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

Date: February 7, 2013

340B DRUG PRICING PROGRAM NOTICE
Release No. 2013-2

CLARIFICATION ON USE OF THE MEDICAID EXCLUSION FILE

This policy release is being issued to restate the use of the HRSA Medicaid Exclusion File for avoiding duplicate discounts that could result when a drug is discounted under the 340B Drug Pricing Program (340B Program) and subject to a Medicaid rebate.

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 the Healthcare Systems Bureau of the Health Resources and Services Administration (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 average manufacturer price reduced by the Medicaid rebate percentage (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 Medicaid drug rebate for the same drug.

Medicaid Exclusion File

Section 340B(a)(5)(A)(ii) required the Secretary to establish a mechanism to ensure that covered entities comply with the requirement prohibiting duplicate discounts. HRSA established the Medicaid Exclusion File as the mechanism to prevent duplicate discounts for drugs subject to Medicaid rebates. 58 Fed. Reg. 34058 (June 23, 1993). The HRSA 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.

Covered entities must determine whether they will use 340B drugs for their Medicaid patients ("carve-in") or whether they will purchase drugs for their Medicaid patients through other mechanisms ("carve-out"). Covered entities are required to inform HRSA (by providing their Medicaid billing number) at the time they enroll in the 340B Program if they will purchase and dispense 340B drugs for their Medicaid patients ("carve-in"). This information will be reflected on the HRSA Medicaid Exclusion File so states and manufacturers know that drugs purchased under that Medicaid billing number are not also eligible for a Medicaid rebate. If a covered entity which houses many different clinics, only some of which are 340B-eligible, 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, covered entities must discuss an alternative arrangement with the states to accomplish this objective. If a covered entity decides to "carve-out," it does not have to submit its Medicaid billing number to HRSA, and its Medicaid billing number will not be listed on the HRSA Medicaid Exclusion File.

When registering a new covered entity, the registrant must include all Medicaid billing numbers utilized by the covered entity to bill Medicaid with 340B drugs. Participating covered entities can add or delete Medicaid billing numbers by using an online change request form (http://opanet.hrsa.gov/opa/CRPublicSearch.aspx). Changes to how a covered entity uses 340B drugs for its Medicaid patients will be effective on a quarterly basis only.

Covered Entity Compliance

Covered entities attest to the accuracy of their information on the HRSA Medicaid Exclusion File during annual recertification. Covered entity billing information must be accurate, verifiable, and transparent at all times to ensure integrity of the HRSA Medicaid Exclusion File and to prevent violations of the statutory prohibition on duplicate discounts. HRSA and manufacturer 340B Program audits review, in part, covered entity compliance with the duplicate discount prohibition. If an audit reveals that a covered entity's information on the HRSA 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. HRSA provides the Medicaid Exclusion File as the official data source to determine whether drugs billed to Medicaid under a billing number listed on the HRSA Medicaid Exclusion File were purchased under the 340B Program in order to prevent duplicate discounts. In the event that a covered entity that is listed on the HRSA Medicaid Exclusion File is unable to use a 340B drug in a particular instance, it must have a mechanism in place to notify the state Medicaid agency. HRSA encourages states and entities to work together to ensure records are accurate and auditable.

A June 2011 HHS OIG report noted that states reported issues with the HRSA Medicaid Exclusion File and indicated that some state Medicaid agencies are not utilizing the HRSA Medicaid Exclusion File as directed in HRSA's published guidelines (OIG Report on State Medicaid Policies and Oversight Activities Related to 340B Purchased Drugs at http://www.hrsa.gov/opa/programrequirements/reports/medicaidpoliciesandoversities062011.pdf). OPA is committed to the accuracy of the HRSA Medicaid Exclusion File and urges state Medicaid agencies to inform HRSA at OPAexclusion@hrsa.gov of any discrepancies in the HRSA Medicaid Exclusion File so the information can be examined and updated when appropriate.