

through the Part D sponsor, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

Subpart W—Medicare Coverage Gap Discount Program

SOURCE: 77 FR 22172, Apr. 12, 2012, unless otherwise noted.

§ 423.2300 Scope.

This subpart implements provisions included in sections 1860D–14A and 1860D–43 of the Act. This subpart sets forth requirements regarding the following:

- (a) Condition for coverage of applicable drugs under Part D.
- (b) The Medicare Coverage Gap Discount Program Agreement.
- (c) Coverage gap discount payment processes for Part D sponsors.
- (d) Provision of applicable discounts on applicable drugs for applicable beneficiaries.
- (e) Manufacturer audit and dispute resolution processes.
- (f) Resolution of beneficiary disputes involving coverage gap discounts.
- (g) Compliance monitoring and civil money penalties.
- (h) The termination of the Discount Program Agreement.

§ 423.2305 Definitions.

As used in this subpart, unless otherwise specified—

Applicable discount means 50 percent or, with respect to a plan year after plan year 2018, 70 percent of the portion of the negotiated price (as defined in this section) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Applicable number of calendar days means, with respect to claims for reimbursement submitted electronically, 14 days, and otherwise, 30 days.

Date of dispensing means the date of service.

Labeler code means the first segment of the Food and Drug Administration national drug code (NDC) that identifies a particular manufacturer.

Manufacturer means any entity which is engaged in the production, prepara-

tion, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user.

Medicare Coverage Gap Discount Program (or Discount Program) means the Medicare coverage gap discount program established under section 1860D–14A of the Act.

Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) means the agreement described in section 1860D–14A(b) of the Act.

Medicare Part D discount information means the information sent from CMS or the TPA to the manufacturer along with each quarterly invoice that is derived from applicable data elements available on prescription drug events as determined by CMS.

National Drug Code (NDC) means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product and package size and type.

Negotiated price for purposes of the Discount Program, means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

(i) Includes all price concessions (as defined in § 423.100) from network pharmacies or other network providers; and

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(ii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, non-pharmacy price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale; and

(3) Excludes any dispensing fee or vaccine administration fee for the applicable drug.

(4) In connection with applicable drugs dispensed by an out-of-network provider in accordance with the applicable beneficiary's Part D plan out-of-network policies, the negotiated price means the plan allowance as set forth in § 423.124, less any dispensing fee or vaccine administration fee.

Other health or prescription drug coverage means any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries, including, in the case of employer group health or waiver plans, other than basic prescription drug coverage as defined in § 423.100.

Third Party Administrator (TPA) means the CMS contractor responsible for administering the requirements established by the CMS to carry out section 1860D–14A of the Act.

[77 FR 22172, Apr. 12, 2012, as amended at 86 FR 6131, Jan. 19, 2021; 87 FR 27902, May 9, 2022]

§ 423.2310 Condition for coverage of drugs under Part D.

(a) *Covered Part D drug coverage requirement.* Except as specified in paragraph (b) of this section, in order for coverage to be available under Medicare Part D for applicable drugs of a manufacturer, the manufacturer must do all of the following:

(1) Participate in the Discount Program.

(2) Have entered into and have in effect an agreement described in § 423.2315(b).

(3) Have entered into and have in effect, under terms and conditions specified by CMS, a contract with the TPA.

(b) *Exception to covered drug coverage requirement.* Paragraph (a) of this section does not apply to an applicable drug if CMS has made a determination that the availability of the applicable drug is essential to the health of beneficiaries enrolled in Medicare Part D.

§ 423.2315 Medicare Coverage Gap Discount Program Agreement.

(a) *General rule.* The Medicare Coverage Gap Discount Program Agreement (or Discount Program Agreement) between the manufacturer and CMS must contain the provisions specified in paragraph (b) of this section, and may contain such other provisions as are established in a model agreement consistent with section 1860D–14A (a)(1) of the Act.

(b) *Agreement requirements.* The manufacturer agrees to the following:

(1) All the applicable requirements and conditions set forth in this part and general instructions.

(2) Reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s) invoiced to the manufacturer within a maximum of 3 years of the date of dispensing based upon information reported to CMS by Part D sponsors.

(3) Pay each Part D sponsor in the manner specified by CMS within 38 calendar days of receipt of the invoice and Medicare Part D Discount Information for the applicable discounts included on the invoice, except as specified in § 423.2330(c)(3).

(4) Provide CMS with all labeler codes for all the manufacturer's applicable drugs and to promptly update such list with any additional labeler codes for applicable drugs no later than 3 business days after learning of a new code assigned by the FDA.

(5) Collect, have available, and maintain appropriate data, including data related to manufacturer's labeler codes, FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount