

Understanding Discounts Under Federal Law: State Program Opportunities

by

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Overview

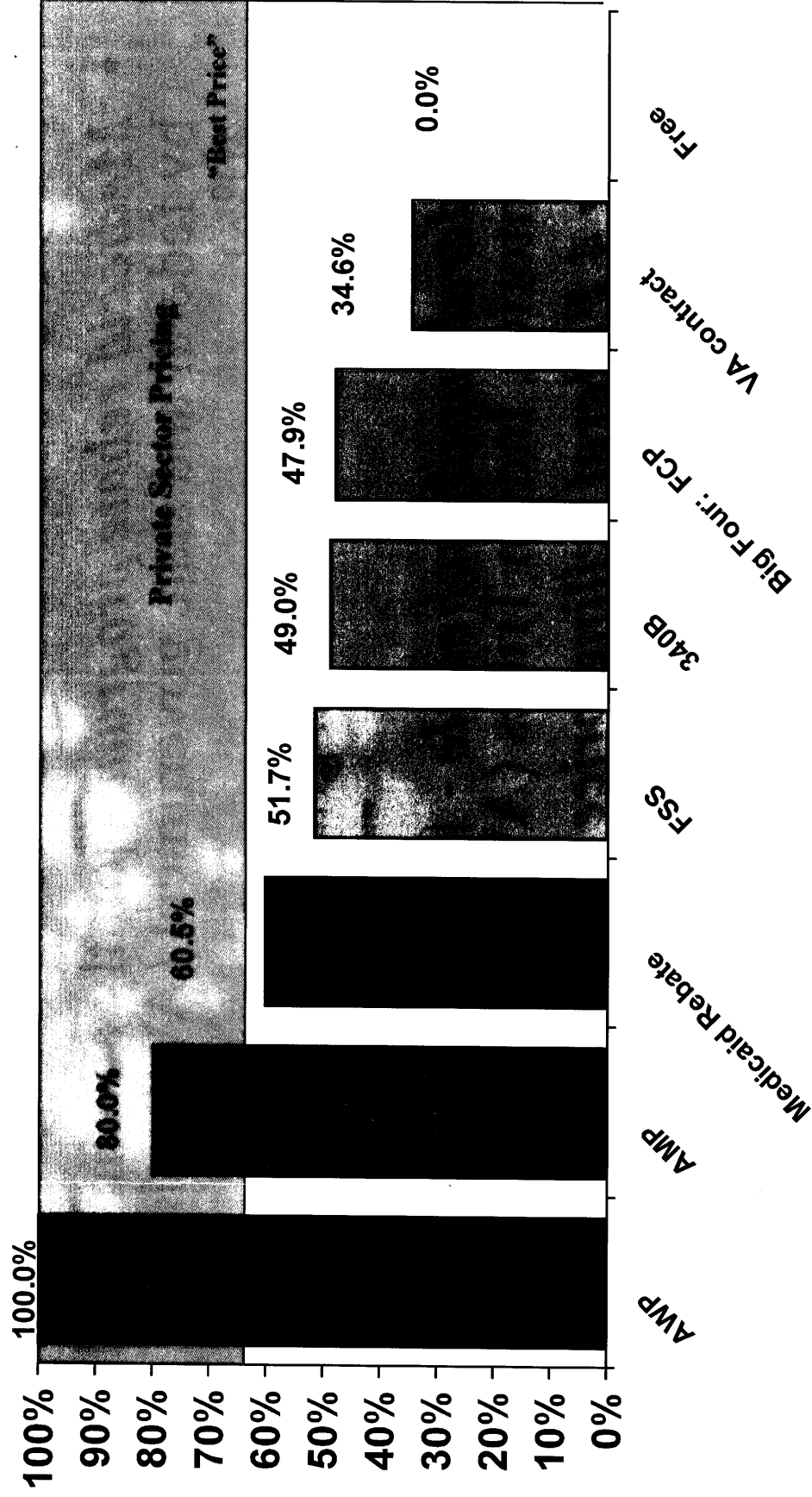
- Federal framework
- State models
- How states can save on drug costs
- Avoiding litigation
- Impact of Medicare prescription drug legislation

Existing Federal Framework:

Five Federal Drug Discount 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%)

Existing Federal Framework: Comparison of Federal 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.

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Existing Federal Framework: Medicaid Rebate Program

- Patient uses retail pharmacies participating in Medicaid
- Manufacturers and retail pharmacies are required to give discounts prescribed by law
- Manufacturer discounts are given to state Medicaid agencies in the form of rebates, since Medicaid is a payor, not a purchaser, of drugs
- 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, Florida, Michigan and other states have established supplemental rebate programs using preferred drug lists (PDLs) and prior authorization for non-PDL drugs

Existing Federal Framework: 340B Program

- Eligible entities include high Medicaid acute care hospitals owned by or under contract with state or local government; community health centers; ADAPs; family planning clinics; AIDS, TB and STD clinics; and other HRSA grantees
- Use of drugs limited to “patients” of 340B covered entity

Existing Federal Framework: 340B Program (cont'd)

- Manufacturer discounts are applied “up front” (340B entities are purchasers not payors) and are calculated using the Medicaid rebate formula; but 340B pricing is better because (1) sales do not involve retail pharmacies thereby avoiding retail mark-ups and (2) 340B providers regularly negotiate sub-ceiling prices
- Medicaid must be billed at acquisition cost to avoid duplicate discounts

Existing Federal Framework: Federal Ceiling Price

- Available only to the Big 4 (VA, DOD, PHS and Coast Guard)
- Manufacturer up front discount for brand name drugs is non-federal AMP (non-FAMP) minus 24 percent
- FCP discounts are comparable to 340B pricing except they extend to inpatient drug prices but not generic drugs
- Big 4 are permitted to negotiate sub-ceiling prices

Existing Federal Framework: Federal Supply Schedule

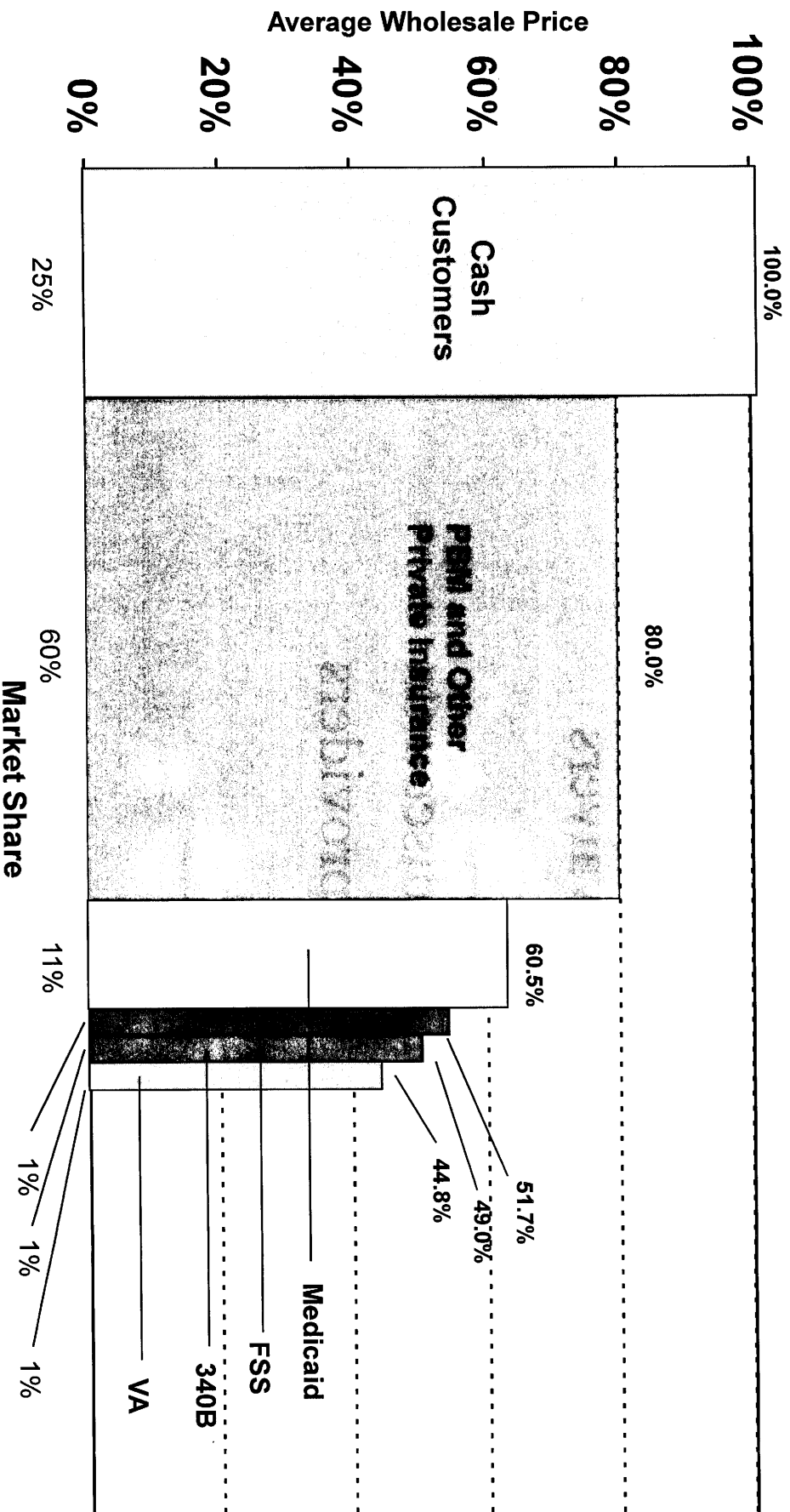
- Prior to enactment of FCP program, virtually all federal agencies, including the Big 4, purchased their drugs through FSS
- FSS pricing is only available to federal agencies, U.S. territories, tribal governments, and others
- In contrast to the FCP and 340B programs, FSS prices are negotiated rather than prescribed by law
- “Most favored customer” price is starting point in negotiations to obtain below-market prices

Existing Federal Framework:

VA Contract Program

- FCP program allows the Big 4 to negotiate sub-ceiling prices
- VA has been particularly successful using a national formulary and a competitive bidding process to select one or a limited number of contractors to supply drugs within specified therapeutic classes
- Because the VA is vertically integrated, compliance with the national formulary is easier to achieve
- According to a 1999 GAO report, these national contract prices were about 33 percent below FSS which is about 65 percent below AWP
- VA and DOD are collaborating on purchasing to increase volume

Existing Federal Framework: Market Share Comparison



* Chart is based on rough estimates

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State Models: Multiple Strategies Have Emerged

- State subsidy/rebate programs
- Pharmacy Plus/1115 waivers
- Supplemental rebates
- Mandatory pharmacy discounts
- Partnering with 340B providers
- Bulk purchasing
- Other initiatives

State Models: State Subsidy/Rebate Programs

- Most common state model – in 26 states according to the National Conference of State Legislatures
- Virtually all are for seniors only
- Similar to Medicaid drug rebate program except no federal funding; these programs are generally funded by state revenue, patient co-pays and deductibles, pharmacy discounts, and manufacturer rebates
- Best price exemption allows below-market pricing from manufacturers through the payment of rebates
- States struggling to maintain level funding

State Models: Pharmacy Plus/1115 Waivers

- States can apply for 1115 waivers to expand Medicaid eligibility for pharmacy benefit only
- CMS has developed a model 1115 waiver application called “Pharmacy Plus” to simplify the application process
- Creates two funding sources for states: manufacturer Medicaid rebates and federal matching funds
- Another benefit is the best price exemption which allows states to negotiate supplemental rebates without affecting a manufacturer’s Medicaid rebate obligation
- Many states are seeking to refinance their senior drug subsidy programs through Pharmacy Plus

State Models: Supplemental Rebates

- Manufacturers pay a second rebate to have their drugs included on the state's preferred drug list (PDL) and to avoid prior authorization requirements for non-PDL drugs
- States can use this approach to negotiate supplemental rebates for drugs purchased for Medicaid recipients (CA, FL), non-Medicaid patients (ME), or both (MI)
- Pharmaceutical industry is fighting this model vigorously in legislatures, governors' offices, and the courts

State Models: Mandatory Pharmacy Discounts

- Pharmacies are prohibited from charging above specified prices
- For example, California prohibits pharmacies from charging Medicare beneficiaries more than Medi-Cal prices
- Savings are relatively small and come from pharmacies rather than manufacturers

State Models: Partnering with 340B Providers

- Every state has 340B providers, especially community health centers, disproportionate share hospitals and state and local health departments
- Texas recently partnered with UTMHB to give the state correctional population access to 340B pricing, saving over \$10 million per year

State Models: Partnering with 340B Providers (cont'd)

- Utah secured a federal waiver to enter into a sole source contract with University of Utah's home care division to serve hemophiliacs on Medicaid requiring factor product
- Other strategies include: paying enhanced dispensing fees or providing other incentives for 340B providers to enroll into the 340B program and to bill Medicaid at acquisition cost, and encouraging Medicaid managed care organizations to buy through 340B

State Models: Bulk Purchasing

- States purchase or pay for drugs through different agencies: Medicaid, corrections, health departments, state employees, mental health facilities, substance abuse facilities, schools, etc.
- Bulk purchasing concept is to consolidate purchasing using a common PDL to reduce prices

State Models: Bulk Purchasing (cont'd)

- Smaller states are exploring bulk purchasing across states lines in order to increase volume; e.g. Northeast Legislative Association on Prescription Drug Prices and West Virginia state employee program
- South Carolina, Vermont and Wisconsin are attempting to purchase jointly with Michigan using Michigan's PDL in order to negotiate supplemental rebates for Medicaid

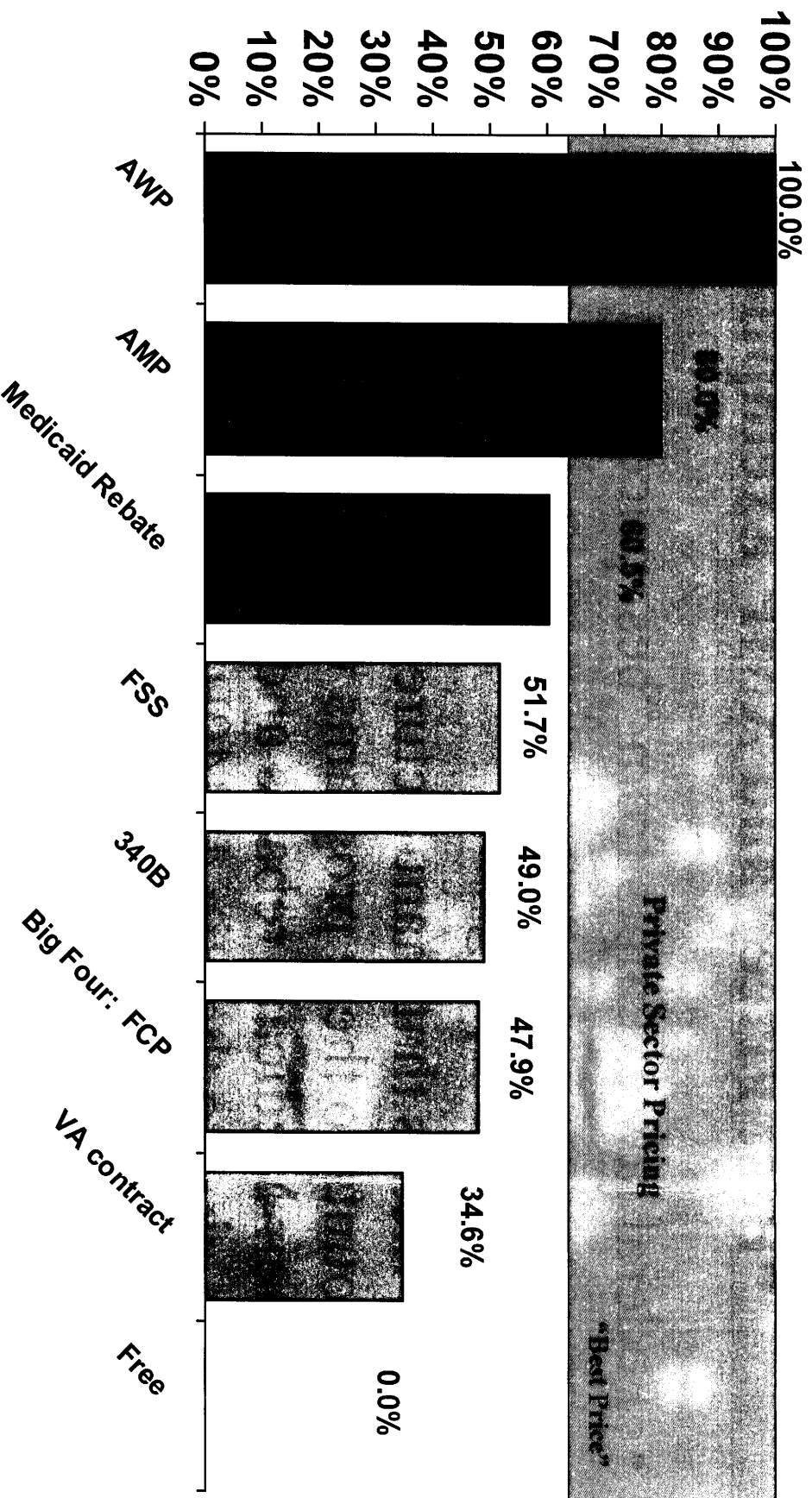
State Models: Other Initiatives

- Formation of buyer's clubs, similar to the Medicaid card that CMS is advocating
- Outsourcing to PBMs
- Establishing “clearinghouses” to facilitate patient and provider access to manufacturer patient assistance programs
- Tax credits
- Regulation of PBMs and drug company “detailers”

How States Can Save: Some Models Are Better Than Others

- Price comparison chart revisited
- Getting better than “best price”
- How the VA does it
- Application to states
- Bulk purchasing and the need for two-tiered pricing

State Savings: Price Comparison Revisited



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.

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Existing Federal Framework: Medicaid

“Best Price” and AMP Exemptions

- Federal law exempts from “best price” and AMP prices charged by manufacturers to the five federal drug discount programs
- This means that manufacturers can give deep discounts to these programs without affecting the size of their Medicaid rebates and the discounts that they must give to the Big 4, 340B covered entities, etc.

Existing Federal Framework: Medicaid “Best Price” and AMP Exemptions (cont’d)

- By contrast, manufacturers have a disincentive to give deep discounts to all other purchases because it will lower their AMP and, for brand name drugs, their best price
- Disincentive is stronger for brand name manufacturers because best price changes are more costly than AMP changes (averages change more slowly)

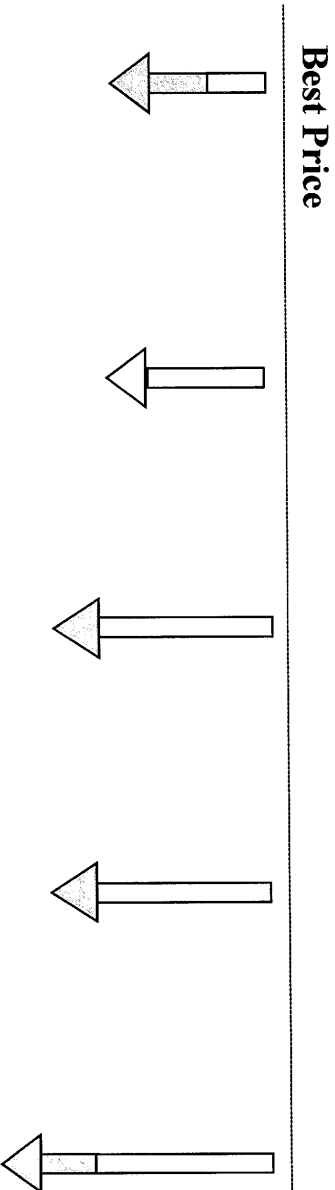
State Savings: Getting Better Than “Best Price”

How the VA does it:

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

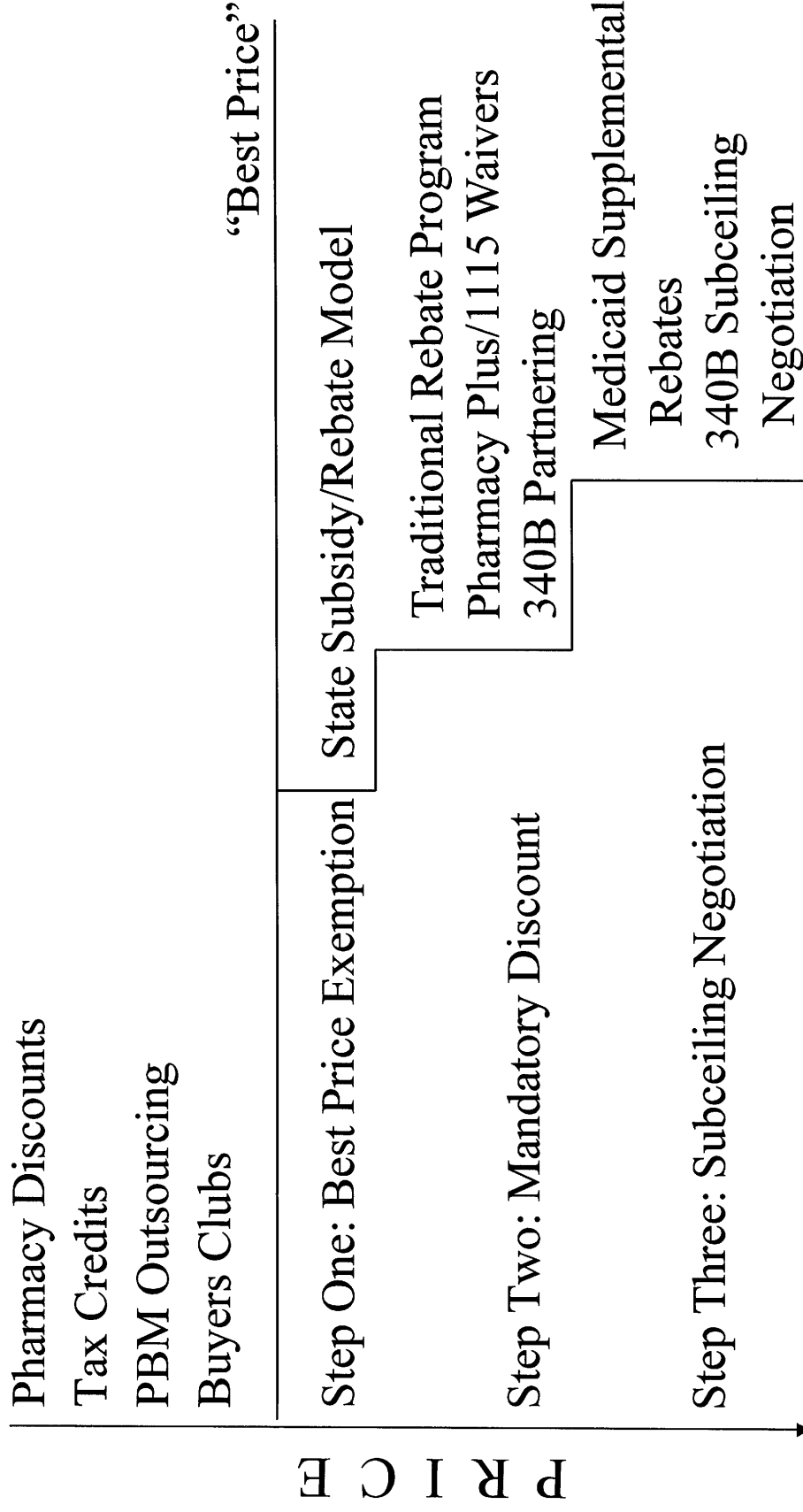
State Savings: Getting Better Than “Best Price”

Medicaid (with Supplemental Rebates)	Federal Agencies (minus Big 4)	340B (Public Hospitals, FQHCs, etc.)	Big 4 (VA, DOD, PHS & Coast Guard)	VA National Contracts
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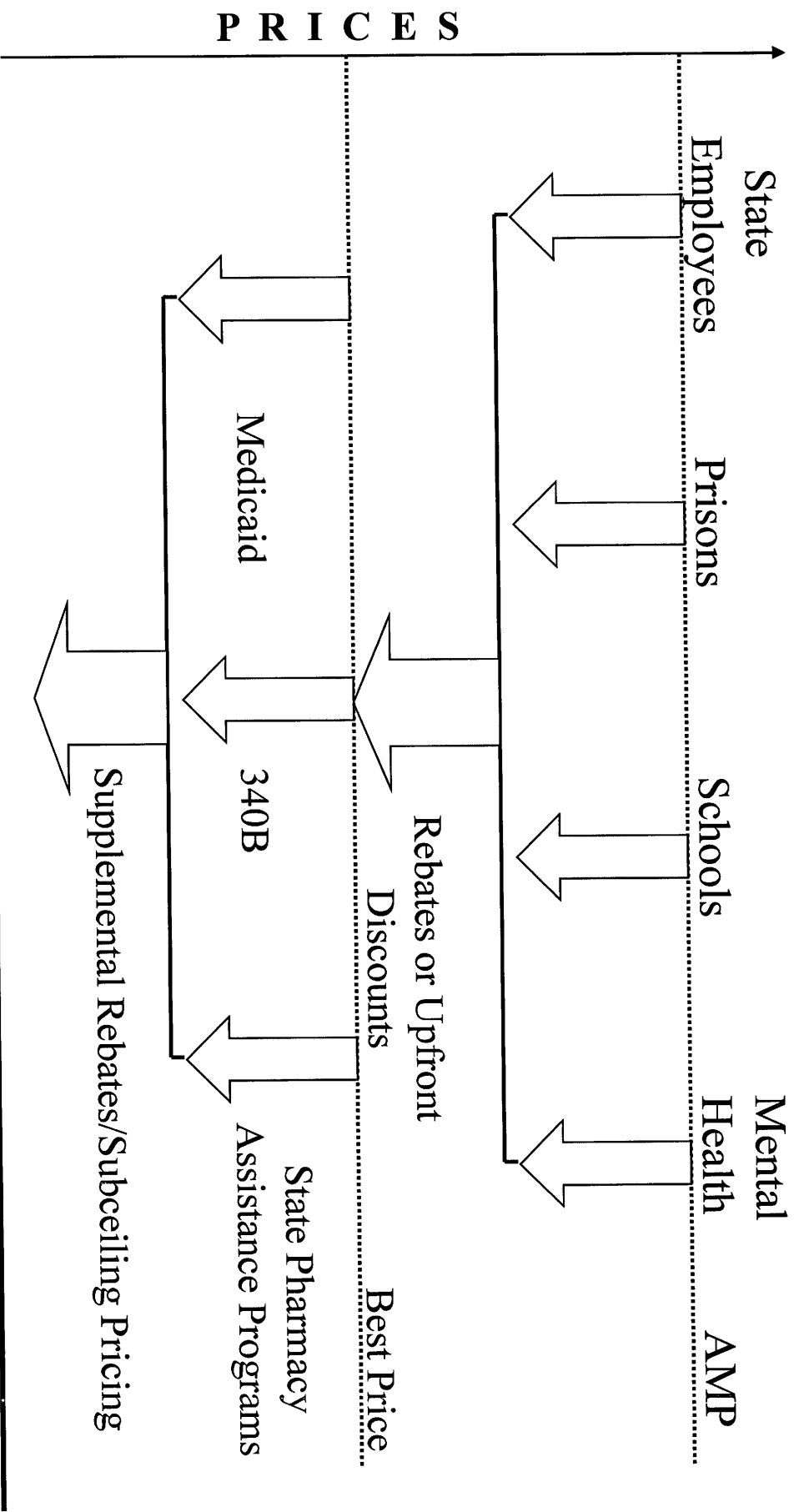
Shaded area = supplemental rebates or subceiling discounts

State Savings: How Do the Models Compare?



“Best Price”

State Savings: Bulk Purchasing and Need for 2-Tiered Pricing



Avoiding the Costs and Delays Associated with Litigation

- Legal issues to be aware of
- Lessons learned

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Avoiding Litigation: Issues to Be Aware Of

- *Commerce Clause* – Tying in-state prices to out-of-state prices is problematic if it has the practical effect of regulating out-of-state prices
- *Supremacy Clause/Preemption* – State programs may not conflict with federal law, especially the federal requirement that Medicaid State Plan’s be within the “best interests” of Medicaid recipients

Avoiding Litigation: Issues to Be Aware Of

(cont'd)

- *Administrative procedures (federal & state)* – State programs must follow federal and state procedural requirements and may not act in an arbitrary and capricious manner
- *Confidentiality of pricing* – AMP, “best price” and other information disclosed by manufacturers in connection with the Medicaid rebate program are confidential

Avoiding Litigation: Lessons Learned

- *No formularies* – Covered outpatient drugs may not be excluded from Medicaid coverage, although their coverage may be conditioned upon prior authorization
- *Observe Medicaid's “best interest”* – State Plan amendments should be drafted with sufficient detail to allow CMS to evaluate whether they are within Medicaid recipients’ “best interests”
- *Follow federal/state procedures* – Hearings, notice-and-comment, waiting periods and other procedural requirements must be observed

Avoiding Litigation: Lessons Learned (cont'd)

- *Keep pricing confidential* – Aggregate pricing data, use price ranking systems, convene meetings behind closed doors, and use other techniques to keep prices out of the public domain
- *1115 waivers need state “payment”* – Pharmacy-only 1115 expansion waivers may not be approved by CMS if the state makes no payment or only nominal payment for the drugs
- *No new Medicaid “best price”* – Mandating that manufacturers give FSS or Medicaid rebate discounts will likely increase the rebates that manufacturers must pay to other states in violation of Commerce Clause

Impact of Medicare Prescription Drug Legislation

- Predicted effects on market
- Market share charts revisited

Medicare Drug Benefit: Predicted Effects on Market

- Medicare PBM contractors will negotiate lower prices for seniors, especially because the prices will be exempt from Medicaid best price and AMP calculations
- Manufacturers will raise prices for other segments of the market which will increase best price and AMP

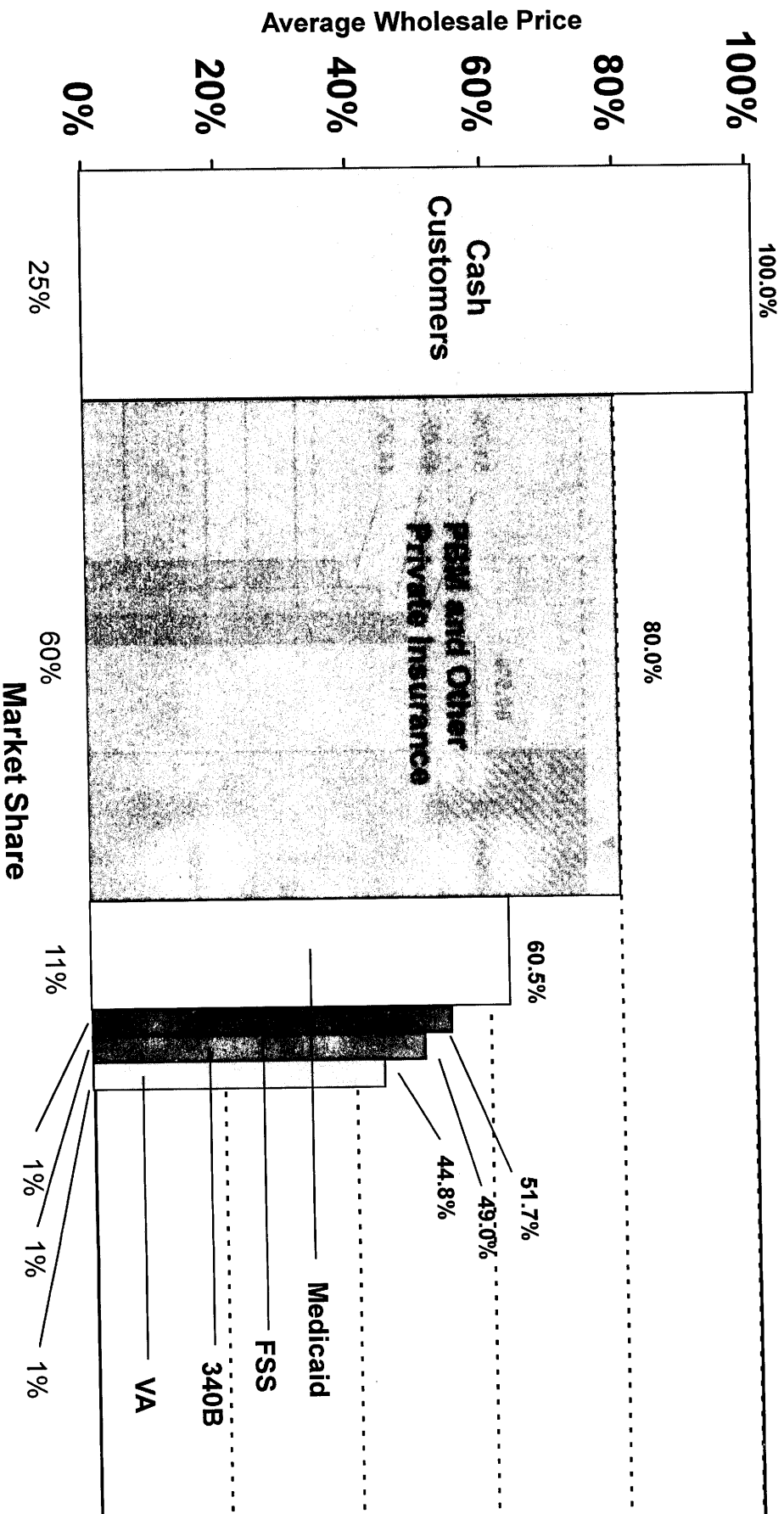
Medicare Drug Benefit: Predicted Effects on Market (cont'd)

- For Medicaid, 340B and FCP programs, innovator drug prices will not increase much (except for new drugs) due to CPI-U restriction
- Sectors hurt the most: cash customers, non-senior private insurance and FSS

Medicare Drug Benefit: Implications for States

- Private market strategies used by states to lower drug costs will be even less effective
- States' use of supplemental rebates, 340B partnerships, 1115 waivers and bulk purchasing will be more critical
- State pharmacy assistance programs for seniors will be phased out or redirected at subsidizing co-pays, deductibles and gaps in coverage

Medicare Drug Benefit: Comparison of Prices in Current Market *

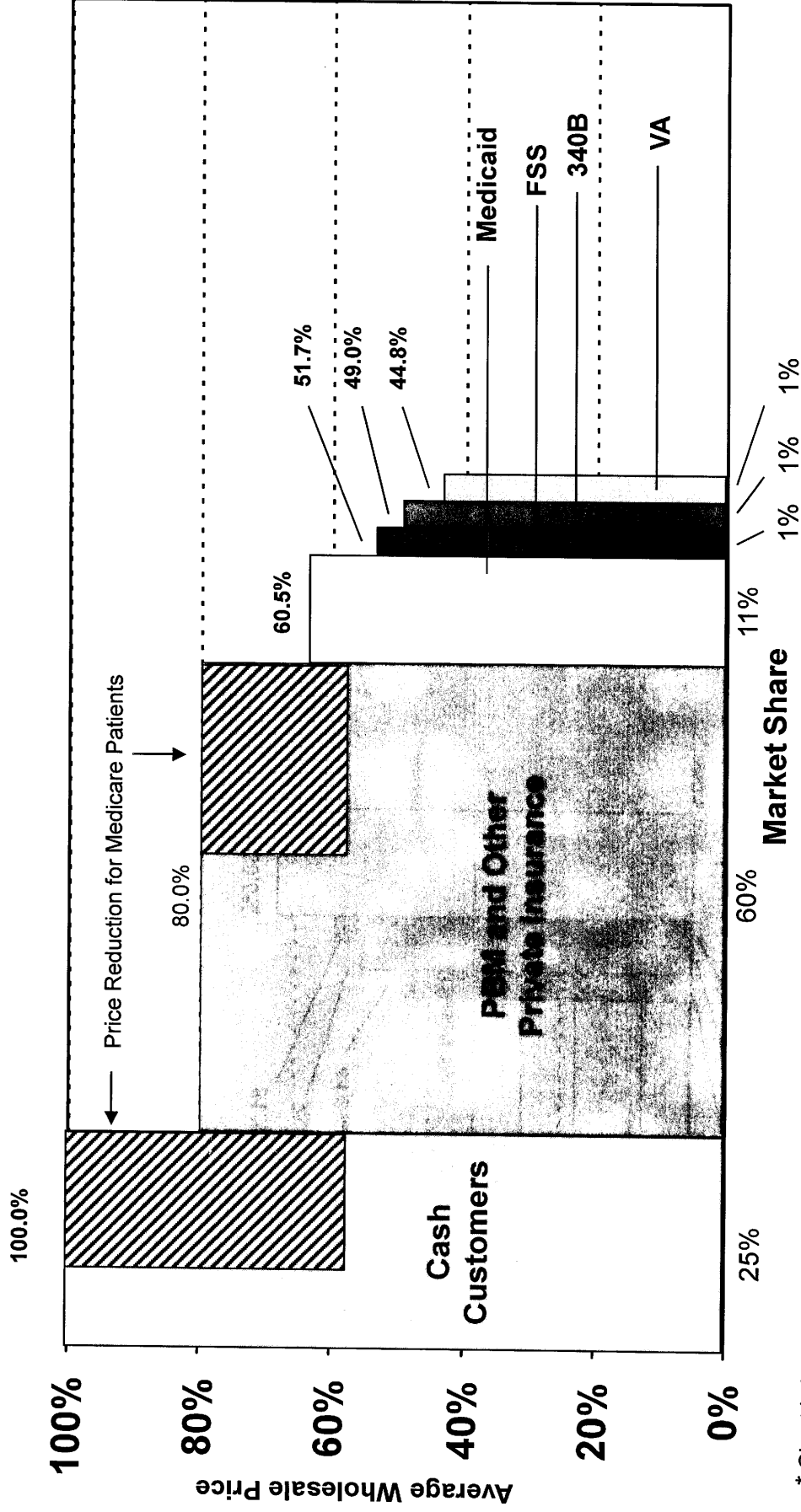


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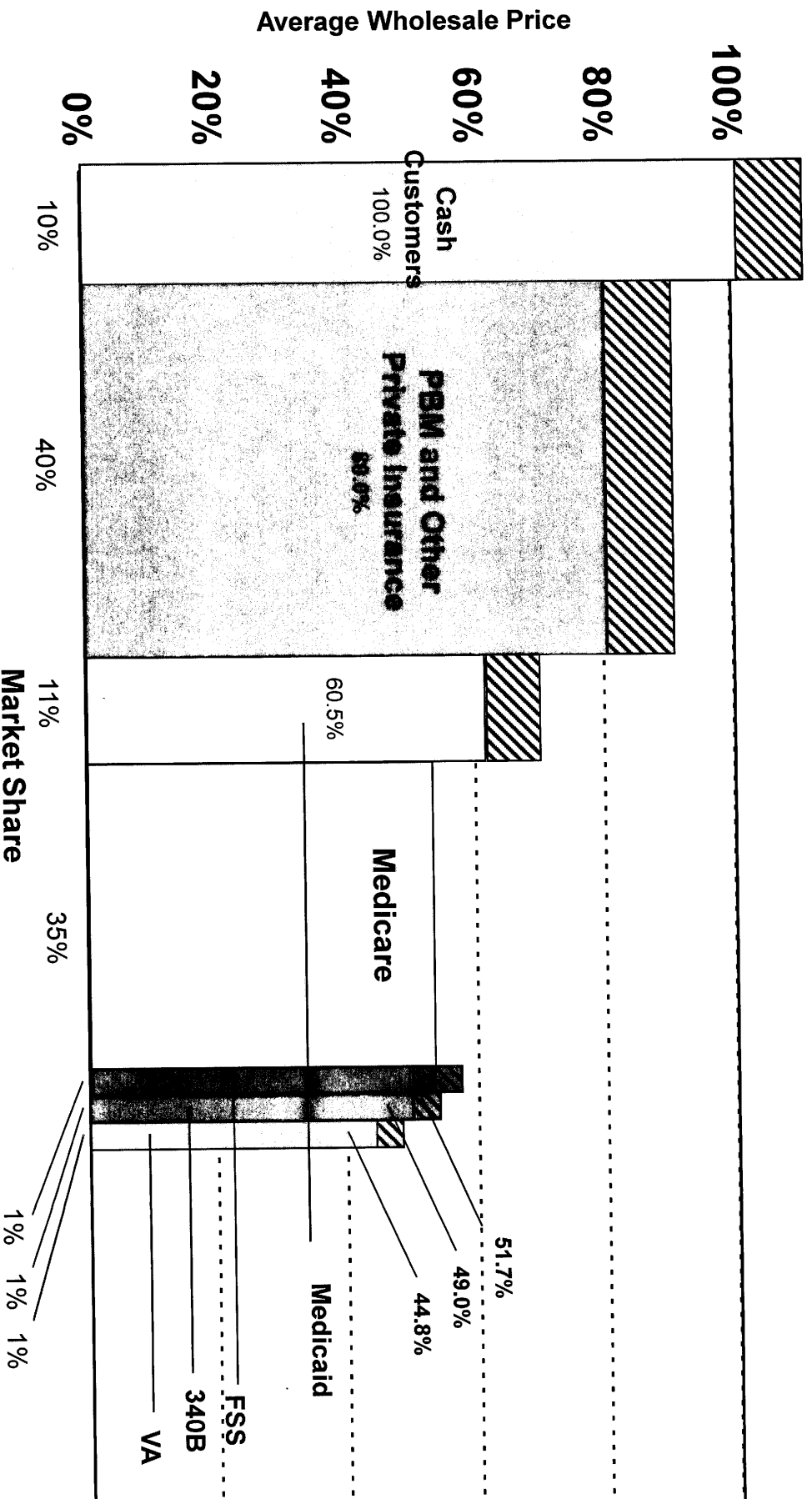
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Medicare Drug Benefit: Possible Impact Of Lower Prices*



* Chart is based on rough estimates

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