

CRS Report for Congress

Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid, and Medicare Policies

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Summary

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173) addressed seniors' rising out-of-pocket costs of prescription drugs by providing a mechanism for beneficiaries to obtain affordable prescription drug insurance coverage. The Medicare prescription drug benefit, otherwise known as Part D, was designed to take advantage of market competition. In accordance with market competition principles, the drug plans that administer the drug benefit are corporations who may rely on rebate negotiation and price-volume discounts as a way to affect prices.

A provision in the MMA, termed the “noninterference” provision, prevents the federal government from acting as a third party by negotiating the prices that the drug plans would pay to pharmaceutical manufacturers. Both the new Speaker of the House and new Senate Majority Leader have reportedly expressed their support for repealing the “noninterference” provision, and regard it as a priority for consideration in the 110th Congress. Should the provision be repealed, Congress may wish to provide guidance on how it expects prices to be negotiated. In order to clarify and inform the debate, this report provides an overview of the pharmaceutical pricing policies used by the Department of Veterans Affairs (VA) and Medicaid — the largest federal purchasers of prescription drugs, other than Medicare.

The Veterans Health Administration (VHA) operates the nation's largest integrated direct health care delivery system. Unlike Medicare, which operates as an insurer by reimbursing beneficiaries for the cost of medical care provided by doctors and other providers in private practice as well as by private and public hospitals, VHA provides care directly to veterans largely in VA clinics and VA hospitals. Currently VA utilizes four contracting mechanisms to acquire its pharmaceutical supplies: (1) the Federal Supply Schedule (FSS); (2) performance based incentive agreements (3) pricing under the Veterans Health Care Act of 1992, and (4) National Standardization Contracts.

Medicaid, a state administered program that operates under broad federal rules, directly controls drug prices by putting a federal ceiling on reimbursements for drug products available from multiple sources and by requiring drug manufacturers to pay rebates to states for drugs purchased on behalf of Medicaid enrollees. States further control overall drug costs through multiple methods, including using formularies and preferred drug lists, requiring that Medicaid enrollees make copayments, and requiring generic substitution.

Several options exist for affecting out-of-pocket and overall prescription drug costs, including 1) establishing a federal price ceiling for Medicare (like Medicaid); 2) mandating that manufacturers provide larger rebates to Part D plans (like Medicaid); or 3) establishing a Medicare pharmacy purchasing system (like the VA).

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Introduction

One of the motivating factors for Congress to create Medicare Part D in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173) was seniors' rising out-of-pocket drug costs. Prior to MMA, 38% of Medicare beneficiaries did not have drug insurance coverage.¹ People without sufficient drug insurance were paying drug prices that were 15% higher on average than the prices paid by insurance companies.² Some Medicare beneficiaries who did not have drug insurance coverage coped with these higher prices by filling fewer of their prescriptions and taking medications less frequently than their doctors recommended.³

Medicare Part D provides voluntary insurance coverage of drugs for beneficiaries, albeit at a high price to the federal government.⁴ The federal cost of Part D benefits is estimated to be \$44.7 billion in 2007.⁵ Medicare Part D was designed to take advantage of market competition. In accordance with market competition principles, the drug plans that administer the drug benefit are corporations who may rely on rebate negotiation and price-volume discounts as a way to affect prices.

¹ For more statistics on drug coverage in the Medicare population from 1996-1999, see Mary A. Laschober, Michelle Kitchman, et al., "Trends in Medicare Supplemental Insurance and Prescription Drug Coverage, 1996-1999," *Health Affairs*, February 2002, W127-138.

² From the *Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices* (Washington: DHHS, April 2000).

³ One study found that Medicare beneficiaries with drug coverage were 6%-17% more likely to fill their prescriptions and medicate than beneficiaries without drug coverage. For more information on this statistic and others, see Bruce Stuart and James Grana, "Ability to Pay and the Decision to Medicate," *Medical Care*, vol. 36, no. 2 (February 1998), p. 202-211.

⁴ For more information about MMA, see CRS Report RL31966, *Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, by Jennifer O'Sullivan, Hinda Chaikind, Jennifer L. Boulanger, Paulette C. Morgan, and Sibyl Tilson.

⁵ For more details, see the March 2006 Baseline Budget Projections from the U.S. Congressional Budget Office, available at [<http://www.cbo.gov/budget/factsheets/2006b/medicare.pdf>]. Last accessed December 19, 2006. Although more recent CBO budget projections are available for aggregate Medicare spending, the March 2006 baseline contains the most recent detailed projections for Medicare Part D.

A provision in the MMA, termed the “noninterference” provision, prevents the federal government from being a third party in drug price negotiations between the Part D drug plans and pharmaceutical manufacturers. Both the new Speaker of the House and new Senate Majority Leader have expressed their support for repealing this “noninterference” provision, and regard it as a priority for consideration in the 110th Congress.⁶ Furthermore, one poll indicates that about 85% of Americans also seem to support repealing the provision and allowing the government to negotiate prices.⁷

Should the “noninterference” provision be repealed, Congress may wish to provide guidance on how they expect the Secretary of Health and Human Services (HHS) to negotiate prices. A debate could occur about the options and mechanisms of a new drug pricing policy for the Medicare drug plan. In order to clarify and inform the debate, this report provides an overview of the pharmaceutical pricing policies used by the Department of Veterans Affairs (VA) and Medicaid — two of the largest federal purchasers of prescription drugs, other than Medicare. This report first provides a brief background of the current U.S. pharmaceutical pricing for Medicare, and the implications of this policy. The report then discusses the types of pricing policies used by the VA and Medicaid to stem the rise in drug expenditures. The report concludes by discussing the implications of negotiating drug prices and options that may lower costs for the Medicare Part D Program and its beneficiaries.

Drug Prices Versus Formularies

Prices and formularies are often perceived to be intertwined because formularies are the most frequently used incentive in drug price negotiations. Importantly, other “carrots and sticks” may be available to drug price negotiators, and an open formulary does not necessarily preclude price negotiation. A formulary is a set of drugs for which a Part D drug plan, or other health insurer, has agreed to pay a portion of the costs; the formulary may also specify contingencies for payment.⁸ Drug pricing policies do not dictate formularies. A drug pricing policy may have no

⁶ For more details, see press release from the Senate Democratic Communications Center, “Reid: Congress Must Improve Medicare Part D,” December 8, 2006; See also Drew Armstrong, “Democrats’ First 100 Hours: Big Pharma Braces for Heavier Federal Hand in Drug Pricing Policy,” *CQ Weekly*, November 20, 2006; See also Rebecca Adams, “Pharma Braces for Battle,” *CQ Weekly*, November 27, 2006. On January 12, 2007, the House of Representatives passed H.R. 4 on a 255-170 vote. H.R. 4 requires the Secretary of HHS to negotiate Medicare drug prices.

⁷ A poll by the Harvard School of Public Health and Kaiser Family Foundation indicates that 85% of adults (92% of Democrats, 85% of Independents, and 74% of Republicans) support allowing the federal government to negotiate drug prices for the Medicare program. For more information, see The Henry J. Kaiser Family Foundation, “Public Sees Health Care Prices as Unreasonable and Wants Government to Take Steps to Lower Them,” December 8, 2006. Available at [<http://www.kff.org/kaiserpolls/pomr120806nr.cfm>]; accessed December 15, 2006.

⁸ A drug formulary is a continually updated list of medications and related information, representing the clinical judgement of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease.

bearing on which drugs will or will not be included in a formulary. Adopting a drug pricing policy from Medicaid, the VA, or even another country does not imply that the formulary is also adopted. In contrast, knowing the extent to which a formulary will include or exclude pharmaceuticals may help to determine which drug pricing policies would make the most sense. For example, if a formulary was to include every drug on the market, a competitive bidding process would not be the most sensible drug pricing policy, since those policies generally involve accepting the best bid and rejecting the other bidders. In contrast, a competitive bidding process may be a reasonable option for a formulary that only includes one drug in each drug class.⁹ However, simply having a competitive bidding process for pharmaceutical pricing does not provide any information about the inclusiveness of the formulary, because the resulting formulary may include one, two, or even five drugs in each drug class.

Medicare Pharmaceutical Pricing

Under current law, prescription drugs for Medicare beneficiaries are provided through prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA-PD) plans. Unlike MA-PDs, which cover the costs of the entire set of Medicare benefits (Parts A, B, and D), the PDPs only cover the costs of prescription drugs (Part D).¹⁰ The plans have contracts with the Centers for Medicare and Medicaid Services (CMS) to provide prescription drug coverage to Medicare beneficiaries. Individually and with a great deal of flexibility, the plans construct benefit packages (including the formulary, deductible, co-payments, and utilization management tools), arrange a network of pharmacies to dispense the drugs, and negotiate prices and/or rebates with the pharmaceutical manufacturers.¹¹

Enrollees are required to make copayments (which is the *entire* price if the drug is not covered¹²) and pay premiums that may be affected by the negotiated prices (i.e., the lower the prices paid by the plan, the lower the amounts the plan must charge in premiums). Beneficiaries' satisfaction or dissatisfaction with their drug plan is likely to be related to the amount they pay for drugs, among other factors.

⁹ For definitions of drug classes in the Medicare Part D program, see the CMS Medicare formulary guidelines, available at [<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidance.pdf>], and the example formulary, which is available at [<http://www.usp.org/pdf/EN/mmg/drugListingV2.0-2006-02-06.pdf>].

¹⁰ Part B also covers the cost of some drugs. For more information on Part B drugs, see CRS Report RL31419, *Medicare: Payments for Covered Part B Prescription Drugs*, by Jennifer O'Sullivan.

¹¹ For more information on PDPs, see "The Nuts and Bolts of PDPs," by Mary Ellen Stahlman, George Washington University, *National Health Policy Forum*, Issue Brief no. 817, November 8, 2006.

¹² A drug may not be covered if either the drug is not on the plan's formulary or if a beneficiary's total drug spending is in the "doughnut hole" — the common term for drug expenditures between \$2,400 and \$5,451 in 2007.

Medicare Formularies

Part D plans are required to include two drugs in each therapeutic class, except if only one drug is available. The CMS requires coverage of “all or substantially all” drugs for some mental illnesses, including antidepressants, antipsychotics, and anticonvulsants. Anticancer drugs, immunosuppressants, and HIV/AIDS drugs are also included in the “all or substantially all” list of formulary drug classes. Plans can neither change their formularies without CMS approval, nor drop coverage for persons currently using the drug, except at the beginning of the calendar year.

These minimum requirements do not imply that beneficiaries have access to every drug, or its chemical equivalent, that they may be prescribed. For example, the MMA did not require Part D plans to cover the costs of any drugs in the “doughnut hole” — the common term for beneficiaries’ drug expenditures between \$2,400 and \$5,451 in 2007. While a few plans are offering coverage in the “doughnut hole” in 2007, most of this coverage is for generic drugs only.¹³ Moreover, any system that grants patients the freedom to choose their own plan will have some inefficiencies, namely that patients may not select the best plan for their needs. Nonetheless, polls indicate that most patients are satisfied with their drug plans.¹⁴

Negotiation

A legal impediment to changing the way Medicare drugs are priced is the “noninterference” provision in MMA. Specifically, this provision forbids the Secretary of Health and Human Services (HHS) from negotiating the price of prescription drugs on behalf of Medicare beneficiaries.¹⁵ The MMA states, “in order

¹³ For more details, see the recent study by Jack Hoadley, Elizabeth Hargrave, Katie Merrell, Juliette Cubanski, and Tricia Neuman, “Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings,” *The Henry J. Kaiser Family Foundation*, November 2006, available at [<http://www.kff.org/medicare/upload/7589.pdf>]. Last accessed December 27, 2006.

¹⁴ The satisfaction rate varies among polls. A poll conducted by the Henry J. Kaiser Family Foundation, *Seniors’ Early Experiences with Their Medicare Drug Plans* (conducted June 8-18, 2006), indicated that 81% of beneficiaries are “very satisfied” or “somewhat satisfied;” poll details are available at [<http://www.kff.org/kaiserpolls/upload/7546.pdf>]. Last accessed December 27, 2006. A Wall Street Journal Online/Harris Interactive Health-Care poll found that 75% of beneficiaries are “very satisfied” or “somewhat satisfied.” For more details see Harris Interactive, *Seniors Satisfied with Medicare Drug Plans; Seven in Ten Enrollees Say their Plan has Saved them Money on Prescription Drugs*, November 20, 2006 [<http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=1123>]. Last accessed December 27, 2006.

¹⁵ In October 2001, as the anthrax attack was unfolding on Capitol Hill, then-Secretary of Health and Human Services (HHS) Tommy Thompson sought to purchase a large amount of the preferred antibiotic, ciprofloxacin (“Cipro”) from the manufacturer, Bayer Corporation, at a reduced price. Thompson made headlines with his negotiating tactics, including a threat to override the drug’s patent. The Strategic National Stockpile, the HHS program to assure treatments for victims of bioterrorism and other emerging health threats, was established following an appropriation in FY1999, and flowed from the Secretary’s

(continued...)

to promote competition under this part and in carrying out this part, the Secretary - (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary to institute a price structure for the reimbursement of covered Part D drugs.”¹⁶ The conference report adds that, “conferees expect PDPs to negotiate price concessions directly with manufacturers.”¹⁷ The pharmaceutical pricing policies discussed later in this report could not be implemented in the Medicare program without allowing the Secretary of HHS, or some other authority, to negotiate with the pharmaceutical manufacturers for Part D drugs.

Repealing the “noninterference” clause may lead to changing the drug pricing policy for Medicare. If Congress repeals the provision and allows the Secretary of HHS to negotiate drug prices, it may also wish to provide some guidance as to what type of drug pricing policy they want the Secretary of HHS to negotiate and what the goals of such a pricing policy would be. Since the number of different drug pricing policies is innumerate, examining policies that have been applied in other settings may help in exploring the options.

In theory, the federal government may be able to leverage its market share to negotiate lower prices. The extent to which the federal government could negotiate lower prices than the Part D drug plans is unknown. In fact, some argue that market powers have already achieved lower prices.¹⁸ Without more knowledge about the extent to which prices could be lowered, it is impossible to predict whether a new pricing policy would lead to lower costs for Medicare beneficiaries, the federal government, or other U.S. consumers.

Possible Ripple Effects. Importantly, any new drug pricing policy for Medicare may have ripple effects on manufacturers’ research and development of new pharmaceuticals, Part D drug plans’ role and ability to compete, pharmacies’ profits, as well as other U.S. consumers. The size of these ripples will depend upon the type of pricing policy selected, and the extent to which the federal government negotiates lower prices. Possible implications, including the ripple effects from applying the VA or Medicaid drug pricing policies to Medicare, are explored in the conclusions of this report.

¹⁵ (...continued)

general authorities to control disease. Explicit statutory authority for the stockpile was established in 2002 (P.L. 107-188). The authority of the Secretary to negotiate prices when procuring for the stockpile, while not explicit in law, is implicit, and derives from his general authority to enter into contracts for goods and services under federal programs.

¹⁶ Section 1860D(11)(I) of the Social Security Act.

¹⁷ For more information, see House Conference Report 108-391, p.461.

¹⁸ For more information, see the January 10, 2007 letter from the Congressional Budget Office to the Honorable John D. Dingell, Chairman of the House Energy and Commerce Committee, available at [<http://www.cbo.gov/ftpdocs/77xx/doc7722/hr4.pdf>].

In order to clarify some of the key differences between the Medicare, VA, and Medicaid systems, **Table 1** provides some details about the number of beneficiaries, costs, and certain elements of these three federal programs.

Table 1. Comparison of Medicare, VA, and Medicaid Drug Programs

	Medicare	VA ¹⁹	Medicaid
Number of beneficiaries	22.5 million in PDPs or MA-PDs, 15.8 million in other drug insurance plans, 4.4 million did not have drug coverage in 2006 ²⁰	4.4 million VA pharmacy users in 2006	41.7 million with drug coverage in 2004 ²¹
Federal pharmaceutical expenditures in 2006 (est.)	\$44.7 billion ²²	\$3.4 billion	\$23.5 billion ²³
Percentage of prescriptions that are generic	56.5% in PDPs, 65.9% in MA-PDs ²⁴	68%	53.8%

¹⁹ All VA data received directly from the Department of Veterans Affairs (VA).

²⁰ Of the 42 million Medicare beneficiaries, approximately 22.5 million were enrolled in Part D plans, as of June 11, 2006. The remaining 19.5 million beneficiaries either did not have prescription drug coverage (4.4 million), had coverage from a Medicare-subsidized retiree plan (6.9 million), had coverage from a federal retiree plan (3.5 million), or had other creditable drug coverage (5.4 million). Press Release from the CMS — June 14, 2006.

²¹ This number excludes 4.9 million Medicaid beneficiaries who are over age 65 since the elderly, beginning in 2006, no longer receive drug coverage under the Medicaid program. CRS tabulations of data from CMS MSIS State Summary Datamart.

²² March 2006 Baseline Budget Projections from the U.S. Congressional Budget Office, op.cit.

²³ Medicare and Medicaid estimates from the Centers for Medicare and Medicaid Services, *Projected National Health Expenditures*. Available at [<http://www.cms.hhs.gov/nationalhealthexpenddata/>]. Last accessed December 27, 2006. PhRMA member companies estimated \$164 billion in 2005 sales. For more details, see Pharmaceutical Research and Manufacturers of America (PhRMA), *PhRMA Membership Survey, 2006*. Available at [<http://www.phrma.org/files/2006%20Industry%20Profile.pdf>]. Last accessed December 27, 2006.

²⁴ Data from CMS Plan Reported Data (per 2006 Medicare Part D Plan Reporting Requirements) for the first two quarters of 2006.

Number of prescriptions filled annually	780 million (in 2006) ²⁵	120 million (in FY2006)	584 million (in 2005)
Maximum out-of-pocket costs	\$328.20 average annual premium, \$265 annual deductible, 25% for costs \$265 - \$2,400, 100% for costs \$2,400 - \$5,451.25, 5% for costs \$5,451.26 and up. ²⁶	\$0 premium, \$8 for 30-day supply of drugs (for health conditions not connected to military service), \$960 annual limit, after which the prescription is free for Priority Groups 2-6 veterans. ²⁷	\$0 premium, \$1 - \$5 copays per prescription ²⁸
Appeals process for non-formulary drugs	Physicians submit a declaration stating that all covered Part D drugs on any tier would not be as effective for the individual or would have an adverse effect on the individual or both. Plan makes decision on appeal.	Physicians submit a request stating that the drug is medically necessary.	States are required to have a prior authorization review process in place to consider requests for non-preferred drugs.

²⁵ Data estimated by projecting the average monthly prescriptions filled for beneficiaries in PDPs or MA-PDs for January - August 2006. Monthly prescriptions filled for beneficiaries available from CMS at [http://www.cms.hhs.gov/prescriptiondrugcovgenin/02_enrollmentdata.asp?]. Last accessed December 27, 2006.

²⁶ Cost-sharing amounts are those specified for “standard coverage.” Specific co-payments may vary by enrollee and Part D drug plan.

²⁷ VA provides a full prescription drug benefit including both formulary and non-formulary drugs. For a description of priority groups see, CRS Report R.L. 33409, *Veterans Medical Care: FY2007 Appropriations*, by Sidath Viranga Panangala.

²⁸ Amounts are for 2005. As of March of 2006, states have additional options for cost sharing for prescription drugs that certain Medicaid beneficiaries can be charged. Those with income above 100% of poverty can have higher copays for drugs as long as total aggregate cost sharing for all services do not exceed 5% of family income and as long as the copayment amounts do not exceed between 10% and 20% of the cost of the drug (depending on family income and on whether the state is using a tiered copayment system).

The VA Pharmaceutical Purchasing System

Among those who have been arguing for the federal government to negotiate the prices of prescription drugs under the Medicare Part D Program, considerable attention has been paid to the VA pharmaceutical procurement model.²⁹ Before discussing VA's pharmacy procurement system, it is essential to understand that the veterans health care system is an integrated (closed) system, where physicians and other clinical staff are employees of the VA. Unlike Medicare, which administers medical care through the private sector, the VA provides care directly to veterans. The VA purchases its pharmaceutical needs directly from manufacturers and provides prescription medications to veterans through its pharmacies and its own consolidated mail outpatient pharmacy (CMOP) network. This closed system contributes towards successfully implementing a national formulary, which does not exist in Medicare or Medicaid. The section below discusses the VA's contracting techniques used to purchase pharmaceuticals. That is followed by an overview of VA's formulary management process.

Currently, the VA utilizes four contracting mechanisms to acquire its pharmaceutical supplies: (1) the Federal Supply Schedule (FSS); (2) performance-based incentive agreements, or Blanket Purchase Agreements (BPAs); (3) pricing under the Veterans Health Care Act of 1992 (P.L. 102-585); and (4) national standardization contracts.³⁰ On a drug-by-drug basis, the VA selects the mechanism that offers the lowest price.

Federal Supply Schedule (FSS). The FSS is a price catalog that contains almost everything the federal government uses, from nuts and bolts, to pharmaceuticals, to paper clips, to fire engines. The General Services Administration (GSA) has delegated to the VA's National Acquisition Center (NAC) the responsibility for the FSS program for medical care related supplies, equipment, pharmaceuticals, and professional services.³¹ The FSS currently contains about 17,000 pharmaceutical products.³² Of this number, about 36% are brand name drugs, and 64% are generic drugs. The FSS is open to all federal agencies in the executive, legislative and judicial branches — including the VA, Department of Defense (DOD), Public Health Service (PHS), Bureau of Prisons — and several other

²⁹ “Yes. Let the Government Bargain with Drugmakers,” *The Philadelphia Inquirer* December 6, 2006, Editorial, p. A23; “Driving down Drug Prices,” *The Boston Globe* November 27, 2006, Editorial, p. A8; “Lowering Medicare Drug Prices” *The New York Times*, November 14, 2006, Section A, p. 26.

³⁰ Under its current contract with McKesson (the VA wholesale pharmaceutical distributor), the VA obtains an additional 5% discount off the contract price for prompt payment.

³¹ VA NAC currently administers the following schedules: Pharmaceuticals; Medical Equipment and Supplies; Dental Equipment and Supplies; Patient Mobility Devices; X-Ray Film, Equipment and Supplies; Diagnostic, Reagents, Test Kits and Sets; Clinical Analyzer, Laboratory Cost-Per-Test; and Professional and Allied Healthcare Staffing Services.

³² The total number of products listed on the FSS is greater than 17,000 because FSS may list the same drug in different dosage amounts, different dosage forms such as tablets and capsules, and package sizes.

purchasers including the District of Columbia, and Indian tribal governments. VA's NAC Federal Supply Schedule Service is responsible for establishing, soliciting, negotiating, awarding, and administering the FSS. In general, FSS contracts are multi-year (minimum of five years) and multiple award contracts, which means multiple companies supplying comparable products and services, at varying prices, are awarded contracts.

VA's NAC announces and posts solicitations that include all categories of commercially marketed health care products including pharmaceuticals, grouped under Special Item Numbers (SINs).³³ A contracting officer evaluates each proposal based on the drug manufacturer's discounting policies. When evaluating proposals, discounting policies of the manufacturer's competitors are not considered. Under GSA procurement regulations, FSS prices for brand name drugs must be no greater than the prices manufacturers charge their Most-Favored Customers (MFC) under comparable terms and conditions.³⁴ In general, MFC is the customer, or class of customers, which receives the best discount and/or price arrangement on a given item from a manufacturer or supplier. To help VA's contracting officers determine the MFC pricing, pharmaceutical manufacturers are required to provide VA a commercial price list for the proposed items, and are also required to disclose their recent pricing granted to MFCs.³⁵

In general, when awarding a contract to a drug manufacturer, the VA's NAC has to determine the following: 1) whether the government was offered a fair and reasonable price; 2) whether the manufacturer is responsive and responsible; 3) whether the manufacturer completed all certifications and regulatory requirements in their entirety; 4) whether the past performance history of the manufacturer is satisfactory; 5) whether the manufacturer is financially capable; and 6) whether awarding the contract to the drug manufacturer is in the overall best interest of the government.

Performance-based Incentive Agreements (Blanket Purchase Agreements). Under each awarded FSS contract there is a Blanket Purchase Agreement (BPA) clause, which allows the VA to further negotiate with the drug manufacturers and receive additional discounts. The most commonly negotiated BPAs revolve around market share agreements such as a commitment of the VA to buy a specific volume or quantity of drugs over a specified period of time in exchange for receiving an additional discount. In general, BPAs differ from national

³³ Solicitation notices can be viewed at: [<http://www.fbo.gov/spg/VA/index.html>]. Vendors can request a solicitation copy by submitting a written request or by downloading solicitations from the VA at [<http://www1.va.gov/oamm/oa/dbwva/index.cfm>]. accessed January 3, 2007.

³⁴ See 48 C.F.R. §538.270.

³⁵ The manufacturer must also provide a list that includes the following information for each item offered: 1) name of the proposed item, this includes the generic name, trade/brand name; 2) proposed FSS price; 3) proposed discount off the commercial price list; 4) either actual or estimated commercial annual sales for each item offered; 5) either actual or estimated annual government sales for each item offered.

contracts (see below) because they are not competitively bid.³⁶ The VA can also elect to include one or more other FSS customers in a BPA. According to the VA, performance-based incentive agreements provide an additional discount of 5%-15% off the FSS price.

Pricing under the Veterans Health Care Act of 1992. The Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) required that pharmaceutical manufacturers provide rebates to state Medicaid programs on outpatient drugs based on the lowest prices the manufacturers charged their commercial and government customers. With the passage of this legislation, drug manufacturers stopped giving discounts to many of their government purchasers including the VA. In response, Congress enacted the Veterans Health Care Act of 1992 (P.L. 102-585). Section 603 of this act required pharmaceutical companies to list covered drugs on the FSS as a condition of continued participation in the Medicaid program.³⁷ It also required them to roll back price increases, and created statutorily mandated ceiling prices for sales to the four largest federal purchasers of pharmaceuticals: the VA (including state veterans nursing homes receiving grants under Section 1741 of Title 38, United States Code), DOD, PHS (including the Indian Health Service), and Coast Guard.³⁸ These four agencies are commonly known as the “Big 4.” Furthermore, Section 603 of P.L.102-585 required pharmaceutical companies to adhere to the statutory requirements by signing a master agreement and pharmaceutical pricing agreement.³⁹

Under P.L. 102-585, pharmaceutical manufacturers agree to sell the “Big 4” agencies each covered drug at no more than 76% of the non-federal average manufacturers price (non-FAMP), minus any additional discounts as determined each year.⁴⁰ Furthermore, under current law, when the drug manufacturer raises the price of a drug faster than the rate of inflation based on the Consumer Price Index (CPI), then the manufacturer must offer an additional discount, in an amount that will

³⁶ In some circumstances BPAs are awarded after an abbreviated competition among FSS contractors with similar products.

³⁷ Covered drugs are single source drugs, innovator multiple source drugs, and biological products. A single source drug is a brand-name drug that is still under patent and thus is usually available from only one manufacturer. Under Section 603 of P.L. 102-585, an innovator multiple source drug is a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration. This definition would include multiple manufacturers’ licensed versions of a single drug that was granted a new drug application (NDA) approval. The definition does not include true generics that were approved under an abbreviated new drug application (ADNA).

³⁸ 38 U.S.C. 8126(a).

³⁹ The master agreement is a document that is signed by the manufacturer and the VA. The agreement contains responsibilities of the manufacturer and the VA, and dispute resolution processes and terms of termination. The pharmaceutical pricing agreement is an addendum to the master agreement that contains a complete list of a manufacturer’s covered drugs and a federal ceiling price (FCP) for each drug. By signing the document the manufacturer certifies the accuracy of all specified FCPs.

⁴⁰ Non-FAMP is the weighted average price paid by wholesalers, less any discounts, chargebacks, or similar price reductions. These exclude prices paid by the federal government.

ensure that the non-FAMP price does not exceed the percentage change in the CPI.⁴¹ The federal ceiling price (FCP) is calculated using the following formula:

$$\text{FCP} = (\text{annual non-FAMP} \times .76) - \text{additional discounts}$$

Under current law, manufacturers of covered drugs who do not offer their products on the FSS, and who do not offer products under P.L.102-585, are prohibited from contracting with the “Big 4” agencies and Medicaid.⁴² As stated before, the FCP is only available to the “Big 4”; other federal agencies must pay the FSS price, which is higher if the manufacturer maintains a different FCP and FSS price for the same covered drug. This is also known as “dual pricing.” Drug companies can elect to have dual price lists, that is, to give federal ceiling prices to VA, DOD, PHS, and Coast Guard, and provide negotiated FSS prices to all other federal customers. If the pharmaceutical companies don’t elect to have dual prices, all FSS eligible federal customers will receive the FCP. It should be noted that FSS prices could be lower than the FCP, and that the FCP acts as a price ceiling and not a price floor. At present, 3,921 pharmaceutical products on the FSS equal the FCP, and 1,897 drugs are below the FCP.

National Standardization Contracts. The VA also uses national standardization contracts to purchase pharmaceuticals. Depending on what drug is purchased, other agencies such as DOD, PHS, and the Bureau of Prisons can participate in these contracts. The Department seeks competitive bids from manufacturers for products that are therapeutically equivalent within specific drug classes, and contracts with those manufacturers whose products it believes provide the best value based on medical effectiveness, safety and price, in exchange for including their products on the VA’s national formulary and committing to use products throughout the VA health care system.⁴³ These contracts are also known as “committed use contracts” because the VA commits to use a specific drug instead of another therapeutically interchangeable drug, and to guarantee drug companies a high volume of use in exchange for lower prices. These are one-year contracts with the option to renegotiate the contract. In FY2005, the VA purchased \$446 million worth of pharmaceuticals through national contracts. According to the VA, national contract prices are an additional 10%-60% lower than the FSS prices.

⁴¹ 38 U.S.C. 8126 (c).

⁴² 38 U.S.C. 8126 (a)(4).

⁴³ Government Accountability Office, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Price Changes*, GAO/HEHS-00-118, p. 15.

Formulary Management in the VA

It is important to understand the VA's formulary management process because it has a direct bearing on the purchasing mechanisms. Prior to 1995, the VA's 156 medical centers managed their pharmaceutical needs through individual formularies. The Department's Drug Product and Management division based in Hines, Illinois, managed and monitored drug usage and purchasing for those facilities, but had no utilization oversight responsibilities.⁴⁴ In September 1995, the VA established a Pharmacy Benefit Management (PBM) Health Care Strategic Group, tasked with establishing a national formulary, managing pharmaceutical costs, and overseeing pharmacologic guideline development for common diseases within the VA health care system.⁴⁵ In November 1995, as part of its reform efforts the VA created a nationwide system of Veterans Integrated Service Networks (VISNs), consisting of 21 geographically defined networks, and each entity was instructed to create a formulary. To develop their formularies each VISN generally combined their medical center formularies, and on April 30, 1996, VISN formularies became effective. To ensure that all veterans have access to pharmaceuticals — no matter where they live in the U.S — the VA established a national formulary by combining the core of drugs common in the VISN formularies. The national formulary took effect on June 1, 1997. The standardization helped the VA lower its prescription drug costs through bulk purchases: “from a system standpoint, this standardization not only defined the core national pharmacy benefits package, but also provided leverage for bulk purchasing, and with that, contracting within drug classes when appropriate.”⁴⁶ According to the VA, the overall strategy of creating a formulary process is to create a comprehensive pharmaceutical benefit offered to all VA patients seeking care in the VA. VA's PBM continuously reviews formulary decisions to ensure that patients achieve the desired outcomes.

The VA's formulary management process involves the VA Medical Advisory Panel (MAP), the VISN formulary leaders committee, VA's clinical subject matter experts, and the VA PBM staff. The MAP consists of 12 field-based practicing physicians, one DOD physician, and six clinical pharmacists. The PBM staff's role is facilitative, except for clinical subject matter specialists who provide input when selecting drugs. Based on input from the above-mentioned stakeholders, VA's PBM reviews pharmaceutical purchases and identifies high-usage pharmaceutical items. The team reviews these products based on patient treatment, treatment protocol, and patient outcome.

Currently, the VA's national formulary consists of 1,294 dosage-specific drug entries. Of these, 44% are brand name medications and 56% are generic drugs. Based on the amount of drugs that are dispensed (30-day equivalent prescription volume), VA dispenses about 68% generic drugs and 32% brand name drugs.

⁴⁴ Sales, Mariscelle, et.al, “Pharmacy Benefits Management in the Veterans Health Administration: 1995 to 2003,” *The American Journal of Managed Care*, Vol. 11, no. 2 (Feb. 2005), p.104.

⁴⁵ Ibid, p.105.

⁴⁶ Ibid, p. 106.

Restrictiveness of VA's National Formulary. There have been several recently published reports stating that the VA national formulary is overly restrictive and that applying a "VA-style formulary process to the Medicare prescription drug program would significantly reduce physician and patient choice of drugs."⁴⁷ Furthermore, some reports have stated that the drugs used in the VA health system are older than the drugs used in the rest of the U.S. health care system.⁴⁸ However, in a previous study the National Academy of Sciences found that the "VA national formulary was not overly restrictive, and the limited available evidence suggests that it has probably meaningfully reduced drug expenditures without demonstrable adverse effects on quality."⁴⁹ Moreover, the VA has provided its clinicians guidelines on prescribing non-formulary drugs to veterans when it is medically necessary.

Non-formulary Requests. According to the VA guidelines, each VISN must have in place an evidence-based and timely process for approving expeditiously the use of non-formulary drugs by local physicians. In general, non-formulary requests are reviewed and the requester is notified of the decision within 96 hours of the receipt of a complete non-formulary request.⁵⁰ The VA guidelines state that "as always, the prescriber must use his or her best clinical judgment when selecting the most appropriate pharmacotherapy for a specific patient in a specific clinical situation."⁵¹

Medicaid Pharmaceutical Pricing

Medicaid is composed of 50 state (and the District of Columbia) administered programs that provide coverage of health care services, including pharmaceuticals, to certain low-income individuals. The state programs operate independently under broad federal guidelines. The states and the federal government, however, share in the cost of each program based on a statutory formula. The federal share of program expenditures, subject to both a federal floor and ceiling, ranged, in FY2006, from a low of 50% to a high of 76%. For each \$1 of state spending on Medicaid services, a state is able to claim a federal matching payment of \$1 to \$1.52.

⁴⁷ The Pharmaceutical Research and Manufacturers of America (PhRMA), *Comparison of Compounds on the Formularies of Medicare Prescription Drug Plans (Pdps) and the Department of Veterans Affairs Veterans Health Administration (VA) National and Regional Formularies*, December, 2006, p. 11, available at [http://www.phrma.org/files/VHA_WhitePaperDec2006Final.pdf] accessed January 6, 2007.

⁴⁸ Frank R. Lichtenberg, "Older Drugs, Shorter Lives? An Examination of the Health Effects of the Veterans Health Administration Formulary," The Manhattan Institute, *Medical Progress Report*, no.2, Oct. 2005.

⁴⁹ Blumenthal D, Herdman R, eds; VA Pharmacy Formulary Analysis Committee, Division of Health Care Services, Institute of Medicine. *Description and Analysis of the VA National Formulary*. Washington, DC: National Academy Press; January 2000.

⁵⁰ Department of Veterans Affairs, Veterans Health Administration, VHA DIRECTIVE 2001-044, *VA NATIONAL FORMULARY PROCESS*, July 24, 2001.

⁵¹ Ibid.

Reimbursement levels for all Medicaid covered items and services, including prescription drugs, are set by the states. Unlike many other Medicaid items and services, however, prescription drug prices are subject to upper limits established in federal law that restrict the amount of federal matching payments available for those products. In addition, federal law also requires manufacturers whose drugs are made available to Medicaid beneficiaries, to pay rebates to states. The Medicaid rebates were established to achieve a “best price” policy — based on the philosophy that Medicaid as a health coverage program of last resort should have access to the lowest prices offered to other drug purchasers in the market.

In addition, states can and do aggressively negotiate for lower Medicaid drug prices. Many states administer their own upper limit payment formulas, generally intended to keep prices below the federal upper limits. Many states also have negotiated supplemental rebates, over and above those required under federal law. These rebates are often related to the state formularies. For example, under Florida’s Medicaid supplemental rebate program, manufacturers that agree to pay the supplemental rebates will have their products included on the states’ list of preferred drugs. All others are subject to prior authorization.⁵²

Federal Upper Limits. Medicaid’s federal upper payment (FUL) levels are calculated consistent with a statutory formula and based on data submitted by pharmaceutical manufacturers. The FULs apply separately to multiple source and to all “other” drugs and are applied in the aggregate to each state’s spending for drugs. The FULs for multiple source drugs, defined to include any drug for which there is at least one other drug sold and marketed during the period that is rated as therapeutically equivalent and bioequivalent, are calculated by the CMS and are periodically published in the state Medicaid Manual. For these multiple source drugs, the FUL, beginning January 1, 2007, is equal to 250% of the “average manufacturer price” (AMP) for the product computed without regard to prompt pay discounts. The AMP is a price reported to CMS by manufacturers, and is calculated to be the average price at which manufacturers sell a drug product to wholesalers.

Each state must assure the Secretary that its Medicaid spending for multiple source drugs is in accordance with the upper limits plus reasonable dispensing fees. The effect of the FUL requirement is that, when a lower-cost “generic” equivalent exists for a brand-name drug, a state can only claim federal matching share for a reimbursement level that is tied to the generic price even if the brand-name drug is actually furnished. The state has incentives, therefore, to establish policies to encourage the substitution of lower-cost generic equivalents for the brand-name counterparts. The upper limit for multiple source drugs does not apply if a physician provides handwritten certification on the prescription that a specific brand is medically necessary for a particular recipient. The brand name would then be dispensed subject to the limits applicable to “other” drugs.

⁵² For more detailed information on Medicaid drug coverage, states’ payment formulas and supplemental rebates, see CRS Report RL30726, *Prescription Drug Coverage Under Medicaid*, by Jean Hearne.

All “other” drugs include brand-name drugs and multiple source drugs for which a specific FUL limit has not been established. The upper limit that applies to “other” drugs is the lower of the estimated acquisition cost (EAC) plus a reasonable dispensing fee or the provider’s (usually a pharmacy’s) usual and customary charge to the general public. The EAC is the state Medicaid agency’s best estimate of the price generally paid by pharmacies to acquire the drug. States may use another payment method as long as, in the aggregate, a state’s payments for “other” drugs are below the payment levels determined by applying the upper limit for “other” drugs.

Medicaid Rebates. Rebates are computed and paid by pharmaceutical manufacturers each quarter based on utilization information supplied by the state programs. The formula for calculating Medicaid rebates is different based on which of the two following groups the drug falls into. The first group includes single source drugs (generally, those still under patent) and “innovator” multiple source drugs (drugs originally marketed under a patent or original new drug application (NDA) but for which generic competition now exists). Rebates for the drugs in the first group are equal to the greater of 15.1% of the AMP and the difference between the AMP and the best price. Additional rebates are required if the weighted average prices for all of a given manufacturer’s single source and innovator multiple source drugs rise faster than inflation, as measured by the consumer price index for all urban consumers.

The second class includes all other “non-innovator” multiple source drugs (generics). Rebates for non-innovator multiple source drugs are equal to 11% of the AMP.

Medicaid Formularies. There is no federal Medicaid formulary, although states are able to establish formularies for their Medicaid programs. However, federal rules impede states from establishing restrictive formularies. First, federal rebate policies essentially ensure that all drugs sold by a manufacturer are made available to Medicaid beneficiaries if the manufacturer participates in the rebate program. In addition, states are required to cover any non-formulary drug (with the exception of drugs in 10 specific categories) that is specifically requested and approved in advance through a defined process (generally referred to as prior authorization). The 10 categories of drugs that states are allowed to exclude from coverage include drugs used (a) to treat anorexia, weight loss or weight gain; (b) to promote fertility; (c) for cosmetic purposes or hair growth; (d) for the relief of coughs and colds; (e) for smoking cessation; and (f) prescription vitamins and mineral products (except prenatal vitamins and fluoride preparations); (g) non-prescription drugs; (h) barbiturates; (i) benzodiazepines; and (j) drugs requiring tests or monitoring that can only be provided by the drug manufacturer.⁵³

In 2005, 25 state agencies report having established preferred drug lists for their Medicaid programs. States use other mechanisms as well to discourage unnecessary drug spending. Mandatory generic substitution, dispensing limits, prior

⁵³ By law, all of these categories (except for smoking cessation) are excluded from Medicare Part D coverage.

authorization, and beneficiary co-payments are all additional tools states report using to keep control of drug spending.

Negotiating Drug Prices for Medicare

Depending on the policy outcome the Congress wishes to achieve by establishing the authority for the Secretary to negotiate drug prices, there are a number of alternative ways to go about doing so. Medicaid and the VA provide models for a few of these alternatives. If, for example, Congress' primary objective is to lower the overall cost of the program, a set of ceiling prices may be sufficient to achieve such an objective. If, on the other hand, the primary purpose of such actions would be to lower overall costs, while minimizing the number of parties who are negatively affected by policy, then mandated rebates could be appropriate. However, none of those approaches directly impact the premiums drug plans might charge or co-payments that beneficiaries face at the pharmacy; rather, indirect effects are possible. If Congress' primary objective is to impact those amounts, an explicit policy targeted at cost sharing or premiums could ensure those objectives are met. The following section identifies a few alternative approaches that Congress may consider.

Option 1: Establish a Medicare ceiling price. One way in which lower drug prices might translate into lower overall costs is through a Medicare ceiling price.⁵⁴ Ceiling prices could be established to resemble Medicaid's federal upper limits, or the federal supply schedule prices. There are however, both administrative, and other complications to establishing such a system. Without combining such a policy with a national Medicare formulary — and the threat of excluding high priced drugs from such a formulary — CMS may not be able to negotiate adequately favorable ceiling prices. Also, a ceiling price policy does not necessarily translate into lower costs at the pharmacy counter for beneficiaries, nor does it translate into lower purchasing prices for pharmacies. Other policies could be combined with ceiling prices to ensure lower prices for beneficiaries or pharmacies.

Finally, ceiling prices that reduce reimbursements significantly could have indirect effects on beneficiary access to future innovative drug products, and even economic impacts on other payers and providers. For example, manufacturers may lose profits, which may adversely affect pharmaceutical research and development, as well as increase costs for non-Medicare consumers. Pharmaceutical manufacturers have argued that lower profits impede their ability to research and develop new disease treatments.⁵⁵ This argument has been both supported and refuted by many

⁵⁴ For more information on price ceilings, see CRS Report RL33781, *Pharmaceutical Costs: An International Comparison of Government Policies*, by Gretchen A. Jacobson.

⁵⁵ For more information, see Pharmaceutical Research and Manufacturers of America (PhRMA), *What Goes Into the Cost of Prescription Drugs? ... And Other Questions About Your Medicines*. Available at [http://www.phrma.org/files/Cost_of_Prescription_Drugs.pdf]. Last accessed December 27, 2006.

academics.⁵⁶ The manufacturers may also choose to recoup the lost profits by increasing the drug prices for other consumers. Such a policy would need to be carefully crafted to minimize unintended consequences.

Option 2: Mandate that Manufacturers Provide Rebates to Part D Plans. Another way of lowering out-of-pocket payments for beneficiaries might be to mandate larger rebates from manufacturers to Part D drug plans. This system could resemble Medicaid's rebate system. Larger rebates would lower Part D drug plans' net costs of drugs for beneficiaries. Assuming market competition works in the Part D Program, lower net costs could be passed onto beneficiaries in the form of lower premiums, and perhaps also lower copayments. Alternatively, manufacturers could provide these rebates directly to the CMS. If market competition does not fully work, Congress might need to require that Part D plans pass lower costs onto beneficiaries through reduced premiums.

As previously discussed, lower Medicare profits for manufacturers may adversely affect pharmaceutical research and development, and may also increase costs for non-Medicare consumers. However, larger rebates may not adversely affect wholesalers or pharmacists.

Option 3: Establish a Medicare Pharmacy Purchasing System. A new Medicare pharmacy purchasing system would be another option that might help translate lower manufacturer drug prices for Medicare Part D into lower out-of-pocket and overall costs for beneficiaries. One example of such a system could resemble the VA's mail-order pharmacy system. The new Medicare pharmacy purchasing system could negotiate drug prices and purchase drugs from manufacturers or wholesalers, and then distribute the drugs and receive payment from beneficiaries.

This approach is potentially the most administratively burdensome of the options, since it would require developing a Medicare pharmacy distribution system. Pharmacists may experience increased administrative costs if they were to be required to track and purchase drugs separately for their Medicare customers, since pharmacists rarely track drugs by payer under the current system. Some of the burden could be alleviated through heavy use of a mail-order system.

If a mail-order system is established, pharmacists, and possibly wholesalers, could lose profits because they would lose Medicare business. The Part D plans might have a considerably reduced role in the new system. As with any price reduction, manufacturers' profits from Medicare might be reduced and they may choose to recoup lost profits by increasing drug prices to other consumers. Finally, a complete mail-order system is not a realistic option because many beneficiaries may prefer to talk to their pharmacist directly, and may not wish to participate in a mail-order program.

⁵⁶ For examples of academic research on the subject, see John A. Vernon, "Examining The Link Between Price Regulation and Pharmaceutical R&D Investment," *Health Economics*, January 2005; 14(1): 1-16. See also Jerry Avorn, *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs* (Knopf, New York, 2004).