# Open Payments System Quick Reference Guide
# Manual Data Entry

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## 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 CMS Enterprise Identity Management system (EIDM) 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 page of the Open Payments website (https://www.cms.gov/OpenPayments/About/Resources.html).

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 their 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 (including principal investigator) and teaching hospital, included in the records to ensure that it is current. To assist with this validation, CMS provides a Validated Physician List (VPL) and CMS Teaching Hospital Lists.

- The VPL zip file consists of two character separated values (CSV) VPL files; one for Physicians with an 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. Note: 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.
- The Teaching Hospital Lists (listed by reporting cycle) include all teaching hospitals that should be included in Open Payments reporting. It can be accessed via the Resources page (https://www.cms.gov/OpenPayments/About/Resources.html) 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.
    - For Program Years 2014 and later, use the hospital's "Doing Business As" name as the hospital name in the submitted record. The "Doing Business As" name is found in the Teaching Hospital List under the heading of "Hospital Name."
    - For 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. Note that 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 are able to utilize the "Payment Navigation Bar", located on top of the record, to go directly to a specific page, assuming there are no errors on the page they are currently on.

**Note: Manual data entry does not complete the submission process. Once a record is manually entered, it must then undergo final submission and attestation for the submission to be complete.** Refer to the quick reference guide "Final Submission and Attestation" for additional guidance.

### *Manual Entry of General Payments Data*

1. Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/. Select the "Submissions" tab on the menu bar and then select the "Manual Data Entry" button on the "Submissions" landing page.
2. On the "Add Payment" page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year for the record you wish to enter. Select the "Continue" button to proceed to "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" or "Teaching Hospital" as appropriate from the Covered Recipient Type drop-down, and enter the demographic information related to the physician or teaching hospital. Refer to the Validated Physician List (VPL) and CMS Teaching Hospital Lists.
4. Select the "Continue" button or the "Products" icon on the "Payment Navigation Bar" to proceed to "Associated Related Products" page.
   a. For Program Years 2013 to 2015 select "Covered", "Non-Covered", "None", or "Combination" from Product Indicator drop-down.
   b. For Program Years 2016 and Onwards select either "Yes" or "No" from the Related Product Indicator drop-down. If "Yes" is selected "Associated Drug, Device, Biological, or Medical Supply Information" section is displayed.
5. 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.

**Note**: there are significant changes between Program Years 2013-2015 and Program Year 2016 and Onwards:

a. For Program Years 2013 to 2015 you may only enter up to five associated covered drugs/biologicals and up to five devices/medical supplies per record.
    i. A maximum of ten products (i.e. drug, device, biological or medical supply) can be added for a record.
b. Note: You must provide the name of the covered drug or biological when providing a National Drug Code (NDC) for that covered drug or biological in a valid format.
    i. For Program Year 2016 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.
c. 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.**

6. Select the "Add" button to save the information for each product added.
7. 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.

   **NOTE**: The record receives the warning 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 combination is not valid against the CMS approved dataset.
8. Enter all required information on the "General Payment or Other Transfer of Value Information" page.
    a. Select the "Continue" button or the "General Information" icon on the "Payment Navigation Bar" to proceed to the "General Record Information" page.
9. Enter all required information on the "General Record Information" page.
    a. 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 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.
    b. If a delay is requested for an ineligible record, the system will not accept the record and will display an error message.

   c. Refer to the quick reference guide "Requesting or Updating a Delay in Publication" for details on what records are eligible and how delays function.
10. Select the "Continue to Review" button or the "Review & Save" icon on the "Payment Navigation Bar" to proceed to the "Review and Save" page.
11. 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.
12. 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*

1. Log in to the Open Payments system, via the CMS Enterprise Portal at https://portal.cms.gov/. Select the "Submissions" tab on the menu bar and then select the "Manual Data Entry" button on the "Submissions" landing page.
2. On the "Add Payment" page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year for the record you wish to enter. Select the "Continue" button to proceed to "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 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 "Associated Related Products" page.
   a. For Program Years 2013 to 2015 select "Covered", Non-Covered", "None", or "Combination" from Product Indicator drop-down.
   b. For Program Years 2016 and onwards select either "Yes" or "No" from the Related Product Indicator drop-down. If "Yes" is selected "Associated Drug, Device, Biological, or Medical Supply Information" section is displayed.
5. Enter information for the "Associated Drug, Device, Biological, or Medical Supply Information" section. All required fields are marked with an asterisk (*).
6. 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.
Note: there are significant changes between Program Years 2013-2015 and Program Year 2016 and onwards:

a. For Program Years 2013 to 2015 you may only enter up to five associated covered drugs/biologicals and up to five devices/medical supplies per record.
    i. A maximum of ten products (i.e. drug, device, biological or medical supply) can be added for a record.
    Note: You must provide the name of the covered drug or biological when providing a National Drug Code (NDC) for that covered drug or biological in a valid format.
b. For Program Year 2016 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.
    i. 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.**

7. Select the "Add" button to save the information for each product added.
8. 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.
NOTE: The record receives the warning 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 combination is not valid against the CMS approved dataset. 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.
    Note: 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.
    b. If a delay is requested for an ineligible record, the system will not accept the record and will display an error message.
    c. Refer to the quick reference guide "Requesting or Updating a Delay in Publication" for details on what records are eligible and how delays function.
9. Select the "Continue" button or the "Principal Investigator Demographics" icon on the "Payment Navigation Bar" to proceed to "Principal Investigator Demographic" page.

    a. At least one Principal Investigator is required when the recipient type is a “Non-Covered Recipient Entity” or “Non-Covered Recipient Individual.”

10. Select the “Continue to Review” button or the “Review & Save” icon on the “Payment Navigation Bar” to proceed to the “Review and Save” page.
11. 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.
12. Once the record is accurate, select the “Save Record” button to submit the record for matching validations

### *Manual Entry of Ownership/Investment Interests Data*

1. Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/. Select the "Submissions" tab on the menu bar and then select the "Manual Data Entry" button on the "Submissions" landing page.
2. On the "Add Payment" page, use the drop-down menus to select the Payment Category, Entity Making Payment Registration Name, and Program Year for the record you wish to enter. Select the "Continue" button to proceed to "Physician Demographic Information" page.
   - "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.
7. 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.
8. Once the record is accurate, select the "Save Record" button to submit the record for matching validations.

### Step 2b: Copy/ Duplicate Record

1. 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 and 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

1. Log in to the Open Payments system via the CMS Enterprise Portal at https://portal.cms.gov/. Select the "Submissions" tab on the menu bar. Under the "Review Submitted Payment Records" section of the page, select the reporting entity and program year of the records to be reviewed, then select the "Review Records" button.
2. The "Review Records" page displays the total number of records in each record status for the program year, sorted by payment category.
3. 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.
4. Select the "Record ID" link for an individual record on the "Payment Category" page to view record details. Licenses that were expired during the program year will display expired license warning message(s) on the individual record's "Record ID" page. Warnings pertaining to Drug name and/or NDC will also be displayed 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

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

Note: 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 in a given calendar year:

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

| Calendar Year | Program Years- Not Eligible for delay in publication renewal |
|---|---|
| 2018 | 2013 |
| 2019 | 2013 and 2014 |
| 2020 | 2013, 2014 and 2015 |
| 2021 | 2013, 2014, 2015 and 2016 |

All data submission resources can be found on the Resources page of the CMS Open Payments website at https://www.cms.gov/OpenPayments/About/Resources.html.

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