



Public Hospital Pharmacy Coalition

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(A Coalition of the National Association of Public Hospitals and Health Systems)

An Overview of The Section 340B Drug Discount Program

Background:

To address the high costs of pharmaceuticals, Congress created the Medicaid rebate program in 1990, which requires drug companies to enter into a rebate agreement with the Secretary of Health and Human Services as a precondition to doing business with Medicaid. The agreement specified that, for each outpatient drug covered under the Medicaid plan, the manufacturer of that drug must give its "best price" to Medicaid, i.e. Medicaid cannot be charged more than the lowest price paid by any other purchaser of the drug. As a result of this law, many pharmaceutical companies had a disincentive to continue giving deep discounts on drugs because they would have to extend the same discounts to Medicaid. Therefore, many manufacturers raised their best prices, increasing the burden on federal- and state-supported providers and undermining the anticipated savings from the program.

To correct this situation, Congress, in November 1992, enacted Section 340B of the Public Health Service Act (created under Section 602 of the Veterans Health Care Act of 1992), which requires pharmaceutical manufacturers participating in the Medicaid program to enter into a second agreement with the Secretary under which the manufacturer agrees to provide discounts on covered outpatient drugs purchased by specified government-supported facilities, called "covered entities," that serve the nation's most vulnerable patient populations. The amount of these discounts is comparable to the best price discounts to which Medicaid is entitled under the 1990 rebate program; however, covered entities are free to negotiate even deeper discounts than the best price amount.

Who is eligible to participate in the 340B Program?

The definition of "covered entities" includes certain high-volume disproportionate share hospitals (DSHs), as well as specified grantees of the Public Health Service, including certain federally qualified health centers (FQHCs), state operated AIDS drug assistance programs (ADAPs), 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. Over 8000 participating covered entity sites and close to 600 pharmaceutical companies are affected by the law.

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Who is administering the 340B Program?

The Program is administered by the Office of Pharmacy Affairs (OPA), formerly the Office of Drug Pricing, which is located within the Bureau of Primary Health Care, Health Resources and Services Administration, U.S. Public Health Service, 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. The fax number is (301) 594-4982. The web site is located at www.hrsa.gov/odpp.

How does the Program operate?

The law requires that, as a condition for Medicaid paying for a pharmaceutical manufacturer's outpatient drugs, the manufacturer must enter into a contract with the HHS Secretary in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined by a statutory formula. For most drugs, the discount is the average manufacturer price reduced by a rebate percentage that is equivalent to the Medicaid rebate amount. Covered entities receive a minimum discount of approximately 15 percent for name brand prescription drugs and 11 percent for generic and over-the-counter drugs, and are entitled to an additional discount if the price of a drug has increased faster than the rate of inflation. In addition, covered entities are free to negotiate discounts that are lower than the maximum allowable statutory price.

How do covered entities go about obtaining discounts?

Manufacturers can check the OPA web site each quarter to determine which covered entities are participating in the program. The manufacturer may not charge more than the 340B ceiling price regardless of whether the covered entity purchases pharmaceuticals through a wholesaler or directly from the manufacturer. OPA is currently implementing a provision of Section 340B mandating the creation of a "prime vendor" program. It has selected AmeriSource-Bergen to handle price negotiation and drug distribution responsibilities. A covered entity does not have to join the prime vendor program in order to participate in the 340B program. OPA is hopeful that since the prime vendor has the potential to control a large volume of pharmaceuticals and move market share, it can negotiate favorable prices and develop a national distribution system that would not be possible for covered entities individually.

To whom may the covered entities dispense the discounted drugs?

Section 340B prohibits the resale or transfer of discounted outpatient drugs to any one 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 or disqualification from the Program. Manufacturers and the OPA have the right to audit the records of the covered entities to protect against diversion.

Are there billing restrictions?

The law says that a drug purchased under Section 340B shall not be subject to both a 340B discount and a Medicaid rebate. OPA has established a mechanism for covered entities to comply with this provision. Covered entities that bill Medicaid submit their pharmacy Medicaid provider numbers to OPA which then submits them to state Medicaid agencies. The provider numbers are then used by the Medicaid agencies to identify covered entity pharmacy bills and exclude them from the rebate program. In addition, covered entities may not bill Medicaid more than acquisition cost plus a dispensing fee. With respect to covered entities that do not bill Medicaid individually, drug purchases are not billed as separate cost items; therefore, there is no possibility for a duplicate discount to occur. There are no billing restrictions applicable to drugs dispensed to non-Medicaid patients.

What if a covered entity facility lacks an "in-house" pharmacy?

OPA has developed guidelines to allow such facilities to contract with a local community pharmacy to act as its agent. Under these guidelines the covered entity is required to purchase the pharmaceuticals and the contractor provides all pharmacy services. A "ship to - bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the covered entity for the drugs that it purchased but ships the drugs directly to the contract pharmacy. In addition, the contractor must provide the covered entity quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records. The contractor is also required to establish and maintain a tracking system to prevent diversion of drugs to individuals who are not patients of the covered entity.

How much do Section 340B participants save in the Program?

Pharmaceutical prices available under Section 340B are significantly lower than both retail and wholesale prices. Based on a recent analysis of 200 popular outpatient drugs, 340B prices are, on average, 54 percent lower than the average wholesale price (AWP). Another recent survey found 340B prices to be 24 percent lower than that available to group purchasing organizations. Hospital participants have experienced an average of over \$2 million in savings annually.

How do you receive the latest information on the Program?

The Office of Pharmacy Affairs web site disseminates information for those participating in the Program. This information includes the names of participating covered entities and manufacturers, Federal Register notices, and current Program guidelines. To access the site, log on to www.hrsa.gov/odpp.

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