

**§ 423.2305, Nt.**

**42 CFR Ch. IV (10–1–23 Edition)**

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 amount such network entity will receive, in total, for a particular drug;

(2) Is reduced by those discounts, direct or indirect subsidies, rebates, other 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.

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]

EFFECTIVE DATE NOTE: At 87 FR 27902, May 9, 2022, § 423.2305 was amended by revising paragraphs (1) and (2) of the definition of “Negotiated price”; and designating the undesignated paragraph following the definition of “Negotiated price” as paragraph (4), effective Jan. 1, 2024. For the convenience of the user, the revised text is set forth as follows:

**§ 423.2305 Definitions.**

\* \* \* \* \*

*Negotiated price* \* \* \*

(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

(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

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**§ 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