Prescription Drug Pricing

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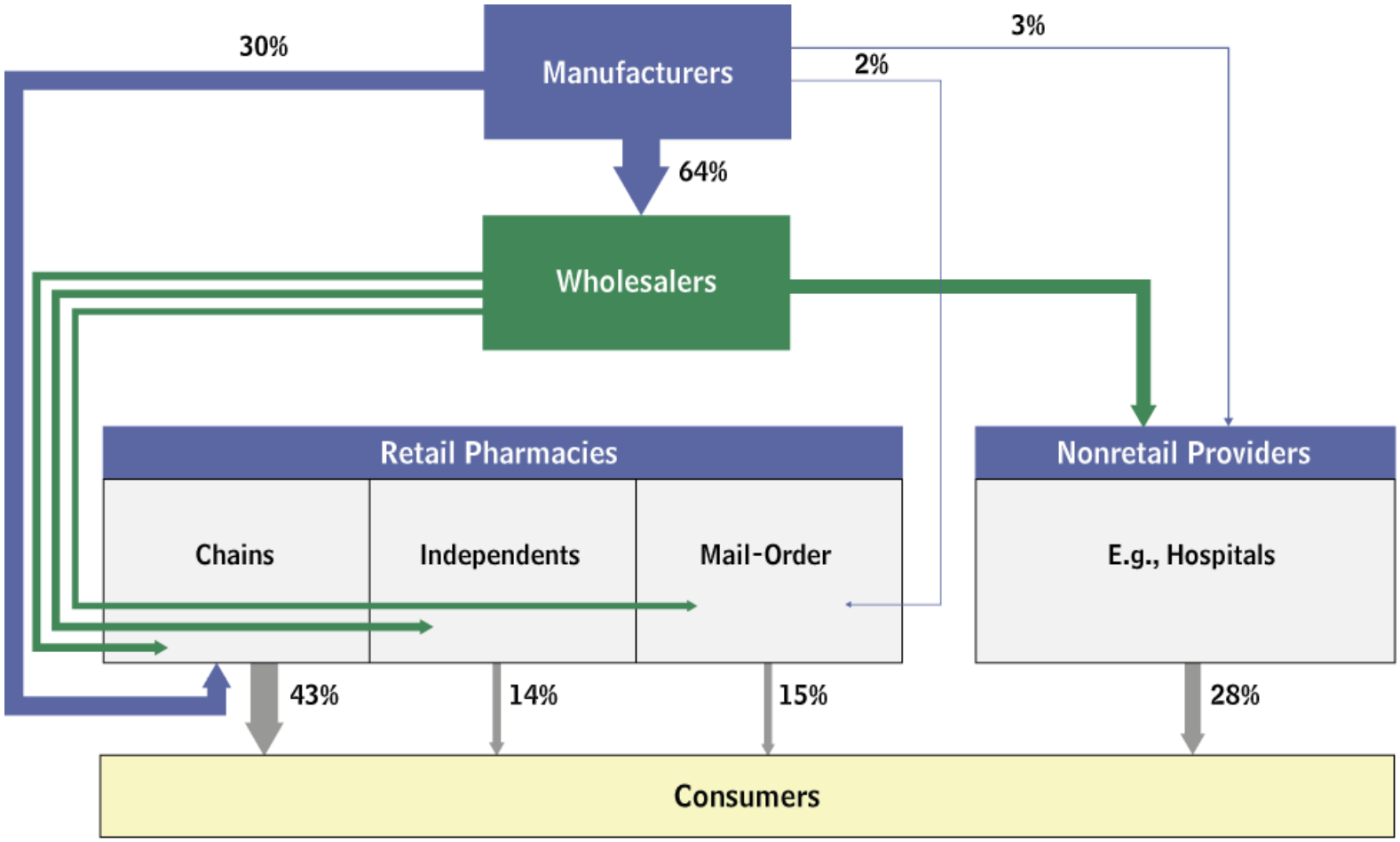
Manufacturers' Shipments of Drugs Through the Supply Chain



Key Prices in the Pharmaceutical Market

- **Average Manufacturer Price (AMP): the average price paid to manufacturers for drugs distributed through retail pharmacies.**
- **Wholesale Acquisition Cost (WAC): A publicly available list price that approximates what retail pharmacies pay wholesalers for single source drugs.**
- **Average Wholesale Price (AWP): A publicly available list price used as the basis for setting payment rates to pharmacies.**

Factors that Affect Competition and Pricing of Brand-Name Drugs

- Is the brand-name drug protected by a patent that prevents generic entry?
- Are there therapeutic substitutes?
- Age of the drug – has it been replaced by newer improved therapies?

Drug Prices Also Affected by Purchaser's Bargaining Power

- Purchasers able to guide utilization between therapeutically similar brand-name drugs tend to pay lower prices
- Manufacturers may pay a rebate in exchange for preferred placement on a formulary
- A formulary is a tiered list of drugs approved for coverage under a drug benefit

Results from CBO Paper on Pricing of Single-Source Brand-Name Drugs

For a set of top selling single-source brand-name drugs and their close competitors CBO found:

- Conventional pharmacies paid on average 83 percent of the AWP
- Mail Order pharmacies paid on average no more than 78% of the AWP
- Other types of non-federal purchasers paid no more than 74% of the AWP

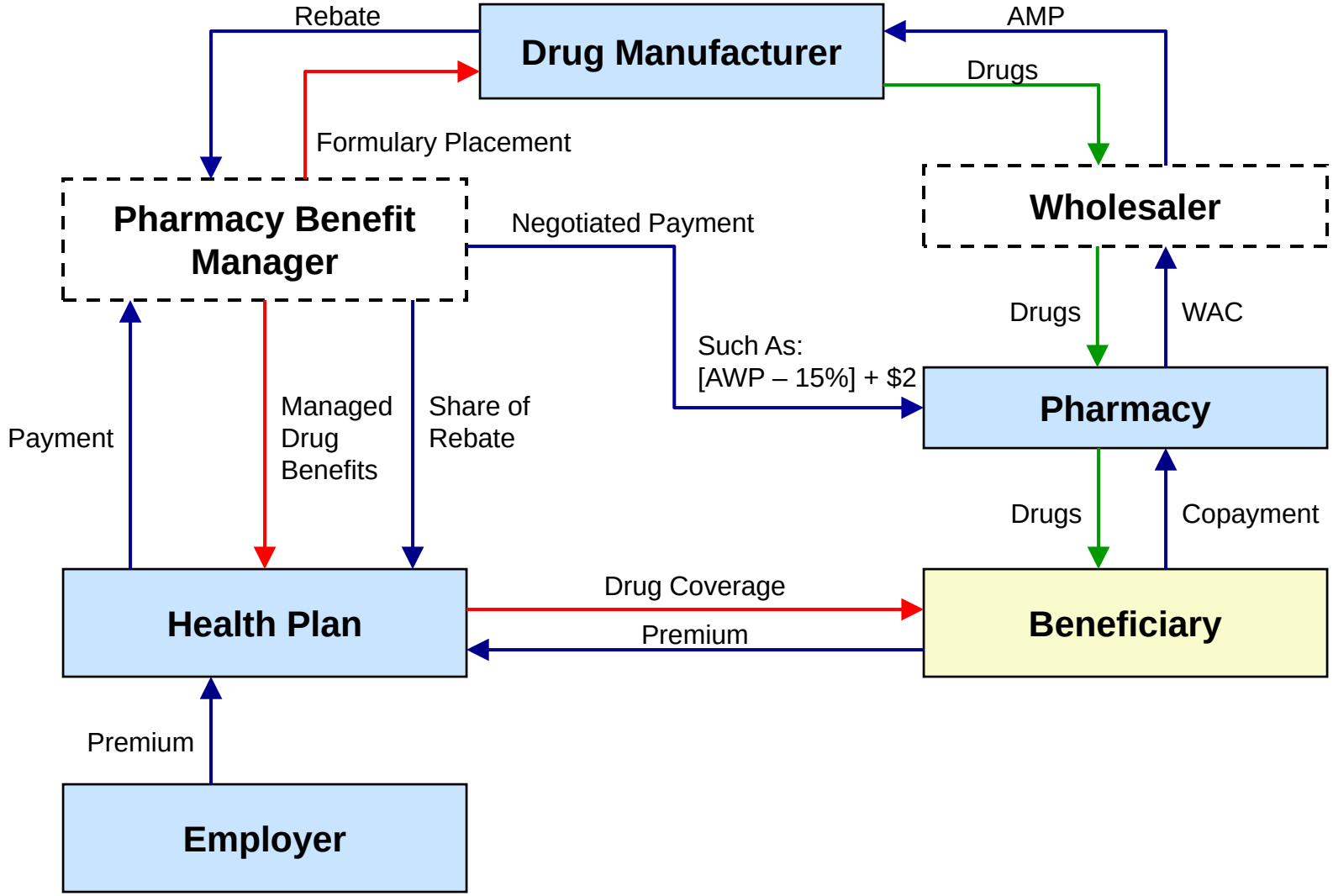
Generic Drugs

- List prices (WAC, AWP) not good predictors of acquisition cost of generic drugs
- Pharmacies can negotiate over generic prices – choose which generic to stock
- Generic drugs make up about half of all prescriptions dispensed; the mark-up on generic prescriptions is an important source of revenue for pharmacies

Pharmacy Benefit Managers (PBMs)

- Manage drug benefits on behalf of health plans by performing:
  claims administration, reviews of drug utilization, and formulary management.
- Negotiate with manufacturers for rebates based on formulary placement
- Negotiate with a network of retail pharmacies over payment rates

Flow of Funds for Single-Source Brand-Name Drugs Purchased at a Retail Pharmacy and Managed by a Pharmacy Benefit Manager for an Employer's Health Plan



Pricing Approaches of Federal Programs

Statutorily Defined Pricing	Statutorily Defined Pricing Plus Negotiations	Negotiations through Private Plans
Medicare Part B	VA	Medicare Part D
	Medicaid	

Medicare Part B

- Drug spending under Medicare Part B is about $10 billion per year.
- Most Medicare Part B drugs are administered in a physician's office.
- Medicare Part B usually pays the average sales price (ASP) plus 6%. The ASP is the average price paid to the manufacturer across all distribution channels.

Department of Veterans Affairs

- VA negotiates Federal Supply Schedule Prices (generally no higher than the most-favored commercial customer price). FSS prices are available to other direct federal purchasers.
- VA pays no more than the federal ceiling price (a statutory price).
- Based on the use of a formulary, VA negotiates additional discounts.

Medicaid

- The Federal Government paid $9 billion for prescription drugs under Medicaid in 2007 (net of rebates).
- State Medicaid Agencies pay pharmacies for brand-name drugs based on a formula such as AWP – 12% plus a dispensing fee. (Formula varies by state).
- States pay for generic drugs based on the federal upper limit or a state Maximum Allowable Cost plus a dispensing fee.

Medicaid

- Manufacturers are required to pay a statutory rebate on all drugs purchased through Medicaid's FFS program
- Medicaid's rebate on brand-name drugs is equal to the larger of: 15.1% of the AMP, or the difference between the AMP and the manufacturer's best price
- An additional rebate is paid if a brand-name drug's price rises faster than the CPI-U.
- State Medicaid agencies may use preferred drug lists to negotiate for supplemental rebates

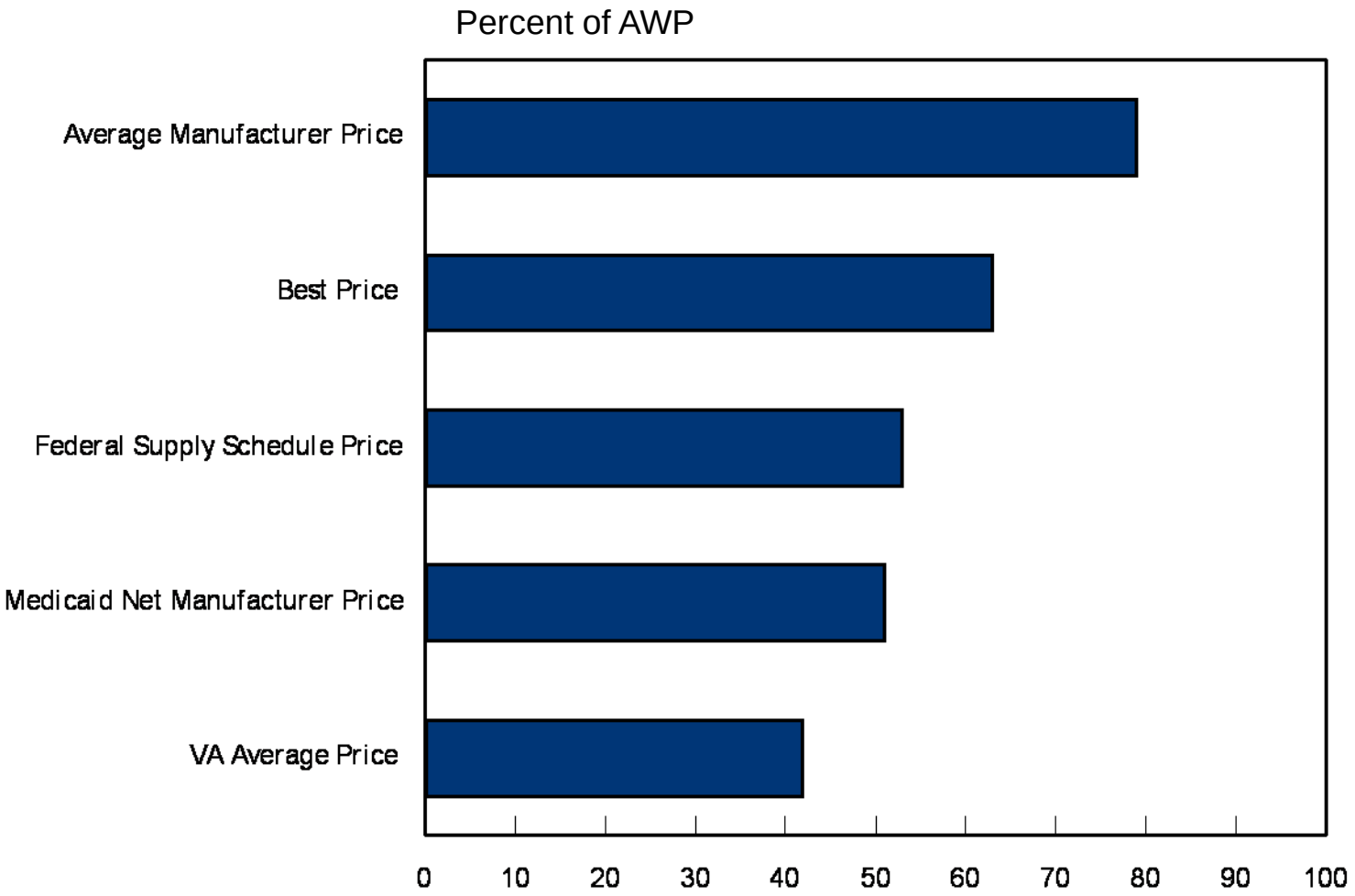
Medicare Part D

- In 2008, about 25 million Medicare beneficiaries were enrolled in Part D. CBO estimates that total federal spending for the Part D benefit will be $49 billion in 2009.
- The benefit is delivered through stand-alone prescription drug plans (PDPs) and Medicare Advantage drug plans (MA-PDs).
- Overall the federal government subsidizes about 75% of the cost of the standard benefit and beneficiary premiums pay for the remainder.

Medicare Part D

- PDPs and MA-PDs establish formularies and negotiate prices with drug manufacturers and retail pharmacies
- Drug manufacturers pay rebates to PDPs and MA-PDs based on formulary placement.
- PDPs and MA-PDs compete for enrollees based on premiums, formularies and cost-sharing.
- MMA “noninterference” clause prohibits HHS from negotiating drug prices.

Estimated Prices Paid to Manufacturers for Brand-Name Drugs, 2003



Source: CBO based on data from IMS Health, the Centers for Medicare & Medicaid Services, and the Department of Veterans Affairs.

Follow-on Biologics

- Total annual spending on biological products in the U.S. is over $40 billion.
- About 75% of that spending is for biological products that could lose patent protection over the next 10 years.
- For brand-name drugs approved under the Food Drug and Cosmetic Act, an abbreviated pathway exists to bring generic drugs to market following patent expiration.
- No such abbreviated pathway exists for biologics approved under the Public Health Service Act.

Follow-on Biologics

- CBO has estimated that introducing an abbreviated approval pathway for follow-on biologics could save $8.1 billion in mandatory spending over the 2010 to 2019 period.
- Since the program would take time to implement, most of those savings would occur during the last 5 years of that period.
- Many complex issues need to be addressed in designing such a pathway.

Related CBO Products

- *Prescription Drug Pricing in the Private Sector*, January 2007.
- *Prices for Brand-name Drugs Under Selected Federal Programs*, June 2005
- *Budget Options, Volume 1: Health Care*, December 2008
- Cost Estimate for S.1695, *Biologics Price Competition and Innovation Act of 2007*

CBO Budget Analysts Prescription Drugs

- Medicare Part D – Rebecca Yip & Ellen Werble
- Medicaid Drugs – Andrea Noda & Rebecca Yip
- Follow-on Biologics, FDA – Julia Christensen & Ellen Werble
- Medicare Part B – Lara Robillard
- Kate Massey and Tom Bradley – Unit Chiefs