

**PHARMACEUTICAL DISCOUNTS UNDER
FEDERAL LAW:
STATE PROGRAM OPPORTUNITIES**

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*National Conference of State Legislatures
5th Health Policy Conference*

Prescription Drugs: Cost and Coverage

November 16, 2001
Seattle, Washington

Topics

- Overview of State Experimentation in Drug Assistance Programs
- Background on U.S. Pharmaceutical Market
- Federal Drug Discount Programs
- Intersection of Federal and State Programs: Risks and Opportunities
- Analysis of State Drug Assistance Program Options

Overview of State Experimentation in Drug Assistance Programs

States are experimenting with a wide range of approaches:

- (1) State subsidy/rebate model
- (2) PBM outsourcing
- (3) Manufacturer ceiling prices
- (4) 1115 waiver expanded drug benefit
- (5) Mandatory pharmacy discounts
- (6) Buyers' clubs
- (7) Bulk purchasing
- (8) Using 340B covered entities

26 states have established drug assistance programs, primarily models (1) and (5); models (2), (3), (4), (6) and (7) are mostly in the implementation stage; model (8) has not been enacted

Background on U.S. Pharmaceutical Market

Three areas:

- Private sector pricing
- Public sector pricing
- Comparison of prices

Background on U.S. Pharmaceutical Market: Private Sector Pricing

- *Cash customers* - patient uses retail pharmacies; no discounts by either manufacturers or retail pharmacies (AWP)
- *Pharmacy benefit managers and insurers* - patient uses retail pharmacies; PBM or insurer negotiates discounts from manufacturers (rebates) and from participating pharmacies (AWP minus 20-40 percent)
- *Institutional purchasers* - patient does not use retail pharmacies; HMOs, hospitals, and other institutions negotiate discounts from manufacturers and avoid retail mark-up (AWP minus 20-40 percent)

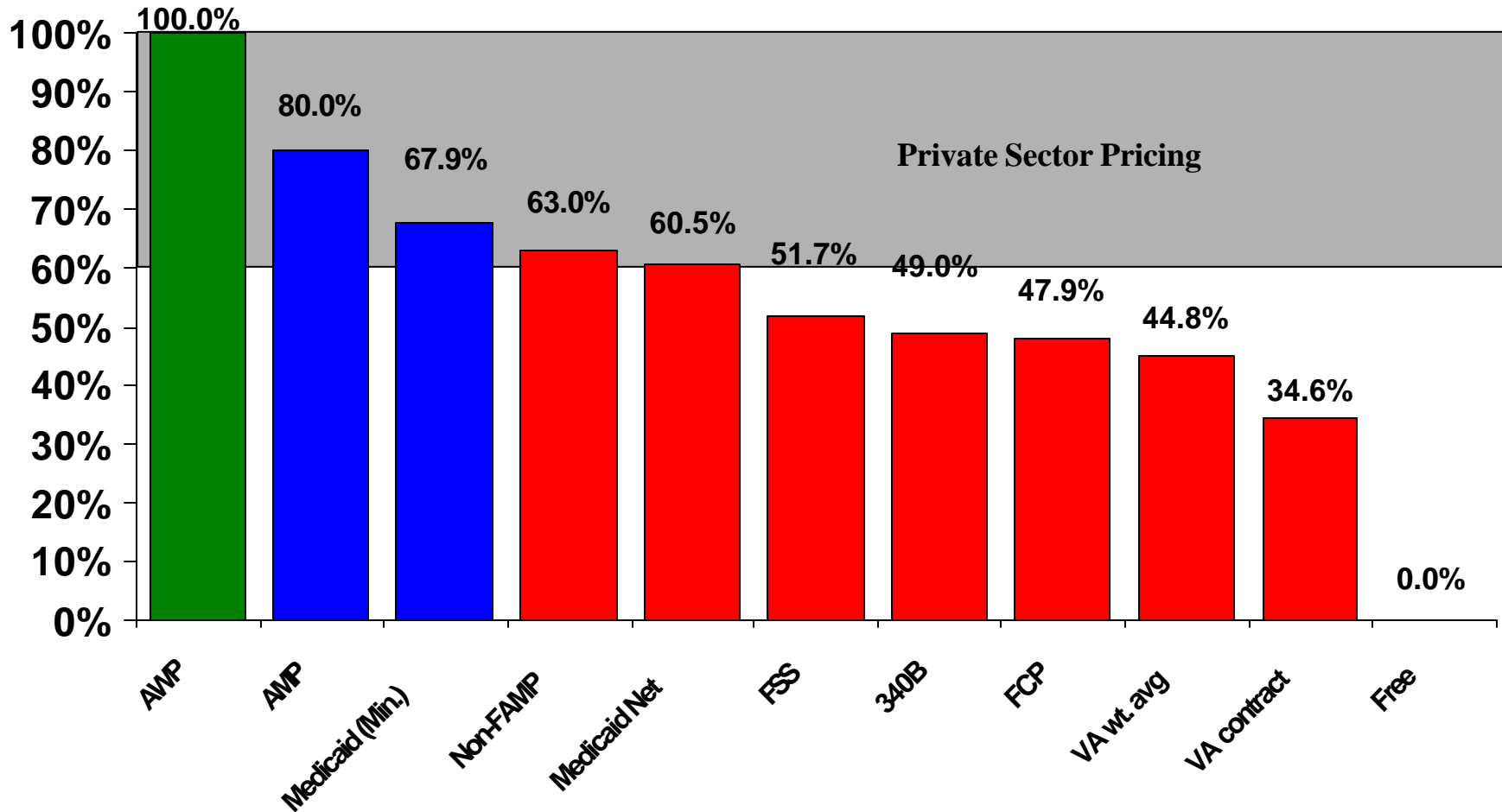
Background on U.S. Pharmaceutical Market: Public Sector Pricing

Federal Programs:

- ***Medicaid rebate program*** - jointly administered by federal and state government (AWP minus 40%)
- ***340B program*** - federal grantees (AWP minus 51%)
- ***Federal supply schedule*** - federal agencies, U.S. territories, Indian Tribes (AWP minus 48%)
- ***Big 4 Federal ceiling price*** - VA, DOD, PHS and Coast Guard (AWP minus 52%)
- ***VA contract*** - VA only (as low as AWP minus 65%)

State Programs - 26 programs, most of them are payor programs funded by state revenue, manufacturer rebates and patient co-pays

Background on U.S. Pharmaceutical Market: Comparison of Prices



Source: Data derived from [Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes](#), U.S. General Accounting Office, GAO/HEHS-00-118, August 2000 and [How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Market](#), Congressional Budget Office Papers, January 1996.

Background on U.S. Pharmaceutical Market: Comparison of Prices

Illustrative Example of Pricing for Brand Name Prescription Drugs

	Cash Customers (No 3 rd Party Payment at Point of Sale)	Insurers and PBMs	HMO ^c	Medicaid	Federal Supply Schedule
List price (AWP)	\$50				
Manufacturer's price (manufacturer to wholesaler or other entity)	\$40 (AWP-20%)	\$40 ^b (AWP-20%)	\$34 (AWP-33%)	\$40 ^b	\$24 (AWP-52%)
Acquisition price (wholesaler to pharmacy)	\$41	\$41	n/a ^a	\$41	n/a ^a
Retail price at pharmacy (total of amounts paid by customer and reimbursed by 3 rd party payer)	\$52 (AWP+ 4%)	\$46 ^b (AWP-13% +\$2.50)		\$41 +\$2.50	
Retail price, less typical manufacturer rebate	n/a ^a	\$30 to \$44 (5% to 35% rebate)		\$30 to \$37 (15.1% to 30% rebate)	
Ultimate (net) amount paid by final purchaser and/or consumer	\$52	\$30 to \$44	\$34 (avg.)	\$30 to \$37 \$34 (avg.)	\$24

a. n/a = not applicable b. without rebate c. This column refers only to HMOs that buy directly from manufacturers

Source: General Accounting Office

Federal Drug Discount Programs

- ***Medicaid rebate program*** - patient uses retail pharmacies; manufacturers and retail pharmacies are required to give discounts prescribed by law; Medicaid rebate for brand name drugs is “best price” or AMP minus 15.1 percent, whichever is lower, plus an additional rebate if prices rise faster than rate of inflation; California and Florida have established supplemental rebate programs using prior authorization for non-formulary drugs
- ***340B program*** - institutional purchaser model limited to safety net providers (community health centers, public hospitals, ADAPs, federally-funded clinics, etc); up front discount based on Medicaid rebate formula but 340B “covered entities” negotiate sub-ceiling prices

Federal Drug Discount Programs

- ***Federal ceiling price*** - institutional purchaser model limited to Big 4 (VA, DOD, PHS and Coast Guard); up front discount for brand name drugs is non-federal AMP (non-FAMP) minus 24 percent; Big 4 negotiate sub-ceiling prices
- ***Federal supply schedule*** - institutional purchaser model limited to federal agencies, U.S. territories, tribal governments, and others; “most favored customer” price is starting point in negotiations to obtain below-market prices
- ***VA contract*** - VA program for negotiating prices below FCP using national formulary for select drugs

Intersection of Federal and State Programs

Five points:

- Constitutional limits
- Medicaid “best price” exemption
- Duplicate discount and other problems
- Getting better than Medicaid “best price”
- Price versus access

Intersection of Federal and State Programs: Constitutional Limits

- *Commerce clause* - tying in-state prices to out-of-state prices is a violation if it has the practical effect of regulating out-of-state prices
- *Federal preemption* - explicit and implicit preemption
- *Maine litigation* - dispute over whether state can encourage discounts for non-Medicaid patients by conditioning Medicaid coverage of a company's drugs (via prior authorization) on providing those discounts
- *Vermont and Maine 1115 waivers* - expands Medicaid eligibility but only for drug benefit funded by manufacturer rebates and patient co-pays

Intersection of Federal and State Programs: Medicaid “Best Price” Exemption

- Federal law exempts from “best price” formula prices of drugs purchased through the five federal drug discount programs *and by “state pharmaceutical assistance programs”*
- What is a “state pharmaceutical assistance program”?
- HCFA Release No. 29 says “state-funded only”
- Does exemption cover outsourced programs? PBM rebates? Bulk purchasing with other state purchasers of drugs? County-funded programs?

Intersection of Federal and State Programs: Duplicate Discounts and Other Problems

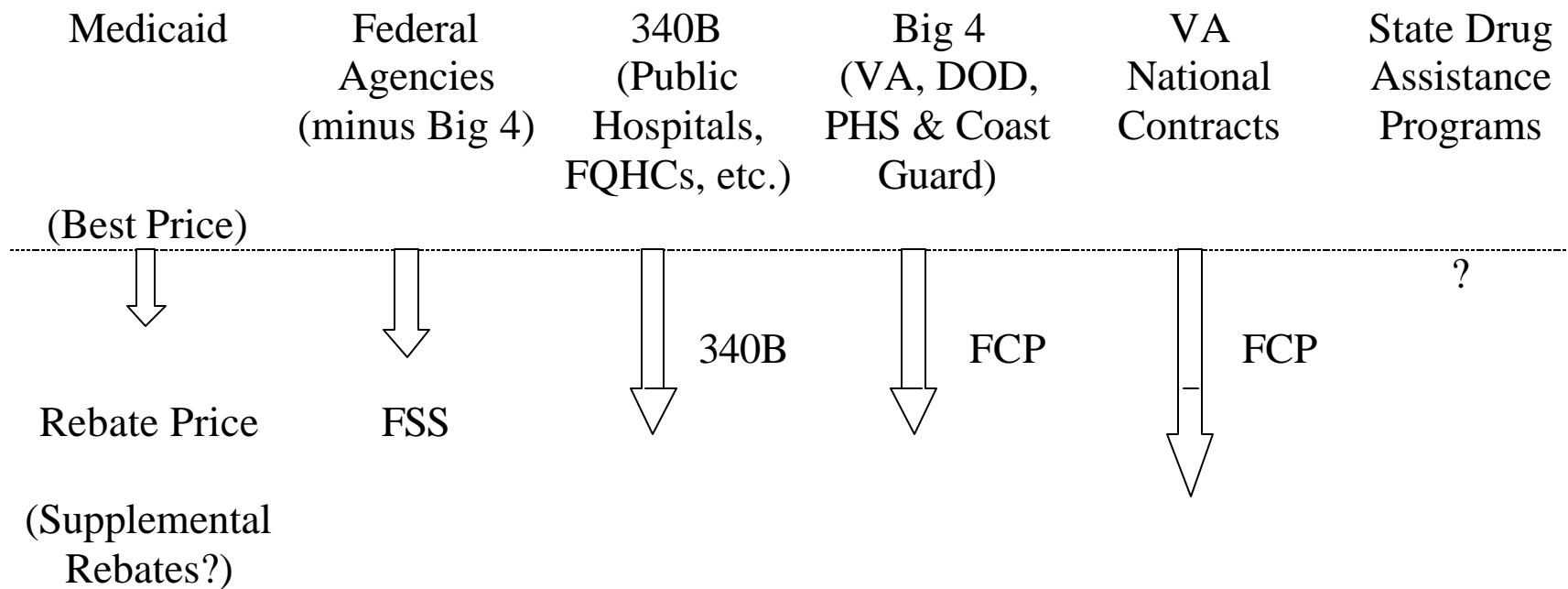
- ***Duplicate discounts*** - for example, if a client of a state subsidy/rebate program has a prescription filled at a 340B clinic
- ***Non-FAMP*** - state discounts may be included in Non-FAMP which increases manufacturer discounts to the Big 4
- ***Disqualification of 340B hospitals*** - 340B hospitals are prohibited from entering group purchasing arrangements, so including 340B hospitals in a state bulk purchasing program could disqualify them from 340B

Intersection of Federal and State Programs: Getting Better than Medicaid “Best Price”

How the VA does it:

- Element one: best price exemption
- Element two: mandatory discounts
- Element three: subceiling negotiation

Intersection of Federal and State Programs: Getting Better than Medicaid “Best Price”



Intersection of Federal and State Programs: Price Versus Access

- Subsidy/rebate model is more expensive than an institutional purchaser model because the former includes retail pharmacies that mark up cost of drugs and services
- Institutional purchasers are better able to move market share through use of formularies
- Exclusion of retail pharmacies may limit access although mail order and contract pharmacies may help

Analysis of State Drug Assistance Program Options

Model	Best Price Exemption?	Manufacturer Discounted Price?	Subceiling Negotiation?	Duplicate Discount Problem?	Non-FAMP Problem?	Access Issues?
(1) State Subsidy/Rebate Model	Yes	Yes, manufacturer sales price minus state rebate	No, unless state has sufficient leverage to negotiate supplemental rebates like California/Florida	Yes, if clients also receive discounted drugs from 340B providers	No, unless rebates are processed through wholesalers rather than paid directly to state	No assuming adequate participation of retail pharmacies
(2) PBM Outsourcing	Unclear if manufacturer rebates are based on PBM's business beyond just state program	Yes, manufacturer sales price minus PBM rebate	No	Same as above	Same as above	Same as above
(3) Manufacturer Ceiling Price Tied to Medicaid Best Price, FSS, etc.	Yes	Yes, assuming that the ceiling price is enforceable without violating U.S. Constitution (e.g., Maine case)	No, unless state has sufficient leverage to negotiate supplemental rebates like California/Florida	Same as above	Same as above	Same as above
(4) 1115 Waiver Expanded Benefit	Yes	Yes, Medicaid rebate discount	Same as above	Same as above	No	Same as above
(5) Pharmacy Discounts	No	No	No	No	No	Same as above
(6) Buyer's Club	No	Yes, plan's negotiated prices with manufacturers	No	Yes, if clients also receive discounted drugs from 340B providers	No	Same as above
(7) Bulk Purchasing	Unclear if purchasing cooperative includes entities other than state-funded drug assistance programs	Yes, cooperative's negotiated prices with manufacturers	No	Same as above	Yes, unless negotiated discounts take the form of rebates paid directly to state	Same as above
(8) Steering Clients to 340B Covered Entities	Yes	Yes, 340B ceiling price	Yes	Yes, if state also receives rebates for 340B-discounted drugs	Yes	Yes, unless mail order, contract pharmacy arrangements included