Centers for Medicare & Medicaid Services, HHS 

§ 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.

(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 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 physician covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (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 physician covered recipients. In the case of a covered recipient who is a physician, 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 physician, 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 physician 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. The name(s) of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply. Applicable manufacturers may report up to five covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value. If the payment or other transfer of value was related to more than five covered drugs, devices, biologicals, or medical supplies, the applicable manufacturer should report the five covered drugs, devices, biologicals, or medical supplies that were most closely related to the payment or other transfer of value.

(i) For drugs and biologicals, applicable manufacturers must report the
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name under which the drug or biological is or was marketed and the relevant National Drug Code(s), if any. If the marketed name has not yet been selected, the applicable manufacturer must indicate the name registered on clinicaltrials.gov.

(ii) For devices and medical supplies, applicable manufacturers must report at least one of the following:

(A) The name under which the device or medical supply is or was marketed.

(B) The therapeutic area or product category for the device or medical supply.

(iii) If the payment or other transfer of value is not related to a covered drug, device, biological or medical supply, applicable manufacturers must indicate “non-covered product.”

(iv) If the payment or other transfer of value is not related to any drug, device, biological, or medical supply (covered or not), applicable manufacturers must indicate “none.”

(v) If the payment or other transfer of value is related to at least one covered drug, device, biological, and medical supply and at least one non-covered drug, device, biological, or medical supply, applicable manufacturers must report the name(s) of the covered drug, device, biological or medical supply (as required by paragraphs (c)(8)(i) and (ii) of this section) and may indicate “non-covered products” in addition.

(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, stock option, or any other ownership interest.

4. 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 (xvii) of this section, using the designation that best describes the nature of the payment or other transfer of value, or separable
(A) If paid to a physician covered recipient, all of the following must be provided:
  (i) The physician’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 physician maintains a license) and State(s) in which the license is held.
  (4) Specialty.
  (5) Primary business address of the physician(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) and for drugs and biologicals, the relevant National Drug Code(s), if any.
  (v) Information about each physician 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).
  (iii) Principal investigator(s) (as required in paragraph (f)(1)(v) of this section).

(g) Special rules for payments or other transfers of value related to continuing education programs. (1) Payments or other transfers of value provided as
compensation for speaking at a continuing education program are not required to be reported, if all of the following conditions are met:

(i) The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following:
   (A) The Accreditation Council for Continuing Medical Education.
   (B) The American Academy of Family Physicians.
   (C) The American Dental Association’s Continuing Education Recognition Program.
   (D) The American Medical Association.

(ii) The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

(2) Payments or other transfers of value that do not meet all of the requirements in paragraph (g)(1) of this section, must be reported as required by this section.

(i) Payments or other transfers of value that meet the requirements in paragraph (g)(1)(i) of this section, but not also (g)(1)(ii) or (g)(1)(iii) of this section or both, must be reported under the nature of payment category “Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.”

(ii) Payments or other transfers of value that do not meet the requirements in paragraph (g)(1)(i) of this section should be reported under the nature of payment category “Compensation for serving as a faculty or as a speaker for an accredited or certified continuing education program.”

(iii) Payments or other transfers of value for speaking engagements not related to medical education should be reported under the nature of payment category “Compensation for services other than consulting, including serving as a speaker at an event other than a continuing education program.”

(h) 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.

(i) 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.

(2)(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 (i)(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
§ 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) 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.

(3) In the case of a covered recipient who is a physician, 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.

(4) 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.

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