

Date: May 23, 2012

**340B DRUG PRICING PROGRAM NOTICE**

Release No. 2011-1.1

(Replaces No. 2011-1 dated November 21, 2011)

**CLARIFICATION OF NON-DISCRIMINATION POLICY**

This policy release is being issued to restate the Health Resources and Services Administration's (HRSA) policy with regard to manufacturer limitations or conditions on sales of covered outpatient drugs to eligible 340B entities (discrimination against 340B covered entities) 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 under the 340B statute 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 formula when selling covered outpatient drugs to particular covered entities listed in the statute. This agreement, known as the Pharmaceutical Pricing Agreement (PPA), must be signed by a manufacturer as a condition for participating in Medicaid. Signing the PPA does not prohibit a manufacturer from charging a price for a covered outpatient drug that is lower than the 340B ceiling price. A manufacturer may not condition the offer of 340B discounts upon a covered entity's assurance of compliance with section 340B provisions.

**Alternate Allocation Procedures**

HRSA has policy in place to ensure that manufacturers have the ability to develop alternate allocation procedures during situations when the available supply of a covered drug is not adequate to meet market demands. These allocation procedures, however, must demonstrate that 340B providers are treated the same as non-340B providers. The 1994 guideline (59 Fed. Reg. 25110 (May 13, 1994)) states that "manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective" and that "manufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." This policy is consistent with section 340B(a)(1) of the Public Health Service Act which requires manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

In order to reduce the potential for disputes and ensure alternate allocation procedures are transparent to all stakeholders, the Office of Pharmacy affairs (OPA) requests manufacturers to provide notification to OPA in writing (e.g., email, mail, or facsimile) prior to actual implementation. Where feasible, this information should be submitted at least four weeks before the implementation date, with a plan that includes:

- A description of product information (Drug Name, Dosage, Form and NDC)
- Details for a non-discriminatory practice for restricted distribution to all purchasers, including 340B covered entities, which includes each of the following components:
  - Explanation of product's limited supply and rationale for restricted distribution among all purchasers

- How manufacturers will impose restrictions on non-340B purchasers
- Specific details of the drug allocation plan, including a mechanism that incorporates potential 340B sales to covered entities and sales to non-340B covered entities that may not have a previous history of purchasing the restricted drug
- Dates the restricted distribution begins and concludes
- Plan for notification of wholesalers and 340B covered entities

When submitted in a timely fashion, OPA will publish all submitted allocation plans on its website ([www.hrsa.gov/opa](http://www.hrsa.gov/opa)) on the date of implementation. If OPA has concerns about the allocation plan, it will work with the manufacturer to incorporate mutually agreed upon revisions to the plan prior to posting the plan on the HRSA/OPA website. Covered entities that have concerns regarding the manner in which a particular plan is implemented are first encouraged to resolve them in good faith with manufacturers. Where such issues are not resolved, covered entities should contact OPA for appropriate action or involvement of other federal agencies (e.g., Office of Inspector General, Department of Justice) to bring the issue to resolution. Although prior notification by manufacturers is not currently required, HRSA believes that voluntarily providing OPA with timely notification will benefit manufacturers as well as covered entities by reducing the chance for misunderstandings about the requirements of the 340B Program and lessen the potential for disputes.

Manufacturers must comply with federal and state requirements regarding the distribution and sale of drugs. Accordingly, this policy does not require manufacturers to offer drugs to a covered entity under circumstances that would violate federal or state law.