

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]

§ 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.

(6) Direct and indirect payments or other transfers of value provided to a physician holding an ownership or investment interest, 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 or applicable group purchasing organization on behalf of a physician owner or investor, must be reported by the applicable manufacturer or applicable group purchasing organization in accordance with the requirements for reporting payments or other transfers of value in § 403.904(c) through (h). The terms “applicable manufacturer and applicable group purchasing organization” must be substituted for “applicable manufacturer,” and “physician owner or investor” must be substituted for “covered recipient” in each place they appear.

[78 FR 9521, Feb. 8, 2013, as amended at 79 FR 68001, Nov. 13, 2014]

§ 403.908 Procedures for electronic submission of reports.

(a) *File format.* Reports required under this subpart must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.

(b) *General rules.* (1) If an applicable manufacturer made no reportable payments or transfers of value in the previous calendar year, nor had any reportable ownership or investment interests held by a physician or a physician’s immediate family member (as defined in § 403.902) during the previous calendar year, the applicable manufacturer is not required to file a report.

(2) If an applicable group purchasing organization had no reportable ownership or investment interests held by a physician or physician’s immediate family member during the previous calendar year, the applicable group purchasing organization is not required to file a report.

(c) *Registration.* (1) Applicable manufacturers that have reportable payments or other transfers of value, ownership or investment interests, or both, are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(2) Applicable group purchasing organizations that have reportable ownership or investment interests are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(3) During registration, applicable manufacturers and applicable group purchasing organizations must name two points of contact with appropriate contact information.

(d) *Other rules.* (1) *Consolidated reports.* (i) An applicable manufacturer under paragraph (1) of the definition that is under common ownership with separate entities that are also applicable manufacturers under paragraph (1) of the definition may, but is not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests, for all of the entities.

(ii) An applicable manufacturer under paragraph (1) of the definition of applicable manufacturer and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of applicable manufacturer may, but are not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests.

(iii) If multiple applicable manufacturers (under paragraph (1) or (2) of the definition or both paragraphs of the definition) submit a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers, and the report must identify the specific entity that provided each payment.

(iv) A single payment or other transfer of value reported in a consolidated report must only be reported once by one applicable manufacturer.

(v) The applicable manufacturer submitting a consolidated report on behalf of itself and other applicable manufacturers under common ownership, as permitted under this paragraph, is liable for civil monetary penalties imposed on each of the applicable manufacturers whose reportable payments or other transfers of value were included in the consolidated report, up to the annual maximum amount specified in § 403.912(c) for each individual applicable manufacturer included in the report.

(2) *Joint ventures.* If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported—

(i) In the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and

(ii) Only once by one applicable manufacturer.

(e) *Attestation.* Each report, including any subsequent corrections to a filed report, must include an attestation by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief. For applicable manufacturers choosing to submit a consolidated report in accordance with paragraph (d)(1) of this section, the applicable manufacturer submitting the consolidated report must attest on behalf of itself, in addition to each of the other applicable manufacturers included in the consolidated report.

(f) *Assumptions document.* Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document, explaining the reasonable assumptions made and

methodologies used when reporting payments or other transfers of value, or ownership or investment interests. The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.

(g) *45-day review period for review and error correction.* (1) *General rule.* Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the public. In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public.

(2) *Notification.* CMS notifies the applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review.

(i) Applicable manufacturers and applicable group purchasing organizations are notified through the points of contact they identified during registration.

(ii) Covered recipients—

(A) Are notified using an online posting and notifications on CMS's listserves.

(B) May also register with CMS to receive notification about the review processes.

(iii) The 45-day review period begins on the date specified in the online notification.

(3) *Process.* (i) An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure Web site to view only the information reported specifically about itself.

(ii) Covered recipients and physician owners or investors are able to review data submitted about them for the previous reporting year.

(iii) If the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor agrees with the information reported, the applicable manufacturer, applicable group pur-

chasing organization, covered recipient, or physician owner or investor may electronically certify that the information reported is accurate.

(iv) If a covered recipient or physician owner or investor disagrees with the information reported, the covered recipient or physician owner or investor can initiate a dispute, which is sent to the appropriate applicable manufacturer or applicable group purchasing organization to be resolved between the parties.

(v) Covered recipients and physician owners or investors may initiate disputes at any time after the 45-day period begins, but before the end of the calendar year, but any changes resulting from disputes initiated outside the 45-day period, may not be made until the next time the data is refreshed.

(4) *Data disputes.* (i) In order to be corrected prior to the publication of the data, applicable manufacturers and applicable group purchasing organizations must notify CMS of resolved disputes and changes to the information submitted by no later than 15 days after the end of the 45-day period (that is, 60 days after the 45-day review period begins).

(ii) Disputes which are not resolved by 15 days after the end of the review and correction period, may still be resolved, but any changes resulting from the disputes may be made until the next time the data is refreshed.

(iii) If the dispute is not resolved by 15 days after the end of the 45-day review and correction period, CMS publicly reports and aggregates the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, but marks the payment or other transfer of value or ownership or investment interest as disputed.

(h) *Errors or omissions.* (1) If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission.

(2) Upon receipt, CMS notifies the affected covered recipient or physician owner or investor that the additional

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information has been submitted and is available for review. CMS updates the Web site at least once annually with corrected information.

[78 FR 9521, Feb. 8, 2013, as amended at 84 FR 63187, Nov. 15, 2019]

§ 403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.

(a) *General rule.* Certain research payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement may be delayed from publication on the Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances:

(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.

(2) Clinical investigations regarding a new drug, device, biological, or medical supply.

(b) *Research or development agreement.* The research or development agreement must include a written agreement, a research protocol, or both between the applicable manufacturer and covered recipient.

(c) *Date of publication.* Payments or other transfers of value eligible for delayed publication must be reported to CMS (in the manner required in § 403.904(f)) on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:

(1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by FDA.

(2) Four calendar years after the date the payment or other transfer of value was made.

(d) *Notification of delayed publication.* (1) 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

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all payments publicly in the first year of public reporting.

(2) An applicable manufacturer must continue to indicate annually in its report that FDA approval, licensure, or clearance of the new drug, device, biological or medical supply to which the payment or other transfer of value is related, is pending.

(3) An applicable manufacturer must notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, to which the payment is related (or the new application of the existing drug, device, biological, or medical supply), is approved by the FDA.

(4) Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.

(5) If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.

(e) *Confidentiality.* Information submitted and eligible for delayed publication is considered confidential and will not be subject to disclosure under 5 U.S.C. 552, or any similar Federal, State, or local law, until on or after the date on which the information made available to the public as required in this section.

§ 403.912 Penalties for failure to report.

(a) *Failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than \$1,000, but not more than \$10,000, as adjusted annually under 45 CFR part 102 for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization (regardless of whether the applicable manufacturer