

**GAO**

Testimony

Before the Subcommittee on Federal  
Workforce, Postal Service, and the District of  
Columbia, Committee on Oversight and  
Government Reform, House of Representatives

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For Release on Delivery  
Expected at 10:00 a.m. EDT  
Wednesday, June 24, 2009

## PRESCRIPTION DRUGS

# Overview of Approaches to Control Prescription Drug Spending in Federal Programs

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Accountability \* Integrity \* Reliability

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Highlights of [GAO-09-819T](#), a testimony before the Subcommittee on Federal Workforce, Postal Service, and the District of Columbia, Committee on Oversight and Government Reform, House of Representatives

## Why GAO Did This Study

Millions of individuals receive prescription drugs through federal programs. The increasing cost of prescription drugs has put pressure to control drug spending on federal programs such as the Federal Employees Health Benefits Program (FEHBP), Medicare Part D, the Department of Veterans Affairs (VA), the Department of Defense (DOD), and Medicaid. Prescription drug spending within the FEHBP in particular, which provides health and drug coverage to about 8 million federal employees, retirees, and their dependents, has been a significant contributor to FEHBP cost and premium growth. The Office of Personnel Management (OPM), which administers the FEHBP, predicted that prescription drugs would continue to be a primary driver of program costs in 2009.

GAO was asked to describe approaches used by the FEHBP to control prescription drug spending and summarize approaches used by other federal programs. This testimony is based on prior GAO work, including *Prescription Drugs: Oversight of Drug Pricing in Federal Programs* ([GAO-07-481T](#)) and *Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs* ([GAO-07-358T](#)) and selected updates from relevant literature on drug spending controls prepared by other congressional and federal agencies.

View [GAO-09-819T](#) or key components. For more information, contact John E. Dicken at (202) 512-7114 or [dickenj@gao.gov](mailto:dickenj@gao.gov).

## PRESCRIPTION DRUGS

### Overview of Approaches to Control Prescription Drug Spending in Federal Programs

#### What GAO Found

FEHBP uses competition among health plans to control prescription drug spending, giving plans an incentive to rein in costs and leverage their market share to obtain favorable drug prices. Most FEHBP plans contract with pharmacy benefit managers (PBMs) to help administer the prescription drug benefit. In a 2003 report, GAO found that the PBMs reduced drug spending by: negotiating rebates with drug manufacturers and passing some of the savings to the plans; obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies operated by the PBMs; and using other techniques that reduce utilization of certain drugs or substitute other, less costly drugs. While OPM does not negotiate drug prices or discounts for FEHBP, it attempts to limit spending through annual premium and benefit negotiations with plans, including the encouragement of spending controls such as generic substitution.

Other federal programs use a range of approaches to control prescription drug spending.

- Medicare—the federal health insurance program for the elderly and disabled—offers an outpatient prescription drug benefit known as Medicare Part D that uses competition between plan sponsors and their PBMs to limit drug spending, in part through the ability to negotiate prices and price concessions with drug manufacturers and pharmacies. Plans are required to report these negotiated price concessions to the Centers for Medicare & Medicaid Services (CMS), to help CMS determine the extent to which they are passed on to beneficiaries.
- VA and DOD pharmacy benefit programs for veterans, active duty military personnel, and others may use statutorily mandated discounts as well as negotiations with drug suppliers to limit drug spending. VA and DOD have access to a number of prices to consider when purchasing drugs—including the Federal Supply Schedule prices that VA negotiates with drug manufacturers—paying the lowest of all available prices.
- The Medicaid program for low-income adults and children is subject to aggregate payment limits and drug payment guidelines set by CMS. Medicaid does not negotiate drug prices with manufacturers, but reimburses retail pharmacies for drugs dispensed to beneficiaries at set prices. An important element of controlling Medicaid drug spending is the Medicaid drug rebate program, under which drug manufacturers are required by law to provide rebates for certain drugs covered by Medicaid. Under the rebate program, states take advantage of prices manufacturers receive for drugs in the commercial market that reflect discounts and rebates negotiated by private payers.

In addition, Part D, VA and DOD, and Medicaid use techniques similar to FEHBP to limit drug spending, such as generic substitution, prior authorization, utilization review programs, or cost-sharing requirements.

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here as you examine approaches to control the rising spending for prescription drugs within the Federal Employees Health Benefits Program (FEHBP). As you know, the FEHBP provides health coverage, including prescription drug coverage, to about 8 million federal employees, retirees, and their dependents. As with other public and private employer-sponsored health plans, prescription drug spending has been a significant contributor to FEHBP cost and premium growth. Projected increases in the costs of prescription drugs alone would have accounted for about a 3 to 5 percent annual increase in FEHBP premiums from 2002 through 2007. The Office of Personnel Management (OPM), the federal agency that administers the FEHBP, predicted that prescription drugs would continue to be a primary driver of program costs in 2009.<sup>1</sup>

Because of the importance of controlling prescription drug spending by the federal government, you asked us to describe prescription drug spending control approaches used by the FEHBP and summarize the approaches used by other federal programs. Accordingly, my testimony today will describe the approach used by FEHBP to control prescription drug spending and summarize approaches used under Medicare, the Department of Veterans Affairs (VA), the Department of Defense (DOD), and Medicaid. My remarks are based on prior work performed from 2003 to 2009 on federal programs that purchase or cover prescription drugs, with selected updates from relevant literature on drug spending controls prepared by other congressional and federal agencies.<sup>2</sup> We used various methodologies to complete our work; please see the individual products for the details. Our work was performed in accordance with generally

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<sup>1</sup>OPM, *News Release: OPM Announces Open Season for Health Benefits, Dental and Vision Insurance, and Flexible Spending Accounts* (Sept. 25, 2008).

<sup>2</sup>A list of related GAO products is included at the end of this statement. For other reports we reviewed, please see, for example, Congressional Budget Office, *Budget Options Volume 1: Health Care* (Washington, D.C.: Dec. 2008); Congressional Budget Office, *The Health Care System for Veterans: An Interim Report* (Washington, D.C.: Dec. 2007); Congressional Research Service, *Medicare Part D Prescription Drug Benefit: A Primer* (Washington, D.C.: Aug. 20, 2008); Congressional Research Service, *Prescription Drug Coverage Under Medicaid* (Washington, D.C.: Feb. 6, 2008); Congressional Research Service, *Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid, and Medicare Policies* (Washington, D.C.: Apr. 13, 2007); Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Washington, D.C.: Aug. 2005); and Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Mar. 2009).

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accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

The FEHBP is the largest employer-sponsored health insurance program in the country. Through it, about 8 million federal employees, retirees, and their dependents received health coverage—including for prescription drugs—in 2008. Coverage is provided under competing plans offered by multiple private health insurers under contract with OPM, which administers the program, subject to applicable requirements. In 2009, 269 health plan options were offered by participating insurers, 10 of which were offered nationally while the remaining health plan options were offered in certain geographic regions. According to OPM, plans must cover all medically necessary prescription drugs approved by the Food and Drug Administration (FDA), but plans may maintain formularies that encourage the use of certain drugs over others.<sup>3</sup> Enrollees may obtain prescriptions from retail pharmacies that contract with the plans or from mail-order pharmacies offered by the plans. In 2005, FEHBP prescription drug spending was an estimated \$8.3 billion.

Medicare—the federal health insurance program that serves about 45 million elderly and disabled individuals—offers an outpatient prescription drug benefit known as Medicare Part D. This benefit was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) beginning January 1, 2006.<sup>4</sup> As of February 2009, Part D provided federally subsidized prescription drug coverage for nearly 27 million beneficiaries. The Centers for Medicare & Medicaid Services (CMS), part of the Department of Health and Human Services (HHS), manages and oversees Part D. Medicare beneficiaries may choose a Part D plan from multiple competing plans offered nationally or

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<sup>3</sup>Formularies include lists of prescription drugs, grouped by therapeutic class (groups of drugs that are similar in chemistry, method of action, and purpose of use), that health plans or insurers encourage physicians to prescribe and beneficiaries to use.

<sup>4</sup>Pub. 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.

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in certain geographic areas by private sponsors, largely commercial insurers, under contract with CMS. Part D plan sponsors offer drug coverage either through stand-alone prescription drug plans for beneficiaries in traditional fee-for-service Medicare or through Medicare managed care plans, known as Medicare Advantage. In 2009, there were over 3,700 prescription drug plans offered. Under Medicare Part D, plans can design their own formularies, but each formulary must include drugs within each therapeutic category and class of covered Part D drugs. Enrollees may obtain prescriptions from retail pharmacies that contract with the plans or from mail-order pharmacies offered by the plans. Medicare Part D spending is estimated to be about \$51 billion in 2009.

The VA pharmacy benefit is provided to eligible veterans and certain others. As of 2006, about 8 million veterans were enrolled in the VA system.<sup>5</sup> In general, medications must be prescribed by a VA provider, filled at a VA pharmacy, and listed on the VA national drug formulary, which comprises 570 categories of drugs. In addition to the VA national formulary, VA facilities can establish local formularies to cover additional drugs. VA may provide nonformulary drugs in cases of medical necessity. In 2006, VA spent an estimated \$3.4 billion on prescription drugs.

The DOD pharmacy benefit is provided to TRICARE beneficiaries, including active duty personnel, certain reservists, retired uniformed service members, and dependents.<sup>6</sup> As of 2009, there were about 9.4 million eligible TRICARE beneficiaries. In addition to maintaining a formulary, DOD provides options for obtaining nonformulary drugs. Beneficiaries can obtain prescription drugs through a network of retail pharmacies, nonnetwork retail pharmacies, DOD military treatment facilities, and DOD's TRICARE Mail-Order Pharmacy. In 2006, DOD spent \$6.2 billion on prescription drugs.

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<sup>5</sup>Of the almost 8 million veterans enrolled, about 5 million received health care services. Additionally, there were over 4 million pharmacy users in VA in 2006.

<sup>6</sup>DOD 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.

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Medicaid, a joint federal-state program, finances medical services for certain low-income adults and children.<sup>7</sup> In fiscal year 2008, approximately 63 million beneficiaries were enrolled in Medicaid.<sup>8</sup> While some benefits are federally required, outpatient prescription drug coverage is an optional benefit that all states have elected to offer. Drug coverage depends on the manufacturer's participation in the federal 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 and then receive reimbursements from states for the acquisition cost of the drug and a dispensing fee. Medicaid outpatient drug spending has decreased since 2006 because Medicare Part D replaced Medicaid as the primary source of drug coverage for low-income beneficiaries with coverage under both programs—referred to as dual eligible beneficiaries.<sup>9</sup> In fiscal year 2008, Medicaid outpatient drug spending was \$9.3 billion—including \$5.5 billion as the federal share—which was calculated after adjusting for manufacturer rebates to states under the Medicaid drug rebate program.

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## FEHBP Uses Competition between Health Plans to Control Prescription Drug Costs

FEHBP uses competition among health plans as the primary measure to control prescription drug spending and other program costs. Under an annual “open season,” enrollees may remain enrolled in the same plan or select another competing plan based on benefits, services, premiums, and other such factors. Thus, plans have the incentive to try to retain or increase their market share by providing the benefits sought by enrollees along with competitive premiums. In turn, the larger a plan's market share, the more leverage it has for obtaining favorable drug prices on behalf of its enrollees and controlling prescription drug spending.

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<sup>7</sup>Medicaid consists of 56 distinct programs created within broad federal guidelines and administered by state Medicaid agencies. The 56 Medicaid programs include 1 for each of the 50 states; the District of Columbia; Puerto Rico; and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, and the Virgin Islands. Within a framework established by federal statutes, regulations, and policies, each state (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program.

<sup>8</sup>Approximately 6 million of the 63 million Medicaid beneficiaries were 65 years or older in 2008.

<sup>9</sup>Part D includes different levels of premium and cost-sharing assistance for dual eligible beneficiaries as well as assistance for other eligible beneficiaries who have low incomes and modest assets but do not meet the eligibility requirements for Medicaid.

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Similar to most private employer-sponsored or individually purchased health plans, most FEHBP plans contract with pharmacy benefit managers (PBMs) to help them administer the prescription drug benefit and control drug spending. In a 2003 report reviewing the use of PBMs by three plans representing about 55 percent of total FEHBP enrollment, we found that the PBMs used three key approaches to achieve savings for the health plans:

- negotiating rebates with drug manufacturers and passing some of the savings to the plans;
- obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies operated by the PBMs; and
- using other intervention techniques that reduce utilization of certain drugs or substitute other, less costly drugs.<sup>10</sup> For example, under generic substitution PBMs substituted less expensive, chemically equivalent generic drugs for brand-name drugs; under therapeutic interchange PBMs encouraged the substitution of less expensive formulary brand-name drugs for more expensive nonformulary drugs within the same drug class; under prior authorization PBMs required enrollees to receive approval from the plan or PBM before dispensing certain drugs that are high cost or meet other criteria; and under drug utilization review PBMs examined prescriptions at the time of purchase or retrospectively to assess safety considerations and compliance with clinical guidelines, including appropriate quantity and dosage.

The PBMs were compensated by retaining some of the negotiated savings. The PBMs also collected fees from the plans for administrative and clinical services, kept a portion of the payments from FEHBP plans for mail-order drugs in excess of the prices they paid manufacturers to acquire the drugs,

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<sup>10</sup>GAO, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies*, [GAO-03-196](#) (Washington, D.C.: Jan. 10, 2003).

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and in some cases retained a share of the rebates that PBMs negotiated with drug manufacturers.<sup>11</sup>

While OPM does not play a role in negotiating prescription drug prices or discounts, it does attempt to limit prescription drug spending through its leverage with participating health plans in annual premium and benefit negotiations. Each year, OPM negotiates benefit and rate proposals with participating plans and announces key policy goals for the program, including those relating to spending control. For example, in preparation for benefit and rate negotiations for the 2007 plan year, OPM encouraged proposals from plans to continue to explore the appropriate substitution for higher cost drugs with lower cost therapeutic alternatives, such as generic drugs, and the use of tiered formularies or prescription drug lists. OPM also sought proposals from plans to pursue the advantages of specialty pharmacy programs aimed at reducing the high costs of infused and intravenously administered drugs.<sup>12</sup> In preparation for 2010 benefit and rate negotiations, OPM reiterated its desire for proposals from plans to substitute lower cost for higher cost therapeutically equivalent drugs, adding emphasis to using evidence-based health outcome measures.<sup>13</sup>

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## Other Federal Programs Use a Range of Approaches to Control Prescription Drug Spending

Medicare Part D uses a competitive model similar to FEHBP, while other federal programs use other methods, such as statutorily mandated prices or direct negotiations with drug suppliers.

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<sup>11</sup>In the private market, 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. Manufacturers pay PBMs through rebates or other payments to be included on plan formularies and to capture greater market share for their drugs.

<sup>12</sup>U.S. Office of Personnel Management Insurance Services Program, *Federal Employees Health Benefits Program Call Letter No. 2006-09* (Washington, D.C.: Apr. 4, 2006).

<sup>13</sup>U.S. Office of Personnel Management Insurance Services Program, *Federal Employees Health Benefits Program Call Letter No. 2009-08* (Washington, D.C.: Apr. 20, 2009).



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## Medicare Part D Uses Competing Prescription Drug Plans

Medicare Part D follows a model similar to the FEHBP by relying on competing prescription drug plans to control prescription drug spending. As with the FEHBP, during an annual open season Part D enrollees may remain enrolled in the same plan or select from among other competing plans based on benefit design, premiums, and other plan features. To attract enrollees, plans have the incentive to offer benefits that will meet beneficiaries' prescription drug needs at competitive premiums. The larger a plan's market share, the more leverage it has for obtaining favorable drug prices on behalf of its enrollees and controlling prescription drug spending. As a result, Part D plans vary in their monthly premiums, the annual deductibles, and cost sharing for drugs. Plans also differ in the drugs they cover on their formulary and the pharmacies they use.

Part D uses competing sponsors to generate prescription drug savings for beneficiaries, in part through their ability to negotiate prices with drug manufacturers and pharmacies. To generate these savings, sponsors often contract with PBMs to negotiate rebates with drug manufacturers, discounts with retail pharmacies, and other price concessions on behalf of the sponsor. MMA specifically states that the Secretary of HHS may not interfere with negotiations between sponsors and drug manufacturers and pharmacies.<sup>14</sup> Even though CMS is not involved in price negotiations, it attempts to determine whether beneficiaries are receiving the benefit of negotiated drug prices and price concessions when it calculates the final plan payments. Sponsors must report the price concession amounts to CMS and pass price concessions onto beneficiaries and the program through lower cost sharing, lower drug prices, or lower premiums. Similar to OPM, CMS also negotiates plan design with participating plans and announces key policy goals for the program, including those relating to spending control. For example, in preparation for 2010 benefit and rate negotiations, CMS noted that one of its goals is to establish a more transparent process so that beneficiaries will be able to better predict their out-of-pocket costs.

Part D sponsors or their PBMs also use other methods to help contain drug spending similar to FEHBP plans. For example, most plans assign covered drugs to distinct tiers, each of which carries a different level of cost sharing. A plan may establish separate tiers for generic drugs and

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<sup>14</sup>The Secretary may also not require a particular formulary or institute a price structure for the reimbursement of Medicare Part D drugs. Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2098 (codified at 42 U.S.C. § 1395w-111(i)).

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brand-name drugs—with the generic drug tier requiring a lower level of cost sharing than the brand-name drug tier. Plans may also require utilization management for certain drugs on their formulary. Common utilization management practices include requiring physicians to obtain authorization from the plan prior to prescribing a drug; step therapy, which requires beneficiaries to first try a less costly drug to treat their condition; and imposing quantity limits for dispensed drugs. Additionally, all Part D plans must meet requirements with respect to the extent of their pharmacy networks<sup>15</sup> and the categories of drugs they must cover.<sup>16</sup> Plan formularies generally must cover at least two Part D drugs in each therapeutic category and class, except when there is only one drug in the category or class or when CMS has allowed the plan to cover only one drug.<sup>17</sup> CMS has also designated six categories of drugs of clinical concern for which plans must cover all or substantially all of the drugs.<sup>18</sup>

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## VA and DOD Use Statutorily Mandated Prices and Negotiate Directly with Drug Suppliers

While FEHBP and Medicare Part D use competition between health plans to control prescription drug spending, VA and DOD rely on statutorily mandated prices and discounts and further negotiations with drug suppliers to obtain lower prices for drugs covered on their formularies.

VA and DOD have access to a number of prices to consider when purchasing drugs, paying the lowest available.

- *Federal Supply Schedule (FSS) prices.* VA's National Acquisition Center negotiates FSS prices with drug manufacturers, and these prices are available to all direct federal purchasers.<sup>19</sup> FSS prices are intended to be

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<sup>15</sup>All prescription drug plans must have a contracted pharmacy in their network that is within 2 miles of 90 percent of urban beneficiaries, 5 miles of 90 percent of suburban beneficiaries, and 15 miles of 70 percent of rural beneficiaries. 42 C.F.R. §423.120(a)(1)(2008).

<sup>16</sup>Under the MMA, prescription drug plans must cover drugs within each therapeutic category and class of Part D drugs. Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2085 (codified at 42 U.S.C. § 1395w-104(b)(3)(C)).

<sup>17</sup>42 C.F.R. §423.120(b)(2)(2008).

<sup>18</sup>Part D plan formularies must include all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic drug categories.

<sup>19</sup>VA and DOD directly purchase drugs from manufacturers for their beneficiaries. FEHBP, Medicare Part D, and Medicaid provide reimbursement for drugs dispensed to beneficiaries.

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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-name drugs on the FSS to receive reimbursement for drugs covered by Medicaid.<sup>20</sup> 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.<sup>21</sup>
- *Blanket purchase agreements and other national contracts.* Blanket purchase agreements and other national contracts with drug manufacturers 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 and help control drug spending. Both VA and DOD use their own national, standard formulary to obtain more competitive prices from manufacturers that have their drugs listed on the formulary. VA and DOD formularies also encourage the substitution of lower cost drugs determined to be as or more effective than higher cost drugs. 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. VA and DOD 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

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<sup>20</sup>See 38 U.S.C. § 8126(a)(4).

<sup>21</sup>See 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.

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2004, VA's prime vendor discount was 5 percent, while DOD's discounts averaged about 2.9 percent within the United States. Additionally, similar to FEHBP and Medicare Part D, DOD uses utilization management methods to limit drug spending including prior authorization, dispensing limitations, and higher cost sharing for nonformulary drugs and drugs dispensed at retail pharmacies.

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### Medicaid Uses Aggregate Payment Limits, Drug Pricing Guidelines, and Required Rebates

Unlike VA and DOD, Medicaid programs do not negotiate drug prices with manufacturers to control prescription drug spending, but reimburse retail pharmacies for drugs dispensed to beneficiaries at set prices. CMS sets aggregate payment limits—known as the federal upper limit (FUL)—for certain outpatient multiple-source prescription drugs.<sup>22</sup> CMS also provides guidelines regarding drug payment. States are to pay pharmacies the lower of the state's estimate of the drug's acquisition cost to the pharmacy, plus a dispensing fee, or the pharmacy's usual and customary charge to the general public; for certain drugs the FUL or the state maximum allowable costs may apply if lower.<sup>23</sup>

In addition to these retail pharmacy reimbursements, Medicaid programs also control prescription drug spending through the Medicaid drug rebate program.<sup>24</sup> Under the drug rebate program, drug manufacturers are required to provide quarterly rebates for covered outpatient prescription drugs purchased by state Medicaid programs. Under the rebate program, states take advantage of the prices manufacturers receive for drugs in the commercial market that reflect the results of negotiations by private payers such as discounts and rebates. For brand-name drugs, the rebates are based on two price benchmarks per drug that manufacturers report to

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<sup>22</sup>Federal regulations set specific limits for multiple-source drugs for which there are two or more therapeutically equivalent products.

<sup>23</sup>States may establish their own methodologies for estimating retail pharmacies' drug acquisition costs. Most states choose to estimate these costs by taking a percentage discount from the average wholesale price. The usual and customary charge for a drug is the full retail price that individuals without prescription drug coverage pay when purchasing drugs at a retail pharmacy. Some states also administer a maximum allowable cost program for selected multiple-source drugs with the maximum price at which the state will reimburse those medications.

<sup>24</sup>See 42 U.S.C. § 1396r-8.

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CMS: best price<sup>25</sup> and average manufacturer price (AMP).<sup>26</sup> The relationship between best price and AMP determines the unit rebate amount and thus the overall size of the rebate that states receive. 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 brand-name drug's AMP rises faster than inflation as measured by the change in the consumer price index, the manufacturer is required to provide an additional rebate to the state Medicaid program. In addition to brand-name drugs, states also receive rebates for generic drugs. For generic drugs, the basic unit rebate amount is 11 percent of the AMP. A state's rebate for a drug is the product of the unit rebate amount plus any applicable additional rebate amount and the number of units of the drug paid for by the state's Medicaid program. In addition to the rebates mandated under the drug rebate program, states can also negotiate additional rebates with manufacturers.

Like FEHBP and Medicare Part D participating plans, Medicaid programs also use other utilization management methods to control prescription drug spending including prior authorization and utilization review programs, dispensing limitations, and cost-sharing requirements.

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

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<sup>25</sup>Best 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.

<sup>26</sup>AMP 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.

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## Contacts and Acknowledgments

For future contacts regarding this testimony, please contact John E. Dicken at (202) 512-7114 or at [dickenj@gao.gov](mailto:dickenj@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Randy DiRosa, Assistant Director; Rashmi Agarwal; William A. Crafton; Martha Kelly; and Timothy Walker made key contributions to this statement.

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# Related GAO Products

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*Federal Employees Health Benefits Program: Enrollee Cost Sharing for Selected Specialty Prescription Drugs.* [GAO-09-517R](#). Washington, D.C.: April 30, 2009.

*Medicare Part D Prescription Drug Coverage: Federal Oversight of Reported Price Concessions Data.* [GAO-08-1074R](#). Washington, D.C.: September 30, 2008.

*DOD Pharmacy Program: Continued Efforts Needed to Reduce Growth in Spending at Retail Pharmacies.* [GAO-08-327](#). Washington, D.C.: April 4, 2008.

*DOD Pharmacy Benefits Program: Reduced Pharmacy Costs Resulting from the Uniform Formulary and Manufacturer Rebates.* [GAO-08-172R](#). Washington, D.C.: October 31, 2007.

*Military Health Care: TRICARE Cost-Sharing Proposals Would Help Offset Increasing Health Care Spending, but Projected Savings Are Likely Overestimated.* [GAO-07-647](#). Washington, D.C.: May 31, 2007.

*Federal Employees Health Benefits Program: Premiums Continue to Rise, but Rate of Growth Has Recently Slowed.* [GAO-07-873T](#). Washington, D.C.: May 18, 2007.

*Prescription Drugs: Oversight of Drug Pricing in Federal Programs.* [GAO-07-481T](#). Washington, D.C.: February 9, 2007.

*Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs.* [GAO-07-358T](#). Washington, D.C.: January 11, 2007.

*Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs.* [GAO-07-239R](#). Washington, D.C.: December 22, 2006.

*Federal Employees Health Benefits Program: Premium Growth Has Recently Slowed, and Varies among Participating Plans.* [GAO-07-141](#). Washington, D.C.: December 22, 2006.

*Medicaid: States' Payments for Outpatient Prescription Drugs.* [GAO-06-69R](#). Washington, D.C.: October 31, 2005.

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*Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States.* [GAO-05-850T](#). Washington, D.C.: June 22, 2005.

*Mail Order Pharmacies: DOD's Use of VA's Mail Pharmacy Could Produce Savings and Other Benefits.* [GAO-05-555](#). Washington, D.C.: June 22, 2005.

*Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States.* [GAO-05-102](#). Washington, D.C.: February 4, 2005.

*Contract Management: Further Efforts Needed to Sustain VA's Progress in Purchasing Medical Products and Services.* [GAO-04-718](#). Washington, D.C.: June 22, 2004.

*Medicare: Observations on Program Sustainability and Strategies to Control Spending on Any Proposed Drug Benefit.* [GAO-03-650T](#). Washington, D.C.: April 9, 2003.

*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.