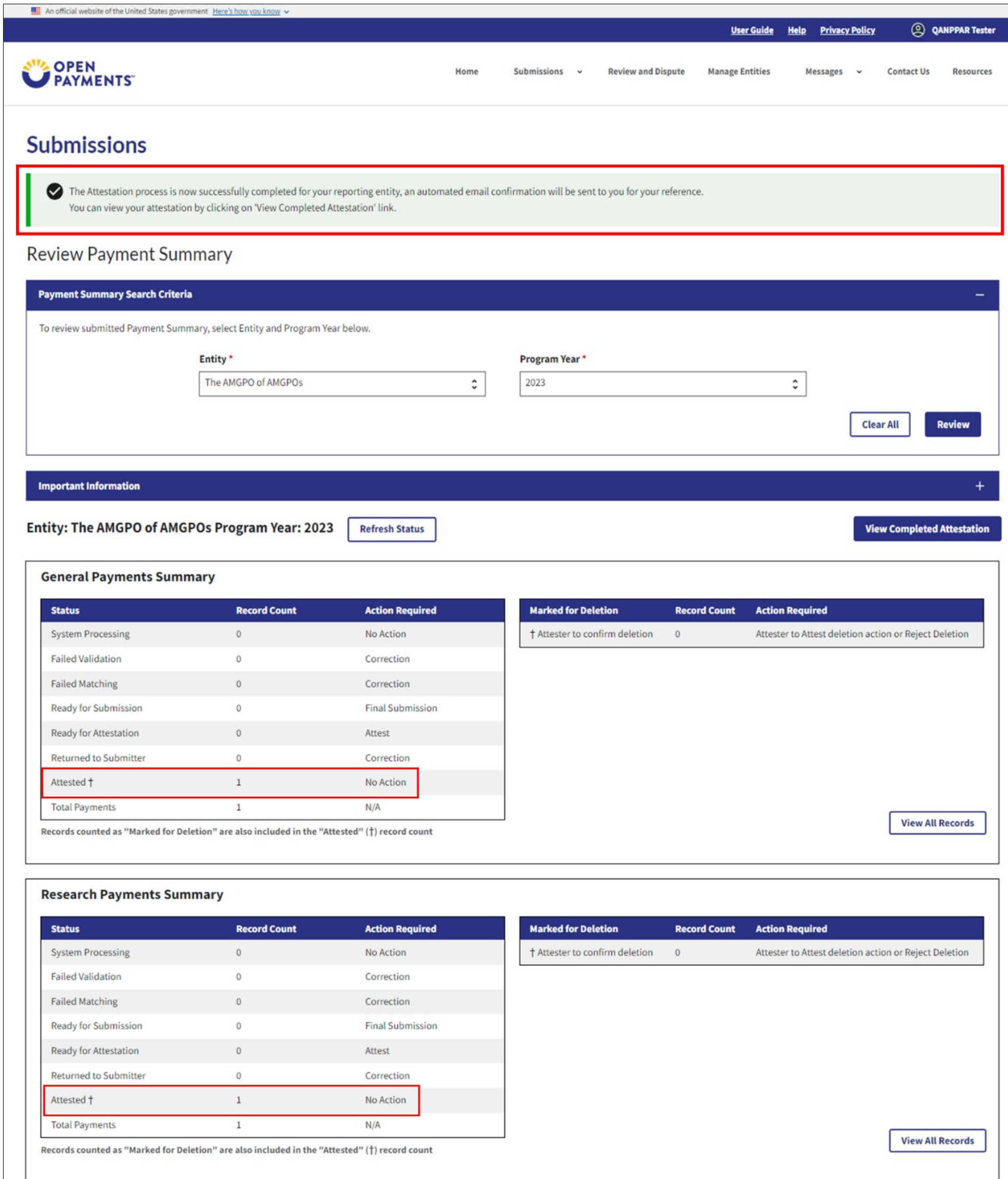
Figure 287: Review & Attest Page: Attest Button



Step 9: Review the confirmation message at the top of the “Review Payment Summary” page that states the attestation process is now successfully completed.

Note the record(s) attested to will appear in the “Attested” column, and Review & Attest Page-> Attest Button the Open Payments system will send an email to all attester(s) notifying them of the success of the attestation.

Figure 288: Review Payment Summary: Attestation Confirmation Message

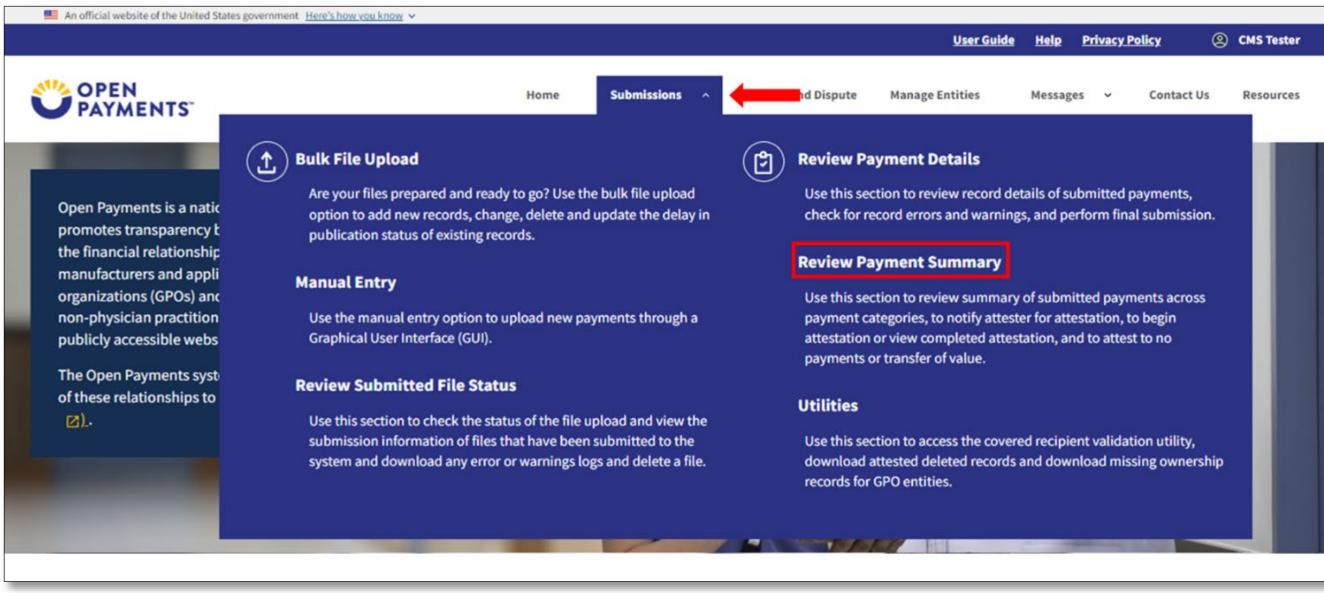


4.15c: Attesting to No Data in the Open Payments System

The following instructions show the step-by-step pages for attesting that the reporting entity has no data. Please note that no records can be in the "Attested" status to complete these steps.

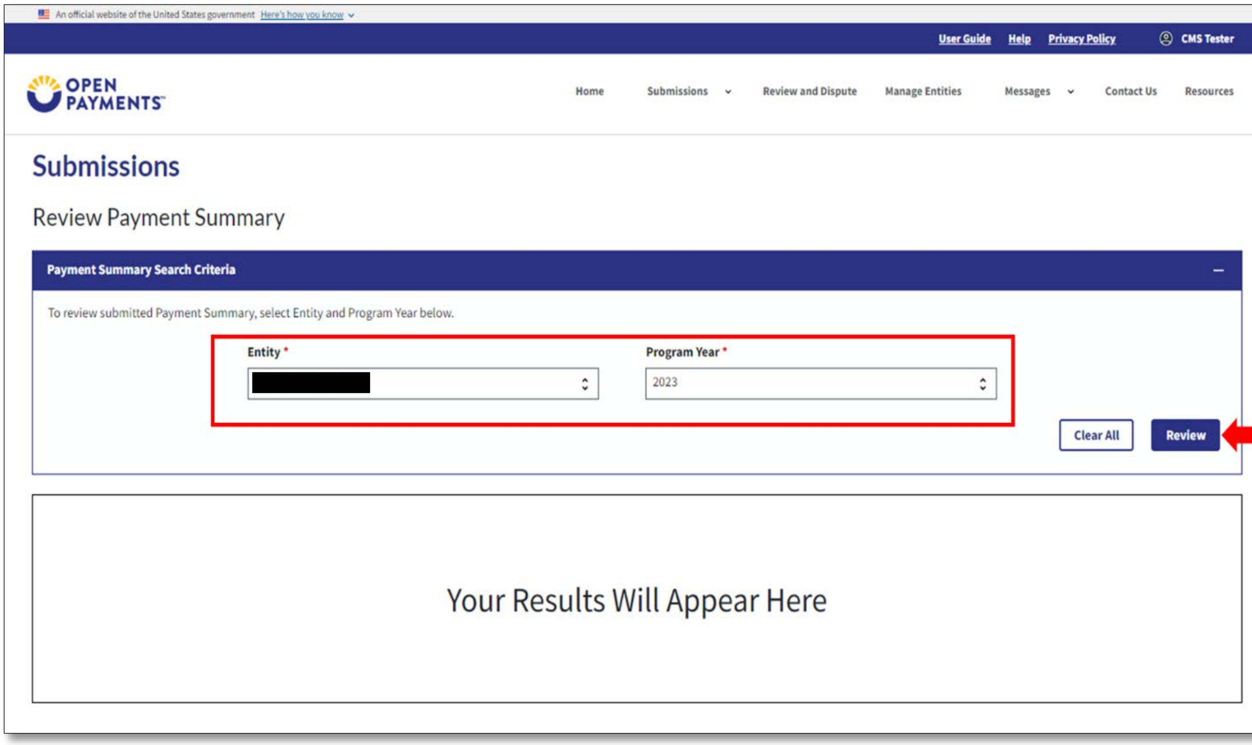
Step 1: Log in to the Open Payments system, select the **Submissions** tab on the toolbar, and then select **Review Payment Summary**.

Figure 289: Submissions Tab: Review Payment Summary



Step 2: Select the entity and program year from the drop-down lists and select the **Review** button.

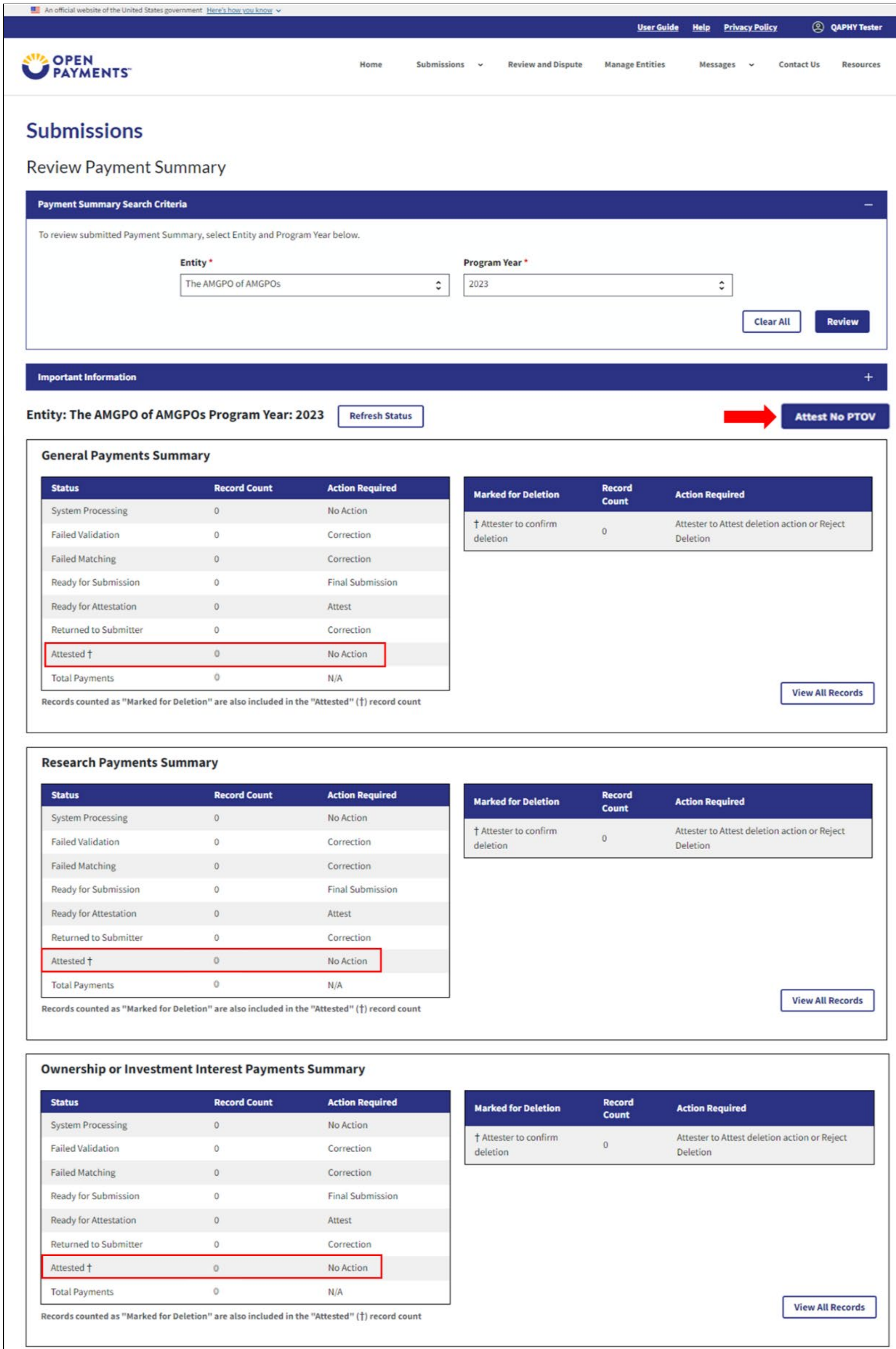
Figure 290: Review Payment Summary



<u>Step 3:</u> Select the **Attest No PTOV** button on the “Review Payment Summary” page.

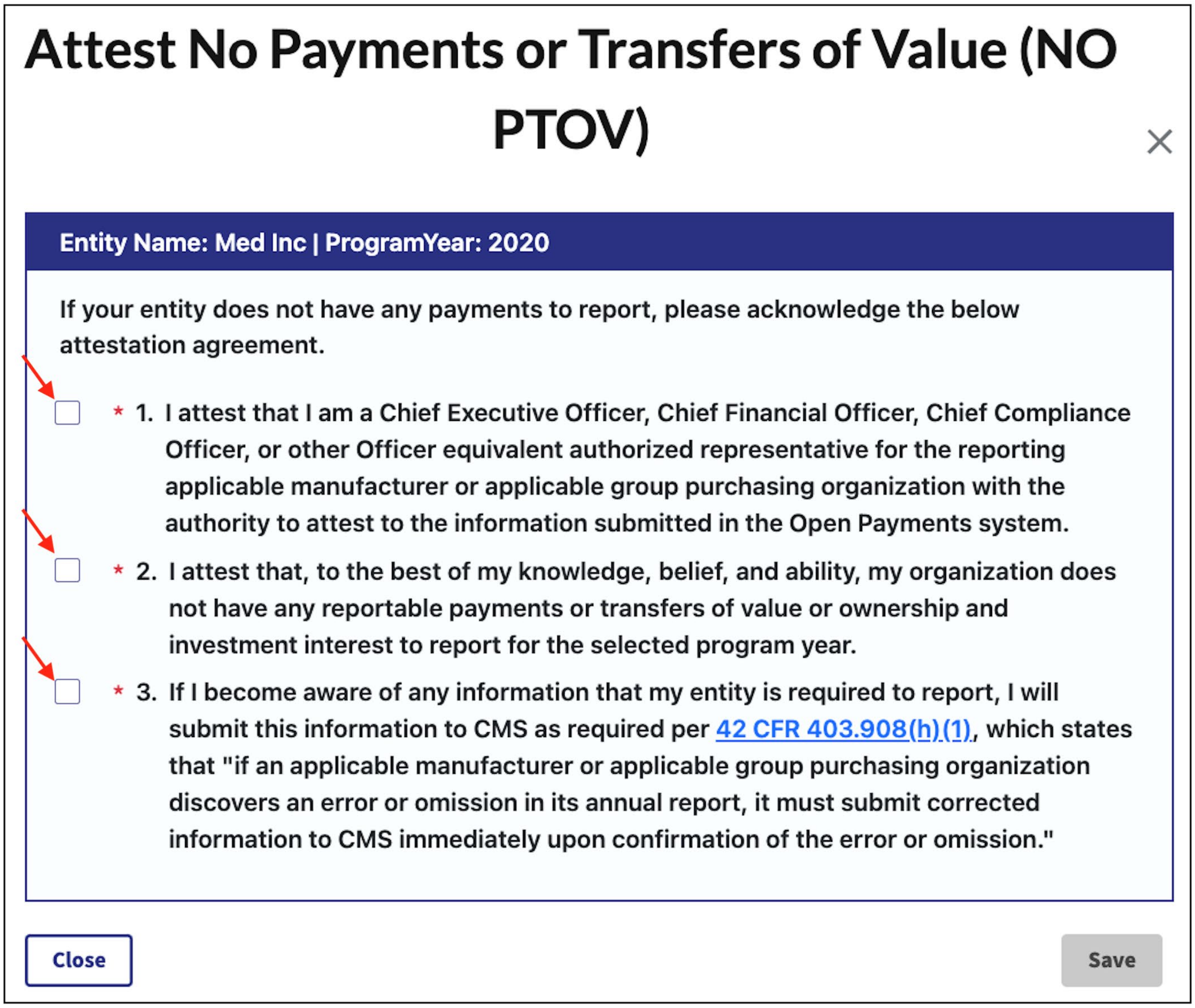
If the **Attest No PTOV** button is not available, check that no records for the program year are in the “Attested” status or the officer has not declared "no PTOV or ownership and investment interest to report for any program year" from the "Manage Entities" page.

Figure 291: Review Payment Summary: Attest No PTOV Button



Step 4: Agree to statements on the "Attestation Agreement" page to complete attestation of no payments or transfers of value by selecting options 1 through 3 and select the **Save** button.

Figure 292: Attestation Agreement



You will be brought back to the "Review Payment Summary" page. A confirmation message will indicate that "You have successfully updated the no PTOV indicator for the Program Year". The Open Payments system will send an email to all attester(s) notifying them of the success of the attestation.

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, NPPs, and teaching hospitals. The "resolved, no change" action acknowledges that the applicable manufacturer or applicable GPO and the physician, NPPs, or teaching hospital 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 covered recipients identified in records have an opportunity to review those records. The covered recipient may affirm the information is correct, or if they find discrepancies with the submitted data, they can initiate a dispute within the Open Payments system. reporting entities can then work with the disputing party to resolve the dispute.

Note: A 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.

Ongoing dispute resolution may take place outside of the Open Payments system.

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).

Reporting entities should work with the disputing party directly to resolve disputes. CMS will not mediate disputes between covered recipients and reporting entities.

The process is outlined in the figure below.

Figure 293: Review, Dispute, and Correction Process

Review Activities	Dispute Activities	Correction Activities
• Covered Recipients may review data submitted about them before it is published, also known as pre-publication Review and Dispute.	• Physicians, NPPs, and teaching hospitals dispute information reported about them or their institutions if they find inaccuracies. • 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 pre-publication review, dispute, and correction period. This period begins with a 45-day period for covered recipients to review, dispute, and work with the reporting entity to resolve the dispute(s). 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 covered recipients.

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/Resources.

If you cannot resolve a dispute with a covered recipient 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, reporting entities must re-submit the record with the revisions to the Open Payments system. Then, the revised record must be re-attested to by the reporting entity 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:

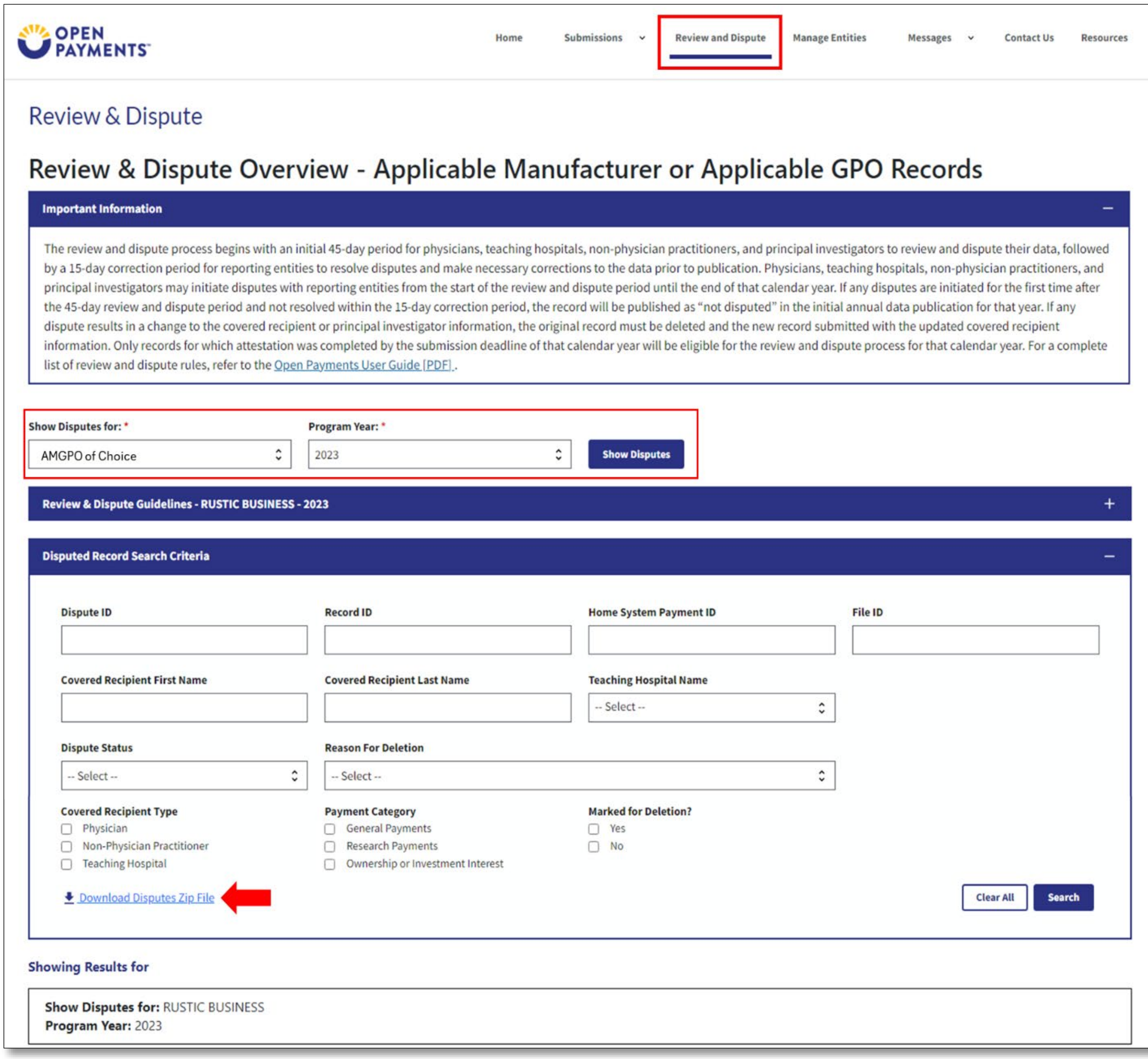
- **Initiated:** Indicates that a covered recipient has initiated a dispute against a record submitted by an applicable manufacturer or applicable GPO.
- **Acknowledged**: Indicates that an applicable manufacturer or applicable GPO has received and acknowledged a dispute initiated against them by a covered recipient.
- **Resolved No Change**: Indicates that the applicable manufacturer or applicable GPO and the covered recipient have resolved the dispute in accordance with the guidance in the Final Rule and no changes were made to the disputed record.
- **Resolved**: Indicates that disputed data was corrected and then re-submitted and re-attested to by the applicable manufacturer or applicable GPO.
- **Withdrawn**: Indicates that a covered recipient has withdrawn a dispute they initiated against a record submitted by an applicable manufacturer or applicable GPO.

5.1c: Exporting Disputed Data

The Open Payments system allows users to download disputed data into a separate CSV file. Records are exported into a pipe ("|") delimited CSV file by selecting the link labeled "Download Disputes" from your entity's "Review and Dispute" page. The file will be compressed into a ZIP file and 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 294: Download Disputes Zip File Hyperlink



Section 5.2: Acknowledging Disputes and Resolving Disputes with No Change

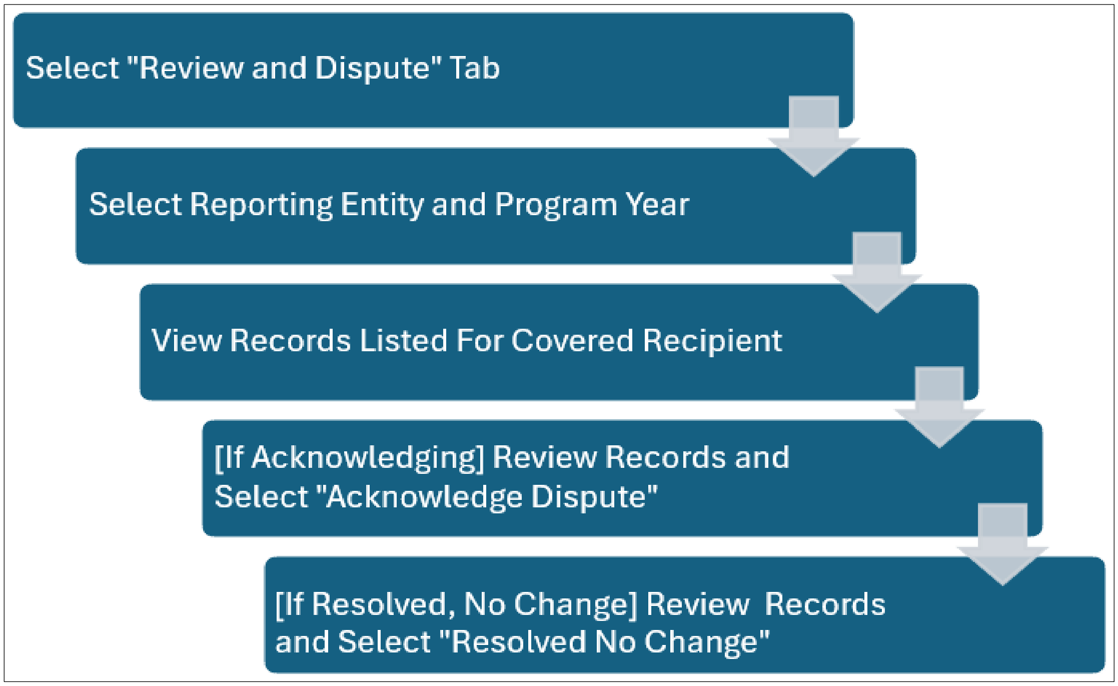
Applicable Manufacturers and Applicable GPOs have the option to acknowledge disputes initiated by covered recipients. This status does not indicate agreement or acceptance of the dispute by the reporting entity and is only meant to serve as a notification to the covered recipient that the dispute has been received by the reporting entity. The acknowledgement email can serve as a receipt, confirming to the disputing party that the dispute has been received.

When the dispute status is changed to “Acknowledged” or “Resolved, No Change,” the covered recipient will receive an email notification of the status update. This email notification may help reduce the chance of a covered recipient 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 covered recipient 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 covered recipient view, only after the record regains "attested" status.

The five steps of the process are given in the figure below.

Figure 295: Acknowledging Disputes and Resolving Disputes with No Change Process

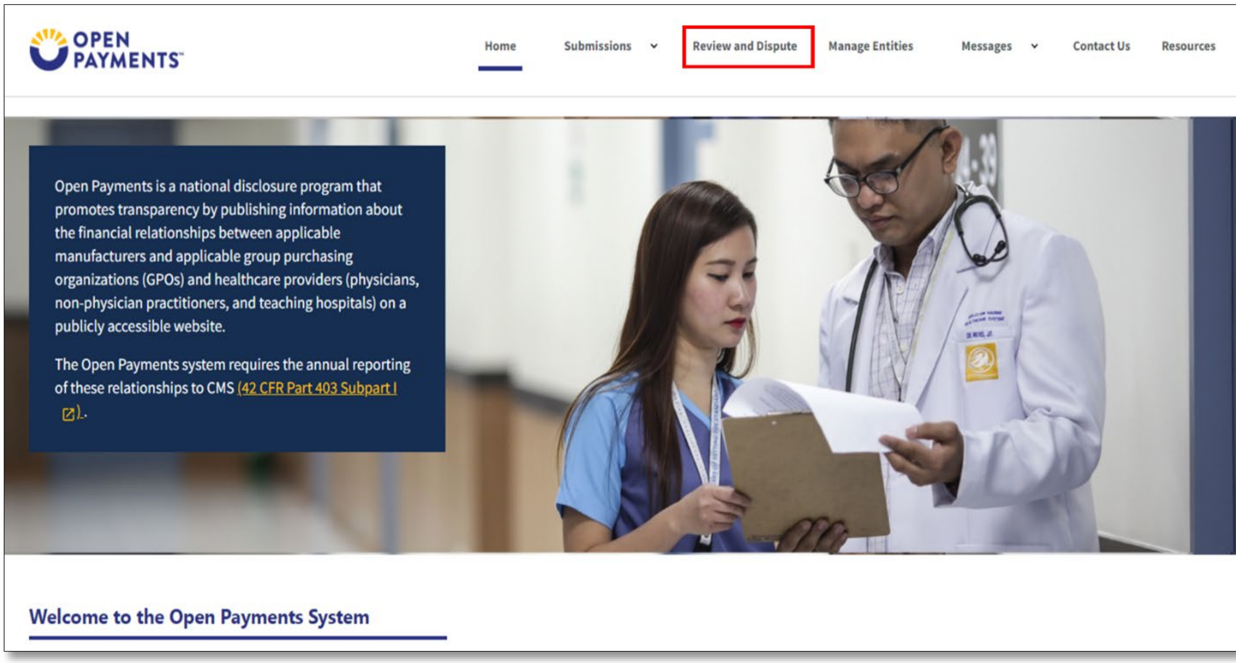


The specific steps to acknowledge a dispute and to set a disputed record to the status of "Resolved, No Change," are given below.

5.2a: Acknowledging a Dispute

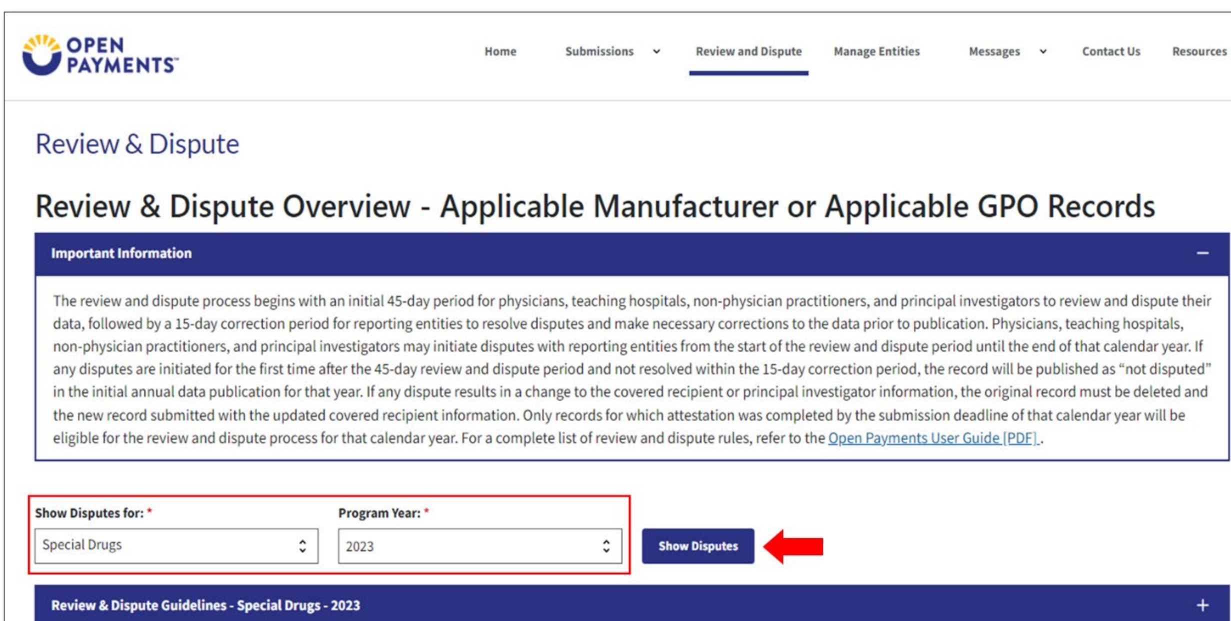
<u>Step 1:</u> Log in to the Open Payments system and select the **Review and Dispute** tab on the tool bar.

Figure 296: Open Payments System Home Page: Review and Dispute Tab



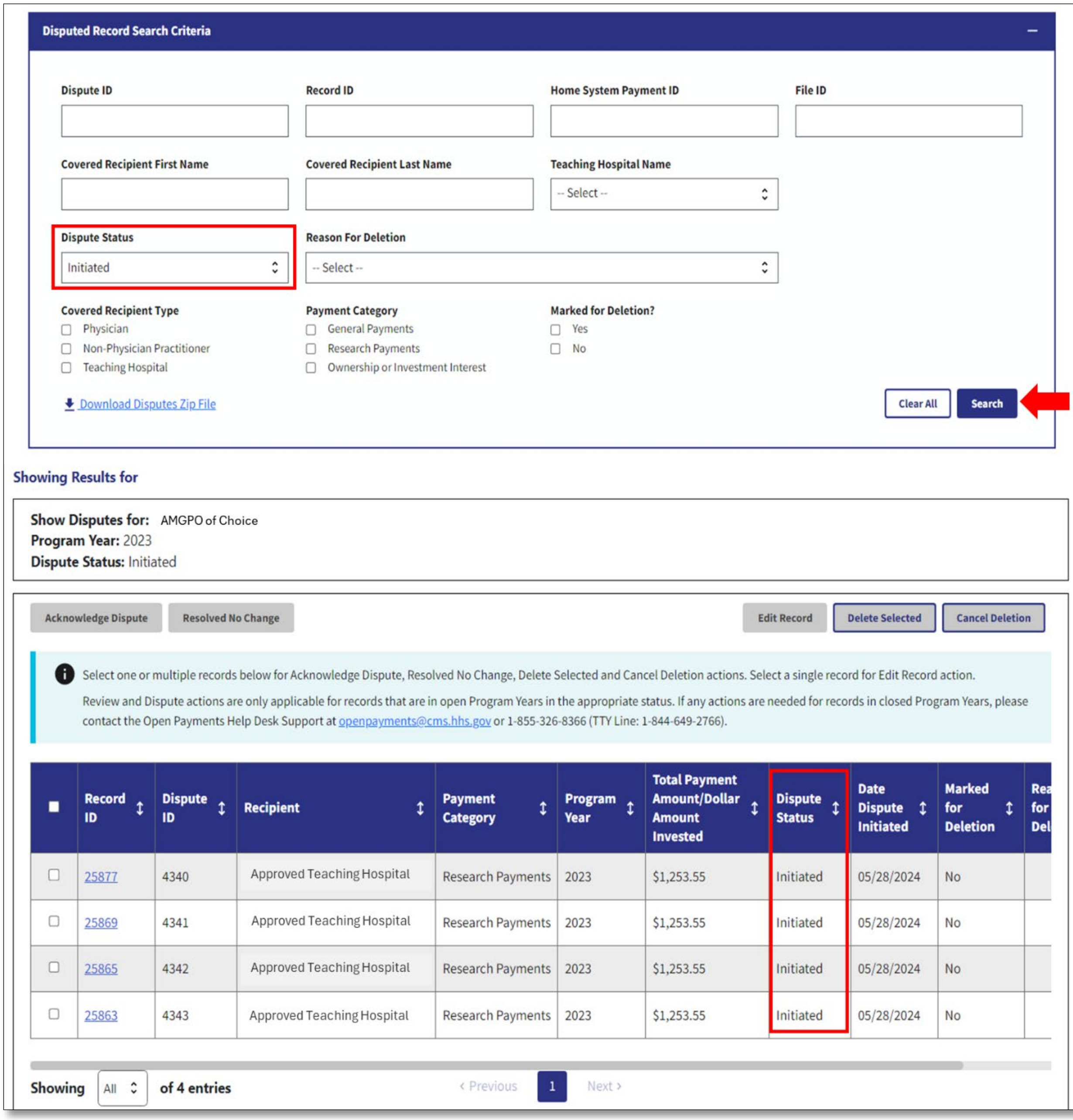
Step 2: Select the reporting entity and the program year from the drop-down menus. When finished, select the **Show Disputes** button. This will show users a list of all disputes for the selected entity in that program year.

Figure 297: Review & Dispute Overview Page: Show Disputes Button



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."

Figure 298: Review & Dispute Page: Disputed Record Search Criteria



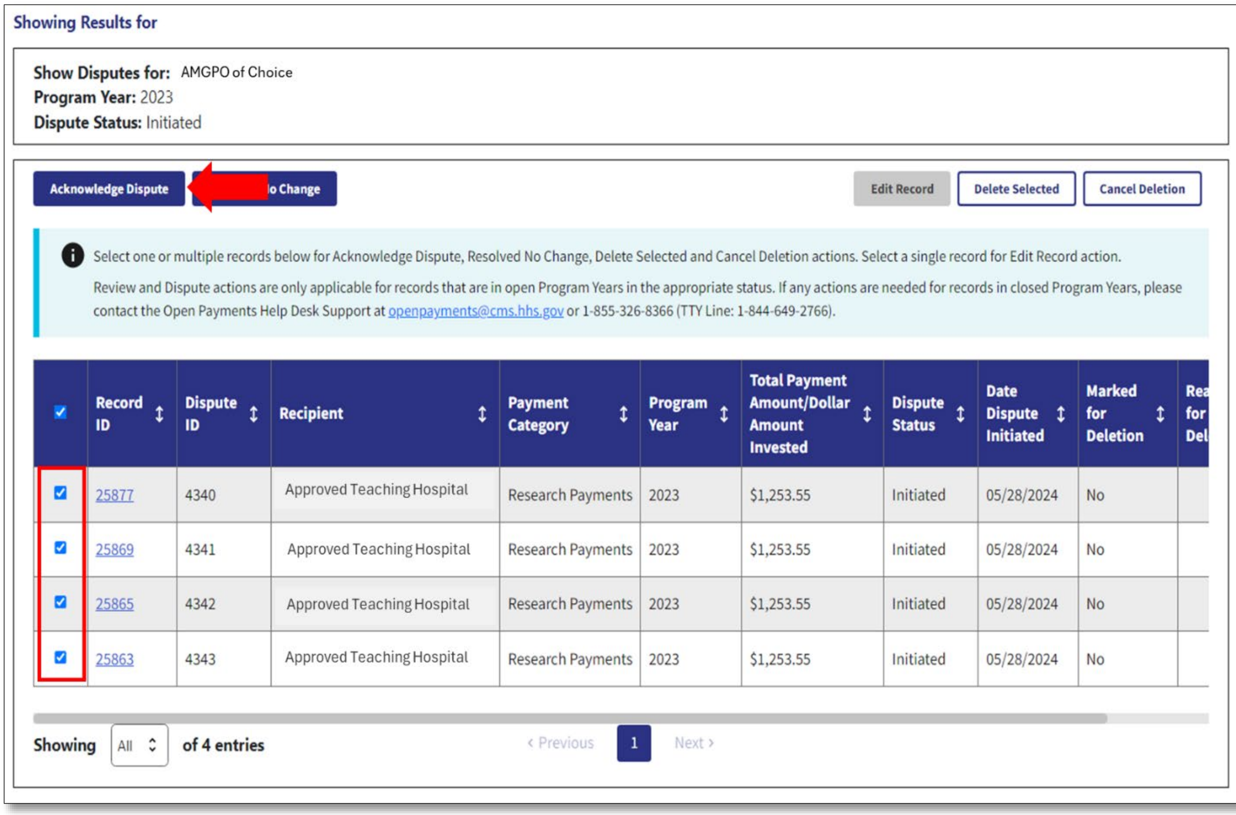
To view details about a disputed record by selecting the **View** hyperlink for the record under the "Action" column or by selecting the **Record ID** hyperlink under the "Record ID" column.

To view the detailed history for a record's disputes by selecting the **View** hyperlink for the record under the "Dispute History" column.

For instructions on how to export this data, see Section 5.1c.

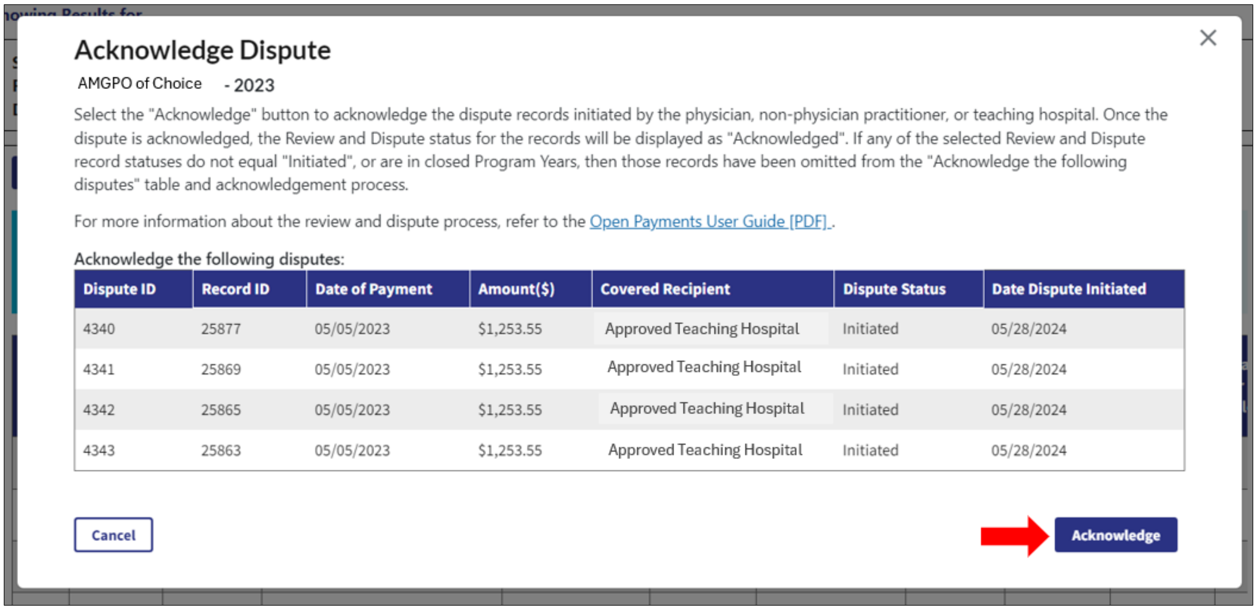
Step 4: Select the disputed record(s) to acknowledge, and then select **Acknowledge Dispute**. Note: Record(s) must be in "Initiated" status to acknowledge dispute(s).

Figure 299: Review & Dispute Page: Acknowledge Dispute Button



Step 5: Review the information displayed on the "Acknowledge Dispute" window. When finished, select the **Acknowledge** button.

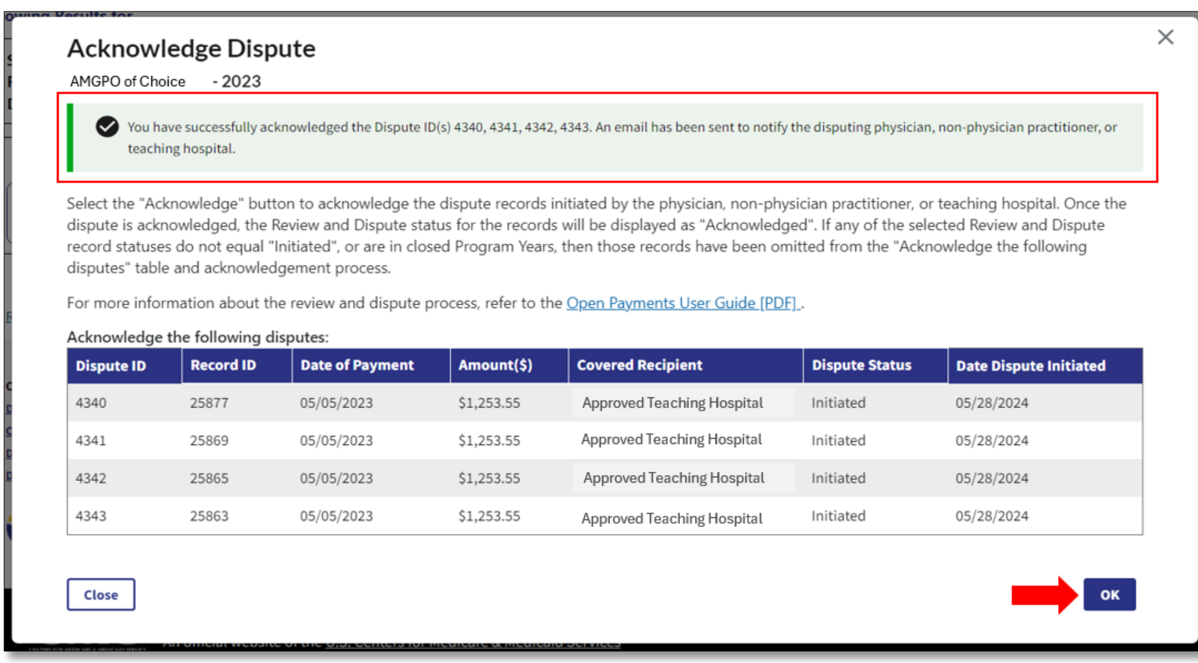
Figure 300: Acknowledge Dispute Window: Acknowledge Button



Step 6: Review the notification message to confirm you successfully acknowledged the selected dispute(s) and then select the **Ok** button.

An email notification will also be sent to the covered recipient informing them that their dispute has been acknowledged.

Figure 301: Acknowledge Dispute Window: Confirmation Message

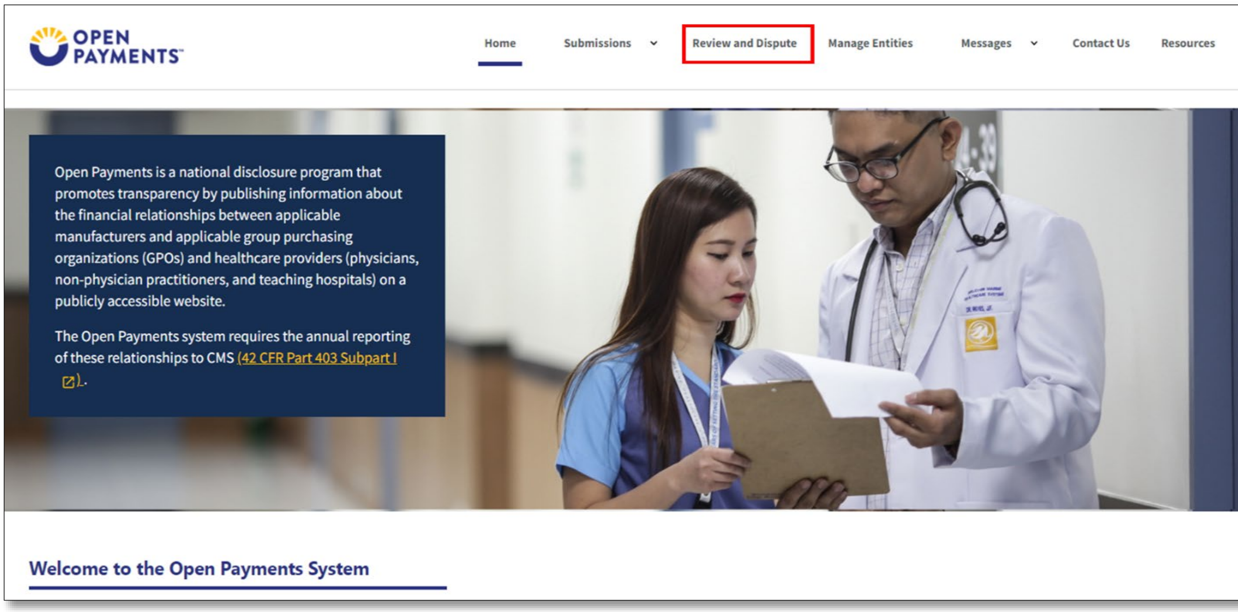


5.2b: Resolved, No Change Disputes

The “Resolved, No Change” status means that the reporting entity and the covered recipient 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.

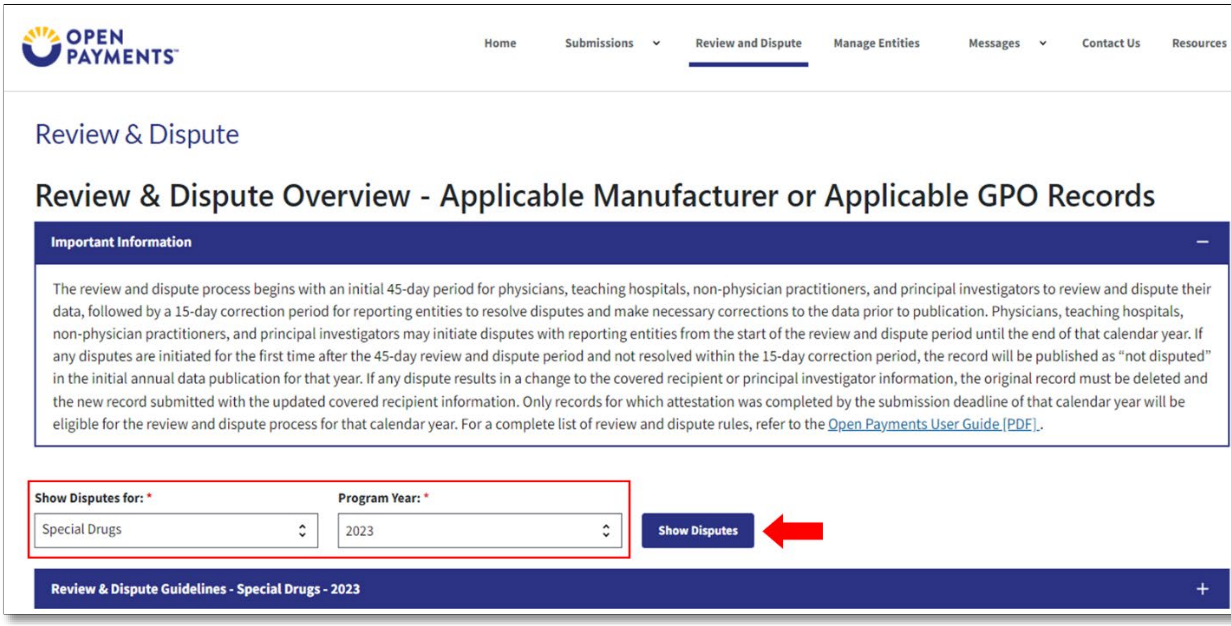
Step 1: Log in to the Open Payments system and select the **Review and Dispute** tab on the tool bar.

Figure 302: Open Payments System Home Page: Review and Dispute Tab



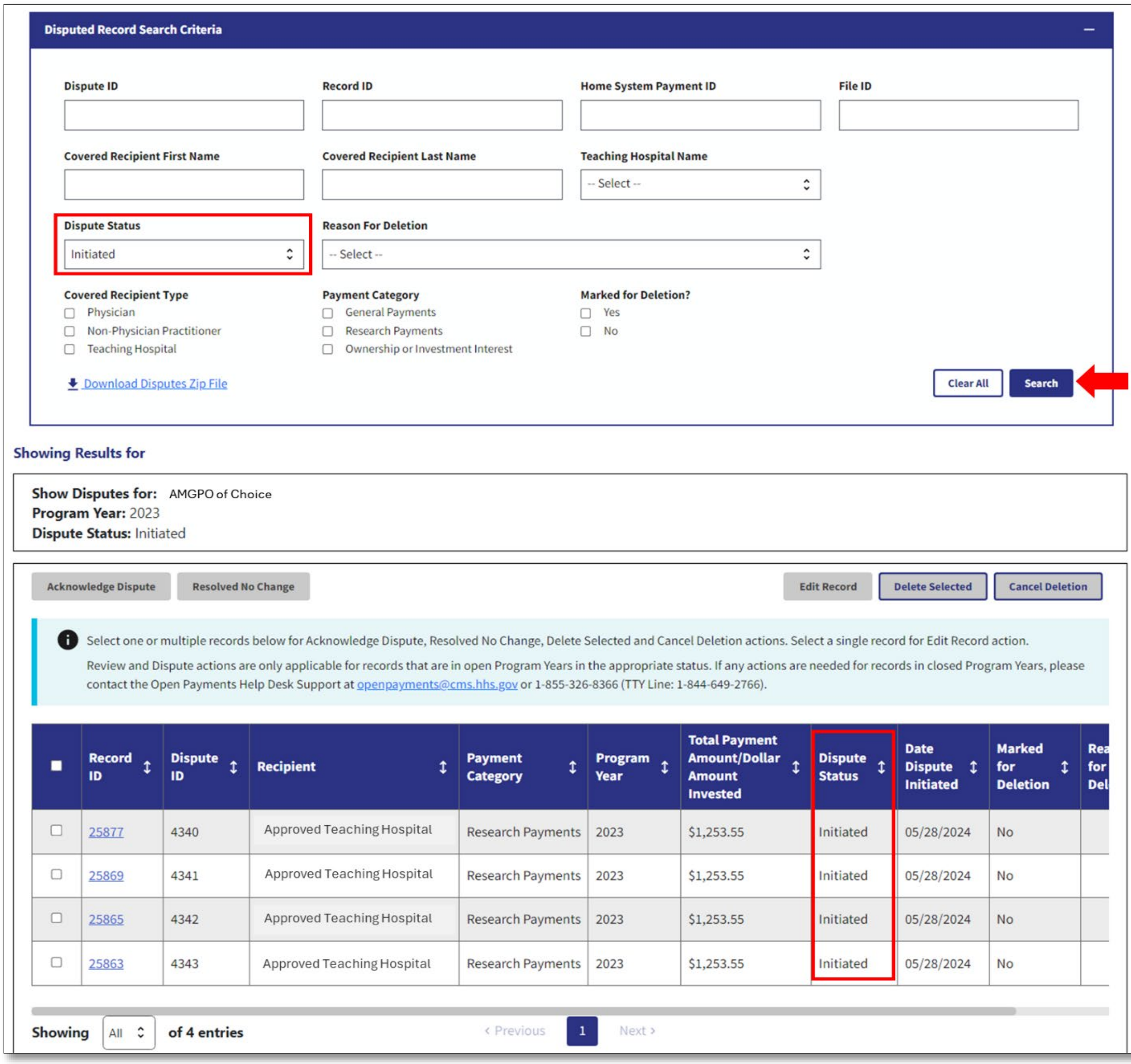
Step 2: Select the reporting entity name and the program year from the drop-down menus. When finished, select **Show Disputes**. This will show you a list of all disputes for the selected entity in that program year.

Figure 303: Review & Dispute Overview Page: Show Disputes Button



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.

Figure 304: Review & Dispute Page: Disputed Record Search Criteria



To view details about a disputed record by selecting the **Record ID** hyperlink under the “Record ID” column.

To view the detailed history for a record’s dispute by selecting the **View** hyperlink for the record under the “Dispute History” column.

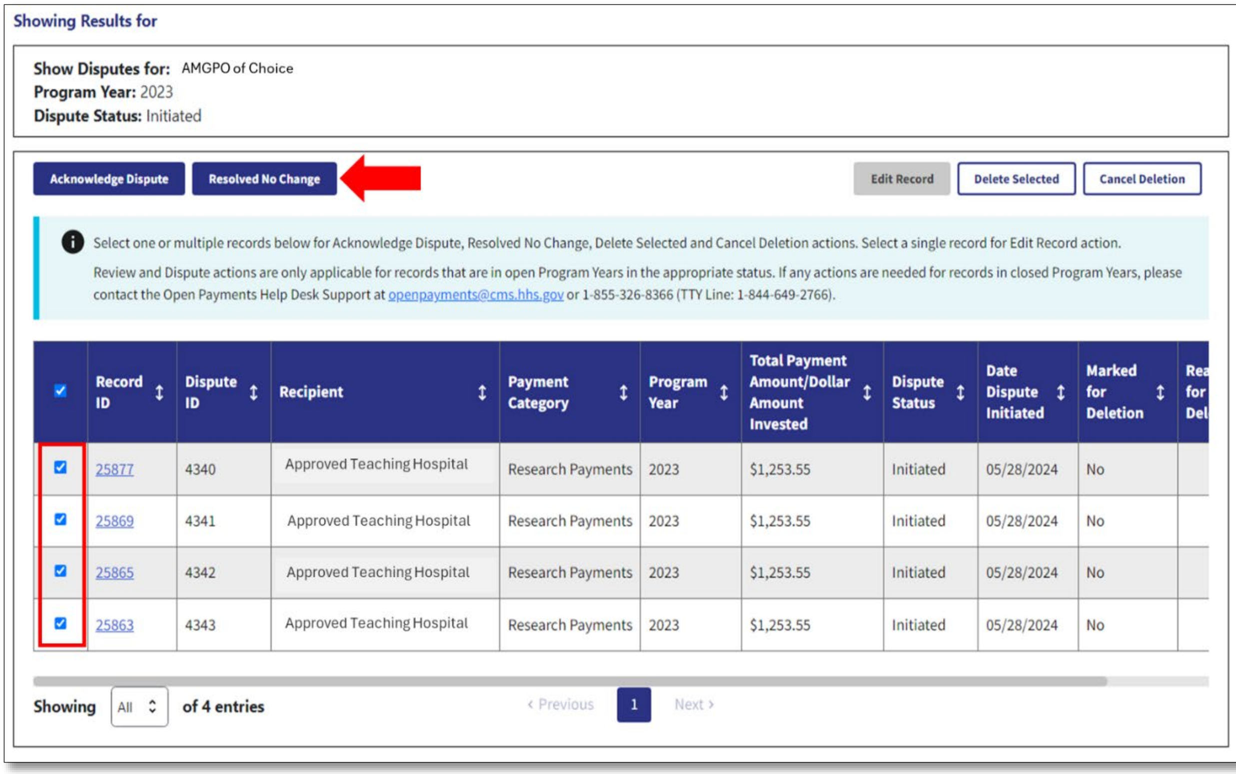
Step 4: Select the disputed record(s) users wish to resolve with no changes, and then select the **Resolved No Change** button.

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 covered recipient 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.

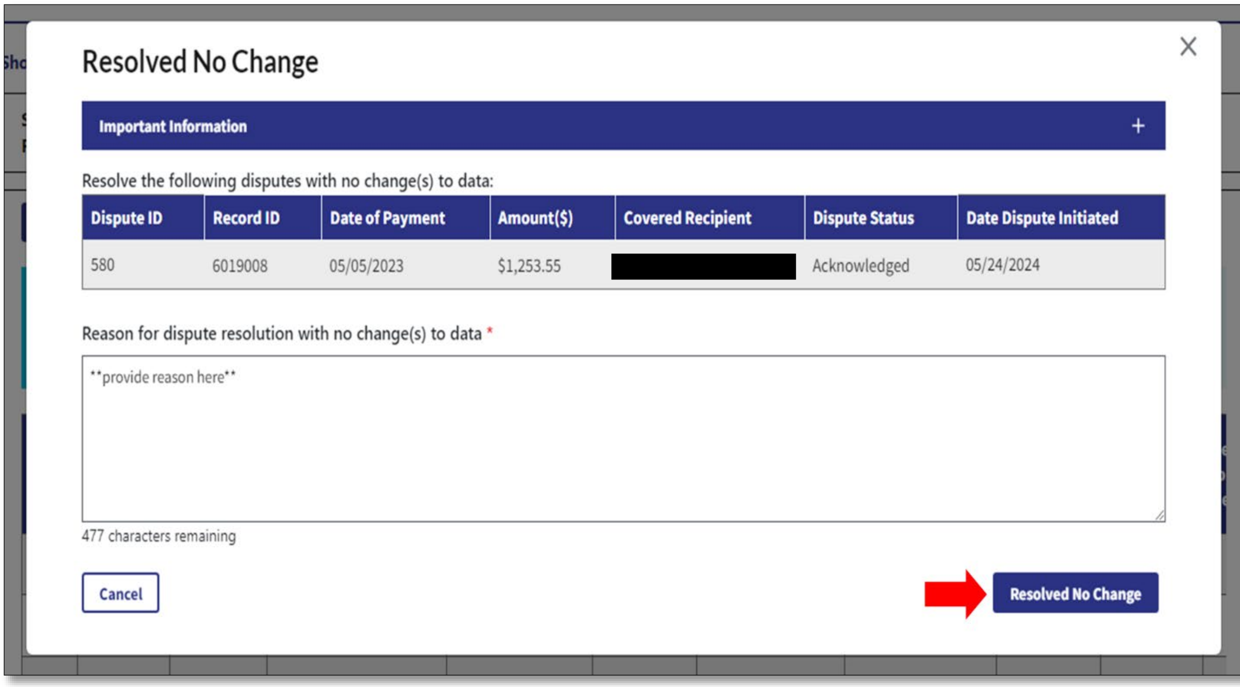
Figure 305: Review & Dispute Page: Resolved No Change Button



Step 5: In the “Reason for dispute resolution with no change(s) 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.

Figure 306: Resolved No Change Window and Button



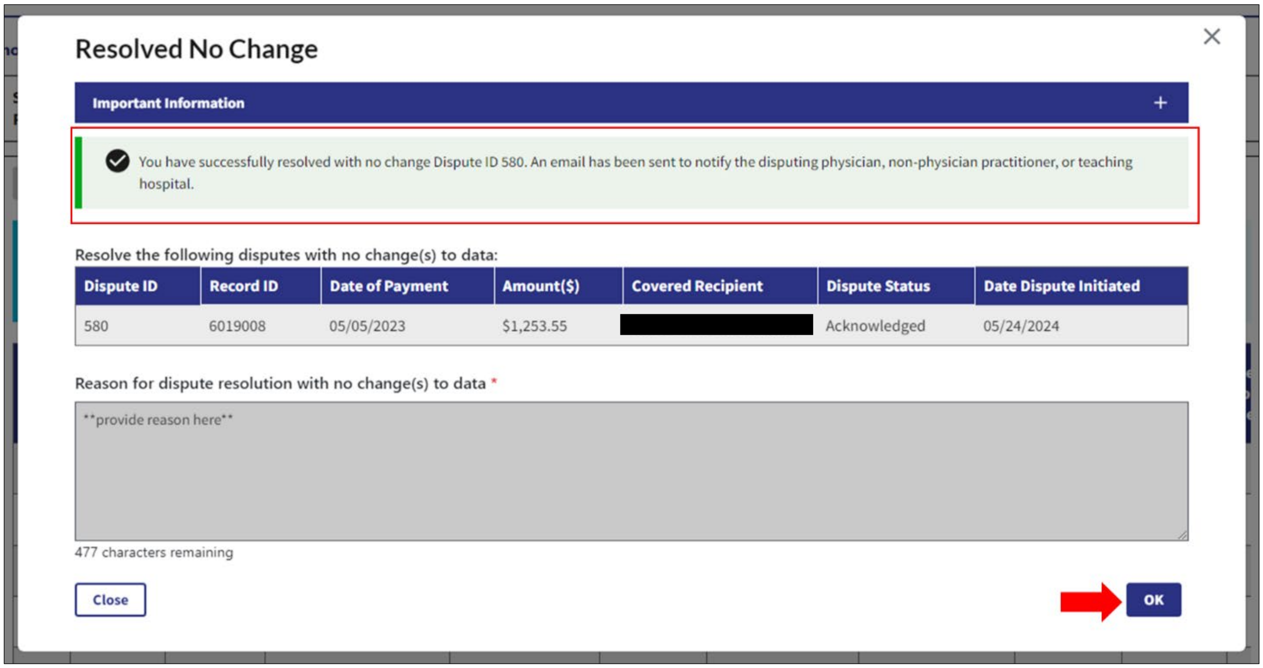
The record's dispute status will change to "Resolved No Change." An email notification will be sent to the covered recipient informing them that their dispute has been resolved with no changes made to the data. The email will include the explanation provided in the "Reason for dispute resolution with 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 reason for dispute resolution with no change(s) to the data text will be sent to all the covered recipients included in the disputes marked.

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 covered recipient.

Step 6: Review the notification message to confirm you successfully resolved with no change(s) to the selected dispute(s) and then select the **OK** button.

Figure 307: Resolved No Change Confirmation Window



The covered recipient 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 the covered recipient, the reporting entity should work directly with the disputing party to correct the disputed data.

If a correction to a record is needed to resolve a dispute, the record must be edited and saved with its corrections; pushed through final submission; and attested for successful dispute resolution. The following editing options can be used to correct disputed records in the Open Payments system:

- Corrections to disputed records can be done via bulk file upload, as the “Record ID” for the record(s) must be included in the re-submission file.
- Corrections to disputed records can be done manually, as the record(s) should be in the Open Payments system and edited individually using the “edit” function.

If the dispute resolution changes any of the fields that identify the covered recipient and/or if the wrong covered recipient was reported, the original record must be <u>deleted</u> and <u>resubmitted as a new record</u>. The following covered recipient identifying fields are provided below:

- For physicians and NPPs (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/Resources, for publication rules.

5.3a: Edit Information and Resubmit Record

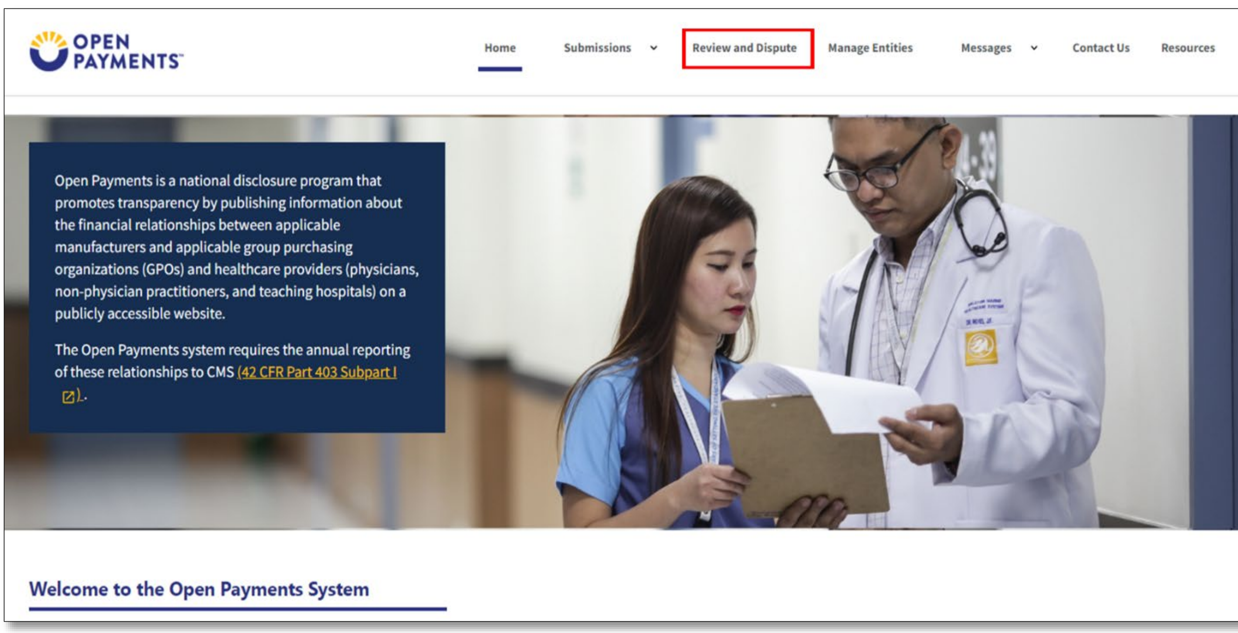
To edit a record via bulk file upload:

- Create a bulk data file that contains the records to be corrected.
- Set the "Resubmission Indicator" to "Y" for each record.
- Enter the original "Record ID" created by the Open Payments system in the "Resubmitted Payment Record ID" field.
- Once you have prepared the resubmission 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.

To manually edit an individual disputed record using the "Edit" function, follow the steps below.

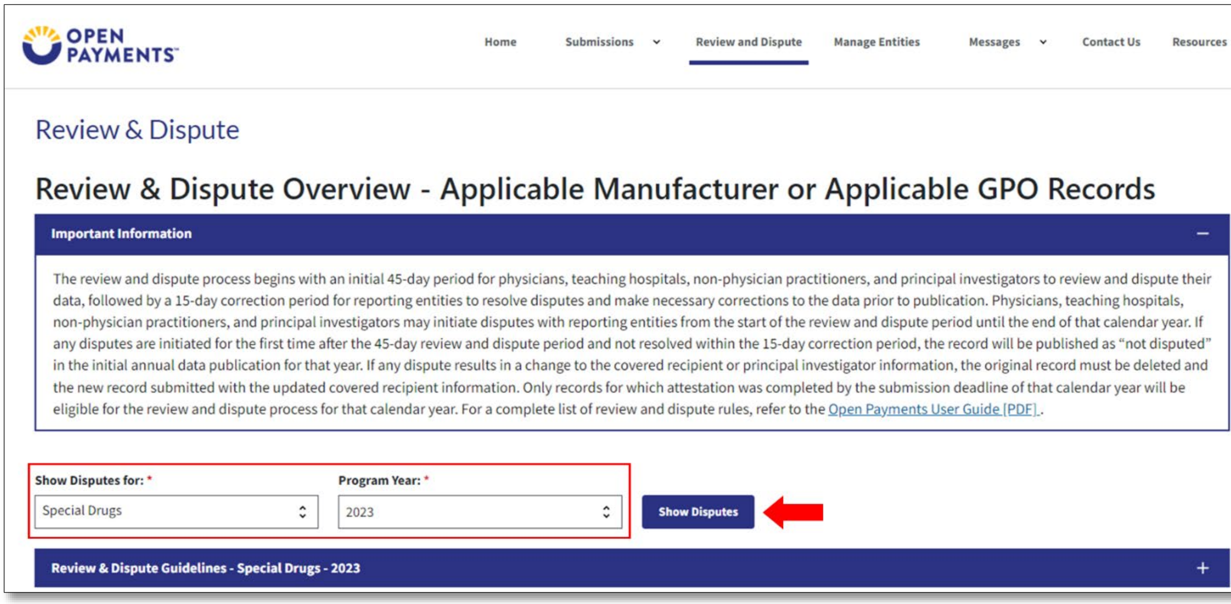
Step 1: Log in to the Open Payments system and select the **Review and Dispute** tab on the tool bar.

Figure 308: Open Payments System Home Page: Review and Dispute Tab



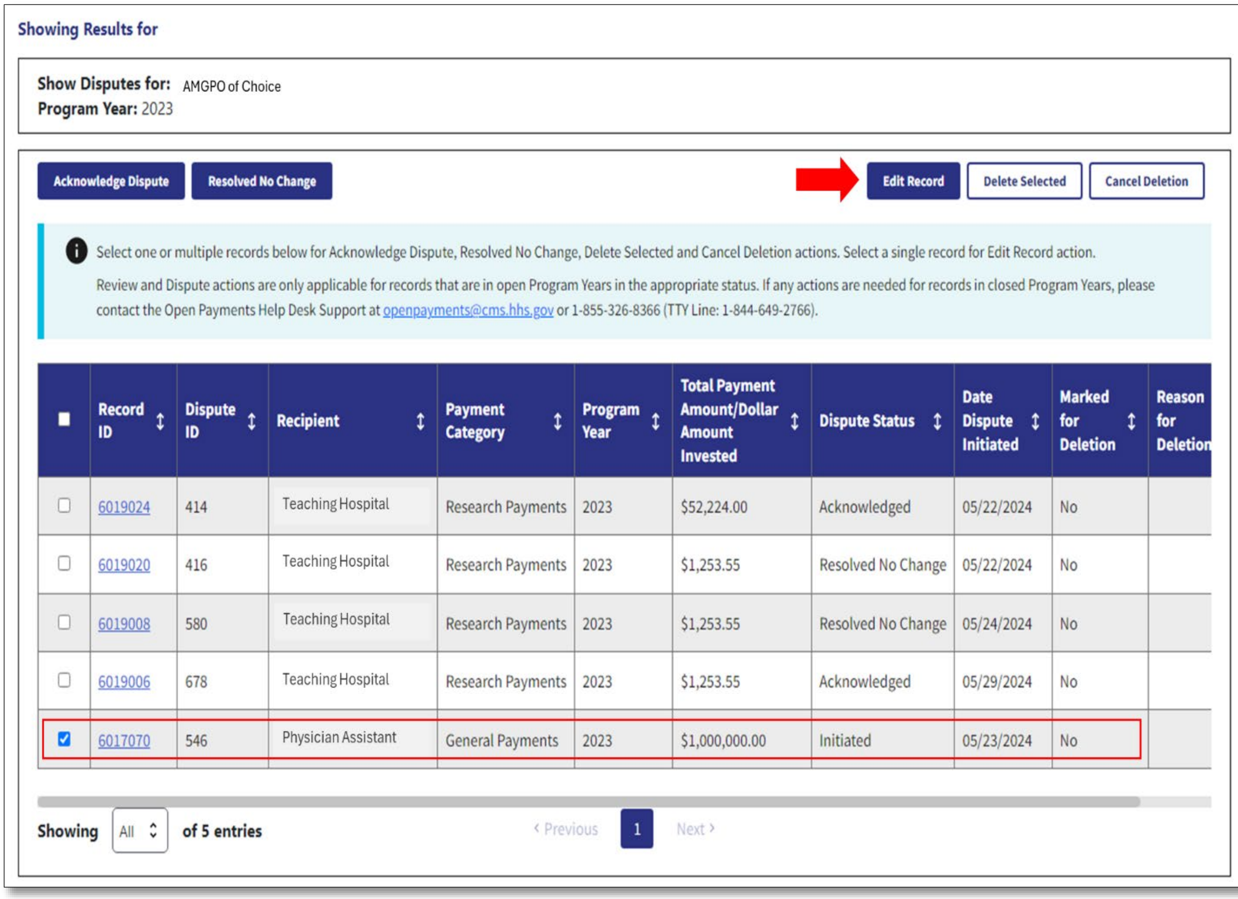
Step 2: Select the reporting entity and the program year, for which you wish to edit disputed records, from the drop-down menus. When finished, select the **Show Disputes** button.

Figure 309: Review & Dispute Overview Page: Show Disputes Button



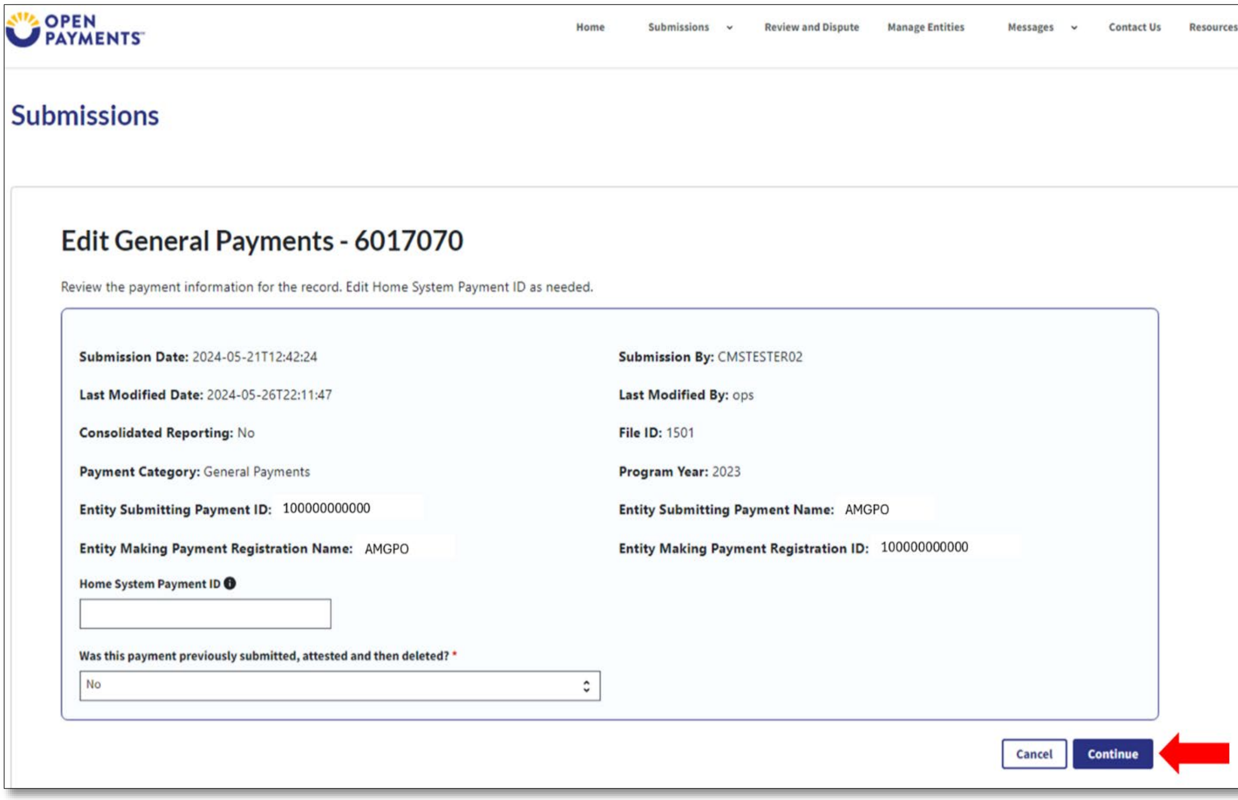
Step 3: On the Review and Dispute page, select the disputed record and then select the **Edit** button.

Figure 310: Edit Hyperlink



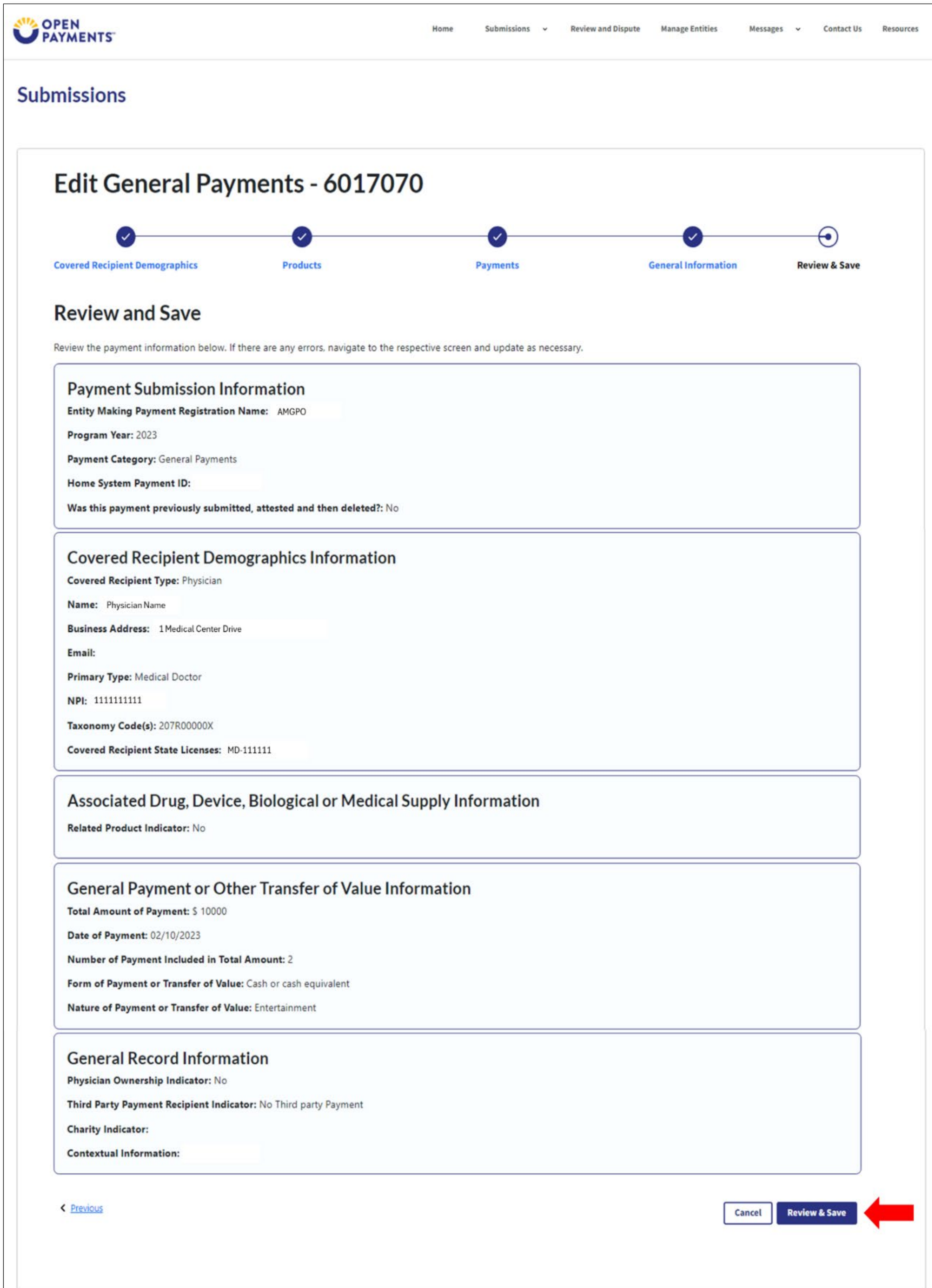
Step 4: Select the **Continue** button to proceed through the manual edit Graphical User Interface (GUI) to correct the field that corresponds with the covered recipient's reason for dispute.

Figure 311: Manual Edit GUI: Continue Button



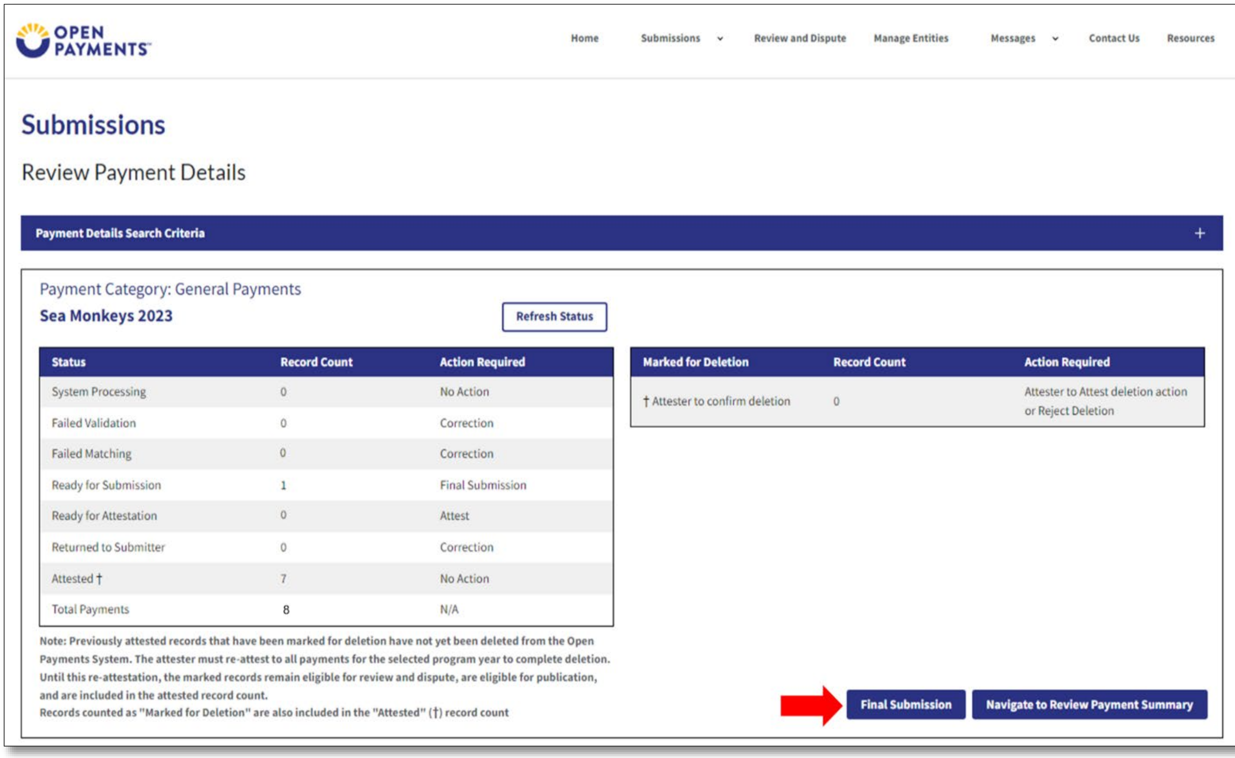
Step 5: Select **Review & Save** button after the disputed record is corrected.

Figure 312: Manual Edit Review & Save Page and Button



Step 6: Complete **Final Submission** on the "Review Payment Details" page if you are done correcting disputed records.

Figure 313: Review Payment Details Page: Final Submission Button



Step 7: Perform Attestation on the corrected records. Please refer to Section 4.15b "Attesting to Data in the Open Payments System" for complete instructions on how to attest data. If you do not hold the Attester role, please notify the Attester that the corrected records are "Ready for Attestation".

The disputed record will 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 covered recipient under the "Deleted and In-progress Records" tab with an "In Progress" status.

An email notification is sent to the covered recipient who initiated the dispute. If the individual who initiated the dispute is an Authorized Representative with dispute access, an email notification is sent to their physician or NPP 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.

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."

5.3b: Re-Submission and Attestation of Corrected Data

Entities submitting corrected data must complete both final submission and attestation to the corrected data for the updates to be included in the public posting. Once attestation is complete, the records will be automatically placed in a review and dispute status of "Resolved." No further action is needed from the reporting entity.

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

If a record is deleted and replaced after the submission closing date, the Open Payments system will treat the record as a newly arriving late record rather than a correction. The new records will not be included in the current publication cycle and will be identified as eligible for review and dispute for a future publication.

Once a record is deleted, it will no longer be visible to the covered recipient 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 with 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 covered recipient identified in it "Available for Review and Dispute" tab.

The attester will need to attest to the accuracy of all corrected 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 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 4.15b.

Chapter 6: Messages and Compliance

This chapter provides detailed information on how Applicable Manufacturers and Applicable GPOs can 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.

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 Messages** 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 -** 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, download associated communication documents, respond, and upload a file to be viewed by the CMS Compliance Team.

6.1: System Messages

Reporting entity users can 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 can 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.

If you are not actively associated with 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 are not displayed.

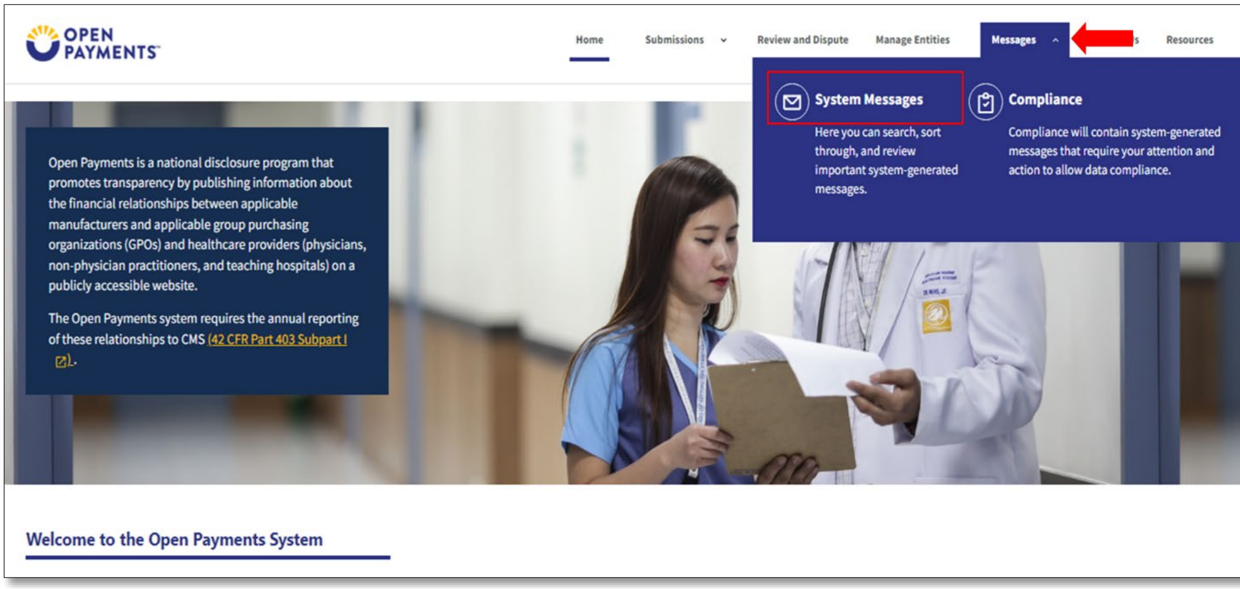
If you are actively associated with at least one entity, on landing, you are presented with only the search criteria. You are required to select values from the search criteria and select the “Search” button before system generated messages are displayed in the result data table. There are no default results on page landing.

6.1a: Instructions for searching messages

Step 1: Log in to the Open Payments system and select the “Messages” tab on the tool bar and then select **System Messages**.

- If you only hold the role of submitter and/or attester for your reporting entity, you will only see the “System Messages” option.
- If you hold the role of officer and/or compliance for your reporting entity, you will see both the “System Messages” and “Compliance” options.

Figure 314: Open Payments Messages Tab: System Messages Option

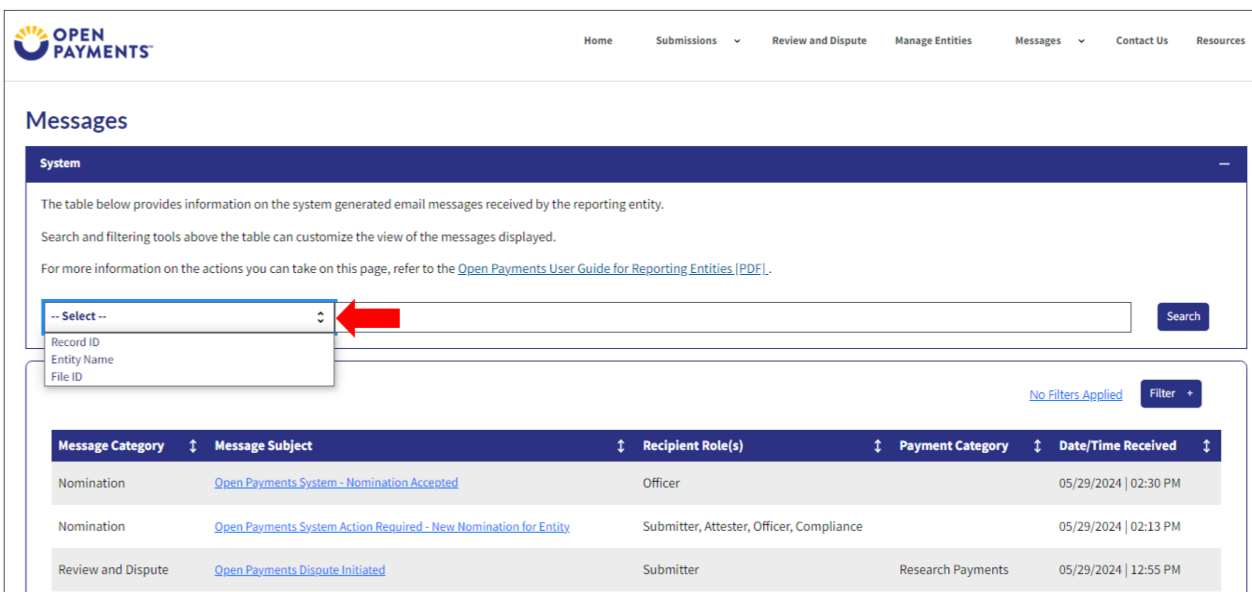


Step 2: On the "Messages" page, you can search based on the following search criteria:

- Entity Name
- File ID (only applicable for Message Category of "File Processing")

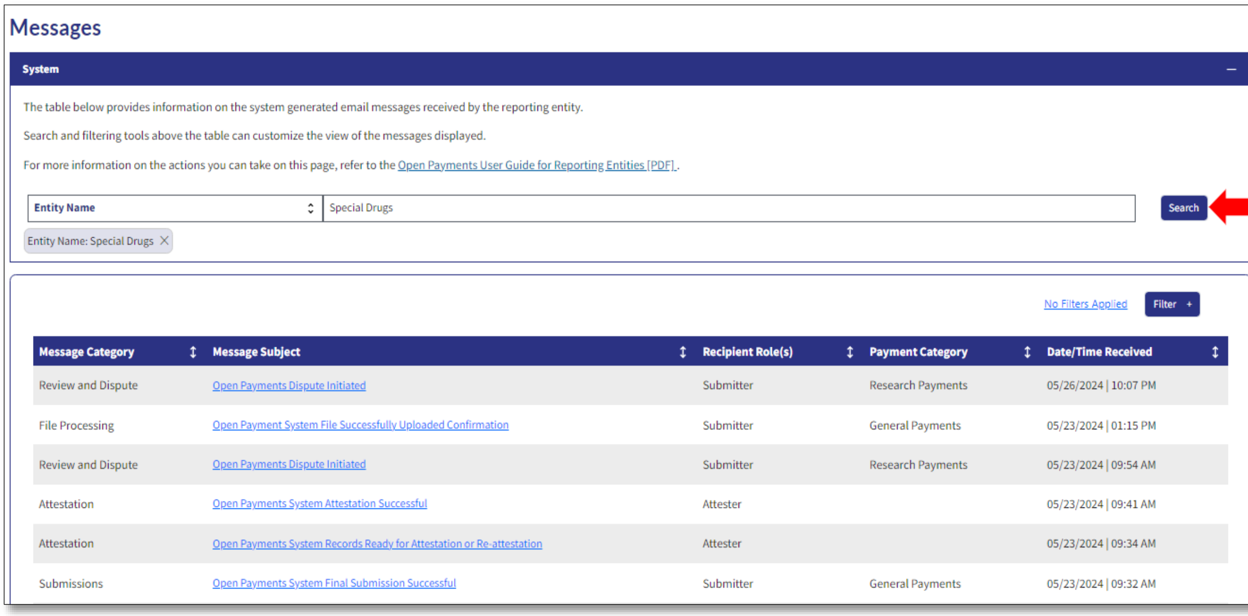
Record ID (only applicable for Message Category of "Review and Dispute")

Figure 315: System Messages Page: Search Criteria



<u>Step 3a:</u> 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 from newest to oldest.

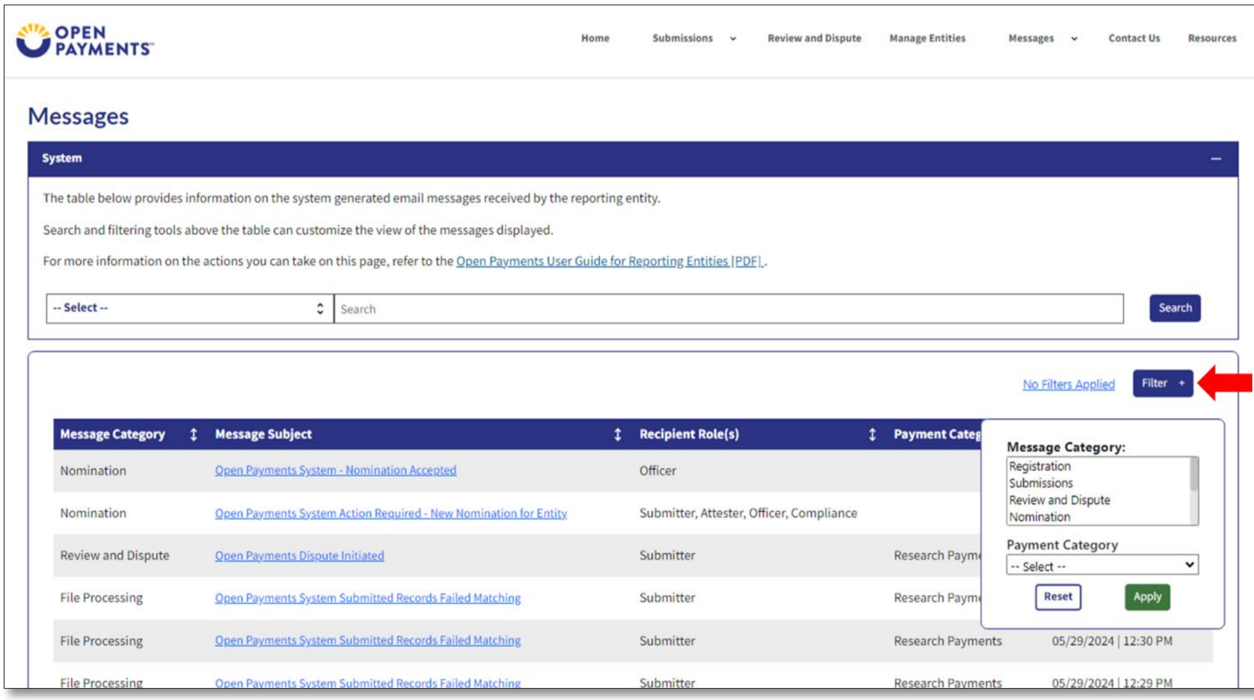
Figure 316: Search Button for System Messages



Step 3b: Select the **Filter** button to help refine your search results based on the following criteria:

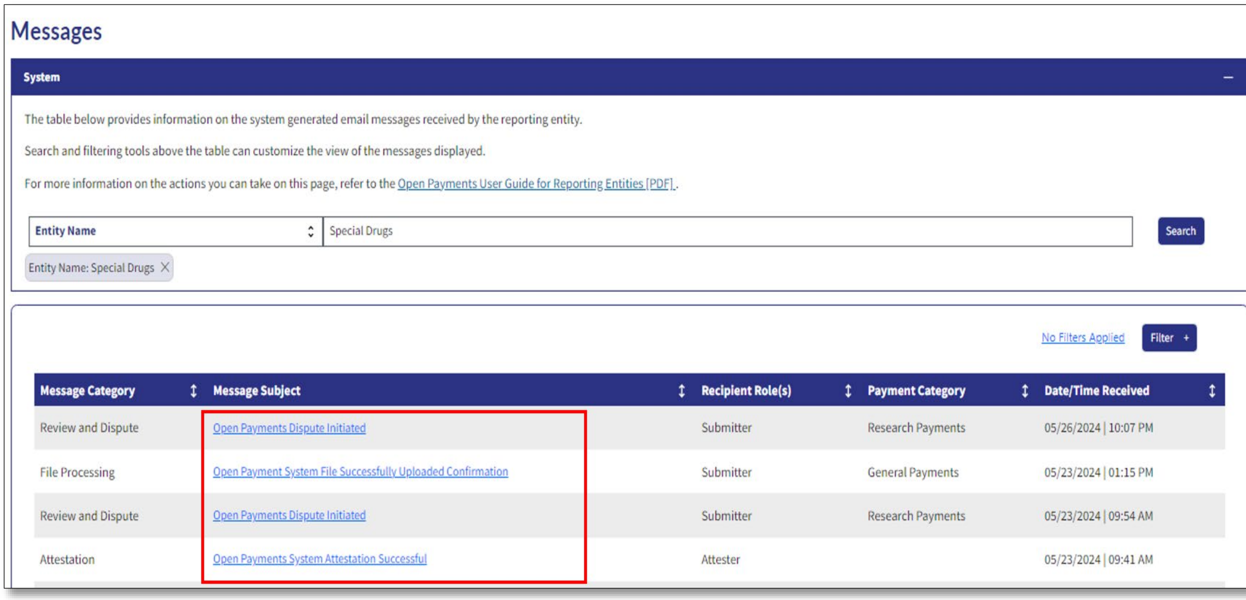
- Message Category
- Payment Category (only applicable for Message Category of "Submissions", "Review and Dispute", "File processing")

Figure 317: System Messages Search Results Filter Button



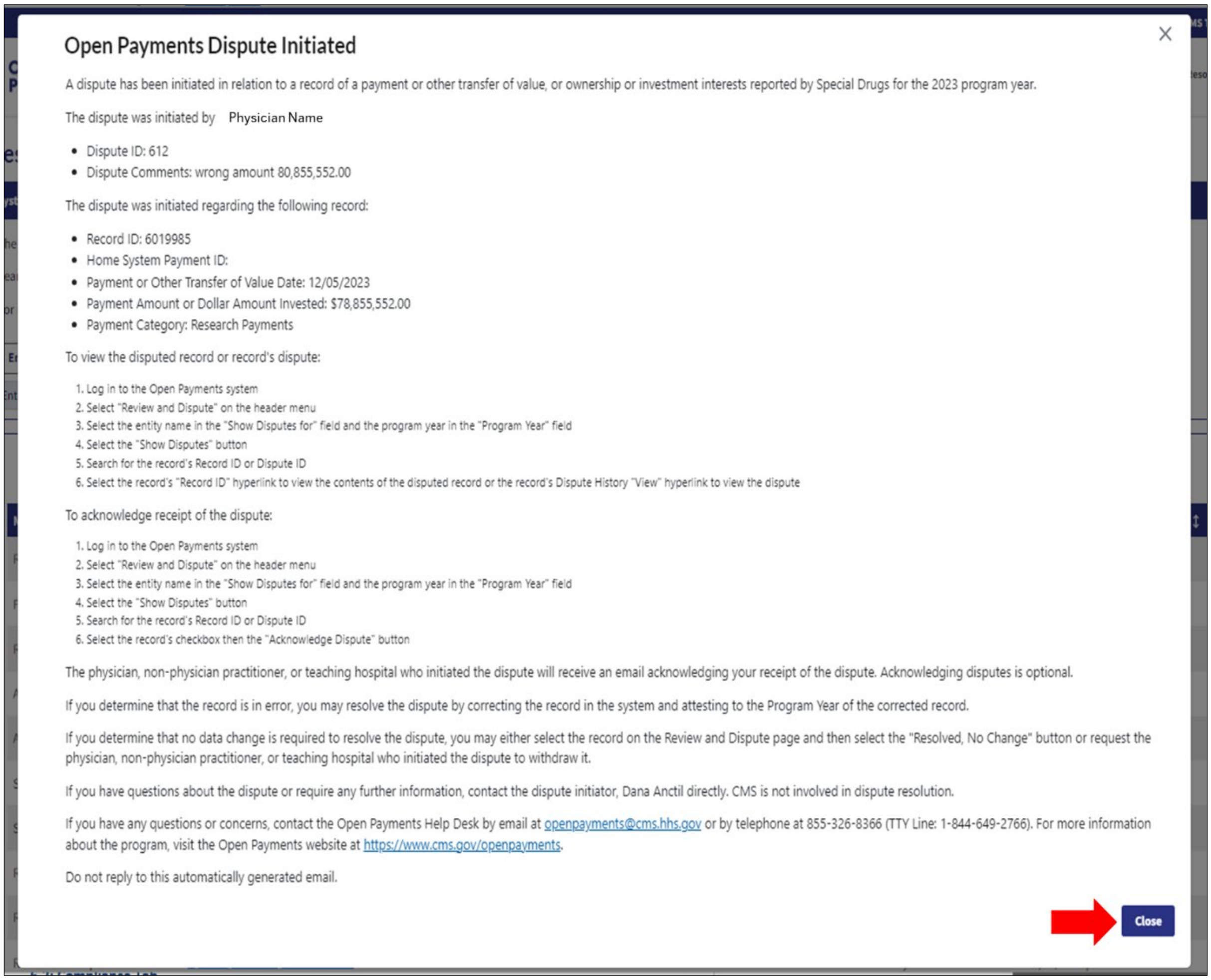
Step 4: Select the message subject hyperlink under the "Message Subject" column for the message you wish view.

Figure 318: Message Subject Hyperlink



Step 5: View the full message displayed in the pop-up window and select the **Close** button when done.

Figure 319: Full Message Window: Close Button



6.2: Compliance Tab

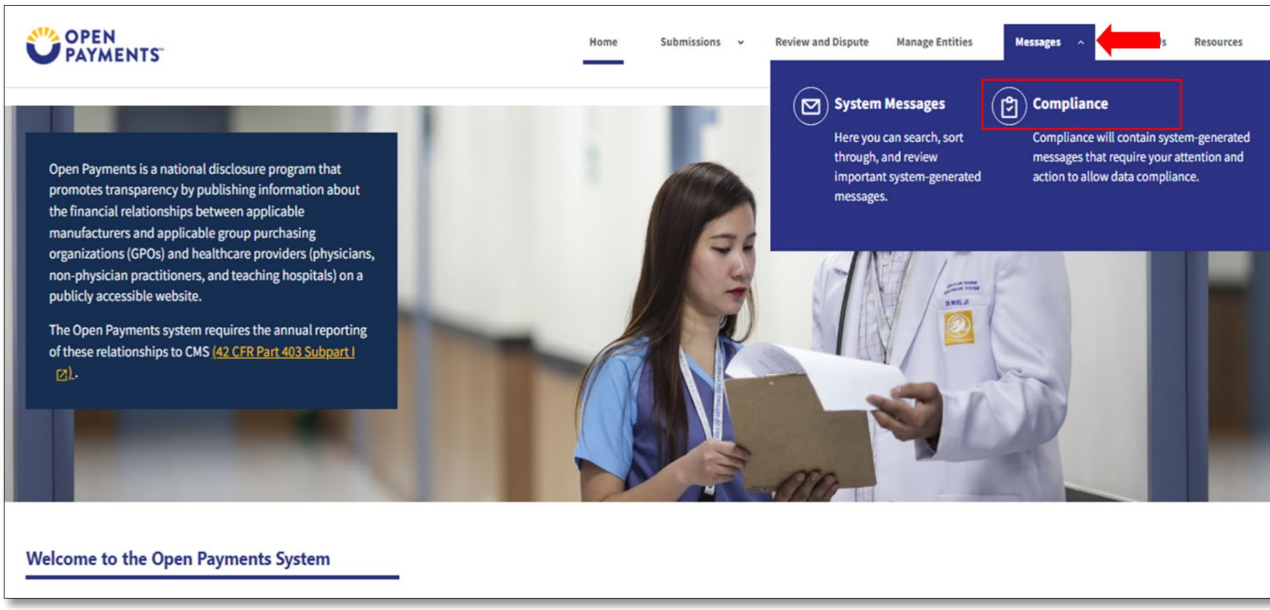
This functionality is available only for reporting entity users who have the officer role or the compliance role. See Section 3.3: Open Payments System Users and User Roles for more information on how to assign a user a compliance role.

When a compliance communication is uploaded by the CMS compliance team, an email notification is received by the reporting entity's officers, compliance user(s), and primary point of contact.

6.2a: Instructions for Searching Compliance Communications

Step 1: Log in to the Open Payments system at https://openpayments.system.cms.gov using your IDM credentials and select the **Messages** tab on the tool bar and then select **Compliance**.

Figure 320: Messages Tab Compliance Option



Step 2: You will be able to view all Compliance communications. For each communication, you can view the following details in the table.

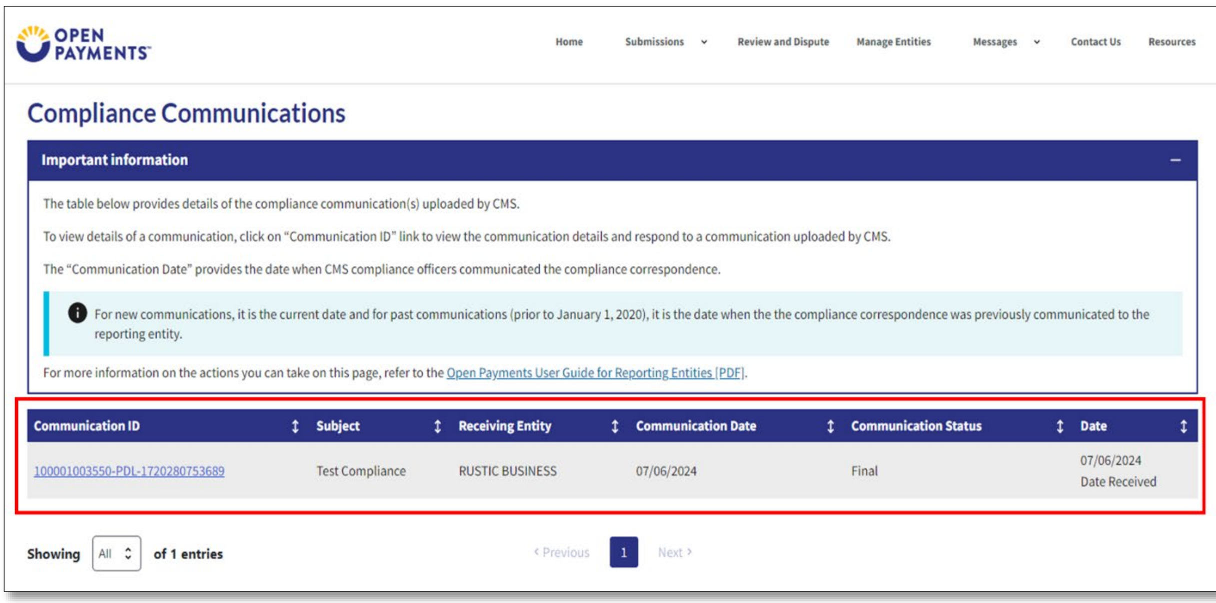
- Communication ID: A unique ID to view the details of a communication chain
- Subject
- Receiving Entity
- Communication Date: Date when the compliance correspondence was communicated by CMS
- Communication Status (Draft or Final) – Reporting entities will only be able to see communications from CMS that are in a "Final" status. Reporting entities may also upload documents, which will be shown in "Draft" status before they are finalized.
- Date: Displays date and label for "Date Received" and "Date Responded"
    - "Date Received" indicates when your entity received the CMS compliance communication.

  - “Date Responded” indicates when your entity responded to the CMS compliance communication.

Upon selecting the Communication ID, you can view the details of a communication. The "Communication Date" provides the date when the compliance correspondence was communicated by the CMS compliance officer. Note:

For new communications, it is the current date and for past communications (prior to January 2020). It is the date when the compliance correspondence was previously communicated to you. The “Date Responded” provides the date when you last responded to CMS for the communication.

Figure 321: Compliance Communication Table

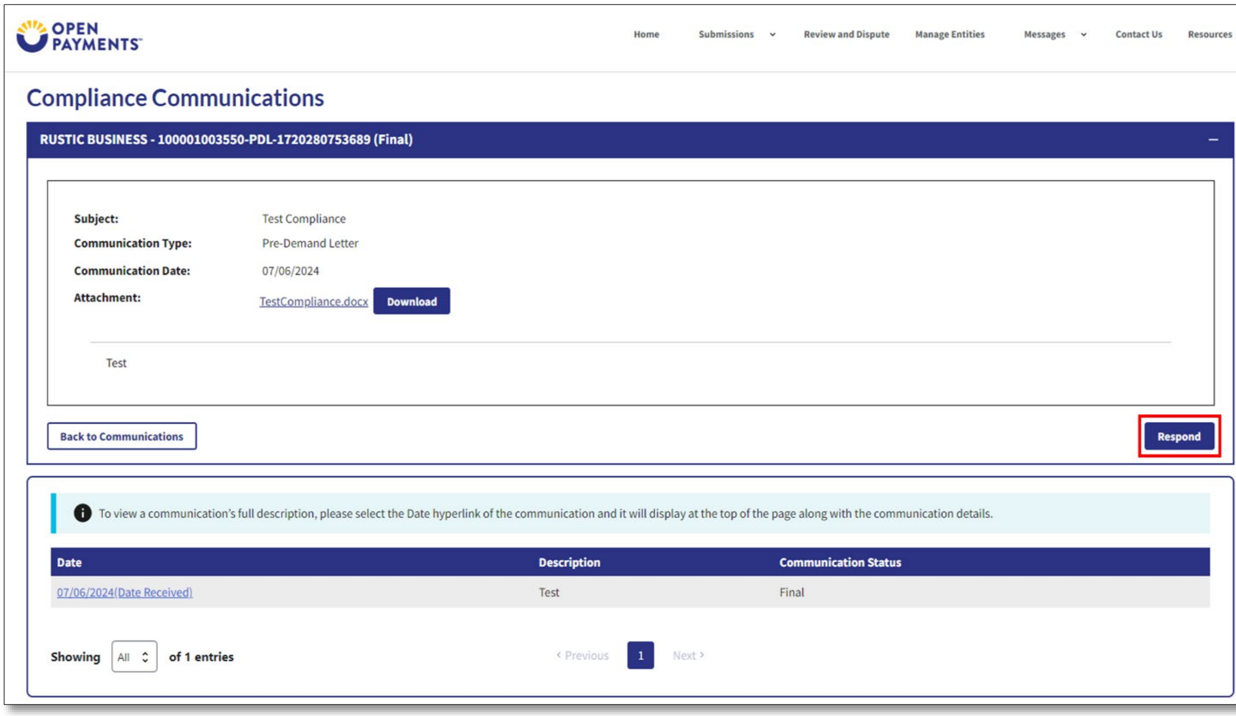


6.2b: Compliance Communications Page

Upon selection of the **Communication ID** link, you will be able to view the complete details of that communication. This page will display the communication in the order it was last received or sent in descending order, and provides the ability to view, download, and respond to the compliance communication uploaded by CMS.

- To respond to a communication, select the **Respond** button. This button will not be available when there is already a draft response created.
- To download a compliance document, select the **Download** button next to the communication to be downloaded.
- To delete a draft compliance communication, select the "Delete" button. This button will no longer be available after you select the **Finalize** button.
- To edit a communication, select the **Edit** button. You can edit a communication if it is in “Draft” status. This button will no longer be available after the communication is finalized.
- To finalize the compliance communication, use the **Finalize** button. This sends the response to CMS.

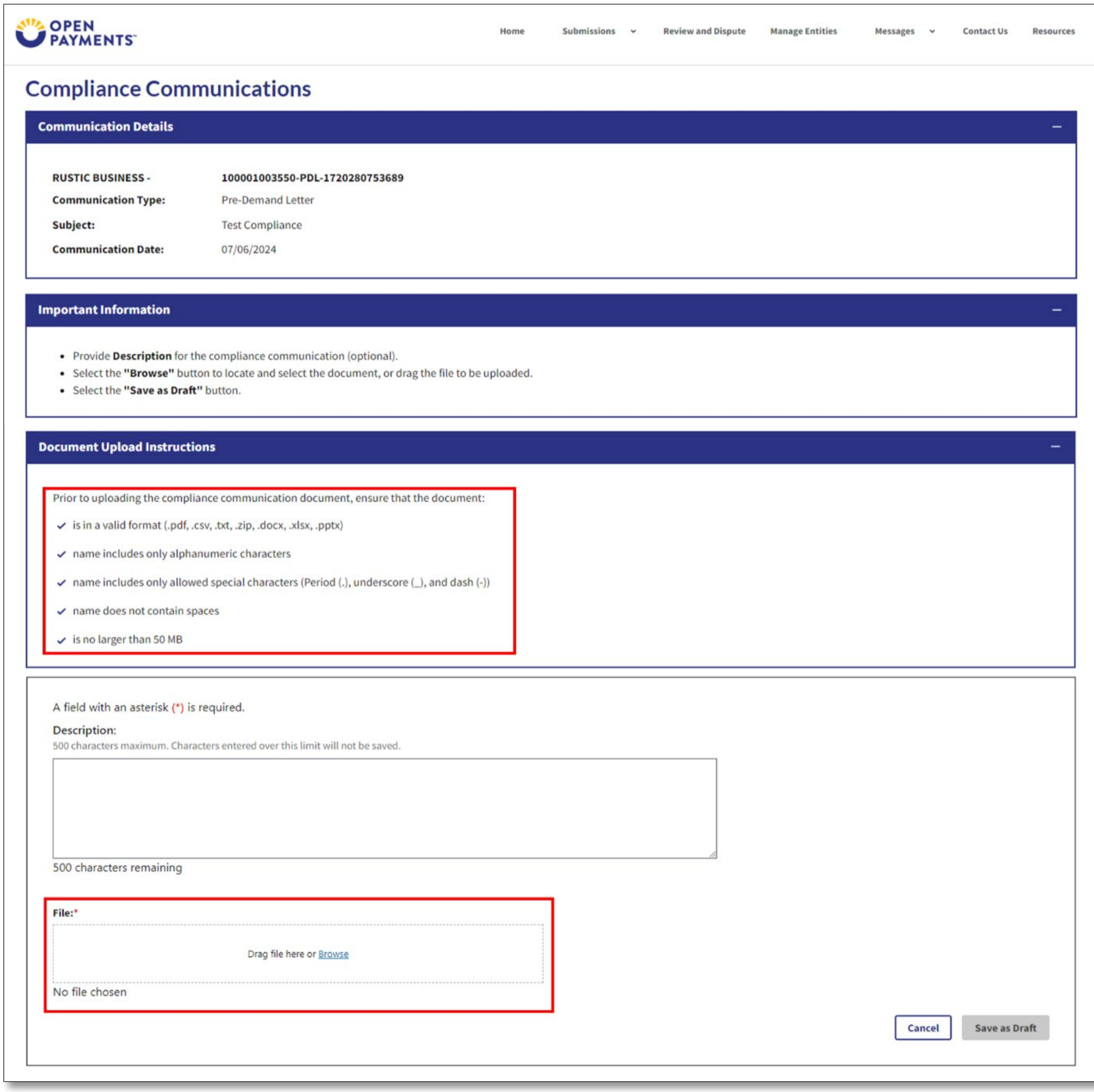
Figure 322: Compliance Communications Page



6.2c: Upload Response to Compliance Communication Page

Upon receiving a CMS communication, you will have the ability to respond to the compliance communication received. Select the **Respond** button to navigate to the “Upload Response to Compliance Communication” page.

Figure 323: Upload Response to Compliance Communication



To respond to a compliance communication, follow the steps identified below.

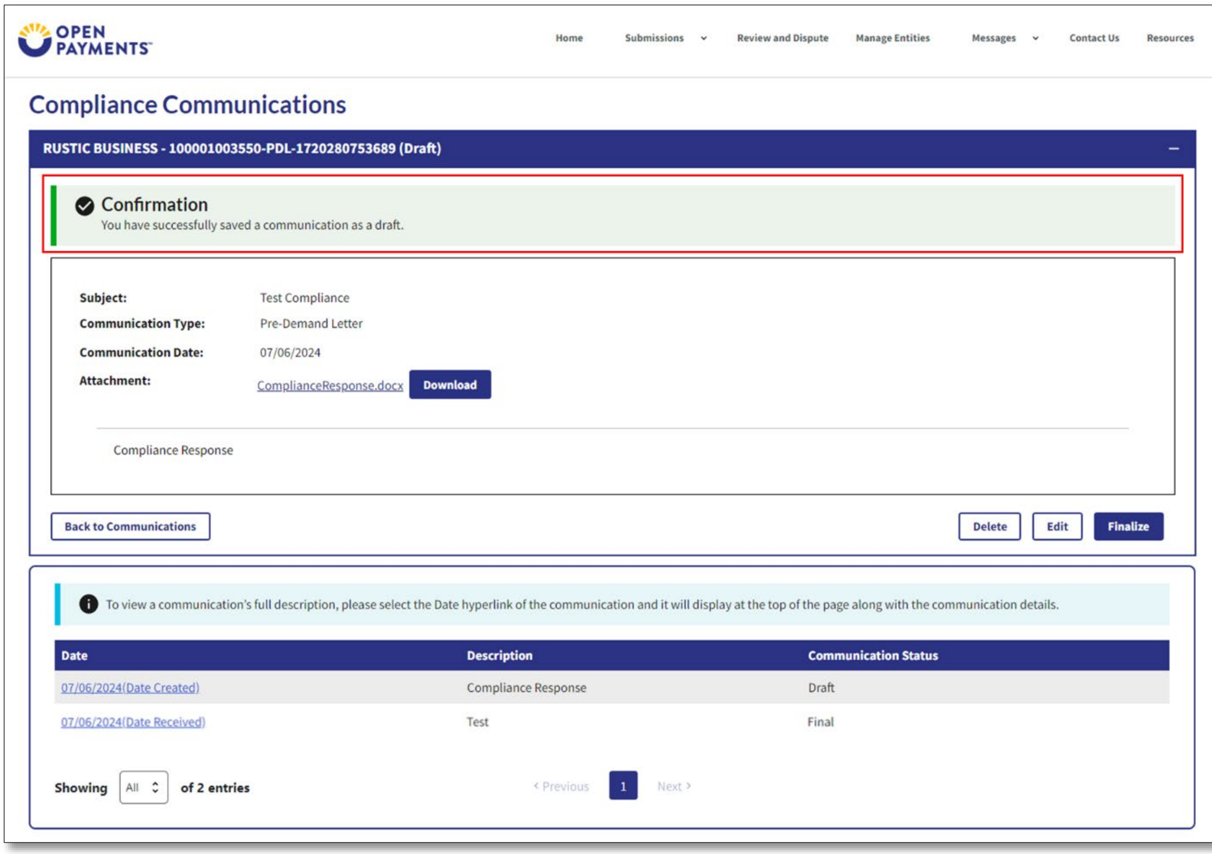
Prior to uploading the compliance communication document, ensure that the document is in a valid pdf, .csv, .txt, .zip, .docx, .xlsx, or .pptx format. Document name must include only alphanumeric characters and the three allowed special characters (period (.), underscore (_), and dash (-)). Document names must not contain spaces. The document must be no larger than 50 MB.

- Provide description for the compliance communication. This is optional.
- Select the **Choose File** button to locate and select the document to be uploaded.
- Select the **Upload** button.

- Select **Yes** on the confirmation message to process with upload or select **No** to cancel the upload.

Communication ID, Communication Date, and Subject sections will be auto populated. Once the compliance communication upload is successfully completed, you will be navigated back to the Communication Details page. The compliance communication will be added as a draft version.

Figure 324: Compliance Communications Page: Confirmation Message

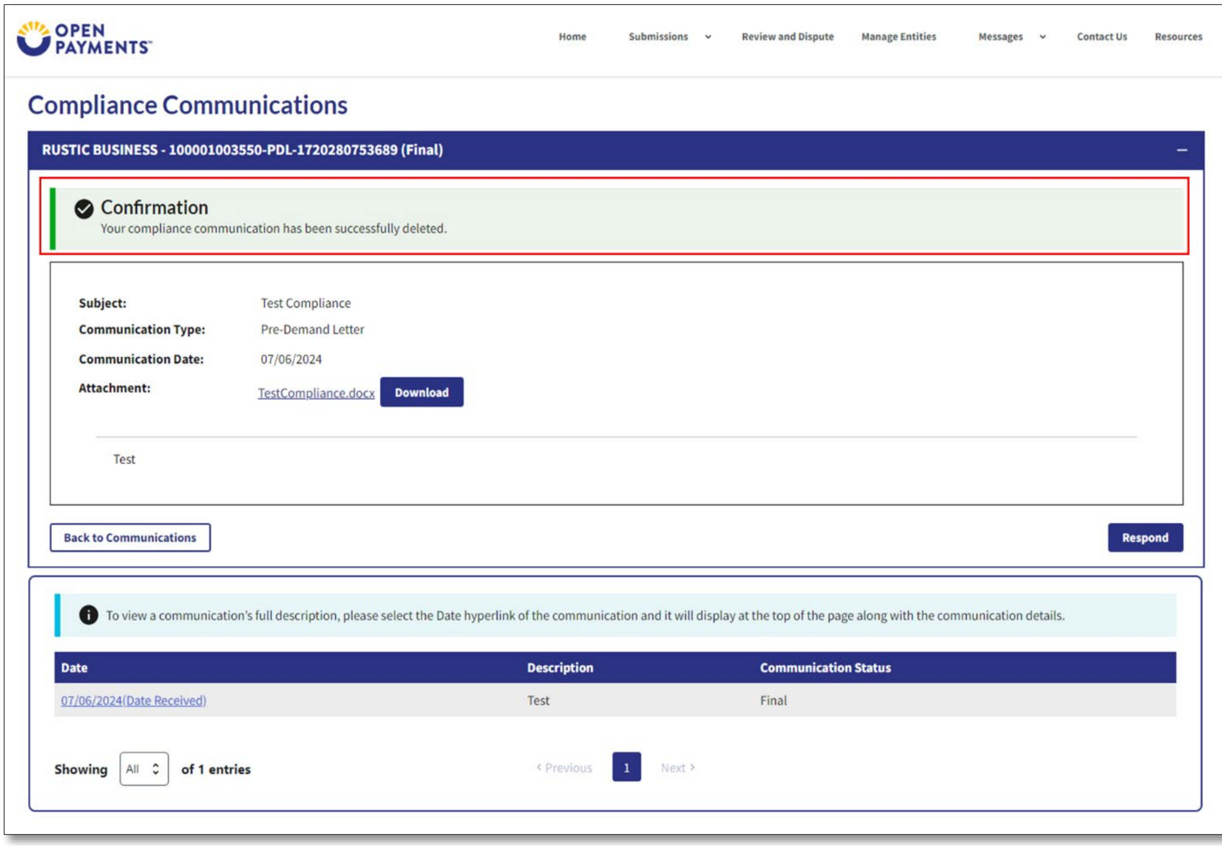


Once the communication is added as draft version, you will see an expandable view of the message text. Upon expanding the communication, you can either edit, delete, or finalize the communication.

Upon selecting the **Delete** button, a confirmation message will appear allowing you to select either **Yes** to delete the communication or **No** to cancel the action.

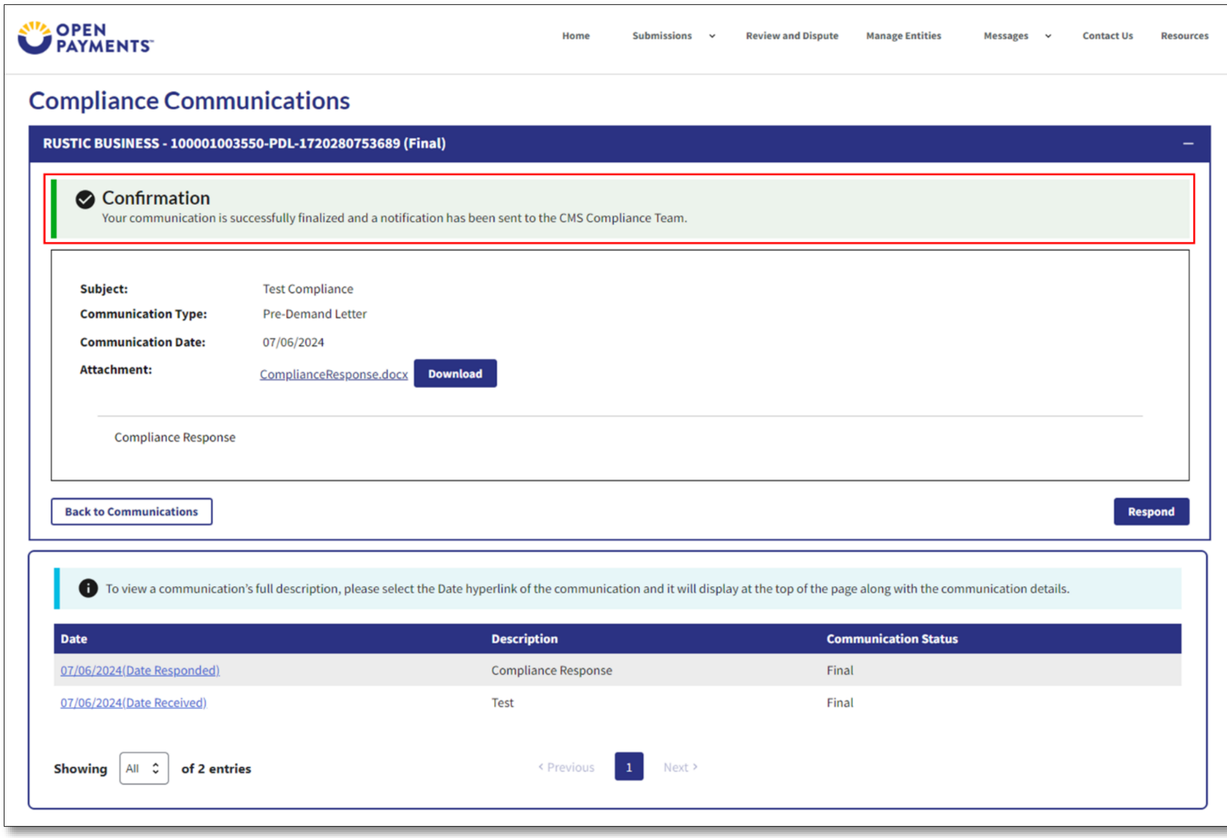
Upon selecting **Yes**, the draft communication will be deleted and you will see a confirmation message on the screen. This action will delete only the draft communication and does not delete any previous communications. Also, the **Delete** button will not appear for the communications that are in final status.

Figure 325: Confirmation Message



Upon selecting the **Finalize** button, the confirmation message will allow you to select either **Yes** to finalize the communication or **No** to cancel the action. Upon selecting the **Yes**, the "Communication Status" changes from draft to final. This action will notify the CMS Compliance team about the response. When a communication is finalized, a confirmation message will be provided on the page. Upon selecting the **No**, the user action will be cancelled.

Figure 326: Confirmation Message



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, re-packagers, re-labelers, 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 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), physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife or anesthesiologist assistant (see *Non-Physicians Practitioners* 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, non-physician practitioner 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 physician 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.

Non-Physician Practitioners:

The Open Payments program expanded the definition of covered recipients to include the following Non-Physician Practitioners:

- Physician Assistant (PA): an individual who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.
- Nurse Practitioner (NP): an individual who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.
- Clinical Nurse Specialist (CNS): an individual who is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and holds a master's degree in a defined clinical area of nursing from an accredited educational institution.
- Certified Registered Nurse Anesthetist (CRNA)/Anesthesiologist Assistant (AA): a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists.
- Certified Nurse-Midwife (CNM): a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary or has been certified by an organization recognized by the Secretary.

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/Resources. 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 327: 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

Special Character	Description
{	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 328: 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

Foreign Character	Convert to English Character
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/Resources.

Disclosure

- **Disclaimer:** The contents of this document do not have the force and effect of law and are not meant to bind the public in any way unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.
- **Activities/persons addressed by this document:** Guidance for applicable manufacturers and applicable group purchasing organizations to understand how to comply with Open Payments, including how to operationalize the collecting and reporting of data.
- **Date of document issuance:** January 2025
- **Replacement / Revision Status:** Revision to previous versions
- **Agency Identifier:** OBRHI CFRG 4179
- **Summary of Document:** A one-stop-shop resource to help applicable manufacturers and group purchasing organizations (GPOs) understand in detail how the Open Payments system works.
- **Citation to statutory provision/regulation applicable to this document:**
    - **Statute citation:** Social Security Act SEC. 1128G. [42 U.S.C. 1320a-7h]
    - **Rule citation:** 42 C.F.R. §403.900-14