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PRESCRIPTION DRUGS

An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs

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Highlights of [GAO-07-358T](#), a testimony before the Committee on Finance, U.S. Senate

Why GAO Did This Study

Rising prescription drug spending has led the United States and other countries to seek ways to negotiate lower prices with drug manufacturers. Currently, the Medicare Part D benefit, which offers outpatient prescription drug benefits to beneficiaries including elderly and certain disabled people, comprises competing prescription drug plans overseen by the Centers for Medicare & Medicaid Services. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 prohibits the Secretary of Health and Human Services from interfering with price negotiations between Part D plan sponsors and drug manufacturers and pharmacies. Some Members of Congress have proposed amending the statute to allow the Secretary of Health and Human Services to negotiate directly with drug manufacturers on behalf of Part D beneficiaries.

GAO was asked to describe how prescription drug prices are negotiated. This testimony provides an overview of such efforts (1) by governments in other countries; (2) by U.S. private payers, such as employer-based health plans; and (3) by federal programs other than Medicare Part D. This testimony is based on previous GAO reports from 2002 through 2006 on federal programs that purchase or cover prescription drugs and other relevant literature from congressional agencies and federal or international organizations.

www.gao.gov/cgi-bin/getrpt?GAO-07-358T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact John E. Dicken at (202) 512-7119 or dickenj@gao.gov.

PRESCRIPTION DRUGS

An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs

What GAO Found

Governments in other countries use a range of approaches to limit the amount they pay to acquire drugs:

- Ceiling prices establish a maximum price manufacturers may charge for their products. Purchasers may sometimes negotiate more favorable prices directly with drug manufacturers.
- Reference prices use local or international price comparisons of drugs classified in a group as therapeutically similar to determine a single or maximum price for all drugs in that group.
- Profit limits control how much profit a drug manufacturer may earn per product or within a specified period of time.

Other factors—such as scope of coverage and national formularies, which are generally lists of preferred drugs—influence drug price negotiations.

In the U.S. private health insurance market, health plans typically contract with pharmacy benefit managers (PBM) to help manage their prescription drug benefits. PBMs negotiate rebates or payments with drug manufacturers, encourage substitution of generic drugs for therapeutically similar brand drugs, and negotiate discounted prices with networks of retail and mail-order pharmacies, passing along at least some of the savings to health plans and enrollees. PBMs influence price negotiations with manufacturers through formulary development and management and through the large market share they often represent.

Approaches for negotiating drug prices vary among federal programs in the United States. In part, these approaches depend on whether the programs purchase and distribute drugs directly or reimburse retail pharmacies or other providers for dispensing or delivering drugs. While the approaches used by federal programs in the United States reflect U.S. laws, markets, and health care delivery and financing, there are also elements common to some of the approaches used by other countries and by private payers. Some federal programs set ceiling prices, others establish prices by referencing prices negotiated by private payers in the commercial market, and still others rely on negotiations with manufacturers, directly or through private health plans. For example, the Departments of Veterans Affairs's and Defense's prices for a prescription drug may be the lowest of a ceiling price, other established price, or a price negotiated with the manufacturer. State Medicaid programs, joint federal-state programs that finance medical services for certain low-income adults and children, reimburse retail pharmacies for drugs dispensed to beneficiaries at set prices. The programs receive rebates from manufacturers that are meant to take advantage of the prices for drugs in the commercial market and are required to reflect discounts and rebates negotiated by private payers with manufacturers. For health benefits offered to federal employees, retirees, and dependents, rather than negotiating with manufacturers, the government contracts with participating health plans that typically use PBMs to negotiate drug prices and offer other pharmacy benefit, administrative, and clinical services.

Mr. Chairman and Members of the Committee:

I am pleased to be here today as you examine approaches for prescription drug pricing and negotiations. In the United States and in other countries, the rising cost of prescription drugs continues to pose significant financial burdens on governments, private payers, and individuals responsible for paying for drugs. This has led to a wide range of market-based and governmental approaches to reduce drug spending. Some of these approaches rely on negotiations between payers for prescription drugs and drug manufacturers.

In the United States, prescription drugs are a particular focus for the federal government as Medicare—the federal health insurance program that serves nearly 43 million elderly and disabled individuals—begins the second year of its voluntary outpatient prescription drug benefit. This benefit, known as Medicare Part D, was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) beginning January 1, 2006.¹ Medicare beneficiaries may choose a Part D plan from multiple plans offered by private sponsors, largely commercial insurers, under contract with the Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services (HHS) that administers Medicare. These plans differ in the drugs they cover, the pharmacies they use, and the prices they negotiate with drug manufacturers and pharmacies. In addition, costs to the enrollee for the monthly premium, the annual deductible, and copayments for covered drugs vary by plan.

While the Medicare Part D benefit is characterized by multiple competing prescription drug plans that are overseen by CMS, MMA prohibits the Secretary of Health and Human Services from interfering with price negotiations between Part D plan sponsors and drug manufacturers and pharmacies.² Some Members of Congress, contending that the combined purchasing power on behalf of all Medicare Part D beneficiaries could be used as leverage, have proposed amending the law to provide for the

¹Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (codified at 42 U.S.C. §§ 1395w-101 to 1395w-152). MMA redesignated the previous part D of title XVIII of the Social Security Act as part E and inserted a new part D after part C.

²Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2098 (codified at 42 U.S.C. § 1395w-11(i)).

Secretary of Health and Human Services to negotiate directly with drug manufacturers.³

As Congress considers these issues for Medicare Part D, you asked that we broadly describe the variety of approaches used to negotiate drug prices. Specifically, my remarks today will provide an overview of the approaches used to negotiate drug prices by governments in other countries, by private payers in the United States, and by federal programs other than Medicare Part D.⁴ My remarks are primarily based on our previous reports from 2002 through 2006 on federal programs that purchase or cover prescription drugs, which were done in accordance with generally accepted government auditing standards, as well as other relevant literature on approaches in the United States and other countries prepared by congressional agencies and international and federal organizations.⁵

In summary, a wide range of approaches is used by other countries and by private payers and federal programs in the United States to negotiate drug prices. The approaches governments in other countries use include the following:

- Ceiling prices restrict market negotiations by setting maximum prices purchasers can pay for drugs. Ceiling prices allow purchasers to negotiate lower prices directly with drug manufacturers.

³For example, H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007, was introduced on January 5, 2007. It would require the Secretary of Health and Human Services to negotiate Part D drug prices on behalf of Medicare beneficiaries.

⁴For this testimony, we reviewed information summarizing approaches used by members of the Organisation for Economic Co-operation and Development (OECD). The OECD includes 30 member countries that “share a commitment to democratic government and the market economy,” and OECD’s work includes developing publications and statistics on economic and social issues. <http://www.oecd.org> (accessed January 9, 2007). As appropriate, we present examples of drug pricing approaches used in five OECD member countries other than the United States.

⁵A list of related GAO products is included at the end of this statement. For additional information on approaches used by other countries, U.S. private payers, and federal programs, see, for example, Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (Washington, D.C., 2005); Congressional Research Service, *Federal Drug Price Negotiation: Implications for Medicare Part D* (Washington, D.C., 2007); Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Washington, D.C., 2005); and Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation* (Washington, D.C., 2004).

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- Reference prices use local or international price comparisons of drugs classified in a group as therapeutically similar to determine a single or maximum price for all drugs in that group.
 - Profit limits establish controls on drug manufacturers' profits that require manufacturers to pay rebates or lower prices if profits exceed certain levels.

Other key factors—such as scope of coverage and national formularies, which are generally lists of preferred drugs—influence drug price negotiations.

Private payers in the United States, including employer-based health plans and private insurers, typically contract with pharmacy benefit managers (PBM). PBMs negotiate rebates or payments with manufacturers and prices with retail pharmacies, and they provide other related administrative and clinical services. PBMs compete in the private market based on their ability to negotiate reduced prices and contain costs, and PBMs may receive compensation from health plans and from retaining some of the savings they negotiate with pharmacies or manufacturers. PBMs influence price negotiations with manufacturers through formulary development and management and through the large number of health plan enrollees they typically represent.

Approaches for negotiating drug prices vary among federal programs in the United States. Factors contributing to this variation include the use of formularies and whether the programs purchase and distribute drugs, reimburse retail pharmacies or other providers for drugs dispensed and delivered, or contract with private health plans that provide and manage pharmacy benefits. For example, the Department of Veterans Affairs (VA) and the Department of Defense (DOD) often purchase drugs from suppliers, then distribute drugs to beneficiaries through internal facilities or mail-order pharmacies. State Medicaid programs, on the other hand, reimburse retail pharmacies for drugs dispensed to beneficiaries at set prices. While the approaches used by federal programs in the United States reflect the laws governing them, markets, and health care delivery and financing, there are also elements common to some of the approaches used by other countries and by private payers. Some federal programs set ceiling prices, others establish prices by referencing prices negotiated by private payers in the commercial market, and still others rely on negotiations with manufacturers, either directly or through private health plans. For example, VA's and DOD's prices for particular prescription drugs included on their formularies may be the lowest of a ceiling price, a

price listed on a federal supply schedule (FSS), or the price negotiated with a manufacturer. For health benefits offered to federal employees, retirees, and their dependents, the federal government uses a different approach, modeled after other large U.S. employers' health benefits. Under this approach, rather than the government negotiating with manufacturers, the government contracts with participating health plans that typically use PBMs to negotiate drug prices, manage formularies, and offer other pharmacy benefit, administrative, and clinical services.

Background

Prescription drug spending, paid for by a mix of public and private payers, has outpaced total health care spending in the United States and other countries in recent years. In the United States, federal programs either directly purchase and distribute prescription drugs or reimburse pharmacies or other providers for drugs dispensed or delivered.

Prescription Drug Spending and Cost Containment Strategies in Other Countries and the United States

According to the Organisation for Economic Co-operation and Development (OECD), drug spending in member countries (including the United States) increased on average by about 6 percent a year from 1998 through 2003.⁶ On average, growth in drug spending outpaced the growth in spending for total health expenditures. Among OECD member countries, the share of public and private spending for prescription drugs varies, but in 2004 public sources accounted for the bulk of spending in most countries.

In the United States, rising prescription drug prices and increased spending have been a concern to federal and state governments and to private payers, including private insurers and employer-based health plans. CMS reports that total national spending by all public and private payers for prescription drugs from retail outlets increased on average by about 11 percent a year from 1998 through 2005—faster than the average 7 percent a year increase in total U.S. health expenditures for the same period.⁷ CMS also reports that national spending by all public and private

⁶Growth in drug spending for these nations includes both prescription and over-the-counter drugs.

⁷Centers for Medicare & Medicaid Services, Trustees, National Health Expenditure, Historical Data (Baltimore, MD: Centers for Medicare & Medicaid Services, 2007), http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp (accessed January 9, 2007). These figures reflect spending on prescription drugs through retail outlet sales, but do not account for nonretail outlet sales, such as those for drugs dispensed in inpatient hospital or nursing home facility settings.

payers for prescription drugs from retail outlets totaled about \$201 billion in 2005. Nearly three-quarters (73 percent) of this spending came from private funds—including private insurance and out-of-pocket payments—while the remaining share came from public sources. The public share includes the federal government’s share of total spending for prescription drugs from retail outlets. Federal spending for prescription drugs was about 16 percent of the total, or \$33 billion, in 2005. However, these data precede the 2006 establishment of Medicare Part D, which increased public and federal shares of prescription drug expenditures.

In the face of rising prescription drug spending, the governments of other countries, U.S. private payers, and federal programs have applied both demand- and supply-side measures to contain prescription drug spending. Demand-side measures are aimed at wholesalers, retailers, doctors, and patients and include such strategies as prescribing guidelines, generic substitution policies, and fixed and tiered copayments. Supply-side measures are aimed at limiting the cost of prescription drugs by negotiating prices and by requiring or encouraging the use of certain drugs through formularies established by a government, health plan, or federal program. Formularies have long been used to control the cost and utilization of prescription drugs. Some formularies are more restrictive than others; open formularies provide coverage for both listed and nonlisted drugs, and closed formularies generally provide coverage only for drugs that are included on the list. Many other formulary approaches fall somewhere in between, encouraging the use of listed drugs by charging higher copayments for those not listed. Under a tiered cost-sharing approach, for example, generic and preferred drugs require lower copayments than brand and nonpreferred drugs. Health plans that use formularies typically have provisions that enable enrollee access to nonformulary drugs when they are medically necessary and allow patients to appeal coverage decisions.

In the U.S. private market, PBMs offer health plans a variety of prescription drug management services, including negotiating rebates with manufacturers, negotiating price discounts with retail pharmacies, operating mail-order prescription services, managing drug formularies, and processing claims. PBMs also provide health plans with clinical services, such as formulary development and management, prior authorization and drug utilization reviews to screen prescriptions for such issues as adverse interactions or therapy duplication, and substitution of

generic drugs for therapeutically equivalent brand drugs.⁸ Health plans pay PBMs fees for these administrative and clinical services as well as for retail and mail-order drug costs. PBMs may also retain savings from or have other financial incentives to negotiate lower drug prices and rebates. In 2004, an estimated 200 million people, or about 68 percent of the U.S. population, were enrolled in private health plans that used PBMs.⁹

Federal Programs

Beyond Medicare Part D, a range of federal programs, established by statute, in the United States offer drug benefits to individuals meeting various eligibility criteria. These programs cover a broad and varying array of prescription brand and generic drugs.¹⁰ These drugs are made available to beneficiaries through multiple approaches, ranging from direct purchase and provision by federal programs to contracts with private insurers and PBMs to provide drug coverage.

The VA pharmacy benefit is provided to eligible veterans and certain others. In general, medications must be prescribed by a VA provider, filled at a VA pharmacy or through a VA Consolidated Mail Outpatient Pharmacy, and listed on the VA national drug formulary, which comprises 570 categories of drugs. In addition to the VA national drug formulary, VA facilities can establish local formularies to cover drugs not on the national formulary. VA may provide nonformulary drugs in cases of medical necessity.¹¹ In 2005, VA spent \$4.2 billion on drugs and medicines.

⁸Therapeutically equivalent drug products can be substituted with the full expectation that they will produce the same clinical effect as the prescribed drugs.

⁹PricewaterhouseCoopers. *The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation*. A report prepared at the request of Pharmaceutical Care Management Association. July 2004.

¹⁰Brand drugs are single-source and multisource drugs that are marketed under a proprietary, trademark-protected name. Single-source drugs include those brand drugs that have no generic equivalent on the market and are generally available from only one manufacturer. Brand multisource drugs include those brand drugs that have generic equivalents available from multiple manufacturers and are marketed under a proprietary name. Generic drugs include multisource drugs that are chemically identical to their branded counterparts and are generally marketed by multiple manufacturers under a nonproprietary name.

¹¹In a 2000 report, the Institute of Medicine characterized the VA formulary as “not overly restrictive.”

The DOD pharmacy benefit is provided to TRICARE beneficiaries,¹² including active duty and retired uniformed service members. In addition to maintaining a formulary, DOD provides options for obtaining nonformulary drugs. Beneficiaries can get prescription drugs through network retail pharmacies, nonnetwork retail pharmacies, DOD military treatment facilities, and DOD's TRICARE Mail Order Pharmacy. In 2005, DOD spent \$5.4 billion on prescription drugs.

Medicaid is the joint federal-state program that finances medical services for certain low-income adults and children. While some benefits are federally required, prescription drug coverage is an optional benefit that all states have elected to offer. State Medicaid programs, though varying in design, cover both brand and generic drugs. Drug coverage depends on the manufacturer's participation in the Medicaid drug rebate program, through which manufacturers pay rebates to state Medicaid programs for covered drugs used by Medicaid beneficiaries. Retail pharmacies distribute drugs to Medicaid beneficiaries, then receive reimbursements from states for the acquisition cost of the drug and a dispensing fee. In 2004, Medicaid outpatient drug spending peaked at \$31 billion—including \$19 billion as the federal share—which was calculated after adjusting for manufacturer rebates to states under the Medicaid drug rebate program. Medicaid spending on outpatient prescription drugs is expected to decrease with the transition of prescription drug coverage for dual eligibles—those eligible for both Medicaid and Medicare—to the Medicare Part D program.

The 340B drug pricing program gives more than 12,000 entities of various types—community health centers, AIDS clinics, and disproportionate share hospitals¹³ among them—access to discounted drug prices, called 340B ceiling prices.¹⁴ These entities must enroll in the program, which is administered by the Health Resources and Services Administration. The program requires drug manufacturers to offer covered drugs to enrolled

¹²DOD provides health care through TRICARE—a regionally structured program that uses contractors to maintain provider networks to complement health care provided at military treatment facilities.

¹³Disproportionate share hospitals are hospitals that serve a relatively large volume of low-income patients and are eligible for payment adjustments under Medicare's prospective payment system or under Medicaid.

¹⁴The 340B drug pricing program is named for the statutory provision that authorizes it, section 340B of the Public Health Service Act (codified at 42 U.S.C. § 256b).

entities at or below 340B ceiling prices.¹⁵ Enrolled entities establish their own formularies and may dispense drugs through in-house pharmacies, dispensing physicians, or contracted retail pharmacies. Enrolled entities spent an estimated \$3.4 billion on drugs in 2003.

Medicare, the federal health insurance program that serves the nation's elderly and certain disabled people, in addition to the outpatient prescription drug benefit offered in Part D, covers certain other drugs through Part B.¹⁶ Drugs covered by Part B are typically administered by physicians or other medical professionals rather than by patients themselves. These drugs include, for example, those furnished in conjunction with dialysis services or durable medical equipment. In 2005, Medicare paid more than \$9 billion for drugs covered under Part B.

The Federal Employees Health Benefits Program (FEHBP) is the largest employer-sponsored health insurance program in the country. Through it, about 8 million federal employees, retirees, and their dependents receive prescription drug coverage through participating private health insurance plans. Most of these plans contract with PBMs to manage their drug benefits. The drugs covered vary by plan, but are typically part of relatively broad formularies of drugs. In general, beneficiaries have several options for obtaining drugs, including through retail or mail-order pharmacies. In 2005, FEHBP prescription drug spending was an estimated \$8.3 billion.

¹⁵Drug manufacturers must participate in the 340B drug program in order to get their drugs covered by Medicaid.

¹⁶The Medicare Part B program covers a broad range of medical services, including physician, laboratory, and hospital outpatient department services and durable medical equipment.

Approaches Used by Other Countries for Negotiating Drug Prices

According to the OECD, member countries that offer subsidized drug programs are grappling with how to manage increased drug spending given limited budgets. These countries have three main approaches to limiting the amount they pay to acquire drugs:

- ceiling prices,
- reference prices, and
- profit limits.

Ceiling prices. Ceiling prices restrict market negotiations by setting maximum prices purchasers can pay for drugs. Ceiling prices allow purchasers to negotiate lower prices directly with drug manufacturers. One approach is for a government to set prices for drugs and prohibit sales at greater prices. In France and Australia, for example, a government committee sets the prices at which drugs must be purchased and reimbursed. Alternatively, a government may set a price ceiling and allow purchasers to negotiate more favorable prices with manufacturers directly. In Canada, the Patented Medicines Prices Review Board sets the maximum price a manufacturer can charge direct purchasers. It can impose fines on any manufacturer that attempts to sell a drug at a price greater than the established ceiling. An additional method used to control prices is for a government to set reimbursement rates for new drugs at low levels; because any price above the set reimbursement rate would be an out-of-pocket expense to the consumer, the reimbursement rate effectively becomes the market price.

Reference prices. Reference prices use local or international price comparisons of drugs classified in the same therapeutic group to determine a single or maximum price for all drugs in that group. The therapeutic group of drugs can encompass old and new drugs, including brand or generic drugs. The lowest priced drug may then establish the maximum price for the entire therapeutic group. Germany, for example, sets such prices based on local price comparisons of drugs classified in the same therapeutic group.

Profit limits. Profit limits control the amount of profit a drug manufacturer may earn on a product or within a specified period of time. If the established threshold is exceeded, the manufacturer is required to accept a price cut or pay rebates to the government. In the United Kingdom, for example, there are limits on the profits that a drug manufacturer can earn on sales to the National Health Service.

Several other key factors can influence drug price negotiations in OECD countries. Unlike the United States, many OECD countries, such as Australia and France, have universal health care systems that allow a mandated, relatively more unified approach to drug pricing. While these countries vary in their government's respective share of drug spending, some set national, uniform maximum prices to be paid by all purchasers, including private payers. Many countries also establish national formularies that define which drugs are to be covered by all purchasers.

Approaches Used by U.S. Private Payers for Negotiating Drug Prices

In the United States, private payers represent the largest source of prescription drug spending. These payers, including employer-based health plans and private health insurers, typically contract with PBMs to help manage their prescription drug benefits. PBMs employ several cost containment strategies for lowering drug prices for the health plans and enrollees they represent. PBMs negotiate rebates or payments with manufacturers and prices with networks of retail and mail-order pharmacies, passing along at least some of the savings to health plans and enrollees. Manufacturers and pharmacies agree to these price concessions in exchange for both the large number of enrollees PBMs represent and the ability of PBMs to influence enrollee choice of drugs and pharmacies.

One of the key ways PBMs influence price negotiations with manufacturers is through formulary development and management. PBMs may assist health plans in developing or managing a formulary that the health plan will cover. Health plans often provide financial incentives, such as lower enrollee cost-sharing, to encourage use of preferred drugs listed on the formulary.¹⁷ Since PBMs represent a large number of enrollees, manufacturers have a strong interest in having their drugs listed on plan formularies. Manufacturers pay PBMs through rebates or other payments to be included on plan formularies and to capture greater market shares for their drugs. For example, many mail-order pharmacies are owned by PBMs, and PBMs can obtain greater manufacturer rebates or payments by dispensing a high volume of the manufacturer's drug.

The extent to which pharmacy discounts and manufacturer rebates or payments are shared with health plans and enrollees depends on contractual arrangements with the health plan and the plan's benefit design. For example, PBMs negotiate contracts with health plans and their

¹⁷In some cases, a plan may charge more or may not provide coverage for drugs not listed on the plan's formulary.

networks of pharmacies separately, which means that health plans may pay PBMs higher prices for drugs than the PBM negotiated between itself and the pharmacy. Similarly, PBMs often set up contractual arrangements with manufacturers based on manufacturers' entire line of products rather than per drug. Further, PBMs may retain a portion of the rebates or payments they receive associated with individual health plans or all the health plans they represent. PBMs may also obtain additional rebates or payments from manufacturers for administering formularies or providing certain services, such as encouraging the use of one therapeutically similar drug over another.

Approaches Used by U.S. Federal Programs for Negotiating Drug Prices

Approaches for negotiating drug prices vary among federal programs in the United States. While these approaches reflect the laws that govern them, markets, and health care delivery and financing, there are also elements common to some of the approaches used by other countries and by private payers. Some federal programs set ceiling prices, others establish prices by referencing prices negotiated by private payers in the commercial market, and still others rely on negotiations with manufacturers, either directly or through private health plans. For example, VA's and DOD's prices for particular prescription drugs may be the lowest of an FSS price, a ceiling price, or the price that each agency can negotiate directly with the manufacturer. The FEHBP uses a different approach, modeled after other large U.S. employers' health benefits; health plans participating in the FEHBP typically contract with PBMs to negotiate drug prices and offer other pharmacy benefit, administrative, and clinical services. Further, like many of the other OECD countries, U.S. federal programs use a mix of strategies to contain prescription drug spending. Many federal programs have formularies that define which drugs are to be covered. While some federal programs' formularies are comprehensive and some are more restrictive than others, the programs use lists of covered drugs as the basis for negotiations with drug manufacturers.

VA and DOD

VA and DOD have several options available to obtain favorable prices for drugs covered on their formularies. Both agencies pay the lowest of several prices available for a given drug, and both can negotiate with suppliers to receive additional discounts. In addition, both have adopted certain practices that affect negotiations, such as the use of formularies, or that otherwise contribute to lower costs, such as the use of mail-order pharmacies.

VA and DOD have access to a number of prices to consider when purchasing drugs.

- *FSS prices.* VA's National Acquisition Center negotiates FSS prices with drug manufacturers. These prices are available to all federal purchasers. FSS prices are intended to be no more than the prices manufacturers charge their most-favored nonfederal customers under comparable terms and conditions. Under federal law, drug manufacturers must list their brand drugs on the FSS to receive reimbursement for drugs covered by Medicaid.¹⁸ All FSS prices include a fee of 0.5 percent of the price to fund VA's National Acquisition Center.
- *Federal ceiling prices.* Federal ceiling prices, also called Big Four prices, are available to VA, DOD, the Public Health Service, and the U.S. Coast Guard. These prices are mandated by law to be 24 percent lower than nonfederal average manufacturer prices.¹⁹
- *Blanket purchase agreements.* Blanket purchase agreements are national contracts with drug manufacturers that allow VA and DOD—either separately or jointly—to negotiate prices below FSS prices. The lower prices may depend on the volume of specific drugs being purchased by particular facilities, such as VA or military hospitals, or on being assigned preferred status on VA's and DOD's respective national formularies.

In a few cases, individual VA and DOD medical centers have obtained lower prices through local agreements with suppliers than they could have through the national contracts, FSS prices, or federal ceiling prices.

In addition, VA's and DOD's use of formularies, pharmacies, and prime vendors can further affect drug prices. VA and DOD formularies encourage the substitution of lower-cost drugs determined to be as effective or more effective than higher-cost drugs. Both VA and DOD use prime vendors, which are preferred drug distributors, to purchase drugs from manufacturers and deliver the drugs to VA or DOD facilities.²⁰ VA and DOD

¹⁸See 38 U.S.C. § 8126(a)(4).

¹⁹See 38 U.S.C. § 8126(a)(2). The nonfederal average manufacturer price is the weighted average price of a single form and dosage unit paid by wholesalers to a manufacturer, taking into account cash discounts or similar price reductions. Big Four prices, in general, do not apply to generic drugs.

²⁰As of June 2004, VA used one prime vendor, while DOD used five prime vendors that serviced different geographic areas.

receive discounts from their prime vendors that also reduce the prices that they pay for drugs. For DOD, the discounts vary among prime vendors and the areas they serve. As of June 2004, VA's prime vendor discount was 5 percent, while DOD's discounts averaged about 2.9 percent within the United States.

Medicaid

Unlike VA and DOD, state Medicaid programs do not negotiate drug prices with manufacturers, but reimburse retail pharmacies for drugs dispensed to beneficiaries at set prices. Under the Medicaid drug rebate program,²¹ drug manufacturers provide quarterly rebates for covered outpatient prescription drugs purchased by state Medicaid programs. The rebates are meant to take advantage of the prices manufacturers receive for drugs in the commercial market and are required to reflect the results of negotiations by private payers such as discounts and rebates.

The rebates are based on two prices per drug that manufacturers report to CMS: best price²² and average manufacturer price (AMP).²³ The relationship between best price and AMP determines the unit rebate amount and thus the overall size of the rebate that states receive for a brand drug. The basic unit rebate amount is the greater of two values: the difference between best price and AMP or 15.1 percent of AMP. If the drug's AMP rises faster than inflation, the manufacturer is required to provide an additional rebate to the state Medicaid program.²⁴ A state's rebate for a brand drug is the product of the unit rebate amount plus any

²¹See 42 U.S.C. § 1396r-8.

²²Best price is the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, or nonprofit or government entity, with some exceptions. Among other things, sales made through the FSS, single-award contract prices of any federal agency, federal depot prices, and prices charged to DOD, VA, Indian Health Service, and Public Health Service are not considered in determining best price.

²³AMP is defined by statute as the average price paid to a manufacturer for a drug by wholesalers for drugs distributed to the retail pharmacy class of trade. Under the rebate agreement manufacturers negotiate with HHS, AMP does not include prices to government purchasers based on the FSS, prices from direct sales to hospitals or health maintenance organizations, or prices to wholesalers when they relabel drugs they purchase under their own label.

²⁴State Medicaid programs receive an additional rebate for brand drugs when a drug's AMP rises faster than inflation, as measured by changes in the consumer price index.

applicable additional rebate amount and the number of units of the drug paid for by the state's Medicaid program.

The 340B Drug Pricing Program

Entities eligible for the 340B drug pricing program can purchase covered outpatient prescription drugs from manufacturers at or below statutorily defined prices, known as 340B ceiling prices, that take advantage of discounts resulting from the Medicaid drug rebate program. These prices are the maximum amount eligible entities can pay for covered drugs, and the program allows for eligible entities to negotiate more favorable prices directly with drug manufacturers. As such, the 340B drug pricing program offers covered entities access to a prime vendor with which they can contract to negotiate discounts at or below the mandatory 340B ceiling price.

State AIDS drug assistance programs (ADAP) are examples of entities eligible for the 340B drug pricing program. ADAPs participating in the 340B program use either the 340B direct purchase option or the 340B rebate option. Under the direct purchase option, ADAPs purchase drugs from drug manufacturers or through a third party, such as a drug purchasing agent, and ADAPs receive the 340B price discount up front. In addition, ADAPs using this option can access the prime vendor program to assist in negotiating discounts at or below the mandatory 340B ceiling price. Under the rebate option, ADAPs typically contract with entities such as a pharmacy network or PBM for the purchase of covered drugs and later request a 340B rebate directly from the drug manufacturers. ADAPs using the rebate option do not have access to the prime vendor program.

Medicare Part B

Like Medicaid, Medicare does not purchase drugs but rather reimburses physicians for drugs covered under Part B. The maximum Medicare reimbursement for covered Part B drugs is statutorily defined using the average sales price (ASP) plus 6 percent.²⁵ ASP is the average price for a drug based on a manufacturer's sales to all purchasers in the United States, with certain exceptions. Under this reimbursement methodology,

²⁵See 42 U.S.C. § 1395w-3a.

Medicare takes advantage of the prices negotiated by private payers, as ASP is required to reflect the discounts and rebates they negotiate.²⁶

FEHBP

The FEHBP is generally modeled after other large U.S. employers' health benefits, including that participating health plans typically rely on PBMs to negotiate drug prices and offer other pharmacy benefit, administrative, and clinical services. In a 2003 report²⁷ that reviewed the use of PBMs by three FEHBP plans representing about 55 percent of FEHBP enrollment, we found that the PBMs used three key approaches to achieve savings for FEHBP participating health plans:

- passing on certain rebates negotiated with manufacturers to the plans;
- obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies; and
- using intervention techniques that reduce utilization of certain drugs or substitute other, less costly drugs.

The FEHBP plans we reviewed also had formularies that include most therapeutic categories, and these formularies had few restrictions on which drugs enrollees could obtain. Each plan also provided enrollees access to nonformulary drugs, although sometimes with higher cost-sharing requirements than for the preferred formulary drugs.

The PBMs were compensated through various methods, including retaining some portion of the negotiated savings rather than passing the full portion to the FEHBP plans. These compensation methods also included collecting fees from FEHBP plans for administrative and clinical services; retaining a portion of the payments from the FEHBP plans for mail-order drugs in excess of the prices negotiated with manufacturers to acquire the drugs; and in some cases retaining a share of the rebates the PBMs negotiated with drug manufacturers.

²⁶The MMA also required HHS to implement a competitive acquisition program (CAP) for certain Medicare Part B drugs. The CAP is a voluntary program, which began in July 2006, that offers physicians the option to acquire many drugs they use in their practice from an approved CAP contractor.

²⁷ *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*. GAO-03-196. Washington, D.C.: January 10, 2003.

Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions that you or other Members of the Committee may have.

Contacts and Acknowledgments

For future contacts regarding this testimony, please contact John E. Dicken at (202) 512-7119 or at dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Martha Kelly, Assistant Director; Rashmi Agarwal; and Timothy Walker made key contributions to this statement.

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