Fundamentals of Drug Pricing and the 340B Drug Pricing Program

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Learning Objectives

By the end of this session, participants will be able to:

1. Describe the fundamentals of drug pricing in the United States.
2. Analyze pricing benchmarks central to AIDS Drug Assistance Program (ADAP) procurement and payment of outpatient medications.
3. Navigate 340B Drug Pricing Program policies and procedures relevant to ADAPs.

Presentation Roadmap

1. Setting the Stage
2. Drug Pricing Fundamentals
3. 340B Drug Pricing Program Overview
4. Questions and Discussion

Setting the Stage

Zidovudine (AZT) Pricing

Following the March 1987 U.S. Food and Drug Administration (FDA) approval of AZT (Retrovir), the first antiretroviral with demonstrated efficacy as a treatment for AIDS, concerns emerged regarding the high cost of the drug – approximately $9,000 a year in 1987; roughly $23,500 in 2023 dollars – and the access challenges faced by people with HIV with limited insurance and financial resources.

Enter AIDS Drug Assistance Programs

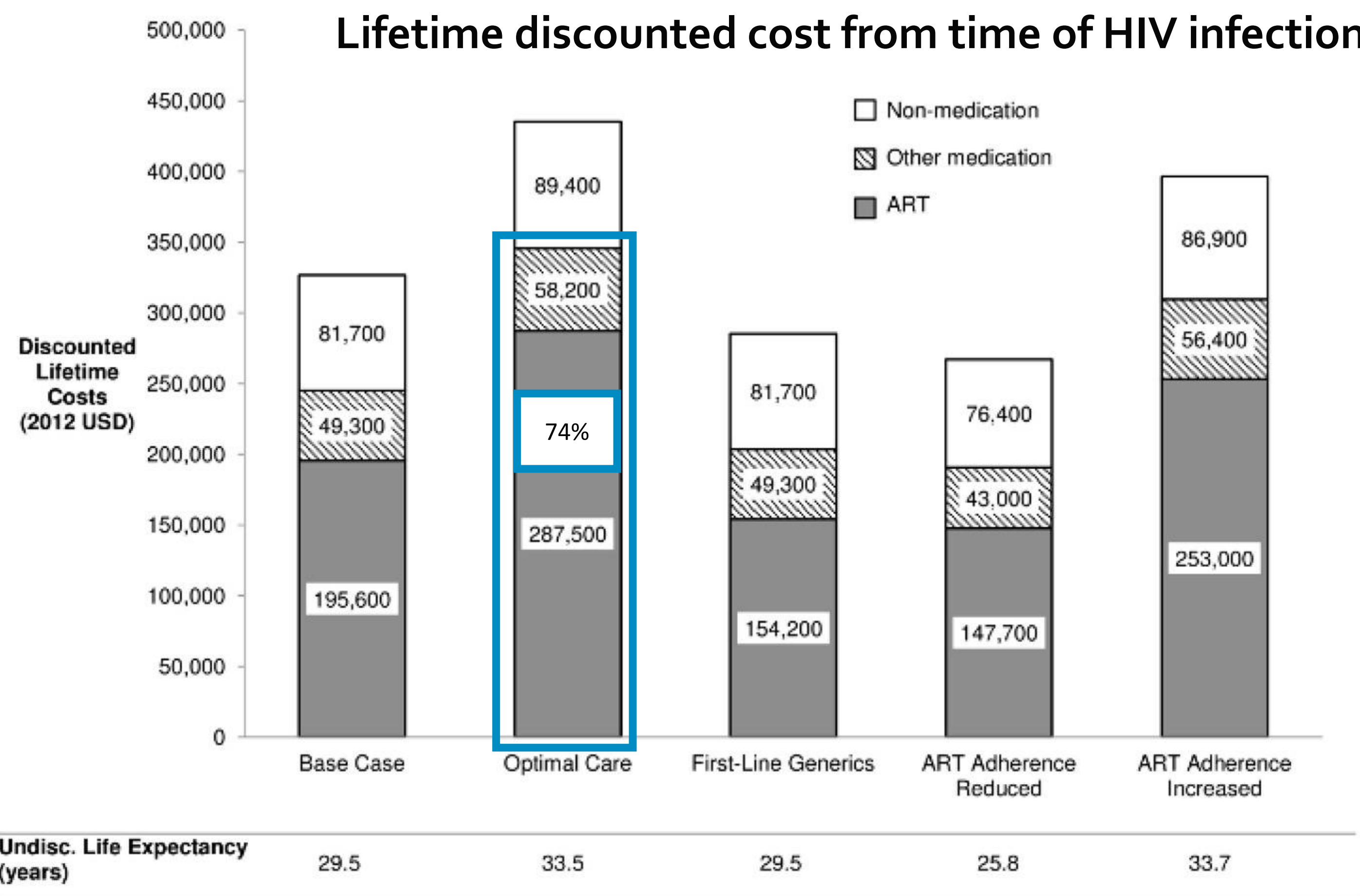
- HRSA launched the AZT Drug Reimbursement Program in late 1987, with Congressional funds appropriated to states to support purchasing of the drug for uninsured and underinsured people living with HIV.
- Laid groundwork for ADAPs authorized by Congress under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990.
- Since Fiscal Year (FY) 1996, Congress has specifically earmarked funding for ADAPs through Ryan White HIV/AIDS Program (RWHAP) Part B, which is allocated by formula to states and territories.

High Prescription Drug Costs: Current Considerations

- Current annual costs of preferred first-line single-tablet regimens (STRs): **$33K – $46K**[1]
- Antiretrovirals annual spending in the US: **$26 billion**[2]
  - 5th highest specialty class
- ADAP prescription drug expenditures and dispensing costs in CY2021: **$1.4 billion**[3]

[1] Micromedex Red Book [database]. Merative. 2023.
[2] The Uses of Medicines in the U.S. Spending and Usuage Trends and Outlook to 2025. IQVIA Institute. 2021
[3] 2023 National RWHAP Part B ADAP Monitoring Project Annual Report. NASTAD. 2023

High Prescription Drug Costs: Current Considerations



[1]Schackman BR, et al. Med Care. 2015 Apr;53(4):293-30.

ADAPs and Drug Pricing

- As a federally funded program, RWHAP ADAP recipients are required to acquire drugs “in the most economical manner feasible” (42 CFR part 50, subpart E).

Drug Pricing Fundamentals

Drug Pricing Terms of Relevance to State Programs – I

TERM	DESCRIPTION
Average wholesale price (AWP)	The wholesaler's catalog or list price and often the benchmark used for pricing of drugs for government and private payers. Public price; reported in Merative Micromedex's Red Book and First DataBank's MedKnowledge.
Wholesale acquisition cost (WAC)	The price set by drug manufacturers and negotiated with wholesalers. Public price reported by manufacturers; reported in Merative Micromedex's Red Book and First DataBank's MedKnowledge.
Medicaid ceiling price	Medicaid Drug Rebate Program (MDRP) establishes rebates for all prescription drugs covered under states' Medicaid payment model. Federal unit rebate amount (URA) calculations are used to determine the confidential rebates that must be offered to state Medicaid programs.
340B Drug Pricing Program ceiling price	340B Drug Rebate Program extends URAs to eligible health care organizations and covered entities, such as federally qualified health centers, Ryan White HIV/AIDS Program grantees, AIDS Drug Assistance Programs, and TB clinics in order to set a **confidential** maximum, or "ceiling," price for outpatient drugs.

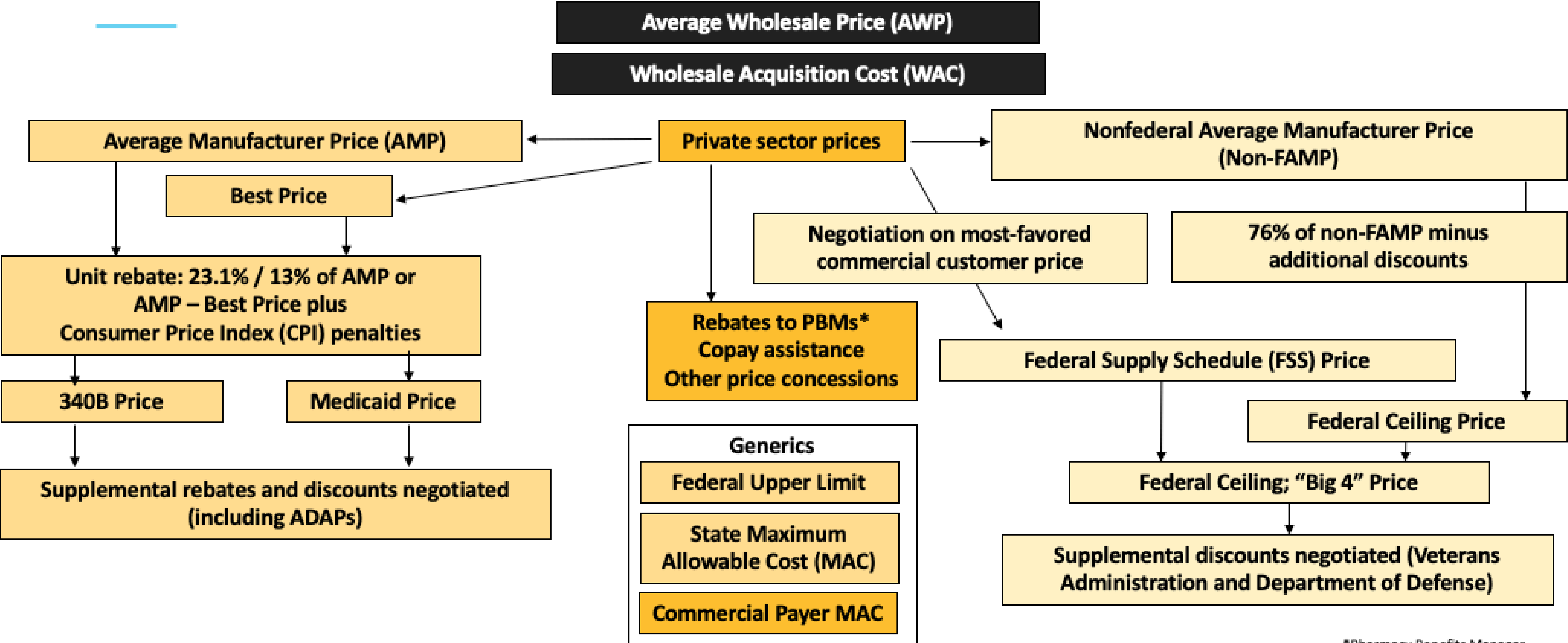
Drug Pricing Terms of Relevance to State Programs – II

TERM	DESCRIPTION
Average Manufacturer Price (AMP)	The average price paid to manufacturers by wholesalers for most drugs sold to retail community pharmacies. Confidential price reported to CMS by manufacturers and is used to calculate the for MDRP and 340B. Most ADAPs do not have access to AMP data.
Best Price	The lowest drug price available to wholesalers, retailers, providers, HMOs, nonprofit entities, or government entities in the U.S. in any pricing structure (including capitated payments). Confidential price reported to CMS and used, along with AMP, to calculate the URA for the Medicaid and 340B. Most ADAPs do not have access to Best Price data.
Supplemental Discount/Rebate	Manufacturers can provide supplemental discounts or rebates to Medicaid and 340B programs. ADAP Crisis Task Force negotiates sub-340B prices with major antiretroviral manufacturers for all ADAPs; Apexus negotiates sub-340B prices with many manufacturers for all 340B covered entities (including ADAPs).

Drug Pricing Terms of Relevance to State Programs – III

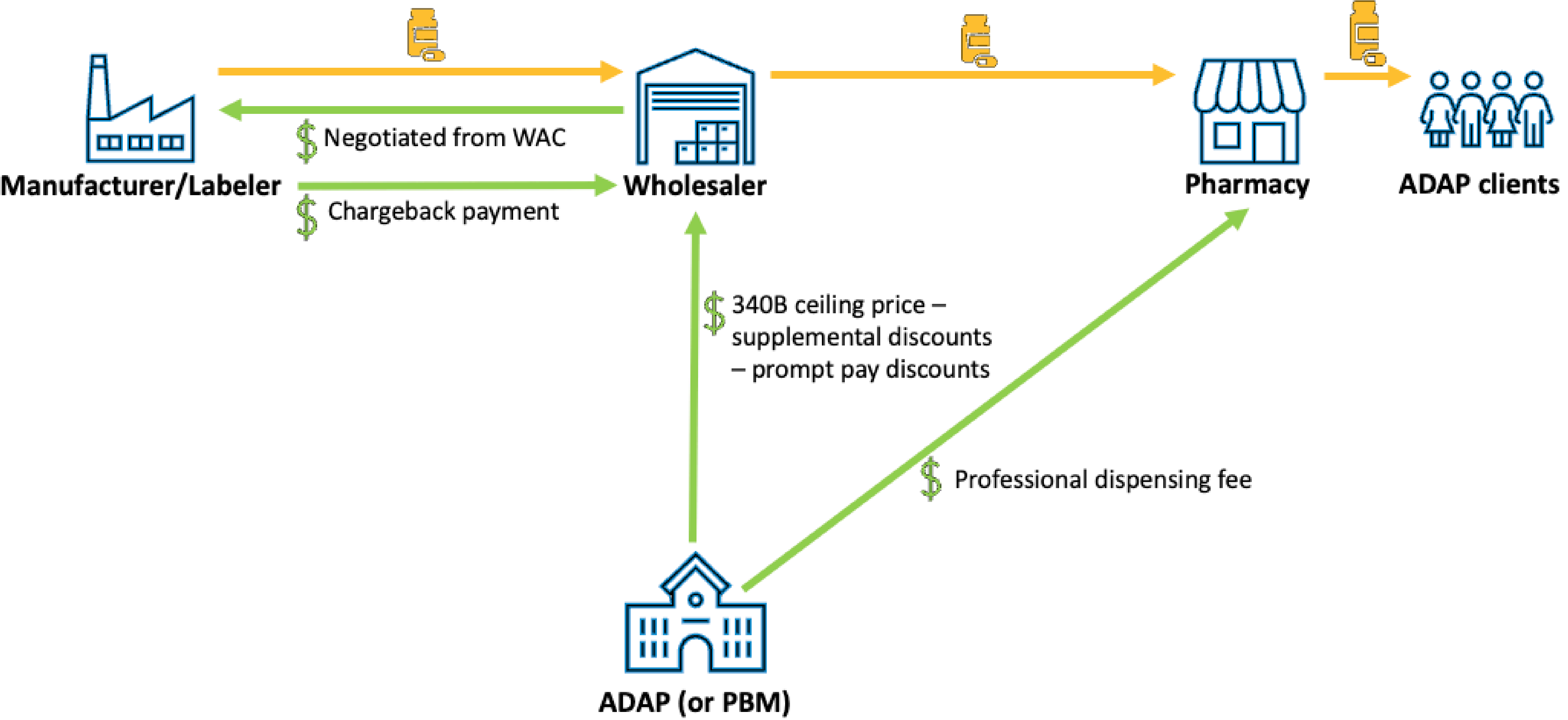
TERM	DESCRIPTION
Actual Acquisition Cost (AAC)	Actual prices paid to acquire drug products marketed or sold by manufacturers.
National Average Drug Acquisition Cost (NADAC)	Survey-based of average prices at which pharmacies purchase prescription drugs from manufacturers or wholesalers; can be used to calculate AAC.
Federal Upper Limit (FUL)	Federally established maximum price (175% of the lowest published price) for a drug product, if there are three (or more) generic versions of the product rated therapeutically equivalent (A-rated) and at least three suppliers.
State Maximum Allowable Cost (SMAC)	Optional State Medicaid program to achieve additional savings by setting lower reimbursement amounts for more multiple- source drugs than are included in the FUL program.

U.S. Drug Pricing: It's Complicated

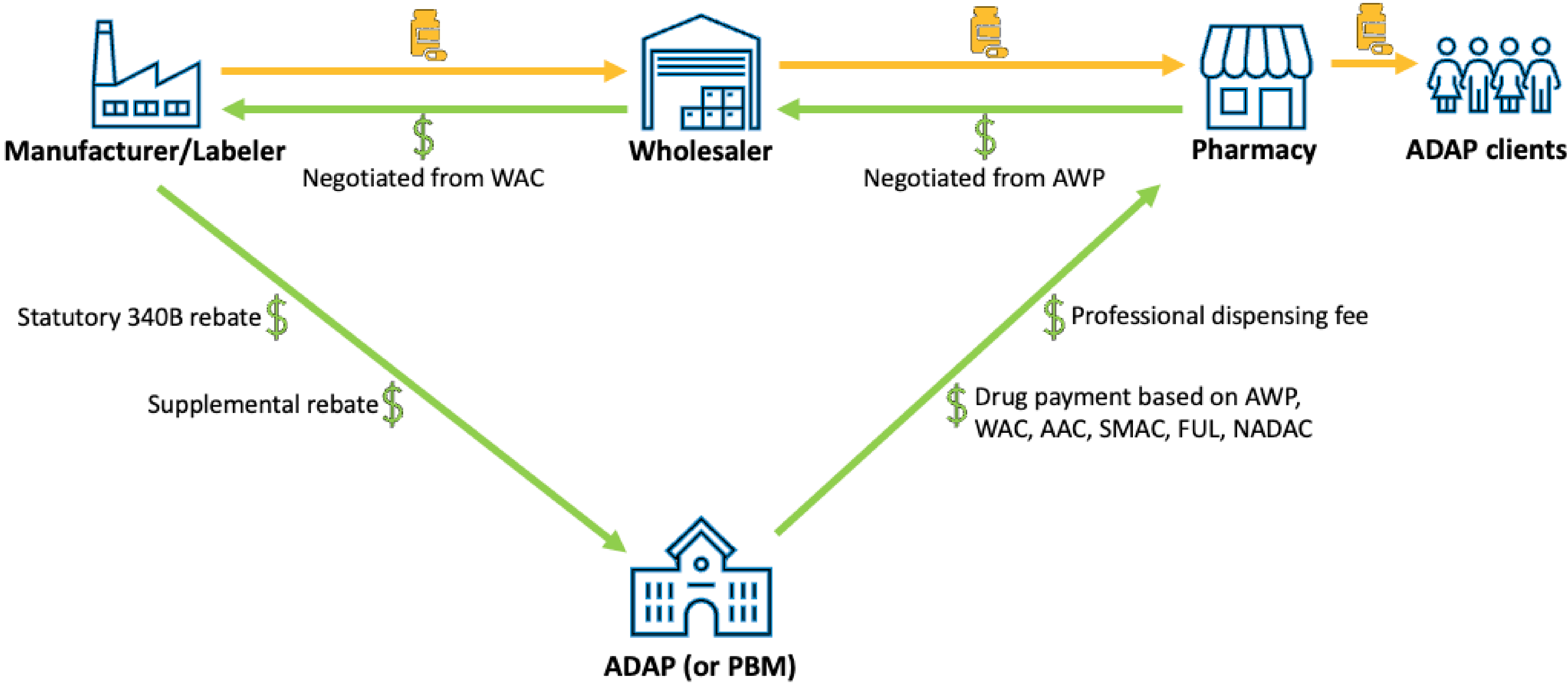


*Pharmacy Benefits Manager

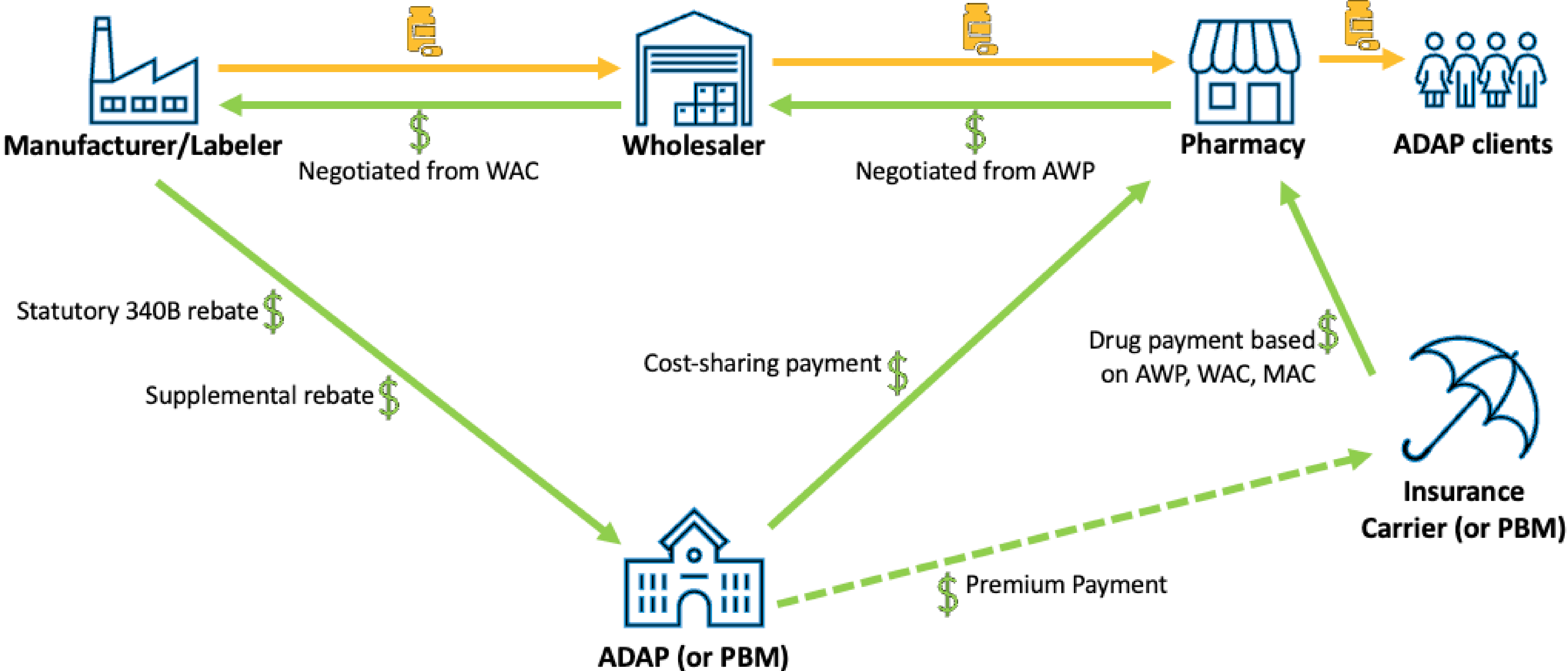
Direct Purchase ADAP Serving Full-Pay Medication Clients via 340B Contract Pharmacy



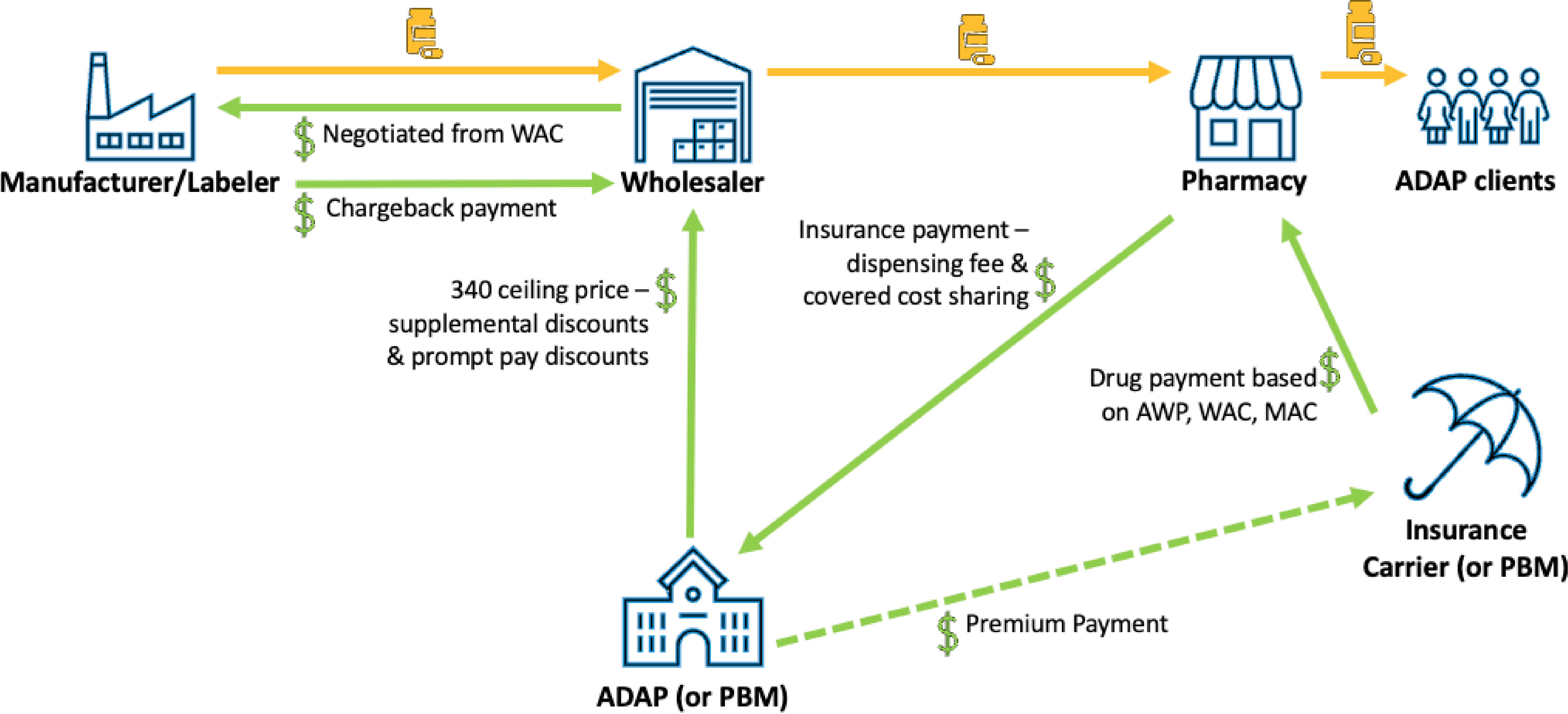
Rebate ADAPs Serving Full-Pay Medication Clients via Retail Pharmacy



Rebate ADAPs Serving Insured Clients via Retail Pharmacy



Direct Purchase ADAP Serving Insured Clients via 340B Contract Pharmacy



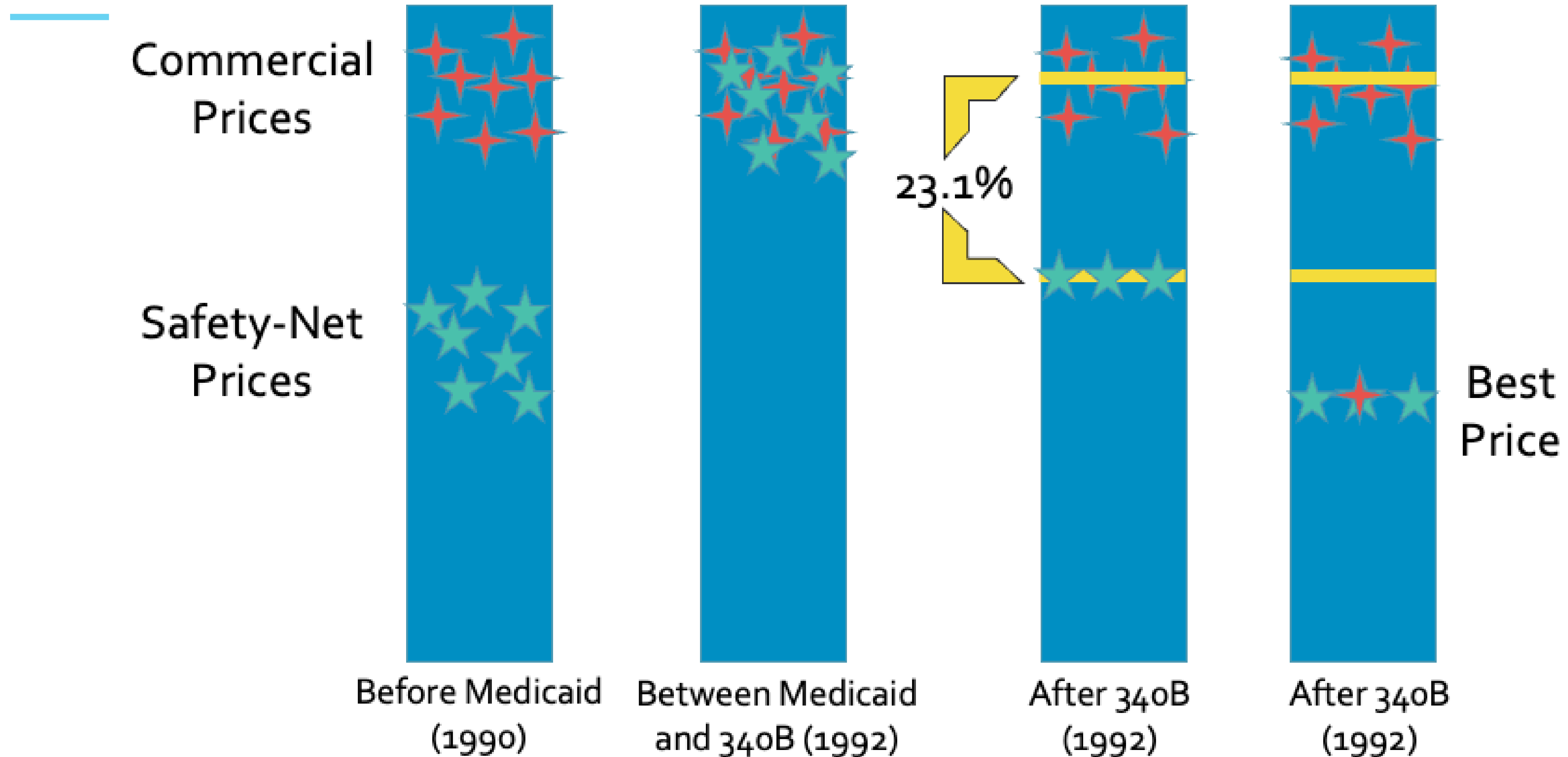
340B Drug Pricing Program Overview

340B Background

- The 340B Drug Pricing Program was created by Congress in 1992 following adoption of the Medicaid Drug Rebate Program.
- Allows certain federal grantees and hospitals ("covered entities") to obtain discounted prices on outpatient drugs from manufacturers.
- Resulting cost-containment and revenue helps to "stretch scarce Federal resources as far as possible, with the intent of reaching more eligible patients and providing more comprehensive services."[1]

[1] Language from a House Energy and Commerce Committee report on legislation that eventually became section 340B of the Public Health Service Act (U.S. House of Representatives 1992).

340B Background - Graphically



Manufacturers and 340B

- Manufacturers are not required to participate; strong incentives to do so.
  - Participation is the only way to receive Medicare Part B and Medicaid reimbursement.
- Manufacturer may not condition the offer of 340B discounts upon a covered entity's assurance of compliance with 340B.

Clarification on nondiscrimination policy. 340B Drug Pricing Program notice. Release no. 2011–1.1. HRSA. 2012

340B Covered Drugs & Biologics

- Prescription drugs and biologics other than vaccines
- FDA-approved insulin
- Over-the-counter drugs with prescription
- Excludes inpatient drugs
- Hospitals added under ACA (e.g., critical access hospitals) are excluded from purchasing orphan drugs at 340B discount price

340B Covered Entities

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 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)

340B Patient Definition

- The covered entity (CE) established a relationship with the individual, such that the CE maintains records of the individual's health care; and
- The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the CE; and
- The individual receives a health care service or range of services from the CE which is consistent with the service or range of services for which grant funding … has been provided to the entity.

340B Patient Definition – ADAPs

- The covered entity has established a relationship with the individual, suc… nd
- The … pro… les hea… res…
- The … m the CE which is consistent with the service or range of services for which grant funding … has been provided to the entity

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.

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility. HRSA. 1996.

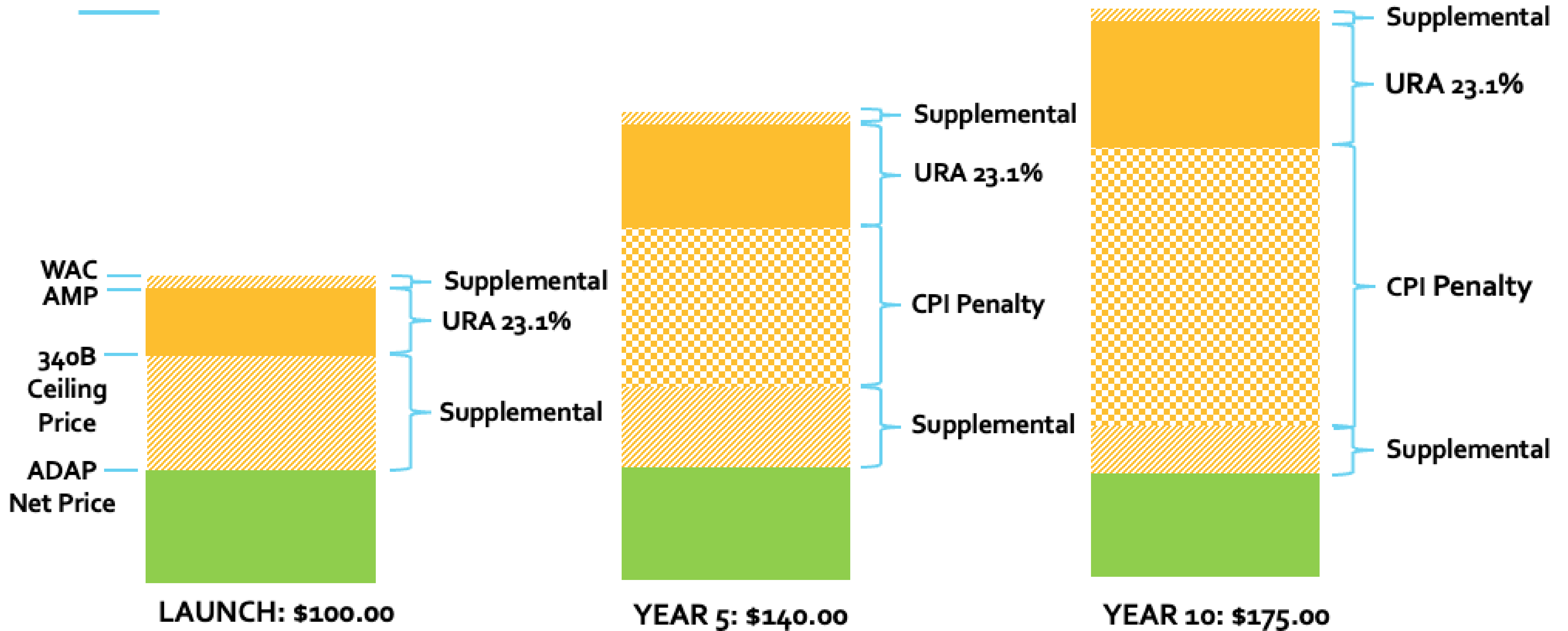
340B Discount and Rebate Basics

- ADAPs are the only covered entities that can choose to receive a 340B rebate from a drug manufacturer.
- 340B CEs are subject to a minimum discount/rebate of 23.1% off AMP for branded drugs (13% generics); "Best Price" adjustments are also possible.
- When a manufacturer takes a price increase that exceeds the Consumer Price Index for All Urban Costumers (CPI-U), an additional rebate – or "inflation penalty" – is added to the base discount.

Voluntary Supplemental Discounting

- Manufacturers are free to provide voluntary supplemental (sub-ceiling) discounting to 340B covered entities
  - Similarly avoid triggering AMP and/or Best Price
- Sub-ceiling prices are available via:
  - Negotiations between Apexus Prime Vendor Program and manufacturers
  - Negotiations between ADAP Crisis Task Force and manufacturers (available only to AIDS Drug Assistance Programs)
  - Voluntary provision by manufacturers to covered entities
- Catalog prices available to 340B covered entities reflect manufacturer ceiling or sub-ceiling price plus additional wholesaler discounting

Anatomy of an ADAP Discount/Rebate Over Time



340B Pricing Data Sources

- AMP and BP data are highly confidential and accessible to Medicaid programs via Centers for Medicare and Medicaid Services (CMS)
- 340B ceiling prices are confidential and accessible to 340B covered entities via the HRSA Office of Pharmacy Affairs Information System (340B OPAIS)
- NASTAD uses publicly-available wholesale acquisition cost (WAC) as surrogate for branded (single-source) drug AMPs in 340B estimates
- All ACTF-negotiated agreements with manufacturers housed on NASTAD's Online Technical Assistance Platform

340B Requirements and Best Practices

- ✓ Avoid duplicate discounts (Medicaid)
- ✓ Avoid diversion of 340B-discounted/rebated drugs
- ✓ ADAPs subject to both HRSA OPA and drug manufacturer audits
- ✓ Avoid "double dipping" (e.g., 340B rebates on dispenses subject to 340B discounts)
- ✓ Annual recertifications of Office of Pharmacy Affairs direct purchase ("RWIID") and rebate ("RWIIR") 340B designations (usually throughout February)
- ✓ Maximum time period for submission of claims of one year within the range of standard business practices[1]

[1] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility. HRSA. 1996.

Dispute Resolution

- ADAPs are encouraged to:
  - address any claim or invoice questions directly with manufacturer within 30 day;
  - review disputed claims noted in Reconciliation of State Invoices (ROSIs); and
  - use normal business procedures with manufacturers in event of late rebate payments; prolonged or frequent delays may require HRSA OPA dispute resolution process.

Questions and Discussion

Thank you!

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