



Open Payments

Applicable Manufacturers & Applicable GPOs: Registration, Data Submission, and Attestation

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

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

January 2023

CMS Disclaimer: This information is a summary of the final rule implementing Open Payments (Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests [CMS-5060-F], codified at 42 CFR Parts 402 and 403). The summary is not intended to take the place of the final rule which is the official source for information on the program.

Outline

- Target Audience & Learning Objectives
- Program and System Overview
- Reporting Entity Registration and Recertification
- Data Submission & Error Correction
- Final Submission & Attestation
- Next Steps & Available Resources

Target Audience & Learning Objectives

- Target audience:
 - Applicable Manufacturers and Applicable Group Purchasing Organizations (GPOs), collectively referred to as reporting entities who must submit data to the Open Payments system to comply with regulatory reporting requirements
- Learning objective:
 - Understand high-level instructions on how to register, submit, and attest data
 - Open Payments system enhancements

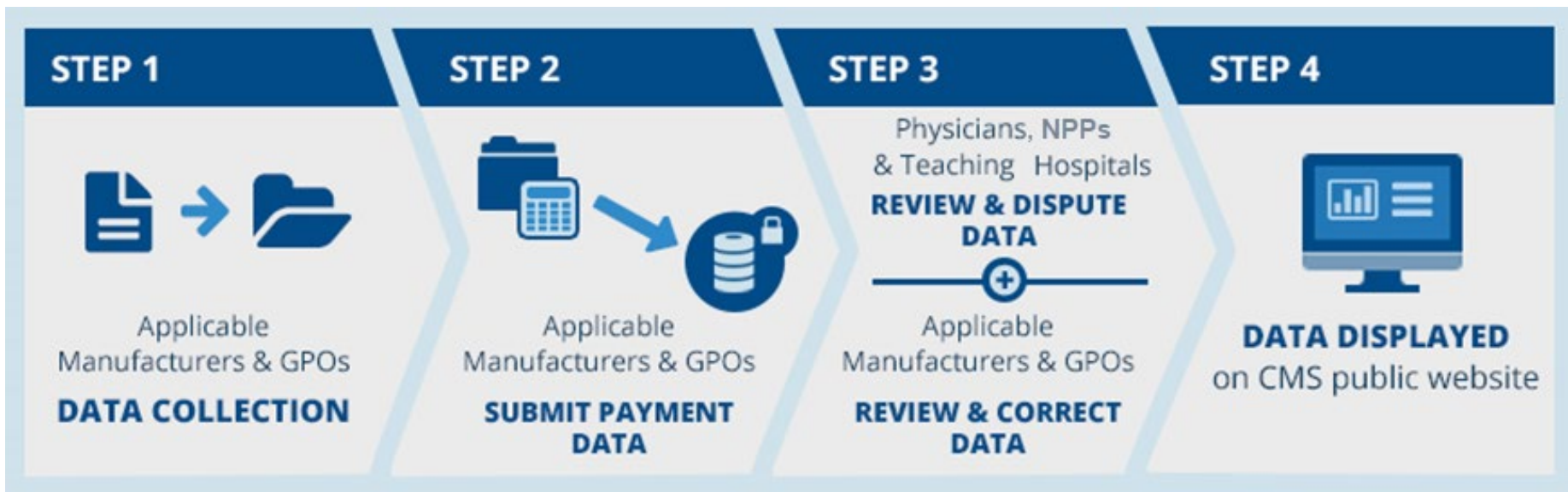
Key Terms

- **Reporting Entities** – refers to pharmaceutical and medical device manufacturers and their distributors who are required to report payments and other transfers of value to Open Payments; also referred to as Applicable Manufacturers and Applicable Group Purchasing Organizations (AM/GPOs)
- **Covered Recipients** – refers to physicians, non-physician practitioners (NPPs) and teaching hospitals receiving payments or other transfers of value from Applicable Manufacturers and Applicable Group Purchasing Organizations (AM/GPOs)
 - NPPs include Physician Assistant (PA), Nurse Practitioner (NP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist or Anesthesiologist Assistant (CRNA/AA) and Certified Nurse-Midwife (CNM)

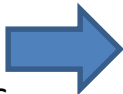
For a complete list of key terms for Open Payments, refer to the Open Payments User Guide for Reporting Entities or Open Payments User Guide for Covered Recipients

Program and System Overview

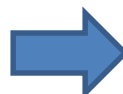
Open Payments Process Flow



Reporting entities collect payment data for a program year, which runs from January 1 to December 31



Reporting entities submit their data for the program year to the Open Payments system



Covered recipients review and, if necessary, dispute submitted data. Reporting entities resolve disputes



Program year data is published for public viewing in accordance with the publication guidelines

Program Year 2022 Timeline

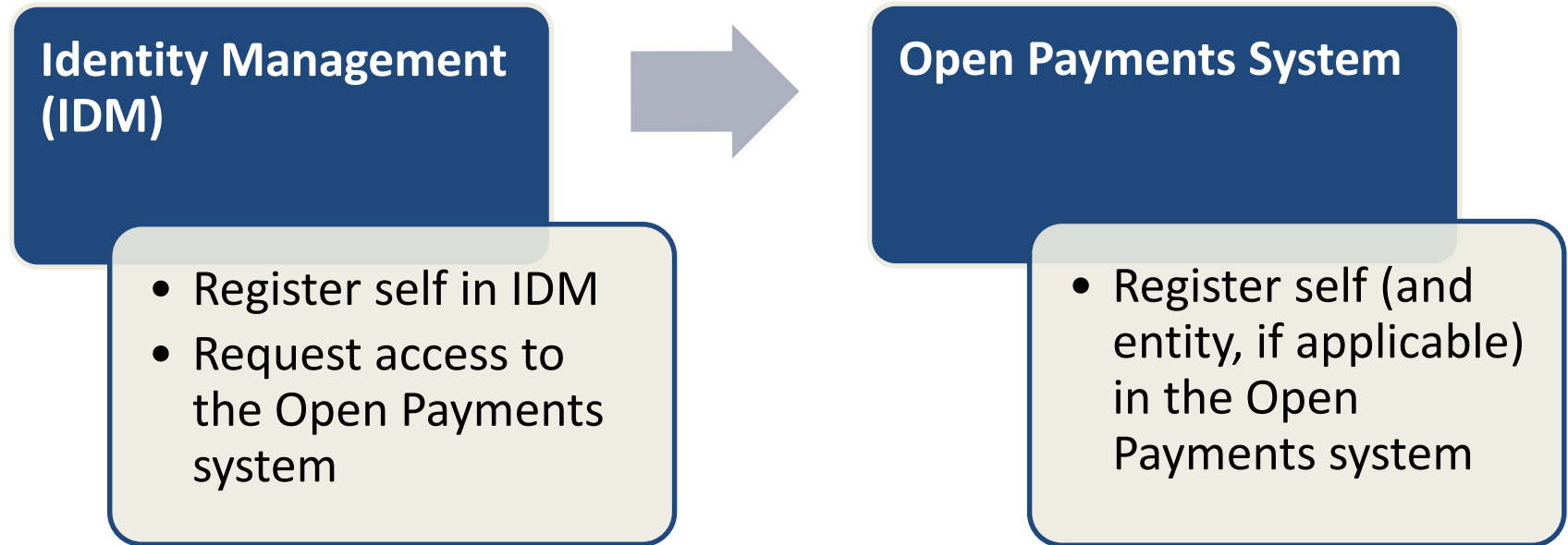


Note: Review and Dispute activities start on April 1st and can continue until end of the calendar year. The end dates provided on this slide are the cutoff for disputes and corrections to appear in the June 30, 2023 data publication.

***Anticipated date**

Reporting Entity Registration and Recertification

Two-Step Registration Process



1. Before registering for the Open Payments system, an individual must first register with the CMS Identity Management (IDM) system and request access to the Open Payments system
2. Once the individual has successfully registered with IDM, that individual can register him- or herself (and if necessary, their reporting entity) with the Open Payments system

If an individual has registered for Identity Management and requested access to Open Payments system in the past, it is not necessary to do so again

IDM Overview

- **Successful registration in both IDM and the Open Payments system is required for each individual who wishes to access the Open Payments system and perform any system-related functions**
- Individuals who request electronic access to CMS-protected information or systems (such as IDM) must first have their identities verified
- For step-by-step instructions on how to register in IDM, refer to the quick reference guide “Identity Management (IDM) Registration”
- For returning IDM users who need help with User ID or password, visit <https://portal.cms.gov> or call the Open Payments Help Desk at 1-855-326-8366 or TTY line call at 1-844-649-2766.
 - **Note: IDM locks user accounts after 60+ days of inactivity and deactivates accounts after 180+ days of inactivity. Users must call the Open Payments Help Desk to reinstate a deactivated account.**

Open Payments System Registration

- Reporting entities must register in the Open Payments system to submit, attest, correct, and view records of payments, other transfers of value, and ownership/investment interests
- Open Payments system registration can only be completed **after** IDM registration
- Reporting entities must be registered and individuals who wish to use the system on behalf of a reporting entity must also register themselves
- The individual who registers the reporting entity will be required to register him/herself for the role of officer with the reporting entity in the Open Payments system
- Prepare the required information before beginning registration

Open Payments System Registration (cont.)

- **Registration must be completed in one session; users cannot partially save entries for completion at a later time. Sessions time out after 30 minutes of inactivity**
- For a complete list of required information for registration refer to the quick reference guide “Required Fields for Registration”
- The following fields are used to successfully vet an entity during registration or when an entity profile is modified to change the following fields:
 - Entity’s Legal Name, State and Country
 - Tax Identifier Number (TIN)/Employee Identification Number (EIN)
 - Dun and Bradstreet DUNS Number (D&B)
- For additional guidance on system registration, refer to the quick reference guide “Applicable Manufacturer and Applicable GPO Registration and Recertification”

Entity Recertification

- Reporting entities that have previously registered must complete the recertification process annually
- Recertification must be completed by an individual who holds an officer role with the reporting entity in the Open Payments system
- Reporting entities can recertify beginning January 1 of each calendar year
- Once recertified, entities can perform user role management activities as well as view and download previously submitted data
- Data submission, editing, and deletion of records **cannot** be performed until the start of the submission period

Entity Recertification (cont.)

- Recertification confirms reporting entity details in the Open Payments system are accurate
 - During recertification, officers can update outdated or inaccurate reporting entity information
 - Information can be updated at any time, not only during recertification
- Re-vetting of the reporting entity will occur if any of the following fields in the entity's profile change:
 - Entity's Legal Name, State and Country
 - Tax Identifier Number (TIN)/Employee Identification Number (EIN)
 - Dun and Bradstreet DUNS Number (D&B)
- The quick reference guide “Applicable Manufacturer and Applicable GPO Registration and Recertification” provides additional guidance on the recertification process

Vetting

- Vetting verifies that the applicable manufacturer or applicable GPO is a valid reporting entity
 - After the reporting entity's registration has been submitted in the Open Payments system or a previously registered entity's name, state, country, TIN/EIN, or DUNS number is changed in the entity's profile, the system will vet the reporting entity
- All the officer(s), primary and backup point of contacts who are affiliated with the entity will receive an email confirming vetting success or failure.
 - If vetting is successful, the officer(s) may begin performing actions in the system for the reporting entity
 - If vetting fails, update the entity information and re-submit for vetting or contact the Open Payments Help Desk for assistance
- To ensure successful vetting, provide as much information as possible during registration

Vetting (cont.)

- Vetting status of a reporting entity is available on the affiliated user's Open Payments home page until the entity is vetted successfully; once successfully vetted, an entity's vetting status is given on the "Manage Entities" page
- **A reporting entity cannot take any system actions until it has been successfully vetted**
- Entities with a foreign addresses must contact the Open Payments Help Desk for manual vetting
 - The Open Payments system will allow reporting entity nominees to register with foreign addresses while registering or accepting nomination
- If the vetting status remains in "Vetting in Progress" for 48 hours or more, users can contact the Open Payments Help Desk for resolution
- Refer to the Open Payments User Guide for Reporting Entities for more information on vetting

Data Submission & Error Correction

Data Submission Process

- **During the Calendar Year 2023 data submission period, reporting entities are required to submit data regarding payments and other transfers of value made to covered recipients, and ownership or investment interests, for Program Year 2022 (January 1 – December 31, 2022)**
- Data can be submitted to the Open Payments system in two ways:
 - Bulk file upload using either Character-separated Values (CSV) files or a ZIP file containing CSV files
 - Manual data entry of each data record through the Open Payment system's Graphic User Interface
- Archived Program Years may only be viewed and may not be submitted or edited
 - Archived Program Years: 2013, 2014, 2015, and 2016

Data Submission Process (cont.)

- Reporting entities may choose to use either or both of these submission methods to report transactions
- CMS encourages reporting entities with a smaller volume of records to use manual data entry, as preparing CSV files requires data handling expertise and may require additional software tools in order to prepare the files
- The system checks each record for validation and matching errors
- **All errors in the record must be corrected before final submission and attestation can occur**

Data Submission Process (cont.)

- Submitters will receive notifications, via onscreen messages or emails, at various stages of the upload and submission process. These will notify the submitter of the success or failure of their submissions and note the existence of any matching or validation errors
- Reporting entities may choose to have their data prepared and submitted by a third-party organization
 - The role of submitter is the only role third-party companies can fulfill within the Open Payments system on behalf of a reporting entity; attestation must be completed by the reporting entity
- Refer to the submissions-related quick reference guides for more information on data submission

Data Submission Process Flow

STEP 1

Log into Open Payments System

Submitter logs into Open Payments System

STEP 2

Upload Data

Two Options Available:

1. Bulk Data Upload (CSV Files)
2. Manual Entry (Graphic User Interface)

Bulk File Upload:

- Accepted file formats include CSV or ZIP files containing CSV files
- Files may not exceed 250MB in size
- Use the correct template for desired program year and payment type

Manual Data Entry using Graphic User Interface (GUI)

STEP 3

Data Validation & Matching

System performs data validation & matching:

- For bulk file upload, system notifies failure or success via email
- For manual data entry, validation checks are in real time and displayed on user interface; matching checks are performed after upload and displayed on Record ID pages of records

STEP 4

Final Submission

- A submitter can perform Final Submission if there are any records in "Ready for Submission" status and there are no records in "System Processing" status.
- When the submitter selects the "Notify Attester" button, a notification that records are available to attest will be sent to the Attester.

STEP 5

Attestation

- Attester receives an email notification that records are in "Ready for Attestation" status
- Attester attests to the accuracy, completeness, and timeliness of the data
- Attestation is conducted for all records for that program year, across all three payment types

Bulk File Upload

- Reporting entities with large volumes of data to report will likely want to upload bulk data files
- The two acceptable file formats for bulk data upload are:
 - CSV (Character-Separated Values) that use pipes (|) as field delimiters
 - Sample files, also referred to as templates, are available on the Resources page of the Open Payments website and within the Open Payments application for submitters
 - Files must be prepared using the correct template for the program year
 - ZIP (must contain only pipe-delimited CSV files)
- Each file can contain only one payment type: general payments, research payments, or ownership and investment interests
- Maximum file size accepted, for both CSV and ZIP files, is 250 MB. There is no limit to how many files that may be uploaded into the system

Bulk File Upload (cont.)

- In addition to adding new records to the system and resubmitting previously submitted records, the bulk file upload process can be used to:
 - Delete existing records from the Open Payments system
 - Update the delay in publication status of existing records in the Open Payments system
- The purpose of a record (New, Resubmission, Delete, Update Delay) is communicated via the Resubmission File Indicator field
 - A bulk file can contain records for only one purpose (i.e., all records in a file must have the same indicator in the “Resubmission File Indicator” field)
- The “Review File Status” page allows the submitters to view the status of the submitted files and select File ID hyperlink to view error log, warning log or delete file from “File Details Page”
- Refer to the quick reference guide “Bulk File Upload” for more information on the Resubmission File Indicator changes

Manual Data Entry

- Manual data entry is completed via the Graphical User Interface (GUI)
- Manual entry can be used in conjunction with bulk data file uploads
- Reporting entity submitters can copy/duplicate payment details across multiple program years through the User Interface (UI). This reduces the effort of entering the same data repeatedly
- The quick reference guide “Manual Data Entry” provide additional guidance on completing manual data submission

Validation and Matching Errors

- After records are uploaded, the Open Payments system will begin validating and matching the data
- This may uncover errors that must be corrected for the records to be submitted successfully
- Users can view matching errors and/or warnings on the record “Overview” page while editing a record
- There are three basic types of errors for data submitted to the Open Payments system:
 1. File validation errors
 2. Record validation errors/warnings
 3. Data matching errors

File Validation Errors

- 1. File Validation Errors:** Applies only to records submitted via bulk file upload. The system will fail a file's upload if validation errors are detected.

File errors may include:

- Submitted file size is larger than 250 MB
- File is not in CSV or ZIP format
- File is missing a header row and/or columns, or has incorrect number of columns
- Payment category of the sample file used to create the submitted file and payment category selected when uploading the file do not match
- Resubmission File Indicator does not correspond with the selection on the user interface

For a complete list of file validation errors, refer to the quick reference guide “Identifying Validation and Matching Errors”

Record Validation Errors/ Warnings

- 2. Record Validation Errors/ Warnings:** The system will fail a record if the information in the record does not match the formatting accepted by the system
- Record formatting is explained in detail in the Submission Data Mapping Document available on the Resources page of the Open Payments website
 - Manually entered records undergo formatting checks during data entry
 - Records submitted via bulk file upload undergo checks as part of the file submission process
 - Common validation errors/warnings include:
 - Invalid characters in the data element
 - Required data element left blank
 - Too many or too few characters in the data element
 - Invalid value in the data element
 - Data element value does not match the CMS approved data set
 - NOTE: Records can be submitted successfully with a warning provided there are no other errors on the record.

Data Matching Errors

- 3. Data Matching Errors:** The system will fail a record if the covered recipient information in a record cannot be matched to a valid covered recipient using existing CMS resources and information

Examples of data matching errors include:

- The Teaching Hospital Name in a record does not match the value for the corresponding Hospital Name in the CMS Teaching Hospital List
- The Teaching Hospital Address in a record does not match the value for the corresponding Teaching Hospital NPPES (National Plan & Provider Enumeration System) Business Address in the CMS Teaching Hospital List
- The Physician or Non-Physician Practitioner Name in a record does not match the information in validation sources used by Open Payments
- The Physician/Non-Physician Practitioner or Principal Investigator license in a record is not active throughout the Open Payments Program as per validation sources used by Open Payments

Error Notifications

- **Errors in records submitted via bulk file** are communicated to submitters via email
 - Errors in File Validation are detailed in the notification email
 - Errors in Record Validation and Matching are detailed in a downloadable error log.
 - In the error log file, the column “Data Element Value” displays the invalid value
- **Errors in records submitted via manual data entry** are communicated through two methods
 - Errors/warnings at the Record Validation level are communicated during the record entry process through onscreen error messages
 - Errors/warnings at the Matching level are identified within the Open Payments system and can be found on the record “Overview” page or by searching records with a “Failed Matching” status

Error Notifications (cont.)

- Error logs contain error codes that identify the reason for record failure; error codes are explained in the “Error and Warning Code Key,” available on the Resources page of the Open Payments website
- Submission errors must be corrected and the records re-submitted for records to be successfully submitted
- Refer to the quick reference guides “Identifying Validation and Matching Errors” and “Correcting Validation and Matching Errors” for additional guidance on how to address the error notifications
 - Open Payments validates drug and medical device information against the CMS approved datasets that are provided annually by the U.S. Food & Drug Administration (FDA). Refer to the full dataset reference files and corresponding instruction documents for additional guidance on how to address these specific errors

Warning Notifications

- Records containing licenses that were valid after August 1, 2013 for physicians or January 1, 2022 for NPPs, but were expired during the entirety of the program year of the record will not fail matching due to the expired licenses; however, they will trigger warnings to the user.
- Records submitted with warnings will be flagged with a warning icon on the “Record ID” column of the payment category page. The warning will also appear on the individual record’s “Record ID” page.
- If the record(s) were submitted via bulk file, the “Review File Status” page will display the uploaded file with status “Processed with Warning”. This status is also displayed on the bulk file’s “File ID” page and the warning log for the bulk file that contains expired license warnings for each relevant record, with the specific expired license(s) specified or the Medical Device or Medical Supply Name and Primary Device Identifier combination.

Warning Notifications (cont.)

- Submitters should review the license information on records that triggered warnings. 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.
- Warning logs contain warning codes that identify the reason for record warnings; warning codes are explained in the “Error and Warning Code Key,” available on the Resources page of the Open Payments website.
- Refer to the quick reference guides “Identifying Validation and Matching Errors” and “Correcting Validation and Matching Errors” for additional guidance on how to address warnings.

Final Submission & Attestation

Final Data Submission

- All records uploaded to the Open Payments system must go through a final data submission and attestation to be considered reported
- All records in a payment category for a program year go through final submission simultaneously regardless of how they were submitted
 - Note: Final submission may take several hours depending upon the size of the submission. The user will receive an automated email notifying them that the final submission was successfully processed.
- Utilize the “Notify Attester” button to send an email to the attester that the records are ready for attestation or re-attestation
 - Note: The “Notify Attester” button will only be enabled if all records are in “Attested” or “Ready for Attestation” status

Attestation

- Attestation legally affirms and certifies that information submitted on behalf of a reporting entity is accurate and complete – only users holding the role of Attester may attest
- Attesters will receive email notifications when there are records in “Ready for Attestation” status and the “Notify Attester” button is selected
- Attestation occurs after all errors are corrected, matching is successful, records have undergone final submission, and all records for the program year are in “Ready for Attestation” status

Attestation (cont.)

- Re-attestation is required when any previously attested data is changed, including any data fields, delay in publication indicator, or when a record that was in attested status is deleted
- Attestation must be done for **all** records submitted for a program year, **not** individual records, file submissions, or payment types
- For the submission to be considered “on time”, attestation must be completed by the reporting deadline for the program year. Data submissions that are not attested to by the reporting deadline will be considered late and may be subject to civil monetary penalties

Attestation: Assumptions

- Attesters can provide an assumptions statement during the attestation process
- Assumptions explain the reasonable assumptions made and methodologies used when reporting payments, other transfers of value, or ownership or investment interests
- Assumptions are documented in a free-form text field during the attestation process
- Assumptions may be a maximum of 8,000 characters (including spaces)
- Assumptions can be edited later
- Refer to the quick reference guide “Final Submission and Attestation” for additional guidance on the attestation process

Delay in Publication

- Reporting entities can request a one-year delay in publication for eligible payment records, as well as request a renewal of the delay after a previous one expires
 - **Records may only be delayed from publication up to four years from the date of payments**
- Eligible payment records may be delayed for publication if the payment or other transfer of value is related to:
 - 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; or
 - Clinical investigations regarding a new drug, device, biological, or medical supply.
- The request for a delay must be renewed each year; if a request is not renewed each year by the end of the data submission period, the record will be eligible for publication in the current publication cycle

Delay in Publication

- Delays can be renewed via bulk file upload or manual editing of records via graphic user interface.
- Records can only be delayed from publication for 4 years from the year of payment (i.e., the record's program year); records attributed to Program Years 2015, 2016 and 2017 are no longer eligible for a delay in publication in 2022 and will be published in the June 2023 Data Publication.

Delay in Publication – Delay Limits

- Open Payments updates the “Delay in Publication Indicator” status of all records each January based upon the records’ age and prior delay status
 - Records that did not have a delay requested in the previous year will remain in a “No Delay Requested” status
 - Records that had a delay requested in the previous year and have not reached the renewal limit will be updated to a “Pending Renewal” status
 - Records that had a delay requested in the previous year and have reached the renewal limit will be updated to a “Limit Reached” status
- After renewing any requests for delays in publication, all records for that program year must be re-attested to for the request for delay to be confirmed
- The quick reference guide “Requesting or Updating a Delay in Publication” provides additional guidance on the delay in publication process

Next Steps and Available Resources

Next Steps

For New Reporting Entities

- Register in IDM and request access to the Open Payments system
- Register self and reporting entity (if applicable) in the Open Payments system
- Assign user roles

For Returning Reporting Entities

- Ensure IDM account has not been deactivated due to inactivity and reset password if necessary
- Recertify reporting entity information and provide required review and dispute contact information
- Confirm user roles

Covered Recipient Validation Resources

- Resources to help reporting entities ensure accurate data submission include:
 - Validated Physician List – Accessed through the Open Payments system on the “Submissions” page.
 - The Validated Physicians List (VPL) contains two separate files listing all the physicians; one includes physicians with NPIs, and the other includes physicians without an NPI.
 - Includes supplemental file for each program year that lists physicians with at least one inactive license for that program year.
 - The VPL is **not** an exhaustive list of all physicians who should be included in Open Payments reporting.

Covered Recipient Validation Resources

- Resources to help reporting entities ensure accurate data submission include:
 - Validated Non-Physician Practitioners List – Accessed through the Open Payments system on the “Submissions” page.
 - The Validated Non-Physician Practitioners List (VNPPL) contains two separate files listing all the NPPs; one includes NPPs with NPIs, and the other includes NPPs without an NPI.
 - Includes supplemental file for each applicable program year that lists NPPs with at least one inactive license for that program year.
 - The VNPPL is **not** an exhaustive list of all Non-Physician Practitioners who should be included in Open Payments reporting.

Covered Recipient Validation Resources

- Resources to help reporting entities ensure accurate data submission include:
 - Teaching Hospital Lists
 - 2023 Reporting Cycle: Teaching Hospital List is now available
 - Teaching Hospital Lists for previous program years are available for records that need to be created or edited and can be found on the Resources page of the Open Payments website
 - Submissions should be made using the hospital’s “doing business as” name instead of legal name

Available Resources

- Review available resources on the CMS Open Payments Resources page at <https://www.cms.gov/OpenPayments/Resources>:
 - Open Payments User Guide for Reporting Entities
 - Tutorials
 - Error and Warning Code Key
 - Quick Reference Guides:
 - Identity Management (IDM) Registration
 - Required Fields for Registration
 - Applicable Manufacturer and Applicable GPO Registration and Recertification
 - Bulk File Upload
 - Manual Data Entry
 - Identifying Validation and Matching Errors
 - Correcting Validation and Matching Errors
 - Final Submission and Attestation
 - Requesting or Updating a Delay in Publication

Available Resources

- If you are looking for information on the Covered Recipient expansion, new nature of payment categories, or device IDs, refer to the tutorial for “Open Payments Expansion of Covered Recipients, Validating and Standardizing Medical Devices, & Natures of Payments” on the CMS resources page
- Register for CMS email notifications via the Open Payments website to receive email updates about Open Payments
- For additional questions, contact the Open Payments Help Desk
 - Email: openpayments@cms.hhs.gov
 - Phone: 1-855-326-8366 or 1-844-649-2766 (TTY line)

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 who must submit data to the Open Payments system to comply with regulatory and reporting requirements.
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