

AN OVERVIEW OF THE SECTION 340B DRUG PRICING PROGRAM

Background:

In November 1992, Congress enacted Section 340B of the Public Health Service Act, which requires pharmaceutical manufacturers, as a condition for having Medicaid cover and pay for their drugs, to offer discounts on certain outpatient drugs purchased by specified facilities, called "covered entities that serve the nation's most vulnerable patient populations. Congress established the 340B Program to ensure that discounts already provided to the Medicaid program would be made available to these publicly supported safety net providers thereby saving federal, state and local government millions of dollars in drug costs.

Who is eligible to participate in the 340B Program ?

The definition of "covered entities" includes specified federally funded clinics such as community health centers, migrant health clinics, the Ryan White CARE Act Title I, Title II and Title III programs, tuberculosis, black lung, family planning and sexually transmitted disease clinics, **hemophilia treatment centers**, public housing primary care clinics, homeless clinics, Urban Indian clinics and Native Hawaiian health centers. It also includes certain public high-volume disproportionate share hospitals, and state operated AIDS drug assistance programs. Some 6,400 covered entities and over 500 pharmaceutical companies are affected by the law.

How does the Program operate?

The law conditions Medicaid reimbursement for a pharmaceutical manufacturer's outpatient drugs on the manufacturer's agreement to charge covered entities a price for covered outpatient drugs that will not exceed an amount determined by a statutory formula. For most drugs, the discount is equivalent to the "best price" rebates to which Medicaid is entitled. Covered entities are free to negotiate discounts that are lower than the maximum allowable statutory price.

What has the Program achieved?

Since the law took effect, it has saved covered entities and the taxpayers that support them hundreds of millions of dollars in outpatient drug costs. Pharmaceutical prices available under Section 340B are significantly lower than both retail and wholesale prices. Based on a recent analysis of 100 popular outpatient drugs, 340B prices are, on average, 34 percent lower than a major wholesaler's price. These savings have been and will continue to be critical to the ability of these safety net providers to meet the pharmaceutical needs of their patients at a time when traditional sources of public funding are rapidly drying up.



How does the Program ensure discounted drugs are not improperly diverted?

Section 340B prohibits the resale or transfer of discounted outpatient drugs to anyone other than a patient of the covered entity. The penalty for failing to comply with this anti-diversion provision is forfeiture of the discounts back to the manufacturer and/or disqualification from the Program. Manufacturers and the Office of Pharmacy Affairs have the right to audit the records of the covered entities to protect against diversion. To date, no documented instances intentional diversion have occurred.

Are normal billing practices observed?

Congress was careful to ensure that drugs purchased at a discount under the 340B Program are not also subject to a Medicaid rebate. A mechanism has been established to allow state Medicaid agencies to identify covered entity pharmacy bills and exclude them from the rebate program. In addition, covered entities are prohibited from billing Medicaid more than acquisition cost plus a dispensing fee. Together, these requirements have effectively prevented duplicate discounts. Because there is no risk of duplicate discounts with non-Medicaid patients, Congress imposed no further billing restrictions.

Who is administering the Program?

The Program is administered by the Office of Pharmacy Affairs (OPA) which is located within the Special Programs Branch, Health Resources and Services Administration, Department of Health and Human Services. OPA is responsible for interpreting and implementing Section 340B, overseeing compliance with Section 340B, and assisting the covered entities in obtaining discounts. The phone number for OPA is 1-800-628-6297 or (301) 594-4353 and their fax number is (301) 594-4982. Their web site is located at <http://www.hrsa.gov/opa>