340B and AIDS Drug Assistance Programs: Getting the Best Price

March 2024

Prescription drug expenditures are one of the fastest growing segments of health care spending. Three major factors driving the growth in prescription drug spending are utilization, unit costs, and drug mix (i.e., shifts in utilization toward newer, costlier medications). All three of these factors, combined with increased demand for AIDS Drug Assistance Program (ADAP) services, contribute to significant drug expenditures for state and territorial ADAPs.

Controlling drug expenditures is a priority for all ADAPs providing antiretrovirals and other essential medications to uninsured and underinsured people with HIV. Indeed, federal funds allocated to ADAPs to acquire drugs must be utilized "in the most economical manner feasible."[i] This includes securing discounts on outpatient prescription drugs available to certain federal grantees through participation in the 340B Drug Pricing Program, which enables eligible entities – including ADAPs – to "stretch scare federal resources, allowing them to reach more eligible patients and provide more comprehensive services."[ii]

FEDERAL DRUG PRICING LEGISLATION & PROGRAMS

Congress has established programs that allow Medicaid programs and certain other federally funded programs to receive drug discounts. The structure of 340B Drug Pricing Program discounts follows from the rebate mechanism Congress created for the Medicaid program. Therefore, it is helpful to understand how drug prices are determined for the Medicaid program and how those prices differ from prices available to safety net entities such as ADAPs and other Ryan White HIV/AIDS Program (RWHAP) recipients and subrecipients.

Omnibus Budget Reconciliation Act of 1990 (Medicaid Drug Rebate Program): 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 under the Medicaid Drug Rebate Program (MDPR). The Medicaid rebate is calculated from the Average Manufacturer Price (AMP), which is the average price paid to manufacturers, excluding sales to federal purchasers and certain other purchasers, including ADAPs.

The Medicaid rebate paid is the greater discount of either:

1. the Unit Rebate Amount (URA), which is a statutory minimum rebate percentage plus an "inflation penalty," or
2. the AMP minus the Best Price (BP), which is the lowest price paid by the manufacturer's "best" customer)

The URA includes a minimum rebate percentage off the current quarter AMP (23.1% for brand name drugs, discussed below) plus an inflation penalty, which is calculated by comparing the AMP increase of the drug over the previous quarter, to the inflation rate for that quarter, as measured by the Consumer Price Index – Urban (CPI-U). If the price increase exceeds the CPI-U, the inflation penalty is the difference between the prior quarter AMP increased by the CPI-U and the current quarter AMP. By including an inflation penalty within the URA, OBRA provided Medicaid programs with a level of protection against drug price inflation.

Veterans Health Care Act of 1992 (340B Drug Pricing Program): In response to concerns from drug manufacturers that the discounted sales to many safety net providers

were included in BP calculations – consequently reducing BP and thereby increasing the rebate amount they would have to pay Medicaid programs – the Veterans Health Care Act (VHCA) of 1992 sought to establish a formal mechanism for extending discounted prescription pricing to safety net purchasers. The VHCA created a new purchasing program under Section 340B of the Public Health Service Act (PHSA), resulting in what continues to be known as the 340B Drug Pricing Program. This federal drug discount program allows specific hospitals and Public Health Service (PHS) grantees, including ADAPs, to access the same discounts as Medicaid programs. The 340B Drug Pricing Program also exempts sales to these "covered entities" from inclusion in the BP calculation.

Discounts vs. Rebates: What's the Difference?

A discount is a reduction in the purchase price, while a rebate is a partial refund after the sale. Most 340B covered entities can purchase outpatient prescription drugs at a discount from wholesalers and other distributors. Medicaid and many ADAPs don't purchase medications directly; they receive rebates from manufacturers to ensure best possible pricing.

Patient Protection and Affordable Care Act of 2010: The Patient Protection and Affordable Care Act (ACA) of 2010 and the Health Care and Education Affordability Reconciliation Act of 2010 increased the Medicaid minimum rebate percentage for brand name drugs from 15.1% to 23.1%, thereby increasing the discount available to 340B covered entities. The discount on generic drugs was increased from 11% to 13%.

The Office of Pharmacy Affairs (OPA), which is located within the Health Resources and Services Administration (HRSA), administers the 340B Drug Pricing Program.

MANUFACTURERS & 340B

Manufacturers are not required to participate in the 340B Drug Pricing Program. However, a manufacturer must participate in the program for its drugs to be eligible for purchase under the Medicare Part B or Medicaid programs. If a manufacturer wishes for any of its drugs to be covered under these programs, all of its outpatient prescription drugs must be available under the 340B Drug Pricing Program, subject to some exceptions. In practice, nearly all manufacturers participate in the 340B program and nearly all U.S. Food and Drug Administration (FDA)-approved medications intended for outpatient use are available under the 340B Drug Pricing Program.

ADAPS & 340B

While participation in the 340B Program is not technically required for ADAPs, it is the primary way in which ADAPs can ensure they are receiving the best price available for a drug, which is required.

As per a final HRSA notice regarding patient and entity eligibility under Section 602 of the VHCA of 1992, all ADAP clients are unique in that they categorically meet the patient definition for the 340B Drug Pricing Program if they are enrolled as an ADAP client:

> *An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.*[iii]

Like all 340B covered entities, ADAPs must annually "recertify" their eligibility for the program via the HRSA Office of Pharmacy Affairs Information System (OPAIS), usually in February. If a covered entity fails to recertify by the deadline, it may not recertify until the following quarter, and the recertification will not be in force until the subsequent quarter. This creates a six-month period where the covered entity is not eligible for discounts under the 340B Drug Pricing Program. It is therefore imperative that the ADAP's Authorizing Official recertify their eligibility for the 340B Drug Pricing Program in a timely manner.

Additional 340B Drug Pricing Program requirements are described below.

340B PRICING

Outpatient medications[1] subject to discounting under the 340B Drug Pricing Program are defined in section 1927(k) of the Social Security Act. These include:

- Prescription drugs and biologics other than vaccines
- FDA-approved insulin
- Over-the-counter drugs dispensed with a prescription

The Centers for Medicare & Medicaid Services (CMS) maintains a list of drugs that are reported by manufacturers under the Medicaid Drug Rebate program and thus subject to discounting under the 340B Drug Pricing Program.

Where a discount required under the 340B Drug Pricing Program is applied to an outpatient medication, the result is a 340B ceiling price, which is the maximum statutory price a manufacturer can charge a covered entity. Manufacturers must report to CMS changes to the AMP and BP on a quarterly basis. The 340B ceiling price is then recalculated following each submission, meaning that the 340B ceiling price could change four times a year.

Manufacturers may also voluntarily sell drugs to covered entities at prices below those required by the 340B Drug Pricing Program. For ADAPs, these supplemental discount agreements are typically negotiated for HIV medications through the ADAP Crisis Task Force, convened by NASTAD, and for many other prescription drugs through the 340B Prime Vendor Program, managed by Apexus. These supplemental discount agreements result in "sub-ceiling prices" for set periods of time, which allow covered entities to use this fixed drug price to better forecast their annual expenditures.

Please note, if the 340B ceiling price drops below the voluntary sub-ceiling price in a particular quarter, manufacturers are required to provide the covered entity with that lower price. Therefore, while a negotiated sub-ceiling price effectively establishes a maximum price for covered entities, covered entities are still entitled to any discounts below that price for the period in which those discounts are available.

340B Drug Pricing Program Covered Entities

State and territorial ADAPs are among several 340B Drug Pricing Program covered entity types defined in section 340B(a)(4) of the PHSA:

Health Centers

- Federally Qualified Health Centers
- Federally Qualified Health Center Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers

Hospitals

- Children's Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals

HRSA Ryan White HIV/AIDS Program (RWHAP_ Recipients/Subrecipients

- RWHAP Providers
- AIDS Drug Assistance Programs

Specialized Clinics

- Black Lung Clinics
- Comprehensive Hemophilia Treatment Centers
- Title X Family Planning Clinics
- STD Clinics (Section 318)
- Tuberculosis Clinics (Section 317)

CDC Section 318 Grantees/Sub-grantees

- CDC Division of STD Prevention (DSTDP)
- CDC Division of HIV/AIDS Prevention (DHP)
- Division of Viral Hepatitis (DVH)

[1] Any medication dispensed or administered for inpatient use is excluded from the 340B Drug Pricing Program.

340B DISCOUNTING AND REBATING MECHANISMS FOR ADAPS

ADAPs typically purchase drugs using one of three systems: Direct Purchase, Rebate, Dual Purchase. ADAP mechanisms to secure 340B or sub-340B pricing for outpatient prescription drugs will depend on which purchasing system is used.

With a **direct purchase mechanism**, the ADAP (or third-party vendor on its behalf) purchases all medications on its formulary at 340B- or any applicable sub-340B-discounted prices directly from a wholesaler, specialty distributor, or manufacturer. Directly purchased medications are typically dispensed to ADAP clients via one of the following pharmacy structures:

- **Central pharmacy:** A pre-purchased inventory of 340B- and sub-340B-discounted medications is maintained at a central pharmacy, typically owned, and operated by, the state or territorial health department; medications are directly dispensed to ADAP clients or distributed to other pharmacies for dispensing to ADAP clients.
- **Contract pharmacy(ies):** Like other 340B covered entities, ADAPs with direct purchase mechanisms may contract with a third-party pharmacy (or network of third-party pharmacies, typically retail pharmacies) to dispense 340B- and sub-340B-discounted medications to ADAP clients. Two primary models are:
    - **Pre-purchased inventory model**, where the ADAP's 340B- and sub-340B-purchased drugs are kept in stock at the contract pharmacy and dispensed to ADAP clients.
    - **Replenishment inventory model**, where non-340B-purchased drugs are kept in stock at the pharmacy and used to fill prescriptions on behalf of the ADAP. The contract pharmacy alerts the ADAP (or its third-party vendor) that dispensing has occurred and the ADAP replaces ("replenishes") the drug with a drug it purchases at the 340B- or sub-340B-discounted price.

A direct purchase ADAP (or its contract pharmacy) may also dispense 340B- or sub-340B-discounted medications to insured ADAP clients. The pharmacy bills the client's insurance plan for the dispensed medications at usual-and-customary payment rates, resulting in reimbursements to the pharmacy that can be higher than the ADAP's acquisition costs for the drugs. The difference between the insurance reimbursement and the cost of the services (i.e., medication acquisition cost, pharmacy dispensing fees) is program income and must be used in accordance with HRSA HAB expenditure rules.[iv]

With a 340B **rebate mechanism**, established via federal guidelines in 1998,[v] the ADAP reimburses retail pharmacies a pre-determined amount at the point of sale for non-340B-purchased drugs dispensed to ADAP clients. The ADAP then invoices drug manufacturers for the appropriate 340B- or sub-340B discount amount for the number of units of each medication dispensed. The rebate amount is typically the difference between the AMP and the 340B ceiling price, with some manufacturers providing voluntary supplemental rebates constituting the difference between wholesale acquisition cost (WAC) and a guaranteed sub-340B net unit price.

Manufacturers that receive appropriate claims from an ADAP participating in the 340B Drug Pricing Program are required to provide rebates that meet or exceed the 340B discount. Manufacturers that do not provide a rebate are considered by HRSA to be out of compliance.

In addition to submitting rebate claims on non-340B retail pharmacy dispenses where the ADAP is the primary payor of the medication, ADAPs may submit "partial pay" claims to manufacturers on non-340B retail pharmacy dispenses where a third-party insurer (e.g., commercial insurance, Medicare) is the primary payor of the medication under the following circumstances:[vi]

- The ADAP pays the deductible for the client's medication under the insurance policy, regardless of whether the program also pays the health insurance premium; or

- The ADAP pays the copayment or coinsurance for the client's medication under the insurance policy, regardless of whether the program also pays the health insurance premium.

Any rebates directly generated by a federal dollar expenditure must be used in accordance with RWHAP statutory requirements and HRSA HAB policy.[vii]

340B DRUG PRICING PROGRAM COMPLIANCE

As 340B covered entities, ADAPs must adhere to the rules and regulations of the 340B Drug Pricing Program:

Duplicate Discounts. Federal law requires 340B covered entities, including ADAPs, to comply with mechanisms to prevent manufacturers from paying duplicate discounts, which may occur if a covered entity bills a state Medicaid program for covered outpatient drugs that are subject to rebates under the MDRP.[viii]; ADAPs must have mechanisms in place to prevent duplicate discounts. These include:

1. ADAPs with rebate mechanisms that submit partial-pay rebate invoices to manufacturers should exclude 340B claims for medications dispensed to clients subject to coverage by Medicaid, regardless of any cost-sharing payment assistance provided by the ADAP.
2. ADAPs with direct purchase mechanisms that submit reimbursement drug payment invoices to third-party payers must determine whether they will use 340B-discounted drugs for their Medicaid clients (carve-in). ADAPs that carve-in are required to inform HRSA (by providing their Medicaid provider number/NPI) that they will purchase and dispense 340B-discounted drugs for their Medicaid patients. If an ADAP decides to bill Medicaid for drugs purchased under 340B with a Medicaid provider number/NPI, then ALL drugs billed to that number must be purchased under 340B and that Medicaid provider number/NPI must be listed in the HRSA Medicaid Exclusion File. Otherwise, ADAPs must refrain from billing Medicaid for 340B-discounted drugs dispensed to Medicaid beneficiaries enrolled in the state or territorial ADAP.

In addition to duplicate discount prohibitions involving medication dispenses covered by state Medicaid programs, manufacturers prohibit duplicate 340B discounts. An individual may receive services from, and thus be considered a patient of, both an ADAP and another covered entity – for example, an ADAP-funded insurance program client receiving HIV care and support services from a RWHAP Part C clinic – and thus both covered entities would be eligible for the 340B discount. However, only one covered entity is permitted to receive the statutorily defined 340B price, by rebate or discount, for a patient's prescription.

NASTAD has developed a technical assistance resource, "Best Practices for Shared ADAP and Other 340B Covered Entity Clients," to assist ADAPs in navigating and preventing duplicate 340B discounting. This resource was not supported by HRSA nor has it been approved by HRSA.

Diversion. 340B covered entities, including ADAPs, may only dispense covered outpatient drugs purchased at 340B prices to persons who are "patients" of the covered entity.[ix] Dispensing drugs purchased by the ADAP at 340B- or sub-340B-discounted prices, or subject to 340B and/or voluntary supplemental rebate claims submitted to manufacturers, to persons who are not enrolled in the ADAP constitutes diversion.

Program Audits. ADAPs are required to maintain auditable records documenting compliance with 340B Drug Pricing Program requirements.[x] Like all 340B covered entities, state and territorial ADAPs are subject to audit by manufacturers or by HRSA OPA. Any covered entity that fails to comply with 340B Drug Pricing Program requirements may be liable to manufacturers for refunds of the discounts obtained.

State or territorial ADAPs with questions regarding this resource should reach out to NASTAD's Health Care Access team: HCA@NASTAD.org.

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ENDNOTES

[i] 42 CFR part 50, subpart E

[ii] Health Resources and Services Administration Office of Pharmacy Affairs [Internet]. 340B Drug Pricing Program; 2023 Dec [cited 2023 Dec 19]. Available from: https://www.hrsa.gov/opa

[iii] Heath Resources and Services Administration. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility; 1996 Oct [cited 2024 Jan 10]. Available from: https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf.

[iv] Health Resources and Services Administration HIV/AIDS Bureau. Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income. Policy Clarification Notice (PCN) #15-03; 2015 [cited 2024 Jan 10]. Available from: https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/pcn-15-03-program-income.pdf.

[v] 63 Fed. Reg. 35239 (June 29, 1998). Available from: https://www.govinfo.gov/content/pkg/FR-1998-06-29/pdf/98-17142.pdf

[vi] Health Resources and Services Administration HIV/AIDS Bureau. Program Letter; 2005 Apr 29 [cited 2024 Jan 10]. Available from: https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/adap-340b.pdf.

[vii] Health Resources and Services Administration HIV/AIDS Bureau. Utilization and Reporting of Pharmaceutical Rebates. Policy Clarification Notice (PCN) #15-04; 2019 Jan [cited 2024 Jan 10]. Available from: https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/pcn-15-04-pharmaceutical-rebates.pdf.

[viii] Health Resources & Services Administration. 340B Drug Pricing Program. Program Requirements. Duplicate Discount Prohibition; 2020 Jul. [Cited 2024 Jan 15]. Available from: https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion.

[ix] Heath Resources and Services Administration. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility; 1996 Oct [cited 2024 Jan 10]. Available from: https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf.

[x] Health Resources & Services Administration. 340B Drug Pricing Program. Program Integrity; 2023 Jul. [Cited 2024 Jan 15]. Available from: https://www.hrsa.gov/opa/program-integrity.

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