
42 C.F.R. § 447.510

Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include the following:

(1) AMP, calculated in accordance with § 447.504.

(2) Best price, calculated in accordance with § 447.505.

(3) Customary prompt pay discounts, which are reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period.

(4) Prices that fall within the nominal price exclusion, which are reported as an aggregate dollar amount and include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) for the rebate period.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.* (1) A manufacturer must report to CMS any revision to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due. Any revision request that exceeds 12 quarters will not be considered, except for the following reasons:

(i) The change is a result of the drug category change or a market date change.

(ii) The change is an initial submission for a product.

(iii) The change is due to termination of a manufacturer from the MDR program for failure to submit pricing data and must submit pricing data to reenter the program.

(iv) The change is due to a technical correction; that is, not based on any changes in sales transactions or pricing adjustments from such transactions.

(v) The change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or Department of Justice (DOJ) investigation.

(vi) The change is a result of a VBP arrangement, as defined in § 447.502, requiring the manufacturer to make changes outside of the 12-quarter rule in this paragraph (b), when the outcome must be evaluated outside of the 12-quarter period.

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