DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Healthcare System Bureau
Office of Pharmacy Affairs

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340B DRUG PRICING PROGRAM NOTICE
Release No. 2011-2

CLARIFICATION OF PENNY PRICING POLICY

This policy release is being issued to clarify HRSA's long-standing policy with regards to 340B ceiling prices that are zero prices, known as the "penny pricing" policy, under the 340B Drug Pricing Program (340B Program).

Background

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities." Manufacturers who participate in Medicaid are required to enter into an agreement with the Secretary under which the manufacturer must agree to charge a price that will not exceed the amount determined under a statutory pricing formula when selling covered outpatient drugs to particular covered entities listed in the statute.

340B Pricing

In order to calculate the 340B ceiling price, the Unit Rebate Amount (URA) is subtracted from the Average Manufacturer Price (AMP) for the smallest unit of measure, which is then multiplied by the drug package size. The following formula is used for calculating 340B ceiling prices:

340B Ceiling Price = [(AMP) – (URA)] * Drug Package Size

Under the Medicaid Drug Rebate Program, the Centers for Medicare and Medicaid Services (CMS) indexes quarterly AMPs to the rate of inflation (Consumer Price Index adjusted for inflation-urban). Section 1927(c)(2)(A) of the Social Security Act provides that if the AMP increases at a rate faster than inflation, the manufacturer pays an additional rebate amount which is reflected in an increased URA. Historically, because of the basic rebate and the inflation factor, Section 1927(c)(2)(A) could increase the rebate amount manufacturers must pay to the States, and result in negative 340B prices. Now, based on the provision in section 1927(c)(2)(D) of the Social Security Act that limits the unit rebate amount to 100% of the AMP, effective January 1, 2010, an increase in the basic rebate and inflation factor would not result in a negative 340B price, but could result in a zero 340B price.

Penny Pricing Procedures

HRSA recognizes that when the URA equals the AMP in the calculation of the 340B ceiling price, it is not reasonable for a manufacturer to set a zero 340B ceiling price. In these cases, the manufacturer should charge $0.01 per unit of measure for zero priced drugs. It is not appropriate for a manufacturer to use the prior quarter pricing, wholesale acquisition cost (WAC), or any other non-340B contract price in place of the penny pricing because 340B ceiling prices must be based on the immediately preceding calendar quarter. Using the prior quarter pricing or some other price in place of penny pricing would nullify the pricing penalty (AMP increasing faster than inflation) when the 340B ceiling price decreases because of changes to the AMP.

Examples:

- If the smallest unit of measure used to calculate AMP and URA as reported to CMS is a single tablet, and the drug is packaged in bottles of 100, then the 340B price for that bottle would be $1.00 ($0.01 * 100 = $1.00).
- If the smallest unit of measure used to calculate the AMP and URA is the bottle of 100 tablets, then the appropriate charge for that bottle is $0.01.
- If the smallest unit of measure used to calculate AMP and URA as reported to CMS is a milliliter of liquid, and the drug is packaged in a 100 ml bottle, then the 340B price for that bottle would be $1.00 ($0.01 * 100 = $1.00).

Alternate Allocation Procedures

When a 340B price drops to a penny price, a manufacturer may anticipate challenges with equitable market distribution of the drug, and should develop a plan for non-discriminatory, restricted distribution to all purchasers, including 340B covered entities. Manufacturers must notify the Office of Pharmacy Affairs of this plan in writing (e.g., email, mail, or facsimile), at least 4 weeks before the proposed restricted distribution implementation date. Plans to restrict sales must be applied to all purchasers of the affected drug and must be applied equitably to 340B and non-340B providers. For more details on allocation plans, refer to 340B Drug Pricing Program Notice Release No. 2011-1.