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. 2011-3

CLARIFICATION OF MANUFACTURER AUDITS OF 340B COVERED ENTITIES

This policy release is being issued to restate HRSA's long-standing policy with regards to 340B audits of covered entities by participating manufacturers 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.

Program Prohibitions

Covered entities that choose to participate in the 340B Program shall comply with:

- Section 340B(a)(5)(A) of the PHS Act- PROHIBITING DUPLICATE DISCOUNTS OR REBATES—A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act; and
- Section 340B(a)(5)(B) of the PHS Act – PROHIBITING RESALE OF DRUGS—With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

Section 340B(a)(5)(C) of the PHS Act requires covered entities to permit a manufacturer to determine if a covered entity is complying with section 340B(a)(5)(A) and (B) of the PHS Act.

Manufacturer Audit Guidelines

Manufacturers should continue to follow the existing Manufacturer Audit Guidelines in the Federal Register at 61 FR 65406 that HRSA published December 12, 1996, to conduct audits. As stated in the guidelines, prior to conducting an audit, manufacturers must submit audit work plans to HRSA for review. Audit work plans should be submitted to HRSA at least 45 days in advance of conducting an audit of a covered entity.

If manufacturers have concerns or specific issues with diversion and violations of duplicate discounts by covered entities, we encourage manufacturers, after attempting to resolve the matters directly with covered entities, to submit their audit plans to HRSA per the audit guidelines. OPA will work with manufacturers in its consideration of submitted audit work plans, and will respond within 15 calendar days with an approval or denial of the submitted work plan. Covered entities should be informed at least 15 days in advance of a conducting an audit.

A link to the Manufacturer Audit Guidelines can be found here Federal Register Final Notice (December 12, 1996 (Vol. 61, No. 240, pp. 65406-65413)) Regarding Section 602 of the Veterans Health Care Act of 1992 Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19.