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

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 into 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.
• **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.
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
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 “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.
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
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 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