Prescription Drug Pricing

Anna Cook
Julie Somers
Julia Christensen

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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- Age of the drug – has it been replaced by newer improved therapies?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

1. **Drug Manufacturer**
   - AMP
   - Drugs

2. **Wholesaler**
   - WAC
   - Drugs

3. **Pharmacy**
   - Such As: [AWP – 15%] + $2
   - Drugs
   - Copayment

4. **Pharmacy Benefit Manager**
   - Formulary Placement
   - Negotiated Payment
   - Managed Drug Benefits
   - Share of Rebate

5. **Health Plan**
   - Payment
   - Premium
   - Drug Coverage

6. **Beneficiary**
   - Premium

7. **Employer**
   - Premium

8. **Managed Drug Benefits**

- **Rebate**
- **Share of Rebate**
- **Drug Coverage**
- **Premium**
- **Payment**
Pricing Approaches of Federal Programs

- **Statutorily Defined Pricing**
  - Medicare Part B

- **Statutorily Defined Pricing Plus Negotiations**
  - VA
  - Medicaid

- **Negotiations through Private Plans**
  - Medicare Part D
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.
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


- 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

- *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