

Overview of Drug Pricing for Public Programs

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MUCH OF THE PRICING INFORMATION IN THIS
PRESENTATION**

U. S. Drug Pricing Systems for Public Programs

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- **U.S. is the only “high-income” country with no direct or indirect national price controls**
- Highly competitive drug market with strong direct to consumer and direct to provider marketing
- USA Today noted that between 1998 and 2005 the pharmaceutical industry spent \$758 million on lobbying, more than any other industry
 - Employed 1,274 federal lobbyists, more than 2 for every member of Congress
- The system of pricing and rebates is complex and lacking in transparency

Who pays what?

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- There are different prices for different sectors of the care system; and different prices within the sectors depending **on which entities have the most leverage or “purchasing power”**
 - Most deals are private and confidential
- Public programs get some protections in the form of mandatory rebates, price increase protections, and discounted prices
- There is a lot of room for manipulation of the system
- Brand name drugs are exclusively marketed by the company that develops them and are protected by patents
 - Drug companies can and do take increases on their drugs at will

HIV Drugs

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- Very few generic drugs; the drugs that do have generic brands are not in wide-spread use as single drugs
- The cost of treating HIV disease is increasing at about 12% - 14% annually, about the same as the cost of treating cancer and more than the cost of treating MS
- HIV advocates are one of the few, or maybe only community, that engages directly with industry on pricing
 - Fair Pricing Coalition
 - ADAP Crisis Team

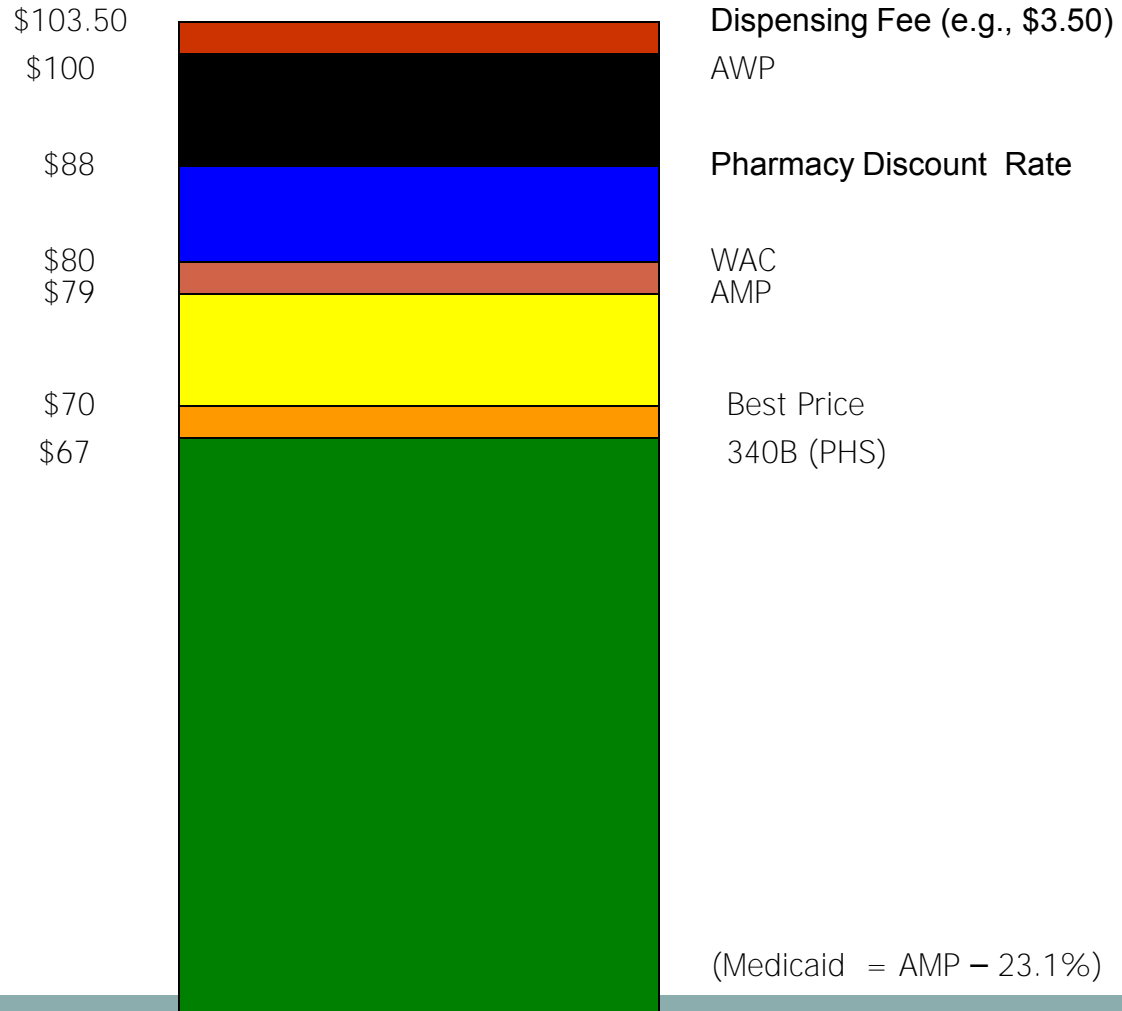
HIV Drugs

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- Not a lot of leverage in the private market
 - However, FPC has been successful in keeping new drugs in reasonable price ranges compared to other drugs on the market
- Approximately 70% of the U.S. HIV drug market is in the public programs
 - This estimate may be off since people who are eligible for Medicaid and Medicare together have moved to the Medicare Part D benefit which is a private benefit
 - More leverage in the public market because of mandatory rebates, some protection against price increases, public health pricing structures, and the ability to negotiate supplemental rebates

Drug Pricing Schedule Hypothetical Drug = \$100.00 Average Wholesale Price (AWP)

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Drug Terms – 1

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- **Dispensing Fee:** The charge for the professional services provided by the pharmacist.
- **Average Wholesale Price (AWP):** A national average of prices charged by wholesalers to pharmacies, calculated by pricing services (e.g., MediSpan). As a result of lawsuits, this pricing schedule will be discontinued in 2011.
- **Pharmacy Discount Price:** The price paid to the Pharmacy by a program (i.e., ADAP, Medicaid) for drugs.
- **Wholesale Acquisition Cost (WAC):** Sometimes called “List Price” or “Retail Price”. WAC is the price set by manufacturers.

Drug Terms – 2

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- **Average Manufacturer Price (AMP):** The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies.
 - A confidential price – held by Centers for Medicaid and Medicare Service – supposed to have been made public in 2006
 - The price off which the Medicaid rebate price is calculated
- **Best Price:** The lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts or other pricing adjustments.
 - Only includes private market prices
- **340B (PHS) Price:** The maximum price that manufacturers can charge covered entities participating in the Public Health Service's 340B drug discount program.
- **Wholesaler Discount:** Discount offered by wholesalers to direct purchasers for large volume and prompt payment.

Drug Terms - 3



- **Federal Upper Limit Price (FUL):** Federally established maximum price (150% 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.
- **Acquisition Cost (AC):** The net cost of a drug paid by a pharmacy and includes discounts, rebates, chargebacks and other adjustments.
- **ADAP Supplemental Discount/Rebate:** An additional discount for direct purchase states or rebate for pharmacy network states, negotiated by the ADAP Crisis Task Force.
- **Medicaid Supplemental Rebate:** Additional rebates negotiated by state program
- **National Drug Code (NDC)** – standardized drug coding system used in retail pharmacy transactions. The 11 digit number identifies the manufacturer/labeler (first 5 digits), drug - strength, dosage and formulation (next 4 digits) and packaging size (last 2 digits).

Unit Rebate Amount (URA)

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- The rebate amount paid by a manufacturer to ADAP/Medicaid for each unit (e.g., capsule) by NDC of drug.
- URA is calculated quarterly by Centers for Medicare & Medicaid Services based on data submitted by the drug companies.
- The 340B Price is calculated by subtracting the URA from AMP.

URA Calculation

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Brand name drugs:

- Minimum of 15.1% of AMP (likely to change to 23.1% under health care reform)
OR
- Difference between AMP and Best Price, if larger (Best Price adjustment)
PLUS
- Additional rebate if AMP price increases exceed inflation rate of the Consumer Price (Urban) Index. Inflation calculated back to initial introduction of the drug

Generic Drugs

- 11% of AMP

Pharmacy Network Distribution Model

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- Program reimburses a broad network of retail pharmacies for dispensing drugs to patients.
- Model used by Medicaid, private insurance companies and 50% of ADAPs.
- Cost = Pharmacy Discount Rate + Dispensing Fee – Rebate
- Reimbursement rates may be multi-tiered
Example: Lowest of:
 - 1) Brand Name Drugs = AWP-12% + \$3.50 (Dispensing Fee)
 - 2) Multi-source Drugs = FUL price + \$4.50 (Dispensing Fee)
 - 3) Acquisition Cost = 340B price paid by hospital/clinic + Dispensing Fee (no rebate with #3)

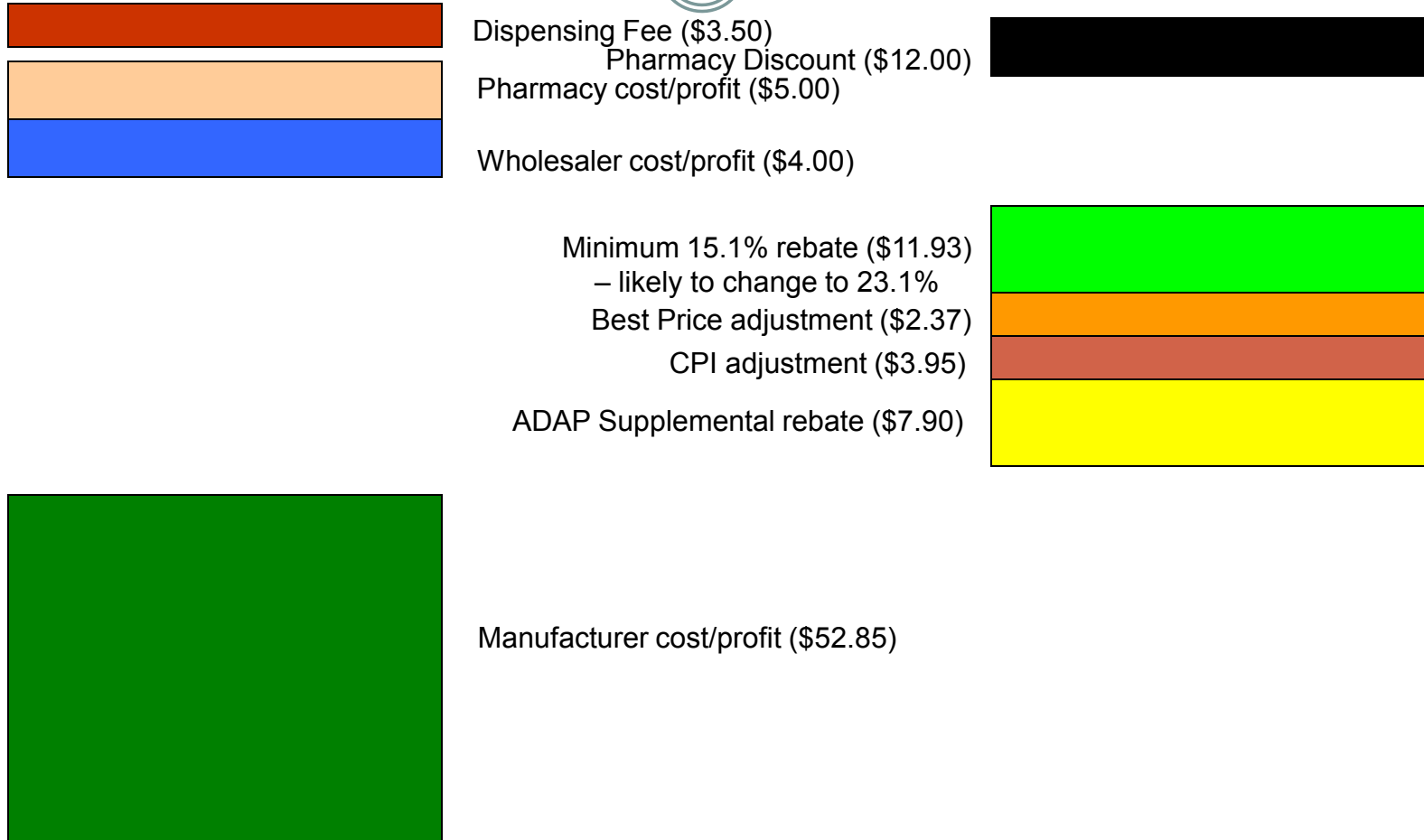
Medicaid Pharmacy Network Model

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- Medicaid mandatory rebate increases from 15.1% AMP to 23.1% AMP retroactive to January 1, 2010 under health care reform law
 - A portion of that 8% additional rebate will go back to the Federal Government
 - Consistent with historical mandatory rebates because of Medicaid entitlement status
 - However, many states negotiated supplemental rebates prior to HCR and now will have to return portion to the Federal Government
 - ✦ Unclear if states will negotiate further supplemental rebate
 - HCR also allow states to collect rebate on drugs provided through Medicaid managed care capitated rates
 - ✦ Potential new revenue source for some states

Pharmacy Network Cost - Example

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ADAP Net Cost = \$65.35 (DF + Pharmacy + Wholesaler + Manufacturer)

Direct Purchase Model

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- Program purchases drugs directly from wholesaler at 340B (PHS) pricing schedule.
- Model used by public hospitals, community health centers and 50% of ADAPs.
- Cost = 340B price + Distribution System Costs.
- Distribution System Costs are variable based on approach, size and existing infrastructure.

Direct Purchase Distribution System Cost may include:

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Central Pharmacy

- Central pharmacy costs (staffing, storage, loss due to expiration).
- Shipping (and losses).
- Local distribution sites (pharmacy operating costs, dispensing fees, and drugs not dispensed).

Mail Order

- Profit, central pharmacy cost and shipping, but usually no local site distribution costs.

Direct Purchase Model Issues

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- Cost to program may be reduced if distribution costs are spread out across existing health care infrastructure.
- Limited distribution sites (patient transportation).
Alternative: ship to retail pharmacies = shipping & dispensing costs.
- Potential delays in filling (shipping time).
Alternative: inventory replacement = pharmacy cooperation.
- Mail Order
 - confidentiality and stable housing issues.
 - save on shipping with 90 day supply.
 - 90 days supply = waste with regimen changes and clients who transition to other payers.

Direct Purchase Costs

Example - \$100.00 AWP

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AWP Price (\$100.00)



Distribution and Dispensing Costs (\$??.??)

AMP Price (\$79.00)

Minimum 15.1% discount (\$11.93)
– will likely increase under HCR

Best Price adjustment (\$2.37)

CPI adjustment (\$3.95)

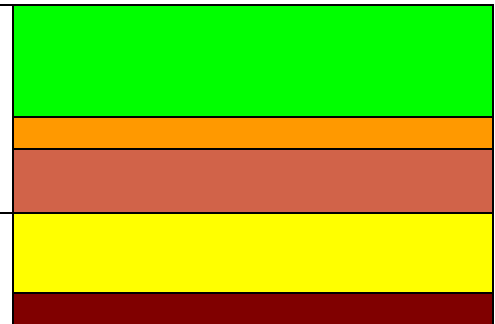
340 B Price (\$60.75)

ADAP Supplemental rebate (\$7.90)

Wholesaler Discount (\$1.59)



Manufacturer cost/profit (\$52.85)



ADAP Net Cost = Manufacturer + Distribution & Dispensing

Hybrid Purchasing Model

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- Program contracts with a 340B entity to purchase medications at 340B (PHS) pricing schedule.
- Model employed by several ADAPs (i.e., KY, UT) utilizing the pharmacy infrastructure of a hospital.
- **340B entity purchases all drugs (ADAP's & hospital's) at 340B price** and does not maintain separate inventories.
- Hospital provides detailed reports of drugs dispensed to ADAP – which allows filing for ADAP supplemental rebates.
- $\text{Cost} = 340\text{B price} + \text{Distribution System Costs} - \text{Rebates}$.
- Distribution System Costs may be billed as a dispensing fee and/or hospital costs (i.e., pharmacy staff, shipping).

Hybrid Model Purchase Costs

Example - \$100.00 AWP

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AWP Price (\$100.00)



Distribution and Dispensing
Costs (\$???.??)

AMP Price (\$79.00)

Minimum 15.1% discount (\$11.93)



Best Price adjustment (\$2.37)

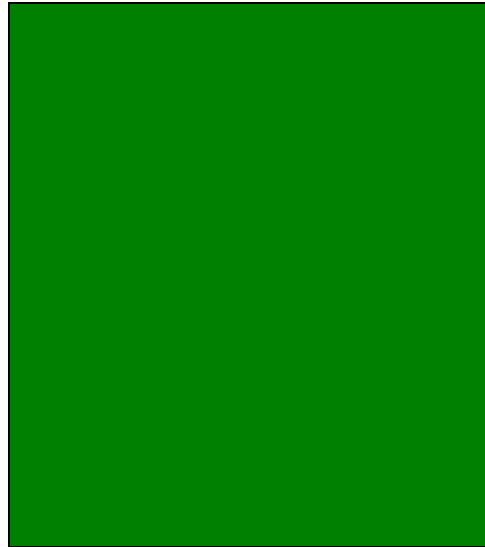


CPI adjustment (\$3.95)



340 B Price

ADAP Supplemental rebate (\$7.90)



340 B Entity Purchase Price (\$60.75)

ADAP Net Cost = 340B Price + Distribution & Dispensing - Rebate

Dual Systems

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- The Direct Purchase model is not able to coordinate benefits with private insurance or Medicare Part D plans.
- Since the implementation of Part D in 2006, many Direct Purchase ADAPs have had to develop a second component using a pharmacy network in order to wrap around and leverage private insurance and Medicare Part D.
- Very cost effective since ADAPs receive a full rebate for each prescription, while paying only a portion of the cost of the drug.

Generics

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- The cost of generic drugs may be significantly higher for rebate states than direct purchase states.
- The AMP of generics may be a much lower percentage of AWP than brand name drugs.
- This results in a very large profit margin to the pharmacy/wholesaler (spread between pharmacy discount rate and AMP), and a smaller rebate (11% of a smaller AMP).
- If there are multiple manufacturers of a generic, then a Federal Upper Limit (FUL) price is established which may reduce the reimbursement rate to pharmacies.

Generic Cost

Example - \$90.00 AWP

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AWP Price (\$90.00)



Distribution and Dispensing
Costs (\$??.??)

AMP Price (\$45.00)

Minimum 11.1% discount (\$4.95)



340 B Price (\$40.05)



Manufacturer cost/profit (\$40.05)

ADAP Net Cost = Manufacturer + Distribution & Dispensing

Pharmacy Network Costs – Generic Example

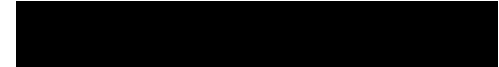
AWP - \$90.00

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Dispensing Fee (\$4.50)

Pharmacy Discount (\$10.80)



Wholesaler/Pharmacy cost/profit
(\$34.20)

Minimum 11% rebate (\$4.95)

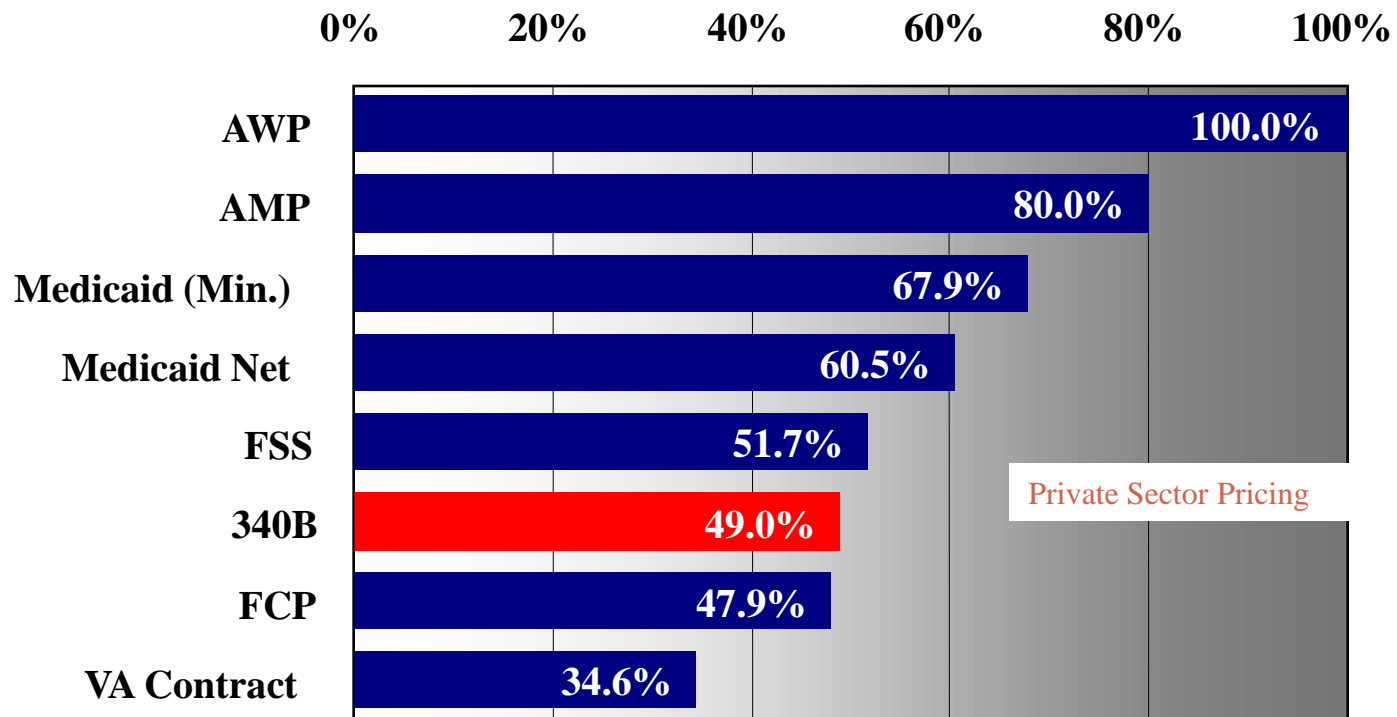


Manufacturer cost/profit (\$40.05)

ADAP Net Cost = \$78.75 (DF + Pharmacy + Wholesaler + Manufacturer)

Estimated Prices For Selected Public Purchasers, as Percent AWP
von Oehsen; *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*

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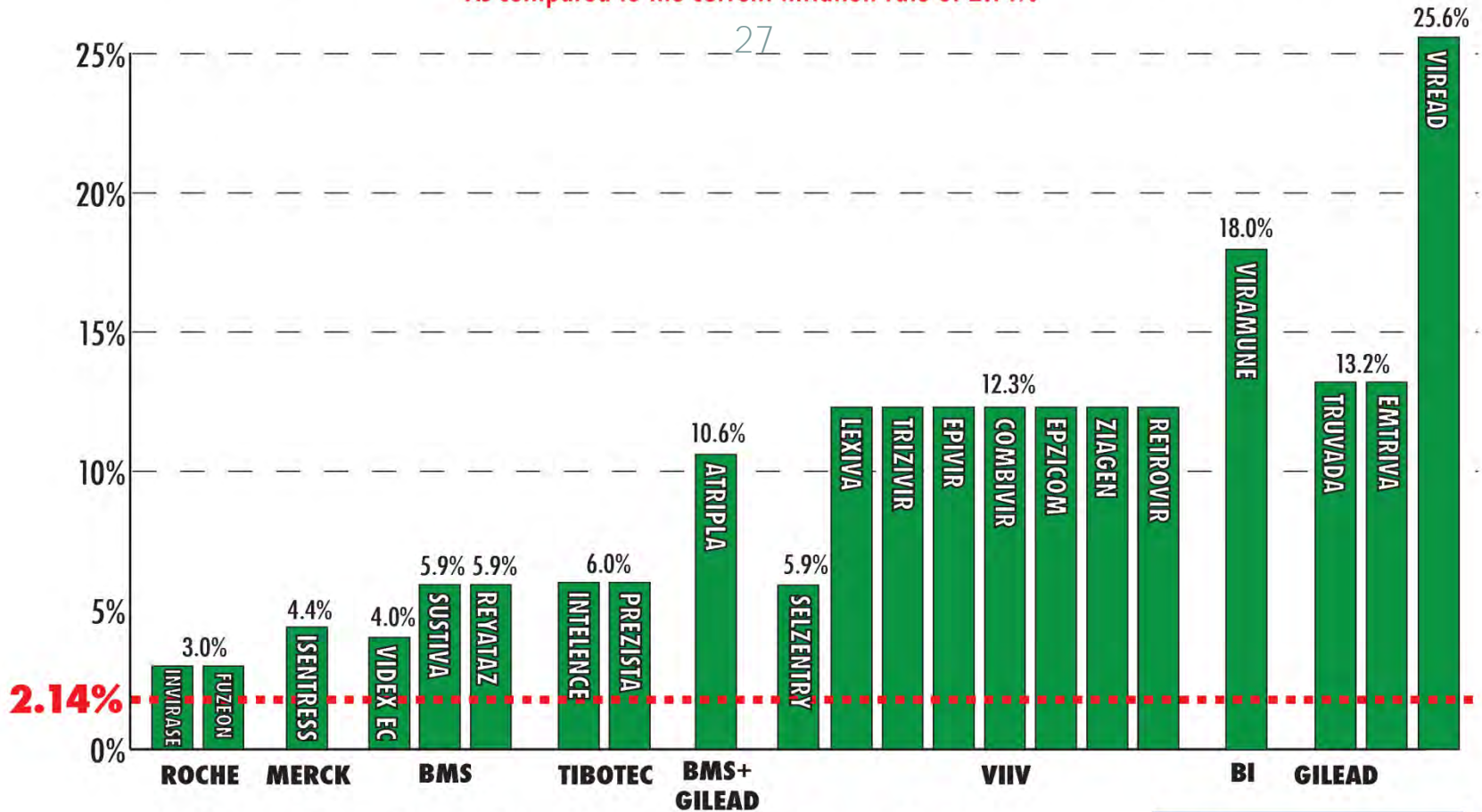
Health Care Reform

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- Health Care Reform increased the mandatory rebate that industry has to pay to public programs and likely will deepen the discount offered to 340B programs
 - Change from AMP – 15.1% to AMP – 23.1%
- It also requires a 50% discount on brand name drugs that are purchased during the coverage gap in Medicare Part D
- In anticipation of health care reform, prices have been rising dramatically
- Public programs are protected through the consumer price index penalty
 - What will the rising AMP do to discounts/rebates
 - What will it do to the discount rate in the coverage gap until the gap is effectively filled (2020)

HIV Drug Price Increase Rates in a 12-month period*, as of April, 2010

As compared to the current inflation rate of 2.14%



*Rate of increase is based on the 12-month period prior to the latest date of increase of each drug

FPC

Fair Pricing Coalition

What You Can Do

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- Learn about your ADAP and Medicaid pricing and distribution of HIV drugs
- Join ATAC and learn more about drug pricing
- Follow FPC efforts, sign on, make calls, write letters
- Support the ADAP Crisis Team by signing on and **supporting your own ADAP's effort on pricing**