

OPEN PAYMENTS

Creating public transparency into industry –
provider financial relationships

2021 Program Expansion

Open Payments Team

December 16, 2020

Centers for Medicare & Medicaid Services
Center for Program Integrity



About Open Payments

- Open Payments is a national disclosure program that promotes a transparent and accountable healthcare system.
- Each year applicable manufacturers and group purchasing organizations (GPOs) collect data regarding payments or transfers of value they have made to physicians and teaching hospitals. Then in the following calendar year they submit this information to CMS for publication.

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 group purchasing organizations (GPOs).

- Covered recipients

- Currently refers to physicians and teaching hospitals receiving payments or other transfers of value from reporting entities.
- Beginning in January 2021, “covered recipients” will include: Physician assistants, Nurse practitioners, Clinical nurse specialists, Certified registered nurse anesthetists (including Anesthesiologist assistants) and Certified nurse-midwives.

Program Year 2020 Timeline

OPEN PAYMENTS

Program timeline



Program Year 2019 Data Publication

Program Year 2019 Data Publication



Total U.S. Dollar Value

\$10.03 Billion



Total Records Published

10.98 Million



General Payments
\$3.56 Billion



Research Payments
\$5.23 Billion



Ownership & Investment
\$1.24 Billion

- On June 30, 2020, CMS published the Program Year 2019 data, as well as newly submitted and updated records from previous program years.
- The Program Year 2019 data publication marks the seventh Open Payments Program reporting cycle.
- The data will be refreshed in early January 2021 to reflect any changes that occurred after the initial data publication.

Stakeholders for Program Year 2019



Physicians Receiving Payments

- 615,000



Teaching Hospitals Receiving Payments

- 1,196



Companies Making Payments

- 1,602

COVID-19 Reporting Impacts

- **Include the phrase “COVID-19 Impact” in your assumptions statement with the explanation of circumstances and, if applicable, include reference to any related help desk ticket numbers. This will be used to help evaluate potential cases of non-compliance.**
- *Remember: your organization is still required to submit and attest to all reportable calendar year 2019 data as soon as possible.*
- The full Open Payments COVID-19 announcement is available at: <https://www.cms.gov/OpenPayments/FAQs/FAQs-openpayments>
- CMS will not know the impacts of COVID-19 on reporting until the data is analyzed after the June 2021 publication.

SUPPORT for Patients and Communities Act

- The SUPPORT Act was passed in the fall of 2018 and included new Open Payments provisions.
- Covered Recipient definition expanded to include:
 - Physician Assistants
 - Nurse Practitioners
 - Clinical Nurse Specialists
 - Certified Registered Nurse Anesthetists & Anesthesiologist Assistants
 - Certified Nurse-Midwives
- Publication of National Provider Identifiers (NPIs)
- This is effective for data collection beginning in calendar year 2021.
(Program Year 2021 data will be reported to CMS in 2022)

Additional Program Updates Beginning in 2021

- Reporting Requirements for the 'device identifier' component of the unique device identifier for devices and medical supplies
- Nature of Payment Updates
 - Three new categories will be added:
 - Debt forgiveness
 - Long term medical supply or device loan
 - Acquisitions
 - The two categories related to medical education programs will be combined into one single category.

Preparing for 2021 – Device Reporting

- There are preliminary resources available to help you prepare for the new device reporting requirements. Access these on the [Changes for Reporting Entities page](#).
- **Preliminary Medical Device and Medical Supply Reference Data**
 - This preliminary reference data includes medical device and medical supply names and Primary Device Identifier Information for all the medical device and medical supplies listed in the Food and Drug Administration (FDA) Global Unique Device Identification Database Directory (GUDID) through June 30, 2020.
- **Medical Device and Medical Supply Name and Primary Device Identifier Instructions Document**
 - The instructions document provides details about the use of the Device Name and Primary Device Identifier dataset.
- **Device Reporting FAQs**
 - A selection of frequently asked questions and CMS answers specific to device data reporting
 - Includes new FAQ #2007

Device Reporting FAQ Summary

- **FAQ #2007:** Which marketed names and device identifiers should an entity report when a single transaction is related to multiple products or multiple device identifiers?
 - If one payment or transfer of value is associated with multiple devices, up to five can be reported. Each product may be reported with a combination of the marketed name (brand name) and one device identifier. The reporting entity determines the combination(s), but are encouraged to note any assumptions made or methodologies used to determine which device brand names and device identifiers to report in the assumptions statement.
- Additional FAQs related to device reporting: #8258, #9132, #8392, and #9124.

Preparing for 2021 – Covered Recipient Expansion

- A series of new FAQs related to reporting on the added covered recipients is available on the [Changes for Reporting Entities](#) page
 - New FAQs: #2008, #2009, #2010, #2011, #2012 and #2013
- Preliminary Program Year 2021 Data Submission Mapping Document
- Preliminary Program Year 2021 Change Summary Document
- Preliminary Sample Files for Program Year 2021
- Taxonomy Code List including taxonomies for non-physician practitioners

Preliminary Non-Physician Practitioner List

- Preliminary Non-Physician Practitioner List (PnPPL)
 - This list is designed to help reporting entities pre-validate their data before submitting it to CMS
 - Similar to the Validated Physician List, the PnPPL represents a subset of all reportable providers
 - Includes identifying information for providers registered in CMS systems

Note: The PnPPL is accessible within the Open Payments system. You must be registered and affiliated with a reporting entity within the system to access the PnPPL.

Covered Recipient Expansion FAQ Summary

- **FAQ #2008:** Some states do not have separate licensing programs for some of the non-physician practitioner types. How should reporting entities decide which provider type to report for a given provider if it is not specified in the data?
 - Reporting entities should use their best knowledge of the provider and the credential(s) the provider practices under, and follow the definitions provided in the final rule (42 C.F.R. §403.902) to make determinations on which providers are reportable, regardless of whether they are identified in reference data sources.
- **FAQ #2009:** Will reporting entities be required to identify the specific types of non-physician practitioners in their reports?
 - Yes, reporting entities will be required to specify at least one provider type for each reported non-physician practitioner and will be allowed to make multiple selections for providers who carry multiple credentials.

Covered Recipient Expansion FAQ Summary Cont'd

- **FAQ #2010:** Will all non-physician practitioners be required to obtain National Provider Identifier (NPI) numbers?
 - No, Open Payments does not require non-physician practitioners to obtain NPIs.
- **FAQ #2011:** How should I report non-physician practitioners that do not have NPIs?
 - For non-physician practitioners without an NPI, reporting entities may report up to 5 state licenses on the payment record.
 - Matching will be performed based on the combination of first name, last name, and state license information. Please note that reported providers do not have to have a specific PA, NP, CNS, CRNA or CNM credential associated with their state license to be successfully validated. CMS is aware that not all states license providers for each of the listed credentials and will be able to validate reported data regardless of whether reported license(s) are for a specific non-physician practitioner type or a broader category of Registered Nurse.

Covered Recipient Expansion FAQ Summary Cont'd

- **FAQ #2012:** How will CMS validate information about non-physician practitioners?
 - CMS will use a combination of data contained in the NPPES and PECOS systems, a commercial data source of aggregated data from state boards, and other sources to validate reported data on non-physician practitioners (PAs, NPs, CNSs, CRNAs, CNMs).
- **FAQ #2013:** Where can reporting entities find the definition of the non-physician practitioner types?
 - The non-physician practitioner terms are defined in the rule, 42 C.F.R. §403.902.

Tips for Preparing for 2021

- Familiarize yourself and your teams with the new reporting requirements and definitions.
- Share the expansion information with the providers you interact with
 - A resource has been created to help familiarize the newly added providers with Open Payments. We encourage you to refer them to this page to help them learn more about the program and how they can prepare for these changes.
<https://www.cms.gov/OpenPayments/Program-Participants/Newly-Added-Covered-Recipients>
 - A “one-pager” hand out is available for download and print. This can be shared with covered recipients to help them learn about the program.
Download at:
<https://www.cms.gov/files/document/open-payments-overview-handout.pdf>
- Review the updated [Final Rule](#)

Questions & Answers

Questions & Answers

Does CMS have any insight into whether certain state and local sunshine laws will go away due to the expansion?

- CMS does not have any insight into whether or how local and state laws may be affected by the Open Payments program expansion. Please consult 42 CFR § 403.914(a) for General provisions regarding preemption of state laws.

As a pharmaceutical manufacturer, if one of your products has a delivery method via a device, is that device reportable now (for example, an asthma pump)?

- CMS cannot comment on a company's individual circumstances. However, whether a device is reportable has not changed with the additional requirements for reporting device data. I would recommend reviewing the regulation defining reportable products. In general, if a company Manufactures or distributes and holds title to a device that requires FDA pre-market approval, it should be reported in that record's information.

Questions & Answers

Does CMS anticipate any large data issues with the specialty expansion starting next year?

- CMS is enhancing its systems to receive the increased volume of data and at this time does not anticipate any issues.

We recognize that collecting and ensuring the proper validation of data on the newly added covered recipient types and complying with the additional related device reporting requirements may create some challenges for the industry. We've been working on helping the industry make this transition as smooth as possible by providing detailed resources, such as the submission mapping document (our data dictionary), Non-Physician Practitioner List, Non-Physician Practitioner taxonomy code list and FDA's reference data on device IDs and names as far ahead of the 2021 data collection start as possible.

Questions & Answers

Will the long term loans category be available for Research payments?

- Nature of Payment field only applies to General payments and isn't available for Research payments.

Questions & Answers

- **Can CMS provide additional detail regarding the three categories of value that will be added?**

(Debt forgiveness, Long term medical supply, and Acquisitions)

- At this time, CMS does not have formal guidance on how to use these new categories or detailed definitions aside from what is stated in the final rule. We will be updating the “nature of payment” categories webpage in the near future with more information and examples for how these categories may be used.

Right now, reporting entities are free to interpret them to fit their own business and reporting processes. We ask that the reporting entities note any methodologies and assumptions used when reporting to us in the assumptions documents accompanying their submissions.

Questions & Answers

How will standardizing reporting for pharmaceuticals and device manufacturers aid the public in understanding industry interactions with physicians?

- This will help us standardize the way in which related product information appears in the public data which, we believe, it will make the information about payments associated with devices easier to interpret for the patients and other members of the public.

Questions & Answers

What conclusions/takeaways would you like attendees to bring back to their senior management?

- The main takeaways from our presentation is that these changes to Open Payments, including new covered recipients, device identifiers, and new nature of payment categories, will affect data beginning January 1, 2021.
- CMS is not able to waive or postpone any of the newly added reporting requirements due to COVID 19 pandemic and the implementation will continue on the statutorily mandated timeline.
- There are many resources available on cms.gov/OpenPayments to aid the industry in the transition and our helpdesk is ready to assist with any questions you may have.

Stay Connected

- **VISIT THE OPEN PAYMENTS WEBSITE**

- For resources including Open Payments FAQs and more information about the program visit <https://cms.gov/openpayments>

- **SUBSCRIBE TO THE LISTSERV**

- Receive program updates through the Open Payments listserv
- Subscribe at our Contact Us page

- **SEARCH THE DATA**

- Access the Open Payments data at <https://openpaymentsdata.cms.gov>

- **HAVE QUESTIONS OR NEED HELP?**

- Email: openpayments@cms.hhs.gov
- Call: 1-855-326-8366 (TTY Line: 1-844-649-2766)
- Monday through Friday, from 9:00 a.m. to 5:00 p.m. (ET), excluding Federal holidays.