

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 Program, for a period of not less than 10 years from the date of payment of the invoice.

(6) Comply with the audit and dispute resolution requirements in § 423.2330.

(7) Electronically list and maintain up-to-date electronic FDA listings of all NDCs of the manufacturer, including providing timely information about discontinued drugs to enable the publication of accurate information regarding what drugs, identified by NDC, are in current distribution.

(8) Maintain up-to-date NDC listings with the electronic database vendors for which the manufacturer provides NDCs for pharmacy claims processing.

(9) Enter into and have in effect, under terms and conditions specified by CMS, an agreement with the TPA that has a contract with CMS under section 1860D-14(A)(d)(3) of the Act.

(10) Pay quarterly invoices directly to accounts established by Part D sponsors via electronic funds transfer, or other manner if specified by CMS, within the time period specified in paragraph (b)(3) of this section and within 5 business days of the transfer to provide the TPA with electronic documentation of such payment in a manner specified by CMS.

(11) Use information disclosed to the manufacturer on the invoice, as part of the Medicare Part D Discount Information, or upon audit or dispute only for purposes of paying the discount under the Discount Program.

(c) *Timing and length of agreement.* (1) For 2011, a manufacturer must enter into a Discount Program Agreement not later than 30 days after the date of establishment of the model Discount Program Agreement.

(2) For 2012 and subsequent years, for a Discount Program Agreement to be effective for a year, a manufacturer must enter into a Discount Program Agreement not later than January 30th of the preceding year.

(3) Unless terminated in accordance with § 423.2345, the initial period of a Discount Program Agreement is 24 months and the agreement is automatically renewed for a 1-year period on January first each year for a period of 1 year thereafter.

(d) *Compliance with requirements for administration of the Program.* Each manufacturer with an agreement in effect under this subpart must comply with the requirements imposed by CMS or the third party administrator (as defined in § 423.2305) for purposes of administering the program.

§ 423.2320 Payment processes for Part D sponsors.

(a) *Interim payments.* CMS provides monthly interim coverage gap discount program payments as necessary for Part D sponsors to advance coverage gap discounts to beneficiaries.

(b) *Coverage Gap Discount Reconciliation.* CMS reconciles interim payments with invoiced manufacturer discount amounts made available to each Part D plan's enrollee under the Discount Program.

§ 423.2325 Provision of applicable discounts.

(a) *General rule.* On behalf of the manufacturers, Part D sponsors must provide applicable beneficiaries with applicable discounts on applicable drugs at the point-of-sale.

(b) *Discount determination.* (1) Part D sponsors must determine the following:

(i) Whether an enrollee is an applicable beneficiary (as defined in § 423.100).

(ii) Whether a Part D drug is an applicable drug (as defined in § 423.100).

(iii) The amount of the applicable discount (as defined in § 423.2305) to be provided at the point-of-sale.

(2) Part D sponsors must make retroactive adjustments to the applicable discount as necessary to reflect changes to the claim or beneficiary eligibility determined after the date of dispensing.

(3) Part D sponsors must determine whether any affected beneficiaries need to be notified by the Part D sponsor that an applicable drug is eligible for Part D coverage whenever CMS specifies a retroactive effective date for a

labeler code and notify such beneficiaries.

(c) *Exception to point-of-sale requirement.* Part D sponsors must provide an applicable discount for applicable drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims, if such claims are payable under the Part D plan.

(d) *Collection of data.* Part D sponsors must provide CMS with appropriate data on the applicable discounts provided by the Part D sponsors in a manner specified by CMS.

(e) *Supplemental benefits.* (1) An applicable discount must be applied to beneficiary cost-sharing after supplemental benefits (as defined in § 423.100) have been applied to the claim for an applicable drug.

(2) No applicable discount is available if supplemental benefits (as defined in § 423.100) eliminate the coverage gap so that a beneficiary has zero cost-sharing.

(f) *Other health or prescription drug coverage.* An applicable discount must be applied to beneficiary cost-sharing when Part D is the primary payer before any other health or prescription drug coverage is applied.

(g) *Pharmacy prompt payment.* Part D sponsors must reimburse a network pharmacy (as defined in § 423.100) the amount of the applicable discount no later than the applicable number of calendar days after the date of dispensing of an applicable drug. For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

§ 423.2330 Manufacturer discount payment audit and dispute resolution.

(a) *Third-party Administration (TPA) audits.* (1) Manufacturers participating in the Discount Program may conduct periodic audits, no more often than annually, directly or through third parties as specified in this section.

(2) The manufacturer must provide the TPA with 60 days notice of the reasonable basis for the audit and a description of the information required for the audit.

(3) The manufacturer must have the right to audit a statistically significant sample of data and information held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with the manufacturer's FDA-assigned labeler code(s). Such data and information will be made available on-site, and with the exception of work papers, such information cannot be removed from the audit site.

(4) The auditor for the manufacturer may release only an opinion of the audit results and is prohibited from releasing other information obtained from the audit, including work papers, to its client, employer, or any other party.

(b) *Manufacturer audits.* (1) A manufacturer is subject to periodic audit by CMS no more often than annually, directly or through third parties, as specified in this section.

(2) CMS provides the manufacturer with 60 days notice of the audit and a description of the information required for the audit.

(3) CMS has the right to audit appropriate data, including data related to a manufacturer's FDA-assigned labeler codes, 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 Program.

(c) *Dispute resolution.* (1) Manufacturers may dispute applicable discounts invoiced to the manufacturer on quarterly invoices by providing notice of the dispute to the TPA in a manner specified by CMS within 60 days of receipt of the information that is the subject of the dispute.

(2) Such notice must be accompanied by supporting evidence that is material, specific, and related to the dispute in a manner specified by CMS.

(3) The manufacturer must not withhold any invoiced discount payments pending dispute resolution with the sole exception of invoiced amounts for applicable drugs that do not have labeler codes provided by the manufacturer to CMS in accordance with § 423.2306(b)(4) of this subpart. If payment is withheld in accordance with this paragraph, the manufacturer must