

# NATIONAL ADAP MONITORING PROJECT

**NASTAD**  
NATIONAL ALLIANCE  
OF STATE AND TERRITORIAL  
AIDS DIRECTORS

THE HENRY J.  
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 AIDS Treatment Data  
**Network**

## ***ISSUE BRIEF: AIDS Drug Assistance Programs— Getting the Best Price?***

**April 2002**

Prepared by

Chris Aldridge  
Arnold Doyle

*National Alliance of State and Territorial AIDS Directors*

**The National Alliance of State and Territorial AIDS Directors (NASTAD)** represents the nation's chief state health agency staff who have programmatic responsibility for administering AIDS healthcare, prevention, education, and supportive service programs funded by state and federal governments. State AIDS Directors in all 50 U.S. states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the U.S. Pacific Islands are represented by NASTAD with an office in Washington, D.C. Programs administered by NASTAD members serve every population affected by and infected with HIV.

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## Introduction

There has been increasing national attention to the growth in prescription drug expenditures, one of the fastest growing segments of health care spending. Drug prices are one of the key factors driving expenditure growth. The average retail price of prescription drugs increased more than three times the rate of inflation between 1998 and 2000.<sup>1</sup> For state AIDS Drug Assistance Programs (ADAPs), which provide HIV medications to uninsured and underinsured HIV-infected individuals, containing the cost of drugs has become vital. According to data collected for the National ADAP Monitoring Project, monthly per capita costs for state ADAPs rose 81% between FY 1996 and FY 2000, including a 9% increase between June 1999 and June 2000 alone.<sup>2</sup> The Health Resources and Services Administration (HRSA) estimates that the average cost of Highly Active Antiretroviral Therapy (HAART) is \$10,000 to \$12,000 per year.<sup>3</sup> These costs may be higher for some individuals due to the use of newer, costlier drugs and the increasing use of combination therapy consisting of four or more antiretroviral drugs to boost effectiveness or as “salvage” therapy.<sup>4</sup>

This report examines how ADAPs purchase and dispense drugs, and the drug discount programs that assist states in containing ADAP costs. The report discusses the federal 340B Program, enacted under the Veterans Health Care Act (VHCA) of 1992, reviews other cost-savings strategies, and examines opportunities for and barriers to ADAPs securing additional discounts.

## A Brief History of ADAPs

In 1987, Congress first appropriated funds to assist states in providing the relatively costly drug AZT [the first antiretroviral approved by the Food and Drug Administration (FDA)] to AIDS patients. State health departments were directed by Congress to use these AZT Assistance Program funds to purchase and deliver AZT to eligible individuals. In order to carry out this directive, states had to choose an available drug purchasing and distribution system in their jurisdiction.

Several states with an already existing central, state-operated pharmacy and/or a network of local or county health departments with pharmacy services opted to

purchase drugs directly from wholesalers though the central state system and distribute them via local health departments or other local outlets accessible to clients (e.g., private physician offices). A few, largely rural, states chose to contract with a single public entity (e.g., a public or university hospital) to purchase and distribute AZT on their behalf. The majority of states, however, lacking such a central drug purchasing and distribution system, decided to rely on existing retail pharmacy networks. States mainly use these networks to provide pharmacy services to Medicaid beneficiaries, reimbursing these pharmacies for the cost of beneficiary medications plus a dispensing fee. As discussed later, the type of drug purchasing and distribution system chosen has a profound impact on the availability of drug discount mechanisms in a given jurisdiction.

### **AIDS Drug Assistance Programs (ADAPs)**—

ADAPs provide medications approved by the Food and Drug Administration (FDA) to individuals with HIV/AIDS who are uninsured and underinsured. All 50 states, Guam, Puerto Rico, the Virgin Islands, and the District of Columbia operate ADAPs. ADAPs are discretionary programs that depend upon annual appropriations for funding. In addition to funds appropriated under Title II of the Ryan White CARE Act, ADAPs may also receive state funds and funds from Title I Eligible Metropolitan Areas. States possess a great deal of flexibility in how they design their programs including the determination of eligibility requirements, formularies, and purchasing and distribution systems. This flexibility has resulted in wide variations in ADAP programs across the country.

As AIDS treatment options increased, AZT Assistance Programs began to expand to cover other approved antiretroviral medications and drugs to prevent and treat opportunistic infections, as federal and state resources allowed. These programs were subsumed under Title II of the Ryan White CARE Act upon its initial passage in 1990 and became commonly known as ADAPs. Since 1996, Congress has earmarked funds under Title II of the CARE Act specifically for ADAPs. All 50 states, Guam, Puerto Rico, the Virgin Islands, and the District of Columbia currently operate ADAPs.

The primary goal of state ADAPs is to provide FDA-approved HIV-related medications to uninsured and underinsured individuals living with HIV. The CARE

Act gives each state broad authority to set its own financial and clinical eligibility requirements for ADAP. States also determine the ADAP formulary—the listing of drugs that will be available to ADAP clients. This flexibility has led to significant variation in ADAPs across jurisdictions.<sup>5</sup>

**Medicaid Rebate**—A rebate received on drugs purchased for a state’s Medicaid program. The rebate received is defined as the greater of 15.1% of AMP or AMP minus the Best Price (BP) for brand name drugs. The rebate for generic drugs is 11% of AMP.

## The 340B Program

*Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992*

In 1990, Congress passed the Omnibus Budget Reconciliation Act (OBRA), which attempted to limit the price state Medicaid programs pay for medications. OBRA 1990 created a statutory rebate on drugs for Medicaid programs: the Medicaid Rebate. The Medicaid rebate is based on the average manufacturer’s price (AMP), the average price paid by purchasers excluding sales to federal purchasers and state drug assistance programs. For brand name drugs, the rebate is either 15.1% off the AMP, *or* the AMP minus the Best Price (BP), the lowest price paid by the manufacturer’s “best” customers—whichever results in the greater discount. The statutory discount for generic drugs is set at about 11% off the AMP. Therefore, the lower the BP, the more chance Medicaid programs have to achieve greater than 15.1% discounts off covered drugs. Because sales to federal and state health care programs other than Medicaid were originally included in the calculation of BP, drug manufacturers became reluctant to offer discount pricing to additional government entities/programs since it might potentially lower the BP and thereby increase the rebate amount manufacturers have to pay to all Medicaid programs.

**Average Manufacturer’s Price (AMP)**—the average price at which a manufacturer sells a particular drug to purchasers, not including sales to federal purchasers or state drug assistance programs. The AMP often represents the baseline from which discounts and rebates are calculated.

The Veterans Health Care Act (VHCA) of 1992 sought to remedy this situation and increase access for additional government agencies to discount pricing by creating, among other things, the 340B Program. This federal drug discount program, outlined under section 602 of the VHCA, allows specific Public Health Service (PHS) grantees, including state ADAPs, to access the same discounts as Medicaid programs. In addition, the 340B Program exempts entities that take advantage of these discounts, called “eligible entities,” from inclusion in the BP calculation. In essence, manufacturers were required to offer Medicaid discounts to certain federally funded programs outside Medicaid; however, the discounts would not cause a reduction in the BP and therefore would not trigger larger discounts to Medicaid programs.

**Best Price (BP)**—as defined by the VHCA of 1992, is the lowest price at which a manufacturer sells a particular drug to its “best” customers, including wholesalers, retailers, providers, non-profits, and some government entities. Prices paid by 340B entities, the Big Four agencies (see Federal Ceiling Price below) and certain other purchasers are excluded from the BP calculation. The Medicaid Drug Rebate Program, operated by the Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS), determines both the AMP and the BP. CMS considers these prices proprietary and does not make them available to 340B entities or the general public.

*How the 340B Program Works for ADAPs*

While OBRA 1990 set a statutory rebate mechanism for state Medicaid programs, the 340B program, authorized by the VHCA of 1992, set a ceiling price for covered drugs—the maximum price at which a particular drug can be sold to 340B entities—that matches the Medicaid rebate percentage for that drug in a particular quarter. In other words, whatever the statutory Medicaid rebate percentage is on a drug for a

**340B Ceiling Price**—the highest price a 340B entity can be charged for a particular drug. The ceiling price is essentially the same as the price (minus pharmacy dispensing fees and other administrative costs) paid by state Medicaid programs after accounting for the Medicaid rebate. CMS calculates the price quarterly for each drug.

particular quarter (e.g., the standard 15.1% off the AMP), the 340B ceiling price on that same drug at the same time will also be 15.1% off the AMP.

As discussed earlier, state ADAPs purchase and distribute drugs in one of two main ways: either directly, through a state pharmacy or single public entity, or indirectly, by using a retail pharmacy network to purchase and distribute drugs on behalf of the ADAP. The first type of ADAP is often called a “direct purchaser,” while the second is referred to as a “reimbursement-type” ADAP, since it actually reimburses retail pharmacies for purchasing and distributing drugs on its behalf. In this way, reimbursement-type ADAPs function much like state Medicaid programs.

**Average Wholesale Price (AWP)**—the average price at which wholesalers sell a given drug to retailers; it is substantially higher than the AMP. Retailers will add an additional retail mark-up to the AWP for private pay customers.

For ADAPs that are direct purchasers, the 340B Program allows them to receive the discount price at the point of sale (i.e., when they purchase the drug from the wholesaler). The discount price is the statutorily defined 340B ceiling price, plus an allowable 1% wholesaler mark-up. Reimbursement-type ADAPs, however, must first reimburse a retail pharmacy for the drug at a higher price [usually the average wholesale price (AWP), which is the average price charged by wholesalers, minus a negotiated discount], plus a pharmacy dispensing fee, and then apply to the drug manufacturer for a rebate. A *simplified* illustration is presented in the accompanying table.

Since reimbursement-type ADAPs pay a higher price for drugs but receive the same rebate percentage as the direct purchasing ADAPs (i.e., the rebate percentage is always calculated off the AMP), direct purchasing ADAPs have lower final drug costs than their reimbursement type counterparts. It is difficult, however, to assess the final costs to a given state, since there are other expenses associated with drug distribution. These expenses—the retail “mark up” and dispensing fees paid to retail pharmacies by reimbursement-type ADAPs that cover drug storage, dispensing, recording, and pharmacist fees—may not be apparent in a direct purchasing model. In a direct purchase system, these overhead costs may be spread across other units of the state health department and therefore are not reflected in the final cost of a particular drug to the ADAP.<sup>6</sup>

Both types of ADAPs are somewhat protected under the 340B Program from excessive drug price increases. When the official discount/rebate percentage is calculated, inflationary increases are also factored into the final discount/rebate through use of the Consumer Price Index, a formula designed to measure the rate of inflation. If a manufacturer raises the price of a particular covered drug beyond the rate of inflation in a particular quarter, the excess increase above inflation must be reflected in an enhanced discount or rebate to 340B entities. However, a manufacturer may enact a significant price increase on a particular drug—and not be required to provide 340B grantees with additional discounts/rebates—if the manufacturer has not raised the drug’s price in the line with the CPI rate over time. This is because the manufacturer may *cumulatively* calculate the “allowable” CPI increase from a “baseline” (either the original price when the drug was approved for commercial sale or the resulting price from the most recent date when the drug’s price was last raised).

*ADAP Participation in the 340B Program*

Participation in the 340B Program is not mandatory but is strongly encouraged by HRSA, the federal agency that oversees state ADAPs. ADAPs that do not participate are required to show HRSA that they are receiving 340B or better prices/discounts on formulary drugs. According to HRSA, 48 of the 54 ADAPs currently participate in the 340B Program. Twenty-two ADAPs participate as direct purchasers and 26 participate as reimbursement-type ADAPs. Pennsylvania’s ADAP does not need to participate since

Direct Purchase ADAP		Reimbursement-Type ADAP	
AMP	\$100	AMP	\$100
Minus the 340B discount (~15% off the AMP)	-\$15	AWP	\$125
Plus wholesaler markup	+\$1	Minus negotiated discount (AWP — 10%)	-\$12.50 (10% of \$125)
		Plus dispensing fee	+\$5
		Subtotal	= \$117.50
		Minus 340B rebate (~15% off the AMP)	-\$15
Final ADAP cost	= \$86	Final ADAP cost	= \$102.50

state law requires manufacturers to provide rebates to all state agencies purchasing medications. Minnesota's ADAP does not participate because a relatively large number of its clients are able to access HIV drugs through subsidized insurance coverage, and the ADAP has arranged adequate voluntary rebate agreements with manufacturers for the drugs that must be accessed through ADAP.

#### *Prime Vendor Program*

Participants in the 340B Program may also participate in the 340B Prime Vendor Program. A “prime vendor” is an entity that negotiates with manufacturers on behalf of a group of drug purchasers, whose purchasing powers exceed that of a single entity, in order to obtain reduced drug prices. HRSA has chosen a prime vendor to negotiate additional discounts (i.e., lower than the 340B ceiling price or sub-340B ceiling price) for participants, including ADAPs. However, the prime vendor can only negotiate up-front price discounts and not enhanced rebates (larger than the defined 340B rebate); therefore, reimbursement-type ADAPs cannot take advantage of this program because they do not obtain discounts at the point-of-sale. As noted below, the current prime vendor has been relatively unsuccessful in negotiating sub-340B ceiling prices.

**Prime Vendor Program**—The “prime vendor” negotiates with drug manufacturers on behalf of a group of purchasers, in this case 340B entities, to achieve lower prices. Because the group has larger purchasing power than any one entity, the prime vendor can theoretically achieve greater discounts. In September 1999, HRSA chose Bergen Brunswig Drug Company as the prime vendor for the 340B Program. Because the Veterans Administration (VA) has previously included sub-340B ceiling prices negotiated by the prime vendor in calculations used to determine discounts for several government agencies, the prime vendor has had limited success in negotiating sub-340B prices. In October 2001, the VA excluded sub-340B ceiling prices from these calculations to increase the bargaining power of the prime vendor.

#### *Other Cost Saving Mechanisms*

In addition to the 340B Program, there are other options available to states to help limit ADAP drug costs. Many states have been able to move a significant number of

ADAP clients onto cost-effective insurance purchasing and continuation programs. Thirty-three states indicated having such programs from data gathered for the National ADAP Monitoring Project in 2000.<sup>7</sup> Through these programs, states may use Ryan White CARE Act funds, including a portion of ADAP dollars and/or state funding, to cover insurance premiums, deductibles, and co-pays to maintain clients on comprehensive health care coverage—including prescription drug coverage—usually for a fraction of the cost it would require to purchase HIV-related drugs for each individual. These programs tend to provide clients access to a full range of services including primary care, hospitalization, emergency room visits, and lab work—potentially creating savings across all CARE Act and other state programs. However, the ability of a state to develop and maintain such programs depends on many factors including the existence of a statewide high-risk insurance pool and/or local insurance regulation. Therefore, this is not an option in all jurisdictions.

Rising expenditures and increasing demand may also force states to attempt to control costs by limiting access to their ADAPs. At times, states may restrict their formularies, tighten eligibility standards (such as income or medical criteria), cap expenditures, or implement waiting lists. While generally used as temporary measures to avoid fiscal crisis, some states have continually used these measures due to the overwhelming demands on their ADAPs. Demand on state ADAPs is also affected by the generosity of state Medicaid programs and availability of other indigent drug purchasing programs.

#### *Can ADAPs Get Better Drug Prices?*

This issue brief has reviewed the major cost savings programs available to ADAPs: primarily through the 340B Program and, to a lesser extent, through insurance

**Federal Ceiling Price (FCP)**—the maximum price that may be charged for drugs sold to the Veterans Administration (VA), Department of Defense (DOD), Public Health Service (PHS), and Coast Guard. FCP is based on non-FAMP, the average manufacturer price charged to non-federal purchasers as determined by the VA. Non-FAMP is calculated differently than and is usually lower than AMP. Given their purchasing power, these agencies often negotiate lower prices than the FCP.

purchasing and continuation programs and state-mandated drug discounts (e.g., Pennsylvania). States likely will continue to explore insurance purchasing and continuation programs. In some cases, states have explored state drug pricing regulations in order to reduce the cost of drugs for their public programs, including ADAP. Are there other options for state ADAPs to purchase drugs at lower prices or to receive greater rebates than is currently possible under the 340B Program?

#### *Federal Ceiling Price and the Federal Supply Schedule*

The Federal Ceiling Price (FCP), authorized under section 603 of the Veteran's Health Care Act, provides significant discounts on drugs to four large government agencies, known as the "Big Four": the Veterans Administration (VA), Department of Defense (DOD), Public Health Service (PHS), and the Coast Guard. Drug prices for the Big Four may not exceed 76% of the non-Federal average manufacturer's price (non-FAMP), a weighted average of manufacturer's prices paid by non-federal entities. In other words, these four agencies are able to purchase drugs and receive a discount that is almost 25% below the non-FAMP—a level of discount that is not often achieved under the 340B Program. Because the VA defines non-FAMP differently from AMP, non-FAMP is often lower than AMP.

#### **Non-Federal Average Manufacturer's Price (non-FAMP)**

—the weighted average of manufacturer's prices paid by non-federal government purchasers. In October 2001, the VA excluded sub-340B ceiling prices negotiated by the Prime Vendor from inclusion in non-FAMP to increase the bargaining power of the prime vendor. Sub-340B ceiling prices negotiated by individual 340B entities are still included in the non-FAMP calculation.

The VA also manages several Federal Supply Schedules (FSS) that define the quantities of and prices paid by the federal government (including the Big Four agencies) for medical goods. The FSS allows agencies to purchase drugs in small quantities and still receive discounts associated with purchasing in bulk. Because the VA manages the purchasing of medications for the entire federal government, all federal agencies may access the FSS. However, prices for these other government entities (i.e., other than the Big Four) are usually based

**Federal Supply Schedule (FSS)**—administered by the Department of Veterans Affairs, the FSS defines the quantities and prices paid by federal agencies for medical goods. The FSS is equal to or better than the price offered by the manufacturer to its most-favored non-federal customer. FSS applies to all government purchasers; therefore prices may be higher for non-Big Four government entities. Big Four entities may also access the FSS but do not pay more than the FCP.

on prices drug companies offer to their best commercial customers and may not be as low as federal ceiling prices. Still, many manufacturers allow all federal government agencies (not including federal grantees such as ADAPs) to purchase at the federal ceiling price due to the simplicity of keeping one price list.

Currently, ADAPs are not able to directly access medications through the FSS or at the FCP. Only the District of Columbia, which obtains drugs through an agreement with the DOD, has access to prices paid by the Big Four.<sup>8</sup> In addition, the FSS and FCP are not designed for agencies or entities that use a reimbursement mechanism, including reimbursement-type ADAPs. A recent report from the Office of the Inspector General recommended that ADAPs be permitted to purchase at the FCP in order to allow at least the direct purchasing ADAPs to secure the lower FCP.<sup>9</sup> It is unclear whether this is likely, considering that previous efforts to expand FCP and the FSS to other entities (such as federal grantees) have failed.<sup>10</sup>

#### *Use of the 340B Prime Vendor Program to Obtain Lower Than 340B Pricing*

As discussed earlier, 340B direct purchasers should theoretically be able to obtain lower prices by participating in the 340B Prime Vendor Program. However, the way in which the VA had previously calculated federal ceiling prices presented a barrier to successful implementation of the Prime Vendor Program. The VA bases its calculation of the federal ceiling price for a particular drug on non-FAMP. Since 340B grantees are federal grantees, their drug purchases had not been included in this calculation except when a 340B grantee or group of grantees (such as through the prime vendor) got a price below the 340B ceiling price. The VA considered these sub-340B ceiling prices *commercial or privately negotiated prices* that lowered

non-FAMP, thereby lowering the FCP. Because of this, many drug companies were reluctant to sell drugs to 340B entities, including ADAPs, at prices below the 340B ceiling prices over concern that this would lower the prices paid by the Big Four agencies. This issue had prevented the 340B Prime Vendor from being able to negotiate prices below the 340B ceiling price for eligible entities, in effect setting a limit on the discounts that ADAPs and other 340B grantees can receive.<sup>11</sup>

In October 2001, the VA announced a change in how it calculates non-FAMP. In a letter to drug manufacturers, the VA stated it would no longer include sub-340B prices negotiated by the prime vendor in the calculation of non-FAMP.<sup>12</sup> In theory, this change should increase the ability of the prime vendor to negotiate better prices than the 340B ceiling price since manufacturers will no longer be concerned that these lower prices will in turn lower the FCP. This change does not impact sub-340B ceiling prices that eligible entities negotiate on their own, making it unlikely that individual entities will be able to negotiate lower prices, and thereby creating an incentive to participate in the Prime Vendor Program. At this point, it remains unclear what impact this change will actually have on participation in the Prime Vendor Program or if the prime vendor will be able to better negotiate sub-340B ceiling prices.

### *Future Trends*

The cost of prescription drugs will continue to be a pressing issue for all entities involved in drug purchasing, including ADAPs. According to data collected for the National ADAP Monitoring Project, many states report that they will continue to seek out additional cost containment strategies for ADAPs. One strategy involves shifting costs to other programs with greater resources. Several states have submitted 1115 HIV Medicaid expansion waivers to CMS or are in the process of developing a waiver request to expand their Medicaid programs to cover uninsured, non-disabled individuals with HIV. Three states currently have approval from CMS to implement such waivers: Maine, Massachusetts, and the District of Columbia.<sup>13</sup> Federal legislation has also been proposed to expand Medicaid programs in this fashion without requiring states to request a waiver. States are also looking at ways to expand access to other state run programs that can provide medications. In all of these instances, such coverage expansions depend greatly on economic and political factors within a given jurisdiction.

In addition, purchasing and continuation of health insurance coverage will continue to be important options available to state ADAPs, providing access to comprehensive health care coverage that includes drugs. While analysis by the Office of the Inspector General has indicated that such programs provide cost savings to ADAP, their full benefit across all CARE Act and other state programs has not been studied. It is important to note that all of these strategies may merely shift costs to other programs and do not address the overall price of medications. To address the price of drugs across all public programs that purchase medications, some states are considering legislation that will allow them to control prices for state drug purchasers.

Finally, state ADAPs, in conjunction with community advocates, have formed an ad-hoc group called the Coalition for Fair Pricing, which negotiates with the manufacturers of new HIV treatments to obtain lower prices. The Coalition usually negotiates with a given manufacturer prior to a HIV drug receiving FDA approval to obtain a discount/rebate below the 340B ceiling price. Recently, this ad-hoc coalition has been successful in obtaining better initial prices on several new HIV treatments such as Sustiva and Viread. These sub-340B ceiling prices pertain only to ADAPs and are not automatically available to other 340B entities.

## **Conclusion**

This report has summarized the primary methods that state ADAPs may utilize to control the rising cost of prescription drugs. It has also outlined several other cost-saving options that are viable alternatives in some, but not all, jurisdictions and discussed barriers to ADAP participation. Finally, the report highlighted additional existing options, including the FSS and the FCP that could provide greater savings if ADAPs were given access. Barriers to these programs will not be removed without a collaborative effort between state and federal policymakers, ADAP managers and drug manufacturers. However, this effort may move forward slowly given the sometimes competing interests of making HIV treatments available to uninsured and underinsured individuals, protecting current drug discount programs, and maintaining a reasonable profit from the sale of prescription drugs.

# End Notes

- 1 The Henry J. Kaiser Family Foundation, *Prescription Drug Trends: A Chartbook Update*, November 2001.
- 2 National Alliance of State and Territorial AIDS Directors, The Henry J. Kaiser Family Foundation, and the AIDS Treatment Data Network, *National ADAP Monitoring Project: Annual Report*, March 2001.
- 3 Health Resources and Services Administration, *The ADAP Manual: AIDS Drug Assistance Program of the Ryan White CARE Act*, 1999. Highly Active Antiretroviral Therapy (HAART) generally consists of three antiretrovirals that work in tandem to lower HIV viral load (the presence of HIV genetic particles in the blood stream).
- 4 A regimen used after a person develops resistance to the majority of available therapies is sometimes referred to as “salvage” therapy. These therapies often involve four or more drugs, as opposed to the standard three drug regimens.
- 5 For more information on ADAP funding, drug coverage, eligibility and program status, please refer to the *National ADAP Monitoring Project Annual Report*, March 2001, published by The Henry J. Kaiser Family Foundation.
- 6 Health Resources and Services Administration, *The ADAP Manual: AIDS Drug Assistance Program of the Ryan White CARE Act*, 1999.
- 7 National Alliance of State and Territorial AIDS Directors, The Henry J. Kaiser Family Foundation, and the AIDS Treatment Data Network, *National ADAP Monitoring Project: Annual Report*, March 2001.
- 8 This is due to the District of Columbia’s special political status and, therefore, is not a viable option for other jurisdictions.
- 9 The Office of the Inspector General estimates that opening the FCP solely to 340B grantees will have little impact on manufacturers since purchases by all 340B entities only comprise 1% of the total domestic pharmaceutical market, and savings would likely result in increased sales as program restrictions are lifted. See, Office of the Inspector General, *AIDS Drug Assistance Program Cost Containment Strategies*, OEI-05-99-00610, September 2000.
- 10 For example, section 1555 of the Federal Acquisitions Streamlining Act (FASA), sought to extend FSS prices to state and local governments but was strongly opposed by the pharmaceutical industry, other industries on the FSS list, the Veteran’s Administration and the Department of Defense. While FASA was passed in 1994, implementation of section 1555 was delayed and then the entire section was ultimately repealed.
- 11 There is nothing in statutory language that requires the VA to consider below 340B prices as non-federal/commercial prices.
- 12 Department of Veterans Affairs, *Letter to Manufacturers of Covered Drugs*, October 19, 2001.
- 13 Currently only Massachusetts has implemented its waiver. Maine has been unable to negotiate deeper discounts on pharmaceuticals necessary to achieve cost neutrality required by law. The District of Columbia is finalizing the details of its implementation.

# Glossary

**340B Ceiling Price**—the maximum price a 340B entity can be charged for a drug. Defined as the lesser of AMP minus the Medicaid discount (15.1%) or AMP minus the manufacturer’s BP. This price is essentially the same as the Medicaid price after rebate.

**AIDS Drug Assistance Programs (ADAPs)**—ADAPs provide FDA approved HIV/AIDS medications to people living with HIV/AIDS who are uninsured and underinsured.

**Average Manufacturer’s Price (AMP)**—the average price at which a manufacturer sells a particular drug to purchasers, not including sales to federal purchasers or state drug assistance programs. The Centers for Medicare and Medicaid Services (CMS) determines AMP on a quarterly basis.

**Average Wholesale Price (AWP)**—the price at which wholesalers sell a given drug to retailers. It is substantially higher than the AMP.

**Best Price (BP)**—the lowest price at which a manufacturer sells a particular drug to its “best” customers, including wholesalers, retailers, providers, non-profits, and some government entities. Prices paid by 340B entities, the Big Four Agencies and certain other purchasers are excluded from the BP calculation. CMS determines the BP.

**Big Four Agencies**—Agencies with access to the FCP. They include: Department of Veterans Affairs (VA), Department of Defense (DOD), Public Health Service (PHS), and the Coast Guard.

**Consumer Price Index (CPI)**—an official index that measures the rate of inflation growth.

**Direct Purchase ADAPs**—ADAPs that directly purchase their medications from a wholesaler. These ADAPs receive 340B discounts at the time of purchase.

**Federal Ceiling Price (FCP)**—the maximum price a Big Four entity may be charged for a drug. Defined as 76% of non-FAMP.

**Federal Supply Schedule (FSS)**—defines the quantities and prices at which federal agencies may purchase medical goods. The FSS is equal to or better than the price offered by the manufacturer to its most-favored non-federal customer. Because the FSS is available to all federal agencies, prices may be higher for other federal agencies than the FCP paid by the Big Four agencies. Big Four agencies may access the FSS but do not pay more than the FCP. The FSS is administered by the Department of Veterans Affairs.

**Medicaid Rebate**—a rebate received on drugs purchased for a state’s Medicaid program. The rebate received is defined as the greater of 15.1% of AMP or AMP minus the Best Price (BP) for brand name drugs. The rebate for generic drugs is 11% of AMP.

**Non-Federal Average Manufacturer’s Price (non-FAMP)**—calculated by the VA, the weighted average of manufacturer’s prices paid by non-federal government purchasers. Non-FAMP is calculated differently than and produces a different result from AMP.

**Prime Vendor**—the “prime vendor” negotiates with drug manufacturers on behalf of a group of purchasers, in this case 340B entities, to achieve lower prices.

**Reimbursement-Type ADAPs**—ADAPs that reimburse pharmacies for medications purchased to serve ADAP clients. These ADAPs submit rebates to drug manufacturers to receive the 340B discount.

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