§ 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.
4. 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...