



Open Payments

Expansion of Covered Recipients, Validating and Standardizing Medical Devices, & Natures of Payments

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

November 2020

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.

Agenda

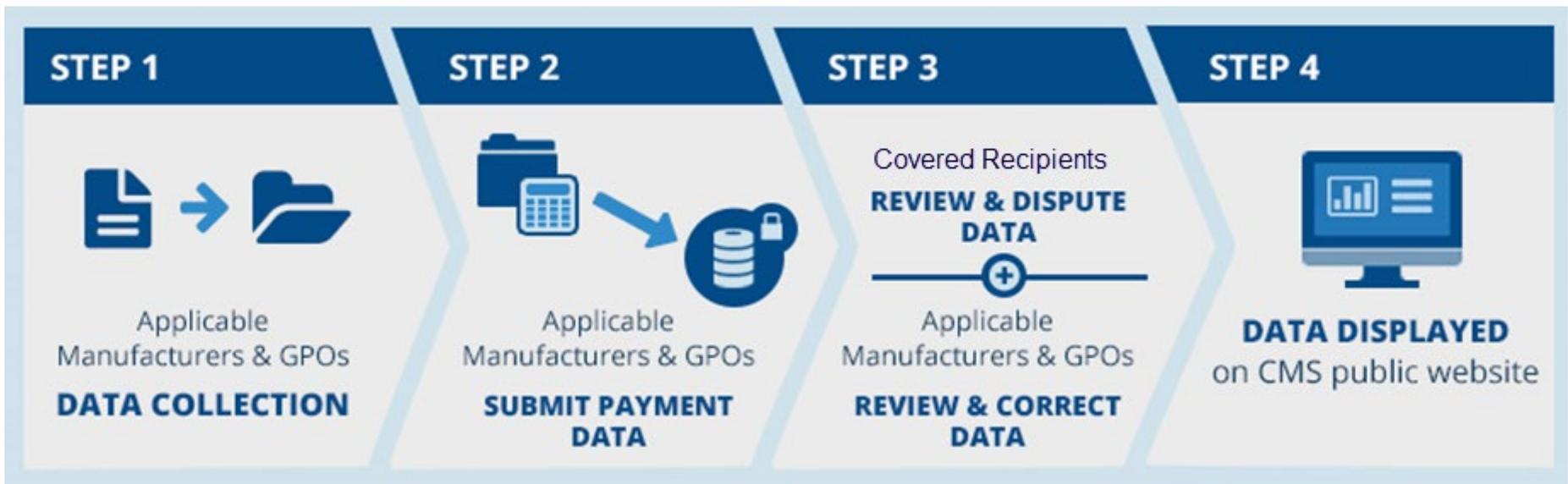
- Target Audience & Learning Objectives
- Open Payments Program
- Open Payments Definitions
- Expansion of Covered Recipients
- Validating and Standardizing Medical Devices
- Natures of Payment
- Available Resources

Target Audience & Learning Objectives

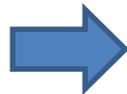
- Target audience:
 - Reporting entities who want to gain an understanding of the addition of the new Covered Recipient Non-Physician Practitioner types in the Open Payments System
- Learning objectives:
 - Understand a high-level overview of how Non-Physician Practitioners are introduced in to the Open Payments program
 - Learn how the Open Payments System validates medical devices and medical supplies
 - Understand the updated information on Nature of Payment categories

Open Payments Program

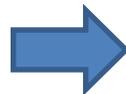
Open Payments Process Flow



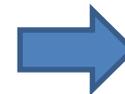
Reporting entities annually collect payment data for a program year, (January 1 to December 31.)



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.



Data is published for public viewing in accordance with the publication guidelines.

Open Payments Definitions

Reporting Entities and Covered Recipients

- **Reporting Entity** 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 Recipient*** refers to Physicians, Non-Physician Practitioners, and Teaching Hospitals receiving payments or other transfers of value from applicable manufacturers and applicable group purchasing organizations (AM/GPOs)

*The term “Covered Recipient” now includes Non-Physician Practitioners along with Physicians and Teaching hospitals in the Open Payments program

Covered Recipients: Non-Physician Practitioner

The Open Payments program will expand 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.

Covered Recipients: Non-Physician Practitioner

- **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.

Covered Recipients: Non-Physician Practitioner (Contd.)

- **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

Expansion of Covered Recipients

Expansion of Covered Recipients

- Beginning in Program Year 2021 (January 1, 2021 – December 31, 2021), certain payments or transfers of value made by reporting entities to individuals that meet the definition of a covered recipient, including the five new provider types as added by the SUPPORT Act, will be reportable for the purpose of Open Payments
- Applicable Manufacturers can report on Non-Physician Practitioners for general and research payment categories only
- Group Purchasing Organizations (GPOs) cannot report any general, research payment or ownership/investment for Non-Physician Practitioners, however they can report on Non-Physician Practitioners as a Principal Investigator on the research payment
- Reporting entities will submit the data collected in calendar year 2021 to CMS in calendar year 2022. Covered recipients will have the opportunity to review and if necessary, dispute the data prior to the annual data publication

Validating and Standardizing Medical Devices

Validating and Standardizing Medical Devices

- For Program Year 2021, the Open Payments system will validate medical device and medical supply data
- The new field of “Primary Device Identifier” has been added to the Associated Related Products page for general and research payments only

Associated Drug, Device, Biological, or Medical Supply Information

*Covered or Non-Covered Product Indicator:	Indicate Drug, Device, Biological, or Medical Supply:	Product Category or Therapeutic Area:
<input type="text" value="Please Select"/>	<input type="text" value="Please Select"/>	<input type="text"/>
Marketed Name of Drug, Device, Biological, or Medical Supply:	Associated Drug or Biological NDC: 9999-9999-99 OR 99999-999-99 OR 99999-9999-9 ?	Primary Device Identifier: ?
<input type="text"/>	<input type="text"/>	<input type="text"/>

Add

Validating and Standardizing Medical Devices (Conti.)

- The name of the marketed medical device or medical supply must be provided when:
 - The product indicator is selected as covered
 - The product indicator is selected as non-covered and the Primary Device Identifier is provided

Associated Drug, Device, Biological, or Medical Supply Information

* Covered or Non-Covered Product Indicator: Please Select ▾	Indicate Drug, Device, Biological, or Medical Supply: Please Select ▾	Product Category or Therapeutic Area: <input type="text"/>
Marketed Name of Drug, Device, Biological, or Medical Supply: <input type="text"/>	Associated Drug or Biological NDC: 9999-9999-99 OR 99999-999-99 OR 99999-9999-9	Primary Device Identifier: <input type="text"/>

Add

Validating and Standardizing Medical Devices (Conti.)

- On general and/or research payment records, the system generates a warning, if the Medical Device or Medical Supply Name and Primary Device Identifier combination is not valid. However, the user can continue with the record submission without fixing the warning message(s)

The screenshot displays a web application interface for "Open Payments (Sunshine Act)". A modal window with a dark blue header and a white body is centered on the screen. The header contains a warning icon and the text "Attention:". The body text reads: "The following warning(s) has been identified during Medical Device and/ or Medical Supply Name and Primary Device Identifier validation against the CMS approved data source- GUIDID dataset when the record is processed. Make corresponding correction(s) as necessary to successfully match the Device and Medical Supply name/ Primary Device Identifier in the record and to clear the warning(s). The record can still be successfully submitted with these warnings." Below this text is a bulleted list: "Warning: The Marketed Name of Drug, Device, Biological, or Medical Supply and Primary Device Identifier combination does not match. (Device : A123)". At the bottom of the modal, there are two buttons: "Edit" and "Continue". The background interface shows a sidebar with "Home", "Add Research", "Overview", and "Associated Re" buttons. The main content area has a "Review & Save" button. At the bottom of the page, there is a note: "Select 'Yes' or 'No' from the Related Product Indicator drop-down list. If 'Yes' is selected, enter the applicable information for the Associated covered drugs, devices, biologicals, or medical supplies. Select 'Add' after completing each entry. At least one product must be added if the Related Product Indicator value is set to 'Yes'. You may enter up to five drugs, biologicals, devices, or medical supplies for each record. To Download the list(s) of Drug Names & National Drug Codes (NDC) and/or Medical Device or Medical Supply Names and Primary Device Identifiers with respective instruction document(s), see the Resources tab."

Validating and Standardizing Medical Devices (Conti.)

- The “List of Medical Device or Supply Name and Primary Device Identifier” CSV reference file and Instructions document PDF is available for users on the Open Payments System Resources page and the CMS Open Payments website Resources 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

Open Payments Resources

Links to the Open Payments resources are available below.

For help obtaining a PDF viewer, go to the [CMS.gov Help](#) page.

Resources

- [Open Payments User Guide for Reporting Entities \[PDF\]](#)
- [Open Payments User Guide for Covered Recipients \[PDF\]](#)
- [Open Payments FAQ's \[PDF\]](#)
- [CMS Resources Website](#)
- [Error Code Key \[XLSX\]](#)
- [List of Drug Names and National Drug Codes \(NDC\)](#)
- [List of Medical Device or Medical Supply Names and Primary Device Identifier](#)

Reporting Templates

Report templates are available through the links below. Download the template(s) for the program year(s) and payment category/categories for the records to be submitted. The system will reject files prepared with an incorrect payment category or program year template.

Research

- [PY 2013 - 2015 CSV Template File: Research Payments \[CSV\]](#)
- [PY 2016 - 2020 CSV Template File: Research Payments \[CSV\]](#)
- [PY 2021 and Onwards CSV Template File: Research Payments \[CSV\]](#)

General

- [PY 2013 - 2015 CSV Template File: General Payments \[CSV\]](#)
- [PY 2016 - 2020 CSV Template File: General Payments \[CSV\]](#)
- [PY 2021 and Onwards CSV Template File: General Payments \[CSV\]](#)

Ownership

- [PY 2013 and Onwards CSV Template File: Physician Owner/Investor \[CSV\]](#)

Natures of Payment

Natures of Payment

- The Open Payments program will include new categories and combine categories of Natures of Payment specifically for Program Year 2021-Onwards
- The following three new Nature of Payment categories will be added for Program Year 2021-Onwards:
 - Debt Forgiveness
 - Long-Term Medical Supply or Device Loan
 - Acquisitions
- The three new Nature of Payment categories will operate prospectively and will *not* be reportable for previous Program Years 2013-2020

Nature of Payment - Combined Categories

- The following two Nature of Payment categories are now combined and named as **“Compensation for serving as faculty or as a speaker for a medical education program”**
 - Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
 - Compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program
- The above two Nature of Payment categories will be reportable and editable for Program Years 2013 – 2020
- The above two Nature of Payment categories will be reportable under the new category name beginning with Program Year 2021 data submission and subsequent Program Years

Available Resources

- Explore the Resources Page for more Open Payments information including tutorials and FAQs
 - <https://www.cms.gov/OpenPayments/About/Resources>
- Subscribe to the Listserv
 - Receive program updates through the Open Payments listserv
 - Subscribe at our Contact Us Page (<https://www.cms.gov/OpenPayments/Contact-Us/Contact-Us>)
- Visit the Changes for Reporting Entities Page for the latest news and resources regarding the program expansion
 - <https://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Changes-for-Reporting-Entities>
- Open Payments Help Desk:
 - Email: openpayments@cms.hhs.gov
 - Call: 1-855-326-8366 (TTY Line: 1-844-649-2766)

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 anyway, 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 on Expansion of Covered Recipients (EOCR), Device and Natures of payment (NOP) for Program Year 2021 and onwards.
- **Date of document issuance:** January 22, 2021
- **Replacement / Revision Status:** New
- **Agency Identifier:** CPI DSPG DDI 356
- **Summary of Document:** An overview of Expansion of Covered Recipients (EOCR), Device reporting and Natures of Payment (NOP) for Program Year 2021 and onwards.
- **Citation to statutory provision/regulation applicable to this document:**
 - **Statute citation:** SEC. 1128G. [42 U.S.C. 1320a-7h]
 - **Rule citation:** 42 C.F.R. §403.900-14