Open Payments System Quick Reference Guide Manual Data Entry

Introduction

The Open Payments system allows Applicable Manufacturers and Applicable Group Purchasing Organizations (GPOs), hereafter collectively referred to as "reporting entities", to submit payments or other transfers of value and ownership or investment interests information via bulk file uploads or manual data entry. This quick reference guide provides a high-level overview of how to submit data to the Open Payments system via manual data entry.

Prerequisites

- User is registered in Centers for Medicare & Medicaid Services (CMS) Identity Management system (IDM) and has obtained access to the Open Payments system.
- Reporting entity is registered in the Open Payments system.
- Reporting entity has recertified in the Open Payments system, if necessary.
- User who submits payment information holds the submitter user role for the reporting entity.

Types of Payments

Open Payments categorizes payments and transfers of value into three payment types. For a complete list of all data elements collected for each payment type, including detailed descriptions for each field, refer to the Submission Data Mapping Documents located on the Resources for Reporting Entities page of the Open Payments website).

A general description of the payment types is shown below.

- **General Payments**: Payments or other transfers of value made that are not in connection with a research agreement or research protocol.
- **Research Payments**: Payments or other transfers of value made in connection with a formal research agreement or research protocol.
- **Ownership/Investment Interests**: Information about ownership or investment interest that physicians or the physician's immediate family members have in reporting entities.

Note: Applicable GPOs should not submit general or research payment records for physicians without submitting an ownership/investment interest record for that same physician for that program year.



Actions

Step 1: Confirm Demographic Information in Records

- Prior to data submission, check the demographic information for each physician, non-physician practitioner (NPP) and teaching hospital. To assist with this validation, CMS provides a Validated Physician List (VPL), Non-Physician Practitioner List (NPPL) and CMS Teaching Hospital Lists.
 VPL Notes: The VPL zip file consists of two comma separated values (CSV) VPL files; one for Physicians with a National Provider Identifier (NPI) and the other for Physicians without an NPI. The VPL zip file also includes a supplement file for each reportable program year that includes inactive licenses for each physician for that the corresponding program year.
- The VPL can only be accessed within the Open Payments system, on the "Submissions" tab. The VPL is not an exhaustive list of all physicians who should be included in Open Payments reporting.
- Physicians who do not appear on the VPL may still be successfully matched. The VPL is merely a tool to help prepare records. Check with the National Plan and Provider Enumeration System (NPPES) for information on physicians that cannot be found on the VPL.

NPPL Notes

- The NPPL is a reference data file in CSV format, which includes 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).
- The NPPL can only be accessed within the Open Payments system, on the "Submissions" tab. The NPPL is **not** an exhaustive list of all NPPs who should be included in Open Payments reporting.
 - NPPs who do not appear on the NPPL may still be successfully matched. The NPPL is merely a tool to help prepare records. Check with the National Plan and Provider Enumeration System (NPPES) for information on NPPs that cannot be found on the NPPL.

Teaching Hospital List Notes:

• The Teaching Hospital Lists (listed by reporting cycle) include all teaching hospitals that should be included in Open Payments reporting. The Teaching Hospital Lists can be accessed via the Resources for Reporting Entity page

(<u>https://www.cms.gov/OpenPayments/Resources/Reporting-Entities</u>) on the Open Payments website. Select the teaching hospital list for the program year you are submitting data for, and then select a corresponding teaching hospital from that list.

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

Step 2a: Perform Manual Data Entry

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

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.

Note:

- Manual data entry does not complete the submission process. Once a record is manually entered, it must undergo final submission and attestation for the submission to be complete.
 Refer to the quick reference guide "Final Submission and Attestation" for additional guidance.
- 2. Program years that are older than seven years from the current program year will no longer be eligible for submissions and are considered closed program year(s). Reporting entities can only view previously submitted records for closed program years.

Manual Entry of General Payments Data

- 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 and then select the "Manual Data Entry" button on the "Submissions" landing page.
- 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 you wish to enter. Select the "Continue" button to proceed to the "Covered Recipient Demographic Information" page.
 - a) "Home System Payment ID" is an optional field that can be used to enter the ID number that your reporting entity uses to identify the payment.
- 3. On the "Covered Recipient Demographic Information" page select either "Physician", "Non-Physician-Practitioner", or "Teaching Hospital" as appropriate from the "Covered Recipient Type" drop-down, and enter the demographic information related to the physician or NPP or teaching hospital. Refer to the Validated Physician List (VPL), Non-Physician Practitioner List (NPPL) and CMS Teaching Hospital Lists.
- 4. Select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to the "Associated Related Products" page.



- a) For Program Years 2016-2020 select either "Yes" or "No" from the Related Product Indicator drop-down. If "Yes" is selected, the "Associated Drug, Device, Biological, or Medical Supply Information" section is displayed.
- b) For Program Years 2021-2022 select either "Yes" or "No" from the Related Product Indicator drop-down. If "Yes" is selected, the "Associated Drug, Device, Biological, or Medical Supply Information" section is displayed.
- c) For Program Years 2023 and onwards select either "Yes" or "No" from the Related Product Indicator drop-down. If "Yes" is selected, the "Associated Drug, Device, Biological, or Medical Supply Information" section is displayed.

Enter information for the "Associated Drug, Device, Biological, or Medical Supply Information" section. All required fields are marked with an asterisk (*).

The Drug Name and National Drug Code (NDC) reference file and PDF Instructions document are zipped together and are available within the Open Payments system Resources tab for all users to download.

The Medical Device and Medical Supply Name and Primary Device Identifier reference file and PDF instructions document are zipped together and are available within the Open Payments system Resources tab for all users to download.

- For Program Years 2016-2020, and Program Years 2021 and Onwards "Product Category or Therapeutic Area" information is required if you select "Yes" for "Related Product Indicator" and "Covered" for "Covered or Non-Covered Product Indicator". Based on your selections on the page, corresponding fields are displayed for data selection/entry. If the product has an NDC, enter it in the "Associated Drug or Biological NDC" field.
 - A maximum of **five** products (i.e., drug, device, biological or medical supply) can be added for a record.

Note: Special characters not present on standard English-language keyboards are not permitted in the text fields.

Select the "Add" button to save the information for each product added.

The record will receive a hard error after the user clicks "Add" to add a product if the Drug or Biological Name entered by the user is not valid against the CMS approved dataset OR if the NDC is provided but the Drug or Biological Name and NDC <u>combination</u> is not valid against the CMS approved dataset. The user must correct the error before adding another product or before proceeding with the submission process.

The record receives a hard error if the Medical Device or Medical Supply Name and Primary Device Identifier entered by the user is not valid against the CMS approved dataset. The user must correct the error before adding another product or before proceeding with the submission process. 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.



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.

- 5. Enter all required information on the "General Payment or Other Transfer of Value Information" page. Select the "Continue" button or the "General Information" icon on the "Payment Navigation Bar" to proceed to the "General Record Information" page.
- 6. Enter all required information on the "General Record Information" page.
 - a) Users may request a delay in publication if the payment meets certain conditions.
 - b) Per the Final Rule, records can only be delayed from publication for 4 years from the year of payment (i.e., the record's program year). Refer to *Table 1* for details on the calendar year in which the program year is not eligible for delay in publication.
 - c) If a delay is requested for an ineligible record, the system will not accept the record and will display an error message.
 - d) Refer to the quick reference guide "Requesting or Updating a Delay in Publication" for details on what records are eligible and how delays function.
- 7. Select the "Continue to Review" button or the "Review & Save" icon on the "Payment Navigation Bar" to proceed to the "Review and Save" page.
- 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 item from "Payment Navigation Bar", located on top of the page, to go directly to the desired page.
- 9. Once the record is accurate, select the "Save Record" button on the "Review and Save" page to submit the record for matching validations.

Manual Entry of Research Payments Data

- 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 and then select the "Manual Data Entry" button on the "Submissions" landing page.
- 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 you wish to enter. Select the "Continue" button to proceed to the "Recipient Demographic Information" page.
 - a) "Home System Payment ID" is an optional field that can be used to enter the ID number that your reporting entity uses to identify the payment.
- 3. On the "Recipient Demographic Information" page select "Covered Recipient Physician," "Covered Recipient Non-Physician-Practitioner," "Covered Recipient Teaching Hospital," "Non-Covered Recipient Entity," or "Non-Covered Recipient Individual" from the Recipient Type drop-down. Enter corresponding demographic information related to the recipient.



Note: Demographic information is not requested for "Non-Covered Recipient Individual". Proceed to Step 4.

- 4. Select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to the "Associated Related Products" page.
 - a) For Program Years 2016-2020, select either "Yes" or "No" from the Related Product Indicator drop-down. If "Yes" is selected, the "Associated Drug, Device, Biological, or Medical Supply Information" section is displayed.
 - b) For Program Years 2021 -2022select either "Yes" or "No" from the Related Product Indicator drop-down. If "Yes" is selected, the "Associated Drug, Device, Biological, or Medical Supply Information" section is displayed.
 - c) For Program Years 2023 and onwards select either "Yes" or "No" from the Related Product Indicator drop-down. If "Yes" is selected, the "Associated Drug, Device, Biological, or Medical Supply Information" section is displayed.

Enter information for the "Associated Drug, Device, Biological, or Medical Supply Information" section. All required fields are marked with an asterisk (*).

The Drug Name and National Drug Code (NDC) reference file and PDF Instructions document are zipped together and made available within the Open Payments system Resources tab for all users to download.

The Medical Device and Medical Supply Name and Primary Device Identifier reference file and PDF instructions document are zipped together and are available within the Open Payments system Resources tab for all users to download.

- For Program Years 2016 and onward "Product Category or Therapeutic Area" information is required if you select "Yes" for Related Product Indicator and "Covered" for "Covered or Non-Covered Product Indicator". Based on your selections on the page, corresponding fields are displayed for data selection/entry. If the product has an NDC, enter it in the "Associated Drug or Biological NDC" field.
 - A maximum of **five** products (i.e., drug, device, biological or medical supply) can be added for a record.

Note: Special characters that are not on standard English-language keyboards are not permitted in the text fields.

Select the "Add" button to save the information for each product added.

The record will receive a hard error after the user clicks "Add" to add a product if the Drug or Biological Name entered by the user is not valid against the CMS approved dataset OR if the NDC is provided but the Drug or Biological Name and NDC <u>combination</u> is not valid against the CMS approved dataset. The user must correct the error before adding another product or before proceeding with the submissions process.



The record receives a hard error if the Medical Device or Supply Name and Primary Device Identifier entered by the user is not valid against the CMS approved dataset. The user must correct the error before adding another product or before proceeding with the submissions process. 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.

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.

- 1. Enter all required information on the "Research Payment or Other Transfer of Value Information" page.
 - a) Users may request a delay in publication if the payment meets certain conditions.
 - b) Per the Final Rule, records can only be delayed from publication for 4 years from the year of payment (i.e., the record's program year). Refer to *Table 1* for details on the calendar year in which the program year is not eligible for delay in publication.
 - c) If a delay is requested for an ineligible record, the system will not accept the record and will display an error message.
 - d) Refer to the quick reference guide "Requesting or Updating a Delay in Publication" for details on what records are eligible and how delays function.
- 2. Select the "Continue" button or the "Principal Investigator Demographics" icon on the "Payment Navigation Bar" to proceed to the "Principal Investigator Demographic" page.
 - a) Beginning from Program Year 2021, "Principal Investigator Covered Recipient Type" is required.
 - b) At least one Principal Investigator is required when the recipient type is a "Non-Covered Recipient Entity" or "Non-Covered Recipient Individual."
- 3. Select the "Continue to Review" button or the "Review & Save" icon on the "Payment Navigation Bar" to proceed to the "Review and Save" page.
- 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 item from the "Payment Navigation Bar", located on top of the page, to go directly to the desired page.
- 5. Once the record is accurate, select the "Save Record" button to submit the record for matching validations.



Manual Entry of Ownership/Investment Interests Data

- 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 and then select the "Manual Data Entry" button on the "Submissions" landing page.
- 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 you wish to enter. Select the "Continue" button to proceed to the "Physician Demographic Information" page.
 - a) "Home System Payment ID" is an optional field for you to provide the identification number that your reporting entity uses to identify the payment.
- 3. Enter all required information on the "Physician Demographic Information" page.
- 4. 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.
- 5. Enter all required information on the "Ownership or Investment Information" page.
- 6. Select the "Continue to Review" button or the "Review & Save" icon on the "Payment Navigation Bar" to proceed to the "Review and Save" page.
- 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 item from the "Payment Navigation Bar", located on top of the page, to go directly to the desired page.
- 8. Once the record is accurate, select the "Save Record" button to submit the record for matching validations.

Step 2b: Copy/Duplicate Record

- Select "Copy" to make a duplicate copy of the payment record through the User Interface (UI). The "Copy" hyperlink is in the "Payment Category" page, record view grid for every record under the Action column, regardless of the record status. The "Copy" buttons are on the view "Record ID" page.
- 2. The user can update the program year on the newly copied record on the "Payment Overview" page. The payment category of the copied record will not be editable.
- 3. Follow all Manual Data Entry steps from step 3 onwards as needed to update the copied record. The copied record will have to be saved for successful creation of the record.

Step 3: Review Records

 Log in to the Open Payments system via the CMS Enterprise Portal at <u>https://portal.cms.gov/</u>. Select the "Submission" tab on the menu bar. Under "Review Submitted Payment Records," select the payment type, reporting entity and program year you wish to view, then select "Review Detail". This brings you to the selected "Payment Category" page.



2. Select the "Record ID" link for an individual record on the "Payment Category" page to view record details. Licenses that expired during the program year will display expired license warning message(s) on the individual record's "Record ID" page.

In addition, these records will be flagged with a warning icon on the "Payment Category" page. **Note:** License Warnings will only be displayed for the payment records that were successfully matched. 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.

The "Record ID" page for records that failed matching will contain an error message that explains the matching error(s). Note: The "Record ID" page also displays a warning message, when the record is in "Ready for Submission" status and contains any expired license(s) for the reported program year.

Step 4: Perform Final Submission and Attestation

1. Once records are successfully processed, they must undergo final submission and attestation in the Open Payments system to be considered submitted.

Record(s) can undergo Final Submission if at least one record is in "Ready for Submission" status and no records are in "System Processing" status. Only records in "Ready for Submission" status will be updated to "Ready for Attestation". A record can undergo attestation only when all records for that program year are in "Ready for Attestation" or "Attested" status. Refer to the quick reference guide "Final Submission and Attestation" for additional guidance.

Next Steps

- Correct data submission errors, if necessary
- Complete final submission and attestation

Additional Resources

Table 1 lists the program years which are not eligible for delay in publication renewal and program years not eligible for submission in a given calendar year:

Calendar Year	Program Years- Not Eligible for delay in publication renewal	Program Years- Not Eligible for Submissions
2018	2013	N/A
2019	2013 and 2014	2013
2020	2013, 2014 and 2015	2013 and 2014
2021	2013, 2014, 2015 and 2016	2013, 2014 and 2015
2022	2013, 2014, 2015, 2016 and 2017	2013, 2014, 2015 and 2016

Table 1: Delay in Publication and Submissions Not Eligible Program Years per Calendar Year



Data submission resources can be found on the Resources page

(<u>https://www.cms.gov/OpenPayments/Resources</u>) and for the Reporting Entities page (<u>https://www.cms.gov/OpenPayments/Resources/Reporting-Entities</u>) of the CMS Open Payments website.

The Open Payments User Guide for Reporting Entities covers the entire data submission process in detail and provides step-by-step instructions for various scenarios.

Quick reference guides relevant to data submission and your next steps include:

- Identifying Validation and Matching Errors
- Correcting Validation and Matching Errors
- Record Deletion
- Consolidated Reporting
- Payment Category Page
- Requesting or Updating a Delay in Publication
- Final Submission and Attestation



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 reporting entities on how to submit payments or other transfers of value and ownership or investment interests information via manual data entry.
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