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. 2013-1

# STATUTORY PROHIBITION ON GROUP PURCHASING ORGANIZATION PARTICIPATION

This policy release is being issued to clarify the 340B Drug Pricing Program's (340B Program) policy regarding the statutory prohibition against obtaining covered outpatient drugs through a group purchasing organization (GPO) for certain covered entities.

## Background

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act (PHSA), "Limitation on Prices of Drugs Purchased by Covered Entities." The Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA) administers the 340B Program.

Disproportionate share hospitals (DSH), children's hospitals, and free-standing cancer hospitals participating in the 340B Program under 42 U.S.C. 256b(a)(4)(L) and (M) are subject to 42 U.S.C. 256b(a)(4)(L)(iii), which states that in order to participate in the 340B Program, these entities may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."

Since the beginning of the 340B Program, HRSA has addressed violations of this prohibition in guidelines published in the Federal Register, stating that if a covered entity subject to this prohibition participates in a GPO, the covered entity "will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices." 59 FR 25113 (May 13, 1994). Final children's hospital guidelines state that "a children's hospital will have to certify that it will not participate in a group purchasing organization (GPO) or other group purchasing arrangement for covered outpatient drugs as of the effective date of participation as listed in the 340B covered entity database." 74 FR 45210 (September 1, 2009). This document serves to further explain and clarify HRSA's position on questions that have arisen as the marketplace has changed.

## Scope of GPO Prohibition and Certification of Compliance

Compliance with the GPO prohibition is an eligibility requirement for certain categories of eligible entities. Upon registration for the 340B Program, an authorizing official of a DSH, children's hospital, or free-standing cancer hospital must sign an acknowledgement of this statutory requirement. The covered entity must also attest to compliance with the GPO prohibition during the 340B annual recertification process. This requirement is reviewed during HRSA 340B Program audits. It is HRSA's longstanding position that a covered entity enrolled in the 340B Program subject to the GPO prohibition and listed on the OPA 340B database may not use a GPO for covered outpatient drugs at any point in time. If a covered entity is unable to purchase a covered outpatient drug at the 340B price, written notification should be sent to OPA immediately detailing the covered outpatient drug(s) involved, the manufacturer, and the process by which the entity was notified that the purchase could not be made. HRSA reviews all allegations brought to our attention to ensure compliance with program requirements.

**Outpatient Clinic Sites and Areas of the Hospital where GPO Prohibition Applies**

Hospitals and their off-site outpatient clinic sites that are registered on the OPA 340B database as participating in the 340B Program are subject to the GPO prohibition and cannot purchase any covered outpatient drugs through a GPO or other group purchasing arrangement. A hospital subject to the GPO prohibition may not purchase covered outpatient drugs through a GPO for any of its clinics/departments within the four walls of the hospital (same physical address) under any circumstance. However, certain off-site outpatient facilities of the hospital may use a GPO for covered outpatient drugs if those off-site outpatient facilities meet all of the following criteria:

1. Are located at a different physical address than the parent;
2. Are not registered on the OPA 340B database as participating in the 340B Program;
3. Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and
4. The hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B database.

Organizations that are not part of the 340B covered entity are not subject to the GPO prohibition; however, the 340B covered entity is still prohibited from having organizations purchase covered outpatient drugs through a GPO on its behalf or otherwise receive covered outpatient drugs purchased through a GPO. A 340B covered entity purchases and maintains title to the drugs, not a contract pharmacy (see 75 Fed. Reg. 10272, 10277 (March 5, 2010)). Therefore, a hospital subject to the GPO prohibition cannot use a GPO for covered outpatient drugs, even if the drugs are dispensed at a contract pharmacy.

**Date of GPO Prohibition Compliance**

340B covered entities subject to the GPO prohibition must stop obtaining covered outpatient drugs through a GPO before the first day the covered entity is eligible to purchase 340B drugs and listed on the OPA 340B database. If a covered entity has GPO-purchased drugs remaining in inventory once enrolled in the 340B Program, those drugs may be used until expended; however, purchasing from a GPO should cease.

**Compliance through "Replenishment"**

Through HRSA's 340B Program integrity initiatives, HRSA has become aware that some hospitals subject to the GPO prohibition have been purchasing covered outpatient drugs through a GPO and subsequently either (1) "replenishing" through accounting by "replacing" the GPO purchased drug with a drug purchased under 340B; or (2) otherwise reclassifying the method of purchase after dispensing. HRSA has not authorized this GPO replenishment model. The GPO prohibition is violated upon use of a GPO to obtain covered outpatient drugs and cannot be fixed or cured by subsequently changing the characterization through accounting or other methods. Hospitals using such models should immediately cease this practice or be found in violation of the GPO prohibition. If a covered entity violates the GPO prohibition, it will be removed from the 340B Program as it will no longer be eligible for participation.

A 340B covered entity subject to the GPO prohibition should purchase using a non-GPO account and only replenish with 340B drugs once 340B patient eligibility is confirmed and can be documented through auditable records. Covered entities electing to use this or any other replenishment model must be able to demonstrate compliance with the GPO prohibition through auditable records.

**Sanctions**

Since the GPO prohibition is an eligibility requirement, covered entities found in violation will be considered ineligible and immediately removed from the 340B Program. Covered entities may also be subject to repayment to manufacturers for the time period for which the violation occurred. Covered entities removed from the 340B Program for GPO prohibition violations must demonstrate the ability to comply with the GPO prohibition to be considered eligible to reenter the 340B Program during the next regular enrollment period.

If a GPO prohibition violation occurs at a parent site, all outpatient clinics, contract pharmacies, or sites enrolled that are related to the covered entity 340B ID will be removed from the 340B Program with the parent. The covered entity “parent” is responsible for ensuring compliance with all outpatient clinics, contract pharmacies, and sites that participate in the 340B Program.