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User Guide for Reporting Entities

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

CREATING PUBLIC TRANSPARENCY INTO INDUSTRY-PHYSICIAN FINANCIAL RELATIONSHIPS

September 2020

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

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INTRODUCTION

Purpose of the Open Payments User Guide

This Open Payments User Guide includes definitions, descriptions, screenshots, tools, and tips designed to help applicable manufacturers and applicable group purchasing organizations (AM/GPOs), collectively referred to as "reporting entities", better understand how to comply with Open Payments (the Sunshine Act), including how to operationalize the collecting and reporting of data.

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

- Introduction to Open Payments
- Introduction to Reporting and Data Collection
- Applicable Manufacturer and Applicable Group Purchasing Organization (AM/GPO) Registration
- Data Submission and Attestation
- Review, Dispute and Correction
- Additional Information and Resources

Version	Date Published	Description	Version Updates
1.0	August 2013	Initial Release	Chapters 1, 2, 3, & 4
2.0	June 2014	Update	Chapters 1, 2, 3, 4, & 7
3.0	July 2014	Update	Chapters 5, 8, & 9
3.1	August 2014	Update	Minor corrections and updates
4.0	December 2014	Update	Updates made to Chapter 5
5.0	January 2015	Update	Chapter 10 and updates for registration and data submission
6.0	March 2015	Update	Updates for registration and data submission
7.0	April 2015	Update	Updates for review and dispute
8.0	June 2015	Update	Updated Chapter 10 for PY2014 data publication
9.0	January 2016	Update	Updated throughout to reflect system updates in Jan 2016
10.0	June 2016	Update	Updated publication chapter, added to glossary
11.0	January 2017	Update	Updated to reflect changes to registration and data submission
12.0	June 2017	Update	Updated publication chapter, removed outdated information
13.0	September 2017	Update	Updated to reflect system updates
14.0	January 2018	Update	Updated to reflect system updates
15.0	March 2018	Update	Updated to reflect system updates for Review and Dispute
16.0	January 2019	Update	Updated to reflect system updates
17.0	September 2019	Update	Updated to reflect system updates
18.0	January 2020	Update	Updated to reflect system updates
19.0	September 2020	Update	Updated to reflect system updates

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

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

Section 1.1: Program Overview

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

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

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

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

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

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

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

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

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

- Payments or other transfers of value made to physicians and teaching hospitals.
- Certain ownership or investment interests held by physicians or their immediate family members.
- Applicable GPOs are required to annually report to CMS:
 - o Payments or other transfers of value made to physician owners or investors.
 - Certain ownership or investment interests held by physicians or their immediate family members.

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

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

1.1d: Key Dates for Open Payments Program Years

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

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

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

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

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

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

- June Publication Initial Publication
 - 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 30, 2017 data publication included the initial publication of Program Year 2016 data and republication of prior program years. The early 2018 data publication, also referred to as the "data refresh" included the refresh publication of Program Year 2016 data and republication of prior program years.

Registration for the Open Payments system, and the ability to dispute data, is available year-round.

The table below outlines the annual Open Payments Program Timeline.

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

Table 1: Open Payments Program Year Timeline

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

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

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

- **Step 1:** Determine if the entity <u>operates in the United States</u> (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 <u>activities</u> 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 <u>covered products</u>. See the reference guide in **Figure 2.**
- <u>Step 4:</u> 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.

- <u>Step 5:</u> Determine if the entity <u>operates in the United States</u> (includes any territory, possession, or commonwealth of the United States). See the reference guide in **Figure 3.**
- <u>Step 6:</u> Determine if the entity engages in <u>activities</u> of an applicable GPO. See the reference guide in **Figure 3.**
- <u>Step 7:</u> Determine if the entity's products are covered drugs, devices, biologicals, or medical supplies, or <u>covered products.</u> See the reference guide in **Figure 3.**
- **Step 8:** If the entity possesses the characteristics illustrated in Figure 3, the entity is determined to be an applicable GPO in Open Payments.

If the entity does not possess the characteristics as illustrated in **Figure 3**, the entity is not determined to be an applicable GPO in Open Payments.

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

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

Figure 1:	Determining if an En	tity Is an Applica	ble Manufacturer
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Figure 2 provides a reference guide for determining if a drug, device, biological, or medical supply purchasing entity is an applicable GPO in accordance with Open Payments. **Figure 2** also outlines the characteristics of applicable GPOs.

Characteristic	Group Purchasing Organization IF
Operate in US?	 Entity's physical location is within the United States and/or it conducts activities within the United States. This includes any territory, possession, or commonwealth of the United States.
Activities	 Purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.
	 Reimbursed by Medicare, Medicaid, or Children's Health Insurance Program AND
Covered products	 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.

Figure 2: Determining if an Entity Is an Applicable GPO

Section 1.3: Who Are Entities Reporting On

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

- Doctors of medicine or osteopathy practicing medicine or surgery
- Doctors of dental medicine or dental surgery practicing dentistry
- Doctors of podiatric medicine
- Doctors of optometry
- Chiropractors

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

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

Section 1.4: Open Payments System Overview

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

Applicable manufacturers, applicable GPOs, physicians, and teaching hospitals who participate in the Open Payments program must register in the Open Payments system. **Figure 3** provides a high-level process flow.

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

Figure 3: High-Level Process Flow for Open Payments

1.4a: Open Payments Browser Requirements

The Open Payments system is a web-based application and should be run only on Internet Explorer (version 8 or higher) or Mozilla Firefox.

1.4b: Functionalities within the Open Payments System

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

Key functions of Open Payments system users include the following:

- For applicable manufacturers/applicable GPOs: Register in the system, submit data into the system, verify the data, and attest to the accuracy of the data.
- For physicians/teaching hospitals: Register in the system, review the data supplied by applicable manufacturers and/or applicable GPOs, and dispute or affirm the data.

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

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

1.4c: Setting Email Filters to Accept Open Payments Emails

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

1.4d: Accessibility Guidance

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

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

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

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

1.4d (2): Useful JAWS Keystrokes

The keystrokes given in **Figure 4** find the next occurrence of a particular element on a page. Using the Shift key at the same time will find the previous occurrence. These shortcuts allow a screen reader user to quickly jump their screen reader between the form fields on each page or explore the overall structure of the page by jumping between the different headings on the page that denote the start of different content areas on the page.

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

Figure 4: Useful JAWS Keystrokes

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

Section 1.5: Additional Information and Resources

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

1.5a: Open Payments Website

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

1.5b: Open Payments Resources

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

1.5c: Open Payments Help Desk

The Open Payments Help Desk serves as the single point of contact for all Open Payments-related inquiries. The Help Desk offers guidance on Open Payments, actions users can take in the system, and technical support. You can submit inquiries to <u>openpayments@cms.hhs.gov</u> or call 1-855-326-8366. For **the TTY line, call 1-844-649-2766.** The Help Desk's hours of operation are posted on the Open Payments website.

1.5d: Open Payments Mailing List

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

Figure 5: Receive Email Updates



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

Figure 6: New Subscriber screen on the CMS website

Deles and Free	
Primary Ema	ail Address
	a primary email address. You will use this to access and update your modify your subscriber preferences.
Email Address	* Subscriber@yopmail.com
Confirm Email Address	*
Email Delive	ry Preference
If you would like below.	to change how subscription updates are delivered to you, select an option
Send updates	immediately by email
O Send updates	daily by email
O Send updates	weekly by email
	rity updates may be sent regardless of your delivery preferences.
Certain high prior	
Optional Pas	
Optional Pas Enter an optiona	ssword al password to add password protection to your subscriber preferences.
Optional Pas	
Optional Pas Enter an optiona	al password to add password protection to your subscriber preferences.

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

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

	CENTERS FOR MEDICARE & MEDICARD STRVICES WWW.Cms.gov www.medicaid.gov www.medicare.gov
Ce	uick Subscribe for Subscriber@yopmail.com nters for Medicare & Medicaid Services (CMS) offers updates on the topics below. bscribe by checking the boxes; unsubscribe by unchecking the boxes.
	cess your subscriber preferences to update your subscriptions or modify your passwore email address without adding subscriptions.
è	🖲 🗆 Medicare
9	C Medicare-Medicaid Coordination
3	[⊕] □ Innovations
	□ □ Regulations & Guidance
	Administrative Simplification
	CMS eHealth
	EHR Incentive Program Email Updates
	🗉 🗌 Open Payments
	General Updates on Open Payments
	Physicians and Teaching Hospitals
	Applicable Manufacturers and Group Purchasing Organizations
1	🖲 🗌 Research, Statistics, Data, & Systems
1	[■] □ Outreach & Education
	€ □ Regional Office Lists
	■ □ Office of Acquisition and Grants Management
	[⊕] □ OIS Portal Project
2	E Developers
1	[®] □ Resources & Tools
5	UBMIT CANCEL
	Your contact information is used to deliver requested updates or to access your subscriber preferences.

Reporting and Data Collection

Chapter 2: Introduction to Reporting and Data Collection

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

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

A complete listing of metadata elements used for payments data input into the Open Payments system can be found in the "Submission Data Mapping Document." Due to changes in record formats, there are two versions of the Submission Data Mapping document, one for Program Years 2013-2015 and one for Program Year 2016-2020. Both are available on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html. These documents provide specific, detailed descriptions of the information that must be collected by reporting entities to document general, research, and physician ownership/investment interest payments.

Section 2.1: General Payments Reporting and Data Collection

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

- **Submission File Information** contains metadata elements collected to properly identify and attribute submitted files.
- **Recipient Demographic Information** identifies the recipient of the general payment or other transfers of value.
- Associated Drug, Device, Biological, or Medical Supply Information identifies the drug, device, biological, or medical supply that is related to the payment or other transfers of value.
- **Payment or Other Transfers of Value Information** specifies information regarding the general payment or other transfers of value.
- **General Record Information** captures other general information about the payment or other transfers of value.

On the Resources page of the Open Payments website

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

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

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

Home	Submissions	Review and Dispute	Manage Entities	O My Profile	Messages	Resources
Open Pa	ayments I	Resources				
Links to the Open	Payments resources	are available below.				
For help obtaining	g a PDF viewer, go to t	he CMS.gov Help page.				
Resources						
 Open Paym CMS Resou Error Code						
Reporting 1	Templates					
		the links below. Download the repared with an incorrect payr			tegory/categories for the	e records to be
Research						
		Research Payments [CSV] Research Payments [CSV]				
General						
		General Payments [CSV] General Payments [CSV]				
Ownership						
b						

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

Section 2.2: Research Payments Reporting and Data Collection

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

- **Submission File Information** contains metadata elements collected to properly identify and attribute submitted files.
- **Recipient Demographic Information** identifies the recipient of the research payments or other transfers of value.
- Associated Drug, Device, Biological or Medical Supply Information identifies the drug, device, biological, or medical supply that is related to the payment or other transfers of value.
- **Payment or Other Transfers of Value Information** specifies information regarding the research payment or other transfers of value.
- **Research-related Information** captures specific information about payments or other transfers of value for research activities.

On the Resources page of the Open Payments website

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

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

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

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

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

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

- **Submission File Information** contains metadata elements collected to properly identify and attribute submitted files.
- **Physician Demographic Information** identifies the recipient of the ownership or investment interests.
- **Ownership or Investment Information** captures information about the ownership or investment.

On the Resources page of the Open Payments website

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

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

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

Registration

Chapter 3: Applicable Manufacturer and Applicable GPO Registration

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

This chapter is divided into the following sections:

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

Section 3.1: Two-Step Registration Process Overview

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

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

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

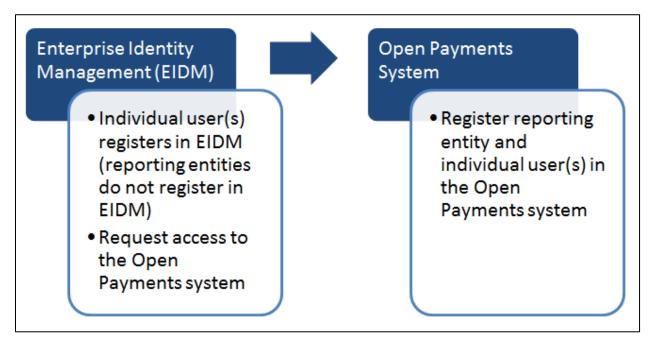


Figure 9: Applicable Manufacturer and Applicable GPO Registration

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

Enterprise Identity Management (EIDM) is an identity management and services system that (1) serves as an identity proofing tool to verify a person's identity and (2) provides you with access to CMS applications, including Open Payments. Registering in EIDM provides you with log in credentials **required** for access to the Open Payments system. You will be able to set up your own log in credentials in the form of a user ID and password during the EIDM registration process. To begin the registration process, access EIDM via the CMS Enterprise Portal at <u>https://portal.cms.gov</u>. A list of EIDM FAQs is available on the CMS portal at

<u>https://portal.cms.gov/wps/portal/unauthportal/help/</u>, and information about EIDM registration can be found on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html.

If you already have EIDM credentials, you can move to 3.2c: Requesting Access to Open Payments with EIDM Credentials for instructions on how to request access to the Open Payments application.

EIDM will lock your account if no account activity is reported for 60 or more days. When you log in after 60-days, the system will display the "Unlock My Account" view. To unlock the account, enter the user ID and correctly answer all challenge questions. Then enter a new password in the input fields of "New Password" and "Confirm New Password". If the account does not reactivate, contact the Open Payments Help Desk by phone at 1-855-326-8366. For the TTY line, call 1-844-649-2766.

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

3.2a: System Requirements

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

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

3.2b: EIDM New User Registration

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

CMS.gov Enterprise Portal		Find Your Application	Help About	E-Mail Alerts
		Ó		Y
	CMS.gov Enterprise Portal	- 11		
Us	rID			
Pa	sword			
	gree to our Terms & Conditions			
	Login			1
For	ot your <u>User ID</u> or your <u>Password</u> ?			
	New User Registration			7
				15
				1

Figure 10: CMS Enterprise Portal Public Landing Page

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

Step #1: Choose Your Application			
Step 1 of 3 - Select your application from the dropdown. You will then need to agree to the terms.			
Open Payments: Physician Payments Sunshine Act	*		
Terms & Conditions	2	-	
OMB No. 0938-1236 Expiration Date: 04/30/2017 OMB No.0938-1236 Expiration Date: 04/30/2017 (OMB Re-Certification Pending) Papenwork Reduction Act Consent to Monitoring			
By logging onlo this website, you consent to be monitored. Unauthorized attempts to upload information and/or change information on this web site are sit unabilitied and an existing to neuronation under the Constructor Ensure and Ahures Art of 1068, and Ensure 1812 C. Soc. 1001 and 1020. Mix encourance units for	ctly v		
I agree to the terms and conditions Next Cancel			

Figure 11: Choose Your Application page

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

Data fields to be completed are the following:

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

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

CMS.gov Enterprise Portal					📑 Find Your Application	Help	O About	E Mail Alerts
	Step #2: Register Step 2 of 3 · Please enter your personal a All fields are required unless marked	nd contact information.	nation					
	First Nante Karen	Enter Middle Name (r	optional)	Last Name Miller	Suffix (optional)			
	Social Society Number (optional) 123456789	Birth M August	onth V	Birth Date Bi 16 ¥ 197	eth Year 2 🗸			
	Is Your Address US Based?			Enter Home Address #2 (optio	na)			
	City	State		Xip Code				
	Baltimore	Maryland	*	21244	Enter Zip+4 (optional)			
	E-mail Address- karen.miller@yopmail.com			e E-mail Address Ier@yopmail.com				
	Phone Number 1234567890	×						
	Back	ext Cancel						

Figure 12: Register Your Information page

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

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

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

CMS.gov Enterprise Portal					Find Your Application	1 Help	About	E-Mail Alerts
	Step #3: Create U			& Challenge Questions				
ssword Requirements ur Password must be changed at least every 60	User ID Tester1							
vui Password must be changed at least every 60 ys. Be a minimum of 8 and a maximum of 20 aracters. Password can be changed once every hours. Contain at least 1 letter, 1 number and 1 ecial character. Contain at least 1 upper case d 1 lower case letter. Be different from previous	Password	Confirm Password						
swords used. Not contain your User ID. Not takin commonly used words. The following scial characters may not be used $? > ()^{+*}/18$.	What is your favorite radio station?		*	Challmage Question #1 Answer ABC				
	What is a relative's telephone number	r that is not your own?	×	Challenge Question #2 Answer 123456789				
	What is the name of the manager at y	our first job?	*	Challenge Question #3 Answer ABCD				
	Back	ext Cancel						

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

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

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

CMS.gov Enterprise Portal				Find Your Application	9 Help 1 About	E-Mail Alerts
	Registration Sum		ing.			
	Open Payments: Physician Payments	Sunshine Act		v		
	All fields are required unless marked ' First Name		Last Name			
	Karen	Enter Middle Name (optional)	Miller	Suffix (optional)		
	Social Security Number (optional) 123456789	Birth Month August 🗸	furth Date Birth Ye 16 ¥ 1972	w		
	Home Address #1 123 Main Street		Enter Home Address #2 (optional)			
	City Baltimore	State Maryland V	Zip Code 21244	Enter Zip+4 (optional)		
	E-mail Address karen.miller@yopmail.com		m E-mail Address iller@yopmail.com			
	Phone Number 1234567890					
	User ID Tester1					
	Password	Confirm Password				
	What is your favorite radio station?	~	Security Quistion #1 Anawor ABC			
	What is a relative's telephone number	that is not your own?	Security Question #2 Answer 1234567890			
	What is the name of the manager at yo	ur first job? 🗸 🗸	Security Question #3 Answer ABCD			
	Submit User	Cancel				

Figure 14: Registration Summary page

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

Figure 15: Confirmation page

III Find Y	our Application	Help	About
Confirmation Your ID has been successfully registered with CMS Enterprise Portal. An e-mail has been sent to your registered e-mail address. You can now login by clicking his	×		
	♥Confirmation		

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

3.2c: Requesting Access to Open Payments with EIDM Credentials

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

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

CMS.gov Enterprise Portal		🔡 Find Your Application 🛛 Help 🚯 About 🔛 E-Mail Alerts
		0
	CMS.gov Enterprise Portal	
	OPUser1	
	Agree to our <u>Terms & Conditions</u>	
	Login	
11-1977	Forgot your <u>User ID</u> or your <u>Password</u> ?	
	目	
	New User Registration	
Lattered !!		

Figure 16: CMS.gov Enterprise Portal landing page

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

Figure 17: My Portal Page

CMS.gov My Enterprise Portal	😫 Mary Moore 🛩 🛛 Help 🛛 😫 Log Out
My Portal	
Use the below link to request access to CMS Systems/Applications.	
2+	
Presuvents/Adda Appan	

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

Figure 18: My Access Pa	ige
-------------------------	-----

CMS.gov My Enterprise Portal			😧 Mary Moore 👻 😰 Help 👘 🕒 Log Out
Access Catalog Open Payments	REQUEST ADMIN ROLE	My Access	
Event Preparent The Care Payments against activities the reporting management of Carlot Internation (24.44.5%) Sectors 31.7 (Successful) Barras 31.7 (Successful)		You currently do not have access to any applications. Please use the access called to request access to the applications.	
		My Pending Requests You do not have any pending inquests at this time.	

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

"Applicable Manufacturer, GPO, Physician or Teaching Hospital" from the "Role" drop-down menu. Select the "Submit" button when complete.

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

	My Enterprise Portal	\varTheta Mary Moore 👻 🛛 Help	🕞 Log Out
CMS.gov (1) envision rock (2) Access My Access Research Manage My Access Annual Certification			

Figure 19: Request New System Access Page

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

Figure 20: Identity Verification Information Page

ader mode Off Access	Control of the second se
My Access	Identity Verification
cess	To protect your privacy, you will need to complete identity. Verification successfully, before requesting access to the selected role. Below are a few items to kiep in mind.
ew and Manage My cess mual Certification	Ensure that grouts are sentently cover legit many survey three surveys of theme dates during and femal address controll, legit and and and cover personal information to sent your dentity with Expense, an extend legits) Variations provide Justity Variations movies Expense using information from your credit report to help confirm your dentity. As a result, you may see an entry called a "soft negat" conjust Expense rend report. Soft majories do not alloct your credit score and you do not incur any changes related to Berning Many and to have access to our period and credit report to help confirm your dentity, and are question to you, to aud on data to in the "fast Period Confirmed Legits". A set the "fast Period Confirmed Legits" and the "fast Period Confirmed Legits" and the "fast Period Confirmed Legits". A set the "fast Period Confirmed Legits" and the "fast Period Confirmed Legits" and the "fast Period Confirmed Legits". A set the "fast Period Confirmed Legits" and the "fast Period Confirmed Legits". A set the "fast Period Confirmed Legits" and the "fast Period Confirmed Legits". A set the "fast Period Confirmed Legits"
	il you diet to proteet new, you will be prompted with a Terms and Conditions, statement that asplans how your Personal Isentitable Information (PD) is used to confirm your starting. To contruct the process, welch Terri
	Land Coved

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

Figure 21: Terms and Conditions Page

CMS.gov	My Enterprise Portal O Mary Moore - O Help (+	Log Ou
Access	Terms and Conditions	
equest New System	OMB No. 0936-1236 Expiration Date: 04/39/2017 (OMB Re-Certification Pending) Experience: Reduction_Act	
ew and Manage My	Protecting Your Privacy	
nual Certification	Protecting your Privacy is a top priority at CMS. We are committed to ensuring the security and confidentiality of the user registering to EDNI. Prease read the CMS Privacy Act Statement - which describes how we use the information you provide.	
	"Personal" information in described as data that is unique to an individual, such as a name, address, teleptone number, social security number, and date of brith (IDCB). DNS is very aware of the privacy concerns around PII data. In fact, we share your concerns. We will only colde admitted to with your defetty. Your afformation will be discloted to Experian, an isotenia authentication serves providers. It halp us will your defetty. The admitted to with Experian data will be discloted to Experian. An isotenia authentication serves providers. It halp us will your defetty. The admitted to ad	ct person an verifie
	HHS Rules Of Behavior	
	We encourage you to read the 1915 Pukes of Retractor, which provides the appropriate use of all HHS information technology resources for Department users, including Federal employees, contractors, and other system users.	
	Linkin read the 1495 Rolas of Bathound for Philipped User Accounts addenates to the 1495 Rolas of Bathound (HS Rol), elsculater another the ROL (ACCOUNT) 20005 and used added 24/24. 2011), and usebated and agree to comply with tepressions i understand that voicino i Rolas (Rolas Concentrational terration) and the Rolas of Bathound (HS Ros af Rolas of Bathound (HS Rolas of Bathound (HS Rolas of	ederal .
	Identity Verification	
_	I understand that the identity proofing services being inquested are regulated by the Far Credit Reporting Act and that my explicit consent is required to use these services. I understand that any special procedures established by CMS for identity proofing using Experian have been be services requested by CMS to Experian will be used solely to confirm the applicant's identity to avoid fraudulent transactions in the applicant's name.	in met ar
	I agree to the terms and conditions.	
	Ref	

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

CMS.gov N	ty Enterprise Portal
creen reader mode Off Accessibility My Access Request New System Access View and Manage My Access Annual Certification	
	Enter your E-mail address, as it will be used for account related communications.
	Enter your date of birth in MMIDD^YYYY format, as it may be required for Identity Verification.
	Next

Figure 22: Your Information Page

<u>Step 8:</u> Verify your identity by answering the identity proofing questions. The identity proofing questions are created by Experian based upon the information you entered during EIDM registration as well as information in Experian's databases. Experian also performs a soft credit inquiry to verify your identity. **Identity proofing does not affect your credit score.** Soft credit inquiries are visible only to you and only appear on credit reports produced by Experian. Credit inquiries are not visible to lenders. If you order a credit report from Experian, you will see an entry of inquiry by the Centers for Medicare & Medicaid Services with CMS's address and the date of request. If you have questions about Experian's verification process, please refer to Experian Customer Assistance at http://www.experian.com/help/.

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

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

CMS.gov	My Enterprise Portal	9
n reader mode Off Accessi	blify Settings	
My Access	Verify Identity Verify Identity	
Beauent New System Andrea Wew and Manage My Access Annual Certification	You may have opened a mortgage loan in or around October 2017. Please select the lender to whom you currently make your mortgage payments. If you do not have a mortgage, select NONE OF THE ABOVEDOES NOT AP	ųγ.

Figure 23: Verify Identity Page

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

Figure 24: Successful Confirmation	n Message Page
------------------------------------	----------------

CMS.gov N	Ay Enterprise Portal Dility Settings
My Access	Complete Step Up
Request New System Access	You have successfully completed the Remote Identity Proofing process.
<u>View and Manage My</u> <u>Access</u> Annual Certification	Next

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

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

<u>Step 10:</u> Following step 9 you will be taken to the "Multi-Factor Authentication (MFA) Information" registration page. During the MFA registration process, you will have the option of registering a Phone/Tablet/PC/Laptop, Text Message Short Message Service (SMS), Interactive Voice Response (IVR), or Email to add an additional level of security to your account. It is **not required** to complete this step to obtain access to the Open Payments system. You may also register the device(s) at a later time. Refer to the "Enterprise Portal User Manual," available at <u>https://portal.cms.gov</u> for more information on the MFA process.

CMS.gov M	Ay Enterprise Portal 🙆 Mary Moore 🛩 🛛 Help 🛛 Ge Log Out
Screen reader mode Off Accessib	A second s
My Access	Multi-Factor Authentication Information
Request New System	Adding a Security Code to your login also known as Multi-Factor Authentication (MFA) can make your login more secure by providing an extra layer of protection to your user name and password. You may choose to add this additional level of security to prevent unauthorized access to your account.
View and Manage My Access	To access a CMS application which requires a Security Code to be input at the time of login, select "Add MFA" and follow the on-screen instructions to add the additional level of security
Annual Certification	Select "Skip MFA" to skip adding the additional level of security and to continue with the role request. If you choose to skip MFA now, you can always add it later to your account by accessing the "My Proble" link from the Welcome menu on the top right corner of the page
	Select Cancel to end the fole request.
	Nay WA And WA Crowd

Figure 25: Multi-Factor Authentication Information Page

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

Figure 26: Multi-Factor Authentication Information Page

ly Access	Multi-Factor Authentication Information
iquest New System Cess	Adding a Security Code to your login also known as Multi-Factor Authentication (MFA) can make your login more secure by providing an extra layer of protection to your user name and passwork. You may choose to add this additional level of security to prevent unauthorized access to your account.
eve and Manage My Ideas	To access a CMS application which requires a Security Code to be input at the time of login, select "Add MFA" and follow the on-screen instructions to add the additional level of security
rual Certification	Select "Skip MFA" to skip adding the additional level of security and to continue with the role request. If you choose to skip MFA now, you can always add it later to your account by accessing the "My Profile" link from the Welcome menu on the top right corner of the page.
	Select "Cancel" to end the role request.
	Skip WYA Consul

Figure 27: Successful Completion! Page

CMS.gov My Enterprise Portal		\varTheta Mary Moore 👻	Ø Help	🕒 Log Out	
Screen reader mode Off Accessibility Settings My Accesss	Successful Completion1				•
Request New System Access	Your request has successfully considered. You will need to logout and then log in to access the OPENRATMENTS Application. Select DK to continue or				
View and Manipa My Access Armual Certification					

Step 11a: To proceed with MFA, select, "Add MFA."

Figure 28: Multi-Factor Authentication Information Page

cms.gov	ty Enterprise Portal O Many Moore 👻 O Help 😰 Log Out
My Access	Multi-Factor Authentication Information
inquest New System cons lew and Manage My coss	Adding a Security Code to your login also brown as Multi-Factor Authentication (MFA) can make your login more secure by providing an exits layer of protection to your user name and password. You may choose to add the additional level of security to prevent unauthorized access to your account.
rmual Certification	Select "Skip MFA" to skip adding the additional level of security and to continue with the role request. If you choose to skip MFA now, you can always add it later to your account by accessing the "My Profile" link from the Welcome menu on the top right corner of the page Select "Cancer It even the role request."

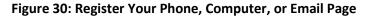
Select the device you wish to register. Depending on the device you choose to register, you will be asked to provide information about that device. You may only register one device at a time. Additional devices may be added later through the EIDM profile settings. Enter the required information for the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



Toy can associate the Security Code to your profile by registering your Phone, Computer or E-mail Select the index below to find out more information about the regions You can associate the Security Code to your profile by registering your Phone, Computer or E-mail Select the index below to find out more information about the regions your Certification You can associate the Security Code Reycone (SMS) > Team Team Address Many Monet@Description Select the IFA Device Type that you are only allowed too alternate to register your device within two attempts please log out, then log back in to fir appan Select the IFA Device Type that you are only allowed too attempts to register your device within two attempts please log out, then log back in to fir appan Select the IFA Device Type that you are to use to log to scare applications from the draptown menu below. Win Device Type: Image Many Monet@Depenetpremit The E-mail address on your profile will addressible used for the E-mail option. Your e-mail address cannot be drapped at the time of MFA registration. To duringe your E-mail, please telect 'Qange E-Mail Address' from the 'Qange My rhote' menu		Ay Enterprise Portal	\varTheta Mary Moore 👻	@ Help	E Log Out
Adding a Security Code to your login able known as Multi-Pactor Authentication (MPA) can make your agon more secure by providing an lotter layer of protection to your user name and passand? CMS Adding a Security Code to your login able known as Multi-Pactor Authentication (MPA) can make your agon more secure by providing an lotter layer of protection to your user name and passand? CMS Adding a Security Code to your login able known as Multi-Pactor Authentication (MPA) can make your agon more secure by providing an lotter layer of protection to your user name and passand? Phoenal TableSEC Aagop > Phoenal TableSEC Aagop > Interactive Voice Response (VR) > E-mail Please note that you are only allowed hew attempts to register your MPA devices. If you are unable to register your device within two attempts please logit out, then log back in to try agan Select the IPA Device Type: Interactive (SMS) > E-mail May MovingGregorepayment The E-mail Address on your profile will automatically be used for the E-mail oppon, Your e-mail address cannot be dranged at the time of MPA registration. To drange your E-mail, please select 'Qiange E-fail Address' from the 'Qiange My rhothe' mark					
Bit Phone TAblePCC.Exptp is usit Certification P Fast Message Shore(SMS) > Fast Message Shore(KMS) P Fast Message Shore(KMS) > E-mail Pease note that you are only allowed too attempts to register your device within the attempts please log out, then log back in to try again • MFA Device Type: Ferret Pease note that you are only allowed too attempts to register your device within the attempts please log out, then log back in to try again • MFA Device Type: Ferret Pease note • MFA Device Type: Ferret Pease note • The E-mail Address on your portife will automatically be used for the E-mail option. Your e-mail address cannot be dranged at the time of MFA registration. To change your E-mail, please belet: "Dange E-Mail Address" from the 'Qange My choile' mer	uest New System 195				
Select the MFA Device Type that you want to use to login to secure applications from the dropdown minu below. MFA Device Type: If-eff IV E-mail Address on your profile will automatically be used for the E-mail option. Your e-mail address cannot be changed at the time of MFA registration. To change your E-mail, please belect 'Change E-Mail Address' from the 'Change My Profile' men	19	I≫ Text Message Short Message Service (SMS) I≫ Interactive Volce Response (IVR)			
• MA Device Type: E-mer (Y) E-mail Address: Mary Moore@openpayment The E-mail address on your profile will automatically be used for the E-mail option. Your e-mail address cannot be changed at the time of MFA registration. To change your E-mail, please extent (Dange E-Mail Address' from the 'Dange My Profile' mer					
The E-mail address on your profile will automatically be used for the E-mail option. Your e-mail address cannot be changed at the time of MFA registration. To change your E-mail, please when't (Parepe E-Mail Address' from the 'Qarage My Profile' ner	-				
			ge E-Mail Address' from the '	Change My Prof	lie' menu.
•MFA Device Description		- MFA Devce Description			

You will receive a confirmation that the MFA device you entered has been successfully registered.

Select the "OK" button to continue.



CMS.gov	Viy Enterprise Portal	😧 Mary Moore 👻 🥹 Help 🛛 🗘 Log Out
Screen reader mode Off Access		
Bequest New System Access Very and Manage My Access Annual Certification		

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

Figure 31: Successful Completion! Page

CMS.gov My Enterprise Portal		\varTheta Mary Moore 👻 😧 Help	E Log Out
reen reader mode OP Accessibility Settings My Access Rouvent time Vortem Access Yore and Marcosc My Access Access Access Access Access Access Access Access	Successful Completion! Your request has successfully completed. You will need to togo at and then log on to access the OPENPAYMENTS Application. Soliect 'OK' to continue	-	

"My Access" page displays the System(s) and Roles(s) you have access to.

ader mode Off Accessi	bility Settings					
	Manage Access Pend	ng Requesta				
Access	View and Manage My Access					
quest New System	Select (Add & Role' or Termove s	Role' to manage your ectens for a system.				
icess ew.and Manage My icess	Systems	My Roles	Additional Details	Remove a Role	Add a Role	
cess mual Certification	OPENPARTENTS Applaant	Report to Messferture: SPCI. Propinger in The	T.	Record for	Billatur	

Section 3.3: Open Payments Users and User Roles

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

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

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

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

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

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

Figure 33: Open Payments User Roles

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

Section 3.4 Registering Applicable Manufacturers and Applicable GPOs

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





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

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

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

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

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

Figure 35: Entity Profile Fields

OMB Control No: 0938-1237 Expiration Date: XX/20XX

Open Payments User Guide_for_Reporting_Entities_September-2020

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

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

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

Figure 36: User Profile Fields

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

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

Important Notes:

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

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

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

Figure 37: Open Payments Home Screen



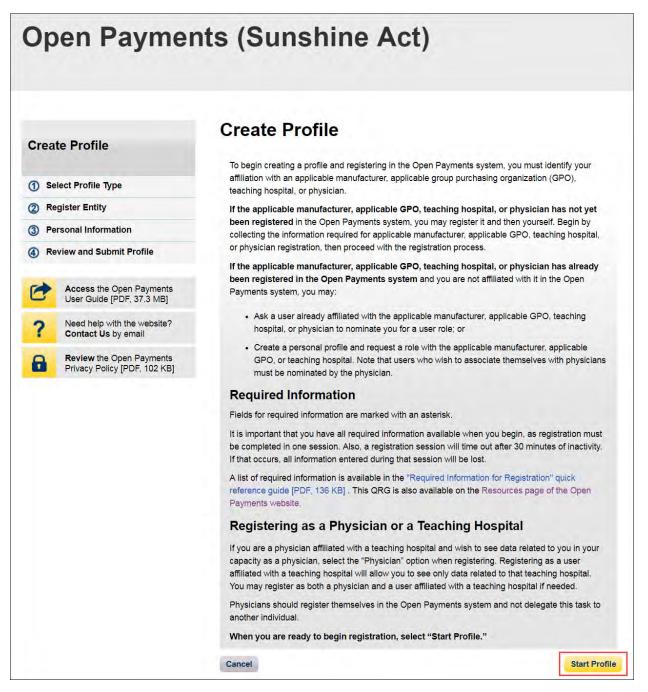
<u>Step 2:</u> The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" when you are ready to begin the registration process.

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



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

Figure 39: Create profile page



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

Figure 40: Select Profile Type page

Op	en Paymer	nts (Sunshine Act)					
Crea	te Profile	Select Profile Type					
orea	ite i rome	A field with an asterisk (*) is required.					
() s	elect Profile Type	If you received a nomination ID and/or a registration ID in an email notifying you of your nomination for a user role, begin creating your profile by selecting the "I have a Nomination ID and/or a Registration ID"					
2 Re	egister Entity	link.					
③ Personal Information		If you did not receive a nomination ID and/or a registration ID in an email, begin creating your profile by indicating below whether you are a physician or are affiliated with an applicable manufacturer or					
4 Re	eview and Submit Profile	applicable GPO, teaching hospital, or physician.					
0	Access the Open Payments User Guide (PDF, 37,3 MB)	Note: If you are a physician who is affiliated with a teaching hospital and wish to view payments made directly to you, you should register yourself as a physician and not as a teaching hospital. Registering as a teaching hospital user will allow you to view only records submitted to the teaching hospital.					
?	Need help with the website? Contact Us by email	If you have any questions regarding the user type you should register as, please contact the Open Payments Help Desk openpayments@cms.hhs.gov for guidance.					
8	Review the Open Payments Privacy Policy [PDF, 102 KB]	*Required: Select the type of entity or covered recipient you are affiliated with OR the "I have a Nomination ID and/or a Registration ID" link.					
		Applicable manufacturer or applicable group purchasing organization (GPO)					
		Physician Teaching hospital					
		OR					
		I have a Nomination ID and/or a Registration ID					
		Cancel					

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

Open Payments (Sunshine Act) Find an Entity Create Profile A field with an asterisk (*) is required. To find an entity in the Open Payments system, enter the entity's Taxpayer Identification Number (TIN)/Employer Identification Number (EIN) below. Select Profile Type If the Entity's TIN/EIN Is Not Found (2) Register Entity If the TIN/EIN entered does not return any results, the entity has not yet been registered within the Open (3) Personal Information Payments system. You may register the entity by selecting the "Register Your Entity on Open Payments" link. Note: You must also register yourself for the officer user role when registering an entity. You may hold (4) Review and Submit Profile more than one user role. If the Entity's TIN/EIN Is Found Access the Open Payments User Guide [PDF, 37.3 MB] If the TIN/EIN search returns results, check the results to see if the entity you wish to register with is listed. If the entity is not listed, you may register the entity by selecting "Other." If the search results contain the Need help with the website? entity you wish to associate yourself with, you may select that entity and proceed with creating your Contact Us by email personal profile and nominating yourself for a role with that entity. Review the Open Payments Privacy Policy [PDF, 102 KB] Required: Enter the TIN/EIN of the entity. *Enter TIN/EIN: 99-9999999 Find 34-5678901 Cancel Back

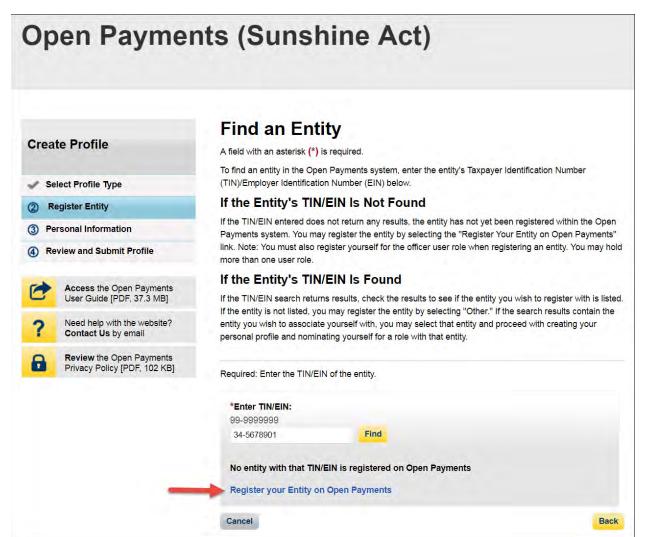
Figure 41: Find and Entity page

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

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

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

Figure 42: Find an Entity page



<u>Step 7:</u> Enter the reporting entity's information. All required fields will be marked with an asterisk (*). You will not be able to proceed with registration until all of the required fields have been entered. Take care to use proper field formatting required by the system. For example, when entering the entity phone number and Taxpayer Identification Number/Employer Identification Number (TIN/EIN), you must include the hyphen ("-") in the proper place within the field to pass field validation.

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

Additional Information on the fields for entity registration:

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

• Applicable manufacturer

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

- applicable manufacturer-drugs/biologicals
- applicable manufacturer-devices/medical supplies
- applicable manufacturer-drugs/biologicals and devices/medical supplies
- applicable manufacturer-physician-owned distributor
- applicable manufacturer-hospital-owned distributor
- applicable manufacturer-distributor/supplier (non-hospital, non-physician-owned)
- Applicable GPO
 - If GPO is selected, an entity must select one of the following business types:
 - GPO-drugs/biologicals
 - GPO-devices/medical supplies
 - GPO- drugs/biologicals and devices/medical supplies
 - GPO-physician-owned

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

	Register Entity	
eate Profile	A field with an asteriak (*) is required.	
Select Profile Type	Complete the information below to create a profile for an	approache manufacturer or applicable GPG
legister Britty	"Entity's Legal Name:	
Entity Information Your Roles	ARCDE Medice	
Your Roles Nominate Additional Roles ersonal Information	*Reporting Entity Type: # Applicable Manufacturer	
riser and Submit Profile	Crose Purchasing Organization	
	"Business Type:	
Access the Open Payments User Guide (PDF, 37,3 MB)	Applicable manufacture/ drugs/biological	
	Food & Drug Administration (FDA) Establishment This is a 10-digit number	Identifier:
Need help with the website? Contact Us by email		
Review the Open Payments Privacy Policy [PDP: 102 KB]	Data Universal Numbering System (D-U-N-SII Num Tris is a B-digit number	iber):
	*URL of Parent Company: http://www.or.https.finnes.or.wnne	
	Www.Ems.gov	
	Production Andrews	
	Business Address	
	"Country:	
	Limited Station	
	*Business Address, Line 1: 7500 Security Red	
	Business Address, Line 2:	
	"City Name:	"State:
	Ballerove	Maryland
	"Zip Code: 99990 0000	"Business Telephone Number: 100-000-0000
	21244	555-559-5595
	Business Ownership Information	
	"Type of Ownership:	
	Corporation	
	*Taxpayer identifier Number (TIN)/Employer identi 05.000000	fication Number (EIN):
	99-1000000 34-5678901	
	"Doing Business As (DBA) Neme:	
	ABCDE Medical	
	"Will this entity's information be submitted in a co on behalf of another entity(? View, my entity's date will be submitted in a como * No, my entity's date will not be submitted in a co i don't know whether my entity's date will be subm	troiger beholderer
	Points of Contact	
	The two identified points of contact will receive import Payments	ant notification emails regarding Open
	Payments. Bains anterest as a coint of context does not register t	that incluids al in the Onen Desmants & star
	Being entered as a point of contact does not register to give that individual access to the system individuals or access the Open Paymenta system.	must be registered in the system if they war
	Primary Point of Contact	
	'Name:	*Business Telephone Number: 1989-9999-9999 or Maximum 20 digm 203-303-3030
	Mary Smith	303-333-3323
	"This at the Entity: Manager	*Business Bmail Address: operpayments_gupmail.com
	Backup Point of Contact	
	"Name:	*Business Telephone Number: 989-899-9999 or Maximum 20 signs
	Joe Miller	446-446-4464
	"Title at the Entity:	Business Email Address:
	Server Manager	operpayments 1 ((tyopmeil.com
	Contact Information for Review an	
	In the "Contect Information" box below, provide contex who are assisting with the dispute resolution process, for physicians and teaching hospitals	You may also include additional instruction
	Note: the contents of the "Contact Information" bos with	i be visible to the covered recipients
	Note: the contents of the "Contact Information" box wi associated with the records during the review process entered in this field.	. The contents will be displayed exactly as
	"Contact Information:	
	500 sharactara maximum. Charactara entered poer Please contact Mary Smith	train more call And the Second
	475 characters remaining	
	Cancel	Back 0

Figure 43: Register Entity page

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

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

Figure 44: Your Role page

Open Paymer Applicable Manufacturer or Group Purchasing Or	nts (Sunshine Ac ganization Switch User Type	et)
Home Submissions F	teview and Dispute Manage Entities	My Profile Messages Resources
Home Submissions F Create Profile Select Profile Type Register Entity Entity Information Your Roles Nominate Additional Roles Personal Information Review and Submit Profile Access the Open Payments User Guide [PDF] Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF]	 Your Role A field with an asterisk (*) is required. Select your user role(s) below. Note that the indiriole. You may hold more than one user role. An entity may have a maximum of 12 active user compliance role. You may nominate other users of the user roles are as follows: Officer Updates the applicable manufacturer or an nominations for user roles. Can deactivate other users from the entity. Can review and download compliance met opplicable manufacturer or applicable of the submitter role can be held by individual applicable manufacturer or applicable GPO. Attester Attests to the accuracy, completeness, and manufacturer or applicable GPO. Can submit assumptions made in the reportive structurer or applicable GPO. Can submit assumptions made in the reportive structure or applicable GPO. Can review and download compliance met opplicable GPO. Can submit assumptions made in the reportive structurer or applicable GPO. Compliance Can review and download compliance met opplicable GPO. 	vidual who registers an entity must register for the officer user rs, with up to 5 users in an officer role and up to 2 users in the on the next screen or after registration is complete. oplicable GPO profile information and can approve and modify ssages on behalf of the applicable manufacturer or applicable u behalf of the applicable manufacturer or applicable GPO. als from third-party entities who submit records on behalf of the
	(EIDM) profile. You may edit these fields as need not change the corresponding information in you telephone number, select the role(s) you wish to	ted. However, changing this information in Open Payments will r EIDM profile. Enter in your business email and business hold, and select the "Continue" button.
	*First Name: Karen	Middle Name:
	*Last Name: Miller	Suffix (Jr., Sr., etc.):
	*Business Email Address:	*Business Telephone Number: 999-999-9999 or Maximum 20 digits 444-444-4444
	Indicate the role(s) you will hold in the Open P access level of attesters, submitters and comp Highest Level of Role © Officer Reporting-related Roles © Submitter © Attester Compliance-related Roles © Compliance	Payments system. Only an officer may manage the oliance role.

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

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

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

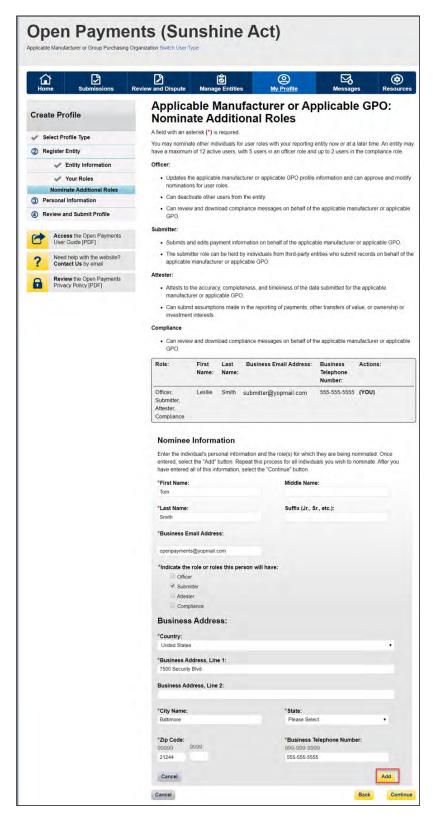
Figure 45: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles page

Crea	te Profile				ifacturer or A onal Roles	pplicab	le GPO	
	elect Profile Tune	A field with an	asterisk (*) i	s required				
	elect Profile Type				or user roles with your reportin			
2) R	egister Entity		m of 12 acti	ve users, v	with 5 users in an officer role a	and up to 2 users i	n the compliano	e role.
	Entity Information	Officer:	the applicat	la manufa	cturer or applicable GPO profi	le information and	can anorous a	nd mode
	Vour Roles		ons for user		cturer or applicable GPO proli	ite information and	can approve an	ia moai
3) P	ersonal Information	Can dea	ctivate other	users from	n the entity.			
R	eview and Submit Profile	 Can revi GPO. 	ew and down	nload com	pliance messages on behalf o	f the applicable m	anufacturer or a	pplicabl
2	Access the Open Payments User Guide [PDF]	Submitter: - Submits	and edits pa	iyment info	rmation on behalf of the appli	cable manufacture	er or applicable (GPO.
?	Need help with the website? Contact Us by email				by individuals from third-party licable GPO.	entities who subr	nit records on be	half of
8	Review the Open Payments Privacy Policy [PDF]		the accuration the		teness, and timeliness of the D.	data submitted for	the applicable	
		investme	mit assumpti nt interests.	ions made	in the reporting of payments,	other transfers of	value, or owner:	ship or
		Compliance • Can revi GPO.	ew and dow	nload com	pliance messages on behalf o	f the applicable m	anufacturer or a	pplicabl
		Role:	First Name:	Last Name:	Business Email Address:	Business Telephone Number:	Actions:	
		Officer, Submitter, Attester, Compliance	Karen	Miller	openpayments@yopmail.com	n 555-555-5555	(YOU)	

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

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

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



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

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

Figure 4	47: Applicable	Manufacturer or	Applicable	GPO: Nominate	Additional Roles page

		Туро					
Create Profile				facturer or A onal Roles	pplicabl	e GP	0:
Select Profile Type	A field with an a	sterisk (*) i	s required.				
	Confirmation:						
2 Register Entity				essfully added.			
Entity Information				r user roles with your reporting vith 5 users in an officer role ar			
Vour Roles	Officer:						
Nominate Additional Roles 3 Personal Information		he applicab	la manufa	cturer or applicable GPO profile	e information and	C30 30000	and modif
	C 1 4 4 4 4 4 4 4 4	ins for user		surer or applicable GPO profile	e montation and	can approv	e and moun
Review and Submit Profile	Can dead	tivate other	users from	the entity.			
Access the Open Payments User Guide [PDF]	 Can review and download compliance messages on behalf of the applicable manufacturer or appl GPO. 						or applicabl
? Need help with the website? Contact Us by email	Submitter: • Submits and edits payment information on behalf of the applicable manufacturer or applicable GPO.						ble GPO.
Review the Open Payments Privacy Policy [PDF]	 The submitter role can be held by individuals from third-party entities who submit records on behalf of the applicable manufacturer or applicable GPO. 						
	Attester:						
	 Attests to the accuracy, completeness, and timeliness of the data submitted for the applicable manufacturer or applicable GPO. 						
		 Can submit assumptions made in the reporting of payments, other transfers of value, or ownership or investment interests. 					
	Compliance						
	Can revie GPO.	w and dowr	nload comp	pliance messages on behalf of	the applicable ma	anufacturer	or applicable
	Role:	First Name:	Last Name:	Business Email Address:	Business Telephone Number:	Actions:	
	Officer, Submitter, Attester, Compliance	Karen	Miller	openpayments@yopmail.com	555-555-5555	(YOU)	
	Submitter	Tom	Smith	openpayments@yopmail.com	555-555-5555	Edit	Delete
	Add						

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

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

	Enter Personal Info	rmation
Create Profile	A field with an asterisk (*) is required.	
A Autor Durite Taxa	Provide personal and business information be	elow to create your user profile.
Select Profile Type		populated from your CMS Enterprise Identity Management sys
Register Entity	(EIDM) profile. You may edit the prepopulated Payments will not change the corresponding	I fields as needed. However, changing this information in Oper information in your EIDM profile.
3 Personal Information	Once you have entered the information, selec	t the "Continue" button.
Review and Submit Profile	Your Name	
Access the Open Payments	*First Name:	*Last Name:
User Guide [PDF]	Leslie	Smith
? Need help with the website? Contact Us by email	Middle Name:	Suffix (Jr., Sr., etc.): 21244
Review the Open Payments Privacy Policy [PDF]	Your Business Contact Informatio	
	Enter your business or entity information.	
	*Business Email Address:	*Job Title:
	openpayments@yopmail.com	Senior Analyst
	*Country:	
	United States	•
	*Business Address, Line 1:	
	7500 Security Blvd.	
	Business Address, Line 2:	
	*City Name:	*State:
	Baltimore	Maryland
	*Zip Code: 99999 9999	*Business Telephone Number: 999-999-9999
	21244	555-555-5555

Figure 48: Enter Personal Information page

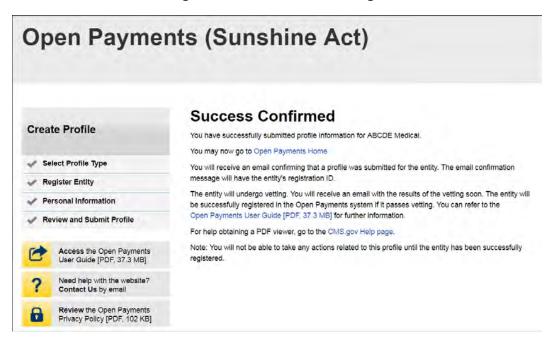
<u>Step 12:</u> Review the information entered for your reporting entity and personal profile. Select the "Back" button at the bottom of the page to go back and edit any information. Once you have reviewed the information and determined it to be correct, select the "Continue" button.

	nts (Sunshine Act)						
licable Manufacturer or Group Purchasing Org	anization switch User Type						
	Review and Submit Profile						
reate Profile	Review the information on this page to ensure it is correct. Select the "Back" button to navigate to the pre-						
	pages to correct any invalid information. Select the "Continue" button to submit your profile.						
Select Profile Type							
Register Entity	Entity's Legal Name: ABCDE Medical Reporting Entity Type: Applicable Manufacturer						
Personal Information	Business Type: Applicable manufacturer-drugs/biological						
Review and Submit Profile	Food & Drug Administration (FDA) Establishment Identifier:						
Access the Open Payments	Data Universal Numbering System (D-U-N-S® Number):						
User Guide [PDF]	URL of Parent Company: www.cms.gov						
Need help with the website? Contact Us by email	Business Address:						
Review the Open Payments	Country: United States						
Privacy Policy [PDF]	Business Address, Line 1: 7500 Security Blvd.						
	Business Address, Line 2:						
	City Name: Baltimore						
	State: Maryland						
	Zip Code: 21244						
	Business Telephone Number: 555-555-5555						
	Business Ownership Information						
	Type of Ownership: Corporation						
	Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 22-3635343						
	Doing Business As (DBA) Name: ABCDE Medical						
	Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? No, my entity's data will not 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 Smith Business Telephone Number: 333-333-3333						
	Title at the Entity: Manager Business Email Address: openpayments@yopmail.com						
	Backup Point of Contact Name: Joe Miller Business Telephone Number: 444-444-4444						
	Title at the Entity: Senior Manager Business Email Address:						
	openpayments@yopmail.com						
	Contact Information for Review and Dispute						
	Contact Information:						
	Please contact Mary Smith						
	Nominations:						
	Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Name: Name: Name: etc.):						
	Officer, Karen Miller openpayments@yopmail.com Submitter, Attester,						
	Compliance Submitter Tom Smith openpayments@yopmail.com						
	openpayments@yopman.com						

Figure 49: Review and Submit Profile Page

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

Figure 50: Success Confirmed Page



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

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

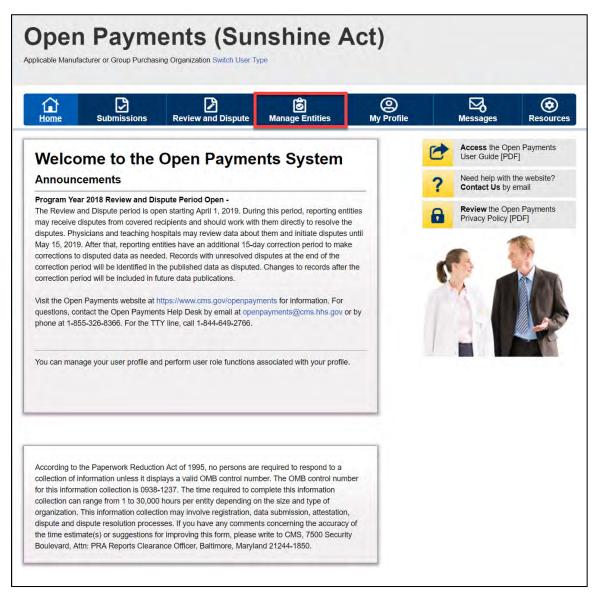
If the reporting entity's registration is unsuccessful, Open Payments will send an email notification to the officer(s) and points of contact stating the entity could not be successfully verified and registered. Contact the Open Payments Help Desk at <u>openpayments@cms.hhs.gov</u> or 1-855-326-8366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

3.4b: Registering an Entity (Returning System Users)

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

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

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



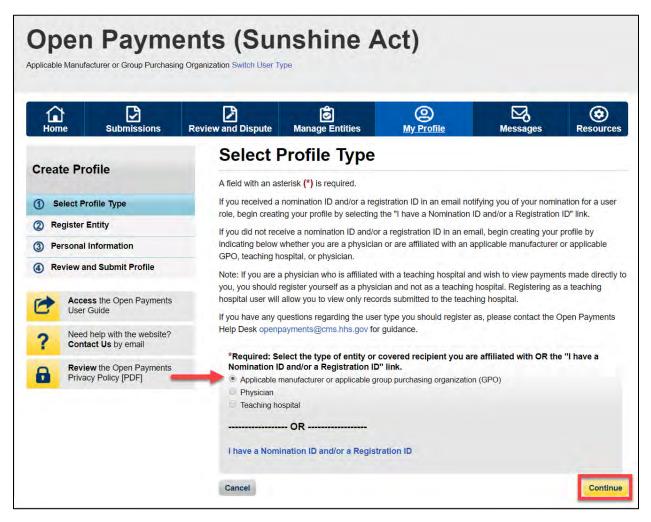
Step 2: Select "Register New Entity."

Figure 52: Manage Entities page

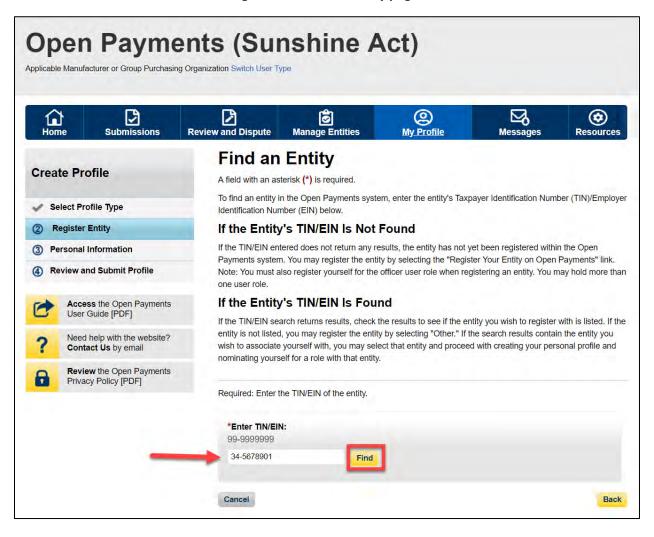
Home	Submissions	Review and Dis	pute M	lanage Entities	() My Profile	M		Resource	
Manage Entities							Access the Open Payments User Guide [PDF]		
						0 N	Need help with the website? Contact Us by email		
The entities you are associated with are listed below. Select an entity from the list below to view the entity's profile and, if you hold the officer role, manage user roles affiliated with the entity.							Review the Open Payments Privacy Policy [PDF]		
hose entities.	ng recertification must to . Entity recertification re ates (as necessary), and	quires that an active c	fficer within t	he Open Payments sy			1	-	
	de to the Entity Name, T				-	E.		KAN	
vonou.						1			
voltou.									

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

Figure 53: Select Profile Type page



<u>Step 4:</u> Once your entity type is selected, provide the reporting entity's Taxpayer Identification Number/Employer Identification Number (TIN/EIN). This will be the entity's Employer Identification Number (EIN), a nine-digit number used by the entity for tax reporting. The format for the TIN/EIN is 99-9999999. Enter the entity's TIN/EIN in the space provided and select "Find." Figure 54: Find and Entity page

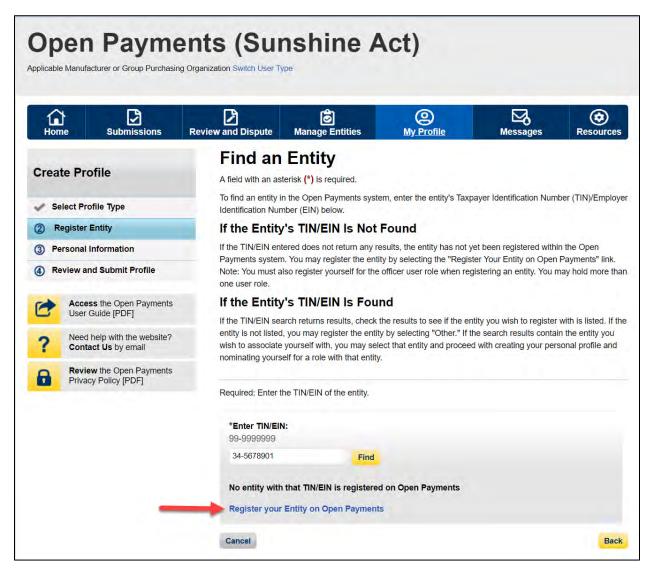


<u>Step 5:</u> The system will perform a search for that TIN/EIN to determine if it has already been registered.

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

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

Figure 55: Find an Entity page



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

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

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

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

Additional Information on the fields for entity registration:

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

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

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

• Applicable GPO

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

- GPO-drugs/biologicals
- GPO-devices/medical supplies
- GPO- drugs/biologicals and devices/medical supplies
- GPO-physician-owned
- GPO-hospital-owned
- GPO-hospital and physician-owned
- GPO-non-hospital, non-physician-owned
- GPO-government-owned
- The **Primary** and **Backup Points of Contact** are individuals who will serve as the points of contact for the reporting entity and CMS. These must be separate individuals. They do not have to be registered in the Open Payments system.

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

	Register Entity	
eate Profile	A field with an asterisk (*) is required	
Select Profile Type	Complete the information below to create a pr	ofile for an applicable manufacturer or applicable GPO
Register Entity Entity Information	*Entity's Legal Name: ABCDE Medical	
Your Roles Nominate Additional Roles	"Reporting Entity Type:	
Personal Information	Applicable Manufacturer Group Purchasing Organization	
Review and Submit Profile	Business Type:	
Access the Open Payments User Guide (PDF)	Applicable manufacturer-drugs/biological	
Need help with the website? Contact Us by email	Food & Drug Administration (FDA) Estab This is a 10-digit number	lishment Identifier:
Review the Open Payments Privacy Folicy [PDF]	Data Universal Numbering System (D-U- This is a 0-digit number	N-S® Number):
	*URL of Parent Company: http://www.or.https//www.or.www	
	www.cms.gov	
	Business Address	
	Enter the business address below	
	*Country: United States	
	Business Address, Line 1:	
	7500 Security Bivs. Business Address, Line 2:	
	Business Address, Line Z.	
	*City Name: Batumore	*State: Maryland
	*Zip Code: 00000 0909 21244	*Business Telephone Number: 000.000-0000 000-000-0000
	21246	320-002-0008
	Business Ownership Inform	
	Enter the business ownership information 5 "Type of Ownership:	elow
	Corporation	
	*Taxpayer identifier Number (TIN)Emplo 00.900000 34.5570501	ver Identification Number (EIN):
	"Doing Business As (DBA) Name: ABCDE Medical	
	"Will this entity's information be submit on behalf of another entity? Ver, my entry's data will be submit * No. my entry's data will not be submit i I don't know whether my entry's data	tted in a consolidated report
	Points of Contact	
	The two identified points of contact will rece	eve important notification emails regarding Open
	Payments. Being entered as a point of contact does no give that individual access to the system in access the Open Payments system	t register that individual in the Open Payments system or dividuals must be registered in the system if they want to
	Primary Point of Contact	
	"Name:	*Business Telephone Number: 999-999-9999 or Maximum 20 digits
	Mary Smith	555-555-5555
	*Title at the Entity: Manager	*Business Email Address: openpayments@yopmail.com
	Backup Point of Contact "Name:	*Business Telephone Number: 000-003-0000 or Maximum 20 riligin
	Joe Miller	555-555-5555
	*Title at the Entity: Senior Manager	*Business Email Address: opengayments@yopmail.com
	Contact Information for Rev in the "Contact Information" for being pro- who are associating with the dispute resolution for physiciania and teaching hospitals.	iew and Dispute rde contact information for individual(s) from your entity n process. You may also include additional instructions
	Note: the contents of the "Contact Informati	on' bux will be yeable to the covered recipients in process. The contents will be displayed exactly as
	*Contact information: 500 cheateries maaimam. Chatalocters an Contact Mary Swith	samed oven if values is well not be surved
	All'2 characters and and	
	482 characters remaining	Back

Figure 56: Register Entity page

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

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

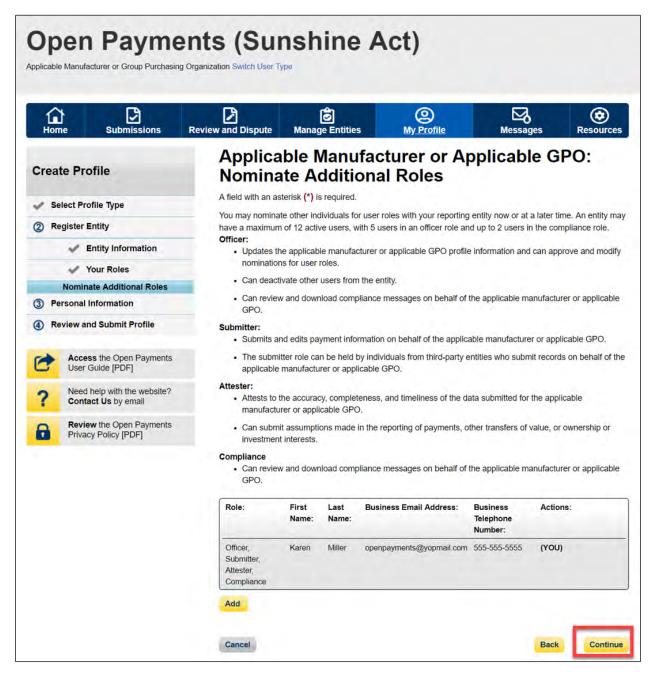
Home	Submissions R	eview and Dispute	Manage Entities	(A) My Profile	Messages	Resources		
		Your Rol	e					
Create	Profile	A field with an aster	isk (*) is required					
/ Sele	ect Profile Type		e(s) below. Note that the more than one user role.	individual who registers a	an entity must register fo	or the officer use		
2) Reg	ister Entity		a maximum of 12 active	users, with up to 5 users	in an officer role and up	to 2 users in th		
	Entity Information		u may nominate other us	ers on the next screen or	after registration is con	nplete		
	/our Roles	The user roles are a	as follows:					
	Iominate Additional Roles	Officer:						
	sonal Information	 Updates the a nominations f 	applicable manufacturer of or user roles	or applicable GPO profile	information and can ap	prove and modil		
A) Rev	iew and Submit Profile	Can deactivate other users from the entity.						
1	Access the Open Payments User Guide (PDF)	 Can review and download compliance messages on behalf of the applicable manufacturer or applicable GPO. 						
~	Need help with the website?	Submitter:						
2	Contact Us by email	· Submits and	edits payment information	n on behalf of the applica	ble manufacturer or app	plicable GPO		
8	Review the Open Payments Privacy Policy [PDF]		r role can be held by indiv anufacturer or applicable		thes who submit recor	ds on behalf of t		
		Attester:						
			accuracy, completeness	and timeliness of the da	ta submitted for the app	vicable		
		manufacturer or applicable GPO. Can submit assumptions made in the reporting of payments, other transfers of value, or ownership or 						
		investment in		oporengi or polymonia, or		a Summaruh a		
		Compliance						
		 Can review a GPO. 	nd download compliance	messages on behalf of t	ne applicable manufacti	urer or applicabl		
		(EIDM) profile. You not change the com	last name have been pro may edit these fields as r esponding information in select the role(s) you wis	eeded. However, changi your EIDM profile. Enter	ng this information in O in your business email	pen Payments w		
		*First Name:		Middle Na	me:			
		Leslie						
		*Last Name: Smith		Suffix (Jr.	, Sr., etc.):			
		"Business Emai	I Address:		Telephone Number: 1999 or Maximum 20 d	lians		
		openpayments@	yopmail.com	555-555-5				
			s) you will hold in the Op testers, submitters and c		ly an officer may manas	je lhe		
		Highest Level o	fRole					
		 Officer Reporting-relate 	d Roles					
		✓ Submitter						
		✓ Attester	ted Poles					
		Attester Compliance-related Roles						

Figure 57: Your Role page

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

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

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



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

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

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

	ganization Switch User	Туре						
						0.7.0		
reate Profile	Nomin	ate A	dditi	facturer or Ap onal Roles	рпсар	e GPO:		
Select Profile Type	A field with an a							
Register Entity				r user roles with your reporting vith 5 users in an officer role and				
Entity Information	Officer:							
Your Roles	Updates	the applicat	le manufa	cturer or applicable GPO profile	information and	can approve and modify		
Nominate Additional Roles		ons for user						
Personal Information	Can dead							
Review and Submit Profile	 Can revie GPO. 	w and down	nload com	bliance messages on behalf of t	he applicable ma	inufacturer or applicable		
	Submitter:							
Access the Open Payments User Guide [PDF]		and edits pa	vment info	rmation on behalf of the applica	ble manufacture	r or applicable GPO.		
Need help with the website? Contact Us by email	The subr	nitter role ca	in be held	by individuals from third-party er icable GPO.				
Review the Open Payments	Attester:							
Privacy Policy [PDF]	Attests to	the accura	cy, comple	teness, and timeliness of the da	ta submitted for t	the applicable		
		urer or appl						
		nit assumpti nt interests.	ons made	in the reporting of payments, ot	her transfers of v	alue, or ownership or		
		Compliance						
		w and dow	nioad com	pliance messages on behalf of t	he applicable ma	inufacturer or applicable		
	GPO.	w and oow	noau com	nance messages on benan or o	ne applicable ma	indiacturer or applicable		
	Role:	First Name:	Last Name:	Business Email Address:	Business Telephone	Actions:		
	Officer, Submitter,	Tom	Smith	openpayments@yopmail.com	Number: n 555-555- 5555	(YOU)		
	Attester,							
	Nominee	e Inform	ation					
	Nominee Enter the ind entered, sele	ividual's per ct the "Add"	sonal infor button. Re	mation and the role(s) for which speat this process for all individu select the "Continue" button.				
	Nominee Enter the ind entered, sele have entered *First Name	ividual's per ct the "Add" I all of this ir	sonal infor button. Re	epeat this process for all individu	uals you wish to r			
	Nomined Enter the ind entered, sele have enterec *First Name Tom	ividual's per ct the "Add" I all of this ir	sonal infor button. Re	epeat this process for all individu select the "Continue" button. Middle Nam	uals you wish to r e:			
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	Nominee Enter the ind entered, sele have entered "First Name Tom "Last Name	ividual's per ct the "Add" I all of this ir	sonal infor button, Re nformation,	epeat this process for all individu select the "Continue" button. Middle Nam	uals you wish to r e:			
	Nominee Enter the ind entered, sele have enterec *First Name Tom *Last Name Smith	ividual's per ct the "Add" I all of this ir	sonal infor 'button. Re formation,	epeat this process for all individu select the "Continue" button. Middle Nam	uals you wish to r e:			
	Nomineer Enter the ind entered, sele have entered. "First Name Tom "Last Name Smith "Business E openpaym "Indicate th	ividual's per ct the "Add" all of this ir : : : : : : : : : : : : : : : : : : :	sonal infor button. Re nformation, sss: nail.com	epeat this process for all individu select the "Continue" button. Middle Nam	uals you wish to r e:			
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	Nominer Enter the ind entered, sele have entered. "Farst Name Smith "Business E openpaym "Indicate th Openpaym "Indicate th Openpaym Indicate th Indicate th Indi	vidual's per ct the "Add" all of this in : : : : : : : : : : : : : : : : : : :	sonal information, button, Rr formation, sss: hail.com les this pre sss:	speat this process for all individu select the "Continue" button Middle Nam Suffix (Jr., S	uals you wish to r e:	nominate. After you		
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	Nominer Enter the ind entered, sele have not "first Name Smith "Business B "openpaym "Indicate th @ Open @ Sub @ S	vidual's per ct the "Add" all of this ir : : : : : : : : : : : : : : : : : : :	sonal information, button, Rr formation, sss: hail.com les this pre sss:	speat this process for all individu select the "Continue" button Middle Nam Suffix (Jr., S	uals you wish to r e:	nominate. After you		
	Nominer Inter the ind entered, selec frant Name Smith *Issiness F openpaym *Indicate th Open Mainter *Sub- Com Business F *County: Unded State *Sub- State *Sub- Sub- *Sub-	vidual's per ct the "Add" all of this ir : : : : : : : : : : : : : : : : : : :	sonal information, button, Rr formation, sss: hail.com les this pre sss:	speat his process for all individu select the "Continue" button. Middle Nam Suffix (Jr., S rson will have: "State: Maryland	e: ir., etc.):	nominate. After you		
	Nominer Enter the ind entered, sele have entered. First Name Tom *Business E openpaym *Indicate th indicate th i	vidual's per ct the "Add" all of this ir : : : : : : : : : : : : : : : : : : :	sonal information, button, Rr formation, sss: hail.com les this pre sss:	speat his process for all individ select the "Continue" button. Middle Nam Suffix (Jr., S rson will have: "State: Maryland "Business T 999-999-901	elephone Numt	nominate. After you		
	Nominer Enter the ind entered, sele have retar Name Tom "Last Name Smith "Business E "Sub- "	vidual's per ct the "Add" all of this in : : : : : : : : : : : : : : : : : : :	sonal information, button, Rr formation, sss: hail.com les this pre sss:	speat his process for all individ select the "Continue" button. Middle Nam Suffix (Jr., S rson will have: "State: Maryland "Business 1	elephone Numt	nominate. After you		

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

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

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

Hon		eview and Dispute		e Entitie	My Profile	Messad		Resources
	te Profile	Applica	able N	Manu	facturer or Aponal Roles			
🗸 Se	elect Profile Type	A field with an a	sterisk (*) is	s required.				
(2) Re	egister Entity	Confirmation: • Your non	ninee has b	een succ	essfully added.			
5	Entity Information	You may nomina	ate other inc	dividuals fo	or user roles with your reporting			
	Your Roles	have a maximur Officer:	n of 12 activ	ve users, v	with 5 users in an officer role an	d up to 2 users in	n the compli	ance role.
	Nominate Additional Roles	 Updates t 			cturer or applicable GPO profile	e Information and	can approv	e and modify
3 Pe	rsonal Information	Can dead	ins for user		the entity			
4 Re	eview and Submit Profile				pliance messages on behalf of	the applicable ma	anufacturer	or applicable
0	Access the Open Payments User Guide [PDF]	Submitter: • Submits a	and edits pa	yment info	rmation on behalf of the applic	able manufacture	er or applica	ble GPO.
?	Need help with the website? Contact Us by email				by individuals from third-party e icable GPO.	entities who subm	nit records o	n behalf of th
8	Review the Open Payments Privacy Policy [PDF]		the accurac urer or appli		teness, and timeliness of the da D.	ata submitted for	the applicat	ble
			nit assumpti nt interests.	ons made	in the reporting of payments, o	ther transfers of	value, or ow	nership or
		Compliance • Can revie GPO.	w and dowr	nload comp	pliance messages on behalf of	the applicable ma	anufacturer	or applicable
		Role:	First Name:	Last Name:	Business Email Address:	Business Telephone Number:	Actions:	
		Officer, Submitter, Attester, Compliance	Karen	Miller	openpayments@yopmail.com	565-555-5655	(YOU)	
		Submitter	Tom	Smith	openpayments@yopmail.com		Edit	Delete

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

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type **Review and Submit Profile Create 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 "Continue" button to submit your profile. Select Profile Type 🛹 Register Entity Entity's Legal Name: ABCDE Medical Reporting Entity Type: Applicable Manufacturer Personal Information Business Type: Applicable manufacturer-drugs/biological Review and Submit Profile Food & Drug Administration (FDA) Establishment Identifier: Data Universal Numbering System (D-U-N-S® Number): Access the Open Payments User Guide [PDF] C URL of Parent Company: www.cms.gov Need help with the website? Contact Us by email ? **Business Address:** Review the Open Payments Privacy Policy [PDF] Country: United States a Business Address, Line 1: 7500 Security Blvd. Business Address, Line 2: City Name: Baltimore State: Maryland Zip Code: 21244 Business Telephone Number: 555-555-5555 **Business Ownership Information** Type of Ownership: Corporation Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 22-3635343 Doing Business As (DBA) Name: ABCDE Medical Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? No, my entity's data will not 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 Smith Business Telephone Number: 333-333-3333 Title at the Entity: Manager Business Email Address: openpayments@yopmail.com Backup Point of Contact Business Telephone Number: 444-444-4444 Name: Joe Miller Title at the Entity: Senior Manager Business Email Address: openpayments@yopmail.com **Contact Information for Review and Dispute** Contact Information Please contact Mary Smith Nominations: Role: First Last Middle Name: Name: Name: Suffix (Jr., Sr., Business Email Address: etc.): Officer, Karen Miller openpayments@yopmail.com Submitter. Attester, Compliance Tom Smith Submitter openpayments@yopmail.com Cancel Back Continue

Figure 61: Review and Submit Profile page

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



Figure 62: Success Confirmed page

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

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

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

Section 3.5: Entity Recertification

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

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

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

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

To recertify a reporting entity, follow these steps.

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

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

Home	Submissions	Review and Dispute	Manage Entities	(Q) My Profile		Messages	Resource
Welco	ome to the	Open Payme	nts System		C	Access the Op User Guide [PD	
Annound	cements		2 Y Y Y S 2 Y Y Y	_	?	Need help with Contact Us by	
The Review a may receive of disputes. Phy May 15, 2019 corrections to correction pe correction pe visit the Oper questions, co	disputes from covered re ysicians and teaching ho 9. After that, reporting er o disputed data as neede eriod will be identified in t eriod will be included in fu en Payments website at i pontact the Open Paymen	en starting April 1, 2019. Duri ecipients and should work with ospitals may review data abountities have an additional 15-d ed. Records with unresolved the published data as dispute	h them directly to resolve the tit them and initiate disputes u ay correction period to make disputes at the end of the d. Changes to records after the ments for information. For	he	8	Review the Opprivacy Policy [
You can man	nage your user profile an	d perform user role functions	associated with your profile.				

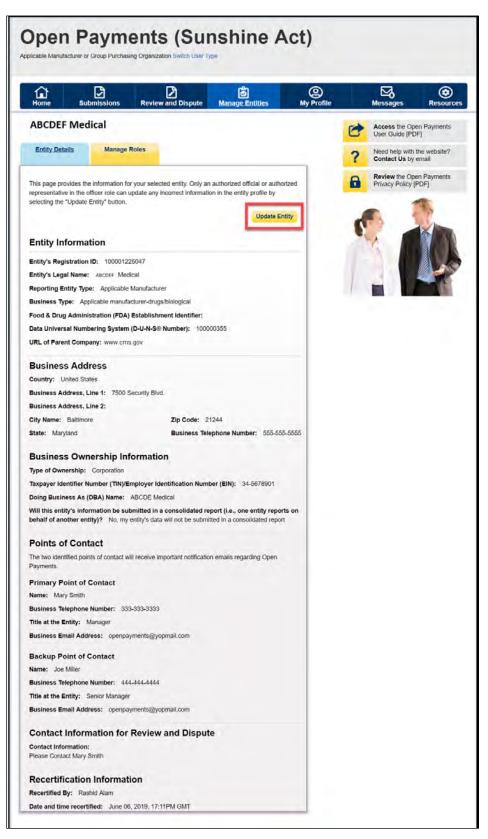
Step 2: From the "Manage Entities" page, select the hyperlink for the entity you wish to recertify.

Figure 64: Manage Entities Page

Home	Submissions	Review and Disp	ute <u>M</u>	lanage Entities	Q My Profile	Me	ssages	Resource
Mana	ge Entities						cess the Op er Guide [PD	en Payments 0F]
				Register New En	tity		ed help with ntact Us by	the website? email
	you are associated with a profile and, if you hold the				N		view the Ope vacy Policy [I	en Payments PDF]
those entities	ding recertification must b s. Entity recertification re lates (as necessary), and	quires that an active offi	cer within th	he Open Payments sy			1	-
Changes ma vetted.	ade to the Entity Name, T	IN, or DUNS Number field	elds will cau	use your entity to be re	-	C,		1XA
Your En	tities					1		
Name: ABCDEF Medic Pending Recen	cal 10	egistration ID: 00000355013	Status: Vetted	Date Verified: 05/24/2019 8:30:01				
	al 1(00000325011	Vetted	05/24/2019 8:30:01				

<u>Step 3</u>: On the entity page, select the "Update Entity" button.

Figure 65: Entity Information page



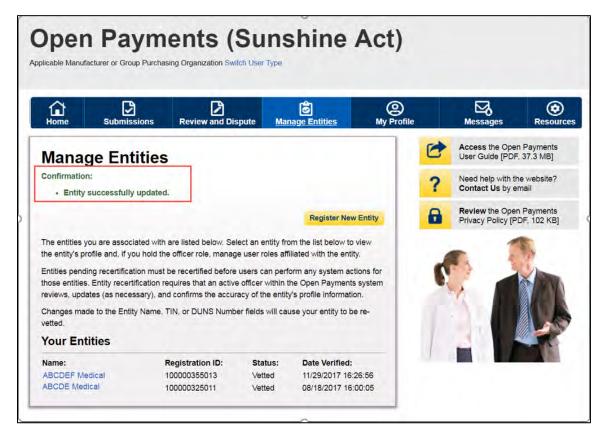
<u>Step 4</u>: Review the entity information and edit the fields as needed. Note that the reporting entities must supply a point of contact for review and dispute activities that will be used to aid in review and dispute activities. This review and dispute contact information will be visible on your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

Mand Dispute 1			? Nesd help w Contact Us	Control of the second s
innerd Merdiffer:	Submit button to save y		? Nesd help w Contact Us	th the website by email
innerd Merdiffer:	Submit" button to save y	eur		
innerd Merdiffer:	Submit button to save y			
innerd Merdiffer:	Dobrit butin to save ;			
* Number):				
* Number):			13	
* Number):				
* Number):				
* Number):				
"State:				
"State:		*		
Maryland				
Business Tel	ephone Number:			
999-999-9999 123-456-7890		-		
	ber (EIN):			
in a consolidated n	eport (i.e., one entity			
be submitted in a con	solidated report			
important notification	n emails regarding Oper			
*Business Tel	ephone Number:			
999-999-9999 123-456-7891	or Maximum 20 digits			
joe smithigabo	detmedical crms gov			
"Business Tel 999-999-9999	ephone Number: or Maximum 20 digits			
123-456-7892				
*Business En tons miller@ab	edefmedical cms gov			
tion process. You me als. box will be visible to process. The content	ey also include additions the covered recipients s will be displayed exac			
ed over this limit wi	not be saved.			
	ese-eses 123-62-7000 123-62-7000 ISA ISANSTICATION NUM ISA ISANSTICATION NUM ISA ISANSTICATION NUM ISA ISANSTICATION NUM ISANSTICATION	In a consolidated report () a, one entry in a consolidated report () a, one en	with the second seco	Bit Sub Control It Sub Contrel It Su

Figure 66: Entity Information page in an editable view

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

Figure 67: Manage Entities page showing entity successfully updated confirmation message



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

Section 3.6: Nominations

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

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

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

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

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

- First name
- Last name
- Job title
- Business address
- Business phone
- Email address

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

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

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

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

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

Figure 68: Self-Nomination Process



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

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

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

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

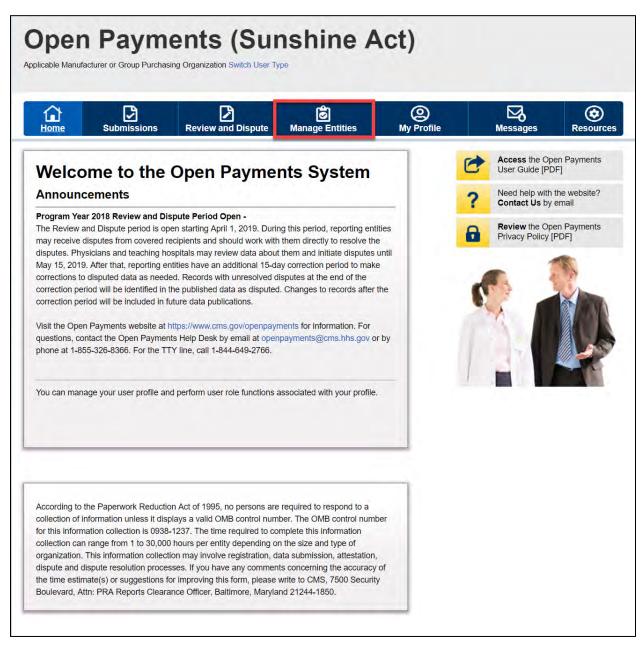
User Role Status	Meaning
Nominated	The individual has been nominated for the user role with the reporting entity.
Nomination Approved	The individual's nomination has been approved by an officer. The individual has not yet accepted or declined the nomination.
Declined	The individual declined the user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

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

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

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

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



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

	Submissions	Review and Dispu	ute <u>M</u> a	anage Entities	O My Profile		Messages	Resource
Manade	e Entities					0	Access the Ope User Guide [PD	
				Register New En	tity	?	Need help with Contact Us by	
		are listed below. Select a officer role, manage us			N	8	Review the Ope Privacy Policy [I	
hose entities. En	ntity recertification re-	be recertified before user quires that an active office l confirms the accuracy of	icer within th	ne Open Payments sys			1	-
Changes made to vetted.	o the Entity Name, T	IN, or DUNS Number fie	elds will cau	se your entity to be re	-	C		1×

Figure 71: Manage Entities Page

<u>Step 3:</u> Select the "Manage Roles" tab.

Figure 72: Manage Entities Page

â	Dissions	2	ð	9		5	۲
Home Sub		Review and Dispute	Manage Entities	My Profile	-	Messages Access the Op	Resource
		com.			6	User Guide [PD	DF]
Entity Details	Manage Ro	185			?	Need help with Contact Us by	
	icer role can upo	our selected entity. Only a sate any incorrect information	n authorized official or autho ion in the entity profile by Update En			Review the Op Privacy Policy	
Entity Informat	on					1	1 A
Entity's Registration I	b : 1000012250	047					
Entity's Legal Name:	ABCDE Medica	al				- C	
Reporting Entity Type	Applicable Ma	anufacturer			1		
Business Type: Appl	cable manufacti	urer-drugs/biological					
Food & Drug Adminis	ration (FDA) E	stablishment Identifier:					
Data Universal Numbe	ring System (D	-U-N-S® Number): 100	000355				
URL of Parent Compa	ny: www.cms.e	com					
Business Addr	ess						
Country: United State	s						
Business Address, Lin	e 1: 7500 Sec	curity Blvd.					
Business Address, Li	ne 2:						
City Name: Baltimore		Zip Code:	21244				
State: Maryland		Business Te	lephone Number: 555-555	5-5555			
Business Owne	ership Info	rmation					
Type of Ownership:							
Taxpayer Identifier Nu	mber (TIN)/Emp	oloyer Identification Nun	ber (EIN): 34-5678901				
Doing Business As (D	BA) Name: Al	3CDE Medical					
			eport (i.e., one entity repor itted in a consolidated repor				
Points of Conta	ct						
The two identified point Payments.	s of contact will i	receive important notificati	on emails regarding Open				
Primary Point of C	ontact						
Name: Mary Smith							
Business Telephone N	umber: 333-3	33-3333					
Title at the Entity: Ma							
Business Email Addre	ss: openpaym	ents@yopmall.com					
Backup Point of C	ontact						
Name: Joe Miller							
Business Telephone N		44-4444					
Title at the Entity: Se							
Business Email Addre	ss: openpaym	ients@yopmail.com					
	ation for R	eview and Dispu	te				
Contact Information: Please Contact Mary Si	nith						
Description	-						
Recertification Recertified By: Rash		n					

Step 4: Select "Nominate New Role."

Figure 73: Entity's Manage Roles tab

	3	D		ð	Q		⊠	۲
		Review and D	ispute <u>Ma</u>	nage Entities	My Profile		Messages	Resourc
BCDE Me	edical					0	Access the Op User Guide [PD	
Entity Details	Manage Ro	les				?	Need help with Contact Us by	
Select the "Modify" bu Select the "Deactivate entity. Note: An officer may i the entity.	e User" button by a	a user's name	to remove that u	ser completely fro	om your	6	Privacy Policy [
An explanation of the MB] .	statuses below ca	in be found in t	the Open Payme	ents User Guide (f		ſ		
Name:	Role:	Status:	Actions:			1	-	-
Karen Miller	Attester	Approved	Modify					
	Submitter	Approved						

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

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

Figure 74: Nominate New Role page

Home BCDE M Entity Details	Submissions edical	Review and Dispute		My Profile		Messages	Resour
	euicai		<u>Manage Entities</u>		-	Access the Ope	
Entity Details					6	User Guide [PDI	F]
	Manage I	Roles			?	Need help with t Contact Us by e	
Nominate N	ew Role				8	Review the Ope Privacy Policy [F	
A field with an aste	risk (*) is required.				-	r nvacy r oncy [r	011
		ole on Open Payments for you	r entity.			- 1	A.
*First Name:		Middle Name:				13 1	in
Mary		Midule Name.					A DO
*Last Name:		0					
Davis		Suffix (Jr., Sr., et	(c.):				
*Business Email /	Address:					311	
openpayments@yo	pmail.co						
***		in the second					
*Indicate the role	or roles this pers	on will have:					
Submitter							
Attester							
Compliance	e						
*Country:							
Please Select				•			
*Business Addres 7500 Security Blvd							
Business Addres	s, Line 2:			-			
*City Name:		*State:					
Baltimore		Maryland					
*Zip Code: 99999 9999		*Business Telep 999-999-9999	hone Number:				
21244		444-444-4444					

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

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

		-				_		
	issions R	teview and Disp	ute Mana	ge Entities	(O) My Profile		Messages	Resour
BCDE Me	dical					C	Access the Op User Guide [PD	
Entity Details	Manage Ro	les			_	?	Need help with Contact Us by	
Confirmation: • You have succe	essfully submitte	ed Role Informat	ion.			8	Review the Op Privacy Policy [
Select the "Nominate Modify" but Select the "Modify" but Select the "Deactivate	ton by a user's na	me to add or ren	nove a role for a	n already affiliate	d user.		N 1	1
entity.							5	
lote: An officer may m	odify or deactivat	e another officer	but cannot deac		s from			1 M
Note: An officer may m he entity. An explanation of the s				tivate themselve			5	
Note: An officer may make entity. An explanation of the s				tivate themselve	₽, 37.3			
Note: An officer may make entity. An explanation of the s				tivate themselve	₽, 37.3			
Note: An officer may m he entity. An explanation of the s	tatuses below ca	n be found in the	Open Payment	tivate themselve	₽, 37.3			
Note: An officer may m he entity. An explanation of the s (18) . Name:	tatuses below ca Role:	n be found in the Status:	Open Payments Actions:	tivate themselve	₽, 37.3			
	Role: Attester	n be found in the Status: Approved	Open Payments Actions:	tivate themselve	₽, 37.3			

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

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

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

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

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

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

Figure 76: Accepting Nominations



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

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

Open Payments (Sunshine Act) Access the Open Payments User Guide [PDF, 37.3 MB] Welcome to the Open Payments System Need help with the website? ? Our records indicate that you have not yet registered in the Open Contact Us by email Create Payments system. Before you can perform any actions in the system, you must first create your profile and complete the registration process. My Profile Review the Open Payments 8 Privacy Policy [PDF, 102 KB] **Getting Started** Open Payments (the Sunshine Act) is a national disclosure program that promotes transparency by publishing the financial relationships between applicable manufacturers and applicable group purchasing organizations (GPOs) and healthcare providers (physicians and teaching hospitals) on a publicly accessible website. The Open Payments system enables the annual reporting of these relationships to CMS Register in the Open Payments System To perform actions in the system, you must register and associate yourself with a type of reporting entity or covered recipient. You may select applicable manufacturer or applicable GPO, physician, or teaching hospital Dirichter and the last test and the set of the

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

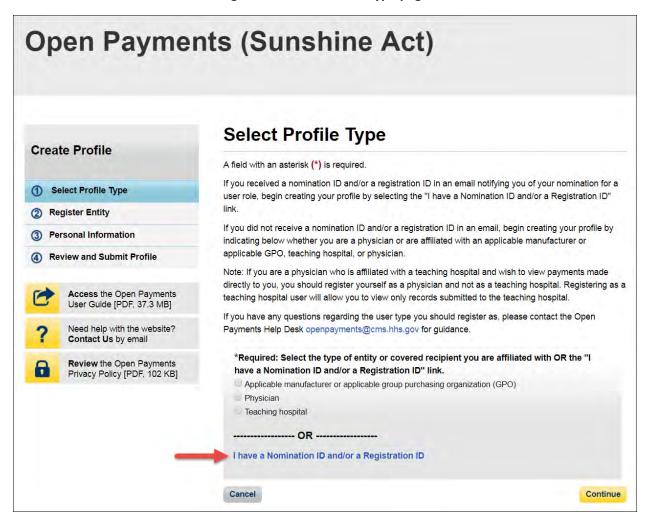
<u>Step 2:</u> Read the instructions on the "Create Profile" page. Once done, select "Start Profile" at the bottom of the page.

Figure 78: Create Profile page

Create Profile	Create Profile		
Select Profile Type	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, or physician.		
2 Register Entity	If the applicable manufacturer, applicable GPO, teaching hospital, or physician has not yet		
③ Personal Information	been registered in the Open Payments system, you may register it and then yourself. Begin by collecting the information required for applicable manufacturer, applicable GPO, teaching hospit or physician registration, then proceed with the registration process.		
4 Review and Submit Profile	If the applicable manufacturer, applicable GPO, teaching hospital, or physician has already		
Access the Open Payments User Guide (PDF, 37.3 MB)	been registered in the Open Payments system and you are not affiliated with it in the Open Payments system, you may:		
? Need help with the website? Contact Us by email	 Ask a user already affiliated with the applicable manufacturer, applicable GPO, teaching hospital, or physician to nominate you for a user role; or 		
Review the Open Payments Privacy Policy [PDF, 102 KB]	 Create a personal profile and request a role with the applicable manufacturer, applicable GPO, or teaching hospital. Note that users who wish to associate themselves with physicians must be nominated by the physician. 		
	Required Information		
	Fields for required information are marked with an asterisk.		
	It is important that you have all required information available when you begin, as registration must be completed in one session. Also, 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, 136 KB]. This QRG is also available on the Resources page of the Open Payments website.		
	Registering as a Physician or a Teaching Hospital		
	If you are a physician affiliated with a teaching hospital and wish to see data related to you in your capacity as a physician, select the "Physician" option when registering. Registering as a user affiliated with a teaching hospital will allow you to see only data related to that teaching hospital. 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.		

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

Figure 79: Select Profile Type page



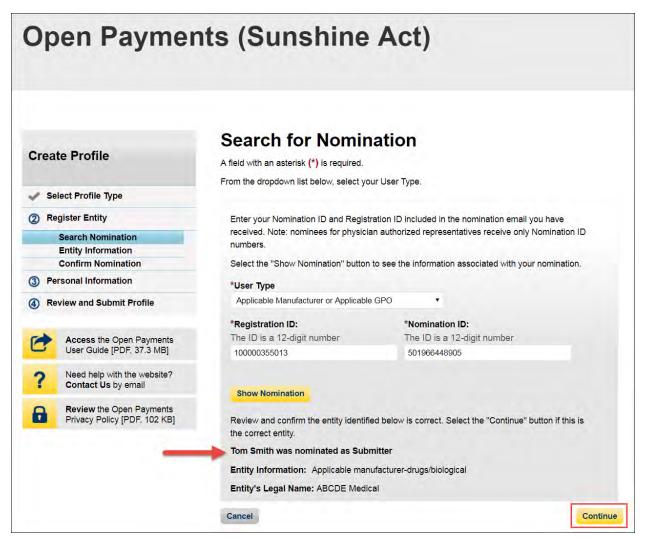
<u>Step 4:</u> Select the User Type "Applicable Manufacturer or Applicable GPO." Enter the registration ID and nomination ID that you received in the nomination notification email and then select "Show Nomination."

Figure 80: Search for Nomination page

Open Paymen	ts (Sunshine A	ct)
Create Profile	Search for Nomination	on
Select Profile Type	From the dropdown list below, select your User	r Type.
2 Register Entity Search Nomination Entity Information		D included in the nomination email you have orized representatives receive only Nomination ID
Confirm Nomination	Select the "Show Nomination" button to see	the information associated with your nomination.
3 Personal Information	*User Type	
Review and Submit Profile	Applicable Manufacturer or Applicable GPO	· · · · · · · ·
Access the Open Payments User Guide [PDF, 37.3 MB]	*Registration ID: The ID is a 12-digit number 100000355013	*Nomination ID: The ID is a 12-digit number 501966448905
? Need help with the website? Contact Us by email	Show Nomination	
Review the Open Payments Privacy Policy [PDF, 102 KB]		
	Cancel	

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

Figure 81: Search for Nomination page



<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 82: Confirm Entity page

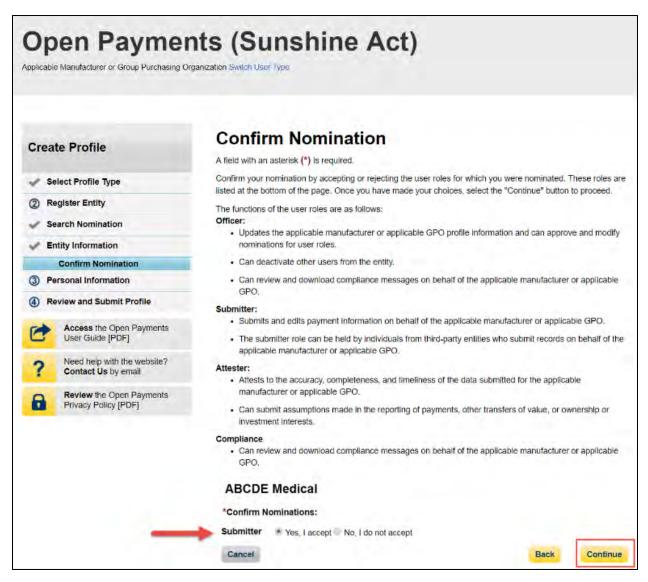
Create Profile	Confirm Entity			
Sreate Frome	Below is the information for your se Select "Continue" button to begin or	lected entity. Review and confirm the entity identified below is correc reating your user profile.		
Select Profile Type				
2) Register Entity	Entity's Registration ID: 1000	00355013		
Search Nomination	Entity's Legal Name: ABCDE I	Medical		
	Reporting Entity Type: Applica	able Manufacturer		
Entity Information Confirm Nomination	Business Type: Applicable manufacturer-drugs/biological			
3 Personal Information	Food & Drug Administration (FDA) Establishment Identifier:			
Review and Submit Profile	Data Universal Numbering System (D-U-N-S® Number):			
	URL of Parent Company: www	/.cms.gov		
Access the Open Payments User Guide [PDF, 37.3 MB]	Business Address			
? Need help with the website? Contact Us by email	Country: United States			
	Business Address, Line 1: 750	00 Security Blvd		
Review the Open Payments Privacy Policy [PDF, 102 KB]	Business Address, Line 2:			
	City Name: Baltimore	State: Maryland		
	Zip Code: 21244	Business Telephone Number: 555-555-5555		
	Business Ownership	Information		
	Type of Ownership: Corporation	on		
	Taxpayer Identifier Number (TI	N/Employer Identification Number (EIN): 12-3456789		
	Doing Business As (DBA) Nam			
		don't know whether my entity's data will be submitted in a		

<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're sure you want to reject these roles. If you confirm your choice to reject the roles, you will not be able to perform any actions on behalf of the reporting entity and the nominator will receive an email notifying him or her that you rejected the nominations. The nominator will then be allowed to nominate other people for the roles.

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

Figure 83: Confirm Nomination Page



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

Figure 84: Enter Personal Information page

Open Paymer	nts (Sunshine A	ct)			
	Enter Personal Infor	mation			
Create Profile	A field with an asterisk (*) is required.				
Select Profile Type	Provide personal and business information be	low to create your user profile.			
Register Entity	Your first name and last name have been prepopulated from your CMS Enterprise Identity Management systen (EIDM) profile. You may edit the prepopulated fields as needed. However, changing this information in Open				
(3) Personal Information	Payments will not change the corresponding in				
Review and Submit Profile	Once you have entered the information, select	t the "Continue" button.			
	Your Name				
Access the Open Payments User Guide [PDF]	*First Name:	*Last Name:			
	Lesllie	Smith			
? Need help with the website? Contact Us by email	Middle Name:	Suffix (Jr., Sr., etc.):			
Review the Open Payments Privacy Policy [PDF]	Your Business Contact Informatio Enter your business or entity information. *Business Email Address: openpayments5@yopmail.com	n *Job Title: Director			
		Difector			
	*Country: United States				
	*Business Address, Line 1:				
	7500 Security Blvd.				
	Business Address, Line 2:				
	*City Name:	*State:			
	Baltimore	Maryland •			
	* Zip Code: 99999 9999	*Business Telephone Number: 999-999-999			
	21244	555-555-5555			
	Cancel	Back Continue			

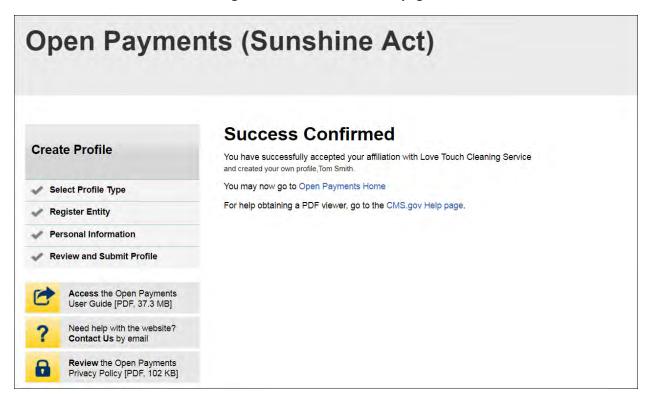
<u>Step 9:</u> You will be asked to review the information you have entered. To correct any errors, select the "Back" button at the bottom of the page to return to previous pages and make your corrections. If the information is correct, select "Continue."

		Review and Submit Profile
Crea	te 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 "Continue" button to submit your profile.
/ Se	lect Profile Type	
Re	gister Entity	Entity's Registration ID: 100000355013
		Entity's Legal Name: ABCDE Medical
Pe	rsonal Information	Reporting Entity Type: Applicable Manufacturer
R	eview and Submit Profile	Business Type: Applicable manufacturer-drugs/biological
		Food & Drug Administration (FDA) Establishment Identifier:
2	Access the Open Payments User Guide [PDF, 37.3 MB]	Data Universal Numbering System (D-U-N-S® Number):
?	Need help with the website? Contact Us by email	URL of Parent Company: www.cms.gov
8	Review the Open Payments	Business Address:
-	Privacy Policy [PDF, 102 KB]	Country: United States
		Business Address, Line 1: 7500 Security Blvd
		Business Address, Line 2:
		City Name: Baltimore
		State: Maryland
		Zip Code: 21244
		Business Telephone Number: 444-444-4444
		Business Ownership Information
		Type of Ownership: Corporation
		Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789
		Doing Business As (DBA) Name: ABCDE Medical AMGPO
		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 Last Middle Suffix (Jr., Sr., Business Email Address: Name: Name: Name: etc.):
		Submitter Tom Smith openpayments5@yopmail.com

Figure 85: Review and Submit Profile page.

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

Figure 86: Success Confirmed page



3.6c: Accepting a Nomination (Returning System Users)

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

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



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

Figure 88: My Profile page

Home s	Submissions	Review and		Ø Manage Entities	(2) My.Profile		Messages	Resource
y Profile	9					0	Access the Ope User Guide [PD	
Qverview	Profile D	etails.	My Roles & Nominations		_	?	Need help with t Contact Us by e	
and the second second								
	s information about the statuses below			ments User Guide (PD	F, 37.3	8	Review the Ope Privacy Policy (P	
An explanation of t	the statuses below			ments User Guide [PD	F, 37.3	8		
An explanation of t MBJ . Profile Name Karen Miller	the statuses below			ments User Guide (PD	F, 37.3	8		
An explanation of t MBJ . Profile Name Karen Miller	the statuses below			ments User Guide [PD	F, 37.3	8		
An explanation of t MB] . Profile Name Karen Miller Your Author	the statuses below	can be found in		ments User Guide (PD Status:	F, 37.3	8		
An explanation of t MB] . Profile Name	the statuses below e rized Roles Enti	can be found in			F, 37.3	8		
An explanation of t MB] . Profile Name Karen Miller Your Author Role:	the statuses below e rized Roles Enti ABC	can be found in		Status:	F, 37.3	8		
An explanation of t MB] . Profile Name Karen Miller Your Author Role: Officer	the statuses below rized Roles Enti ABC ABC	can be found in tty: CDE Medical		Status: Requested	F, 37.3	8		

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

Figure 89: My Roles and Nominations tab

Home	Submissions	Review and Dispute	Anage Entities	() My Profile	Nessages	Resourc
y Profi	le			C	Access the Ope User Guide [PD	
Overview	Profile D	Details My Rol Nomina		?	Need help with t Contact Us by	
		ntity with which you are aff ditional roles for your affilia	filiated. You have the option ated entitles.	to 🔒	Review the Ope Privacy Policy [F	
and a second						
An explanation	of the statuses below	can be found in the Oper	Payments User Guide [PD	F, 37.3	. 1	1
An explanation	-		Payments User Guide (PD	F, 37.3	61	No.
An explanation ((IB) . Accept a Role			n Payments User Guide (PD	F; 37.3		KA
An explanation (IB) Accept a Role My Roles		ole	Paymenta User Guide (PD Status:	F; 37.3		Ń
An explanation MBJ Accept a Role My Roles Role:	Request a Re	ole		F, 37.3		Ò
An explanation	Request a Re Nam ABC	ole ne:	Status:	F, 37.3		

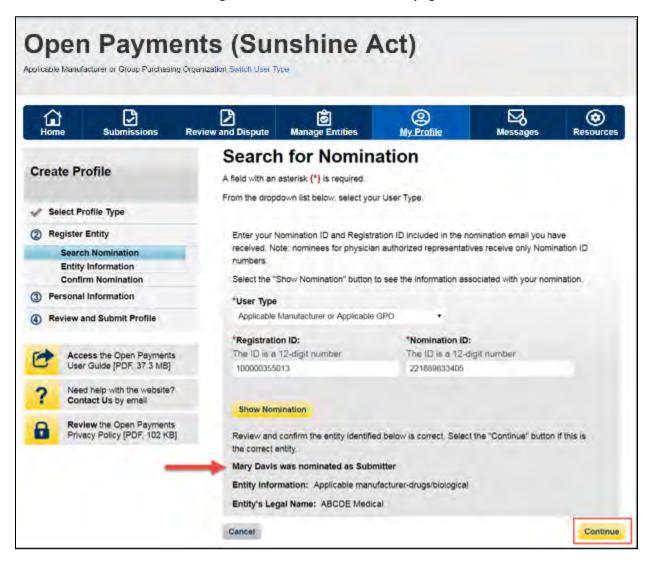
<u>Step 4:</u> Enter the registration ID and nomination ID provided in the email notification and select "Show Nomination."

Figure 90: Search for Nomination page

Home	Submissions	Review and Dispute	🔊 Manage Entities	(Q) My Profile	Messages	Resources
Create Pr	ofile	A field with an a	for Nomina sterisk (*) is required.			
Select Pr	ofile Type	From the dropdo	wn list below, select your	r User Type.		
Entity	Entity n Nomination Information	numbers.	mination ID and Registra a: nominees for physician now Nomination" button to	authorized representat	ves receive only Nomin	nation ID
3 Personal	Information	*User Type				
Review as	nd Submit Profile		anufacturer or Applicable (spo •		
	ss the Open Payments Guide [PDF, 37.3 MB]	*Registration The ID is a 1 10000035501	2-digit number	*Nomination ID The ID is a 12-c 221889833405	and the second se	
Cont	I help with the website? act Us by email ew the Open Payments by Policy (PDF, 102 KB)	Show Nomin	hallon			
	all must be and row row!	Cancel				

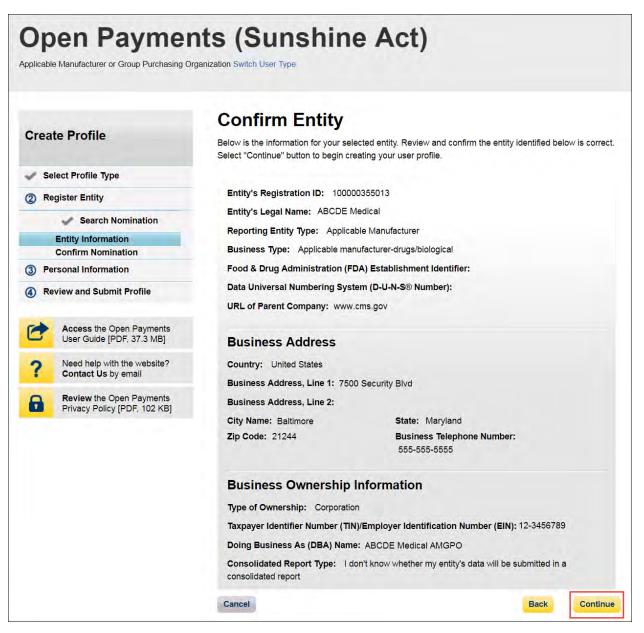
<u>Step 5:</u> Review the nomination information displayed. If the information is correct, select "Continue." If the information is incorrect, select "Cancel" and contact the reporting entity's authorized official.

Figure 91: Search for Nomination page



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

Figure 92: Confirm Entity page



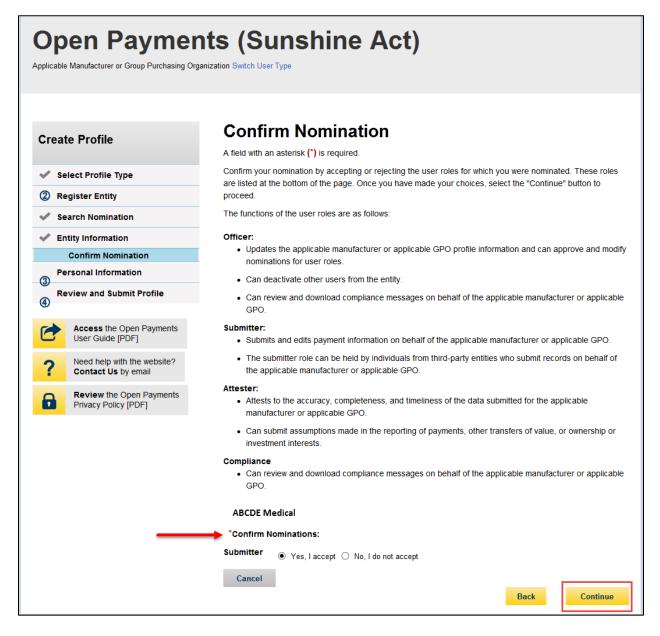
<u>Step 7:</u> Select "Yes, I accept" for roles you accept and "No, I do not accept" for roles you do not accept.

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.

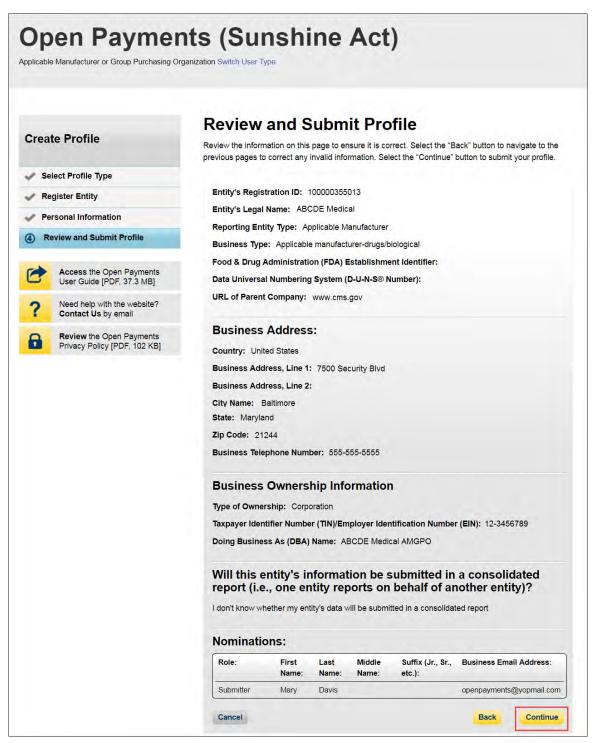
If you accept one or all roles and select "Continue," you will continue the nomination confirmation process.

Figure 93: Confirm Nomination page



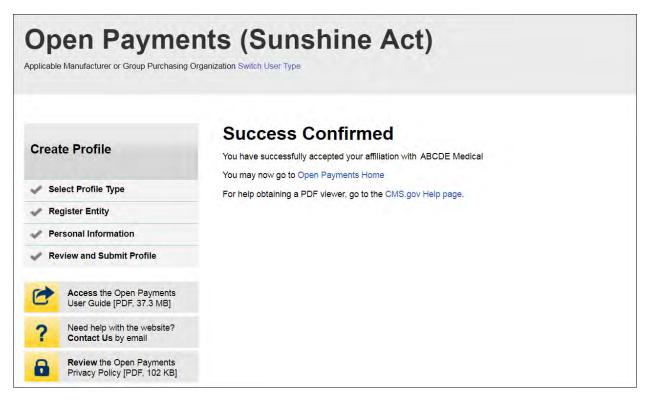
<u>Step 8:</u> Review the reporting entity information and personal profile. Select the "Back" button at the bottom of the page to go back and edit any personal information. If the entity information is not correct, select "Cancel" and contact your reporting entity's authorized official. If the information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

Figure 94: Review and Submit Profile Page



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

Figure 95: Success Confirmed Page



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

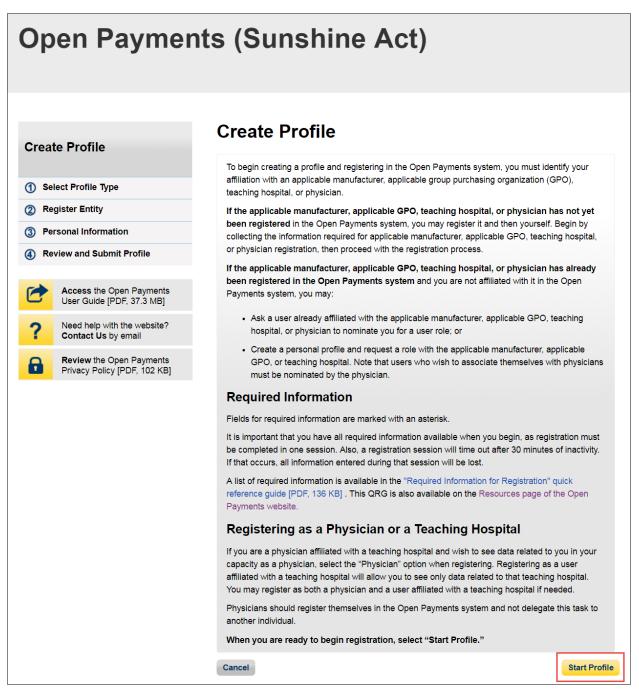
<u>Step 1:</u> Log in to the CMS Enterprise Portal at <u>https://portal.cms.gov</u> using your EIDM credentials and navigate to the Open Payments home page. The on-screen text contains important information regarding the registration process. Read the on-screen text and select "Create My Profile" to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

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



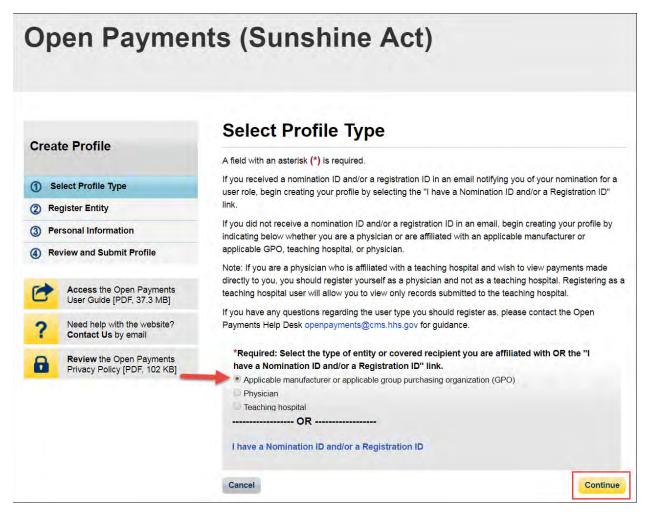
<u>Step 2:</u> The on-screen text contains important information regarding creating the reporting entity and individual profile. Read the on-screen text and select the link to the quick reference guide "Required Fields for Registration" for a list of information required during registration. Select "Start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

Figure 97: Create Profile Page



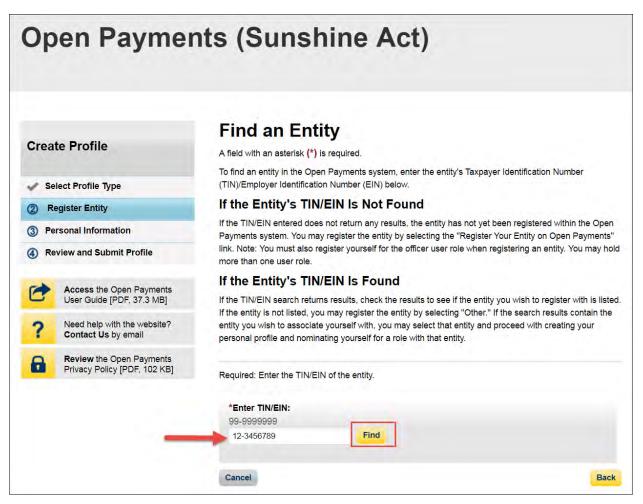
Step 3: Select the profile type "Applicable Manufacturer or Applicable GPO" and select "Continue."

Figure 98: Select Profile Type page



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

Figure 99: Find an Entity page



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

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

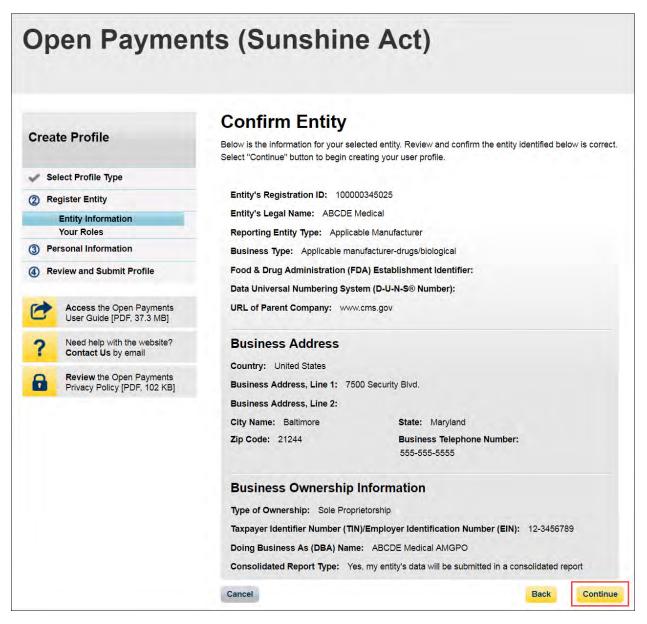
Figure 100: Find an Entity page

Open Payme	nts (Sunshine Act)
Create Profile	Find an Entity A field with an asterisk (*) is required. To find an entity in the Open Payments system, enter the entity's Taxpayer Identification Number
Select Profile Type	(TIN)/Employer Identification Number (EIN) below.
2 Register Entity	If the Entity's TIN/EIN Is Not Found
③ Personal Information	If the TIN/EIN entered does not return any results, the entity has not yet been registered within the Open Payments system. You may register the entity by selecting the "Register Your Entity on Open Payments"
Review and Submit Profile	link. Note: You must also register yourself for the officer user role when registering an entity. You may hold more than one user role.
Access the Open Payments User Guide [PDF, 37.3 MB] Need help with the website? Contact Us by email	If the Entity's TIN/EIN Is Found If the TIN/EIN search returns results, check the results to see if the entity you wish to register with is listed If the entity is not listed, you may register the entity by selecting "Other." If the search results contain the entity you wish to associate yourself with, you may select that entity and proceed with creating your personal profile and nominating yourself for a role with that entity.
Review the Open Payments Privacy Policy [PDF, 102 KB]	Required: Enter the TIN/EIN of the entity.
_	*Enter TIN/EIN: 99-9999999 12-3456789 Find *For the TIN/EIN entered above, the following entities were identified: ABCDE Medical (Entity's Registration ID: 100000345025) Other: I want to register a subsidiary or other affiliate with the same TIN/EIN
	Cancel Back Continue

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

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

Figure 101: Confirm Entity page



<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 102: Your Role page

Open Payme	ents (Sunshine A g Organization Switch User Type	Act)	
Home Submissions	Review and Dispute Manage Entities	O My Profile	Messages Resources
Create Profile	Your Role A field with an asterisk (*) is required. To associate yourself with a reporting entity i	in the Open Payments sy	rstern, you must nominate yourself for one
Select Profile Type	or more user roles. The user roles are as fol	lows:	
② Register Entity	Officer:		
Entity Information	 Updates the applicable manufacturer on nominations for user roles. 	or applicable GPO profile	information and can approve and modify
Your Roles (3) Personal Information	Can deactivate other users from the e	ntity.	
	Can review and download compliance	messages on behalf of t	the applicable manufacturer or applicable
④ Review and Submit Profile	GPO.		
Access the Open Payments	Submitter:		
User Guide [PDF]	Submits and edits payment informatio		
? Need help with the website? Contact Us by email	 The submitter role can be held by indi- applicable manufacturer or applicable 		ntities who submit records on behalf of the
Review the Open Payments Privacy Policy [PDF]	Attester: • Attests to the accuracy, completeness manufacturer or applicable GPO. • Can submit assumptions made in the investment interests. Compliance • Can review and download compliance GPO.	reporting of payments, of	
	*First Name:	Middle Na	
	Leslie		ame.
	*Last Name:	Suffix (.Ir	., Sr., etc.):
	Smith		
	*Business Email Address:		s Telephone Number: 9999 or Maximum 20 digits
	openpayments@yopmail.com	555-555-5	
	Indicate your role(s) in the Open Payment attesters, submitters, compliance users, a officer with the reporting entity has approv your nomination is approved. Highest Level of Role	nd other officers. Your ro	le(s) is/are not confirmed until an
	Cancel		Back Continue

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

Figure 103: Enter Personal Information page

Open Payme	nts (Sunshine A	ct)
	Enter Personal Infor	mation
Create Profile	A field with an asterisk (*) is required.	
Select Profile Type	Provide personal and business information bel	low to create your user profile.
		opulated from your CMS Enterprise Identity Management syster fields as needed. However, changing this information in Open
Register Entity	Payments will not change the corresponding in	
③ Personal Information	Once you have entered the information, select	t the "Continue" button.
Review and Submit Profile	Your Name	
Access the Open Payments	*First Name:	*Last Name:
User Guide [PDF]	Lesllie	Smith
? Need help with the website? Contact Us by email	Middle Name:	Suffix (Jr., Sr., etc.):
Review the Open Payments Privacy Policy [PDF]	Your Business Contact Informatio Enter your business or entity information.	n
	*Business Email Address:	*Job Title:
	openpayments5@yopmail.com	Director
	*Country:	
	United States	
	*Business Address, Line 1:	
	7500 Security Blvd.	
	Business Address, Line 2:	
	*City Name:	*State:
	Baltimore	Maryland •
	* Zip Code: 99999 9999	*Business Telephone Number: 999-999-9999
	21244	555-555-5555
	Cancel	Back Continue

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

Figure 104: Review and Submit Profile page

Perior the information on this page to ensure it is correct. Select the "Back button to avaigate to the previous pages to correct any invalid information. Select the "Continue" button to submit your profile. Personal Information Entity's Registration ID: 100000345025 Entity's Legal Name: ABCDE Medical Reporting Entity Type: Applicable Manufacturer Business Type: Applicable Manufacturer Business Type: Applicable Manufacturer Business Type: Applicable manufacturer.drugs/biological Food & Drug Administration (FDA) Establishment Identifier: Data Universal Numbering System (Du-N-S® Number): URL of Parent Company: www.cms.gov Business Address; Country: United States Business Address, Line 1: 7050 Security Bivd. Business Address, Line 2: City Name: Battimore State: Manyland Zip Code: 21244 Business Telephone Number: S55-555-5555 Business Telephone Number: Sole Proprietorship Taxpayer Identifier Number (TRN/Employer Identification Number (BIN): 12-3456739 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Ye s. my entity's data will be submitted in a consolidated report	Create Profile	Review and Submit Profile
 Register Entity Personal Information Review and Submit Profile Access the Open Payments User Guide (PDF. 37.3 MB) Need help with the website? Cond & Drug Administration (FDA) Establishment Identifier: Data Universal Numbering System (D-U-N-S0 Number): URL of Parent Company: www.cms.gov Business Address. Business Address. Line 1: 7500 Security Blvd. Business Address, Line 2: City Name: Baltimore State: Maryiand Zip Code: 21244 Business Telephone Number: 555-555.5555 Business Address (TR) Profile Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity dentifier Number (I.e., Srift Name: etc.): Officer, Lesie Smith opensyments (dentification Number) 		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 "Continue" button to submit your profile.
Image: Network Personal Information Image: Network Personal Personal Information Image: Network Personal Personal Information Image: Network Personal Personal Personal Information Image: Network Personal Perso	Select Profile Type	
 Personal information Review and Submit Profile Access the Open Payments User Guide (PDF, 37.3 MB) Need help with the website? Contact Us by small Review the Open Payments Privacy Policy (PDF, 102 KB) Review the Open Payments Privacy Policy (PDF, 102 KB) Business Address: Country: United States Business Address, Line 1: 7500 Security Bivd. Business Address, Line 2: City Name: Baitmore State: Maryland Zip Code: 21244 Business Telephone Number: 555-555 Business Telephone Number: 535-555-5555 Business A (DBA) Name: ABCDE Medical AM/GPO Will this entity's information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AM/GPO Will this entity's information te submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Name: Name: Name: Suffix (Jr., Sr., Business Email Address: Cofficer, Lesile Smith openpayments@yopmat.com 	Register Entity	Entity's Registration ID: 100000345025
Review and Submit Profile Coress the Open Payments Coress the Open Payments Cores of dude [PDF, 73 MB] Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF, 102 KB] Business Address: Country: United States Business Address, Line 1: 7500 Security Blvd. Business Address, Line 2: City Name: Battimore State: Maryland Zip Code: 21244 Business Telephone Number: 555-555.555 Business Adgress As Collect Interview (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Officer, Losie Smith coresitient and the suffix (Jr., Sr., Business Email Address: Officer, Losie Smith coresitient and the suffix (Jr., Sr., Business Email Address: Officer, Losie Smith coresitient and the suffix (Jr., Sr., Business Email Address: Openpayments@yopmail.con	Personal Information	Entity's Legal Name: ABCDE Medical
Second a Drug Administration (FDA) Establishment identifier: Access the Open Payments User Guide (PDF, 37.3 MB) Review the Open Payments Privacy Policy (PDF, 102 KB) Business Address: County: United States Business Address, Line 1: 7500 Security Bivd. Business Address, Line 2: City Name: Baltimore State: Maryland Zip Code: 21244 Business S Womership: Soboreship: Business Address, Line 1: 7500 Security Bivd. Business Address, Line 2: City Name: Baltimore State: Maryland Zip Code: 21244 Business Address Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Cifficer, Name: Name: Suffix (/r, Sr., Business Email Address: Name:		Reporting Entity Type: Applicable Manufacturer
Access the Open Payments User Guide (PDF: 37.3 MB) Data Universal Numbering System (D-U-N-S@ Number): URL of Parent Company: www.cms.gov Review the Open Payments Privacy Policy (PDF: 102 KB) Data Universal Numbering System (D-U-N-S@ Number): URL of Parent Company: www.cms.gov Business Address: Privacy Policy (PDF: 102 KB) Business Address: Country: United States Business Address, Line 1: 7500 Security Blvd. Business Address, Line 2: Citty Name: Baltimore Business Address, Line 2: Citty Name: Baltimore State: Maryland Zip Code: 21244 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Name: Name: Name: etc.):	W Review and Submit Prome	Business Type: Applicable manufacturer-drugs/biological
User Guide (PDF: 37.3 MB) Data Universal Numbering System (D-U-N-S@ Number): Weed help with the website? Contact Us by email URL of Parent Company: www.cms.gov Business Address: Business Address: Privacy Policy (PDF: 102 KB) Business Address, Line 1: 7500 Security Bivd. Business Address, Line 1: 7500 Security Bivd. Business Address, Line 2: City Name: Baltimore State: Maryland Zip Code: 21244 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information to be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Last: Middle Suffix (Jr., Sr., Business Email Address: Name: Officer, Lestie Smith openpayments@yopmail.con		Food & Drug Administration (FDA) Establishment Identifier:
Review the Open Payments Privacy Policy (PDF, 102 KB) Business Address: Country: United States Business Address, Line 1: 7500 Security Bivd. Business Address, Line 2: City Name: Baltimore State: Maryland Zip Code: 21244 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First: Last: Middle: Suffx (Jr., Sr., Business Email Address: Name: Name: Name: etc.): Officer, Leslie: Smith openpayments@yopmail.con		Data Universal Numbering System (D-U-N-S® Number):
Review the Open Payments Privacy Policy [PDF: 102 KB] Country: United States Business Address, Line 1: 7500 Security Bivd. Business Address, Line 2: City Name: Baltimore State: Maryland Zip Code: 21244 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Name: Name: etc.): Officer, Leslie Smith openpayments@yopmail.con		URL of Parent Company: www.cms.gov
Country: United states Business Address, Line 1: 7500 Security Blvd. Business Address, Line 2: City Name: Baltimore State: Maryland Zip Code: 21244 Business Telephone Number: 555-5555 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Ves. my entity's data will be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Name: Name: Submitter, Leslie Smith openpayments@yopmail.con		Business Address:
Business Address, Line 2: City Name: Battimore State: Maryland Zip Code: 21244 Business Telephone Number: 555-555-5555 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Officer, Leslie Smith openpayments@yopmail.con	Privacy Policy [PDF, 102 KB]	Country: United States
City Name: Baltimore State: Maryland Zip Code: 21244 Business Telephone Number: 555-555-5555 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address:: Officer, Leslie Smith openpayments@yopmail.com		Business Address, Line 1: 7500 Security Blvd.
State: Maryland Zip Code: 21244 Business Telephone Number: 555-555-5555 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Ves. my entity's data will be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Officer, Leslie Smith openpayments@yopmail.com		Business Address, Line 2:
Zip Code: 21244 Business Telephone Number: 555-555-5555 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: etc.): Officer, Leslie Smith openpayments@yopmail.con		City Name: Baltimore
Business Telephone Number: 555-5555 Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Neare: First: Name: Name: Name: Name: Visition openpayments@yopmail.con		State: Maryland
Business Ownership Information Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Net: First Vame: Name: Name: Name: Name: Name: Visition openpayments@yopmail.com		Zip Code: 21244
Type of Ownership: Sole Proprietorship Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Name: Name: Name: etc.): Officer, Leslie Smith openpayments@yopmail.com		Business Telephone Number: 555-555-5555
Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Name: Last Middle Suffix (Jr., Sr., Business Email Address: etc.): Officer Leslie Smith openpayments@yopmail.com		Business Ownership Information
Doing Business As (DBA) Name: ABCDE Medical AMGPO Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Name: Name: Name: Name: Officer, Leslie Submitter, openpayments@yopmail.com		Type of Ownership: Sole Proprietorship
Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Name: Name: Name: Name: Officer, Leslie Submitter, Smith		Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789
report (i.e., one entity reports on behalf of another entity)? Yes, my entity's data will be submitted in a consolidated report Nominations: Role: First Name: Last Name: Middle suffix (Jr., Sr., Business Email Address: etc.): Officer Leslie Smith openpayments@yopmail.com Submitter, Submitter, Smith openpayments@yopmail.com		Doing Business As (DBA) Name: ABCDE Medical AMGPO
Nominations: Role: First Name: Last Name: Middle Name: Suffix (Jr., Sr., etc.): Business Email Address: etc.): Officer, Submitter, Leslie Smith openpayments@yopmail.com		
Role: First Name: Last Name: Middle Name: Suffix (Jr., Sr., etc.): Business Email Address: Officer, Submitter, Leslie Smith openpayments@yopmail.com		Yes, my entity's data will be submitted in a consolidated report
Name: Name: etc.): Officer, Leslie Smith openpayments@yopmail.com Submitter, Submitter, Smith openpayments@yopmail.com		Nominations:
Submitter,		
		Submitter,

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

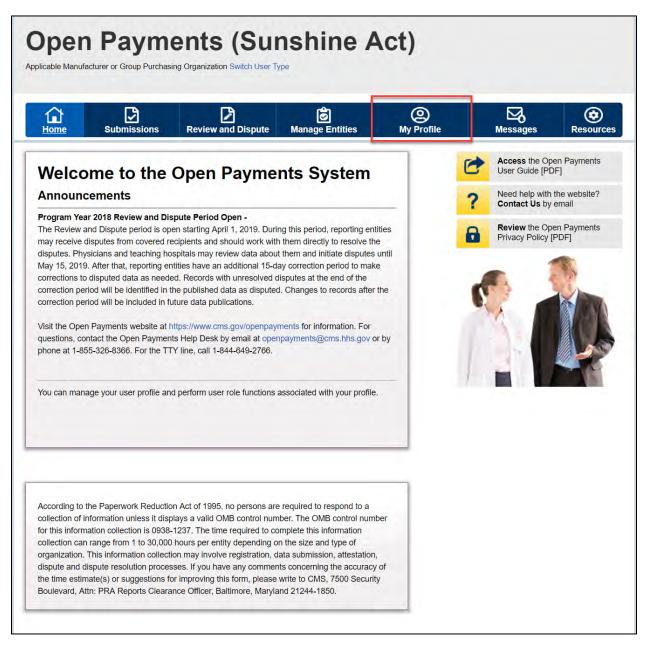
Figure 105: Success Confirmed page



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

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

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



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

Figure 107: My Profile page

Home S		Review and Dispute	Ø Manage Entities	@ My Prolife		Messages	Resource
y Profile				and the second	0	Access the Op User Guide (PC	en Payments
Overview	Profile Det	ails My Role Nominat		_	?	Need help with Contect Us by	the website?
This page contains	information about yo	our authorized role(s)			8	Review the Op	
MB] :			Payments User Guide (PC	€. 37,3		Privacy Policy	(PDF. 102 KB)
MBJ : Profile Name Leslie Smith			Payments User Guide (PC	4 , 37,3	đ	Privacy Policy	
MBJ :: Profile Name Lesle Smith Your Authori		an be found in the Open	Payments User Guide (PC Status:	¢. 37.3	ď	Privacy Policy	
An explanation of the MBJ : Profile Name Leslie Smith Your Authori Role: Officer	ized Roles	an be found in the Open		¢. 37.3	ď	Privacy Policy	
MBJ :: Profile Name Leslie Smith Your Authori Role:	ized Roles Entity ABCD	an be found in the Open	Status:	F, 37,3	ď	Privacy Policy	

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

Figure 108: My Roles and Nominations tab

Home Su	Dmissions Review	and Dispute Ma	ම් nage Entitles	(Q) My Prafile		Messages	Resource
y Profile					0	Access the Op User Guide (PD	
Overview	Profile Details	My Roles & Nominations		_	?	Need help with I Contact Us by I	
	roles for each entity with with so or request additional role	and the second second second	franka and a second	to.	8	Review the Ope Privacy Policy (F	n Payments PDF. 102 KB]
accept additional role		s for your affiliated entit	tes.			Review the Ope Privacy Policy (1	Payments PDF. 102 KB]
Accept additional role An explanation of the Accept a Role	es or request additional role e statuses below can be fou	s for your affiliated entit	tes.		•	Review the Ope Privacy Policy (1	Payments PDF: 102 KBJ
An explanation of the MEL. Accept a Role My Roles	es or request additional role e statuses below can be fou	s for your affiliated entit	tes.		•	Review the Ope	PDF 102 KB)
An explanation of the An explanation of the Mej . Accept a Role My Roles Role:	es or request additional role e statuses below can be fou Request a Role	s for your affiliated enti nd in the Open Payme	ties. Ints User Guide (PD)		•	Review the Open Privacy Policy (1	PDF 102 KBJ
accept additional role An explanation of the ME[.	es or request additional role e statuses below can be fou Request a Role Name:	s for your affiliated enti nd in the Open Payme	tes. nts User Guide (PD) Status:		•	Review the Open Privacy Policy (1	Payment PDF, 102 K

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

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

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

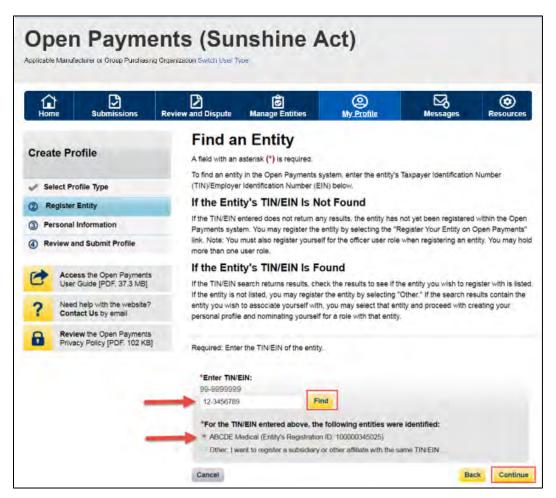
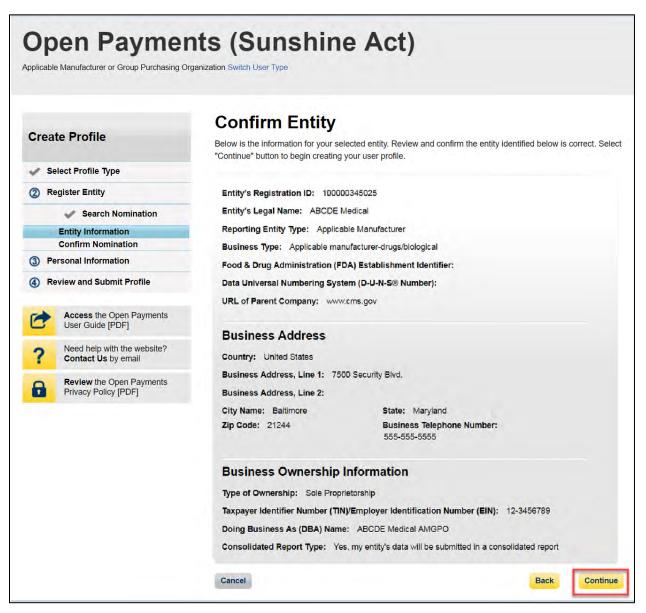


Figure 109: Find an Entity page

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

Figure 110: Confirm Entity page



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

Figure 111: Your Role page

Open Payme Applicable Manufacturer or Group Purchasing	•	nine A	.ct)		
Home Submissions	Review and Dispute Manag	ge Entities	O My Profile	Messages	Resources
Create Profile	Your Role A field with an asterisk (*) is				
 Select Profile Type 	To associate yourself with a or more user roles. The use			em, you must nomina	te yourself for one
2 Register Entity	Officer:				
Entity Information			r applicable GPO profile in	formation and can ap	prove and modify
Your Roles	nominations for user Can deactivate other		titv		
③ Personal Information			messages on behalf of the	applicable manufactu	urer or applicable
④ Review and Submit Profile	GPO.				
Access the Open Payments User Guide [PDF]	Submitter: • Submits and edits pa	ayment information	on behalf of the applicabl	e manufacturer or app	blicable GPO.
? Need help with the website? Contact Us by email	The submitter role ca applicable manufacture	-	iduals from third-party enti SPO.	ties who submit recor	ds on behalf of the
	investment interests.	ions made in the r	eporting of payments, othe nessages on behalf of the		
	*First Name:		Middle Nam	e.	
	Lesllie				
	*Last Name: Smith		Suffix (Jr., s	Sr., etc.):	
	*Business Email Addre	ess:		Telephone Number: 99 or Maximum 20 d	ligits
	openpayments@yopmail.	.com	555-555-555		
	attesters, submitters, cor	mpliance users, ar entity has approve wed. PS	system. Only an officer m d other officers. Your role(d your self-nomination. Yo	s) is/are not confirme	d until an
	Cancel			Back	Continue

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

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type Review and Submit Profile **Create 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 "Continue" button to submit your profile. Select Profile Type Entity's Registration ID: 100001225047 Register Entity Entity's Legal Name: ABCDEF Medical Personal Information Reporting Entity Type: Applicable Manufacturer **Review and Submit Profile** (4) Business Type: Applicable manufacturer-drugs/biological Food & Drug Administration (FDA) Establishment Identifier: Access the Open Payments User Guide [PDF] Data Universal Numbering System (D-U-N-S® Number): 100000355 URL of Parent Company: www.cms.com Need help with the website? Contact Us by email **Business Address:** Review the Open Payments Privacy Policy [PDF] Country: United States Business Address, Line 1: 7500 Security Blvd. **Business Address, Line 2:** City Name: Baltimore State: Maryland Zip Code: 21244 Business Telephone Number: 555-555-5555 **Business Ownership Information** Type of Ownership: Corporation Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 34-5678901 Doing Business As (DBA) Name: ABCDE Medical Will this entity's information be submitted in a consolidated report (i.e., one entity reports on behalf of another entity)? No, my entity's data will not be submitted in a consolidated report Nominations: Role: First Last Middle Suffix (Jr., Sr., Business Email Address: Name: etc.): Name: Name Officer Leslie Smith openpayments@yopmail.com Loslia Smith openpayments@yopmail.com Submitter openpayments@yopmail.co Attester Leslie Smith openpayments@yopmail.com Compliance Leslie Smith Continue Back Cancel

Figure 112: Review and Submit Profile page

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

Figure 113: Success Confirmed page



3.6f: Approving or Modifying Nominations (Officers Only)

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

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

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

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type ige Entitie (2) My Profile **⊠**₀ ⊿ \odot w and Disput Mess Access the Open Payments Welcome to the Open Payments System User Guide [PDF] Announcements Need help with the website? Contact Us by email Program Year 2018 Review and Dispute Period Open -Review the Open Payments Privacy Policy [PDF] The Review and Dispute period is open starting April 1, 2019. During this period, reporting entities may receive disputes from covered recipients and should work with them directly to resolve the disputes. Physicians and teaching hospitals may review data about them and initiate disputes until May 15, 2019. After that, reporting entities have an additional 15-day correction period to make corrections to disputed data as needed. Records with unresolved disputes at the end of the correction period will be identified in the published data as disputed. Changes to records after the correction period will be included in future data publications. Visit the Open Payments website at https://www.cms.gov/openpayments for information. For questions, contact the Open Payments Help Desk by email at openpayments@cms.hhs.gov or by phone at 1-855-326-8366. For the TTY line, call 1-844-649-2766. You can manage your user profile and perform user role functions associated with your profile. According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The OMB control number for this information collection is 0938-1237. The time required to complete this information collection can range from 1 to 30,000 hours per entity depending on the size and type of organization. This information collection may involve registration, data submission, attestation, dispute and dispute resolution processes. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

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

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

Figure 115: Manage Entities Page



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

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User and Dispute (2) My Profile Messag 2 ide E ۲ **ABCDE Medical** Access the Open Payments User Guide [PDF, 37.3 MB] 0 Entity Details Manage Roles Need help with the website? Contact Us by email ? Review the Open Payments Privacy Policy [PDF, 102 KB] This page provides the information for your selected entity. Only an authorized official or authorized 0 representative in the officer role can update any incorrect information in the entity profile by selecting the "Update Entity" button. **Entity Information** Entity's Registration ID: 100000355013 Entity's Legal Name: ABCDE Medical Reporting Entity Type: Applicable Manufacturer Business Type: Applicable manufacturer-drugs/biological Food & Drug Administration (FDA) Establishment Identifier: Data Universal Numbering System (D-U-N-S® Number): URL of Parent Company: www.cms.gov **Business Address** Country: United States Business Address, Line 1: 7500 Security Blvd Business Address, Line 2: City Name: Baltimore Zip Code: 21244 State: Maryland Business Telephone Number: 555-555-5555 **Business Ownership Information** Type of Ownership: Corporation Taxpayer Identifier Number (TIN)/Employer Identification Number (EIN): 12-3456789 Doing Business As (DBA) Name: ABCDE Medical AMGPO 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 Primary Point of Contact Name: John Smith Business Telephone Number: 999-999-9999 Title at the Entity: Officer Business Email Address: openpayments@yopmail.com **Backup Point of Contact** Name: Jane Doe Business Telephone Number: 555-555-5555 Title at the Entity: Officer Business Email Address: openpayments1@yopmail.com **Contact Information for Review and Dispute** Contact Information: New entity **Recertification Information** Recertified By: Karen Miller Date and time recertified: April 26, 2017, 14:17PM GMT

Figure 116: Entity details page

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

Home Subr	missions I	Review and D	ispute	Ø Manage Entities	O My Profile		Messages	Resource
BCDE Me	dical					C	Access the Ope User Guide [PDI	
Entity Details	Manage Ro	les				?	Need help with t Contact Us by e	
	tton by a user's na		emove a role	al to fill a role within yo for an already affiliat	ed user.	0	Privacy Policy [F	PDF. 102 KB]
ntity. lote: An officer may m							5 1	
entity. Note: An officer may m he entity. An explanation of the s	nodify or deactivat	te another offic	er but cannol	t deactivate themselve ments User Guide [PI	or from	C		KD
entity. Note: An officer may m he entity. An explanation of the s	nodify or deactivat	te another offic	er but cannol	t deactivate themselve	or from	C		
entity. Note: An officer may m he entity. An explanation of the s	nodify or deactivat	te another offic	er but cannol	t deactivate themselve ments User Guide [PI	or from	6		
entity. Note: An officer may m he entity. An explanation of the s AIB] . Name:	nodify or deactivat	te another offic In be found in t	er but cannoi he Open Pay	t deactivate themselve ments User Guide [PI	or from	0		
entity. Note: An officer may m he entity. An explanation of the s AIB] . Name:	nodify or deactivat statuses below ca Role:	te another offic n be found in t Status:	er but cannol he Open Pay Actions:	t deactivate themselve ments User Guide [PI	or from	0		
entity. Note: An officer may m he entity. An explanation of the s wB].	nodify or deactivat statuses below ca Role: Attester	te another offic in be found in t Status: Approved	er but cannol he Open Pay Actions:	t deactivate themselve ments User Guide [PI	or from			
entity. Note: An officer may m he entity. An explanation of the s wB].	nodify or deactivat statuses below ca Role: Attester Submitter	te another offic in be found in t Status: Approved Approved	er but cannol he Open Pay Actions:	t deactivate themselve ments User Guide [PI	es from DF, 37.3 New Role			
entity. Note: An officer may m the entity. An explanation of the s MB] . Name: John Miller	nodify or deactivat statuses below ca Role: Attester Submitter Officer	te another offic In be found in t Status: Approved Verified	er but cannol he Open Pay Actions: Modify	t deactivate themselve ments User Guide [Pl Nominate N	es from DF, 37.3 New Role			

Figure 117: Manage Roles tab

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

Figure 118: Red box circles confirmation message

Home St	ubmissions	Review and Di	ispute Mar	age Entities	O My Profile	Messages	Resource
BCDE M	edical				C	Access the Ope	
Entity Details	Manage Ro	les			?	Need help with t Contact Us by	he website?
Confirmation:	user, Leslie Smith	has been ann	roved for the O	fficer role	6	Review the Ope Privacy Policy [F	
entity.				er completely from yo			Í
n explanation of the //B] .	statuses below ca	in be found in the	e Open Paymen	ts User Guide (PDF, 3	37.3	3	
				Nominate New	Role		1
	Role:	Status:	Actions:				
Name:	2010	Approved	Modify				
	Attester	Contraction of the second s					
	Attester Submitter	Approved					
Name: John Miller		Approved Verified			_		
	Submitter		Modify	Deactivate Use	_		

To modify the nomination, select "Modify."

Figure 119: Manage Roles tab

Home Su	Ibmissions	Review and Dis	pute Mar	ම් nage Entities	(Q) My Profile		Messages	Resourc
BCDE M	edical					C	Access the Ope User Guide [PDF	
Entity Details	Manage Ro	bles				?	Need help with th Contact Us by e	
entity.		a user's name to r	emove that use	an already affiliated er completely from y ctivate themselves	our			5
entity. Note: An officer may the entity. An explanation of the	modify or deactiva	a user's name to r te another officer	emove that use but cannot dea	er completely from y	our	¢		
entity. Note: An officer may the entity. An explanation of the	modify or deactiva	a user's name to r te another officer	emove that use but cannot dea	er completely from y	our from . 37.3	4		
entity. Note: An officer may the entity. An explanation of the	modify or deactiva	a user's name to r te another officer	emove that use but cannot dea	er completely from y activate themselves i ts User Guide (PDF	our from . 37.3	¢		
entity. Note: An officer may the entity. An explanation of the MB] .	modify or deactiva e statuses below ca	a user's name to r te another officer an be found in the	emove that use but cannot dea Open Paymen	er completely from y activate themselves i ts User Guide (PDF	our from . 37.3	d		
entity. Note: An officer may the entity. An explanation of the MB] . Name:	modify or deactiva e statuses below ca Role:	a user's name to r te another officer an be found in the Status:	emove that use but cannot dea Open Paymen Actions:	er completely from y activate themselves i ts User Guide (PDF	our from . 37.3	6		
entity. Note: An officer may the entity. An explanation of the MB] . Name:	modify or deactiva e statuses below ca Role: Attester	a user's name to r te another officer an be found in the Status: Approved	emove that use but cannot dea Open Paymen Actions:	er completely from y activate themselves i ts User Guide (PDF	our from . 37.3			
entity. Note: An officer may the entity. An explanation of the MB] . Name:	r modify or deactiva e statuses below ca Role: Attester Submitter	a user's name to r te another officer an be found in the Status: Approved Approved	emove that use but cannot dea Open Paymen Actions:	er completely from y activate themselves i ts User Guide (PDF	our from . 37.3 v Role			
entity. Note: An officer may the entity. An explanation of the MB] . Name: John Miller	modify or deactiva e statuses below ca Role: Attester Submitter Officer	a user's name to r te another officer an be found in the Status: Approved Approved Verified	emove that use but cannot dea Open Paymen Actions: Modify	er completely from y activate themselves i ts User Guide (PDF Nominate New	our from .37.3 v Role er			

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

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

Figure 120: Manage Roles tab

Home Submissions Re	eview and Dispute	Manage Entities	(2) My Profile	Messages	Resource
BCDE Medical			C	Access the Op User Guide [PD	
Entity Details Manage Roles			?	Need help with Contact Us by	
eslieSmith			0	Review the Op Privacy Policy [
A field with an asterisk (*) is required.			-	1 Hvacy I olicy [1.011
				- 1	12
*First Name:	Middle Name:				- P1
Leslie					
*1 4 Manuar				SA DE	
*Last Name: Smith	Suffix (Jr., Sr., etc	c.):			
Simur					
*Business Email Address:					
openpayments@yopmail.com			1		
*Indicate the role or roles this person wi	ll have:				
Officer					
Submitter					
Attester					
Compliance					
*Country:					
United States					
-					
*Business Address, Line 1: 7500 Security Blvd.					
1000 Security Divu.					
Business Address, Line 2:					
*City Name:	*State:				
*City Name: Baltimore	MD				
Battinore	in D				
*Zip Code:	*Business Telepl	none Number:			
99999 9999	999-999-9999				
21244	555-555-5555				

You will receive an onscreen confirmation of the information submission.

Figure 121: Manage Roles tab

Home Sub	missions	Review and Dis	pute Man	age Entities	(2) My Profile		Messages	Resour
BCDE Me	dical					0	Access the Ope	
Entity Details	Manage Ro	les			_	?	Need help with th Contact Us by e	he website?
Confirmation: • You have succ	essfully submitte	ed Role Informat	tion			8	Review the Oper Privacy Policy [P	
entity. Note: An officer may m the entity. An explanation of the s MB].		e another officer		ts User Guide (PDF, 3)	m 7.3			
Note: An officer may n the entity. An explanation of the s		e another officer		ctivate themselves fro	m 7.3			Ų
Note: An officer may m the entity. An explanation of the s MB] . Name:	statuses below ca	e another officer n be found in the	Open Paymen	ctivate themselves from	m 7.3			
Note: An officer may m the entity. An explanation of the s MB] . Name:	statuses below ca Role:	e another officer n be found in the Status:	Open Payment Actions:	ctivate themselves from	m 7.3			
Note: An officer may m the entity. An explanation of the s MB] . Name:	Role: Attester	e another officer n be found in the Status: Approved	Open Payment Actions:	ctivate themselves from	m 7.3			
Note: An officer may m the entity. An explanation of the s MB] . Name:	Role: Attester Submitter	e another officer n be found in the Status: Approved Approved	Open Payment Actions:	ctivate themselves from	m 7.3			
Note: An officer may m the entity. An explanation of the s Ma] . Name: John Miller	Role: Attester Submitter Officer	e another officer n be found in the Status: Approved Verified	Open Payment Actions: Modify	ctivate themselves from ts User Guide (PDF, 3) Nominate New R	m 7.3			
Note: An officer may m the entity. An explanation of the s MB] Name: John Miller Tom Smith	Role: Attester Submitter Officer Submitter	e another officer n be found in the Status: Approved Approved Verified Accepted	Open Payment Actions: Modify Modify	ctivate themselves from the User Guide (PDF, 3) Nominate New R Deactivate User	m 7.3			

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

3.6g: Deactivating Users (Officers Only)

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

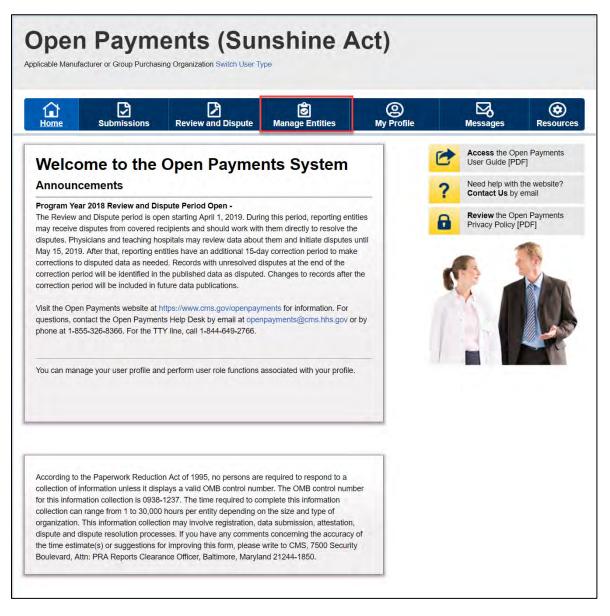
Note that officers cannot deactivate themselves, though an officer can deactivate another officer. If you wish to be deactivated, contact the Open Payments Help Desk or another individual who holds the user role of officer in your reporting entity. Note that a reporting entity must have at least one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

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

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

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

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



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

Figure 123: Manage Entities Page

Home	Submissions	Review and Dispute		Entities	(O) My Profile		Messages	Resource
Mana	ge Entities	5			-1	0	Access the Oper User Guide [PDF	
	go			Register New Er	ntity	?	Need help with th Contact Us by e	
		n are listed below. Select an he officer role, manage user			W.	8	Review the Oper Privacy Policy (P	
those entities	s. Entity recertification r	t be recertified before users requires that an active office nd confirms the accuracy of	er within the C	Open Payments sy			. 1	1
Changes ma vetted.	de to the Entity Name,	TIN, or DUNS Number field	ds will cause ;	your entity to be re	b-	0		× m
Your En	tities							
		Registration ID: S	tatus:	Date Verified:				

<u>Step 3:</u> On the "Entity Details" page, select the "Manage Roles" tab.

Figure 124: Manage Roles Tab

Home Su	Demissions I	Review and Dis	pute <u>Man</u>	age Entities	O My Profile		Messages	Resou
BCDE M	edical					0	Access the Op User Guide [PD	
Entity Details	Manage Ro	les				?	Need help with Contact Us by	
piecrule pedentan					iir ii			-
lote: An officer may he entity. In explanation of the (B] .	modify or deactivat	e another officer	but cannot dea	r completely from yo ctivate themselves fr ts User Guide (PDF, i Nominate New	om 37.3	6		
lote: An officer may he entity. In explanation of the (B] . Name:	modify or deactivat statuses below ca	e another officer n be found in the	but cannot dea Open Payment	ctivate themselves fr	om 37.3	6		
lote: An officer may he entity. In explanation of the (B] . Name:	modify or deactivat statuses below car Role:	e another officer n be found in the Status:	but cannot dea Open Payment Actions:	ctivate themselves fr	om 37.3			
lote: An officer may he entity. In explanation of the (B] . Name:	modify or deactivat statuses below car Role: Attester	e another officer n be found in the Status: Approved	but cannot dea Open Payment Actions:	ctivate themselves fr	om 37.3	C		
lote: An officer may he entity. An explanation of the (B] . Name:	modify or deactivat statuses below car Role: Attester Submitter	e another officer n be found in the Status: Approved Approved	but cannot dea Open Payment Actions:	ctivate themselves fr	om 37.3 Role	C		
he entity. An explanation of the //B] . Name: John Miller	Role: Attester Officer	e another officer n be found in the Status: Approved Verified	but cannot dea Open Payment Actions: Modify	ctivate themselves fr ts User Guide (PDF, 1 Nominate New	om 37.3 Role	C		

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

Figure 125: Deactivate User on Manage Roles Tab

Home Sut	Demissions	Review and Dis	pute <u>Man</u>	age Entities	(Q) My Profile		Messages	Resource
BCDE Me	edical					0	Access the Ope User Guide [PDF	
Entity Details	Manage Ro	les				?	Need help with t Contact Us by a	
Select the "Modify" bu Select the "Deactivate					iser.		Privacy Policy [P	
entity. Note: An officer may r the entity. An explanation of the MB].	modify or deactivat	te another officer	but cannot dea	ctivate themselves fr	om	¢		in the
Note: An officer may r the entity. An explanation of the	modify or deactivat	te another officer	but cannot dea	ctivate themselves fr	our Iom 37.3	đ		
Note: An officer may r the entity. An explanation of the	modify or deactivat	te another officer	but cannot dea	ctivate themselves fr s User Guide (PDF,	our Iom 37.3	6		
Note: An officer may r the entity. An explanation of the MB) .	nodify or deactivat	te another officer	but cannot dea Open Payment	ctivate themselves fr s User Guide (PDF,	our Iom 37.3	d		
Note: An officer may r the entity. An explanation of the MBJ . Name:	nodify or deactivat statuses below ca Role:	te another officer n be found in the Status:	but cannot dea Open Payment Actions:	ctivate themselves fr s User Guide (PDF,	our Iom 37.3	ď		
Note: An officer may r the entity. An explanation of the MBJ . Name:	nodify or deactivat statuses below ca Role: Attester	te another officer In be found in the Status: Approved	but cannot dea Open Payment Actions:	ctivate themselves fr s User Guide (PDF,	our Iom 37.3	6		
Note: An officer may r the entity. An explanation of the MBJ . Name:	nodify or deactivat statuses below ca Role: Attester Submitter	te another officer n be found in the Status: Approved Approved	but cannot dea Open Payment Actions:	ctivate themselves fr s User Guide (PDF,	om 37,3 Role	6		
Note: An officer may r the entity. An explanation of the MB] . Name: John Miller	nodify or deactivat statuses below ca Role: Attester Submitter Officer	te another officer In be found in the Status: Approved Verified	but cannot deal Open Payment Actions: Modify	ctivate themselves fr s User Guide (PDF, Nominate New	om 37,3 Role	6		

<u>Step 5:</u> 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.

Entity Details	Manage Ro	les		?	Need help with the website? Contact Us by email
Select the "Modify" bu Select the "Deactivate entity.	itton by a user's na User" button by a	ame t user	minate a new individual to fill a role within your entity. o add or remove a role for an already affiliated user. 's name to remove that user completely from your ther officer but cannot deactivate themselves from	•	Review the Open Payments Privacy Policy [PDF, 102 KB]
the entity.					AX IN
An explanation of the	statuses below ca	n be	Deactivate User		
MB] . Name:	Role:	Sta	Selecting this option will deactivate Tom Smith from your entity. They will no longer be able to perform actions on behalf of your entity. Reminder: Entitles must have at least one active officer in		
John Miller	Attester	Ap	the Open Payments system. Select "Continue" to deactivate		
	Submitter	Ap	this user, or select "Cancel" to return to the previous page.		
	Officer	Ve	Cancel		
Tom Smith	Submitter	Ac			
Karen Miller	Submitter	Act	epted Modify Deactivate User		
Leslie Smith	Submitter		nination Modify		
	Attester		nination		

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

Figure 127: Confirmation Message on Mage Roles Tab

Home Su	Dissions	Review and Dis	oute Man	age Entities	(A) My Profile		Messages	Resourc
BCDE Me						C	Access the Ope	in Payments
Entity Details	Manage Ro	ies				2	Need help with t	he website?
				-		-	Contact Us by e	PITIAII
confirmation:						8	Review the Ope Privacy Policy (P	
- The selected u	user, Tom Smith, I	has been deactiv	vated.	_	_		. mary . mary .	and the real
Select the "Deactivate intity.	e User" button by a	user's name to r	nove a role for a remove that use		user, our	C		KAN
Select the "Deactivate entity. Note: An officer may r he entity. An explanation of the	e User [®] button by a modify or deactivat	user's name to r le another officer	nove a role for i remove that use but cannot dea	an already affiliated ar completely from y ctivate themselves	user, our from	C		
Select the "Deactivate entity. Note: An officer may r he entity. An explanation of the	e User [®] button by a modify or deactivat	user's name to r le another officer	nove a role for i remove that use but cannot dea	an already affiliated ar completely from y ctivate themselves	user, our from ; 37.3			
Elect the "Deactivate ntity. Note: An officer may r he entity. In explanation of the (B).	e User [®] button by a modify or deactivat	user's name to r le another officer	nove a role for i remove that use but cannot dea	an already affiliated er completely from y ctivate themselves ts User Guide (PDF	user, our from ; 37.3			
Celect the "Deactivate initity. Note: An officer may r he entity. In explanation of the (B).	e User [~] button by a modify or deactivat statuses below ca	user's name to r le another officer n be found in the	nove a role for a remove that use but cannot dea Open Paymen	an already affiliated er completely from y ctivate themselves ts User Guide (PDF	user, our from ; 37.3	C		
Celect the "Deactivate initity. Note: An officer may r he entity. In explanation of the (B).	e User" button by a modify or deactivat statuses below ca Role:	e another officer n be found in the Status:	nove a role for a remove that use but cannot dea Open Paymen Actions:	an already affiliated er completely from y ctivate themselves ts User Guide (PDF	user, our from ; 37.3	0		
Select the "Deactivate entity. Note: An officer may r he entity. An explanation of the (B).	e User" button by a modify or deactivat statuses below ca Role: Attester	a user's name to r te another officer n be found in the Status: Approved	nove a role for a remove that use but cannot dea Open Paymen Actions:	an already affiliated er completely from y ctivate themselves ts User Guide (PDF	user, our from ; 37.3	C		
Select the "Deactivate entity. Note: An officer may r he entity. An explanation of the (B).	e User" button by a modify or deactivat statuses below ca Role: Attester Submitter	a user's name to r te another officer n be found in the Status: Approved Approved	nove a role for a remove that use but cannot dea Open Paymen Actions:	an already affiliated er completely from y ctivate themselves ts User Guide (PDF	user, our from . 37,3 w Role	0		
Select the "Deactivate entity. Note: An officer may r he entity. An explanation of the MB] . Name: John Miller	e User" button by a modify or deactivat statuses below ca Role: Attester Submitter Officer	a user's name to r the another officer in be found in the Status: Approved Approved Verified	nove a role for a remove that use but cannot dea Open Paymen Actions: Modify	an already affiliated ar completely from y ctivate themselves ts User Guide (PDP Nominate Ner	user, our from . 37,3 w Role	0		

Section 3.7: Vetting

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

3.7a: Entity Vetting

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

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

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

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

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

3.7b: Vetting Timeframe

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

Data Submission and Attestation

Chapter 4: Data Submission and Attestation

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

This chapter is divided into the following sections:

- Data Submission contains information on data submission for the Open Payments system.
- **Preparing Your Data** contains information on how to prepare data files, payment types, and location of data submission resources.
- **Bulk File Upload** contains information and instructions for the preparation and upload of CSV files (or ZIP file containing CSV files) for submission through the Open Payments system.
- **Manual Data Entry Using the Graphic User Interface** contains information about submitting information to the Open Payments system through a graphical user interface (GUI).
- **Record Validation and Matching** contains information about how submitted records are verified in the Open Payments system for accuracy.
- **Correcting Validation and Matching Errors** contains information about how to understand error reporting and how to correct errors in submitted records.
- **Deleting Records** contains information about how to delete individual records and entire CSV files.
- **Final Submission of Data** contains information about the final data submission process after all records are uploaded and ready for submission.
- **Delay in Publication** contains information about the requirements and rules for requesting delays in publication for certain types of records.
- **Consolidated Reporting** contains information about reporting entities under common ownership having their data collectively submitted by one entity in the group in consolidated reports.

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

Section 4.1: Overview of Data Submission and Attestation

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

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

Figure 128: The Four Steps of Data Submission and Attestation



Notes:

- Applicable manufacturers and applicable GPOs must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the reporting entity's compliance for five years from the date of publication.
- Data reporting is complete <u>only</u> after electronic attestation is received for the program year.
- To assist with the preparation of data for submission, CMS has made resources available to help reporting entities confirm physician and teaching hospital identifying information. Physician identifying information can be found in the Validated Physician List (VPL). The documents can be downloaded from the "Submissions" page of the Open Payments system. Teaching hospital identifying information can be found in the Teaching Hospital list, which can be downloaded from the Resources page of the Open Payments website at https://www.cms.gov/openpayments/About/Resources.html.
- If the physician license information is not active in any program year (beginning with Program Year 2013 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

Section 4.2: Data Submission

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

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

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

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

Section 4.3: Preparing Your Data

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

4.3a: Covered Recipient Demographic Resources

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

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

- For Program Years 2014 and later, use the hospital's "Doing Business As" name as the hospital name in the submitted record. The "Doing Business As" name is found in the Teaching Hospital List under the heading of "Hospital Name."
- For Program Year 2013 records, use the hospital's legal business name as the hospital name in the submitted record.
- For the address for the hospital in the submitted record, use the "NPPES Business Address" in the Teaching Hospital List.

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

4.3b: Validation Utility for Physicians

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

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

- Select the "Validate Physician" button located on the bottom of the "Submissions" Page.
- Submit physician information using the upload functionality on the Physician Validation page.

4.3b (1): Validating Physician Instructions

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

Figure 129: Submissions Tab

Home	Submissions	Review and Dispute	Manage Entities	(Q) My Profile	Messages	Resources
Submis	ssions					? User Guid
A field with an a	sterisk (*) is required.					
Applicable manu System.	ufacturers and applicable	e GPOs must submit paym	ents, or other transfers of value, and	ownership or inve	estment interests to the O	pen Payments
	yment Data					
		er can submit information to	the Open Payments system. Select	Bulk File		
	ial Data Entry below.	1			Download the P List	nysician
	sources tab for the Open ates for the Bulk File Upl		anual Data Entry to submit records u syments manual entry online form.	100 C	The Validated Physician I Physician with Inactive Li	
	ulk File Upload		Manual Data Entry	1	Supplement File per Prog	gram Year below
					should not be shared put Validated Ph	ysician Lists
					License(s) S	n with Inactive
Review Su	Ibmitted Payme	nt Records			per Program	Tear
o review record	ds, select the entity who below, then select "Revi		ew and the program year for the reco		Download the R Templates	eporting
		*Select Program Year:			To download reporting ter Resources tab.	mplates, see the
drop-down lists			 Review Records 			
drop-down lists		2018	Review Records			
drop-down lists Select Entity: ABCDEF Me	edical 🔻	2018				
drop-down lists Select Entity: ABCDEF Me Review Su	edical •	2018 Status				
drop-down lists Select Entity: ABCDEF Me Review Su Once a file for y	edical	2018 Status	details by selecting "Review File Sta	tus."		
Irop-down lists Select Entity: ABCDEF Me Review Su	edical	2018 Status		tus."		
Irop-down lists Select Entity: ABCDEF Me Review Su Droce a file for y Review File S	edical	2018 Status mitted, you may review the		tus."		
Irop-down lists Select Entity: ABCDEF Me Review Su Once a file for y Review File S Physician	edical ubmitted File(s) rour entity has been subr tatus Matching Valida	2018 Status mitted, you may review the ation Utility				
drop-down lists *Select Entity: ABCDEF Me Review Su Droce a file for y Review File S Physician	edical ubmitted File(s) rour entity has been subr tatus Matching Valida ian matching information	2018 Status mitted, you may review the ation Utility	details by selecting "Review File Sta			

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

Figure 130: Validate Physicians Button

Open Pay Applicable Manufacturer or Grou		-		ine A	(ct)		
Home Submis		Review and Dispu		e Entities	Q My Profile	Messages	Resources
Submissions							? <u>User Guide</u>
A field with an asterisk (*) is re Applicable manufacturers and System.	applicable	GPOs must submit pay	ments, or other	transfers of value	e, and ownership or ir	nvestment interests to th	e Open Payments
Submit Payment Da Only users who hold the role of Upload or Manual Data Entry I	of submitte	r can submit information	to the Open Pa	vments system. S	Select Bulk File	Download the List	Physician
Refer to the Resources tab for reporting templates for the Bul Bulk File Upload	lk File Uplo	ad. Open I		ntry to submit rec al entry online fo ata Entry	-	and Phys	e License(s) Program Year below publicly. Physician Lists ician with Inactive) Supplement File
To review records, select the e drop-down lists below, then se	-	w Records."		ogram year for th	e records from the	Download the Templates	
*Select Entity: ABCDE Medical	•	*Select Program Year	:	Review Rec	ords	Resources tab.	
Review Submitted F Once a file for your entity has Review File Status Physician Matching To verify physician matching ir information on the new page. Validate Physician	been subm	nitted, you may review th		-			
						Contac	t Us Privacy Polic

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

Element	Description	Format
APPLICABLE_MANUFACTURER_OR_APPLICAB LE_GPO_ID	Enter the Applicable Manufacturer's/Appli cable GPO's Registration ID in this data field	System generated field
PHYSICIAN_FIRST_NAME	Enter the textual first name of the physician (covered recipient) receiving the payment or other transfer of value.	Free form text
PHYSICIAN LAST NAME	Enter the textual last name of the physician (covered recipient) receiving the payment or other transfer of value	Free form text
PHYSICIAN_NPI	Physician (not the NPI of any group the physician belongs to)	Numeric digits only
PHYSICIAN_PRIMARY_TYPE	Enter Primary type of medicine practiced by the covered recipient physician.	The following codes are in this field: "1" = Medical Doctor; "2" = Doctor of Osteopathy; "3" = Doctor of Dentistry; "4" = Doctor of Podiatric Medicine; "5" = Doctor of Optometry; "6" = Chiropractor
PHYSICIAN_LICENSE_STATE_AND_LICENSE_N UMBER_1	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999

Figure 131: Physician Validation Data Fields Table

Element	Description	Format
PHYSICIAN_LICENSE_STATE_AND_LICENSE_N UMBER_2	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999
PHYSICIAN_LICENSE_STATE_AND_LICENSE_N UMBER_3	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999
PHYSICIAN_LICENSE_STATE_AND_LICENSE_N UMBER_4	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999
PHYSICIAN_LICENSE_STATE_AND_LICENSE_N UMBER_5	Enter the paired state and official state license number of the covered recipient physician. May include up to 5 "Physician License State and License Number" pairs, if a physician is licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999

Figure 132: Physician Validation Page

Home	Submissions	Review and Dispute	Manage Entities	Q My Profile	Messages	Resource
Physic	cian Valida	ation			Download the P List	hysician
To submit you uploading you file specificati	ur validation file, ensure	alidation file, follow the steps i that the file is in a valid .csv fi y download the Open Paymen	le format and conforms to t		The Validated Physician Physician with Inactive L Supplement File per Pro should not be shared pu	icense(s) gram Year below blicly.
be larg	the "Browse" button to er than 50 MB. the "Upload File" button	o locate and select your file. N	ote: Individual data files car	not	and Physicia	ysician Lists an with Inactive upplement File Year
will see the fil only include the 'Refresh Stat column will be *File:	e details and results in t ne physician profiles wit us" button to refresh file e available upon succes	tton, the file will be submitted the table below for 90 days aff th error(s) and their respective e status. A downloadable resul isful processing of the file.	error codes. Select the	and the second se	Download the V Template The physician validation available through the line Physician Va	template is below.
	lid .csv file. Maximum	of 50 MB per file.			Template	
Upload File						
			Refresh Sta	itus		
Show	ving 10 * of 0 Er	ntries Page 1 of 1	Page v			
Validation File ID: ♦	File Name: 🤇	> File Status: ♦ Dat	nitted Submitted e:♦ By:♦ Results F	ile:		
No records fou	nd.					

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

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

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

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

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

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

Figure 133: Choose file Pop-Up Window

Home	Submissions	Review and Dispute	🔊 Manage Entities	O My Profile	Messages	Resource
Organize Cuick acc Desktop Downloo Downloo	ads 🖈		Search Desktop	× •	Download the Physican Lists The Validated Physician Lists Supplement File per Program should not be shared publicly Walidated Physican we be chosed by the per Program Year Pr	and se(s) Year below ian Lists ith Inactive ement File
Dictures	File name:	sful processing of the file.	Microsoft Excel 97-2003 Wor Open Cance		Download the Valid Template	plate is ow.

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

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

Figure 134: Physician Validation with Download Option

Home	Submissions	Review and Dis	pute	Manage En	tities	(2) My Profile		Messages	Resourc
Phys	sician Validati	on				1		load the Ph	ysician
	n an asterisk (*) is required.						List The Validated Physician Lists and		
Confirmat									
	have successfully refreshed	d the page data.						with Inactive Lice ant File per Progra	
			steps ider	ntified below.	Prior to			t be shared publi	
To submit your physician matching validation file, follow the steps identified below. Prior to uploading your validation file, ensure that the file is in a valid .csv file format and conforms to the ile specifications. If needed, you may download the Open Payments Physician Validation Template available on the right sidebar on this page.								Validated Phys and Physician License(s) Sup	with Inactive
1. Sele be la	ect the "Browse" button to loc arger than 50 MB.		ir file. Note	e: Individual d	ata files cannot			per Program Y	
	ect the "Upload File" button.						Down Templ	load the Val	lidation
	select the "Upload File" button e file details and results in the								
	le the physician profiles with er							ician validation te through the link b	
	Status" button to refresh file sta I be available upon successful			file link in the	results file		E	Physician Vali	
		proceeding of the						Template	
File:	valid .csv file. Maximum of 5	0 MB per file							
	File No file chosen	o we her me.							
	The second second								
Unlaced E									
Upload F	110								
				6	Refresh Status				
Sh	owing 10 * of 2 Entries	s – Page	1 of 1	Pag	ge 1 -				
Validation File ID: 0	File Name: 🔿	File Status:	Submitted Date: O	Submitted By: O	Results File:				
PV-111	Physician_Validation.csv	Submitted Successfully	06/17/2019	Leslie Smith	Download				
PV-110	Physician_Validation.csv	Submitted Successfully	06/17/2019	Leslie Smith	Download				
		and the second sec							

Section 4.4: Bulk File Upload

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

Bulk files may be used to perform four actions:

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

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

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

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

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

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

4.4a: Delay Limit Reached

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

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

- No Delay R & D on New Product Limit Reached
- No Delay C.I. on New Product Limit Reached

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

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

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

4.4b: Creating CSV Files

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

The sample files for all three payment types are available on the Resources page of the Open Payments website (<u>https://www.cms.gov/OpenPayments/About/Resources.html</u>). 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.

CMS.go	V					Sear
nters for Medicare &		ces				
edicare Medicaid/CHIP	Medicare-Medic Coordination	aid Private	Innovation Center	Regulations & Guidance	Research, Statistics, Data & Systems	Outreach a Education
me > Open Payments > Resou	urces					
Open Payments		Explore the Dat	ta 🕶 🕴 Program P	articipants -	FAQs Contact	Us
		Resources	105	and the second second		
About			site visitors as well	as specific resources fr	or applicable manufacturers and	GPOs and
How Open Payments Work	KS	resources for physicia			applicable manufacturers and	GPUS and
		the Open Payments • PY 2016-2020 The CSV same	system. CSV Sample File: 0 ple file to be used fo	Seneral Payments (CS) or submitting general pa Research Payments (C3)	syments for PY 2016.	uad datā in
		The CSV samp	ple file to be used fo	r submitting research p General Payments (C	payments for PY 2016.	
				r submitting general pa Research Payments (syments for PY 2013-2015.	
					payments for PY 2013-2015.	
		The CSV samp	ple file to be used fo	r submitting ownership	n Owner/Investor (CSV) /investment interests for PY 201 Owner/Investor has not change	
		Use the files below a encountered after su	and the second se	t data submissions a	nd understand any error code	s
******		This version is occur by the er name in the Op	for use with 2016 d nd of March 2018. / pen Payments syste	A spreadsheet that prov am and shows the corre	SX) mission. Data submission for this indes an explanation of each dat seponding field name in the CSV	ta element / sample files
MS & HHS Websites	Tools	Helpful Links				
edicare.gov	Acronyms	Web Policies & Impo	ortant Links			
Medicare.gov	Archive	Careers			Receive Emai	I Updates
idicaid gov	Contacts	For Developers			Type your email here	Submit
sureKidsNow.gov	Glossary	Plain Language			At- t	
althCare.gov		Privacy Settings Freedom of Informat	linn Art			
4S gov/Open		No Fear Act	IION ACI			
		Nondiscrimination/A	ccessibility		Connect with	
		HHS.gov	and a second		A D U	10 2
		Inspector General				
		Inspector General USA.gov				

Figure 135: CMS Open Payments website "Resources" page

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

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

Home		Review and Dispute	o Manage Entities	O My Profile	Messages	Resources
Open Pay	ments F	esources				
Links to the Open Pa	yments resources a	are available below.				
For help obtaining a F	PDF viewer, go to th	ne CMS.gov Help page.				
Resources						
Open Payments CMS Resources Error Code Key	s FAQ's [PDF] s Website	ered Recipients [PDF] ug Codes (NDC)				
Reporting Ten	nplates					
			e template(s) for the program ment category or program ye		tegory/categories for the	e records to be
Research						
		Research Payments [CSV] Research Payments [CSV]				
General						
		General Payments [CSV] General Payments [CSV]				
Ownership						

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

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

- To prepare general payment and research payment records for Program Years 2016-2020, refer to the guidance in the "PY 2016-2020 Submission Data Mapping Document." The names of the sample files and templates vary depending upon where you locate them:
 - On the "Resources" page of the Open Payments website, the sample files are named "PY 2016-2020 CSV Sample File: General Payments" and "PY 2016-2020 CSV Sample File: Research Payments."
 - On the "Resources" tab within the Open Payments system, the templates are named "PY 2016-2020 CSV Template File: General Payments" and "PY 2016-2020 CSV Template File: Research Payments."
- To prepare physician owner/investor records for Program Years 2016-2020, refer to the guidance in the "PY 2016-2020 Submission Data Mapping Document." The names of the sample files and templates vary depending upon where you locate them:
 - On the "Resources" page of the Open Payments website, the sample files are named "PY 2013 - Onwards CSV Sample File: Physician Owner/Investor."
 - On the "Resources" tab within the Open Payments system, the template is named "PY 2016-2020 CSV Template File: Physician Owner/Investor."
- To prepare payment records of any type from program years before 2016, refer to the guidance in the "PY 2013-2015 Submission Data Mapping Document." The names of the sample files and templates vary depending upon where you locate them:
 - On the "Resources" page of the Open Payments website, the templates are named "PY 2013-2015 CSV Sample File: General Payments," "PY 2013-2015 CSV Sample File: Research Payments," and "PY 2013 and Onwards CSV Sample File: Physician Owner/Investor."
 - On the "Resources" tab within the Open Payments system, the templates are named "PY 2013 - 2015 CSV Template File: General Payments," "PY 2013 - 2015 CSV Template File: Research Payments," and "PY 2013 and Onwards CSV Template File: Physician Owner/Investor."

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

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

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

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

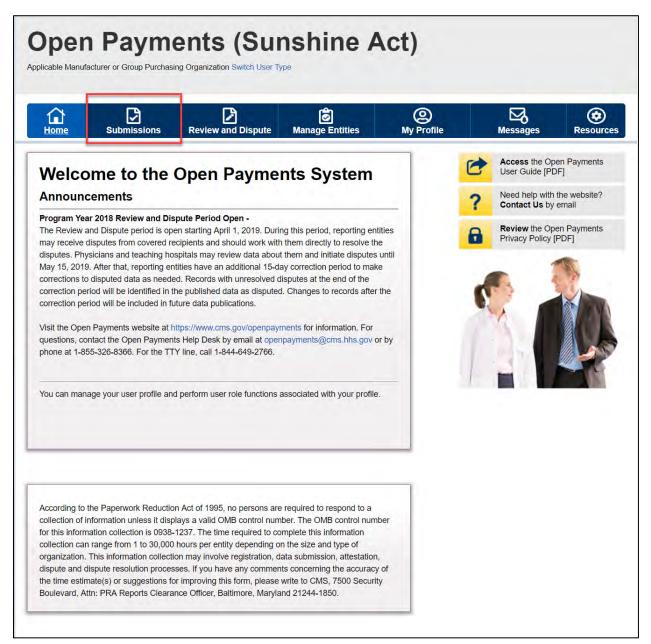
Whether you are using Excel or Open Office, it is important to perform the following final checks before submitting your file:

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

4.4c: Bulk File Upload Instructions

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

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



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

Figure 138: Submission Landing page

	nissions Review	and Dispute Manage Ent	ities My Profile	Messages	Resourc
Submission	S				P User Gu
field with an asterisk (*) is	s required.	5 - 2			
pplicable manufacturers a ystem.	nd applicable GPOs must	submit payments, or other transfe	rs of value, and ownership or i	investment interests to the	e Open Payments
Submit Payment I	Data				
	States and the state of the	information to the Open Payments	system Select Bulk File		
pload or Manual Data Ent		mormation to the open rayment.	System. Select Buik File	Download the List	Physician
tefer to the Resources tab eporting templates for the I Bulk File Upla	Bulk File Upload.	Select Manual Data Entry to Open Payments manual entr Manual Data En	y online form.	The Validated Physicia Physician with Inactive Supplement File per P should not be shared p	e License(s) rogram Year belo
Review Submitted	d Payment Recor	ds		and Physic	Physician Lists cian with Inactiv Supplement Fil Im Year
review records, select th		u wish to review and the program	year for the records from the	Download the Templates	Reporting
Select Entity:	*Select Pr	ogram Year:		To download reporting	templates, see th
ABCDEF Medical	• 2018	The second se	eview Records	Resources tab.	
Review Submitted	d File(s) Status				
nce a file for your entity h	as been submitted, you m	ay review the details by selecting	Review File Status."		
Review File Status					
hysician Matchii	ng Validation Uti	lity			
		/alidate Physician" button below a	nd upload physician		
nformation on the new pag	e.				

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

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

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

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

Figure 139: Upload Payments page

Home	Bubmissions	Review and Dispute	Manage Entitles	O My Profile	Messages	Reso
Uploa	d Payment	s			Download the P	hysiciar
A field with an	asterisk (*) is required				List	Links and
ensure that the needed, you m	e file is in a valid file for	mat (.csv or .zip) and conform Open Payments Reporting	r to uploading your payment ns to the file specifications. If Templates available on the		The Validated Physician Physician with Inactive L Supplement File per Pro should not be shared pu	license(s) gram Year b blicly.
file indic larger th 2. Select th	ator that apply to the file an 250 MB.	e's payment records. Note: I locate and select your file.	rogram year and resubmissic ndividual data files cannot be		Validated Pr and Physicia License(s) S per Program	an with Inac Supplement 1 Year
Once you sele	ct the "Submit File to O	pen Payments" button, the fi	le and records within it will be the file processing via email.		Download the V Template	
"Payment Cat	tegory:				available through the link	
General Paym	nents	×			Physician Va Template	alidation
"Reporting En	ntity:					
ABCDE Me	dical	*				
Program Yes	ar:					
2018		~				
Resubmissio	on File Indicator:					
New Submiss	ion	~				
*File: Must be a val	id .csv or .zip file. Max	mum of 250MB per file				
CSV-Samp	le2018.csv Browse	<u></u>				
	o Open Payments					

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

Figure 140: Confirmation Message on Uploads Payments Page

Home Submissions Rev	iew and Dispute	🔊 Manage Entities	O My Profile		Messages	Resource
Upload Payments				C	Access the Ope User Guide [PDF	
A field with an asterisk (*) is required.			- L	2	Need help with the Contact Us by e	
Your file has been received and will notifying you of the results of these		ns. You will receive emai	Is	•	Review the Open Privacy Policy [P	n Payments
To submit your payment file, follow the steps ensure that the file is in a valid file format (.c needed, you may download the latest Open "Resources" tab of the Open Payments syst	sv or .zip) and confo Payments Reporting	rms to the file specification	ns. If	Dowr List	nload the Phy	ysician
 Select the appropriate payment categ file indicator that apply to the file's pay larger than 250 MB. Select the "Browse" button to locate 3. Select the "Submit File to Open Paym Once you select the "Submit File to Open Paym 	and select your file. ents" button. ayments" button, the	Individual data files cannot file and records within it w	vill be	Physicia Supplen	dated Physician Lis an with Inactive Lice nent File per Progra not be shared public Validated Phys and Physician License(s) Sup per Program Yi	ense(s) am Year belov cly. ician Lists with Inactive plement File
*Payment Category:						
General Payments				Dowr	load the Val	idation
*Reporting Entity:				Temp	late	
ABCDE Medical	,				sician validation ter	
*Program Year:				available	e through the link b	
2017					Physician Valid Template	ation
*Resubmission File Indicator:						
New Submission						
File: Must be a valid .csv or .zip file. Maximum Choose File No file chosen	of 250MB per file.					

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

See Section 4.8 for details on record correction and resubmission.

4.4d: Review File Status page

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

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

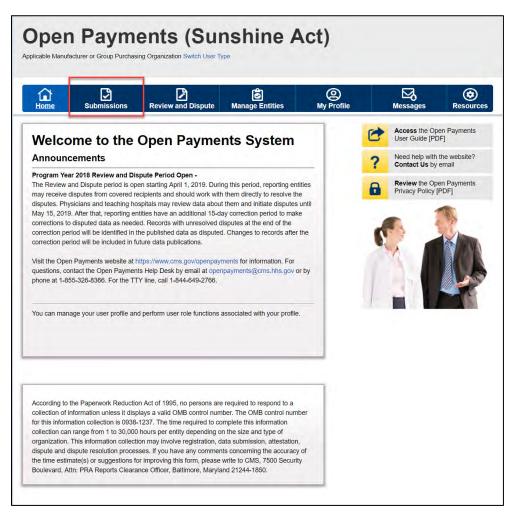


Figure 141: Open Payments system landing page for returning system users

<u>Step 2:</u> You will be brought to the "Submissions" page. Select the "Review File Status" button under the Review Submitted Files(s) Status section. Note: This section is only available for users with a submitter role.

Figure 142: Review File Status Button

Home Subn	nissions	Review and		Manage		(A) My Prof	ile	Messages	Resourc
Submission	s								? User G
A field with an asterisk (*) is	required.								
Applicable manufacturers a System.	nd applicable	e GPOs must sub	mit payments,	or other tra	nsfers of value	, and ownersh	ip or investm	ent interests to the 0	Open Payments
Submit Payment I	Data								
Only users who hold the role	2	r can submit info	mation to the 0	Open Paym	ents system. S	Select Bulk File	Do	wnload the F	hysician
Jpload or Manual Data Entr	ry below.	1					Lis		nysician
Refer to the Resources tab eporting templates for the E			Select Manual Open Paymer			ords using the rm.		Validated Physician sician with Inactive I	
Bulk File Uplo	bad		N	Anual Data	Entry		Sup	plement File per Pro uld not be shared pu	ogram Year belo
Review Submitted	l Pavme	nt Records						and Physici	nysician Lists an with Inactive Supplement File n Year
To review records, select the frop-down lists below, then	e entity whos	se records you wi	sh to review an	id the progr	am year for the	e records from		wnload the F mplates	Reporting
Select Entity:		*Select Progra	m Year:					ownload reporting to	emplates, see th
ABCDEF Medical	•	2018			Review Rec	ords	NC5	ources tab.	
Review Submitted	File(s)	Status							
Once a file for your entity ha			view the detail	ls hv selecti	ing "Review Fi	le Status "			
Review File Status		ninco, you may re				io otatuo.			
Physician Matchir	ng Valida	ation Utility							
the second se	information	, select the "Valid	ate Physician"	button belo	w and upload	physician			
To verify physician matching nformation on the new page									
To verify physician matching									

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

- File ID
- File Name
- File Status
- Submitted Date
- Submitted By (i.e. User First Name and Last Name Corresponding to EIDM ID)
- Payment Category
- Program Year
- Submission Type
- Entity
- Deleted Date
- Deleted By (i.e. User First Name and Last Name Corresponding to EIDM ID)

The displayed files may have the following file statuses:

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

Figure 143: Review File Status page

Home Submissio	ns Revi	ew and Dispute	Manage I			Profile	N	lessages		ources
Review File Sta	atus									
he table below displays informat nd payment categories. To acce										am years
se the Search and Filtering tool				in of Result	mission me,	seleçi ine	пуреннкец н	e io in the tat	JIC.	
A		2.0.072.00.0			2					
File Status: In Process Rejected Submitted Successfully Submitted with Errors Processed with Warning System Failure Occurred Rejected - File Infected Deleter1		Payment Category General Payments Research Payments Ownership or Invest	5		Program 3665 2019 2018 2017 2016 2015 2014 2013	Teat.		Ĵ.		
Entity:		Submission Type:				ion Start	Date:			
Lexton Construction, LLC		New Submission Resubmission Renew Delay in Put Delete	blication		2018010 Submiss	ion End C	Date:			
								8		
Search Clear All howing Results for: ubmission Start Date: 2018010	11									
	Showing	50 + of 1 Ent		Page 1	-	_	ge + +		Y	
File N ID: File N	ame:	File Status:	Submitted Date:	Submitted By:	Payment Category:	Program Year:	Type of Submission:	Entity:	Deleted Date:	By:
0313 research_file_11_20_2016.c	5V	Submitted Successful	09/24/2019	Karen Miller	General Payments	2016	New Submission	ABCDE Medical	N/A	N/A
	Showing	50 + of 1 En		Page 1		Pa	ge 1 +		1	

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

Figure 144: File ID Home Page

	2 6	@	
	and Dispute Manage Entities	My Profile	Messages Resour
File ID: 10313		C	Access the Open Payments User Guide [PDF]
Details about the File Submittee	1	0	Need help with the website?
If any records have errors, download this file's err		he 🧧	Contact Us by email
file, identifying records by Record ID and Home S deleted by selecting the "Delete File" button.			Review the Open Payments Privacy Policy [PDF]
2016 General Payments ABCDE	Medical		
Original Upload File Name:	2016_General_Lexton_Construction_with ors.csv	n_err	
Type of Submission:	New Submission		
Original /Resubmission Date:	9/24/2019 2:58 PM		
Submitted By:	Jane Smith	1	
File Size:	8 KB	1	
File Type:	CSV		_
Program Year:	2016		
Payment Category:	General Payments		
File Status:	Submitted with Errors		
Number of Records in File:	13		
Number of Records Successfully Uploaded:	13		
Error Log:	10313_General Payments		
Error Log:	10313_General Payments		

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

4.4e: Review Records

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

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

- 2. Select the "Submissions" tab on the menu bar. Under the "Review Submitted Records" section of the page, select the reporting entity and program year of the records to be reviewed, then select the "Review Records" button.
- 3. The "Review Records" page displays the total number of records in each record status for the program year, sorted by payment category. Record must be in "Ready for Submission" status to undergo Final Submission. Any records that are in "Failed Validation" or "Failed Matching" status must be corrected before they are eligible for "Final Submission".

Records in the submission process will be in one of the following statuses:

- a. **System Processing** Records which the Open Payments system is still processing and validating.
- b. Failed Validation Records that did not pass field validation checks.
- c. **Failed Matching** Records that were not successfully matched to a valid covered recipient.
- d. **Ready for Submission** Records which are successfully validated and matched, and are ready for final submission.
- 4. Select the "Refresh Status" button to update the counts for all payment categories. Once the "Refresh Status" button is selected, all other buttons on the "Review Records" page will be disabled until the page has been refreshed and a confirmation message will display when the refresh action is completed.
- 5. Select the "View All" button next to a payment category to go to the "Payment Category" page and view the individual records for that category.
- 6. Select the "Record ID" link for an individual record on the "Payment Category" page to view the record details. The "Record ID" page displays the record's error messages including those related to matching, and the expired license warning. In the case of expired license related warnings, a warning icon (A) is also displayed next to the "Record ID" on the Payment Category page.
- 7. Select the "File ID" link to view details about the submitted file. File Upload Statuses are displayed on the File ID page and on the File Modal:
 - a. **Submitted Successfully** File uploaded successfully.
 - b. **Submitted with Errors** The file is uploaded successfully but one or more records in the file are in "Failed Validation" or "Failed Matching" status.
 - c. Processed With Warning File contains records with late submission and/or expired license warnings. Users should review the warnings that are issued. No action is required for late submission warnings, however the user should determine if corrections or deletions are required for records with an expired license warning. If it is confirmed that the information is valid, the record can continue through final submission without further updates. Associated Error Log file displays specific warning message(s). NOTE: If the physician license information is inactive in any program year (beginning with Program Year 2013 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

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

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

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

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

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

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

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

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

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

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

4.5a: Manual Entry of General Payments Data

To enter general payments data manually, follow these steps:

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

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

Home	Submissions	Review and Dispute	e Manage Entities	(Q) My Profile	Messages	Resource
L Submis	sions					? User Gui
A field with an as	sterisk (*) is required.				1.00.00	
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	yment Data					
			the Oren Brennets eveter 0	alast Dulla Cila		
	al Data Entry below.	er can submit information to	the Open Payments system. So		Download the Pl _ist	hysician
Refer to the Reso	ources tab for the Open	Payments Select M	lanual Data Entry to submit reco	na manual d	The Validated Physician L	lists and
eporting templat	tes for the Bulk File Uplo	oad. Open Pa	ayments manual entry online for		Physician with Inactive Li Supplement File per Prog	
Bu	Ik File Upload		Manual Data Entry		hould not be shared pub	
					Validated Phy and Physicia	/sician Lists n with Inactive
					License(s) Su per Program	upplement File Year
Review Su	bmitted Payme	nt Records				
	s, select the entity whos below, then select "Revie		ew and the program year for the		Download the Re Templates	eporting
Select Entity:		*Select Program Year:			o download reporting ter Resources tab.	mplates, see the
ABCDEF Me	dical •	2018	• Review Reco			
	bmitted File(s)	Status				
Review Su	ur optitu bas boon subr	nitted, you may review the	details by selecting "Review File	e Status."		
	our entity has been sub-					
Once a file for yo	atus					
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Once a file for yc Review File Sta Physician I	atus Matching Valida an matching information le new page.		ician" button below and upload p	physician		

<u>Step 2:</u> Select the "Manual Data Entry" button from the "Submissions" page.

Figure 146: Manual Data Entry Button

Home Submissions	Review and Dispute Manage Entitie	es My Profile	Messages	Resource
Submissions				? User Gu
A field with an asterisk (*) is required				
Applicable manufacturers and applica	ble GPOs must submit payments, or other transfers	of value, and ownership or in	nvestment interests to the O	pen Payments
Submit Payment Data				
	itter can submit information to the Open Payments s	ystem. Select Bulk File	Download the Pl List	hysician
Refer to the Resources tab for the Op eporting templates for the Bulk File I			The Validated Physician I Physician with Inactive Li Supplement File per Proc	cense(s)
Bulk File Upload	Manual Data Entry			licly
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Review Submitted Paym To review records, select the entity w drop-down lists below, then select "R "Select Entity: ABCDEF Medical Review Submitted File(s	neent Records hose records you wish to review and the program yea eview Records." *Select Program Year: 2018 • Revi	ar for the records from the	should not be shared pub Validated Phy and Physicia License(s) St per Program	ysician Lists n with Inactive ipplement File Year eporting
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<u>Step 3:</u> On the "Add payment" page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year for the record to be entered.

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

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

Figure 147: Add Payment Page

Home Sa	ubmissions	Review and Dispute	🙆 Manage Entitles	Q My Profile		Messages	Resource
Add Paym	ent						? User Goid
field with an asterisk (") is required.						
o enter a payment, trar	nsfer of value, o	r ownership or investment inter	rest, enter the following	information.			
"Payment Category:		*Entity Making Payment I	Registration Name:	"Program Year:		Home System Paym	ent ID: 😧
Please Select	~	Please Select	Y	Please Select	~		

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

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

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

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

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

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

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

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

Figure 148: Covered Recipient Demographic Information page	Figure	148:	Covered	Recipient	Demographic	Information	page
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Home Submissions	Review and Dispute	Manage Entities			ssages	Resources
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Covered Recipient Type: Teaching Hospital			V			
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		his is a 9-digit number				
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Recipient Business Address						
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United States		~				
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7500 Security Blvd.						
City	"State:		ZIP Code:			
City:	aute.		99999 or 999	99.9999		
Baltimore	Maryland		21244			
Email Address:						
TestUser@openpayments.com						
						-
					Back	Continue
Eancel						

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

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

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

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

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Manyland	MD-123456789	Edit				
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Figure 149: Covered Recipient Demographic Information page

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

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

For Program Years 2016-2020:

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

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

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

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

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Home	Submissions	Review and Dispute	Ø Manage Entities	(Q) My Profile	Messages	Resources
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Overvi		Recipient <u>Produ</u> raphics	<u>\$</u> ucts Payme	nts General Info		. Save
Select "Yes" or "N devices, biologica	ls, or medical supplies.	Select "Add" after completin	st. If "Yes" is selected, enter ng each entry. At least one p nedical supplies for each re	product must be added if th		
To download the li * Related Produ Please Select	-	onal Drug Codes (NDC) an	d instruction document, see	the <u>Resources</u> tab.		
Cancel					Back	Continue
					Contact Us	Privacy Policy

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

Home <u>Subr</u>			nage Entities	O My Profile	Messages	Resource
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Covered or Non-Covere Please Select larketed Name of Drug,	ed Product Indicator:	Supply: Please Select Associated Drug or I 9999-9999 OR 95	Biological NDC:	•	or Therapeutic Ar	rea:
Associated Drug, De Covered or Non-Covere Please Select Marketed Name of Drug, Medical Supply:	ed Product Indicator:	Supply: Please Select Associated Drug or I 9999-9999 OR 95	Biological NDC:	•	or Therapeutic Ar	ea:

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

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

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

In the "Indicate Drug, Device, Biological, or Medical Supply" drop-down, select the appropriate value. Enter the appropriate information in the "Product Category or Therapeutic Area" and the "Marketed Name of Drug, Device, Biological, or Medical Supply" text fields. If the product is a drug or biological, enter the National Drug Codes (NDC) for the drug or biological in the Associated Drug or Biological NDC field. NDCs are unique identifiers with 12 characters and must be in one of the following formats:

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

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

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

Home	Submissions	Review	and Dispute	Manage Entitie		(A) My Profile	Messages	Resource
Add Gen	eral Pay	ment						2 User Gu
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Figure 152: Add Button on the Add General Payment Page

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

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

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Figure 154: Enter Additional Associated Related Product Information

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

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

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

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

	Attention: The following warning(s) has been identified during Drug Name and/or National Drug Code (NDC) validation against the CMS approved dataset when the record is processed. Make corresponding correction(s) as necessary to successfully match the Drug Name/NDC in the record and to clear the warning(s). The record can still be successfully submitted with these warnings. • Warning: The Marketed Name of Drug, Device, Biological, or Medical Supply does not match the CMS approved dataset. (Biological 1)	Messages	Resources
	Do you want to proceed without correcting the warning(s)? Select "Yes" button to continue without correcting the warning(s) and select "No" button to return to the Associated Related Product page and correct the warning(s).	ion Review	& Save
cL			
nto a	n astensk (*) is required		
bio	or "No" from the Relisted Product Indicator drop-down list. If "Yes" is selected, enter the applicable information fo ogicals, or medical supplies. Select "Add" after completing each entry. At least one product must be added if the You may enter up to five drugs, biologicals, devices, or medical supplies for each record.		
	the list of Drug Name & National Drug Codes (NDC) and instruction document, see the Resources tab		

Figure 155: Drug Information Validation Warning Message

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

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

plicable Manufactur	rer or Group Purchasing Organ	•	shine Act	.)		
Home	Submissions Revi	ew and Dispute	Ö Manage Entities M	(2) Iy Profile	Messages	Resource
dd Gen	eral Payment	t				? <u>User Gui</u>
Overview	Covered Recipie Demographics		<u>\$</u> Payments	General Informa	tion Review & Sa	ve
sociated R	elated Products					
eld with an asteris	sk (*) is required.					
ices, biologicals, to "Yes". You may	or medical supplies. Select "/ y enter up to five drugs, biolog	Add" after completing e gicals, devices, or med	f "Yes" is selected, enter the appl each entry. At least one product n dical supplies for each record. Instruction document, see the Res	nust be added if the F		
Polated Product	Indiaator					
Related Product Yes		-				
ssociated Dru	ıg, Device, Biological, o	or Medical Supply	/ Information			_
SSOCIATED Dru Covered or Non-Covered Product Indicator:	Ig, Device, Biological, Indicate Drug, Device, Biological, or Medical Supply:		/ Information Marketed Name of Drug, Device, Biological, or Medica Supply:	Associated Drug al or Biological NDC:	J Actions:	
Covered or Non-Covered Product	Indicate Drug, Device, Biological, or Medical	Product Category or Therapeutic	Marketed Name of Drug, Device, Biological, or Medica	al or Biological) Actions: Edit Delete	
Covered or Non-Covered Product Indicator:	Indicate Drug, Device, Biological, or Medical Supply:	Product Category or Therapeutic Area:	Marketed Name of Drug, Device, Biological, or Medica Supply:	al or Biological		
Covered or Non-Covered Product Indicator: Covered	Indicate Drug, Device, Biological, or Medical Supply: Drug	Product Category or Therapeutic Area: Therapeutic	Marketed Name of Drug, Device, Biological, or Medica Supply: Biological 1	al or Biological		
Covered or Non-Covered Product Indicator: Covered	Indicate Drug, Device, Biological, or Medical Supply:	Product Category or Therapeutic Area: Therapeutic	Marketed Name of Drug, Device, Biological, or Medica Supply: Biological 1	al or Biological NDC:		
Covered or Non-Covered Product Indicator: Covered Ssociated Dru Covered or Non-Co	Indicate Drug, Device, Biological, or Medical Supply: Drug Ig, Device, Biological, Covered Product Indicator:	Product Category or Therapeutic Area: Therapeutic or Medical Supply *Indicate Drug,	Marketed Name of Drug, Device, Biological, or Medica Supply: Biological 1 / Information	al or Biological NDC:	Edit Delete	
Covered or Non-Covered Product Indicator: Covered SSOCIATED Dru Covered or Non-Covered Covered	Indicate Drug, Device, Biological, or Medical Supply: Drug Ig, Device, Biological, Covered Product Indicator:	Product Category or Therapeutic Area: Therapeutic or Medical Supply *Indicate Drug, Supply: • Device or Associated Drug	Marketed Name of Drug, Device, Biological, or Medica Supply: Biological 1 / Information Device, Biological, or Medical	al or Biological NDC: *Product Catego	Edit Delete	
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Covered or Non-Covered Product Indicator: Covered SSOCIATED Dru Covered or Non-G Covered Covered Rarketed Name of Iedical Supply: Pacemaker	Indicate Drug, Device, Biological, or Medical Supply: Drug Ig, Device, Biological, d Covered Product Indicator: f Drug, Device, Biological, d	Product Category or Therapeutic Area: Therapeutic or Medical Supply *Indicate Drug, I Supply: Device or Associated Drug 9999-999 ?	Marketed Name of Drug, Device, Biological, or Medica Supply: Biological 1 / Information Device, Biological, or Medical v	al or Biological NDC: *Product Catego	Edit Delete	
Covered or Non-Covered Product Indicator: Covered Covered Or Non-G Covered Covered Iarketed Name of Iedical Supply: Pacemaker	Indicate Drug, Device, Biological, or Medical Supply: Drug Ig, Device, Biological, d Covered Product Indicator: f Drug, Device, Biological, d	Product Category or Therapeutic Area: Therapeutic or Medical Supply *Indicate Drug, I Supply: Device or Associated Drug 9999-999 ?	Marketed Name of Drug, Device, Biological, or Medica Supply: Biological 1 / Information Device, Biological, or Medical v	al or Biological NDC: *Product Catego	Edit Delete	Add
Covered or Non-Covered Product Indicator: Covered	Indicate Drug, Device, Biological, or Medical Supply: Drug Ig, Device, Biological, d Covered Product Indicator: f Drug, Device, Biological, d	Product Category or Therapeutic Area: Therapeutic or Medical Supply *Indicate Drug, I Supply: Device or Associated Drug 9999-999 ?	Marketed Name of Drug, Device, Biological, or Medica Supply: Biological 1 / Information Device, Biological, or Medical v	al or Biological NDC: *Product Catego	Edit Delete	

For Program Years 2013-2015:

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

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

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

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

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

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

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

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

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

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

Figure 157: Drug Information Validation Warning Message

ation against the CMS approve ction(s) as necessary to succe arning(s). The record can still Warning: The Marketed Name the CMS approved dataset. (E at the "Edit" button to return to	ed dataset when the record is pro- essfully match the Drug Name/N be successfully submitted with of Drug, Device, Biological, or I biology 1) the Associated Related Product	ocessed. Make corresp DC in the record and to these warnings. Medical Supply does n t page and correct the ecting the warning(s).	ponding to clear Mes not match	ssages Review &	Resol
Related Products		C	Demographics		
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da re w o	dation against the CMS approve rection(s) as necessary to succe warning(s). The record can still • Warning: The Marketed Name the CMS approved dataset. (E ect the "Edit" button to return to	dation against the CMS approved dataset when the record is pro- rection(s) as necessary to successfully match the Drug Name/N warning(s). The record can still be successfully submitted with • Warning: The Marketed Name of Drug, Device, Biological, or I the CMS approved dataset. (Biology 1) set the "Edit" button to return to the Associated Related Product ning(s) or select the "Continue" button to proceed without corre	dation against the CMS approved dataset when the record is processed. Make corresp rection(s) as necessary to successfully match the Drug Name/NDC in the record and to warning(s). The record can still be successfully submitted with these warnings. • Warning: The Marketed Name of Drug, Device, Biological, or Medical Supply does n the CMS approved dataset. (Biology 1) ect the "Edit" button to return to the Associated Related Product page and correct the ning(s) or select the "Continue" button to proceed without correcting the warning(s). Edit C Related Products	Warning: The Marketed Name of Drug, Device, Biological, or Medical Supply does not match the CMS approved dataset. (Biology 1) ect the "Edit" button to return to the Associated Related Product page and correct the ning(s) or select the "Continue" button to proceed without correcting the warning(s). Edit Continue Demographics Related Products	dation against the CMS approved dataset when the record is processed. Make corresponding rection(s) as necessary to successfully match the Drug Name/NDC in the record and to clear warning(s). The record can still be successfully submitted with these warnings. • Warning: The Marketed Name of Drug, Device, Biological, or Medical Supply does not match the CMS approved dataset. (Biology 1) ect the "Edit" button to return to the Associated Related Product page and correct the ning(s) or select the "Continue" button to proceed without correcting the warning(s). Edit Continue Review 8 Related Products

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

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

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

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

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

Figure 158: Product Indicator	Drop-Down Field
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Home Submi	ssions Review and		age Entities	(2) My Profile	Messages	Resource
dd General	Payment			_		User G
•		Ð	\$	=		,
Overview	Covered Recipient Demographics	Products	Payments	General Inform	ation Review	& Save
ssociated Related	d Products			_		
field with an asterisk (*) is r	required.					
ologicals, devices, or medic st and second fields)	ion for the associated cover al supplies, do not skip field	Is between each entr	y, including the first field	d (e.g., if you have two if		
download the list of Drug N	Name & National Drug Code	es (NDC) and instruct	tion document, see the	Resources tab.		
Product Indicator: 🕢 Please Select				_		
Associated Drug, Dev	vice, Biological, or Me	dical Supply Info	ormation			
	vered Drug or Biological 1		National Drug Biological 1:	Code (NDC) of Associ		br
Name of Associated Cov	vered Drug or Biological 2	*	Biological 2:	Code (NDC) of Associ		Dr
Name of Associated Cov	vered Drug or Biological 3	•	Biological 3:	Code (NDC) of Associ		Dr
Name of Associated Cov	vered Drug or Biological 4		Biological 4:	Code (NDC) of Associ		or
Name of Associated Cov	vered Drug or Biological 5	•	Biological 5:	Code (NDC) of Associ		or
Name of Associated Cov	vered Device or Medical S	upply 1:				
Name of Associated Cov	vered Device or Medical S	upply 2:				
Name of Associated Cov	vered Device or Medical S	upply 3:				
Name of Associated Cov	vered Device or Medical S	upply 4:				
Name of Associated Cov	vered Device or Medical S	upply 5:				
Cancel					Back	Conti

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

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

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

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

e	▲ Attention:	
om d	The following warning(s) has been identified during Drug Name and/or National Drug Code (NDC) validation against the CMS approved dataset when the record is processed. Make corresponding correction(s) as necessary to successfully match the Drug Name/NDC in the record and to clear the warning(s). The record can still be successfully submitted with these warnings. • Warning: The Marketed Name of Drug, Device, Biological, or Medical Supply does not match the CMS approved dataset. (Biology 1) Select the "Edit" button to return to the Associated Related Product page and correct the warning(s) or select the "Continue" button to proceed without correcting the warning(s).	Messages Resou
ocia	Demographics	5
		3

Figure 159: Drug Information Validation Warning Message

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

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

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

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

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

ment: "Date of Payment: "Number of Payments included in Total	Home	Submissions	Review and Dis		je Entities	(2) My Profile	Message	s Resource
Covered Racipient Demographics Products Payments General Information Review & Save at or Other Transfer of Value Information	Add Gene	ral Payn	nent					? User Gui
Covered Racipient Demographics Products Payments General Information et or Other Transfer of Value Information) is required. ent or transfer of value information.		,		9	- ¢			
at or Other Transfer of Value Information) is required. Int or transfer of value information. ment: "Date of Payment: "Number of Payments included in Total m 12 digits yyyymmid:	Overview	Covered	Recipient	-	Paymen			rview & Save
) is required. ent or transfer of value information. ment: "Date of Payment: "Number of Payments included in Total in 12 digits yyyymmid: O Amount:		Demo	graphics				-	
ment: "Date of Payment: "Number of Payments included in Total m 12 digits yyyymmid: Amount:								
ment: "Date of Payment: "Number of Payments included in Total m 12 digits yyyymmid: Amount:	Seneral Paym	ent or Other	Transfer of Va	lue Informa	ation			
in 12 digits yyyymmia 0 Amount:			Transfer of Va	lue Informa	ation			
in 12 digits yyyymmia 0 Amount:	field with an asterisk	(*) is required.		lue Informa	ation			
and a subsection of the subsec	field with an asterisk	(*) is required.		lue Informa	ation			
20100210	field with an astensk inter the required pay *Total Amount of P	: (*) is required. ment or transfer of ayment:	value information.	ient	- 16		included in Total	
	field with an astensk nter the required pay "Total Amount of P	: (*) is required. ment or transfer of ayment:	vatue information. "Date of Payn yyyymmidd	ient	"N Al		included in Total	
Transfer of Value: "Nature of Payment or Transfer of Value:	field with an astensk nter the required pay *Total Amount of P 99999.99 and maxi	: (*) is required. ment or transfer of ayment:	vatue information. "Date of Payn yyyymmidd	ient	"N Al		Included in Total	
	field with an astensk inter the required pay *Total Amount of P 99999.99 and maxi	(*) is required. ment or transfer of ayment: mum 12 digits.	value information. Date of Payn yyyymmää 20180218	ent: O	-`* Ai 11111111111111111111111111111111111	mount:	included in Total	
	A field with an astensk	(*) is required.		ilue Informa	ation			
M Consideration Fac	field with an astensk inter the required pay "Total Amount of P 99999 99 and maxi 5485.95 "Form of Payment f	(*) is required. ment or transfer of ayment: mum 12 digits or Transfer of Vali	value information. Date of Payn yyyymmda 20180218 ue:	Nature of Payn	-`* Ai 11111111111111111111111111111111111	mount:		
t Consulting Fee	A field with an astensk Enter the required pay *Total Amount of P 99999 99 and maxi 5485.95	(*) is required. ment or transfer of ayment: mum 12 digits or Transfer of Vali	value information. Date of Payn yyyymmda 20180218 ue:	Nature of Payn	-`* Ai 11111111111111111111111111111111111	mount:		

<u>Step 7:</u> Enter all required information on the "General Record Information" page.

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

- Users may request a delay in publication, if the payment meets certain conditions.
- Note: Per the Final Rule, records can only be delayed from publication for up to 4 years from the year of payment (i.e., the record's program year); records attributed to the Program Year 2013, 2014, and 2015, are no longer eligible for a delay in publication in calendar year 2020.
- If a delay is requested for an ineligible record, the system will not accept the record and will display an error message.

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

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

Open Pay			nine Ad	ct)		
Home Submis		and Dispute Mane	ge Entilies	@ My Profile	Messages	Resources
Add General	Payment					? Her Guide
Qverview	Counsed Recipieur Demographica	Products	\$ Payments	General Inform	nation Review	A See
General Record Info	ermation					
A field with an asseriak (*) is re	quiled					
Enter the required additional in	tomution for the gener	al payment.				
"Physician Ownership Inde C Yee * No	cator;					
"Third Party Payment Recip	pient indicator: O					
No Third Party Payment	(v)					
Charity Indicator: 0		"Delay in Publication o	Research Payment	indicator:		
No	1	No Delay Requested		×		
Contextual Information: 500 characters maximum (histers entend ha	or this root will due to said				
500 characters remaining						

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

Figure 162: Review and Save page

Home	Submissions	Review and Dispute	Manage Entities	(Q) My Profile	Messages R
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Over	vew Covered	Recipient Product raphics		nts General information	Bestew & Save
eview an	d Save Page				
eview the payr	nent information below if	there are any errors, navigate	to the respective screen	and update as necessary.	
Payment Su	ubmission Informatio	on			
Entity Making	Payment Registration M	ame: ABCD Medical			
Program Year	2018 Payment C	Lategory: Genéral Payments	Horr	ne System Payment ID:	
Covered Re	cipient Demographi	es Information			
	plent Type: Physician	cs mornacion			
Name: James	and the second				
Business Add					
7500 Security I					
Baitimore, MD	21244				
United States					
Email Addres					
	Medical Doctor	NPC		Taxonomy Code: 2084	P0602X
Physician Sta IID - MD-12345	te License(s):				
Associated	Drug, Device, Biolo	gical, or Medical Supply	Information		
Related Produ	ict Indicator: Y				
Daharad	Contend or Nos	Indiana Davis Davida	Deschurt Carries an	Machanical Marries of Direct Provider	Reduction & Divise
Related Product	Covered or Nos- Covered Product	Indicate Drug, Device. Biological. or Medical	Therapeutic Area:	Marketed Name of Drug, Device, Biological, or Medical Supply:	Associated Drug or Biological NDC:
	Indicator;	Supply:			
1	Covered	Drug	Therapeutic Area 1	Bological 1	
2	Covered	Device	Cantiology	Paternakar	
and the second sec		sfer of Value Informatio			
	of Payment: \$5,485.95	Date of Payment	20180218		
	yments included in Tota				
		: Cash or cash equivalent			
Nature of Pay	ment or Transfer of Valu	e: Consulting Fee			
General Res	cord Information				
	nership Indicator: N				
and the second second		tor: No Third Party Payment			
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	quals Covered Recipient				
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					Contact Us Priv

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.

Figure 163: Record Saved Successfully page



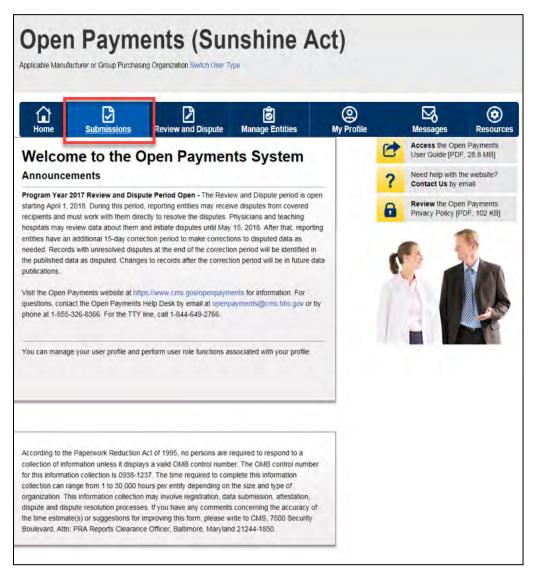
Take note that once the data has been uploaded to the system and undergone all checks including matching validations, it still must go through the Final Submission process in the Open Payments system. Manual data entry only uploads the record and checks it to ensure that it adheres to a valid data format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

4.5b: Manual Entry of Research Payments

To enter research payment data manually, follow these steps:

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

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



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

Figure 165: Manual Data Entry Button on Submissions Landing Page

Home	Submissions	Review and Dispute	🗭 Manage Entities	(Q) My Profile	Messages	Resource
Submiss	sions					? User Gui
A field with an aste	erisk (*) is required.					
Applicable manufa System.	cturers and applicable	GPOs must submit paymen	ts, or other transfers of value	e, and ownership or in	nvestment interests to the C	Open Payments
Submit Payr	ment Data					
Only users who ho Upload or Manual I		r can submit information to ti	ne Open Payments system. S	Select Bulk File	Download the P List	hysician
reporting templates	rrces tab for the Open s for the Bulk File Uplo : File Upload		nual Data Entry to submit rec ments manual entry online fo Manual Data Entry	and the second se	and Physicia	License(s) ogram Year below iblicly. nysician Lists an with Inactive Supplement File
	and the second second	A December				
To review records,	select the entity whos	e records you wish to review	and the program year for th	e records from the	Download the R	Reporting
To review records, drop-down lists bel	and the Constant	e records you wish to review w Records."	and the program year for th	e records from the	Download the R Templates	
	select the entity whos	e records you wish to review	r and the program year for th • Review Rec		Templates	
To review records, drop-down lists bel *Select Entity: ABCDEF Medical	select the entity whos low, then select "Revie	e records you wish to review w Records." *Select Program Year: 2018			Templates To download reporting te	
To review records, drop-down lists bel *Select Entity: ABCDEF Medical Review Subl	select the entity whos low, then select "Revie mitted File(s) \$	e records you wish to review w Records." *Select Program Year: 2018 Status		ords	Templates To download reporting te	
To review records, drop-down lists bel *Select Entity: ABCDEF Medical Review Sub	select the entity whos low, then select "Revie mitted File(s) \$ r entity has been subr	e records you wish to review w Records." *Select Program Year: 2018 Status	- Review Rec	ords	Templates To download reporting te	
To review records, drop-down lists bel "Select Entity: ABCDEF Medical Review Subb Once a file for your Review File State	select the entity whos low, then select "Revie mitted File(s) \$ r entity has been subr	e records you wish to review w Records." *Select Program Year: 2018 Status hitted, you may review the de	- Review Rec	ords	Templates To download reporting te	
To review records, drop-down lists bel *Select Entity: ABCDEF Medical Review Subb Once a file for your Review File State Physician M	select the entity whos low, then select "Revie mitted File(s) \$ r entity has been subrr us latching Valida matching information,	e records you wish to review w Records." *Select Program Year: 2018 Status hitted, you may review the de	- Review Rec	ords le Status."	Templates To download reporting te	

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

Select the "Continue" button to proceed.

Figure 166: Add Payment Page

Home	Submissions	Review and Dispute	Manage Entities	(Q) My Profile	Messages	Resources
Add Pa	yment					? User Guide
	sterisk (*) is required ent, transfer of value, or	ownership or investment inter	rest, enter the following (information.		
"Payment Cat	1245	*Entity Making Payment R		"Program Year:	Home System Payme	- 0

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

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

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

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

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

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

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

Figure 167: Recipient Type Drop-Down for Teaching Hospital

Home Submis			Manage Entities	(2) My Profile	Messages	Resource
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Overview	Becipient Demographics	Products	Payment		ator Review	r & Savn
ecipient Demograp	ohic Information	B				
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slect the recipient type for the		and then enter the	e demographic informat	00.		
and the second		Contraction of				
Recipient Type:						
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Covered Recipient Tea	ching Hospital					
	and a second second					
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Name: ()			ayer ID Number (TIN): s a 9-digit ridimber			
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Research Hospital		This a	s a 9-digit number			
Research Hospital Recipient Business Ad	dress	This a	s a 9-digit number			
Research Hospital Recipient Business Ad	dress	This a	s a 9-digit number			
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Research Hospital Recipient Business Ad Country: United States "Street Address, Line 1: 7500 Security Bird "Citry: Baltimore	-State:	This 8	Street Address Street Address Street Address	Code:		

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

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

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

Figure 168: Recipient Type Drop-Down for Physician

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elect the recipient type for the p	bayment bein	g reported and then ent	er the demographic in	ormation.				
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Covered Recipient Physician				~				
Covered Recipient Phys			200					
'First Name: James	Mid	dle Name:	"Last Na Miller	me:		Suffix:		
Recipient Business Add	ress							
Country: United States			~					
					~			
Street Address, Line 1: 7500 Security Blvd.			Street A	idress, Line	2.			
City:		*State:		*ZIP Code:				
ony.		Suit.			9999-9999			
Baltimore		Maryland	~	21244				
Email Address:								
Covered Recipient Phys	ician Infor	mation						
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Martin Destro	123	This is a 10-digit nur	nder	2084P0016	52			
Medical Doctor	~			2004 0010				
Covered Recipient Phys To enter the covered recipient below. Select the "Add" button license and may have up to 5.	s license info to add the inf	rmation, select a state in formation to the record.	Select the "Add" butto	n again to dis	play another set	of fields. A re	ecord must co	
*State:		*Number: Maximum 25 charac						
Maryland	~	MD-12345		Add				

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

Figure 169: Recipient Type Drop-Down for Entity

Home Submission	s Review and Disput	e Manage Entities		Profile	Messages	Resour
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Non-Covered Recipient Entity						
Non-Covered Recipient En	ntity					
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WXYZ Corp.	SS					
WXYZ Corp. Recipient Business Addre	55					
WXYZ Corp. Recipient Business Addre	55	V				
WXYZ Corp. Recipient Business Addres Country: United States	55		ddress, Line 2:			
WXYZ Corp. Recipient Business Addres Country: United States	55		ddress, Line 2:			
WXYZ Corp. Recipient Business Addres 'Country: United States 'Street Address, Line 1: 7500 Security Blvd.	SS *State:		ddress, Line 2: *ZIP Code: 99999 or 9991	19-5999		
WXYZ Corp. Recipient Business Addres 'Country: United States 'Street Address, Line 1: 7500 Security Blvd.			*ZIP Code:	19-9999		
WXYZ Corp. Recipient Business Addres 'Country: United States 'Street Address, Line 1: 7500 Security Blvd. 'City: Baltimore	*State:	Street A	*ZIP Code: 99999 or 9999	9-9999		
WXYZ Corp. Recipient Business Addres Country: United States Street Address, Line 1: 7500 Security Blvd. City: Baltimore	*State:	Street A	*ZIP Code: 99999 or 9999	19-9999		
WXYZ Corp. Recipient Business Addres 'Country: United States 'Street Address, Line 1: 7500 Security Blvd. 'City:	*State:	Street A	*ZIP Code: 99999 or 9999	99-59999	Back	Conti

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

Figure 170: Product page for Recipient Type

Home	Submissions	Review and Dispute	Manage Entities	(2) My Profile	Messages	Resources
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field with an as	terisk (*) is required. ent type for the paymen		er the demographic informat	ion.		

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

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

For Program Years 2016-2020:

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

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

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

Figure 171: Related Product Indicator Drop-Down

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type								
Home	Submissions	Review and Dispute	Ø Manage Entities	(Q) My Profile	Messages	Resources		
Add Res	search Pay	ment				? <u>User Guide</u>		
	iew Recip Demogr	pient <u>Produ</u> raphics	ucts Payme	nts Princip Investig Demogra	oal Review & ator	a Save		
A field with an ast Select "Yes" or "N devices, biologica set to "Yes". You r	erisk (*) is required. lo" from the Related Proc ls, or medical supplies. S may enter up to five drug:	uct Indicator drop-down lis ielect "Add" after completir s, biologicals, devices, or n	st. If "Yes" is selected, enter ng each entry. At least one p nedical supplies for each re d instruction document, see	product must be added if the cord.				
*Related Produ No Cancel	ict Indicator:	•			Back	Continue		
					<u>Contact Us</u>	Privacy Policy		

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

Open Pa						
Applicable Manufacturer or G		`	shine A	ct)		
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Add Researd						? User Guid
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Overview	Recipient Demographics	Product	<u>ts</u> Payment	·	tor	Save
Associated Relate	d Products					
field with an asterisk (*) is	roquirod					
*Related Product Indicat Yes Associated Drug, De	•	r Medical Supply	y Information			
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Please Select						a:
Please Select	•	Please Select		•		a:
Marketed Name of Drug, Medical Supply:	Device, Biological, or	Associated Dru	g or Biological NDC: DR 99999-999-99 OR 999			a:
Marketed Name of Drug,		Associated Dru 9999-9999-99				a:
Marketed Name of Drug,	Device, Biological, or	Associated Dru 9999-9999-99				a: Add
Marketed Name of Drug,	Device, Biological, or	Associated Dru 9999-9999-99			Back	

Figure 172: Input Fields for Related Product Indicator

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

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

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

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

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

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

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

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

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

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

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

The following warning(s) has been identified during Drug Name and validation against the CMS approved dataset when the record is pro- correction(s) as necessary to successfully match the Drug Name/N the warning(s). The record can still be successfully submitted with • Warning: The Marketed Name of Drug, Device, Biological, or N the CMS approved dataset. (adf)	ocessed. Make corresponding DC in the record and to clear these warnings. Messages	Resource
Select the "Edit" button to return to the Associated Related Product warning(s) or select the "Continue" button to proceed without corre	Edit Continue	User Gu / & Save
ted Related Products	Demographics	
n asterisk (*) is required.		
n asterisk (*) is required. or "No" from the Related Product Indicator drop-down list. If "Yes" is selected ogicals, or medical supplies. Select "Add" after completing each entry. At lea You may enter up to five drugs, biologicals, devices, or medical supplies for	st one product must be added if the Related Product India	

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

Figure 173: Drug Information Validation Warning Message

	nissions Re	eview and Dispute	Manage Entities	(Q) My Profile	Messages	Resource
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ces, biologicals, or mec o "Yes". You may enter	tical supplies. Select up to five drugs, bio	t "Add" after completing plogicals, devices, or m	. If "Yes" is selected, enter g each entry. At least one p ledical supplies for each re- l instruction document, see	product must be added if t cord.		
ices, biologicals, or mec to "Yes". You may enter lownload the list of Drug telated Product Indica fes	tical supplies. Selec: up to five drugs, bic g Name & National E tor:	t "Add" after completing plogicals, devices, or m Drug Codes (NDC) and	g each entry. At least one p edical supplies for each re i instruction document, see	product must be added if t cord.		
ices, biologicals, or mec to "Yes". You may enter download the list of Drug Related Product Indica Yes ssociated Drug, De	tical supplies. Select up to five drugs, bio g Name & National E tor: evice, Biologica	t "Add" after completing logicals, devices, or m Drug Codes (NDC) and I, or Medical Supp or: *Indicate Drug	g each entry. At least one p edical supplies for each re i instruction document, see	roduct must be added if t cord. the Resources tab.		icator value is
ices, biologicals, or mec to "Yes". You may enter download the list of Drug Related Product Indica Yes ssociated Drug, De Covered or Non-Covere	tical supplies. Select up to five drugs, bio g Name & National E tor: evice, Biologica	t "Add" after completing logicals, devices, or m Drug Codes (NDC) and	g each entry. At least one p ledical supplies for each re l instruction document, see	roduct must be added if t cord. the Resources tab.	the Related Product Indi	icator value is
ices, biologicals, or mec to "Yes". You may enter download the list of Drug Related Product Indica Yes ssociated Drug, De Covered or Non-Covere Covered arketed Name of Drug,	tical supplies. Seleci up to five drugs, bio g Name & National E tor: evice, Biologica ed Product Indicato	t "Add" after completing logicals, devices, or m Drug Codes (NDC) and I, or Medical Supp pr: *Indicate Drug Supply: V Device I, or Associated Dr	g each entry. At least one p ledical supplies for each re l instruction document, see	Induct must be added if it cord. the Resources tab.	the Related Product Indi	icator value is
ices, biologicals, or med to "Yes". You may enter lownload the list of Drug Related Product Indica fes ssociated Drug, De Covered or Non-Covere Covered arketed Name of Drug, edical Supply:	tical supplies. Seleci up to five drugs, bio g Name & National E tor: evice, Biologica ed Product Indicato	t "Add" after completing logicals, devices, or m Drug Codes (NDC) and I, or Medical Supp pr: *Indicate Drug Supply: Device I, or Associated Dr 9999-9999-99	g each entry. At least one p redical supplies for each re instruction document, see bly Information g, Device, Biological, or N rug or Biological NDC:	Induct must be added if it cord. the Resources tab.	the Related Product Indi	icator value is
ices, biologicals, or mec to "Yes". You may enter	tical supplies. Seleci up to five drugs, bio g Name & National E tor: evice, Biologica ed Product Indicato	t "Add" after completing plogicals, devices, or m Drug Codes (NDC) and I, or Medical Supp or: *Indicate Drug Supply: Device I, or Associated Dr 9099-9099-9	g each entry. At least one p redical supplies for each re instruction document, see bly Information g, Device, Biological, or N rug or Biological NDC:	Iedical *Product Ca	the Related Product Indi	icator value is

Figure 174: Add Button for Associated Related Products Page

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

	Submissions Re	eview and Dispute	Manage Entities My	Profile	Messages	Resou
dd Rese	earch Paym	ent				<u>User</u>
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	ig, Device, Biologica	I, or Medical Supply	Information			
sociated Dru Covered or	Indicate Drug, Device,	Product Category	Marketed Name of Drug,	Associated Drug	Actions:	
Sociated Dru Covered or Non-Covered Product				-	Actions:	
sociated Dru Covered or Non-Covered Product Indicator:	Indicate Drug, Device, Biological, or Medical	Product Category or Therapeutic	Marketed Name of Drug, Device, Biological, or Medical Supply:	or Biological	Actions: Edit Delet	te
	Indicate Drug, Device, Biological, or Medical Supply:	Product Category or Therapeutic Area:	Marketed Name of Drug, Device, Biological, or Medical Supply:	or Biological		te

Figure 175: Add Button for Additional Associated Product

Figure 176: Input Fields for Additional Associated Related Product

	Payment er or Group Purchasing Organi	•	shine Ac	ct)		
Home Add Rese	Submissions Reviewed	ew and Dispute	Ø Manage Entities	O My Profile	Messages	Resources
Overview	Recipient Demographics	Products	s Payments	Principal Investigator Demographics	Review & 1	Save
devices, biologicals, o set to "Yes". You may	irom the Related Product Indi or medical supplies. Select "A enter up to five drugs, biolog of Drug Name & National Drug	xdd" after completing e gicals, devices, or med g Codes (NDC) and in	f "Yes" is selected, enter the a each entry. At least one produ- lical supplies for each record. Istruction document, see the F	ct must be added if the Re		
Associated Dru Covered or Non-Covered Product Indicator:	g, Device, Biological, o Indicate Drug, Device, Biological, or Medical Supply:		r Information Marketed Name of Drug, Device, Biological, or Med Supply:	Associated Drug dical or Biological NDC:	Actions:	
Covered	Device	Therapeutic Area 1	Biological 1		Edit Delete	
*Covered or Non-C	Drug, Device, Biological, o	Indicate Drug, D Supply: Please Select r Associated Drug	r Information evice, Biological, or Medica g or Biological NDC: R 99999-999-99 OR 99999	•	or Therapeutic Area	:
Cancel Product						Add
Cancel					Back	Continue
					Contact Us	Privacy Policy

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

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

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

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

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

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

licable Manufactu									
Home	Submissions	Review	☑ w and Dispute	🔊 Manage Entiti	ies My	() Profile	Messa) ges	Resource
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eld with an asteri	sk (*) is required.								
lownload the list	of Drug Name & Natio	onal Drug	Codes (NDC) and ir	nstruction docume	ent, see the Reso	urces tab.			
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res ssociated Dru Covered or Non-Covered Product	ug, Device, Biolo Indicate Drug, De	gical, or vice, dical	r Medical Supply Product Category or Therapeutic Area:	Marketed Nam	ne of Drug, gical, or Medical	Associated Drug or Biological NDC:	Actions:		
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res ssociated Dru Covered or Non-Covered Product Indicator: Covered	ug, Device, Biolo Indicate Drug, De Biological, or Med Supply: Device	gical, or vice, dical	Product Category or Therapeutic Area: Therapeutic Area 1	Marketed Nam Device, Biolog Supply: Biological 1		or Biological		Delete	
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res ssociated Dru Covered or Non-Covered Product Indicator: Covered	ug, Device, Biolo Indicate Drug, De Biological, or Mer Supply: Device ug, Device, Biolo	gical, or vice, dical gical, or	Product Category or Therapeutic Area: Therapeutic Area 1 r Medical Supply Indicate Drug, E	Marketed Nam Device, Biolog Supply: Biological 1	gical, or Medical	or Biological NDC:	Edit	_	
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res ssociated Dru Covered or Non-Covered Product Indicator: Covered ssociated Dru covered or Non- Please Select arketed Name o	ug, Device, Biolo Indicate Drug, De Biological, or Med Supply: Device ug, Device, Biolo Covered Product Ind	gical, or vice, dical gical, or dicator:	Product Category or Therapeutic Area: Therapeutic Area 1 r Medical Supply Indicate Drug, I Supply: Please Select Associated Dru 9999-999-9	Marketed Nam Device, Biolog Supply: Biological 1 / Information Device, Biological g or Biological N	gical, or Medical al, or Medical VDC:	or Biological NDC:	Edit	_	
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Figure 177: Edit and Delete Button for Associated Related Product Page

For Program Years 2013-2015:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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Uverview C	Demographics	Products	Payments	General Inform	abon Review	A Save
ssociated Related P	roducts					
eld with an asterisk (*) is requi	red					
er the applicable information fo logicals, devices, or medical su f and second fields)	upplies, do not skip field	Is between each ent	try, including the first fir	eld (e.g., if you have two i		
download the list of Drug Name	a & National Drug Code	is (NDC) and instruc	tion document, see th	e Resources tab.		
Product Indicator: 🕢 Please Select						
	2		100000000			
Associated Drug, Device				in Code (NDC) of Associ	isted Covered Drug	
Name of Associated Coveren	a brug or Biological 1		Biological 1:	ig Code (NDC) of Associ : 19 OR 99999-999-99 OR		or
Name of Associated Covere	d Drug or Biological 2		Biological 2	ug Code (NDC) of Associ : :9 OR 99999-999-99 OR		or
Name of Associated Covered	d Drug or Biological 3	6	Biological 3	ig Code (NDC) of Associ : 99 OR 99999-999-99 OR		or
Name of Associated Covere	d Drug or Biological 4	e.	Biological 4	ig Code (NDC) of Associ : 99 OR 99999-999-99 OR		or
Name of Associated Covered	d Drug or Biological 5	¢	Biological 5	ug Code (NDC) of Associ : :99 OR 99999-999-99 OR		or
Name of Associated Covered	d Device or Medical S	upply 1:				
Name of Associated Covered	d Device or Medical S	upply 2:				
Name of Associated Covered	d Device or Medical S	upply 3:				
Name of Associated Covered	d Device or Medical S	upply 4:				
Name of Associated Covered	d Device or Medical S	upply 5:				
						-

Figure 178: Continue Button for Associated Related Product Page

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

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

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

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

The following warning(s) has been identified during Drug Name and/or National Drug Code (NDC) validation against the CMS approved dataset when the record is processed. Make corresponding correction(s) as necessary to successfully match the Drug Name/NDC in the record and to clear the warning(s). The record can still be successfully submitted with these warnings. • Warning: The Marketed Name of Drug, Device, Biological, or Medical Supply does not match the CMS approved dataset. (Biology 1) Select the "Edit" button to return to the Associated Related Product page and correct the warning(s) or select the "Continue" button to proceed without correcting the warning(s).
Eur
Demographics

Figure 179: Drug Information Validation Warning Message

<u>Step 6:</u> Enter all required information on the "Research Payment or Other Transfer of Value Information" page. Note that only positive dollar values are allowed when reporting payment amounts. Negative dollar values or zeroes are not permitted.

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

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

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

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

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

Home <u>Submissions</u>	Review and Dispute Mana		2 Profile	Messages Resour
dd Research P	ayment			User
	Recipient Products	\$ Payments	Principal Investigator Demographics	Review & Save
	ther Transfer of Value Infor	mation		
field with an asterisk (*) is required nter the required payment or transfe				
	ir or value information.			
Payment Information "Total Amount of Research Paym 99999.99 and maximum 12 digits		*Form of Pa	ayment or Transfer of	f Value:
Expenditure Category				
Enter the percent value for each of	the following as a whole number in the ran	ge of 1 -100 (if applicable)		
Professional Salary Support:	Medical Research Writing or Publication:	Patient Care:	Non-P:	atient Care:
Overhead:	Other:			
Research Information				
	*Delay in Publication of Research Payment Indicator:	Name of Study:	Contex	t of Research:
Pre-Glinical Research Indicator:	✓ Please Select ✓			
"Pre-Clinical Research Indicator: Please Select Clinical Trials.Gov Identifier: Maximum 11 characters, first 3 m	ust be letters.	Research Information L http://www.or.https://ww		

Figure 180: Add Research Payment Page

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

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

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

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

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

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

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

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ect "Add Principal In earch payment reco	vestigator * Repe rd can have up to		incipal investig cipal investiga	n-Covered Recipient in plitors associated with t dors				
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-			_					
Principal Inves	tigator							
"First Name:		Middle Name:		"Last Name:		Suffix:		
Susan				Jones				
*Country: Linned States *Street Address, 1 123 Mark Street	Jine 1:			Street Address	s, Line 2:			
"City:		"State:		ZIP Co	ide:			
Batimore		Maylend		21244	ar 110569-9001			
para line k		- majore		12 1100				
Principal Inves	tigator Inform	nation						
* Primary Type:		NPI: This is a 104	test marilier	"Taxon	omy Code: ()			
Medical Doctor			order some some s	2054PD	x892X			
Principal Inves	tigator Licen	se Information						
the record and oper	n up another set	of Relas. Enter each	state and licer	en enter the license num mie number separately edit or delete any previo	until all licenses f	have been adde	d. A principal in	vestigator
State:		N	mber:	A	ctions:			
Maryland		12	345	1	Edit			
Add								
							Add Princip	al howestlepetter
							-	

Figure 181: Principal Investigator Demographic Page

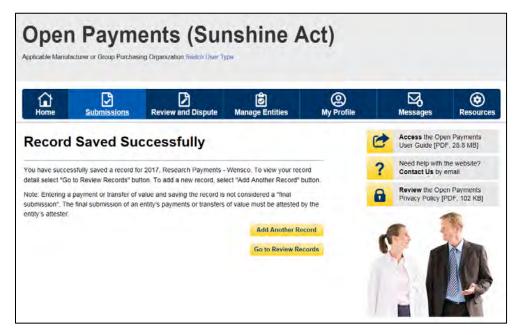
<u>Step 8:</u> Review the payment information entered in the previous pages on the "Review and Save" page. If necessary select the "Back" button at the bottom of the page to go back and edit information. Users can also select an icon from the "Payment Navigation Bar", located on top of the page, to go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

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Home	Submissions	Review and Dispute	Manage Entities	My Profile	Messages	Resources
dd Re	search Pay	ment				? User Guide
Over	view Recij Demog	pient Proc	Jucts Payme	nts Princ Investi Demogr	ipal <u>Review</u> gator	& Save
	d Save Page	there are any errors, navi	gate to the respective screen	n and update as necessa	N	
	ubmission Information Payment Registration N 2017 Payment C		ments Hor	ne System Payment ID:		
	lress: Blvd. 21244		τ	ixpayer ID Number (TIN): 123456789	
	Related Products					
Related Product	Covered or Non- Covered Product Indicator:	Indicate Drug, Device Biological, or Medical Supply:		Marketed Name of Dr Device, Biological, or Supply:		
1 2	Covered	Device Device	Therapeutic Area 1	Biological 1		
	ayment or Other Tra of Research Payment: Category			Form of Payr cash equivale	nent or Transfer of Value nt	e: Cash or
Non-Patient C	Salary Support: are: esearch Indicator: Y	Medical Rese Overhead:	earch Writing or Publicatio	n: Patient Care: Other:		
Name of Stud Context of Re ClinicalTrials.		nent Indicator: R&D on	New Product			
Principal Inve	vestigator Demograj stigator Covered Recipio estigator 1		Y			
Principal Inve	iress: et					
Name: Susan Business Add 123 Main Stree Baltimore, MD	21244			onomy Code: 2084P08	02X	
Name: Susan Business Add 123 Main Stree Baltimore, MD United States Primary Type:		NPI:	Tax			

Figure 182: Review and Save Page

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

Figure 183: Record Saved Successfully Page



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

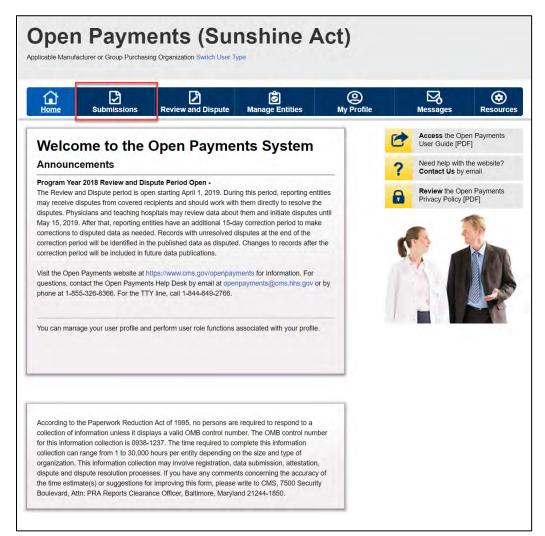
4.5c: Manual Entry of Ownership/Investment Interests Payments

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

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

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

Figure 184: Submissions Tab for Open Payments system landing page for returning system users



<u>Step 2:</u> Select the "Manual Data Entry" button from the "Submissions" page.

Figure 185: Manual Data Entry Button

	sions	Review and Dispute	Manage Entities	O My Profile	Messages	Resource
Submissions						? User Gu
A field with an asterisk (*) is re	equired.					
Applicable manufacturers and System.	applicable	GPOs must submit paymen	ts, or other transfers of value, a	and ownership or inv	estment interests to the O	pen Payments
	ata					
Submit Payment Da			Onen Deimerte ersten St	le et Dulle E''s		
Only users who hold the role o Jpload or Manual Data Entry I		can submit information to the	ne Open Payments system. Se	iect Buik File	Download the P List	hysician
Refer to the Resources tab for	the Open F	Payments Select Mar	nual Data Entry to submit recor	ds using the	The Validated Physician	Lists and
eporting templates for the Bul	lk File Uploa	ad. Open Payı	ments manual entry online form	1.	Physician with Inactive Li Supplement File per Prog	and the second
Bulk File Upload	d		Manual Data Entry		should not be shared put	blicly.
						n with Inactive
					per Program	upplement File Year
Review Submitted I	Paymen	t Records				
To review records, select the e drop-down lists below, then se			and the program year for the r	records from the	Download the R Templates	eporting
Select Entity:		*Select Program Year:			To download reporting te	mplates, see the
Delect Entry.		2018	Review Record	ds	Resources tab.	
ABCDEF Medical						
ABCDEF Medical		11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
	File(s) S	status				
Review Submitted I			etails by selecting "Review File	Status."		
Review Submitted I			stails by selecting "Review File	Status."		
Review Submitted I Once a file for your entity has			etails by selecting "Review File	Status."		
Review Submitted I Once a file for your entity has Review File Status	been submi	itted, you may review the de	etails by selecting "Review File	Status."		
Review Submitted I Once a file for your entity has Review File Status Physician Matching	been submi	itted, you may review the de	etails by selecting "Review File			

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

Select the "Continue" button to proceed.

Figure 186: Add Payment page displaying Payment Category

Home	Submissions	Review and Dispute	Manage Entities	(Q) My Profile	Messages	Resourc
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enter a paymer	nt, transfer of value, o	or ownership or investment inte	rest, enter the following i	information.		
o enter a paymer *Payment Categ		* Entity Making Payment		*Program Year:	Home System Payn	nent ID: 😧

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

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

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

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

Figure 187: Physician Demographic Information page

Home Submiss	towners and	Review and Dispute	Manage Entitie		M	essages	Resou	
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field with an asterisk (*) is requ								
nter the physician demographic	information.							
Physician *First Name:	Middle Name:		"I act N	me.	Suffix:			
Susan		die Hame.	Jones					
Physician Business Add	iress							
Country:								
United States			~					
Street Address, Line 1:			Street A	ddress, Line 2:				
7500 Security Blvd/								
°City:		*State:		*ZIP Code: 99999 or 99999-9999				
Baltimore		Maryland	~	21244				
Email Address:								
Physician Information		NPI:		*Taxonomy Code: ()				
Primary Type:		This is a 10-digit number	r	Taxonomy code.				
Medical Doctor	~			2084P0802X				
Physician License Inform To enter the physician's license Select the "Add" button to add t license and may have up to 5.1	information, the informatio	on to the record. Select the "	"Add" button again	to display another set of	fields. A record I	must contain a		
*State:		*Number: Maximum 25 characters						
Maryland	~	MD-12345		Add				

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

Figure 188: Continue Button for Physician Demographic Information page

Home Submissions	R	eview and Dispute Mar	age Entities	Q My Profile	Mess	· · · · · · · · · · · · · · · · · · ·	esource	
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field with an asterisk (*) is require ter the physician demographic inf								
Physician								
First Name:	Middle Name:		"Last Na	ime:	Suffix:			
Susan			Jones					
Physician Business Addre Country:	55							
United States			~					
Street Address, Line 1:			Street A	ddress, Line 2:				
7500 Security Blvd/								
City:		*State:		"ZIP Code: 99999 or 99999-9999				
Baltimore		Maryland	~	21244				
mail Address:								
Physician Information								
Primary Type:		NPI: This is a 10-digit number		"Taxonomy Code: 🕦				
Medical Doctor	~			2084P0802X				
Physician License Informa To enter the physician's license in Select the "Add" button to add the cense and may have up to 5. You	formation, information	on to the record. Select the "Ade	d" button again	to display another set of	fields. A record mu	ust contain at leas		
State:		Number:		Actions:				
Maryland		MD-12345		Edit				
Add								

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

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

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

Home	Submissions	Rev	iew and Dispute	Manage Entities	(2) My Profile	Messages	Resou	
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ield with an :	asterisk (*) is required.							
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interest Hel	d By:		*Dollar Amount In 99999 99 and max	vested: cimum 12 digits 🚯	*Value of Interest: 99999 99 and maximum	12 digits		
	vered Recipient	~	1565.23		2000			
Physician Co Terms of In	terest:		1565.23	not be saved Q	2000			
Physician Co Ferms of In 30 characte	terest: ers maximum. Character		1565.23	not be saved 😧	2000			
Physician Co Terms of In DO characte	terest: ers maximum. Character		1565.23	not be saved 😧	2000			
Physician Co Terms of In DO characte	terest: ers maximum. Character		1565.23	not be saved.	2000			
Physician Co Ferms of In 30 characte	terest: ers maximum. Character		1565.23	not be saved	2000			
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Physician Co Terms of In 00 characte Enter terms o	terest: ers maximum. Character		1565.23	not be saved	2000			

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

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

Figure 190: Save Record Button for Physician Demographic Information page

Home Submissions	Review and Dispute Manage		9 Profile	Messages	Resourc	
dd Ownership or	Investment Intere	st Record			? User Gi	
Overview	Physician Demographics Information				eview & Save	
eview and Save Page						
eview the payment information below. If the	here are any errors, navigate to the resp	ective screen and updat	e as necessary			
ayment Submission Information	n					
ntity Making Payment Registration Na	ame: ABCD Medical					
rogram Year: 2018 Payment Ca	itegory: Ownership or Investment Inter	rest Home System	Payment ID:			
		est Home System	Payment ID:			
Physician Demographics Inform		est Home System	Payment ID:			
Physician Demographics Information: Iame: Susan Jones Iusiness Address: 500 Security BMd altimore, MD 21244		est Home System	Payment ID:			
Program Year: 2018 Payment Ca Physician Demographics Informa Jame: Susan Jones Jusiness Address: 500 Security Bivd. Jailtmore, MD 21244 Jinited States Email Address:		est Home System	Payment ID:			
Physician Demographics Information ame: Susan Jones business Address: 500 Security Blvd. altimore, MD 21244 inited States mail Address: rimary Type: Medical Doctor hysician State License(s):			Payment ID: faxonomy Code:	2084P0802X		
Physician Demographics Information ame: Susan Jones Insiness Address: 500 Security Blvd. altimore, MD 21244 Inited States mail Address: rrimary Type: Medical Doctor hysician State License(s): ID - MD-12345	ation NPI:			2084P0602X		
Physician Demographics Informa lame: Susan Jones Iusiness Address: 500 Security Blvd. Ialtimore, MD 21244 Inited States imail Address: Imary Type: Medical Doctor Hysician State License(s): ID - MD-12345 Ownership or Investment Inform	ation NPI:					
Physician Demographics Information: Iame: Susan Jones Business Address: 500 Security Bivd Baltimore, MD 21244 Inited States	ation NPI: ation cipient Dollar Amount Invested: S		Taxonomy Code:			

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

Figure 191: Record Saved Successfully page



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

Section 4.6: Record Validation and Matching

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





Details on these types of validation are given below.

4.6a: Validation Step 1: File-Level Validation

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

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

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

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

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

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

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

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

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

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

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

4.6c: Validation Step 4: Record Matching

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

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

Section 4.7 Identifying Errors

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

4.7a: Identifying Errors - Bulk File Upload

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

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

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

- File Validation failure (Step 1): The email describes a file validation failure, the reason for the failure, and, if applicable, the line number of the submitted data file where the failure occurred. Files that fail at this step will have a status of "Rejected" on the "Review Files Status" page. Step 1 validations stop upon finding an error.
- **Pre-Upload Record Validation failure (Step 2):** The email lists the reasons for record rejections, the number of records in the file that failed for each reason, and identifies up to a set number of records for each rejection reason. Files with records that meet this criteria will have a status of "Submitted with Errors" on the "Review File Status" page.
- **Record Validation failure (Step 3):** The email explains that the file has been processed, and one or more records were found to contain validation errors. The email also provides instructions for locating the Error Log that lists the errors found in the records. Files with records that meet this criteria will have a status of "Submitted with Errors" on the "Review File Status" page.
- Matching Validation failure (Step 4): The email explains that records were submitted successfully, but they may contain records in Failed Matching status or records with Warnings. Files with records that meet this criteria will have a status of "Submitted Successfully" or "Processed with Warnings" on the "Review File Status" page.

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

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

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

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

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

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

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

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

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

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

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

4.7a (4) If Errors Occur During Record Validation - Post-Upload (Step 3) or Matching Validation (Step 4) Records that fail Steps 3 or 4 will be saved within the Open Payments system and can be reviewed and edited within the system.

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

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

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

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

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

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

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

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

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

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

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

- **Submitted with Errors** The file is uploaded successfully but one or more of the records in the file are in "Failed Validation" or "Failed Matching" status. An error log will be generated for a file that contains records that generated errors for failed validation or matching.
- **Processed With Warning** The file contains records with late submission and/or expired license warning. Users do not need to take any action for late submission warning, however, they can correct or delete records with expired license warning. If it is confirmed that the information is valid, the record can continue through final submission without further updates.
- **Submitted Successfully** The file uploaded successfully. An error log will be generated for a file that contains records that generated warnings.

<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.

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

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

1	Calibri B I U - Ca Fon		····································	General * \$ * % * *****************************	Styles	Delete * Format * Cells	2* F	int & Find & ilter - Select - Editing	
G17		6	c l						
A	8		c	D		E		F	G
File ID	Record ID	Home Syste	m Payment ID	Payment Record	d Status	Error Mess	sage ID	Data Element	t Value
2836	547933			Failed Validatio	n	E-718			
2836	547933	Test1		Failed Validatio	n	E-778		207UN0902X1	L
2836	547933	Test1		Failed Validatio	n	E-801		1111-7272-0	
2836	547933	Test1		Failed Validatio	n	E-993		10038181210	
2836	547933	Test1		Failed Validatio	n	1-401			
2836	547935	Test2		Failed Validatio	n	E-801		1111-7272-5	
2836	547935	Test2		Failed Validatio	n	E-9022		0	
2836	547935	Test2		Failed Validatio	on	1-401			

<u>Step 5:</u> Once you have determined the error codes for each record, consult the Error Code Key, which is available on the Resources page of the Open Payments website at

<u>https://www.cms.gov/openpayments/About/Resources.html</u> or within the Open Payments system by selecting the "Resources" tab. The Error Code Key lists error IDs along with a description regarding the relevant data element name, an error description, and steps to avoid and correct the error.

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

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

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

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

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

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

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

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

4.7b: Identifying Manual Entry Errors

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

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

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

- Log in to the Open Payments system via the CMS Enterprise Portal at <u>https://portal.cms.gov/</u> and select the "Submissions" tab on the toolbar.
- On the "Review Submitted Records" section, select the entity and program year for the records you wish to review, then select the "Review Records" button
- On the "Review Records" page, find the payment category (general, research, or ownership/investment) of the record(s) you wish to review, then select the "View All" Button. All records submitted for the reporting entity for that payment category and program year will display on the selected Payment Category page.
- Use the filters for "Record Status" to search for records in a "Failed Matching" status.

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

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

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

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

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

4.7c: GPO Users Only - Identifying Recipients Missing Attested Ownership Record This section is for applicable group purchasing organizations (GPOs) users only.

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

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

Figure 194: Submissions page for Group Purchasing Organization users

Home Submissions	Review and D	ispute	Ø Manage Entities	6	(Q) My Profile		Sea angen	Resourc	
Submissions								?	
A field with an asterisk (*) is required. Applicable manufacturers and applicable OP System.	Os must submit	payments, o	r other transfers o	f value, and	ownership or inv	niment etere	sts to the Op	en Payments	
Submit Payment Data									
Only users who hold the role of submitter can submit information to the Open Payments system. Select Bulk File /pload or Manual Data Entry below.							Download the Physician List The Validated Physician Lists and		
Refer to the Resources tab for the Open Pay reporting templates for the Bulk File Upload.			Data Entry to sub- s manual entry on		using the	Suppleme		ram Year below	
Buik File Upload Manual Data Entry							should not be shared publicly. Validated Physician Lists and Physician with Inacti License(s) Supplement Fi per Program Year		
Review Submitted Payment Records						Download the Validation Template The physician validation template is			
To review records, select the entity whose re krop-down lists below, then select "Review F		to neview and	the program yea	for the rec	ords from the		hrough the link Physician Val	below.	
Select Entity: "5	elect Program	Year:					Template		
Please Select P	wase Select		M Bron	w Records					
Review Submitted File(s) Sta									
Drice a file for your entity has been submitte Review File Status	d, you may revie	w the defails	by selecting. 'Rev	new File St	ilus."				
Download Recipients Missin	g Ownersh	nip Reco	rd						
SPO entities are required to report ownership preneral and/or research records for the same IO3 5060. To review physicians that were of werreming record, select the entity you wish VOTE: If there is any physician where the co- interest record in Ready for Attestation status Durnenhiphinewerthemit Interest records for the associated general or research records are is a completed.	e program year ed on general ar to review from 9 kumn value for 1 s' is "No," reviev physician will b	(per the Oper idior research to thop-down is there at lea v your submit e included in	 Payments final in h records who do list below, then s ist one associated istons to verify the your submission. 	ule, 42 C.F not have an elect 'Down 5 Ownership it a corresp If the value	R § attested icad Report " Vinvestment onding is "Yes," the				
Select GPO Entity: Please Select Select	lownicad Repor								
Physician Matching Validatio	on Utility								
	ect the "Validate	Physician' t	utton below and	upload phys	ician				
To verify physician matching information, set information on the new page									

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

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

Section 4.8: Correcting Records

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

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

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

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

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

Changing a record may affect the publication of that record, depending on when the changes are made. For details refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at <u>https://www.cms.gov/openpayments/About/Resources.html</u>.

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

4.8a: Correcting Records via Bulk File Upload

To correct records via bulk file upload:

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

- If the file failed in steps 1 or 2, the Resubmission File Indicator for the records does not need to be changed from the original submission.
- If the record(s) in the file failed in steps 3 or 4, the record(s) must undergo resubmission or deletion and new records submitted in their place.
 - For resubmissions, each corrected record must have its "Resubmission File Indicator" value set to "Y" and the original record's Record ID provided in the updated record's "Resubmitted Payment Record ID" field.
 - If the failed record must be deleted and replaced due to changes in identifying information (per the boldfaced text in the "Correcting Records" section above), consult the Deleting Records section 4.9. Replacement records will be new submissions and should have a "Resubmission File Indicator" value of "N".

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

4.8b: Correcting Records Manually

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

- Log in to the Open Payments system via the CMS Enterprise Portal at <u>https://portal.cms.gov/</u> and select the "Submissions" tab on the toolbar. In the "Review Submitted Records" section, select the reporting entity whose record you wish to view and the program year for that record, and then select the "Review Records" button. On the "Review Records" page, find the payment category (General, Research, or Ownership/Investment) of the record you wish to correct, and select the "View All" button.
- 2. Locate the desired record in the data table at the bottom of the "Payment Category" page. You can use the filtering tools on the page to help find a relevant record. Once you have found the record, select the "Edit" hyperlink in the "Actions" column for that record.
- 3. Update the record information. Users can select an item from the "Payment Navigation Bar" located on top of the page to go directly to their desired page or go through the pages sequentially to fix the error(s). Once all the validations and errors have been fixed the user can navigate to the "Review & Save" page and select the "Save Record" button. NOTE: The system will provide matching errors and/or warnings on the Overview page when the submitter edits payment records with matching errors/warnings.
- 4. The edited records must undergo final submission and attestation. Instructions are available in Section 4.14, Final Submission and Attestation.

Section 4.9: Copy/Duplicate Records

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

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

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

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

The "Copy" button is provided in two places:

- 1. The payment category page, record view grid for every record under the Action column regardless of the record status.
- 2. The view Record ID Page at the top and bottom of the page.

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

4.9a: Copying a Record

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

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

Figure 195: Submissions Tab for Open Payments system landing page for returning system users

	Submissions	Review and Dispute	Manage Entities	(Q) My Profile		Messages	Resourc
Welcor	ne to the (Open Payme	nts System		0	Access the Op User Guide [PI	
Announce				_	?	Need help with Contact Us by	
The Review and		en starting April 1, 2019. Dur	ing this period, reporting enti h them directly to resolve the	and the second	8	Review the Op Privacy Policy	
		Y line, call 1-844-649-2766. I perform user role functions	associated with your profile.	-	1.		
	ormation unless it displ		e required to respond to a nber. The OMB control numb omplete this information	er			

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

Figure 196: Submissions Landing page

Home Submiss	the second se	And Dispute M	lanage Entities	O My Profile	Messages	Resource
Submissions						? User Gui
A field with an asterisk (*) is req	quired.				1 1 1	_
Applicable manufacturers and a System.	pplicable GPOs must s	ubmit payments, or o	other transfers of valu	e, and ownership or i	nvestment interests to the 0	Open Payments
Submit Payment Dat	ta					
Only users who hold the role of		formation to the Ope	en Payments system.	Select Bulk File	Download the F	hycician
Jpload or Manual Data Entry be	elow.	1			List	Ilysician
Refer to the Resources tab for t reporting templates for the Bulk			ata Entry to submit rea manual entry online fo		The Validated Physician Physician with Inactive I	
Bulk File Upload		Man	ual Data Entry		Supplement File per Pro	
Bulk File Upload		Man	ual Data Entry		should not be shared pu Validated Pl	ublicly. hysician Lists
Bulk File Upload		Man	ual Data Entry		should not be shared pu Validated Pl and Physici License(s) S	ublicly. hysician Lists ian with Inactive Supplement File
	ayment Record		ual Data Entry		should not be shared pu Validated Pl and Physici	ublicly. hysician Lists ian with Inactive Supplement File
Review Submitted P	tity whose records you	s		e records from the	should not be shared pu Validated Pl and Physici License(s) S	ublicly. hysician Lists lan with Inactive Supplement File n Year
Review Submitted Particle Review records, select the end drop-down lists below, then select	tity whose records you	S wish to review and th		e records from the	should not be shared pu Validated Pl and Physici License(s) S per Program	ablicly. hysician Lists an with Inactive Supplement File n Year Reporting
Bulk File Upload Review Submitted Particle Submitte	tity whose records you ect "Review Records."	S wish to review and th			should not be shared pu Validated Pl and Physici License(s) S per Program Download the F Templates To download reporting to	ablicly. hysician Lists an with Inactive Supplement File n Year Reporting
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Review Submitted P To review records, select the en drop-down lists below, then sele "Select Entity:	tity whose records you ect "Review Records." *Select Prog 2018 ile(s) Status	S wish to review and th ram Year:	he program year for th	cords	should not be shared pu Validated Pl and Physici License(s) S per Program Download the F Templates To download reporting to	ablicly. hysician Lists an with Inactive Supplement File n Year Reporting
Review Submitted Parton To review records, select the endrop-down lists below, then select "Select Entity: ABCDEF Medical Review Submitted Fit Once a file for your entity has be Review File Status	tity whose records you ect "Review Records." *Select Prog 2018 ile(s) Status een submitted, you may	S wish to review and th ram Year:	he program year for th	cords	should not be shared pu Validated Pl and Physici License(s) S per Program Download the F Templates To download reporting to	ablicly. hysician Lists an with Inactive Supplement File n Year Reporting
Review Submitted Parton review records, select the endrop-down lists below, then select select Entity: ABCDEF Medical Review Submitted Findence a file for your entity has be Review File Status Physician Matching	tity whose records you ect "Review Records." *Select Prog 2018 ile(s) Status een submitted, you may Validation Utilit	S wish to review and th ram Year: review the details b	he program year for th Review Rev y selecting "Review F	ile Status."	should not be shared pu Validated Pl and Physici License(s) S per Program Download the F Templates To download reporting to	ablicly. hysician Lists an with Inactive Supplement File n Year Reporting
Review Submitted Part To review records, select the endrop-down lists below, then select "Select Entity: ABCDEF Medical Review Submitted Fin Once a file for your entity has be	tity whose records you ect "Review Records." *Select Prog 2018 ile(s) Status een submitted, you may Validation Utilit	S wish to review and th ram Year: review the details b	he program year for th Review Rev y selecting "Review F	ile Status."	should not be shared pu Validated Pl and Physici License(s) S per Program Download the F Templates To download reporting to	ablicly. hysician Lists an with Inactive Supplement File n Year Reporting

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

Figure 197: Review Records page with View All button for Research, General and Ownership or Investment Interest payments

Open Pay Applicable Manufacturer or Group			hine A	(ct)			
Home Submiss	sions Rev	ew and Dispute Mar	ලි age Entitles	@ My Profile		Messages	Resource
ABCDEF Med	ical 201	6 - Review R	ecords			Access the Op	en Payments
Below are the records reported year. To edit records (available records, select the "View All" bi	only for a user in a	"submitter" role) or view the	details of the report	ted	?	User Guide [PD Need help with Contact Us by	the website?
Seneral Payments, etc.). f all the records for the entity a role can attest by selecting the			tus, a user in an "att	ester"	8	Review the Op Privacy Policy [en Payments PDF]
f you have further questions or now to attest, use the link availa	how to make fina	submission of records, deta	ilis on status definitio	ons, or		vith this Page	
Select "Notify Attester" to notify attesters affiliated with the repo	attesters that the	e are records that require at		which	What de	Status Definitions o I do If records fa hatching?	
require attestation. Note: Previously attested record the Open Payments system. Th complete the deletion. Records until re-attestation is complete. Records counted as "Marked for Back to Submissions	e attester must re marked for deletio	attest to all payments for the in remain eligible for review,	e selected program y dispute, and publica	rear to tion,	-	I complete final s	
Program Year: 2016 Research Payments				w All			
Status	Record Count	Action Required					
System Processing	0	No Action	_				
Failed Validation	0	Correction					
Failed Matching	0	Correction					
Ready for Submission	0	Final Submission					
Ready for Attestation	0	Attest					
Returned to Submitter	0	Correction					
Attested †	0	No Action					
Total Payments	0						
Marked for Deletion	Record Count	Action Required					
† Attester to confirm deletion of previously Attested records	0	Attester to Attest deletion ac or Reject Deletion	tion				
General Payments			Vie	WAII			
Status	Record Count	Action Required					
System Processing	0	No Action					
Failed Validation	0	Correction					
Failed Matching	0	Correction	_				
Ready for Submission	0	Final Submission					
Ready for Attestation	0	Attest					
Returned to Submitter	0	Correction					
Altested 1	0	No Action					
Total Payments	0						
Marked for Deletion	Record Count	Action Required					
† Attester to confirm deletion of	0	Attester to Attest deletion ac	tion				
previously Attested records	-	or Reject Deletion		-			
Ownership or Investment Inter	est		Vie	WAI			
Status	Record Count	Action Required					
System Processing	0	No Action	-				
Failed Validation	0	Correction					
Failed Matching	0	Correction					
Ready for Submission	0	Final Submission					
Ready for Attestation	0	Attest					
Returned to Submitter	0	Correction					
Attested †	0	No Action					
Total Payments	0						
	1						
Marked for Deletion	Record Count	Action Required					
† Attester to confirm deletion of		Attester to Attest deletion ac	fion				
previously Attested records	0	or Reject Deletion	UCH1				

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

Figure 198: "Copy" Hyperlink from Reporting Entity General Payments Payment Category Page

Home		D	1	2ì	-	ŝ	Ø	1	5	6
	Sut	missions	Review	and Dispute		e Entities	MyPr	ofile	Message	es Resou
Payme	ent Ca	atego	ry: Ge	neral P	ayme	nts - A	BCDE M	edical		
			on submitted re able can custom			ing entity, pri	ogram year, and	payment cate	gory	
										pling to download i of records and dow
hem in multip	io files.									
hat should be	reviewed a	ind correcte	d as required. R	lecords with wa	ming messag	pes only (do a	not have validati	on or matching	errors), will not	re are warning mes I prevent a record I
s	ough final si	ibmission a	nd attestation, a	and therefore an	e not require	to be correct	cted before proc	eeding if the in	normation is del	termined to be valu
Records count with the "Mark	ted as "Mari ad for Delet	ked for Dele ton" status	ition" are also in of "Yes", select	cluded in the "/ the checkbox n	Attested" (†) in exit to them, a	ecord count. Ind then sele	If you wish to re ct the "Cancel D	instate record eletion" buttor	s marked for de	letion, find the reco
for more infor	mation on t	he actions y	you can take on setailed informat	this page, refer	to the "Paym	ents Catego d records re	ry Page" quick n	aference guide	available on the	e Resources page
							er to alle open	alments con	a compare fr ma f	
Genera	al Payn	nents								Refresh Statu
Status			Record	Action R	lequired					-
System Pr			0	No Action						
Failed Vali Failed Mat			0	Correctio						
Ready for	Submissio		0	Final Sub						
Ready for Returned I			6	Attest Correctio						
Attested † Total Payn	nents		0	No Action	n					
Note: Previ	ously attest	ed records	that have been	marked for dele	tion have not	yet been del				
			eligible for publ					ation, the man	ked records ren	nain
Marked fo	r Deletion		Record	Action R	lequired					
† Attester	to confirm	deletion	0	Attester t	o Atlest or F	leject Delet	on			
Back to Rev	ew Records									
Record Sta Please Sel	ect			e ID: xximum 38 dig	ts		Record ID: Maximum 3	8 digits		
System Pri Failed Value	ocessing		1.0							
Failed Mat Ready for 2 Ready for 2	Submission		Ho	me System Pa	iyment ID:		Delay in Pu Please Sel	blication Indi	cator:	
Returned to Attested	o Submitter		-							
Physician	First Name		Ph	ysician Last N	ame:		Physician N			
							This is a 10	digil number		
License St			License N	mber		iress State:		Zip Co		
			License A	umper.				99999		
Please Se	lect				P	ease Select		•		
Teaching H	lospital Na	me:		aching Hospita rs-is a G-digil n			Teaching H This is a 9-4			
	Deletion:		ent Type:			lethod:	Report Type		cord Warnings	0
Marked for			vered Recipient P vered Recipient T			ual Entry ad Files	Single Consolida		Yes No	
Marked for Yes			ad Zip File							
Yes	Clear Al	Downa								
Yes No Search										
Yes No Search										
Yes No Search		s for:	Update Delay In	dicator	Cancel Delet	ion F	leturn to Attests	r Dele	te Selected	Return to Subr
Yes No Search		s for:	Update Delay In	-	_	_		_	_	Return to Subr
Ves No Search Showing Aug	Results	s for:	Showing Home System	10 • of 6 E	ntries	Page 1	of 1	Page 1 Record	* Marked for	Delay in Publics
Vies No Search Showing All D:	Results	Actions:	Showing	10 • of 6 E n Payment Date: 0	Amount(\$)	Page 1 Recipient Type: 0	of 1	Page 1 Record Status:0	* Marked for Deletion: 0	Delay in Publici Indicator:0
Yes No Search Showing All Select Fit All ID:	Results	Actions:	Showing Home System	10 • of 6 E	ntries	Page 1	of 1	Page 1 Record	* Marked for	Delay in Publics
Vies No Search Showing All Select Fig 122	e Record 0 10:0 3 tt5185	Actions:	Showing Home System	10 • of 6 E n Payment Date: 0 20160805	Amount(\$) 0 \$506.00	Page 1 Recipient Type: 0 Physician	of 1 Recipient: 0 Tom Smith	Page 1 Record Status: 0 Ready for Attestation Ready for	* Marked for Deletion: 0	Delay in Public: Indicator:0 No Delay Request
Vies No Search Showing All Select Fig 122	e Record 0 10:0 3 tt5185	Actions: View Eost Copy	Showing Home System	10 • of 6 E n Payment Date: 0	Amount(\$)	Page 1 Recipient Type: 0	of 1 Recipient: 0	Page 1 Record Status: 0 Ready for Attestation Ready for Attestation	* Marked for Deletion: 0 No	Delay in Public Indicator: 0 No Delay Request R&D on New Proc
Vies No Search Showing All Select Fig 122	Results	Actions: View Edd Cdapy View Edd Cdapy View Edd Cdapy View Edd Cdapy View Edd	Showing Home System	10 • of 6 E n Payment Date: 0 20160805	Amount(\$) 0 \$506.00	Page 1 Recipient Type: 0 Physician	of 1 Recipient: 0 Tom Smith	Page 1 Record Status: 0 Ready for Attestation Ready for	* Marked for Deletion: 0 No	Delay in Public: Indicator:0 No Delay Request
No Search Showing All 132 132	Results	Actions: Vew Edit Copy View Eon Copy Vew Eon Copy Vew Eon Copy Vew	Showing Home System	10 • of 6 E n Payment 0 20160805 20160915 20160702	ntries Amount(\$) \$508.00 \$531.50 \$557.00	Page 1 Recipient Type: 0 Physician Physician Physician	of 1 Recipient Q Tom Smith Tom Smith Tom Smith	Page 1 Record Status: 0 Ready for Attestation Ready for Attestation	Marked for Detetion: 0 No No	Delay in Publice Indicator: 0 No Delay Request R&D on New Proc Clinical Investigatio New Product
Vies No Search Showing All 132 132	Results	Actions: View Edit Copy View Edit Copy View Edit Copy View Edit Copy	Showing Home System	10 • of 6 E n Payment Date: 0 20160805 20160915	ntries Amount(\$) \$506.00 \$531.50	Page 1 Recipient Type:0 Physician Physician	of 1 Recipient: Q Tom Smith Tom Smith	Page 1 Record Status: 0 Ready for Attestation Ready for Attestation Ready for	Marked for Detesion: 0 No No	Delay in Publice Indicator: 0 No Delay Request R&D on New Proc
Vies No Search Showing All 132 132	Results Record No:0 T151P5 T151	Actions: View East Copy View East Copy View East Copy View East Copy View East Copy View East Copy	Showing Home System	10 • of 6 E n Payment 0 20160805 20160915 20160702	ntries Amount(\$) \$508.00 \$531.50 \$557.00	Page 1 Recipient Type: 0 Physician Physician Physician	of 1 Recipient Q Tom Smith Tom Smith Tom Smith	Page 1 Record Status: 0 Ready for Attestation Ready for Attestation Ready for Attestation Ready for	Marked for Detetion: 0 No No	Delay in Publice Indicator: 0 No Delay Request R&D on New Proc Clinical Investigatio New Product

Alternatively, according to the second method to copy an existing payment the steps are as follows:

<u>Step 4b-1</u>: At the bottom of the "Payment Category" page is a data table. Find one record from the file you wish to copy. Select the "View" hyperlink in that record's "Actions" column.

Figure 199: "View" Hyperlink from Reporting Entity General Payments Payment Category Page

~		-	_						-	
Home	Su	Demission	a Review a	Nd Dispute		e Entities	My Pr		Message	es Resourc
-		-	ory: Gen		-					
			n on submitted reco table can customiz			ting entity, pro	ogram year, and	payment cate	igory.	
a export the s	search resu	its into a C	SV file, select "Dou	inload Zip Fil	e". This prov	ides a compre	essed file contai	ning the searc	ch results. Attem	pling to download m of records and down
ial should be ontinuing the lecords count ith the "Mark	ds for a rec reviewed i ough final s ted as "Mar ied for Dele	and correct ubmission ked for De tion" status	ed as required. Re- and attestation, an letion" are also incl s of "Yes", select the	d therefore an uded in the "/ e checkbox n	ming messag a not require Attested" (†) : ext to them, a	pes only (do n d to be come record count and then sele	tot have validation to the second sec	on or matchin eeding if the is instate record wetion" butto	g errors), will no nformation is del ds marked for de n	re are warning mess (prevent a record for termined to be valid) letion, find the record
ipen Paymen	its public w	ebsite For	you can take on th detailed informatio	is page, reler n on how to e	to the "Payn dit and subm	ents Catego at records, rel	ry Page" quick n fer to the Open	eference guid Paymants Usa	e available on th er Guide (PDF)	e Resources page o
Genera	al Payr	nents								Refresh Status
Status			Record	Action R	equired					-
System Pr			0	No Action						
Failed Vali Failed Mat			0	Correctio						
Failed Mat Ready for		'n	0	Correction Final Sub						
Ready for	Altestation	1	6	Attest						
Returned t Attested †		er.	0	Correctio No Action						
Total Paym			6	NV PL00						
attester mus	st re-attest	to all paym	s that have been mu wints for the selecte is eligible for publici	d program ye	ar to comple	te deletion. U	infil this re-attest	pen Payments tation, the ma	s system. The riked records ren	navi
Marked fo	r Deletion		Record	Action R	equired					
1 Atlester	to confirm	deletion	0	Attester t	o Atlest or F	Reject Delet	ion.			
Back to Revi	iew Record									
Record Sta	ntus:		File	D:			Record ID:			
Please Sel System Pro	ect			mum 38 digi	5		Maximum 3	8 digits		
Failed Valid Failed Mate	sation		1.1.1.1				100100			
Ready for 3 Ready for 3 Returned to	Submission Attestation		Hom	e System Pa	ryment ID:		Delay in Pu Please Sel	blication Indi	cator:	
Attended Physician I		-		sician Last N			Physician M			
- of model (Phys	and the second re-				-digt number		
License St	ate:		License Nur	nber:	Ad	dress State:		Zip Co		
Please Sel	lect				р	ease Select		•	0000	
Teaching H	iospital Na	me:		hing Hospita is a 5-digit in			Teaching H This is a 0-1	ospital TIN: Sigit member		
Marked for Yes	Deletion:		plent Type; overed Recipient Phy	nician		Method: mail Entry	Report Type Single		cord Warnings: Yes	0
- No			overed Recipient Tea			oud Fires	Consolida	eed 🛛	No	
Search	Clear A	Down	load Zip File							
showing	Result	s for:								
40										
		1.10	Update Delay Indi	cator	Cancel Dele	tion P	Return to Atteste	er Dele	ete Selected	Return to Subm
			Showing 10	+ of 6 E	ntries	Page 1	of 1	Page 1		
Select File All ID:		Actions:	Home System Payment ID: 0	Payment Date: 0	Amount(\$)	Recipient Type: 0	Recipient: 0	Record Status: 0	Marked for Deletion: 0	Delay in Publicat Indicator: 0
		View		20150805		Physician	Tom Smith	Ready for	No	No Delay Requeste
100		1			-			Attestation		
1 112	115185	Copy View			I to the state	Real Property lies	Tom Smith	Ready for Attestation	No	R&D on New Produ
	1 115185	Copy List Copy		20160915	\$531.50	Physician	Tom senen	Autoration		
1 112	-			20160915	\$531.50	Physician	Tom Smith	Ready for Attestation	No	
0 tox	1 115175	Copy View Edi Copy View		20160702	\$567.00	Physician		Ready for Attestation	-	Clinical Investigatio New Product
1 132 0 69 1 132 4 132	1 115175	Copy Vins Esi Copy			-		Tom Smith	Ready for Attestation Ready for Attestation	No	Clinical Investigatio New Product No Dislay Requeste
1 112 1 112 1 112	1: 715175 1: 715171	Copy View Edi Copy View		20160702	\$567.00	Physician	Tom Smith	Ready for Attestation	-	Clinical Investigatio New Product

<u>Step 4b-2:</u> Select the "Copy" Button from either the top of the bottom of the page.



Figure 200: Copy Button on Record ID Page

<u>Step 5:</u> A confirmation pop-up box appear. Select the "Yes" button.

Figure 201: Confirmation pop-up window

		ents (Sui ng Organization Switch User Ty		(ct)		
Home	Submissions	Review and Dispute	Ø Manage Entities	(Q) My Profile	Messages	Resources
Record		1			Access the Op User Guide [P	
Back		e you want to create a copy to start the copy action. S			? Need help with Contact Us by	
Record D	the second se			No Yes	Review the Op Privacy Policy	

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.

Home Submiss	ions Review and		je Entities M	(2) Iy Profile	Messages	Resour
Add General F	Payment					2 User G
Overview	Covered Recipient Demographics	Products	\$ Payments	General Infor	mation Review	& Save
• The selected record has teview the payment information				omplete the reco	rd creation process.]
Entity Making Payment Registration ID: 100000165003	Entity Making Pa Registration Nan ABCDE Medical	ne.	Program Year: 2016		ment Category: eral Payments	

Figure 202: Confirmation message on Add General Payment Page.

Section 4.10: Deleting Records

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

The record deletion process varies depending upon the status of the records to be deleted. Records that had not yet been attested to will be immediately removed from the Open Payments system. Records that had been previously attested to will be placed in a "Marked for Deletion" status rather than immediately deleted.

To complete the deletion of records marked for deletion, the attester for the reporting entity must reattest to the payments for that program year, which includes attesting to the deletion of previously attested records. Until they are attested, and therefore removed from the system, records in "Marked for Deletion" status remain visible to covered recipients and are eligible for publication.

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

4.10a: Deleting a Bulk File

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

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

Figure 203: Submissions Tab for Open Payments system landing page for returning system users

Home	Submissions	Review and Dispute	ठि Manage Entities	(Q) My Profile		Messages	Resourc
Welco	ome to the	Open Payme	ents System		0	Access the Op User Guide [PD	
Announ				_	?	Need help with Contact Us by	
The Review a may receive disputes. Phy May 15, 2019 corrections to correction per correction per visit the Ope questions, cc phone at 1-8	disputes from covered re vsicians and teaching ho a After that, reporting en a disputed data as neede riod will be identified in the riod will be included in fu n Payments website at h ontact the Open Payment 55-326-8366. For the TT	en starting April 1, 2019. Du ccipients and should work w spitals may review data abo tities have an additional 15- id. Records with unresolved ne published data as disput	th them directly to resolve I ut them and initiate dispute day correction period to ma disputes at the end of the ed. Changes to records after yments for information. For enpayments@cms.hhs.gov	he s until ke r the or by	6	Review the Opp Privacy Policy [
collection of i for this inform collection can organization. dispute and o	nformation unless it disp nation collection is 0938- n range from 1 to 30,000 This information collection dispute resolution proces	n Act of 1995, no persons a lays a valid OMB control nu 1237. The time required to o hours per entity depending on may involve registration, ses. If you have any commo r improving this form, pleas	mber. The OMB control nur complete this information on the size and type of data submission, attestatio ents concerning the accurace	n, y of			

uide

 \sim

Contact Us Privacy Policy

Step 2: Under the "Review Submitted Payment Records" heading, select the reporting entity whose records you want to delete and the program year for those records. Select the "Review Records" button.

		Figure 204	4: Submissions	Landing pag	e	
		ents (S sing Organization Switch U	unshine Jser Type	Act)		
Home	Submissions	Review and Disp	ری) ute Manage Entities	(Q) My Profile	Messages	Resource
Submis	sions					? User Gui
A field with an as	sterisk (*) is required.					
Applicable manu System.	facturers and applicabl	e GPOs must submit pay	ments, or other transfers of v	value, and ownership or i	nvestment interests to the	Open Payments
Submit Pay	yment Data					
	hold the role of submitt al Data Entry below.	er can submit information	n to the Open Payments syste	em. Select Bulk File	Download the F List	Physician
reporting templat	ources tab for the Oper tes for the Bulk File Up Ilk File Upload		t Manual Data Entry to submi Payments manual entry onlir Manual Data Entry	Contraction of the second s	The Validated Physician Physician with Inactive Supplement File per Pro should not be shared pu	License(s) ogram Year below
					and Physici	hysician Lists ian with Inactive Supplement File n Year
Review Su	bmitted Payme	ent Records				
	s, select the entity who below, then select "Rev		eview and the program year fo	or the records from the	Download the F Templates	Reporting
*Select Entity: ABCDEF Medica	al 🔹	*Select Program Yea 2018		Records	To download reporting to Resources tab.	emplates, see the
Review Su	bmitted File(s)	Status				

Review File Status

information on the new page. Validate Physician

Physician Matching Validation Utility

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

Once a file for your entity has been submitted, you may review the details by selecting "Review File Status."

To verify physician matching information, select the "Validate Physician" button below and upload physician

Figure 205: Review Records page with View All button for Research, General and Ownership or Investment Interest payments

Home Submissi	ions Revi	lew and Dispute Ma	nage Entities My Profile		Messages	Resource
ABCDEF Medi				F.	Access the Op User Guide (PD	en Payments
Below are the records reported b year. To edit records (available o records, select the "View All" but	only for a user in a	a "submitter" role) or view th	e details of the reported	?	Need help with Contact Us by	the website?
Seneral Payments, etc.), f all the records for the entity are role can attest by selecting the "			itus, a user in an "attester"	8	Review the Ope Privacy Policy [en Payments PDF]
f you have further questions on now to attest, use the link availab			alis on status definitions, or		with this Page	
Select "Notify Attester" to notify a attesters affiliated with the report require attestation.				What d	to I do If records fai natching?	led validation of
Note: Previously attested record he Open Payments system. The complete the deletion. Records r until re-attestation is complete. Records counted as "Marked for	e attester must re marked for deletic	-attest to all payments for th on remain eligible for review	e selected program year to dispute, and publication,		o I complete final s o I complete attesta	
Back to Submissions Program Year: 2016			Refresh Status			
Research Payments			View All			
Status	Record Count	Action Required				
System Processing Failed Validation	0	No Action Correction				
Failed Matching	0	Correction				
Ready for Submission	0	Final Submission				
Ready for Attestation	0	Attest				
Returned to Submitter	0	Correction				
Attested †	0	No Action				
Total Payments	0	1				
Marked for Deletion	Record Count	Action Required				
† Attester to confirm deletion of previously Attested records	0	Attester to Attest deletion as or Reject Deletion	ction			
General Payments			[marked]			
	-	1	View All			
Status System Processing	Record Count	Action Required				
Failed Validation	0	Correction				
Failed Matching	0	Correction				
Ready for Submission	0	Final Submission				
Ready for Attestation	0	Attest				
Returned to Submitter	Ó	Correction				
Attested †	0	No Action				
Total Payments	0					
Marked for Deletion	Record Count	Action Required				
		Attester to Attest deletion ar	tion			
+ Attester to confirm deletion of	0	or Reject Deletion				
	1					
previously Attested records			View All			
previously Attested records		Action Required	View All			
previously Attested records Ownership or Investment Intere Status System Processing	Record Count	Action Required	View All			
proviously Attested records Ownership or Investment Intere Status System Processing Failed Validation	Record Count 0 0	Action Required No Action Correction	View All			
previously Attested records Ownership or Investment Intere Status System Processing Failed Validation Failed Matching	Record Count 0 0 0	Action Required No Action Correction Correction	View All			
previously Attested records Status System Processing Failed Validation Failed Matching Ready for Submission	Record Count 0 0 0 0 0	Action Required No Action Correction Correction Final Submission	View All			
previously Attested records Status System Processing Failed Matching Ready for Attestation Ready for Attestation	Record Count 0 0 0 0 0 0	Action Required No Action Correction Correction Final Submission Attest	View All			
previously Attested records	Record Count 0 0 0 0 0 0 0 0 0 0 0 0 0	Action Required No Action Correction Correction Final Submission Attest Correction	View All			
previously Attested records Dwnership or Investment Intere Status System Processing Failed Validation Ready for Subernission Ready for Attestation Ready for Attestation Returned to Submitter Attested 1	Record Count 0 0 0 0 0 0	Action Required No Action Correction Correction Final Submission Attest	View All			
previously Attested records Dwnership or Investment Intere Status System Processing Failed Validation Ready for Subernission Ready for Attestation Ready for Attestation Returned to Submitter Attested 1	Record Count 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Action Required No Action Correction Correction Final Submission Attest Correction	View All			
	Record Count 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Action Required No Action Correction Correction Final Submission Attest Correction	View All			

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

Figure 206: Reporting Entity General Payments Payment Category page

Horn											
	} ∞	Su	bmissions	Review	w and Disput		e Entities	(Q) My Prof	Ne	Messages	Resource
Payr	men	t C	atego	ory: Ge	neral F	ayme	nts - V	Vensco	2016		
							ing entity pr	ogram year, and p	ayment catego	ry	
To export than 400, them in m	the sear 000 reco sultiple fi	rch resu ords, wil les	uts into a CS I generate a	in on-screen er	Download Zip F ror notification	ile" This provi To correct this	error, adjust	t the filtering criters	a to create sm	ailer subsets of	ting to download mor records and downlo
that shoul	id be rev	sewed a	and correcte	id as required.	Records with w	arning messag	pes only (do:	not have validation	or matching e	rrors), will not p	are warning messag prevent a record from rmined to be valid as
with the " For more	Marked I informat	for Dele	tion" status	of "Yes", selec you can take or	the checkbox this page, refe	next to them, a at to the "Paym	ents Catego	ct the "Cancel Del	etion" button. erence guide a	variable on the	tion, find the records Resources page of t
Gen	eral	Payr	nents								Refresh Status
Status				Record	Action	Required					New York Status
	m Proce	issing		Count 0	No Acti						
Failed	Validat	ion		7	Correct	ion					
	Matching for Sut		m	0	Correct Final Si	ion ibmission					
Ready	for Atte	estation	1	6	Attest						
Atteste	ned to S ed †	ubmitte	н	0	Correct No Acti						
	Paymen	ts		14							
attester	r must re	-attest	to all payme		icted program	ear to complet	le deletion. L	leted from the Ope Intil this re-attestat ecord count.			an -
Marke	d for D	eletion	,	Count	Action	Required					
† Attes	ster to c	onfirm	deletion	0	Attester	to Attest or F	teject Delet	lion			Final Submission
Back to	Review	Record									
	d Status				le ID:			Record ID:			
Syster	e Select m Proces	sing		î N	laximum 38 de	gits		Maximum 38	digits		
Failed	I Validatio Matchin	9			ome System F	avment ID:		Delay in Publ	ication Indica	tor:	
Ready	y for Sub y for Atte ned to Su wd	station						Please Select		•	
Physic	cian Firs	t Name	c	P	hysician Last	Name:		Physician NP This is a 10-d			
Licens	e State:			License I	fumber:	Add	iress State:		Zip Code	e 9000	
Pleas	e Select			•		Pi	ease Select				
Teachi	ing Hos	pital Na	me:		eaching Hospi his is a 6-digit			Teaching Hos This is a 9-dig			
Marke	d for De	letion	Recin	ient Type:		Input N	lethod:	Report Type:	Reco	rd Warnings: 1	0
Yes No			Col	vered Recipient vered Recipient		Man	ual Entry ad Files	Single Consolidate	Ye	5	
Showi			s for:	oad zip Pila							
			1	Update Delay I	ndicator	Cancel Delet	ion I	Return to Attester	Delete	Selected	Return to Submitt
				Showing Home System	10 + of 14	1	-	1 of 2	Page 1 + Record	Marked for	Delay in Publicatio
(All)	File	Record				Amount(\$): 0	Recipient Type: 0	Recipient: O	Status: 0	Deletion: 0	Indicator: ¢
	File I ID:0	Record ID:0	Actions:	Payment ID:			1				
[AII] Select	ID:0		View Edit Copy		20160915	\$531.50	Physician	Tom Smith	Failed Validation	No	R&D on New Produ
Ail] Select All	ID:0 1320 1	ID:0	View Edit			\$531.50 \$1,000,000.00	Teaching	Tom Smith		No No	R&D on New Produ No Delay Requester
Ail] Select All	ID:0 1320 1 N/A	ID:0	View Edit Copy View Edit		20160915		Teaching	-	Validation Ready for	-	

<u>Step 5:</u> On the "File ID" page, select the "Delete File" button.

Figure 207: Delete File Button on File ID Page

Home	Submissions F	Review and Dispute	Ø Manage Entities	(Q) My Profile		Messages	Resource
File IC	D: 355				0	Access the Op User Guide [PI	
5,77,77	about the File Subn	nitted			2	Need help with	
If any record	s have errors, download this	file's error log. The error	r log lists all errors found in	the	<u>۲</u>	Contact Us by	email
	ig records by Record ID and electing the "Delete File" butte		ID. If necessary, this file ca	in be	8	Review the Op Privacy Policy	
	neral Payments AB						
				_	-		
Original Upl	oad File Name:	SGen.csv			1	6	1/h
Type of Sub	mission:	New Submiss	sion			× 1	
Original /Re	submission Date:	6/20/2018 2:4	48 PM				
Submitted E	By:	Tom Smith				1.5	1100
File Size:		5 KB				211	KAK
File Type:		csv			1		
Program Ye	ar:	2017					
Payment Ca	tegory:	General Pay	ments				
File Status:		Submitted W	ith Errors				
Number of F	Records in File:	10					
Number of F	Records Successfully Uploa	aded: 10					

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

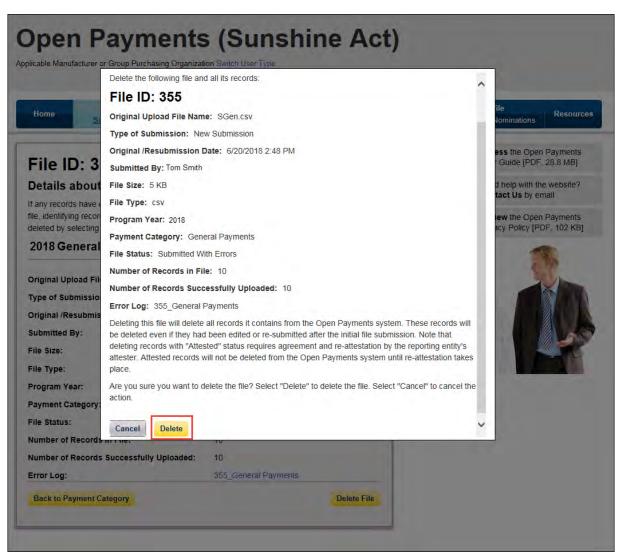


Figure 208: Delete File confirmation message

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

4.10b: Deleting Records via Bulk File Upload

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

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

- Applicable Manufacturer or Applicable GPO Registration ID;
- Consolidated Report Indicator;
- Resubmission File Indicator (must be "D" to delete records);
- Applicable Manufacturer or Applicable GPO Making Payment Registration ID;
- Resubmitted Payment Record ID; and
- Date of Payment (General and Research payment records only).

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

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

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

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

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

4.10c: Deleting a Record Manually

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

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

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

Figure 209: Open Payments system landing page for returning system users

Home Submissi	ions Review and Di	ispute Manage Entities	O My Profile	Messages	Resour
Welcome to	the Open Pa	yments System		Access the Op User Guide [PI	
Announcements			_	? Need help with Contact Us by	
	od is open starting April 1, 2	 O19. During this period, reporting e work with them directly to resolve to 	and	Review the Op Privacy Policy	
questions, contact the Open phone at 1-855-326-8366. Fo	Payments Help Desk by ema r the TTY line, call 1-844-64	openpayments for information, For all at openpayments@cms.hhs.gov 9-2766. unctions associated with your profil	or by		

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

Figure 210: Submissions Landing page

Home	Submissions	Review and Dispute	Manage Entities	(Q) My Profile	Messages	Resource
Submis	sions					? User Gui
A field with an ast	terisk (*) is required.					
Applicable manuf System.	acturers and applicable	GPOs must submit payme	nts, or other transfers of value	e, and ownership or inv	estment interests to the C	Open Payments
Submit Pay	ment Data					
	old the role of submitter I Data Entry below.	can submit information to	the Open Payments system, 3	Select Bulk File	Download the P List	hysician
reporting template	ources tab for the Open es for the Bulk File Uplo k File Upload	and the second sec	anual Data Entry to submit recomments manual entry online for Manual Data Entry	1 C 1 C 1 C 1 C 1 C 1 C 1 C 1 C 1 C 1 C	The Validated Physician Physician with Inactive L Supplement File per Pro	icense(s) gram Year below
	omitted Paymer	at Pecords			and Physicia	anysician Lists an with Inactive supplement File
To review records		e records you wish to revie	w and the program year for th	e records from the	Download the R Templates	leporting
*Select Entity:		*Select Program Year:			To download reporting te Resources tab.	emplates, see the
ABCDEF Medica		2018	+ Review Rec	ords		
Review Sub	omitted File(s) S	Status				
Once a file for yo	ur entity has been subm	itted, you may review the c	letalls by selecting "Review Fl	le Status."		
Review File Sta	itus					
Physician M	Matching Valida	tion Utility				
To verify obvsicia		select the "Validate Physic	ian" button below and upload	physician		
information on the	new page					

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

Figure 211: View All Button for Review record landing page

A			-	0		-	
Home Submissi	ions Revie	ew and Dispute	Manage Entities	(2) My Profile		Messages	Resource
ABCDE Medical	2018 - Rev	iew Record	ls			Access the O	pen Payments
Below are the records reported year. To edit records (available records, select the "View All" bu	only for a user in a	a "submitter" role) or	view the details of the re	ported	?	User Guide [P Need help with Contact Us b	h the website?
General Payments, etc.). If all the records for the entity as role can attest by selecting the				"attester"	8	Review the O Privacy Policy	pen Payments [PDF]
f you have further questions on how to attest, use the link availa	how to make fina	I submission of reco		nitions, or		with this Page	
Select "Notify Attester" to notify attesters affiliated with the repo	attesters that the	re are records that re			What d	o I do if records the hatching?	
require attestation. Note: Previously attested recor	ds that have been	marked for deletion	have not yet been delete	d from		l complete final	submission?
Records counted as "Marked fo Back to Submissions View Attestation Program Year: 2018		o included in the "A		h Status			
Research Payments		1		View All			
Status	Record Count	Action Required No Action	A				
System Processing Failed Validation	0	Correction					
Failed Matching	0	Correction					
Ready for Submission	0	Final Submission					
Ready for Attestation	1	Attest					
Returned to Submitter Attested †	0	Correction No Action					
Total Payments	11	NO PICTORI					
	1	1					
Marked for Deletion † Attester to confirm deletion of previously Attested records	Record Count	Action Required Attester to Attest de or Reject Deletion	eletion action				
General Payments				View All			
Status	Record Count	Action Required					
System Processing	0	No Action					
Failed Validation Failed Matching	3	Correction Correction					
Failed Matching Ready for Submission	3	Final Submission	_				
Ready for Attestation	2	Attest					
Returned to Submitter	0	Correction					
Attested † Total Payments	3 15	No Action					
Marked for Deletion	Record Count	Action Required					
† Attester to confirm deletion of previously Attested records	0	Attester to Attest de or Reject Deletion	eletion action				
Ownership or Investment Inter	rest			10 6H			
Status	Record Count	Action Required		View All			
System Processing	0	No Action					
Failed Validation	0	Correction					
Failed Matching	4	Correction					
Ready for Submission Ready for Attestation	8	Final Submission Attest					
Relation Returned to Submitter	0	Correction					
Attested †	5	No Action					
Total Payments	17						
Marked for Deletion	Record Count	Action Required	-				
† Attester to confirm deletion of	0	Attester to Attest de	eletion action				
		or Reject Deletion					

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

Figure 212: Delete Selected Button for Payment Category page for General Payments

命		3		D	ſ	ව	Ø		⊠₀	۲
Home	ŝi	bmission	ns Review	v and Disput	e Manage	e Entities	My Profi	ile	Messages	Resource
Paym	ent C	ateg	ory: Ge	neral F	Paymer	nts - A	BCDE Med	dical 20	18	
he table belo	w provide	s informati	on on submitted r	ecords for the	selected report	ing entity, pr	ogram year, and pa	ayment catego	ry.	
			e table can custor							
	records, w									ing to download mo records and downlo
hat should be	reviewed	and correct	cted as required.	Records with v	arning messag	es only (do	not have validation	or matching e	rrors), will not p	are warning messa prevent a record from mined to be valid a
	ted as "Ma	rked for D	eletion" are also	ncluded in the	"Attested" (†) n	ecord count	If you wish to reins	state records n	narked for dele	tion, find the record
							ect the "Cancel Dele			
							ry Page" quick refe efer to the Open Pa			Resources page of
Genera	al Pay	ments								
										Refresh Status
Status			Count	Action	Required					
System Pr			0	No Acti						
Failed Val Failed Ma			7	Correct						
Ready for		on	1		ubmission					
Ready for			6	Attest						
Returned Attested †	o suomit	el.	0	Correct No Acti						
Total Payr	nents		14							
attester mu	st re-attest	to all pays		cted program	year to complet	e deletion L	leted from the Oper Until this re-attestati ecord count.			in
Marked fo	- Deletia		Record		Required					
			Count							
† Attester	to confirm	deletion	0	Atteste	to Attest or R	reject Delet	non			Final Submission
Back to Rev	iew Record	is								
Record St	itus:			le ID:			Record ID:			
Please Sel System Pr	ect		- 1V	aximum 38 di	gits		Maximum 38 e	digits		
Failed Vali Failed Mat	dation			ome System I	avment ID:		Delay in Publi	cation Indica	lor	
Ready for Ready for	Submission Atlestation			and of around	-7		Pléase Select	Constructed		
	o Submitter									
Physician	First Nam	e:	Р	hysician Last	Name:		Physician NPI			
							This is a 10-di	igit number		
License St	ate:		License I	lumber:	Add	iress State:		Zip Code		
Please Se	lect				Pk	ease Select		199999	9099	
Teaching H	iospital N	ame:		eaching Hosp les is a 6-digil			Teaching Hos This is a 9-dig			
Marked for Yes	Deletion		ipient Type: Covered Recipient	Physician	Input M	lethod: ual Entry	Report Type:	Reco	rd Warnings: (0
No			Covered Recipient			ad Files	Consolidated			
Search	Clear A	II Dow	mioad Zip File							
howing	Result	s for:								
uŋ			Update Delay I	ndicator	Cancel Delet	ion i	Return to Atlester	Delete	Selected	Return to Submit
u)				and the second se	Entries -	Page	1 of 2 == ==	Contraction of the local division of the loc		
uŋ			Home System		Amount(\$): 0	Recipient Type:0	Recipient:	Record Status: 0	Marked for Deletion: 0	Delay in Publicati Indicator: 0
Select File		Actions	Payment ID: (1		Physician	'Tom Smith	Failed Validation	No	R&D on New Produ
Select File	DID:0	Actions: View Edit Copy	106	20160915	\$531.50	1.1				
Select File All ID: 132	DID:0	View Edit Copy View Edit		20160915	\$1,000,000.00	Teaching Hospital	Tom Smith	Ready for Submission	No	No Delay Requeste
Select Fill All ID: 132	0 ID:0 0 115159 115697	View Edit Copy View Edit Copy View Edit	106	-			Tom Smith Tom Smith		No No	
Select Fill All ID: 132 N/A 132	0 ID:0 0 115159 115697 3 115185	View Edit Copy View Edit Copy View Edit Copy View	106 106 106	20160404 20160805	\$1,000,000.00 \$506.00	Hospital Physician	Tom Smith	Submission Ready for Attestation	No	No Delay Requeste
All ID: 132	0 ID:0 0 115159 115697 3 115185	View Edit Copy View Edit Copy View Edit Copy	106 106	20160404	\$1,000,000.00	Hospital		Submission Ready for		

<u>Step 5:</u> An on-screen message will appear to confirm you want to delete the selected record (s). To proceed with deletion, select the "Yes" button. To cancel, select "No."

				Showing	10	▼ of 8 E	Intries	Page 1 d	of 1	- 1	Page 1 +		
Select All	File ID:Q	Record ID:0	Actions :	Home Syst Payment (D		Payment Date: 0	Amount(\$):	Recipient Type:o	Recipier	to	Record Status: 0	Marked for Deletion: O	Delay In Publication Indicator: O
	2457	535073	View Edit	401-CRD100		20160804	\$14,000.44	Physician			Attested	Yes	No Delay Requested
	2457	535075	Vièw Edit	401-CRD100	C	onfirm	n	• •			Attested	Yes	No Delay Requested
4	2457	535067	View. Edit	401-CRD100	Note	e that deletineement and	ng records wi re-attestation	ete the select th "Attested" : by the report	status requ ting entity's	ires	Attested	Yes	No Delay Requested
	2457	535071	Wew Edit	401-CRD100				I not be delete estation takes		Open	Attested	Yes	No Delay Requested
1	N/A	54006 T	View Edit			ect "Yes" to action.	delete the red	ord(s). Select	t "No" to ca	ncel	Attested	No	R&D on New Product
	2012	548471	View Edit	401-CRD100					No	Yes	Attested	No	Clinical Investigation on New Product
	3013	548063	View Edit	401-GRD 100		20160804	\$300.00	Physician			Attested	Na	No Delay Requested
	2457	535069	View	401-CRD100		20160804	\$14,000,44	Physician			Attested	Yes	No Delay Requested

Figure 213: Confirm Deletion Notification

You will receive an onscreen notification of the deletion.

Figure 214: Sample General Payments Page With Deletion Confirmation Message

		ents (Sui ing Organization Switch User T		Act)		
Home	Submissions	Review and Dispute	🙆 Manage Entities	Q My Profile	Messages	Resources
Confirmation: • Selected deleted f	record(s) have been s rom the Open Paymen Records" page and se	y: General Pa uccessfully deleted except 1 ts system until re-attestation lect the "Notify Attester" bu	for records in "Attested" : n takes place. Note: If atte	status. Selected record(ested records have beer	s) in "Attested" status n selected for deletion,	go back to the
Search and filter To export the se	ing tools above the table arch results into a CSV cords, will generate an o	submitted records for the sel e can customize the view of the file, select "Download Zip File in-screen error notification. To	ne data. ". This provides a compres	sed file containing the set	arch results. Attempting	
messages that s	hould be reviewed and	"Record ID" hyperlink in the t corrected as required. Record mission and attestation, and t	Is with warning messages of	only (do not have validatio	on or matching errors), w	vill not prevent a
		n" are also included in the "At "Yes", select the checkbox ne				, find the records
		can take on this page, refer t ailed information on how to ed				10
General	Payments					

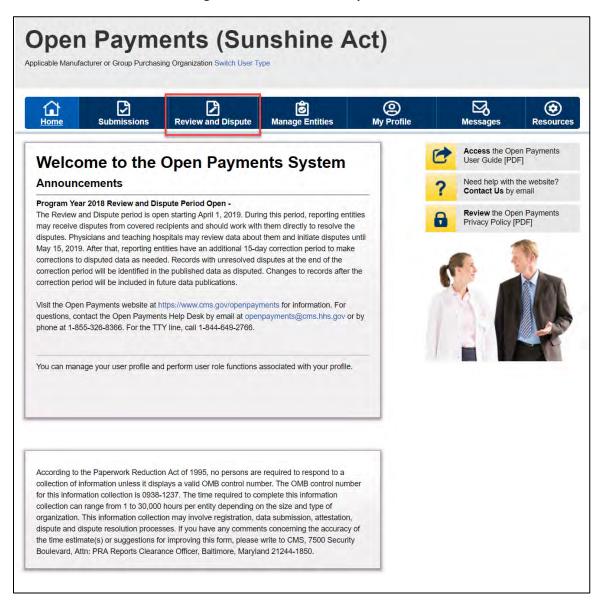
If the record had been previously attested to, it will not be immediately deleted but marked for deletion. To delete records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year.

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 via the CMS Enterprise Portal at <u>https://portal.cms.gov/</u> and select the "Review and Dispute" tab on the toolbar.

Figure 215: Review and Dispute Tab



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

Figure 216: Show Disputes Button

Home Submissions Review and Dispute	Manage Entities	(Q) My Profile		Messages	Resource
Review and Dispute Overview			0		pen Payments PDF, 28.8 MB]
A field with an asterisk (*) is required.		_	?	Need help with Contact Us by	
Applicable Manufacturer or Applicable GPO	Records		-	Review the O	pen Payments
Select a reporting entity and program year from the drop-down list be Disputes." This will display records relating to payments or other trans investment interests for the selected reporting entity and program year	sfers of value, or owners	hip or	6		[PDF, 102 KB]
The review and dispute process begins with an initial 45-day period for hospitals, and principal investigators to review and dispute their data, correction period for reporting entities to resolve disputes and make r data prior to publication.	followed by a 15-day	the			
Physicians, teaching hospitals, and principal investigators may initiate entities from the start of the review and dispute period until the end of					
If any disputes are initiated for the first time after the 45-day review an resolved within the 15-day correction period, the record will be publish initial annual data publication for that year.					
If any dispute results in a change to the covered recipient or principal original record must be deleted and a new record submitted with the information.					
Only records for which attestation was completed by the submission will be eligible for the review and dispute process for that calendar ye		year			
For a complete list of review and dispute rules, refer to the Open Pay	ments User Guide [PDF	i.			
*Show Disputes for:					
ABCD Medical					
*Program Year:					
2017 •					

<u>Step 3:</u> At the bottom of the "Review and Dispute" page, there is a data table. To delete a record, select that record in the data table by selecting the corresponding checkbox and select the "Delete Selected" button. A confirmation message will be displayed prompting the user to confirm if they would like to delete the record or not.

Figure 217: Review and Dispute Record

L Hon	ť	-	٢		2	0	3	9		⊠₀	۲
		Su	bmission	ns Review	w and Dispute	Manage	Entities	My Profil		Messages	Resource
			-					BCDE Med			
				on on submitted i table can custo			ng entity, pro	gram year, and pay	ment categor	y.	
							the a combine	ecod file containing	The courts of	with Attend	ing to download mo
han 400	,000 re	cords, wi	l generate	an on-screen er	ror notification	To correct this	error, adjust	the filtering criteria	to create sma	iller subsets of	records and downle
that shou	uld be n	eviewed a	and correc	ted as required.	Records with w	arning messag	es only (do r	ot have validation (or matching er	rors), will not p	are warning messa revent a record fro mined to be valid a
Records	counte	d as "Mar	ked for De	eletion" are also	included in the	"Attested" (†) re	ecord count	If you wish to reins' t the "Cancel Dele	tate records m	narked for dele	ion, find the record
or more	e inform	ation on I	the actions	s you can take or	h this page, refe	r to the "Payme	ents Categor	y Page" quick refer	ence guide av	vailable on the Ruide [PDF].	Resources page of
Gen	neral	Payr	nents								
Statu				Record	Action	Required					Refresh Status
		cessing		Count							
	m Pro			7	No Actio Correcti						
	d Match			0	Correcti						
Read	y for S	ubmissio		1		bmission					
		testation Submitt		6	Attest						
Attest		Juomit		0	No Actio						
Total	Payme	ints		14							
atteste	er must	usly attest re-attest view and	to all payr	is that have been nents for the sele re eligible for put	ected program y	ear to complete	e deletion U	eted from the Open ntil this re-attestatio cord count.	Payments sy on, the marked	stem. The d records rema	in
Marke	ed for	Deletion		Record	Action	Required					
			deletion	Count		to Attest or R	olast Dalat				
T Alte	ister to	conarm	detecion	U	Anester	to Anest or R	elect Delet	on			Final Submission
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Retur	med to I	Submitter									
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Licens	se Stat	e:		License	Number:	Add	ress State:		Zip Code	99999	
Pleas	se Sele	a		•		Pie	ase Select	•			
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		Deletion:	Real	plent Type:		Input M	ethod:	Report Type:	Record	d Warnings: 1	0
Marke	ed for f	second.			Physician	D Mars		Single	Ves		
Marke	5			overed Recipient overed Recipient				Consolidated	- No		
Yes No	5	Clear A	0 g								
Show	s	Clear A Result	D C	overed Recipient							
Show	s		Dow B Dow	overed Recipient nioad Zip File Update Delay I	Teaching Hospit	al D Uploy	ad Files	Consolidated	Delete	Selected	Return to Submit
Select	ch ing F	Result	s for:	overed Recipient nicad Zip File Update Delay I Showing	ndicator	Cancel Deleti Entries	on R Page 1 Recipient	Consolidated	Delete Page 1 + Record	Marked for	
Show	s ing File ID:0	Record ID:0	Actions:	overed Recipient nioad Zip File Update Delay I	Indicator 10 • of 14 Date: 0	Cancel Deleti Entriés Amount(\$): 0	lon R Page 1 Recipient Type:0	eturn to Attester	Delete Page 1 + Record Status:0	Marked for Deletion: 0	Delay in Publicati Indicator: 0
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Show (Au)	s rch ing F ID:0 1320	Record ID:0 115159	Actions: View Edit Copy View Edit Edit Copy View	Update Delay 10 Bhowing Home System ID. 106	ndicator 10 × of 14 Payment 20160915 20160404	Cancel Deles Entries Amount(\$):0 \$1,000,000.00 \$500,00	on R Page T Recipient Type: 0 Physician Teaching Hospital	etum to Attester etum to Attester of 2 en en Recipient: o Tom Smith Tom Smith	No Delete Page 1 + Record Status: 0 Failed Validation Ready for Ready for	Marked for Deletion: () No	Delay in Publica Indicator: ¢ R&D on New Prod No Delay Request

<u>Step 4:</u> An on-screen message will appear to confirm the user wants to delete the selected record. Select "Yes" to delete the selected record. Select "No" to cancel.

Physic	cian Fir	rst Name	:	Physicia	in Last Na	me: T	eaching H	ospital Name:				
							Please Sele	ct			\checkmark	
Review	w and [Dispute \$	Status:				ayment Ca		Recipient			
Initiat					Yes		General P		Physicia			
	wledge	d Change			🗌 No	L	Research	Payments	Teachin	g Hospital		
Withd	lrawn	onange			Con	firm						
Show [AII]	ing l	Result	ts for:		agreeme attester. Payment	deleting records with that and re-attestation attested records will s system until re-atte es" to delete the rec	by the repo not be dele estation take	rting entity's ted from the Op es place. ct "No" to cance	en el res inge		Search Clear A	cel Deletion
				Showin					Page	1		
Select All	Action	Record ID≎	Home System Payment ID≎	Dispute ID ≎	Recipient	Amount or Dollar Amount Invested \$	Value Of Interest≎	Dispute Status	Jate Dispute Initiated ≎	History of Disputes	Delay in Publication of Research Payment Indicator≎	Marked for Deletion:≎
	View Edit	672652		1001221	Tom Smith	\$5,485.95		Resolved No Change	2018-09-13	View	No	No
	View Edit	672652		1001219	Tom Smith	\$5,485.95		Withdrawn	2018-09-13	View	No	No
	View Edit	672652		1001220	Tom Smith	\$5,485.95		Withdrawn	2018-09-13	View	No	No
				Showin	ng 10 💽	of 3 Entries	Ref Pa	ge 1 of 1 🛛 🔛	► Page	1		

Figure 218: Confirm Deletion Notification

<u>Step 5:</u> An on-screen message displays to confirm the deletion of the selected record.

Figure 219: Deletion Confirmation Message for General Payments

1 Home	Submissions	Review and Dispute	Manage Entities	@ My Profile	Messages	Resourc
1. Home	Submissions	Review and Dispute	Manage Entities	My Profile	Messages	

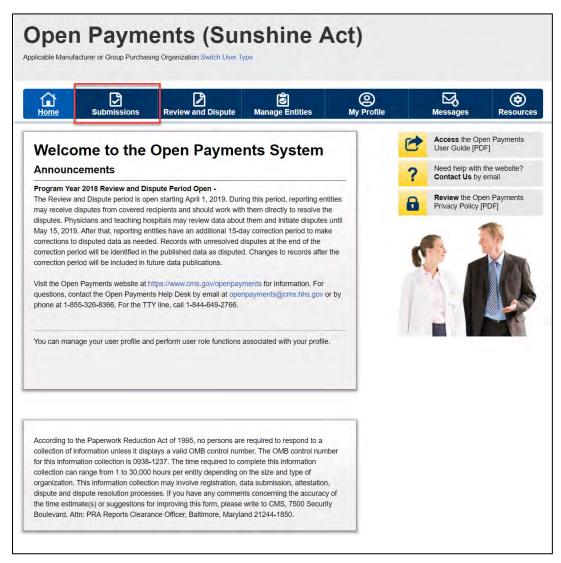
If the record had been previously attested to, it will not be immediately deleted but marked for deletion. To delete records marked for deletion, the attester for the reporting entity must re-attest to the payments for that program year. If the record is in "Attested" status, the record is "Marked for Deletion" until the record is re-attested to. If the record is in the process of being updated and has not been reattested to, the record will be deleted without having to be re-attested to. The system will notify the covered recipient when a disputed record is deleted as part of a Review and Dispute action.

4.10c (3) Deleting a Record from the "Review File Status" Page

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

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

Figure 220: Open Payments system landing page for returning system users



<u>Step 2:</u> Under the "Review File Status" heading, select the "Review File Status" button.

Figure 221: Review File Status Button on Submissions Home Page

Home	Submissions	Review and Disput	te Manage Entities	(Q) My Profile	Messages	Resource
Submiss	ions					? User Gui
field with an asteri	isk (*) is required.					
pplicable manufact ystem.	turers and applicable	e GPOs must submit payr	nents, or other transfers of value	e, and ownership or inv	estment interests to the O	pen Payments
Submit Paym	nent Data					
only users who hold lpload or Manual D		r can submit information t	to the Open Payments system.	Select Bulk File	Download the P List	hysician
	ces tab for the Open for the Bulk File Uplo		Manual Data Entry to submit rec ayments manual entry online for		The Validated Physician I Physician with Inactive LI Supplement File per Prog	cense(s)
Bulk F	File Upload		Manual Data Entry		should not be shared put Validated Phy and Physicia	olicly. ysician Lists n with Inactive upplement File
o review records, s	elect the entity whos	e records you wish to rev	iew and the program year for th	e records from the	Download the R Templates	eporting
Select Entity:		*Select Program Year:			To download reporting ter	mplates, see the
ABCDEF Medical	•	2018	· Review Rec	ords	Resources tab.	
Review Subn	nitted File(s)	Status				
once a file for your o	entity has been subn	nitted, you may review the	e details by selecting "Review F	ile Status."		
Review File Status	•					
hysician Ma	atching Valida	ation Utility				
		, select the "Validate Phys	sician" button below and upload	physician		
nformation on the n	ew page.					

<u>Step 3:</u> Select the File ID link for the file you wish to delete.

Figure 222: File ID link on Review File Status Page

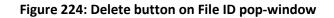
e table be I paymen	Submissions EW File Status Note: Status N	Review a	and Dispute		Entities		Profile	N	lessages	s R	
e table be I paymen	elow displays information on										Resource
l paymen											
	t categories. To access the l	files submitte	d on or after Jar	n 1st, 2019 f	or the reportin	g entities yo	ou are asso	ciated with ac	ross all a	vailable pro	gram yea
e the Sea					sion or Resub	mission file,	select the	hyperlinked fil	e ID in the	e table.	
	arch and Filtering tool to cust	omize your vie	ew of the file inf	ormation.							
ile Statu	IS:	Pav	ment Category	<i>r</i> :		Program	Year:				
Rejected		▲ Ge	neral Payments			2018			-	•	
	d Successfully d with Errors		search Payment nership or Inves		st	2017 2016					
	ed with Warning Failure Occurred				~	2015 2014					
	- File Infected					2013 2010					
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intity:			mission Type:				ion Start I	Date:			
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Search	Clear All										
owin	B 14 6										
	g Results for:										
	g Results for: n Start Date: 20180101										
	n Start Date: 20180101	nowing 50	v of 12 Er	ntries 🖂	A Page 1	of 1 🔛	► Pa	ge 1 v			
e	n Start Date: 20180101	owing 50	• of 12 Er File Status:	tries solutions	Page 1 Submitted By:	of 1 Payment Category:	Program Year:	ge 1 v Type of Submission:	Entity:	Deleted Date:	Deleted
e e	n Start Date: 20180101 St File Name:	lowing 50	File Status: Processed	Submitted Date:	Submitted	Payment	Program Year:	Type of		Date:	
omission	n Start Date: 20180101	nowing 50	File Status:	Submitted	Submitted By:	Payment Category:	Program	Type of Submission:	Entity: Wensco	Date:	Deleted
e :: 20 A	n Start Date: 20180101 St File Name:	nowing 50	File Status: Processed with Warning	Submitted Date: 09/10/2019	Submitted By: ARDALAN ENKESHAFI	Payment Category: Research Payments Ownership	Program Year: 2016	Type of Submission: New Submission	Wensco	Date:	N/A
e e	n Start Date: 20180101 St File Name:	nowing 50	File Status: Processed with	Submitted Date:	Submitted By: ARDALAN ENKESHAFI ARDALAN	Payment Category: Research Payments	Program Year:	Type of Submission: New		Date:	
e e	A Start Date: 20180101	lowing 50	File Status: Processed with Warning Submitted	Submitted Date: 09/10/2019	Submitted By: ARDALAN ENKESHAFI ARDALAN	Payment Category: Research Payments Ownership or Investment Interest	Program Year: 2016	Type of Submission: New Submission New	Wensco	Date:	N/A
pomission le 10 10 10 10 10 10 10 10 10 10	ABCDE_Medical_2018.csv	nowing 50	File Status: Processed with Warning Submitted Successfully	Submitted Date: 09/10/2019 05/13/2019	Submitted By: ARDALAN ENKESHAFI ARDALAN ENKESHAFI	Payment Category: Research Payments Ownership or Investment Interest Ownership or	Program Year: 2016 2016	Type of Submission: New Submission New Submission	Wensco Wensco	Date: N/A N/A	N/A N/A
pomission le 10 10 10 10 10 10 10 10 10 10	A Start Date: 20180101	nowing 50	File Status: Processed with Warning Submitted	Submitted Date: 09/10/2019	Submitted By: ARDALAN ENKESHAFI ARDALAN ENKESHAFI	Payment Category: Research Payments Ownership or Investment Interest Ownership	Program Year: 2016	Type of Submission: New Submission New Submission	Wensco	Date: N/A N/A	N/A
Image: Constraint of the second se	ABCDE_Medical_2018.csv	lowing 50	File Status: Processed with Warning Submitted Successfully	Submitted Date: 09/10/2019 05/13/2019	Submitted By: ARDALAN ENKESHAFI ARDALAN ENKESHAFI	Payment Category: Research Payments Ownership or Investment Interest Ownership or Investment	Program Year: 2016 2016	Type of Submission: New Submission New Submission	Wensco Wensco	Date: N/A N/A N/A	N/A N/A

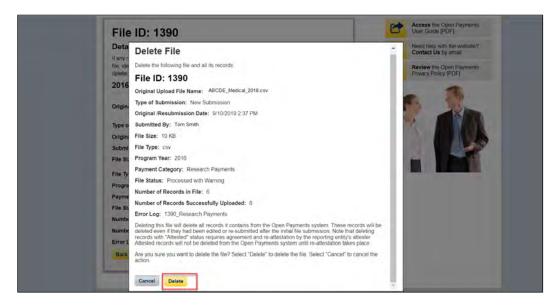
<u>Step 4:</u> Select the Delete button from the File ID Page.

Figure 223: Delete Button on File ID Page

			ð	9	. ⊠o	۲
Home	Submissions F	eview and Dispute	Manage Entities	My Profile	Messages	Resource
File IC): 1390				Access the Op User Guide [PD	
	bout the File Subm	nitted			Need help with	the website?
	s have errors, download this f		log lists all errors found in th	le l	Contact Us by	email
file, identifying	g records by Record ID and H	Iome System Payment I			Review the Op	
	electing the "Delete File" butto				Privacy Policy	PDF1
2010 Res	search Payments	ABCDE Medica			- 1	100
Original Uple	oad File Name:	ABCDE Medic	2010		A	
		ABODE_MEDIC	a_2010.CSV			
Type of Subr	mission:	New Submiss	ion			
Original /Res	submission Date:	9/10/2019 2:3	7 PM		100	
Submitted B	ly:	Tom Smith			1.1.1	
File Size:		10 KB				Contra to
File Type:		CSV				
Program Yea	ar:	2016				
Payment Cat	tegory:	Research Pay	ments			
File Status:		Processed with	Ih Warning			
Number of R	Records in File:	6				
	Records Successfully Uploa	ded: 6				
Number of R	tecords successfully opioa					

<u>Step 5:</u> From the pop-up window, select the Delete button to delete the file.





You will be redirected to the File ID home page and a confirmation message will be present, confirming the payment file has been deleted.

Figure 225: Confirmation Message on File ID page

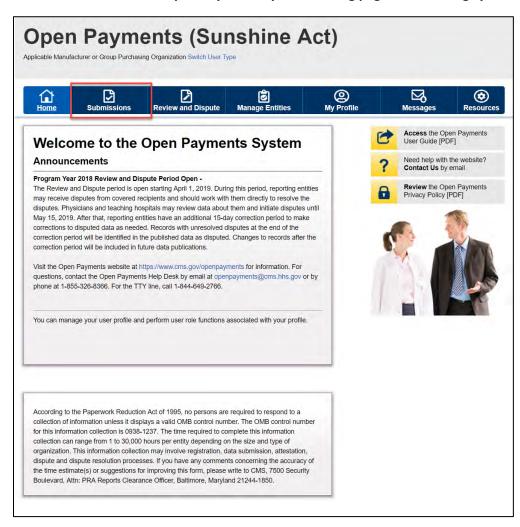
~	-		-	~		-
Home	Submissions F	Review and Dispute	Manage Entities	() My Profile	Messages	Resource
Confirmation	c:			- (Access the Op User Guide [PD	
	ed record(s) have been suc Selected record(s) in "Atte			1 ¹¹	> Need help with	
Payme	nts system until re-attesta of for deletion, go back to	tion takes place. Note:	If attested records have b		Contact Us by	email
Atteste	er" button to send an email require re-attestation.	notification to all attes	ters that there are record	(e)	Review the Op Privacy Policy	
File ID	: 1390			_		
	bout the File Subn	aittad			-	
	have errors, download this t		log lists all orrors found in th	20	N	3 m
file, identifying	records by Record ID and I	Home System Payment I	•			A STA
	lecting the "Delete File" butto				1. 1.	
2016 Res	earch Payments A	BCDE Medical				1
Original Uplo	ad File Name:	ABCDE Medic	ol 2019 cov		1	
		ABODE_medic	a_2010.csv			
Type of Subr	nission:	New Submiss	ion			
Original /Res	ubmission Date:	9/10/2019 2:3	7 PM			
Submitted By	y:	Tom Smith				
File Size:		10 KB				
File Type:		CSV				
Program Yea	r.	2016				
Payment Cat	egory:	Research Pay	ments			
File Status:		Processed wit	h Warning			
Number of R	ecords in File:	6				
Number of R	ecords Successfully Uploa	ided: 6				
Error Log:		1390_Researc	ch Payments	-		

4.10d: Viewing Records Marked for Deletion

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

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

Figure 226: Submissions Tab on Open Payments system landing page for returning system users.



<u>Step 2:</u> From the "Submissions" tab, use the drop-down lists under the "Review Submitted Payment Records" heading to select the reporting entity and program year then select the "Review Records" button.

Home Submissions	Review ar	Dispute	o Manage Entities	O My Profile	N	Messages	Resource
Submissions							? User G
A field with an asterisk (*) is required.						1	
pplicable manufacturers and applica	ble GPOs must su	bmit payments	s, or other transfers of valu	e, and ownership or	investment inte	erests to the Op	en Payments
Submit Payment Data							
Only users who hold the role of submi Jpload or Manual Data Entry below.					List	oad the Ph	
						ted Physician L	ists and
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eporting templates for the Bulk File U Bulk File Upload Review Submitted Paym o review records, select the entity wh rop-down lists below, then select "Re Select Entity: ABCDEF Medical • Review Submitted File(s buce a file for your entity has been su Review File Status	Ipload. Internet Records: Internet Records: Internet Records." Internet Records." Internet Records." Internet Records: Internet Records: I	Open Payme 5 vish to review a ram Year:	ents manual entry online fo Manual Data Entry and the program year for th Review Ref	erre. ne records from the	Physician Supplement should not	with Inactive Lic th File per Prog be shared publy Validated Physician License(s) Su per Program ' Doad the Reates ad reporting ten	ense(s) ram Year belo licly. sician Lists n with Inactiv pplement Fil Year
eporting templates for the Bulk File U Bulk File Upload Review Submitted Paym To review records, select the entity wf trop-down lists below, then select "Re Select Entity: ABCDEF Medical • Review Submitted File(s	Ipload. Internet Records Inose records you very Records." *Select Progr 2018 () Status I) Status Interd, you may dation Utility	Open Paym S vish to review a ram Year: review the deta	ents manual entry online fo Manual Data Entry and the program year for th Review Review Review F alls by selecting "Review F	erecords from the	Physician Supplement should not	with Inactive Lic th File per Prog be shared publy Validated Physician License(s) Su per Program ' Doad the Reates ad reporting ten	ense(s) ram Year belo licly. sician Lists n with Inactiv pplement Fil Year

Figure 227: Review Records Button on Submissions Landing Page

<u>Step 3:</u> Select "View All" next to the payment category for the records you wish to review. If records are still processing select the "Refresh Status" button to refresh the status of the records as they are processed. Note that once the "Refresh Status" button is selected, all other buttons on the "Review Records" page will be disabled until the page has been refreshed. A confirmation message is displayed when the refresh action is completed as described above and displayed in the figure below.

Figure 228: Refresh Status Button for Reporting Entity Review Records page.

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iome Submissions	Reviewa	and Dispute Manage Entitie	s My Profile		Messages	Reso
ABCDE Medica	al 2018 ·	 Review Record 	s	F+	Access the Op	
year. To edit records (available or records, select the "View All" but	only for a user in a	ategorized by the status for the selec submitter role) or view the details of fic payment category (e.g., Research	f the reported	?	User Guide [Pl Need help with Contact Us by	the websit
General Payments, etc.). If all the records for the entity are role can attest by selecting the "E		Attestation" or "Attested" status, a use of All Records" button.	r in an "attester"	8	Review the Op Privacy Policy	
	how to make final	submission of records, details on sta	tus definitions,		with this Page	
Select "Notify Attester" to notify a	attesters that there	e are records that require attestation. eive an email notification that there ar		What d	o I do if records fa natching?	
require attestation.					I complete final :	submission
the Open Payments system. The	attester must re- s marked for dele	marked for deletion have not yet been attest to all payments for the selected tion remain eligible for review, dispute	program year		i complete attest	
		o included in the "Attested" (†) record	count			
Back to Submissions		0000 00 000 0000				
View Attestation						
Program Year: 2018			Refresh Status			
Research Payments		L	View All			
Status	Record Count	Action Required	THE PAR			
System Processing	0	No Action				
Failed Validation	0	Correction				
Failed Matching	0	Correction				
General Payments			Man All			
General Payments			View All			
Status	Record Count	Action Required	View All			
Status System Processing	0	No Action	View All			
Status System Processing Failed Validation	0 0	No Action Correction	View All			
Status System Processing Failed Validation Failed Matching	0 0 0	No Action	View All			
Status System Processing Failed Validation Failed Matching Ready for Submission	0 0 0 0	No Action Correction Correction	View All			
Status System Processing Failed Validation Failed Matching	0 0 0	No Action Correction Correction Final Submission	View All			
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<u>Step 4</u>: On the following page, in the Record Status filter box, check the box for "Yes" under the heading "Marked for Deletion." Select the Search" button. This will display all the records "Marked for Deletion."

Figure 229: Marked For Deletion Button on Reporting Entity General Payments page

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Hom		Sub	missions		and Dispute	Mana	ge Entitles	(Q) My Prof	11e	Messages	Resource
ay	me	nt Ca	ateg	ory: Ger	neral F	ayme	ents -	ABCDE	Medica	1 2018	
e table	e below	provides	informatio	n on submitted re	cords for the	selected rep	orting entity,	program year, and	payment catego	ry.	
				table can custom							
an 400		cords, will						pressed file contain ist the filtering crite			
essage	es that s	hould be	reviewed	and corrected as	required. Rec	ords with wa	iming messag	flagged with a warn ges only (do not har ed to be corrected t	ve validation or	matching errors), will not prevent a
								t. If you wish to rei		narked for delet	ion, find the record
or more	inform	ation on t	he actions	you can take on t	this page, ref	er to the "Par	ments Cales	elect the "Cancel De fory Page" quick re refer to the Open P	ference guide a		
Ger	neral	Payn	nents								
Status				Record	Action	- autred					Refresh Status
	n Proce	reing		Count	No Action	Required					
Failed	Validat	tion		0	Correcti	on					
	Matchi for Su	ng bimission		2	Correcti Final Su	on bmission					
		estation		0	Attest	-					
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atteste	er must	re-attest i	o ali payn	ients for the selec pute, are eligible t	ted program	year to comp	lete deletion.	leleted from the Op Until this re-attesta attested record cou	ation, the marke		
Marke	d for D	eletion		Record Count		Required					
† Atte	ster to a	onfirm de	letion	0	Attester	to Attest or F	Reject Deletio	n			
Back to	Review	w Records									
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		ing bmission lestation		Но	me System I	Payment ID:		Delay in Pub	lication Indicat	ior:	
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Ye Ye	5.		□ ce	wered Recipient Pl		I M	anual Entry	Single	🗆 Yes		
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Seat	ch	Char Al	Down	load Zip File							
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				Update Delay Ini	dicator	Cancel De	letion	Return to Attester	Delete	Selected	Return to Submit
								1 of 1	-1.(200)		
Select	-				T	4 Entries	1	1 011	Page 1 V	Marked for	
	File ID:0	Record ID:Q	Actions:	Payment ID: 0	Payment Date: 0	Amount(\$):	Recipient Type: O	Recipient: O	¢	Deletion: O	Delay in Publicat Indicator: 0
1	358	660122	View Edit	106	20171231	\$5.29	Physician	James Miller	Failed Matching	No	No Delay Requeste
-	N/A	872110	View		20170218	\$5,485.75	Physician	James Miller	Failed Matching	No	No Delay Requeste
	1		Edil	-		-		James Miller	Returned to	Na	No Delay Requeste
_	200	10011234	VIEW.	106							
)	355	660126	Edit	106	20171231	\$5.29	Physician	James Miller	Submitter Returned to Submitter	No	No Delay Requeste

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.

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

Figure 230: Submissions Tab for Open Payments System Landing Page

Home	Submissions	Review and Dispute	Anage Entities	O My Profile	Messages	Resourc
Welco	me to the	Open Payme	ents System		Access the Op User Guide [PI	
Announc				_	? Need help with Contact Us by	
The Review a		pute Period Open - en starting April 1, 2019. Dur cipients and should work wit	• • • •	and a second	Review the Op Privacy Policy	
You can mana	ige your user profile and	d perform user role functions	associated with your profil	ə.		
collection of in	formation unless it disp	n Act of 1995, no persons ar lays a valid OMB control nur	mber. The OMB control nur	nber		
collection can organization.	range from 1 to 30,000 This information collection	1237. The time required to a hours per entity depending on may involve registration, ses. If you have any comme	on the size and type of data submission, attestation			

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

Figure 231: Review Records for Open Payments System Landing Page

Home Submi		and Dispute	🙆 Manage Entities	O My Profile	Mess	3 sages	Resource
Submissions							? User Gu
A field with an asterisk (*) is r	equired.						
Applicable manufacturers and System.	l applicable GPOs must	submit payments,	or other transfers of value	e, and ownership or i	nvestment interes	ts to the Op	en Payments
Submit Payment D	ata						
Only users who hold the role		information to the	Open Payments system.	Select Bulk File	Download	d the Dh	veleion
Jpload or Manual Data Entry	below.	1			List	a the Ph	ysiciali
	A set of the set of th						
			I Data Entry to submit rec nts manual entry online fo	the second se	The Validated Physician with		
	Ilk File Upload.	Open Payme		the second se	Physician with Supplement Fi	Inactive Lico le per Progr	ense(s) am Year belov
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eporting templates for the Bu	ılk File Upload. d	Open Payme	nts manual entry online fo	the second se	Physician with Supplement Fi should not be s Val	Inactive Lico le per Progr shared publi idated Physician ense(s) Sup Program Y	ense(s) am Year belov cly. sician Lists with Inactive oplement File ear
eporting templates for the Bu Bulk File Uploa Review Submitted	IIk File Upload. Payment Recor entity whose records yo	Open Payme	nts manual entry online fo	rm.	Physician with Supplement Fi should not be Val	Inactive Lice le per Progr shared publi idated Physician ense(s) Sup Program Y	ense(s) am Year belov cly. sician Lists with Inactive oplement File ear
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eporting templates for the Bu Bulk File Uploa Review Submitted for review records, select the irop-down lists below, then su Select Entity: ABCDEF Medical	IIk File Upload. d Payment Recor entity whose records yo elect "Review Records." *Select Pro 2018	Open Payme ds	nts manual entry online fo	rm.	Physician with Supplement Fi should not be a	Inactive Lic le per Progr shared publi idated Physician ense(s) Suy Program Y d the Re s eporting tem	ense(s) am Year belov cly. sician Lists with Inactive pplement File ear porting
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eporting templates for the Bu Bulk File Uploa Review Submitted for review records, select the drop-down lists below, then su Select Entity: ABCDEF Medical Review Submitted Droce a file for your entity has	IIk File Upload. Payment Recor entity whose records yo elect "Review Records." *Select Pro 2018 File(s) Status been submitted, you main g Validation Util	Open Payme ds u wish to review ar ogram Year:	Its manual entry online for Annual Deta Entry Ind the program year for the Review Rec Is by selecting "Review F	irm.	Physician with Supplement Fi should not be a	Inactive Lic le per Progr shared publi idated Physician ense(s) Suy Program Y d the Re s eporting tem	ense(s) am Year belov cly. sician Lists with Inactive pplement File ear porting

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

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

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

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

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

Open Pay				,			
Home Submissio	ne Bevie	w and Dispute	Ø Manage Entities	(Q) My Profile		Messages	Resou
ABCDE Medica				ing rome			
Below are the records reported b				ram	6	Access the Op User Guide [PD	
year. To edit records (available o records, select the "View All" but					2	Need help with Contact Us by	the website?
General Payments, etc.)					-	Review the Op	
If all the records for the entity are role can attest by selecting the "E				attester"		Privacy Policy [
If you have further questions on h or how to attest, use the link avail			s, details on status defin	nitions,	-	with this Page	-
Select "Notify Attester" to notify a		And the second second	uire attestation. All activ	e		Status Definitions	(
attesters affiliated with the report require attestation.						o I do if records fa atching?	iled validatio
Note: Previously attested record						I complete final s	
the Open Payments system. The to complete the deletion. Record:				m year	How do	I complete attesta	ation?
publication, until re-attestation is	complete.						
Records counted as "Marked for	Deletion" are also	o included in the "Atte	sted" (†) record count.				
Back to Submissions							
Program Year: 2018			Refrest	Status			
Research Payments			V	ew All			
Status	Record Count	Action Required					
System Processing	0	No Action					
Failed Validation Failed Matching	8	Correction					
Ready for Submission	2	Final Submission					
Ready for Attestation	2	Attest	1				
Returned to Submitter	1	Correction					
Attested †	0	No Action					
Total Payments	38						
Marked for Deletion	Record Count	Action Required					
† Attester to confirm deletion of previously Attested records	0	Attester to Attest del or Reject Deletion	etion action				
General Payments			V	ew All			
Status	Record Count	Action Required					
System Processing	0	No Action					
Failed Validation	2	Correction					
Failed Matching Ready for Submission	0	Correction Final Submission					
Ready for Attestation	0	Attest					
Returned to Submitter	2	Correction					
Attested †	0	No Action					
Total Payments	4						
Marked for Deletion	Record Count	Action Required					
† Attester to confirm deletion of	0	Attester to Attest del	letion action				
previously Attested records		or Reject Deletion					
Ownership or Investment In	terest						
		Aster Destant	V	ew All			
Status System Processing	Record Count	Action Required					
Failed Validation	0	Correction					
Failed Matching	5	Correction					
Ready for Submission	3	Final Submission					
Ready for Attestation	0	Attest					
Returned to Submitter	0	Correction					
Attested †	0	No Action					
Total Payments	8						
	Record Count	Action Required					
Marked for Deletion	Record Count	Renon Required					

Figure 232: View All Button for Open Payments system landing page

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

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

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

Users can download the record information returned by searches on this page to a CSV file by selecting the "Download Zip File" link on the page. The download file will contain all of the columns of data displayed on the Payment Category page. Filters applied on the page will be applied to the download. Downloaded data files cannot exceed the acceptable limit of 400,000 records. If your record volume exceeds the record limit, apply filtering criteria to create smaller subsets of records and download them in multiple files.

Note: The filter for Teaching Hospital CCN should not be used for downloading failed records, as it only returns records that have been successfully validated and matched. It will not return records with a status of "Failed Validation" or "Failed Matching."

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L) me	Su	Dmissio	ns Review ar		Mana	ge Entities	(O) My Profile		Essages	Resources
Pav	me	ent C	ated	jory: Res					Medica	1 2018	
				tion on submitted reco							
				ne table can customiz							
an 400		ecords, w		a CSV file, select "Don te an on-screen error							
o view lessag	all field es that rom co	ts for a re should be	e reviewe	ect the "Record ID" hy d and corrected as re al submission and att	quired. Reco	ords with wa	iming messages o	nly (do not have v	alidation or mat	ching errors),	will not prevent a
e valid		Ad as "Ma	rked for I	Deletion" are also incl	ided in the "	Attested" (1) record count if y	or wish to reinsta	te records mark	ed for deletion	n find the records
				tus of "Yes", select the							
or mor pen Pa	e inforr ayment	nation on Is public v	the actio rebsite. F	ns you can take on thi or detailed informatio	s page, refe	r to the "Pa edit and sul	yments Category F amit records, refer	age" quick refere	nce guide availa ients User Guid	ble on the Re e IPDF, 28.6 (sources page of th MB).
Res	sear	ch Pa	ymer	its							Refresh Status
Statu	s			Record	Action R	equired					Refressi Status
		essing		Count	No Action	1					
Failed	d Valida d Match	ning		8 25	Correctio Correctio	n					
		ubmission itestation		2 2	Final Sub Attest	mission					
	ned to	Submitter		1	Correctio No Action						
	Payme	ents		38	AV ACOOL						
attest	ter mus	t re-attest	to all par	ds that have been ma ments for the selecte	d program y	ear to comp	elete deletion. Until	this re-attestation			
rema	in eligit	ole for rev	iew and d	tispute, are eligible for Record	publication	and are in	luded in the attest	ed record count.			
		Deletion		Count	Action R						
† Alle	ester to	confirm d	eletion	0	Attester I	o Attest or F	Reject Deletion			Fir	nal Submission
Back t	o Revie	w Recon	is								
	rd Stat	and the second		File				Record ID:			
Plan	so Sale	et.			D: mum 38 dig	iffs.		Maximum 38 dig	rts		
Syst Faile	em Pro ed Valid ed Matc	cessing ation									
Real	dy for S dy for A	ubmission ttestation		Hom	e System P	ayment ID:		Delay in Publica	tion Indicator:	753	
Retu	urned to	Submitter						Please Select		~	
Phys	ician F	irst Nam	e:	Phys	ician Last M	lame:		Physician NPI:			
								This is a 10-digit	number		
Licer	ise Sta	ite:		License Nur	iber:	4	ddress State:		Zip Code: 99999	9999	
Plea	ise Sela	ict .					Please Select	2			
Teac	hing H	ospital N	ame:		hing Hospit			Teaching Hospit	al TIN:		
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				and the second second							
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				Non-Covered Recipient	Individual						
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how	vina	Result	s for:								
li											
				Update Delay Indi	ator	Cancel De	letion Retu	Im to Attester	Delete Sele	cted F	Return to Submitter
				Showing 30	✓ of 38	Entries	Page 1 of	4 pr pr P2		_	
Select	File	Record	Actions	Home System	Payment	Amount	Recipient Type: 0		Record	Marked for	Delay in Publication
	ID: ¢	ID:0		Payment ID: O	Date: Q	(\$): 0		recepter Q	Status: Q	Deletion: \$	Indicator: 0
1	373	850344	View Edit	Expiry licenses and active licenses PI failed validation-	20170130	\$9.13	Covered Recipient Physician		Failed Matching		No Delay Requester
3	373	660350	View Edit	Pifaledmatch	20170130	\$9.13	Covered Recipient Physician		Failed Matching	No	No Delay Requested
1	356	860156	View Edi	NCR4-with Incorrect PIFN	20170130	\$9.27	Non-covered Recipient Individual	N/A	Failed Matching	No	No Delay Requested
2	356	050160	View Edit	NCR3- Missing NCR entity name	20170130	\$9.25	Non-covered Recipient Entity	N/A	Failed Validation	No	No Delay Requested
1	258	660140	View Edit	Expiry licenses and active licenses	20170130	\$9.13	Covered Recipient Physician		Failed Matching	No	No Delay Requester
2	373	660325	View Edit	Expiry licenses and active licenses	20170130	\$9.13	Covered Recipient Teaching Hospital		Failed Validation	No	No Delay Requester
1	373	660362	View	NR3-PI Falledmalching	20170130	\$9.26	Non-covered Recipient Entity	N/A	Failed Matching	No	No Delay Requester
		680364	View	2017_Research	20171231	\$1,000.99	Covered Recipient		Failed Matching	No	No Delay Requested
2	N/A:			and the second se	Contraction of the local division of the loc	1	Physician				
2	N/A 373	660362	View		20170130	\$9.27	Non-covered	NA	Ready for	No	No Delay Requestar
	1	-		NCR4-with missing PIFN	20170130	\$9.27 \$9.27	Non-covered Recipient individual Non-covered Recipient individual	N/A N/A	Ready for Submission Failed Validation	No	No Delay Requested

Figure 233: Final Submissions Button for sample Research Payments page

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

Figure 234: Confirm Final Submission page

		ents (Sui		Act)		
Home	Submissions	Review and Dispute	🔊 Manage Entities	(Q) My Profile	Messages	Resources
Confirm	Final Sub	omission			Access the Op User Guide [PI	
Confirm the final s	submission for this data	a category.			Need help with	
that record (e.g.,) edited. To change	physician first name an e covered recipient ider nust delete the original	I submission, the covered rec d last name, NPI, license info ntifying information in a record record and submit a new reco	rmation) is locked and cann I that has undergone final		Review the Op Privacy Policy	en Payments
ABCDE Me	dical					in
2018 Resear	ch Payments					The MA
Total Value:	\$18.53					
Submitter N	ame: Karen Miller	r.			31	
Cancel			Submit as Final Submi	11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		

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

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

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

Figure 235: Reporting Entity Review Records Page

Home Submissi	ons Revie	w and Dispute	Ø Manage Entities	(2) My Profile		Messages	Resources
ABCDE Medic						Access the Op	en Payments
Confirmation: • You have successfully s	submitted your re	cords to Open Payme	ents.		0	User Guide [PD Need help with	
Below are the records reported t ear. To edit records (available of ecords, select the "View All" but	only for a user in a	"submitter" role) or vie	w the details of the reported		1	Contact Us by Review the Op Privacy Policy	email en Payments
Seneral Payments, etc.). f all the records for the entity an			" status, a user in an "atteste	e.	Help	with this Page	
ole can attest by selecting the " I you have further questions on	how to make final	submission of records.	details on status definitions,			Status Definitions o I do if records fa	
r how to attest, use the link ava select "Notify Attester" to notify	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		re attestation. All active		failed n	natching?	
ittesters affiliated with the repor equire attestation.					1000	I complete final s	
Vote: Previously attested record he Open Payments system. The o complete the deblenon, Record sublication, until re-attestation is Records counted as "Marked for Back to Submissions Program Year: 2018	e attester must re- is marked for dele complete.	attest to all payments fi tion remain eligible for	or the selected program year review, dispute, and				
Research Payments			View Al				
Status		Action Required					
System Processing Failed Validation	0	No Action Correction					
Failed Matching	25	Correction					
Ready for Submission	0	Final Submission					
Ready for Attestation	4	Attest					
Returned to Submitter	1	Correction					
Attested †	0	No Action					
Total Payments	38						
Marked for Deletion	Record Count	Action Required					
† Attester to confirm deletion of previously Attested records		Attester to Attest dele or Reject Deletion	tion action	1			
General Payments			View Al				
Status	Record Count	Action Required					
System Processing	0	No Action					
Failed Validation	0	Correction					
Failed Matching	2	Correction					
Ready for Submission	0	Final Submission					
Ready for Attestation	0	Attest					
Returned to Submitter	2.	Correction No Action					
Attested † Total Payments	4	No Action					
Marked for Deletion		Action Required	line mellon				
† Attester to confirm deletion of previously Attested records	0	Attester to Attest dele or Reject Deletion	tion action				
Numera bia na kaunatan ant k			-				
Ownership or Investment I		Action Required	View Al				
System Processing	0	No Action					
Failed Validation	0	Correction					
Failed Matching	5	Correction					
Ready for Submission	3	Final Submission					
Ready for Attestation	0	Attest	-				
Returned to Submitter	0	Correction					
Attested † Total Payments	0	No Action					
and all the set				-			
	Deserved October	Action Required					
Marked for Deletion † Attester to confirm deletion of	A Design and a second second	Attester to Attest dele					

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

Section 4.12: Delay in Publication

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

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

A delay in publication can only be requested up to a period of four years from date of payment (i.e., the record's program year). After four years have elapsed, the delayed records will be published.

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

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

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

4.12a: Eligibility for Delay in Publication

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

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

After four (4) years from the year of payment (i.e., the record's program year) have elapsed, records are no longer eligible for delay, and will be eligible for publication in the next publication cycle.

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

- No Delay R & D on New Product Limit Reached
- No Delay C.I. on New Product Limit Reached

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

4.12b: Initially Requesting a Delay in Publication

When submitting a new record, users can request a delay in its publication as part of the record creation process if it is eligible.

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

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

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

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

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

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

4.12c: Updating a Delay in Publication

Users may request that payment records have their publication delayed for up to four years after the date of payment. The request for a delay must be renewed each year.

If this request is not renewed each year by the end of the data submission period, the record will be automatically flagged for publication in the next publication cycle.

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

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

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

Delayed records that are no longer eligible for a delay but are in "Returned to Submitter" status will not be updated to a "Limit Reached" delay status. These records must be edited and the Delay in Publication Indicator changed to "No Delay Requested" as they are no longer eligible.

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

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

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

4.12c (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.

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

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

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

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

Figure 236: Reporting Entity General Payments Page

	_		-	-		_		_		-	_
Hor		Su) bmissio		nd Dispute	Mana	ge Entities	O My Profile		Messages	Resour
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				ion on submitted reco							
				e table can customiz							
				CSV file, select "Dov e an on-screen error							
hem in r											
nessage	es that om con	should be	reviewed	ct the "Record ID" hy d and corrected as re al submission and att	quired. Reco	rds with wa	rning messages or	nly (do not have val	lidation or ma	tching errors),	will not prevent
				eletion" are also inclu						ked for deletion	n, find the reco
				us of "Yes", select the						lable on the De	
				or detailed information							
-											
Res	ear	ch Pa	ymen	ts							
				Record							Refresh Status
Statu	n Proc	essing		Count	Action Re	ryuned					
Failed	Valida	tion		8 25	Correction						
Ready		bmission		0	Final Sub						
Return	ned to s	estation Submitter		4	Attest Correction						
Attest Total	ed † Payme	nts		0 38	No Action						
Note:	Previo	usly attes	ted record	ds that have been ma	arked for dele	tion have n	ot yet been delete	d from the Open Pa	ayments syste	em. The	
				ments for the selecte spute, are eligible for					me marked n	ecords	
Marke	d for D	Deletion		Record	Action Re	quired					
† Atte	ster to	confirm d	eletion	0	Attester to	Attest or R	leject Deletion				
Back to	Revie	w Record	s								
	rd Stat			File				Record ID:			
Such	se Seler em Proc	Accina		Mask	mum 38 digi	ts		Maximum 38 digit	5		
Faile	d Valida d Match	ning ubmission		Hom	e System Pa	yment ID:	-	Delay in Publicati	on Indicator		1
Read	ly for At rned to	ubmission testation Submitter						Pending Renewal			
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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 onscreen 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.

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

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

- Applicable Manufacturer or Applicable GPO Registration ID;
- Consolidated Report Indicator;
- Resubmission File Indicator (must be "R" for this process);
- Applicable Manufacturer or Applicable GPO Making Payment Registration ID;
- Resubmitted Payment Record ID (the "Record ID" assigned to the original record by the Open Payments system);
- Date of Payment; and
- Delay in Publication of Research Payment Indicator.
 - <u>To renew a delay in publication:</u> Set the indicator to '1' if you are requesting a delay because the record relates to research and development on a new product, or '2' if you are requesting a delay because the record relates to clinical investigation on a new product.
 - <u>To indicate a delay is no longer requested:</u> Set the indicator to '3,' which indicates no delay is requested.

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

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

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

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

4.12c (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.

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

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

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

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

You will receive email notifications regarding your file and record processing statuses. If the file fails filelevel 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.

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

4.12c (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.

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

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

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

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

<u>To Renew a Delay in Publication</u>: From the "Delay in Publication of Research Payment Indicator" dropdown, select either "R&D on New Product" or "Clinical Investigation on New Product." For a general payment record, ensure that the name of the research study is displayed in the "Contextual Information" field, as well as any additional information you deem helpful or appropriate regarding the payment or other transfer of value.

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

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

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

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

4.12c (3)b: Updating the Delay in Publication Indicator via Manual Data Entry - Using Delay in Publication Update Functionality

You can update the delay of publication of eligible general and research payment record(s) from the Payment Category page using the "Update Delay Indicator" button.

Records updated through this process do not undergo re-validation and re-matching.

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

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

This functionality is not available for records that are not eligible for a delay in publication.

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

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

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

<u>Step 4:</u> Select the "Update Delay Indicator" button.

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

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

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

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

4.12d: Delay in Publication - Publication Impact

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

- Records with a Delay in Publication status of "Delay Requested" will not be published in the next publication cycle.
- Records with a Delay in Publication status of "No Delay Requested," "No Delay R&D on New Product Limit Reached," or "No Delay C.I. on New Product Limit Reached" will be published in the next publication cycle.
- If no action is taken on records with a Delay in Publication status of "Pending Renewal" by the end of the submission period, the records will be eligible for publication. These records will be published in the next publication cycle.

Section 4.13: Consolidated Reporting

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

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

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

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

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

4.13a: Performing Consolidated Reporting

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

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

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

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

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

Entity A made a consolidated report submission for itself, Entity B, and Entity C. Entities A, B, and C are all registered within the Open Payments system. Within the bulk data file, each record lists Entity A's information in the "Applicable Manufacturer or Applicable GPO Name" and "Applicable Manufacturer or Applicable GPO Registration ID" fields. The "Applicable Manufacturer or Applicable GPO Making Payment Name" and "Applicable Manufacturer or Applicable GPO Making Payment Name" and "Applicable Manufacturer or Applicable GPO Making Payment Registration ID" fields for each record contains the information for the entity that made that particular payment (Entity A, B, or C).

The submitter of the file must hold the role of submitter for all three entities, A, B, and C. Similarly, the attester must have the role of attester for all three entities, A, B, and C. to attest to records from all three entities.

Once the submission is accepted in the Open Payments system, the payment records for Entity B and Entity C would be listed under those individual entities, and will not be listed under Entity A. When the data is published, the records for Entity A, Entity B, and Entity C will be listed under their own names.

Section 4.14: Third Party Data Submitters

Applicable manufacturers and applicable GPOs may choose to have their data prepared and submitted by a third party organization. Third party organizations may format, prepare, and submit data on behalf of a reporting entity. The role of submitter is the only role third party companies can fulfill within the Open Payments system on behalf of a reporting entity. **A specific individual within the third party must be identified as the submitter, not the third party itself.**

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

Section 4.15: Attestation and Assumptions

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

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

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

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

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

The attester has the option of submitting an assumptions statement during the attestation process. Assumptions explain the reasonable assumptions made, methodologies used, and unusual circumstances that may have occurred when reporting payments, other transfers of value, or ownership or investment interests. Assumptions will be documented in a free-form text field during the attestation process. Users can choose to write free-form text or cut and paste text from another document. Assumptions cannot be longer than 8,000 characters (including spaces) and can be edited later. Users who knowingly submit to the Open Payments system any misrepresentation or any false, incomplete, or misleading information, may be guilty of a criminal act punishable under law and may be subject to civil penalties in accordance with the Open Payments system disclaimer and Title 18 U.S.C Section 1030.

4.15a: Attestation Statements in the Open Payments System

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

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

The text in the Open Payments system reads as follows:

- 1. I attest that I am a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer for the reporting applicable manufacturer or applicable GPO with the authority to attest to the information submitted in the Open Payments system.
- 2. I attest that the information reported is timely, accurate, and complete to the best of my knowledge and belief.
- 3. I attest that my entity is only reporting payments or other transfers of value associated with covered drugs, devices, biologicals, or medical supplies based on one or more of the reasons listed below.

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

- a. My entity's gross revenue from covered drugs, devices, biologicals or medical supplies constituted less than 10 percent of gross revenue during the fiscal year preceding the reporting year.
- b. My entity is under common ownership, as defined by 42 C.F.R. § 403.902, with an applicable manufacturer and provides assistance or support to an applicable manufacturer with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological, or medical supply. Therefore, my entity is only required to report payments or other transfers of value associated with covered drugs, devices, biologicals or medical supplies which my entity provided assistance and support to an applicable manufacturer.
- c. My entity has a separate operating division that does not manufacture any covered drugs, devices, biologicals, or medical supplies. Therefore, my entity is only required to report payments or other transfers of value to covered recipients related to the

activities of these separating operating divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply.

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

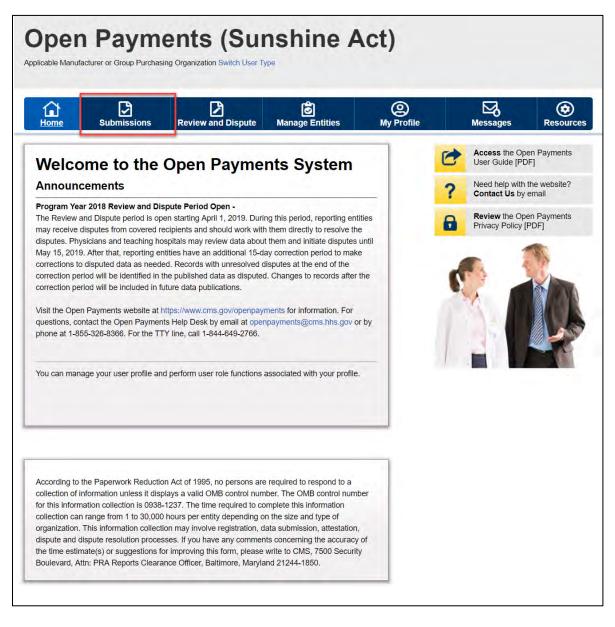
Note: In the event of data submitted as a consolidated report, each individual entity within the consolidated report must attest to the accuracy of its own data. See Section 4.12 for more information on consolidated reporting.

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.

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

Figure 237: Open Payments system landing page for returning system users



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

Home	Submissions	Review and Dis	pute Manage Entitie	es My Profile		Messages	Resourc
Submiss	sions						? User Gu
A field with an aste	erisk (*) is required.					1	
Applicable manufa System.	cturers and applicable	e GPOs must submit p	ayments, or other transfers	of value, and ownership	or investment in	nterests to the O	pen Payments
Submit Payr	ment Data						
Only users who ho Jpload or Manual I		r can submit informati	on to the Open Payments s	vstem. Select Bulk File	Down List	load the Pl	hysician
	and planting product	Daumanta Cal	at Manual Data Entry to au		-		ists and
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Review Sub	s for the Bulk File Uplo File Upload mitted Paymel select the entity whos	Ope o	In Payments manual entry o Manual Data Entry Manual Data Entry review and the program yea	nline form.	Physician Suppleme should no	n with Inactive Li ent File per Prog to be shared pub Validated Phy and Physicia License(s) St per Program	cense(s) gram Year belov licly. ysician Lists n with Inactivu pplement File Year Porting
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Figure 238: Review Records Button on Submissions Landing Page

Step 3: On the "Review Records" page, select the "Begin Attestation of All Records" button.

If the "Begin Attestation of All Records" button is not available, check that all records for the program year are in "Ready for Attestation" or "Attested" status. If they are not, contact a submitter for the

reporting entity and alert him or her that records need to be advanced to "Ready for Attestation" status (i.e., undergo final submission) before attestation can begin.

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

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type Review and Dispute (2) My Profile bmissi **⊠**₀ ٢ Ø Messages **ABCDE Medical 2018 - Review Records** Access the Open Payments User Guide [PDF, 28.8 MB] Below are the records reported by the entity and categorized by the status for the selected program year. To edit records (available only for a user in a "submitter" role) or view the details of the reported records, select the "View All" button under a specific payment category (e.g., Research Payments, Need help with the website? Contact Us by email ? General Payments, etc.). Review the Open Payments Privacy Policy [PDF, 102 KB] If all the records for the entity are in a "Ready for Attestation" or "Attested" status, a user in an "attester" role can attest by selecting the "Begin Attestation of All Records" button. If you have further questions on how to make final submission of records, details on status definitions, Help with this Page or how to attest, use the link available on the right hand navigation **Record Status Definitions** Select "Notify Attester" to notify attesters that there are records that require attestation. All active What do I do if records failed validation or failed matching? attesters affiliated with the reporting entity will receive an email notification that there are records which require attestation How do I complete final submission? Note: Previously attested records that have been marked for deletion have not yet been deleted from the Open Payments system. The attester must re-attest to all payments for the selected program year How do I complete attestation? to complete the deletion. Records marked for deletion remain eligible for review, dispute, and publication, until re-attestation is complete Records counted as "Marked for Deletion" are also included in the "Attested" (†) record count. Back to Submissions Begin Attestation of All Records View Attestation Notify Attester Program Year: 2018 Refresh Status **Research Payments** View All Status Record Count Action Required System Processing No Action Failed Validation Correction Failed Matching Correction Ready for Submission Ready for Attestation Final Submission Attest leturned to Submitter Correction Attested † No Action Total Payme Marked for Deletion Record Count Action Required † Attester to confirm deletion of previously Attested records Attester to Attest deletion action or Reject Deletion **General Payments** View All Status Record Count Action Required System Processing No Action Failed Validation Correction Failed Matching Correction Ready for Submission Ready for Attestation Final Submission Attest Returned to Submitter Correction Attested † No Action Total Paym Marked for Deletion Record Count Action Required † Attester to confirm deletion of 0 Attester to Attest deletion actio or Reject Deletion previously Attested records Ownership or Investment Interest View All Status Record Count Action Required System Processing No Action Correction Failed Validation Failed Matching Correction Ready for Submission Final Submis eady for Attestation Attest Returned to Submitter Correction Attested † No Action Total Payments Marked for Deletion Record Count Action Required † Attester to confirm deletion of 2 Attester to Attest deletion action or Reject Deletion previously Attested records

Figure 239: Ready for Attestation Button on Reporting Entity Review Records Page

<u>Step 4:</u> On the "Confirm Payments" page, review the detailed summary of records being attested to for the program year, displayed per payment category.

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

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

Figure 240: Next Button for Confirm Payments Page

Home Submissions R	eview and Dispute Manage Entities	(Q) My Profile	e Me	ssages R
test	Confirm Payments Select "Go to Review Records" to review ar	nd confirm the subr	nitted records, or se	elect "Next" to move
Confirm Payments	next page.			
Add Assumptions	Note that the number of records marked for records marked for deletion ("Total Value of			
	previously attested and are now marked for	deletion. These re	cords will be remov	ed from the Open F
Agree to Attestations Review and Attest	system after re-attestation is complete. Rec "Attested" record count.	ords counted as "N	larked for Deletion'	are also included i
Viser Guide [PDF, 28.8 MB]	ABCDE Medical General Payments			
Contact Us by email	Record Status	Total Number of Records	Total Amount (\$)	
Review the Open Payments Privacy Policy [PDF, 102 KB]	Ready For Attestation	0	\$0.00	
, indep i oney [i on , ioz (co]	Attested	0	\$0.00	
	Marked for Deletion	0	\$0.00	
	Total for Records Included in Attestation	0	\$0.00	
	Research Payments			
	Record Status	Total Number of Records	Total Amount (\$)	
	Ready For Attestation	0	\$0.00	1
	Attested	0	\$0.00	
	Marked for Deletion	0	\$0.00	
	Total for Records Included in Attestation	0	\$0.00	
	Ownership or Investment Interest			
	Record Status	Total Number of Records	Total Amount Invested (\$)	Total Value of Interest (\$)
	Ready For Attestation	4	\$43.96	\$4.00
	Attested	21	\$224.04	\$21.00
	Marked for Deletion	2	\$20.48	\$2.00
	Total for Records Included in Attestation	23	\$247.52	\$23.00

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

Type or paste your assumptions into this field, which has an 8,000-character limit. The text field allows all special characters found on a standard U.S. keyboard, not including ALT+NUMPAD ASCII Key characters. This text field can be edited later.

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

Figure 241: No Radio Button on Add Assumptions page

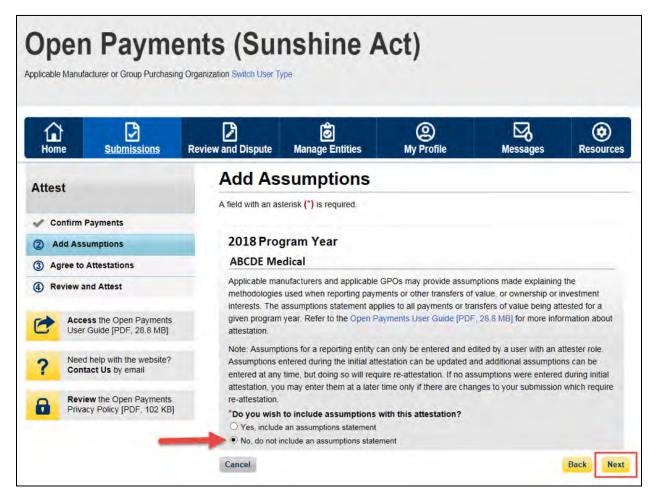
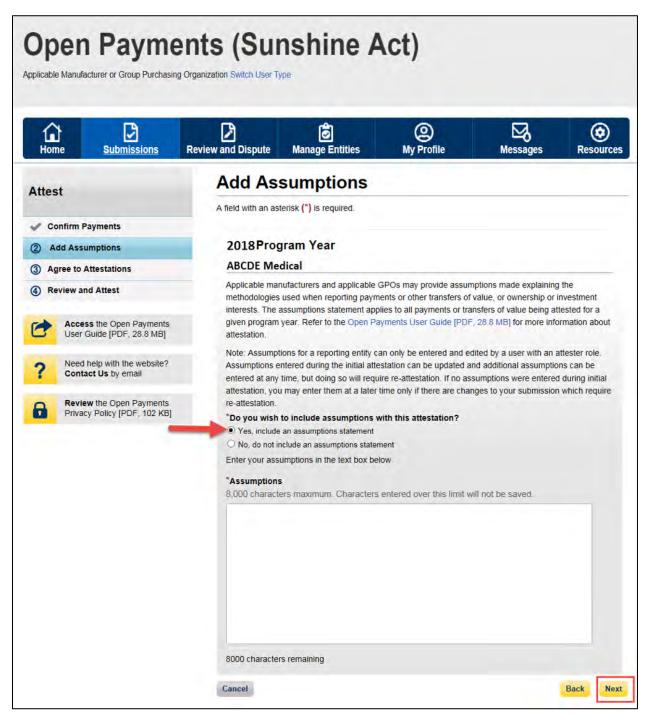


Figure 242: Yes Radio Button on Add Assumptions page



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

Open Payments (Sunshine Act) (i) Ö **⊠**₀ ٢ Agree to Attestations Attest A field with an asterisk (*) is required Please review the information entered and confirm your atte to each of the statements below. ts by sei Confirm Payments Add Assumptions Note that the number of records marked for deletion ("Records Marked for Deletion") and the total value of records marked to deletion ("Charl Value of Records Marked for Deletion") represent records that were previously attracted and a now marked to deletion. These records will be removed from the Open Paymer system after re-attractation is complete. Records counded as "Marked for Deletion" are also included in the "Matter" attract. When complete, elsect "Ostimus". () Agree to Attesta Review and Attest Note: You must, at a minimum, select the first two checkboxes to proceed with the attr corrections, select the "Back" button Access the Open Payments User Guide [PDF, 28.8 MB] ? Need help with the we Contact Us by email 2018 Program Year ABCDE Medical Review the Open Payments Privacy Policy [PDF, 102 KB] Total Records 🕑 Payment Category Total Number of Total Amount (5) General Payments \$0.00 \$0.00 Research Payments a Total Number of Records Total Amount Invested (\$) Payment Category Total Value of Interest (\$) mership or Invest \$247.52 Assumptions View the Assumptions Attestation Agreement The section below contains the altestation statements presented in the Open Payments system. Applicable manufacturers and applicable OPOs are required to contime the attestation statements below by selectiling the checkbookers ento each of the applicable statements. The user must at an mmmum, select the checkbookers next to the first two statements to proceed with the attestation pro-Additionally, when an entity has deleted one or more records having been previously attested to topplication manufacturers and applicable GPOs will be required to re-aftest and confirm the attes statements show there will set the checksoase service to each applicable statement. This use at a minimum, select the checkboxes next to the first two statements to proceed with the re-aftest and the statement is shown as the statement. The use the statement is the statement the statement. The use the statement shows the statement are statement to proceed with the re-aftest and the statement is the statement is the statements to proceed with the re-aftest and the statement is the statement is the statement is the statement is the statement. The statement is the statement is the statement is the statement is the statement. 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 b. The payment or ather transfer of value is related to research or application of an existing drug, device, biological, or medical supply.
 c. The payment or other transfer of value is related to clinical invest of a new 5.1 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 socilicable manufacturers. applicable manufactures, 6.1 am attesting to the action that my entity has deleted one or more re-previously attested, and I am re-attesting that my entity's information repo-complete to the best of my knowledge and belief. Nagadurga Chinappred 3. more records, which have been tion reported is accurate and 8/29/2018 1:29 PM Cancel Back Cont

Figure 243: Agree to Attestations Page

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

Figure 244: Review and Attest Page

Home	Submissions	Review and Dispute	o Manage Entiti	es My Pr		essages	Resou
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		Research Paymer	nts	Ó	\$0.00		_
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		Ownership or Inve	estment Interest	23	\$247.52	\$23.0	0
		View the Assumption Attestation Ag	greement	a Officer Chief Finan	cial Officer, Chief Cor	noliance Officer or	other
		Officer for the repo	orting applicable		blicable GPO with the		
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		James Miller					
		8/29/2018 1:29 PM	M				
		Cancel				Bac	k A

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

	sions Revi	ew and Dispute M	Ó	2			6
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General Payments etc.)	e only for a user in a	"submitter" role) or view	the details of the reported		?	User Guide [PE Need help with Contact Us by	DF, 28.8 ME
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† Attester to confirm deletion previously Attested records	ot 0	Attester to Attest deletion or Reject Deletion	on action				
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Ready for Submission	0	Final Submission					
Ready for Attestation	0	Attest					
	0	Correction					
Returned to Submitter Attested †	0	No Action					

Figure 245: Reporting Entity Review Records Page

Review and Dispute

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

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

This chapter is divided into the following sections:

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

Section 5.1: Review, Dispute, and Correction Overview

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

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

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

Dispute resolution takes place outside of the Open Payments system. Nevertheless, the status of the dispute resolution should be captured within the Open Payments system.

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CMS will not mediate disputes between physicians, physician principal investigators, teaching hospitals, and reporting entities. Reporting entities should work with the disputing party directly to resolve disputes. Only users who hold the role of submitter with the applicable manufacturer or applicable GPO will be able to perform activities related to review, dispute, and correction of record(s).

The process is outlined in **Figure 246**, below.

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

Figure 246: Review, Dispute, and Correction Process

5.1a: Review, Dispute and Correction Period

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

Note that although there is a distinct review, dispute, and correction period, these activities can be performed throughout the year. The designated review and dispute period only affects when and how the dispute is displayed in the initial data publication and subsequent data refresh. For details on data publication, and how the timing of disputes and corrections impacts how the data is published, refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at https://www.cms.gov/openpayments/About/Resources.html.

If you cannot resolve a dispute with a physician, teaching hospital, or physician principal investigator within the 60-day review, dispute, and correction period for a program year, all parties should continue to seek a resolution until the dispute is resolved. Once the dispute is resolved and any necessary corrections are made, the data will be updated in a subsequent publication based on when the corrections were made in the Open Payments system.

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

5.1b: Review and Dispute Statuses

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

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

This chapter explains how applicable manufacturers and applicable GPOs acknowledge, resolve with no change, and resolve disputes with corrections in the Open Payments system.

Email notifications are sent to alert applicable manufacturers, applicable GPOs, physicians, teaching hospitals, and physician principal investigators of review and dispute activities in the Open Payments system. These emails contain information necessary to locate the record in the Open Payments system and may contain contact information in the dispute details. The Reporting Entity Contact Information for disputes, included in your entity's profile, is available on the "Record ID" page of each individual record.

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5.1c: Exporting Disputed Data

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

Figure 247: Download Disputes Zip File Hyperlink

Applicable Manufacturer or Group F			(Suns	shine	e Aci	.,				
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Section 5.2: Acknowledging Disputes and Resolving Disputes with No Change

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

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

When a record undergoes revision to address a dispute, that record will be visible to the physician, teaching hospital, or physician principal investigators identified in it, under the "Deleted and In Progress Records" tab until the record is re-attested. The record will return to the "Available for Review and Dispute" tab of the physician, teaching hospital, or physician principal investigators view, only after the record regains "attested" status.

The five steps of the process are given in Figure 248 below.



Figure 248: Acknowledging Disputes and Resolving Disputes with No Change Process

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

5.2a: Acknowledging a Dispute

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

Figure 249: Review and Dispute Tab on Open Payments System Landing Page

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<u>Step 2:</u> Select the reporting entity name and the program year from the drop-down menus. When finished, select the "Show Disputes" button. This will show users a list of all disputes for the selected entity in that program year.

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type w and Dispute Manage Entities (A) My Profile \Box_{a} ۲ Home 2 Resources Message Access the Open Payments **Review and Dispute Overview** User Guide [PDF, 28.8 MB] Need help with the website? A field with an asterisk (*) is required. Contact Us by email Applicable Manufacturer or Applicable GPO Records Review the Open Payments Select a reporting entity and program year from the drop-down list below, then select "Show Privacy Policy [PDF, 102 KB] Disputes." This will display records relating to payments or other transfers of value, or ownership or investment interests for the selected reporting entity and program year that are disputed. The review and dispute process begins with an initial 45-day period for physicians, teaching hospitals, and principal investigators to review and dispute their data, followed by a 15-day correction period for reporting entities to resolve disputes and make necessary corrections to the data prior to publication. Physicians, teaching hospitals, and principal investigators may initiate disputes with reporting entities from the start of the review and dispute period until the end of that calendar year If any disputes are initiated for the first time after the 45-day review and dispute period and not resolved within the 15-day correction period, the record will be published as not disputed in the Initial annual data publication for that year. If any dispute results in a change to the covered recipient or principal investigator information, the original record must be deleted and a new record submitted with the updated covered recipient information. Only records for which attestation was completed by the submission deadline of that calendar year will be eligible for the review and dispute process for that calendar year. For a complete list of review and dispute rules, refer to the Open Payments User Guide [PDF] Show Disputes for: ABCD Medical ٠ "Program Year: 2017 Show Disputes

Figure 250: Show Disputes for and Program Year Fields on Review and Dispute landing page

<u>Step 3:</u> On the "Review and Dispute" page, find the disputed record(s) to acknowledge. Users may filter the records using the search criteria options to help locate the correct record(s), such as filtering for records with a Review and Dispute status of "Initiated."

- View details about a disputed record by selecting the "View" hyperlink for the record under the "Action" column or by selecting the "Record ID" hyperlink under the "Record ID" column.
- View the detailed history for a record's disputes by selecting the "View" hyperlink for the record under the "History of Disputes" column.

For instructions on how to export this data, see Section 5.1c.

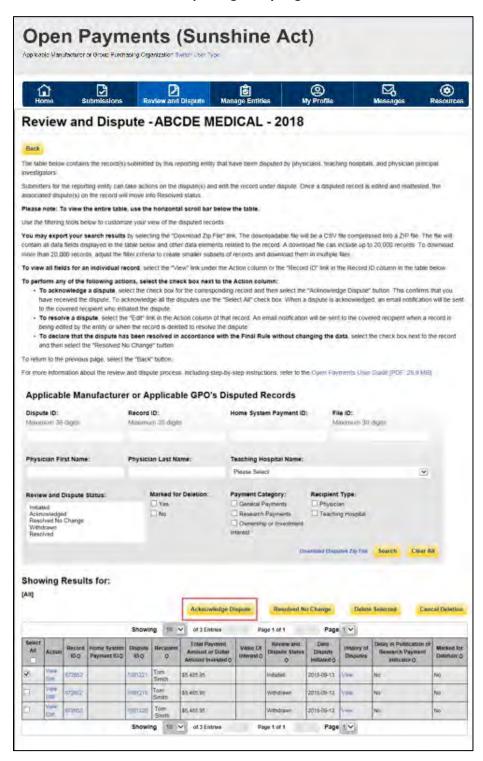
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Figure 251: Search Button on Review and Dispute Reporting Entity Page

<u>Step 4:</u> Select the disputed record(s) to acknowledge, and then select "Acknowledge Dispute." Note: Record(s) must be in "Initiated" status to acknowledge dispute(s). Open Payments User Guide_for_Reporting_Entities_September-2020

Figure 252: Acknowledge Dispute Button on Acknowledge Dispute" Button on Review and Dispute Reporting Entity Page



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

Figure 253: Acknowledge Button on Acknowledge Disputes Page

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

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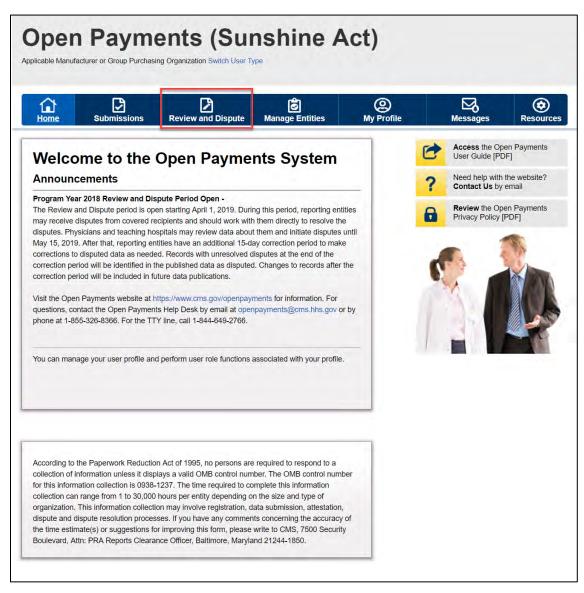
Figure 254: Acknowledge Confirmation Message

5.2b: Resolved, No Change Disputes

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

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

Figure 255: Review and Dispute Tab on Open Payments System Landing Page



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

Figure 256: Review and Dispute Landing Page

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<u>Step 3:</u> 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. Open Payments User Guide_for_Reporting_Entities_September-2020

- View details about a disputed record by selecting the "View" hyperlink for the record under the "Action" column or by selecting the "Record ID" hyperlink under the "Record ID" column.
- View the detailed history for a record's dispute by selecting the "View" hyperlink for the record under the "History of Disputes" column.

<u>Step 4</u>: Select the disputed record(s) users wish to resolve with no changes, and then select the "Resolved No Change" button.

Note: Disputed Record(s) must be in "Initiated" or "Acknowledged" status to resolve dispute(s) with no changes.

Users may only resolve disputes with no changes if the reporting entity and the disputing physician, teaching hospital, or physician principal investigator have resolved the dispute in accordance with the guidance in the Final Rule.

For instructions on how to export this data, see Section 5.1c.

Figure 257: Resolved no Change on Review and Dispute Reporting Entity Page

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<u>Step 5:</u> In the "Reason for dispute resolution with no change to the data" box, enter the reason the dispute has been resolved with no changes. When finished, select the "Resolved No Change" button.

The text box can contain up to 4,000 characters, including spaces. All special characters found on a standard U.S. keyboard can be used, not including ALT+NUMPAD ASCII Key characters.

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

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

Figure 258: Reason for Dispute Resolution With No Change to the Data Text Box

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		nter the reason(s) why the acters, including spaces.	dispute has b	een resolved with no	changes to the data. 1	'he text	
resolved with r physician was	to changes made to able to verify that the forward with resolu-	a dispute that has been re- o the data because there is he payment amount of "six ving the dispute without ch	s now agreem	ent relating to the re I five hundred dollar	ported payment amoun s" dollars is correct. The	t. The erefore,	
		ason for dispute resolution incipal investigator who di			ill be sent in an email to	the	
across multiple to the data" bo assigned "Res	e covered recipients x will be sent to all olved No Change"	ended that the user selecti s at the same time. The sa of the physicians, teaching status at that time. If you h ss for each individual cove	me text used in g hospitals, or have multiple c	n the "Reason for di principal investigato	spute resolution with no rs whose disputes were	o change	
	n is confirmed by th	he selection of "Resolved I		ne status of the disp	ute status will be displa	yed as	
		elect "Cancel." Open Paym	ents User Gui	de [PDF, 28.8 MB].			
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	the same defined with the state	with no change to the da		-			
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4000 character	rs remaining					-	

The following confirmation message will be displayed on the page.

Figure 259: resolved no change confirmation message

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-	ou hav	e succes	ssfully resolv	ed the se	lected dis	pute(s) with no cl	hanges to th	e data. An ema	ail has been	sent to not	tify the covered re	cipient.
Back The tabl		contain	s the record(s)	submitter	d by this re	porting entity that	have been di	sputed by physi	icians, teach	ing hospital	s, and physician pri	ncipal
			ting entity can in the record wi				the record u	nder dispute. Or	nce a dispute	ed record is	edited and reattest	ed, the
	19.00					al scroll bar below	the table.					
Jse the	filtering	tools be	low to custom	ze your v	iew of the d	disputed records.						
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Note that the physician, teaching hospital, or physician principal investigator may initiate a new dispute for the same record if the dispute has not been resolved to their satisfaction.

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

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

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

If the dispute is due to the Physician Demographic Information being incorrect, the record must be deleted and the updated record with the correct demographic information must be resubmitted. To delete a record from the "Review and Dispute" tab, see Section 4.9c.

After re-attestation to the corrected records is complete, the physician, teaching hospital, or physician principal investigator will receive an email notification that the record(s) has been edited and the dispute resolved. If to resolve the dispute the record needs to be deleted, the system will notify the covered recipient when a disputed record is deleted.

The five steps of the correction and resolution process are given in **Figure 230** below.



Figure 260: Correction and Resolution Process

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

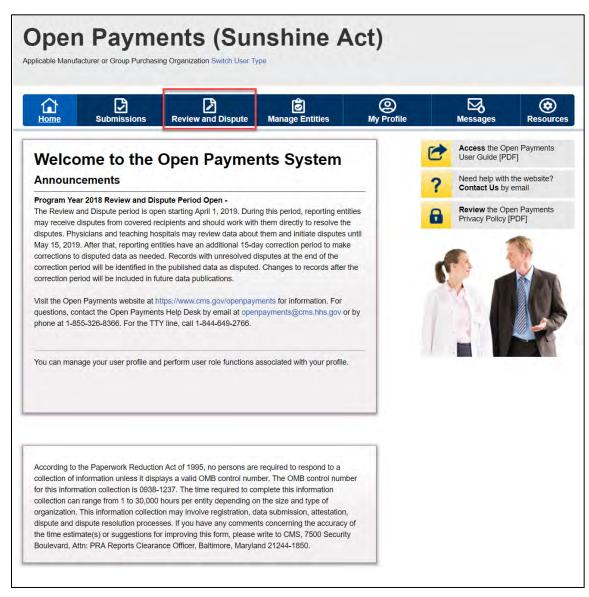
- For physicians (including principal investigators), these identifying fields are First Name, Last Name, NPI, License State, and License Number.
- For teaching hospitals, these identifying fields are Teaching Hospital Name, the hospital address fields, and Taxpayer Identification Number.

Deletion and resubmission may affect the publication timing of the record. Refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at <u>https://www.cms.gov/openpayments/About/Resources.html</u>, for publication rules.

5.3a: Edit Information and Resubmit Record

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

Figure 261: Review and Dispute Tab



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

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Select a reporting entity and pro Disputes." This will display recor	gram year from the drop-down list ds relating to payments or other to elected reporting entity and progra	t below, then select "Show ransfers of value, or ownershi	q	6	Review the O Privacy Policy	
hospitals, and principal investiga	begins with an initial 45-day period tors to review and dispute their di- titlies to resolve disputes and mail	ata, followed by a 15-day	le			
	nd principal investigators may init w and dispute period until the en					
the series of the second s	e first time after the 45-day review ction period, the record will be put that year.	a production of the product of the second				
	e to the covered recipient or princ and a new record submitted with t					
	n was completed by the submissi dispute process for that calendar		ear			
For a complete list of review and under "Resources" in the CMS C	dispute rules, refer to the User G open Payments website.	Suide [PDF, 37.3 MB] located				
*Show Disputes for:						
ABCDE Medical						
*Program Year:						
2018						

Figure 262: Show Dispute For and Program Year Drop-Down

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

To view details about a disputed record, select the "View" hyperlink under the "Actions" column. Users can also view the detailed history for a record's disputes by selecting the "View" link under the "History of Disputes" column. For dispute resolution, a useful filter would be to filter for records with a "Review and Dispute Status" of "Acknowledged" and/or "Initiated," as you can only update and/or correct record(s) with a review and dispute status of "Initiated" or "Acknowledged." For instructions on how to export this data, see Section 5.1c.

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

Figure 263: Edit Hyperlink

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

Note: Fields that identify the record's covered recipient including principal investigators cannot be changed once a record is in a "Ready for Attestation" or "Attested" status. If those fields need to be corrected, the original record must be deleted and then re-submitted as a new record. The relevant fields are as follows:

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

If a reporting entity user edits or deletes a disputed record, an email notification is sent to the covered recipient who initiated the dispute. If the individual who initiated the dispute is a physician's authorized representative with dispute access, an email notification is sent to the physician listed on the record as well. Email notifications are also sent to principal investigators and teaching hospital authorized officials/representatives who disputed a record. All users that have an active dispute for that record will be notified only once per record.

Resubmission and deletion may affect the publication timing of the record. Refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at <u>https://www.cms.gov/openpayments/About/Resources.html</u> for data publication rules.

The dispute history of a record that has been updated will show versions of the record prior to the resubmission as having a status of "Inactive."

Once the record has been changed, it must be re-attested to be made available to the covered recipient under the "Available for Review and Dispute" tab, and the dispute is considered resolved. Until then, the record will be available to the physician or teaching hospital under the "Deleted and In-progress Records" tab with an "In Progress" status. See Section 5.3b.

5.3b: Re-Submission and Re-Attestation

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

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

If a record is deleted and replaced after the submission closing date, the Open Payments system will treat the record as a newly arriving late record rather than a correction. The new records will not be included in the current publication cycle and will be identified as eligible for review and dispute for a future publication. Once a record is deleted, it will no longer be visible to the physicians, teaching hospitals, or physician principal investigators identified in it under the "Available for Review and Dispute" tab. The record will display under the "Deleted and In-progress Records" tab with status "Deleted". Any disputes associated to the deleted record will not be available once the record has been deleted. A record marked for deletion but not yet deleted is still visible to the physicians, teaching hospitals, or physician principal investigators identified in it "Available for Review and Dispute" tab.

The attester will need to re-attest to the accuracy of all re-submitted or deleted data. An attester can only attest to records that have been successfully submitted and validated. Additionally, the attester may decline to attest and request that some or all of the data submitted be returned to the submitter for corrections and review. The attester can select one or more records to return to the submitter and then select the "Return to Submitter" button. The submitter must perform the corrective actions requested by the attester or indicate that no action is required, then select the "Return to Attester" button to notify the attester that records are ready for attestation. For more detailed instructions on attestation of data, see Section 4.14.

For detailed instructions on submitting data, see Chapter 4. For details on how data resubmission affects publication dates, refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at <u>https://www.cms.gov/openpayments/About/Resources.html</u>.

Chapter 6: Messages and Compliance

This chapter provides detailed information on how applicable manufacturers and applicable GPOs are able to track system generated emails for all users and how to review and download electronic correspondence uploaded by the CMS compliance team using the Messages tab. **Note: Only the officer and/or compliance user can access compliance messages upon successful acceptance of the role.**

This chapter is divided into the following sections:

- **System Tab** contains information on system generated email notifications sent and how to search for and view emails sent by the Open Payments system in the past 12 months.
 - Compliance Tab contains information on the compliance related communications sent by the CMS Compliance Team to applicable manufacturers and applicable GPOs on how to view compliance communication information and download associated communication PDF documents.

6.1: System Tab

Reporting entity users have the ability to view system generated messages sent in the past 12 months to any role within the reporting entity. A system generated email is an email generated by the Open Payments System in response to any action performed in the Open Payments system. For example, during the registration process, once a reporting entity registers on the CMS Open Payments system, an email is sent out to the reporting entity confirming registration. This is a system generated email that is able to be viewed on the "System" tab. NOTE: only the officer and the compliance role will be able to view both the system and compliance tab on the "Messages" home page.

The "System" tab is accessible from the "Messages" home page. The "Messages" home page is accessible by clicking the "Messages" tab from the CMS Open Payments home screen banner on the CMS Open Payments home page. Once you are redirected to the "Messages" page from the CMS Open Payments home page, click on the "System" tab to view the following searchable fields: (1) Entity Name, (2) File ID, (3) Record ID, (4) Message Category, and (5) Payment Category. All of these fields are optional to refine your search.

If you are not actively associated to any entity, onscreen text is displayed explaining that you are not currently actively associated with any organization. In this case, the search criteria and table is not displayed.

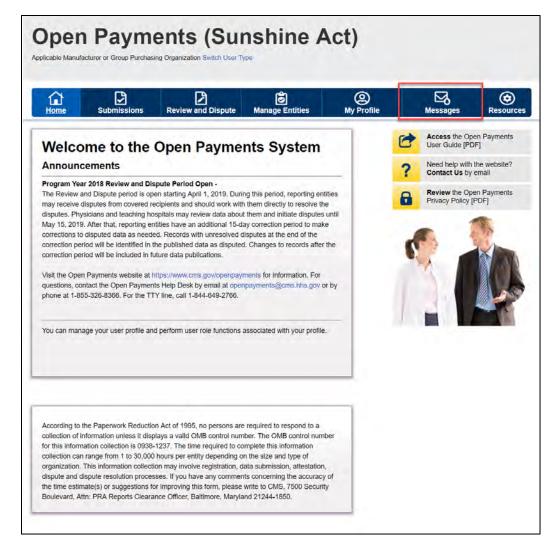
If you are actively associated with at least one entity, on landing, you are presented with only the search criteria. You are required to select values from the search criteria and select the "Search" button before system generated messages are displayed in the result data table. There are no default results on page landing.

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6.1a: Instructions for searching messages

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

Figure 264: Messages Tab



<u>Step 2a:</u> If you only hold the role of submitter and/or attester for your reporting entity, you will be brought directly to the "Messages" page.

Figure 265: Messages Page

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<u>Step 2b:</u> If you hold the role of officer and/or compliance for your reporting entity, you will be brought to the "Messages" page containing the "System" sub-tab and the "Compliance" sub-tab. Select the "System" sub-tab.

Figure 266: System Tab in Messages Page

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<u>Step 3:</u> You can search based on the following search criteria:

- Entity Name
- File ID (only applicable for Message Category of "File Processing")
- Record ID (only applicable for Message Category of "Review and Dispute")
- Message Category
- Payment Category (only applicable for Message Category of "Submissions", "Review and Dispute", "File processing")

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

Home	Submissions	Review and Dispute	Manage Entities	O My Profile	Messages	Resource
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System	Complia	ance				
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Figure 267: Entity Name, File ID, Record ID, Message Category, and Payment Category Fields

<u>Step 4:</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 by newest to oldest. You will see an expandable row section that displays more details about each of the messages.

Figure 268: Search Button for System Tab

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

Figure 269: Message Expandable Arrow

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	Review and Dispute							
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<u>Step 6:</u> Select the "View Full Message" to view the full message. The message will be displayed in a popup window.

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ne table below provides info	rmation on the sy	stem generated email me	essages receiver	d by the reporting entity.		
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ABCDEF Medical		Maximum 38 digits		Maximum 38 digits		
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Figure 270: View Full Message Button

6.2: Compliance Tab

Only reporting entity users, who have officer role or the compliance role, can access the compliance communications. See Section 3.3: Open Payments Users and User Roles for more information on how to assign a user a compliance role. When a compliance communication is uploaded by the CMS compliance team for your entity, an email notification is received by the reporting entity officers, compliance user(s) and primary point of contact

6.2a: Instructions for Searching Compliance Communications

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

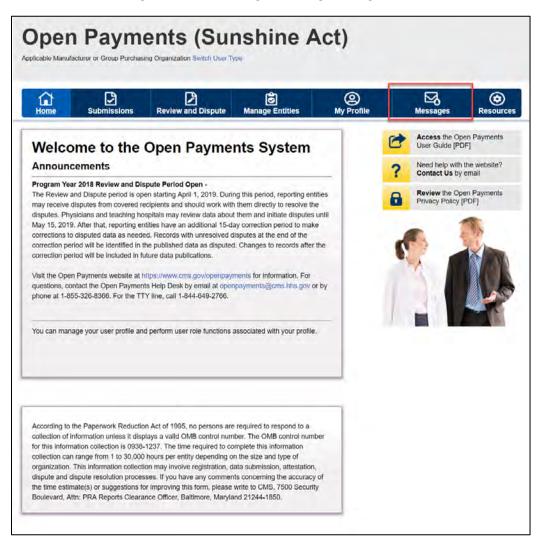


Figure 271: Home Page Showing Messages Tab

<u>Step 2:</u> You will be brought to the "Messages" page. Select the "Compliance" tab. **NOTE: This** functionality is available only for the officer and/or Compliance role.

Home Submissions	Review and Dispute	Manage Entities	(2) My Profile	Messages	Resource
essages					
System Compl	iance				
he table below provides information	n on the system generated ema	ill messages received by th	ne reporting entity.		
earch and filtering tools above the	table can customize the view of	the messages displayed.			
or more information on the actions	you can take on this page, refe	r to the Open Payments U	ser Guide for Reporting E	ntities (PDE)	
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			1000 C	and the set is	
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Entity Name:	File ID: Maximum 38 digits	Rec		and boats	
Entity Name: ABCDEF Medical		Rec	ord ID:		
ABCDEF Medical	Maximum 38 digits	Rec	ord ID:	and the second	
ABCDEF Medical Message Category:	Maximum 38 digits	Rec	ord ID:	and the second	
ABCDEF Medical Message Category: Registration Submissions	Maximum 38 digits	Rec	ord ID:		
ABCDEF Medical Message Category: Registration Submissions Review and Dispute	Maximum 38 digits	Rec	ord ID:		
ABCDEF Medical Message Category: Registration Submissions Review and Dispute Nomination Nomination Reminder	Maximum 38 digits	Rec	ord ID:		
ABCDEF Medical Message Category: Registration Submissions Review and Dispute Nomination	Maximum 38 digits	Rec	ord ID:		
ABCDEF Medical Message Category: Registration Submissions Review end Objoute Nomination Normation Remunder Attestation	Maximum 38 digits	Rec	ord ID:		
ABCDEF Medical Message Category: Registration Submissions Review and Dispute Nomination Nomination Nomination Nomination Reminder Attestation File Processing	Maximum 38 digits	Rec	ord ID:		

Figure 272: Compliance Tab on Messages Home Page

<u>Step 3:</u> You will be able to view all Compliance communications. Select the expandable arrow next to the communication you wish to view. You will see an expandable view of the message text. You will also see a "Download PDF" button. Select the "Download PDF" button to download the compliance document related to each communication.

Figure 273: Download PDF Button

Compliance	2				
			to the particular former state		a second as
		the second distribution of the second s		he reporting entity. The	e "Download
the actions you o	can take on this page, ref	er to the Open Payments U	ser Guide for Reporting E	nuties [PDF].	
Show	ving 10 🔻 of 1 Entr	ries 👒 < Page 1 of 1	Page 1 +		
Subject		Receiving En	tity Date R	eceived Attacl	hment
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Appendix A: Glossary of Terms for Open Payments

Note: The text of the Open Payments Final Rule (42 C.F.R. § 403.902) is available at https://www.cms.gov/OpenPayments/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf.

Applicable Manufacturer:

Applicable manufacturers are entities that operate in the United States and (1) are engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological, or medical supply is solely for use by or within the entity itself or by the entity's own patients (this definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological, or medical supply); or (2) are entities under common ownership with an entity described in part (1) of this definition, which provides assistance or support to such entities with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply. (See 42 C.F.R. § 403.902)

Applicable Group Purchasing Organization (GPO):

Applicable group purchasing organizations (GPOs) are entities that operate in the United States and purchase, arrange for, or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies for a group of individuals or entities, but not solely for use by the entity itself. (See 42 C.F.R. § 403.902)

Assistance or Support:

Assistance or support means to provide a service or services needed to produce, prepare, propagate, compound, convert, market, promote, sell, or distribute a covered drug, device, biological, or medical supply. (See 42 C.F.R. § 403.902)

Biologicals:

For the purpose of Open Payments, biologicals are defined as in Section 1927(k)(2)(B) of the Social Security Act, which includes a cross-reference to licensure under Section 351 of the Public Health Service Act ("PHS Act").

Common Ownership:

Common ownership is when the same individual, individuals, entity, or entities directly or indirectly own five-percent or more of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations. (See 42 C.F.R. § 403.902)

Consolidated Report:

A consolidated report is a report filed by an applicable manufacturer, which includes payments or other transfers of value to covered recipients, physician owners or investment interests for the applicable manufacturer filing and applicable manufacturers under common ownership. (See 42 C.F.R. § 403.908(d))

Covered Recipients:

Covered recipients are any physicians (see <u>Physicians</u> for an extensive explanation of how Open Payments defines this group) who are not employees of the applicable manufacturer that is reporting the payment; or teaching hospitals that receive payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. (See 42 C.F.R. § 403.902)

General Payments:

Payments or other transfers of value not made in connection with a research agreement or research protocol as required in Open Payments.

Non-Covered Recipient Entity:

Non-covered recipient entities are entities that do not meet the Open Payments definition of a covered recipient (see 42 C.F.R. § 403.902). Non-covered recipient entities may include non-teaching hospitals or clinics. A payment or other transfer of value to a non-covered recipient entity is reportable if it is a research payment with at least one associated covered recipient principal investigator.

Non-Covered Recipient Individual:

Non-covered recipient individuals are individuals who do not meet the Open Payments definition of a covered recipient (see 42 C.F.R. § 403.902). Non-covered recipient individuals may include non-physician employees of a teaching hospital or physician-owned practice. A payment or other transfer of value to a non-covered recipient individual is reportable if it is a research payment with at least one associated covered recipient principal investigator.

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Open Payments:

Open Payments is a national transparency program which requires:

- Applicable manufacturers of covered drugs, devices, biologicals, or medical supplies to report information about payments or other transfers of value to physicians and teaching hospitals to CMS every year.
- Applicable manufacturers and applicable group purchasing organizations (GPOs) to report information about ownership and investment interests held by physicians or their immediate family members to CMS every year.
- Applicable GPOs to report information about payments or other transfers of value made to physicians owners and investment interests to CMS every year.

Physicians:

For the purposes of Open Payments, physicians are defined as doctors of medicine or osteopathy practicing medicine or surgery, doctors of dental medicine or dental surgery practicing dentistry, doctors of podiatric medicine, doctors of optometry, or chiropractors, all legally authorized to practice by their state.

Physician Owners or Investors:

Physicians who have an ownership or investment interests in an applicable manufacturer or applicable group purchasing organization. Applicable manufacturers and applicable group purchasing organizations are required to report ownership or investment interests held by a physician or a physician's immediate family member in an applicable manufacturer or applicable group purchasing organization.

Research Payments:

Payments or other transfers of value made in connection with a research agreement or research protocol as required in Open Payments.

Special Characters:

Characters that are neither letters nor numbers. Special characters include punctuation, spaces, and other non-alphanumeric symbols.

Special characters are required in registration fields where appropriate. For example, the "@" symbol and the period are required in email address fields, while dashes are required in telephone number fields.

Data elements of submitted records may contain only the special characters allowed per the "Submission Data Mapping Document," which is found on the Resources page of the Open

Payments website at <u>https://www.cms.gov/OpenPayments/About/Resources.html</u>. 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.

Special Character	Description
+	Plus sign
&	Ampersand
t	Apostrophe
*	Asterisk
@	At sign
\	Backslash
٨	Caret
•	Colon
,	Comma
\$	Dollar sign
Space	Space character
=	Equal
!	Exclamation mark
/	Forward slash
`	Grave accent
>	Greater than
-	Minus sign/hyphen
(Left parenthesis
{	Left curly brackets
[Left square brackets
<	Less than
%	Percent
	Period
#	Pound
?	Question mark
11	Quotation marks
)	Right parenthesis
}	Right curly brackets
]	Right square brackets
;	Semi-colon
	Ріре
~	Tilde
+	Plus sign

Figure 274: Special Characters Allowed in Free-Text Fields

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.

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	0
Ó	0
Ô	0
Õ	0
Ö	0
Ø	0
Ù	U
Ú	U
Û	U
Ü	U

Figure 275: Conversions for Foreign Language Characters

Teaching Hospital:

Teaching hospitals are hospitals that receive payment for Medicare direct graduate medical education (GME), IPPS indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. (See 42 C.F.R. § 403.902). The full list of affected teaching hospitals can be found on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html.

Appendix B: Submission Error Codes

Error codes generated by the Open Payments system for records with validation errors can be found in the Error Code Key, which is located on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/About/Resources or within the Open Payments system by selecting the "Resources" tab.