
42 C.F.R. § 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.

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