



Open Payments Frequently Asked Questions (FAQs) : Device Data Reporting

This document is designed as a resource for the Open Payments Frequently Asked Questions (FAQs) in relation to the changes regarding device data reporting effective Program Year (PY) 2021.

A comprehensive list of frequently asked questions about the Open Payments program can be found on the [Open Payment website](#).

All FAQs presented in this document are current as of July 31, 2020.

FAQ #2007

Question:

Which marketed names and device identifiers should an entity report when a single transaction is related to multiple products or multiple device identifiers?

Answer:

If the payment or transfer of value is related to multiple devices or medical supply products, the reporting entity may report up to five products. Each product may be reported with a combination of the marketed name (brand name) and one device identifier. If a reported device is associated with multiple device IDs, it is up to reporting entity's discretion to identify the representative device ID for that product. Reported brand names and device identifiers will be validated against the information from the Global Unique Device Identification Database (GUDID). Reporting entities are responsible for making a determination about which combination(s) of brand names and device identifiers to report, 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.

FAQ #8258

Question:

Is a medical device considered a covered product for purposes of the Open Payments reporting requirements if a test performed using the device is eligible for payment under Medicare, Medicaid, or CHIP, but not the device itself (e.g., MRI machines, CT, x-rays, ultrasounds machines)?

Answer:

Yes, if a medical device is used to perform a service that is reimbursable under Medicare, Medicaid, or CHIP, the device is considered a covered product for purposes of Open Payments, so long as it is of the type that by law requires premarket approval by or premarket notification to the FDA, per the definition in 42 C.F.R. § 403.902.

FAQ #9132

Question:

Is an applicable manufacturer with both covered and non-covered products required to report payments or other transfers of value associated with a non-covered device, for example a device that is still in its development phase, which does not have pre-market approval by, nor required to have premarket notification to, the FDA and even when the device will only be used in the preclinical laboratory setting and not on humans?

Answer:

Yes, applicable manufacturers of at least one covered drug, device, biological or medical supply are required to report all payments or other transfers of value, unless the applicable manufacturer meets one of the reporting limitations, as described in 42 C.F.R. § 403.904(b); in that case the applicable manufacturer is only required to report payments or other transfer of value related to covered drugs, devices, biological, or medical supplies. Reporting limitations include: (1) applicable manufacturers with total revenue from covered drugs, devices, biological, or medical supplies constituting less than 10 percent of total revenue during the fiscal year preceding the reporting year, (2) an entity meets the definition of an applicable manufacturer because it is under common ownership with such applicable manufacturer and provides assistance and support to such applicable manufacturer, (3) the applicable manufacturer has separate operating divisions that do not manufacture any covered drugs, devices, biologicals or medical supplies, and (4) the applicable manufacturer is only manufacturing a covered drug, device, biological, or medical supply because it is under written agreement to manufacture the covered drug, device, biological, or medical supply, does not hold the FDA approval, licensure, or clearance for the covered drugs, device, biological, or medical supply, and is not involved in the sale marketing, or distribution of the covered drugs, device, biological, or medical supply. In the instance of pre-clinical research, applicable manufacturers only need to report the research institution, principal investigator(s) (including their name, National Provider Identifier, State professional license number(s), specialty and business address) and total payment. See 78 FR 9484.

FAQ #8392

Question:

Are entities currently in the research and development phase for drugs which, are at the time not approved by the FDA, subject to Open Payments reporting requirements?

Answer:

An applicable manufacturer, as defined by 42 CFR 403.902, is an entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, or is under common ownership with an applicable manufacturer and provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product. A covered drug is any drug for which (1) payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP), either separately (such as through a fee schedule or formulary) or as part of a bundled payment, and (2) requires a prescription to be dispensed. The question of whether you fall within the definition of an

“applicable manufacturer” depends in part on whether payment is available for any of your products under Medicare, Medicaid, or CHIP. While most products for which payment is available under these programs will have already received FDA clearance or approval, there are some exceptions. See 78 FR 9465. For that reason, we did not set FDA approval or clearance as a bright line test for determining whether a product is considered to be a “covered” product. If payment is not currently available under Medicare, Medicaid, or CHIP for your product at this time, then you would not be considered an applicable manufacturer for purposes of the reporting requirements; however, if payment is available (for example, under the Medicare Clinical Trial Policy), then you would be considered an applicable manufacturer. Note that the preamble addresses the situation where an entity with no covered products becomes an applicable manufacturer because, for example, its only product receives FDA approval. See 78 FR 9463. In that situation, an entity has a grace period of 180 days following its product becoming “covered” to begin complying with the data collection and reporting requirements.

FAQ #9124

Question:

When an entity with no covered products becomes an applicable manufacturer or applicable group purchasing organization (GPO) because payment becomes available for one of the company’s products under Medicare, Medicaid, or CHIP (for example, because a manufacturer’s only product received FDA approval), must the entity report payments or other transfers of value previously made to physicians and teaching hospitals?

Answer:

When an applicable manufacturer or applicable GPO that did not previously have any other covered products becomes subject to the Open Payments data collection and reporting requirements, they will be granted a grace period of 180 days following a product becoming “covered” to begin complying with the data collection and reporting requirements. Therefore, retroactive reporting is not required.