perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

Physician-owned distributorship, for the purposes of determining the existence of a reportable ownership or investment interest under this subpart, means an entity that:

(1) Meets the definition of an applicable manufacturer or applicable group purchasing organization as defined in this section, and

(2) Meets at least one of the following two conditions:

(i) Has a minimum of 5 percent direct or indirect ownership or investment interest in the applicable manufacturer or applicable group purchasing organization held by a physician or a physician's immediate family member, or

(ii) A physician or a physician's immediate family member receives compensation from the applicable manufacturer or group purchasing organization in the form of a commission, return on investment, profit sharing, profit distribution, or other remuneration directly or indirectly derived from the sale or distribution of devices by the applicable manufacturer or group purchasing organization in which the physician or physician's immediate family member has ownership.

(3) This physician owned distributor definition does not apply for purposes of any other laws or regulations, including, but not limited to, section 1877 of the Act, the regulations at 42 CFR part 411, subpart J, section 1128B of the Act, or the regulations at 42 CFR 1001.952.

Related to a covered drug, device, biological, or medical supply means that a payment or other transfer of value is made in reference to or in connection with one or more covered drugs, devices, biologicals, or medical supplies.

Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.

Short term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 cumulative days per calendar year or a quantity of 90 cumulative days of average daily use per calendar year, to permit evaluation of the device or medical supply by the covered recipient.

Third party means another individual or entity, regardless of whether such individual or entity is operating in the United States.

Unique device identifier means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 801.40 and 830.3.

[78 FR 9521, Feb. 8, 2013, as amended at 79 FR 68000, Nov. 13, 2014; 84 FR 63185, Nov. 15, 2019; 85 FR 10, Jan 2, 2020; 86 FR 65659, Nov. 19, 2021]

§ 403.904 Reports of payments or other transfers of value to covered recipients.

(a) *General rule.* (1) Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and direct and indirect 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 during the preceding calendar year, must be reported by the applicable manufacturer to CMS on an annual basis.

(2) For CY 2013, only payments or other transfers of value made on or after August 1, 2013 must be reported to CMS.

(3) An applicable manufacturer or applicable group purchasing organization that has reported payments or transfers of value under the scope of this section may not remove, delete, or alter any record/(s) unless an error is discovered in the information that had been furnished, or the record is otherwise believed to meet exceptions for reporting.

(b) *Limitations.* Certain limitations on reporting apply in the following circumstances:

(1) Applicable manufacturers for whom total (gross) revenues from covered drugs, devices, biologicals, or medical supplies constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals or medical supplies.

(2) Applicable manufacturers under paragraph (2) of the definition in § 403.902 are only required to report payments or other transfers of value that are related to a covered drug, device, biological, or medical supply for which they provided assistance or support to an applicable manufacturer under paragraph (1) of the definition.

(3) Applicable manufacturers under either paragraph (1) or (2) of the definition in § 403.902 that have separate operating divisions that do not manufacture any covered drugs, devices, biologicals, or medical supplies (for example, animal health divisions) are only required to report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply. This includes reporting of payments or other transfers of value that are related to covered drugs, devices, biologicals, or medical supplies made by applicable manufacturers to covered recipients through these operating divisions.

(4) Applicable manufacturers that do not manufacture a covered drug, device, biological, or medical supply except when under a written agreement to manufacture the covered drug, device, biological, or medical supply for another entity, do not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and are not involved in the sale, marketing, or distribution of the product, are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.

(c) *Required information to report.* A report must contain all of the following information for each payment or other transfer of value:

(1) *Name of the covered recipient.* For non-teaching hospital covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (NPPES) (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

(2) *Address of the covered recipient.* Primary business address of the covered recipient, including all the following:

(i) Street address.

(ii) Suite or office number (if applicable).

(iii) City.

(iv) State.

(v) ZIP code.

(3) *Identifiers for non-teaching hospital covered recipients.* In the case of a covered recipient the following identifiers:

(i) The specialty.

(ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a non-teaching hospital covered recipient, the field may be left blank, indicating that the applicable manufacturer could not find one.

(iii) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license), and the State(s) in which the license is held.

(4) *Amount of payment or other transfer of value.* A payment or other transfer of value made to a group of covered recipients should be distributed appropriately among the individual covered recipients 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.

(5) *Date of payment or transfer of value.* The date of each payment or other transfer of value.

(i) For payments or other transfers of value made over multiple dates (rather than as a lump sum), applicable manufacturers may choose whether to report each payment or other transfer of value as separate line item using the dates the payments or other transfers of value were each made, or as a single line item for the total payment or

other transfer of value using the first payment date as the reported date.

(ii) For small payments or other transfers of value reported as a single line item, applicable manufacturers must report the date that the first bundled small payment or other transfer of value was provided to the covered recipient.

(6) *Form of payment or transfer of value.* The form of each payment or other transfer of value, as described in paragraph (d) of this section.

(7) *Nature of payment or transfer of value.* The nature of each payment or other transfer of value, as described in paragraph (e) of this section.

(8) *Related covered drug, device, biological or medical supply.* Report the marketed or brand name of the related covered drugs, devices, biologicals, or medical supplies, and therapeutic area or product category unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply.

(i) For drugs and biologicals—

(A) If the marketed name has not yet been selected, applicable manufacturers must indicate the name registered on *clinicaltrials.gov*.

(B) Any regularly used identifiers must be reported, including, but not limited to, national drug codes.

(ii) For devices, if the device has a unique device identifier (UDI), then the device identifier (DI) portions of it must be reported, as applicable.

(iii) Applicable manufacturers may report the marketed name and therapeutic area or product category for payments or other transfers of value related to a non-covered drug, device, biological, or medical supply.

(iv) Applicable manufacturers must indicate if the related drug, device, biological, or medical supply is covered or non-covered.

(v) Applicable manufacturers must indicate if the payment or other transfer of value is not related to any covered or non-covered drug, device, biological or medical supply.

(9) *Eligibility for delayed publication.* Applicable manufacturers must indicate whether a payment or other transfer of value is eligible for delayed publication, as described in § 403.910.

(10) *Payments to third parties.* (i) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the payment or transfer of value must be reported in the name of that covered recipient.

(ii) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the name of the entity that received the payment or other transfer of value (if made to an entity) or indicate ''individual'' (if made to an individual). If a covered recipient performed a service, but neither accepted the offered payment or other transfer of value nor requested that it be made to a third party, the applicable manufacturer is not required to report the offered payment or other transfer of value unless the applicable manufacturer nonetheless provided it to a third party and designated such payment or other transfer of value as having been provided on behalf of the covered recipient.

(11) *Payments or transfers of value to physician owners or investors.* Must indicate whether the payment or other transfer of value was provided to a physician or the immediate family of the physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.

(12) *Additional information or context for payment or transfer of value.* May provide a statement with additional context for the payment or other transfer of value.

(d) *Reporting the form of payment or other transfer of value.* An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms of payment that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value.

(1) Cash or cash equivalent.

(2) In-kind items or services.

(3) Stock.

(4) Stock option.

(5) Any other ownership interest.

(6) Dividend, profit or other return on investment.

(e) *Reporting the nature of the payment or other transfer of value.* (1) *General rule.* The categories describing the nature of a payment or other transfer of value are mutually exclusive for the purposes of reporting under subpart I of this part.

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xviii) of this section, using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

(i) Consulting fee.

(ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.

(iii) Honoraria.

(iv) Gift.

(v) Entertainment.

(vi) Food and beverage.

(vii) Travel and lodging (including the specified destinations).

(viii) Education.

(ix) Research.

(x) Charitable contribution.

(xi) Debt forgiveness.

(xii) Royalty or license.

(xiii) Current or prospective ownership or investment interest.

(xiv) Compensation for serving as faculty or as a speaker for a medical education program.

(xv) Long term medical supply or device loan.

(xvi) Grant.

(xvii) Space rental or facility fees (teaching hospital only).

(xviii) Acquisitions.

(f) *Special rules for research payments.* All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules.

(1) Research-related payments or other transfers of value to covered recipients, including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)):

(i) Name of the research institution, individual or entity receiving the payment or other transfer of value.

(A) If paid to a non-teaching hospital covered recipient, all of the following must be provided:

(*1*) The non-teaching hospital covered recipient's name as listed in the NPPES (if applicable).

(*2*) National Provider Identifier.

(*3*) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license) and State(s) in which the license is held.

(*4*) Specialty.

(*5*) Primary business address of the non-teaching hospital covered recipient(s).

(B) If paid to a teaching hospital covered recipient, list the name and primary business address of teaching hospital.

(C) If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list the name and primary business address of the entity.

(ii) Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.

(iii) Name of the research study.

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section); for drugs and biologicals, the relevant National Drug Code(s), if any; and for devices and medical supplies, the relevant device identifier, if any, and the therapeutic area or product category if a marketed name is not available.

(v) Information about each non-teaching hospital covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

(vi) Contextual information for research (optional).

(vii) ClinicalTrials.gov identifier (optional).

(2) For pre-clinical studies (before any human studies have begun), only report the following information:

(i) Research entity name (as required in paragraph (f)(1)(i) of this section).

(ii) Total amount of payment (as required in paragraph (f)(1)(ii) of this section).

(ii) Principal investigator(s) (as required in paragraph (f)(1)(v) of this section).

(g) *Special rules for reporting food and beverage.* (1) When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff). The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage.

(2) Applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event.

(h) *Exclusions from reporting.* The following are excluded from the reporting requirements specified in this section:

(1) Indirect payments or other transfers of value (as defined in § 403.902), where 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 during the reporting year or by the end of the second quarter of the following reporting year.

(2)(i) For CY 2013, payments or other transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.

(ii) For CY 2014 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (h)(2)(i) of this section must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. CMS will publish the values for the next reporting year 90 days before the beginning of the reporting year.

(iii) Payments or other transfers of value of less than $10 in CY 2013 (or less than the amount described in paragraph (h)(2)(i) of this section for CY 2014 and subsequent calendar years) provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be reported nor included for purposes of the $100 aggregate threshold in CY 2013 (or the aggregate threshold calculated in accordance paragraph (h)(2)(i) of this section for CY 2014 and subsequent calendar years), even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.

(iv) When reporting payments or other transfers of value under the $10 threshold for CY 2013 (or under the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) for covered recipients that exceed the aggregate threshold for the reporting year, applicable manufacturers may (but are not required to) report all small payments to a particular covered recipient that fall within the same nature of payment category as a single payment or other transfer of value.

(3) Product samples, including coupons and vouchers that can be used by a patient to obtain samples, which are not intended to be sold and are intended for patient use.

(4) Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply.

(5) Short term medical supply or device loan.

(6) Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(7) A transfer of anything of value to a non-teaching hospital covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

(8) Discounts, including rebates.

(9) In-kind items used for the provision of charity care.

(10) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

(11) In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for healthcare expenses, payments for the provision of health care to employees and their families.

(12) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

(13) In the case of a non-teaching hospital covered recipient, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

(14) A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship.

[78 FR 9521, Feb. 8, 2013, as amended at 79 FR 68000, Nov. 13, 2014; 84 FR 63186, Nov. 15, 2019; 86 FR 65659, Nov. 19, 2021]

§ 403.906 Reports of physician ownership and investment interests.

(a) *General rule.* (1) Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests 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.

(2) For CY 2013, only ownership or investment interests held on or after August 1, 2013 must be reported to CMS.

(b) *Identifying information.* Reports on physician ownership and investment interests must include the following identifying information:

(1) Name of the physician (as listed in the National Plan & Provider Enumeration System (if applicable), including first and last name, middle initial, and suffix (for all that apply), and an indication of whether the ownership or investment interest was held by the physician or an immediate family member of the physician.

(2) Primary business address of the physician, including the following:

(i) Street address.

(ii) Suite or office number (if applicable).

(iii) City.

(iv) State.

(v) ZIP code.

(3) The following information for the physician (regardless of whether the ownership or investment interest is held by an immediate family member of the physician):

(i) The specialty.

(ii) National Provider Identifier (if applicable and as listed in NPPES).

(iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) Dollar amount invested by each physician or immediate family member of the physician.

(5) Value and terms of each ownership or investment interest.