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 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

was a part of a consolidated report) with respect to failures to report in an annual submission of information will not exceed $150,000 as adjusted annually under 45 CFR part 102.

(b) *Knowing failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that knowingly 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 $10,000, but not more than $100,000, 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 group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to knowing failures to report in an annual submission of information will not exceed $1,000,000 as adjusted annually under 45 CFR part 102.

(c) *Total annual civil monetary penalties.* The amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization under paragraphs (a)(1) and (b)(1) of this section are—

(1) Aggregated separately;

(2) Subject to separate aggregate totals under paragraphs (a)(2) and (b)(2) of this section, with a maximum combined annual total of $1,150,000 as adjusted annually under 45 CFR part 102.

(d) *Determinations regarding the amount of civil monetary penalties.* In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:

(1) The length of time the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer or applicable group purchasing organization knew of the payment or other transfer of value, or ownership or investment interest.

(2) Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report.

(3) Level of culpability.

(4) Nature and amount of information reported in error.

(5) Degree of diligence exercised in correcting information reported in error.

(e) *Record retention and audits.* (1) *Maintenance of records.* (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(ii) The items described in paragraph (e)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

(2) *Audit.* HHS, CMS, OIG or their designees may audit, inspect, investigate and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(3) The requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.

(f) *Use of funds.* Funds collected by the Secretary as a result of the imposition of a civil monetary penalty under this section must be used to carry out the operation of this subpart.

(g) *Notice, hearings, appeals, and collection.* Civil monetary penalties imposed under this section are subject to the provisions set forth in subparts A

and B of part 402 of this chapter, including those pertaining to notice, opportunity for a hearing, appeals procedures, and collection of penalties.

[78 FR 9521, Feb. 8, 2013, as amended at 81 FR 61561, Sept. 6, 2016; 82 FR 42749, Sept. 12, 2017]

§ 403.914 Preemption of State laws.

(a) *General rule.* In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.

(b) *Information collected for public health purposes.* (1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.

(2) Governmental agencies include, but are not limited to, the following:

(i) Agencies that are charged with preventing or controlling disease, injury, disability.

(ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

Subpart K—Access to Identifiable Data for the Center for Medicare and Medicaid Models

SOURCE: 79 FR 68001, Nov. 13, 2014, unless otherwise noted.

§ 403.1100 Purpose and scope.

The regulations in this subpart implement section 1115A of the Act. The intent of that section is to enable CMS to test innovative payment and service delivery models to reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under titles XVIII, XIX, and XXI of the Act. The Secretary is also required to conduct an evaluation of each model tested.

§ 403.1105 Definitions.

For purposes of this subpart—

Applicable titles means Titles XVIII, XIX, or XXI of the Act.

§ 403.1110 Evaluation of models.

(a) *Evaluation.* The Secretary conducts an evaluation of each model tested under section 1115A of the Act. Such evaluation must include an analysis of the following:

(1) The quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary.

(2) The changes in spending under the applicable titles by reason of the model.

(b) *Information.* Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including ''protected health information'' as that term is defined at 45 CFR 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary.

Subpart L—Requirements for Direct-to-Consumer Television Advertisements of Drugs and Biological Products To Include the List Price of That Advertised Product

SOURCE: 84 FR 20757, May 10, 2019, unless otherwise noted.

§ 403.1200 Scope.

(a) *Covered pharmaceuticals.* Except as specified in paragraph (b) of this section, this subpart applies to advertisements for a prescription drug or biological product distributed in the United States for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act.