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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

January 2024

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

Revision History

Version	Date Published	Description	Version Updates
1.0	August 2013	Initial Release	Chapters 1, 2, 3, & 4
2.0	June 2014	Update	Chapters 1, 2, 3, 4, & 7
3.0	July 2014	Update	Chapters 5, 8, & 9
3.1	August 2014	Update	Minor corrections and updates
4.0	December 2014	Update	Updates made to Chapter 5
5.0	January 2015	Update	Chapter 10 and updates for registration and data
			submission
6.0	March 2015	Update	Updates for registration and data submission
7.0	April 2015	Update	Updates for review and dispute
8.0	June 2015	Update	Updated Chapter 10 for PY2014 data publication
9.0	January 2016	Update	Updated throughout to reflect system updates in Jan 2016
10.0	June 2016	Update	Updated publication chapter, added to glossary
11.0	January 2017	Update	Updated to reflect changes to registration and data submission
12.0	June 2017	Update	Updated publication chapter, removed outdated information
13.0	September 2017	Update	Updated to reflect system updates
14.0	January 2018	Update	Updated to reflect system updates
15.0	March 2018	Update	Updated to reflect system updates for Review and Dispute
16.0	January 2019	Update	Updated to reflect system updates
17.0	September 2019	Update	Updated to reflect system updates
18.0	January 2020	Update	Updated to reflect system updates
19.0	September 2020	Update	Updated to reflect system updates
20.0	January 2021	Update	Updated to reflect system updates
21.0	February 2021	Update	Updated to reflect EIDM to IDM Migration changes
22.0	July 2021	Update	Updated to reflect system updates
23.0	January 2022	Update	Updated to reflect system updates
23.1	January 2022	Update	Updated to reflect system updates
24.0	September 2022	Update	Updated to reflect system updates
25.0	January 2023	Update	Updated to reflect system updates
25.1	April 2023	Update	Updated to reflect new IDM password requirements
25.2	August 2023	Update	Updated to reflect new IDM updates
25.3	December 2023	Update	Updated to reflect 24.2 system updates

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

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

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

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

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

Disclosure of the financial relationships between industry and healthcare providers is not intended to signify an inappropriate relationship, and Open Payments does nothing to prohibit such transactions. Collaborations among the medical product industry, physicians, NPPs and teaching hospitals contribute to the design and delivery of life-saving drugs, devices, biologicals, and medical supplies. However, these relationships may also influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care and may potentially lead to increased healthcare costs.

While disclosure alone is not sufficient to differentiate between the beneficial financial relationships and those that may create conflicts of interest, transparency will shed light on the nature and extent of the relationships that exist and discourage development of inappropriate relationships.

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

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

Applicable manufacturers of covered products, and entities under <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, NPPs, 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, NPPs, 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 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, NPPs, 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 2020 took place in February and March of 2021.

The review and dispute period occurs after the submission period ends and extends for at least 45 days. During this period, physicians, NPPs, 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/Resources.

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

June Publication - Initial Publication

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

Early Year Publication - Refresh Publication

- \circ $\;$ 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, 2020 data publication included the initial publication of Program Year 2019 data and republication of prior program years. The 2021 data refresh included f updates to Program Year 2019 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, NPPs, and teaching hospitals review the reported data and dispute any data they believe is inaccurate; industry makes corrections to the data (reflected in the initial publication)	Review, Dispute, and Correction period: April-May
Initial program year initial data publication Prior program year data refresh publication	On or by June 30
Physicians, NPPs, and teaching hospitals continue to review and dispute data; industry continues to make corrections to the data (reflected in the data refresh publication)	June - December 31
Open Payments data refresh	Early in the following year

Figure 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, NPPs, or teaching hospitals to report relevant data regarding the payment or other transfers of value to CMS.

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

<u>Step 1:</u>	Determine if the entity <u>operates in the United States</u> (including any territory, possession, or commonwealth of the United States). See the reference guide in Figure 2.
<u>Step 2:</u>	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 .
<u>Step 3:</u>	Determine if the entity's products are covered drugs, devices, biologicals, or medical supplies, or <u>covered products</u> . See the reference guide in Figure 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

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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.**
- <u>Step 8:</u> 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 2 provides a reference guide for determining if a drug, device, biological, or medical supply manufacturer is an applicable manufacturer in accordance with Open Payments. **Figure 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. 			

Figure 2: Determining if an Entity Is an Applicable Manufacturer

Characteristic	Type 1 Manufacturer IF	Type 2 Manufacturer IF
Covered Products	 Reimbursed by Medicare, Medicaid, or Children's Health Insurance Program AND 	 Same as Type 1 Manufacturer.
	 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. 	

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

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

Figure 3: 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 any physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist or anesthesiologist assistant, or certified nurse-midwife who is not a bona fide employee of the applicable manufacturer that is reporting the payment and teaching hospitals.

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

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

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

- Physician Assistant
- Nurse Practitioner
- Clinical Nurse Specialist
- Certified Registered Nurse Anesthetist or Anesthesiologist Assistant
- Certified Nurse-Midwife

A teaching hospital is any institution that received a payment for Medicare direct Graduate Medical Education (GME), Inpatient Prospective Payment System (IPPS) Indirect Medical Education (IME), or psychiatric hospital IME programs under 1886(d) (5) (B), 1886(h), or 1886(s) of the Social Security Act during the last calendar year for which such information is available.

Additionally, 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) stepparent, stepchild, stepbrother, or stepsister; (4) father, mother, daughter, son, brother, or sister-in-law; (5) grandparent or grandchild; or the (6) spouse of a grandparent or grandchild.

Section 1.4: Open Payments System Overview

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

Applicable manufacturers, applicable GPOs, physicians, NPPs, and teaching hospitals who participate in the Open Payments program must register in the Open Payments system. **Figure 4** provides a high-level process flow.

Data Collection	Applicable manufacturers and applicable GPOs collect data about their financial relationships with physicians, non- physician practitioners, and teaching hospitals.
IDM Registration	Applicable manufacturers, applicable GPOs, physicians, non- physician practitioners, 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, non- physician practitioners, 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, non-physician practitioners, 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 4: High-Level Process Flow for Open Payments

1.4a: Open Payments Browser Requirements

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

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

1.4b: Functionalities within the Open Payments System

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

Key functions of Open Payments system users include the following:

For applicable manufacturers/applicable GPOs: Create an entity profile in the system, submit data into the system, verify the data, and attest to the accuracy of the data.

For physicians/NPPs/teaching hospitals: Register in the system, review the data supplied by applicable manufacturers and/or applicable GPOs, and dispute or affirm the data.

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

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

1.4c: Setting Email Filters to Accept Open Payments Emails

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

1.4d: Accessibility Guidance

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

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

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

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

1.4d (2): Useful JAWS Keystrokes

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

Figure 5: Useful JAWS Keystrokes

Кеу	What it finds	Why this is useful
F	Form field	The F key allows users to move from form field to form field. Most pages in the Open Payments website are made of forms. The F key allows JAWS users to determine what fields are on the Open Payments form pages quickly.
н	Heading	The H key allows users to move from heading to heading. Headings define the structure of many pages. Moving between sections of an Open Payments page allows for a quick guide to page structure and a way to access sections easily.

Section 1.5: Additional Information and Resources

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

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, NPPs, and teaching hospitals understand and participate in the Open Payments program. These resources cover topics such as registration, data collection and submission, the review and dispute process, and data publication. They can be found on the Resources page of the Open Payments website, at https://www.cms.gov/OpenPayments/Resources.

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 6: Receive Email Updates



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

Figure 7: New Subscriber Screen on the CMS Website

Primary Ema	ail Address
You must enter a subscriptions or i	a primary email address. You will use this to access and update your modify your subscriber preferences.
Email Address	* Subscriber@yopmail.com
Confirm Email	*
 Send updates i 	immediately by email
 Send updates of Send updates of 	daily by email
Send updates Send updates Certain high prior	weekly by email rity updates may be sent regardless of your delivery preferences.
O Send updates of O Send updates of O Send updates of O Send updates of Certain high prior Optional Pass	weekly by email rity updates may be sent regardless of your delivery preferences. ssword
 Send updates of Send updates of Certain high prior Optional Pass Enter an optional Password 	weekly by email rity updates may be sent regardless of your delivery preferences. ssword al password to add password protection to your subscriber preferences.
Send updates (Send updates (Send updates (Certain high prior Optional Pass Enter an optional Password Confirm Passwor	weekly by email rity updates may be sent regardless of your delivery preferences. ssword al password to add password protection to your subscriber preferences.

Under the Section "Open Payments," select "General Updates on Open Payments" and then the "Submit" button at the bottom of the page to join the mailing list. You may also select either the boxes entitled "Physicians and Teaching Hospitals", "Non-Physician Practitioner" 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 8: Checkboxes for selecting email updates on the Quick Subscribe screen

Centers for Medicare & Medicaid Services www.ems.gov www.medicaid.gov www.medicare.gov
Quick Subscribe for subscriber@yopmail.com
Centers for Medicare & Medicaid Services (CMS) offers updates on the topics below. Subscribe by checking the boxes; unsubscribe by unchecking the boxes.
Access your subscriber preferences to update your subscriptions or modify your password or email address without adding subscriptions.
🗄 🗆 Medicare Tools & Information
🙂 🗆 Medicare-Medicaid Coordination
🕀 🗆 Innovations
⊕ □ Regulations & Guidance
🗄 🗌 Research, Statistics, Data, & Systems
Outreach & Education
Office of Acquisition and Grants Management
CMS Internal Communications
Gegional Office Lists
🗄 🗆 Resources & Tools
🗄 🗌 WETG Email Updates
⊞ □ Chief Technology Office
□ □ Open Payments
General Updates on Open Payments
Physicians and Teaching Hospitals
Applicable Manufacturers and Group Purchasing Organizations
□ Non-physiclan practitioner
⊡ CMS System Notifications/Outages
I IQIES S&C
🗄 🗌 Provider Compliance
🗄 🗌 OIS Portal Project
🕀 🗌 Master Data Management (MDM)
Submit Cancel
Your contact information is used to deliver requested updates or to access your subscriber preferences.
Privacy Policy Cookie Statement Help

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 data elements used for payment data input into the Open Payments system can be found in the "Submission Data Mapping Document." Due to changes in record formats, there are three versions of the Submission Data Mapping document, one for Program Year 2016-2020 and one for Program Years 2021-2022, and 2023-onwards. The two documents are available on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/Resources. These documents provide specific, detailed descriptions of the information that must be collected by reporting entities to document general, research, and physician ownership/investment interest payments.

Section 2.1: General Payments Reporting and Data Collection

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

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

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

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

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

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

On the Resources page of the Open Payments website

(<u>https://www.cms.gov/OpenPayments/Resources</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 in the "Resources" tab of the Open Payments system.

Figure 9: Open Payments System "Resources" Tab for submitters displaying available reporting templates



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

Section 2.2: Research Payments Reporting and Data Collection

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

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

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

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

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

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

On the Resources page of the Open Payments

website(<u>https://www.cms.gov/OpenPayments/Resources</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 three research payments sample files, one for PY 2016-2020, one for PY 2021 to 2022, and one for 2023 and onwards.

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

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

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

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

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

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

On the Resources page of the Open Payments website <u>https://www.cms.gov/OpenPayments/Resources</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 are two physician ownership/investment sample files: One for PY 2016 to 2022, and one for PY 2023 and onwards.

Registration

Chapter 3: Applicable Manufacturer and Applicable GPO Registration

This chapter provides information on registering in CMS's Identity Management system (IDM) via the CMS Enterprise Portal at https://portal.cms.gov and registering in the Open Payments system. All applicable manufacturers and applicable GPOs that make payments or other transfers of value to covered recipients and physician owners or investors for the Open Payments program must complete registration for both systems (IDM and Open Payments) prior to reporting payments or other transfers of value made to physicians, NPPs, and teaching hospitals. 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. Each individual user is required to create their own account.

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 IDM via the CMS Enterprise Portal, as well as creating an entity profile in the Open Payments system.

IDM Registration, which provides details on registering for IDM 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 IDM to obtain log in credentials. Once you have registered in IDM, you are able to create your entity profile in the Open Payments system.

Open Payments registration is completed in two steps, illustrated in Figure 10. First, users must obtain IDM 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 10: Applicable Manufacturer and Applicable GPO Registration

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

Identity Management (IDM) is an identity management and services system that (1) serves as an identity proofing tool to verify a person's identity and (2) provides you with access to CMS applications, including Open Payments. Registering in IDM provides you with login credentials **required** for access to the Open Payments system. You will be able to set up your own login credentials in the form of a user ID and password during the IDM registration process. IDM credentials allows you to log in to the CMS Enterprise Portal and request access to various CMS applications, including the Open Payments system.

To begin the registration process, access IDM via the CMS Enterprise Portal at <u>https://portal.cms.gov</u>. A list of IDM FAQs is available on the CMS portal at <u>CMS Enterprise Portal - Help Center</u>, and information

about IDM registration can be found on the Resources page of the Open Payments website at <u>https://www.cms.gov/OpenPayments/Resources</u>.

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

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

IDM will automatically remove your account if you have not logged in for two years or more. Once removed, the account cannot be reactivated again and you will be required to set up a new account using steps in Section 3.2b through 3.2d, followed by steps in Section 3.4.

3.2a: System Requirements

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

Disable pop-up blockers prior to accessing CMS Enterprise Portal.

Use one of the following browsers with JavaScript enabled:

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

3.2b: IDM New User Registration

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

<u>Step 1:</u> On the CMS Enterprise Portal page, select **New User Registration** to continue.

CMS.gov Enterprise Portal	🖬 Applications 😔 Help 🕕 About
	~
Login Login	with PIV Card
CA	S.gov Enterprise Portal
UserID is a	required field
Password	s a required field
▼ lagreet	o the Terms & Conditions
	Login
Forgot your Need to unit	Jser ID or your Password? ek your account?
	New User Registration
	All all a

Figure 11: CMS Enterprise Portal Public Landing Page

<u>Step 2:</u> On the "Select Your Application" page, select "Open Payments" 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.

CMS.gov Enterprise Portal		Applications	? Help	() About
	Step #1: Select Your Application			
	Step 1 of 3 - Select your application from the dropdown. You will then need to agree to the terms & conditions.			
	Select Your Application			
	Novitasphere			
	One Program Integrity System (OnePI)			
	OneMAC			
	Open Payments			
	PARHM Dashboard			
	Payment Recovery Information System (PRIS) - RAC & RADV Appeals			

<u>Step 3:</u> Accept the Terms and Conditions of the CMS Enterprise Portal page and then select **Next** to continue.



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

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

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

"PII" is information that can be used to uniquely identify, contact, or locate a single person, or can be used with other sources to uniquely identify a single individual. Personal information collected will be used for the purpose of verifying your identity only. <u>Step 4:</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)
- Date of Birth (Month, Date, Year)
- Is Your Address US Based (Yes/No)
- Home Address, City, State, Zip Code
- Personal Email Address
- Confirm Email Address
- Personal Phone Number

Enter your legal name, current home address, primary phone number, and email address correctly. IDM collects personal information only to verify your identity with Experian, an external identity verification provider (explained in the next section). If this information is not validated successfully and identity proofing fails, contact the Open Payments Help Desk at 1-855-326-8366.

Figure 12: Register Your Information Page

CMS.gov Enterprise Portal					Applications	? Help	i About
	Step #2: Register Step 2 of 3 - Please enter your personal an All fields are required unless marked (op	Your Information d contact information. ptional).					
	Enter First Name	Enter Middle Name (optional)	Enter Last Name	Suffix (optional)			
	Select Birth Month 🗸	Select Birth Date 🗸	Select Birth Year 🗸				
	Is Your Home Address U.S. Bas	sed?					
	Enter Home Address Line 1		Enter Home Address 2 (optional)				
	Enter City	Select State 🗸	Enter ZIP Code	Enter ZIP+4 Code (optional)			
	Enter Email Address		Confirm Email Address				
	Enter Phone Number				_	_	
	Back	Next	Cancel		Hov helj	v can I o you?	

NOTE FOR INDIVIDUALS WITH FOREIGN ADDRESSES: Individuals with addresses outside of the United States can register in IDM 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 5:</u> On the "Create User ID, Password & Security Question/Answer" page, create an IDM user ID and password in accordance with the guidance provided below. You will be asked to select a security question and provide a security answer. Select the **Next** button when finished.

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

Figure 13: Create User ID, Password & Security Question/Answer Page

Step #3: Create User ID, Password & Security Question/Answer	
Step 3 of 3 - Please create User ID and Password. Select a Security Question and provide Answer.	
Enter User ID	
Enter Decoverd	
Security answer to be used in case you forget your password or you need to unlock your account.	
Select Your Security Question	~
Enter Security Answer	
Back Next Cancel	

- The CMS Portal User ID must:
 - Must be between 6 74 characters and contain at least one letter;
 - Can contain alphanumeric characters;
 - Allowed special characters are limited to hyphens (-), underscores (_), apostrophes ('), and periods (.)
 - The @ symbol is allowed only if the User ID is in a valid email address format (j.doe@abc.edu or 123@abc.com)
 - Cannot contain 8 consecutive numbers;
 - Cannot begin or end with special characters;
 - Cannot contain more than 1 consecutive special character;
- Password Requirements:
 - Password must be a minimum of 15 characters;
 - Password must contain: 1 upper case and 1 lower case letter, and 1 number;
 - The following special characters may be used: "!#\$%&'()*+,-./\:;<=>?@[]^_`{
 - Password cannot contain: Parts of User ID, First Name, Last Name, common passwords;
 - Password can only be changed once every 24 hours;
 - Password must be different from the last 6 passwords;
 - Password must not exceed 60 chars.;
- Confirm password:
 - Confirm password;
 - Enter the same password;
- Select your security question:
 - Select a question from the dropdown list of questions;
- Security answer:
 - Can contain alphanumeric characters;
 - Can contain spaces;
 - Must be at least 4 characters;
 - Cannot contain part of the security question;
 - Your security answer will be required in order for you to reset your password or unlock your account;

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

Figure	14: New	User	Registration	Summary F	age
					0-

Application Description : Open Payments is a national disclosure program that promotes a transparent and accountable health care system by making indications and providers and group purchasing organizations (GPOs) and health care providers available to the public. The Op (OPS) is used by applicable manufacturers and group purchasing organizations (GPOs) and health care providers available to the public. The Op (OPS) is used by applicable manufacturers and group purchasing organizations (GPOs) and health care providers available to the public. The Op (OPS) is used by applicable manufacturers and GPOs to report payments and other transfers of value made to covered recipients, as well as certain informations interests held by physicians or physicians' immediate family members. OPS is also available for covered recipients and preprint is related to review and dispute of reported data. Covered recipients may use OPS for activities related to review and dispute. Covered free physicians, non-physician practitioners and teaching hospitals. For more information and full definitions of covered recipient types visit the Open Payments. First Name Karen Enter Middle Name (optional) Last Name Miller Suffix (optional)	ing the financis en Payments Sy ormation regard rovides cipients include ments website
Application Description : Open Payments is a national disclosure program that promotes a transparent and accountable health care system by making relationships between applicable manufacturers and group purchasing organizations (GPOs) and health care providers available to the public. The Open (OPS) is used by applicable manufacturers and GPOs to report payments and other transfers of value made to covered recipients, as well as certain information in the ownership or investment interests held by physicians or physicians' immediate family members. OPS is also available for covered recipients and p functionalities related to review and dispute of reported data. Covered recipients may use OPS for activities related to review and dispute. Covered Recipients are physicians, non-physician practitioners and teaching hospitals. For more information and full definitions of covered recipient types visit the Open Payments. First Name Karen Enter Middle Name (optional) Last Name Miller Suffix (optional)	ing the financia ren Peyments 9 ormation regard rovides cipients include ments website (
Fint Name Last Name Karen Enter Middle Name (optional) Miller Suffix (optional)	
	0
	4
Birth Month Birth Date Birth Year	
April V 1 V 1976 V	
Home Address Line 1 7100 Security Bivd Enter Home Address 2 (optional)	
City State ZIP Code	
Baltimore Maryland V 21244 Enter ZIP+4 Cor	de (optional)
Email Address	
karen.miller@yopmail.com karen.miller@yopmail.com	
222-222-2222	
All fields are required unless marked (optional).	
User ID karenimiller Enter Password	
User ID karenmiller Enter Password Confirm Password Security Question	
User ID karenmiller Enter Password Security Question What is the toy/stuffed animal you liked the most as a kid?	

<u>Step 7</u>: A "Confirmation" page is displayed acknowledging successful registration in IDM. Select the "CMS.gov Enterprise Portal" link (top left) or the **Login** link in the green window to take you to the CMS Enterprise Portal home page. Note that profile configuration can take up to 24 hours. If you are unable to log in after that timeframe, call the Open Payments Help Desk at 1-855-326-8366. For the TTY line, call 1-844-649-2766.

Figure 15: Confirmation Page

CMS.gov Enterprise Portal	Applications	? Help	i About	🖂 Email Alerts
Confirmation Your User ID has been successfully registered with CMS Enterprise Portal. An email has been sent to your registered email ac You can now login.	ldress.		×	
				-

Step 8: Request access to the Open Payments system.

3.2c: Requesting Access to Open Payments with IDM Credentials

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

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



Figure 17: CMS.gov Enterprise Portal Landing Page

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



Figure 18: Registering a Multi-Factor Authentication (MFA) Device

Next, enter the information for your MFA (in figure 19, the user selected "Text Message (SMS)" as their MFA device).



Figure 19: Entering Device MFA Information

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

Figure 20: "My Portal" Page

CMS.gov My Enterprise Portal		•	🖲 Karen Miller 👻	0 Help	🕀 Log Out
	My Portal	Add Application			
		Previous Login: <u>View Login History</u>			
	Welcome to CMS Enterprise Portal. Welcome Karen Miller to CMS Enterprise Portal Vorus esteted on Properses application during your registration. You can request access to this application by clicking here You may request access to other applications by selecting 'Add Application' button.	2			
	Learn how to add Multi-Factor Authentication (MFA) devices via My Profile in the Manage MFA Devices	section.			

Step 3: Select Open Payments from the dropdown. There are three roles that are applicable for users:

Reporting Entity Officer or Teaching Hospital Authorized Official Role: Only US users that are registering a NEW reporting entity profile (applicable manufacturer or applicable group purchasing organization) not already registered in the Open Payments system or a NEW teaching hospital profile, should choose this role. Go to Step 3a (below) to request this role.

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

Only US and foreign (those users that do not have a US-based address and/or a US Social Security number) physicians, non-physician practitioners, and users nominated for a role by a covered recipient/registered entity should choose this role including reporting entity officers and teaching hospital authorized officials who were nominated (or are self-nominating). Users who will be registering a NEW reporting entity profile (applicable manufacturer or applicable group purchasing organization) or users registering a NEW teaching hospital profile should NOT choose this role. **Go to Step 3a (below) to request this role.**

Open Payments Foreign User Role: Only foreign users (those users that do not have a US-based address and/or a US Social Security number) who are registering a NEW reporting entity profile (applicable manufacturer or applicable group purchasing organization) not already registered in the Open Payments system) or a NEW teaching hospital profile, should choose this role. **Note:** After selecting this role, users should wait for an email from the Open Payments Help Desk that will provide additional information. **Go to Step 3c (below) to request this role**.

	Select a Role	
	CMS Compliance	
-	Government Agents File Transfer Research File Transfer	
6	Reporting Entity Officer or Teaching Hospital Authorized Official	
	Physician, Non-Physician Practitioner, Teaching Hospital Authorized Representative, or Reporting Entity Submitter/Attester/Compliance	

Figure 21: "Request Application Access" Page

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

1) Select the Reporting Entity Officer or Teaching Hospital Authorized Official Role, and then select Next.



2) Next, select Launch to begin Identity Verification (RIDP).



3) Select Next to begin.

CMS.gov My Enterprise Portal	i My Apps		.IDM Foreign ▼	😯 <u>Help</u>	🕩 <u>Log Out</u>
Step #1: Iden	tity Verification Overv	view			
To complete this role request, it about you.	is important to note that Experian, a trusted and reliable	e agent, needs to collect	further details		
Please ensure that you have ent birth, and your personal e-mail a	ered your full legal name, current home address, your p address correctly to ensure a seamless and secure proce	ersonal primary phone n ess.	umber, date-of-		
For additional information or as http://www.experian.com/help.	sistance, we encourage you to visit the Experian Custom	ner Assistance website:			
Experian identity verification is l <u>Help Desk</u> to verify your identity	limited to US addresses and US territories only. If you ha	we a foreign address plea	ase call your <u>Tier 1</u>		
Next	Cancel				

4) Experian will perform a soft credit inquiry to verify your identity. Identity proofing does not affect your credit score. Soft credit inquiries are visible only to the user and only appear on credit reports produced by Experian. Credit inquiries are not visible to lenders. If you order a credit report from Experian, you will see an entry of inquiry by the Centers for Medicare & Medicaid Services with CMS's address and the date of request. If you have questions about Experian's verification process, please refer to Experian Customer Assistance at <u>http://www.experian.com/help/</u>.

5) After reading the Terms and Conditions, select Next.

CMS.gov My Enterprise Portal	III My Apps	•	🛢 Karen Miller 🔻	🛛 Help	🕒 Log Out
	Step #2: Accept Terms & Conditions				
	OMB No. 0938-1230 Expiration Date: 08/31/2025 Paperwork Reduction Act		*		
	Protecting Your Privacy				
	Protecting your Privacy is a top priority at CMS. We are committed to ensuing the security and confidentiality of the user registering to EIDM. Please read the CMS. Privacy Act Statement, which describes how we use the information you provide.				
	Personal information is described as data that is unique to an individual, such as a name, address, telephone number, Social Security Number, and date of birth (DCI CMS is wery aware of the provey concerns around PI data. In fact, we share your concerns. We will only collect personal information vite our owney your identity. Your information will be disclosed to Expension, an external advertectation service provider, to the just verify your identity. In collected, we will validate your Social Security Number with Expension only for the purposes of verifying your identity. Expension verifies the information you give us against their records. We may also use your answ to the challenge questions and other PII to later identity you in case you forget or misplace your User (D. Password. HHS Rulles of Behavior.	B). vers			
	We encourage you to read the <u>HHS Rules of Behavior</u> , which provides the appropriate use of all HHS information technology resources for Department users, include Federal employees, contractors, and other system users.	ing			
	I have read the HHS Dulne of Rohavier for Dividend Lie e Accounte (addeedum to the HHS Dulne of Rohavier (HHS DoB), document number HHS DCIO 2012 2002	26	*		
10	✓ Lagree to the Terms & Conditions Back Next C	Cancel			

- 6) When entering your information into the Identity Verification screen, ensure you enter only your personal information. <u>You will only have three attempts to enter information that</u> <u>matches the Experian database.</u>
- 7) Tips for successfully completing Identity Verification:

Full Legal Name:

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

Social Security Number:

• Ensure that Social Security Number fields are filled in correctly. Users can review and edit these fields prior to sending the information to Experian.

Date of Birth:

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

Current Residential Address:

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

Personal Phone Number

- Enter a personal landline phone number (if you have one).
- A cell phone can be used, but a residential landline is preferred.
- 8) After reviewing the above information enter your information in the spaces provided, and then select **Next.**

CMS.gov My Enterprise Portal			🔳 Му Аррз	i -				٠	🛢 Karen Miller 🔻	0 Help	🕪 Log Out
	Step #3: Enter Your I	nformatior	ı								
	Please select the checkbox only if you have o Verification Support Services, your personal info	ontacted the Experian Verif mation on this screen must	ication Support Services match what you provide	and have successfull d Experian when con	y been verified. spleting the one	If you have succe i-time verification	ssfully been verified by the Experian with them to successfully move forward				
	Enter your legal first name and last name, as it m All fields are required unless marked (optiona	ay be required for Identity (),	Verification.								
	First Name Karen	Middle Name (optional)		Last Name Miller			Suffix (optional)	~			
	Social Security Number	Birth	Month 🗸	Birth Date	~	Birth Year 1976	~				
	Is Your Address US Based?										
	Home Address Line 1 7100 Security Blvd			Enter Home Add	fress Line 2 (opt	ional)					
	City Baltimore	State Maryland	~	ZIP Code 21244	Enter ZI	P+4 Code (option	al)				
	Phone Number 210-602-4955										
	Email Address karen.miller@yopmail.com		Confirm Email karen.miller	l Address Byopmail.com							
	Changing your email address will remove any email MFA register a new email MFA in "Manage MFA Devices".	that you currently have. You cu	11								
	Check here if you have read and verified the int	ormation above is accurate	and complete as required	S by Identity Verificat	ion.						

9) If RIDP is successful, you will receive the confirmation notice. Select **Next** to continue.

🕑 Confirm	mation	×
You have suc	cessfully completed the Remote Identity Proofing process.	
		-

- 10) If RIDP is unsuccessful, note the response code, and follow the directions in the Error message. If the Error message refers you to the "Tier 1 Help Desk", call the Open Payments Help Desk at 1-855-326-8366. For the TTY line, call 1-844-649-2766.
- 11) Once you have completed Identity Verification, enter a brief justification for being granted this role, and select **Submit**.

Request Application Access	
# The following is the step-by-step process for requesting a role in a CMS Enterprise Portal application. A summary of each step ta be presented with all your role related information to review at the last step. Please note that the number of steps and the questions you are requesting and your current level of access.	ken will be shown after each step. You will asked will vary depending on the role that
1 Select an Application	✓ Completed
✓ Open Payments	
2 Select a Role	✓ Completed
 Applicable Manufacturer, GPO, Physician, Non-Physician Practitioner, or 	r Teaching Hospital
3 Enter Reason for Request	
Enter a Reason for Request	
Required field.	
	Submit

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

CMS.gov My Enterprise Portal	III Му Арра	🕒 Komen Miller 🐱 😧 Help – 🗗 Log Out
Request Appl	ication Access	
Select an Applit	nion	✓ creater) Ø 100
V Dpen Payro	Confirmation »	
🔞 Select a Role	Are pop sare you want to proceed?	or oregonal Britan
🖌 Applicable N	Cancel CK	
Enter Reason fo	r Request	
vol		
		Submit
		Lant

13) Review the information and select **OK**.

CMS.gov My Enterprise Porta	I Ш≣муАрря .	•	🛛 Karen Miller 🔫	🕑 Help	🕞 Log Out
1	Confirmation		×		
R	roor don reversion or entropy accessionly accesses. lequest New Application Access Acknowledgement wir MM reversion accession wir war accession with a second second accession				
Pi Ya Or hit	ease use this number in all correspondence concerning this request. will receive an email when your request has been processed. new your creasest is appointed then you will never be log out and then log back into the Enterprise Portal system to access the application via the tile on the My Portal Landing page. If you double, please contact the lier 1 help Desk associated with your application.	you are st	SIL		
	ок				

14) After selecting **OK**, log out of the system and log back in to continue to the next steps.

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

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

2 Selec	t a Role	
Physic	ian, Non-Physician Practitioner, Teaching Hospital Authorized Representative, or Reporting Entity Submitter/Attester/Compliance	× 🗸
Record Reco	le Description: Select this role if you are a submitter, attester, or compliance user of an applicable manufacturer or GPO trying to report data; or a physician, physician sentative, non-physician practitioner, non-physician practitioner representative; or a teaching hospital representative trying to access attributed data. Non-Physician itioners include: Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist/Anesthesiologist Assistant and Certified Nurse-Mi	dwife.

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

0	Select a Role	Completed
	 Physician, Non-Physician Practitioner, Teaching Hospital Authorized Representative, or Reporting Entity Submitter/Attester/Compliance 	
3	Enter Reason for Request	
	Enter a Reason for Request	
	Tengared Test.	Submit

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

CMS.gov My Enterprise Portal	12 Му Арря	O Koren Miller 🛥 😡 Holp 🛛 De Log Out
Request Applic	ation Access	
👩 Select an Applicati	on	✓ Lindistad Ø 108
💙 Open Paymen	Confirmation *	
🙆 Select a Role	Are you sare you want to proceed?	erenteri Ur une
🖌 Applicable Ma	Cancel CK	
Enter Reason for R	equest	
Vol		
		Submit
		junes!

4) You will receive a Confirmation page. Select OK, then log out and back in again to begin creating your Open Payments profile.

CMS.gov Wy Interpret Ports	E Hy hear	d tara tilar w	•146	⇒ logM
0	Confirmation	•		
Reep form 0 There is Annual Sector Sector	enerst New Application Access Acksowledgement 00 apart factors assessfully substant 01 apart factors assessfully substant 02 aparts factors and the special Mandatom, (PA), Physician, New Physician Phadeloner, at Nachog Registral one in Special Remains accidenter a 344344 (Particle sensition in the temporation processing the requirement) 03 and the proceeding the requirement 04 and the proceeding the requirement 05 and the proceeding the pr			

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

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



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

Select a Role	 Complete Edit
✓ Open Payments Foreign User	
Enter Reason for Request	
Enter a Reason for Request	
Required field.	
	Submit

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

CMS.gov My Enterprise Portal	HE My Appa	٠	😝 Koren Miller 🐱 📦 Halp 🛛 Log Out
Request Applic	cation Access		
O Select an Applicat	ion		🛩 communiti 😿 100
V Open Paymen	Confirmation »		
👩 Select a Role	Art you save you want to proceed?		er organisti Drate
🗸 Applicobie Ma	Canoel CK		
👩 Enter Reason for 6	lequest		
101			
			Submit
			Lara

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



3.2d: Adding Multi-Factor Authentication (MFA)

To add Multi-Factor Authentication (MFA),

<u>Step 1:</u> Navigate to My Profile and select Manage MFA Devices.

CMS.gov My Enterprise Portal	⊞ My Арря	٠	Karen Miler	-	IIclp	€→ Log Oul
My Profile	View My Profile					
View Profile	First Name: Karen					
Change Pro/ile	Middle Name:					
Change Business Contact Information	Last Name: Miller					
Change Password	Date of Birth: 01/14/1980 Email Address: karen.miller@vopmail.com					
Change Security Question	Phone Number: 11444-944-4444					
Manage MFA Devices	Home Address Line 1: 123 Main Street					
	Home Address Line 2:					
	City: Baltimore					
	State: MU ZIP Code: 21244					
	ZIP+4 Code:					_
						Тор

Figure 16: My Profile

Step 2: Select "Register a Device".

Figure 17:	Manage MFA	Device	Register	a Device Page
------------	------------	--------	----------	---------------

CMS.gov My Enterprise Portal	III My Apps		•	🔒 Karen Miller 👻	Help	C+ Log Out
My Profile	Manage Multi-Factor A	uthentication (MFA	A) Devi	ices		
Level View Profile	Device Type	Identifier	Status	Ac	tions	
Change Profile	Email	admin@abcmedic.com	Active	Edit		
Change Business Contact Information	Register a device					
Change Password						
Change Security Question and Answer						
Manage MFA Devices						

<u>Step 3:</u> Select the device you wish to register.



CMS.gov My Enterprise Portal	III Му Арря		• •	🖌 Karen Miller 👻 😗 Help 🕞 Log Out
My Profile				
	Manage Multi-Factor A	uthentication (MFA	A) Devi	ces
View Profile	Device Type	Identifier	Status	Actions
Change Profile	Email	admin@abcmedic.com	Active	Edit
Change Business Contact Information	Register Multi-Factor A	uthentication (MEA		
Change Password	Adding a MFA Code to your login, als by providing an extra layer of protect	o known as Multi-Factor Authen	tication (MF	= FA), can make your login more secure
Change Security Question and Answer	Select the MFA device type	that you want to use to I	ogin	
Manage MFA Devices	Select MFA Device			~
	Select MFA Device Text Message (SMS) Interactive Voice Response (IN Google Authenticator Okta Verify	/R)		

<u>Step 4:</u> Depending on the device you choose to register, you will be asked to provide information about that device (Phone number). Enter the required information for the device you are registering and select "Send MFA Code".

My Profile				
	Manage Multi-Factor A	uthentication (MF	A) Devi	ces
Level View Profile	Device Type	Identifier	Status	Actions
Change Profile	Email	admin@abcmedic.com	Active	Edit
Change Business Contact Information				
Change Password	Register Multi-Factor A	Authentication (MF	A) Dev	ICE (MFA), can make your login more secure
Change Security Question and Answer	by providing an extra layer of protect Select the MFA device type	tion to your User ID and Pass that you want to use to	word. 0 login	
Manage MFA Devices	Text Message (SMS)			~
	Text Message (SM The SMS option will send your MFA to provide a ten (10) digits U.S. phor service charges may apply for this o Enter Phone Number Required field. Send MFA Code	IS) Code directly to your mobile of ne number for a mobile device ption.	levice via a that is cap	text message. This option requires you vable of receiving text messages. Carrier

Figure 19: Send MFA Code

<u>Step 5:</u> Enter the code sent to your device and select "Add Device" to successfully add your MFA Device.

Figure 20: Enter MFA Device Code

The MFA code has been sent to y code in 30 seconds.	rour MFA device. If you are having trouble, we can resend the MFA	
Re-send MFA Code		
Enter Code Received		
Add Device	Cancel	

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

Figure 21: Manage MFA Devices Page

CMS.gov My Enterprise Portal		i⊟ My Ap;	DS		٠	😫 Karen Miller 🔻	Help	€→ Log Out
My	Profile	Manage Multi-Factor	Authentication (MFA	A) Devi	ces			
L	View Profile	Device Type	Identifier	Status	Actions			
	Change Profile	Email	karenmiller@yopmail.com	Active	Edit			
	Change Business Contact Information	Text Message (SMS)	+1 555-555-5555	Active	Edit Remove			
	Change Password							
	Change Security Question	Register a devi	ce					
S	Manage MFA Devices							

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 maintain at least one officer in the entity profile. The officer must 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 32, below.

User Roles	Functions	Requirements
	 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
Officer	 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
	May nominate individuals for user roles	If nominated, must either
Submitter	 May edit payments or other transfers of value and ownership/investment interests submitted to the Open Payments system 	accept or reject the nomination
	 Receives emails regarding data disputed by physicians, NPPs and teaching hospitals 	
Attestor	 Attest to accuracy of the data in the Open Payments system on behalf of the applicable manufacturer or applicable GPO May pominate individuals for user roles 	 Must be an officer of the applicable manufacturer or applicable GPO as required in the Open Payments Final Rule at
Allester	• Way nonlinate individuals for user fores	42 C.F.R. § 403.908(e)
		 If nominated, must either accept or reject the nomination
	 May view and download compliance communications for their reporting entity 	 Not required to be an officer of the applicable manufacturer or
Compliance	Respond to any compliance	applicable GPO
	communications sent by CMS	 If nominated, must either accept or reject the nomination

Figure 22: Open Payments User Roles

Section 3.4 Registering Applicable Manufacturers and Applicable GPOs

Once your reporting entity has decided who should fill the required user roles, you can begin Open Payments registration. You will enter the required information for your reporting entity profile, user personal profile, and nominees for each user role. Reporting entity registration has five steps, as shown in **Figure 33.** Details on these steps are included later in this section.

Figure 23: Entity Registration



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

During registration, the authorized official must select the user role of officer to complete the registration process. The entire registration process takes approximately 30 minutes and must be completed in a single session. You cannot save partially completed entries for completion later. You will be able to edit, manage, or update a profile once it is created. Note that the system does not 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 34 and **Figure 35** detail which fields are required and which fields are optional when creating an entity and user profile. It is important to have this information on-hand prior to beginning the registration process.

Figure 24: Entity Profile Fields

Fields	Required or Optional?
Reporting Entity Type	Required
Reporting Entity Legal Name	Required
Business Type	Required
Doing Business As (DBA) Name	Required
Reporting Entity Business Address	Required
Reporting Entity Business Phone Number	Required
Reporting Entity Type of Ownership	Required

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Fields	Required or Optional?
Taxpayer Identifier Number (TIN)/ Employer Identification Number (EIN)	Required
Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS)	Optional
Food and Drug Administrator (FDA) Establishment Identifier (FEI)	Optional
Uniform Resource Locator (URL) of Parent Company*	Required
Consolidated Report Indicator (Y/N) (default N)	Required
Primary Point of Contact Name	Required
Primary Point of Contact Business Phone Number	Required
Primary Point of Contact Title at the Entity	Required
Primary Point of Contact Email Address	Required
Backup Point of Contact Name	Required
Backup Point of Contact Business Phone Number	Required
Backup Point of Contact Title at the Entity	Required
Backup Point of Contact Email Address	Required
Contact Information for Review and Dispute	Required

If the reporting entity does not have a URL, enter the value <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

Figure 25: User Profile Fields

Fields	Required or Optional?
Email Address	Required

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

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 IDM credentials and navigate to the Open Payments home page. Select the Application link.



Figure 26: 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 27: 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 28: Create Profile Page



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

Figure 29: Select Profile Type Page



<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."

Figure 30: 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 31: Find an Entity Page

Open Paymen	its (Sunshine Act)
Croata Profila	Find an Entity
Create Frome	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 Register Entity	(TIN)/Employer Identification Number (EIN) below. If the Entity's TIN/EIN Is Not Found
Personal Information Review and Submit Brofile	If the TIN/EIN entered does not return any results, the entity has not yet been registered within the Open Payments system. You may register the entity by selecting the "Register Your Entity on Open Payments" link. Note: You must also register yourself for the officer user role when registering an entity. You may hold
	more than one user role. If the Entity's TIN/EIN Is Found
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
Contact Us by email	personal profile and nominating yourself for a role with that entity.
Privacy Policy [PDF, 102 KB]	Required: Enter the TIN/EIN of the entity.
	*Enter TIN/EIN: 99-9999999
	34-5678901 Find
_	Register your Entity on Open Payments
	Cancel Back

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

• Applicable GPO

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

- GPO-drugs/biologicals
- GPO-devices/medical supplies
- GPO- drugs/biologicals and devices/medical supplies
- GPO-physician-owned distributorship
- GPO-hospital-owned
- GPO-hospital and physician-owned
- GPO-non-hospital, non-physician-owned
- GPO-government-owned

- The **Primary** and **Backup Points of Contact** are individuals who will serve as the points of contact for the reporting entity and CMS. These must be separate individuals. They do not have to be registered in the Open Payments system.
- The **Primary and Backup Points of Contact** fields are to provide contact information for individual(s) from your entity who will assist with the dispute resolution process. Individuals listed as contacts for review and dispute do not have to be registered in the Open Payments system. The contents of the "Review and Dispute Primary Point of Contact" and 'Review and Dispute Backup Point of Contact" fields will be visible to the covered recipients associated with the records during the review process. The contents will be displayed exactly as entered in these fields.

Figure 32: Register Entity Page

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<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.

Open Paymen Applicable Manufacturer or Group Purchasing Orga	ts (Sunshine Act)
Home Submissions Rev	view and Dispute Manage Entities M	(2) Contraction (Contraction)
Create Profile	Your Role A field with an asterisk (*) is required.	
✓ Select Profile Type	Select your user role(s) below. Note that the individua role. You may hold more than one user role.	al who registers an entity must register for the officer user
2 Register Entity	An entity may have a maximum of 12 active users, wi compliance role. You may nominate other users on th	ith up to 5 users in an officer role and up to 2 users in the e next screen or after registration is complete.
Entity Information	The user roles are as follows:	
Nominate Additional Roles	Officer:	
Personal Information Personal Submit Profile	 Updates the applicable manufacturer or application nominations for user roles. 	able GPO profile information and can approve and modify
(a) Review and Submit Frome	Can deactivate other users from the entity.	
Access the Open Payments User Guide [PDF]	 Can review and download compliance messag GPO. 	es on behalf of the applicable manufacturer or applicable
Need help with the website?	Submitter:	
Contact Us by email	Submits and edits payment information on beh	alf of the applicable manufacturer or applicable GPO.
Review the Open Payments Privacy Policy [PDF]	 The submitter role can be held by individuals fr applicable manufacturer or applicable GPO. 	rom third-party entities who submit records on behalf of the
	Attester:	
	Attests to the accuracy, completeness, and time	eliness of the data submitted for the applicable
	manufacturer or applicable GPO.	
	 Can submit assumptions made in the reporting investment interests. 	of payments, other transfers of value, or ownership or
	Compliance	
	Can review and download compliance messag GPO	es on behalf of the applicable manufacturer or applicable
	Your first name and last name have been prepopulate (EIDM) profile. You may edit these fields as needed. I not change the corresponding information in your EIC telephone number, select the role(s) you wish to hold	ad from your CMS Enterprise Identity Management system However, changing this information in Open Payments will M profile. Enter in your business email and business , and select the "Continue" button.
	*First Name:	Middle Name:
	Karen	
	*Last Name:	Suffix (Jr., Sr., etc.):
	Miller	
	*Business Email Address:	*Business Telephone Number: 999-999-9999 or Maximum 20 digits
	openpayments@yopmail.com	444-444-4444
	Indicate the role(s) you will hold in the Open Paym access level of attesters, submitters and compliand Highest Level of Role Officer Reporting-related Roles Submitter Submitter Compliance-related Roles Compliance	ents system. Only an officer may manage the ce role.
	Cancel	Back

Figure 33: Your Role Page

<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 34: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles Page

reat	te Profile	Applica Nomina	able M ate Ao	/lanu dditi	facturer or A onal Roles	pplicab	e GPO:
. So	lect Profile Type	A field with an a	sterisk (*) is	s required.			
Re	agister Entity	You may nomina	ate other ind	lividuals fo	or user roles with your reporting	ng entity now or at	a later time. An entity r
9 10	Entity Information	Officer:		e users, v	nur 5 users in an onicer role a	and up to 2 users i	r the compliance role.
	Your Roles	Updates t	he applicabl	le manufa	cturer or applicable GPO prot	file information and	can approve and mod
	Nominate Additional Roles	nominatio	ns for user i	roles.			can approve and mea
3) Pe	rsonal Information	Can deac	tivate other	users fron	n the entity.		
Re	eview and Submit Profile	 Can revie GPO. 	w and down	load com	bliance messages on behalf o	of the applicable ma	anufacturer or applicab
2	Access the Open Payments User Guide [PDF]	Submitter: • Submits a • The subm	ind edits pay	yment info n be held	rmation on behalf of the appl	icable manufacture	r or applicable GPO.
?	Contact Us by email	applicable	e manufactu	rer or app	icable GPO.		
a	Review the Open Payments Privacy Policy [PDF]	Attester: • Attests to manufacture • Can subn invectment	the accurac urer or appli nit assumption	;y, comple cable GP0 ons made	teness, and timeliness of the D. In the reporting of payments,	data submitted for other transfers of	the applicable value, or ownership or
		Compliance	it interests.				
		Can revie GPO.	w and down	lload com	bliance messages on behalf o	of the applicable m	anufacturer or applicab
		Role:	First Name:	Last Name:	Business Email Address:	Business Telephone Number:	Actions:
		Officer, Submitter,	Karen	Miller	openpayments@yopmail.com	m 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 35: 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 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 36: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles Page		-			
rigule 30. Applicable Mallulactulei Ol Applicable GPO. Nollilliate Auultiolial Noles Page	Eiguro 26. Applicable	Manufacturor or	Applicable CDO:	Nominato Ad	ditional Poloc Dago
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	Applica	able N	/ anu	facturer or A	pplicabl	e GP	0:
create Profile	Nomina	ate A	dditi	onal Roles			
Select Profile Type	A field with an a	sterisk (*) is	s required.				
Register Entity	Confirmation:						
Entity Information	Your non	ninee has b	een succ	essfully added.			
	You may nomina have a maximur	ate other inc n of 12 activ	lividuals fo /e users, w	r user roles with your reportin vith 5 users in an officer role a	g entity now or at a nd up to 2 users ir	a later time. h the compli	An entity ance role.
Your Roles	Officer:						
Personal Information	 Updates t 	he applicab	le manufa	cturer or applicable GPO profi	le information and	can approv	e and mod
Poview and Submit Profile	nominatio	ns for user	roles.				
Review and Submit Profile	Can deac	tivate other	users from	n the entity.			
Access the Open Payments User Guide [PDF]	 Can revie GPO. 	w and dowr	nload comp	pliance messages on behalf of	f the applicable ma	anufacturer	or applicat
Need help with the website?	Submitter:						
Contact Us by email	Submits a	ind edits pa	yment info	rmation on behalf of the applic	cable manufacture	r or applical	ble GPO.
Review the Open Payments Privacy Policy [PDF]	The subm applicable	iitter role ca e manufactu	n be held l rer or appl	by individuals from third-party icable GPO.	entities who subm	it records or	n behalf of
	Attester:						
	Attests to manufacte	the accurac urer or appli	cy, complet	teness, and timeliness of the c D.	data submitted for	the applicat	ble
	Can subm investmen	nit assumpti nt interests.	ons made	in the reporting of payments,	other transfers of v	value, or ow	nership or
	Compliance						
	 Can revie GPO. 	w and dowr	nload comp	pliance messages on behalf of	f the applicable ma	anufacturer	or applicat
	Role:	First Name:	Last Name:	Business Email Address:	Business Telephone Number:	Actions:	
	Officer, Submitter, Attester, Compliance	Karen	Miller	openpayments@yopmail.com	1 555-555-5555	(YOU)	
	Submitter	Tom	Smith	openpayments@yopmail.com	1 555-555-5555	Edit	Delete

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

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

Figure 37: Enter Personal Information Page

Open Paymer	nts (Sunshine A	ict)
Create Profile	Enter Personal Info	rmation
Select Profile Type	Provide personal and business information be	elow to create your user profile.
🖋 Register Entity	Your first name and last name have been pre (EIDM) profile. You may edit the prepopulated	populated from your CMS Enterprise Identity Management syste d fields as needed. However, changing this information in Open
3 Personal Information	Payments will not change the corresponding	Information in your EIDM profile.
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		21244
Privacy Policy [PDF]	Your Business Contact Information	on
	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 21244	*Business Telephone Number: 999-999-9999 555-555-5555
	Cancel	Back Contin

<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.

/ Se	te Prome	Review the inform	Review and Submit Profile Review the information on this page to ensure it is correct. Select the "Back" button to navigate to the pre					
- 36	lest Profile Ture	pages to correct a	iny invalid in	formation.	Select the '	Continue" button to	submit your profile.	
P Ro	nister Entity	Entity's Logal	Name: ABC	DE Madici	a			
Pe	rsonal Information	Reporting Enti	ity Type: Ap	plicable M	" anufacturer			
	aview and Submit Profile	Business Type	: Applicable	manufact	urer-drugs/l	piological		
9	eview and Submit Frome	Food & Drug A	Administrati	on (FDA)	Establishm	ent Identifier:		
*	Access the Open Payments	Data Universa	I Numbering	g System (D-U-N-S®	Number):		
د	User Guide [PDF]	URL of Parent	Company:	www.cm	s.gov			
?	Need help with the website? Contact Us by email	Business	Addres	5:				
L L	Review the Open Payments	Country: Unite	d States					
2	Privacy Policy [PDF]	Business Add	ress, Line 1	: 7500 Se	curity Blvd.			
		Business Add	ress, Line 2	:				
		City Name: Ba	altimore					
		State: Marylar	nd					
		Zip Code: 212	244					
		Business Tele	phone Num	ber: 555-	555-5555			
		Business	Owners	hip Infe	ormatio	n		
		Type of Owner	rship: Corpo	oration				
		Taxpayer Iden	tifier Numb	er (TIN)/En	nployer Ide	entification Numbe	r (EIN): 22-3635343	
		Doing Busines	ss As (DBA)	Name: Al	BCDE Medi	cal		
		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 regarents.					emails regarding Open	
		Being entered as a point of contact does not register that individual in the Op give that individual access to the system. Individuals must be registered in the access the Open Payments system.				n the Open Payments system red in the system if they want	n Payments system or system if they want to	
		Primary Poi	nt of Con	tact				
		Name: Mary Si	mith Nonces	ar.		susiness Telephon	e Number: 333-333-3333	
		nue at the En	ary. wanage	и	ľ	openpayments@yo	pmail.com	
	Backup Point of Contact							
	Title at the Ent	tity: Senior I	Manager		Business Email Ad	dress:		
				a		openpayments@yo	pmail.com	
		Contact Ir	nformati	on for l	Review	and Dispute		
		Contact Inform	nation: Mary Smith					
		News with the	mary omith					
		Role:	First	Last	Middle	Suffix (Jr., Sr.,	Business Email Address:	
			Name:	Name:	Name:	etc.):		_
		Officer, Submitter, Attester,	Karen	Miller			openpayments@yopmail.co	m
		Compliance						

Figure 38: 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 39: 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 an existing entity in 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 IDM 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 40: Open Payments System Landing Page for returning system users.



Step 2: Select "Register New Entity."

Figure 41: Manage Entities Page

Dpen Dicable Manufac	Payme turer or Group Purchasi	ents (Sun:	shine /	Act)			
Home	Submissions	Review and D	Dispute	Ø Manage Entities	() My Profil	e	Messages	Resources
Manaq	e Entities					C	Access the Ope User Guide [PDI	en Payments F]
U				Register New	Entity	?	Need help with t Contact Us by e	he website? email
The entities you the entity's prof	u are associated with a ile and, if you hold the	re listed below. Sel officer role, manag	lect an entity fi le user roles a	rom the list below to v ffiliated with the entity	iew	•	Review the Ope Privacy Policy [F	n Payments PDF]
Entities pending those entities. E reviews, update Changes made vetted.	g recertification must b Entity recertification rec es (as necessary), and to the Entity Name, T	e recertified before quires that an active confirms the accur IN, or DUNS Numb	users can per e officer within racy of the enti er fields will ca	form any system acti the Open Payments ity's profile information ause your entity to be	ons for system n. re-	(61	
Your Entit	ies							
Name: ABCDE Medical	R (10)	egistration ID: 0000355013	Status: Vetted	Date Verified: 05/24/2019 08:3	0:01			

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

Figure 42: 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 43: Find and Entity Page



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

If the TIN/EIN returns a match, it means your reporting entity has already been registered in the Open Payments system. 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 44: 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 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 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 **Primary and Backup Points of Contact** fields provide contact information for individual(s) from your entity who will assist with the dispute resolution process. Individuals listed as contacts for review and dispute do not have to be registered in the Open Payments system. The contents of the "Review and Dispute Primary Point of Contact" and 'Review and Dispute Backup Point of Contact" fields will be visible to the covered recipients associated with the records during the review process. The contents will be displayed exactly as entered in these fields.

Figure 45: Register Entity Page

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<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	Review and Dispute Manage Entities	Omega Mage Omega Omega <th< th=""></th<>
	Your Role	
reate Profile	A field with an asterisk (*) is required.	
Select Profile Type	Select your user role(s) below. Note that the inc	dividual who registers an entity must register for the officer u
Register Entity	An entity may have a maximum of 12 active use	ers, with up to 5 users in an officer role and up to 2 users in
Entity Information	compliance role. You may nominate other users	s on the next screen or after registration is complete.
Your Roles	The user roles are as follows:	
Nominate Additional Roles	Officer:	
Personal Information	Updates the applicable manufacturer or a nominations for user roles.	applicable GPO profile information and can approve and mo
Review and Submit Profile	Can deactivate other users from the entit	ty.
Access the Open Payments User Guide [PDF]	Can review and download compliance m GPO.	essages on behalf of the applicable manufacturer or applica
Need help with the website?	Submitter:	
Contact Us by email	Submits and edits payment information o	on behalf of the applicable manufacturer or applicable GPO.
Review the Open Payments Privacy Policy [PDF]	 The submitter role can be need by individing applicable manufacturer or applicable GF 	uais from third-party entities who submit records on behalf o PO.
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	*First Name: Leslie	Middle Name:
	*Last Name: Smith	Suffix (Jr., Sr., etc.):
	*Business Email Address:	*Business Telephone Number: 999-999-9999 or Maximum 20 digits
	openpayments@yopmail.com	555-555-5555
	Indicate the role(s) you will hold in the Open access level of attesters, submitters and com Highest Level of Role Officer	Payments system. Only an officer may manage the npliance role.
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Figure 46: 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 47: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles Page

Open Payme Applicable Manufacturer or Group Purchasin	g Organization Switch User Ty	nsh /pe	ine	Act)			
Home Submissions	Review and Dispute	Manag	e Entities	<u>My Profile</u>	Messa) ges R	esources
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Select Profile Type	A field with an as	terisk (*) is	s required.				414
② Register Entity	have a maximum	of 12 activ	ve users, wi	user roles with your reportin h 5 users in an officer role a	g entity now or at nd up to 2 users i	a later time. An n the compliand	entity may
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③ Personal Information	GPO.	and down	lioad compl	ance messages on benall of	r the applicable m	anufacturer or a	аррисаріе
A Review and Submit Profile	Submitter:						
Access the Open Payments User Guide (PDF)	Submits an The submit applicable Attester: Attests to t	iter role ca manufactu he accurac	n be held by rer or applic	v individuals from third-party able GPO.	entities who subn	nit records on b	ehalf of the
Review the Open Payments Privacy Policy [PDF]	Can submi investment	rer or appli t assumption interests.	cable GPO.	the reporting of payments,	other transfers of	value, or owner	rship or
	Compliance • Can review GPO.	and down	nload compli	ance messages on behalf o	f the applicable m	anufacturer or a	applicable
	Role:	First Name:	Last Name:	Business Email Address:	Business Telephone Number:	Actions:	
	Officer, Submitter, Attester, Compliance	Karen	Miller	openpayments@yopmail.con	n 555-555-5555	(YOU)	
	Add						
	Cancel					Back	Continue

<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 48: Applicable Manufacturer or Applicable GPO: Nominate Additional Roles Page

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Repeat the process until you have entered 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 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."

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Home Su	bmissions	Review and Dispute	Manag	je Entities	<u>My Profile</u>	:	Messaç	jes	Resourc
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Select Profile Typ	be	A field with an as	sterisk (*) is	s required.					
Register Entity		Confirmation: Your nom	inee has b	een succe	essfully added.				
💉 Entity Ir	formation	You may nomina	te other inc	lividuals fo	r user roles with your re	porting en	tity now or at	a later time.	An entity r
Vour Ro	les	have a maximum Officer:	n of 12 activ	/e users, w	ith 5 users in an officer	role and u	p to 2 users ir	n the compli	ance role.
Nominate Add	litional Roles	Updates the nomination	ne applicab	le manufac roles.	turer or applicable GPC	profile in	formation and	can approv	e and mod
Personal Informa	tion	Can deact	ivate other	users from	the entity.				
Review and Subr	nit Profile	Can review GPO.	w and down	iload comp	liance messages on be	half of the	applicable ma	anufacturer	or applicat
Access the C User Guide [F	pen Payments PDF]	Submitter: • Submits and	nd edits pay	yment infor	mation on behalf of the	applicable	e manufacture	r or applica	ble GPO.
Need help wit	th the website? by email	The submi applicable	itter role ca manufactu	n be held b rer or appli	y individuals from third- cable GPO.	party enti	ies who subm	nit records o	n behalf of
Review the C Privacy Policy	pen Payments / [PDF]	Attester: • Attests to t	the accurac	cy, complet	eness, and timeliness o	f the data	submitted for	the applical	ble
		Can subm investment	it assumption tinterests.	ons made i	n the reporting of paym	ents, othe	r transfers of	value, or ow	nership or
		Compliance • Can review GPO.	v and down	nload comp	liance messages on bel	half of the	applicable ma	anufacturer	or applicat
		Role:	First Name:	Last Name:	Business Email Addre	ess: Bi Te N	usiness Ilephone umber:	Actions:	
		Officer, Submitter, Attester, Compliance	Karen	Miller	openpayments@yopma	ail.com 55	5-555-5555	(YOU)	
		Cubacittar	Tom	Conith	opoppaumonts@vopm	ail.com 56			

<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] 0 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 8 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 Name: Name: Middle Suffix (Jr., Sr., Business Email Address: Name: etc.): Karen Miller Officer, openpayments@yopmail.com Submitter. Attester, Compliance Tom Smith Submitter openpayments@yopmail.com Cancel Back Continue

Figure 50: 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 51: 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 IDM 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 52: Open Payments System Landing Page for returning system users



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

Figure 53: Manage Entities Page

Oper Applicable Manu	n Paymo facturer or Group Purchasi	ents (Suns ch User Type	shine /	Act)			
Home	Submissions	Review and D	ispute <u>N</u>	Anage Entities	O My Profile		Messages	Resources
Mana	ge Entities					1	Access the Oper User Guide [PDF	n Payments]
L				Register New I	Entity	?	Need help with th Contact Us by er	e website? mail
The entities the entity's p	you are associated with a profile and, if you hold the	are listed below. Sele officer role, manage	ect an entity fr e user roles af	om the list below to v filiated with the entity.	iew	6	Review the Oper Privacy Policy [PI	n Payments DF]
Entities pend those entitie reviews, upo	ding recertification must b s. Entity recertification red lates (as necessary), and adde to the Entity Name T	e recertified before quires that an active confirms the accura	users can perf officer within acy of the entit	form any system action the Open Payments s ty's profile information	ons for system n.			
vetted.				use your enaly to be				
	titles		Statuo	Data Varifiadu			· 2) /	
ABCDEF Medio Pending Recer	cal - 10 tification	0000355013	Vetted	05/24/2019 8:30:01			BAL.	
ABCDE Medic	al 10	0000325011	Vetted	05/24/2019 8:30:01				

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

Figure 54: Entity Information Page

Open Payments (Sunshine Act)	
Links to Open Pageweits Submikations. Review and Dispose Manage Entrifies. My Resources	(2) Profila Maxazgat
ABCDE Medical	Access the Open Payments User Guide (PDF)
Distry Details Manage Roles Indicate No Paymental Transfers of Value to Report	? Need help with the website? Contract Ux by email
This page provides the information for your selected entry. Only an subtorized official or subtorized representative in the officer role can update any inconect information in the entry profile by selecting the "Update Entry" button.	Review the Open Payments Privacy Policy (PDP)
Entity Information	st 🕵 👗
Entryk Registereten (D: 10000000700 Entryk Legel Network ADCCE Nacioni Entryk Legel Network ADCCE Nacioni	
Daalmaan Type: Applicatie manufacture dagettiologicale Facel & Francisco Administrative (FAA) Franklinger Hamilton	
Data Urkensel Numbering System (D-U-H-SA Number): URL of Parent Company: www.com.com	
Business Address County: Units Stees	
Dustiness Address, Line 1: 7500 Security Bird Dustiness Address, Line 3:	
City Name: Boltimore Zip Code: 21244	
Szec: Maryland Dustness Telephone Number: 555-555-5555	
Business Ownership Information	
Will this why/n information be submitted in a consolidated report (i.e., one anthry reports on behalf of another entry)? No, my write/n data-will not be submitted in a consolidated report Points of Contact	
The two identified points of contact will receive important notification enable regarding Open Payments.	
Name: May Smith	
Eusiness Telephone Number: 333-333-3333	
Dustress Enail Address:	
Beckup Point of Contact Name: Jos Miler	
Dustress Telephone Number: 444-444-4444	
Destinant Entell Address:	
Contact Information for Review and Dispute	
The contents of the "Review and Dispute Primary Point of Contact" and "Review and Dispute Backup Point of Contact" fields will be visible to the covered recipients associated with the records.	
during the review process. The contents will be displayed exactly as entered in these fields. Herease and Dispute Primary Point of Contact	
Name:	
Title At the Critity: Dualness Talachore Number:	
Dusiness Telephone Disension:	
Dualmass Email Address:	
Nevrew and Drapute Backup Point of Contact Name:	
Tide at the Distry:	
Business Telephone Number:	
Doornaa magpana Doornaan Doornaa Email Addreas:	
Recertification Information	
Date and time recentified: May 11, 2022, 15 19PM GMT	

<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 recertification box for the option applicable to your entity:says, "I re-certify that the entity information entered above is accurate." Then select the "Submit" button. Beginning with Program Year 2023, you have the additional option to recertify your entity as having no payments to report for the program year.

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CDE Medical		Arran to Door Domain
Concern Reported	Ladina Mi Pressent	Law Guile (PDF)
Confidence	Transfers of Ukbe to Report	? Found help with the switcher? Comment like by small
Entity Information		Review the Open Payments Privacy Policy (PDP)
feld with an astrolog (*) is required.		-
Tris page alibys you to update your entit pdates.	y information. Select the "Submit" button to save your	
hely/a Reglamation ID: 10000000074	0	
Dinity's Legal Name:		
Reporting Entity Type:		
Applicable Development		
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Applicable rearrangements and the physical	~	
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ana Universal Numbering System (D- Nic Is a R-digit number	J-NGA Number):	
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This Benny Ried		
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Figure 55: Entity Information Page in an editable view

In the "Review and Dispute Primary Point of C	Iontact" and "Review and Dispute Backup Point of
Context" fields below, provide the context info who will be assisting with the dispute resolution	enation for up to two individuals from your entity in process.
Note: The contents of the 'Review and Disput Dispute Backup Folnt of Context' fields will be the records during the review process. The co fields.	a Primary Point of Contact" and "Review and widdle to the covered recipients associated with memory will be displayed exactly as entered in these
Review and Dispute Primary Point	t of Contect
'Name:	Tide with Entity:
"Duxineux Telephone Number: 998-998-9999 or Maximum 20 digits	Euxineux Telephone Extension: Maximum 10 digits
Duniment Dirall Address:	
Review and Dispute Backup Poin	t of Contact
Name	Tide at the Datity:
Dustness Telephone Number: 999-999-9999 or Maximum 20 digits	Dualmaas Talaphoras Extension: Maximum 10 digits
Gusiness Email Address:	
Annual Recentrication If you Entry is reartifying and has reportable investment interact to be reported for the curr attestation:	payments or transfers of value or ownership and at program year, please acknowledge the below
O'lle-centify that the entity information ar	nered above is accurate.
Name If you take on, after re-certification, deci- tionalises of value or overleichig and investmen- previous program years, you may update the tab. Select the westy, and Disc on the "Indicate tab and failaw the instructions to indicate the value or overething and investment interest to investment in termstates.	Ide that your workly close NCT have payments of the intervent to report for the current program year or indicator by ravigating to the "liferage Cratites" in this Report "ravident of value to Report" rub- jou do not have any payments or transfers of agont.
Annual Recentification AND does	NOT have Payment(a) to Report
If your Entity is recentlying and does NOT has overwhip and investment interest to be report advowing the below attestations:	e reportable payments or transfers of value or ted for the current program year, please
	entered above in accurate.
2. I speet that I am a Chief Decusive Office "2. I speet that I am a Chief Decusive Office manufacture or applicable group purchas the information automized in the Open Pay Discourses."	er, Chief Financial Officer, Chief Compliance est representative for the reporting applicable ing organization with the authority to state to metal system.
1.1 stress that, to the best of my knowledg have any reportable payments or transfers to report for the selected program year.	a, belief, and ability, my organization does not of value or ownership and investment interest
¹⁴ If I became sweek of any information th this information to CHG as required per 10 applicable menufacturer or applicable gra- or ontikkion in its annual report, it muse as upon confirmation of the error or onlikion	st my writty is required to report, I vill automit (CR: 403.000)(YI), which scass, that "If an ap punchasing organization discovers an error brink convexed information to CMS immediately ."
Nose: If you later on, after re-certification, dec	ide that your entity has payments or transfers of
case or converse, and events in a primary	by navigating to the "Manage Endber" tab. Select
buildings have been and change on a company.	
the entity, and Click on the "Indicase No Paym folice the instructions to indicate that you have investment interest to record.	ents' Transfers of value to Report' sub-tab and e payments or transfers of value or ownership and

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

Figure 56: Manage Entities Page showing entity successfully updated confirmation message

oplicable Manufacturer or Group Purchasing Organization Switch User Type									
Home Submiss	sions Review and D	ispute <u>Ma</u>	nage Entities	(Q) My Profile		Messages	Resour		
Manage Ent	ities				1	Access the Open User Guide [PDF,	Payments , 37.3 MB]		
Confirmation: • Entity successfully	updated.				?	Need help with th Contact Us by er	e website? mail		
			Register Ne	w Entity	8	Review the Open Privacy Policy [P[Payments DF, 102 KB]		
The entities you are associ the entity's profile and, if yo Entities pending recertificat those entities. Entity recerti reviews, updates (as neces	ated with are listed below. S u hold the officer role, mana ion must be recertified befor fication requires that an acti sary), and confirms the acci	elect an entity fro ge user roles aff e users can perf ve officer within t uracy of the entit	om the list below to illiated with the ent form any system a the Open Payment y's profile informat	o view ity. ctions for ts system ion.	6				
Changes made to the Entity vetted.	y Name, TIN, or DUNS Num	ber fields will ca	use your entity to I	be re-	ſ				
tour Entities									
Name:	Registration ID:	Status:	Date Verified						
ABODEF Medical	100000355013	velled	11/29/2017 16	.20.00					

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 can perform certain tasks in the Open Payments system once they accept the nomination. Once a reporting entity is successfully registered in the Open Payments system, you can begin nominating additional users to fill user roles. There are two ways that individuals can be nominated for a user role:

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

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 a 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 act on your nomination within 10 days, the nomination will expire. The process for accepting or rejecting your nomination(s) is shown in Sections 3.6b and 3.6c.

If the nomination is accepted, you will 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 IDM credentials 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 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 IDM credentials to access Open Payments. The following figure depicts the selfnomination 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 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)

Figure 58: User Role Statuses for Reporting Entities

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

Nominations can be made when registering a new reporting entity or after the entity has been successfully registered. 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 IDM 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 59: 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.

Dpen Pa	yments (Suns tch User Type	shine /	Act)			
Home Submit	ssions Review and D	Dispute <u>N</u>	lanage Entities	(Q) My Profile		Messages	Resources
Manage Ent	tities				1	Access the Ope User Guide [PD	en Payments F]
-			Register New E	intity	?	Need help with Contact Us by	the website? email
The entities you are assoc the entity's profile and, if yo	iated with are listed below. Se ou hold the officer role, manag	lect an entity fro le user roles aff	om the list below to vi filiated with the entity.	ew	6	Review the Ope Privacy Policy [I	en Payments PDF]
Entities pending recertificat those entities. Entity recert reviews, updates (as nece	tion must be recertified before ification requires that an active ssary), and confirms the accur	users can perf e officer within racy of the entit	form any system actio the Open Payments s y's profile information	ns for ystem			
Changes made to the Enti- vetted.	ty Name, TIN, or DUNS Numb	er fields will ca	use your entity to be r	e-			
Your Entities							
Name: ABCDE Medical	Registration ID: 100000355013	Status: Vetted	Date Verified: 05/24/2019 08:30	:01	4		

Figure 60: Manage Entities Page

Step 3: Select the "Manage Roles" tab.

Figure 61: Manage Entities Page



Step 4: Select "Nominate New Role."

Figure 62: Entities Manage Roles Tab

Entity Details Ma Select the "Nominate New Role Select the "Modify" button by a Select the "Deactivate User" but entity.	nage Role "button to user's nam tton by a u	es to nominate a me to add or user's name	Dispute a new individ remove a re	Manage	Entities	(My	Profile	?	Messages Access the O User Guide [P Need help with Contact Us b	Popen Payments PDF, 37.3 MBJ h the website? y email
Select the "Nominate New Role Select the "Modify" button by a Select the "Deactivate User" bu entity.	al mage Role " button to user's nan tton by a u	es to nominate a me to add or user's name	a new individ remove a re	dual to fill a	role within y			?	Access the O User Guide [P Need help wit Contact Us b	Open Payments PDF, 37.3 MB] h the website? y email
Entity Details Ma Select the "Nominate New Role Select the "Modify" button by a Select the "Deactivate User" bu entity.	nage Role " button to user's nan tton by a u	es to nominate a me to add or user's name	a new indivic remove a re	dual to fill a	role within y	vour optit :		?	Need help wit Contact Us b	h the website? y email
Select the "Nominate New Role Select the "Modify" button by a Select the "Deactivate User" bu entity.	" button to user's nan tton by a u	o nominate a me to add or user's name	a new individ remove a re	dual to fill a	role within y	our optite			Baulau the O	
the entity.	deactivate	e another offic	to remove t cer but canr	that user co	Iready affilia mpletely fro ate themselv	vour entity. ated user. om your ves from		0	Privacy Policy	(PDF, 102 KB)
An explanation of the statuses I MB] .	below can	n be found in	the Open P	ayments U	ser Guide [F	PDF, 37.3 New Role				
Name: Ro	ole:	Status:	Actions:							T P
Karen Miller At	tester	Approved	Modify							
Su	Ibmitter	Approved								
Of	ficer	Verified								

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 63: Nominate New Role Page

Home Submissions	Review and Dispute	Manage Entities	(Q) My Profile		Messages	Resou
BCDF Medical					Access the Op	en Pavments
				6	User Guide [PD	۶F]
Entity Details <u>Manage</u>	Roles			?	Need help with Contact Us by	the website? email
Nominate New Role				8	Review the Op	en Payments
A field with an asterisk (*) is required	4				Privacy Policy [PDFJ
Nominate someone who will have a	role on Open Payments for yo	ur entity.				A CONTRACTOR
First Name:	Middle Name:				a an	
Mary				C.	1	S ZA
Last Name:	Suffix (Jr., Sr.,	etc.):				
Davis		,				
Business Email Address:						K
openpayments@yopmail.co						
орепраулента@уорлал.co						
*Indicate the role or roles this per	son will have:					
Officer						
Submitter						
Attester						
Compliance						
Country:						
Please Select			•			
Business Address, Line 1:						
7500 Security Blvd.						
Duningga Address Line 2:						
Susiness Address, Line 2.						
City Name:	*State:					
Baltimore	Maryland		•			
iZin Codo:	*Pueinese Tele	nhono Numbori				
210 Code: 99999 9999	999-999-9999	phone Number:				

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

Figure 64: Entities Manage Roles Tab confirming success of nomination



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

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

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

You will be notified of your nomination for a role and must access the Open Payments system via the CMS Enterprise Portal and either accept or reject your nomination. You will use the registration ID and

nomination ID received in the nomination email to complete your profile in the Open Payments system and receive access to the functions for that specific role.

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

The process for accepting nominations is outlined in Figure 75, below.

Figure 65: 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 IDM credentials, navigate to the Open Payments home page, and select "Create My Profile."

Figure 66: 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.



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

Figure 68: 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 69: Search for Nomination Page

Open Applicable Manufa	Cturer or Group Purchasin	ents (Sui g Organization Switch User T	nshine /	Act)		
Home	Submissions	Review and Dispute	ठि Manage Entities	O <u>My Profile</u>	Messages	Resources
Create Pro	ofile	Search A field with an as From the dropdo	for Nomina sterisk (*) is required. wn list below, select your U	tion Jser Type.		
 Select Pro Register E Search Entity I Confirm Personal I 	Interry Nomination nformation n Nomination nformation	Enter your Not received. Note receive only N Select the "Sh *User Type	mination ID and Registration and the construction of the construc	on ID included in the nomi or Non-Physician practition see the information associ	nation email you have ner authorized representa ated with your nominatio	atives n.
Review an Acces User 0 Need Conta	as the Open Payments Guide help with the website? ct Us by email	Applicable Ma *Registration The ID is a 12 10000000078	anufacturer or Applicable GF I D: 2-digit number 0	*Nomination ID: The ID is a 12-digit 221872775579	number	
Revie Privac	w the Open Payments y Policy [PDF]	Show Nomin Cancel	nation			

<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 70: 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 71: Confirm Entity page

Open Payment	ts (Sunshine Act)
Create Profile	Confirm Entity Below is the information for your selected entity. Review and confirm the entity identified below is correct. Select "Continue" button to begin creating your user profile.
 Select Profile Type Register Entity Search Nomination Entity Information Confirm Nomination Personal Information Review and Submit Profile Access the Open Payments User Guide [PDF, 37.3 MB] 	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
Need help with the website? Contact Us by email Review the Open Payments 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: 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 Consolidated Report Type: I don't know whether my entity's data will be submitted in a consolidated report Cancel Back

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

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

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

Figure 72: Confirm Nomination Page



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

Figure 73: Enter Personal Information Page

Open Payment	s (Sunshine Ad	ct)
Create Profile	Enter Personal Inform	nation
Select Profile Type	Provide personal and business information below	w to create your user profile.
✓ Register Entity	(EIDM) profile. You may edit the prepopulated field	elds as needed. However, changing this information in Open
③ Personal Information	Payments will not change the corresponding info	prmation in your EIDM profile.
Review and Submit Profile	Once you have entered the information, select the	ne "Continue" button.
9	Your Name	
Access the Open Payments	*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 Information Enter your business or entity information. *Business Email Address:	*Job Title:
	openpaymentee@yopmail.com	
	*Country:	-
	United States	
	*Business Address, Line 1:	
	Business Address, Line 2:	
	*City Name:	*State:
	Baltimore	Maryland •
	*Zip Code: 99999 9999	*Business Telephone Number: 999-999-9999
	21244	000-000-0000
	Cancel	Back

<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."

Figure 74: 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 75: 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 IDM 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 76: Open Payments System Landing Page for returning system users



<u>Step 2:</u> Select the "My Roles and Nominations" tab.

Figure 77: My Profile Page

A.		-	-	-	0			
Home S	Submissions	Review and Disp	ute Manage	2 Entities	(2) My Profile		Messages	Resourc
Dusfile								
y Profile	•					0	Access the Ope User Guide [PDi	en Payments F, 37.3 MB]
Overview	Profile De	etails My No	Roles & minations			?	Need help with t Contact Us by e	the website? email
This page contains	information about	your authorized role	(s)			8	Review the Ope	n Payments
This page contains An explanation of ti	information about the statuses below (your authorized role can be found in the ((s) >pen Payments Us	er Guide (PDF	37.3	8	Review the Ope Privacy Policy [F	en Payments PDF, 102 KB]
This page contains An explanation of t MB] .	information about the statuses below	your authorized role can be found in the ((s) Open Payments Us	ser Guide (PDF	37.3	6	Review the Ope Privacy Policy (F	PDF, 102 KB]
This page contains An explanation of the MB] . Profile Name	s information about the statuses below P	your authorized role can be found in the ((s) Open Payments Us	ser Guide (PDF	; 37.3	•	Review the Ope Privacy Policy (F	en Payments PDF, 102 KB]
This page contains An explanation of ti MB] . Profile Name Karen Miller	s information about the statuses below e	your authorized role can be found in the ((s) Open Payments Us	ser Guide (PDF	; 37.3	6	Review the Ope Privacy Policy (F	en Payments PDF, 102 KBJ
This page contains An explanation of the MB] . Profile Name Karen Miller Your Author	s information about the statuses below e ized Roles	your authorized role can be found in the ((s) Open Payments Us	ser Guide (PDF	; 37.3	6	Review the Ope Privacy Policy (F	en Payments PDF, 102 KBJ
This page contains An explanation of ti MB] . Profile Name Karen Miller Your Author Role:	information about the statuses below e 'ized Roles Enti	your authorized role can be found in the ((s) Open Payments Us	ser Guide (PDF	, 37.3	6	Review the Ope Privacy Policy (F	an Payments PDF, 102 KBJ
This page contains An explanation of ti MB] . Profile Name (aren Miller Your Author Role: Officer	information about the statuses below e fized Roles Enti ABC	your authorized role can be found in the (ty: :DE Medical	(s) Open Payments Us	ser Guide (PDF Status: Requested	, 37.3	6	Review the Ope Privacy Policy (F	an Payments PDF, 102 KBJ
This page contains An explanation of ti MB] . Profile Name Caren Miller Your Author Role: Officer Submitter	information about the statuses below e fized Roles Entiti ABC ABC	your authorized role can be found in the (ty: :DE Medical :DE Medical	(s) Open Payments Us F	ser Guide (PDF Status: Requested Requested	, 37.3	e C	Review the Ope Privacy Policy (F	an Payments PDF, 102 KBJ
This page contains An explanation of ti MB] . Profile Name Karen Miller Your Author Role: Officer Submitter Attester	e ized Roles Enti ABC ABC ABC	your authorized role can be found in the (ty: :DE Medical :DE Medical :DE Medical	(s) Dpen Payments Us F F F	ser Guide (PDF Status: Requested Requested Requested	, 37.3	C	Review the Ope Privacy Policy (F	an Payments PDF, 102 KBJ

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

Figure 78: My Roles and Nominations tab

plicable Manufacti	Payme urer or Croup Purchesin	ents (Su a Organization Switch User	nshine /	Act)			
Home	Submissions	Review and Dispute	Ø Manage Entities	O My Profile		Messages	© Resources
ly Profi	le				6	Access the Oper User Guide [PDF	n Payments ; 37.3 MB]
Overview	Profile D	etails My Rol Nomina	es & tions		?	Need help with th Contact Us by e	ne website? mail
Below are your	user roles for each er	tity with which you are affiliated for your affili	iliated. You have the optic	n to	8	Review the Oper Privacy Policy [P	n Payments DF, 102 KB]
An explanation	of the statuses below	can be found in the Open	Payments User Guide [P	DF, 37.3			
Accept a Role	Request a Ro	ble					
Accept a Role My Roles Role:	Request a Ro	e:	Status:			5.6	
Accept a Role My Roles Role: Officer	Request a Re Nam ABC	e: DE Medical	Status: Requested				

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

Figure 79: Search for Nomination Page

Ope Applicable Man	n Payme	ents (Su g Organization Switch User	nshine /	Act)		
Home	Submissions	Review and Dispute	o Manage Entities	O My Profile	Messages	Resources
Create P	Profile	A field with an a From the dropdo	for Nomina sterisk (*) is required. own list below, select your (tion Jser Type.		
 Registe Sear Entiti Comi Personal 	er Entity rch Nomination ty Information firm Nomination al Information	Enter your No received. Not receive only f Select the "Sl *User Type	omination ID and Registration e: nominees for Physician of Nomination ID numbers. how Nomination" button to	on ID included in the nomin or Non-Physician practition see the information associa	nation email you have er authorized represent ated with your nominatic	atives on.
Review	and Submit Profile cess the Open Payments er Guide ed help with the website?	Applicable M *Registration The ID is a 1	lanufacturer or Applicable GF n I D: 2-digit number	*Nomination ID: The ID is a 12-digit	number	
Co Priv	ntact Us by email view the Open Payments vacy Policy [PDF]	Show Nomi Cancel	nation			

<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 80: 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 81: Confirm Entity Page



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

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

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

Figure 82: 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 83: 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 users who hold the role of officer with that entity that you have accepted your nomination.

Figure 84: 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 IDM 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 85: 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 86: Create Profile Page

Create Profile Select Profile Type Register Entity Personal Information Review and Submit Profile Mathematical Submit Profile Secess the Open Payments User Guide Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF]	To begin creating a profile and registering in the Open Payments system, you must identify your affiliatio with an applicable manufacturer, applicable group purchasing organization (GPO), teaching hospital, physician, or non-physician practitioner. Users with provider type of Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist or Anesthesiologist Assistant, or Certified Nurse-Midwlfe are called Non-Physician Practitioner in the Open Payments system. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has not registered in the Open Payments system, you may register them and then yourself. For reporting entities, prior to beginning registration, collect the information required for reporting entity registration, then proceed with the registration process. For reporting teaching hospital, physician, or non-physician practitioner registration, prior to beginning registration, collect the information required for covered recipient registration, then proceed with the registration process. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner registration, beginning registration process.
 Select Profile Type Register Entity Personal Information Review and Submit Profile Access the Open Payments User Guide Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF] 	To begin creating a profile and registering in the Open Payments system, you must identify your affiliatio with an applicable manufacturer, applicable group purchasing organization (GPO), teaching hospital, physician, or non-physician practitioner. Users with provider type of Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist or Anesthesiologist Assistant, or Certified Nurse-Midwife are called Non-Physician Practitioner in the Open Payments system. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has not registered in the Open Payments system, you may register them and then yourself. For reporting entities, prior to beginning registration, collect the information required for reporting entity registration, then proceed with the registration process. For reporting teaching hospital, physician, or non-physician practitioner registration, prior to beginning registration, collect the information required for covered recipient registration, then proceed with the registration process. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner registration process.
 Register Entity Personal Information Review and Submit Profile Access the Open Payments User Guide Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF] 	 physician, or non-physician practitioner. Users with provider type of Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist or Anesthesiologist Assistant, or Certified Nurse-Midwife are called Non-Physician Practitioner in the Open Payments system. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has not registered in the Open Payments system, you may register them and then yourself. For reporting entities, prior to beginning registration, collect the information required for reporting entity registration, then proceed with the registration process. For reporting teaching hospital, physician, or non-physician practitioner registration, then proceed with the registration process. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has already been registered in the Open Payments system and you have not affiliated with them in the
 Personal Information Review and Submit Profile Access the Open Payments User Guide Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF] 	Assistant, or Certified Nurse-Midwife are called Non-Physician Practitioner in the Open Payments system. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has not registered in the Open Payments system, you may register them and then yourself. For reporting entities, prior to beginning registration, collect the information required for reporting entity registration, then proceed with the registration process. For reporting teaching hospital, physician, or non-physician practitioner registration, prior to beginning registration, collect the information required for covered recipient registration, then proceed with the registration process. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has already been registered in the Open Payments system and you have not affiliated with them in the
 Review and Submit Profile Access the Open Payments User Guide Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF] 	system. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitione has not registered in the Open Payments system, you may register them and then yourself. For reporting entities, prior to beginning registration, collect the information required for reporting entity registration, then proceed with the registration process. For reporting teaching hospital, physician, or non-physician practitioner registration, prior to beginning registration, collect the information required for covered recipient registration, then proceed with the registration process. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has already been registered in the Open Payments system and you have not affiliated with them in the
Access the Open Payments User Guide Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF]	 In the oppinger interpretation of the open Payments system, you may register them and then yourself. For reporting entities, prior to beginning registration, collect the information required for reporting entity registration, then proceed with the registration process. For reporting teaching hospital, physician, or non-physician practitioner registration, prior to beginning registration, collect the information required for covered recipient registration, then proceed with the registration process. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitioner has already been registered in the Open Payments system and you have not affiliated with them in the
Access the Open Payments User Guide Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF]	For reporting entities, prior to beginning registration, collect the information required for reporting entity registration, then proceed with the registration process. For reporting teaching hospital, physician, or non-physician practitioner registration, prior to beginning registration, collect the information required for covered recipient registration, then proceed with the registration process. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitione has already been registered in the Open Payments system and you have not affiliated with them in the
 Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF] 	For reporting teaching hospital, physician, or non-physician practitioner registration, prior to beginning registration, collect the information required for covered recipient registration, then proceed with the registration process. If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practition has already been registered in the Open Payments system and you have not affiliated with them in the
Review the Open Payments Privacy Policy [PDF]	If the applicable manufacturer, applicable GPO, teaching hospital, physician, or non-physician practitione has already been registered in the Open Payments system and you have not affiliated with them in the
	Open Payments system you may
	 Ask a user already affiliated with the reporting entity or covered recipient to nominate you for a user role; or
	 Create a personal profile and request a role with the reporting entity or covered recipient user. No that users who wish to associate themselves with physicians or non-physician practitioner must be nominated by the physician or non-physician practitioner.
	Required Information
	Fields for required information are marked with an asterisk.
	It is important that you have all required information available when you begin because registration must be completed in one session. A registration session will time out after 30 minutes of inactivity. If that occurs, all information entered during that session will be lost.
	A list of required information is available in the "Required Information for Registration" quick reference guide [PDF]. This QRG is also available on the Resources page of the Open Payments website.
	Registering as a Physician or a Teaching Hospital
	If you are a physician who works at a teaching hospital and wish to see data related to you in your capacity as a physician, select the "Physician or Non-Physician Practitioner" option when registering. Registering as a user affiliated with a teaching hospital will allow you to see only data related to that teaching hospital and not your records. You may register as both a physician and a user affiliated with a teaching hospital if needed.
	Physicians should register themselves in the Open Payments system and not delegate this task to another individual.
	Registering as a Non-Physician Practitioner
	If you are registering as a Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist or Anesthesiologist Assistant, or Certified Nurse-Midwife, select the "Physician or Non-Physician Practitioner" option when registering. If you are a Physician Assistant, Nurse Practitioner, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist or Anesthesiologist Assistant, or Certified Nurse-Midwife who works at a teaching hospital and wish to see data related to you in your capacity as a non-physician practitioner, select the "Physician or Non-Physician Practitioner" option when registering.
	When you are ready to begin registration, select "Start Profile."

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

Figure 87: 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 88: Find an Entity Page



<u>Step 5:</u> 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 89: Find an Entity Page

Open Payments (Sunshine Act)



<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 90: 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.

Open Payme	ents (Sur	nshine A	Act)		
licable Manufacturer or Group Purchasin	g Organization Switch User Ty	pe			
1		Ô	2	⊠	۲
Home Submissions	Review and Dispute	Manage Entities	<u>My Profile</u>	Messages	Resource
reate Profile	Your Ro)IE			
	To associate your	self with a reporting entity	in the Open Payments sys	stem, you must nominat	te yourself for c
Select Profile Type	or more user role	s. The user roles are as fo	lows:		
 Entity Information 	Updates the	e applicable manufacturer	or applicable GPO profile	information and can ap	prove and mod
Your Roles	nomination	s for user roles.			
Personal Information	Can deactive Can review	vate other users from the e	ntity. e messages on behalf of th	ne applicable manufactu	urer or applicab
) Review and Submit Profile	GPO.				
Access the Open Payments	Submitter:				
Need help with the website?	Submits an The submit	d edits payment information ter role can be held by ind	n on behalf of the applica viduals from third-party er	ole manutacturer or app itities who submit recore	ds on behalf of
Contact Us by email	applicable	manufacturer or applicable	GPO.		
Review the Open Payments Privacy Policy [PDF]	Attester:		and timeliness of the des	a submitted for the apprecia	liaabla
	Allesis to tr manufactur	er or applicable GPO.	, and unreiness of the da	a submitted for the app	licable
	 Can submit investment 	assumptions made in the interests.	reporting of payments, oth	ner transfers of value, o	r ownership or
	Compliance				
	Can review GPO.	and download compliance	e messages on behalf of th	ne applicable manufactu	urer or applicab
	*****		84:-1-11- 61-		
	Lesllie			me.	
	*Last Name:		Suffix (Jr.	Sr., etc.):	
	Smith				
	*Business Em	ail Address:	*Business 999-999-9	Telephone Number: 999 or Maximum 20 d	ligits
	openpayments	@yopmail.com	555-555-5	555	
	Indicate your ro attesters, subm officer with the your nominatio	ble(s) in the Open Paymen hitters, compliance users, a reporting entity has appro n is approved.	ts system. Only an officer and other officers. Your rol ved your self-nomination.	may manage the acces e(s) is/are not confirmed You will be notified via e	s levels of d until an email if
	Highest Level	of Role			
	Cofficer Reporting-rela	ated Roles			
	Submit	ter			
	Compliance-r	elated Roles			
	Compli 🗹	ance			
	Cancel			Back	Contin

Figure 91: Your Role Page

<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 all the information, select the "Continue" button.

Figure 92: Enter Personal Information Page

Open Paymen	ts (Sunshine A	ct)
Create Profile	Enter Personal Inform A field with an asterisk (*) is required.	
 Select Profile Type Register Entity 	Your first name and last name have been prepo (EIDM) profile. You may edit the prepopulated fi Payments will not change the corresponding inf	with create your user prome. pulated from your CMS Enterprise Identity Management system ields as needed. However, changing this information in Open formation in your EIDM profile.
③ Personal Information④ Review and Submit Profile	Once you have entered the information, select t	the "Continue" button.
Access the Open Payments User Guide [PDF]	*First Name:	*Last Name: 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 Information Enter your business or entity information. *Business Email Address: openpayments5@yopmail.com	*Job Title: Director
	*Country: United States	٣
	*Business Address, Line 1: 7500 Security Blvd.	
	*City Name:	*State-
	Baltimore	Maryland v
	*Zip Code: 99999 9999 21244	*Business Telephone Number: 999-999-9999 555-555-5555
	Cancel	Back

<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.

Open Payments (Sunshine Act) 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: 100000345025 Register Entity Entity's Legal Name: ABCDE Medical Personal Information Reporting Entity Type: Applicable Manufacturer (4) Review and Submit Profile Business Type: Applicable manufacturer-drugs/biological Food & Drug Administration (FDA) Establishment Identifier: 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 Need help with the website? Contact Us by email **Business Address:** Review the Open Payments 8 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: 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: Middle Suffix (Jr., Sr., Business Email Address: First Last Name: Name: Name: etc.): Officer. Leslie Smith openpayments@yopmail.com Submitter Attester Continue Cancel Back

Figure 93: Review and Submit Profile Page

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

Figure 94: Success Confirmed Page

Open Payments (Sunshine Act)

Create Profile

Success Confirmed You have successfully requested to be affiliated with ABCDE Medical.

Select Profile Type

Register Entity

Personal Information

Review and Submit Profile



You may now go to Open Payments Home

You will receive an email when your nomination is approved. You can refer to the Open Payments User Guide [PDF, 37.3 MB] for further information.

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

Note: You will not be able to take any actions related to this profile until the entity has been successfully registered.

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 IDM 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 95: Open Payments System Landing Page for returning system users



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

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type (2) My Prolite ¤₀ ً₿ ۲ £ ⊵ ۵ Review and Dispute Messages Resources Manage Entities My Profile Access the Open Payments User Guide [PDF, 37.3 MB] C Overview **Profile Details** My Roles & Need help with the website? Contact Us by email ? Nominations Review the Open Payments Privacy Policy [PDF, 102 KB] This page contains information about your authorized role(s) 8 An explanation of the statuses below can be found in the Open Payments User Guide (PDF, 37.3 MB] **Profile Name** Leslie Smith Your Authorized Roles Status: Role: Entity: ABCDE Medical Officer Requested Submitter ABCDE Medical Requested Attester ABCDE Medical Requested **Recent Notifications** There are no recent notifications for this profile.

Figure 96: My Profile Page

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

Figure 97: My Roles and Nominations tab

)pen		ents (Su	nshine A	Act)		
Home	Bubmissions	Review and Dispute	ල් Manage Entitles	@ My.Profile	Messages	Resource
y Prot	file			e	Access the Ope User Guide (PD	in Payments F, 37.3 MB]
Overview	w Profile	Details My Role Nominal	ions	1	Need help with t	he website? email
Below are you sccept additio	ur user roles for each o onal roles or request as	entity with which you are aff dditional roles for your affilia	liated. You have the option ted entities.	n to	Review the Ope Privacy Policy (F	n Payments PDF, 102 KB]
Below are you accept additio An explanatio MB] . Accept a Ro My Roles	ur user roles for each o onal roles or request a on of the statuses below le Request a f	entity with which you are aff dditional roles for your affilia w can be found in the Open Role	liated. You have the option ted entities. Payments User Guide [PC	n 10 0F, 37.3	Review the Ope Privacy Policy (1	in Payments PDF, 102 KBJ
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<u>Step 4:</u> Enter the Taxpayer Identification Number/Employer Identification Number (TIN/EIN) of the reporting entity that you want to associate yourself with. The TIN must be nine digits, with a dash after the second digit. Select "Find."

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

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



Figure 98: 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 99: 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	100:	Your	Role	page
--------	------	------	------	------

Open Payme	organization Switch User Type	shine A	Act)		
Home Submissions	Review and Dispute	Ø Manage Entities	Q <u>My Profile</u>	Messages	Resources
Create Profile	Your Role A field with an asteri	e sk (*) is required.			
Select Profile Type	To associate yoursel or more user roles.	lf with a reporting entity The user roles are as fo	in the Open Payments sys llows:	tem, you must nomina	te yourself for one
 Register Entity Entity Information Your Roles 	Officer: • Updates the a nominations for	pplicable manufacturer or user roles.	or applicable GPO profile i	nformation and can ap	prove and modify
③ Personal Information	Can deactivate	e other users from the e	entity.		
④ Review and Submit Profile	Can review an GPO.	nd download compliance	e messages on behalf of th	e applicable manufact	urer or applicable
Access the Open Payments User Guide [PDF] Point Need help with the website? Contact Us by email Review the Open Payments Privacy Policy [PDF]	Submitter: Submits and e The submitter applicable ma Attester: Attests to the imanufacturer Can submit as investment int Compliance Can review ar GPO.	edits payment information role can be held by ind nufacturer or applicable accuracy, completeness or applicable GPO. assumptions made in the erests.	on on behalf of the applicat ividuals from third-party en GPO. 5, and timeliness of the dat reporting of payments, oth e messages on behalf of th	le manufacturer or ap tities who submit recor a submitted for the app er transfers of value, o e applicable manufact	blicable GPO. ds on behalf of the blicable or ownership or urer or applicable
	*First Name:		Middle Nar	ne:	
	*Last Name: Smith		Suffix (Jr.,	Sr., etc.):	
	*Business Email	Address:	*Business	Telephone Number:	
	openpayments@)	ronmail.com	999-999-99	999 or Maximum 20 o	ligits
	Indicate your role attesters, submitte officer with the rep your nomination is Highest Level of Ø Officer Reporting-relate Ø Submitter Ø Attester Compliance-relat Ø Complian	(s) in the Open Paymer pers, compliance users, a porting entity has appro s approved. Role d Roles ted Roles ce	ts system. Only an officer i and other officers. Your role ved your self-nomination. Y	may manage the acces e(s) is/are not confirme fou will be notified via a	ss levels of d until an email if
	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.

Figure 101: 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 102: 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 IDM 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 (2) My Profile Manage Entities ⊠ **3** ۲ Home ⊵ ⊿ Message w and Disput Access the Open Payments User Guide [PDF] Welcome to the Open Payments System Need help with the website? Announcements Contact Us by email Program Year 2018 Review and Dispute Period Open -The Review and Dispute period is open starting April 1, 2019. During this period, reporting entities Review the Open Payments Privacy Policy [PDF] 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 103: Open Payments system landing page for returning system users

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



Figure 104: 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.



Figure 105: 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.

Figure 106: Manage Roles tab

licable Manufacturer or C	Broup Purchasing C	rganization Swit	Sun tch User Type	shine /	Act)			
Home Sub	missions I	Review and D	Dispute	o Manage Entities	() My Profile		Messages	Resource
BCDE Me	dical					1	Access the Ope User Guide [PDF	n Payments F, 37.3 MB]
Entity Details	Manage Ro	les				?	Need help with ti Contact Us by e	he website? email
Select the "Nominate I	New Role" button	to nominate a	new individua	al to fill a role within y	our entity.	8	Review the Ope Privacy Policy [P	n Payments PDF, 102 KB]
Select the "Deactivate entity. Note: An officer may m the entity.	User" button by a	e another offic	to remove that	t user completely from	es from	\$		
Select the "Deactivate entity. Note: An officer may m the entity. An explanation of the s MB].	User" button by a nodify or deactivat	e another offic	to remove that	t user completely from t deactivate themselv ments User Guide [P	es from DF, 37.3 New Role	C		
Select the "Deactivate entity. Note: An officer may m the entity. An explanation of the s MB] .	User" button by a nodify or deactivat statuses below ca Role:	and to add of a user's name to add of a user's name to a nother offic n be found in the Status:	to remove that er but cannot the Open Pay Actions:	t deactivate themselv ments User Guide [P	es from PDF, 37.3 New Role	C		
Select the "Deactivate entity. Note: An officer may m the entity. An explanation of the s MB] . Name: John Miller	User" button by a nodify or deactivat statuses below ca Role: Attester	e another offic n be found in t Status:	Actions: Modify	t user completely from t deactivate themselv ments User Guide [P	PDF, 37.3 New Role	6		
Select the "Deactivate entity. Note: An officer may m the entity. An explanation of the s MB] . Name: John Miller	User" button by a nodify or deactivat statuses below ca Role: Attester Submitter	and to add of a user's name to add of a user's name to a nother offic n be found in the found in the status: Approved Approved	to remove that er but cannot the Open Pay Actions: Modify	t user completely from t deactivate themselv ments User Guide [P	PDF, 37.3 New Role	6		
Select the "Deactivate entity. Note: An officer may m the entity. An explanation of the s MB] . Name: John Miller	User" button by a nodify or deactivat statuses below ca Role: Attester Submitter Officer	and to add of a user's name to add of a user's name to a nother offic n be found in the found in the status: Approved Approved Verified	Actions:	t deactivate themselv ments User Guide [P	es from PDF, 37.3 New Role	0		
Select the "Deactivate entity. Note: An officer may m the entity. An explanation of the s MB] . Name: John Miller Tom Smith	User" button by a nodify or deactivat statuses below ca Role: Attester Submitter Officer Submitter	and to add of a user's name t e another offic n be found in t Status: Approved Approved Verified Accepted	Actions: Modify	t deactivate themselv ments User Guide [P Nominate Deactivate Use	PDF, 37.3 New Role	6		
Select the "Deactivate entity. Note: An officer may m the entity. An explanation of the s MB] . Name: John Miller Tom Smith Karen Miller	User" button by a nodify or deactivat statuses below ca Role: Attester Submitter Officer Submitter Submitter	and to add of a user's name to add of a user's name to a nother offic n be found in the found in	Actions: Modify Modify	Deactivate Use	rc duser. myour PDF, 37.3 New Role	6		

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

Figure	107:	Red	box	circles	confirmation	message
1.9410		n.c.a	NOA	cii cico		message

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type											
Home Submis	sions	Review and Dispu	ute Mar	nage Entities	O My Profile		Messages	Resources			
ABCDE Medi	cal					1	Access the Ope User Guide [PDf	n Payments -, 37.3 MB]			
Entity Details	<u>Manage Ro</u>	les				?	Need help with the Contact Us by e	he website? email			
Confirmation: • The selected user,	Leslie Smith	, has been approve	ed for the C	officer role.		a	Review the Ope Privacy Policy [F	n Payments PDF, 102 KB]			
Select the "Nominate New Role" button to nominate a new individual to fill a role within your entity. Select the "Modify" button by a user's name to add or remove a role for an already affiliated user. Select the "Deactivate User" button by a user's name to remove that user completely from your entity. Note: An officer may modify or deactivate another officer but cannot deactivate themselves from the entity. An explanation of the statuses below can be found in the Open Payments User Guide [PDF, 37.3 MB]. Nominate New Role											
Name:	Role:	Status:	Actions:								
John Miller	Attester	Approved	Modify								
	Submitter	Approved									
	Officer	Verified									
Tom Smith	Submitter	Accepted	Modify	Deactivate L	Jser						
Karen Miller	Submitter	Accepted	Modify								
Leslie Smith	Officer	Approved	Modify	Deactivate U	Jser						
To modify the nomination, select "Modify."

Figure 108: Manage Roles tab

Dicable Manufacturer or C	Byme Broup Purchasing (nts (S	Sunsh th User Type	ine A	ct)			
Home Sub	missions	Review and Di	spute <u>Manage</u>	Entities	O My Profile		Messages	Resource
ABCDE Me	dical						Access the Open User Guide [PDF, I	Payments 37.3 MB]
Entity Details	Manage Ro	les				?	Need help with the Contact Us by em	website?
An explanation of the s MB] . Name:	tatuses below ca Role:	n be found in the Status:	e Open Payments U Actions:	ser Guide [PDF,	37.3 Role			
John Miller	Attester	Approved	Modify					
	Submitter	Approved						
	Officer	Verified						
Tom Smith	Submitter	Accepted	Modify D	eactivate Use	r			
Karen Miller	Submitter	Accepted	Modify C	eactivate Use	r			

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 109: Manage Roles tab

1 Home	Submissions	Review and Dispute	Manage Entities	O My Profile		Messages	Resour
BCDE	Medical				1	Access the Op User Guide [PE	en Payments)F]
Entity Detail	s <u>Manage R</u>	Roles			?	Need help with Contact Us by	the website? email
slieSmit	h storisk (*) is required				6	Review the Op Privacy Policy [en Payments [PDF]
* First Name: Leslie *Last Name:		Middle Name:	etc.):		0		
Smith							
*Business Em	ail Address:					· BY	
openpayments	@yopmail.com					. 🖻	
*Indicate the r	ole or roles this perse	on will have:					
Officer							
Submitt	er						
Attester							
Complia	ance						
*Country:							
United States				•			
*Business Add	Iress, Line 1:						
7500 Security	Blvd.						
Business Addr	ress, Line 2:						
*City Name:		*State:					
Baltimore		MD		•			
*Zip Code:	999	*Business Tele 999-999-9999	phone Number:				
99999 30							

You will receive an onscreen confirmation of the information submission.

Figure 110: Manage Roles tab

Dpen Pa plicable Manufacturer or f	ayme Group Purchasing (nts (S Irganization Switch	uns User Type	hine A	Act)			
Home Sub	missions	Review and Disp	pute <u>Ma</u> r	age Entities	(Q) My Profile		Messages	Resources
ABCDE Me	dical					1	Access the Oper User Guide [PDF	n Payments 37.3 MB]
Entity Details	Manage Rol	les				?	Need help with th Contact Us by e	ne website? mail
Confirmation:	6 .11					8	Review the Oper Privacy Policy [P	n Payments DF, 102 KB]
An explanation of the s	tatuses below car	n be found in the (Open Paymen	ts User Guide [PDI	F, 37.3 w Role	4		- An
Name:	Role:	status:	Actions:					
And the Rest of States of		A second second	Advantia .					
John Miller	Attester	Approved	Modify					
John Miller	Attester Submitter Officer	Approved Approved Verified	Modify					
John Miller Tom Smith	Attester Submitter Officer Submitter	Approved Approved Verified Accepted	Modify	Deactivate Us	ier			
John Miller Tom Smith Karen Miller	Attester Submitter Officer Submitter Submitter	Approved Approved Verified Accepted Accepted	Modify Modify Modify	Deactivate Us Deactivate Us	er er			
John Miller Tom Smith Karen Miller Leslie Smith	Attester Submitter Officer Submitter Submitter Submitter	Approved Approved Verified Accepted Accepted Nomination Approved	Modify Modify Modify Modify	Deactivate Us Deactivate Us	er er			

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 IDM 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 111: Open Payments System Landing Page for returning system users

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

Figure	112:	Manage	Entities	Page
1 ISUIC	*** .	manage	LITCICS	I USC

Open Pay	yments (S p Purchesing Organization Switch	Suns User Type	hine /	Act)			
Home Submiss	sions Review and Dis	pute <u>Mar</u>	age Entities	O My Profile		Messages	Resources
Manage Ent	ities				1	Access the Ope User Guide [PDF	n Payments 7, 37.3 MB]
-			Register N	w Entity	?	Need help with the Contact Us by e	he website? mail
The entities you are associ the entity's profile and, if yo	ated with are listed below. Sel ou hold the officer role, manag	ect an entity fro e user roles aff	om the list below filated with the er	o view tity.	8	Review the Ope Privacy Policy (P	n Payments PDF, 102 KB1
Entities pending recertificat those entities. Entity recerti reviews, updates (as neces	tion must be recertified before ification requires that an active ssary), and confirms the accur	users can perfo officer within t acy of the entit	form any system a the Open Paymer y's profile informa	actions for its system tion.			5
Changes made to the Entity vetted.	y Name, TIN, or DUNS Numb	er fields will cau	use your entity to	be re-	3		X
Your Entities							ABR
Name: ABCDE Medical	Registration ID: 100000355013	Status: Vetted	Date Verified 04/26/2017 1	l: 0:20:02			
					1		

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

Figure 113: Manage Roles Tab

vicable Manufacturer o	Croup Purchasing C	IIILO (C	DUNSI N User Type	nine A	(Ct)			
Home Su	bmissions	Review and Dis	pute <u>Man</u>	age Entities	() My Profile		Messages	Resource
BCDE M	edical					1	Access the Op	en Payments
Entity Details	Manage Ro	les				?	Need help with Contact Us by	the website? email
Select the "Nominate	New Role" button	to nominate a ne	w individual to f	fill a role within you	r entity.	8	Review the Op Privacy Policy [en Payments PDF, 102 KB]
select the modify b	ation by a user's na	ame to add or ren	nove a role for a	sh a ready amilated	user.			
Select the "Deactivat entity. Note: An officer may	e User" button by a modify or deactivat	e another officer	ternove that use	r completely from y	from		1	A.
Select the "Deactivat entity. Note: An officer may the entity. An explanation of the MB].	e User" button by a modify or deactivat statuses below ca	a user's name to i le another officer n be found in the	emove that use but cannot dea Open Payment	ctivate themselves	from 7, 37.3	C		
Select the "Deactivat entity. Note: An officer may the entity. An explanation of the MB] .	e User" button by a modify or deactivat statuses below ca	a user's name to i le another officer n be found in the	emove that use but cannot dea Open Payment	r completely from y ctivate themselves ts User Guide (PDF Nominate Net	your from 7, 37.3 w Role	6		
Select the "Deactivat entity. Note: An officer may the entity. An explanation of the MB] . Name:	e User" button by a modify or deactivat statuses below car Role:	a user's name to i le another officer n be found in the Status:	temove that use but cannot dea Open Payment Actions:	tr completely from y ctivate themselves ts User Guide (PDF Nominate Net	your from 7, 37.3 w Role	0		
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Select the "Deactivat entity. Note: An officer may the entity. An explanation of the MB] . Name: John Miller	e User" button by a modify or deactivat statuses below car Role: Attester Submitter	a user's name to i te another officer n be found in the Status: Approved Approved	emove that use but cannot dea Open Payment Actions: Modify	r completely from y ctivate themselves ts User Guide (PDF Nominate Net	your from 7, 37.3 w Role			
Select the "Deactivat entity. Note: An officer may the 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 i te another officer n be found in the Status: Approved Approved Verified	emove that use but cannot dear Open Payment Actions: Modify	tr completely from y ctivate themselves ts User Guide (PDF	rom 7, 37.3 w Role	C		
Select the "Deactivat entity. Note: An officer may the entity. An explanation of the MB] . Name: John Miller Tom Smith	e User" button by a modify or deactivat statuses below car Role: Attester Submitter Officer Submitter	a user's name to i te another officer in be found in the Status: Approved Approved Verified Accepted	Actions: Modify	ctivate themselves ts User Guide (PDF Nominate Ner	your from 7, 37.3 w Role			
Select the "Deactivat entity. Note: An officer may the entity. An explanation of the MB] . Name: John Miller Tom Smith Karen Miller	e User" button by a modify or deactivat statuses below car Role: Attester Submitter Officer Submitter Submitter	a user's name to i te another officer in be found in the Status: Approved Approved Verified Accepted Accepted	Actions: Modify Modify Modify	ctivate themselves ts User Guide [PDF Nominate Ner Deactivate Us Deactivate Us	your from 5, 37.3 w Role er			

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

Figure 114: Deactivate User on Manage Roles Tab

splicable Manufacturer or C	3 yme	nts (S	Sunsl	hine A	ct)			
Home Subr	missions	Review and Dis	pute <u>Man</u>	age Entities	() My Profile		Messages	Resource
ABCDE Me	dical					1	Access the Op User Guide [PD	en Payments F, 37.3 MB]
Entity Details	Manage Ro	les				?	Need help with Contact Us by	the website? email
Note: An officer may me the entity. An explanation of the st MB1.	odify or deactivat tatuses below ca	te another officer n be found in the	Open Payment	ctivate themselves	from , 37.3	C		Kha
Name:	Role:	Status:	Actions:	Nominate New	v Role		2	
Name:	Role:	Status:	Actions:	Nominate New	v Role		2	
Name: John Miller	Role: Attester	Status: Approved	Actions: Modify	Nominate New	v Role			
Name: John Miller	Role: Attester Submitter	Status: Approved Approved	Actions: Modify	Nominate New	v Role		10	
Name: John Miller	Role: Attester Submitter Officer	Status: Approved Approved Verified	Actions: Modify	Nominate New	v Role			
Name: John Miller Tom Smith	Role: Attester Submitter Officer Submitter	Status: Approved Approved Verified Accepted	Actions: Modify Modify	Nominate New	v Role			

<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 Rol	les	_			?	Need help with the website? Contact Us by email
Select the "Nominate Ne Select the "Modify" butto Select the "Deactivate U entity.	ew Role" button t on by a user's na Jser" button by a	to nor ame to user'	ninate a new individua add or remove a role s name to remove tha	al to fill a role within y for an already affiliat t user completely fror	our entity. ed user. n your		Review the Open Payments Privacy Policy [PDF, 102 KB]
Note: An officer may mo the entity.	dify or deactivat	e ano	ther officer but cannot	deactivate themselve	es from	S.	
An explanation of the st	atuses below car	n he	Deactivate U	ser			
MB].			Selecting this option v entity. They will no lor behalf of your entity.	vill deactivate Tom S nger be able to perfor	mith from your m actions on		
Name:	Role:	Sta	Pomindor: Entitios m	ist have at least one	activo officor in		
John Miller	Attester	Ap	the Open Payments s	system. Select "Contir	nue" to deactivate		
	Submitter	Ap	this user, or select "Ca	ancel" to return to the	previous page.		
	Officer	Ve	Cancel		Continue		
Tom Smith	Submitter	Ac					
Karen Miller	Submitter	Acc	epted Modi	fy Deactivate	Jser		
Leslie Smith	Submitter	Non App	nination roved Modi	fy			
	Attester	Non App	nination roved				

Figure 115: Manage Roles Tab. A pop-up message is displayed to "Deactivate User"

Figure 116: Confirmation Message on Mage Roles Tab

Dpen P	Croup Purchesing (nts (S Organization Switch (unsi Jser Type	nine /	Act)			
Home Sut	missions	Review and Disp	ute <u>Man</u>	ge Entities	() My Profile	;	Messages	Resource
BCDE Me	dical					1	Access the Ope User Guide (PDI	n Payments F, 37.3 MB]
Entity Details	Manage Ro	les				?	Need help with t Contact Us by e	he website?
Confirmation:				7		8	Review the Ope Privacy Policy [P	n Payments PDF, 102 KB]
the entity. An explanation of the MB] .	statuses below ca	n be found in the C	pen Payment	s User Guide [PI	DF, 37.3	4		
Name:	Role:	Statue	Actions:					
John Miller	Attester	Anoroved	Modify					
	Submitter	Approved	mouny					
	Officer	Verified						
	Submitter	Accepted	Modify	Deactivate U	ser			
Karen Miller								
Karen Miller Leslie Smith	Submitter	Nomination Approved	Modify					

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

3.7b: Vetting Timeframe

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

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

Data Submission and Attestation

Chapter 4: Data Submission and Attestation

This chapter on data submission and attestation provides detailed information on how applicable manufacturers and applicable GPOs can 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, NPPs 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, NPPs and teaching hospitals to review and dispute.

Figure 127 provides an overview of the data submission and attestation process.

Figure 117: 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, NPP and teaching hospital identifying information. Physician identifying information can be found in the Validated Physician List (VPL). Non-Physician Practitioner identifying information can be found in the Validated Non-Physician Practitioner List (VNPPL). The documents can be downloaded from the "Submissions" page of the Open Payments system. Teaching hospital identifying information can be found in the Teaching Hospital list, which can be downloaded from the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/Resources.

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

If the NPP license information is not active beginning with Program Year 2021 to present and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

Section 4.2: Data Submission

The data submission process requires reporting entities to submit detailed information regarding payments or other transfers of value made to physicians, NPPs 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/Resources.

Section 4.3: Preparing Your Data

Chapter 2 of this User Guide presents detailed descriptions of the information that must be collected for submission 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), NPP (including all principal investigators) and teaching hospital included in the records to ensure that it is current and accurate. To assist with this validation, CMS provides the Validated Physicians List (VPL), the Validated Non-Physician Practitioners List (VNPPL) and the CMS Teaching Hospital List.

• The Validated Physicians List (VPL) contains two separate files, one listing physicians who have an NPI, 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. Note: The Validated Physician List is a very large file and, depending on your network characteristics and software, may take a long time to download or fail to download. Additionally, the number of rows in the VPL file may be larger than the maximum rows your Microsoft Excel version supports. If you can't download the file, we recommend engaging your IT support staff. If you can download the file but are unable to open it in MS Excel or get a message that the data has been truncated, we recommend trying alternative programs such as MS Access, Universal Viewer, Editpad, Notepad++, or any other software your organization has available for large datasets.

- The Validated Non-Physician Practitioners List (VNPPL) is a reference data file that lists information about Physician Assistants (PA), Nurse Practitioners (NP), Clinical Nurse Specialists (CNS), Certified Registered Nurse Anesthetists or Anesthesiologist Assistants (CRNA/AA), and Certified Nurse-Midwives (CNM), collectively called NPPs. The VNPPL contains two separate files, one listing NPPs who have an NPI, and the second listing NPPs without NPI and have been reported on in the Open Payments system. The VNPPL is **not** an exhaustive list of all NPPs who should be reported in the Open Payments program. It can only be accessed 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/Resources</u>).
 - Use the hospital's "Doing Business As" name as the hospital name in the submitted record. The "Doing Business As" name is found in the Teaching Hospital List under the heading of "Hospital Name."
 - For the address for the hospital in the submitted record, use the "NPPES Business Address" column in the Teaching Hospital List.

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 2018-2020 dataPY 2021-2022, and 2023 and Onwards data.) The "Data Element Name", Column B in the "Submission Data Mapping Document," can be mapped to the "CSV Element Name" column of the sample file (template). You may also use this document as a guide when entering payments manually. Submission Data Mapping Documents can be found on the Resources page on the Open Payments website (https://www.cms.gov/OpenPayments/Resources).

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

If you hold a submitter role for a reporting entity, you can access the covered recipient validation tool to validate information on physician and/or NPP profiles, prior to reporting that physician and/or NPP on the payment record. You must use the specific Covered Recipient validation template provided on the Open payments "Validate Covered Recipient" page to upload physician and/or NPP profile information for validation. Once the validation process is completed, you can download the results file for any physician and/or NPP that were not successfully matched. Note: When you upload the physician and/or NPP information to the system, the information is matched using the CMS validated resources.

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

- Select the "Validate Covered Recipient" button located on the bottom of the "Submissions" Page.
- Submit physician and/or NPP information using the upload functionality on the Covered Recipient Validation page.

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

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

Figure 118: Submissions Tab

Open Paym Applicable Manufacturer or Group Purchas	ents (Su sing Organization Switch Us	unshine A	Act)		
Home Submissions	Review and Disput	🔊 te Manage Entities	O My Profile	Messages	Resources
Submissions					? User Guid
A field with an asterisk (*) is required. Applicable manufacturers and applicabl System.	e GPOs must submit payn	nents, or other transfers of valu	e, and ownership or ir	vestment interests to the C	pen Payments
Submit Payment Data					
Only users who hold the role of submitte Upload or Manual Data Entry below. Refer to the Resources tab for the Oper reporting templates for the Bulk File Upload	er can submit information t n Payments Select t load. Open P	to the Open Payments system. Manual Data Entry to submit red ayments manual entry online fo Manual Data Entry	Select Bulk File	Download the P List The Validated Physician Physician with Inactive Li Supplement File per Prog should not be shared put	hysician Lists and icense(s) gram Year below blicty
Review Submitted Payme	nt Records			File Download Hel Validated Ph and Physicia License(s) St per Program	p @ ysician Lists n with Inactive upplement File Year
To review records, select the payment to drop-down lists below, then select "Revi	ype, entity whose records iew Detail".	*Select Brogram Yea	gram year from the	Download the N Physician Practi	on- itioner List
Please Select P Review Records - Summa	lease Select	Please Select	Review Detail	The Non-Physician Pract Program Year below sho publicly. Non-Physicia List	itioner List per uld not be shared an Practitioner
To view submission summary and/or att program year from the drop-down lists b	test records, select the ent below, then select "Review	tity whose records you wish to r v Summary".	eview and the	Download the R	eporting
*Select Entity: Please Select	*Select Program Year: Please Select	Review Sur	nmary	To download reporting te Resources tab.	mplates, see the
Review Submitted File(s)	Status				
Once a file for your entity has been sub	mitted, you may review the	e details by selecting "Review F	ile Status."		
Review File Status					
To verify provider matching information, information on the new page. The Cove and non-physician information to profile	select the "Validate Cove red Recipient Validation u s prior to reporting that cov	red Recipient" button below and tility can be used by submitters vered recipient on the payment	d upload provider to upload physician record.		
Validate Covered Recipient					
				Contact Us	A Privacy Polic

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

Figure 119: Validate Covered Recipient Button

Open Payments Applicable Manufacturer or Group Purchasing Organizati	S (Sur ion Switch User Typ	shine A "	Act)		
Home Submissions Review	and Dispute	් Manage Entities	O My Profile	Messages	Resources
Submissions					? User Guid
A field with an asterisk (*) is required. Applicable manufacturers and applicable GPOs must System.	submit payments,	, or other transfers of value	e, and ownership or i	nvestment interests to the C	open Payments
Submit Payment Data					
Only users who hold the role of submitter can submit Upload or Manual Data Entry below. Refer to the Resources tab for the Open Payments reporting templates for the Bulk File Upload.	information to the Select Manua Open Payme	Open Payments system. S al Data Entry to submit rec ints manual entry online fo	Select Bulk File ords using the rm.	Download the P List The Validated Physician Physician with Inactive Li	hysician Lists and icense(s)
Bulk File Upload	ds	Manual Data Entry		Supplement File per Prog should not be shared put File Download Hel Walidated Ph and Physicia License(s) Si per Program	gram Year below blicly. P vsician Lists n with Inactive upplement File Year
Fo review records, select the payment type, entity wh drop-down lists below, then select "Review Detail". *Select Payment Type: *Select Entity:	ose records you w	vish to review, and the prop *Select Program Year	gram year from the	Download the N Physician Practi	on- itioner List
Please Select Please Select Review Records - Summary		Please Select	Review Detail	Program Year below sho publicly. Non-Physicia List	uld not be share
To view submission summary and/or attest records, s program year from the drop-down lists below, then se	elect the entity wh lect "Review Sum	nose records you wish to re mary".	eview and the	Download the R Templates	eporting
*Select Entity: *Select Pro	ogram Year: ect	✓ Review Sum	imary	To download reporting te Resources tab.	mplates, see the
Review Submitted File(s) Status Once a file for your entity has been submitted, you ma Review File Status Covered Recipient Validation Utilit To verify provider matching information, select the "Validation on the new page. The Covered Recipient and non-physician information to profiles prior to report Validate Covered Recipient	ay review the deta	ils by selecting "Review Fi ecipient" button below and an be used by submitters 1 recipient on the payment i	le Status " I upload provider to upload physician record.		
				Contact IIs	Privacy Poli

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

Element	Description	Format
APPLICABLE_MANUFACTURER_OR_APP LICABLE_GPO_ID	Enter the Applicable Manufacturer's/Applicable GPO's Registration ID in this data field	Free form text
COVERED_RECIPIENT_TYPE	Enter the covered recipient type either physician or NPP. Allowed values include "1" = Physician "10" = Non-Physician Practitioner	Less than or equal to 20 digits
COVERED_RECIPIENT_FIRST_NAME	Enter the textual first name of the physician or NPP receiving the payment or other transfer of value.	Free form text
COVERED_RECIPIENT_LAST_NAME	Enter the textual last name of the physician or NPP receiving the payment or other transfer of value	Free form text
COVERED_RECIPIENT_NPI	Physician or NPP NPI (not the NPI of any group the physician or NPP belongs to)	Numeric digits only
COVERED_RECIPIENT_PRIMARY_TYPE	Enter Primary type of medicine practiced by the covered recipient Physician or NPP. Allowed values include "1" = Medical Doctor; "2" = Doctor of Osteopathy; "3" = Doctor of Dentistry; "4" = Doctor of Podiatric Medicine; "5" = Doctor of Optometry; "6" = Chiropractor "101" = Physician assistant "102" = Nurse practitioner "103" = Clinical nurse specialist "104" = Certified Registered Nurse Anesthetist "105" = Certified nurse-midwife "106" = Anesthesiologist Assistant	If Covered Recipient Type = "1" (Physician) then enter only one value between Covered Recipient Primary Type= "1" and Covered Recipient Primary Type= "6" as applicable OR "10" (NPP) then enter up to 6 comma separated values between Covered Recipient Primary Type= "101" and Covered Recipient Primary Type= "106" as applicable
COVERED_RECIPIENT_LICENSE_STATE _AND_LICENSE_NUMBER_1	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999

Figure 120: Covered Recipient Validation Data Fields Table

Element	Description	Format
COVERED_RECIPIENT_LICENSE_STATE _AND_LICENSE_NUMBER_2	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999
COVERED_RECIPIENT_LICENSE_STATE _AND_LICENSE_NUMBER_3	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999
COVERED_RECIPIENT_LICENSE_STATE _AND_LICENSE_NUMBER_4	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999
COVERED_RECIPIENT_LICENSE_STATE _AND_LICENSE_NUMBER_5	Enter the paired state and official state license number of the covered recipient Physician or NPP. May include up to 5 "Covered Recipient License State and License Number" pairs, if a Physician or NPP licensed in multiple states.	Unique pair of the state and license number in the following format: AA- 9999999999999999999999999999999999

Figure 121: Covered Recipient Validation Page

Dpen	Payme	ents (Su organization Switch User 1	nshine A	Act)			
1 Home	Submissions	Review and Dispute	C Manage Entities	O My Profile	• N	Messages	Resource
Cover A field with an	ed Recipie asterisk (*) is required.	nt Validatior	1		Downle List	bad the Pl	nysician
To submit you uploading you file specificatio Template avail	r covered recipient mate r validation file, ensure t ons. If needed, you may lable on the right sideba	thing validation file, follow th hat the file is in a valid .csv download the Open Payme r on this page.	e steps identified below. F file format and conforms to nts Covered Recipient Va	Prior to o the lidation	Physician Suppleme should not	with Inactive Lie nt File per Prog be shared pub	cense(s) Iram Year below Ilicly.
1. Select th be large 2. Select th	ne "Browse" button to r than 50 MB. ne "Upload File" button.	locate and select your file. I	Note: Individual data files (cannot		Validated Hel Validated Phy and Physician License(s) Su per Program	P 🚱 /sician Lists n with Inactive Ipplement File Year
will see the file only include th Status" button available upon	e details and results in the e provider profiles with of to refresh file status. A successful processing	te table below for 90 days a error(s) and their respective downloadable results file lin of the file.	fer the upload. The result error codes. Select the "F k in the results file column	is will Refresh o will be	Downle Physic The Non-F Program Y	oad the No ian Practi Physician Practi Year below shou	O n- tioner List tioner List per uld not be share
Must be a vali	id .csv file. Maximum o Browse	f 50 MB per file.			publicly.	Non-Physicia List	n Practitioner
Upload File			Refresh	Status	Downle Templa The cover	bad the Va ate	alidation
Showin Validation File ID:≎	ng 10 🗸 of 0 Ent	ries 🖂 🖂 Page 1 of File Status: Dat	1 → Page ✓ nitted Submitted re:≎ By:≎ Result	s File:	is available	e through the lir Covered Reci Template	nk below. i pient Validatic
No records fou	nd. ng 10 🔽 of 0 Ent	ries 🕢 🛹 Page 1 of	1 → → Page ✓				

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

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

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

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 "Browse" 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 "Covered Recipient Validation" page.

	Covered Recipient Va	alidation	Download the Physician List
	A field with an asterisk (*) is required. To submit your covered recipient matching valid uploading your validation file, ensure that the file file specifications. If needed, you may download Template available on the right sidebar on this c	The Validated Physician Lists and rior to Physician with Inactive License(s) the Supplement File per Program Year belo dation should not be shared publicly.	
Change Sila	 Select the "Browse" button to locate an be larger than 50 MB. Select the "Upload File" button. 	d select your file. Note: Individual data files ca	annot
$\leftarrow \rightarrow \checkmark$	This PC > Desktop	Search Desktop	Download the Non- Physician Practitioner Lis
Arganize	Personal_Desktop	Date modified Typ 11/13/2019 10:37 File	The Non-Physician Practitioner List per Program Year below should not be shar publicly. Non-Physician Practitioner List
📔 Docum	ents 🖈 🗸 K	V All Files (*,*) Open Cance	Download the Validation Template The covered recipient validation templa is available through the link below.
	Validation File ID:☆	File Status: Submitted Date: Submitted By: Results	File:
	No records found.		
	Showing 10 🗸 of 0 Entries 🖂	A Page 1 of 1 - Page	

Figure 122: Browse Pop-Up Window

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

<u>Step 5</u>: Click the "Download" button to download the results file. The results file, which is a pipe delimited .csv file inside of a .zip file and will include only the profiles with errors. If the system found a successful match on the entered physician and/or NPP profile then the results file will not include that NPP profile. The system will display the results file for 90 days after the upload within the Open Payments system.

Figure 123: Covered Recipient Validation with Download Option

Open Applicable Manufac	Payme turer or Group Purchasin	ents (Su g Organization Switch User T	nshine A	Act)			
h ome	Submissions	Review and Dispute	Ø Manage Entities	(Q) My Profile	(Me	ssages	Resources
Covere A field with an a To submit your	ed Recipiel asterisk (*) is required. covered recipient matc	nt Validation	e steps identified below. F	Prior to	Downloa List The Validate Physician wit	d the Ph d Physician L th Inactive Lic	ysician ists and ense(s)
file specification Template availa 1. Select th be larger 2. Select th	ns. If needed, you may able on the right sideba ie "Browse" button to r than 50 MB. ie "Upload File" button.	download the Open Paymer r on this page. locate and select your file. N	its Covered Recipient Va	idation	File Dowr	Supplement File per Program Year below should not be shared publicly. File Download Help ? Validated Physician Lists and Physician with Inactive License(s) Supplement File per Program Year	
Once you select will see the file only include the Status" button t available upon	t the "Upload File" but details and results in th e provider profiles with e to refresh file status. A o successful processing o	on, the file will be submitted e table below for 90 days at error(s) and their respective fownloadable results file lini of the file.	for validation and matchii ter the upload. The result error codes. Select the "F < in the results file column	ng. You s will Refresh will be	Downloa Physicia The Non-Phy	ad the No In Practit	on- ioner List ioner List per
File: Must be a valie	d .csv file. Maximum o Browse.	f 50 MB per file.			publicly.	ar below shou on-Physician ist	Id not be shared
Upload File Showing	a 10 🗸 of 1 Entri	es 🗤 🛹 Page 1 of 1	Refresh S	Status	Downloa Template The covered is available th	ad the Va e recipient valio	lidation dation template k below.
Covered_Recip	File Name:☆	File Status: Subm ⇒ Submitted Successfully 07/02	iitted Submitted By:≎ Result 2021 Karen Miller Dowr	s File:		overed Recij emplate	pient Validation
< Showing	g 10 🗸 of 1 Entri	es 🧃 🤜 Page 1 of 1	▶ ► Page 1				

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

Figure 124: Results File Data Elements

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

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

Section 4.4: Bulk File Upload

The Open Payments system allows 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 if the file size remains below 250MB, it is recommended that bulk files contain no more than 400,000 records, as this is the limit that can be downloaded in the system at any one time.

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.

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

4.4a: Delay Limit Reached

Per the Final Rule, records can only be delayed from publication for four-years from the year of payment (i.e., the record's program year). As such, records attributed to Program Years 2014-2019 are no longer eligible for a delay in publication, and will be included in the June 2024 publication.

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

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

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

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

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

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

4.4b: Creating CSV Files

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

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

Figure 125: CMS Open Payments website "Resources" page

SUBMISSION SAMPLE FILES Use the sample files below to format your data correctly for upload into the Open Payments system. Program Year 2023 ONLY use these files for records dated from January 1, 2023 and onward: CSV Sample File: General Payments (CSV) CSV Sample File: Research Payments (CSV) Program Years 2021 to 2022 ONLY use these files for records dated from January 1, 2021-December 31, 2022: CSV Sample File: General Payments (CSV) CSV Sample File: Research Payments (CSV) Program Years 2018 to 2020 ONLY use these files for records dated from January 1, 2018 - December 31, 2020: CSV Sample File: General Payments (CSV) CSV Sample File: Research Payments (CSV) Program Years 2018 and Onwards: Physician Owner/Investor This sample file should be used for submitting ownership/investment interests for all program years. CSV Sample File: Physician Owner/Investor (CSV)

Reporting templates are 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 126: Open Payments system "Resources" tab for submitters displaying available reporting templates

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type									
Home	Submissions	Review and Dispute	Ø Manage Entities	O My Profile	Messages	(Resources			
Open P	ayments R	esources							
Links to the Oper	n Payments resources a	re available below.				10			
For help obtainin	g a PDF viewer, go to th	e CMS.gov Help page.							
Open Payn Open Payn Open Payn Open Payn CMS Reso Error and V List of Drug List of Med Reporting	nents User Guide for Rep nents User Guide for Covo nents FAQ's (PDF) urces Website Varning Code Key [XLSX] varnies and National Dru ical Device or Medical Su Templates	orting Entities [PDF] ared Recipients [PDF] g Codes (NDC) pply Names and Primary Devi	ce Identifier						
Report templates submitted. The s	are available through the stress of the stre	e links below. Download the pared with an incorrect payr	e template(s) for the progra ment category or program y	m year(s) and payment ca /ear template.	tegory/categories for the	e records to be			
Research • PY 2018 - : • PY 2021 - : • PY 2023 ar General • PY 2018 - : • PY 2021 - : • PY 2021 - : • PY 2023 ar	2020 CSV Template File: I 2022 CSV Template File: Id Onwards CSV Templat 2020 CSV Template File: 2022 CSV Template File: I d Onwards CSV Template	Research Payments [CSV] Research Payments [CSV] e File: Research Payments [C General Payments [CSV] e File: General Payments ICS	SV] VI						
Ownership • PY 2018 ar	nd Onwards CSV Templat	e File: Physician Owner/Inves	tor [CSV]						

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 2023 and Onwards,

refer to the guidance in the "PY 2023 and Onwards 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 2023 and Onwards CSV Sample File: General Payments" and "PY 2023 and Onwards CSV Sample File: Research Payments." On the "Resources" tab within the Open Payments system, the templates are named "PY 2023 and Onwards CSV Template File: General Payments" and "PY 2023 and onwards CSV Template File: Research Payments."

To prepare general payment and research payment records for Program Years 2021-2022, refer to the guidance in the "PY 2021-2022 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 2021 and Onwards CSV Sample File: General Payments" and "PY 2021 and Onwards CSV Sample File: Research Payments."
- On the "Resources" tab within the Open Payments system, the templates are named "PY 2021 and Onwards CSV Template File: General Payments" and "PY 2021 and onwards CSV Template File: Research Payments."

To prepare general payment and research payment records for Program Years 2018-2020, refer to the guidance in the "PY 2018-2020 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 2018-2020 CSV Sample File: General Payments" and "PY 2018-2020 CSV Sample File: Research Payments."
- On the "Resources" tab within the Open Payments system, the templates are named "PY 2018-2020 CSV Template File: General Payments" and "PY 2018-2020 CSV Template File: Research Payments."

To prepare physician owner/investor records for any Program Years, refer to the guidance in the "PY 2023 and Onwards 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 2018 - Onwards CSV Sample File: Physician Owner/Investor."
- On the "Resources" tab within the Open Payments system, the template is named "PY 2018 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 the required data within the columns. Ensure all data has been entered correctly and save the file. You must save the file as a CSV file.

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

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

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

4.4c: Bulk File Upload Instructions

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

Figure 127: 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 128: Submission Landing Page

Home <u>s</u>	Submissions	Review a	Dispute	o Manage Entitie	s	O My Profile		Messages	Resource
Submissio	ons								? User Gu
A field with an asterisk	(*) is required	l. able GPOs must si	ubmit payments,	, or other transfers	of value, a	nd ownership or	investment i	nterests to the O	pen Payments
iystem. Submit Payme	nt Data								
)nly users who hold th Jpload or Manual Data	e role of subm Entry below.	nitter can submit in	ormation to the	Open Payments s	/stem. Sel	ect Bulk File	Down List	load the Pł	nysician
efer to the Resources porting templates for Bulk File	tab for the O the Bulk File I Upload	pen Payments Upload.	Select Manua Open Payme	al Data Entry to sul ents manual entry o Manual Data Entry	omit record nline form	Is using the	The Valio Physiciar Supplem should no	lated Physician L n with Inactive Lie ent File per Prog ot be shared pub	ists and cense(s) ram Year belo licly.
Review Submit	ted Payn	nent Record	s				File Do	Validated Phy and Physicial License(s) Su per Program	vsician Lists n with Inactive opplement File Year
o review records, sele rop-down lists below,	ect the paymen then select "R	nt type, entity whos eview Detail".	e records you w	vish to review, and	the progra	m year from the	Down Physi	load the No cian Practi	on- tioner Lis
Please Select		Please Select	•	Please Select		Review Detail	The Non- Program publicly.	Physician Practi Year below shou	tioner List per Ild not be shar
Review Record	ls - Sumn	nary					Ē	Non-Physicia List	n Practitioner
o view submission su rogram year from the	mmary and/or drop-down list	attest records, sel is below, then sele	ect the entity wh ct "Review Sum	iose records you w mary".	ish to revi	ew and the	Down Temp	load the Re lates	eporting
Select Entity: Please Select	~	*Select Prog Please Select	ram Year: t	Revi	ew Summ	агу	To downl Resource	oad reporting ter es tab.	mplates, see th
Review Submit	ted File(s	s) Status							
once a file for your ent	ity has been s	ubmitted, you may	review the deta	ils by selecting "Re	view File	Status."			
Review File Status									
overed Recip	ient Valio	lation Utility	0						
o verify provider mate	hing informati	on, select the "Vali	date Covered R	ecipient" button be an be used by sub	low and up mitters to u	oload provider upload physician			
nformation on the new nd non-physician info	mation to pro	files prior to reporti	ng that covered	recipient on the pa	vment rec	ord.			

<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 129: Upload Payments Page

Open Payme Applicable Manufacturer or Group Purchasing	nts (Su Drganization Switch User T	nshine /	Act)	
Home Submissions	Review and Dispute	Ø Manage Entities	O My Profile	Messages Resources
Upload Payments A field with an asterisk (*) is required. To submit your payment file, follow the si ensure that the file is in a valid file format needed, you may download the latest Op "Resources" tab of the Open Payments s 1. Select the appropriate payment ca file indicator that apply to the file's larger than 250 MB. 2. Select the "Browse" button to loo	eps identified below. Prices identified below. Prices or .zip) and conforrent en Payments Reporting " system. tegory, reporting entity, p payment records. Note: I	r to uploading your payme ns to the file specifications Templates available on the rogram year and resubmis ndividual data files cannot	nt file, If Sion be	Download the Physician List The Validated Physician Lists and Physician with Inactive License(s) supplement File per Program Year below should not be shared publicly. File Download Help ? Walidated Physician Lists and Physician with Inactive License(s) supplement File per Program Year below should not be shared publicly. File Download Help ? Walidated Physician Lists and Physician with Inactive License(s) Supplement File per Program Year
3. Select the "Submit File to Open Pa Once you select the "Submit File to Open submitted for validation and matching. You "Payment Category: General Payments "Reporting Entity: ABCDE Medicals	ayments" button. In Payments" button, the find ou will receive a status of	le and records within it will the file processing via ema	be iii.	Download the Non- Physician Practitioner List The Non-Physician Practitioner List per Program Year below should not be shared publicly.
*Program Year: 2018 *Resubmission File Indicator: New Submission *File:	Y			Download the Reporting Templates To download reporting templates, see the Resources tab.
Must be a valid .csv or .zip file. Maximu Samplefile.csv (<u>Browse</u> Submit File to Open Payments	um of 250MB per file.			

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

Figure 130: Confirmation Message on Uploads Payments Page

Open Paym	ents (Sul	nshine A	Act)	
Home Submissions	Review and Dispute	ි Manage Entities	O My Profile	Messages Resources
Upload Paymen A field with an asterisk (*) is require Confirmation: • Your file has been received notifying you of the results To submit your payment file, follow ensure that the file is in a valid file fineeded, you may download the late "Resources" tab of the Open Paymon 1. Select the appropriate paymon file indicator that apply to the larger than 250 MB. 2. Select the "Browse" button 3. Select the "Browse" button	tts ad. J and will undergo validations of these validations. The steps identified below. Prio ormat (.csv or .zip) and conforr ist Open Payments Reporting 1 ents system. ent category, reporting entity, p file's payment records. Note: I to locate and select your file. en Payments' button.	s. You will receive emails or to uploading your payment to the file specifications. Templates available on the rogram year and resubmiss ndividual data files cannot in the second se	nt file, If sion be	Download the Physician List The Validated Physician Lists and Physician with Inactive License(s) Supplement File per Program Year below should not be shared publicly. File Download Help @ Validated Physician Lists and Physician with Inactive License(s) Supplement File per Program Year
Once you select the "Submit File to submitted for validation and matchin "Payment Category: General Payments	Open Payments" button, the fing. You will receive a status of	le and records within it will the file processing via ema	be il.	The Non-Physician Practitioner List per Program Year below should not be shared publicly. Non-Physician Practitioner List
*Reporting Entity: ABCDE Entity *Program Year:	V			Download the Validation Template
2021 *Resubmission File Indicator: New Submission	V V			available through the link below. Physician Validation Template
*File: Must be a valid .csv or .zip file. Mu Brow Submit File to Open Payments Cancel	aximum 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 and/or NPP licenses or late submissions. Such records should be reviewed for accuracy from the warning log but can proceed to final submission without correction.

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.
- If the NPP license information is inactive beginning with Program Year 2021 to present and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

See Section 4.8 for details on record correction and resubmission.

4.4d: Review File Status page

Reporting entity users with a submitter role may check the status of their file upload from the "Review 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 IDM credentials, navigate to the Open Payments home page, and select the "Submissions" tab.

Figure 131: Open Payments System Landing Page for returning system users

Home	Submissions	Review and Dispute	Manage Entities	(My Profile		Messages	Resource
Welcor	me to the (Dpen Payme	ents System		1	Access the Op User Guide [PI	oen Payments DF]
Announce	ements				?	Need help with Contact Us by	the website? email
Program Year The Review and may receive dis	2018 Review and Disp d Dispute period is ope sputes from covered rec	oute Period Open - n starting April 1, 2019. Du cipients and should work wi	ring this period, reporting e th them directly to resolve t	htities	8	Review the Op Privacy Policy	en Payments [PDF]
correction period Visit the Open I questions, cont phone at 1-855	od will be included in fut Payments website at ht act the Open Payments -326-8366. For the TTN	ure data publications. tps://www.cms.gov/openpa s Help Desk by email at op / line, call 1-844-649-2766.	yments for information. For enpayments@cms.hhs.gov	or by			
You can manag	ge your user profile and	perform user role functions	s associated with your profi	e.			
According to the collection of infe for this informatic collection can re- organization. The dispute and dis the time estimation	e Paperwork Reductior ormation unless it displition collection is 0938- ange from 1 to 30,000 i his information collectic pute resolution process te(s) or suggestions for	a Act of 1995, no persons a ays a valid OMB control nu 237. The time required to nours per entity depending on may involve registration, ess. If you have any comme improving this form, pleas	re required to respond to a mber. The OMB control nur complete this information on the size and type of data submission, attestatio ants concerning the accurate write to CMS, 7500 Secu	nber n, y of ity			

<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 132: Review File Status Button

Home Su	bmissions	Review and Dispute	Ø Manage Entities	(Q) My Profile	Messages	Resources
Submissio	ns		, , , , , , , , , , , , , , , , , , ,			? User Guid
A field with an asterisk (* Applicable manufacturers System.) is required. and applicable	GPOs must submit paymen	ts, or other transfers of valu	le, and ownership or in	vestment interests to the C	Open Payments
Submit Paymen	t Data					
Only users who hold the Upload or Manual Data E Refer to the Resources to reporting templates for the	role of submitter intry below. ab for the Open F e Bulk File Uploa	can submit information to th Payments ad. Select Man	ne Open Payments system. Nual Data Entry to submit re nents manual entry online f	Select Bulk File	Download the P List The Validated Physician Physician with Inactive L	hysician
Bulk File U Review Submitte	^{pload} ed Paymen	t Records	Manual Data Entry		File Download Hei Validated Ph and Physicic License(s) S per Program	blicly. Ip ? hysician Lists an with Inactive hypement File h Year
To review records, select drop-down lists below, th *Select Payment Type: Please Select Review Records	s the payment typen select "Review" Sel	e, entity whose records you w Detail". ect Entity: ase Select	*Select Program Yea	ogram year from the r: Review Detail	Download the N Physician Pract The Non-Physician Prac Program Year below sho publicly.	on- itioner List titioner List per ould not be shared an Practitioner
To view submission sum program year from the dr	mary and/or attes op-down lists be	st records, select the entity v low, then select "Review Su	whose records you wish to mmary".	review and the	Download the R	eporting
*Select Entity: Please Select		*Select Program Year: Please Select	Review Su	mmary	To download reporting te Resources tab.	emplates, see the
Review Submitte Once a file for your entity Review File Status Covered Recipie To verify provider matchi information on the new p and non-physician inform Validate Covered Recip	ed File(s) S has been submi ent Validati ng information, s age. The Covere ation to profiles p ient	ttatus tted, you may review the de on Utility @ elect the "Validate Covered d Recipient Validation utility prior to reporting that covered	tails by selecting "Review f Recipient" button below an can be used by submitters ed recipient on the payment	File Status." Id upload provider to upload physician t record.		
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 IDM ID)
Payment Category
Program Year
Submission Type
Entity
Deleted Date

Deleted By (i.e. User First Name and Last Name Corresponding to IDM 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 133: Review File Status Page

Home Submissi	ons Revie	w and Dispute	Manage E] Entities	(My	9 Profile	м	essages	(Res	ourc
eview File St	atus									
e table below displays informa I payment categories. To acce	tion on files submi ess the File ID page	tted on or after Jar e of a processed N	n 1st, 2019 for ew Submissio	the reportin n or Resubi	g entities yo nission file,	u are asso select the	ciated with ac hyperlinked file	ross all availa e ID in the tab	able progra ble.	im ye
e the Search and Filtering too	to customize your	view of the file info	ormation.							
ile Status:	F	ayment Category	<i>r</i> :		Program	Year:				
In Process Rejected Submitted Successfully Submitted with Errors Processed with Warning System Failure Occurred Rejected - File Infected Deleted	*	General Payments Research Payment Ownership or Inves	s tment Interest	~	3665 2019 2018 2017 2016 2015 2014 2013			•		
Intity:	s	ubmission Type:			Submissi	ion Start I	Date:			
Lexton Construction, LLC	~	New Submission Resubmission Renew Delay in Pu Delete	blication	<u></u>	2018010 Submissi	ia 🗊 1 ion End D id 🚺	ate:			
Search Clear All	01									
	Showing	50 v of 1 En	tries 🗔 🖂	Page 1	of 1 🔛	► Pag	ge 1 v			
ile File I	lame:	File	Submitted	Submitted	Payment	Program	Type of	Entity:	Deleted	Del
D:		Status:	Date:	By:	Category:	Year:	Submission:		Date:	

Note: To access the Error Log and Warning 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 and the Warning Log. Select the "Error log" hyperlink at the bottom of the page to download and view the error log (or) select the "Warning Log" hyperlink at the bottom of the page to download and view the warning log. You can delete a file using the "Delete File" button.

Home Submissions	Review and Dispute	🔊 Manage Entities	O My Profile		Messages	Resources
File ID: 1000940				6	Access the Ope User Guide [PDI	n Payments ⁻]
Details about the File S	ubmitted			2	Need help with t	he website?
If any records have errors, download the file's warning log. The records ca ID. If necessary, this file can be delet	the file's error log. If any reco n be identified by the Record ed by selecting the "Delete F	ad nent	•	Review the Ope Privacy Policy [F	n Payments PDF]	
2021 Research Paymen	ts ABCDE Medical				1	
Original Upload File Name:	Valid_File_R	S_Warning.csv				2 hours
Type of Submission:	New Submiss	sion		C.		NA SA
Original /Resubmission Date:	11/18/2021 9	32 AM				
Submitted By:	Ted Smith				1 2	
File Size:	7 KB				- BIA	
File Type:	CSV					
Program Year:	2021					
Payment Category:	Research Pag	yments				
File Status:	Processed wi	th Warning				
Number of Records in File:	2					
Number of Records Uploaded:	2					
Error Log:	1000940_Res	search Payments Error(s)				
Warning Log:	1000940_Res	search Payments Warning(s	;)			
Back to Review File Status		Delete	File			

Note: Listed below are alternate ways to access the Error Log/ Warning Log for files "Submitted Successfully", "Submitted with Errors" or "Submitted with Warnings".

- On the Submissions page, under the "Review Submitted Payment Records" section, select the Payment Type, select the Entity and Program Year from the dropdowns and select the "Review Detail" button. On the "Payment Category" page, search the "File ID". The "File ID" link will display the "File ID" page that contains the Error Log and Warning Log.
- 2) On the Submissions page, under the "Review Records Summary" section, select the Entity and Program Year from the dropdowns and select the "Review Summary" button. Once on the "Review Records-Summary" 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 and Warning 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>.
- Select the "Submissions" tab on the menu bar. Under the "Review Records Summary" section of the page, select the reporting entity and program year of the records to be reviewed, then select the "Review Details" 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.
 - Note: You can also navigate to the payment category page by selecting the submissions page. Under the "Review Submitted Payment Records" section, select the Payment Type, select the Entity and Program Year from the dropdowns and select the "Review Detail" button.
- 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 Warning 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) or if the non-physician practitioner license information is inactive in any program year (beginning with Program Year 2021 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

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/Resources</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 2016-2020, and one for Program Years 2021 and onwards. All of them 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.

Group Purchasing Organizations (GPOs) cannot report any general, research payment, or ownership/ investment record, for NPPs; however, they can report NPPs as a principal investigator on the research payment. 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 can utilize the "Payment Navigation Bar", located on top of the record, to go directly to a specific page, assuming there are no errors on the page they are currently on.

4.5a: Manual Entry of General Payments Data

To enter general payments data manually, follow these steps:

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

Figure 135: Open Payments System Landing Page for returning system users

Le Home <u>Sub</u>	missions	Review and Dispu	ute Manag	Entities	O My Profile	Messages	Resource
Submission	IS						? User Gu
A field with an asterisk (*) Applicable manufacturers a System.	is required. and applicab	le GPOs must submit pay	ments, or other t	ransfers of value,	and ownership or i	nvestment interests to th	ne Open Payments
Submit Payment	Data						
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rop-down lists below, ther	n select "Rev	view Detail".	you wish to rev	ew, and the prog	an year nom the	Download the	Non-
Select Payment Type:	*9	Select Entity:	*Selec	t Program Year:		The Non Physician P	CTITIONET LIS
Please Select	- Summa	Please Select	Please	e Select	Review Detail	Program Year below publicly.	should not be shan
o view submission summ rogram year from the dro	ary and/or at p-down lists	ttest records, select the en below, then select "Revie	ntity whose recor w Summary".	ds you wish to re	view and the	Download the	Reporting
Select Entity:		*Select Program Yea	r:			To download reportin	g templates, see tr
Please Select	~	Please Select	~	Review Sum	nary	Resources tab.	
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overed Recipier	nt Valida	tion Utility 💡					
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o verify provider matching nformation on the new pag	g information ge. The Cove tion to profile	, select the "Validate Cov ered Recipient Validation es prior to reporting that c	ered Recipient" t utility can be use overed recipient (d by submitters to on the payment re	upload provider upload physician ecord.		

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

Figure 136: Manual Data Entry Button

Submissions			Manage Entities	My Profile	Messages	Resource
Submissions	5					? User Gui
A field with an asterisk (*) is Applicable manufacturers an System.	required. d applicable GPOs	must submit payment	s, or other transfers of valu	e, and ownership or ir	ivestment interests to the	Open Payments
Submit Payment D	ata					
Only users who hold the role Upload or Manual Data Entry Refer to the Resources tab fr	of submitter can so below.	ubmit information to the	e Open Payments system. ual Data Entry to submit re	Select Bulk File	Download the List The Validated Physicia	Physician
Review Submitted	uik File Upload. ad Payment Re	open Paym	Manual Data Entry	Jmn.	Physician with Inactive Supplement File per P should not be shared p File Download H Validated F and Physic License(s) per Progra	: License(s) rogram Year below publicly. elp ? Physician Lists cian with Inactive Supplement File im Year
To review records, select the drop-down lists below, then s *Select Payment Type: Please Select	Payment type, ent select "Review Deta *Select Er Please Se	ity whose records you ail". htity: elect	*Select Program Yea	ngram year from the r: Review Detail	Download the Physician Prac The Non-Physician Pra Program Year below s	Non- ctitioner List actitioner List per should not be share
Review Records - S	Summary				publicly. Non-Physi List	cian Practitioner
To view submission summar program year from the drop-o	y and/or attest reco down lists below, th	rds, select the entity w en select "Review Sur	vhose records you wish to r mmary".	eview and the	Download the Templates	Reporting
*Select Entity: Please Select	*Sele Pleas	ct Program Year: se Select	Review Sur	nmary	To download reporting Resources tab.	templates, see the
Review Submitted	File(s) Statu	s				
Once a file for your entity has	s been submitted, y	ou may review the de	tails by selecting "Review F	ile Status."		
Review File Status						
Covered Recipient	Validation L	Jtility 💡				
	nformation, select t	he "Validate Covered	Recipient" button below an	d upload provider		

<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.

If the payment is being entered as a result of a payment that was previously submitted, attested and then deleted, you must enter the record id of the previously deleted record id.

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

Jpen plicable Manufactu	Paymo	ents (Sui ing Organization Switch User Ty	nshine /	Act)		
Home	Submissions	Review and Dispute	🔊 Manage Entities	O My Profile	Messages	Resources
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Figure 137: Add Payment Page

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

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

<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/Resources</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).

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

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

Home Submission	ns Review and Dispu	te Manage Entities	() My Profile	Messages	Resource
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Figure 138: Covered Recipient Demographic Information Page

<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/Resources</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 your information, select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to "Associated Related Products" page.

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type ً ⊿ ٩ 図 ۲ ٦ G Review and Dispute Ma My Profile Messag Add General Payment ? User Guide Ð Ś 0 ~ Review & Save Payments Overview **Covered Recipient** Products General Information Demographic Covered Recipient Demographic Information 🖺 A field with an asterisk (*) is required. Enter the covered recipient demographic information. Covered Recipient Type: Physician ~ Physician "First Name: Middle Name: "Last Name: Suffix: Miler James Recipient Business Address Country: United States ¥ Street Address, Line 1: Street Address, Line 2: 7500 Security Blvd. "City: State: ZIP Code: 99999 or 99999-9999 Baltimore Maryland 21244 Email Address: Physician Information Primary Type: NPI: "Taxonomy Code: () This is a 10-digit number 2084P0802X Medical Doctor ¥ Physician License Information To enter the covered recipient's license information, select a state in which the recipient is licensed and enter the accompanying license number in the fields below. Select the "Add" button to add the information to the record. Select the "Add" button again to display another set of fields. A record must contain at least 1 license and may have up to 5. You may edit or delete any previously entered license information by selecting the "Edit" or "Delete" buttons. State Number: Actions: Maryland MD-123456789 Edit Add Continue Cancel Back \sim ۵

Figure 139: Covered Recipient Demographic Information Page

<u>Step 4c</u>: For NPP (applicable for 2021 and onwards only): Enter information as requested on the page below. Required fields are marked with asterisks. Consult the Validated Non-Physician Practitioner List (VNPPL), downloadable from the "Submissions" tab, to confirm the identifying information for the NPP.

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

To fill in the taxonomy code value(s), refer to the taxonomy code list on the Resources page of the Open Payments website (<u>https://www.cms.gov/OpenPayments/Resources</u>). Taxonomy codes not on the taxonomy code list cannot be entered. If the NPP's taxonomy code is not available, select the code that most closely represents the NPP's specialty. You can enter up to 6 taxonomy codes.

To add the NPP'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 NPP 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 NPP's state licenses have been added. You can enter up to five licenses. NOTE: If the NPP license information is inactive in any program year (beginning with Program Year 2021 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

When you have entered all 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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James		Willer				
Recipient Business Country: United States	Address	V				
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City:	*State:		*ZIP Code:			
Baltimore	Maryland		21244	99-9999		
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Add Covered Recipient L To enter the covered recipi below. Select the "Add" but	License Information ent's license information, select a ton to add the information to the r	state in which the recipien record. Select the "Add" bu	t is licensed and en itton again to displa	ter the accompanying y another set of fields	license number in	the fields ntain at least
icense and may have up to	5. You may edit or delete any pr	eviously entered license in	formation by selecti	ing the "Edit" or "Dele	te" buttons.	
State: Maryland	MD-123456789	Edit	Delete			

Figure 140: 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 2018-2020, 2021-2022, and 2023 and onwards:

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 141: Associated Related Products Page for Program Years 2016-2020, 2021 and onwards

Open Applicable Manufac	Payme turer or Group Purchasin	ents (Su g Organization Switch User	nshine /	Act)		
Home	Submissions	Review and Dispute	Manage Entities	() My Profile	Messages	Resources
Add Ger	neral Paym	ent				? <u>User Guide</u>
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Associated	Related Produc	ots				
A lield with an aste Select "Yes" or "No devices, biological: set to "Yes". You m To download the list	orrisk (**) is required. b" from the Related Pro- s, or medical supplies. 3 hay enter up to five drug st of Drug Name & Natio	duct Indicator drop-down lis Select "Add" after completi s, biologicals, devices, or r onal Drug Codes (NDC) an	st. If "Yes" is selected, ente ng each entry. At least one medical supplies for each n d instruction document, se	r the applicable information product must be added if th scord. e the Resources tab.	for the associated covere ne Related Product Indica	ed drugs, tor value is
*Related Product	ct Indicator:	T				
Cancel					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.

Figure 142: Associated Related Products Page for Program Years 2018-2020, 2021-2022, and 2023 and onwards

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Home <u>Sub</u>	omissions R	Review and Dispute	Manage Entities	My Profile	Messages	Resourc
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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 noncovered 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.

Drug or Biologicals and National Drug Codes (NDC):

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

9999-9999-99

99999-999-99

99999-9999-9

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

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

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

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

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

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

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

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

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

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

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

The following validations are performed for the PDI field:

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

The submitter receives an error message if any of these validations fail. You cannot continue with record submission without fixing the error. To address the error, please refer to the Medical Device and Medical Supply Name and Primary Device Identifier dataset reference file on the CMS Resources Page to identify the correct PDI and Device Name combination to use for submissions.

Figure 143: Add Button on the Add General Payment Page

Open Payme Applicable Manufacturer or Group Purchasing G	nts (Sui Organization Switch User T	nshine A	Act)		
Home Submissions	Review and Dispute	Manage Entities	O My Profile	Messages	Resources
Add General Payme	ent		my riono	moodagoo	? <u>User Guide</u>
Overview Covered Re Demogra	ecipient <u>Produ</u> phics	<u>¢</u> <u>cts</u> Paymer	nts General Info	ormation Review	& Save
A field with an asterisk (*) is required. Select "Yes" or "No" from the Related Productevices, biologicals, or medical supplies. Se set to "Yes". You may enter up to five drugs, To Download the list(s) of Drug Names & Narespective instruction document(s), see the letter *Related Product Indicator:	ct Indicator drop-down list lect "Add" after completin biologicals, devices, or m ational Drug Codes (NDC) Resources tab.	. If "Yes" is selected, enter g each entry. At least one p edical supplies for each red and/or Medical Device or N	the applicable informatior roduct must be added if t cord /ledical Supply Names ar	n for the Associated cove the Related Product Indic nd Primary Device Identif	ered drugs, cator value is fiers with
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*Marketed Name of Drug, Device, Biolog Medical Supply:	gical, or Associated Di 9999-9999-99 9999-9 €	rug or Biological NDC: OR 99999-999-99 OR 99	Primary Devi	ice Identifier: 🕑	
					Add
Cancel				Back	Continue

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

Figure 144: Add Button on the Associated Related Products Page for Program Years 2016-2020, 2021 and onwards

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Figure 145: Enter Additional Associated Related Product Information

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Covered or Non-Covered Product	Indicate Drug, Device, Biological, or Medical Supply:	Product Category or Therapeutic	Marketed Name of Drug, Device, Biological, or	Associated Drug or Biological NDC	Primary Device : Identifier:	Actions:		
Covered or Non-Covered Product Indicator:	Indicate Drug, Device, Biological, or Medical Supply:	Product Category or Therapeutic Area:	Marketed Name of Drug, Device, Biological, or Medical Supply:	ion Associated Drug or Biological NDC	Primary Device : Identifier:	Actions:		
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Covered or Non-Covered Product Indicator: Covered	Indicate Drug, Device, Biological, or Medical Supply: Drug	Product Category or Therapeutic Area: STERILE DILUENT	Marketed Name of Drug, Device, Biological, or Medical Supply: STERILE DILUENT	ion Associated Drug or Biological NDC	Primary Device : Identifier:	Actions: Edit	Delete	
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Covered or Non-Covered Product Indicator: Covered SSOCiated Dr overed or Non-C Covered larketed Name of dical Supply:	Indicate Drug, Device, Biological, or Medical Supply: Drug Ug, Device, Biolo Covered Product Indic	Product Category or Therapeutic Area: STERILE DILUENT gical, or Medic ator: *Indicate Supply: Device gical, or Associat 9999-99	Marketed Name of Drug, Device, Biological, or Medical Supply: STERILE DILUENT Call Supply Information Drug, Device, Biological Porug, Device, Biological Ni 29-99 OR 99999-999-999	ion Associated Drug or Biological NDC ion II, or Medical *	Primary Device : Identifier: Product Categr Cardiology rimary Device	Actions: Edit	Delete	

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.

Upon entering the drug or device details and clicking on "Add", the system will generate an error message if the reported data does not match with the CMS approved data set.

To address errors, please refer to the drug and device reference datasets and instructions that are available on the CMS Resources page.

Home Submissions Review	and Dispute Manage	Entities M	(2) y Profile	Messages	Resources
Add General Payment					? User Guide
Overview Covered Recipient Demographics	Products	\$ Payments	General Informat	ion Review &	Save
Associated Related Products					
A field with an asterisk (*) is required.					
You have the following errors on t	he page:				
Error: The Marketed Name of Drug, Device, CMS approved dataset. (Test : 1234-5678-09	Biological, or Medical Supp))	bly and Associated Dru	ug or Biological NDC	combination does	not match the
Select "Yes" or "No" from the Related Product Indicat devices, biologicals, or medical supplies. Select "Add set to "Yes". You may enter up to five drugs, biological To Download the list(s) of Drug Names & National Dru respective instruction document(s), see the Resource	or drop-down list. If "Yes" is s " after completing each entry. als, devices, or medical suppli ug Codes (NDC) and/or Medi s tab.	elected, enter the applic At least one product m es for each record cal Device or Medical S	cable information for the ust be added if the Re upply Names and Prir	he Associated covere elated Product Indicat mary Device Identifie	ed drugs, tor value is rs with
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Covered ~	Drug	~	Test		
*Marketed Name of Drug, Device, Biological, or Medical Supply:	Associated Drug or Biolog 9999-9999-99 OR 99999- 9999-9 O	gical NDC: 999-99 OR 99999-	Primary Device Id	entifier: 😧	
]		Add
Cancel				Back	Continue

Figure 146: Drug Information Validation Error Message

If there are no other errors upon selecting the "Continue" button, you can proceed to the "General Payment or Other Transfer of Value Information" page.

	Figure 147: Edit and Delete	Button for Associated	Related Product	Information
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Open Applicable Manufactur	Payment er or Group Purchasing Organi	S (Sun zation Switch User Typ	shine Act)		
Home Add Gene	Submissions Revie eral Payment	ew and Dispute	Manage Entities M	O y Profile	Messages	Resources ? User Guide
Overview	Covered Recipier Demographics	nt <u>Product</u> :	S Payments	General Informa	ation Review & S	Save
Associated R	elated Products					
Set to "Yes". You may To download the list of "Related Product I Yes Associated Dru Covered or	r enter up to five drugs, biolog of Drug Name & National Drug ndicator: Ig, Device, Biological, o Indicate Drug, Device,	jicals, devices, or mec g Codes (NDC) and in pr Medical Supply Product Category	tical supplies for each record. Instruction document, see the Reso V Information Marketed Name of Drug,	Associated Drug	g Actions:	
Non-Covered Product Indicator:	Biological, or Medical Supply:	or Therapeutic Area:	Device, Biological, or Medica Supply:	I or Biological NDC:		
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Associated Dru *Covered or Non-O Covered Marketed Name of Medical Supply: Pacemaker Cancel Product	ig, Device, Biological, c Covered Product Indicator: Drug, Device, Biological, o	or Medical Supply *Indicate Drug, I Supply: ■ Device r Associated Drug 9999-999-99 C 9999-9 C	v Information Device, Biological, or Medical ▼ g or Biological NDC: NR 99999-999-99 OR 99999-	*Product Catego Cardiology	ry or Therapeutic Are	a: Add
Cancel					Back	Continue

<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.

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type \Box_{3} മ ۲ 2 И പ് Ы **Review and Dispute** Home Submissions Manage Entities My Profile Resources Messao Add General Payment ? User Guide Ð =: 0 48 Overview **Covered Recipient** Products General Information Review & Save Payments Demographics General Payment or Other Transfer of Value Information A field with an asterisk (*) is required. Enter the required payment or transfer of value information. "Number of Payments Included in Total "Total Amount of Payment: *Date of Payment: 99999.99 and maximum 12 digits yyyymmdd 0 Amount: 5485.95 20180218 首 1

"Nature of Payment or Transfer of Value:

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Back

Contact Us

Continue

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Privacy Polic

Figure 148: General Payment or Other Transfer of Value Information Page

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

Consulting Fee

*Form of Payment or Transfer of Value:

Cash or cash equivalent

Cancel

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. Note that for covered recipient NPPs, ownership indicator is not applicable.

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

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 149: Continue to Review Button on General Records Information Page

Open Pa Assists o Manufacturer or Ga	yments	S (Sul	nshine . ‴	Act)		
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500 characters remaining						
Cancel					Back	Continue to Review

<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.

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Figure 150: Review and Save page

Figure 151: Review and Save Page – 2021-2022

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Review the payment inform	nation below. If	f there are any e	errors, navigate to	the respective scre	en and update as r	necessary.		
Payment Submissi Entity Making Payment Program Year: 2021	ion Informa Registration I Payment (ation Name: ABCDE Category: Gen	Medical eral Payments	H	ome System Payn	nent ID:		
Covered Recipient Covered Recipient Type Name: James Miller Business Address: 7500 Security Blvd Baltimore, MD 21244 United States	Demograp	ohics Inform	nation					
Primary Type: Nurse Practitioner Certified Nurse-Midwife Covered Recipient Staty	e License(s):			NPI:		Taxonomy C 363LW0102X	ode:	
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Cancel							Back	Save Record
							Contact Us	

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 152: 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 IDM credentials, navigate to the Open Payments home page, and select the "Submissions" tab from the home page.

Figure 153: Open Payments system landing page for returning system users

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type	
Home Submissions Review and Dispute Manage Entities My Prof	ile Messages Resources
Welcome to the Open Payments System	Access the Open Payments User Guide [PDF, 28.8 MB]
Announcements	Need help with the website? Contact Us by email
Program Year 2017 Review and Dispute Period Open - The Review and Dispute period is open starting April 1, 2018. During this period, reporting entities may receive disputes from covered recipients and must work with them directly to resolve the disputes. Physicians and teaching	Review the Open Payments Privacy Policy [PDF, 102 KB]
nospirais may review data about them and initiate disputes until May 15, 2018. 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 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.	

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

Figure 154: Manual Data Entry Button on Submissions Landing Page

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Review Records - Su	mmary			Non-Physicia List	In Practitioner
Fo view submission summary and program year from the drop-dowr	d/or attest records, select the n lists below, then select "Rev	entity whose records you wish to riew Summary".	o review and the	Download the Re	eporting
Select Entity:	*Select Program Ye	ear:	ummany	To download reporting te	mplates, see th
	· Flease Select			Resources tab.	
Review Submitted Fil	e(s) Status				
Once a file for your entity has bee	en submitted, you may review	the details by selecting "Review	/ File Status."		
Review File Status					
Covered Recipient Va	lidation Utility 💡				
To verify provider matching inform nformation on the new page. The and non-physician information to	nation, select the "Validate Co covered Recipient Validatio profiles prior to reporting that	overed Recipient" button below a n utility can be used by submitte covered recipient on the payme	and upload provider rs to upload physician nt record.		
Validate Covered Recipient					
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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. You may enter the Home System Payment ID (if applicable) of the record you will submit. The Home System Payment ID is the identifier associated with the payment transaction in your home system.

If the payment is being entered because of a payment that was previously submitted, attested and then deleted, you must enter the record id of the previously deleted record id.

Select the "Continue" button to proceed.

Open Pa Applicable Manufacturer or Gro		ents (Sui ng Organization Switch User T	nshine A	Act)			
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						Contact Us	Privacy Policy

Figure 155: Add Payment Page

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

<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/Resources</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).

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 156: Recipient Type Drop-Down for Teaching Hospital

Open Pa	yment up Purchasing Organ	IS (SUI	nshine	Ac	t)		
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Baltimore	М	laryland	×	21244			
Email Address:							
Cancel						Back	Continue
						Contact Us	Privacy Policy

<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/Resources</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 your information, select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to the "Associated Related Products" page.

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waryiano	MD-12345	Auu		
ancel				Back
				- (

Figure 157: Recipient Type Drop-Down for Physician

<u>Step 4c</u>: **For Covered Recipient Non-Physician Practitioner**: Enter information as requested on the page below. Required fields are marked with asterisks. Consult the Validated Non-Physician Practitioner List (VNPPL), downloadable from the "Submissions" tab, to confirm the identifying information for the NPP.
To add the NPP's primary type, multi-select up to six valid values as per reference data list. Use ctrl button to choose multiple values from the list.

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/Resources</u>) for a complete listing of the available taxonomy codes. Taxonomy codes not on the taxonomy code list should not be entered. If the NPP's taxonomy code is not available, select the code that most closely represents the NPP's specialty.

To add the NPP'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 NPP 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 NPP's state licenses have been added. You can enter up to five licenses. NOTE: If the NPP license information is inactive in any program year (beginning with Program Year 2021 to present) and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching. When you have entered all your information, select the "Associated Related Products" page.

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Figure 158: Recipient Type Drop-Down for Non-Physician Practitioner

<u>Step 4d:</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 159: Recipient Type Drop-Down for Entity

Open Pa	yments up Purchasing Organiza	S (Suns ion Switch User Type	shine	Act)			
Home Submis	sions Review	and Dispute N	lanage Entities	(Q) My Prof	ile	Messages	Resources
Add Researc	h Paymen	t	_				? User Guide
Overview	<mark>Recipient</mark> Demographics	Products	Pay	\$ ments	Principal Investigator Demographics	Review &	Save
Recipient Demogra	phic Information	on 🗟					
A field with an asterisk (*) is n Select the recipient type for th	equired. le payment being repor	ted and then enter the	e demographic info	ormation.			
*Recipient Type: Non-Covered Recipient Entit	y			V			
Non-Covered Recipier *Name:	nt Entity						
WXYZ Corp.							
Recipient Business Ad *Country:	ddress						
United States			~				
*Street Address, Line 1: 7500 Security Blvd			Street Ad	dress, Line 2:			
*City:	*Sta	te:		*ZIP Code: 99999 or 99999-99	999		
Baltimore	Mar	yland	~	21244			
Email Address:							
Cancel						Back	Continue
						Contact Us	Privacy Policy

<u>Step 4e:</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 160: Product page for Recipient Type

Open Applicable Manufa		ents (Su g Organization Switch User T	nshine /	Act)		
Home	Submissions	Review and Dispute	🔊 Manage Entities	O My Profile	Messages	Resources
Add Re	search Pay	ment				? User Guide
Recipient I A field with an as Select the recipie	view Reci Demog Demographic Inf sterisk (*) is required. ent type for the payment I	pipient rraphics Formation	er the demographic inform	nts Princip Investig Demogra ation.) val Review ator phics	& Save
*Recipient Typ Non-Covered F	pe: Recipient Individual			V		
Cancel					Back	Continue
					Contact Us	Privacy Policy

<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 2018-2020, 2021-22, and 2023 and onwards:

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 161: Related Product Indicator Drop-Down

Open Applicable Manufa		ents (Su g Organization Switch User 1	nshine A	Act)		
Home	Submissions	Review and Dispute	ठि Manage Entities	O My Profile	Messages	Resources
Add Re	search Pay	ment				? <u>User Guide</u>
Overv	iew Reci Demog	Dient <u>Produ</u> raphics	ccts Payme	nts Princip Investig: Demograp	bal Review & ator phics	Save
Associated A field with an ast	Related Produc	ts				
Select "Yes" or "N devices, biologica set to "Yes". You i	lo" from the Related Proc als, or medical supplies. S may enter up to five drug	luct Indicator drop-down lis Select "Add" after completin s, biologicals, devices, or n	t. If "Yes" is selected, enter ig each entry. At least one p nedical supplies for each re	the applicable information product must be added if th cord.	for the associated covere ne Related Product Indica	ed drugs, tor value is
To download the I	list of Drug Name & Natio	nal Drug Codes (NDC) and	d instruction document, see	the Resources tab.		
*Related Produ No	uct Indicator:	•				
Cancel					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.

Figure 162: Input Fields for Related Product Indicator

Open Pa Applicable Manufacturer or Gr	yments	S (Sun ation Switch User Typ	shine /	Act)			
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Add Researc	ch Paymen	it					? <u>User Guide</u>
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Overview	Recipient Demographics	Product	<u>s</u> Payme	ents	Principal Investigator Demographics	Review &	Save
o Download the list(s) of Dr espective instruction docum *Related Product Indicate Yes	rug Names & National D nent(s), see the Resourc or:	rrug Codes (NDC) a	nd/or Medical Device or	Medical Su	oply Names and Prir	nary Device Identifie	rs with
Associated Drug, D	evice, Biological,	or Medical Su	pply Information				
*Covered or Non-Covered	d Product Indicator:	Indicate Drug, D Supply:	Device, Biological, or N	ledical	Product Category	or Therapeutic Are	a:
Please Select	~	Please Select		~			
Marketed Name of Drug, Medical Supply:	Device, Biological, or	Associated Dru 9999-9999-99 C 9999-9 🍞	g or Biological NDC: DR 99999-999-99 OR 9	9999-	Primary Device Id	entifier: 🕜	
							Add

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 noncovered 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.

Drug or Biologicals and National Drug Codes (NDC):

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

9999-9999-99

99999-999-99

99999-9999-9

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

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

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

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

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

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

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

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

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

- All zeroes
- Any leading or trailing spaces

- Consecutive spaces
- Special characters not permitted in the Open Payments System

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

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

The following validations are performed for the PDI field:

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

The submitter receives an error message if any of these validations fail. You cannot continue with record submission without fixing the error. To address the error, please refer to the Medical Device and Medical Supply Name and Primary Device Identifier dataset reference file on the CMS Resources Page to identify the correct PDI and Device Name combination to use for submissions.

Figure 163: Drug Information Validation Error Message

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u have the	following error	s on the pa	ge:					
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Error: The M CMS approv	arketed Name of Drug, ed dataset. (Test : 9999	-9999-99)	and of moulour suppry and	J				
Error: The M CMS approv ect "Yes" or "No" rices, biologicals, to "Yes". You ma	from the Related Produc or medical supplies. Sel y enter up to five drugs,	ct Indicator drop-(ect "Add" after co biologicals, devic	down list. If "Yes" is selecte pompleting each entry. At lea es, or medical supplies for	d, enter the applicable st one product must b each record	information for added if the F	the Associat Related Produ	ed covered Ict Indicator	drugs, r value is
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If there are no other errors upon selecting the "Continue" button, you can proceed to the "General Payment or Other Transfer of Value Information" page.

Figure 164: Add Button for Associated Related Products Page

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Home <u>Subr</u> dd Resear	nissions R ch Paym	eview and Dispute ent	Manage Entities	My	Profile	Messages	Resource ? <u>User Gu</u>
Overview	Recipient Demograph	t <u>Proc</u> ics	lucts Paym	nents	Principal Investigator Demographics	Review	& Save
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If you have another product to add to the record, select "Add" again to open another set of data entry fields. A record may contain up to five products.

Figure 165: Add Button for Additional Associated Product

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Figure 166: Input Fields for Additional Associated Related Product

Image: The state is a state of the stat	icable Manufactur	Payme er or Group Purchasing (nts Drganizatio	on Switch User Ty	nshin	e Act)			
dd Research Payment Durwiew Recipient Recipient Engraphics Payments Pincipiant Sociated Related Products dwt an asterisk (*) is required. d**** You may enter up to five drugs, biological, d	Home	Submissions	Review a	and Dispute	🔊 Manage Entiti	es My	O Profile	Messages	Resou
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If you need to correct or delete the product information after adding it, select the "Edit" or "Delete" buttons in the table of saved products.

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

Figure 167: Edit and Delete Button for Associated Related Product Page

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

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.

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Figure 168: Add Research Payment Page

<u>Step 7:</u> If the record has one or more principal investigators associated with it, select "Yes" from the "Principal Investigator Covered Recipient Physician Indicator" drop-down box on the "Principal Investigator Demographic" page. For Program Year 2021 and onwards, select "Yes" from the "Principal Investigator Covered Recipient 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. For Program Year 2021 and onwards, select either Covered Recipient Physician or Covered Recipient Non-Physician Practitioner from the Principal Investigator Covered Recipient Type drop-down. 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 add the Principal Investigator physician's primary type, select single valid values as per reference data list. To add the Principal Investigator NPP's primary type, multi-select up to six valid values as per reference data list. Use ctrl button to choose multiple values from the list.

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/Resources</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 Non-Physician Practitioner, 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 Non-Physician Practitioner" and the "Principal Investigator Covered Recipient Indicator" is set to "Yes," then enter at least one covered Principal Investigator. The Covered Recipient NPP should not 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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Figure 169: Principal Investigator Demographic Page

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Figure 170: Principal Investigator Demographic Page (2021 and onwards)

<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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elated roduct search P al Amount penditure fessional 1 n-Patient C -Clinical R ay in Publi ne of Stud itext of Re iicalTrials.	Covered or Non- Covered Product Indicator: Covered Covered ayment or Other Trr of Research Payment: Category Salary Support: are: esearch Indicator: Y cation of Research Pay y: search: Gov Identifier: rmation Link:	Indicate Drug, Device, Biological, or Medical Supply: Device Device ansfer of Value Informa \$2,356.55 Date of Paymen \$2,356.55 Date of Paymen Medical Reseat Overhead: ment Indicator: R&D on Ne	Product Category or Therapeutic Area 1 Cardiology ttion tt: 20180506 ch Writing or Publication	Marketed Name of Drug, Device, Biological, or Medi Suppy: Biological 1 Pacemaker Form of Payment cash equivalent : Patient Care: Other:	Associated Drug or Biological NDC:
elated search P al Amount al Amount openditure fessional : -Patient C -Cinical R y in Public icearch Info nei of Stud text of Re icearch Info ncipal Inve cipal Inve	Covered or Non- Covered Product Indicator: Covered Covered ayment or Other Trra of Research Payment: Category Salary Support: are: esearch Indicator: Y cation of Research Pay y: search: Gov Identifier: rmation Link: vestigator Demogra stigator 1	Indicate Drug, Device, Biological, or Medical Supply: Device Device S2,356.55 Date of Paymer Medical Reseau Overhead: ment Indicator: R&D on No phics lent Physician Indicator: Y	Product Category or Therapeutic Area: Therapeutic Area 1 Cardiology ttion tt: 20180506 Ch Writing or Publication w Product	Marketed Name of Drug, Device, Biological, or Med Suppy: Biological 1 Pacemaker Form of Payment cash equivalent : Patient Care: Other:	Associated Drug or Biological NDC:
slated oduct	Covered or Non- Covered Product Indicator: Covered Cov	Indicate Drug, Device, Biological, or Medical Supply: Device Device S2.356.55 Date of Paymet S2.356.55 Date of Paymet Medical Reseat Overhead: ment Indicator: R&D on Ne phics Ient Physician Indicator: Y	Product Category or Therapeutic Area: Therapeutic Area 1 Cardiology ttion ttion therapeutic Area 1 Cardiology ttion therapeutic Area 1 ttion therapeutic Area 1 ttion ttoon ttion ttion ttion ttion ttion ttoon	Marketed Name of Drug, Device, Biological, or Medi Suppy: Biological 1 Pacemaker Form of Payment cash equivalent : Patient Care: Other:	Associated Drug or Biological NDC:
search P search P al Amount benditure colinical R search P reason colinical R search Info colinical R search Info ncipal Inve search Info ncipal Inve search Info ncipal Inve susan statest of Re susan statest of Re susan states	Covered or Non- Covered Product Indicator: Covered Covered Covered ayment or Other Trra of Research Payment: Category Salary Support: are: esearch Indicator: Y cation of Research Pay y: search: Gov Identifier: rmation Link: vestigator Demogra stigator Covered Recip estigator 1 Jones ress: at 21244 : Medical Doctor	Indicate Drug, Device, Biological, or Medical Supply: Device Device S2,356.55 Date of Paymer Medical Resear Overhead: ment Indicator: R&D on No phics lent Physician Indicator: Y NPI:	Product Category or Therapeutic Area 1 Cardiology ttion tt 20180506 ch Writing or Publication w Product	Marketed Name of Drug, Device, Biological, or Medi Suppy: Biological 1 Pacemaker Form of Payment cash equivalent : Patient Care: Other: nomy Code: 2084P0802X	Associated Drug or Biological NDC:

Figure 171: Review and Save Page

Open Payment	zation Switch User	nshir _{Type}	ne Ac	ct)		
Home Submissions Revi	w and Dispute	Ø Manage Er	ntities	(Q) My Profile	Messages	Resources
Add Research Payme	nt					? User Guide
Overview Recipient Demographics	Produ	Jucts	\$ Payments	Principal Investigator	Review	& Save
Review and Save Page				Demographic	<u>s</u>	
Review the payment information below. If there are	e any errors, navig	ate to the respec	tive screen and	update as necessary.		
Payment Submission Information Entity Making Payment Registration Name: A Program Year: 2021 Payment Categor	BCDE Medical y: Research Payn	nents	Home Sy	stem Payment ID:		
Recipient Demographics Informatio Recipient Type: Covered Recipient Non-Physic Name: James Miller Business Address: 7500 Security Blvd Baitimore, MD 21244 United States Email Address:	P n cian Practitioner					
Primary Type: Nurse Practitioner Clinical Nurse Specialist Certified Registered Nurse Anesthelist Covered Recipient State License(s): MD - MD-12345		NPI:		Taxon 363LW 363LG 363LX	omy Code: 0102X 0600X 0001X	
Associated Related Products Related Product Indicator: N						
Research Payment or Other Transfe Total Amount of Research Payment: \$1,000.0	er of Value Inf 00 Date of Payme	ormation ent: 20210704		Form of Payment of items and services	or Transfer of Value	e: In-kind
Expenditure Category						
Professional Salary Support: Non-Patient Care: Pre-Clinical Research Indicator: Y Delay in Publication of Research Payment Inc Name of Study: Context of Research: Clinical Trials.Gov Identifier: Research Information Link:	Medical Rese: Overhead: dicator: No Delay	arch Writing or I	Publication:	Patient Care: Other:		
Principal Investigator Demographic Principal Investigator Covered Recipient India Principal Investigator 1	S cator: Y					
Covered Recipient Type: Covered Recipient N Name: Susan Jones Business Address: 123 Main Street Baltimore, MD 21244 United States	lon-Physician Prac	titioner				
Primary Type: Nurse Practitioner Certified Nurse-Midwife Principal Investigator State License(s): MD 12335		NPI:		Taxonomy 363LW010 363LX000 ⁻	Code: 2X IX	
Cancel					Back	Save Record

Figure 172: Review and Save Page (2023 and Onwards)

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 173: 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:

- 1) Group Purchasing Organizations (GPOs) must report Ownership/Investment Interest Payments only if there is a corresponding General/Research Payment reported for that physician in that program year.
- 2) Reporting Entities cannot report Ownership/Investment Interest Payments for Non-Physician Practitioner

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

Figure 174: Submissions Tab for Open Payments system landing page for returning system users

)pen Dicable Manufa	Cturer or Group Purchasi	ents (Su ng Organization Switch User T	nshine A	Act)			
Home	Submissions	Review and Dispute	Ø Manage Entities	O My Profile		Messages	Resources
Welco	me to the (Open Payme	nts System		1	Access the Ope User Guide [PD	en Payments IF]
Announc	ements			_	?	Need help with Contact Us by	the website? email
Program Yea The Review a may receive d	r 2018 Review and Dis nd Dispute period is oper isputes from covered re	pute Period Open - en starting April 1, 2019. Duri cipients and should work wit	ng this period, reporting ent h them directly to resolve th	ities e	8	Review the Ope Privacy Policy [I	en Payments PDF]
corrections to correction peri correction peri Visit the Open questions, cor phone at 1-85 You can mana	disputed data as neede od will be identified in tt od will be included in fu Payments website at h tact the Open Payment 5-326-8366. For the TT ge your user profile and	d. Records with unresolved in e published data as dispute ture data publications. ttps://www.cms.gov/openpay is Help Desk by email at ope Y line, call 1-844-649-2766.	disputes at the end of the d. Changes to records after ments for information. For npayments@cms.hhs.gov c associated with your profile	r by			
According to ti collection of in for this inform collection con	ne Paperwork Reduction formation unless it disp tion collection is 0938- range from 1 to 30,000	n Act of 1995, no persons ar lays a valid OMB control nun 1237. The time required to co hours per entity depending c	e required to respond to a nber. The OMB control num omplete this information in the size and type of	ber			

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

Figure 175: Manual Data Entry Button

Home <u>Submissions</u> Review and Dispute Manage Entities My Profile	Messages Resource
Submissions	? User G
A field with an asterisk (*) is required. Applicable manufacturers and applicable GPOs must submit payments, or other transfers of value, and ownership or i System.	nvestment interests to the Open Payments
Submit Payment Data	
Only users who hold the role of submitter can submit information to the Open Payments system. Select Bulk File Jpload or Manual Data Entry below. Refer to the Resources tab for the Open Payments reporting templates for the Bulk File Upload. Select Manual Data Entry to submit records using the Open Payments manual entry online form.	Download the Physician List The Validated Physician Lists and Physician with Inactive License(s)
Bulk File Upload Manual Data Entry Review Submitted Payment Records	Supplement File per Program Year below should not be shared publicly. File Download Help @ Validated Physician Lists and Physician with Inactive License(s) Supplement File per Program Year
 o review records, select the payment type, entity whose records you wish to review, and the program year from the frop-down lists below, then select "Review Detail". *Select Payment Type: *Select Entity: *Select Program Year: 	Download the Non- Physician Practitioner Lis
Please Select Please Select Please Select Review Detail Review Records - Summary	Program Year below should not be sha publicly.
To view submission summary and/or attest records, select the entity whose records you wish to review and the program year from the drop-down lists below, then select "Review Summary".	Download the Reporting Templates
Select Entity: * Select Program Year: Please Select V Please Select V	To download reporting templates, see t Resources tab
Review Submitted File(s) Status Drice a file for your entity has been submitted, you may review the details by selecting "Review File Status." Review File Status Covered Recipient Validation Utility ? Fo verify provider matching information, select the "Validate Covered Recipient" button below and upload provider nformation on the new page. The Covered Recipient Validation utility can be used by submitters to upload physician and non-obviscian information to profiles prior to reporting that covered recipient on the payment record.	

<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.

If the payment is being entered because of a payment that was previously submitted, attested and then deleted, you must enter the record id of the previously deleted record id.

Select the "Continue" button to proceed.

Figure 176: Add Payment page displaying Payme	ent Category
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Open pplicable Manufa	Paym acturer or Group Purchas	ents (Sui ing Organization Switch User T	nshine A	Act)			
Home	Submissions	Review and Dispute	o Manage Entities	O My Profile		Messages	Resources
Add Pay	yment						? User Guid
*Payment Cate	ent, transfer of value, or	*Entity Making Payment R	rest, enter the following in equivalent terms in the following in the second seco	*Program Year:		Home System Paym	ent ID: 😧
Please Select	×	Please Select	~	Please Select	~		
Was this payr	ment previously subm	itted, attested and then dele	eted?				
Please Select			~				
ancel							Continu
						Contact Us	Privacy Pol

<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/Resources</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 177: Physician Demographic Information page

Home Subm	issions F	Leview and Dispute	Manage Entitie	s My Profile	Mess	a ges	Resourc
dd Ownersł	nip or Ir	ivestment l	nterest F	Record	_		? User Gu
Overview		Physician Demogra Information	phic	\$ Ownership or Investmen Information	t	Review & Sav	/e
hysician Demogra	phic Inform	nation 🖹					
ield with an asterisk (*) is n ter the physician demograp	equired. hic information.						
Physician							
First Name: Susan	Mide	lle Name:	*Last Na	me:	Suffix:		
Physician Business A Country:	ddress						
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							
Primary Type:		NPI: This is a 10-digit number	er	*Taxonomy Code: 🕕			
Medical Doctor	~			2084P0802X			
	ormation	select a state in which the n to the record. Select the	recipient is license "Add" button again	d and enter the accompanies of the set of	nying license numbe fields. A record mus	er in the fields I st contain at lea	below. ast 1
Physician License Info To enter the physician's licen Select the "Add" button to ad icense and may have up to	d the information 5. You may edit	or delete any previously e	ntered license infor	mation by selecting the "E	un of Delete Dut		
Physician License Info Fo enter the physician's licent Select the "Add" button to ad icense and may have up to "State:	dd the informatio 5. You may edit	or delete any previously e *Number: Maximum 25 characters	ntered license infor	mation by selecting the "E	un of Delete but		

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.

	Submissions	Review and Dispute	Manage Entities	My Profile	Messages	Resource
dd Ow	nership o	r Investment	Interest F	Record	1	? User Gu
	Overview	Physician Demo Informatio	<u>graphic</u> D	\$ Ownership or Investment Information	Revie	w & Save
ysician D	emographic In	formation 🛼	L		4	
eld with an ast	erisk (*) is required.					
er the physicia	n demographic informa	ition.				
nysician irst Name:		Middle Name:	"Last Na	ime:	Suffix:	
usan			Jones			
treet Addres: 500 Security Bl ity: altimore nail Address:	, Line 1: vvd/	" State: Maryland	Street A	ddress, Line 2: *ZIP Code: 99999 or 99999-9999 21244		
nysician Inf	formation					
rimary Type:		NPI: This is a 10-digit nur	nber	*Taxonomy Code: 🚺		
fedical Doctor		¥		2084P0802X		
enter the phy enter the phy lect the "Add" ense and may State:	cense Information sician's license informa button to add the infor have up to 5. You may	ation, select a state in which mation to the record. Select y edit or delete any previousi Number:	the recipient is license the "Add" button again y entered license infor	d and enter the accompanyin to display another set of fiel mation by selecting the "Edit Actions:	ng license number in the ds. A record must conta " or "Delete" buttons	e fields below. ain at least 1
		MD-12345		-		

Figure 178: Continue Button for Physician Demographic Information page

<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.

Open pplicable Manufac	Payme cturer or Group Purchasir	en ng Orga	ts (Su	nshine	e /	Act)				
Home	Submissions	Rev	view and Dispute	🔊 Manage Entitie	25	(Q) My Profile	[Me:	ssages	Re	sources
Add Ow	nership or	r Inv	vestment	Interest	Rec	cord			U	? ser Guide
			-			~				
	Overview		Physician Demog	graphic n	Own	ership or Investment Information		Review	& Save	
Ownership	or Investment I erisk (*) is required.	nfori	nation							
Enter the required	ownership or investme	ent inter	est information.							
*Interest Held E	Ву:		*Dollar Amount In 99999.99 and may	vested: kimum 12 digits 🚯		*Value of Interest: 99999.99 and maximun	n 12 digits	0		
Physician Cover	red Recipient	~	1565.23			2000				
*Terms of Inter 500 characters	est: maximum. Characters	entere	d over this limit will	not be saved.						
Enter terms of in	iterest.									
476 characters r	remaining									
Cancel							Ba	ck	Continue	to Review
								Contact	le Drive	

Figure 179: 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 180: Save Record Button for Physician Demographic Information page

Open Payment	ts (Sunshin	e Act)		
Home Submissions Revi	iew and Dispute Manage Ent	ities My Profile	Messages	Resources
Add Ownership or Inv	vestment Interest	Record		? User Guide
Overview	Physician Demographics Information	\$ Ownership or Investment Information	Review 8	<u>Save</u>
Review and Save Page				
Payment Submission Information Entity Making Payment Registration Name: Program Year: 2018 Payment Categor	ABCD Medical y: Ownership or Investment Interest	Home System Payment ID:		
Physician Demographics Information	1			
Name: Susan Jones Business Address: 7500 Security Blvd. Baltimore, MD 21244 United States				
Email Address: Primary Type: Medical Doctor Physician State License(s): MD - MD-12345	NPI:	Taxonomy Code	: 2084P0802X	
Ownership or Investment Information	ı			
Interest Held By: Physician Covered Recipier Terms of Interest: Enter terms of interest.	Dollar Amount Invested: \$1,56	5.23 Value of Interest	\$2,000.00	
Cancel			Back	Save Record
			Contact Us	Privacy Policy

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

Figure 181: 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 to become eligible for final submission and attestation. The steps are shown in the figure below.

Figure 182: Validation Steps



Details on these types of validation are given below.

4.6a: Validation Step 1: File-Level Validation

Bulk files undergo validations before the records within the file are uploaded. If a file fails any of the 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 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/Resources</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. Records containing NPP licenses that were valid after January 1, 2023 but were expired during the entirety of the

program year of the record will **not** fail matching due to the expired licenses but will trigger warnings to the user. Refer to Section 4.7, "Identifying Errors," for details.

Section 4.7 Identifying Errors

The Open Payments system notifies users of errors in records 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 these 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 these 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 these 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 warning log associated with the bulk file. Records with expired license related warnings are also identified with a warning icon (A) next to the Record ID on the Payment Category page

Note that if a bulk file submission makes it past Step 1, all 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 Payment Records" section, select the payment type, entity and program year for the records you wish to review, then select the "Review Detail" 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 3:</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 covered recipient NPP 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 2 or 3 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. A warning 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 (or) select "Warning Log" hyperlink at the bottom of the page to download the warning 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.
E	م 1	• Ə - İ 4	° È lè la la la la de l	↓ ⊼↓ 🗁 📲 ○ 🏎	ye 🏭 🔻	1910_	Research F	Payments.csv	[Read-Onl	y] - Excel		
F	File Home Insert Page Layout Formulas Data Review View 🖓 Tell me what you want to do											
	<mark>∎ </mark>	ut opv. z	Calibri • 11 •	A A ≡ ≡ ≫ •	F Wrap Text	General	-	≠		Normal		
Pas *	te 🝼 F	ormat Painte	r B I U - 🖾 - 🖄	• <u>A</u> • = = = •	Merge & Ce	nter • \$ • % •	€.0 .00 .00 →.0	Conditional Formatting *	Format as Table *	Neutral		
	Clipbe	pard	ra Font	G A	lignment	5 Number	Fa					
L1()	T	$\times \checkmark f_x$									
	А	В	С	D	E	F	G	н	1	J		
1	File ID	Record ID	Home System Payment ID	Payment Record Status	Error Message ID	Data Element Value						
2	1910	126725	null	Failed Validation	E-408	Charles						
3	1910	126729	null	Failed Validation	E-9052	A1234						
4												

Figure 183: Sample Error report in Excel showing error message ID's and Data Element Values

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

Figure 184: Sample Warning report in Excel showing warning message ID's and Data Element Values

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Fi	le Hor	ne Insert	t Page Layout Formulas	: Data Review Vi	iew 🛛 🖓 Tell me wł	hat you want to do			
-	Cut		Calibri • 11 • A	Ă ≡ ≡ ₩.	🚏 Wrap Text	General	- 🔢 💷	Normal	Bad Good
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	Clipboard	r _a	Font	ra Alignr	ment	5 Number	6		Styles
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1	A	В	С	D	E			F	
1	File ID	Record ID	Home System Payment ID	Payment Record Status	Warning Message	Data Element Value			
2	2210	132338	null	Migrated to Target	I-407	Triptorelin : 9999-999	9-99, Triptorelin pamoat	e : 3333-3333-11, Tr	rastuzumab : 4333-4442-22
3	2210	132336	null	Migrated to Target	I-407	Triptorelin : 9999-999	9-99, Triptorelin pamoat	e : 3333-3333-11, Tr	rastuzumab : 4333-4442-22
4									

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

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 a late payment, a warning message will be listed in the downloadable warning 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.

If the NPP license information is inactive beginning with Program Year 2021 to present and/or if the license cited on the reported payment record is inactive throughout the Open Payments program, the payment record fails matching.

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:

<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 Payment Records" section, select the payment type, entity, and program year for the records you wish to review, then select the "Review Detail" 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 3:</u> 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 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 warning log for the bulk file will 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 185: Submissions page for Group Purchasing Organization users

Open Payments Applicable Manufacturer or Group Purchasing Organization	(Sunshine)	Act)	System <u>Messages</u> <u>Compliance</u> Messages
Home Submissions Review at	nd Dispute Manage Entities	(Q) My Profile	Messages Resources
Submissions			? User Guide
A field with an asterisk (*) is required. Applicable manufacturers and applicable GPOs must si System.	ubmit payments, or other transfers of val	ue, and ownership or in	westment interests to the Open Payments
Only users who hold the role of submitter can submit in	formation to the Open Payments system	. Select Bulk File	Download the Physician
Refer to the Resources tab for the Open Payments reporting templates for the Bulk File Upload.	Select Manual Data Entry to submit rr Open Payments manual entry online Manual Data Entry	ecords using the form.	List The Validated Physician Lists and Physician with inactive License(s) Supplement File per Program Year below should not be shared publicly. File Download Help @ Validated Physician Lists and Physician with inactive
Review Submitted Payment Record To review records, select the payment type, entity whos drop-down lists below, then select "Review Detail". *Select Payment Type: *Select Entity: Please Select Please Select	S e records you wish to review, and the p *Select Program Ye Please Select	rogram year from the ar: Review Detail	License(s) supplement File per Program Year Download the Non- Physician Practitioner List per Program Year below should not be shared publicly. Non Physician Practitioner
To view submission summary and/or attest records, see program year from the drop-down lists below, then sele *Select Entity: *Select Prog ABCDE Medical 2021	ect the entity whose records you wish to ct "Review Summary". ram Year: Review St	review and the	List Download the Reporting Templates To download reporting templates, see the Resources tab.
Review Submitted File(s) Status Once a file for your entity has been submitted, you may Review File Status Download Recipients Missing Owne	review the details by selecting "Review ership Record	File Status."	
GPO entities are required to report ownership/investme general and/or research records for the same program 403.906; To review physicians that were cited on gene ownership record, select the entity you wish to review fn NOTE: If there is any physician where the column value interest record in Ready for Attestation status' is "No." Ownership/investment interest record for the physician associated general or research records are identified an is completed.	In therest payments for physicians that year (per the Open Payments final rule, ral and/or research records who do not om the drop-down list below, then selec for i's there at least one associated Ow eview your submissions to verify that a will be included in your submission. If th d will meet the regulation cited above a	have been cited on 42 C F R. § have an attested t "Download Report." nership/Investment corresponding e value is "Yes," the fter your attestation	
Select GPO Entity: Please Select Download R Covered Recipient Validation Utility	report		
To verify provider matching information, select the "Vali information on the new page. The Covered Recipient V and non-physician information to profiles prior to report Validate Covered Recipient	date Covered Recipient" button below a alidation utility can be used by submitter ng that covered recipient on the paymer	nd upload provider s to upload physician tt record.	
			Contact Us Privacy Policy

- 3. In the downloaded Zip file, save or open the Excel file to review the recipients specified on general/research records that are missing an attested ownership/investment interest record in the same program year as the general/research record. The report shows the following information:
 - a. GPO Making Payment Name
 - b. GPO Making Payment Registration ID
 - c. Program Year
 - d. Covered Recipient First Name
 - e. Covered Recipient Last Name
 - f. General Payment Sample Record ID(s) that the covered recipient is included on (separated by semicolon): This field includes up to 25 latest general payment record IDs that are associated with the physician/NPP. Only those in Ready for Submission, Returned to Submitter, Ready for Attestation, Attested, and Attested as Marked for Deletion statuses are included.
 - g. Research Payment Sample Record ID(s) that the covered recipient is included on (separated by semicolon): This field includes up to 25 latest research payment record IDs that are associated with the physician/NPP. The listed physician can be a covered recipient or a principal investigator of a research record. Only those in Ready for Submission, Returned to Submitter, Ready for Attestation, Attested, and Attested as Marked for Deletion statuses are included.
 - h. 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 NPPs (including principal investigators): First Name, Last Name, NPI, License State, and License Number.

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

Changing a record may affect the publication of that record, depending on when the changes are made. For details refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at <u>https://www.cms.gov/OpenPayments/Resources</u>.

Note: if a record containing multiple 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>

Upon identifying all the erroneous records (rejected or failed), consolidate them in a bulk upload template. Using the "error log" and "error and warning code key" document, correct the record details accordingly. 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 (4.7a(2) or 4.7a(3)), 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 (4.7a(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. This Record ID for each record can be obtained either from the payments category page or the error log file.
- 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 Payment Records" section, select the payment type, reporting entity whose record you wish to view and the program year for that record, and then select the "Review Detail" 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 can copy/duplicate payment records within the Open Payments system and allow the editing of those records without going through the entire data entry process.

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

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

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 186: Submissions Tab for Open Payments system landing page for returning system users



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

Figure 187: Submissions Landing Page

Home <u>Submissions</u> Rev	iew and Dispute	🔊 Manage Entities	(Q) My Profile		Messages	Resource
Submissions						? User Gui
field with an asterisk (*) is required. pplicable manufacturers and applicable GPOs r ystem.	nust submit paymen	its, or other transfers of valu	e, and ownership or in	ivestment in	terests to the O	pen Payments
bubmit Payment Data	omit information to th	he Open Payments system.	Select Bulk File	Down	oad the Pl	hveician
Ipload or Manual Data Entry below. Refer to the Resources tab for the Open Paymer eporting templates for the Bulk File Upload.	its Select Mar Open Payr	nual Data Entry to submit rea ments manual entry online fo	cords using the orm.	List The Valid Physician Supplement	ated Physician I with Inactive Li ent File per Prog	Lists and cense(s) gram Year below
Bulk File Upload	cords	Manual Data Entry		should no File Do	t be shared pub wnload Hel Validated Phy and Physicia License(s) Su per Program	Nicly. P C ysician Lists n with Inactive upplement File Year
o review records, select the payment type, entit	y whose records you	wish to review, and the pro	gram year from the	D		
Select Payment Type: "Select Ent General Payments I ABCDE Me	i ity: Idical	*Select Program Year 2021	r: Review Detail	Physic The Non- Program publicly.	Physician Practi Physician Practi Year below shou	tioner List itioner List per uld not be share
o view submission summary and/or attest recor rogram year from the drop-down lists below, the	ds, select the entity en select "Review Su	whose records you wish to r immary".	eview and the	Downl Templ	oad the Reates	eporting
Select Entity: *Selec Please Select V Please	t Program Year: e Select	Review Sur	nmary	To downlo Resource	oad reporting ter s tab.	mplates, see the
Review Submitted File(s) Status	6					
once a file for your entity has been submitted, yo	ou may review the de	etails by selecting "Review F	ile Status."			
Review File Status						
Download Recipients Missing C PO entities are required to report ownership/inv eneral and/or research records for the same pro 30.90). To review physicians that were cited on whership record, select the entity you wish to re IOTE: If there is any physician where the column therest record in Ready for Attestation status' is whership/investment Interest record for the phy sociated general or research records are ident is completed.	Swmership Re restment interest pay gram year (per the in a general and/or res view from the drop-on n value for "is there i "No," review your su sician will be include ifled and will meet th	ecord yments for physicians that h Open Payments final rule, 4 earch records who do not ha down list below, then select: at least one associated Own bibmissions to verify that a cc ed in your submission. If the le regulation cited above afti	ave been cited on 2 C.F.R. § ave an attested "Download Report." hership/Investment prresponding value is "Yes," the er your attestation			
Select GPO Entity: Please Select Down	aload Report					
overing provider matching information, select th	tility 🚱 e "Validate Covered	Recipient" button below and	d upload provider			

<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 188: "Copy" Hyperlink from Reporting Entity General Payments Payment Category Page

Home Sub	missions	Review a	nd Dispute	Manage	Entities	() My Profil	e	Messages	Resou
avment Ca	tegor	v: Gen	eral Pa	vmer	nts - A	BCDE M	ledical	2021	
e table below provides i	nformation or	submitted reco	ords for the sele	ected reporti	ng entity, prog	gram year, and pa	yment categor	y.	
arch and filtering tools a	bove the tab	le can customiz	e the view of th	e data.					
export the search result an 400,000 records, will em in multiple files.	s into a CSV generate an i	file, select "Do on-screen error	wnload Zip File' notification. To	. This provi correct this	des a compres error, adjust ti	ssed file containin he filtering criteria	g the search r to create sma	esults. Attempt iller subsets of	ing to download records and dov
view all fields for a reco	rd, select the eviewed and	e "Record ID" hy corrected as re	perlink in the ta quired. Record	ible below. I s with warni	Record(s) flagi ng messages	ged with a warning only (do not have	g icon (Å) ide validation or r	ntify that there natching errors	are warning i), will not prever
cord from continuing thro valid as-is.	ugh final sub	mission and at	lestation, and th	erefore are	not required to	o be corrected be	fore proceedir	ig if the informa	ation is determin
cords counted as "Mark	ed for Deletic	on" are also incl	uded in the "Att	ested" (†) re	ecord count. If	you wish to reinst	ate records m	arked for delet	ion, find the reco
th the "Marked for Deleti	on" status of	"Yes", select th	e checkbox nex	d to them, a	nd then select	the "Cancel Dele	tion" button.		
r more information on th en Payments public wel	e actions you usite. For det	u can take on th alled informatio	is page, refer to n on how to edi	the "Paym t and submi	ents Category t records, refe	Page" quick refer r to the Open Pay	ence guide av ments User G	ulde [PDF].	Resources page
General Paym	ents								
Help with this Page									Refresh Statu
Status		Record Count	Action Re-	quired					
System Processing		0	No Action						
Failed Validation		0	Correction						
Falled Matching Ready for Submission		0	Final Subr	ission					
Ready for Attestation		0	Attest						
Returned to Submitter		0	Correction						
Attested † Total Payments		0	No Action						
Neter Draviously attests	d rooordo thu	, 1 hous hoos mu	arlead for deletin	n hous not	unt hoon doloi	ad from the Onen	Devenante eu	atom The	
attester must re-attest to remain eligible for review	all payment	s for the selecte , are eligible fo	ed program yea r publication, ar	r to complet nd are includ	e deletion. Un led in the atte	til this re-attestation sted record count.	on, the marked	records	
Marked for Deletion		Record	Action Re-	quired					
+ Attester to confirm d	eletion	0	Attester to	Attest or R	eiect Deletio	n			
lavigate to Submissions							Nav	igate to Reviev	v Records - Sum
System Processing		File	ID: imum 38 digits			Record ID: Maximum 38 di	gits		
Failed Validation Failed Matching									
Ready for Submission Ready for Attestation		Hom	e System Pay	ment ID:		Delay in Public	ation Indicat	or:	
Returned to Submitter Attested						Please Select		~	
Covered Recipient Firs	st Name: 🕜	Cove	ered Recipient	Last Name	•	Covered Recip	ient NPI:		
						This is a 10-dig	it number 🕜		
License State:		License Nur	nber:	Add	ress State:		Zip Code:	9999	
Please Select	~			Ple	ase Select	~	99999		
Teaching Hospital Nan	ne:	Teac	hing Hospital	CCN:		Teaching Hosp	ital TIN:		
			is a o-aigit na			This is a o-argu	number		
Marked for Deletion:	Recipien	t Type:		In	put Method:	Report Ty	pe: F	Record Warnin	ngs: 🕜
Yes	Covere	ed Recipient Phy	sician		Manual Entry	Single	[Yes	
L No	Covere Covere	ed Recipient Tea ed Recipient Nor	ching Hospital I-Physician Prac	titioner	Upload Files	Consoli	dated .	No	
Search Clear All	Download	l Zin Filo							
Clear All	, Cowmodu								
howing Results	for								
in in the second s	101.								
.,	Ur	idate Delay Indi	cator C	ancel Deleti	on Re	turn to Attester	Delete S	Selected	Return to Subr
		Showing 10	of 1 Ent	rios	Page 1 c	sf1	Page 1		
			- or rem		. age 10				
Select		Home System	Payment	Amount	Recipient T	ype: Recipient:	Record Status:≎	Marked for Deletion:☆	Delay in Public Indicator:
Select File Record II	D: Actions:	Payment ID: ¢	Date:☆	(3).0					
Select All ID: N/A 79200388	D: Actions: View Edit	Payment ID: ¢	Date: \$	\$500.00	Non-Physicia Practitioner	n James Miller	Failed Matching	No	No Delay Requ
Select All ID: ♦ Record II ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦ ♦	D: Actions: View Edit Copy	Payment ID: ¢	Date: \$	\$500.00	Non-Physicia Practitioner	n James Miller	Failed Matching	No	No Delay Requ

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 189: "View" Hyperlink from Reporting Entity General Payments Payment Category Page

	Submissions	Baylayr	Dispute		O Mu Drofilo		۲
Home		Review		manage Entities	My Profile	messages	Resourc
aymen	t Catego	ry: Gen	eral Pay	ments - A	BCDE Med	cal 2021	
e table below pr	ovides information	on submitted rec	ords for the selecte	d reporting entity, pro ata	gram year, and payment o	ategory.	
export the sear	ch results into a CS	V file, select "Do	wnload Zip File". T	his provides a compre	ssed file containing the se	arch results. Attemp	ting to download m
an 400,000 reco em in multiple fil	rds, will generate ar es.	1 on-screen erro	notification. To co	rrect this error, adjust	the filtering criteria to crea	te smaller subsets of	records and down
view all fields for	or a record, select th	he "Record ID" h	vperlink in the table	below. Record(s) flag	ged with a warning icon (identify that there 	are warning
essages that she cord from contin valid as-is.	uld be reviewed an uing through final su	d corrected as r ubmission and a	equired. Records w testation, and there	ith warning messages fore are not required	only (do not have validati to be corrected before pro	on or matching error ceeding if the inform	s), will not prevent a ation is determined
cords counted a	is "Marked for Dele	tion" are also inc	luded in the "Attest	ed" (†) record count.	f you wish to reinstate rec	ords marked for dele	tion, find the record
r more informati	ion on the actions w	n res , select ti ou can take on ti	is name refer to th	e "Payments Categor	Page" quick reference of	uon. iide available on the	Resources page o
en Payments p	ublic website. For d	etailed information	on on how to edit ar	nd submit records, ref	r to the Open Payments	Jser Guide [PDF].	resources page o
General I	^o ayments						
Help with this	Page						Refresh Status
Status		Record Count	Action Requi	red			
System Proce	asing	0	No Action				
Failed Validati	on	0	Correction				
Ready for Sub	9 mission	0	Final Submiss	ion			
Ready for Atte	station	0	Attest				
Returned to S	ubmitter	0	Correction				
Autested † Total Payment	s	1	No Action				
Note: Previous	v attested records ti	hat have been m	arked for deletion h	ave not vet been dele	ted from the Open Payme	nts system. The	
attester must re remain eligible f	-attest to all paymer for review and dispu	nts for the select ite, are eligible fo	ed program year to or publication, and a	complete deletion. Un ire included in the atte	til this re-attestation, the r sted record count.	narked records	
Marked for D	eletion	Record	Action Requi	red			
† Attester to c	onfirm deletion	0	Attester to Att	est or Reject Deletio	n		
System Proces Failed Validatio Failed Matching Ready for Subr Ready for Attes Returned to Su Attested	sing n J nission tation bmitter	Hor	ne System Payme	nt ID:	Maximum 38 digits Delay in Publication In Please Select	ndicator:	
Covered Recip	ient First Name: 🕝	Cov	ered Recipient La	st Name: 🚱	Covered Recipient NF	1:	
					This is a 10-digit numb	ver 😧	
License State:		License Nu	mber:	Address State:	Zip	Code:	
				Diseas Salast	999	99 9999	
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Please Select Teaching Hosp Yes Yes Search Search Select File I I Select File I I I I I I I I I I I I I I I I I I I	etion: Recipier Cove Cove Cove Cove Sults for:	nt Type: wed Recipient Pich wed Recipient Te red Recipient Te ad Zip File pdate Delay Ind Showing 1 Home Syster Payment ID:	visian aching Hospital In-Physician Practitio in Payment i Date: o Date: o Date: o	el Deletion R Amoust Fair Upload Files Page 1 Amoust Recipient R Construction R R R R R R R R R R R R R R R R R R R	Report Type: Single Consolidated Hum to Attestar of 1 Page The Page New Statestar Page Recipient: Seaturn an James Falled	Record Warni Yes No elete Selected I V Marked for Deletion:0 No	Return to Submit
Please Select Teaching Hosp Marked for Del Yes Ves Search G howing Re II III III IIII IIII IIII IIII IIII	etion: Recipie Cov Cov Cov Cov Cov Cov Cov Cov Cov Cov	Int Type: srea Recipient Ph srea Recipient Ph srea Recipient No ad Zip File Showing 1 Home Syster Payment ID:	visidan hching Hospital n-Physician Practition incattor Cance or Cance or Cance	Input Method: Manual Entr Upload Files Upload Files Bloeletion R a Page 1 Amount Recipient 1 (5): 0 00 00 Practitioner	Recipient Page ype: Recipient State Miller State	eleto Selocted	Return to Submit

<u>Step 4b-2:</u> Select the "Copy" Button from the top of the page.

Figure 190: Copy Button on Record ID Page



<u>Step 5:</u> A confirmation pop-up box appears. Select the "Yes" button.

Figure 191: Confirmation pop-up window



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

Note that, while copying records,

- The fields may differ based on the Program Year selected. E.g., Covered Recipient NPP is available only from PY 2021 and onwards.
- The fields may differ based on the Covered Recipient type selected. E.g., you can select a single primary type for Covered Recipient Physician whereas multi-select up to six primary types for Covered Recipient NPP
- If you change the Covered Recipient type few fields including "Country", "Primary Type" and "Taxonomy code", will switch to blank and will allow you to select those values.
- When you view an existing record (uploaded before January 2022) that failed validation for Drug
 or Biological Name or Drug/Biological Name and NDC combination with a soft warning, the
 system warning message will continue to be displayed. When you copy the record and click on
 "Continue" button at the bottom of the "Products" page, an error message will be displayed
 indicating the incorrect values of Drug or Biological Name or Drug/Biological Name and NDC
 combination.
- When you view an existing record (uploaded before January 2023) that failed validation for Device or Medical Supply or Device/Medical Supply and Primary Device Identifier (PDI) combination with a soft warning, the system warning message will continue to be displayed.
 When you copy the record and click on "Continue" button at the bottom of the "Products" page, an error message will be displayed indicating the incorrect values of Device or Medical Supply or Device/Medical Supply and PDI combination.

Open Pay	ments (Su	nshine A	ct)		
Applicable Manufacturer or Group I	Purchasing Organization Switch User	Туре	-		
	L3	Ê	0		
Home Submission	ons Review and Dispute	Manage Entities	My Profile	Messages	Resources
Add General P	ayment				? User Guide
•		\$		~	
Overview	Covered Recipient Prod	ucts Payments	General Info	mation Review	& Save
	Demographics				
Payment Overview					
Confirmation:					
The selected record has	been copied from Record ID: 115	185. Edit and save this record	I to complete the reco	rd creation process.	
Review the payment information	for the record. Enter the Home Sys	tem Payment ID as needed.			
Entity Making Payment	Entity Making Payment	*Dramow Vaam	Pay	ment Category:	
Registration ID:	Registration Name:	2016	Ge	neral Payments	
100000165003	ABCDE Medical				
Home System Payment ID:					
Home System Payment ID:					
Home System Payment ID: 6					
Cancel					Continue
Cancel					Continue
Cancel					Continue

Figure 192: 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 have not yet been attested to will be immediately removed from the Open Payments system. You must provide a reason for deleting attested records. The following reasons may be used for deleting previously attested records:

- Correction to Covered Recipient Information (But to Same Covered Recipient)
- Different Covered Recipient
- Record Should Have Been Reported by a Different Applicable Manufacturer or Applicable GPO
- Payment Had Not Been Furnished to the Covered Recipient

- Disputed by Covered Recipient
- Correction at CMS's Request
- Duplicate Record(s)
- Incorrect Record Classification
- Check was Voided or Not Cashed
- De Minimis was Not Met
- Record Meets Reporting Exception
- Other

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

To complete the deletion of 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 193: Submissions Tab for Open Payments System Landing Page for returning system users



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

Home Submissions Rev	view and Dispute	e Manage	Entities	O My Profile		Messages	Resource
Submissions							? User Guid
field with an asterisk (*) is required. upplicable manufacturers and applicable GPOs system.	must submit paym	ents, or other ti	ansfers of value	, and ownership or in	nvestment ir	iterests to the O	pen Payments
Submit Payment Data							
Only users who hold the role of submitter can su Ipload or Manual Data Entry below.	bmit information to	the Open Pay	ments system. S	elect Bulk File	Down	oad the Pl	hysician
Refer to the Resources tab for the Open Paymen eporting templates for the Bulk File Upload.	nts Select M Open Pa	lanual Data Ent syments manua Manual Da	ry to submit reco I entry online for ta Entry	ords using the m.	LIST The Valid Physician Suppleme should no	ated Physician I with Inactive Li ent File per Prog it be shared pub	Lists and cense(s) gram Year below blicly.
Review Submitted Payment Re	cords				File Do	Wnload Hel Validated Phy and Physicia License(s) Su per Program	p ? ysician Lists n with Inactive upplement File Year
o review records, select the payment type, entit rop-down lists below, then select "Review Deta	ty whose records y if".	ou wish to revi	ew, and the prog	ram year from the	Down	oad the N	on-
Select Payment Type: *Select En General Payments ABCDE Me	tity: edical	*Select 2021	Program Year:	Review Detail	Physic The Non- Program publicly.	cian Practi Physician Practi Year below shor	tioner List itioner List per uld not be share
Review Records - Summary					Ē	Non-Physicia List	In Practitioner
rogram year from the drop-down lists below, the Select Entity: Please Select Please	e Select	Summary".	Review Sum	mary	Down Templ To downle Resource	oad the Re ates bad reporting ter is tab.	eporting
Review Submitted File(s) Statu							
Dince a file for your entity has been submitted, yo	ou may review the	details by sele	ting "Review Fil	e Status."			
Review File Status							
Download Recipients Missing O	Ownership R	Record					
SPO entities are required to report ownership/im eneral and/or research records for the same por 3096). To review physicians that were cited o wnership record, select the entity you wish to or OTE: If there is any physician where the colum iterest record in Ready for Attestation status' is sociated general or research records are iden is completed.	vestment interest p ogram year (per th n general and/or re eview from the drop n value for "Is ther "No," review your (sician will be inclu lifted and will meet	ayments for ph e Open Payme esearch record p-down list belo e at least one a submissions to ided in your sui the regulation	visicians that har nts final rule, 42 s who do not hav w, then select "E issociated Owne verify that a cor omission. If the v cited above after	ve been cited on C.F.R. § ve an attested Download Report." rrship/Investment responding value is "Yes," the r your attestation			
Select GPO Entity: Please Select Down	nload Report						
Covered Recipient Validation U	tility 😧						
o verify provider matching information, select th normation on the new page. The Covered Reci nd non-physician information to profiles prior to Validate Covered Recipient	e "Validate Covere pient Validation util reporting that cove	ed Recipient" b lity can be used ered recipient c	utton below and I by submitters to n the payment re	upload provider o upload physician ecord.			

Figure 194: Submissions Landing Page

<u>Step 3:</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 195: Reporting Entity Payment Category Page

	Cube	3	Baulaud		Mana	Ô	۲		⊠,	۲
Pavme	nt Ca		. Review	earch	Pavn	ge Endues nonts - /		Aedica	1 2021	Resource
ne table below	provides inf	ormation on	submitted re	cords for the	selected repo	orting entity, progra	am year, and paym	nent category.		
earch and filter	ing tools ab	ove the table	e can custom	iize the view o	of the data.					
export the se an 400,000 re	arch results cords, will ge	into a CSV r enerate an o	file, select "D in-screen erro	ownload Zip F or notification.	File*. This pro	wides a compress his error, adjust the	ed file containing t e filtering criteria to	he search resu create smaller	Its. Attempting r subsets of rec	to download mo cords and downlo
em in multiple	files.				. A star			A		
view all tierus essages that s	for a record	i, select the viewed and c	"Record ID" i	required. Rec	e table below ords with war	 Record(s) flagge rning messages or 	ed with a warning # nly (do not have va	con (A) Idental didation or mat	y that there are ching errors), w	warning will not prevent a
cord from com valid as-is.	inuing throu	gh final suor	nission and a	attestation, an	d therefore a	re not requirea to	be corrected berui	e proceeding #	the information	a is determineu
cords counter	d as "Market for Deletio	d for Deletion	n" are also in "Yes" select '	cluded in the	"Attested" (†)) record count. If y	ou wish to reinstate	e records mark	ed for deletion,	, find the record
or more inform	ation on the	actions you	can take on f	this page, refe	ar to the "Pay	ments Category P	Page" quick referen	ice guide availa	able on the Res	sources page of
cen Payments	public webs	ite. For deta	illed informati	ion on how to	edit and sub	mit records, refer	to the Open Payme	ents User Guid	e [PDF].	
Researc	h Payr	nents								
Help with th	is Page								F	Refresh Status
Status			Record	Action	Required					
System Proc	essing		0	No Actio	on					
Failed Vanue Failed Match	ntion		1	Correcti	on ion					
Ready for Si	ubmission		2	Final Su Attest	ubmission					
Returned to	Submitter		0	Correcti	ion					
Total Payme	ents		4	190.7.0	n					
Note: Previou attester must	sly attested	records that all payments	t have been n for the selec	narked for del	letion have no vear to comp	ot yet been delete	d from the Open Pathis re-attestation,	ayments syste the marked re	m. The cords	
remain eligibl	a for review	and dispute,	are eligible f	or publication	, and are incl	luded in the attest	ed record count.			
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Covered Rec	ipient First	Name: 😯	Co	vered Recipi	ent Last Nan	ne: 😧	Covered Recipier This is a 10-digit r	nt NPI: number 😮		
License Stat	e:		License Ni	umber:	A	ddress State:		Zip Code:		
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Teaching ris	spital marine	c	Thi	is is a 6-digit	number 🕜		This is a 9-digit n	umber		
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□ No		Covered	d Recipient Te vered Recipie	aching Hospit ant Entity	al	Upload Files	Consolida	ted 🗆 t	40	
		Non-Co Covered	vered Recipie d Recipient N	int Individual on-Physician F	ractitioner					
Search	Clear All	Download	Zip File							
howiny	esuns .	or:						_		
		Upt	date Delay Inc	dicator	Cancel Del	letion Retu	irn to Attester	Delete Sele	ected R	eturn to Submit
						Perce 1 of	Pa		_	
		51 	howing	0 V or +	Entries	Page 1 or	1 Pr Pr re	Record	Marked for	Delay in
ielect File	Record	Actions: F	ayment ID:☆	Date:¢	\$	Recipient Type:	:♦ Recipient:♦	Status: 0	Deletion: \$	Publication Indicator: <
Select All ID:◊	Record ID:⊘			20210704	\$1,000.00	Covered Recipient Non-Physician	t James Miller	Failed Matching	No	No Delay Requested
Select All ID: ♦	Record ID: ↓ 79200390	View Edit				Practitioner	a	Failed		No Delay
Select All D:\$ N/A	Record ID: ♦ 79200390	View Edit Copy View		-		Covered Recipien	Los Trees	Paneo	No	Requested
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Select All □:¢ 12;¢ 12789 12789 12789	Record ID: 0 79200390 79200394 79200395 79200396	View Edit Copy View Edit Copy View Edit Copy View Edit Copy		20210102 20210101 20210102	\$76,767.22 \$76,767.22 \$76,767.22	Non-Physician Practitioner Covered Recipient Physician Covered Recipient Non-Physician Practitioner	t Brandon Ross t JENNIFER SNYDER	Validation Ready for Submission Ready for Submission	No	No Delay Requested No Delay Requested

<u>Step 4:</u> On the "File ID" page, select the "Delete File" button.

Figure 196: Delete File Button on File ID Page

Home Submissions	Review and Dispute	Ø Manage Entities	O My Profile		Messages	Resource
File ID: 141306				0	Access the Op User Guide [PE	en Payments DF]
Details about the File Su	bmitted			2	Need help with	the website?
If any records have errors, download the file's warning log. The records can ID. If necessary, this file can be deleted	he file's error log. If any reco be identified by the Record d by selecting the "Delete Fi	nt	•	Review the Op Privacy Policy [en Payments [PDF]	
2021 General Payments					1	35
Original Upload File Name:	ValidFile_GP.0					
Type of Submission:	New Submiss	ion		C.		1 ANA
Original /Resubmission Date:	12/3/2021 2:0	9 PM				
Submitted By:	Ted Smith				1 2	
File Size:	3 KB				·B·A.	KIK
File Type:	CSV			1		
Program Year:	2021					
Payment Category:	General Payn	nents				
File Status:	Submitted with	h Errors				
Number of Records in File:	2					
Number of Records Uploaded:	2					
Error Log:	141306_Gene	eral Payments Error(s)				
Warning Log:	141306_Gene	eral Payments Warning(s)				
Back to Payment Category		Delete F	le			

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



Figure 197: 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 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.

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

Step 5: Choose the file and select the "Submit File to Open Payments" button.

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

Upon successful processing of this bulk file, the records it includes that have not yet been attested to will be deleted. 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 198: Open Payments System Landing Page for returning system users



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

Figure 199: Submissions Landing Page



<u>Step 3:</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.

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Payment Catego	ory: Ger	neral Pay	ment	s - AB(CDE Me	dical 20	21	
Confirmation: You have successfully clear	ed the previoue	yentered eastch	criteria.					
The table below provides information	on submitted re	cords for the select	ed reporting	ently program	year, and payme	nt category.		
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tran 400,000 records, will generate : tem in multiple files.	an on-screen erro	r notification. To co	med this ear	or, adjust the 9	tering criteria to c	reate scrulier sui	basis of records	s and downica
To view all fields for a record, select that should be reviewed and correct continuing through final submission : s.	the "Record ID" h ed as required. R and attestation, a	yperfinit in the table accords with warnin nd therefore are no	a baicov. Rec g messages t required to	ord(x) flagged only (do not ha be connected b	with a warming ico ve validation or m efore proceeding	n (♠) identify th atching errors), i If the information	at there are wa will not prevent. It determined	ming messag a record from to be valid as-
Records counted as "Marked for Del	etion" are also in	luded in the 'Atter	ded" (T) reco	rd count. If you	with to reinstate	records marked	for deletion, fin	d the records
with the "Marked for Deletion" status For more information on the actions	of "Yes", select t you can take on t	he checkbox nexts his page, refer to t	o them, and te ''Payment	then select the s Category Pag	"Cancel Deletion" pi [*] quick reference	r button. e-guide available	on the Resour	cas page of t
Open Payments public website. For	detailed informati	on on how to edit a	nd submit re	cords, refer to	the Open Phymer	to Univ Guide P	PDF).	
General Payments								
Help with this Page								and Richard
Status	Record	Action Reg	ind				_	
System Processing	Court	No Action						
Failed Validation	0	Correction						
Ready for Submission	1	Final Submit	nion					
Returned to Submitter	ě	Correction						
Attested † Total Payments	1	No Action						
Nose: Previously attented records	that have been	writed for deletion	have not yet	been deleted	ton the Open Pa	yments system.	The	
atiester must re-atiest to all paym eligible for review and dispute, an	ents for the selec eligible for publ	ted program years ication, and are inc	o complete d luded in the s	eletion. Until th stended record	is re-attestation, t count.	he marked reco	da remain	
Marked for Deletion	Record	Action Reg	ind					
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Figure 200: Delete Selected Button for Payment Category Page

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

alternate reason for deleting the record must be entered in the field "Other Reason for Deletion." To proceed with deletion, select the "Delete" button. To cancel, select "Cancel."

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				Showing	10	✓ of 12 Entr	ies 阔 🔜	Page 1 of 2	e> ei Pa	ige 1 🗸			
Select All	File Record Actions: Home System Payment ID: Payment Date: Amount(\$): Recipient Type: Recipient: Record Status:										Marked for Deletion: ≎	Reason For Deletion: ≎	
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	View Mark												
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	5001	5950238	View Edit Copy			20230101	\$1,013.88	Physician	Mark Stellingworth	Ready for Submission	No		
				Showing	10	✓ of 12 Entr	ies 🗔 🖂	Page 1 of 2	н Ра	ige 1 🗸			

Figure 201: Confirm Deletion Notification

You will receive an onscreen notification of the deletion.

Figure 202: Sample General Payments Page with Deletion Confirmation Message

Open Applicable Manufa	Cturer or Group Purchasin	ents (Su ng Organization Switch User 1	nshine /	Act)		
Home	Submissions	Review and Dispute	Manage Entities	O My Profile	Messages	Resources
Paymer	nt Category	: General Pa	ayments - A	BCDE Medio	al 2018	
Confirmation: • Selected r deleted fro "Review R re-attestat	ecord(s) have been su om the Open Payments Records" page and sele tion.	ccessfully deleted except s system until re-attestatio ect the "Notify Attester" bu	for records in "Attested" n takes place. Note: If at atton to send an email no	status. Selected record(tested records have been tification to all attesters t	s) in "Attested" status selected for deletion, hat there are record(s)	will not be go back to the which require
The table below p Search and filteri To export the sea than 400,000 rec them in multiple f	provides information on a ng tools above the table arch results into a CSV fi ords, will generate an or files.	submitted records for the se can customize the view of t lle, select "Download Zip Fili n-screen error notification. T	lected reporting entity, pro- he data. e ^w . This provides a compre o correct this error, adjust i	gram year, and payment ca ssed file containing the sea the filtering criteria to create	itegory. Irch results. Attempting to smaller subsets of reco	to download more ords and download
To view all fields messages that sh record from conti be valid as-is.	for a record, select the " nould be reviewed and c nuing through final subm	Record ID" hyperlink in the orrected as required. Recorn hission and attestation, and	table below. Record(s) flag ds with warning messages therefore are not required to	ged with a warning icon (A only (do not have validatio to be corrected before proc	 identify that there are n or matching errors), w eeding if the information 	warning ill not prevent a is determined to
Records counted with the "Marked	as "Marked for Deletion for Deletion" status of "Y	" are also included in the "A res", select the checkbox ne	ttested" (†) record count. If ext to them, and then selec	f you wish to reinstate reco t the "Cancel Deletion" but	rds marked for deletion, on.	find the records
For more informa Open Payments	tion on the actions you opublic website. For detail	can take on this page, refer led information on how to e	to the "Payments Category dit and submit records, refe	Page" quick reference gui to the Open Payments U	de available on the Res ser Guide [PDF, 28.8 M	ources page of the B].
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 203: 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 204: Show Disputes Button

Dpen plicable Manufa	Payme acturer or Group Purchasin	ents (Sui ng Organization Switch User T	nshine /	Act)			
Home	Submissions	Review and Dispute	Ø Manage Entities	O My Pro	file	Messages	e Resources
Review	w and Disp	ute Overviev	V		C	Access the Op User Guide [Pl	oen Payments DF]
A field with an	n asterisk (*) is required.				?	Need help with Contact Us by	the website? email
Applicab Select a repor Disputes". Thi or investment	Ie Manufactures rting entity and program is will display records rel interests for the selecte	r or Applicable GP year from the drop-down list ating to payments or other tr d reporting entity and progra	D Records below, then select "Show ansfers of value, or owner m year that are disputed.	ship		Review the Op Privacy Policy	een Payments [PDF]
The review an hospitals, non followed by a necessary cor	nd dispute process begin h-physician practitioners, 15-day correction period rrections to the data prio	is with an initial 45-day perio and principal investigators to I for reporting entities to reso r to publication.	d for physicians, teaching o review and dispute their lve disputes and make	data,			
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If any disputes resolved within initial annual o	s are initiated for the firs in the 15-day correction data publication for that y	t time after the 45-day review period, the record will be pub year.	/ and dispute period and n lished as not disputed in t	ot			
If any dispute original record information.	results in a change to th d must be deleted and a	e covered recipient or princi new record submitted with th	pal investigator information ne updated covered recipie	n, the ent			
Only records f will be eligible	for which attestation was for the review and disp	completed by the submission ute process for that calendar	on deadline of that calenda year.	ır year			
For a complet	te list of review and dispu	ute rules, refer to the Open F	ayments User Guide [PDF	Ð.			
*Show Dispu	ites for:						
Please Select	t						
*Program Ye	ar:						
Show Dispu	tes						

<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.

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Review and Dis	Jule	- coor pins	- 2023	
Back				
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physiciani non-physician practitioner Submitters for the reporting entity ca	n take art	ions on the discute(s) and	f edit the record under dispute	Once a disputed record is edited and reattested, the
associated dispute(s) on the record v	vill move	nto Resolved status.		
Please note: To view the entire tab	le, use th	e horizontal soroll bar t	below the table.	
Use the filtering tools below to custor	nize your	view of the disputed reco	rds.	
You may export your search result contain all data fields displayed in the	ts by sele a table be	cting the "Download Zip F low and other data eleme	File" link. The downloadable file ints related to the record. A dow	will be a CSV file compressed into a ZIP file. The file will mload file can include up to 20.000 records. To download r
than 20,000 records, adjust the filter	criteria to	create smaller subsets of	records and download them in	multiple files.
To view all fields for an individual	record, s	elect the "View" link under	r the Action column or the "Rec	ord ID" link in the Record ID column in the table below.
To perform any of the following as To acknowledge a dispute, s	elect the	eot the oheok box next theck box for the corresp	to the Aotion column: onding record and then select t	the "Acknowledge Dispute" button. This confirms that you it
received the dispute. To ackno	wledge a	I the disputes use the "Se	elect All" check box. When a dis	spute is acknowledged, an email notification will be sent to
 To recoive a dispute, select t 	he "Edit" I	ne. Ink in the Action column of	of that record. An email notificat	ion will be sent to the covered recipient when a record is b
edited by the entity or when th To deplace that the dispute h	e record i	s deleted to resolve the di	ispute. with the Final Rule without o	hanging the data select the check how payt to the record
then select the "Resolved No (Dhange" t	utton.		
To return to the previous page, select	t the "Bac	k" button.		
For more information about the revie	w and dis	pute process, including st	tep-by-step instructions, refer to	the Open Payments User Guide [PDF].
Applicable Manufactur	er or A	Applicable GPU's	s Disputed Records	
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Figure 205: Review and Dispute Record

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

on-screen message will appear to confirm the user wants to delete the selected record. Select "Delete" to delete the selected record. Select "Cancel" to cancel.

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Review and Dispute State	us: 🚹	Ma	arked for D	eletion:	Payment	Category:	Re	cipient Typ	e:		
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Reason For Deletion: Correction to Covered Rec Different Covered Recipien Record Should Have Been Payment Had Not Been Fu	A reason for delet for delet	for deleting ing the reco ion apply o	open Payl ng the recor ord(s) must nly to attest	d(s) must be s be entered in ted records.	elected. If " the field "O	Other" is se ther Reaso	elected, an a n for Deletio	alternate rea on". The rea	ason Isons		
Disputed by Covered Recip Correction at CMS's Reque Duplicate Record(s) Incorrect Record Classifica	Select "I	Delete" to o	lelete the re	cord(s). Selec	t "Cancel" f	o cancel th	e action.		- 66		
~ · · · · · · · · ·	Pleas	se Select	ettorn.						✓ Search	Clear A	
nowing Results f	Cance	D	elete								
ŋ				Acknowledge	Dispute	Reso	lved No Cha	ange	Delete Selected	Can	cel Deleti
		Showing	10 🗸	of 1 Entries	14 4	Page 1 of 1	10 H	Page 1	~		
elect All Action Record ID \Diamond	Home System Payment ID≎	Dispute ID¢	Recipient ♦	Total Payment Amount or Dollar Amount Invested⊘	Value Of Interest ♦	Review and Dispute Status ≎	Date Dispute Initiated ≎	History of Disputes	Delay in Publication of Research Payment Indicator⊘	Marked for Deletion: ♦	Reaso For Deletio ≎
View 5950122		1001287	Monica	\$100.00		Initiated	2023-09-	View	N/A	No	

Figure 206: Confirm Deletion Notification

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





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 208: 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 209: Review File Status Button on Submissions Home Page

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type	
Home Submissions Review and Dispute Manage Entities My Profile	Messages Resources
Submissions	? User Guide
A field with an asterisk (*) is required. Applicable manufacturers and applicable GPOs must submit payments, or other transfers of value, and ownership or in System.	nvestment interests to the Open Payments
Submit Payment Data	
Only users who hold the role of submitter can submit information to the Open Payments system. Select Bulk File Upload or Manual Data Entry below.	Download the Physician
Refer to the Resources tab for the Open Payments reporting templates for the Bulk File Upload. Bulk File Upload Review Submitted Payment Records	The Validated Physician Lists and Physician with inactive License(s) Supplement File per Program Year below should not be shared publicly. File Download Help @ Validated Physician Lists and Physician with inactive License(s) Supplement File per Program Year
To review records, select the payment type, entity whose records you wish to review, and the program year from the drop-down lists below, then select "Review Detail". *Select Payment Type: General Payments ABCDE Medical Call Review Detail	Download the Non- Physician Practitioner List The Non-Physician Practitioner List per Program Year below should not be shared publicly
Review Records - Summary	Non-Physician Practitioner List
To view submission summary and/or attest records, select the entity whose records you wish to review and the program year from the drop-down lists below, then select "Review Summary". *Select Entity: Please Select Please Select Review Summary	Download the Reporting Templates To download reporting templates, see the Resources tab.
Davian Submitted File/c) Status	
Once a file for your entity has been submitted, you may review the details by selecting "Review File Status." Review File Status Download Recipients Missing Ownership Record	
GPO entities are required to report ownership/investment interest payments for physicians that have been cited on general and/or research records for the same program year (per the Open Payments final rule, 42 C.F.R. § 403.906). To review physicians that were cited on general and/or research records who do not have an attested womership records, select the entity you wish to review from the drop-down list below, then select "Download Report." NOTE: If there is any physician where the column value for 'is there at least one associated Ownership/Investment Interest record in Ready for Attestation status" is "No," review your submissions to verify that a corresponding Ownership/investment Interest record for the physician will be included in your submission. If the value is "Yes," the associated general or research records are identified and will meet the regulation cited above after your attestation is completed.	
*Select GPO Entity: Please Select Download Report	
Covered Recipient Validation Utility 😡	
To verify provider matching information, select the "Validate Covered Recipient" button below and upload provider information on the new page. The Covered Recipient Validation utility can be used by submitters to upload physician and non-physician information to profiles prior to reporting that covered recipient on the payment record. Validate Covered Recipient	
	Contact Us Privacy Policy

<u>Step 3:</u> Select the File ID link for the file you wish to delete.

Figure 210: File ID link on Review File Status Page

Г но Rev	me <u>Submissions</u>						/ O \		~ 1		(c)
Rev		Revi	ew and Dispute	Manago	e Entities	My	Profile	N	lessage	s I	Resourc
he tabl	/iew File Stat	us									
1 C	le below displays information	on files subn	nitted on or after Jar	n 1st, 2019 f	or the reportin	g entities yo	ou are ass	ociated with ac	ross all a	vailable pro	ogram ye
na pay se the	Search and Filtering tool to c	ne File ID pai :ustomize yoi	ge of a processed N ur view of the file inf	formation.	SION OF RESUD	nission file,	select the	nyperlinked til	e ID in th	e tadie.	
File S	Status:		Payment Categor	v:		Program	Year:				
Reje	acted	A	General Payments	ts	*	2018				•	
Subr	mitted Successfully mitted with Errors		Ownership or Inves	stment Interes	st	2016 2015					
Syste	erred - File Infected	- 12				2014 2013					
Dele	eted	-				2010			-	,	
Entity											
Wensco			Submission Type:	:		Submiss	ion Start	Date:			
	y. ISCO	•	Submission Type: New Submission Resubmission	:	*	Submiss yyyymme	dd 🚹	Date:	-		
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<u>Step 4:</u> Select the Delete File button from the File ID Page.

Figure 211: Delete Button on File ID Page

Home	Submissions	Review and Dispute	🔊 Manage Entities	O My Profile		Messages	Resources
File ID:	: 141306				1	Access the Op User Guide [PD	en Payments PF]
Details ab	out the File Su	ıbmitted			?	Need help with Contact Us by	the website? email
If any records h the file's warnin ID. If necessary	have errors, download ng log. The records car y, this file can be delete	the file's error log. If any reco n be identified by the Record ed by selecting the "Delete Fi	rds have warnings, download ID and Home System Paymer Ie" button.	nt		Review the Op Privacy Policy [en Payments PDF]
2021 Gene	eral Payments					1	1
Original Uploa	d File Name:	ValidFile_GP.	CSV				2
Type of Submi	ission:	New Submiss	ion				
Original /Resu	bmission Date:	12/3/2021 2:0	9 PM				
Submitted By:		Ted Smith				12	
File Size:		3 KB					KAK
File Type:		CSV					
Program Year:		2021					
Payment Cate	gory:	General Payn	nents				
File Status:		Submitted wit	h Errors				
Number of Red	cords in File:	2					
Number of Red	cords Uploaded:	2					
Error Log:		141306_Gene	eral Payments Error(s)				
Warning Log:		141306_Gene	eral Payments Warning(s)				
Back to Paym	nent Category		Delete Fi	le			

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



Figure 212: Delete button on File ID pop-up window

You will be redirected to the File ID home page and a confirmation message will be present, confirming the payment file has been deleted.

Figure 213: Confirmation Message on File ID page

Home	Submissions	Review and Dispute	🔊 Manage Entities	O My Profile		Messages	Resources
Confirma	tion:				1	Access the Op User Guide [PD	en Payments F]
 Selecter status. Paymer 	d record(s) have been Selected record(s) in ' hts system until re-atte	successfully deleted exce Attested'' status will not b station takes place. Note:	pt for records in "Atteste e deleted from the Open If attested records have I	d" been	?	Need help with Contact Us by	the website? email
selected Attester which re	d for deletion, go back r" button to send an er equire re-attestation.	to the "Review Records" nail notification to all attes	page and select the "Noti sters that there are record	fy I(s)	8	Review the Ope Privacy Policy [I	en Payments PDF]
FILE ID Details at If any records I the file's warnin ID. If necessar	: 2507 cout the File Su have errors, download t ng log. The records can y, this file can be delete	bmitted he file's error log. If any record be identified by the Record d by selecting the "Delete Fi	rds have warnings, downlo ID and Home System Payr le" button.	ad	C		
2021 Gen	eral Payments	Nova Drug Manufa	octurers	_			60
Original Uploa	ad File Name:	Drug_Device_	2021_General_Payments.	csv			PP
Type of Subm	ission:	New Submiss	ion				
Original /Resu	ubmission Date:	11/16/2021 3:	47 PM				
Submitted By	:	Amanda Bush	1				
File Size:		7 KB					
File Type:		CSV					
Program Year	:	2021					
Payment Cate	egory:	General Payn	nents				
File Status:		Submitted with	h Errors				
Number of Re	cords in File:	8					
Number of Re	cords Uploaded:	8					
Error Log:		2507_Genera	I Payments Error(s)				
Warning Log:		2507_Genera	I Payments Warning(s)				
Back to Revi	ew File Status		Delete	File			

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 214: Submissions Tab on Open Payments System Landing Page for returning system users.



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

Home Submissions Review a	nd Dispute	🙆 Manage Ent	ities	O My Profile		Messages	Resource
Submissions							? User Gui
field with an asterisk (*) is required. pplicable manufacturers and applicable GPOs must s ystem.	ubmit paymen	its, or other transfe	ers of value,	and ownership or in	nvestment ir	iterests to the C	pen Payments
Submit Payment Data							
nly users who hold the role of submitter can submit in pload or Manual Data Entry below.	nformation to ti	ne Open Payment	s system. Se	elect Bulk File	Down	oad the P	hysician
efer to the Resources tab for the Open Payments sporting templates for the Bulk File Upload.	Select Mar Open Payr	nual Data Entry to ments manual entr Manual Data En	submit reco y online forr try	rds using the n.	LIST The Valid Physician Suppleme should no	ated Physician with Inactive Li ent File per Proj t be shared put	Lists and icense(s) gram Year below plicly.
Review Submitted Payment Record	ls				File Do	Wnload Hel Validated Ph and Physicia License(s) Si per Program	p ysician Lists n with Inactive upplement File Year
o review records, select the payment type, entity who rop-down lists below, then select "Review Detail".	se records you	u wish to review, a	nd the prog	am year from the	Down	oad the N	on-
Select Payment Type: *Select Entity: General Payments Select Entity: ABCDE Medical	2	*Select Prog	jram Year:	Review Detail	Physic The Non- Program publicly.	cian Practi Physician Pract Year below sho	itioner List itioner List per uld not be share
Review Records - Summary					F	Non-Physicia List	an Practitioner
o view submission summary and/or attest records, se rogram year from the drop-down lists below, then sel Select Entity: *Select Pro- Please Select Y Please Sele	dect the entity ect "Review Su gram Year: ct	whose records you immary".	u wish to rev eview Sumr	nary	Down Templ To downli Resource	load the R ates bad reporting te s tab.	eporting
eview Submitted File(s) Status							
nce a file for your entity has been submitted, you ma	v review the de	tails by selecting	'Review File	e Status."			
Review File Status							
ownload Recipients Missing Own	ershin Re	cord					
PO entities are required to report ownership/investme neeral and/or research records for the same program 03.966; To review physicians that were cited on gen- menship record, select the entity you with for veiew OTE: If there is any physician where the column value reters record in Ready for Attestation staturs ''s hon'' wnership/investment interest record for the physician sociated general or research records are identified a completed.	ent interest pay year (per the eral and/or res from the drop- e for "Is there review your su will be include and will meet th	yments for physici Open Payments fi earch records who down list below, th at least one assoc ubmissions to verif ed in your submiss ie regulation cited	ans that hav nal rule, 42 of do not hav en select "D iated Owner y that a corr ion. If the via above after	e been cited on C.F.R. § e an attested ownload Report." ship/Investment esponding alue is "Yes," the your attestation			
Select GPO Entity: Please Select Download	Report						
overed Recipient Validation Utility	0						
o verify provider matching information, select the "Va formation on the new page. The Covered Recipient V nd non-physician information to profiles prior to repor Validate Covered Recipient	lidate Covered /alidation utility ling that cover	Recipient" button / can be used by s ed recipient on the	below and i ubmitters to payment re	upload provider upload physician ecord.			

Figure 215: Submissions Landing Page

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



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A can be can also by selecting be "Regard Metazian of AR Records", details on status definitions, if you have further questions on how to make that advertision of records, details on status definitions, if we have the reporting entry with receive an entral soft and can any status definitions, which is advertision of records, details on status definitions, and advertises affinited out with records methy three records with an any advertise of the definition that Pereor methods with records methy three records with three records on the right channel may three we an entral soft of definition that Pereor methods for definition that three are records with a data water and advertises affinited out three records with three been marked for defetion have not yet been defeted from the opping Physichs system. The attester must re-latest to all payments by the soft of the releve, dispute, and usuation in three the soft of definition of the defetion frame eligible for releve, dispute, and usuation in three soft of defetion releve, dispute, and usuation of the defetion releve. dispute methods with the defetion of the defetion releve, dispute methods with the defetion releve. dispute methods with the defetion of the defetion releve, dispute methods. The defetion releve advectation. The defetion releve advectation in three releves the defetion releve. dispute methods with the defetion releve advectation in three releves the defetion releves. Defetion releves the defeti	a can atter by selecting the "Begin Attention of A Records' bution. Image: Comparison of the maximum of the main shade attention of the maximum of the maxim	General Payments, etc.). f all the records for the entity are	in a "Ready for i	Attestation" or "Attested" status, a	user in an "attester"	-	2	Review the	e Open P	ayment
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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 217: Marked for Deletion Button on Reporting Entity General Payments page

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Ready for Attestation		0	Attest						
Returned to Submitter Attested †		0	Correction						
Total Payments		1	140 /						
Note: Previously atteste	d records that ha	ve been ma	rked for deletion h	have not y	et been delete	ed from the Open	Payments sys	stem. The	
attester must re-amesi to remain eligible for review	all payments to, v and dispute, are	the selected e eligible for	bublication, and	are include	ed in the attes	I this re-attestant led record count.	on, the marked	records	
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Marked for Deletion		Count	Action Requi	íred					
† Attester to confirm u	eletion	0	Attester to Au	lest or Ke	ject Deletion	I			
System Processing Failed Validation Failed Matching Ready for Submission Ready for Attestation Returned to Submitter		Maxir): num 38 digits e System Payme	nt ID:		Maximum 38 di Delay in Public Please Select	.gits ation Indicate	or:	
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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 IDM credentials. Navigate to the Open Payments home page and select the "Submissions" tab.

Figure 218: Submissions Tab for Open Payments System Landing Page



<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 Summary" button.

Figure 219: Review Records for Open Payments System Landing Page

Open Payments Applicable Manufacturer or Group Purchasing Organization	(Sunshine A Switch User Type	Act)	
Home Submissions Review ar	Dispute Manage Entities	O My Profile	Messages Resources
Submissions			? User Guid
A field with an asterisk (*) is required. Applicable manufacturers and applicable GPOs must su System.	ubmit payments, or other transfers of value	e, and ownership or ir	ivestment interests to the Open Payments
Submit Payment Data			
Only users who hold the role of submitter can submit int Upload or Manual Data Entry below.	ormation to the Open Payments system.	Select Bulk File	Download the Physician List
Refer to the Resources tab for the Open Payments reporting templates for the Bulk File Upload.	Select Manual Data Entry to submit rec Open Payments manual entry online fo Manual Data Entry	ords using the rm.	The Validated Physician Lists and Physician with Inactive License(s) Supplement File per Program Year below should not be shared publicly. File Download Help ?
Review Submitted Payment Records	s		and Physician with Inactive License(s) Supplement File per Program Year
drop-down lists below, then select "Review Detail". *Select Payment Type: General Payments ABCDE Medical Review Records - Summary	*Select Program Year 2021	Review Detail	Download the Non- Physician Practitioner List The Non-Physician Practitioner List per Program Year below should not be share publicly.
To view submission summary and/or attest records, sek program year from the drop-down lists below, then select *Select Entity: Please Select Please Select Please Select	ect the entity whose records you wish to re at "Review Summary". Tram Year: t Review Sum	eview and the	Download the Reporting Templates To download reporting templates, see the Resources tab.
Review Submitted File(s) Status Once a file for your entity has been submitted, you may Review File Status Download Recipients Missing Owne GPO entities are required to report ownership/investme general and/or research records for the same program y 403.906, To review physicians that were cited on gene wonership record, select the entity you wish to review fr NOTE: If there is any physician where the column value interest record in Ready for Attestation status" is "No," r Womership/Investment Interest record for the physician associated general or research records are identified ar is committed	review the details by selecting "Review F ership Record In Interest payments for physicians that ha year (per the Open Payments final rule, 42 rail and/or research records who do not ha on the drop-down list below, then select ' for 'ls there at least one associated Own eview your submissions to verify that a co lib be included in your submission. If the d will meet the regulation cited above after	lie Status." ave been cited on 2 C F.R. § we an aftested Download Report." ership/Investment rresponding value is YCs." the ry our attestation	
*Select GPO Entity: Please Select Download R Covered Recipient Validation Utility To verify provider matching information, select the "Valii information on the new page. The Covered Recipient V and non-physician information to profiles prior to reporti Validate Covered Recipient	eport date Covered Recipient" button below and diatation utility can be used by submitters ng that covered recipient on the payment	ł upioad provider to upioad physician record.	
			Contact Us Privacy Poli

<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.

		D)	r 常		6			6
Home Submiss	ons Revie	ew and Dispute	Manage En	tities I	My Profile		Messages	Reso
ABCDE Medie	al 2018:	- Review	Recor	ds			Access the O	pen Paymen
Below are the records reported year. To edit records (available	by the entity and only for a user in	categorized by the s a "submitter" role) o	tatus for the sele r view the details	ected program s of the reported		0	User Guide [P	UF, 28.8 ME
records, select the "View All" b General Payments, etc.).	utton under a spec	ific payment catego	ry (e.g., Researd	h Payments,		?	Contact Us b	y email
If all the records for the entity a role can attest by selecting the	re in a "Ready for "Begin Attestation	Attestation" or "Attes of All Records" butt	sted" status, a u on.	ser in an "attester"			Review the O Privacy Policy	pen Paymen (PDF, 102 k
If you have further questions of	how to make fina	I submission of reco	rds, details on s	tatus definitions,		Help	with this Page	e
Select "Notify Attester" to notify	attesters that the	re are records that re	equire attestation	n. All active		Record	Status Definition	ns
attesters affiliated with the report require attestation.	orting entity will rec	eive an email notific	ation that there	are records which		What d failed n	o I do if records f hatching?	failed validati
Note: Previously attested reco the Open Payments system. The to complete the deletion. Reco publication, until re-attestation	rds that have been ne attester must re rds marked for del is complete.	marked for deletion -attest to all paymer etion remain eligible	have not yet be the for the select for review, disp	en deleted from ed program year ute, and		How do	I complete final	submission? station?
Records counted as "Marked fi	or Deletion" are als	o included in the "A	ttested" (†) reco	rd count.				
Back to Submissions								
Program Year: 2018				Refresh Status				
Research Payments				View All				
Status	Record Count	Action Required						
System Processing	0	No Action						
Failed Validation	8	Correction						
Failed Matching	25	Correction						
Ready for Submission	2	Final Submission						
Ready for Attestation	2	Attest						
Returned to Submitter	1	Correction						
Attested †	0	No Action						
Total Payments	38				ļ			
	-							
Marked for Deletion	Record Count	Action Required						
previously Attested records	0	or Reject Deletion	teletion action					
					_			
General Payments				View All				
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						
Attested †	0	No Action						
Total Payments	4							
Marked for Deletion	Record Count	Action Required						
† Attester to confirm deletion of previously Attested records	f o	Attester to Attest o	deletion action					
					-			
Ownership or Investment	Interest Record Count	Action Required		View All				
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 †	10	INO Action						

Figure 220: View All Button for Open Payments System Landing Page

Note that you can also navigate to "Payment Category Page" by selecting the payment type, entity and program year from "Review Records – Summary" section and select "Review Detail" 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 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."

Open Payments (Sunshine Act) 2 **⊠**₀ ۲ ⊿ ge Ei 9 Payment Category: Research Payments - ABCDE Medical 2018 The table below provides information on submitted records for the selected rep rting entity, program year, and payment catego Search and filtering tools above the table can customize the view of the data To export the search results into a CSV file, select "Download ZIp File". This provides a compressed file containing the search results. Attempting to download more ham 400.000 records, will generate an on-screen error notification. To correct this error, adjust the filtering criteria to create smaller subsets of records and download them in multiple files. To view all fields for a record, select the "Record ID" hyperink in the table below. Record(s) flagged with a warning icon (A) identify that there are warning messages that should be reviewed and corrected as required. Records with warning messages only (do not have validation or matching encor), will not previewed more continuing through final submission and attestation, and therefore are not required to be corrected before proceeding if the information is determ be valid as-is. Records counted as "Marked for Deletion" are also included in the "Attested" (†) record count. If you wish to reinstate records marked for deletion, find the records with the "Marked for Deletion" status of "Yes", select the checkbox next to them, and then select the "Cancel Deletion" button. For more information on the actions you can take on this page, refer to the "Payments Category Page" quick reference guide available on the Reso Open Payments public website. For detailed information on how to edit and submit records, refer to the Open Payments User Guide (PDF, 28.8 MB **Research Payments** Refresh Status Record Action Required Status No Action inal Su have been marked for deletion have not yet been deleted from the Open Payments sys for the selected program year to complete deletion. Until this re-attestation, the marked are eligible for publication, and are included in the attested record count. Record Count 0 Action Required Marked for Deletion Attester to Attest or Reject Deletion † Attester to confirm dele Back to Review Records Record Status: File ID: Maximum 38 digits Record ID: Maximum 38 digits lease Select sing Delay in Publication Indi Please Select sician First Name Physician Last Name: Physician NPI: This is a 10-dig License State Address Stat Zip Code V Please Select ~ Please Select ing Hospital Name Teaching Hospital CCN hing Hospital TIN: ecipient Type: Covered Recipient Physician Covered Recipient Teaching Hospital Non-Covered Recipient Entity Input Method: Manual Entry Upload Files Record Yes nings: 📀 Yes Single Consolidated No vient Individu Search Clear All Download Zip File Showing Results for: [AII] Update Delay Indicator Cancel Deletion Return to Attester Delete Selected Return to Submitte Showing 10 v of 38 Entries ... Page 1 of 4 Page 1 Select All ID: ↓ Record ID: ↓ ID: ↓ Marked for Deletion: ¢ Home System Payment ID: � Payment Amount Date: 0 (\$): 0 Recipient Type: 0 Record Status: ◊ Indicator: ¢ Recipient: O overed Recipient Expiry licenses and active licenses 20170130 \$9.13 Failed Matc to Delay Re 0170130 \$9.13 Failed Ma NCR4-with Incorrect \$9.27 170130 Failed Mat Delay Rec Recipient Indi 0170130 \$9.26 ailed alidation o Delay R entity name Expiry licenses and active licenses \$9.13 20170130 ailed Ma No Delay Request Expiry licenses and active licenses Failed 20170130 \$9.13 lo Delay Re R3-PI Fal 20170130 \$9.26 ailed Ma o Delay Re 2017_Research 20171231 \$1,000.99 Failed Mat No Delay Requested ysician ady for 0170130 \$9.27 Recipient Individual Submis Failed Validation NCR4-with missing PIFN 20170130 \$9.27 No Delay Requested Recipient Individual N/A Showing 10 v of 38 Entries - Page 1 of 4 v Page 1 v

Figure 221: 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 222: Confirm Final Submission Page

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				
Confirm	n Final Sub	mission			1	Access the Oper User Guide [PDF	n Payments , 28.8 MB]				
Confirm the final	submission for this data	category.			? Need help with the website? Contact Us by email						
Note: Once a reco that record (e.g., edited. To change submission, you r	ord has undergone final physician first name and covered recipient ident nust delete the original r	submission, the covered rec last name, NPI, license info ifying information in a record ecord and submit a new rec	ipient identifying information irmation) is locked and car I that has undergone final ord with updated covered	on in Inot be	6	Review the Open Privacy Policy [PI	Payments DF, 102 KB]				
receipient identify	ing information.						AL AL				
ABCDE Me	dical										
2018 Resear	ch Payments										
Total Value:	\$18.53										
Submitter N	ame: Karen Miller					SY.					
Cancel			Submit as Final Subm	nission							

Note that the Final Submission process can take several hours to complete, especially during peak submission times. You will receive an automated email notifying you that the final submission was successfully processed.

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.

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organizatio (2) My Profile v and D age Er Messag ۲ Mana ABCDE Medical 2021 - Review Records -Access the Open Payments User Guide [PDF] 0 Summary Need help with the website? Contact Us by email Confirmation: ? Your records have been submitted to Open Payments. Once the records have processed successfully, an automated email confirmation will be sent to you. Review the Open Payments Privacy Policy [PDF] 8 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 Help with this Page records, select the "View All" button under a specific payment category (e.g., Research Payments, General Payments, etc.). Record Status Definitions If all the records for the entity are in a "Ready for Attestation", a user in an "attester" role can attest by What do I do if records failed validation or failed matching? selecting the "Begin Attestation of All Records" button If you have questions on how to complete final submission of records, details on status definitions, or How do I complete final submission? how to attest, use the "Help with this Page" link available on the right hand navigation. How do I complete attestation? Select "Notify Attester" to notify attesters that there are records that require attestation. All active attesters affiliated with the reporting entity will receive an email notification that there are records which require attestation. 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 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 Program Year: 2021 Refresh Status **Research Payments** View All Record Count Action Required Status System Processing No Action Failed Validation Correction Failed Matching Correction ady for Submission Final Submission eady for Attestation Attest Returned to Submitter Correction Attested † No Action Total Payments 5 Marked for Deletion Record Count Action Required + Attester to confirm deletion Attester to Attest deletion 0 of previously Attested records action or Reject Deletion **General Payments** View All Status Record Count Action Required System Processing No Action 0 Correction Failed Validation Failed Matching Correction Ready for Submission Final Submission Ready for Attestation Attest Returned to Submitter Correction Attested † No Action Total Payments Marked for Deletion Record Count Action Required + Attester to confirm deletion Attester to Attest deletion 0 of previously Attested records action or Reject Deletion **Ownership or Investment Interest** View All Status Record Count Action Required No Action System Processing Failed Validation Correction Failed Matching Correction Ready for Submission Final Submission Ready for Attestation Attest Returned to Submitter Correction Attested + No Action Total Payments Marked for Deletion Record Count Action Required + Attester to confirm deletion Attester to Attest deletion 0 of previously Attested records action or Reject Deletion

Figure 223: Reporting Entity Review Records Page

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

Section 4.12: Delay in Publication

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

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

A delay in publication can only be requested for up to a period of four years from date of payment (i.e., the record's program year). After four years have elapsed, the delayed records will be published.

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

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

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

4.12a: Eligibility for Delay in Publication

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

Research or development of a new drug, device, biological, or medical supply.

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

Clinical investigations regarding a new drug, device, biological, or medical supply.

After four (4) years from the year of payment (i.e., the record's program year) have elapsed, records are no longer eligible for delay, and will be eligible for publication in the next publication cycle.

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

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

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

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

4.12b: Initially Requesting a Delay in Publication

When submitting a new record, users can request a delay in its publication as part of the record creation process if it is eligible.

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

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

Ownership/investment records cannot be delayed.

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

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

4.12c: Updating a Delay in Publication

Users may request that payment records have their publication delayed for up to four years after the date of payment. The request for a delay must be renewed each year.

If this request is not renewed each year by the end of the data submission period, the record will be automatically flagged for publication in the next publication cycle.

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

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

For program years that have reached the delay limit, users will be prevented from requesting a delay in publication of new or updated records. These records will automatically be made available for publication.

Delayed records that are no longer eligible for a delay but are in "Returned to Submitter" status will not be updated to a "Limit Reached" delay status. These records must be edited, and the Delay in Publication Indicator changed to "No Delay Requested" as they are no longer eligible.

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

After renewing delay in publication flags via manual editing or bulk file upload, <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 Payment Records" section on the "Submissions" home page, select the payment type, entity whose records you wish to review and the program year for those records. Select "Review Detail" button.

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

Figure 224: Reporting Entity General Payments Page

Home Sub	missions	Review	and Disput	te Mana	Entities	O My Profile			Resource
avment Ca	ategor	/: Res	earch	ı Pavn	nents -		/ledica	1 2021	
e table below provides i	nformation on	submitted re	cords for the	selected rep	orting entity, pro	gram year, and payn	nent category.		
arch and filtering tools a	bove the table	can custom	ize the view	of the data.					
an 400,000 records, will am in multiple files	generate an o	ne, select of n-screen erro	ownoad zip or notification	. To correct th	his error, adjust 1	the filtering criteria to	create smaller	subsets of rec	cords and downl
view all fields for a reco essages that should be r cord from continuing thre valid as-is. ecords counted as "Mark th the "Marked for Delet ir more information on th son Payments nuble.	rd, select the eviewed and o uugh final subr red for Deletion on" status of " e actions you beite. For deta	Record ID" I orrected as i nission and a " are also in r'es", select 1 can take on 1	nyperlink in t required. Re attestation, a cluded in the the checkbo: this page, re ion on how h	he table below cords with wa nd therefore a "Attested" († k next to therm fer to the "Pay n edit and suit	v. Record(s) flag rning messages ire not required 1) record count. It , and then selec ments Category mill records, refe	ged with a warning i only (do not have va to be corrected befor f you wish to reinstat t the "Cancel Detetto Page" quick referer to the Coren Paym	con (Å) identif lidation or mat e proceeding if e records mark n° button. ice guide avails	y that there an ching errors), v the informatio red for deletion able on the Re:	e warning vill not prevent a n is determined , find the record sources page of
Research Pay	ments	inco informa	on on now e	o cuir unu suc	nin records, rec	a wate open i ayar		e le tra le	
Help with this Page	mento								Johnsh Status
		Record							cerresh Status
Status		Count	Action	Required					
Failed Validation		1	No Act Correc	tion					
Failed Matching		1	Correc	tion					
Ready for Submission Ready for Attestation		0	Final S Attest	upmission					
Returned to Submitte		0	Correc	tion					
Total Payments		4	NO ACT	iorit.					
Note: Previously atteste	d records that	have been r	narked for d	eletion have n	ot yet been dele	ted from the Open P	ayments syste	m. The	
attester must re-attest to remain eligible for revie	v and dispute,	for the select are eligible f	ted program or publicatio	year to comp n, and are inc	lete deletion. Un Juded in the atte	til this re-attestation, sted record count.	the marked re	cords	
Marked for Deletion		Record	Action	Required					
t Attester to confirm of	leletion	Count 0	Atteste	r to Attest or	Reject Deletio	n			
								Fin	al Submission
Failed Validation Failed Matching Ready for Submission Ready for Attestation Returned to Submitter Attested		Ho	me System	Payment ID:		Delay in Publicat Please Select	ion Indicator:		
Covered Recipient Fin	st Name: 🚱	Co	vered Recip	ient Last Na	me: 🕢	Covered Recipier This is a 10-digit	nt NPI: number 🕜		
License State:		License Nu	umber:	А	ddress State:		Zip Code:		
Please Select	~				Please Select		99999	9999	
Teaching Hospital Nar	ne:	Tea	ching Hos	oital CCN:		Teaching Hospita	al TIN:		
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Marked for Deletion: Yes No	Recipient Coveren Coveren Non-Co Non-Co Coveren Coveren	Type: I Recipient Pf Recipient Te vered Recipie vered Recipient No	vysician iaching Hosp nt Entity nt Individual on-Physician	ital Practitioner	Input Method: Manual Entry Upload Files	Report Type Single	ted I	ord Warnings (es 40	÷ 0
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nowing Results m	TOP:								
	Upc	ate Delay Inc	licator	Cancel Del	Retion	turn to Attester	Delete Sele	ected R	eturn to Submit
	s	nowing 1	0 🔽 of 4	Entries	Page 1	of 1 🔛 🛌 Pa	age 1		
All ID:♦ ID:♦	Actions: P	ome System ayment ID: �	Payment Date:0	Amount(\$):	Recipient Typ	e:0 Recipient:0	Record Status:☆	Marked for Deletion: \$	Delay in Publication Indicator: (
N/A 7920039	View Edit		20210704	\$1,000.00	Covered Recipion Non-Physician	ant James Miller	Failed Matching	No	No Delay Requested
12789 7920039	View 4 Edit		20210102	\$76,767.22	Covered Recipie Non-Physician	ant Lan Tran	Failed	No	No Delay Requested
12789 7920039	Copy View 5 Edit		20210101	\$76,767.22	Practitioner Covered Recipie	ant Brandon	Ready for	No	No Delay
NIA 7000	Copy View		20210101	676 707 70	Physician Covered Recipion	Ross JENNIFER	Submission Ready for	Ne	Requested No Delay
/920039	2 COR		20210102	3/0,/6/.22	inon-Physician	SNYDER	Submission	140	Requested

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.

<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 Research payment category 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> 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."

<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 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 Section 4.11c (3) 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> <u>Step 2:</u> select the "Submissions" tab on the toolbar. On the "Review Submitted Payment Records" menu, select the payment type, reporting entity whose record you wish to view and the program year for that record, and then select "Review Detail." <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 to hold such a position within all 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 the reporting entities included in the consolidated report. For each record:

Set the "Consolidated Indicator" field in each record within the file to "Y."

Provide the name and Open Payments registration ID for the entity <u>submitting</u> the consolidated report in the fields "Applicable Manufacturer or Applicable GPO Name" and "Applicable Manufacturer or Applicable GPO Registration ID."

Provide the name and Open Payments registration ID for the entity that <u>made the individual payment or</u> <u>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 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 IDM credentials and navigate to the Open Payments home page. Select the "Submissions" tab on the Open Payments system home page.

Figure 225: Open Payments System Landing Page for returning system users



<u>Step 2:</u> Select the entity and program year from the drop-down lists of "Review Records – Summary" section and then select the "Review Summary" button.

Home Submissions	Review and Dispute	Manage Entities	(Q) My Profile	N	Nessages	Resourc
Submissions						? User Gu
field with an asterisk (*) is required. pplicable manufacturers and applicable ystem.	GPOs must submit payme	nts, or other transfers of valu	e, and ownership or in	vestment int	erests to the O	pen Payments
Submit Payment Data	can submit information to t	he Open Payments system.	Select Bulk File			
product of Manual Data Entry below. efer to the Resources tab for the Open porting templates for the Bulk File Uplo Bulk File Upload	Payments Select Ma ad. Open Pay	nual Data Entry to submit ree ments manual entry online fo Manual Data Entry	cords using the rm.	Downle List The Valida Physician Supplement should not File Dow	ted Physician I with Inactive Li nt File per Prog be shared pub vnload Hel Validated Phy and Physicia	hysician Lists and cense(s) yram Year belo ilicly. p ? ysician Lists n with Inactiv
Review Submitted Paymer	t Records				License(s) Su per Program	ipplement Fil Year
select Payment Type: *Se General Payments I AB Review Records - Summar o view submission summary and/or atte	w Detail". lect Entity: CDE Medical Y st records, select the entity	*Select Program Year 2021 V whose records you wish to r	Review Detail	Downle Physic The Non-F Program Y publicly.	Dad the No ian Practi Physician Pract ear below show Non-Physicia List	ON- tioner List per uld not be shar
rogram year from the drop-down lists be	low, then select "Review S	ummary".		Downlo Templa	oad the Re ates	eporting
Select Entity: Please Select	*Select Program Year: Please Select	Review Sur	nmary	To downlo Resources	ad reporting te tab.	mplates, see ti
Review Submitted File(s) S	Status					
nce a file for your entity has been subm Review File Status	itted, you may review the d	etails by selecting "Review F ecord	ile Status."			
PO entities are required to report owner eneral and/or research records for the s 03.906). To review physicians that were whership record, select the entity you w DTE: If there is any physician where the therest record in Ready for Attestation st whership/investment Interest record for sociated general or research records a completed.	ship/investment interest pa ame program year (per the cited on general and/or res ish to review from the drop- column value for 'is there atus' is 'No," review your s the physician will be includ re identified and will meet t	yments for physicians that h Open Payments final rule, 4: search records who do not h down list below, then select at least one associated Own ubmissions to verify that a cc ed in your submission. If the he regulation cited above after	ave been cited on 2 C.F.R. § vve an attested Download Report." ership/Investment irresponding value is "Yes," the er your attestation			
Select GPO Entity: Please Select	Download Report					
overify provider matching information, s formation on the new page. The Covere nd non-physician information to profiles	elect the "Validate Covered ed Recipient Validation utilit prior to reporting that cover	d Recipient" button below and y can be used by submitters red recipient on the payment	d upload provider to upload physician record.			

Figure 226: Review Summary Button on Submissions Landing Page

<u>Step 3:</u> On the "Review Records - Summary" 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.

Home Submissi	ons Revie	ew and Dispute Mana	ge Entities	O My Profile		Messages	Resource
ABCDE Medic	al 2021 ·	- Review Rec	ords -		1	Access the Ope User Guide [PD	n Payments
Below are the records reported by year. To edit records (available of	by the entity and c only for a user in a	ategorized by the status for th "submitter" role) or view the	e selected program details of the reported		?	Need help with t Contact Us by e	he website? email
records, select the "View All" but General Payments, etc.).	ton under a speci	ic payment category (e.g., Re	esearch Payments,		8	Review the Ope Privacy Policy [F	n Payments PDF]
f all the records for the entity are selecting the "Begin Attestation of	e in a "Ready for A of All Records" but	ttestation", a user in an "attes ton.	ster" role can attest by		Help	with this Page	
f you have questions on how to	complete final sub	mission of records, details or	status definitions, or		Record	Status Definitions	
now to attest, use the "Help with	this Page" link av	ailable on the right hand navig	gation.		What de) I do if records fai atching?	ed validation o
attesters affiliated with the report	ting entity will rece	ive an email notification that t	here are records which	ı	How do	I complete final su	ibmission?
require attestation.					How do	I complete attesta	tion?
Note: Previously attested record the Open Payments system. The to complete the deletion. Record publication, until re-attestation is	is that have been i attester must re- is marked for dele complete	marked for deletion have not attest to all payments for the tion remain eligible for review	vet been deleted from selected program year , dispute, and			·	
Records counted as "Marked for	Deletion" are also	included in the "Attested" (†)	record count.	-			
Back to Submissions		Begin Att	Notify Attests				
Program Year: 2024			Polyoch State				
Perearch Poumorte			Refresh Status				
Research Payments	Deservi Oran	Antion Domuire d	View Al	<u> </u>			
Status System Processing	Record Count	Action Required	_				
Failed Validation	0	Correction					
Failed Matching	0	Correction					
Ready for Submission	0	Final Submission					
Ready for Attestation	2	Attest					
Returned to Submitter	0	Correction					
Attested †	0	No Action					
Total Payments	2			_			
Marked for Deletion	Record Count	Action Required					
† Attester to confirm deletion of previously Attested records	0	Attester to Attest deletion action or Reject Deletion					
General Payments			View Al				
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	-				
Attested †	0	No Action	-				
Total Payments	1	no readin	_				
Marked for Deletion	Record Count	Action Required		_			
† Attester to confirm deletion	0	Attester to Attest deletion					
of previously Attested records		action or Reject Deletion		_			
Ownership or Investr	nent Interes	t	View Al				
Status	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	0	Correction					
Attested †	0	No Action					
Total Payments	0						
Marked for Deletion	Record Count	Action Required					
T Attester to confirm deletion		Attester to Attest deletion					

Figure 227: 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 228: Next Button for Confirm Payments Page

Open Payme Applicable Manufacturer or Group Purchasing	organization Switch User Type	Act)			
Home Submissions	Review and Dispute Manage Entities	(Q) My Profile	e Me	ssages R	esources
Attest	Confirm Payments Select "Go to Review Records" to review an	nd confirm the subi	nitted records, or se	elect "Next" to move	to the
Confirm Payments	next page.	deleties (ID ecced			
2 Add Assumptions	records marked for deletion ("Total Value of	f Records Marked	for Deletion") repres	sent records that we	re
Agree to Attestations	previously attested and are now marked for	deletion. These re	cords will be remov	ed from the Open F	Payments
Agree to Attestations	"Attested" record count.	orus counted as "I	Naiven Ini Deletion.	are also included i	n are
Access the Open Payments User Guide [PDF, 28.8 MB]	2018 Program Year ABCDE Medical				
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		
	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		
	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	
			Got	o Review Records	
	Cancel				Next

<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 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 229: No Radio Button on Add Assumptions Page



Figure 230: 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."



Figure 231: 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.

Open Paymen Applicable Manufacturer or Group Purchasing Org	nts (Sunshine ganization Switch User Type	e Act)			
Home Submissions Re	eview and Dispute Manage Entition	es My Pro) ofile M	essages Re	sources
Attest Confirm Payments Add Assumptions Agree to Attestations Review and Attest	Review and Atter Review the attestation agreement pr selecting the "View the Assumptions Note that the number of records mar records marked for deletion ("Total V previously attested and are now mar system after re-attestation is comple "Attested" record count. Select the "Attest" button to confirm	est voided below. If you e "hyperlink. ked for deletion ("Rec value of Records Mari ked for deletion. The te. Records counted a your attestation. To m	entered assumptions y cords Marked for Delet ked for Deletion") repu se records will be rem as "Marked for Deletic hake any changes, se	you may review them I tion") and the total val resent records that we oved from the Open P n" are also included in lect the "Back" button.	by re ayments n the
Access the Open Payments User Guide [PDF, 28.8 MB] Need help with the website? Contact Us by email	2018 Program Year ABCDE Medical				_
Review the Open Payments Privacy Policy [PDF, 102 KB]	Payment Category General Payments Research Payments	Total Number of Records 0 0	Total Amount (\$) \$0.00 \$0.00		
	Payment Category Ownership or Investment Interest	Total Number of Records 23	Total Amount Invested (\$) \$247.52	Total Value of Interest (\$) \$23.00	
	View the Assumptions Attestation Agreement I attest that I am a Chief Executive Officer for the reporting applicable information submitted in the Open I attest that the information reporter belief. James Miller 8/29/2018 1:29 PM Cancel	e Officer, Chief Finand manufacturer or app Payments system. ed is timely, accurate,	ial Officer, Chief Con licable GPO with the and complete to the	npliance Officer, or oth authority to attest to th best of my knowledge Back	er e and Attest

Figure 232: Review and Attest Page

You will be brought back to the "Review Records" page. The record(s) attested to will appear in the "Attested" column. The Open Payments system will send an email to all attester(s) notifying them of the success of the attestation.

Applicable Manufacturer or Group	Purchasing Organi	zation Switch User T		,,,			
Home Submissi	ions Revi	ew and Dispute	🖉 Manage Entities	O My Profile		Messages	Resource
ABCDE Medic	al 2021	- Review	Records -		- >	• • ! 0	
Summary						User Guide [P	DF]
Below are the records reported t year. To edit records (available o	by the entity and c only for a user in a tton under a speci	ategorized by the st "submitter" role) or fic payment categor	atus for the selected program view the details of the reported		?	Need help with Contact Us by	h the website? y email
General Payments, etc.).	and and a open	no paymont outogor	y (e.g., ressearen raymone,			Review the O Privacy Policy	pen Payments [PDF]
f all the records for the entity are selecting the "Begin Attestation (e in a "Ready for A of All Records" bu	Attestation", a user i tton.	n an "attester" role can attest by		Help	with this Pag	qe
f you have questions on how to	complete final sul	omission of records,	details on status definitions, or		Record	Status Definition	IS
now to attest, use the "Help with	this Page" link av	ailable on the right i	hand navigation.		What de	o I do if records f natching?	failed validation o
attesters affiliated with the report	ting entity will rece	eive an email notifica	ation that there are records which	h	How do	I complete final	submission?
require attestation.	to that have be	marked for delet	have not yet have deleted t		How do	I complete attes	station?
View Attestation Program Year: 2021			Refresh Statu	s			
Research Payments			View A				
Status			VIEWA	-			
o , o .	Record Count	Action Required					
System Processing	Record Count 0	Action Required No Action					
System Processing Failed Validation	Record Count 0 0 0	Action Required No Action Correction					
System Processing Failed Validation Failed Matching Ready for Submission	Record Count 0 0 0 0 0	Action Required No Action Correction Correction					
System Processing Failed Validation Failed Matching Ready for Submission Ready for Attentation	Record Count 0 0 0 0 0 0 0 0	Action Required No Action Correction Correction Final Submission					
System Processing Failed Validation Failed Matching Ready for Submission Ready for Attestation Returned to Submitter	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					
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System Processing Failed Validation Failed Matching Ready for Submission Ready for Attestation Returned to Submitter Attested † Total Payments Marked for Deletion † Attester to confirm deletion of previously Attested records General Payments Status System Processing Failed Validation Failed Matching Ready for Submission Ready for Submission Ready for Submission	Record Count 0 0 0 0 0 0 0 0 0 0 0 0 2 2 Record Count 0 0 0 0 0 0 0 0 0	Action Required No Action Correction Final Submission Attest Correction Action Required Attester to Attest e action or Reject D Action Required No Action Correction Correction Correction Final Submission Attest	Jeletion eletion				
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System Processing Failed Validation Failed Matching Ready for Submission Ready for Attestation Returned to Submitter Attested † Total Payments Marked for Deletion † Attester to confirm deletion of previously Attested records Status System Processing Failed Validation Failed Matching Ready for Attestation Returned to Submitter Attester to Submitter Attester to Submitter	Record Count 0 0 0 0 0 0 0 0 0 0 0 2 Record Count 0	Action Required No Action Correction Final Submission Attest Correction Monetain Action Required Attester to Attest action or Reject D Action Required No Action Correction Final Submission Attest Correction No Action	Jaletion View A				
System Processing Failed Validation Failed Matching Ready for Submission Ready for Attestation Returned to Submitter Attested † Total Payments Marked for Deletion † Attester to confirm deletion of previously Attested records Status System Processing Failed Validation Failed Matching Ready for Submission Redurned to Submister Attested † Total Payments	Record Count 0 0 0 0 0 0 0 0 0 0 0 2 Record Count 0 0 0 0 0 0 0 0 0 0 0 0 0 1	Action Required No Action Correction Correction Final Submission Attest Correction Action Required Attester to Attest action or Reject D Action Required No Action Correction Correction Correction Correction Attest No Action No Action Correction Correcti	Jeletion eletion				
System Processing Failed Validation Failed Matching Ready for Submission Returned to Submitter Attested † Total Payments Marked for Deletion † Attester to confirm deletion of previously Attested records Status System Processing Failed Validation Failed Matching Ready for Submission Returned to Submitter Attested † Total Payments	Record Count 0 0 0 0 0 0 0 0 0 0 0 0 2 Record Count 0 0 0 0 0 0 0 0 0 1 Record Count	Action Required No Action Correction Correction Final Submission Attest Correction Action Required Action Required Action Required No Action Correction Correction Final Submission Attest Correction No Action Correction Correction No Action Correction Correction No Action Correction Correction No Action Correction	Jeletion eletion				
System Processing Failed Validation Failed Validation Ready for Submission Returned to Submitter Attested † Total Payments Marked for Deletion † Attester to confirm deletion of previously Attested records Status System Processing Failed Validation Failed Matching Ready for Submission Returned to Submitter Attested † Total Payments Marked for Deletion # Attested to the submitter Attested to Confirm deletion # Attester to confirm deleti	Record Count 0 0 0 0 0 0 0 0 0 2 Record Count 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 Record Count	Action Required No Action Correction Correction Final Submission Attest Correction Action Required Action Required No Action Correction Correction Final Submission Attest Correction No Action Correction Correction Correction Attest Action Required Attester to Attest Correction No Action Correction Correctio	Jeletion				

Figure 233: Reporting Entity Review Records Page

4.15c: Attesting to No Data in the Open Payments System

The following instructions show the step-by-step pages for attesting that the reporting entity has no data. Please note that no records can be in the "Attested" status to complete these steps.

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

Figure X: Open Payments System Landing Page for returning system users

Home	Submissions	Review and Dispute	🔊 Manage Entities	O My Profile		Messages	Resourc
Welco	ome to the C	Open Payme	ents System		1	Access the Op User Guide [PD	en Payments DF]
Annound	cements			_	?	Contact Us by	email
Program Yea The Review a may receive d	and Dispute period is oper disputes from covered rec	nute Period Open - n starting April 1, 2019. Dur ipients and should work wit	ing this period, reporting ent h them directly to resolve th	ities e	6	Review the Op Privacy Policy [en Payments PDF]
correction per correction per Visit the Oper questions, coi phone at 1-85 You can mana	riod will be identified in the riod will be included in fut in Payments website at htt intact the Open Payments 55-326-8366. For the TTY age your user profile and	e published data as dispute ure data publications. ps://www.cms.gov/openpay Help Desk by email at ope / line, call 1-844-649-2766. perform user role functions	d. Changes to records after ments for information. For npayments@cms.hhs.gov c associated with your profile	r by			
According to t collection of ir for this inform collection can organization. dispute and d the time estim Bouleward. At	the Paperwork Reduction nformation unless it displa- tation collection is 0938-1 range from 1 to 30,000 h This information collection ispute resolution process nate(s) or suggestions for the PBA Reports Clearan	Act of 1995, no persons ar ays a valid OMB control nur 237. The time required to c iours per entity depending of n may involve registration, es. If you have any comme improving this form, please o Officer Eatimore, Marci	e required to respond to a mber. The OMB control numi- omplete this information on the size and type of data submission, attestation nts concerning the accuracy e write to CMS, 7500 Securit and 21244, 1850	, , of y			

<u>Step 2:</u> Select the entity and program year from the drop-down lists of "Review Records – Summary" section and then select the "Review Summary" button.

Open Payments (Sunshine Act) ŵ Ð ٦ (a) My Profi **⊠**₀ \odot Mass ? Submissions Us A field with an asterisk (*) is required. Applicable manufacturers and applicable GPOs must submit payments, or other transfers of value, and ownership or investment interests to the Open Payments System Submit Payment Data Only users who hold the role of submitter can submit information to the Open Payments system. Select Bulk File **Download the Physician** Upload or Manual Data Entry below. List Refer to the Resources tab for the Open Payments Select Manual Data Entry to submit records using the Open Payments manual entry online form. The Validated Physician Lists and reporting templates for the Bulk File Upload. Physician with Inactive Licenseis) Supplement File per Program Year below should not be shared publicly. Bulk File Upload Manual Data Entry File Download Help Validated Physician Lists and Physician with Inactive License(s) Supplement File per Program Year 1 **Review Submitted Payment Records** To review records, select the payment type, entity whose records you wish to review, and the program year from the drop-down lists below, then select "Review Detail" Download the Non-**Physician Practitioner List** Select Payment Type: "Select Entity: "Select Program Year: The Non-Physician Practitioner List per ABCDE Medical 2021 Review Detail General Payments Program Year below should not be shared publicly Non-Physician Practitioner **Review Records - Summary** To view submission summary and/or aftest records, select the entity whose records you wish to review and the program year from the drop-down lists below, then select "Review Summary" **Download the Reporting** Templates "Select Entity: "Select Program Year: To download reporting templates, see the Review Summary Please Select Please Select esources tab. **Review Submitted File(s) Status** Once a file for your entity has been submitted, you may review the details by selecting "Review File Status." Review File Status **Download Recipients Missing Ownership Record** GPO entities are required to report ownership/investment interest payments for physicians that have been cited on general and/or research records for the same program year (per the Open Payments final rule, 42 C.F.R. § 403.905). To review physicians that were cited on general and/or research records who do not have an attested ownership record, select the entity you wish to review from the drop-down list below, then select "Download Report. NOTE: If there is any physician where the column value for "is there at least one associated Ownership Investment interest record in Ready for Attestation status" is "No," review your submissions to verify that a corresponding Ownership/Investment interest record for the physician will be included in your submission. If the value is "Yes," the associated general or research records are identified and will meet the regulation cited above after your attestation is completed "Select GPO Entity: Download Report Please Select Covered Recipient Validation Utility @ To verify provider matching information, select the "Validate Covered Recipient" button below and upload provider tion on the new page. The Covered Recipient Validation utility can be used by submitters to upload physician and non-physician information to profiles prior to reporting that covered recipient on the payment record. Validate Covered Recipient Contact Us Privacy P

Figure X: Review Summary Button on Submissions Landing Page

<u>Step 3:</u> On the "Review Records - Summary" page, select the "Attest No PTOV" button.

If the "Attest No PTOV" button is not available, check that no records for the program year are in the "Attested" status or the officer has not declared "no PTOV or ownership and investment interest to report for any program year" from the "Manage Entities" page.

Back to Submissions			Attest No PTOV
Program Year: 2023			Refresh Status
Research Payments			View 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	
for Attestation	0	Attest	1
Returne	0	Correction	1
Attested †	0	No Action	1
Total Payments	0		
Marked for Deletion	Record Count	Action Required	_
Attester to confirm deletion of previously Attested recently	0	Attester to Attest deletion	
or previously Attested records		action of Reject Deletion	
General Payments			View 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	
for Mestation	0	Attest	1
Returned	0	Correction	
Attested †	0	No Action	1
Total Payments	0		1
Marked for Deletion	Record Count	Action Required	-
+ Attester to confirm deletion	0	Attester to Attest deletion	
Ownership or Investr	ment Interes	•	View 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	
for Attestation	0	Attest	
Returner	0	Correction	1
Attested †	0	No Action	
Total Payments	0		
· · · · · · · · · · · · · · · · · · ·			
Marked for Deletion	Record Count	Action Required	
+ Attester to confirm deletion	0	Attester to Attest deletion	
of previously Attested records	Č	action or Reject Deletion	

Figure X: No PTOV Button on Reporting Entity Review Records Page

<u>Step 4:</u> Agree to statements on the "Attestation Agreement" page to complete attestation of no payments or transfers of value by selecting options 1 through 3 and clicking the "Save' button.





You will be brought back to the "Review Records" page. A confirmation message will indicate that "You have successfully updated the no PTOV indicator for the Program Year". The Open Payments system will send an email to all attester(s) notifying them of the success of the attestation.

Figure X: 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, NPPs, and teaching hospitals. The "resolved, no change" action acknowledges that the applicable manufacturer or applicable GPO and the physician, NPPs, or teaching hospital have resolved the dispute in accordance with the guidance in the Final Rule, and no changes to the data were needed.

Correction and Resolution of Disputed Data provides information on how Applicable Manufacturers and Applicable GPOs can make corrections to disputed data to resolve disputes.

Section 5.1: Review, Dispute, and Correction Overview

When an applicable manufacturer or applicable GPO has submitted records regarding payments, other transfers of value, or physician ownership or investment interests to the Open Payments system, the physicians, NPPs 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 principal investigator may only dispute his or her association with a research payment record and his or her own personal identifying information.

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

Dispute resolution takes place outside of the Open Payments system. Nevertheless, the status of the dispute resolution should be captured within the Open Payments system.

CMS will not mediate disputes between covered recipients 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 the **figure** below.

Review Activities	Dispute Activities	Correction Activities
 Covered Recipients may review data submitted about them before it is published. 	 Physicians, NPPs, and teaching hospitals dispute information reported about them or their institutions if they find inaccuracies. Principal investigators may only dispute their association with a research payment record and 	 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
	their personal identifying information - they may not dispute other information, such as the amount	and Applicable Manufacturers and Applicable GPOs re- submit and attest to corrected records, if

Figure 234: 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 covered recipients 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 covered recipients.

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/Resources.

If you cannot resolve a dispute with a covered recipient within the 60-day review, dispute, and correction period for a program year, all parties should continue to seek a resolution until the dispute is resolved. Once the dispute is resolved and any necessary corrections are made, the data will be updated in a subsequent publication based on when the corrections were made in the Open Payments system.

When a dispute resolution results in changes to or deletion of a record, 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 covered recipient has initiated a dispute against a record submitted by an applicable manufacturer or applicable GPO.
- Acknowledged: Indicates that an applicable manufacturer or applicable GPO has received and acknowledged a dispute initiated against them by a covered recipient.
- Resolved No Change: Indicates that the applicable manufacturer or applicable GPO and the covered recipient have resolved the dispute in accordance with the guidance in the Final Rule and no changes were made to the disputed record.
- Withdrawn: Indicates that a covered recipient 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, physician, NPP, teaching hospital, and principal investigator of review and dispute activities in the Open Payments system. These emails contain information necessary to locate the record in the Open Payments system and may contain contact information in the dispute details. The Reporting Entity Contact Information for disputes, included in your entity's profile, is available on the "Record ID" page of each individual record.

5.1c: Exporting Disputed Data

The Open Payments system now allows users to download disputed data into a separate CSV file. Records are exported into a pipe ("|") delimited CSV file by selecting the link labeled "Download Disputes" from your entity's "Review and Dispute" page. The file will be compressed into a ZIP file. It will contain all data fields displayed in the table and other data elements related to the dispute. Downloaded data files cannot exceed the acceptable limit of 20,000 records. If your record volume exceeds the record limit, apply filtering criteria to create smaller subsets of records and download them in multiple files. To download, select the "Download Disputes Zip File" hyperlink. Figure 235: Download Disputes Zip File Hyperlink

Open Payn Applicable Manufacturer or Group Purch	nents (S	unshine Iser Type	e Act)			
Home Submissions	Review and Dispu	ute Manage Entiti	es My Pro) ofile N	Messages	Resources
Review and Disp	oute - ABCDI	E Medical -	2021			
The table below contains the record(s physician/ non-physician practitioner	s) submitted by this reporting principal investigators.	g entity that have been d	sputed by physicians	, teaching hospitals,	non-physician practi	tioners, and
Submitters for the reporting entity can associated dispute(s) on the record w	take actions on the dispute ill move into Resolved statu	e(s) and edit the record u us.	nder dispute. Once a	disputed record is ed	dited and reattested,	the
Please note: To view the entire tabl	e, use the horizontal scro	Il bar below the table.				
Use the filtering tools below to custon	nize your view of the dispute	ed records.				
You may export your search results contain all data fields displayed in the than 20,000 records, adjust the filter of	by selecting the "Downloa table below and other data criteria to create smaller sub	ad Zip File" link. The down elements related to the osets of records and dow	nloadable file will be a ecord. A download file nload them in multiple	a CSV file compresse e can include up to 2 e files.	ed into a ZIP file. The 0,000 records. To do	e file will ownload more
To view all fields for an individual r	ecord, select the "View" line	k under the Action colum	n or the "Record ID" li	ink in the Record ID	column in the table t	oelow.
To perform any of the following act • To acknowledge a dispute, so received the dispute. To acknow covered recipient who initiated • To resolve a dispute, select the edited by the entity or when the • To declare that the dispute has then select the "Resolved No C To return to the previous page, select	ions, select the check bo: elect the check box for the c wedge all the disputes use the dispute. In the "Edit" link in the Action cc record is deleted to resolve as been resolved in accor change" button. the "Back" button.	x next to the Action col corresponding record and the "Select All" check bo olumn of that record. An e e the dispute. dance with the Final Ru	umn: then select the "Ackr When a dispute is a mail notification will b Ile without changing	nowledge Dispute" bi acknowledged, an en be sent to the covere g the data, select the	utton. This confirms nail notification will b d recipient when a re check box next to ti	that you have le sent to the ecord is being he record and
For more information about the review Applicable Manufacture	v and dispute process, incluer or Applicable G	iding step-by-step instruc	tions, refer to the Ope	en Payments User G	uide [PDF].	
Dispute ID: Maximum 38 digits	Record ID: Maximum 38 digits	Home Syst	em Payment ID:	File ID: Maximum 38 di	igits	
Covered Recipient First Name	Covered Recipient Las	st Name Teaching H Please Sel	ospital Name: act		~	
Review and Dispute Status: Initiated Acknowledged Resolved No Change Withdrawn Resolved	Marked for Dele	tion: Payment C General I Research Ownersh Interest	Ategory: Rec Payments I Payments Payments Paymen	cipient Type: Physician Teaching Hospital Non-Physician ctitioner	Secret Clear	
Showing Results for: [AII]	A	cknowledge Dispute	Resolved No Cha	ange Delete S	Selected Car	icel Deletion
	Showing 10 v of	1 Entries 🤜 🤜 P	age 1 of 1 🔛 🔛	Page 1 ~	Palaat	
Select All Action Record ID ♦ ID ♦ Action Control ID ♦	e Dispute Recipient t ID ID ≎ ≎	Total Payment Amount or Dollar Amount Invested ≎	Of and Dispute Ini Status ◊	Date Dispute itiated ⇔ History of Disputes	Delay in Publication of Research Payment Indicator ≎	Marked for Deletion:≎
Uiew 79200396	5365 Brandon Ross	\$76,767.22	Initiated 202 07	21-07- View	No	No
	Showing 10 v of	1 Entries 🤜 P	age 1 of 1 🔛 🕨	Page 1 ~		

Section 5.2: Acknowledging Disputes and Resolving Disputes with No Change

Applicable Manufacturers and Applicable GPOs have the option to acknowledge disputes initiated by covered recipients. This status does not indicate agreement or acceptance of the dispute by the reporting entity and is only meant to serve as a notification to the covered recipient that the dispute has been received by the reporting entity. The acknowledgement email can serve as a receipt, confirming to the disputing party that the record exists, and the dispute has been received.

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

When a record undergoes revision to address a dispute, that record will be visible to the covered recipient identified in it, under the "Deleted and In Progress Records" tab until the record is re-attested. The record will return to the "Available for Review and Dispute" tab of the covered recipient view, only after the record regains "attested" status.

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



Figure 236: 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 IDM credentials, navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.

Figure 237: Review and Dispute Tab on Open Payments System Landing Page

)pen Dicable Manufa	Paym acturer or Group Purchas	ents (Sui ing Organization Switch User T	nshine A	Act)			
Home	Submissions	Review and Dispute	🗭 Manage Entities	() My Profil	e	Messages	Resources
Welco	me to the	Open Payme	nts System		C	Access the Op User Guide [PI	en Payments DF]
Annound	ements			_	?	Need help with Contact Us by	the website? email
Program Yea The Review a may receive d disputes. Phys	ar 2018 Review and Dis and Dispute period is op disputes from covered re sicians and teaching ho	spute Period Open - en starting April 1, 2019. Duri ecipients and should work with spitals may review data about	ng this period, reporting en n them directly to resolve th t them and initiate disputes	ntities ne s until	•	Review the Op Privacy Policy	en Payments [PDF]
corrections to correction per correction per Visit the Oper questions, co phone at 1-85	disputed data as needer iod will be identified in tr iod will be included in fund n Payments website at in ntact the Open Paymen 55-326-8366. For the TT	ed. Records with unresolved of he published data as disputed uture data publications. https://www.cms.gov/openpay ts Help Desk by email at oper Y line, call 1-844-649-2766.	lisputes at the end of the d. Changes to records after ments for information. For apayments@cms.hhs.gov	r the	C		
You can mana	age your user profile an	d perform user role functions	associated with your profile	9.			
According to t	the Paperwork Reductio	on Act of 1995, no persons are	e required to respond to a				
collection of ir for this inform collection can organization. dispute and d the time estim	nformation unless it disp ation collection is 0938- in range from 1 to 30,000 This information collecti ispute resolution proces pate(s) or suggestions fr	Alays a valid OMB control num 1237. The time required to cc hours per entity depending o ion may involve registration, d sses. If you have any commer	here. The OMB control num omplete this information in the size and type of lata submission, attestation its concerning the accurac	nber n, y of			

<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.

Figure 238: Show Disputes for and Program Year Fields on Review and Dispute Landing Page

Home Submissions Review and Dispute Manage Entities My Profile		Messages Resources
Review and Dispute Overview	1	Access the Open Payments User Guide [PDF]
A field with an asterisk (*) is required.	?	Need help with the website? 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 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.		Privacy Policy [PDF]
The review and dispute process begins with an initial 45-day period for physicians, teaching hospitals, non-physician practitioners, 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, non-physician practitioners, 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: ABCDE Medical		
2021		
Show Disputes		

<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.

Figure 239: Search Button on Review and Dispute Reporting Entity Page

Open Payn Applicable Manufacturer or Group Purc	nents (Sun hasing Organization Switch User Type	shine Ac	:t)		
Home Submissions	Review and Dispute	😥 Manage Entities	(O) My Profile	Messages	Resources
Review and Disp	oute - ABCDE M	edical - 2021			
Back The table below contains the record(s physician/ non-physician practitioner Submitters for the reporting entity car associated dispute(s) on the record w	s) submitted by this reporting entity the principal investigators. In take actions on the dispute(s) and fill move into Resolved status.	that have been disputed by pl edit the record under dispute	nysicians, teaching hospi . Once a disputed record	tals, non-physician prac	titioners, and
Please note: To view the entire tab	le, use the horizontal scroll bar be	elow the table.			
You may export your search result contain all data fields displayed in the than 20,000 records, adjust the filter of To view all fields for an individual r	s by selecting the "Download Zip Fi table below and other data elemen rriteria to create smaller subsets of record, select the "View" link under	us. le" link. The downloadable file its related to the record. A dow records and download them in the Action column or the "Rec	e will be a CSV file compr vnload file can include up n multiple files. cord ID" link in the Recor	ressed into a ZIP file. Th o to 20,000 records. To o d ID column in the table	e file will Iownload more below.
received the dispute. To ackno covered recipient who initiated • To resolve a dispute, select th edited by the entity or when the • To declare that the dispute h then select the "Resolved No C To return to the previous page, select For more information about the review Applicable Manufactur	wiedge all the disputes use the "Sel the dispute. • "Edit" link in the Action column of e record is deleted to resolve the dis as been resolved in accordance v change" button. the "Back" button. w and dispute process, including ste er or Applicable GPO's	ect All" check box. When a di that record. An email notifica spute. with the Final Rule without of sp-by-step instructions, refer to Disputed Records	spute is acknowledged, a tion will be sent to the co changing the data, selec o the Open Payments Us	an email notification will vered recipient when a t the check box next to the Guide [PDF].	be sent to the record is being the record and
Dispute ID: Maximum 38 digits	Record ID: Maximum 38 digits	Home System Paymen	t ID: File ID: Maximum	38 digits	
Covered Recipient First Name	Covered Recipient Last Name	Teaching Hospital Nam Please Select	le:		
Review and Dispute Status: Initiated Acknowledged Resolved No Change Withdrawn Resolved	Marked for Deletion: Yes No	Payment Category: General Payments Research Payments Ownership or Investme Interest	Recipient Type: Physician Teaching Hospita Non-Physician Practitioner Download Disputes Zip Fi	lie Search Clear	All
Showing Results for:					
	Acknowle	dge Dispute Resolve	d No Change Del	ete Selected Ca	ncel Deletion
	Showing 10 v of 1 Entrie	es 🖂 🖂 Page 1 of 1	→ → Page 1 →		
Select AII Action Record ID ↔ Hom Syste Paymer	e Dispute Recipient Amount	Payment t or Dollar t Invested ¢ Revia and Dispus Statu	ew Date Dispute Histor ute Initiated≎	y of ttes Publication of Research Payment Indicato ¢	Marked for Deletion:≎
U View 79200396	5365 Brandon Ross \$76,767.	22 Initiated	2021-07- 07 View	No	No
<u> </u>	Showing 10 v of 1 Entrie	es 🖂 🖂 Page 1 of 1	▶ ► Page 1 ∨		

<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).

Figure 240: Acknowledge Dispute Button on Acknowledge Dispute" Button on Review and Dispute Reporting Entity Page

Open Paym	asing Organization Switch User Type	shine A	.ct)		
Home Submissions	Review and Dispute	Ø Manage Entities	O My Profile	Messages	Resources
Review and Disp	ute - ABCDE M	edical - 202	1		
Back The table below contains the record(s physician/ non-physician practitioner p Submitters for the reporting entity can) submitted by this reporting entity t rincipal investigators. take actions on the dispute(s) and	hat have been disputed by	y physicians, teaching ho ute. Once a disputed rec	spitals, non-physician pr	ractitioners, and ted, the
associated dispute(s) on the record w	Il move into Resolved status.				
Please note: To view the entire table	e, use the horizontal scroll bar be	elow the table.			
You may export your search results contain all data fields displayed in the than 20,000 records, adjust the filter c	to be selecting the "Download Zip Fil table below and other data elemen riteria to create smaller subsets of r	Is. e" link. The downloadable ts related to the record. A records and download the	file will be a CSV file con download file can include m in multiple files.	mpressed into a ZIP file. e up to 20,000 records. T	The file will o download more
To view all fields for an individual re	ecord, select the "View" link under	the Action column or the "	Record ID" link in the Re	cord ID column in the tal	ole below.
To perform any of the following act • To acknowledge a dispute, se received the dispute. To acknow covered recipient who initiated • To resolve a dispute, select th edited by the entity or when the • To declare that the dispute he then select the "Resolved No C To return to the previous page, select Express dispute the the dispute the the select.	ons, select the check box next to lect the check box for the correspon idedge all the disputes use the "Self he dispute. "Edit" link in the Action column of record is deleted to resolve the dis is been resolved in accordance w hange" button. the "Back" button.	b the Action column: hding record and then select act All" check box. When a that record. An email notif pute. hth the Final Rule witho	ect the "Acknowledge Dis a dispute is acknowledge fication will be sent to the ut changing the data , so	spute" button. This confir d, an email notification v e covered recipient when elect the check box next	ms that you have vill be sent to the a record is being to the record and
Applicable Manufacture	er or Applicable GPO's	Disputed Record	ds	, occi oute (i or j.	
Maximum 38 digits	Maximum 38 digits	Home System Paym	Maximu	ım 38 digits	
Covered Recipient First Name	Covered Recipient Last Name	Teaching Hospital N Please Select	lame:		~
Review and Dispute Status: Initiated Acknowledged Resolved No Change Withdrawn Resolved	Marked for Deletion: Yes No	Payment Category: General Payments Research Payment Ownership or Inves Interest	Recipient Type Physician Teaching Hos stment Non-Physicia Practitioner Download Disputes Zi	: n p File <u>Search</u> Cle	ear All
Showing Results for: [All]	Acknowled	dge Dispute Reso	lved No Change	Delete Selected	Cancel Deletion
	Showing 10 v of 1 Entrie	s 🖂 🖂 Page 1 of 1	Page 1	~	
Select All Action BC¢ Paymen ¢	n Dispute Recipient Amount t ID ID ♦	ayment or Dollar Invested ↓ Interest ↓ Di St	eview and ispute iatus ☆	story of sputes Publication of Research Payment Indica ♦	of Marked for Deletion: \diamondsuit
U View 79200396	5365 Brandon Ross \$76,767.	22 Initia	ated 2021-07- 07 Vie	w No	No
	Showing 10 v of 1 Entrie	s 🖂 🔫 Page 1 of 1	I I Page 1	~	

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

Figure 241: Acknowledge Button on Acknowledge Disputes Page

	ß			6	9		⊠,	۲
Home	Submissions	Review and	Dispute	Manage Entities	My Profil	e Me	essages	Resource
A DODE MA	dical - 2021							
Back Back Select the "Ackr teaching hospita "Acknowledged" To return to the p For more inform	nowledge" button to I. Once the dispute previous page, sele ation about the rev	o acknowledge the d e is acknowledged, t ect "Cancel." iew and dispute pro	isputed records he Review and I cess, refer to the	initiated by the phys Dispute status for th Open Payments U	sician, non-physician he record will be disp Jser Guide [PDF].	ı practitioner, or layed as		
Back Select the "Ackr teaching hospita "Acknowledged" To return to the p For more inform Acknowledg	nowledge" button to I. Once the dispute previous page, selvent ation about the rev ge the following Becord ID	o acknowledge the d e is acknowledged, t ect "Cancel." iew and dispute pro ng disputes:	isputed records he Review and I cess, refer to the	initiated by the phys Dispute status for th e Open Payments U	sician, non-physician ne record will be disp Jser Guide [PDF].	practitioner, or layed as	Data Disputa	
Back Select the "Ackrr teaching hospita "Acknowledged" To return to the p For more inform Acknowledg Dispute ID	nowledge" button to I. Once the dispute previous page, sele ation about the rev ge the followin Record ID	o acknowledge the d e is acknowledged, t ect "Cancel." iew and dispute pro ng disputes: Date of Payment	isputed records he Review and I cess, refer to the Amount (\$)	initiated by the phys Dispute status for th e Open Payments U Covered Recipient	sician, non-physician ne record will be disp Jser Guide [PDF]. Review and Dispute Status	a practitioner, or layed as	Date Dispute Initiated	

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

Figure 242: Acknowledge Confirmation Message

Open Payn Applicable Manufacturer or Group Purch	nents (Suns nasing Organization Switch User Type	shine A	ct)			
Home Submissions	Review and Dispute N	lanage Entities	O My Profile	Me	essages	Resources
Review and Disp	oute - ABCDE Me	dical - 202	1			
Confirmation: • You have successfully ackno or teaching hospital. Back The table below contains the record(g physician/ non-physician practitioner J Submitters for the reporting entity can associated dispute(s) on the record w Please note: To view the entire tabl Use the filtering tools below to custon You may export your search result contain all data fields displayed in the than 20,000 records, adjust the filter of To view all fields for an individual r To perform any of the following act • To acknowledge a dispute, so received the dispute. To acknow covered recipient who initiated • To resolve a dispute, select the • To declare that the dispute No C To return to the previous page, select For more information about the review Applicable Manufacture	wledged the selected dispute(s). A s) submitted by this reporting entity the orincipal investigators. I take actions on the dispute(s) and ec it is the actions on the dispute(s) and ec it is the actions on the dispute(s) and ec it is the action of the dispute fecords is by selecting the "Download Zip File" table below and other data elements ariteria to create smaller subsets of re ecord, select the "View" link under the ions, select the "View" link under the ions, select the check box next to 1 lect the check box for the correspond wledge all the disputes use the "Select the dispute. I "Eaid" link in the Action column of the record is deleted to resolve the disput as been resolved in accordance with thange" button. the "Back" button. v and dispute process, including step- er or Applicable GPO'S E	n email has been sent at have been disputed b dit the record under disp ow the table. ' link. The downloadable related to the record. A cords and download the e Action column or the ' the Action column or the ' the Action column or the ' the Action column or the the Action column or the the Action column or the the Action column or the the Ac	to notify the dispu- icy physicians, teach oute. Once a dispute e file will be a CSV f download file can in em in multiple files. "Record ID" link in th lect the "Acknowled a dispute is acknow fifcation will be sent out changing the di- fer to the Open Payi ds	ng hospitals, no ng hospitals, no nd record is edit le compressed nclude up to 20 ne Record ID cc ge Dispute" but ledged, an ema to the covered ata , select the c ments User Gui	n, non-physician practi on-physician practi ted and reattested, linto a ZIP file. The 000 records. To do olumn in the table t ton. This confirms all notification will b recipient when a re check box next to th ide [PDF].	tioners, and tioners, and the file will winload mor below. that you hav e sent to the eccord is bein he record an
Dispute ID: Maximum 38 digits	Record ID: Maximum 38 digits	Home System Payr	nent ID: Fil Ma	e ID: aximum 38 dig	its	
Covered Recipient First Name	Covered Recipient Last Name	Teaching Hospital I Please Select Payment Category:	Name:	Type:	~	
Initiated Acknowledged Resolved No Change Withdrawn Resolved	Yes	General Payments Research Payment Ownership or Inve Interest	s Physicia tts Teachin stment Non-Ph Practitioner	g Hospital ysician ttes Zip File	Search Clear A	MI
Showing Results for: [All]	Acknowledg	ge Dispute Reso	olved No Change	Delete Se	lected	cel Deletion
Select All □ Action Record ID ↔ Home Syster Payment ↔	Showing 10 ∨ of 1 Entries n Dispute Recipient Total Payr t ID ID ◊ Recipient Amount joilar Amilian Dollar Amilian Invested	Page 1 of Page 1 of Value Of Interest I⇔	1 Pag view and ute Status \diamond Initiated	History of Disputes	Delay in Publication of Research Payment Indicator≎	Marked for Deletion:∢
View 79200396	5365 Brandon Ross \$76,767.22	Ackno	owledged 2021-07 07	View	No	No
	Showing 10 v of 1 Entries	Page 1 of	1 🕞 🖬 Pag	je 1 ~	~	· · · · · · · · · · · · · · · · · · ·

5.2b: Resolved, No Change Disputes

The "Resolved, No Change" status means that the applicable manufacturer or applicable GPO and the physician, NPP, teaching hospital, or 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 IDM credentials and navigate to the Open Payments home page, and select the "Review and Dispute" tab on the menu bar.

Figure 243: Review and Dispute Tab on Open Payments System Landing Page

Home	Submissions	Review and Dispute	Ø Manage Entities	O My Profile	N	Aessages	Resource
Welcom	ne to the	Open Payme	nts System			Access the Oper User Guide [PDF	n Payments
Announce	nents		-	_	? !	Need help with th Contact Us by e	ne website? mail
Program Year 2 The Review and may receive disp	018 Review and Dis Dispute period is ope utes from covered re	pute Period Open - en starting April 1, 2019. Duri cipients and should work witl	ng this period, reporting ent n them directly to resolve th	e	6	Review the Oper Privacy Policy [P	n Payments DF]
corrections to dis correction period correction period Visit the Open Pa questions, contar phone at 1-855-3	puted data as neede will be identified in th will be included in fu ayments website at h t the Open Payment 26-8366. For the TT	d. Records with unresolved of the published data as disputed ture data publications. ttps://www.cms.gov/openpay is Help Desk by email at open Y line, call 1-844-649-2766.	lisputes at the end of the d. Changes to records after ments for information. For apayments@cms.hhs.gov o	the or by	C		
You can manage	your user profile and	I perform user role functions	associated with your profile		17.		
According to the collection of infor for this informatic collection can rar organization. Thi dispute and dispute the time estimate	Paperwork Reduction mation unless it disp on collection is 0938- nge from 1 to 30,000 s information collecti ute resolution proces (s) or suggestions for	n Act of 1995, no persons arr lays a valid OMB control nun 1237. The time required to co hours per entity depending o on may involve registration, o ses. If you have any commer r improving this form, please	e required to respond to a hber. The OMB control numi mplete this information in the size and type of lata submission, attestation, its concerning the accuracy write to CMS, 7500 Securit	, , , of y			

<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 244: Review and Dispute Landing Page

Home	Submissions	Review and Dispute	Manage Entities	My Profile		Messages	Resource
Revie	w and Disp	oute Overviev	N		1	Access the Op User Guide [PI	en Payments DF]
A field with ar	n asterisk (*) is required	•			?	Need help with Contact Us by	the website? email
Applicab	le Manufacture	r or Applicable GP	O Records		-	Review the On	en Payments
Select a repo Disputes". Th investment in	rting entity and program is will display records re terests for the selected	year from the drop-down list lating to payments or other tr reporting entity and program	below, then select "Show ansfers of value, or owners year that are disputed.	ship or		Privacy Policy	[PDF]
The review ar hospitals, nor followed by a necessary co	nd dispute process begin -physician practitioners 15-day correction perio rrections to the data prio	ns with an initial 45-day perio , and principal investigators t d for reporting entities to reso or to publication.	d for physicians, teaching o review and dispute their o blve disputes and make	lata,			
Physicians, te disputes with calendar year	eaching hospitals, non-p reporting entities from t r.	hysician practitioners, and pr ne start of the review and dis	incipal investigators may ir pute period until the end of	itiate that			
If any dispute resolved with initial annual	es are initiated for the firs in the 15-day correction data publication for that	t time after the 45-day review period, the record will be put year.	v and dispute period and no plished as not disputed in th	bt ne			
If any dispute original record information.	results in a change to t d must be deleted and a	ne covered recipient or princi new record submitted with th	pal investigator informatior ne updated covered recipie	, the nt			
Only records will be eligible	for which attestation wa e for the review and disp	s completed by the submission ute process for that calendar	on deadline of that calenda year.	r year			
For a complet	te list of review and disp	ute rules, refer to the Open F	Payments User Guide [PDF	1.			
*Show Dispu ABCDE Med	utes for: lical	~					
2021		~					
Show Dispu	ites						

<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.

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 covered recipient have resolved the dispute in accordance with the guidance in the Final Rule.

For instructions on how to export this data, see Section 5.1c.

Figure 245: Resolved no Change on Review and Dispute Reporting Entity Page

Open Payn Applicable Manufacturer or Group Purch	nents (Suns asing Organization Switch User Type	shine A	ct)		
Home Submissions	Review and Dispute	T anage Entities	O My Profile	Messages	Resources
Review and Disp	oute - ABCDE Me	dical - 202	1		
Back The table below contains the record(s physician/ non-physician practitioner Submitters for the reporting entity can associated dispute(s) on the record w Please note: To view the entire table Use the filtering tools below to custon You may export your search result contain all data fields displayed in the than 20,000 records, adjust the filter of To view all fields for an individual r To perform any of the following act • To acknowledge a dispute, select th edited by the entity or when the • To declare that the dispute ho) submitted by this reporting entity th principal investigators. take actions on the dispute(s) and e ill move into Resolved status. e, use the horizontal scroll bar bel ize your view of the disputed records to by selecting the "Download Zip File table below and other data elements riteria to create smaller subsets of re secord, select the "View" link under th itons, select the check box next to viect the check box for the correspon viedge all the disputes use the "Selec the dispute. e "Edit" link in the Action column of th rescord is deleted to resolve the disp is been resolved in accordance wi hange" button. the "Back" button.	at have been disputed by dit the record under disp ow the table. 5. " link. The downloadable related to the record. A cords and download the use Action column: ding record and then sele to Ali" check box. When a hat record. An email notifute. the Final Rule witho	y physicians, teaching ute. Once a disputed file will be a CSV file download file can incl m in multiple files. Record ID" link in the ect the "Acknowledge a dispute is acknowled fication will be sent to ut changing the data) hospitals, non-physician p record is edited and reattes compressed into a ZIP file. ude up to 20,000 records. T Record ID column in the tal Dispute" button. This confir dged, an email notification v the covered recipient when a, select the check box next	ractitioners, and ted, the The file will o download more ble below. ms that you have vill be sent to the a record is being to the record and
For more information about the review Applicable Manufacture Dispute ID: Maximum 38 digits	r and dispute process, including step er or Applicable GPO's I Record ID: Maximum 38 digits	-by-step instructions, ref Disputed Record Home System Paym	er to the Open Payme ds nent ID: File I Maxi	nts User Guide [PDF]. ID: imum 38 digits	
Covered Recipient First Name	Covered Recipient Last Name	Teaching Hospital N Please Select	lame:		~
Review and Dispute Status: Initiated Acknowledged Resolved No Change Withdrawn Resolved	Marked for Deletion:	Payment Category: General Payments Research Payment Ownership or Inves Interest	Recipient Ty Physician ts Teaching H stment Non-Physi Practitioner Download Dispute	r pe: Hospital ician s Zip File <u>Search</u> Cle	ear All
Showing Results for: [All]	Acknowled	ge Dispute Reso	lved No Change	Delete Selected	Cancel Deletion
	Showing 10 v of 1 Entries	Page 1 of 1	I 🕨 🖬 Page	1 ~	
Select All Action Record ID ◊ Home Syster Paymen ◊	e Dispute Recipient Amount of Amoun	yment or Dollar Value Of nvested Interest☆ Di St	eview and ispute atus⊘ Date Dispute Initiated ≎	History of Disputes Disputes Disputes Disputes Disputes Disputes Disputes Disputes Disputes Disputes Disputes Delay in Publication d Payment Indic: Other Disputes	of Marked for Deletion: ≎
Edit 79200396	5365 Drandon / Ross \$76,767.23 Showing 10 v of 1 Entries	2 Initia	ated 07	View No	No

<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 covered recipient informing them that their dispute has been resolved with no changes made to the data. The email will include the explanation provided in the "Reason for dispute resolution with no change to the data" box. If disputes on multiple records are resolved without changes in the same action (e.g., multiple records are selected and then the "Resolved No Change" button is selected), the explanation provided in the "Reason for dispute resolution with no change to the data" text will be sent to all 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, NPP, teaching hospitals (including principal investigators); otherwise, the disputing covered recipient may see an explanation that was meant for a different covered recipient.

Figure 246: Reason for Dispute Resolution with No Change to the Data Text Box

Home	Submissio	ns Reviel	w and Dispute	Manao	© In Entities My	O Profile	Messages	Resource
	Cubinissio			manag		Tronic	messages	Resourc
Resolve	ed No	Change)					
A field with an as	sterisk (*) is re	quired.						
ABCDE Me	dical - 20	21						
Back								
A reporting entity have resolved the dispute resoluti	e dispute in ac ion does not r	"Resolved No C cordance with the equire a change	<pre>;hange" to ackn e guidance in the to the data by</pre>	owledge that e Final Rule. the reporting	the reporting entity and th This action should only I g entity.	e covered recipier be taken when	t	
n the free-form t	ext box below, up to 4,000 ch	enter the reason aracters, includin	i(s) why the disp g spaces.	ute has been	resolved with no changes	to the data. The te	ext	
For example, the resolved with no covered recipien Therefore, we ar box, select "Res	explanation for changes made it was able to v re moving forw olved No Char	or a dispute that h to the data beca rerify that the pay ard with resolving nge".	has been resolve ause there is now ment amount of g the dispute with	ed with no cha w agreement "six thousand nout changing	ange to the data could say relating to the reported pa I and five hundred dollars" I the data." After entering r	"This dispute is yment amount. Th dollars is correct. easons into the te	e Kt	
Note that the cor physician, teachi	ntents of the "F	leason for dispute	e resolution with	no change to	the data" box will be sent	in an email to the		
As a result, it is s nultiple covered	strongly recom	mended that the internet in ernet in the internet int	user selecting "F e same text use	pai investigati Resolved No (d in the "Reas	or who disputed the record Change" refrain from maki son for dispute resolution	l(s). ng that selection a with no change to	cross	
As a result, it is s multiple covered data" box will be disputes were as hat you repeat ti Once the action i Resolved No Ch Fo return to the p	strongly recom recipients at ti sent to all of ti ssigned "Resol he "Resolved to is confirmed by nange." previous page,	mended that the ne same time. Th ne physicians, tea ved No Change" proce to Change proce the selection of select "Cancel."	user selecting "F le same text use aching hospitals, status at that tin ess for each indi "Resolved No C Open Payments	pai investigati Resolved No (d in the "Rea: non-physicia he. If you have vidual covere thange," the s User Guide [or who disputed the record Change" refrain from maki son for dispute resolution in practitioner, or principal e multiple covered recipier d recipient. tatus of the dispute status PDF].	I(s). Ing that selection a with no change to investigators whose ts, it is recommen will be displayed a	cross he ded as	
As a result, it is s multiple covered data" box will be disputes were as hat you repeat ti Once the action i Resolved No Ch fo return to the p Resolve the	strongly recom recipients at th sent to all of th ssigned "Resol he "Resolved 1 is confirmed by nange." previous page, following of	mended that the ne same time. Th ne physicians, tea ved No Change" vo Change" proce / the selection of select "Cancel." (disputes with	user selecting "F le same text use aching hospitals, status at that tin ess for each indi "Resolved No C Open Payments n no change	pai investigati Resolved No (d in the "Rea: non-physicia ne. If you have vidual covere thange," the s User Guide [es to the d	or who disputed the record Change" refrain from maki son for dispute resolution in practitioner, or principal e multiple covered recipier d recipient. tatus of the dispute status PDF]. ata:	I(s). Ing that selection a with no change to investigators whose ts, it is recommen will be displayed a	cross he ded as	
As a result, it is s multiple covered data" box will be disputes were as hat you repeat ti Once the action i "Resolved No Cf fo return to the p Resolve the Dispute ID	strongly recom recipients at ti ssent to all of ti ssigned "Resol he "Resolved I is confirmed by nange." previous page, following (Record ID	mended that the he same time. Th ne physicians, tea ved No Change" proce v the selection of select "Cancel." (disputes with Date of Payment	Attooner, or princi user selecting "F le same text use aching hospitals, status at that tin ess for each indi "Resolved No C Open Payments h no change Amount (\$)	Resolved No (d in the "Rea: non-physicia non-physicia ne. If you have vidual covere thange," the s User Guide [es to the d Recipient	or who disputed the record Change" refrain from maki son for dispute resolution in n practitioner, or principal e multiple covered recipier d recipient. tatus of the dispute status PDF]. ata: Review and Dispute Status	I(s). Ing that selection a with no change to investigators whose tts, it is recommen will be displayed a will be displayed a Record Status	cross the ded as Dispute Date Initiated	
As a result, it is s multiple covered data" box will be disputes were as that you repeat ti Once the action i "Resolved No Cr To return to the p Resolve the Dispute ID 5365	strongly recom I recipients at ti sent to all of ti ssigned "Resol he "Resolved I is confirmed by hange." previous page, following of Record ID 79200396	mended that the he same time. Th ne physicians, tea ved No Change" proce y the selection of select "Cancel." (disputes with Date of Payment 2021-01-01	utuoner, or princi user selecting "F ee same text use aching hospitals, status at that tin esss for each indi "Resolved No C Open Payments h no change Amount (\$) \$76,767.22	pai investigati Resolved No (d in the "Rea: non-physicia he. If you have vidual covere thange," the s User Guide [es to the d Recipient Brandon Ross	or who disputed the record Change" refrain from maki son for dispute resolution i n practitioner, or principal e multiple covered recipier d recipient. tatus of the dispute status PDF]. ata: Review and Dispute Status Acknowledged	I(s). Ing that selection a with no change to investigators whose its, it is recommend will be displayed a Record Status Attested	cross the se ded as Dispute Date Initiated 2021-07-07	

The following confirmation message will be displayed on the page.

Figure 247: resolved no change confirmation message

Open Payn Applicable Manufacturer or Group Purch	nents (Sun hasing Organization Switch User Typ	ishine A	.ct)		
Home Submissions	Review and Dispute	Ø Manage Entities	O My Profile	Messages	Resources
Review and Disp	oute - ABCDE M	ledical - 202	:1		
Confirmation: • You have successfully resolv	red the selected dispute(s) with	no changes to the data. /	An email has been sent	to notify the covered r	ecipient.
The table below contains the record(s physician/ non-physician practitioner)) submitted by this reporting entity principal investigators.	that have been disputed b	y physicians, teaching ho	ospitals, non-physician p	practitioners, and
Submitters for the reporting entity can associated dispute(s) on the record w	take actions on the dispute(s) and ill move into Resolved status.	I edit the record under disp	oute. Once a disputed rec	ord is edited and reatte	sted, the
Please note: To view the entire tabl	e, use the horizontal scroll bar b	elow the table.			
Use the filtering tools below to custon You may export your search result: contain all data fields displayed in the than 20,000 records, adjust the filter of	nize your view of the disputed reco s by selecting the "Download Zip F table below and other data eleme riteria to create smaller subsets of	rds. ile" link. The downloadable nts related to the record. A records and download the	e file will be a CSV file con download file can include em in multiple files.	mpressed into a ZIP file e up to 20,000 records.	. The file will To download more
To view all fields for an individual r	ecord select the "View" link under	the Action column or the !	Record ID" link in the Re	cord ID column in the ta	ble below
to acknowledge a dispute, so received the dispute. To acknow covered recipient who initiated To resolve a dispute, select th edited by the entity or when the To declare that the dispute h then select the "Resolved No C To return to the previous page, select For more information about the review	vedu the criteck box for the correspondence of the correspondence of the spute. If the dispute, the dispute, the dispute, the dispute, the "Edit" link in the Action column or record is deleted to resolve the dispute record is deleted to resolve the dispute near the "Back" button. If the "Back" button.	onding record and then set lect All" check box. When if that record. An email not spute. with the Final Rule withc	er the Acknowledge bis a dispute is acknowledge ification will be sent to the out changing the data, s fer to the Open Payments	d, an email notification of covered recipient when elect the check box nex User Guide [PDF].	rms that you have will be sent to the n a record is being t to the record and
Applicable Manufacture	er or Applicable GPO's	Disputed Record	ds		
Dispute ID: Maximum 38 digits	Record ID: Maximum 38 digits	Home System Payn	nent ID: File ID: Maximu	ım 38 diaits	
Covered Recipient First Name	Covered Recipient Last Nam	e Teaching Hospital M Please Select	Name:		~
Review and Dispute Status: Initiated Acknowledged Resolved No Change Withdraw Resolved	Marked for Deletion:	Payment Category: General Payments Research Payment Ownership or Inve Interest	Recipient Type Physician ts Physician ts Teaching Hos stment Non-Physicia Practitioner Download Disputes 21	; pital n p File Search Cl	ear All
Showing Results for: [AII]			herd No Okener		Control Politika
	Acknowle	edge Dispute Reso	Ived No Change	Delete Selected	Cancel Deletion
	Showing 10 v of 1 Entrie	es 🦂 🖂 Page 1 of 1	I I I I I I I I I I I I I I I I I I I	*	
Select All Action B C C C C C C C C C C C C C C C C C C	n Dispute Recipient Amount ID ID ≎ ≎ Amount	Payment : or Dollar : Invested ♦ Value Of Interest ♦ Ev St	iew and Date Ispute Dispute atus ⇔ Initiated ≎	story of sputes sputes Additional sputes Payment Indic ¢	of Marked for Deletion:≎
View 79200396	5365 Brandon Ross \$76,767	22 Res	nge 07 Vie	w No	No
	Showing 10 v of 1 Entrie	es 🔫 Page 1 of 1	Page 1	~	

Note that the covered recipient may initiate a new dispute for the same record if the dispute has not been resolved to their satisfaction.

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

Once a dispute is initiated by the covered recipient, the reporting entity should work directly with the disputing party to correct the disputed data. CMS will not mediate disputes between covered recipients 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. 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 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 covered recipient 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 the **figure** below.

Figure 248: 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 NPPs (including principal investigators), these identifying fields are First Name, Last Name, NPI, License State, and License Number.

For teaching hospitals, these identifying fields are Teaching Hospital Name, the hospital address fields, and Taxpayer Identification Number.

Deletion and resubmission may affect the publication timing of the record. Refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at https://www.cms.gov/OpenPayments/Resources, for publication rules.

5.3a: Edit Information and Resubmit Record

<u>Step 1:</u> Log in to the CMS Enterprise Portal at <u>https://portal.cms.gov</u> using your IDM 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

Home Submissions	Review and Dispute	Ø Manage Entities	O My Profile	Message	es Resourc
Welcome to the	Open Payme	nts System		Access t User Guid	he Open Payments de [PDF]
Announcements				? Need hel	p with the website? Us by email
Program Year 2018 Review and D The Review and Dispute period is o may receive disputes from covered	ispute Period Open - pen starting April 1, 2019. Duri recipients and should work wit	ing this period, reporting en h them directly to resolve th	tities	Review the Privacy P	he Open Payments olicy [PDF]
correction period will be identified in correction period will be included in Visit the Open Payments website at questions, contact the Open Payme phone at 1-855-326-8366. For the T	the published data as dispute future data publications. https://www.cms.gov/openpay nts Help Desk by email at ope TY line, call 1-844-649-2766.	d. Changes to records after ments for information. For npayments@cms.hhs.gov c	br by		
You can manage your user profile a	nd perform user role functions	associated with your profile			
According to the Paperwork Reduct collection of information unless it dis for this information collection is 093	ion Act of 1995, no persons arr splays a valid OMB control nun 3-1237. The time required to co	e required to respond to a nber. The OMB control num omplete this information	ber		
organization. This information collect dispute and dispute resolution proce	to nours per entity depending c stion may involve registration, c esses. If you have any commen	on the size and type of data submission, attestation nts concerning the accuracy	, / of		

<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.

Home	Submissions	Review and Dispute	o Manage Entities	O My Profile		Messages	Resources
Reviev	v and Disp	oute Overviev	w		1	Access the Op User Guide [PI	en Payments DF]
A field with an a	asterisk (*) is required				?	Need help with Contact Us by	the website? email
Applicabl	e Manufacture	r or Applicable GP	O Records			Boview the Op	on Poymonts
Select a reporti Disputes". This investment inte	ing entity and program will display records re erests for the selected r	year from the drop-down lis lating to payments or other t eporting entity and program	t below, then select "Show ransfers of value, or owners year that are disputed.	ship or		Privacy Policy	[PDF]
The review and hospitals, non- followed by a 1 necessary corr	d dispute process begin physician practitioners 5-day correction perior ections to the data prior	ns with an initial 45-day perio , and principal investigators f d for reporting entities to reso r to publication.	od for physicians, teaching to review and dispute their of olve disputes and make	data,			
Physicians, tea disputes with re calendar year.	aching hospitals, non-p eporting entities from t	hysician practitioners, and p ne start of the review and dis	rincipal investigators may ir pute period until the end of	itiate that			
If any disputes resolved within initial annual da	are initiated for the firs the 15-day correction ata publication for that	t time after the 45-day review period, the record will be pu year.	w and dispute period and no blished as not disputed in th	ot ne			
If any dispute r original record information.	esults in a change to tl must be deleted and a	ne covered recipient or princ new record submitted with t	ipal investigator informatior he updated covered recipie	n, the nt			
Only records for will be eligible for the second se	or which attestation wa for the review and disp	s completed by the submissi ute process for that calenda	on deadline of that calenda r year.	r year			
For a complete	list of review and disp	ute rules, refer to the Open I	Payments User Guide [PDF	1.			
*Show Disput	es for:						
ABCDE Medic	al	~					
*Program Yea	r:	~					
Show Dispute	es						

Figure 250: 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 covered recipients.

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 251: Edit Hyperlink

pplicable Manufacturer or Group Purc	NENTS (S	User Type	nine	ACI	,				
Home Submissions	Review and Disp	<u>pute</u> Mana	ge Entities	M	(2) y Profile	N	Nessages	F	esources
Review and Disp	oute - ABCD)E Medi	cal - 2	021					
Back he table below contains the record(: hysician/ non-physician practitioner	 s) submitted by this reporti principal investigators. 	ing entity that hav	ve been disput	ted by physic	cians, teachir	ng hospitals,	non-physicia	an practit	oners, and
ubmitters for the reporting entity car	take actions on the dispu	ute(s) and edit the	e record under	dispute. Or	ice a disputed	d record is ed	dited and rea	attested,	he
ssociated dispute(s) on the record v	rill move into Resolved sta	atus. roll bar below th	e table						
se the filtering tools below to custor	nize your view of the dispu	uted records.							
ou may export your search result ontain all data fields displayed in the an 20,000 records, adjust the filter	s by selecting the "Downlo table below and other da criteria to create smaller s	oad Zip File" link. ita elements relati ubsets of records	The download ed to the reco and download	dable file wil rd. A downlo d them in mi	l be a CSV fil ad file can in ultiple files.	e compresse clude up to 2	ed into a ZIP 20,000 record	file. The ds. To do	file will wnload mo
view all fields for an individual I	ecord, select the "View" li	ink under the Act	ion column or	the "Record	ID" link in the	e Record ID	column in th	e table b	elow.
received the dispute. To ackno covered recipient who initiated To resolve a dispute, select the edited by the entity or when the	wledge all the disputes us the dispute. he "Edit" link in the Action	e the "Select All" column of that re	check box. W cord. An emai	hen a disput	te is acknowle will be sent to	edged, an en	nail notificati d recipient w	ion will be /hen a re	sent to th
To declare that the dispute h then select the "Resolved No.	as been resolved in acco	ordance with the	e Final Rule v	vithout chai	nging the da	ta, select the	e check box r	next to th	e record a
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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 NPPs (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 or NPP's authorized representative with dispute access, an email notification is sent to the physician or NPP listed on the record as well. Email notifications are also sent to principal investigators and teaching hospital authorized officials/representatives who disputed a record. All users that have an active dispute for that record will be notified only once per record.

Resubmission and deletion may affect the publication timing of the record. Refer to the "Methodology and Data Dictionary Document" available on the Resources page of the Open Payments website, at https://www.cms.gov/OpenPayments/Resources 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, NPP 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 covered recipient identified in it under the "Available for Review and Dispute" tab. The record will display under the "Deleted and In-progress Records" tab with status "Deleted". Any disputes associated with the deleted record will not be available once the record has been deleted. A record marked for deletion but not yet deleted is still visible to the covered recipient identified in it "Available for Review and Dispute" tab.

The attester will need to 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 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/Resources</u>.

Chapter 6: Messages and Compliance

This chapter provides detailed information on how Applicable Manufacturers and Applicable GPOs can track system generated emails for all users and how to review and download electronic correspondence uploaded by the CMS compliance team using the Messages tab. **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, download associated communication documents, respond, and upload a file to be viewed by the CMS Compliance Team.

6.1: System Tab

Reporting entity users can view system generated messages sent in the past 12 months to any role within the reporting entity. A system generated email is an email generated by the Open Payments System in response to any action performed in the Open Payments system. For example, during the registration process, once a reporting entity registers on the CMS Open Payments system, an email is sent out to the reporting entity confirming registration. This is a system generated email that can be viewed on the "System" tab. NOTE: only the officer and the compliance role will be able to view both the system and compliance tab on the "Messages" home page.

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 these fields are optional to refine your search.

If you are not actively associated with any entity, onscreen text is displayed explaining that you are not currently actively associated with any organization. In this case, the search criteria and table are not displayed.

If you are actively associated with at least one entity, on landing, you are presented with only the search criteria. You are required to select values from the search criteria and select the "Search" button before system generated messages are displayed in the result data table. There are no default results on page landing.

6.1a: Instructions for searching messages

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

Figure 252: 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	253:	Messages	Page
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essages						
<u>System</u>	Complia	nce				
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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.

Home Submissions	Review and Dispute	Manage Entities	My Profile	<u> </u>	Resou
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System Compli	liance				
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Figure 254: System Tab in Messages Page

<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.

Figure 255: Entity Name, File ID, Record ID, Message Category, and Payment Category Fields

Home Submissions	Review and Dispute	Manage Entities	O My Profile	Messages	Resou
essages					
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<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 from newest to oldest. You will see an expandable row section that displays more details about each of the messages.

Home Submission	s Review and Dispute	Manage Entities	(Q) My Profile	Messages	Resource
essages					
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Figure 256: Search Button for System Tab

<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 2	257: 1	Message	Expanda	ble	Arrow
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			-	-		
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ABCDEF Medical	•					
Message Category:		Payment Category:				
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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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lome Submis	ssions Rev	/iew and Dispute M	lanage Entities	My Profile		Messages	Resource
ssages							
System	Compliance						
e table below provides i arch and filtering tools a	nformation on the s	system generated email me	essages received messages displa	by the reporting entity.			
r more information on th	e actions you can	take on this page, refer to t	the Open Paymer	ts User Guide for Repor	ting Entities [PDF].	
Entity Name:		File ID:		Record ID:			
ABCDEF Medical	•	Maximum 38 digits		Maximum 38 digits			
Message Category:	A	Payment Category:					
Submissions			•				
Nomination							
Nomination Reminder Attestation							
File Processing							
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Figure 258: 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 IDM credentials, navigate to the Open Payments home page, and select the "Messages" tab.

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type and Dis O My Profile \Box_{0} ⊵ ٦ ۲ Access the Open Payments Welcome to the Open Payments System User Guide [PDF] Need help with the website? Announcements Contact Us by email Program Year 2018 Review and Dispute Period Open -Review the Open Payments The Review and Dispute period is open starting April 1, 2019. During this period, reporting entities Privacy Policy [PDF] 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 259: 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.

lome Submissions	Review and Dispute Mana	age Entities	O My Profile	Messages	Resour
ssages					
System Compl	liance				
e table below provides informatio arch and filtering tools above the r more information on the actions	on on the system generated email messa table can customize the view of the me- s you can take on this page, refer to the	ages received by the r assages displayed. Open Payments User	eporting entity. Guide for Reporting E	ntities [PDF] .	
e table below provides informatio arch and filtering tools above the r more information on the actions Entity Name:	n on the system generated email messa table can customize the view of the me syou can take on this page, refer to the of File ID: Maximum 38 digits	ages received by the r assages displayed. Open Payments User Record Maximi	eporting entity. Guide for Reporting E	ntities [PDF] .	
e table below provides informatio earch and filtering tools above the r more information on the actions Entity Name: ABCDEF Medical	n on the system generated email messa table can customize the view of the messa you can take on this page, refer to the f File ID: Maximum 38 digits	ages received by the r essages displayed. Open Payments User Record Maximu	eporting entity. Guide for Reporting E I ID: um 38 digits	ntities (PDF) .	
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Figure 260: Compliance Tab on Messages Home Page

<u>Step 3:</u> You will be able to view all Compliance communications. For each communication, you can view the following details in the table.

- Communication ID: A unique ID to view the details of a communication chain
- Subject
- Receiving Entity
- Communication Date: Date when the compliance correspondence was communicated by the CMS compliance officer
- Communication Status (Draft or Final) The last communication status of a particular Communication.
- Date Responded: Date when you responded to CMS for the communication.
- Date Received (removed replaced by other date fields)

Upon selecting the Communication ID, you can view the details of a communication. The "Communication Date" provides the date when the compliance correspondence was communicated by the CMS compliance officer. Note: For New communications, it is the current date and for past communications (prior to January 2020), it is the date when the compliance correspondence was previously communicated to you. The "Date Responded" provides the date when you last responded to CMS for the communication.

Figure 261: Compliance Communication Table

Dpen Payments (Sunshine Act) Jicable Manufacturer or Group Purchasing Organization Switch User Type						
Home Su	bmissions	Review and Dispute	S Manage Entities	(C) My Profile	Messages	Resource
lessages	Complian					
The table below provi	des details of the	compliance communication	(s) uploaded by CMS.			
To view details of a c respond to a commun	ommunication, se nication uploaded	lect the "Communication ID by CMS.	" to navigate to the "Commu	nication Details" page. C	On this page, the use	has the ability to
the "Communicatio " it is the current date a the reporting entity.	n Date" provides t and for past comm	the date when CMS complianunications (prior to January	ance officer communicated tr / 2020), it is the date when th	ne compliance correspor ne compliance correspor	ndence. Note: For ne Idence was previous	w communications, y communicated to
For more information	on the actions you	u can take on this page, reference wing 10 v of 1 Entr	er to the Open Payments Us	er Guide for Reporting E	Entities [PDF].	
Communication II	D	Subject	Receiving Entity	Communication Date	Communication Status	Date Responded
200001773684-PDL- 1638304196252	Test Compliand	ce	ABCDE Medical	11-30-2021	Final	12-10-2021
	Sho	wing 10 v of 1 Entr	ies 🗔 🤜 Page 1 of 1	► ► Page 1	~	

6.2b: Communication Details Page

Upon selection of the "Communication ID" link on Compliance Messages tab, you will be taken to a new page "Communication Details" where you can view the complete details (received and responded communication(s)) of that communication. This page will display the communications in the order it was last received or sent, one below the other in descending order.

The table below provides the ability to view, download and respond to the compliance communication uploaded by CMS.

- To respond to a communication, select the "Respond" button. This button will not be available when there is already a draft response created.
- To download a compliance document, select the "Download" button next to the communication to be downloaded.
- To delete the draft compliance communication, select the "Delete" button. This button will no longer be available after the user selects the "Finalize" button.
- To edit a communication, select the "Edit" button. You can edit a communication if it is in "Draft" status. This button will no longer be available after the communication is finalized.
- To finalize the compliance communication, use the "Finalize" button. This sends the compliance response back to CMS.

Figure 262: Communication Details Page

Open Payments (Sunshine Act) pplicable Manufacturer or Group Purchasing Organization Switch User Type					
Home S	Submissions	Review and Dispute	ठि Manage Entities	O My Profile	Messages Resource
ABCDE Medica Communication Subject: Test Co The table below provid • To respond to a • To download a • To develte the dr. button. • To edit a communicati • To finalize the c Back	Al - 20000177368 Type: Pre-Dema ompliance des the ability to view, a communication, sele compliance documen raft compliance comm unication, select "Edit tion is finalized. compliance communic	34-PDL-1638304196 and Letter download and respond to ect the "Respond" button. it, select the "Download" to unication, select the "Dek " button. You can edit a co ation, use the "Finalize" to	basis the compliance communi- This button will not be av- button next to the commu- eter button. This button w communication as long as button. This sends the com-	Con ication uploaded by CMS. ailable when there is alread nication to be downloaded. Ill no longer be available af it is in "Draft" status. This b npliance response back to	hmunication Date: 11-30-2021 ly a Draft response created. ter the user selects the "Finalize" utton will no longer be available after CMS.
	Show	ing 10 v of 3 Entr	ies 🖂 🖂 Page 1 d	f1 - Page 1	 ↓
	Date 💡		Com	munication Status	Actions
12-10-2021 (Date F	Responded)		Final		Download
▶ 11-30-2021 (Date R	Responded)		Final		Download
▶ 11-30-2021 (Date R	Received)		Final		Download
	Show	ing 🛛 10 🗸 of 3 Entr	ies 🗔 🤜 Page 1 d	f1 🕟 🖬 Page 1	~

6.2c: Upload Response to Compliance Communication Page

Upon receiving a CMS communication, you will have the ability to respond to the compliance communication received. Click the "Respond" button to navigate to the "Upload Response to Compliance Communication" page.

Figure 263: Upload Response to Compliance Communication

Open Applicable Manufa	Paymo cturer or Group Purchasi	ents (Su	nshine A	Act)		
Home	Submissions	Review and Dispute	Ø Manage Entities	O My Profile	Messages	Resources
Upload ABCDE Med Communicat	Response lical - 200001773 ion Type: Pre-Del	to Complian 684-PDL-1638304196 nand Letter	ice Commui	nication _{Com}	munication Date	: 11-30-2021
A field with an ast	erisk (*) is required.					
To respond a com	pliance communication	, follow the steps identified b	elow.			
Prior to uploading includes only alph spaces. The docu	the compliance communanumeric characters ar nanumeric characters ar ment is no larger than 5	unication document, ensure t nd the three allowed special 50 MB.	hat the document is in a va characters (period (.), unde	lid pdf, .csv, .txt, .zip, .doc rscore (_), and dash (-)). [x, .xlsx, .pptx format. E Document name does	ocument name not contain
1. Provide des 2. Select the ' 3. Select the '	scription for the complia 'Browse/Choose" buttor 'Upload" button.	nce communication.(Optiona n to locate and select the doo	al) cument to be uploaded.			
NOTE: Communic completed, the us Subject: Test (cation ID, Communication er will be navigated bac Compliance	on Date, Subject sections wil	I be auto populated. Once page. The compliance con	the compliance communic nmunication will be added	ation upload is succes as a draft version.	sfully
Description:						
500 characters	maximum. Characters	s entered over this limit will	not be saved.			
500 characters in *File: Must be a valid Choose File	remaining .pdf or .csv or .txt or . No file chosen	zip or .docx or .xlsx or .ppt	< file.			Upload

To respond to a compliance communication, follow the steps identified below.

Prior to uploading the compliance communication document, ensure that the document is in a valid pdf, .csv, .txt, .zip, .docx, .xlsx, or .pptx format. Document name must include only alphanumeric characters and the three allowed special characters (period (.), underscore (_), and dash (-)). Document names must not contain spaces. The document must be no larger than 50 MB.

- Provide description for the compliance communication. This is optional.
- Select the "Choose File" button to locate and select the document to be uploaded.
- Select the "Upload" button.
- Click "Yes" on the confirmation message to process with upload or click on "No" to cancel the upload.

NOTE: Communication ID, Communication Date, and Subject sections will be auto populated. Once the compliance communication upload is successfully completed, you will be navigated back to Communication Details page. The compliance communication will be added as a draft version.

Figure 264: Communication Details Page – Confirmation Message

Open Payı Applicable Manufacturer or Group Pu	MEN rchasing Orga	ts (Sui nization Switch User T	nshine A	vct)	
Home Submission	is Rev	riew and Dispute	Manage Entities	O My Profile	Messages Resources
Communication ABCDE Medical - 20000 Communication Type: Pro Subject: Test Compliance	Deta 1773684-P e-Demand	ils DL-1638304196 Letter	252	Com	munication Date: 11-30-2021
Confirmation:					
 To edit a communication, see the communication is finalize To finalize the compliance of Back 	lect "Edit" buti ed. ommunication	ton. You can edit a co	mmunication as long as it is utton. This sends the compl	s in "Draft" status. This bu	utton will no longer be available after
	Showing	10 v of 4 Entri	es 🖂 🖂 Page 1 of 1	► F Page 1	~
Da	te 😧		Comm	unication Status	Actions
Test Compliance Description			Draft		Edit
12-10-2021 (Date Responded)			Final		Download
11-30-2021 (Date Responded)			Final		Download
▶ 11-30-2021 (Date Received)			Final		Download

Once the communication is added as draft version, you will see an expandable view of the message text. Upon expanding the communication, you can either edit, delete, or finalize the communication.

Upon selecting the "Delete" button, a confirmation message will appear allowing you to select either "Yes" to delete the communication or "No" to cancel the action. Upon selecting "Yes", the draft communication will be deleted, and you will see a confirmation message on the screen. Note that this action will delete only the draft communication and does not delete any previous communications. Also, the "Delete" button will not appear for the communications that are in final status.

Figure 265: Confirmation Message

Home	Submissions	Review and Dispute	Ø Manage Entities	O My Profile	Messages Resources
Communi ABCDE Medica Communication Subject: Test Co	cation De al - 2000017736 Type: Pre-Dem ompliance	≥tails 84-PDL-1638304196 and Letter	252	Com	munication Date: 11-30-2021
Confirmation: • Your complian	ce communication	has been successfully de	leted.		
 To delete the dibutton. To edit a comm the communica To finalize the dibutton. 	raft compliance comm unication, select "Ed tion is finalized. compliance communi	nunication, select the "Dele it" button. You can edit a co cation, use the "Finalize" b	ter button. This button will r mmunication as long as it is utton. This sends the compl	no longer be available afte s in "Draft" status. This bu liance response back to C	r the user selects the "Finalize" Itton will no longer be available after XMS.
Back					Respond
	Show	ving 10 🗸 of 3 Entri	es 🖂 🖂 Page 1 of 1	► ► Page 1	~
	Date 😯		Comm	unication Status	Actions
▶ 12-10-2021 (Date I	Responded)		Final		Download
▶ 11-30-2021 (Date I	Responded)		Final		Download
11-30-2021 (Date I)	Received)		Final		Download
	Show	ving 10 🗸 of 3 Entri	es 🖂 🚽 Page 1 of 1	Page 1	~

Upon selecting the "Finalize" button, the confirmation message will allow you to select either "Yes" to finalize the communication or "No" to cancel the action. Upon selecting the "Yes", the "Communication Status" changes from draft to final. This action will notify the CMS Compliance team about the response. When a communication is finalized, a confirmation message will be provided on the page. Upon selecting the "No", the user action will be cancelled.

Figure 266: Confirmation Message

Open Payments (Sunshine Act) Applicable Manufacturer or Group Purchasing Organization Switch User Type						
Home Submissions F	Review and Dispute	ठि Manage Entities	O My Profile	Messages Resources		
Communication Details ABCDE Medical - 200001773684-PDL-1638304196252 Communication Type: Pre-Demand Letter Communication Date: 11-30-2021 Subject: Test Compliance						
Confirmation:						
Your communication is successfully	finalized and a notific	ation has been sent to th	e CMS Compliance Team	•		
 To download a compliance document, To delete the draft compliance communibutton. To edit a communication, select "Edit" the communication is finalized. To finalize the compliance communication 	select the "Download" b nication, select the "Dele button. You can edit a co tion, use the "Finalize" b	button next to the communi ete" button. This button will ommunication as long as it utton. This sends the com	cation to be downloaded. no longer be available afte is in "Draft" status. This bu pliance response back to C	r the user selects the "Finalize" tton will no longer be available after MS.		
Back				Respond		
Showin	g 10 🗸 of 4 Entr	ies 🖂 🖂 Page 1 of	1 🔛 🖂 Page 1 🔹	~		
Date 😯		Comn	nunication Status	Actions		
12-10-2021 (Date Responded)		Final		Download		
12-10-2021 (Date Responded)		Final		Download		
▶ 11-30-2021 (Date Responded)		Final		Download		
▶ 11-30-2021 (Date Received)		Final		Download		
Showin	ig 10 v of 4 Entr	ies 🖂 🖂 Page 1 of	1 🕨 🕨 Page 1 🗸	~		
Back						

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, re-labelers, and kit assemblers) that do not hold title to any covered drug, device, biological, or medical supply); or (2) are entities under common ownership with an entity described in part (1) of this definition, which provides assistance or support to such entities with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply. (See 42 C.F.R. § 403.902)

Applicable Group Purchasing Organization (GPO):

Applicable group purchasing organizations (GPOs) are entities that operate in the United States and purchase, arrange for, or negotiate the purchase of covered drugs, devices, biologicals, or medical supplies for a group of individuals or entities, but not solely for use by the entity itself. (See 42 C.F.R. § 403.902)

Assistance or Support:

Assistance or support means to provide a service or services needed to produce, prepare, propagate, compound, convert, market, promote, sell, or distribute a covered drug, device, biological, or medical supply. (See 42 C.F.R. § 403.902)

Biologicals:

For Open Payments, biologicals are defined as in Section 1927(k)(2)(B) of the Social Security Act, which includes a cross-reference to licensure under Section 351 of the Public Health Service Act ("PHS Act").

Common Ownership:

Common ownership is when the same individual, individuals, entity, or entities directly or indirectly own five percent or more of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations. (See 42 C.F.R. § 403.902)

Consolidated Report:

A consolidated report is a report filed by an applicable manufacturer, which includes payments or other transfers of value to covered recipients, physician owners or investment interests for the applicable manufacturer filing and Applicable Manufacturers under common ownership. (See 42 C.F.R. § 403.908(d))

Covered Recipients:

Covered recipients are any physicians (see <u>Physicians</u> for an extensive explanation of how Open Payments defines this group), physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife or anesthesiologist assistant (see <u>Non-Physicians Practitioners</u> for an extensive explanation of how Open Payments defines this group)who are not employees of the applicable manufacturer that is reporting the payment; or teaching hospitals that receive payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. (See 42 C.F.R. § 403.902)

General Payments:

Payments or other transfers of value not made in connection with a research agreement or research protocol as required in Open Payments.

Non-Covered Recipient Entity:

Non-covered recipient entities are entities that do not meet the Open Payments definition of a covered recipient (see 42 C.F.R. § 403.902). Non-covered recipient entities may include non-teaching hospitals or clinics. A payment or other transfer of value to a non-covered recipient entity is reportable if it is a research payment with at least one associated covered recipient principal investigator.

Non-Covered Recipient Individual:

Non-covered recipient individuals are individuals who do not meet the Open Payments definition of a covered recipient (see 42 C.F.R. § 403.902). Non-covered recipient individuals may include non-physician employees of a teaching hospital or physician-owned practice. A payment or other transfer of value to a non-covered recipient individual is reportable if it is a research payment with at least one associated covered recipient principal investigator.

Open Payments:

Open Payments is a national transparency program which requires:

- Applicable Manufacturers of covered drugs, devices, biologicals, or medical supplies to report information about payments or other transfers of value to physicians, non-physician practitioner and teaching hospitals to CMS every year.
- Applicable Manufacturers and Applicable group purchasing organizations (GPOs) report information about ownership and investment interests held by physicians or their immediate family members to CMS every year.
- Applicable GPOs report information about payments or other transfers of value made to physician owners and investment interests to CMS every year.

Physicians:

For the purposes of Open Payments, physicians are defined as doctors of medicine or osteopathy practicing medicine or surgery, doctors of dental medicine or dental surgery practicing dentistry, doctors of podiatric medicine, doctors of optometry, or chiropractors, all legally authorized to practice by their state.

Non-Physician Practitioners:

The Open Payments program expanded the definition of covered recipients to include the following Non-Physician Practitioners:

- Physician Assistant (PA): an individual who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.
- Nurse Practitioner (NP): an individual who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.
- Clinical Nurse Specialist (CNS): an individual who is a registered nurse and is licensed to
 practice nursing in the State in which the clinical nurse specialist services are performed;
 and holds a master's degree in a defined clinical area of nursing from an accredited
 educational institution.
- Certified Registered Nurse Anesthetist (CRNA)/Anesthesiologist Assistant (AA): a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the

same requirements as those established by a national organization for the certification of nurse anesthetists.

• Certified Nurse-Midwife (CNM): a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary or has been certified by an organization recognized by the Secretary.

Physician Owners or Investors:

Physicians who have an ownership or investment interests in an applicable manufacturer or applicable group purchasing organization. Applicable Manufacturers and Applicable group purchasing organizations are required to report ownership or investment interests held by a physician or a physician's immediate family member in an applicable manufacturer or applicable group purchasing organization.

Research Payments:

Payments or other transfers of value made in connection with a research agreement or research protocol as required in Open Payments.

Special Characters:

Characters that are neither letters nor numbers. Special characters include punctuation, spaces, and other non-alphanumeric symbols.

Special characters are required in registration fields where appropriate. For example, the "@" symbol and the period are required in email address fields, while dashes are required in telephone number fields.

Data elements of submitted records may contain only the special characters allowed per the "Submission Data Mapping Document," which is found on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/Resources. Note that there are multiple versions of the Submission Data Mapping Document based on program year. Consult the Submission Data Mapping Document for the program year of your records.

Free text fields allow all special characters on a standard U.S. keyboard, excepting ALT+NUMPAD ASCII Key characters. Below are the special characters allowed in free text fields.

Special Character	Description
+	Plus sign
&	Ampersand
I	Apostrophe
*	Asterisk
@	At sign

Figure 267: Special Characters Allowed in Free-Text Fields

Special Character	Description
\	Backslash
۸	Caret
:	Colon
1	Comma
\$	Dollar sign
Space	Space character
=	Equal
!	Exclamation mark
/	Forward slash
Ň	Grave accent
>	Greater than
-	Minus sign/hyphen
(Left parenthesis
{	Left curly brackets
[Left square brackets
<	Less than
%	Percent
	Period
#	Pound
?	Question mark
п	Quotation marks
)	Right parenthesis
}	Right curly brackets
]	Right square brackets
. , , , , , , , , , , , , , , , , , , ,	Semi-colon
	Pipe
~	Tilde
+	Plus sign

Characters used in foreign languages that are not used in English must be converted to English characters to be acceptable to the Open Payments system. Refer to the conversion table below.

Figure	268:	Conversions	for	Foreign	Language	Characters
- Bai C	200.	conversions		10101811	Language	enaracters

Foreign Character	Convert to English Character
À	А
Á	А
Â	А
Ã	А
Ä	А
Å	А

Foreign Character	Convert to English Character
È	E
É	E
Ê	E
Ë	Е
Ì	I
Í	I
Î	Ι
Ï	Ι
Ò	0
Ó	0
Ô	0
Õ	0
Ö	0
Ø	0
Ù	U
Ú	U
Û	U
Ü	U

Teaching Hospital:

Teaching hospitals are hospitals that receive payment for Medicare direct graduate medical education (GME), IPPS indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. (See 42 C.F.R. § 403.902). The full list of affected teaching hospitals can be found on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/Resources.

Appendix B: Submission Error and Warning Codes

Error codes and Warning codes generated by the Open Payments system for records with validation errors can be found in the Error and Warning Code Key, which is located on the Resources page of the Open Payments website at https://www.cms.gov/OpenPayments/Resources or within the Open Payments system by selecting the "Resources" tab.

Disclosure

- **Disclaimer:** The contents of this document do not have the force and effect of law and are not meant to bind the public in any way unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.
- Activities/persons addressed by this document: Guidance for applicable manufacturers and applicable group purchasing organizations to understand how to comply with Open Payments, including how to operationalize the collecting and reporting of data.
- Date of document issuance: January 2024
- Replacement / Revision Status: Revision to previous versions
- Agency Identifier: CPI DASG/CPI DTP/DASG/CPI 3631
- **Summary of Document:** A one-stop-shop resource to help applicable manufacturers and group purchasing organizations (GPOs) understand in detail how the Open Payments system works.
- Citation to statutory provision/regulation applicable to this document:
 - Statute citation: Social Security Act SEC. 1128G. [42 U.S.C. 1320a-7h]
 - **Rule citation:** 42 C.F.R. §403.900-14