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

Date: December 12, 2014 **340B DRUG PRICING PROGRAM**
NOTICE

Release No. 2014-1
(Replaces No. 2013-2 dated February 7, 2013)

CLARIFICATION ON USE OF THE MEDICAID EXCLUSION FILE

This policy release clarifies the use of the 340B Medicaid Exclusion File to prevent duplicate discounts that could result when a drug is discounted under the 340B Drug Pricing Program (340B Program) and subject to a Medicaid rebate. This policy release only applies to Medicaid fee-for-service (MFFS) and further addresses the Health Resources and Services Administration's (HRSA) oversight role.

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 Office of Pharmacy Affairs (OPA) within HRSA administers the 340B Program.

Section 340B of the PHSA requires that participating pharmaceutical manufacturers charge covered entities a price for covered outpatient drugs that does not exceed the 340B ceiling price, as specified in the statute. Section 340B(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a rebate under the Medicaid drug rebate program (MDR program) for the same drug. The MDR program is administered by the Centers for Medicare & Medicaid Services (CMS). While CMS and HRSA have worked collaboratively to ensure compliance with the duplicate discount prohibition, HRSA is specifically responsible for the enforcement of covered entity compliance with this requirement.

340B Medicaid Exclusion File

Pursuant to section 340B(a)(5)(A)(ii), HRSA and CMS, collaborated to establish the 340B Medicaid Exclusion File as the mechanism to prevent duplicate discounts for drugs subject to Medicaid rebates. 58 Fed. Reg. 34058 (June 23, 1993). The 340B Medicaid Exclusion File is available on HRSA's public website (http://opanet.hrsa.gov/opa/CEMedicaidExtract.aspx) to help 340B covered entities, states, and manufacturers avoid duplicate discounts specific to MFFS. HRSA provides the 340B Medicaid Exclusion File as the official data source to determine whether 340B drugs are billed to Medicaid in order to prevent duplicate discounts.

At registration, covered entities inform HRSA whether the covered entity will purchase and dispense 340B drugs to their Medicaid patients ("carve-in") or whether they will purchase drugs for their Medicaid patients through other mechanisms ("carve-out").

A covered entity which elects to carve-in provides to HRSA any Medicaid provider number or National Provider Identifier (NPI) used to bill MFFS for 340B drugs. This information will be

reflected on the 340B Medicaid Exclusion File to notify states and manufacturers that drugs purchased under that Medicaid provider number or NPI are not eligible for a Medicaid rebate. If a covered entity houses many different clinics, only some of which are 340B-eligible, and wants to carve-in, it must obtain a separate Medicaid provider number for the eligible clinics that use 340B drugs when billing Medicaid. For those states which cannot generate additional Medicaid provider numbers for entities, an alternative arrangement with the respective state to accomplish this objective would be needed. If a covered entity decides to carve-out, entirely or for a particular Medicaid provider number or NPI, the covered entity does not submit its Medicaid billing number or NPI to HRSA, and that Medicaid provider number or NPI will not be listed on the 340B Medicaid Exclusion File.

Participating covered entities can change their Medicaid billing status by using an online change request form (http://opanet.hrsa.gov/opa/CRPublicSearch.aspx). Such changes will be effective at the start of the following quarter.

Covered entities that utilize contract pharmacy arrangements are expected to ensure compliance with all the requirements in the Final Notice regarding Contract Pharmacy Services published at 75 Fed. Reg. 10272 (Mar. 5, 2010). Under those guidelines, contract pharmacies are prohibited from using 340B drugs to dispense Medicaid prescriptions and must carve-out unless the covered entity, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts. The covered entity must report any such arrangement to HRSA.

HRSA Oversight and Covered Entity Compliance

Covered entities attest to the accuracy of their information on the 340B Medicaid Exclusion File during annual recertification. Covered entity billing information must be accurate, auditable, and transparent at all times to ensure the integrity of the 340B Medicaid Exclusion File and to prevent duplicate discounts. HRSA's role in overseeing the duplicate discount prohibition is ensuring that covered entities have accurately reflected their Medicaid billing practices on the 340B Medicaid Exclusion File.

HRSA and manufacturer 340B Program audits may review covered entity compliance with the duplicate discount prohibition. If a HRSA audit reveals that a covered entity's information on the 340B Medicaid Exclusion File does not reflect actual billing practices, the covered entity could be found in violation of the duplicate discount prohibition and may be required to repay manufacturers in an amount equal to the reduction in the price of the drug. Through the corrective action process, HRSA will direct covered entities to work with States and manufacturers to determine whether a duplicate discount occurred as a result of the incorrect 340B Medicaid Exclusion File listing. HRSA will not contact the State to determine if a duplicate discount occurred. In the event that a covered entity that is listed on the 340B Medicaid Exclusion File as using 340B drugs for MFFS patients, but is unable to use a 340B drug in a particular instance, it must have a mechanism in place to notify the state Medicaid agency. States should work with CMS regarding their role in the prevention of duplicate discounts.

All covered entities are expected to have written policies and procedures pertaining to the prevention of duplicate discounts, and ensure their database listing is consistent with actual practice. While Medicaid drug rebates were previously limited to MFFS drugs, section 2501(c) of the Patient Protection and Affordable Care Act (Public Law 111-148) amended the Social Security Act (SSA), extending Medicaid drug rebate eligibility to certain Medicaid managed care covered outpatient drugs, effective March 23, 2010. Section 2501(c) further amended the SSA to

specify that covered outpatient drugs covered by a Medicaid Managed Care Organization (MCO) are not subject to a rebate if also subject to a discount under section 340B of the PHSA.

This policy release does not apply to the prevention of duplicate discounts that may occur under MCOs. HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care, and is working with CMS to develop policy in this regard. We are aware that some covered entities have already worked with MCOs and state partners to develop models for the prevention of duplicate discounts. Some covered entities report using a variety of methods including, but not limited to, Bank Identification Numbers and/or Processor Control Numbers to identify patients of MCOs, National Council for Prescription Drug Programs (NCPDP) codes at the individual claim level for claims submitted through a point of sale (POS) system at a retail or clinic pharmacy (contract pharmacy), and UD Modifiers for physician administered claims or drug costs submitted as part of a bundled or capitated rate. In some cases, states may place certain requirements on covered entities regarding the prevention of duplicate discounts. HRSA encourages 340B covered entities to work with their state to develop strategies to prevent duplicate discounts on drugs reimbursed through MCOs.