



The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act was enacted in 1990, reauthorized in 1996 and again in 2000 to provide primary care and support services to low-income and uninsured individuals with HIV/AIDS. The CARE Act is administered by the Health Resources and Services Administration and its HIV/AIDS Bureau.

AIDS DRUG ASSISTANCE PROGRAMS (ADAPs) COST-CONTAINMENT STRATEGIES

Since the creation of ADAPs, States have worked hard to maximize resources in order to provide medications to as many low-income and inadequately insured individuals living with HIV/AIDS as possible. In recent years, however, States have faced enormous challenges as a result of rapid growth in ADAP enrollment, the number of prescriptions per enrollee, and the cost of treatments. Much of this growth has been due to the introduction of new antiretroviral medications.

Combination antiretroviral drug therapy has proven to be highly effective in improving health, extending life and improving the quality of life for people with HIV/AIDS. As a result, the use of combination therapy and a new class of antiretroviral drugs called fusion inhibitors that add an additional \$15,000 to combination therapy, have emerged as the new standard of care. However, the high cost of combination therapy—approximately \$10,000 to \$12,000 per patient per year—has significantly increased pressure on ADAPs to adopt a wide variety of cost-containment strategies designed to maximize resources. These include restructuring their purchasing and distribution system, more aggressive negotiations with pharmacy benefits contractors, closer coordination with Medicaid and Medicaid waiver programs, improved data collection and tracking systems, and participation in the Section 340B Drug Discount Program. Participation in the Section 340B Drug Discount Program is the most frequently used and most effective of these cost-saving strategies available to ADAPs.

Veterans' Health Care Act of 1992

Public Law 102-585, the Veterans' Health Care Act of 1992, was designed to establish price controls that limit the cost of drugs to Federal purchasers and certain grantees of Federal agencies. There are several sections to the Act. Section 601 amends the Medicaid rebate program; Section 602 provides drug discounts to certain grantees and eligible entities; and Section 603 covers what is often referred to as "Department of Defense" pricing and the Federal Supply Schedule.

The Section 340B Drug Discount Program

The Section 340B Drug Discount Program, administered by the Office of Pharmacy Affairs, is authorized under Section 602 of the Veterans' Health Care Act of 1992. Section 340B provides that as a condition for participation in Medicaid, drug manufacturers must sign a pharmaceutical pricing agreement with the Secretary of the Department of Health and Human Services. This agreement states that the price charged for covered outpatient drugs will not exceed the statutory ceiling price (the average manufacturers' price reduced by the Medicaid rebate percentage). Section 340B identifies those entities that are eligible for 340B pricing and specific requirements for participation in the program. Ryan White CARE Act grantees, including ADAPs, are considered "covered entities" and are eligible to participate in the 340B Program. ADAPs have two methods of accessing this program: through a point of purchase discount system or through the ADAP 340B rebate option. (The latter is available only to ADAPs.)

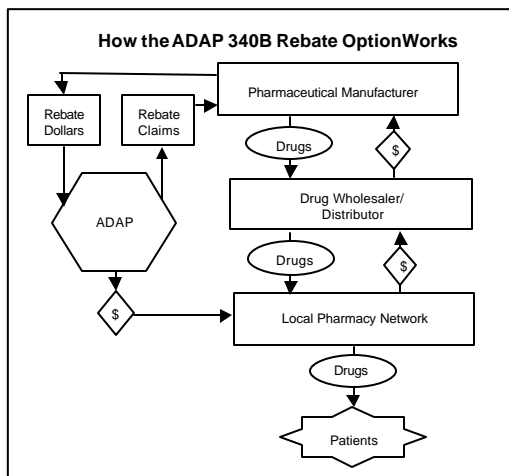
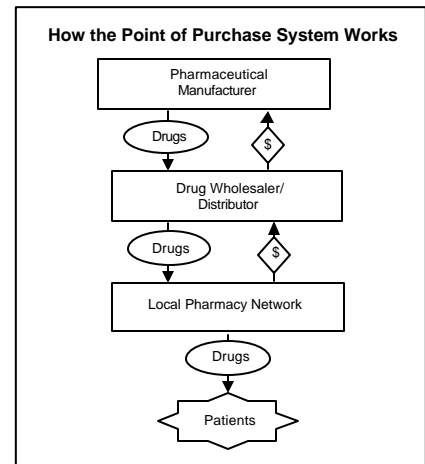
What is ADAP?

AIDS Drug Assistance Programs (ADAPs) are authorized under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. CARE Act-funded programs, including ADAP, are the largest source of Federal funding specifically directed to provide primary care, treatment, and support services for low-income persons living with HIV disease. States are required to use a portion of their funds to provide medications to treat HIV disease, including measures for the prevention and treatment of opportunistic disease.

For FY 2003, States project that approximately 151,730 individuals with HIV disease who have limited or no coverage from private insurance or Medicaid will access ADAPs. In any given month, ADAPs anticipate serving almost 89,537 people.

Point of Purchase Discount: Currently, 22 States and 3 Territories use a point of purchase discount, which calculates a significant discount off the average manufacturers' price of each drug for qualified "covered entities." Participation in the point of purchase system is easiest for States that centrally purchase and dispense medications.

The ADAP 340B Rebate Option: On June 29, 1998, HRSA published a *Federal Register* notice recognizing a rebate option for ADAPs as an alternative method to access the Section 340B Drug Discount Program. This option allows reimbursement model ADAPs to achieve cost savings that are closer to the savings received through the point of purchase system. As of July 2003, 24 States and 1 Territory are registered in the ADAP 340B rebate option. These ADAPs are able to obtain rebates on all covered outpatient drugs on the ADAP formulary through standardized process of submitting and receiving rebate claims from manufacturers.



Negotiated Pharmacy/Wholesaler Discounts

States not participating in the Section 340B Drug Discount Program through point of purchase typically use a network of participating pharmacies. ADAPs reimburse the pharmacies at a negotiated discounted price, which frequently is similar to the amount paid by the State's Medicaid program.

Prime Vendor

HRSA established the Prime Vendor Program on September 9, 1999. This program implements the last part of the 340B statute and is designed to maximise the benefits of the Prescription Drug Program to clients and State ADAPs.

It is expected that the program will improve and expand State ADAP pharmacy services and enhance the effective management of pharmacies while providing savings on the purchase of pharmaceuticals.

Alternative Methods Demonstration Projects Initiative

On June 18, 2001, the Secretary of the Department of Health and Human Services announced this initiative in response to continued requests for increased flexibility among existing 340B Program participants. This new initiative allows organizations participating in the 340B Program to take action to reduce administrative costs while making the purchase of medications easier for ADAP patients. Projects that involve one or a combination of the following features will be considered: (1) the development of a network of covered entities, (2) the use of multiple contracted pharmacy services sites, or (3) the utilization of a contracted pharmacy to supplement in-house pharmacy services.

Other Strategies

In some States where demand outstrips resources, further cost-cutting measures have been adopted. These methods include capping client enrollment, instituting waiting lists, eliminating drugs from formularies, establishing protocols for accessing certain drugs, and limiting per patient expenditures.

ADAP Cost-Saving Plans, FY 2003

Grantee	Section 340B Point of Purchase	Section 340B ADAP Rebate Option*	Voluntary Manufacturer Rebates	Manufacturer Discounts	Pharmacy Discounts	Utilizes Prime Vendor
Alabama	✓				✓	✓
Alaska		✓			✓	
American Samoa (2)						
Arizona	✓					
Arkansas	✓					✓
California		✓		✓	✓	
Colorado	✓					✓
Connecticut		✓				
Delaware	✓		✓			
D.C. (1)						
F. Sts. Micronesia (2)						
Florida	✓					
Georgia	✓			✓		
Guam	✓				✓	✓
Hawaii	✓					✓
Idaho		✓				
Illinois	✓			✓		✓
Indiana		✓				
Iowa	✓					
Kansas		✓			✓	
Kentucky (3)					✓	✓
Louisiana	✓					
Maine		✓	✓	✓		
Marshall Islands (2)						
Maryland		✓				
Massachusetts		✓			✓	
Michigan		✓	✓			
Minnesota		✓			✓	
Mississippi	✓			✓		
Missouri		✓			✓	
Montana	✓					✓
Nebraska	✓		✓			
Nevada	✓			✓		
New Hampshire		✓			✓	
New Jersey		✓			✓	
New Mexico	✓			✓		
New York		✓			✓	
North Carolina		✓			✓	
North Dakota		✓	✓	✓	✓	
Northern Mariana (2)						
Ohio	✓				✓	✓
Oklahoma	✓				✓	✓
Oregon		✓			✓	
Pennsylvania			Mandatory	✓	✓	
Puerto Rico	✓			✓		
Republic of Palau (2)						
Rhode Island		✓			✓	
South Carolina	✓			✓		
South Dakota		✓			✓	
Tennessee	✓					
Texas	✓			✓		
Utah		✓			✓	
Vermont		✓			✓	
Virgin Islands	✓			✓		
Virginia	✓		✓	✓		
Washington		✓			✓	
West Virginia		✓			✓	
Wisconsin		✓			✓	
Wyoming		✓				

Based on information from States in their Ryan White CARE Act FY 2003 Title II grant applications ADAP Profile:

* Denotes activation of status as an ADAP 340B Rebate Option covered entity

(1) DC receives Department of Defense pricing (2) ADAP is developing system (3) KY has a fixed price contract with the Univ. of Louisville Pharmacy. The pharmacy is under a disproportionate share hospital and is able to access 340B pricing. The fixed price contract requires that the ADAP pay AWP (-) 30% - brand named drugs, and AWP (-) 50% - generics. Dispensing fees are absorbed in the discounted price.