



Open Payments Frequently Asked Questions (FAQS)

This document is designed as a resource for the Open Payments Frequently Asked Questions (FAQs).

All FAQs presented in this document are current as of August 6, 2018.

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Data Collection

FAQ #2000

Question:

If an applicable manufacturer or group purchasing organization (GPO) makes a payment or transfer of value to an entity such as a college, university, medical center, or research institute that is not on the teaching hospital list, but is affiliated (e.g., under the same corporate umbrella) with an entity on the teaching hospital list, is this a reportable payment or transfer value?

Answer:

Such a payment or other transfer of value would only be reportable if the applicable manufacturer or GPO requires, instructs, directs, or otherwise causes the payment or transfer of value to be given by the college, university, medical center, or research institute to a covered recipient, which includes a teaching hospital on the teaching hospital list. Such a case would be considered a reportable indirect payment unless an exclusion applies (see 42 CFR 403.904(a) and 403.904(h)).

FAQ #2001

Question:

If a payment or other transfer of value is made to a research institution that is not a teaching hospital for a research study in which the principal investigator is a physician covered recipient, is this a reportable payment or transfer of value?

Answer:

Yes, if a research payment is made to an entity with at least one physician covered recipient principal investigator, it is reportable (see 42 CFR 403.904(f)). The payment would be reported as a payment to a non-covered recipient entity with the physician listed as one of the principal investigators.

FAQ #8159

Question:

Are payments for medical research writing and/or publication included in reporting research payments?

Answer:

Under Open Payments, a payment reported as research falls within a research payment category if it is subject to a written agreement, a research protocol, or both. Payments for medical research writing and/or publication would be included in the research payment if the activity (here, medical research writing/publication) was included in the written agreement or research protocol and paid as a part of the research payment.

FAQ #8165

Question:

If an applicable manufacturer or applicable group purchasing organization (GPO) provides a payment or transfer of value to a continuing education provider to support a continuing education program but did not require, instruct, direct or otherwise cause (including, but not limited to, “encouraging” or “suggesting”) the continuing education provider to provide payments or transfers of value to physician speakers, is the payment considered reportable?

Answer:

No, this payment or other transfer of value would not be reportable because it does not meet the definition of an indirect payment as defined at 42 U.S.C. § 403.902. For example, if an applicable manufacturer or GPO provides payments to a continuing education provider that are unrestricted and are intended to be used at the organization’s full discretion, and the organization chooses on its own volition to use those funds to pay physician speakers, the applicable manufacturer or applicable GPO would not be required to report the payments or transfers of value. These payments are not reportable regardless of whether the applicable manufacturer or applicable GPO learns that the payments went to covered recipient physicians and the identity of the physicians during the reporting year or by the end of the second quarter of the following reporting year because they would not meet the definition of an indirect payment.

FAQ #8167

Question: If an applicable manufacturer makes a payment or transfer of value to a group practice rather than a specified physician, how should the applicable manufacturer correctly report the payment or transfer of value? Should the payment be reported in the name of one physician or to all the physicians included in the group practice?

Answer:

A payment or other transfer of value provided to a group practice (or multiple covered recipients generally) should be attributed to each individual physician covered recipient who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value. Payments or other transfers of value do not necessarily need to be reported in the name of all members of a practice, rather, applicable manufacturers should divide payments or other transfers of value in a manner that most fairly represents the situation. For example, many payments or other transfers of value may need to be divided evenly, others may need to be divided in a different manner to represent who requested the payment, on whose behalf the payment was made, or who was intended to benefit from the payment or other transfer of value.

FAQ #8169

Question:

If an applicable manufacturer contracts with a clinic for consulting services, and the applicable manufacturer requests that a specific physician practicing at the clinic perform the services, is this considered a reportable indirect payment or a payment to a third party?

Answer:

This is considered an indirect payment. Applicable manufacturers are required to report indirect payments made to physicians. A payment is considered indirect if an applicable manufacturer requires, instructs, directs or otherwise causes the third party to provide the payment in whole or in part to a physician. An indirect payment was made to the physician since the applicable manufacturer requested a certain physician at the clinic perform the services. The payment made to the clinic was ultimately transmitted in part to the physician through the clinic.

FAQ #8171

Question:

Are items or materials used to educate physicians, which may indirectly benefit patients, included in the educational materials exclusion?

Answer:

No, the educational material exclusion is limited to materials and items directly benefiting patients or intended for patient use as required by the Affordable Care Act Section 6002. Educational materials, such as medical textbooks or journal reprints, which are educational to covered recipients but are not intended for patient use or directly beneficial to patients are not included in the exclusion.

FAQ #8254

Question:

In which payment category should applicable manufacturers report payments to covered recipients for medical textbooks or journal reprints?

Answer:

Applicable manufacturers must select the nature of payment category that they believe most accurately describes a payment or other transfer of value (See: 42 C.F.R. § 403.904(e)(2)). Therefore, applicable manufacturers must select the nature of payment category that best describes the provision of a medical textbook or journal reprint to a covered recipient. Possible natures of payment applicable to medical textbooks include “education” and “gift,” depending on the circumstances of the transfer of value. The “education” category generally includes payments or other transfers of value that involve the imparting or acquiring of particular knowledge or skills, which can include medical textbooks provided to covered recipients.

FAQ #8260

Question:

Are applicable manufacturers required to report meals, travel, lodging, and other similar expenses made in connection with interviewing prospective employees?

Answer:

Yes, compensation paid by an applicable manufacturer to a physician for expenses made in connection with interviewing the physician for possible employment is considered a reportable payment or other transfer of value.

FAQ #8262

Question:

If a covered recipient does not accept an offered payment or other transfer of value from an applicable manufacturer, but an applicable manufacturer provides the payment or other transfer of value to a separate covered recipient without the prior covered recipient's knowledge, what name should the applicable manufacturer report the payment or other transfer of value under?

Answer:

The applicable manufacturer should report the payment or other transfer of value under the name of the covered recipient who accepted the payment or other transfer of value.

FAQ #8266

Question:

Should all physician covered recipient principal investigators who perform research for the research institution under a research agreement or research protocol be listed on the research reporting templates when reporting research payments, even if such sub-researchers would not normally be considered "principal investigators" in the normal industry understanding of the word - i.e., the sub-researchers are not directing or in charge of the research overall?

Answer:

No, applicable manufacturers are only required to report the names of principal investigators, as that term is normally used in industry, not sub-researchers. Applicable manufacturers reporting research payments may report up to five covered recipient principal investigators for each research payment reported.

FAQ #8272

Question:

If an employee (non-physician) of a teaching hospital receives a transfer of value such as a meal, would that transfer of value need to be reported as a transfer of value to the teaching hospital? Similarly, if employees of a physician's office receive a transfer of value, will that transfer of value need to be reported as a transfer of value to the physician?

Answer:

Non-physician employees of a teaching hospital and non-physician employees of a physician-owned practice or other physician-owned entity are not covered recipients for the purposes of Open Payments. Accordingly, payments or other transfers of value made to these non-physician employees generally do not need to be reported. However, note that such payments to non-physician employees would need to be reported pursuant to 42 C.F.R. §403.904(a) and (c)(10) if the payments were made to the non-physician employees at the request of or designated by the applicable manufacturer on behalf of a covered recipient. In addition, the payments to non-physician employees would need to be reported if they were in fact indirect payments (as defined at §403.902) to a covered recipient (physician or teaching hospital) being made through the non-physician employee. Indirect payments or other transfers of value occur when an applicable manufacturer or applicable group purchasing organization requires, instructs, directs or otherwise causes a third party to provide the payment or other transfer of value, in whole or in part, to a covered recipient. For example, an applicable manufacturer providing equipment to a non-physician employee of a teaching hospital that is intended to benefit the teaching hospital is considered an applicable manufacturer otherwise causing the employee to provide the equipment to the teaching hospital covered recipient.

FAQ #8358

Question:

With respect to the 90-day supplies of single-use/disposable evaluation products that are exempted from reporting, is the 90-day supply calculated on a per-patient basis? Or is it the aggregate supply that would be expected to be used within a 90-day period regardless of the number of patients that are treated?

Answer:

The 90-day supply should be calculated for exclusion purposes not on a per-patient basis but rather on a per-covered recipient usage basis regardless of the number of patients that are treated during that 90-day period. The Open Payments reporting exclusion for providing a 90-day supply of single-use/disposable devices for the purpose of enabling covered recipients to evaluate the items is limited to the aggregate supply that covered recipients would be expected to use during 90 days of average use.

FAQ #8364

Question:

To determine if an applicable manufacturer or applicable group purchasing organization (GPO) has met the aggregate threshold for reporting small payments to a covered recipient or physician owner/investor (see CMS website for current key reporting thresholds), is it required to aggregate small payments or other transfers of value that are made across different nature of payment categories?

Answer:

Yes. To determine if small payments or other transfers of value made to a physician or teaching hospital exceed the aggregate threshold and must be reported, applicable manufacturers and applicable GPOs must combine all payments made across the multiple nature of payment categories. For example, if an applicable manufacturer or applicable GPO made payments to a physician for: (1) six hot dog lunches for \$9 each, (2) three cab fares for \$9 each, and (3) three sporting event tickets for \$9 each, the total payment amount would be calculated to be \$108 and all of these payments must be reported.

FAQ #8370

Question:

How should applicable manufacturers or applicable group purchasing organization determine the value of journal reprints provided to covered recipients?

Answer:

The value of a journal reprint should reflect the cost that an applicable manufacturer or applicable group purchasing organization paid to acquire the reprint from the publisher or other distributor. Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document clarifying any assumptions made to determine the value of journal reprints.

FAQ #8376

Question:

Does CMS have guidelines for how to determine the value of ownership and investment interests?

Answer:

Applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report the cumulative value of an ownership or investment interest. Therefore applicable manufacturers and applicable group purchasing organizations need to report the total value a physician owner or investor or physician owner or investor's immediate family member holds as of the most recent feasible valuation date preceding the end of the calendar year.

CMS does not prescribe a specific formula or methodology to determine the value of ownership and investment interest. Applicable manufacturers and applicable GPOs are encouraged to include documentation about the method used to estimate the value of the ownership or investment in their assumptions statement submitted with their annual report.

FAQ #8378

Question:

What are the requirements for reporting stock options granted by an applicable manufacturer to a covered recipient prior to August 1, 2013, but not exercised until after August 1, 2013?

Answer:

Stock options granted prior to August 1, 2013 are not considered payments or other transfers of value in Open Payments for the data collection period beginning on August 1, 2013 to December 31, 2013. Stock options granted after August 1, 2013 are required to be reported as payments or other transfers of value if provided to a covered recipient. Once the stock option is exercised, causing the physician to become an owner or investor in an applicable manufacturer or applicable group purchasing organization, those investment or ownership interests are required to be reported annually according to the reporting requirements in the Physician Ownership data specification.

FAQ #8382

Question:

Which nature of payment category should applicable manufacturers report payments to physician covered recipients for promotional speaking?

Answer:

Applicable manufacturers and applicable group purchasing organizations should consider the purpose and manner of the payment or other transfer of value and make a reasonable determination. A payment for promotional speaking may be included in the “Compensation for services other than consulting” or “Honorarium” nature of payment category depending on the specific facts. Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document clarifying any assumptions made to determine the nature of payment category.

FAQ #8390

Question:

If an applicable manufacturer or applicable group purchasing organization (GPO) offers buffet meals, snacks, or coffee to physician attendees at a conference or other large-scale event, do the food and beverage offerings need to be reported to the Open Payments program?

Answer:

The question of whether an applicable manufacturer must report buffet meals, snacks, or coffee provided to physician attendees at a large annual conference requires a fact-specific inquiry as to whether it is difficult for the manufacturer “to definitively establish the identities of the physicians who partake in the food or beverage” (78 Fed. Reg. 9479). Reporting is not required when an applicable manufacturer provides buffet meals, snacks, or coffee in settings where it would be difficult to establish the identity of the physicians who partook in the meal or snack, such as when the food and beverages are made available to all conference attendees. This reporting exception does not apply to meals provided to select attendees at conferences where the sponsoring applicable manufacturer can establish the identity of the attendees that partake in the food or beverage.

FAQ #8956

Question:

For purposes of the 90-day exclusion for a loan of a covered device, does the loan begin when an applicable manufacturer provides the covered device to a covered recipient or when the covered device is first used by a covered recipient?

Answer:

The Open Payments reporting exclusion for providing a covered device or device under development for 90 days to permit evaluation of the device or medical supply by the covered recipient begins when an applicable manufacturer provides the covered device to a covered recipient.

FAQ #8958

Question:

If the same medical device is loaned to three different teaching hospitals for a period of 30 days each is that considered one loan subject to the short term loan exclusion? If three identical devices are loaned to three different teaching hospitals is that considered three separate loans subject to the short term exclusion?

Answer:

The short term loan exclusion to permit evaluation of the device or medical supply by the covered recipient applies on a per-covered recipient basis. Therefore, if a manufacturer loans a medical device (whether the same device or not) to different teaching hospital recipients, each for a period of 90 days or less, each loan would be eligible for the exclusion in 42 C.F.R. 403.904(h)(5).

FAQ #8962

Question:

Are applicable manufacturers required to report uncollected payments for a covered device owed by a covered recipient to an applicable manufacturer as a payment or other transfer of value?

Answer:

Yes, debt forgiveness by an applicable manufacturer for the remaining balance of a covered drug, biological, device or medical supply purchased by a covered recipient is considered a payment or transfer of value and reportable for purposes of Open Payments.

FAQ #8964

Question:

Are tax and payments for shipping and handling included in calculating value for a payment or other transfer of value?

Answer:

Yes, tax and payments for shipping and handling are included in the total payment or other transfer of value for Open Payments.

FAQ #8966

Question:

Is a promotional newsletter that consists of journal abstracts and information on patient adherence, which is created by an advertising agency and provided to a physician on behalf of an applicable manufacturer or group purchasing organization (GPO), considered to be a reportable payment or other transfer of value? If so, what “nature of payment” category should the newsletter be reported in?

Answer:

Yes, a promotional newsletter provided to a physician by an applicable manufacturer (either directly or indirectly through an advertising agency) is considered a reportable transfer of value for purposes of Open Payments if the promotional newsletter is valued at the aggregated threshold or more, or if the aggregate amount of payments and transfers of value provided to a covered recipient exceeds the aggregated threshold in a calendar year (see CMS website for current key reporting thresholds). Applicable manufacturers or applicable GPOs must select the “nature of payment” category that best describes the provision of the newsletter to a covered recipient (42 C.F.R. § 403.904(e)(2)).

FAQ #8970

Question:

How should applicable manufacturers and applicable group purchasing organizations report transfer royalties, which are financial interests in a company provided in conjunction with an intellectual property assignment?

Answer:

Transfer royalties are reportable payments or other transfer of value for Open Payments. Transfer royalties are required to be reported using the general payment data specification. The appropriate “nature of payment” category for the payment or transfer of value would be “royalty or license.” The value of a transfer royalty should reflect the cost of the intellectual property that an applicable manufacturer or applicable group purchasing organization would pay to acquire the intellectual property from a covered recipient.

FAQ #8976

Question:

Is a payment or other transfer of value provided by an applicable manufacturer's distributor to a covered recipient considered a reportable indirect payment if the payment or other transfer of value is from the distributor's own resources and the distributor does not hold title to any of the applicable manufacturer's products?

Answer:

Yes, if the applicable manufacturer requires, instructs, directs, or otherwise causes the distributor to provide the payment or transfer of value, in whole or in part, to a covered recipient or a physician owner or investor.

FAQ #8980

Question:

What should distributors that offer a multitude of covered and non-covered products report in the Product Indicator data element (for PY2013-2015) or Related Product Indicator data element (for PY2016 and upcoming years) for payments related to non-covered products?

Answer:

Distributors that are considered applicable manufacturers because they hold title to a covered drug, device, biological or medical supply are subject to the same reporting requirements as all other applicable manufacturers. For PY2013-2015, applicable manufacturers must specify "Non-covered" for the Product Indicator data element to indicate when a payment or other transfer of value was associated with non-covered products. For PY2016 and upcoming years, applicable manufacturers must specify "Yes" for the Related Product Indicator data element and "Non-covered" in the Covered or Non-covered Product Indicator data element to indicate when a payment or other transfer of value was associated with non-covered products.

FAQ #8986

Question:

Is a textbook donation to a medical center library for the general use of all employees reportable?

Answer:

The textbook donation would be considered a reportable event if:

- 1) The medical center library is part of a teaching hospital; or
- 2) The donation was an indirect payment or transfer of value to a designated physician or group of physicians. Payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient, must be reported in the name of the covered recipient, as well as the name of the entity that received the payment at the covered recipient's request or designated on the covered recipient's behalf according to 42 C.F.R. § 403.904(c)(10). Additionally, an indirect payment, defined at § 403.902, is a payment or other transfer of value made by an applicable manufacturer to a covered recipient through a third party, where the applicable manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient. However, CMS does not believe that a payment that ultimately is passed on to a covered recipient has to be reported if the applicable manufacturer "did not intend or expect that a covered recipient would receive any portion of the payment or other transfer of value." (78 Fed. Reg. 9489).

FAQ #8994

Question:

What resources should applicable manufacturers and applicable group purchasing organizations (GPOs) use to accurately identify physicians for Open Payments reporting?

Answer:

To accurately identify physicians for Open Payments reporting, applicable manufacturers and applicable GPOs should obtain the Validated Physician List (VPL). The VPL is available for download on the "Submission" tab in the Open Payments system. The VPL contains information from the National Plan and Provider Enumeration System (NPPES) and other CMS data sources. Applicable manufacturers and applicable GPOs are encouraged to report physician identifiers exactly as they are listed on the latest available VPL to avoid any matching errors. The VPL is not an exhaustive list of all physicians who are subject to Open Payments reporting. Physicians not listed on the VPL may still be considered covered recipients or physician owners or investors under the Open Payments program. If the applicable manufacturer or applicable GPO believes that a physician who is not listed on the VPL meets the definition of a covered recipient or physician owner or investor, that applicable manufacturer or applicable GPO is responsible for reporting the best information it has to identify the physician. Applicable manufacturers and applicable GPOs should check NPPES or other available sources for information on physicians not in the VPL.

FAQ #8998

Question:

Are research payments provided to a Military Medical Center that is not a teaching hospital covered recipient required to be reported for Open Payments?

Answer:

Yes, for research payments, the reporting entity must provide the name of the research institution, individual or entity receiving the payment or other transfer of value as outlined in §403.904(f). If the Military Medical Center receives a research-related payment or other transfer of value, which is ultimately paid in whole or in part to a covered recipient (physician or teaching hospital), it must report information on the payment as indicated at § 403.904(f)(1)(i)(C).

FAQ #9002

Question:

Are dental schools that are affiliated with universities and health care institutions, but do not match the name or address information provided on CMS' teaching hospital list, still considered teaching hospitals for the purposes of reporting?

Answer:

The teaching hospital list compiled by CMS is a complete list of teaching hospital covered recipients. Applicable manufacturers and applicable group purchasing organizations should collect the TIN from a hospital, or in this case, dental school, that they believe is affiliated with a teaching hospital in order to correctly identify the teaching hospital's name and address from the list. Additionally, as discussed in the final rule, a teaching hospital is any institution that received payments under sections 1886(d)(5)(B), 1886(h) or 1886(s) of the Act.

FAQ #9116

Question:

How should an applicable manufacturer or applicable group purchasing organization (GPO) document the appropriate National Drug Code(s) (NDC) when reporting a payment or other transfer of value that is associated with a covered drug or biological?

Answer:

NDCs must be reported in the standard 10-digit NDC format with dashes placed in the appropriate position (e.g., 9999-9999-99, 99999-999-99, or 99999-9999-9). The unique NDCs must be reported for each record and must match the number and order of named drugs or biologicals associated with the record. If no NDC exists for any named drug or biological (for example, if the product is in pre-market trial stages), the NDC field may be left blank.

FAQ #9118

Question:

What value should an applicable manufacturer assign to clinical study drugs that are provided to principal investigators as part of the research agreement?

Answer:

Applicable manufacturers are not required to assign a specific value to clinical study drugs that are provided to principal investigators, rather applicable manufacturers should report the total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol or both, as specified in 42 C.F.R. § 403.904(f)(1)(ii).

FAQ #9120

Question:

Is an applicable manufacturer required to report payments provided to a physician covered recipient for a claim settlement, for example, costs relating to a defective product?

Answer:

No, legal proceedings that require physician involvements are excluded, including, legal defense, prosecutions, settlement or judgment of a civil or criminal action and arbitration or other legal action.

FAQ #9128

Question:

Are applicable manufacturers required to report a physician's name and taxonomy code as listed in the National Plan and Provider Enumeration System (NPPES)?

Answer:

Applicable manufacturers and applicable group purchasing organizations (GPOs) are encouraged to report physician identifiers exactly as they are listed on the latest available Validated Physician List (VPL) to avoid any matching errors. The VPL contains information from NPPES as well as other CMS data sources in order to accurately identify physicians that are subject to Open Payments reporting. The VPL contains information only on physicians who have a National Provider Identifier (NPI) and have been reported on in the Open Payments system; it is not an exhaustive list of all physicians who should be included in Open Payments reporting. Physicians not listed on the VPL may still be considered covered recipients or physician owners or investors under the Open Payments program. If an applicable manufacturer or applicable GPO believes that a physician who is not listed on the VPL meets the definition of a covered recipient or physician owner or investor, that entity is responsible for reporting any payments made to such physician using the best available information to identify them. Applicable manufacturers and applicable GPOs should check NPPES or other available sources for information on physicians not included in the VPL. In the event that the information for a physician given in the VPL differs from that physician's information in NPPES, applicable manufacturers and applicable GPOs should use the information in the VPL. This list can only be accessed from the "Submissions" tab in the Open Payments system.

FAQ #9130

Question:

Why was research removed as a nature of payment category option from the general data specification?

Answer:

The research nature of payment category was removed from the general data specification because all payments or other transfers of value made in connection with an activity that meets the definition of research, as defined at 42 C.F.R § 403.902, are required to be reported using the research data specification according to § 403.904(f). A payment that does not meet the definition of a research payment must be reported using the other nature of payment categories available. (78 Fed Reg. 9482)

FAQ #9134

Question:

Are Federal, state, and local taxes withheld from a physician owner or investor considered reportable payments or other transfers of value?

Answer:

No, Federal, state, and local taxes withheld from a physician owner or investor are not considered reportable payments or other transfer of value.

FAQ #9136

Question:

Is an applicable manufacturer required to report the name of a third party, such as a contract research organization (CRO) that provides an indirect research payment to a covered recipient?

Answer:

No, applicable manufacturers are not required to report the name of the third party, such as a CRO, that indirectly provides a research payment to a covered recipient. Applicable manufacturers are required to report information regarding the covered recipients that ultimately receive the research payments, as specified in 42 C.F.R § 403.904(f).

FAQ #9142

Question:

Is a donation provided to a teaching hospital's foundation by an applicable manufacturer reportable?

Answer:

Yes, if an applicable manufacturer provides a payment or other transfer of value to a teaching hospital's foundation at the request of or designated on behalf of the teaching hospital covered recipient. An applicable manufacturer will also need to report the donation as a payment or other transfer of value made to a teaching hospital covered recipient if the applicable manufacturer requires, instructs, directs, or otherwise causes the teaching hospital's foundation to provide the donation, in whole or in part, to the teaching hospital covered recipient.

FAQ #9144

Question:

Is a hospital that is not listed on the Open Payments teaching hospital list considered a teaching hospital covered recipient for purposes of Open Payments?

Answer:

No. A teaching hospital covered recipient for the purposes of Open Payments is defined at 42 C.F.R. § 403.902 as any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Social Security Act during the last calendar year for which such information is available. The teaching hospital list posted at www.cms.gov/openpayments is the final list of all teaching hospital covered recipients for the purposes of Open Payments for the reporting year specified on the list, and the list will be refreshed every year.

FAQ #9146

Question:

How should an applicable manufacturer report a payment or other transfer of value provided to a teaching hospital that is on the Open Payments teaching hospital list if the applicable manufacturer refers to the teaching hospital by a different name or the manufacturer's internal records have a different address?

Answer:

An applicable manufacturer must report identifiers for a teaching hospital as they appear on the teaching hospital list provided by CMS. If there are minor discrepancies between the hospital name and/or address in your records and the hospital name and/or address provided on the teaching hospital list, the information on the teaching hospital list should be used. The reported Taxpayer Identification Number (TIN) must match exactly the TIN provided on the teaching hospital list. When preparing records, you must refer to the teaching hospital list for the year in which you made the payment or other transfer of value. For example, if you are re-submitting a 2013 Program Year payment record, you must refer to the 2013 reporting cycle teaching hospital list.

Note: Records of a payment or other transfer of value for Program Year 2013 must be submitted as the hospital's "PECOS Legal Business Name" on the 2013 supplemental teaching hospital list. The address to be used for 2013 reporting should be the "NPPES Business Address" that appears in the 2013 supplemental teaching hospital list. For Program Year 2014 payment records and all subsequent program years, the hospital name in a submitted record must be submitted as the "Hospital Name" field (also known as the "Doing Business As" (DBA) name) on the teaching hospital list, and the address should be submitted as the "NPPES Business Address". All teaching hospital lists can be found on the Resources page of the Open Payments website.

FAQ #9148

Question:

Are applicable manufacturers and group purchasing organizations (GPOs) required to report all taxonomy codes for a physician or just the primary taxonomy codes?

Answer:

Applicable manufacturers and GPOs should report only one taxonomy code per physician. CMS provides a Validated Physicians List (VPL) that can be used to identify taxonomy codes for physicians. In the event that a physician is not included on the CMS VPL, applicable manufacturers and GPOs should refer to the National Plan Provider Enumeration System (NPPES) provider taxonomy code list, and may use the primary taxonomy indicated on the Open Payments taxonomy list. (The Open Payments taxonomy lists are available on the Open Payments resource page.) Applicable manufacturers and GPOs may use their internal data to determine a physician's taxonomy code if these other resources do not provide adequate information.

FAQ #9150

Question:

Is a meeting a reportable event if an applicable manufacturer located in the United States conducts the meeting in a foreign country?

Answer:

Yes. Any payments or other transfers of value provided by an applicable manufacturer to covered recipients (or physician owners or investors), wherever made, are required to be reported.

FAQ #10082

Question:

Do applicable manufacturers and group purchasing organizations (GPOs) need to report National Provider Identifier (NPI) for teaching hospitals?

Answer:

No. Applicable manufacturers and applicable GPOs are only required to provide NPIs for physician covered recipients (if the physician has an NPI).

FAQ #10084

Question:

Can a physician reimburse an applicable manufacturer for payments so that no information is reported about them in Open Payments?

Answer:

Some payments or other transfers of value are excluded from reporting; however, no exclusion exists for payments or transfers of value that are later reimbursed. Please review 42 C.F.R. §403.904(h)(1) for information on possible exclusions.

FAQ #10086

Question:

Can all payments made to a covered recipient during a reporting period for the same Nature of Payment category be combined into one payment?

Answer:

Applicable manufacturers have the flexibility to report payments made over multiple dates either separately or as a single line item for the first payment date. In addition, CMS will allow flexibility for what specific date to report for a nature of payment category. For more information, please review 78 FR 9473. Applicable manufacturers must provide the date of payment or other transfer of value. If the payment or other transfer of value is a series of payments (e.g., a consulting fee that is paid every month for three months) or an aggregated set of payments, applicable manufacturers should report the date of the first payment or other transfer of value.

FAQ #10090

Question:

Are there minimum value thresholds that must be met in order for applicable manufacturers and applicable group purchasing organizations (GPOs) to be required to report?

Answer:

Yes, there are specific key (de minimis) thresholds for reporting for applicable manufacturers and applicable GPOs, which are adjusted annually based on the consumer price index. This means that for a calendar year (January 1 – December 31), if a small payment or other transfer of value is less than a certain minimum amount, it is excluded from the reporting requirements under Open Payments. However, if the aggregate amount of payments and other transfers of value to a covered recipient exceeds a minimum aggregate threshold, all payments or other transfers of value must be reported, even if they are smaller than the de minimis threshold on their own. For information on the individual and aggregate de minimum amounts for specific program years, see: <https://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Data-Collection.html>

FAQ #10094

Question:

Because the National Plan and Provider Enumeration System (NPPES) data can be updated by physicians on an ongoing basis, when may applicable manufacturers and applicable group purchasing organizations (GPOs) rely on that information when reporting payments or transfers of value?

Answer:

Applicable manufacturers and applicable GPOs should reference the Validated Physician List (VPL) first. This list can only be accessed on the “Submissions” tab in the Open Payments system. Physicians who do not appear on the VPL may still be successfully matched. Applicable manufacturers and applicable GPOs should check NPPES for information on physicians not included on the VPL. However, since NPPES is updated on a continual basis, applicable manufacturers and applicable GPOs may use other available sources and should make a good faith effort to submit accurate information to CMS.

FAQ #18289

Question:

What values must be reported when an applicable manufacturer or applicable group purchasing organization (GPO) reports an ownership or investment interest by a physician in that entity?

Answer:

When reporting that a physician has an ownership or investment interest in an applicable manufacturer or applicable GPO, this information must be reported in two fields: (1) “Dollar Amount Invested” and (2) “Value of Interest.” “Dollar Amount Invested” is defined as the total amount (in US dollars) of the ownership interest in the applicable manufacturer or applicable GPO that was gained by the physician (or the physician’s immediate family members) during the reporting year only. “Value of Interest” is defined as the cumulative value (in US dollars) of ownership or investment interest in the applicable manufacturer or applicable GPO that is held by the physician (or the physician’s immediate family members) as of the most recent feasible valuation date preceding the reporting date.

FAQ #22569

Question:

What should applicable manufacturers and applicable group purchasing organizations include when reporting the terms of ownership and investment interests?

Answer:

When reporting the terms of an ownership or investment interest, applicable manufacturers and applicable group purchasing organizations should report the type of ownership or investment interest (as defined in 42 CFR § 403.902), including but not limited to stock, stock options, partnership shares, loans, bonds, or other financial instruments that are secured with an entity’s property or revenue or a portion of that property or revenue.

Data Publication

FAQ #12304

Question:

Why does the Open Payments data change over time?

Answer:

Current data publications include a refreshed publication of all records from previous program years. This refresh includes records that were not included in previous publications of that year's data due to the delay in publication flag not being renewed or has expired, revisions, deletions, and additions resulting from data dispute resolution and other data maintenance. These data updates are reflected in the most current data publication, along with all unedited records previously published.

FAQ #12360

Question:

What does CMS publish annually on June 30th?

Answer:

CMS publishes data reported by applicable manufacturers and group purchasing organizations (GPOs) for each Open Payments program year by June 30th of the following year. In addition to new program year data, CMS also refreshes previous program year data. The refreshed data includes data corrections made since the initial publication of data, records that are no longer flagged for delay in publication, newly submitted and attested to data, and removes deleted data.

FAQ #12362

Question:

In what formats is the data presented?

Answer:

CMS delivers Open Payments data in a number of ways to accommodate different users and their interests:

Search Tool: Site visitors can get immediate results using this standard search interface to find detailed information on individual physicians, teaching hospitals, or companies making payments.

Data Explorer: Users can select a dataset then customize the view using filters, sorts, and other actions to create their own, targeted views of the data and visualizations such as charts and graphs.

Data downloads: Users can download the data in comma-separated values (.csv) format, which allows users to open and explore the data using their own software on their own computer. With this option, the user must have robust data viewing software that allows for downloading and viewing data in large datasets.

FAQ #12364

Question:

Does CMS provide any type of summary data?

Answer:

CMS provides summary graphics of key data points on <https://www.cms.gov/openpayments/>. CMS does not provide any other summary presentations of the data. The data is publicly accessible and available for consumers and researchers to extract as they see fit.

FAQ # 12368

Question:

When calculating number of payments a doctor received, should users count entries (rows) or tally the number of payment fields within each payment?

Answer:

Each payment record (row) for a physician does not necessarily constitute a single payment or other transfer of value. Payments or other transfers of value made over multiple dates may be reported either as separate line items for the dates they were made or as a single line item using the first date of payment or transfer of value as the reported date. Users of the data must review the data element “Number of Payments Included in Total Amount.” If this number is “1,” then the payment record (row) consists of a single payment or other transfer of value. However, if this number is greater than 1, then the payment record (row) consists of multiple payments made to the covered recipient.

FAQ #12374

Question:

Are there any submitted records that CMS does not publish?

Answer:

Yes. The Open Payments final rule allows some research payments related to new product development or new uses of an existing product, to be granted a delay in publication for up to four years, or until the Food and Drug Administration (FDA) approval is granted. In addition, if records are not attested or re-attested to by the submission deadline, or if there was a change to the identifying information for a covered recipient (i.e. first/ last name, National Provider Number (NPI), or State License Number) of an attested record after the reporting deadline, they are not included in the initial data publication. For full details on these publication exclusions and limitations, refer to Chapter 8, “Data Publication” of the Open Payments System User Guide, and Section 2.6.1. of the Open Payments Methodology Overview and Data Dictionary. Both are available on the Resources page (<https://www.cms.gov/OpenPayments/About/Resources.html>) of the Open Payments website.

FAQ #12376

Question:

Do physicians and teaching hospitals have a chance to review the financial data reported about them prior to its publication?

Answer:

Yes. During the 45-day physician and teaching hospital review and dispute period, the dollar values and information about each transaction listed are available for review by doctors and teaching hospitals registered in the Open Payments system. They can confirm the information as correct or pursue corrections, via the dispute option, to remove, clarify, or adjust the information that had been attributed to them. This required 45-day review and dispute process affords the opportunity for physicians and teaching hospitals to review and dispute any data they feel is inaccurate or incomplete

FAQ #12378

Question:

What if a physician or teaching hospital registered (or tried to register) prior to review and dispute period, but was unable to dispute records until after review and dispute period ends?

Answer:

Any disputes initiated after review and dispute period ends will not be reflected in the June 30 data publication. These disputes and any subsequent correction to those data will be reflected in the next data refresh.

FAQ #12380

Question:

How often is Open Payments data refreshed or updated?

Answer:

Data is published annually on or by June 30. CMS also refreshes the data once annually, after the initial publication.

FAQ #12386

Question:

Is there a methodology guide available providing technical details about the published data?

Answer:

Yes, the Methodology Overview & Data Dictionary, available on the Resources page (<https://www.cms.gov/OpenPayments/About/Resources.html>) of the Open Payments website, explains the technical specifications of the published data.

FAQ #12388

Question:

How can disputes initiated by physicians and teaching hospitals be resolved?

Answer:

Once the dispute is initiated, it can be resolved in one of three ways:

1. **Resolved** – Disputed data is updated and then resubmitted and re-attested to by the applicable manufacturer or GPO.
2. **Resolved, no change** – Indicates that both the applicable manufacturer or GPO discussed the dispute with the physician or teaching hospital, and both parties determined that no change in the data was necessary. Physicians and teaching hospitals can initiate a new dispute if they disagree with the “resolved, no change” status.
3. **Withdrawn** – A physician or teaching hospital can remove a dispute opened on a record.

FAQ #12394

Question:

How will CMS ensure Open Payments information remains user-friendly for consumers?

Answer:

CMS provides stakeholders the opportunity to submit feedback on the Open Payments program and system during each program year. CMS takes this feedback into consideration when making system and data display enhancements. CMS also meets with various program stakeholders regularly throughout the program year to collect feedback on how to improve consumer-friendliness, and CMS monitors and tests the Open Payments system for consumer usefulness and ease of navigation.

FAQ #18357

Question:

Does CMS publish a covered recipient's NPI on the Open Payments website?

Answer:

No. As required by the statute, CMS does not publish a covered recipient's NPI on the Open Payments website.

Data Submission / Attestation

FAQ #10054

Question:

If an applicable manufacturer or applicable GPO later determines an error across all payments or other transfers of value for meals provided to a specific physician, could an applicable manufacturer or applicable GPO submit a negative value record to offset the error for all payment records regarding meals for the specific physician?

Answer:

No, the Open Payments system will not accept a negative value for a payment or other transfer of value amount. Applicable manufacturers and applicable GPOs are responsible for submitting corrected information regarding their annual report in accordance with 42 C.F.R. § 403.908(h)(1).

FAQ #10074

Question:

When submitting a consolidated report for separate applicable manufacturers and group purchasing organizations (GPOs) that are under common ownership in accordance with 42 C.F.R. § 403.908, must the attester be a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer for all the entities included in the consolidated report?

Answer:

No. The attester of a consolidated report is required to hold an Officer position only within the entity that is submitting the consolidated report. The attester is not required to hold an Officer position in the other entities included in the consolidated report.

FAQ #10080

Question:

How can an applicable manufacturer request a delay in publication for a research-related payment, and how will CMS notify the applicable manufacturer if the delay is approved?

Answer:

Publication of a payment or other transfer of value is delayed when made in connection with (1) research on or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply; or (2) clinical investigations regarding a new drug, device, biological, or medical supply. An applicable manufacturer must indicate on its research report to CMS whether a payment or other transfer of value is eligible for a delay in publication. The absence of this indication in the report will result in CMS posting all payments publicly. If this indication is made, the publication of the payment will be delayed in accordance with 42 C.F.R. §403.910. CMS will not send publication delay approval to the applicable manufacturer.

FAQ #10100

Question:

Including data lines and rows per file submission, what is the total allowable size for the data files?

Answer:

The maximum file submission size for each data file is 250 megabytes (MB). There is no limit to the number of data files that can be submitted, as long as each one is under 250MB. Zipped data files that are under 250MB when zipped and larger than 250MB when unzipped are acceptable. There is no system limitation on the number of data lines or rows allowed in each file.

FAQ #10102

Question:

How will data submissions be transferred to and received by CMS?

Answer:

Data can be submitted to CMS through the Open Payments system via two data submission methods. The first submission method is bulk data file upload via CSV or ZIP file. The second submission method is manual submission through the Graphical User Interface.

FAQ #10104

Question:

Can a data file submission be broken down and submitted in multiple files based on the number of line items?

Answer:

Yes. Data files can be separated and uploaded into multiple files for submission. However, each individual file should not be larger than 250MB in size. There are no system limitations for the number of records allowed in each file or the total number of files that can be uploaded.

FAQ #10106

Question:

Can one attestation cover multiple individually submitted data files, with all of the files as part of the same submission?

Answer:

Yes. When attesters attest to data for a reporting entity, they attest to all of the successfully submitted data files for the selected program year, across all payment categories for that entity, regardless of the means of its submission. Attestation does not occur for each individual data file.

FAQ #10108

Question:

How is data validation performed, and what data elements are checked?

Answer:

Data validation occurs on several levels. The first level of validation is at the file level (i.e., checking the file broadly to make sure it is formatted correctly for the Open Payments system). You will receive immediate feedback via an on-screen message letting you know if the file upload was successful. Shortly thereafter, you will receive a notification email regarding the outcome of the file-level validations. If the file fails validation, the notification email will explain the reason for the failure and the file will not be uploaded to the system. If the file-level checks are successful, the process will move to the second level of validation. The second level of validation is at the record level. The Open Payments system validates each individual record to ensure all required fields are filled and that the fields meet the specifications in the Submission Data Mapping Document. Record-level validations have two stages: pre-upload and post-upload. Records that fail pre-upload validations are not saved in the system and will trigger a notification email that lists the reasons for record failure and identifies which records in the file failed for each reason. Records that fail post-upload validations are saved within the system and trigger a notification email that directs you to a system-generated error report that contains error codes. Refer to the Error Code Key on the Resources page of the Open Payments website for the meanings of the error codes, the data elements involved in each error, and the steps to avoid and correct errors. If the record-level checks are successful, the process will move to the third level of validation. The third level of validation is record matching. The Open Payments system will attempt to match the covered recipient cited in each submitted record to a valid physician or teaching hospital. Records that fail matching will trigger a notification email directing you to an error log.

FAQ #10110

Question:

What is the expected length of time for CMS to complete data validation on submitted data files?

Answer:

The length of time depends upon file sizes and the number of files being processed by the system. During the last two weeks of the submission process, when demand is the highest, the process may take up to 24 hours.

FAQ #10112

Question:

How will an applicable manufacturer or applicable GPO be notified if any portion of their submitted data file has failed data validation or contains any data errors?

Answer:

Data validation occurs on several levels. The first level of validation is at the file level (i.e., checking the file broadly to make sure it is formatted correctly for the Open Payments system). You will receive immediate feedback via an on-screen message letting you know if the file upload was successful. Shortly thereafter, you will receive a notification email regarding the outcome of the file-level validations. If the file fails validation, the notification email will explain the reason for the failure and the file will not be uploaded to the system. If the file-level checks are successful, the process will move to the second level of validation. The second level of validation is at the record level. The Open Payments system validates each individual record to ensure all required fields are filled and that the fields meet the specifications in the Submission Data Mapping Document. Record-level validations have two stages: pre-upload and post-upload. Records that fail pre-upload validations are not saved in the system and will trigger a notification email that lists the reasons for record failure and identify which records in the file failed for each reason. Records that fail post-upload validations are saved within the system and trigger a notification email that directs you to a system-generated error report that contains error codes. Refer to the Error Code Key on the Resources page of the Open Payments website for the meanings of the error codes, the data elements involved in each error, and the steps to avoid and correct errors. If the record-level checks are successful, the process will move to the third level of validation. The third level of validation is record matching. The Open Payments system will attempt to match the covered recipient cited in each submitted record to a valid physician or teaching hospital. Records that fail matching will trigger a notification email directing you to an error log.

FAQ #10114

Question:

In the event of any data errors, will the applicable manufacturer or applicable GPO be returned their whole data file submission, or only the data lines failing validation?

Answer:

It depends on the level of data error that is discovered. If the error is at the file level (i.e., the file is in incorrect format, or does not adhere to the accepted schema - headings are wrong, incorrect number of data elements, etc.), the entire file will be rejected. No records will be saved in the Open Payments system. A notification email will explain the reason for the file's rejection. The file must be re-submitted after it is corrected. If the error is found in an individual record, only the record(s) containing errors need to be re-submitted. Record-level validations have two stages: pre-upload and post-upload, which affects what the system returns. Records that fail pre-upload validations are not saved in the system and will trigger a notification email that lists reasons for record failure and identifies which records in the file failed for each reason. Records that fail during this step will not be available in the user interface for modifications and must be resubmitted for processing. Records that fail post-upload validations are saved within the system and trigger a notification email that directs you to a system-generated error report that contains error codes. Refer to the Error Code Key on the Resources page of the Open Payments website for the meanings of the error codes, the data elements involved in each error, and the steps to avoid and correct errors. Records that fail in this step can either be deleted and resubmitted via the bulk file process, or corrected via the user interface by editing the record. If the record-level checks are successful, the process will move to the third level of validation. The third level of validation is record matching. The Open Payments system will attempt to match the covered recipient cited in each submitted record to a valid physician or teaching hospital. Records that fail matching will trigger a notification email directing you to an error log. Records that fail in this step can either be deleted and resubmitted via the bulk file process, or corrected via the user interface by editing the record.

FAQ #10118

Question:

What is the resubmission process for an applicable manufacturer or applicable GPO to resubmit their corrected data files?

Answer:

After making corrections to the records to be resubmitted, indicate a record is a resubmission by setting the Resubmission File Indicator to "Y," and include the original Payment Record ID in the "Resubmitted Payment Record ID" field. Note that all records in a bulk file must have the same value in the Resubmission File Indicator field (e.g., a file containing resubmitted records must contain only resubmitted records). Once the file is ready, upload the file to the system as with any other bulk file upload. On the Upload Payments page, you must select "Resubmission" from the Resubmission File Indicator drop-down menu, as well as the appropriate Payment Category, Reporting Entity, and Program Year. Refer to the Open Payments System Quick Reference Guide "Bulk File Upload," which is available on the Resources page of the Open Payments website (<https://www.cms.gov/OpenPayments/About/Resources.html>), for more information. You may also correct and re-submit data using the Graphic User Interface instead of bulk file upload. You must correct and resubmit corrected records for all records that failed. Records with no errors do not need to be resubmitted. You may also delete your entire original bulk file or record from the Open Payments system and replace it with a new bulk file or record if you prefer.

FAQ #10120

Question:

Are large amounts of corrected data files capable of being resubmitted?

Answer:

Yes, corrected data files can be submitted through bulk file upload. Note that the 250MB size limit also applies to corrected data files.

FAQ #10122

Question:

If multiple records in a submitted data file have been rejected, can an applicable manufacturer or applicable GPO replace and submit an entirely new data file?

Answer:

Yes, an applicable manufacturer or applicable GPO may submit an entirely new data file to replace an earlier submission if the earlier submission contains extensive errors. To do so, delete the earlier file from the Open Payments system and submit the corrected file.

FAQ #10124

Question:

Are attestations required as part of corrected record resubmissions?

Answer:

If any records are resubmitted, the entirety of the data for the program year must be attested to again.

FAQ #10126

Question:

What is considered a timely submission of data under the Open Payments program, and can a data file be submitted past the deadline?

Answer:

Reporting under the Open Payments program is not considered complete until the official attestation is received. All data for the program year must be submitted and attested to by the 90th day of the following calendar year. Any data submitted after this time will not be posted publicly until the next data publication and will be considered late. Applicable manufacturers and GPOs that submit late data may be subject to civil monetary penalties for noncompliance with program requirements.

FAQ #11968

Question:

What happens if an applicable manufacturer or applicable group purchasing organization (GPO) does not renew a record's delay in publication status?

Answer:

A request for a delay in publication must be renewed each year by the end of the data submission period. If this request is not renewed within this timeframe, the record will automatically be flagged for publication in the next publication cycle. For example, Program Year 2015 records that were not published on June 30, 2016 due to a publication delay request will be published on June 30, 2017 unless the delay in publication request is renewed by the end of the data submission window.

FAQ #11970

Question:

Why am I receiving a "Failed Matching" message for payment records that were successfully processed in a prior year?

Answer:

Payment records that were successfully matched in a prior year may appear as "Failed Matching" in future years if new validations were implemented or if the covered recipient's information changed. These records will need to be reviewed and corrected. For additional guidance, refer to the Open Payments System Quick Reference Guide "Identifying and Correcting Validation and Matching Errors" or the Open Payments User Guide, both of which are located on the Resources page (<https://www.cms.gov/OpenPayments/About/Resources.html>) of the Open Payments website. After consulting this resource, if you are having trouble moving your records out of "Failed Matching" status, contact the CMS Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance.

FAQ #11972

Question:

How do I renew a record's delay in publication status?

Answer:

Payment records may be delayed in publication if the payment or other transfer of value is related to:

- Research or development of a new drug, device, biological, or medical supply;
- Research or development of a new application of an existing drug, device, biological, or medical supply; or
- Clinical investigations regarding a new drug, device, biological, or medical supply. Payment records can be delayed in publication for up to four calendar years after the date of payment. The request for a delay must be renewed each year. If this request is not renewed each year by the end of the data submission period, the record will automatically be flagged for publication in the next publication cycle. Records can be updated via the bulk file process or through the user interface.

For instructions on renewing a record's delay in publication status, refer to the Open Payments System Quick Reference Guide: Requesting or Updating a Delay in Publication located on the Resources page of the Open Payments website (<https://www.cms.gov/OpenPayments/About/Resources.html>).

FAQ #11974

Question:

How do I remove a delay in publication request for a previously submitted record?

Answer:

To remove a delay in publication request on a record, the user may update the delay in publication field for that record to indicate that no delay is requested. If the record was submitted in a prior year and the request is not renewed by the end of the following data submission period, the record will automatically be flagged for publication in the next publication cycle. Refer to the Open Payments System Quick Reference Guide “Requesting or Updating a Delay in Publication”, which is located on the Resources page (<https://www.cms.gov/OpenPayments/About/Resources.html>) of the Open Payments website for additional details regarding the delay in publication functionality.

FAQ #22337

Question:

When may an applicable manufacturer or applicable GPO request a delay in publication for a general payment record and what information must be included?

Answer:

Applicable manufacturers and applicable GPOs may request a delay in publication for a research-related and the payment or transfer of value is connected with: (1) research on or development of a new product (drug, device, biological, or medical supply) or (2) clinical investigation regarding a new product (drug, device, biological, or medical supply). The name of the research study must be included in the contextual information field of a general payment record for which delay in publication is requested. The contextual information field may also be used to include any additional information about the payment or transfer of value that may be helpful or appropriate. Applicable manufacturers and applicable GPOs may request that payment records be delayed in publication for up to four calendar years after the date of payment. Such a request for a delay must be renewed each year. Should the request not be renewed each year by the end of the data submission period, the record will automatically be flagged for publication in the next publication cycle. Records may be updated via the bulk file process or through the user interface. For more information, refer to the Open Payments System Quick Reference Guide “Requesting or Updating a Delay in Publication,” which is located on the Resources page (<https://www.cms.gov/OpenPayments/About/Resources.html>) of the Open Payments website.

FAQ #22669

Question:

What happens when a payment is reported for a physician whose license is expired for that program year?

Answer:

Applicable manufacturers and applicable group purchasing organizations (GPOs) will receive a warning message if they submit a record containing a physician license that CMS sources identify as being expired for the entirety of a record's program year. The warning message, along with an indication of the specific expired license, will be displayed on the individual record's "Record ID" page and in the error log file (records uploaded via bulk file only) once the record has been successfully matched.

Expired license warnings will not prevent a record from successfully processing and going through final submission. However, users should review these records to confirm whether the physician's license is active or expired. If reporting entity confirms the license as expired, it should update the record to remove the expired license. If the expired license number is the only one available for the physician, the entire record can be removed from reporting as providers without any active licenses are not considered covered recipients.

FAQ #22673

Question:

How will I know if the physician license submitted as part of a payment record has been identified as expired per CMS sources?

Answer:

Records containing physician licenses that CMS sources identify as expired during the entirety of the record's program year will receive a warning message. Specifically:

- A warning will appear on an individual record's "Record ID" page that specifies the expired license(s), if any.
- Additionally, if the record(s) were submitted via bulk file:
 - A "Processed with Warning" message will be displayed on the bulk file's "File ID" page; and
 - The error log for the bulk file will contain expired license warnings for each relevant record, with the expired license(s) specified.

Expired license warnings will not prevent a record from successfully processing and going through final submission. However, users should review these records to confirm whether the physician's license is active or expired. If the license is expired, the record should be updated to remove the inactive license. If the physician does not have any licenses that were active in the program year, the record should be deleted.

FAQ #22677

Question:

What happens when a payment is reported for a physician whose license was expired prior to 8/1/2013?

Answer:

For manual submissions, record(s) containing a physician license that expired prior to the start of the Open Payments program, August 1, 2013, may fail matching and the user will receive an error on the user interface. For records submitted via bulk file upload, the error log file may display the failed matching error. If the expired license was the only license available for the physician associated with the record, the record should not be submitted.

Definitions

FAQ #8151

Question:

The definition of an applicable manufacturer excludes distributors or wholesalers that do not hold title to any covered drug, device, biological or medical supply. What is the meaning of “hold title” in this context?

Answer:

A distributor holds title to products once it takes ownership of a particular inventory of products from the seller and possesses the right to re-sell the inventory of the products that it has purchased. Holding title to a covered product in this context is distinct from holding FDA approval, licensure or clearance for a covered product. Distributors and wholesalers (which include repackagers, relabelers, and kit assemblers) that hold title to a covered drug, device, biological or medical supply meets the definition of an applicable manufacturer. Distributors and wholesalers that do not hold title of a covered product will not be subject to the reporting requirements, unless they are under common ownership with an applicable manufacturer and provide assistance or support with respect to a covered drug, device, biological, or medical supply.

FAQ #8155

Question:

Are payments provided to a consulting firm or third party, whom in turn provide the payment (in whole or part), to a physician reportable under the Open Payments?

Answer:

Yes, Open Payments requires reporting of both direct and indirect payments and other transfers of value provided by an applicable manufacturer or applicable group purchasing organization to a covered recipient. An indirect payment is a payment or transfer of value made by an applicable manufacturer, or an applicable group purchasing organization, to a covered recipient, or a physician owner or investor, through a third party, where the applicable manufacturer, or applicable group purchasing organization, requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s), or a physician owner or investor.

FAQ #8157

Question:

Is a blood center an applicable manufacturer?

Answer:

Yes, a blood center is considered to be an applicable manufacturer if the blood center operates in the United States and is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply covered by Medicare, Medicaid, or CHIP.

Additionally, a blood center is considered to be an applicable manufacturer if the blood center is under common ownership, as defined in 42 CFR 403.902 with an applicable manufacturer, and the blood center provides assistance or support to the applicable manufacturer. Assistance and support provided by the blood center to the entity must pertain to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological, or medical supply. A covered drug or biological is any drug or biological 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 (such as under a hospital inpatient /outpatient prospective payment system; and
- (2) Requires a prescription to be dispensed.

FAQ #8161

Question:

What items or materials are considered educational materials and are not reportable transfers of value?

Answer:

Educational materials and items that directly benefit patients, or are intended to be used by or with patients, are not reportable transfers of value. Additionally, the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply are not reportable transfers of value. For example, overhead expense, such as printing and time development of educational materials, which directly benefit patients or are intended for patient use are not reportable transfers of value.

FAQ #8163

Question:

Applicable manufacturers with less than 10% total (gross) revenue from covered drugs, devices, biologicals, or medical supplies have limited reporting requirements regarding payments or other transfers of value provided to covered recipients. Does total (gross) revenue include both domestic sales and global sales, or only domestic sales?

Answer:

Both domestic and global sales are included in the company's total (gross) revenue. Applicable manufacturers with less than 10 percent of total (gross) revenue from covered drugs, devices, biological or medical supplies during the previous fiscal year are required to report only payments or other transfers of value specifically related to covered drugs, devices, biologicals or medical supplies. Applicable manufacturers with less than 10 percent of total gross revenue from covered products during the previous year must register with CMS and attest that less than 10 percent of total (gross) revenues are from covered products, along with their attestation of the submitted data.

FAQ #8256

Question:

Are drugs or biologicals that are reimbursed by Medicare, Medicaid, or CHIP but do not require a prescription and are not over-the-counter products considered covered drugs or biologicals for Open Payments?

Answer:

Yes, drugs and biologicals that are reimbursable under Medicare, Medicaid, or CHIP and that are not over-the-counter products are considered covered drugs or biologicals for Open Payments. The limiting clause requiring a "prescription to be dispensed" in order for a drug or biological to fall within the definition of a "covered drug, device, biological, or medical supply" in 42 C.F.R. § 403.902 is only intended to exclude over-the-counter (OTC) drugs, not those that require administration or authorization by a physician. 78 Fed. Reg. 9465.

FAQ #8270

Question:

Is there a required relationship between the “applicable manufacturer” of a covered device and the entity that provides “necessary and integral assistance or support”?

Answer:

An entity can be considered an applicable manufacturer under prong 2 of the definition at 42 C.F.R. § 403.902 if it is under common ownership with an applicable manufacturer under prong 1 of the definition, and it provides assistance or support to the prong 1 applicable manufacturer with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply. “Common ownership” refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities, including, but not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations. A prong 2 applicable manufacturer is only required to report payments or other transfers of value that are related to a covered drug, device, biological, or medical supply for which it provided assistance or support to the prong 1 applicable manufacturer under common ownership.

FAQ #8366

Question:

Are payments or other transfers of value made, by an applicable manufacturer or applicable group purchasing organization, to a physician's immediate family who hold an ownership or investment interest in an applicable manufacturer or applicable group purchasing organization considered reportable for the purposes of Open Payments?

Answer:

Generally, no. Pursuant to 42 C.F.R. 403.906(a)(1), applicable manufacturers and applicable group purchasing organizations are required to report annually on ownership and investment interests held by a physician or an immediate family member of a physician. Such ownership and investment interests must be reported under the name of the physician -- even if it is the physician's immediate family member that holds the ownership or investment interest -- with an indication of whether the interest is held by the physician or an immediate family member. Under § 403.906(b), however, applicable manufacturers and applicable group purchasing organizations must report the dollar amount invested by a physician or a physician's immediate family member, but for payments or other transfers of value, they are only required to report those to a physician owner/investor (not to an immediate family member of a physician, who has an ownership/investment interest). Note -there are two exceptions: 1) when an applicable manufacturer or applicable group purchasing organization gives a payment/other transfer of value to an immediate family member of a physician on behalf of or at the request of a physician owner or investor (i.e., a third party payment to the family member), or 2) when the payment is provided to the immediate family member of a physician as an indirect payment to be passed through to the physician. In those two scenarios, the payment or transfer of value to the immediate family member of a physician owner/investor must be reported (as a payment or transfer of value to the physician), regardless of whether or not the immediate family member is also an owner/investor.

FAQ #8368

Question:

The final rule states in 42 CFR 403.902 that an "applicable group purchasing organization" is one that purchases, arranges for or negotiates the purchase of a covered product for a "group" of individuals or entities. How many individuals or entities are necessary to be considered a group for the purpose of this definition?

Answer:

Regarding the definition of "applicable group purchasing organization," a 'group' consists of two or more individuals and/or entities.

FAQ #8372

Question:

Does the exemption for reporting payments to medical residents also include payments to “Fellows”?

Answer:

No. The final rule exempted payments to medical residents from the reporting requirements solely due to operational and data accuracy concerns regarding aggregation of payments or other transfers of value to residents, many of whom have neither a National Provider Identifier (NPI) nor a State professional license. Because these same concerns do not generally apply to physicians in Fellowship training, payments to Fellows are not exempt from the reporting requirements.

FAQ #8384

Question:

What is the relationship between Open Payments and the Federal Anti-Kickback statute, False Claims Act or similar legislation?

Answer:

Compliance with Open Payments reporting requirements does not exempt applicable manufacturers, applicable group purchasing organizations, covered recipients, physician owners or investors, immediate family members, other entities, and other persons from any potential liability associated with payments or other transfers of value, or ownership or investment interests under the Federal Anti-Kickback statute, False Claims Act or similar laws. As noted in the preamble of the rule, however, the inclusion of a payment or other transfer of value or ownership or investment interest in Open Payments is not, by itself, an indicator of wrongdoing or illegal conduct.

FAQ #8960

Question:

Are free repairs or services, and/or additional training offered by applicable manufacturers included in the contractual warranty exclusion in 42 C.F.R. 403.904(i)(6) ?

Answer:

Repairs or services and/or additional training provided under a contractual warranty (including a service or maintenance agreement) will also be subject to the exclusion, where the terms of the warranty are set forth in the purchase or lease agreement.

FAQ #8968

Question:

Is a distributor considered an applicable manufacturer if it holds title to devices or drugs from a manufacturer that it distributes or sells to covered recipients, yet payment for all products is limited to commercial insurance and private payer only?

Answer:

Only if an entity manufactures, or distributes at least one drug, device, biological, or medical supply that is covered by Medicare, Medicaid, or CHIP, would it qualify as an applicable manufacturer that must report to the Open Payments program. Of note, if an entity does manufacture or distribute at least one drug, device, biological, or medical supply that is covered by Medicare, Medicaid, or CHIP, that entity must report all payments or transfers of value made to covered recipients, regardless of whether or not they (payments) are related to a covered product. Refer to 42 C.F.R. § 403.902 for the full definition of an applicable manufacturer.

FAQ #8982

Question:

Is a distributor for an applicable manufacturer responsible for reporting to CMS payments or other transfers of value to health care professionals?

Answer:

If a distributor holds title to any covered drug, device, biological, or medical supply, the distributor meets the definition of an applicable manufacturer as defined at 42 C.F.R. § 403.902, and is subject to Open Payments reporting requirements. A distributor holds title to products once it takes ownership of a particular inventory of products from the seller and possesses the right to re-sell the inventory of the products that it has purchased. Applicable manufacturers that have products with titles held by distributors do not need to report payments or other transfers of value made by the distributor to covered recipients. The distributor that holds title will be subject to the same reporting requirements as applicable manufacturers, and thus will be responsible for reporting the transfer of value.

FAQ #8984

Question:

Is a physician located outside of the United States considered a physician covered recipient for purposes of Open Payments?

Answer:

If a physician maintains a current state license to practice medicine in any state in the United States, the physician will be considered a covered recipient for purposes of Open Payments. Within Open Payments, the term “physician” has the same meaning as under Section 1861(r) of the Social Security Act, which generally includes doctors of medicine, osteopathy, dentists, podiatrists, optometrists and chiropractors who are legally authorized to practice by a state. A current state license would render the physician “legally authorized” to practice medicine, regardless of the extent to which they do so. Therefore, a physician who maintains an active license to practice in the United States would be considered a covered recipient, and payments made to such a person would have to be reported, even for services rendered (such as speaking at a public seminar) outside of the U.S. An exception to this covered recipient classification is when a physician is a bona fide employee of an applicable manufacturer that is required to submit reporting information under subsection (a) of Section 1128G of the Social Security Act.

FAQ #8990

Question:

Is leasing a device included in the actions that constitute “assistance or support” to determine if an entity is considered an applicable manufacturer under prong 2 of the definition for an applicable manufacturer at 42 C.F.R § 403.902?

Answer:

Assistance or support, as defined at 42 C.F.R § 403.902, is conduct that is necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. A case-by-case analysis is necessary to determine whether the leasing of a device would constitute assistance or support. For example, leasing a device may constitute assistance or support if supplying the device is necessary or integral to the applicable manufacturer’s ability to produce the covered product.

FAQ #8992

Question:

Is a payment or other transfer of value considered indirect if an applicable manufacturer utilizes a market research company's services to conduct double-blinded market research with primary care physicians, which includes paying physicians for participating?

Answer:

No, a payment or other transfer of value provided to a market research company to conduct double-blinded market research with physicians is not considered an indirect payment. The applicable manufacturer clearly intends a portion of the payment to be provided to physicians, but given that the reason for the third party's involvement is specifically to maintain the anonymity of the respondents and sponsor, we do not intend this to be considered a reportable indirect payment or other transfer of value. Additionally, under section 1128G(e)(10)(A) of the Social Security Act, Open Payments excludes reporting of payments when an applicable manufacturer is unaware of the covered recipient, and the payment to the covered recipient is made indirectly through a third party, such as the market research company, in the above facts.

FAQ #9000

Question:

Is information regarding a physician principal investigator required for reporting if he/she is a military physician?

Answer:

Yes, if a military physician is a physician covered recipient principal investigator for a research study that is identified according to 42 C.F.R. § 403.904(f) then information about the physician covered recipient principal investigator is required to be reported as indicated at § 403.904(f)(1)(v).

FAQ #9004

Question:

Are awards from specialty societies provided to physician covered recipients considered indirect payments if the awards are funded by grants from applicable manufacturers?

Answer:

Yes. Open Payments requires reporting of direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient. An indirect payment, defined by 42 C.F.R. § 403.902, is a payment or transfer of value made by an applicable manufacturer (or an applicable group purchasing organization) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable group purchasing organization) requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s) (or a physician owner or investor). If the applicable manufacturer causes the specialty society, acting as a third party, to provide a payment or transfer of value in whole or in part to a covered recipient, then this may be considered an indirect payment or other transfer of value. In this scenario, the transfer of value is the portion of the grant that would be used to create an award for a covered recipient. However, an applicable manufacturer is not required to report an indirect payment/other transfer of value if, according to 42 C.F.R. § 403.904(h)(1), the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in §403.902) the identity of the covered recipient. The definition of “know” states that a person “knows” if he/she has actual knowledge of the information, or acts in deliberate ignorance or reckless disregard of the information. An example of an applicable manufacturer having the requisite knowledge that a covered recipient received an award from grant funds is if an applicable manufacturer allows a specialty society to use its name in an award for a covered recipient, the applicable manufacturer would easily be able to ascertain the identity of the award’s recipient. Therefore, the applicable manufacturer could be deemed to be acting with deliberate ignorance if it did not follow up with the specialty society regarding the identity of the recipient.

FAQ #9122

Question:

An entity leases employees to an applicable manufacturer for operational purposes, and continues to pay all salaries for the leased employees. Would this assistance and support be enough to consider the entity an applicable manufacturer if the entity is also under common ownership with the applicable manufacturer?

Answer:

Yes, the act of an entity leasing employees to an applicable manufacturer that it is also under common ownership with may constitute assistance and support necessary to consider the entity an applicable manufacturer if the service or services provided by the employees that are leased are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological or medical supply.

FAQ #9154

Question:

Is the loan of a covered device by an applicable manufacturer for training purposes at a Continuing Medical Education (CME) or non-CME event considered a payment or other transfer of value to covered recipients?

Answer:

No. A loan of a covered device by an applicable manufacturer for training purposes at a CME or non-CME event is not considered a payment or other transfer of value provided to a covered recipient if the device was loaned to the CME vendor for training covered recipients at a CME event and the covered recipient did not take possession of the covered device.

FAQ #10014

Question:

For purposes of reporting physician ownership under section 1128(G)(a)(2) of the Social Security Act, does an “immediate family member” of a physician include the lawfully married same-sex spouse of a physician and family members that result from the lawful marriage of individuals of the same sex?

Answer:

Yes. “Immediate family member” is defined in the implementing regulations at 42 C.F.R. § 403.902 as any of the following: (1) Spouse; (2) Natural or adoptive parent, child, or sibling; (3) Stepparent, stepchild, stepbrother, or stepsister; (4) Father-, mother-, daughter-, son-, brother-, or sister-in-law; (5) Grandparent or grandchild; (6) Spouse of a grandparent or grandchild. The term “spouse” is gender-neutral, and is properly read to include lawfully married spouses, including same-sex spouses. In *United States v. Windsor*, 570 U.S. ___, 113 S. Ct. 2675 (2013), the Supreme Court ruled that section 3 of the Defense of Marriage Act, which had defined marriage for federal purposes as between opposite sex spouses, is unconstitutional. In light of this decision, the Department has instituted a policy of treating same-sex marriages on the same terms as opposite-sex marriages to the greatest extent reasonably possible. This FAQ clarifies Windsor’s application to the requirement to report physician ownership under section 1128(G)(a)(2) of the SSA. For purposes of this reporting requirement, the same-sex spouse of a physician and the family members that result from same-sex marriages are considered “immediate family members” if the marriage was celebrated in a state or other jurisdiction, whether foreign or domestic, that permitted the marriage under its laws, or if the states(s) or other jurisdiction(s) where the couple lives recognizes the marriage as a legally valid marriage.

Final Rule Changes

FAQ #11002

Question:

Why did CMS change certain aspects of the Final Rule at Part 403, subpart I, Transparency Reports and Reporting of Physician Ownership or Investment Interests implementing Open Payments?

Answer:

CMS continued to receive feedback from a variety of stakeholders about certain aspects of its reporting requirements after publishing the final rule in February 2013. As a result of the public comments we received during the July 2014 rulemaking process, we believe that the changes we have made are more aligned with the initial intent of the program, and will help the public to determine the nature and extent of financial relationships that occur between the medical manufacturing industry and physicians and teaching hospitals.

FAQ #11004

Question:

Why was the Continuing Education Exclusion § 403.904(g) removed?

Answer:

The overriding comment by stakeholders has been that the reporting requirements are inconsistent because certain continuing education payments are reportable, while others are not. We believe that removal of the exclusion places all present (and future) organizations on the same footing, and essentially levels the requirements across all certified or accredited continuing education programs, without favoring one organization or group of organizations over another. Additionally, it will alleviate any burden associated with determining which organizations have adopted new standards, as well as monitoring organizations' adherence to new standards.

FAQ #11006

Question:

Does removal of the Continuing Education exclusion for physician speakers also remove the exclusion for fees related to physician attendees at continuing education events?

Answer:

CMS intends for fees have been subsidized by an applicable manufacturer through the continuing education organization to be reported, unless the payment meets the indirect payment exclusion at § 403.904(h)(1). If a manufacturer generally subsidizes tuition fees provided to physician attendees for continuing education events, this would be excluded from reporting if the manufacturer is unaware of the identity of the recipient physician attendees. This allows for consistent reporting at continuing education events. We intend for physician attendees whose fees have been subsidized by an applicable manufacturer through the continuing education organization to be reported, unless the payment meets the indirect payment exclusion at § 403.904(h)(1). This allows for consistent reporting at continuing education events. We will provide sub-regulatory guidance specifying tuition fees provided to physician attendees that have been generally subsidized at continuing education events by manufacturers are not expected to be reported. However, if a manufacturer does instruct, direct, or otherwise cause the subsidized tuition fee for a continuing education event to go to a specific physician attendee, the payment will not be excluded, since the indirect payment exclusion only applies if the manufacturer did not know the identity of the physician attendee.

FAQ #11008

Question:

When did the new reporting requirement for physician speaker compensation and physician attendee subsidies associated with continuing education events go into effect?

Answer:

All revisions were implemented for the 2016 program year, with reporting to CMS in 2017. This reporting requirement is not applicable to prior program years (Program Years 2013 – 2015).

FAQ #11010

Question:

Why did CMS add a requirement to report the ‘marketed name’ and therapeutic area or product category of the related covered drugs, devices, biologicals, or medical supplies?

Answer:

In the February 8, 2013 final rule, CMS provided applicable manufacturers with reporting flexibility for determining when the marketed name for all devices and medical supplies may not be useful for the general public. CMS did not define product categories or therapeutic areas in § 403.904(c). However, since implementation of the February 8, 2013 final rule and the development of the Open Payments system, CMS has determined that making the reporting requirements for marketed name across drugs, biologicals, devices and medical supplies will make the data fields consistent and more reliable within the system, and also enhance consumer usage of the data.

FAQ #11012

Question:

Does the new requirement for “marketed name” apply to research payments?

Answer:

No. Manufacturers will continue to have the option to report either a device or medical supply marketed name, therapeutic area, or product category when reporting payments associated with research.

FAQ #11014

Question:

When did the new reporting requirement for “marketed name” go into effect?

Answer:

All revisions were implemented for the 2016 program year, with reporting to CMS in 2017. This reporting requirement is not applicable to prior program years (Program Years 2013 – 2015).

FAQ #11016

Question:

Why did CMS require manufacturers to disaggregate the reporting of stock, stock options, or any other ownership interest into distinct categories?

Answer:

After issuing the February 8, 2013, final rule and the development of the Open Payments system, CMS determined that this specificity will increase the ease of data aggregation within the system, and also enhance consumer usage of the data.

FAQ #11600

Question:

If several applicable manufacturers or group purchasing organizations (GPOs) contribute funding to a Continuing Medical Education (CME) program and there are several speakers, how is this reported?

Answer:

In this scenario, each applicable manufacturer or GPO would need to determine for itself if their respective contribution constitutes a reportable payment or transfer of value. In accordance with the definition of an indirect payment at 42 C.F.R. §403.902, applicable manufacturers or GPOs that contribute funding to a CME program with several speakers are required to report the payments provided to physician speakers if they determine that the payments meet the definition of an indirect payment. An indirect payment is defined at 42 C.F.R. §403.902 as a payment or other transfer of value made by an applicable manufacturer to a covered recipient through a third party, where the applicable manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient. Consistent with the CMS Final Rule (CMS-5060-F), there are instances where indirect payments provided by an applicable manufacturer to a CME program are not reportable. In accordance with 42 C.F.R. §403.904(h)(1), indirect payments or other transfers of value are excluded from reporting where the applicable manufacturer is unaware of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year. If the payment is a reportable payment, then the amount should be equally divided among the known covered recipient speakers.

FAQ #11602

Question:

If an applicable manufacturer gave a contribution to support a medical conference, but did not have any say in the content, speakers, or attendees, would this be considered an unrestricted donation? Or, is the fact that the money was specifically for an educational conference mean that it is, by definition, restricted?

Answer:

Unrestricted donations to a medical conference as described in this FAQ would not be subject to reporting under Open Payments. Although there is no formal definition of an unrestricted donation, in this case we can take that term to mean a grant given by a reporting entity to a professional association for use without any restrictions, pre-conditions, or post-conditions in order to assist the professional or educational association with its administrative or educational needs. In accordance with the definition of an indirect payment at 42 C.F.R. §403.902, an applicable manufacturer that contributes funding to a medical/educational conference would be required to report the payment if the reporting entity determines that it meets the definition of an indirect payment at 42 C.F.R. §403.902. An indirect payment is defined at 42 C.F.R. §403.902 as a payment or other transfer of value made by an applicable manufacturer to a covered recipient through a third party, where the applicable manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient.

FAQ #11638

Question:

Starting with 2016 Open Payments data collection and reporting to CMS in 2017, are payments provided by an applicable manufacturer to a continuing education organization for continuing education events reportable?

Answer:

Yes, the payment is reportable if the applicable manufacturer determines that the payment meets the definition of an indirect payment, and the applicable manufacturer knows or can determine the identity of the covered recipient by the end of the second quarter of the following reporting year. An indirect payment is defined at 42 C.F.R. §403.902 as a payment or other transfer of value made by an applicable manufacturer to a covered recipient through a third party, where the applicable manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient. In accordance with 42 C.F.R. §403.904(h)(1), indirect payments or other transfers of value do not have to be reported if the applicable manufacturer is unaware of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

Participation

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 #8264

Question:

Is study equipment, implantable devices, instrumentation, or other supplies provided to a covered recipient by an applicable manufacturer in connection with a FDA approved clinical trial for use solely in a research project considered a transfer of value?

Answer:

Yes, payments or other transfers of value made in connection with an activity that meets the definition of research and that are subject to a written agreement, a research protocol, or both should be included in the total amount of the research payment. Payments or other transfers of value that are not included in the written agreement or research protocol should be reported separately in the appropriate nature of payment category.

FAQ #8374

Question:

Are payments from an applicable manufacturer to covered recipients in order to purchase products or materials considered payments that are reportable under Open Payments -- for example, an applicable manufacturer purchasing materials, such as reagents, from a teaching hospital?

Answer:

Yes. There is no reporting exclusion for payments made by applicable manufacturers or applicable group purchasing organizations to covered recipients for the purpose of purchasing products or materials.

FAQ #8380

Question:

Are applicable manufacturers or applicable group purchasing organizations responsible for reporting individual stock holdings, which were not stock awarded as a payment but are personal investment by covered recipient physicians?

Answer:

Applicable manufacturers and applicable group purchasing organizations are required to report to CMS on an annual basis all ownership and investment interest in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year. An ownership or investment interest is not reportable if an applicable manufacturer or applicable group purchasing organization did not know about such ownership or investment interest (42 C.F.R. § 403.902). In this context, the word “know” means that a person, with respect to information: (1) has actual knowledge of the information, (2) acts in deliberate ignorance of the truth or falsity of the information, or (3) acts in reckless disregard of the truth or falsity of the information.

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 #8972

Question:

Will CMS issue opinions exempting applicable manufacturers or applicable group purchasing organizations from Open Payments reporting requirements?

Answer:

No, CMS is not issuing advisory opinions exempting applicable manufacturers or applicable group purchasing organizations from Open Payments reporting requirements.

FAQ #8974

Question:

Are distributions to physician owners of LLC units in a physician owned distributor (POD) considered reportable payments or other transfers of value or are they incidents of ownership and not considered reportable?

Answer:

If a POD falls within the definition of an applicable manufacturer or applicable group purchasing organization (or both), then they must report distributions provided to physician owners of LLC units in the POD for purposes of Open Payments.

FAQ #8978

Question:

Is a manufacturer of dental alloys considered an applicable manufacturer for purposes of Open Payments? Are payments or other transfers of value provided to dental labs reportable or only payments or other transfers of value provided to dentists?

Answer:

A manufacturer of dental alloys is considered an applicable manufacturer, as defined by 42 C.F.R § 403.902, if it is an entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (prong 1 of the definition). Additionally, a manufacturer of dental alloys is considered an applicable manufacturer if all of the following criteria are met: the manufacturer of dental alloys provides assistance or support to an entity that meets prong 1 of the definition of an applicable manufacturer of a covered drug, device, biological, or medical supply; the manufacturer of dental alloys and the entity are under “common ownership” (as defined in 42 C.F.R. § 403.902); and the manufacturer of dental alloys’ act of providing alloys to the entity constitutes “assistance or support” to the entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply. The final rule defines assistance or support as being necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product. As an example of assistance or support that would be considered necessary or integral, the preamble mentions an entity that produces the active ingredient for a covered drug, which is then included in the final product. (78 Fed. Reg. 9463.) It seems likely that a manufacturer of dental alloys under common ownership with an applicable manufacturer, which provides alloys that is included in the final product, would be considered to be providing necessary and integral support with respect to the production of that product. Similar to the example in the preamble, supplying alloys would be necessary or integral since the applicable manufacturer could not produce the product without it.

FAQ #8988

Question:

Is a contract research organization (CRO) that performs clinical trials according to protocols for pharmaceutical companies required to report a budgeted amount contracted for medical safety, which is performed by the CRO's employed physician?

Answer:

A CRO that is not an applicable manufacturer is not required to report information under Open Payments. However, an applicable manufacturer providing a payment that meets the definition of research, as defined at 42 C.F.R. § 403.902, to a CRO which is ultimately paid in whole or in part to a covered recipient (physician or teaching hospital), is required to report, as outlined in §403.904(f), the name of the research institution, individual or entity receiving the payment, total amount of the research payment, name of the research study, names of any related covered drugs, devices, biological, or medical supplies, and information about each physician covered recipient principal investigator. The research agreement may include an unbroken chain of agreements as long as they link the applicable manufacturer with the recipient. If the employee of a CRO who is conducting medical safety for clinical trials for a research study is also a physician covered recipient principal investigator then information regarding the physician is required to be reported by the applicable manufacturer under Open Payments.

FAQ #8996

Question:

Are applicable manufacturers that receive research grants from National Institute of Health (NIH) required to report a sub-award from the NIH grant as a research payment, where the applicable manufacturer contracts with medical centers or universities to conduct research?

Answer:

Yes, research payments (meeting the definition of research at 42 C.F.R. § 403.902) from an NIH research grant are required to be reported as payment or other transfer of value for purposes of Open Payments according to the special rules for research payments at § 403.904(f).

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.

FAQ #9126

Question:

Are independent sales representatives that are responsible for taking product orders from covered recipients and may receive a commission, but who do not hold title to any covered drugs, devices, biological, or medical supply and are not employees of applicable manufacturers required to report payments or other transfers of value provided to covered recipients or physician owners or investors?

Answer:

Independent sales representatives are only required to report payments or other transfers of value provided to covered recipients or physician owners or investors if they meet the definition of an applicable manufacturer, as defined by 42 C.F.R § 403.902 or if they are under common ownership with an applicable manufacturer and provide assistance and support to such applicable manufacturer with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological or medical supply. However, applicable manufacturers requiring, instructing, directing or otherwise causing independent sales representatives to provide payments or other transfers of value, in whole or in part, to a covered recipient or physician owner or investor, known as indirect payments defined at § 403.902, are required to be reported by the applicable manufacturer.

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 #9140

Question:

Is a distributor required to report food and beverages that are provided during an open house for a new distributorship center opened by a distributor?

Answer:

Yes. If the distributor meets the definition of an applicable manufacturer, as defined by 42 C.F.R § 403.902, food and beverages provided to covered recipients and physician owners or investors are required to be reported. The applicable manufacturer should divide the value of the food by the number of those who partook in the food. The value of the food still needs to be accounted for even if the event is a large scale event as long as the applicable manufacturer can identify the covered recipients of the food.

FAQ #10076

Question:

Is an applicable manufacturer company that dissolves or is purchased by another company responsible for reporting in Open Payments?

Answer:

If a company meeting the definition of an applicable manufacturer dissolves, it is still responsible for reporting in Open Payments for the period when it was an applicable manufacturer. For example, if Company A meets the definition of an applicable manufacturer and is purchased by Company B, then Company A is responsible for reporting in Open Payments for the period prior to the purchase. However, if Company B meets the definition of an applicable manufacturer upon the purchase of Company A, it too is responsible for reporting in Open Payments beginning with the date of the purchase.

Registration

FAQ #8145

Question:

What information does an applicable manufacturer or applicable group purchasing organization need to provide during registration?

Answer:

Applicable manufacturers and applicable group purchasing organizations need to register with CMS in order to submit data. Personnel representing applicable manufacturers and applicable group purchasing organizations should be prepared to provide information necessary to identify themselves and establish their roles (both within the Open Payments System and the organizations they represent). Data necessary for applicable manufacturer or applicable group purchasing organization registration includes the names of primary and secondary points of contact for the applicable manufacturer or applicable group purchasing organization as well as the name(s) of the individual(s) who will attest to the accuracy of the data submitted. For a complete list of required information for registration refer to the Open Payments System Quick Reference Guide “Required Fields for Registration,” which is available on the Resources page of the Open Payments website. Additional guidance regarding the registration process is available in the Open Payments User Guide and the Quick Reference Guide “Applicable Manufacturer and Applicable GPO Registration and Recertification,” both of which are on the Resources page.

FAQ #9138

Question:

Are all applicable manufacturers and applicable group purchasing organizations required to register for Open Payments?

Answer:

No, only applicable manufacturers and applicable group purchasing organizations that have reportable payments or other transfers of value, ownership or investment interest, or both are required to register.

FAQ #9722

Question:

Who can register in EIDM to access the Open Payments system?

Answer:

Applicable manufacturers, group purchasing organizations (GPOs), physicians, and teaching hospitals can register in EIDM to access the Open Payment system. Select the appropriate role when registering in EIDM. Access to the Open Payments System will not be granted to anyone who does not meet one of these designated roles.

FAQ #9724

Question:

Do I need to provide my social security number to get an EIDM account?

Answer:

This is an optional field, but providing your social security number can facilitate identity verification.

FAQ #10088

Question:

If two or more entities plan to submit a consolidated report, do all entities need to register in Open Payments?

Answer:

Yes. Any entity that fits the definition of an applicable manufacturer or applicable group purchasing organization and has payments or other transfers of value to report must register in the Open Payments System.

FAQ #11966

Question:

Do applicable manufacturers and applicable group purchasing organizations (GPOs) need to recertify their Open Payments system registration each program year?

Answer:

Yes. Each calendar year, applicable manufacturers and applicable GPOs need to recertify their profile information. During recertification, the user must either confirm that the identifying details in the entity's Open Payments profile are accurate or make updates if any information is inaccurate. Note that only those who hold the user role of "Officer" in the Open Payments system for that reporting entity can recertify the entity. If there is no active Officer for the reporting entity, contact the CMS Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance with recertification and nominating/approving a new Officer. For additional guidance on how to recertify, refer to Quick Reference Guide "Applicable Manufacturer and Applicable GPO Registration and Recertification," available on the Resources page of the Open Payments website (<https://www.cms.gov/OpenPayments/About/Resources.html>).

Review, Dispute, and Correction

FAQ #8147

Question:

Does CMS notify covered recipients (physicians and teaching hospitals) when applicable manufacturers or applicable group purchasing organizations (GPOs) report data?

Answer:

The Open Payments system does not generate individual notifications to covered recipients when attributable information has been reported. However, covered recipients may self-subscribe to the Open Payments listserv to receive program related reminders, updates, and information regarding actionable items. These reminders include general notifications such as deadline reminders, program updates, and general announcements. As a reminder, covered recipients' participation in the Open Payments program is voluntary, and as such they are responsible for their own registration in the Open Payments system and review of the data.

FAQ #8268

Question:

When can covered recipients and physician owners or investors initiate a dispute?

Answer:

Covered recipients and physician owners or investors may initiate disputes at any time after the 45 day review and correction period begins, but before the end of the calendar year. Note that any changes resulting from disputes initiated after the 45 day review period may not be published until the next time the data is refreshed. If a dispute is not resolved by 15 days after the end of the 45 day period, we will report the applicable manufacturer or applicable GPO's version of the payment or other transfer of value (or ownership or investment interest), but will mark it as disputed.

FAQ #8360

Question:

Are applicable manufacturers or applicable group purchasing expected to resubmit an entire report with corrections and/or updates or should a resubmitted report only reflect the changes from the originally submitted report (i.e., corrected or previously missed payments or transfers of value)?

Answer:

Applicable manufacturers and applicable group purchasing organizations submitting a report have the ability to retract and resubmit an entire report, submit corrections to a group of records, retract a group of records, or append a group of records that were omitted from the original report submission. Applicable manufacturers and applicable group purchasing organizations have the ability to make corrections and additions after the data submission deadline; however, they may be subject to penalties for submitting data after the deadline. Therefore, applicable manufacturers should register and submit data early to ensure correction activities are completed prior to the deadline.

FAQ #10130

Question:

How does a covered recipient complete the review and dispute process?

Answer:

Physicians and teaching hospitals are able to initiate disputes through the Open Payments system during the review and dispute period, which follows the data submission period each program year. Applicable manufacturers and group purchasing organizations (GPOs) are able to review disputed records and take action to correct the records and resolve any issues directly with physicians and teaching hospitals. Any discussions pertaining to the resolution of a disputed record must take place outside of the Open Payments system between the applicable manufacturer or GPO and the disputing physician or, teaching hospital.

FAQ #10264

Question:

On the Open Payments “Review and Dispute” page, how do I view all of the fields of the records?

Answer:

To view all fields of the record, select the “record ID hyperlink”.

FAQ #10268

Question:

What is the difference between the Review and Dispute statuses of “Resolved No Change” and “Resolved”?

Answer:

Records may have a Review and Dispute status of “Resolved, No Change,” which means that the reporting entity and physician or teaching hospital have resolved the dispute in accordance with the Final Rule and no changes were made to the disputed record. If a record has a status of “Resolved,” the disputed record was updated by the reporting entity and resubmitted in the Open Payments system.

FAQ #11956

Question:

When correcting a payment or other transfer of value record, should the reporting entity submit just the corrected record, or should the reporting entity correct the record and re-upload an entire new data file (which includes the corrected record plus previously submitted records that did not need to be corrected)?

Answer:

Reporting entities should only submit the newly corrected records. They should not re-upload an entire new data file, which includes the corrected record plus previously submitted records that did not need to be corrected. Re-uploading an entire new data file that includes records that did not need to be corrected may not be in compliance with 42 C.F.R. § 403.908(e), which pertains to attesting to each report, including subsequent corrections, and ensuring the submission is reported timely, accurately, and is a complete submission.

FAQ #12208

Question:

I am a physician trying to initiate a dispute for a record that I see published in the Open Payments public data and attributed to me. However, when I log in to the Open Payments system I do not see this record listed on my Review and Dispute page. How can I initiate a dispute against this record?

Answer:

If you see a record published in the Open Payments public data and attributed to you, but you do not see it on your Review and Dispute page in the Open Payments system, that indicates that the record was available for your review in a prior calendar year and is no longer available for review. Records are only made available for review and dispute in the calendar year that they were submitted and attested to. For example, if a reporting entity submitted and attested to a record during the submission window in calendar year 2014, the covered recipient has until December 31, 2014 to review and, if necessary, initiate a dispute on the payment or transfer of value. After the end of the calendar year in which the record was submitted, if you do not see the record on your Review and Dispute page in the Open Payments system but have a concern about the data, you will need to reach out to the reporting entity directly to resolve the dispute. In the event that a reporting entity makes edits to a published record, the covered recipient will have an opportunity to review the edits made on the Review and Dispute page within the Open Payments system, and initiate a dispute if needed.

FAQ #12224

Question:

I'm a physician who is listed as a principal investigator on a research payment reported by an applicable manufacturer or applicable GPO. When I log into the Open Payments system, it appears that the full payment amount referenced in the reported research payment is attributed to me. Why is a research payment that I have not received, attributed to me in the Open Payments system?

Answer:

Each research payment record submitted to the Open Payments system by an applicable manufacturer or applicable GPO is attributed to the physician, teaching hospital, or non-covered recipient that received the payment. As appropriate, the names of physician principal investigators associated with the research payment are also provided. If you are a physician who served as a principal investigator on a research study, you may see the payments associated with that research study listed under your name. This does not necessarily mean the payments are attributed to you. The dollar amount of the record corresponds to the total payment; the amounts are not attributed to each individual on the record. For example, if an applicable manufacturer submits a \$1000 research payment made to a teaching hospital and reports that there are three associated physician principal investigators, all three principal investigators would be listed in the Open Payments system; but the teaching hospital would be listed as the entity that received the \$1000 research payment. As a principal investigator, you may only dispute your own association with the payment or other transfer of value. You should not dispute any other information about the transaction, such as payment amount, nature of payment, etc.

FAQ #20297

Question:

When correcting a payment or other transfer of value record that is in a "Ready for Attestation" or "Attested" status, and the change is to a field that identifies the record's covered recipient or principal investigator, does the record need to be deleted and then re-submitted as a new record?

Answer:

Yes. If fields that identify the record's covered recipient or principal investigators need to be changed in a record that is in a "Ready for Attestation" or "Attested" status, the original record must be deleted and then re-submitted as a new record. The attester is encouraged to use or amend the assumptions statement to note when records have been deleted and then re-submitted, particularly when those records were re-submitted after the submission deadline. For physicians, including principal investigators, the relevant fields that identify the record's covered recipient or principal investigators are: First Name, Last Name, NPI, License State, and License Number. For teaching hospitals, the relevant fields that identify the record's covered recipient or principal investigators are: Teaching Hospital Name, the hospital address fields, and Taxpayer Identification Number.