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. 2012-1

CLARIFICATION OF HRSA AUDITS OF 340B COVERED ENTITIES

This policy release is being issued to restate HRSA's policy with regards to 340B audits of covered entities participating in 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 (PHS Act), "Limitation on Prices of Drugs Purchased by Covered Entities." Per 42 USC 256b(a)(5)(C), the Secretary has the authority to audit covered entities for compliance with 340B Program requirements:

> (C) AUDITING.—A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

Subparagraph (A) under 42 USC 256b(a)(5) prohibits requiring manufacturers to pay discounts or rebates under both the 340B Program and the Medicaid Drug Rebate Program (duplicate discounts). Subparagraph (B) of 42 USC 256b(a)(5) prohibits resale of 340B drugs to a person who is not a patient of the entity (diversion). To clarify the definition of patient in the 340B Program, HRSA issued guidelines concerning patient eligibility in the Federal Register at 61 FR 55156, published October 24, 1996.

HRSA and manufacturers have had the authority to audit covered entities regarding their compliance with diversion of drugs and duplicate discounts since the inception of the 340B Program. As stated in the Government Accountability Office (GAO) September 2011 Report (GAO-11-836), the GAO recommended HRSA conduct selective audits of 340B covered entities to provide additional program oversight, monitor for program violations, and prevent diversion and duplicate discounts. HRSA has recently begun audits of 340B covered entities as part of its efforts toward strengthening program integrity and oversight. Please see Office of Pharmacy Affairs Policy Release No. 2011-3 at http://www.hrsa.gov/opa/Docs/PolicyReleaseManufacturerAudits.pdf for more detailed information on manufacturer audits.

HRSA Audit Strategy

HRSA plans to conduct audits of 340B covered entities, in addition to incorporating a 340B Program component into the A-133 audit submission process.

A-133 audits

The A-133 audit process is a requirement for all non-Federal entities that expend $500,000 or more of Federal awards in a year. These entities are already required to obtain an annual audit in accordance with the Single Audit Act Amendments of 1996, OMB Circular A-133, the OMB Circular Compliance Supplement and Government Auditing Standards. Additional information on A-133 audits is available at http://www.whitehouse.gov/omb/circulars_default. Single audits provide a cost-effective audit for non-Federal entities in that one audit is conducted in lieu of multiple audits of individual programs. Organizations that submit A-133 audits shall be required to review 340B eligibility status, program policies and procedures, internal controls, and records concerning 340B compliance. A-133 audits will be used by HRSA to obtain a better assessment of 340B Program compliance when supplemental protocol specific to 340B is added in FY 2013.

HRSA random and targeted audits

Using an audit protocol specific to the 340B Program, the HRSA random and targeted audits will involve more in-depth review and include a more focused audit of covered entities' 340B Program operations and compliance. The audit protocol will be made publicly available in order to assist covered entities in preparation for an audit. The random audits will first include covered entities randomly chosen from program types determined to be at higher program risk due to volume of purchases, increased complexity of program administration, and use of contract pharmacies. Later random audits will include entities randomly chosen from program types determined to be at lesser risk. Targeted audits may be triggered by allegations of violations of 340B requirements, and are not limited to those made by whistleblowers, manufacturers, or self reporting by covered entities themselves. Selective and targeted audits will include a more thorough investigation of policies and procedures, review of auditable records, and system compliance to prevent diversion and duplicate discounts. The findings from these audits may be used to refer matters to the Office of Inspector General (OIG) or Department of Justice (DOJ).

The findings that are derived from these audits will assist HRSA and all 340B stakeholders to provide additional insights into the status of 340B operations and to assess overall compliance with the 340B Program. These audits will help HRSA and participating covered entities identify and mitigate program risk as well as identify best practices regarding 340B Program compliance.