# Issue Brief

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## KEY POINTS

- The proposed rule sets forth the calculation of the ceiling price and application of civil monetary penalties.
- The 22-page proposal will appear in the June 17 *Federal Register.*

# 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties

The Health Resources and Services Administration, which administers section 340B of the Public Health Service Act, has issued a proposed rule that will apply to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Drug Program. The proposed rule sets forth the calculation of the ceiling price and application of civil monetary penalties.

The 22-page proposal will appear in the June 17 *Federal Register*. A 60-day comment period is provided.

The Department is proposing to revise the following definitions: "ceiling price," "covered entity," "covered outpatient drug," and "manufacturer."

The Department is proposing to add the following definitions: "340B drug," "Average Manufacturer Price (AMP)," "National Drug Code (NDC)," "quarter," and "wholesaler."

The definitions for "Pharmaceutical Pricing Agreement (PPA)," and "Secretary" would remain, and the definitions for "Group purchasing organization (GPO)," "orphan drug," and "participating drug manufacturer" would be moved to a new regulation section.

## CEILING PRICE FOR A COVERED OUTPATIENT DRUG

A manufacturer is required to calculate 340B-ceiling prices for each covered outpatient drug, by National Drug Code on a quarterly basis.

(a) The 340B-ceiling price for a covered outpatient drug is equal to the average manufacturer price for the smallest unit of measure minus the unit rebate amount and will be calculated using six decimal places. To ensure the final price is operational in the marketplace, HRSA then multiplies this amount by the drug's package size and case package size. HRSA will publish the 340B-ceiling price rounded to two decimal places.

(b) When the ceiling price calculation in paragraph (a) above results in an amount less than $0.01 the ceiling price will be $0.01.

(c) A manufacturer must estimate the ceiling price for a new covered outpatient drug as of the date the drug is first available for sale and must provide HRSA an estimated price for each of the first three quarters the drug is available for sale.

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Beginning with the fourth quarter the drug is available for sale, the manufacturer must calculate the ceiling price as described in paragraph (a). A manufacturer must calculate the actual ceiling prices for the first three quarters and refund or credit any covered entity, which purchased the covered outpatient drug at a price greater than the calculated ceiling price. The refunds or credits for the first three quarters must be provided to covered entities by the end of the fourth quarter ceiling.

## MANUFACTURER CIVIL MONETARY PENALTIES

(a) Any manufacturer with a pharmaceutical pricing agreement that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug, may be subject to a civil monetary penalty not to exceed $5,000 for each instance of overcharging a covered entity, as defined in paragraph (b) of regulation section §10.11 (below). This penalty will be imposed pursuant to the procedures at 42 CFR Part 1003. Any civil monetary penalty assessed will be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHSA.

(b) Instance of overcharging. An instance of overcharging is any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price, as defined in §10.10, for that covered outpatient drug.

(1) Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC ordered. This includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent.

(2) Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer.

(3) An instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases.

(4) An instance of overcharging may occur at the time of initial purchase or when subsequent ceiling price recalculations due to pricing data submitted to CMS result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity.

(5) A manufacturer's failure to provide the 340B-ceiling price is not considered an instance of overcharging when a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase. Covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer's refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price.

*Analysis provided for MHA by Larry Goldberg, Goldberg Consulting*