Order Code RL33782

CRS Report for Congress

Federal Drug Price Negotiation: Implications for Medicare Part D

January 5, 2007

Jim Hahn
Health Economist
Domestic Social Policy Division

Prepared for Members and Committees of Congress

Congressional Research Service

Federal Drug Price Negotiation: Implications for Medicare Part D

Summary

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) established a prescription drug benefit for Medicare beneficiaries under Part D, which began on January 1, 2006. One provision of MMA, the "noninterference" clause, expressly forbids the Secretary of Health and Human Services (HHS) from interfering with drug price negotiation between manufacturers and Medicare drug plan sponsors, and from instituting a formulary or price structure for prescription drugs. The framework created by the law emphasizes competition among the Medicare drug plans to obtain price discounts.

The incoming Speaker and the Democratic Party have included "Affordable Health Care" as one of the "Six for '06" initiatives. As part of this effort, they propose to give the Secretary of HHS the authority to negotiate prescription drug prices for Medicare beneficiaries. The majority leader has been reported as stating that the issue will come before the House for a vote on January 12, 2007.

There are a number of approaches that the federal government could adopt to affect prescription drug prices. A few rely on the power of government to dictate an outcome, such as imposing statutory mandates or establishing price ceilings. Others emphasize more market-oriented approaches, such as soliciting competitive bids from voluntary participants. A reference pricing approach combines elements of both. Some of these methods are currently employed by the Department of Veterans Affairs (VA) and the Medicaid program.

The price the VA pays for a drug is the lowest price as determined through one of four methods, less an additional 5% prime vendor discount: (1) the federal ceiling price, (2) federal supply schedule, (3) performance-based incentive agreement, or (4) national standardization contract. Drug reimbursement costs under Medicaid are calculated differently for single-source (only one Food and Drug Administration-approved product) and multiple-source drugs (more than one FDA-approved product). However, for both types of drugs, state reimbursements are determined in aggregate based on either the federal upper limit price (FUL) — a predetermined percentage of a defined reference price — or the estimated acquisition cost.

There are many practical and legislative steps necessary before federal drug price negotiation for Medicare beneficiaries could take place. Initially, the noninterference clause would need to be repealed. However, repealing the noninterference clause may not, in itself, be sufficient to lead to federally negotiated prices. If the Secretary were to engage in activities that affect drug prices on behalf of Medicare Part D beneficiaries, there might be consequences that affect the price of drugs for Medicare beneficiaries as well as other public and private patients, the number and types of drugs that would be available to Part D beneficiaries, the amount of research and development and innovation by pharmaceutical companies, and other sectors of the industry.

This report will be updated.

Contents

Federal Drug Price Negotiations: Implications for Medicare Part D

Introduction

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) established a prescription drug benefit for Medicare beneficiaries under Part D, which began on January 1, 2006. The MMA establishes that Medicare beneficiaries will receive the prescription drug benefit through private organizations, typically insurers or similar risk-bearing organizations, that sponsor prescription drug plans (PDPs) or Medicare Advantage managed care plans that offer the prescription drug benefit (MA-PDs). One provision of MMA, the "noninterference" clause, expressly forbids the Secretary of Health and Human Services (HHS) from interfering with drug price negotiation between manufacturers and Medicare drug plan sponsors, and from instituting a formulary or price structure for prescription drugs.[1] The Medicare drug plans (or their agents) negotiate prices with the drug manufacturers. The framework created by the law emphasizes competition among the Medicare drug plans to obtain price discounts. The Medicare drug plans have incentive to provide the drug benefit to beneficiaries as efficiently as possible while simultaneously attracting enrollees through low premiums and cost-sharing requirements.

The incoming Speaker and the Democratic party have included "Affordable Health Care" as one of the "Six for '06" initiatives. As part of this effort, they propose to give the Secretary of HHS the authority to negotiate prescription drug prices for Medicare beneficiaries. The majority leader has been reported as stating that the issue will come before the House for a vote on January 12, 2007.[2]

This report discusses what it means for the federal government to "negotiate" drug prices under existing public programs,[3] the arguments for and against such activities, and some implications for the pharmaceutical industry, Medicare beneficiaries, and others if similar federal involvement were to occur on behalf of the Medicare Part D program.

---

[1] Section 1860D (i) reads, "NONINTERFERENCE. — In order 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 or institute a price structure for the reimbursement of covered Part D drugs." The conference report adds that "Conferees expect PDPs to negotiate price concessions directly with manufacturers" (H.Rept. 108-391, p. 461).

[2] CQ Today, "Hoyer Lays Out More Details of House Agenda," Jan. 3, 2007.

[3] Most of the federal government's activities regarding the pricing of prescription drugs for public programs would not be characterized as negotiations, where the parties are engaged in a process to determine terms of mutual agreement.

Conceptual Framework for Federal Involvement in Determining Drug Prices and Costs

There are a number of approaches that the federal government could adopt to affect prescription drug prices and expenditures. A few rely primarily on the power of government to dictate an outcome, such as imposing statutory mandates. Others emphasize more market-oriented approaches, such as soliciting competitive bids from voluntary participants. A reference pricing approach combines elements of both by dictating some aspects of the price but also allowing market forces to work. Some of these methods are currently employed by federal government programs (see below), while others have been adopted by governments in other countries.[4] Many of the methods are used together.

Statutory Mandates

Through statutory mandates, the government could set the reimbursement level or the price that the government would pay for each drug, or require that pharmaceutical manufacturers provide a predetermined discount to government purchasers. The federal ceiling price is an example of a statutorily mandated discount. (See discussion below.)

Price Ceilings

The government can set the maximum reimbursement rate for drugs by establishing a price ceiling; drug prices could be less than the ceiling, but not more. The federal ceiling price also falls in this category.

Reference Pricing

Under a reference pricing system, drug reimbursement rates are not directly fixed by the government but are tied through a predetermined manner to another measure that may be dynamic. The reference might be an average price for a group or class of drugs, the average price for a payer or group of payers, or the cost of an alternative treatment. Medicaid's federal upper limit prices and the federal supply schedule both use reference pricing. (See discussion below.)

Competitive Acquisition/Bidding

The government can also solicit and receive bids through a competitive acquisition program, where interested parties (pharmaceutical manufacturers) submit confidential bids that include the prices the company is willing to provide for its product(s). The government would then select the winning bid(s) and award contracts.

---

[4] For more information about drug pricing in other countries, see CRS Report RL33781, *Pharmaceutical Costs: An International Comparison of Government Policies*, by Gretchen A. Jacobson.

Competitive bidding programs, also known as reverse auctions, are already used as the basis for calculating the national average bid amount for the Part D program and for the setting of payment amounts for durable medical equipment (DME) covered under the Medicare program. In describing the DME competitive acquisition program, CMS states that "competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items and services in an efficient manner and at reasonable cost."[5] The MMA also included a provision to establish a competitive bidding demonstration for Medicare managed care beginning in 2010.

Bargaining and Negotiation

The typical formulation of a bargaining or negotiation process involves a mutual discussion and arrangement of the terms of a transaction or agreement. In contrast to a competitive acquisition process where most of the power rests with the buyer, bargaining and negotiation can be more dynamic for each party. The outcome of the process will depend in part on the relative strength of each party's position; monopolists (as the sole provider) or monopsonists (as the only buyer) will have more bargaining power when facing providers or buyers who are but one of many.

Federally Determined Drug Prices and Costs in Practice

The federal government has a track record of active involvement in the determination of drug prices through the experience of the Department of Veterans Affairs in obtaining discounts for VA beneficiaries and through the Medicaid program in obtaining rebates from pharmaceutical manufacturers for states.

Department of Veterans Affairs

The VA obtains prescription drugs at discount through several mechanisms, including negotiated contracts and statutory discounts. The Veterans Health Care Act of 1992 (P.L. 102-585) authorizes the Secretary of Veterans Affairs to negotiate prices for covered drugs on behalf of DOD, the Public Health Service (including the Indian Health Service), and the Coast Guard, in addition to Veterans Affairs. In support of this function, the VA also undertakes many other activities typically associated with pharmacy benefit managers (PBMs) in the private sector, including formulary management.[6]

---

[5] CMS Overview, Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Accessed at [http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/].

[6] Pharmacy benefit managers (PBMs) are companies that administer prescription drug benefits for health care plans. Administrative services include adjudicating claims and managing costs. In addition to formulary management, PBMs typically provide and manage networks of pharmacies willing to accept negotiated discounts on drug prices and dispensing

(continued...)

The price the VA pays for a drug is the lowest price as determined through one of four methods, less an additional five percent prime vendor discount. The four approaches available to the VA are: (1) the federal ceiling price, (2) the federal supply schedule, (3) the blanket purchasing agreements/performance-based incentive agreements, or (4) the national standardization contracts.[7]

Federal ceiling price. Since all pharmaceutical manufacturers have an interest in having their products sold to federal purchasers, all FDA approved drugs are included in the list of "covered drugs." Therefore, for all drugs, the VA receives at least a 24% discount off the non-federal average manufacturer price.[8]

Federal supply schedule (FSS). FSS prices are the lowest prices that manufacturers charge their most-favored nonfederal customers under comparable terms and conditions. These prices are sometimes below the Federal Ceiling Price but not always. The FSS is maintained by the VA's National Acquisition Center (NAC) and is available to all federal purchasers. All FSS prices include a 0.5 percent fee to finance VA's National Acquisition Center.

Pharmaceutical manufacturers have a strong incentive to have their products included on the FSS because Medicaid reimbursement for drugs is contingent on having the drugs on the FSS.[9] In practice, virtually all FDA-approved drugs are included on the FSS. FSS contracts also include a blanket purchasing agreement that allows the VA to negotiate additional discounts.

Blanket Purchasing Agreements/Performance-based Incentive Agreements. These contracts can be initiated by either the VA or by pharmaceutical manufacturers and produce an additional 5 to 15% off FSS. The VA obtains discounts by guaranteeing a high volume of use for the manufacturer's product.

National Standardization Contracts. These contracts typically produce the greatest discounts (from 10 to 60% off FSS) and are negotiated for individual drugs in closed classes on the VA national formulary. The VA is able to obtain favorable prices for these drugs through competitively bid contracts.[10] Most of the VA's contracts are for generic drugs. According to the GAO, generic drugs are easier to

---

[6] (...continued)
fees and may encourage the use of mail-service pharmacies as a cost reduction technique. Clinical services include drug utilization review to prevent potentially dangerous drug interactions.

[7] Much of the information about VA drug pricing was obtained in a briefing for CRS staff by the Pharmacy Benefits Management Strategic Healthcare Group, Department of Veterans Affairs, December 12, 2006.

[8] 38 U.S.C. § 8126(a)(2).

[9] 38 U.S.C. § 8126(a)(4).

[10] The VA selects from among confidential bids submitted by pharmaceutical manufacturers and announces the winning bid. Thus, the process more resembles a round of silent bids rather than a negotiation through which each party bargains with offers and counteroffers.

contract for because these products are already known to be chemically and therapeutically alike, while there is more difficulty in gaining clinical agreement on the therapeutic equivalence of competing brand name drugs.[11]

The VA also obtains an additional discount through its contracts with drug distributors. These organizations, also called wholesalers or prime vendors, purchase the drugs from the manufacturers and deliver them to VA facilities. As of June 2004, the VA contract with the prime vendor provides for an additional 5% discount from the lowest of the four prices described above.

The VA Experience and Medicare Part D. There are many practical and legislative steps necessary before federal drug price negotiation for Medicare beneficiaries could take place. Initially, the noninterference clause would need to be repealed. However, repealing the noninterference clause may not, in itself, be sufficient to lead to federally negotiated prices. The current HHS Secretary is reported to have stated that he does not want the power to negotiate and does not believe that he would be able to "do better than an efficient market."[12] In response, some reports suggest that legislative proposals would also include a mandate for the Secretary to actively negotiate drug prices.

One option for any forthcoming legislation might be to omit detail or specifics. An aide to the incoming Speaker is reported to have stated that Congress does not need "to hammer out all the details. There are a lot of smart people in the Administration, including the Secretary, who can look at how we're buying drugs ... and figure out the best way of negotiating better prices with drug companies."[13]

Should the authority for the Secretary of HHS follow that given to the Secretary of the VA in negotiating drug prices, there is still uncertainty as to whether the activities of HHS will replicate the activities of the VA or whether they would produce similar results. There are substantial differences between Medicare and VA that draw into question whether one experience could be indicative of the other. The VA is a direct provider of care, and has its own health care facilities. As a result, the VA has a national formulary as well as its own warehouses. The VA, through its health care system, is the purchaser of prescription drugs. In contrast, the Medicare program is an insurer that pays for care that is delivered to covered beneficiaries in a myriad of sites. Under the new Part D, which relies on prescription drug plans (PDPs) or Medicare Advantage managed care plans offering a prescription drug benefit (MA-PDs) to provide the drug benefit, Medicare is one step further removed in its relationship with the beneficiary.

Cost-sharing is quite different for Medicare beneficiaries compared with VA beneficiaries, with incentives that might lead to corresponding differences in

---

[11] *VA and DOD Health Care: Factors Contributing to Reduced Pharmacy Costs and Continuing Challenges*, GAO-02-969T, July 22, 2002.

[12] Pear, R., "Power Shift in Congress Revives Health Debate," *New York Times*, January 2, 2007.

[13] Pear, op. cit.

behavior. The VA charges veterans in certain income and eligibility categories an $8 copay for each 30-day-or-less supply of outpatient medication. Also, the VA does not have annual deductible requirements for beneficiaries.[14] As a result, there is no financial incentive for the beneficiary to prefer one drug over another. The Institute of Medicine (IOM) found no adverse health care effects among VA beneficiaries as a result of encouraging providers to use the drugs on the formulary.[15] In contrast, Medicare Part D plans have created more tiers in their Medicare offerings than they have for their non-Medicare business, and instituted varied types of drug utilization management, including step therapy.[16] These financial incentives are aimed toward influencing the choice of drugs by covered Medicare beneficiaries as well as cost-containment.

The VA devotes significant efforts toward the development of its formulary.[17] About 2% of the drug classes on VA's national formulary are designated closed or preferred. For closed classes, VA providers must prescribe and pharmacies must dispense the selected drug, although case-by-case exceptions are allowed. In preferred classes, VA providers and pharmacies are encouraged to prescribe and dispense the preferred drug, but may substitute other drugs in the same class on the formulary without obtaining an exception. These efforts have been successful for the VA, but the implications for Medicare are unclear. Whether CMS would undertake a similar effort and manage the formulary as strictly is uncertain.

Finally, the VA relies substantially on dispensing prescription drugs by mail. About three-quarters of the total prescriptions are processed and distributed through the system of seven Consolidated Mail Outpatient Pharmacies (CMOP). Medicare may not be able to achieve a similarly high degree of consolidation through its many private plans.

Medicaid

While coverage of outpatient prescription drugs is optional for state Medicaid programs, all states covered outpatient prescription drugs for at least some Medicaid

---

[14] Some higher-priority veterans (Groups 2 - 6) have annual co-payment caps of $960 in 2006. There are no copay caps for veterans in the lowest-priority groups consisting of higher-income veterans (Groups 7 and 8) . For additional information, refer to the U.S. Department of Veteran Affairs, "Medicare Part D and VA Prescription Drug Benefits Frequently Asked Questions (FAQs)," accessible at [http://www.va.gov/healtheligibility/Library/FAQs/MedicareDFAQ.asp#vacharge].

[15] Blumenthal, D., and Herdman, R., eds., *Description and Analysis of the VA National Formulary*, IOM, Division of Health Care Services, VA Pharmacy Formulary Analysis Committee (Washington, DC: National Academy Press, 2000).

[16] Step therapy typically requires the use of a more cost-effective drug before filling a prescription for a less cost-effective drug, as determined by the insurer.

[17] The VA has undergone a lengthy transition from numerous local formularies to the adoption of a single national formulary. Prior to 2001, each of the 173 medical centers had its own formulary. In 2001, the VA abolished the local formularies and adopted 22 regional formularies, one for each Veterans Integrated Service Network (VISN). In 2007, the VA is to abolish the regional formularies in favor of the single national formulary.

beneficiaries and well over half of the states covered outpatient drugs for all Medicaid beneficiaries in 2006.[18] Federal regulations require that each state's reimbursement for Medicaid prescription drugs not exceed the lower of (1) its estimated acquisition cost (for the drug itself) plus a dispensing fee (for the professional services in filling and dispensing the prescription), or (2) the provider's usual and customary charge to the public for the drug.[19] As a result, the "prices" of prescription drugs as paid by Medicaid programs are determined in a manner different from the price of drugs in most other settings.

Federal Upper Limit (FUL) and Estimated Acquisition Cost (EAC). Drug reimbursement costs under Medicaid are calculated differently for single source (where there is only one FDA-approved product available for that active ingredient, dosage form, route of administration, and strength) and multiple-source drugs (where more than one FDA-approved product is available). However, for both types of drugs, state reimbursements are determined in aggregate based on a predetermined percentage of a defined reference price. The methodology and basis of the reimbursements changed beginning January 1, 2007, but the underlying concept will remain the same.

Until January 1, 2007, Medicaid reimbursement for multiple-source drugs was based on the federal upper limit (FUL) calculation tied to the average wholesale price (AWP). The FUL is a measure developed by CMS for use by state Medicaid programs in reimbursing drugs that have at least three generic equivalents or on the estimated acquisition cost (EAC) for the drug. The FUL was no more than 150% of the AWP for the least costly therapeutic equivalent. For drugs where CMS does not calculate a FUL, including single-source drugs and drugs for which there are fewer than three equivalents, most states base their calculations for drug reimbursement on the EAC, typically the AWP less a percentage discount.[20]

Beginning January 1, 2007, as a result of the Deficit Reduction Act of 2005 (P.L. 109-171), the AWP will no longer be used as the basis for calculating the FUL or the EAC. While the AWP is meant to reflect the average price at which wholesalers sell a product to retail pharmacies, the AWP is not defined in law or regulation, and as a result, the OIG found that the AWPs used by states to calculate Medicaid drug reimbursement rates were often higher than the prices retail pharmacies pay to purchase the drugs.[21] Instead, the FUL now will be calculated to equal 250% of the "average manufacturer price" (AMP), the average price at which

---

[18] While all states provide outpatient prescription drug coverage for the categorically needy, not all states extend this coverage to the medically needy Medicaid beneficiaries. Most states also cover some over-the-counter (OTC) medications. For more information, see CRS Report RL30726, *Prescription Drug Coverage Under Medicaid*, by Jean Hearne.

[19] Office of Inspector General, HHS, *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price*, OEI-03-05-00200, June 2005.

[20] Office of Inspector General, HHS, *Medicaid Pharmacy — Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products,* A-06-02-00041.

[21] Office of Inspector General, HHS, *Variations in State Medicaid Drug Prices*, OEI-05-02-00681.

manufacturers sell a drug product to wholesalers. This data is reported to CMS by manufacturers.

The Medicaid Experience and Medicare Part D. Though not as involved as the VA's efforts in obtaining drug discounts, the experience of the Medicaid program also holds lessons for the Medicare program. In contrast to the explicit prohibition in the non-interference provision against federally established formularies for Medicare beneficiaries, states are allowed to establish formularies for beneficiaries not enrolled in Medicaid managed care plans.[22] If the non-interference provision is repealed, CMS must still decide whether or not to adopt a formulary and decide how restrictive it might be. At the national level, these decisions would be much more difficult and problematic. If the formulary prohibition is not repealed, then the bargaining power of the Secretary and CMS would be diminished in the absence of the threat of formulary exclusion.

Consequences of Federal Involvement in the Determination of Drug Prices and Costs

If the Secretary were to engage in activities that affect drug prices on behalf of Medicare Part D beneficiaries, the implications could be wide-ranging and potentially quite significant. The direct effects on beneficiaries, drug companies, wholesalers, pharmacy benefit managers are potentially great, but the long-term and secondary effects on the overall population and the industry may also be significant and are important to consider.

Ability to Achieve Discounts

The main argument advanced by advocates for granting the federal government the power to negotiate is that lower prices for prescription drugs might be obtained from pharmaceutical manufacturers and passed on to Medicare beneficiaries. By using the market power of roughly 43.7 million Medicare beneficiaries, proponents argue that the pharmaceutical companies would provide deep discounts to the federal government in order to prevent the loss of a significant portion of their market.

A Government Accountability Office (GAO) study based on data from the mid-1990s found that average VA-negotiated prices are less than 50% of the non-federal average manufacturer's price.[23] In 2000, GAO reported that the prices paid by the Department of Defense (DOD) and VA for 21 brand-name drugs with no generic equivalents were 27% and 30% lower on average than those certified to the Health Care Financing Administration (HCFA, now the Centers for Medicare and Medicaid Services, or CMS) as "best price."[24]

---

[22] Medicaid managed care plans are allowed to have their own formulary.

[23] GAO, *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain*, Washington, June 1997, GAO/HEHS-97-60.

[24] *Drug Prices Paid by DOD and VA are, on Average, Lower Than Those Certified to HCFA*

(continued...)

However, there is uncertainty about the potential effectiveness of the federal government in obtaining drug price discounts that are greater than those currently negotiated by private Medicare Part D plans. The first year of experience with the Medicare prescription drug benefit has produced lower-than-expected program expenditures, which supporters of the program attribute to the lower drug prices that drug plans have been able to negotiate in response to strong competition. Critics counter that the lower expenditures are a result of lower-than-expected enrollment and a preference among enrolled beneficiaries for plans with lower premiums and less generous drug coverage.

The argument that the size of the Medicare market would provide federal negotiators with an advantage over private plans in obtaining discounts from pharmaceutical manufacturers has been questioned.[25] Large PBMs, such as Advance PCS (75 million covered individuals), Medco Health Solutions (65 million) and Express Scripts (57 million) have significant market power and an established track record in negotiating prescription drug discounts for large populations. For these reasons, critics claim that PBMs with large numbers of Medicare Part D enrollees would be able to negotiate discounts and produce savings at least as great as anything that the federal government could negotiate.[26] The Congressional Budget Office (CBO), at the request of congressional leaders, examined the effect of striking the "noninterference" provision and estimated that it would have a negligible effect on federal spending.[27] Similarly, the Chief Actuary at CMS concluded that giving the Secretary the ability to directly negotiate prescription drug prices might not produce additional savings over what private plans negotiate. Both CBO and the CMS Chief Actuary determined that the price concessions extracted by the federal government might not exceed those that private plans might achieve.

The magnitude of any discounts resulting from federal negotiation on behalf of Medicare beneficiaries would depend critically on a number of variables and would likely vary depending on the drug. As the VA's experience illustrates, larger discounts are more likely to be achieved for drugs in classes in which there are many alternatives. This is where the VA's greatest discounts are achieved. For single-source drugs, the government may still be able to obtain substantial discounts, but it may depend on what specific bargaining power is available to the Secretary. As noted above, all pharmaceutical companies have an incentive to have their products

[24] (...continued)
as Best Price, GAO-01-175R, Oct. 31, 2000.

[25] See, for example, Enthoven, A., and Fong, K., "Medicare: Negotiated Drug Prices May Not Lower Costs," Brief Analysis No. 575, National Center for Policy Analysis, Dec. 18, 2006.

[26] One counter argument to this point is that while large PBMs may cover more individuals than the Medicare program, Medicare beneficiaries consume more prescription drugs per capita than those under 65, and so the Medicare market represents a greater share, and therefore more "clout."

[27] Letter from CBO to the Honorable William H. Frist, M.D., *Estimate of the Effect of Striking the "Noninterference" Provision as Added by P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Jan. 23, 2004 [http://www.cbo.gov/showdoc.cfm?index=4986&sequence=0].

listed on the FSS because participation is tied to eligibility for Medicaid reimbursement.

Drug Availability for Beneficiaries

Proponents of a market-based, decentralized approach believe that by having a variety of organizations negotiating different prices, more choices will be available to Medicare beneficiaries and, therefore, better patient outcomes. Instead of being limited to the discounted drugs Medicare negotiates, they say, discounts for the plentitude of organizations offering prescription drug plans will result in a broader range of drugs being discounted. In this view, beneficiaries will then be able to choose the plan that best meets their individual prescription drug needs and acquire them at competitive market prices.

One study finds that the number of drugs available under the VA formulary is more restrictive than those available from private Medicare Part D plans.[28] The report also claims that the drugs on the VA formulary are older than drugs on other privately developed formularies. However, this result is not necessarily an indication that VA beneficiaries are receiving lower-quality health care. A recent study based on a randomized controlled trial showed that older, less expensive anti-psychotic drugs were just as effective and safe in treating schizophrenia as newer drugs that were much more expensive.[29] The VA claims that the decisions that go into managing the formulary are based on a careful review of the scientific evidence, and that the choice of drugs is not solely determined by the lowest price.[30] The VA cites its comparative experience with Vioxx as an example of the effectiveness of its process; the VA never included the drug on its national formulary because of concerns about the scientific evidence regarding the drug's safety.[31]

---

[28] Lichtenberg, F., *Older Drugs, Shorter Lives? An Examination of the Health Effects of the Veterans Health Administration Formulary*, Medical Progress Report No. 2, Manhattan Institute, October 2005.

[29] Jones, P., et al., "Randomized Controlled Trial of the Effect on Quality of Life of Second- vs. First-Generation Antipsychotic Drugs in Schizophrenia," *Archives of General Psychiatry*. Vol. 63, No. 10, October 2006, pp. 1079-87.

[30] Briefing by the Pharmacy Benefits Management Strategic Healthcare Group of the Department of Veterans Affairs, December 12, 2006.

[31] Vioxx is a prescription COX-2 selective, non-steroidal anti-inflammatory drug (NSAID) that was approved by FDA in May 1999 for the relief of the signs and symptoms of osteoarthritis, for the management of acute pain in adults, and for the treatment of menstrual symptoms. Merck & Co., Inc. announced a voluntary withdrawal of Vioxx (rofecoxib) from the U.S. and worldwide market on September 30, 2004, due to safety concerns of an increased risk of cardiovascular events (including heart attack and stroke) in patients on Vioxx. On November 5, 2004, the medical journal *The Lancet* published a meta-analysis of the available studies on the safety of rofecoxib (Jüni et al., 2004) in which the authors concluded that rofecoxib should have been withdrawn several years earlier. For additional information, see the FDA Web page on COX-2 selective NSAIDs at [http://www.fda.gov/cder/drug/infopage/COX2/default.htm].

Innovation and New Drug Development

The effect of decreased revenues on the short- and long-term development of new drugs is an issue of ongoing debate. Pharmaceutical manufacturers have stated that research and development will suffer if retail prices are diminished and returns from investment are squeezed. While this is undoubtedly true in the extreme, the evidence that quantifies the degree to which reductions in retail prices would lead to fewer new products being introduced is controversial and reflects a wide range of potential responses.

Some research claims that the consequence of decreased revenue and profits resulting from low negotiated prices will be reduced investment in research and development, declining innovation, and fewer new drugs brought to market. Other studies indicate that there has not been a strong relationship between the amount of research and development funds expended by the pharmaceutical industry and the introduction of new drug applications to the FDA.

One report claims that government-mandated negotiations would reduce the development of new, life-saving drugs by about a dozen annually, and estimates that "federal price negotiations would yield a loss of 5 million life-years annually, an adverse effect that can be valued conservatively at about $500 billion per year."[32]

Other research suggests that the relationship between pharmaceutical research and development costs and new drugs is not so sensitive. GAO found that over the last decade, the increase in research and development expenditures as reported by the pharmaceutical industry has not been matched by the growth in the number of new drug applications (NDAs). GAO examined all NDAs submitted to the FDA between 1993 and 2004 and found that "despite increasing expenditures on research and development, new drug development, and in particular, development of new molecular entities (NMEs) — potentially innovative drugs containing ingredients that have never been marketed in the United States — has become stagnant."[33]

Consistency and Manageable Choice

Another potential consequence of the federal government negotiating drug prices is that prices might become more consistent and less variable across beneficiaries. Medicare Part D beneficiaries who belong to different PDP/MA-PD plans face different prices, depending on what the individual organizations negotiate and pass on to beneficiaries in savings. In response to the panoply of Medicare drug plans available, some observers, including patient advocacy groups, have suggested that that the plethora of choices is not universally viewed by beneficiaries as a positive outcome.

---

[32] Zycher, B., *The Human Cost of Federal Price Negotiations: The Medicare Prescription Drug Benefit and Pharmaceutical Innovation. Center for Medical Progress,* Manhattan Institute.

[33] *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts,* GAO-07-49, November 2006.

A growing body of research suggests that individuals faced with many choices may find that having more alternatives can be counterproductive. One study found that plans that offered more 401(k) options had lower participation rates compared to plans that offered only a handful of choices; "every ten funds added, other things equal, is associated with a 1.5% to 2% drop in [the] participation rate." [34] Another study found that while grocery store consumers were initially more attracted to a booth displaying 24 jam choices, a higher percentage of consumers who saw only six choices subsequently purchased the jam by a factor of 10. Related work also showed that *ex post* satisfaction was higher among those who had fewer than those who had more choices.[35] As a consequence, some legislators have suggested placing limits on the number of Medicare Part D plans to alleviate the difficulties some beneficiaries have had in choosing from among such a broad set of plans.[36]

Effect on Overall Costs and Population Health

The effect of lower drug prices on overall health care costs and population health is varied. If lower prices lead to a higher rate of filled prescriptions among beneficiaries who previously under-used needed medications, then the increase in prescription drug use may lead to improved outcomes. There is also the potential savings if the increased drug treatments are substitutes for more expensive and less effective care — for instance, if hypertension can be managed with medicines that obviate the need for surgical interventions.

Alternatively, higher out-of-pocket prices for prescription drugs have been found to reduce the use of drugs by patients consistently.[37] Recent research suggests that this effect may also persist over time, with implications for higher overall health care costs. One study found that beneficiaries facing higher out-of-pocket costs for prescription drugs not only use fewer drugs contemporaneously, but the reduction persists and is stronger in the second year. Overall, the expenditure savings on prescription drugs are largely offset by increases in spending for outpatient services, which tend to increase in response.[38]

---

[34] G. Huberman and W. Jiang. "Offerings vs. Choice by 401(k) Plan Participants: Equity Exposure and Number of Funds," *Journal of Finance*, to appear. [http://papers.ssrn.com/sol3/papers.cfm?abstract_id=646601].

[35] S.S. Iyengar and M.R. Lepper "When Choice Is Demotivating: Can One Desire Too Much of a Good Thing?" *Journal of Personality and Social Psychology*, vol. 79, pp. 995-1006, 2000.

[36] For more information, see CRS Report RL33300, *Standardized Choices: Medigap Lessons for Medicare Part D,* by Jim Hahn.

[37] See, for example, Goldman, D. et al., "Pharmacy Benefits and the Use of Drugs by the Chronically Ill," JAMA: *The Journal of the American Medical Association*, May 2004, Vol. 291, No. 19, 2344-2350, and Huskamp, H. et al., "The Effect of Incentive-based Formularies on Prescription Drug Use and Spending," *New England Journal of Medicine*, December 2003, Vol. 349, No. 23, 2224-2232.

[38] Gaynor, M., Li, J., and Vogt, W., "Is Drug Coverage A Free Lunch? Cross-Price Elasticities and the Design of Prescription Drug Benefits," National Bureau of Economic

(continued...)

Impact on Other Sectors of the Pharmaceutical Industry

Federal negotiations on drug prices through the VA and the Medicaid programs have had noticeable effects on the industry. The Medicare program, with a similarly large number of beneficiaries who consume more drugs per capita, might have even more dramatic effects.

The function of wholesalers is often overlooked in discussions about the pharmaceutical industry, but they play an important role in the experience of the VA. Although the VA solicits bids that have allowed for multiple wholesalers, in recent years the VA has awarded the contract to a single company. This contract is highly lucrative; recent estimates place the value of the contract at $3 billion a year for the selected contractor. To illustrate the importance of the VA contract, the share values of the drug distributor AmerisourceBergen Corporation fell 11.6% and the company lowered its 2004 earnings estimate by almost 10% after losing the contract to the McKesson Corporation.[39] The Medicare market for prescription drugs is significantly larger than the VA market, and if structured similarly, the federal contracts with the Medicare program stand to carry similar or greater impacts for the industry.

Effect on Drug Prices in Other Markets

Because of the complex relationships in drug prices across different types of buyers, the effect of changing one price, such as negotiating a discount for Medicare beneficiaries, may have indirect consequences on other prices. In the long run, while drug prices paid by Medicare beneficiaries may fall, overall drug prices may increase for other consumers, specifically for the under-65 population. Under this argument, pharmaceutical companies might increase the prices they charge to other buyers in response to the lower prices negotiated by the federal government for Medicare beneficiaries. Similarly, as the "best price" increases, the prices for other buyers who calculate reimbursements that are referenced to the "best prices" would also rise, potentially affecting both VA prices and Medicaid prices.

Finally, those who oppose government involvement in prescription drug price negotiations claim that the government would be setting prices, not negotiating. They cite the experience in other parts of the Medicare program, where provider reimbursement under Parts A and B are set by the Medicare program, and claim that the federal government would impose a similarly rigid pricing schedule on the prescription drug market. Whether this comes to pass depends on the specifics of how the legislation and subsequent regulations are written, and which approach is chosen to implement any given authority to affect drug prices on behalf or Medicare beneficiaries.

---

[38] (...continued)
Research Working Paper 12758, December 2006.

[39] "McKesson Wins Government Drug Contract," *New York Times*, January 1, 2004.