



TESTIMONY OF

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BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

DECEMBER 15, 2005

Mr. Chairman and Members of the Subcommittee:

My name is Dennis Williams. I am the Deputy Administrator of the Health Resources and Services Administration (HRSA). I am pleased to appear before you today to discuss the oversight and administration of the 340B Drug Pricing Program (340B Program) in light of the recent reports by the Office of the Inspector General.

History of the Program

The 340B Program was created by Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585), which was enacted on November 4, 1992. As established, the 340B Program limits the cost of covered outpatient drugs to certain safety-net providers, referred to as covered entities. These covered entities include: Federally Qualified Health Centers (FQHCs), Hemophilia Treatment Centers, Ryan White Programs, Sexually Transmitted Disease/Tuberculosis Programs (STD/TB), Title X Family Planning (FP) Clinics, Urban/638 Tribal Programs, Federally Qualified Health Center Look-Alikes and certain Disproportionate Share Hospitals (DSHs).

The 340B drug discount prices, commonly referred to as ceiling prices, are based on Average Manufacturers Price and Medicaid Drug Rebates. Pharmaceutical companies that participate in the Medicaid program must sign a Pharmaceutical Pricing Agreement that obligates them to participate in the 340B program. Under the 340B program, the selling price may be lower than the ceiling price, but never greater.

HRSA Oversight and Administration

HRSA administers the 340B program based on Medicaid drug data received from the Centers for Medicaid and Medicare Services (CMS) pursuant to an Intra-Agency Agreement. Through our Office of Pharmacy Affairs (OPA), we: enroll eligible entities in the 340B program; maintain a web accessible database that houses eligible covered entity data, program guidelines and other useful information; calculate the 340B discount price; execute Pharmaceutical Pricing Agreements with drug manufacturers; provide information and technical assistance to covered entities via the Pharmacy Services Support Center (PSSC); administer the Prime Vendor Program; and provide program oversight.

The PSSC, operated under a contract with the American Pharmacists Association, provides expert technical assistance to covered entities that want to access the 340B program and to improve their pharmacy programs.

The new Prime Vendor Program, which operates under a competitively awarded agreement with Health Purchasing Partners International, became effective in September 2004, and has three primary functions to increase value for participating covered entities: 1) negotiate drug prices below the statutorily required 340B ceiling price; 2) enter into favorable distribution agreements with multiple drug wholesalers; and 3) provide discounts on other value-added pharmacy products and services. As of November 2005, approximately 2,000 covered entities participate in the Prime Vendor Program and represent over \$1.7 billion in combined purchases.

Currently, there are a total of over 12,000 participating 340B covered entities. As of October 2005, approximately 650 drug manufacturers have signed Pharmaceutical Pricing Agreements.

The most important benefit of participation in the 340B Drug Pricing Program is the significant savings on pharmaceuticals estimated at 20% to 50% below list price or average wholesale price. We estimate annual 340B purchasing volume of \$4 billion, which represents about 1.7% of the \$230 billion a year pharmaceutical market. We estimate that participating entities can save \$1.5 billion to \$2 billion annually.

In June 2001, the Alternative Methods Demonstrations Projects were initiated to increase access to affordable drugs for uninsured and underinsured patients of covered entities, particularly in rural areas. These projects involve one or a combination of the following three activities: 1) a network of covered entities; 2) multiple contracted pharmacy services sites; or 3) a contracted pharmacy to supplement in-house pharmacy services. As of October, there were 11 approved projects.

2003 OIG Report

In a March 2003 audit, the Office of Inspector General (OIG) found that 5 pharmaceutical manufacturers overcharged 340B covered entities \$6.1 million for sales during the 1-year period ending September 30, 1999.

In September 2004, HRSA sent letters to these companies requesting corrective action plans for repayment of the OIG stated overcharges. To date, we have not received refunds from the companies. We are currently working with CMS to resolve the issues raised by the OIG.

2004 OIG Report

In June 2004, the OIG assessed the accuracy of information contained in 340B Drug Discount Program's database. The OIG recommended that HRSA develop a strategic plan for managing 340B program data. In order to implement the recommended improvements, HRSA contracted with a firm to assist in the completion of these enhancements. We have also entered into a separate contract for the development of the new Web database using the new systems requirements as a guide.

2005 OIG Report

In October 2005, the OIG issued a final report concerning HRSA's oversight of the 340B Program. In this report, the OIG recommended actions to: ensure accurate and timely pricing data; set detailed standards for calculation; create procedures to validate price calculations and prices charged; establish penalties for violations; and, provide access to certain pricing data to help approximate 340B ceiling prices.

HRSA and CMS recently signed an Intra-Agency Agreement (the Agreement). In accordance with the Agreement, we now receive the AMP and the Medicaid Unit Rebate data from CMS to calculate the 340B ceiling prices. In addition, we have increased outreach and technical assistance to covered entities. Currently, we are seeking

voluntary data submissions for the Prime Vendor secure Web site; monitoring compliance with 340B legal and regulatory requirements; and working with the OIG and DOJ in instances of drug diversion. These cases of drug diversion have led us to examine the need to revise program guidelines to more clearly define the patient-provider relationship under the 340B Program. Lastly, we plan to compare pharmaceutical company ceiling price data with market place selling price data on a quarterly basis and follow-up with the respective drug company or wholesaler to resolve discrepancies. Unresolved discrepancies may be referred to the OIG and DOJ for assistance.

With over twelve thousand participating covered entities, the 340B Drug Pricing Program plays an important role in improving the health of the uninsured and underinsured. The 340B Program ensures that federally funded grantees and other safety net health care providers purchase prescription medication at significantly reduced prices. In so doing, this program expands access to affordable pharmaceutical drugs, improves health outcomes and eliminates health disparities among the nations most vulnerable.

Thank you for the opportunity to report on the oversight and administration of the 340B Drug Pricing Program. We look forward to working with the Committee to ensure that the 340B Drug Pricing Program continues to be a valuable Federal resource.