

Tackling Drug Costs

A 100 Day Roadmap

Sean Dickson

NASTAD

with Tim Horn

Treatment Action Group

on behalf of the

FAIR **P**RICING **C**OALITION

About the Fair Pricing Coalition

The Fair Pricing Coalition, founded by the late Martin Delaney of Project Inform, is a national coalition of activists and policy leaders who work on HIV and viral hepatitis drug pricing issues, and to help control drug costs for patients who are privately insured, underinsured and uninsured. The Fair Pricing Coalition also works to ensure access for individuals covered by state AIDS Drug Assistance Programs (ADAPs), Medicare, and Medicaid. For more information about the Fair Pricing Coalition and its history, visit: www.fairpricingcoalition.org.

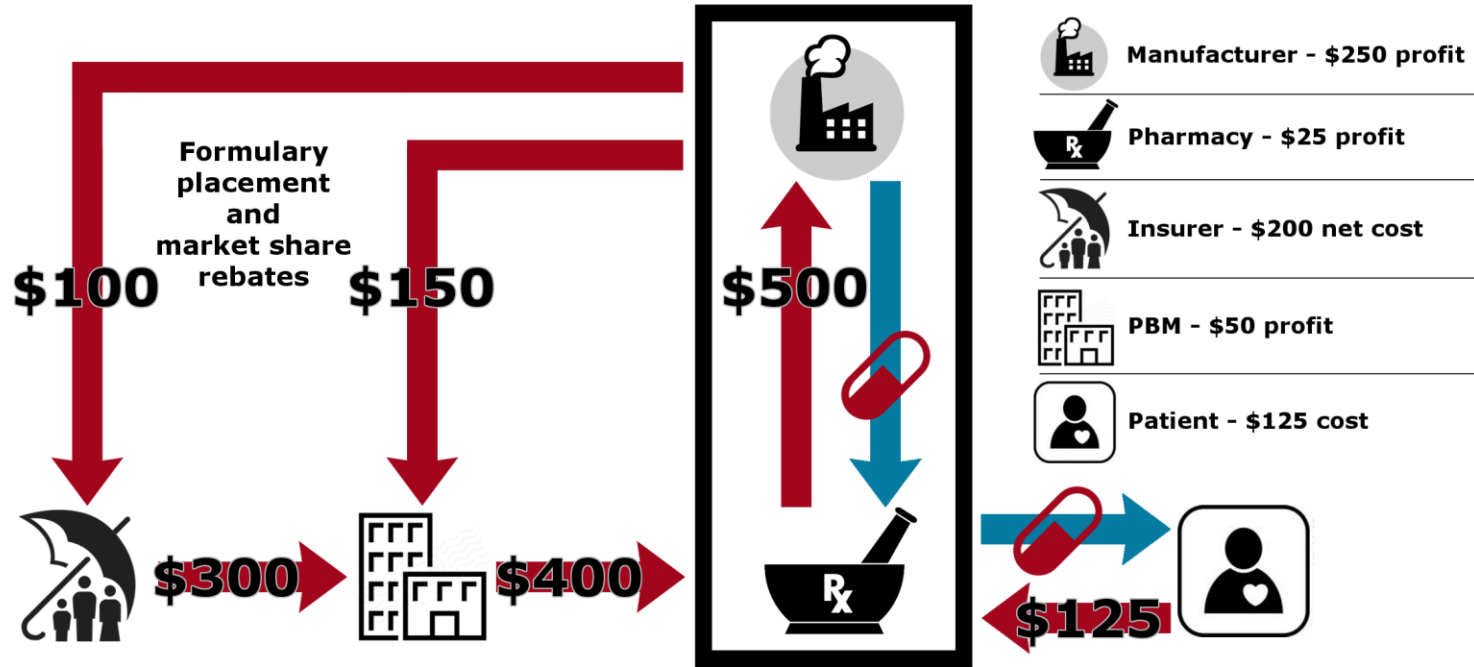
This report is authored by:

Sean Dickson, sdickson@nastad.org (primary contact), Senior Manager, Health Systems Integration, at NASTAD (National Alliance of State & Territorial AIDS Directors) in Washington, DC. www.nastad.org, with

Tim Horn, tim.horn@treatmentactiongroup.org, Deputy Executive Director, HIV & HCV Programs, at Treatment Action Group (TAG) in New York, NY. Tim is also Co-Chair of the Fair Pricing Coalition. www.treatmentactiongroup.org

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Private Market

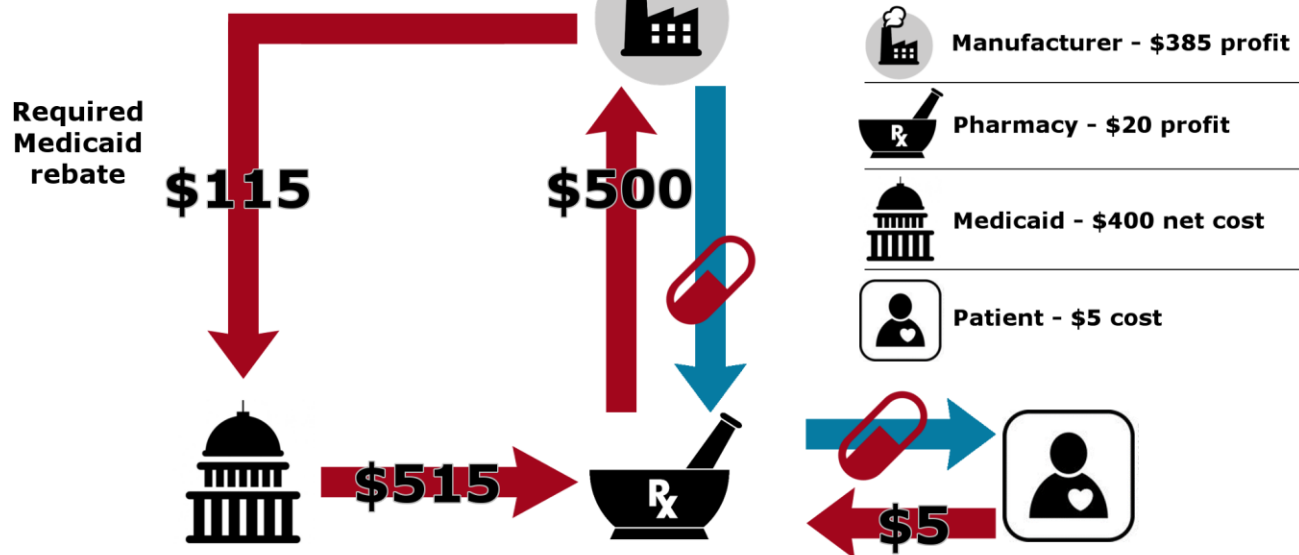


Average Manufacturer Price (AMP) is only calculated from sales and discounts that accrue to retail community pharmacies. Most discounts and rebates, however, accrue to insurers and Pharmacy Benefit Managers (PBMs), so they are not included in AMP.

Trace the Dollars

Fair Pricing Coalition
Tackling Drug Costs: A 100 Day Roadmap

Medicaid



The net Medicaid price depends on AMP. Medicaid reimburses pharmacies for their full costs of purchasing the drug, and the manufacturer pays Medicaid a 23.1% rebate to offset those costs. If AMP is artificially high, however, Medicaid can have higher net costs than private insurers.

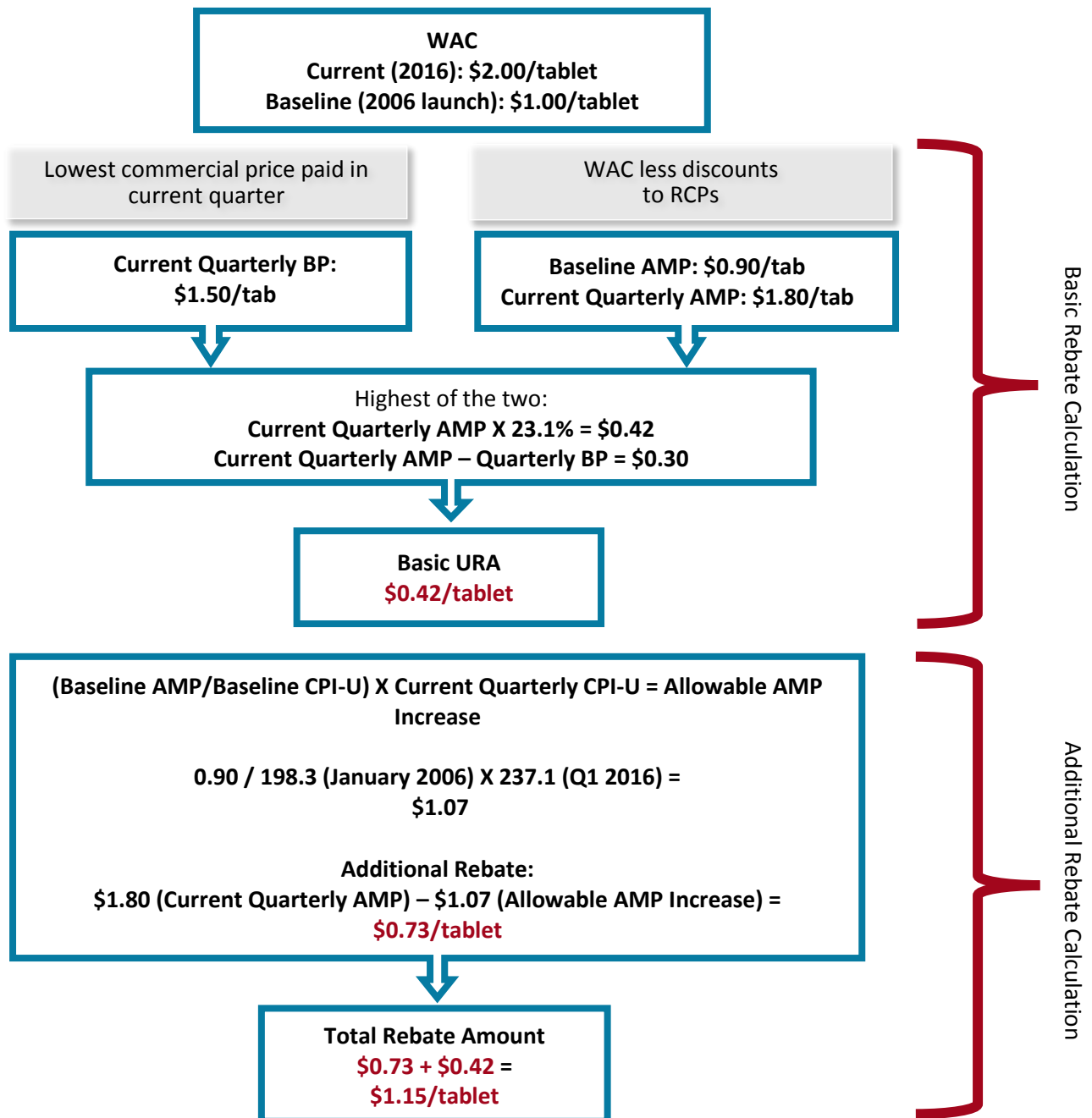
	Metric	Description	Calculations
Commercial	Wholesale Acquisition Cost (WAC)	The price set by drug manufacturers and negotiated with wholesalers. Public price reported by manufacturers.	
	Average Wholesale Price (AWP)	The wholesaler’s catalog or list price and often the benchmark used for pricing of drugs for government and private payers. Public price ; reported in Thomson Micromedex’s <i>Red Book</i> and First DataBank’s <i>Blue Book</i> .	In the absence of AWP or suggested wholesale price provided by the manufacturer, a standard 20% markup over WAC is typically used to calculate the AWP https://micromedex.com/Portals/1/Assets/AWP%20Policy_Oct%202014.pdf .
Medicare Part B	Average Sales Price (ASP)	The price set for drugs covered by Medicare Part B. A public price calculated by CMS and applied to certain classes of drugs: vaccines, injected and infused medications, parenteral nutrition, and transplant drugs, for example. ASP comes out of the Medicare Modernization Act of 2003 (codified at 1847A of the Social Security Act), which aimed to curtail Medicare spending on these expensive drugs. ASPs available at: goo.gl/N6xNgh .	Before ASP, Medicare Part B drug cost reimbursements were frequently based on AWP. With hyperinflation of AWP and purchaser rebates, volume and prompt payment discounts, and cash payments by manufacturers, Medicare reimbursements based on ASP (plus 6%) controls spending by narrowing the spread between what is actually paid for the drug and what is actually billed to Medicare Part B. Not included in the ASP in the physician payment formula used to determine reimbursements for administering providers for administering these drugs.
Medicaid	Medicaid Drug Rebate Program (MDRP)	The MDRP establishes rebates for all prescription drugs covered under states’ Medicaid payment model (42 USC § 1396r-8). Federal unit rebate amount (URA) calculations are used to determine the confidential rebates that must be offered to state Medicaid programs for three categories of drugs: <i>N</i> (non-innovator multiple source drugs; “generics”), <i>S</i> (single-source innovator drugs; traditional “brand-name” name), and <i>I</i> (multiple-source innovator drugs).	URAs for <i>S</i> or <i>I</i> drugs are either a minimum of 23.1% of the AMP <i>or</i> the difference between the AMP and the BP (whichever is larger), <i>plus</i> additional rebates if the AMP increases since the drug’s launch price exceed the consumer price index-all urban consumers (CPI-U) marker of inflation (42 USC § 1396r-8) (see graphic on page 24). The current URA for <i>N</i> drugs is 13% of the AMP, without other mandatory adjustments; beginning with the first quarter of 2017, additional CPI-U “penalties” will also be required. In addition to URAs, many state Medicaid programs negotiate supplemental rebates with manufacturers.

Metric	Description	Calculations
Average Manufacturer Price (AMP)	The average price paid to manufacturers by wholesalers for most drugs sold to retail community pharmacies (RCPs)—specifically independent, chain, supermarket, and mass merchandiser pharmacies, as well as RCPs that purchase drugs purchased directly from the manufacturer (42 CFR §447.504). Confidential price reported to the U.S. Centers for Medicare & Medicaid Services (CMS) by manufacturers and is used to calculate the unit rebate amount (URA) for the Medicaid Drug Rebate Program (MDRP) and 340B Drug Discount Program.	Included in the AMP calculation are sales, nominal price sales, and various discounts, rebates, payments or other financial transactions (42 CFR §447.504). Not included in the AMP calculation are bona fide service fees; returned goods; Medicare coverage gap discounts; prices to other federal programs; sales or price concessions to physicians, insurers, pharmacy benefit managers (PBMs), hospitals, mail order pharmacies, or prisons; manufacturer-sponsored programs (e.g., copay assistance); free goods provided by the manufacturer; or customary prompt pay discounts (42 CFR §447.504).
5i Average Manufacturer Price (5i AMP)	The average price paid to manufacturers for 5i drugs (drugs that are inhaled, infused, instilled, implanted, or injected) that are generally not sold to RCPs (42 CFR §447.507). As with AMP, this is a confidential price reported to CMS and is used to calculate the URA for Medicaid and 340B programs.	The 5i AMP calculation excludes drugs for which 30% or more of sales were to RCPs or wholesalers for drugs distributed to RCPs (42 CFR §447.507). The calculation is applied to 5i drugs sold to physicians; PBMs; HMOs; insurers, hospitals, clinics, and outpatient facilities; long-term care and hospice providers; and mail-order pharmacies, all of which are excluded from standard AMP (42 CFR §447.504). Excluded are prompt-pay discounts; sales to government, charitable, or not-for-profit pharmacies; prices available under other federal programs; bona fide service fees, and either direct or indirect sales to patients (42 CFR §447.504).
Best Price (BP)	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) (42 CFR § 447.505). Confidential price reported to CMS and used, along with AMP, to calculate the URA for the Medicaid and 340B programs.	Included in the BP are applicable discounts, rebates, or other transactions that adjust prices directly or indirectly to all entities in the BP category (42 CFR §447.505). Examples of best price calculation exclusions include: prices charged to certain federal purchases (e.g., those made through the federal supply schedule), patient assistance schemes (e.g., copay assistance programs), discounts or rebates to PBMs, direct-to-patient sales, state pharmacy assistance programs, bona fide service fees, and any prices charged to 340Bcovered entities (42 CFR §447.505).

Medicaid

	Metric	Description	Calculations
340B Program	340B Ceiling Price	The 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 (42 USC § 256b).	The Health Resources and Services Administration (HRSA) obtains AMP and URA data from CMS. HRSA multiplies the total per-pill/unit URA calculation by the package size and case package size to produce the 340B Ceiling Price used by covered entities. Participating entities may negotiate discounts below the ceiling price; they are also allowed to bill public and private payers for reimbursements based on the public list prices with the savings reinvested in patient care and services.
Federal Purchasing	Federal Supply Schedule (FSS)	The FSS is a mechanism for government purchasers to access discounted prices. Manufacturers may choose to offer one discounted price to all federal purchasers, in which case the Federal Ceiling Price (FCP) is used, or be a “dual pricer” and offer the FCP to the “Big Four” purchasers—the Department of Veterans Affairs (VA), as well as the Department of Defense, Public Health Service/Indian Health Service, and the Coast Guard—and a higher price to all other government agencies. FSS prices are public (http://www.va.gov/nac/Pharma/List).	All manufacturers wishing to do business with federal purchases or Medicaid must list their drugs on the FSS (38 USC § 8126). Under dual pricing, the VA negotiates a discounted FSS price for other government agency customers based on sales data from the manufacturer showing its Most Favored Customer (MFC) (General Services Administration Manual Subpart 538.2). Big Four customers receive the FCP. The OGA FSS price is capped by annual inflation, while the Big Four FCP price can be subject to additional discounts if non-FAMP rises faster than inflation (38 USC § 8126).
	Non-Federal Average Manufacturer Price (non-FAMP)	The average price of a drug paid by wholesalers, or other entities that purchase the drug directly from manufacturers, used to calculate the Federal Ceiling Price (FCP), which applies to “Big Four” sales (38 USC § 8126). This confidential price is calculated quarterly and annually by the manufacturer and submitted to the (VA).	Non-FAMP calculation includes any discounts or similar price reductions to wholesalers or direct purchasers of drugs, but excludes any prices paid by the federal government (38 USC § 8126). Also excludes any rebates or discounts to end customers that are not paid to/through wholesalers.
	Federal Ceiling Price (FCP)	The FCP is the maximum price that manufacturers can charge the Big Four. The Big Four prices are publicly available and may be 40% to 50% of the AWP (http://www.va.gov/nac/Pharma/List).	The FCP for a drug is capped at no more than 76% of the previous year’s non-FAMP for the drug; an additional discount may be necessary if the non-FAMP increases higher than the CPI-U. Additionally, the FCP price cannot exceed the previous year’s FSS price (38 USC § 8126). All Big Four agencies can negotiate lower prices; historically, the VA average price is often lower than the price available to the Big Four because the VA negotiates further price reductions using its preferred formulary.

Medicaid Rebate Calculation



Medicaid Math. Quarterly, the Centers for Medicare & Medicaid Services calculates mandatory drug rebate amounts for state Medicaid programs; this calculation also establishes the ceiling price covered entities under the 340B program. This graphic illustrates the calculations for the mandatory basic rebate and the additional rebate “penalty” for drugs with price increases exceeding the consumer price index-urban (CPI-U) marker of inflation.

Abbreviations: **AMP**, average manufacturer price; **Baseline AMP**, the AMP for the first quarter after the drug’s market/launch date; **Baseline CPI-U**, the CPI-U for the month prior to the first quarter after the drug’s launch date; **BP**, best price; **Quarterly AMP**, the AMP for the most recent quarter of sales; **Quarterly CPI-U**, the CPI-U value of the month prior to the quarter being calculated; **RCPs**, retail community pharmacies; **URA**, unit rebate amount; **WAC**, wholesale acquisition cost.