Cooley

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) OPEN PAYMENTS FREQUENTLY ASKED QUESTIONS (FAQ) TRACKER

Current as of February 2017

CMS FREQUENTLY ASKED QUESTIONS (FAQS)
RELATED TO PHYSICIAN PAYMENT SUNSHINE ACT

FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
8368	July 2013	Applicable GPO	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?	Regarding the definition of "applicable group purchasing organization," a 'group' consists of two or more individuals and/or entities.
9122	October 2013	Applicable Manufacturer	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?	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.
8163	April 2013	Applicable Manufacturer	Applicable manufacturers with less than 10% total (gross) revenue 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?	Both domestic and global sales are included in the company's total (gross) revenue. Applicable manufactures 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.
8974	August 2013	Applicable Manufacturer	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?	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.
8392	July 2013	Applicable Manufacturer	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?	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.

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9126	October 2013	Applicable Manufacturer	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?	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.
9124	October 2013	Applicable Manufacturer	Does Open Payments require an entity to report payments or other transfers of value provided to covered recipients or physician owners or investors retroactively once the entity becomes an applicable manufacturer, once the entity has a least one covered drug, biological, device or medical supply?	No, Open Payments does not require retroactive reporting. Entities determined to be applicable manufacturers because they have least one product that became a covered drug, have a grace period of 180 days following a drug, device, biological or medical supply becoming covered to begin complying with the data collection and reporting requirements.
8157	April 2013	Applicable Manufacturer	Is a blood center an applicable manufacturer?	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.
8968	August 2013	Applicable Manufacturer	Is a distributor considered an applicable manufacturer if it holds title to devices and drugs and distributes and sells medical devices and drugs from a manufacturer to hospitals and ambulatory surgery centers or covered recipients for use in surgical procedures, and payment for all products is limited to commercial insurance and private payer only?	An applicable manufacturer, as defined by 42 C.F.R § 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 or a distributor or wholesaler (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply. A "covered device" (including a medical supply that is a device) is any device 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) by law, requires premarket approval by or premarket notification to the FDA. The question of whether a distributor falls within the definition of an applicable manufacturer, as defined in 42 C.F.R. § 403.902, depends in part on whether payment is available for any of the distributor's products under Medicare, Medicaid, or CHIP. A distributor is not considered an applicable manufacturer for purposes of Open Payments if the distributor only distributes and sells a manufacturer's medical devices and drugs and payment is not available under Medicare, Medicaid, or CHIP. However, it is worth noting that under the final rule, if an entity manufactures at least one covered drug, device, biological, or medical supply, then it qualifies as an applicable manufacturer and must report all payments or transfers of value to covered recipients, regardless of whether or not they are related to a covered product. Similarly, if a distributor distributes at least one covered drug, device, biological or medical supply, then it qualifies as an applicable manufacturer and must report all payments or transfers of value to covered recipients, regardless of whether or not they are related to a covered product.

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8982	August 2013	Applicable Manufacturer	Is a distributor for an applicable manufacturer responsible for reporting to CMS payments or other transfers of value to health care professionals?	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.
8978	August 2013	Applicable Manufacturer	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?	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.
8990	August 2013	Applicable Manufacturer	Is leasing 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?	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. An example of assistance or support considered necessary or integral, would be an entity that produces the active ingredient for a covered drug, which is then included in the final product. (78 Fed. Reg. 9463) Based on the limited information supplied in this question, it is difficult to determine whether the provision of a leasing device constitutes assistance or support. However, leasing a device may constitute assistance or support if supplying the device would be necessary or integral to the applicable manufacturer who could not produce the product without the leased device.
8270	June 2013	Applicable Manufacturer	Is there a required relationship between the "applicable manufacturer" of a covered device and the entity that provides "necessary and integral assistance or support"?	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.

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8151	June 2013	Applicable Manufacturer	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?	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.
8972	August 2013	Applicable Manufacturer	Will CMS issue opinions exempting applicable manufacturers or applicable group purchasing organizations from Open Payments reporting requirements?	No, CMS is not issuing advisory opinions exempting applicable manufacturers or applicable group purchasing organizations from Open Payments reporting requirements
10124	June 2014	Attestation	Are attestations required as part of corrected record resubmissions?	If any records are resubmitted, the entirety of the data for the program year must be attested to again.
10074	June 2014	Attestation	Are attesters for applicable manufacturers and applicable GPOs submitting a consolidated report required to be a Chief Executive Office, Chief Financial Officer, Chief Compliance Officer, or other Officer for **all** the entities included in the consolidated report?	No. The attester for the reporting entity submitting a consolidated report is only required to be a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer for that entity that is **submitting** the consolidated report. While the attester for the consolidated report must hold the attester role for all entities included in the consolidated report (so that attester is able to attest on behalf of the entities included in the consolidated report, in accordance with 42 C.F.R § 403.908(e)), that attester does **not** need to hold an Officer role in the other entities included in the consolidated report.
10106	June 2014	Attestation	Can one attestation cover multiple individually submitted data files, with all of the files as part of the same submission?	Yes. When you attest to data, you attest to all of the successfully submitted data files for the selected program year. Regardless of how many files are submitted during the data submission process, users will attest at the same time to all of the data successfully submitted and ready for attestation. In other words, attestation does not occur for each individual data file; it occurs for all files submitted for the selected program year that are ready for attestation.
11966	March 2015	Attestation	Do applicable manufacturers and applicable GPOs need to re-certify their Open Payments system registration each program year?	Yes. Each calendar year, reporting entities (applicable manufacturers or applicable GPOs) need to re-certify their profile information. Specifically, reporting entities that registered in the Open Payments system in the prior calendar year are required to re-certify prior to taking any actions in the Open Payments system in the next calendar year. No submission or dispute resolution activities are available for a registered entity until that entity is re-certified. In addition, viewing previously submitted records will not be available until that entity is re-certified. During re-certification, the user will confirm either that the identifying details in the entity's Open Payments profile are accurate, or the user will update those details in the entity profile 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 re-certify 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 re-certification and nominating/approving a new officer. For additional guidance on how to re-certify, refer to the "Open Payments System Quick Reference Guide: Applicable Manufacturer and Applicable GPO Registration and Re-Certification" located on the Resources page of the Open Payments website.
8964	August 2013	Calculating Payment / Transfer of Value	Are tax and payments for shipping and handling including in calculating value for a payment or other transfer of value?	Yes, tax and payments for shipping and handling are included in the total payment or other transfer of value for Open Payments.

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8364	July 2013	Calculating Payment / Transfer of Value	To determine if an applicable manufacture (or applicable group purchasing organization) has met the $100 aggregate threshold for reporting small payments to a covered recipient or physician owner/investor, is it required to aggregate small payments or other transfers of value different across different nature of payment categories?	Yes. To determine if payments or other transfers of value exceed the $100 threshold and must be reported, applicable manufacturers and applicable group purchasing organizations must aggregate payments of less than $10 across multiple nature of payment categories. For example, if the applicable manufacturer provides a physician with multiple separate payments valued under $10 each and the cumulative amount of those separate payments exceeds $100 during the year (e.g. 6 hot dogs - $9 per hot dog, 3 sporting tickets - $9 per ticket, and 3 cab fares - $9 per cab), the threshold will have been met and these payments must be reported.
12368	July 2015	Calculating Payment / Transfer of Value	When calculating number of payments a doctor received, should users count entries (rows) or tally the number of payment fields within each payment?	Each row indicates one payment, transfer of value, or ownership amount per doctor; counting rows should provide the total number of payments.
8388	July 2013	CME	Are educational materials or items associated with an accredited or certified CME program that meets all three conditions, such as slides or handouts, included in the tuition fees for continuing education events excluded from reporting?	Yes. Educational materials that are included in the tuition fees for an accredited or certified CME program that meets all three exemption conditions, such as handouts, web downloads or printed slides, are excluded from reporting under Open Payments provided that the content does not contain any CME sponsor information, the content is related to the CME program, the value is de minimis, and the funds used for the materials came from the same CME program grant.
8386	July 2013	CME	Are payments for travel, lodging and meals to speakers and faculty of accredited or certified CME events that meet all three conditions established in the final rule included in the total compensations that are exempt from reporting?	Yes. Lodging, travel and meals for speakers of an accredited or certified CME event meeting all three requirements in 42 CFR 403.904(g)(1) will be deemed to be included in the total speaker compensation and, therefore, exempt from reporting under Open Payments. However, travel, lodging and meals and all other natures of payments provided in conjunction with the accredited or certified CME event (with the exception of educational materials included in the tuition fees for an accredited or certified CME program that meets all three exemption conditions, such as handouts, web downloads or printed slides) will need to be reported for physician attendees (who are not speakers). These payments would need to be reported under the appropriate nature of payment categories, such as food and beverage, travel and lodging, or entertainment, as appropriate. The excluding characteristic for meals is when allocating the cost of the meal among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable.
8165	April 2013	CME	Are payments provided to physicians for speaking at a continuing medical education event reportable?	Speaker compensation at continuing education event such as Continuing Medical Education (CME) conference is not required to be reported by an applicable manufacturer if all of the following criteria are met: (1) the CME program meets the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association's Continuing Education Recognition Program, the American Medical Association, or the American Osteopathic Association, (2) the applicable manufacturer does not select or suggest the covered recipient speaker nor does it provide the third party vendor with distinct, identifiable individuals to be considered as speakers for the accredited or certified continuing education programs; AND (3) the applicable manufacturer does not directly pay the covered recipient speaker.
8390	July 2013	CME	If an applicable manufacturer supports an unaccredited educational program at a large annual conference and serves buffet meals, but also provides payment for general sponsorship or has an exhibit booth, will the awareness standards be applicable to the buffet meals provided at the unaccredited program?	The question of whether an applicable manufacturer must report a buffet meal provided to physician attendees at an unaccredited educational program taking place 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) The preamble explains that the exception in 42 CFR 403.904(h)(2) only applies to situations where an applicable manufacturer provides a large buffet meal, snacks or coffee that are made available to all conference attendees and where it would be difficult to establish the identity of the physicians, who partook in the meal or snack. This exception does not apply to meals provided to select attendees at a conference where the sponsoring applicable manufacturer can establish the identity of the attendees.

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8398*	July 2013	CME	Are payments provided as compensation to speakers at CME events run by CME providers that that are accredited or certified by accreditation or certification bodies other than those enumerated in 42 CFR § 403.904(g)(1)(i) eligible for the exclusion from reporting (assuming they also meet the other requirements for exclusion in § 403.904(g)(1))?	No, the list of accrediting or certifying bodies in the final rule at 42 CFR § 403.904(g)(1)(i) is exhaustive; in order to qualify for the exclusion in § 403.904(g)(1), CME events must be run by CME providers that are accredited or certified by one of the accreditation or certification entities in § 403.904(g)(1)(i) and, accordingly, meet the accreditation or certification requirements and standards of any of those specific entities. Payments to speakers at CME events that are not run by CME providers accredited or certified by one of the entities in § 403.904(g)(1) -- or that don't meet either or both of the other two requirements for exclusion in § 403.904(g)(1) -- are reportable payments or other transfers of value for Open Payments. We will consider modifications to this provision in possible future rulemaking.
8256	June 2013	Covered Products	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?	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.
8258	June 2013	Covered Products	Is a medical device considered eligible for payment by Medicare, Medicaid, or CHIP for purposes of Open Payments reporting requirements if a test performed using the device is eligible for payment, but not the device itself (e.g., MRI machines, CT, x-rays, ultrasounds machines)?	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 device 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.
9002	August 2013	Covered Recipients	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?	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 proposed and 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.
10082	June 2014	Covered Recipients	Do applicable manufacturers need to report NPIs for teaching hospitals?	The NPI is not a required field if the covered recipient is a teaching hospital. As stated in 78 FR 9498, reporting the NPI (as listed in NPPES) is required for physicians only. It is the applicable manufacturers' responsibility to demonstrate a good faith effort to obtain an NPI for a physician.
8984	August 2013	Covered Recipients	Is a physician located outside of the United States considered a physician covered recipient for purposes of Open Payments?	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.
8994	August 2013	Covered Recipients	Should applicable manufacturers and applicable group purchasing organizations use the information found in NPPES if they ascertain that their information regarding physicians' unique identifiers is more accurate that what is listed in NPPES?	Applicable manufacturers and applicable group purchasing organizations may obtain information regarding physicians' unique identifiers from their internal sources however the information must be reported accurately as listed in NPPES.
12392	July 2015	Disputes	Can a physician or teaching hospital still register in the Open Payments system and initiate a dispute after the May 20, 2015 deadline?	Physicians and teaching hospitals can register in CMS' Enterprise Portal and the Open Payments system, and initiate disputes in the Open Payments system, at any point in the year. Please note, though, that the review and dispute period officially ended on May 20, 2015, for the 2014 reporting cycle, so any disputes initiated after this date will not be reflected in the June 30, 2015 data publication. These disputes will be reflected in the next data refresh reporting cycle. See the Open Payments System Quick Reference Guide – Review and Dispute Timing and Data Publication for detailed information on how disputes are shown in published records.

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8362	July 2013	Disputes	Do covered recipients have two years from the date the review and correction period begins to initiate a dispute?	No, covered recipients have only until the end of the calendar year to initiate a dispute. (42 CFR 403.908(g)(3)(v)) For example, if an applicable manufacturer reports to CMS on March 31, 2014 all reportable payments or other transfers it provided to covered recipients during the previous year, covered recipients only have until December 31, 2014 to initiate a dispute.
12388	July 2015	Disputes	How can disputes initiated by physicians and teaching hospitals be resolved?	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.
10130	June 2014	Disputes	How does a covered recipient complete the review and dispute process?	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
12208	May 2015	Disputes	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?	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.
12390	July 2015	Disputes	What happens if physicians or teaching hospitals initiated disputes with the reported data before/after the review and dispute period ended on May 20, 2015?	The status of a dispute on a record has several effects on what data is published. Details of how disputes are shown in published records are explained in the Open Payments System Quick Reference Guide – Review and Dispute Timing and Data Publication.
12378	July 2015	Disputes	What if a physician or teaching hospital registered (or tried to register) prior to May 20, 2015, but was unable to dispute records until after May 20?	Review and dispute officially ended on May 20, 2015 for the 2014 reporting cycle. Any disputes initiated after this date will not be reflected in the June 30, 2015 data publication. These disputes and any subsequent correction to those data will be reflected in the next data refresh.
8268	June 2013	Disputes	When can covered recipients and physician owners or investors initiate a dispute?	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 made 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.
9134	October 2013	Exclusions	Are Federal, state, and local taxes withheld from a physician owner or investor considered reportable payments or other transfers of value?	No, Federal, state, and local taxes withheld from a physician owner or investor are not considered reportable payments or other transfer of value.
8960	August 2013	Exclusions	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)?	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.

[1] Source: https://questions.cms.gov/faq.php?id=5005&rtopic=2017
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CMS FREQUENTLY ASKED QUESTIONS (FAQS)
RELATED TO PHYSICIAN PAYMENT SUNSHINE ACT

FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
8956	August 2013	Exclusions	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?	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.
11602	May 2015	Exclusions	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?	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, preconditions, 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.
8958	August 2013	Exclusions	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?	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(i)(5).
9120	October 2013	Exclusions	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?	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.
9154	October 2013	Exclusions	Is the loan of a covered device by an applicable manufacturer for training purposes at a CME or non-CME event considered a payment or other transfer of value to covered recipients?	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.
8358	July 2013	Exclusions	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?	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.

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FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
9004	August 2013	Indirect Payments	Are awards from specialty societies provided to physician covered recipients considered indirect payments if the awards are funded by grants from applicable manufacturers?	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(i)(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.
8155	April 2013	Indirect Payments	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?	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.
11600	June 2014	Indirect Payments	If several applicable manufacturers contribute funding to a continuing medical education (CME) program and there are several speakers, how is this reported?	In accordance with the definition of an indirect payment at 42 C.F.R. §403.902, applicable manufacturers 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.
8992	August 2013	Indirect Payments	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?	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.
8976	August 2013	Indirect Payments	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?	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.

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CMS FREQUENTLY ASKED QUESTIONS (FAQS)
RELATED TO PHYSICIAN PAYMENT SUNSHINE ACT

FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
9136	October 2013	Indirect Payments	Is an applicable manufacturer required to report the name of a third party, such as a clinical research organization (CRO) providing an indirect research payment to a covered recipient?	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 principal investigators, teaching hospitals, nonteaching hospitals or clinics. Applicable manufacturers are required to report information regarding recipients of research payments as specified in 42 C.F.R § 403.904(f).
8169	April 2013	Indirect Payments	Should an applicable manufacturer report a payment was made to a physician or to a clinic if the 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 an indirect payment or a payment to a third party?	This is considered an indirect payment. Applicable manufacturers are required to report indirect payments 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.
10086	June 2014	Nature of Payment / Transfer of Value	Can all payments made to a covered recipient during a reporting period for the same Nature of Payment category be combined into one payment?	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.
8254	June 2013	Nature of Payment / Transfer of Value	In which payment category should applicable manufacturers report payments to covered recipients for medical textbooks or journal reprints?	Applicable manufacturers must select the nature of payment category that they believe most accurately describes a payment or other transfer of value. 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.
8966	August 2013	Nature of Payment / Transfer of Value	Is a newsletter created by an ad agency on behalf of a pharmaceutical client that is an applicable manufacturer, consisting of a few journal abstracts on the disease state and information on patient adherence, a reportable payment or other transfer of value? If so, what "nature of payment" category should the newsletter be reported in? Additionally, can the ad agency as a third party collect and maintain the physician information that is required for reporting?	Yes, a newsletter consisting of a few journal abstracts provided to physician covered recipients from an applicable manufacturer (directly or indirectly) is considered a reportable payment or other transfer of value for purposes of Open Payments if the newsletter is valued at $10 or more or the aggregate amount of payments or transfers of value provided to a covered recipient exceeds $100 in a calendar year. Applicable manufacturers must select the "nature of payment" category that they believe most accurately describes a payment or other transfer of value. (42 C.F.R. § 403.904(e)(2)) Therefore, applicable manufacturers must select the "nature of payment" category that best describes the provision of the newsletter to a covered recipient. The "nature of payment" category applicable to newsletters created by advertising or marketing agencies is "gift," depending on the circumstances of the transfer of value. Third parties, such as an ad agency, can maintain the information collected that is required for reporting by applicable manufacturers.
8382	July 2013	Nature of Payment / Transfer of Value	Which nature of payment category should applicable manufacturers report payments to physician covered recipients for promotional speaking?	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.
18357	[Jan. 2017]	Other	Does CMS publish a covered recipient's NPI on the Open Payments website?	No. As required by the statute, CMS does not publish a covered recipient's NPI on the Open Payments website.

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FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
8384	July 2013	Other	What is the relationship between Open Payments and the Federal Anti-Kickback statute, False Claims Act or similar legislation?	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.
18289	[Jan. 2017]	Ownership & Investment Interests	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?	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 Ownership or Investment 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 Ownership or Investment 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.
8380	July 2013	Ownership & Investment Interests	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?	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.
8366	July 2013	Ownership & Investment Interests	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?	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 that 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, regardless of whether or not the immediate family member is also an owner/investor.

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FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
10014	February 2014	Ownership & Investment Interests	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?	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.
8378	July 2013	Ownership & Investment Interests	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 2015?	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.
8376	July 2013	Ownership & Investment Interests	When reporting ownership or investment interests; what should applicable manufacturers or applicable group purchasing organization report regarding value and terms of each ownership or investment interest?	Applicable manufacturers and applicable group purchasing organizations reporting ownership or investment interests have some flexibility to decide how to report the "value" of such interests. However, they must document the method used to estimate the value of the ownership or investment and may include such documentation if they submit an assumptions document with their annual report. 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.
11966	July 2015	Registration	Do applicable manufacturers and applicable GPOs need to re-certify their Open Payments system registration each program year?	Yes. Each calendar year, reporting entities (applicable manufacturers or applicable GPOs) need to re-certify their profile information. Specifically, reporting entities that registered in the Open Payments system in the prior calendar year are required to re-certify prior to taking any actions in the Open Payments system in the next calendar year. No submission or dispute resolution activities are available for a registered entity until that entity is re-certified. In addition, viewing previously submitted records will not be available until that entity is re-certified. During re-certification, the user will confirm either that the identifying details in the entity's Open Payments profile are accurate, or the user will update those details in the entity profile 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 re-certify 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 re-certification and nominating/approving a new officer. For additional guidance on how to re-certify, refer to the "Open Payments System Quick Reference Guide: Applicable Manufacturer and Applicable GPO Registration and Re-Certification" located on the Resources page of the Open Payments website.

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FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
9138	October 2013	Registration	Are all applicable manufacturers and applicable group purchasing organizations required to register for Open Payments?	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.
9724	February 2014	Registration	Do I need to provide my social security number to get an EIDM account?	This is an optional field, but providing your social security number can facilitate identity verification.
9738	February 2014	Registration	For individuals with a US address who even upon contacting Experian Verification services are experiencing difficulty with EIDM registration.	Please send an email to Open Payments help desk at OpenPayments@cms.hhs.gov for support with registration and data submission.
9728	February 2014	Registration	I am planning on submitting a consolidated report in Phase 2; how is this addressed in Phase 1?	Consolidated reporting is only applicable in Phase 2. In Phase 1, consolidated reports will not be accepted. Individual entities need to submit their aggregate data individually.
9730	February 2014	Registration	I do not see the yellow “Open Payments” button on the portal. Where is it?	You must first request access to Open Payments in order for the yellow button labeled “Open Payments” to appear on the Enterprise Portal homepage. To do this: • Log back in to the CMS Enterprise Portal by clicking “Login to CMS Secure Portal”, accept the Terms and Conditions, and enter your user ID and password. • Once logged in, click “Request Access Now” on the right hand side of the CMS Enterprise Portal home page. • Request access to the Open Payments system by clicking on “Request New Application Access” on the left hand side of the page. • Select “Open Payments” from the drop down menu. • A second drop down will then appear prompting you to select an Open Payments role in the system. • Select “Open Payments User” and then click “Submit”. • You will then see the “Identity Verification” page, click on “Next”. • You will then see the “Terms and Conditions” page, select the check box next to “I agree to the terms and conditions” and click “Next”. • Fill out the requested fields on the “Your Information” page and click “Next”. • On the “Verify Identity” page select the correct answer for each question to verify your identify and when completed click “Next”. • On the “Complete Step Up” page click “Next”. • You will then see an acknowledgement message, click on “OK”. • Then log out of the system by clicking “Log Out” in the upper right hand corner of the page. • Log in to the CMS Enterprise Portal once again by clicking “Login to CMS Secure Portal” and entering your user ID and password. • On the CMS Enterprise Portal home page you should now see a yellow button labeled “Open Payments” next to “My Portal” on the upper left hand side of the page. • When you click on “Open Payments” you should have an option labeled "Registration" appear beneath it. • Click on “Registration” to access details about the first step of Phase 1 of detailed data submission, CMS Enterprise Portal (EIDM Registration). • You will now see the Open Payments Registration Page.
10092	June 2014	Registration	If an entity registered for Phase 1 in Open Payments but later determined that it is not an applicable manufacturer or applicable group purchasing organization (GPO), what action should be taken, if any?	If an entity determines that it is not an applicable manufacturer or applicable GPO, as defined by 42 C.F.R. §403.902, but has inadvertently registered in Open Payments and completed a Phase 1 submission, the entity does not need to take any further action. The aggregate payment amounts reported in Phase 1 will not be made public.

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FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
10088	June 2014	Registration	If two or more entities plan to submit a consolidated report, do all entities need to register in Open Payments?	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.
9734	February 2014	Registration	My EIDM user ID is not formatted as ##-######-### - does it have to be?	No, it does not. We are correcting this error where it appeared in our original instruction document. The user can establish their own EIDM user ID when they first login to the Enterprise portal, and it does need to adhere to the ##-######-### format.
9736	February 2014	Registration	We have received several questions about foreign nationals representing foreign entities with a foreign address and no US address, who are having difficulty with EIDM registration via the CMS Enterprise portal.	Please contact the Open Payments help desk at OpenPayments@cms.hhs.gov or 1-855-326-8366 for support with registration and data submission.
9726	February 2014	Registration	What if the automated identity verification function does not work for me?	A manual work-around will be available, but please be aware that this manual process could take up to two weeks, so early registration is advisable.
8145	April 2013	Registration	What information does an applicable manufacturer or applicable group purchasing organization need to provide during registration?	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). This data includes, for example, the name of the primary point of contact, the name of the secondary point of contact, and the name of the individual that will attest to the accuracy of the data submitted. Additional guidance regarding the registration process is forthcoming.
9732	February 2014	Registration	What is the difference between the "officer" and the "authorized official"?	The authorized official is an entity's executive-level officer who can legally represent their entity and manage the entity's profile within the Open Payments system and therefore begin the chain of trust among the other individuals interacting with the system. Activities specific to the authorized official's role is limited to registering the entity, but authorized officials may also perform other activities as an officer such as approving user role requests made by others, delegating roles to others, as well as submitting and attesting to data. The officer role is initially delegated to individuals within the entity by the authorized official. Once approved in this role, no functional differences exist between the authorized official role and the officer role. An officer may approve other authorized representatives on behalf of the authorized official, manage the entity in the Open Payments system, and delegate roles to others. An officer can also be delegated as a "submitter" or "attester," and can then submit or attest to the validity of data.
9722	February 2014	Registration	When requesting access to Open Payments, which user role should I select from the dropdown?	Select "Applicable Manufacturer, GPO, Physician, or Teaching Hospital user role".
8147	April 2013	Registration	Will CMS notify physicians and teaching hospitals that applicable manufactures or applicable GPO's reported data about them?	Physicians, teaching hospitals, and physician owners or investors will receive a general notification when the reported information is ready for review. However, the physician, teaching hospital, and physician owners or physician investors will only receive this notification if they have previously registered with CMS. We encourage physicians, teaching hospitals, and physician owners or physician investors to register to allow for notification. Additionally, CMS will utilize a general online posting (http://go.cms.gov/openpayments) and notifications on CMS' listserve(s).

[1] Source: https://questions.cms.gov/faq.php?id=5005&rtopic=2017
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CMS FREQUENTLY ASKED QUESTIONS (FAQS)
RELATED TO PHYSICIAN PAYMENT SUNSHINE ACT

FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
8360	July 2013	Report Corrections	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)?	Applicable manufacturers and applicable group purchasing organizations submitting a report will 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 will 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.
10120	June 2014	Report Corrections	Are large amounts of corrected data files capable of being resubmitted?	Yes, corrected data files can be submitted through bulk file upload. Note that the 250MB size limit also applies to corrected data files.
10112	June 2014	Report Corrections	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?	For the first level of data validation which is performed at the file level (i.e., checking the file broadly to make sure it is formatted correctly for the Open Payments system), the submitter will receive immediate feedback via an on-screen message letting them know the file upload was successful or not successful. For the second level of data validation (which checks the record level specifications described in the Data Submission Mapping Document), applicable manufacturers and applicable GPOs will be notified via email of any data validation errors. The email will direct the user to the system-generated error report available in the Open Payments system. The error report will provide a list of all errors the submission has generated and error codes that explain the source of the errors. Users should then refer to the Error Code File Document for a description of the error code, the corresponding data element, and steps to avoid and correct each error. After Final Submission, the Open Payments system will search to match submitted records to a valid physician or teaching hospital. This matching process may take up to several days, and timing will vary based upon the size of the data files. Email notification that contains the results of the matching process will be sent to the data submitter upon completion of this step.
10054	June 2014	Report Corrections	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?	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).
10122	June 2014	Report Corrections	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?	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.
10114	June 2014	Report Corrections	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?	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.), then the entire data submission will be rejected and needs to be re-submitted after it is re-formatted. However, if the error is found in an individual record, only the record(s) containing errors need to be re-submitted. Applicable manufacturers and applicable GPOs will be notified via onscreen text of file level errors; they will be notified via email of record level data validation errors. The email will direct the user to the system-generated error report available in the Open Payments system, which will provide a list of all errors the submission has generated and error codes that explain the source of the errors. Users should then refer to the Error Code File Document for a description of the error code, the corresponding data element, and steps to avoid and correct each error.
10264	June 2014	Report Corrections	On the Open Payments "Review and Dispute" page, how do I view all of the fields in the Review and Dispute table?	To view all columns in the table, use the scroll bar at the bottom of the table to scroll left and right. Some columns contain hyperlinks which, when selected, will allow you to view additional information related to the selected record.

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10126	June 2014	Report Corrections	What is considered a timely re-submission of data? And can corrected data file resubmissions extend past the deadline?	Data submissions to Open Payments for program year 2013 must be made from June 1 - June 30, 2014. All submissions, corrected data file re-submissions, and attestations must occur during this time period. Re-submissions and re-attestations made past the 2013 submission deadline of June 30 will be considered late submissions and will not be publicly posted until the next data refresh.
10268	June 2014	Report Corrections	What is the difference between the Review and Dispute statuses of "Resolved No Change" and "Resolved"?	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.
10118	June 2014	Report Corrections	What is the resubmission process for an applicable manufacturer or applicable GPO to resubmit their corrected data files?	After making corrections to the records to be resubmitted, indicate a record is a resubmission by setting the Resubmission Indicator to "Y," and include the original Payment Record ID in the "Resubmitted Payment Record ID" field. Then upload the file to the system as with any other bulk file upload, including the original Payment Record ID. You may also correct and re-submit data using the Graphic User Interface (instead of bulk file upload) if the number of records to be re-submitted is small. 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 submission from the Open Payments system and replace it with a new submission if you prefer.
11956	June 2014	Report Corrections	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)?	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.
11970	March 2015	Report Corrections	Why am I receiving a "Failed Matching Validation" message for payment records that were accepted last year?	Payment records that were successfully matched in 2014 may now appear as "Failed Matching Validation" in 2015 because all records are now subject to a more stringent matching process that was implemented in early 2015. 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 located on the Resources page of the Open Payments website. After consulting this resource, if you are having trouble moving your records out of "Failed Matching Validation" status, contact the CMS Open Payments Help Desk at openpayments@cms.hhs.gov or 1-855-326-8366 for assistance.
10116	June 2014	Report Corrections	Will every data error in each line item be identified to eliminate resubmissions regarding the same line items?	Yes. Applicable manufacturers and applicable GPOs will be notified via email of any record level data validation errors. The email will direct the user to the system-generated error report in the Open Payments system, which will provide a list of all errors the submission has generated and error codes that explain the source of the errors. The Open Payments error code document provides explanations of the error codes and suggested fixes. All errors in all records in the file will be captured in the error report.

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8153	April 2013	Report Form	If a medical professional society's annual conference is held prior to August 1, 2013 and a physician received a direct payment for consulting or other service, is the date of payment the date of the event?	Applicable manufacturers must report the date that a payment or transfer of value was provided to the covered recipient. In certain circumstances, applicable manufacturers have flexibility to determine the methodology for reporting when the date of the transfer of value was "provided." For example, in the instance of travel benefits, there is flexibility for reporting travel because the purchase date (of airline tickets, for example) may be different than the date the transfer of value is actually "provided" to the covered recipient (i.e., when the physician takes the flight). Applicable manufacturers have some flexibility to choose which payment date they will use in this type of situation; however, the methodology used must be consistent within a single nature of payment category (such as travel). If a physician provides a consulting or other service prior to August 1, 2013, but an applicable manufacture does not pay the physician for the service until August 1, 2013 or after, such payment would be reported because the payment was provided to the physician after the start of the reporting requirements. Applicable manufactures do not have flexibility to designate the date of the physician's service as the "date of payment." Rather, the date of payment would be the date the applicable manufacturer post-marked the check or funds transfer to the physician to compensate him/her for the services rendered.
8980	August 2013	Report Form	What should distributors, which offer a multitude of covered and non-covered products, report in the Product Indicator data element regarding related covered drug, device, biological or medical supply?	Distributors that are considered applicable manufacturers because they hold title to a covered drug, device, biological or medical supply may report "None" in the Product Indicator indicating that the payment or other transfer of value was not associated with any covered drugs, device, biological or medical supply if the payment or other transfer of value was related to the distributor's full line of products, rather than any specific covered products.
8149*	April 2013	Report Form	Will data collection templates be released?	Yes, data collection templates will be released by CMS. The 2013 reporting period data collection templates can be found on the OPEN PAYMENTS website. Please note that the 2013 reporting period data collection templates are currently undergoing final clearance (Paperwork Reduction Act) but the linked templates are what CMS intends to use for 2013 data collection. Data collection templates for future reporting years will be released for applicable manufacturers and GPOs by October 1 of each year.
8260	June 2013	Reportable Payments & Transfers of Value	Are applicable manufacturers required to report meals, travel, lodging, and other similar expenses made in connection with interviewing prospective employees?	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.
8962	August 2013	Reportable Payments & Transfers of Value	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?	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.
8171	April 2013	Reportable Payments & Transfers of Value	Are items or materials used to educate physicians, which may indirectly benefit patients, included in the education materials exclusion?	No, the education 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. Education materials, such as medical textbooks or journal reprints, that are educational to covered recipients but are not intended for patient use or directly beneficial to patients are not included in the exclusion.
8374	July 2013	Reportable Payments & Transfers of Value	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?	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.
10084	June 2014	Reportable Payments & Transfers of Value	Can a physician reimburse an applicable manufacturer for payments so that no information is reported about them in Open Payments?	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(i)(1) for information on possible exclusions.

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8372	July 2013	Reportable Payments & Transfers of Value	Does the exemption for reporting payments to medical residents also include payments to "Fellows"?	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.
8970	August 2013	Reportable Payments & Transfers of Value	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?	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.
9152	October 2013	Reportable Payments & Transfers of Value	If an applicable manufacturer provides compensation to a non-US speaker for a CME in the US, does the payment or other transfer of value provided to the speaker need to be reported?	Yes. If the non-US speaker meets the definition of a physician covered recipient and the event does not meet the criteria specified at 42 C.F.R § 403.904(g)(ii)-(iii) the payment or other transfer of value provided to the speaker needs to be reported, unless the non-US speaker is a physician employee of the applicable manufacturer. In the latter case, the physician employee would have to fulfill the definition of employee as set forth at Section 1877(h) of the Social Security Act.
8272	June 2013	Reportable Payments & Transfers of Value	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?	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.
9140	October 2013	Reportable Payments & Transfers of Value	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?	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.
9142	October 2013	Reportable Payments & Transfers of Value	Is a donation provided to a teaching hospital's foundation by an applicable manufacturer reportable?	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.
9150	October 2013	Reportable Payments & Transfers of Value	Is a meeting a reportable event if an applicable manufacturer located in the United States conducts the meeting in a foreign country?	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.

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8986	August 2013	Reportable Payments & Transfers of Value	Is a textbook donation to a medical center library for the general use of all employees reportable?	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).
10076	June 2014	Reportable Payments & Transfers of Value	Is an applicable manufacturer company that dissolves or is purchased by another company responsible for reporting in Open Payments?	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.
9132	October 2013	Reportable Payments & Transfers of Value	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?	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.
10090	June 2014	Reportable Payments & Transfers of Value	Is there a minimum value threshold that needs to be met in order for applicable manufacturers and applicable group purchasing organizations to be required to report?	There is no minimum value threshold for reporting. However, for CY 2013, payments or other transfers of value less than $10 are excluded from reporting unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in the calendar year.

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11638	May 2015	Reportable Payments & Transfers of Value	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?	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(i)(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.
8161	April 2013	Reportable Payments & Transfers of Value	What items or materials are considered education materials and are not reportable transfers of value?	Education 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.
9128	October 2013	Reporting, General	Are applicable manufacturers required to report a physician's name and taxonomy code as listed in the National Plan & Provider Enumeration System (NPPES)?	Applicable manufacturers and applicable group purchasing organizations (GPO) are required to report a physician's National Provider Identifier and name as listed in NPPES and include first and last name, middle initial, and suffix (for all that apply). Applicable manufacturers and applicable GPOs may use their internal information when reporting a physician's taxonomy code. However, the NPPES provider taxonomy code list should be used as the list of accepted physician specialties.
12374	July 2015	Reporting, General	Are there any records that you are not publishing?	Yes. The Open Payments final rule provides that some research payments related to new product development, or new uses of an existing product, may be granted a delay in publication for up to four years, or until Food and Drug Administration (FDA) approval is received.
12376	July 2015	Reporting, General	Did doctors and teaching hospitals have a chance to review the financial data reported about them?	Yes. During a 45-day physician and teaching hospital review and dispute period that ended on May 20, 2015, the dollar values and information about each transaction listed were available for review by doctors and teaching hospitals registered in the Open Payments system. They could 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.
11974	July 2015	Reporting, General	How do I remove a delay in publication request for a previously submitted record?	A request for a delay in publication must be renewed each year. So, if the record was previously submitted in a prior year and the 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. That means the user doesn't have to do anything to remove the delay in publication request. However, if the previously submitted record was submitted in the current reporting year, follow the instructions in the Open Payments System Quick Reference Guide: Payment Category Page and Delay in Publication located on the Resources page of the Open Payments website.

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12372	July 2015	Reporting, General	How is "de-identified" 2013 data being treated?	2013 data published last year included a set of "de-identified" records which removed payment recipients' identifying information. This was done because CMS could not verify with full confidence that recipient identifiers were attributable to specific physicians or teaching hospitals and may also have included identifying information for multiple individuals. Open Payments has since returned invalid records to the reporting entities for correction and has also enhanced the reporting system's intake process to prevent invalid records from being ingested by the system. As a result, 2013 data records published as "de-identified" in 2014 will be published in 2015 with the recipients' individual information included.
12358	July 2015	Reporting, General	How many records did CMS release on June 30, 2015? What is the value of those records?	For 2014, the data contains 11.4 million records, totaling $6.49 billion. That means that over the program's entire lifespan, 15.7 million records of payments, other transfers of value, and ownership or investment interests are reported on the Open Payments website, totaling $9.9 billion. These records are attributable to over 600,000 physicians and more than 1,100 teaching hospitals.
12380	July 2015	Reporting, General	How often is Open Payments data refreshed or updated?	CMS will collect and publish this data every year. September 30, 2014, was the first publication of this data; it was then refreshed for the first time on December 19, 2014. This year, and for all years after, data publication is on June 30. CMS will also refresh the data once annually, after the initial publication.
9116	October 2013	Reporting, General	How should an applicable manufacturer determine which National Drug Code(s) (NDC) to report for a payment or other transfer of value that is associated with a covered drug or biological?	Applicable manufacturers and applicable group purchasing organizations are required to report any 10-digit NDC corresponding to the covered drug or biological, which includes the labeler code (assigned by the FDA) and the product and package code (assigned by the labeler) that matches a covered drug or biological that is associated with a payment or other transfer of value. Once reported, Open Payments will identify the associated drug or biological using the provided NDC and provide just the marketed covered drug or biological name on its website.
9146	Revised March 2015 (originally published October	Reporting, General	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?	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 anf 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. If you are submitting a record of a payment or other transfer of value for the 2013 program year, the hospital name in the record
8262	June 2013	Reporting, General	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?	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.
8167	April 2013	Reporting, General	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?	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.

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CMS FREQUENTLY ASKED QUESTIONS (FAQS)
RELATED TO PHYSICIAN PAYMENT SUNSHINE ACT

FAQ #[1]	DATE	CATEGORY	QUESTION	ANSWER
12362	July 2015	Reporting, General	In what formats is the data presented?	CMS delivers Open Payments data in a number of ways to accommodate different users and their interests: 1. 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. 2. 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. 3. 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.
10100	June 2014	Reporting, General	Including data lines and rows per file submission, what is the total allowable size for the data files to be submitted in Phase 2?	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.
9144	October 2013	Reporting, General	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?	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 http://go.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.
9148	October 2013	Reporting, General	Is an applicable manufacturer required to report all taxonomy codes for a physician or just the primary taxonomy codes?	Applicable manufacturers will report only one taxonomy code per physician. Additionally, applicable manufacturers may use their internal data to determine a physician's taxonomy code. However, the National Plan & Provider Enumeration System provider taxonomy code list should be used as the list of accepted specialties.
12370	July 2015	Reporting, General	Is any "de-identified" 2014 data being published?	No, no de-identified 2014 data is being published. Since last year, Open Payments has enhanced the reporting system's matching logic (described above) and is now able to match most submitted records to valid physicians and teaching hospitals. In cases where a valid match is not found, the system returns the record to the submitter for correction.
12364	July 2015	Reporting, General	Is CMS planning to provide any type of data summary sheets?	CMS is providing summary graphics of key data points on https://openpaymentsdata.cms.gov/. This new data dashboard will also be available in printable format. Besides that, CMS is not providing any other summary presentations of the data. The data is publically accessible and available for consumers and researchers to extract as they see fit.
12386	July 2015	Reporting, General	Is there a methodology guide available providing technical details about the published data?	Yes, the Methodology Overview & Data Dictionary explains all of the technical specifications of the published data.
12384	July 2015	Reporting, General	Is there a way to get a crosswalk between the specialties listed for providers and the taxonomy codes that accompany them?	The crosswalk for physician specialties is posted on the resource section of the Open Payments website. People can use the following link to access that information – http://cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf

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12382	July 2015	Reporting, General	My organization already downloaded the 2013 data last year; should we download just the new 2014 data this year?	CMS recommends that you re-download the 2013 data this year, in addition to downloading the new 2014 data. The 2013 data that's being published on June 30 includes a number of additional records that were not included in the previous publication or were included only in de-identified form. Additionally, enhancements made since last data publication changed the previous system-assigned unique identifiers like Physician_Profile_ID, Record_ID, and Teaching_Hospital_ID. That means that identifiers in this year's publication will not match identifiers in last year's publication. For example, profile ID 123 used for Dr. John Smith in the last data publication is no longer associated with Dr. John Smith. Re-downloading the 2013 data will ensure that the profile ID your system has for 2013 matches the profile ID for 2014 data. CMS does not anticipate changing the system-assigned unique identifiers again.
10094	June 2014	Reporting, General	Since NPPES data may be updated by physicians on an ongoing basis, at what point in time may applicable manufacturers rely on the data?	Applicable manufacturers may rely on NPI information in NPPES as of 90 days before the beginning of the reporting year. While it is not possible to keep past "versions" of NPPES due to the continual updates, each provider entry is date-stamped to include the date the entry was created, as well as the date of each update, which establishes the information available at any given time.
12304	2015	Reporting, General	There are some differences between the data published in the initial 2013 data publication and the 2013 data files re-published on June 30, 2015. Why is this most recent 2013 data different from previously published 2013 data?	The June 30, 2015 data publication includes a refreshed publication of 2013 program year records. This refresh includes 2013 records that were not in previous publications of that year's data due to record revisions, deletions, and additions as a result of data dispute resolution and other data maintenance. These data updates are now reflected in the June 30, 2015 data publication, along with all 2013 unedited records previously published. In addition, previously de-identified 2013 data is now published as fully identified, provided they passed the publication rules to be included in the June 30, 2015 data publication.
12360	July 2015	Reporting, General	What data is CMS publishing on June 30, 2015?	This is the second reporting cycle for Open Payments, and first full calendar year of reporting. It covers payments, other transfers of value made to physicians and teaching hospitals, and ownership or investment interests held by physicians (or their immediate family members) in applicable manufacturers and applicable group purchasing organizations (GPOs) throughout the entire 2014 calendar year. This reporting cycle also publishes a group of 2013 records with all relevant recipients included; these select 2013 records were previously only available in their de-identified form.
11968	July 2015	Reporting, General	What happens if I do not re-new a record's delay in publication status?	A request for a delay in publication must be re-newed each year. If this request is not re-newed each year, the record will automatically be flagged for publication in the next publication cycle. So, records delayed in publication for the 2013 program year that are not re-newed for delay in publication for the 2014 program year will automatically be published by June 30, 2015.
12394	July 2015	Reporting, General	What is CMS doing to make sure this information is friendly for consumers?	Since first publishing Open Payments data in September 2013, CMS has made many enhancements to the tools available to search and manipulate the data. Shortly after the initial data publication, CMS launched a data search tool to allow for consumer-friendly data searches that allows users to search for their personal physician, or search on criteria such as specialty, location, or types of payments received. Continuing on that path, CMS is providing summary graphics of key data points on https://openpaymentsdata.cms.gov/. This new data dashboard will also be available in printable format. Additionally, in the coming month, CMS will present another new, very detailed search interface that will translate the large datasets into more detailed visualizations. The program does not make assumptions or draw conclusions about the information reported, and CMS is directing consumers who may have questions about the information on the website to use it as one of the many discussion points in their doctor-patient relationship.

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11970	July 2015	Reporting, General	Why am I receiving a "Failed Matching Validation" message for payment records that were accepted last year?	Payment records that were successfully matched in 2014 may now appear as "Failed Matching Validation" in 2015 because all records are now subject to a more stringent matching process that was implemented in early 2015. 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 located on the Resources page of the Open Payments website.
10104	June 2014	Reporting, General	Can a data file submission be broken down and submitted in multiple files based on the number of line items?	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.
10128	June 2014	Reporting, General	Can an applicable manufacturer or applicable GPO submit a dummy test data file submission to verify if their data is formatted correctly?	Yes, applicable manufacturers and applicable GPOs may submit a dummy test data file through the "Submit as Test File" button. The test will validate that the file is a CSV or XML file, or a ZIP file containing a CSV or XML file; if the file size is under 250MB; if the file header is present and is correct; and if the file template and payment category match. The results of the test will be displayed onscreen. Please note that this test does not upload the file to the system. The file is checked and discarded.
10102	June 2014	Reporting, General	How will data submissions be transferred to and received by CMS?	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, XML, or ZIP file (ZIP files may only be uploaded if they contain either CSV or XML files). The second submission method is manual submission through the Graphical User Interface.
10108	June 2014	Reporting, General	Including zip codes, how will data validation be performed on data elements to be validated? And, what checks will be performed on each?	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 the file upload was successful or not successful. If the file level checks are successful, the process will move to the second level of validation, which will be the record level check. The second level of validation includes data validation performed on data elements as they are reviewed against the specifications described in the Data Submission Mapping Document. The Error Code File Document serves as the “go-to” reference for errors made during the data submission process. In the event an error is found in a data file uploaded to the Open Payments system, an error code will be displayed in the system-generated error report. Users should then refer to the Error Code File Document for a description of the error code, the corresponding data element, and steps to avoid and correct each error. Following successful data validation, the file is ready for Final Submission. After Final Submission, the Open Payments system will search to match each submitted record to a valid physician or teaching hospital.
10110	June 2014	Reporting, General	What is the expected length of time for CMS to complete data validation on submitted data files?	First level of data validation: This happens immediately, when the submitter uploads a file into the system. 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 the file upload was not successful. If the file level checks are successful, the process will move to the second level of validation. Second level of data validation: For small data files, this second level of automated validation can happen in seconds. Larger data files could take up to several hours to validate. Once the data files are uploaded, the Open Payments system validates each individual record to ensure the data elements are in the proper format, and checks them against the specifications described in the Data Submission Mapping Document. The Error Code File Document serves as the “go-to” reference for errors made during the data submission process. In the event an error is found in a data file uploaded to the Open Payments system, an error code will be displayed in the system-generated error report. Users should then refer to the Error Code File Document for a description of the error code, the corresponding data element, and steps to avoid and correct each error. Following successful data validation, the file is ready for Final Submission. After Final Submission, the Open Payments system will search to match each submitted record to a valid physician or teaching hospital. This matching process may take up to several days, and timing will vary based upon the size of the data files.

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8996	August 2013	Research	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?	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).
8159	April 2013	Research	Are payments for medical research writing and/or publication included in reporting research payments?	Under OPEN PAYMENTS, a payment reported as research falls within a research payment category if it is subject to either: 1) a written agreement; 2) a contract; or 3) a research protocol. 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.
8998	August 2013	Research	Are research payments provided to a Military Medical Center that is not a teaching hospital covered recipient required to be reported for Open Payments?	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).
10080	June 2014	Research	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?	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.
11974	March 2015	Research	How do I remove a delay in publication request for a previously submitted record?	A request for a delay in publication must be renewed each year. So, if the record was previously submitted in a prior year and the 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. That means the user doesn't have to do anything to remove the delay in publication request. However, if the previously submitted record was submitted in the current reporting year, follow the instructions in the Open Payments System Quick Reference Guide: Payment Category Page and Delay in Publication located on the Resources page of the Open Payments website.
11972	March 2015	Research	How do I re-new a record's delay in publication status?	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 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. For instructions on re-newing a record's delay in publication status, refer to the Open Payments System Quick Reference Guide: Payment Category Page and Delay in Publication located on the Resources page of the Open Payments website.

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11972	July 2015	Research	How do I re-new a record's delay in publication status?	Payment records may be delayed in publication if the payment or other transfer of value is related to: 1. Research or development of a new drug, device, biological, or medical supply; 2. Research or development of a new application of an existing drug, device, biological, or medical supply; or 3. Clinical investigations regarding a new drug, device, biological, or medical supply. Payment records can be delayed in publication for up to four 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. For instructions on re-newing a record's delay in publication status, refer to the Open Payments System Quick Reference Guide: Payment Category Page and Delay in Publication located on the Resources page of the Open Payments website.
12224	May 2015	Research	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?	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.
8988	August 2013	Research	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?	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.
10078*	June 2014	Research	Is data element 43 in the research payment template asking if a Principal Investigator covered recipient received a payment that was reportable in the general payment template?	If a physician covered recipient is indicated in the Covered Recipient Demographic section of the Research Payment submission template (including data elements 10-13) and is also a Principal Investigator for the research study, then data element 43 must be used to indicate that the Principal Investigator of the research study is a covered recipient. If the Principal Investigator covered recipient is the covered recipient physician receiving the payment (identified in data elements 10-13), please indicate "Y" in data element 43. It is not necessary to duplicate the information for the previously indicated Principal Investigator covered recipient in data elements 45-60. If there are multiple Principal Investigators who are covered recipients and who are not indicated in data elements 10-13, please follow the instructions in the Research Payments submission template and provide the identifiers for each of these individuals in data elements 45-60.

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9000	August 2013	Research	Is information regarding a physician principal investigator required for reporting if he/she is a military physician?	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).
8264	June 2013	Research	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?	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.
8266	June 2013	Research	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?	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.
11968	March 2015	Research	What happens if I do not re-new a record's delay in publication status?	A request for a delay in publication must be re-newed each year. If this request is not re-newed each year, the record will automatically be flagged for publication in the next publication cycle. So, records delayed in publication for the 2013 program year that are not re-newed for delay in publication for the 2014 program year will automatically be published by June 30, 2015.
9130	October 2013	Research	Why was research removed as a nature of payment category option from the general data specification?	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). As discussed in the preamble to the final rule research-related payments, which do not meet the definition of research, should be reported using the other nature of payment categories available. (42 Fed Reg. 9482)
9118	October 2013	Value Determinations	What value should an applicable manufacturer assign to clinical study drugs that are provided to principal investigators as part of the research agreement?	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).
8370	July 2013	Value Determinations	How should applicable manufacturers or applicable group purchasing organization determine the value of journal reprints provided to covered recipients?	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.

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