
42 C.F.R. § 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.

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