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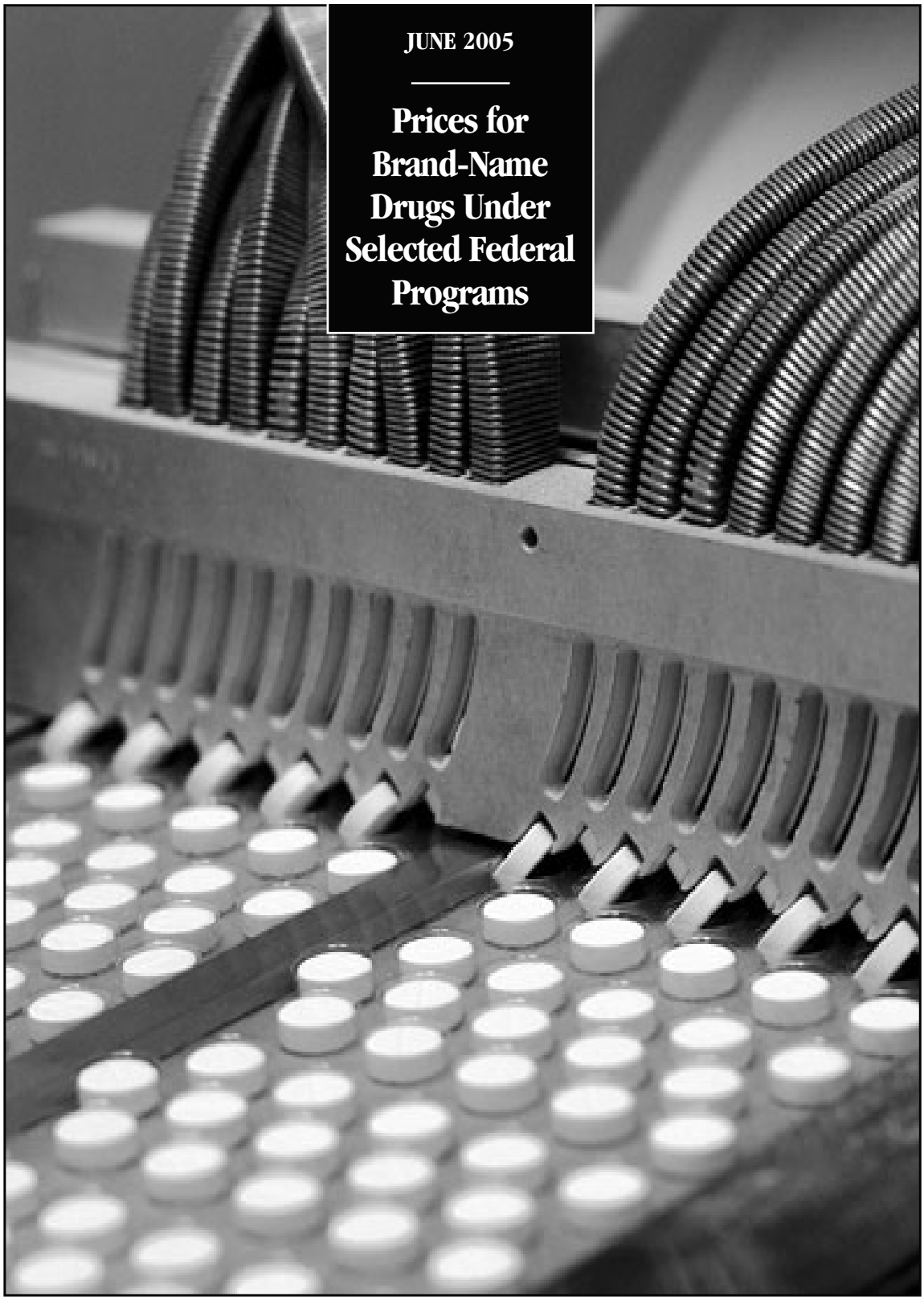
A
CBO
PAPER

JUNE 2005

Prices for Brand-Name Drugs Under Selected Federal Programs



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June 2005

The Congress of the United States ■ Congressional Budget Office

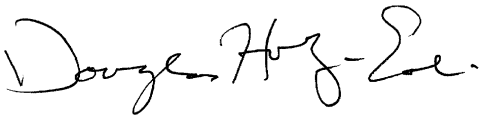
Preface

Federal and state governments are large purchasers of pharmaceuticals, accounting for over 20 percent of total U.S. expenditures for outpatient prescription drugs in 2003. Across government programs, drug prices can vary considerably. The prices that federal and state governments pay for drugs are determined by a combination of statutory rebates or discounts, supplemented by negotiations with drug manufacturers.

This Congressional Budget Office (CBO) paper, prepared at the request of the Senate Majority Leader, describes the processes by which drug prices paid to manufacturers (and, in some cases, to wholesale distributors) are determined and the relative average prices that result under many federal programs. In keeping with CBO's mandate to provide objective, nonpartisan analysis, this paper makes no recommendations.

Julie Somers of CBO's Microeconomic Studies Division and Anna Cook of CBO's Health and Human Resources Division prepared the paper under the supervision of Roger Hitchner, David Moore, Bruce Vavrichek, and James Baumgardner. (Roger Hitchner has since left CBO.) Colin Baker analyzed rebates under the Medicaid program. James Bell and Susan Labovich assisted with data analysis. Tom Bradley served as CBO's internal reviewer. Information and data were provided by the Department of Veterans Affairs, the Department of Defense, and the Centers for Medicare & Medicaid Services. Julia Christensen, Philip Ellis, Tim Gronniger, Arlene Holen, Robert Murphy, Sam Papenfuss, Allison Percy, Eric Rollins, Frank Russek, and Shinobu Suzuki, all of CBO, provided thoughtful comments on drafts, as did Joseph Antos of the American Enterprise Institute for Public Policy Research and John R. Nowak, RPh, of the Department of Veterans Affairs' Pharmacy Benefits Management Strategic Healthcare Group. (The assistance of external reviewers implies no responsibility for the final product, which rests solely with CBO.)

Christine Bogusz edited the paper, and Janey Cohen proofread it. Maureen Costantino designed the cover and Figure 2 and prepared the paper for publication. Lenny Skutnik printed copies of the paper, and Annette Kalicki and Simone Thomas produced the electronic version for CBO's Web site (www.cbo.gov).



Douglas Holtz-Eakin
Director

June 2005

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Summary and Introduction

Purchases of pharmaceuticals by federal and state governments accounted for over 20 percent of total U.S. expenditures for outpatient prescription drugs in 2003.[1] Because the prices that federal and state governments pay for drugs are determined by a variety of statutory rebates or discounts, supplemented by negotiations with drug manufacturers, drug prices can differ considerably across government programs.

This Congressional Budget Office (CBO) paper describes the processes by which prices paid to manufacturers (and, in some cases, to wholesale distributors) are determined and the relative average prices that result under the following federal programs:

- The Federal Supply Schedule (FSS) for pharmaceuticals, which is available to all direct federal purchasers;[2]
- The federal ceiling price (FCP) program, which is available to the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Public Health Service (PHS), and the Coast Guard;
- The Department of Veterans Affairs' pharmaceutical prime vendor program;
- The Department of Defense's TRICARE pharmaceutical program;
- The Medicaid rebate program; and
- The Public Health Service's 340B drug pricing program.

The Medicare program, currently in transition with the implementation of changes required under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), is not included in the discussion.[3]

CBO estimated the average price paid to manufacturers (and, in some cases, to wholesale distributors) under those federal programs in 2003 for a sample of top-selling brand-name prescription drugs relative to the list price (in this paper, the average wholesale price, or AWP), based on the quantities of those drugs sold in the United States. The sample includes 130 drugs that accounted for about 50 percent of U.S. sales through retail pharmacies and about 70 percent of U.S. sales of brand-name drugs through retail pharmacies in 2003.[4] The analysis is restricted to single-source drugs (brand-name drugs still under patent protection) for which purchasers do not have access to generic alternatives.

1. Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, "Table 3: National Health Expenditures, by Source of Funds and Type of Expenditure: Selected Calendar Years 1998-2003," available at www.cms.hhs.gov/statistics/nhe/historical/t3.asp.

2. This paper uses the term "direct federal purchasers" to refer to federal agencies that buy drugs from wholesale distributors or from manufacturers and that provide their own dispensing services.

3. The Federal Employees Health Benefits (FEHB) program also is not included in the discussion. For an analysis of discounts negotiated by pharmacy benefit managers on behalf of FEHB plans, see General Accounting Office, *Pharmacy Benefit Managers: FEHBP Plans Satisfied with Savings and Services, but Retail Pharmacies Have Concerns*, GAO/HEHS-97-47 (February 1997).

4. Based on 2003 data from IMS Health's National Sales Perspectives. In this paper, a brand-name drug is defined by its trade name (for example, Lipitor), and a brand-name drug product is defined by its trade name, strength, and dosage form (for example, Lipitor 10 mg tablet). The analysis includes about 330 different brand-name drug products. See Appendix A for a description of the drug price data sets CBO used and Appendix B for an explanation of the price index methodology used to compare average program prices relative to list price.

Box 1.

An Analysis of Drug Pricing, Not Drug Spending

Drug pricing, as examined in this paper, differs from drug spending in several ways. First, the prices paid to manufacturers for single-source brand-name prescription drugs under selected federal programs do not reflect the final cost of dispensing the drug to the patient. In the Medicaid program, for example, the Medicaid net manufacturer price, or the net price that manufacturers receive for Medicaid sales—the average manufacturer price (AMP) minus the Medicaid rebate—averages about 51 percent of the average wholesale price (AWP). For further details, see Table 1 and Figure 1 in the main text. However, the net final price to Medicaid—that is, the payments to pharmacies minus rebates from manufacturers—averages about 64 percent of the AWP. The difference between those two prices (13 percentage points) is the amount retained by pharmacies and wholesale distributors, who may use it to cover the costs involved in operating a pharmacy or warehouse, including distribution and dispensing costs, as well as payments to owners or stockholders.[1,2]

Second, the sample of brand-name drugs examined in this paper is based on national consumption patterns and does not necessarily reflect purchases made under federal programs.[3] This approach does not capture important cost containment strategies used by federal purchasers. For example, through the use of drug formularies, certain purchasers, such as the Department of Veterans Affairs and the Department of Defense, attempt to steer utilization toward those brand-name drugs for which they get better prices. Most federal programs also encourage the use of generic drugs, when available.

Other factors that affect drug spending over time and that are not included in this analysis are changes in program participation and utilization rates and the introduction of new drugs on the market.

1. For an analysis of the difference between the total amount that state Medicaid agencies paid to pharmacies and the amount that pharmacies and wholesalers paid to purchase the drugs from manufacturers, see Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs* (December 2004).
2. Direct federal purchasers usually dispense drugs within their own facilities, the cost of which is not reflected in this analysis.
3. The sample is restricted to top-selling brand-name drugs for which no generic substitutes are available, weighted by the total number of tablets and capsules sold in the United States (see Appendix B for further details).

The prices paid to manufacturers for brand-name drugs are only one of several factors that determine total drug spending. The cost of dispensing the drug to the patient, the savings generated from the use of generic drugs, and other important factors that also affect total drug spending are summarized in Box 1. Those factors, although important, have not been included in this analysis.

The prices paid to manufacturers vary substantially across government programs (see Figure 1). CBO estimates that the average prices for single-source brand-name prescription drugs for the third quarter of calendar year 2003 range from 53 percent of the list price in the case of the Federal Supply Schedule to 41 percent of the list price in the case of DoD.[5]

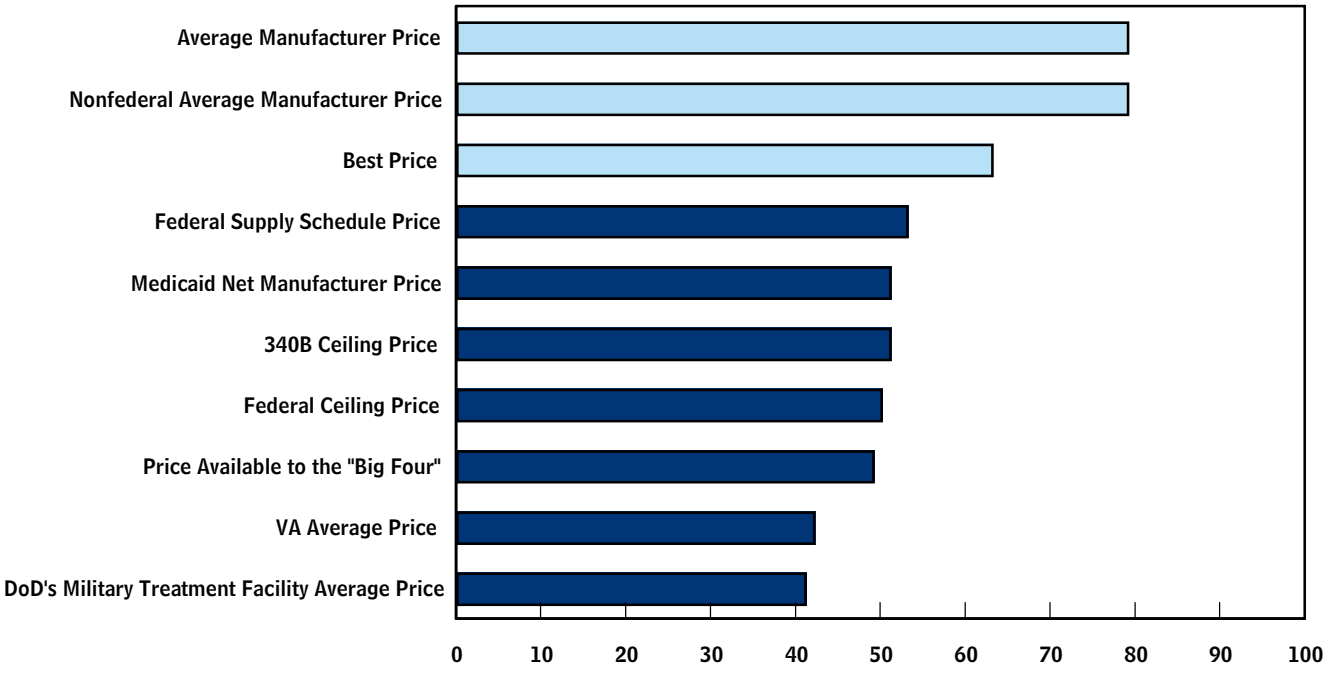
The relationships among the prices reported in this paper are likely to hold only under current regulations and market conditions. Future changes in pricing regulations would be likely to change the relationships among those prices. That is because the price charged to any one purchaser for a particular drug represents strategic decisions on the part of the manufacturer, and that price would be likely to change if it was extended to other purchasers through regulation. For example, when prices from the Federal Supply Schedule for pharmaceuticals program were included in the calculation of Medicaid's best prices (used to calculate Medicaid rebates), FSS prices rose. Moreover, the relationships do not apply to every drug.

5. Results for other quarters in calendar year 2003 are similar.

Figure 1.

Estimated Prices Paid to Manufacturers, Relative to List Price, for Brand-Name Drugs Under Selected Federal Programs, 2003

(Percent)



Source: Congressional Budget Office.

Notes: In this analysis, the list price is the average wholesale price.

The first three bars in the figure are manufacturer-reported private-sector prices.

The study sample includes 130 single-source brand-name prescription drugs that accounted for about 50 percent of U.S. sales through retail pharmacies and about 70 percent of U.S. sales of brand-name drugs through retail pharmacies in 2003. The estimates of average price are based on the quantities of those drugs sold in the United States and, with the exception of the federal ceiling price (FCP), are for the third quarter of 2003. (The FCP is calculated annually, so the estimate of average price is for calendar year 2003.) Results for other quarters in 2003 are similar. Prices exclude dispensing costs (see Box 1).

The "Big Four" are the four largest federal purchasers of pharmaceuticals: the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Public Health Service, and the Coast Guard.

For instance, although the FSS price is lower relative to the AWP than the best price, on average, the FSS price is higher than the best price for about one-fifth of the drugs examined in this analysis.

The AWP is a publicly available, suggested list price for sales of a drug by a wholesaler to a pharmacy or other provider; it is reported in publications such as Thomson Micromedex's *Red Book* and First DataBank's *Blue Book*. However, the AWP is not the actual price that wholesalers charge but is more like a sticker price in the automobile industry.

The AWP was chosen as the main price reference for this paper because it is frequently used to set payment rates in pharmaceutical transactions. For example, state Medicaid agencies, pharmacy benefit managers, and other third-party payers frequently use the AWP to set payment rates to retail pharmacies for providing single-source brand-name drugs to their beneficiaries. In addition, studies have reported savings from the Medicare drug discount

Table 1.

Description and Estimates of Prices Paid to Manufacturers, Relative to List Price, for Brand-Name Drugs Under Selected Federal Programs, 2003

Price	Description of Price and Associated Federal Program	Average Price as a Percentage of List Price
Average Wholesale Price (AWP)	The AWP is a publicly available, suggested list price for sales of a drug by a wholesaler to a pharmacy or other provider. It is not the actual price that wholesalers charge but serves more like a sticker price in the automobile industry. It was chosen as the reference price for this analysis because it is commonly used in pharmaceutical transactions.	100
Average Manufacturer Price (AMP)	The AMP is used to calculate the rebates that manufacturers are required to give to federal and state governments for sales to Medicaid beneficiaries. The AMP is the average price paid to a manufacturer for drugs distributed through retail and mail-order pharmacies. The AMP does not include rebates paid by the manufacturer to third-party payers. Both the AMP and the nonfederal average manufacturer price exclude sales to direct federal purchasers.	79
Nonfederal Average Manufacturer Price (Non-FAMP)	The non-FAMP is used to calculate the maximum price that manufacturers can charge the "Big Four"---the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Public Health Service (PHS), and the Coast Guard---for brand-name drugs. The non-FAMP is the average price paid to the manufacturer by wholesalers (or others who purchase directly from the manufacturer) for drugs distributed to nonfederal purchasers, taking into account any cash discounts or similar price reductions given to those purchasers but not taking into account any prices paid by the federal government. The non-FAMP does not reflect rebates paid by the manufacturer to third-party payers.	79
Best Price	The best price is used to calculate the rebates that manufacturers are required to give to federal and state governments for sales to Medicaid beneficiaries. The best price is the lowest price paid by any private-sector purchaser for the drug product, and it includes discounts, rebates, chargebacks, and other pricing adjustments.	63
Federal Supply Schedule (FSS) Price	All direct federal purchasers of pharmaceuticals can purchase drugs at prices listed in the Federal Supply Schedule for pharmaceuticals (FSS prices). The VA negotiates FSS prices with manufacturers on the basis of the prices that manufacturers charge their most-favored commercial customers under comparable terms and conditions. Furthermore, during a multiyear contract period, those FSS prices may not increase faster than inflation.	53
Medicaid Net Manufacturer Price	The Omnibus Budget Reconciliation Act of 1990 requires manufacturers to pay a rebate to the Medicaid program. For brand-name drugs, the basic rebate is equal to the greater of 15.1 percent of the AMP or the difference between the AMP and the best price. There is an additional rebate if the AMP rises faster than inflation. The Medicaid net manufacturer price is the AMP minus all rebates.	51
340B Ceiling Price	Section 340B of the Public Health Service Act of 1992 extends the Medicaid drug rebate program to PHS-funded clinics and disproportionate share hospitals. Eligible entities are free to negotiate steeper discounts than the Medicaid rebate amount. Not all eligible entities choose to participate in the program, however.	51

Continued

Table 1.

Continued

Price	Description of Price and Associated Federal Program	Average Price as a Percentage of List Price
Federal Ceiling Price (FCP)	The FCP is the maximum price that manufacturers can charge the Big Four for brand-name drugs. It is calculated annually. In the first year of an FSS contract, the FCP equals 76 percent of the previous fiscal year's non-FAMP minus an additional discount if the non-FAMP rises faster than inflation. In subsequent years of a multiyear contract, the FCP also cannot exceed the previous year's FSS price, increased by inflation.	50
Price Available to the Big Four	Under the federal ceiling price program, the Big Four purchase brand-name drugs at a price that cannot exceed the FCP. About two-thirds of the brand-name drug products on the FSS have one FSS price (which cannot exceed the FCP). The remaining one-third of the brand-name drug products have both an FSS price, offered to all non-Big Four purchasers, and an FSS Big 4 price, offered to the Big Four. The price available to the Big Four is the FSS Big 4 price when it exists and is the FSS price offered to all federal purchasers otherwise.	49
VA Average Price	The VA average price for a drug may be lower than the price available to the Big Four because VA negotiates further price reductions using its preferred formulary. The VA average price takes into account all the various pricing schedules and contracts under which VA purchases drugs, and it includes discounts from the prime vendor that averaged about 3 percent of the contract price in 2003, or about 1.4 percent of the AWP.	42
DoD's Military Treatment Facility (MTF) Average Price	The DoD military treatment facility average price for a drug may be lower than the price available to the Big Four because DoD negotiates further price reductions using its preferred formularies. The MTF average price takes into account all the various pricing schedules and contracts under which DoD purchases drugs.	41

Source: Congressional Budget Office.

Notes: In this analysis, the list price is the average wholesale price.

The study sample includes 130 single-source brand-name prescription drugs that accounted for about 50 percent of U.S. sales through retail pharmacies and about 70 percent of U.S. sales of brand-name drugs through retail pharmacies in 2003. The estimates of average price are based on the quantities of those drugs sold in the United States and, with the exception of the FCP, are for the third quarter of 2003. (The FCP is calculated annually, so the estimate of average price is for calendar year 2003.) Results for other quarters in 2003 are similar. Prices exclude dispensing costs (see Box 1 on page 2).

card program (which began June 1, 2004) in terms of percentage discounts off of the AWP.[6] Finally, pharmacies often use the AWP as a basis for pricing prescriptions to cash-paying customers. Therefore, the prices that manufacturers and wholesale distributors charge for brand-name prescription drugs under federal programs are expressed in Table 1 and described in the text below as a percentage of the AWP.

Direct Federal Purchasers

The federal government seeks to obtain prices that are equal to or lower than the lowest prices paid for drugs in the private marketplace. Depending on the program, the government has various measures of "lowest price." In general, manufacturers are required to report to the fed-

6. The AWP also had been used in the Medicare program to calculate payment rates for drug products administered in a physician's office (under Medicare Part B), but the MMA began basing payment for drugs covered under Part B on average sales price (ASP) on January 1, 2005. ASP as defined for the Medicare Part B program is the manufacturer's average price to all nonfederal purchasers in the United States. It includes all volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid drug rebate program).

eral government their average price and their lowest price charged to all nonfederal customers or to some subset of nonfederal customers (see Figure 2). The Medicaid rebate program's average manufacturer price (AMP) and the federal ceiling price program's nonfederal average manufacturer price (non-FAMP) are manufacturer-reported average prices; the Medicaid rebate program's best price and the Federal Supply Schedule program's most-favored commercial (MFC) customer price are manufacturer-reported lowest prices. The exact definition of the average price and the lowest price varies somewhat depending on the program. (Those distinctions will be described in more detail below.) The programs may then require that manufacturers offer their lowest price or deduct some statutory discount or rebate from the average price, as shown in Figure 2.

In some instances, the price with statutory discounts or rebates serves as a starting point for additional negotiations between federal purchasers or their representatives and pharmaceutical manufacturers. Drug manufacturers are willing to negotiate with government purchasers for a variety of reasons related to the extent to which price concessions are expected to increase sales volume, the ability of federal purchasers to consolidate purchasing and reduce manufacturers' transaction costs, and the influence of the federal programs on other purchasers in the market.

Federal Supply Schedule for Pharmaceuticals Program

FSS Price Relative to the AWP: 53 Percent

For federal purchasers, the Federal Supply Schedule for pharmaceuticals program is intended to obtain or beat the lowest prices negotiated for brand-name drugs between manufacturers and their most-favored commercial customers under comparable terms and conditions. The Department of Veterans Affairs negotiates FSS contracts with drug manufacturers to establish prices available to all direct federal purchasers of pharmaceuticals (including VA, DoD, the Public Health Service, the Bureau of Prisons, other federal agencies and institutions, the District of Columbia, U.S. territorial governments, and many Indian Tribal governments). Those prices are commonly referred to as FSS prices. The FSS price lists are publicly available.

Under the Veterans Health Care Act of 1992, drug manufacturers must list their brand-name drugs on the FSS to receive payment for the purchase of drugs by federal agencies and under the Medicaid program.[7] Those FSS prices for brand-name drugs must be no greater than the prices manufacturers charge their most-favored commercial customers under comparable terms and conditions.[8] Furthermore, during a multiyear contract period, those FSS prices may not increase faster than inflation (as measured by the consumer price index for all urban consumers, or CPI-U).[9,10]

In fiscal year 2003, sales under FSS contracts totaled about $4.5 billion for brand-name drugs and about $0.3 billion for generic drugs.[11] For single-source brand-name prescription drugs, CBO estimates that the FSS is about 53 percent of the AWP, on average.[12] That amount is about 10 percentage points less than the Medicaid rebate program's best price, which is defined as the lowest price paid by any private-sector purchaser. One reason that VA may be able to obtain such low FSS prices is that manufacturers may elect to extend federal ceiling prices to all federal purchasers. Also, whereas FSS prices have an inflation-adjustment mechanism, best prices do not.

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7. Public Law 102-585, 38 U.S.C. 8126(a)(4).

8. 48 C.F.R. 538.270.

9. 38 U.S.C. 8126(d). In some cases, the FSS contract price can differ from the price in the FSS price list, for reasons such as temporary price reductions. In those cases, this provision applies to the FSS contract price. For simplicity, the discussion that follows does not distinguish between the FSS price and the FSS contract price.

10. During a multiyear contract period, an FSS price may decrease if prices charged to the most-favored commercial customers on which the contract award was predicated decrease. (See 48 C.F.R. 552.238-75.)

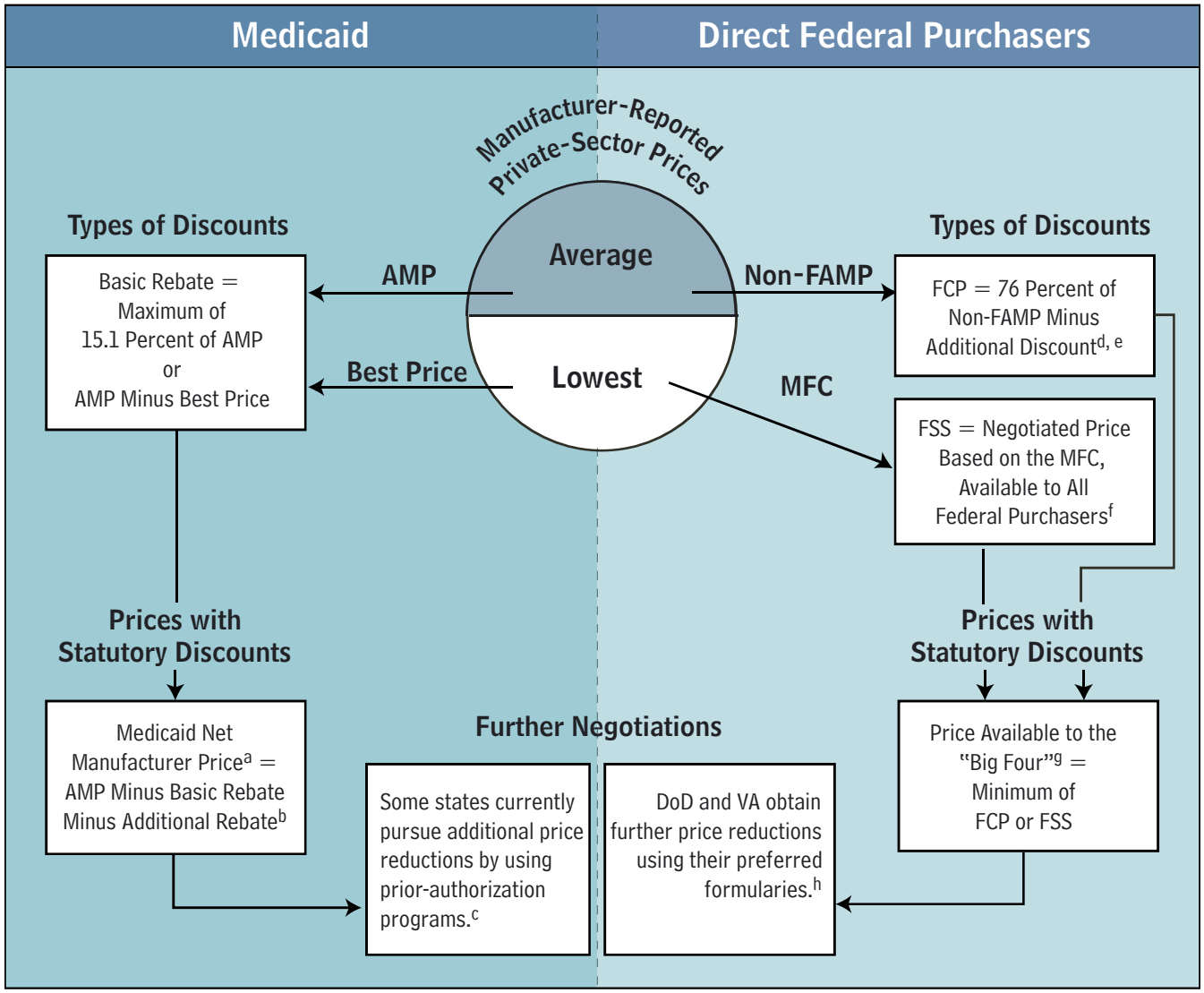
11. E-mail from the VA's National Acquisition Center, April 8, 2005.

12. The Government Accountability Office (formerly the General Accounting Office) found FSS prices to be about 42 percent to 50 percent of the AWP. See General Accounting Office, *VA and DoD Health Care: Factors Contributing to Reduced Pharmacy Costs and Continuing Challenges,* GAO-02-969T (July 22, 2002), Table 1, p. 5.

    A different study found FSS prices to be about 52 percent of the AWP for a sample of 172 commonly used brand-name and generic drug products in the fourth quarter of 2000. See Public Health Institute, Pharmaceuticals & Indigent Care Program, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities* (Oakland, Calif.: PHI, May 2001), Table 3, footnote 6, p. 9; and phone call with Dr. Steven Schondelmeyer of the PRIME Institute at the University of Minnesota on October 5, 2004.

Figure 2.

How Prices Paid to Manufacturers for Brand-Name Drugs Are Determined Under Selected Federal Programs



Source: Congressional Budget Office.

Notes: Pricing provisions depicted are for prices paid to manufacturers for brand-name prescription drugs and do not include distribution and dispensing costs (see Box 1 on page 2).

AMP = average manufacturer price; non-FAMP = nonfederal average manufacturer price; FCP = federal ceiling price; MFC = most-favored commercial customer price; FSS = Federal Supply Schedule price; DoD = Department of Defense; VA = Department of Veterans Affairs.

a. The Medicaid net manufacturer price is also available to 340B-eligible entities.

b. The Medicaid net manufacturer price includes an additional rebate when the AMP rises faster than inflation.

c. States have faced legal challenges from manufacturers for pursuing additional price reductions.

d. The FCP includes an additional discount when the non-FAMP rises faster than inflation.

e. In the second and subsequent years of a multiyear contract, the FCP also cannot exceed the previous year's FSS price, increased by inflation.

f. During a multiyear contract period, FSS prices may not increase faster than inflation.

g. The "Big Four" are the four largest federal purchasers of pharmaceuticals: the Department of Veterans Affairs, the Department of Defense, the Public Health Service (including the Indian Health Service), and the Coast Guard.

h. In general, a formulary is a list of drugs selected by a panel of physicians and pharmacists on the basis of an evaluation of their therapeutic merits, safety, and cost relative to other drugs in the same therapeutic class.

Furthermore, VA may be able to lower FSS prices through negotiations with manufacturers.

The "Big Four" Federal Ceiling Price Program

Under the Veterans Health Care Act of 1992, the Congress also established a separate brand-name drug discount program for the four largest—the Big Four—federal purchasers of pharmaceuticals: VA, DoD, PHS (including the Indian Health Service), and the Coast Guard.[13] The Big Four account for more than 95 percent of purchases made under FSS contracts. The law sets a cap on the prices that manufacturers can charge the four agencies based on a measure of average manufacturer prices and inflation. The price to the Big Four for a brand-name drug is the lower of the FSS price or the cap (see Figure 2).

Nonfederal Average Manufacturer Price Relative to the AWP: 79 Percent

The nonfederal average manufacturer price is the average price paid to a manufacturer by wholesalers (or by others who purchase directly from the manufacturer) for drugs distributed to nonfederal purchasers. It is the measure of the average manufacturer price used to set the cap. It takes into account any cash discounts or similar price reductions but excludes any prices paid by the federal government or any prices found by the Secretary of the VA to be merely "nominal" in amount. (For example, manufacturers sometimes establish such nominal prices for drugs provided to charities or other not-for-profit entities.) In practice, the only cash discounts or similar price reductions taken into account are those given to the wholesale distributor (or to others who purchase directly from the manufacturer). The non-FAMP does not reflect rebates paid by the manufacturer to third-party payers (insurance companies or pharmacy benefit management companies, for example).[14] Non-FAMPs are reported to the VA Secretary. Non-FAMP data are not publicly available. For single-source brand-name prescription drugs, CBO estimates that the non-FAMP for the third quarter of calendar year 2003 is about 79 percent of the AWP, on average.

Federal Ceiling Price Relative to the AWP: 50 Percent

To receive payment for the purchase of drugs by federal agencies and under the Medicaid program, federal law requires manufacturers to provide brand-name drugs to the four agencies at a price not to exceed the federal ceiling price. In the first year of an FSS contract, the FCP equals 76 percent of the previous fiscal year's non-FAMP minus an additional discount if the non-FAMP in the previous one-year period increased faster than inflation (as measured by the CPI-U).[15] In the second and subsequent years of a multiyear contract, the FCP also cannot exceed the previous year's FSS price, increased by inflation (as measured by the CPI-U).[16]

For single-source brand-name prescription drugs, CBO estimates that the non-FAMP for fiscal year 2002 is about 73 percent of the 2003 AWP, on average. Based on that estimate, the 2003 FCP cannot exceed 55 percent of the 2003 AWP, on average.[17] The two additional inflation-adjustment mechanisms lower the FCP by another 5 percentage points, resulting in an FCP for single-source, brand-name prescription drugs of about 50 percent of the 2003 AWP, on average.

Price Available to the Big Four Relative to the AWP: 49 Percent

The price to the Big Four for a brand-name drug is the lower of the FSS price or the FCP. Drug manufacturers can choose to offer all federal purchasers a single FSS price that is less than or equal to the FCP, or they can establish a dual pricing structure. Under that structure, the FSS price (based on the most-favored commercial customer price) is offered to non-Big Four federal purchasers and a second, or "dual," price is offered to the Big Four.

13. 38 U.S.C. 8126.

14. Based on phone conversations with VA staff members, September 2004.

15. The additional discount for the 2003 FCP equals the non-FAMP for the third quarter of calendar year 2002 minus the non-FAMP for the third quarter of calendar year 2001, inflated by the percentage increase in the CPI-U between September 2001 and September 2002. See 38 U.S.C. 8126(c).

16. The 2003 FCP equals the lower of (a) 76 percent multiplied by the non-FAMP for fiscal year 2002 minus any additional discount or (b) the FSS price as of September 30, 2002, inflated by the percentage increase in the CPI-U between September 2001 and September 2002. That is, in subsequent years of a multiyear contract, the FCP may be defined by the FSS price. See 38 U.S.C. 8126(d).

17. The calculation of 55 percent of the 2003 AWP is equal to the non-FAMP for fiscal year 2002 multiplied by 76 percent (73 percent of the 2003 AWP multiplied by 76 percent).

The price offered to only the Big Four—which is less than or equal to the FCP—is sometimes referred to as the FSS Big 4 price to distinguish it from the FSS price, which is available to all federal purchasers. FSS Big 4 price data are publicly available.

About one-third of the brand-name drug products listed on the FSS have FSS Big 4 prices, and the other two-thirds have a single FSS price (available to all federal purchasers) that must be less than or equal to the FCP. Some drugs may have a single FSS price because the FSS price is less than the FCP. Furthermore, because non-Big Four purchases account for such a small share of total purchases from the FSS (less than 5 percent), some manufacturers may choose to extend the FCP for certain drugs to all federal purchasers rather than incur the cost of maintaining two price lists. As mentioned above, that may be one reason why VA obtains FSS prices that are about 10 percentage points less, relative to the AWP, than the Medicaid rebate program's best price.

For single-source brand-name prescription drugs, CBO estimates that the price available to the Big Four is about 49 percent of the AWP, on average. (That estimate includes drugs that have an FSS Big 4 price and drugs that have a single FSS price offered to all federal purchasers.)

Department of Veterans Affairs

VA Average Price Relative to the AWP: 42 Percent

For VA's own purchases, it has been able to obtain lower prices from manufacturers, for example, by entering into competitively bid national contracts in which manufacturers' products are placed on VA's national formulary—a list of approved drugs to be used throughout VA's health care system.[18] From a manufacturer's point of view, the discount offered to VA may be offset by the increase in volume captured at the expense of other manufacturers who produce drugs that are therapeutic substitutes (that is, the drugs are used to treat the same condition). Furthermore, according to VA's Office of Academic Affiliations, more than 76,000 medical and associated health students, residents, and fellows receive some or all of their clinical training at VA facilities each year.[19] Therefore, manufacturers have an additional incentive to ensure that their drugs are used in VA facilities if they expect that prescribing practices learned during training will carry over to post-training practice.

VA also receives a discount for prompt payment from its prime vendor. That vendor provides distribution services to VA and to a few other authorized agencies and handles about 95 percent of VA's pharmaceutical purchases. In 2003, VA's discount from its prime vendor averaged about 3 percent of the contract price, or about 1.4 percent of the AWP.

In fiscal year 2003, VA's drug purchases totaled about $3.4 billion, up from about $2.5 billion two years earlier.[20] CBO obtained expenditure and quantity data for VA purchases made through its prime vendor to estimate the average price, taking into account all the various pricing schedules and contracts under which VA purchases drugs. For single-source brand-name prescription drugs, CBO estimates that VA's average price is about 42 percent of the AWP.

Department of Defense

DoD's Military Treatment Facility Average Price Relative to the AWP: 41 Percent

TRICARE is DoD's managed health care program for active-duty service members and their families, military retirees and their families, and other beneficiaries. Under DoD's TRICARE Pharmacy Program, beneficiaries may fill prescriptions at military treatment facilities (MTFs); through the TRICARE Mail Order Pharmacy (TMOP); at TRICARE network retail pharmacies; or at non-network retail pharmacies. DoD pays federal prices (for example, FSS prices or FSS Big 4 prices) for drugs purchased by TRICARE beneficiaries at MTFs and through TMOP. In 2003, DoD did not have access to federal prices for drugs purchased by TRICARE beneficiaries at

18. In general, a formulary is a list of drugs selected by a panel of physicians and pharmacists on the basis of an evaluation of their therapeutic merits, safety, and cost relative to other drugs in the same therapeutic class.

19. See the Web site for VA's Office of Academic Affiliations, available at www.va.gov/oaa/OAA_Mission.asp.

20. For 2003 spending, see Department of Veterans Affairs, *FY 2005 Budget Submission* (February 2004), vol. 2, p. 2C-11. For 2001 spending, see Department of Veterans Affairs, *FY 2003 Budget Submission* (February 2002), vol. 2, p. 2-141.

network or non-network retail pharmacies.[21] However, DoD has indicated that it intends to apply federal prices to purchases made at network retail pharmacies after September 30, 2004.[22]

Unlike the network and non-network retail pharmacies, MTFs and TMOP fill prescriptions according to drug formularies.[23] MTFs and TMOP may select one or a few drugs from a class with therapeutic substitutes for inclusion on formularies. Thus, for selected drugs, they are able to offer manufacturers increased market share in return for further price concessions and thus obtain prices lower than those available to the Big Four.

DoD's drug purchases totaled about $4 billion in fiscal year 2003, up from a little over $2 billion in 2001.[24] Spending at military treatment facilities accounted for about 40 percent of that 2003 total, retail pharmacies accounted for about 50 percent, and mail order accounted for the remaining 10 percent.[25]

CBO obtained expenditure and quantity data for DoD's MTF purchases to estimate the average price, taking into account all the various pricing schedules and contracts under which DoD purchases drugs. For single-source brand-name prescription drugs, CBO estimates that the average price at military treatment facilities is about 41 percent of the AWP (like the VA's average price, the MTF average price includes distribution costs but not dispensing costs).

21. TRICARE network retail pharmacies are participating pharmacies that provide drugs to TRICARE beneficiaries at an agreed-upon payment rate.

22. See Letter from Steven Thomas, Acting Executive Director, VA National Acquisition Center, to Manufacturers of Covered Drugs, October 14, 2004, available at www1.va.gov/oamm/nac/fsss/files/20041014DearManufacturer.pdf.

23. DoD is in the process of implementing a uniform formulary that will apply to the network and non-network retail pharmacies as well as MTFs and TMOP. See www.tricare.osd.mil/pharmacy/unif_form.cfm.

24. The increase in DoD's pharmaceutical spending is due to several factors, including expansion of drug benefits under the TRICARE Senior Pharmacy program (which began in 2001), increases in the use of retail pharmacies, and growth in drug prices.

25. Data provided by DoD on April 6, 2005.

Medicaid Rebate Program

Unlike direct federal purchasers, the Medicaid program for outpatient drugs works through the retail pharmacy distribution channel. Medicaid beneficiaries fill their prescriptions at their local retail pharmacies, sometimes paying a copayment that is limited to $3 per prescription.[26] The state pays pharmacies for filling those prescriptions on the basis of the state's formula for estimating pharmacy acquisition costs plus a flat dispensing fee of, generally, $3 to $5 per prescription.[27] In a subsequent transaction, the manufacturer issues a rebate to the state Medicaid program.[28] Medicaid's expenditures for prescription drugs, net of those rebates, represent about 15 percent of the U.S. market for outpatient prescription drugs.[29] However, that share is expected to decline in 2006 when responsibility for paying for drugs for dual eligibles (Medicaid beneficiaries who are enrolled in both Medicaid and Medicare) will shift from the Medicaid program to the Medicare prescription drug benefit program. The dual eligibles currently account for about half of Medicaid drug spending.

AMP Relative to the AWP: 79 Percent

The Omnibus Budget Reconciliation Act of 1990 amended the Social Security Act to require manufacturers to give back to the Medicaid program a portion of their revenues from drug sales to Medicaid beneficiaries.[30] (The federal government provides about 57 percent of the funding for the Medicaid program through matching funds.)[31] The rebate is based on the AMP, which is the average price paid to a manufacturer by wholesalers for

26. In certain cases, states have received waivers to charge higher copayments.

27. National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs* (Reston, Va.: National Pharmaceutical Council, 2003), p. 4-41.

28. In 2002, Medicaid rebates totaled $5.9 billion. See Medicaid expenditure data compiled by CMS on the basis of accounting statements (Form CMS-64) submitted by the states, available at www.cms.hhs.gov/medicaid/mbes/ofs-64.asp.

29. Medicaid's expenditures (federal and state) for outpatient prescription drugs, net of rebates, totaled $23.4 billion out of the $162 billion in total U.S. expenditures for outpatient prescription drugs in 2002. See www.cms.hhs.gov/medicaid/mbes/ofs-64.asp and www.cms.hhs.gov/statistics/nhe/historical/t2.asp.

30. 42 U.S.C. 1396r-8.

31. See www.cms.hhs.gov/medicaid/mbes/ofs-64.asp.

drugs distributed to retail and mail-order pharmacies. Whereas the non-FAMP is the average price paid to a manufacturer across both retail and nonretail channels of distribution, the AMP is the average price paid to a manufacturer across only retail channels of distribution (including mail order). Both the AMP and the non-FAMP exclude sales to direct federal purchasers. The AMP data are not publicly available. For single-source, brand-name prescription drugs, CBO estimates that the AMP is about 79 percent of the AWP.[32] Thus, for the sample of drugs examined in this analysis, the estimate of the AMP is the same as the estimate of the non-FAMP, even though their definitions differ slightly.

Best Price Relative to the AWP: 63 Percent

Medicaid's basic rebate for brand-name drugs is equal to the greater of 15.1 percent of the AMP or the difference between the AMP and the best price (the lowest price paid by any private-sector purchaser for the drug product).[33] The best price reflects discounts, rebates, chargebacks, and other pricing adjustments. Best-price data are not publicly available. (Generic drugs are reimbursed under a different formula, and their manufacturers pay a flat rebate of 11 percent of the AMP.) For single-source brand-name prescription drugs, CBO estimates that the best price is about 63 percent of the AWP, on average.

Medicaid Net Manufacturer Price Relative to the AWP: 51 Percent

Manufacturers must extend an additional rebate to Medicaid if the AMP rises faster than inflation (as measured by the CPI-U).[34] For single-source brand-name prescription drugs, CBO estimates that the basic rebate is about 22 percent of the AMP, on average, and the additional rebate averages about 13 percent of the AMP.[35] Expressed as a percentage of the AWP, the two rebates combined equal about 28 percent. Therefore, the net price that manufacturers receive for Medicaid sales (the AMP minus the Medicaid rebate) averages about 51 percent of the AWP, which is 12 percentage points below the best price.[36]

Some states also negotiate supplemental rebates from manufacturers. For example, manufacturers may agree to pay an additional amount if states agree not to require prior authorization before dispensing their drugs. However, states have faced legal challenges from manufacturers for pursuing additional price reductions, and states' negotiating leverage may decline in 2006 when, as mentioned above, responsibility for paying for drugs for dual eligibles will shift from Medicaid to Medicare. At the same time, the change in Medicaid's market share could also affect manufacturers' negotiations with private-sector purchasers and the resulting best-price levels.

The Medicaid net manufacturer price is the portion of Medicaid spending going to manufacturers. Medicaid's payments to pharmacies for brand-name drugs in 2002 were, on average, about 16.3 percent above the AMP (weighted by Medicaid's payments to pharmacies) or, using the estimate of the AMP relative to the AWP, about 92 percent of the AWP.[37] The Medicaid program then receives about 28 percent of the AWP back from manufacturers as rebates, resulting in a net final price to Medicaid of about 64 percent of the AWP. That estimate is not included in Table 1 because, unlike the other estimates in the table, the Medicaid net final price includes dispensing costs. The Medicaid net final price (64 percent of the AWP), which includes distribution and dispensing costs,

32. This estimate is similar to results presented in an earlier CBO study. According to that study, the AMP was about 80 percent of the AWP for 224 top-selling Medicaid brand-name drug products in 1993. See Congressional Budget Office, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry* (January 1996).

33. The Government Accountability Office stated in a recent report that it "found considerable variation in the methods that manufacturers used to determine best price and AMP." See Government Accountability Office, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States,* GAO-05-102 (February 2005), p. 15.

34. The additional rebate for a quarter is calculated by taking the difference between the drug's average price in that quarter (as measured by the AMP) and the drug's inflation-adjusted market introduction price, or base price. (The base price is the AMP in the first quarter in which the drug was marketed or the last quarter of 1990 for older drugs.)

35. The basic rebate is equal to 15.1 percent of the AMP for a little over half of the drugs examined in this analysis (for those drugs, 15.1 percent of the AMP is greater than the difference between the AMP and the best price).

36. The calculation of 51 percent of the average wholesale price is equal to the average manufacturer price minus the Medicaid rebate (79 percent of the AWP minus 28 percent of the AWP).

37. Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs* (December 2004).

is only slightly higher than the best price (63 percent of the AWP), which excludes those costs.

The Public Health Service's 340B Drug Pricing Program

340B Ceiling Prices Relative to the AWP: 51 Percent

Section 340B of the Public Health Service Act, enacted as part of the Veterans Health Care Act of 1992, extends the prices available through the Medicaid drug rebate program to PHS-funded clinics and disproportionate share hospitals.[38] The 340B discount is calculated using the Medicaid rebate formula and is deducted from the manufacturer's selling price rather than paid as a rebate. Eligible entities may negotiate steeper discounts than the Medicaid rebate amount.

Participating entities spent an estimated $3.4 billion for outpatient drugs in calendar year 2003.[39] However, not all eligible entities participate in the program. Some may choose not to participate because of a lack of familiarity with the program or because they may be receiving low prices already. By law, the 340B ceiling price—the maximum price that manufacturers can charge participating entities—equals the Medicaid net manufacturer price, which, based on the drugs included in this analysis, equals 51 percent of the AWP, on average.

38. 42 U.S.C. 256b.

39. Based on a phone call with staff at the U.S. Department of Health and Human Services, Health Resources and Services Administration, on April 7, 2005.

Conclusion

The prices paid to manufacturers for brand-name prescription drugs vary across federal programs, in part because of differences in the statutory rebates or discounts that apply to those programs. In addition, some federal purchasers negotiate with manufacturers for additional price reductions using, for example, preferred formularies.

However, the statutory rebates or discounts have a similar underlying structure even if their specific calculations differ. By law, both Medicaid and the direct federal purchasers using the Federal Supply Schedule receive a price at least as low as a measure of the lowest price available to private-sector purchasers. In cases in which private-sector purchasers are not receiving a large discount, a minimum discount off of an average price takes effect for Medicaid and the Big Four. Furthermore, if manufacturers increase the prices they offer to private-sector purchasers faster than inflation, then Medicaid, the Federal Supply Schedule, and the Big Four have mechanisms in place to boost their discounts.

The price comparisons in this paper reflect prices paid to manufacturers and do not include the final cost of dispensing the drug to the patient. Moreover, except for the average manufacturer price and the nonfederal average manufacturer price, those estimates vary substantially across drugs, and their relative ranking may differ. For example, about one-fifth of the drugs examined in this analysis have a best price that is below the FSS price. And Medicaid pays manufacturers less than the VA for some drugs.

APPENDIX

A

Data Used in This Analysis

The Congressional Budget Office (CBO) estimated the average price paid under federal programs in 2003 for a sample of top-selling single-source brand-name prescription drugs relative to their list prices. The sample includes about 130 drugs defined by their trade name (for example, Lipitor) that accounted for about 50 percent of U.S. sales through retail pharmacies and about 70 percent of U.S. sales of brand-name drugs through retail pharmacies in 2003.

The analysis drew upon data from several different sources. The data came from two private companies that collect and sell information about the pharmaceutical industry (IMS Health and Thomson Micromedex) and from three government agencies—the Department of Veterans Affairs (VA), the Department of Defense (DoD), and the Centers for Medicare & Medicaid Services (CMS).

IMS Health's National Sales Perspectives

CBO purchased IMS Health's National Sales Perspectives data set for 90 narrowly defined therapeutic classes that include 76 of the top 100 outpatient drugs sold in 2003 and their closely related therapeutic substitutes. The data include dollar sales at wholesale prices and extended units of drugs (by National Drug Code, or NDC) purchased in the United States through both retail and nonretail channels of distribution, by quarter, for the years 1999 through 2003.[1] The 90 therapeutic classes account for about 60 percent of U.S. sales at wholesale prices.

1. Retail channels of distribution include independent pharmacies, chain drugstores, food stores with pharmacies, and mail-order pharmacies. Nonretail channels of distribution include nonfederal hospitals, federal facilities, clinics, health maintenance organizations, home health care, long-term care, prisons, universities, and other distribution channels not covered elsewhere.

Thomson Micromedex's *Red Book*

CBO subscribes to Thomson Micromedex's *Red Book* database. The database contains average wholesale prices (AWPs) for prescription and nonprescription drugs, by NDC, with dates for when the price went into effect, as well as other prices and descriptive information.

The Department of Veterans Affairs' Data

The VA provided Federal Supply Schedule (FSS) prices from contracts dating back to 1990. The files include each drug's NDC, starting and ending dates for when the price was in effect, and the price per package. The VA also provided annual federal ceiling prices (FCPs) and nonfederal average manufacturer prices (non-FAMPs), by NDC, dating back to 1993. Finally, the VA provided data from its prime vendor program for the January 1999-September 2004 period. The data include total dollar expenditures and quantities purchased through VA's prime vendor for the VA and a few other federal agencies (the Indian Health Service, the Bureau of Prisons, the Public Health Service, the Department of Health and Human Services, and the Immigration and Naturalization Service), by NDC. FSS price data are publicly available, but FCPs, non-FAMPs, and VA prime vendor data are not.

The Department of Defense's Data

The Department of Defense provided total dollar expenditures and quantities for 2003, by NDC, for about 480 drugs purchased by TRICARE military treatment facilities. The data file was compiled using DoD's Pharmacy Data Transaction Service, with pricing information obtained using the prime vendor's purchase records. The DoD's prime vendor data are not publicly available.

Medicaid's Drug Rebate Program Data

The Centers for Medicare & Medicaid Services provided CBO with quarterly data for the Medicaid drug rebate program. The data include average manufacturer price and best price for drugs covered by Medicaid, by NDC. AMP and best price are private-sector transaction prices reported by manufacturers to CMS so that it can calculate the Medicaid rebate. The AMP in each quarter is the average price paid to a manufacturer by wholesalers during that period for drugs distributed to retail and mail-order pharmacies. The best price in each quarter is the lowest price paid to the manufacturer by any private-sector purchaser. AMP and best-price data are not publicly available. The data also include prescriptions and units dispensed to Medicaid recipients and payments to pharmacies by state Medicaid programs.

APPENDIX

B

Methodology of This Analysis

To determine the weighted average price relative to the average wholesale price (AWP), the Congressional Budget Office (CBO) calculated, for each quarter, the ratio of the cost of buying the U.S. quantities of the drug products in the sample at each price—the Federal Supply Schedule (FSS) price, the price available to the Big Four,[1] the average manufacturer price (AMP), the best price, the nonfederal average manufacturer price (non-FAMP), the federal ceiling price (FCP), the Department of Veterans Affairs (VA) average price, and the Department of Defense's (DoD's) military treatment facility (MTF) average price—divided by the cost of buying them at the AWP. Following the formula for a price index, the mathematical expression for this calculation is:

Weighted Average Price$_k$ Relative to AWP =

$$\frac{\Sigma(P_{k,i}) \bullet (Q_i)}{\Sigma(AWP_i) \bullet (Q_i)},$$

where the subscript k represents one of the program prices under study (FSS price, price available to the Big Four, AMP, best price, non-FAMP, FCP, VA average price, or DoD's MTF average price), where Σ denotes the sum over all drug products in the sample, P is the price per drug product, Q is the U.S. quantity of the drug product (for example, the number of tablets or capsules), and the subscript i represents the drug product i (a drug product is defined by its trade name, strength, and dosage form—for example, Lipitor 10 mg tablet).

To construct the study sample, CBO started with the IMS data set (see Appendix A) and limited it to single-source brand-name prescription drugs (a drug is defined by its trade name—for example, Lipitor) in oral solid dosage forms (that is, tablets or capsules) with 2003 sales to retail channels of distribution (at wholesale prices) of $50 million or more. (Sales are totaled across all forms and strengths of the drug.) That data also provide total extended units (the number of tablets or capsules by strength) sold in the United States, by National Drug Code (NDC), for each quarter in calendar year 2003. Those extended units were used to construct the weights (Q_i) in the above formula.

Pricing Data

Some of the prices studied are published (or appear on a publicly available list) and are in effect for a specified period of time. Those include the AWP and the FSS prices. CBO chose the AWP, FSS price, and FSS Big 4 price in effect at the midpoint of each quarter to represent the quarterly AWP, FSS price, and FSS Big 4 price.[2] Thomson Micromedex's *Red Book* lists AWPs, by NDC, with a date that indicates when the AWP went into effect. The Federal Supply Schedule lists the FSS price and the FSS Big 4 price, by NDC, with contract start and stop dates. For each NDC, the quarterly price available to the Big Four is the FSS Big 4 price for drugs with dual prices and is the FSS price for drugs with single prices.

Other prices are based on sales to private-sector purchasers over a given quarter and are reported by manufacturers to the federal government. Typically, those prices are not publicly available. Under the Medicaid rebate program, manufacturers report to the Centers for Medicare & Medicaid Services quarterly AMPs and best prices by NDC. Under the federal ceiling price program, manufac-

1. The "Big Four" are the four largest federal purchasers of pharmaceuticals: the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard.

2. For the purposes of this analysis, February 15, 2003, is the midpoint of the first quarter of 2003; May 15, 2003, is the midpoint of the second quarter; August 15, 2003, is the midpoint of the third quarter; and November 15, 2003, is the midpoint of the fourth quarter.

turers report the non-FAMP and the FCP to the VA by NDC. The non-FAMP is reported annually and quarterly. The FCP is reported annually.

Estimating Prices for Drug Products

CBO estimated an average product price, weighted across package sizes, under each program for each product ($P_{k,i}$). For each quarter, CBO averaged the AWP, the FSS price, the price available to the Big Four, the AMP, the best price, the non-FAMP, and the FCP across drug package sizes, weighting by the number of tablets or capsules sold in the United States for each package size. That calculation created an average price ($P_{k,i}$) for each brand-name drug product under each program.

Data from VA and DoD included total dollar expenditures and quantities purchased through their prime vendors. For each quarter and for each drug product, CBO summed VA expenditures across package sizes and divided by the total number of tablets (or capsules) summed across package sizes to create a VA average price per drug product ($P_{k,i}$). Similarly, for each quarter and for each drug product, CBO summed DoD's MTF expenditures across package sizes and divided by the total number of tablets (or capsules) summed across package sizes to create a DoD average price per drug product ($P_{k,i}$).

Weighting by U.S. Quantities

The average product prices (AWP, FSS price, price available to the Big Four, AMP, best price, non-FAMP, FCP, VA price, and DoD's MTF price) were matched to the data set of total extended units sold in the United States (Q_i) for each product and for each quarter. Drug products with any one of the average prices missing were deleted, resulting in a final data set with about 330 drug products or about 130 drugs that accounted for about 50 percent of U.S. sales through retail pharmacies and about 70 percent of U.S. sales of brand-name drugs through retail pharmacies in 2003. Following the formula for a price index, CBO estimated a weighted average price relative to the AWP for each program, using as the weight the number of tablets or capsules, by strength, of each drug product sold in the United States.