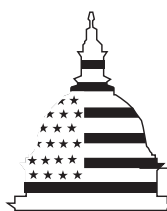


August 2000

PRESCRIPTION DRUGS

Expanding Access to Federal Prices Could Cause Other Price Changes



G A O

Accountability * Integrity * Reliability

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Abbreviations

AMP	average manufacturer price
AWP	average wholesale price
CBO	Congressional Budget Office
DOD	Department of Defense
FCP	federal ceiling price
FSS	federal supply schedule
GSA	General Services Administration
HCFA	Health Care Financing Administration
HMO	health maintenance organization
HRSA	Health Resources and Services Administration
OBRA	Omnibus Budget Reconciliation Act of 1990
NFAMP	nonfederal average manufacturer price
PHS	Public Health Service
VA	Department of Veterans Affairs



United States General Accounting Office
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Health, Education, and Human
Services Division

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August 7, 2000

The Honorable Tom Bliley
Chairman
Committee on Commerce
House of Representatives

The Honorable Michael Bilirakis
Chairman, Subcommittee on Health
and Environment
Committee on Commerce
House of Representatives

Federal departments and agencies can purchase prescription drugs at substantial discounts off market prices through the federal supply schedule (FSS) for pharmaceuticals. Administered by the Department of Veterans Affairs (VA), the FSS for pharmaceuticals is a list of products and their prices that are available to federal entities that purchase prescription drugs.¹ During fiscal year 1999, federal purchasers spent over \$2.75 billion on prescription drugs,² about \$1.5 billion of which was for drugs purchased from the FSS. Also, federal law guarantees substantial drug price discounts to state Medicaid programs and specific public health entities that receive federal assistance.

As the Congress considers adding a prescription drug benefit to Medicare, there is increased interest in understanding the ways that government purchasers have controlled their costs for prescription drugs and whether these methods can be used to reduce prescription drug costs for Medicare beneficiaries. One proposal before the Congress would allow Medicare beneficiaries to purchase drugs from pharmacies at the same prices that are available to federal purchasers or state Medicaid programs. Because of your interest in the issue of expanding Medicare beneficiaries' access to prescription drugs, you asked us to provide you with information on (1) the federal drug price discounts available to federal and nonfederal purchasers

¹ The FSS may list the same drug in different dosage amounts and package sizes. Each listing is considered an individual item or product.

² This total includes all FSS sales to federal purchasers, as well as non-FSS sales associated with contracts VA and the Department of Defense (DOD) have with drug manufacturers.

and the size of those discounts, and (2) the potential effects that extending such discounts to nonfederal purchasers may have on outpatient drug prices paid by federal and nonfederal purchasers.

To address these issues, we obtained information on the drug purchasing methods and prices available to the federal departments and agencies that spend the most on prescription drugs—VA, DOD, and the Public Health Service (PHS). We also obtained information from the Health Care Financing Administration (HCFA) on the rebates state Medicaid programs receive through the Medicaid drug rebate program. In addition, we contacted officials of the Health Resources and Services Administration's (HRSA) Office of Drug Pricing to determine the drug price discounts available to public health entities that receive federal assistance.³ Further, we reviewed several studies relevant to the potential impact of expanding the availability of government drug price discounts to nonfederal purchasers. We conducted our study between December 1999 and June 2000 in accordance with generally accepted government auditing standards.

³The Office of Drug Pricing is now called the Office of Pharmacy Affairs.

Results in Brief

Federal departments and agencies, state Medicaid programs, and numerous nonfederal public health entities have access to prescription drugs at substantially lower prices than many other purchasers. Federal entities can purchase drugs from the FSS at prices that are the same or lower than those drug manufacturers charge their most-favored private purchasers. Under federal law, drug manufacturers must list their brand-name drugs on the FSS to receive reimbursement for drugs covered by Medicaid.⁴ Manufacturers must also sell brand-name drugs listed on the FSS to four federal purchasers—VA, DOD, PHS, and the Coast Guard—at a price at least 24 percent lower than the nonfederal average manufacturer price (NFAMP), a ceiling price that is lower than the FSS price for many drugs.⁵ In addition, VA has obtained some drug prices that are even lower than FSS prices through national contracts based on a competitive-bid process. On average, these contracts have resulted in prices that are about one-third lower than corresponding FSS prices. Federal law also specifies that state Medicaid programs and certain nonfederal purchasers can receive substantial discounts on prescription drug prices. Under the Omnibus Budget Reconciliation Act of 1990 (OBRA), drug manufacturers must provide rebates to state Medicaid programs for their outpatient drugs in exchange for Medicaid coverage.⁶ For brand-name drugs, the minimum rebate is 15.1 percent of the average manufacturer price (AMP).⁷ During fiscal year 1999, the rebates state Medicaid programs collectively received amounted to about 19 percent of overall payments for prescription drugs. The Public Health Service Act also provides some nonfederal purchasers, such as community health centers and certain public hospitals, access to drug prices based on Medicaid rebates.

Mandating that federal prices for outpatient prescription drugs be extended to a large group of purchasers, such as Medicare beneficiaries, could lower

⁴ See 38 U.S.C. sec. 8126, as added by the Veterans Health Care Act of 1992 (P.L. 102-585, sec. 603).

⁵ The NFAMP is the weighted average price of each single form and dosage unit of a drug that is paid to a manufacturer by wholesalers for nonfederal purchasers, taking into account any cash discounts or similar price reductions.

⁶ See P.L. 101-508, sec. 4401.

⁷ The AMP is the weighted average price of each form and dosage unit of a drug that is paid to a manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, taking into account cash discounts or similar price reductions. FSS prices and prices associated with direct sales to HMOs and hospitals are excluded from this calculation.

the prices they pay but raise prices for others. Such price changes could occur because drug manufacturers would be required to charge beneficiaries and federal purchasers the same prices. To protect their revenues, manufacturers could raise prices for federal purchasers. Furthermore, because federal prices are generally based on prices paid by nonfederal purchasers, manufacturers would have to raise prices to these purchasers in order to raise the federal prices. In particular, large private purchasers that tend to pay lower prices, such as health maintenance organizations (HMO) and other insurers, could see their prices rise. While it is not possible to predict the extent or timing of any changes in manufacturer pricing strategies if Medicare beneficiaries gained access to the same prices available to federal purchasers, the experience following implementation of a Medicaid rebate suggests that manufacturers would adjust prices quickly. The magnitude of these potential effects would vary by drug and would depend on a number of factors, including the relationship between the specific federal price extended to Medicare beneficiaries and the price paid by nonfederal purchasers, as well as the number of Medicare beneficiaries with access to the federal price.

Background

Prescription drug expenditures have increased substantially in recent years.⁸ From 1993 to 1998, prescription drug spending grew at an average rate of 12.4 percent per year, compared with a 5 percent average annual growth rate for health care expenditures overall. As a result, prescription drugs account for a growing share of total health care spending, rising from 5.6 percent in 1993 to 7.9 percent in 1998. This dramatic rise in drug outlays has occurred for a number of reasons, including greater utilization of drugs, the substitution of higher-priced new drugs for lower-priced existing ones, and more direct-to-consumer advertising of drugs by manufacturers.

In the face of increasing drug expenditures, large purchasers attempt to control their drug costs, in part, by negotiating lower prices with manufacturers. Some purchasers deal directly with manufacturers while other purchasers have representatives that act on their behalf. For example, pharmacy benefit managers negotiate drug prices for many

⁸ See *Prescription Drugs: Increasing Medicare Beneficiary Access and Related Implications* (GAO/T-HEHS/AIMD-00-100, Feb. 16, 2000). From 1993 to 1998, national expenditures for prescription drugs grew from about \$50.6 billion to about \$90.6 billion.

HMOs and insurers, while group purchasing organizations representing thousands of the nation's hospitals do the same. The leverage purchasers bring to negotiations is based largely on their ability to increase the volume used of a particular drug through mechanisms that influence physicians' prescribing and enrollees' purchasing practices. Using these mechanisms, they can offer manufacturers a larger volume of sales in exchange for bigger discounts.

To control which specific drug products they will purchase and the volume used, HMOs and other insurers frequently create a formulary. A formulary is a list of drugs, grouped by therapeutic class, that a purchaser prefers its physicians to prescribe because of the drugs' medical value and price. Because there are often similar products competing for a share of the market, the greater the purchaser's ability to determine which products it will include on its formulary, the more leverage the purchaser has to exact lower prices from manufacturers.⁹ The purchaser can influence utilization by encouraging physicians to prescribe lower-cost formulary drugs over both higher-cost formulary and nonformulary drugs. The purchaser may also provide financial incentives, such as reduced copayments, to encourage its health plan members to request that physicians prescribe lower-cost formulary drugs, including generics.¹⁰

⁹ Competition can exist between brand-name drugs that are therapeutically equivalent, between brand-name drugs and generic substitutes, and between generic versions of the same drug. Brand-name or innovator drugs generally have a patent on their chemical formulation or on their manufacturing process. While under patent protection, they are called single-source drugs because only the company that holds the patent produces them. After the patent has expired, generic copies of the exact chemical formulation usually become available and the drugs are then referred to as multiple-source drugs.

¹⁰ Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs.

Federal Price Discounts on Prescription Drugs Are Significant for Federal and Nonfederal Purchasers

Federal law enables the federal government to use its leverage as a large purchaser of prescription drugs to secure some of the lowest prices available for pharmaceuticals. Through the FSS and the Medicaid rebate programs, manufacturers must provide many of their drugs at significantly discounted prices in exchange for having their drugs covered by Medicaid. Federal law also sets a ceiling price on FSS brand-name drugs purchased by select federal purchasers and extends prices based on Medicaid rebates to many public health entities that receive federal assistance. In addition, VA has been able to obtain some prices even lower than FSS prices through national contracts with drug manufacturers that channel utilization to specific products.¹¹ Table 1 describes various federal drug prices available to federal and nonfederal purchasers and their relationship to benchmark prices.

¹¹ VA refers to these as committed-use contracts.

Table 1: Pharmaceutical Pricing Terms

Price	Definition
Retail price	The price charged by retail pharmacies to individuals without insurance, known as “cash-paying” customers.
Average wholesale price (AWP)	The average list price that a manufacturer suggests wholesalers charge pharmacies. AWP is typically less than the retail price, which will include the pharmacy’s own price markup. AWP is referred to as a sticker price because it is not the actual price that large purchasers normally pay. For example, in a study of prices paid by retail pharmacies in 11 states, the average acquisition price was 18.3 percent below AWP. ^a Discounts for HMOs and other large purchasers can be even greater. AWP information is publicly available.
AMP	The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. FSS prices and prices associated with direct sales to HMOs and hospitals are excluded. AMP was a benchmark created by OBRA in 1990 to use in determining Medicaid rebates and is not publicly available. The Congressional Budget Office (CBO) estimated AMP to be about 20 percent less than AWP for more than 200 drug products frequently purchased by Medicaid beneficiaries. ^b
NFAMP	The average price paid to a manufacturer by wholesalers for drugs distributed to nonfederal purchasers. NFAMP is not publicly available.
FSS	The price available to all federal purchasers for drugs listed on the FSS. FSS prices are intended to equal or better the prices manufacturers charge their “most-favored” nonfederal customers under comparable terms and conditions. Because terms and conditions can vary by drug, the most-favored customer price may not be the lowest price in the market. FSS prices are publicly available.
Federal ceiling price (FCP)	The maximum price manufacturers can charge for FSS-listed brand-name drugs to VA, DOD, PHS, and the Coast Guard, even if the FSS price is higher. FCP must be at least 24 percent off NFAMP. FCP is not publicly available.
Medicaid rebate net price	The effective outpatient drug price after manufacturer rebates to state Medicaid programs. The basic rebate on brand-name drugs is the greater of 15.1 percent of the AMP or the difference between AMP and the lowest or “best” price the manufacturer charges any purchaser other than Medicaid. Rebates for generic drugs are 11 percent of the AMP. Rebates are larger for brand-name drugs whose AMP increases exceed inflation in the consumer price index. Information on rebate amounts is publicly available; AMP and best price are not.
VA national contract price	The price VA has obtained through competitive bids from manufacturers for select drugs in exchange for their inclusion on the VA formulary. Contract prices are publicly available.

^aSee Office of the Inspector General, *Medicaid Pharmacy—Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs* (Washington, D.C.: HHS, Apr. 1997).

^bSee *CBO Papers: How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry* (Washington, D.C.: CBO, Jan. 1996, p. 20).

FSS and Ceiling Prices

The FSS for pharmaceuticals contains over 17,000 products available to federal departments, agencies, institutions, and several other entities, such as the District of Columbia, U.S. territorial governments, and numerous Native American tribal governments. VA is responsible for administering the FSS and is also the schedule’s largest purchaser—about \$1.2 billion in fiscal year 1999, representing almost 83 percent of all sales at FSS prices.

According to VA, during fiscal year 1999, FSS drug sales totaled about \$1.5 billion—about 1.1 percent of domestic pharmaceutical sales.¹²

Although manufacturers are not required to list their drug products on the FSS, they have financial incentives to do so despite the FSS's relatively low prices. Manufacturers are required to list their brand-name products on the FSS if they wish to receive reimbursement for their drugs under the Medicaid program. Because Medicaid accounts for almost 10 percent of domestic pharmaceutical sales, a manufacturer could lose substantial revenues if it did not have access to this segment of the market.¹³ Also, because sales under the FSS represent only a small segment of the domestic pharmaceutical market, overall revenues are not greatly affected by offering these prices to federal customers. Furthermore, being on the FSS is significant to manufacturers because it enhances the likelihood that their products will be used in VA hospitals, where many of the nations' physicians receive part of their medical training.¹⁴

FSS prices are based on the prices that drug manufacturers charge their "most-favored" private customers. Specifically, under General Services Administration (GSA) procurement regulations, the FSS price is intended to equal or better the price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions.¹⁵ To help VA determine the most-favored customer price, manufacturers are required to provide VA information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery practices. GSA regulations recognize that because the terms and conditions of commercial sales vary, there may be legitimate reasons why the government does not always obtain the most-favored customer price. Hence, under the regulations, VA

¹² According to IMS America, a private vendor of pharmaceutical information, in 1999 the U.S. pharmaceutical market totaled about \$142.4 billion in sales, including sales to federal and nonfederal entities.

¹³ According to HCFA, Medicaid payments minus rebates for prescription drugs for fiscal year 1999 totaled about \$13.7 billion. This figure may slightly overstate the actual market represented by Medicaid sales because Medicaid payments to pharmacies may be greater than the actual amounts pharmacies pay for drugs.

¹⁴ For further discussion of the FSS and how FSS prices are determined, see *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain* (GAO/HEHS-97-60, June 11, 1997).

¹⁵ See 48 C.F.R. sec. 538.270.

may accept a higher price if it determines that (1) the price offered to the government is fair and reasonable, and (2) awarding the contract is otherwise in the best interest of the government.

VA and several other purchasers may actually pay a lower price than the listed FSS price for many drugs, under a provision of the Veterans Health Care Act of 1992.¹⁶ Specifically, in exchange for having their drugs covered by Medicaid, manufacturers must sell their brand-name drugs on the FSS to four federal purchasers—VA, DOD, PHS, and the Coast Guard—at a price that is no higher than 76 percent of the nonfederal average manufacturer price, known as the “federal ceiling price” or FCP. The FSS price for these drugs for other federal purchasers may be higher than this ceiling.

Most drug products covered under the Veterans Health Care Act have FSS prices that are slightly above their FCP. As of February 2000, the FSS prices for products covered under the act were, on average, almost 8 percent above the FCP. About 63 percent of the almost 6,300 products covered under the act¹⁷ had FSS prices that were above the FCP.¹⁸ For these products, the four purchasers protected under the act would pay only the FCP. About 14 percent of the products covered under the act had FSS prices equal to the FCP, and 23 percent had FSS prices that were below the FCP. When the FSS price was lower than the ceiling, it averaged almost 6 percent below the FCP.

FSS prices can also be well below the average wholesale prices that manufacturers suggest wholesalers charge retail pharmacies.¹⁹ Recent FSS prices for 10 drugs commonly prescribed for the elderly were considerably lower than AWP (see table 2).

¹⁶ See P.L. 102-585, sec. 603, codified at 38 U.S.C., sec. 8126. The provision covers innovator multiple-source drugs, insulin, and biological products such as vaccines and antitoxins. The provision does not cover noninnovator multiple-source or generic drugs.

¹⁷ As of February 14, 2000, the FSS included 17,464 drug products; 6,274 were covered under the Veterans Health Care Act and 11,190 were not covered. Noncovered products are generally generic drugs. VA estimates that about 70 percent of its drug expenditures for fiscal year 1999 were for drugs covered under the Act.

¹⁸ About 69 percent of the covered drugs with FSS prices above the FCP had FSS prices that were only 1 percent or less above the ceiling.

¹⁹ Because AWP reflects prices charged the retail level of trade, it is typically higher than average manufacturer prices—AMP and NFAMP—which are charged at the wholesale level.

Table 2: Prices for Select Prescription Drugs Commonly Used by the Elderly, February 2000

Brand-name drug	Therapeutic category	AWP ^a (dollars)	FSS ^b (dollars)	Difference between AWP and FSS prices (percentage)
Lanoxin	Cardiac glycoside	\$20.51	\$10.05	51%
Norvasc	Calcium channel blocker (high blood pressure)	122.86	61.27	50
K-Dur 20	Potassium replacement	49.98	23.73	53
Lipitor	Cholesterol-lowering	169.08	102.28	40
Lanoxin (different strength)	Cardiac glycoside	20.51	10.20	50
Prilosec	Gastrointestinal	119.57	58.73	51
Pepcid	Gastrointestinal	53.13	18.39	65
Glucophage	Oral antidiabetic	64.62	30.60	53
Fosamax	Osteoporosis	60.89	33.74	45
Synthroid	Thyroid	\$30.84	\$20.91	32%

Note: These are the 10 most frequently prescribed drugs in the Pennsylvania Pharmaceutical Assistance Contract for the Elderly in 1999. Several of these drugs have generic versions.

^aMedical Economics Company, *Red Book February 2000 Update*, vol. 19, no. 2 (Feb. 2000).

^bDepartment of Veterans Affairs, *Pharmacy Benefits Management Strategic Healthcare Group*, <http://www.vapbm.org> (cited Feb. 14, 2000).

Prices Related to Medicaid Rebates

Many entities that receive federal assistance also obtain significant drug discounts through federal laws. The most notable are state Medicaid programs, which receive discounts in the form of rebates. Under OBRA, as amended, drug manufacturers must provide all state Medicaid programs a rebate on outpatient prescription drugs in order to have them covered by Medicaid.²⁰ For all brand-name products, the rebate is the greater of either 15.1 percent of AMP, or 100 percent of the difference between the AMP and the manufacturer's best price. The best price is essentially the lowest price offered any domestic purchaser other than state Medicaid programs.²¹ Rebates for generic and over-the-counter drugs must be at least 11 percent of AMP. To protect against substantial price increases, an additional rebate is required for a brand-name product if its AMP increases more than the consumer price index, a measure of overall inflation. During fiscal year 1991, state Medicaid programs paid about \$5.4 billion to pharmacies for prescription drugs and received about \$553 million in rebates from manufacturers. By fiscal year 1999, drug payments had reached about \$17 billion, with rebates in excess of \$3.3 billion.²²

²⁰ Rather than directly purchasing drugs, Medicaid reimburses pharmacies for drugs purchased by Medicaid beneficiaries. Based on a formula set by the state, pharmacies are reimbursed an amount to cover a drug product's ingredient cost, subject to HCFA upper limits, plus a dispensing fee.

²¹ Some prices are excluded in the determination of best price, such as FSS prices, prices charged entities covered under the Veterans Health Care Act, prices to state pharmaceutical assistance programs, prices that are nominal in amount, and single-award contract prices charged any federal agency.

²² Rebates in the earlier years of the rebate program were based on a different percentage of AMP. Also, according to HCFA officials, payments for fiscal year 1999 may be understated because states do not typically submit all payment data to HCFA by the end of the fiscal year.

Since 1992, federal law has also required drug manufacturers to offer certain nonfederal entities access to outpatient drugs at discounted prices as a condition for Medicaid coverage of their outpatient drugs.²³ Specifically, under Section 340B of the Public Health Service Act,²⁴ manufacturers must provide covered entities such drugs at or below a price equal to AMP reduced by the applicable Medicaid rebate percentage.²⁵ Entities eligible for the price discount include hospitals that serve a disproportionate share of Medicaid recipients; community health centers; and health centers that serve migrant, homeless, public housing, and Native American populations.²⁶ A recent study estimates that, during fiscal year 1997, 1,075 entities purchased outpatient drugs at these discounts with a total net purchase amount between \$893 million and \$1.2 billion.²⁷

²³ See Office of Drug Pricing, *The Drug Pricing Program Established by Section 340B of the Public Health Service Act: Information Document* (Washington, D.C., Feb. 1999). The Office of Drug Pricing (now called the Office of Pharmacy Affairs), which is within HRSA's Bureau of Primary Health Care, is responsible for administering the Section 340B program.

²⁴ As added by sec. 602 of the Veterans Health Care Act of 1992.

²⁵ The rebate percentage is the total per-unit Medicaid rebate during a calendar quarter divided by the AMP for the quarter. HRSA's Office of Drug Pricing indicates that the ceiling price does not exceed AMP minus 15.1 percent for brand-name drugs and 11 percent for generic and over-the-counter drugs. An additional rebate is required if any brand-name product's price exceeds the increase in the consumer price index for all items. In addition, covered entities must ensure that drugs are not double discounted—that is, that manufacturers do not pay a Medicaid rebate on drugs already sold to the entities at a discounted price under Section 340B.

²⁶ See P.L. 102-585, sec. 602.

²⁷ See *An Analysis of Purchases, Savings and Participation in the PHS Drug Pricing Program* (Mathematica Policy Research, Inc., Washington, D.C., Sep. 30, 1999).

VA Contract Prices

VA has been able to obtain prices even lower than FSS prices through national contracts with manufacturers for select drugs. VA has obtained such prices because it seeks competitive bids from manufacturers for products that are therapeutically equivalent within specific drug classes.²⁸ VA then contracts with those manufacturers whose products it believes provide the best value, based on both medical effectiveness and price, in exchange for including their products on VA's national formulary and committing to use the products throughout VA's health care system.²⁹ According to VA officials, the winning bids in most cases are the lowest prices offered. During fiscal year 1999, VA purchases under national contracts totaled about \$361.3 million, or about 23 percent of its drug expenditures. By February 2000, VA had 60 national contracts covering about 500 products.³⁰ For the 308 products that had both a national contract price and an FSS price as of February 14, 2000, the national contract price was, on average, about 33 percent lower than the FSS price. Because national contract prices are lower than FSS prices, the price differences between national contract prices and AWP, in turn, can be quite large. For example, the national contract prices for three cholesterol-lowering drugs that are among the top 50 drug products most commonly used by the elderly were, respectively, 70, 72, and 88 percent lower than AWP.³¹

²⁸ VA also negotiates what is known as "blanket purchase agreements" with many manufacturers to obtain prices that are lower than listed FSS prices if VA uses specific product amounts. These agreements differ from national committed-use contracts in that they are not competitively bid and most apply to specific VA purchasers, such as one or more VA hospitals. As of February 14, 2000, there were 52 blanket purchase agreements in effect.

²⁹ See *VA Health Care: VA's Management of Drugs on Its National Formulary* (GAO/HEHS-00-34, Dec. 14, 1999).

³⁰ The contracts cover both brand-name and generic products and include some joint contracts with DOD.

³¹ For additional information on VA national contracting practices and prices, see *DOD and VA Health Care: Jointly Buying and Mailing Out Pharmaceuticals Could Save Millions of Dollars* (GAO/T-HEHS-00-121, May 25, 2000).

Federal Mandates Could Raise Drug Prices for Various Purchasers

Extending federal prices for outpatient prescription drugs to a large group of purchasers, such as Medicare beneficiaries, could lower the prices these purchasers pay, but could raise prices to federal and other purchasers. Drug manufacturers could respond to a mandate that they extend federal prices to a larger share of purchasers by adjusting their prices to others. The larger the group that would be newly entitled to receive a federal price, the greater the incentive for drug manufacturers to raise that price. The Medicaid rebate experience suggests how federal and nonfederal drug price discounts could change if Medicare beneficiaries had access to the same price discounts available to federal purchasers. Following enactment of the rebate program, discounts for outpatient drugs decreased significantly because manufacturers raised the prices they charged large private purchasers.

Potential Price Effects of Combining Market Segments

Drug manufacturers have traditionally sold the same product at different prices to distinct groups or segments of purchasers, such as HMOs, private insurers, hospitals, and retail pharmacies. Manufacturers can segment the market in this manner because the purchasers who receive the lower prices do not, in turn, resell these products to other purchasers. As long as the groups remain independent in this way, manufacturers can tailor the price charged each group. This helps to explain why customers without drug coverage, or cash-paying customers, typically face higher prices at a retail pharmacy than HMOs or other large private purchasers pay.

The prices that manufacturers establish for different groups depend on how price sensitive each group is—that is, the extent to which the group would change the amount of a product it buys if the price rises or falls. For example, HMOs are more price sensitive than retail pharmacies because HMOs exercise control over the particular products they purchase through the use of formularies and other mechanisms that influence physicians' prescribing practices. Conversely, retail pharmacies have limited ability to determine which drugs they must have available because physicians' prescribing practices are largely outside their influence. Retail pharmacies must, therefore, stock a wide range of drug products that meet the needs of all of their customers, regardless of changes in price for those products.

If manufacturers were required to provide their drug products to both retail pharmacies and HMOs at the same prices, these two market segments would no longer be independent. Manufacturers would have to decide whether to provide retail pharmacies the same prices they have typically

provided HMOs, or raise their prices to HMOs to minimize the negative impact on their profits. To assess the potential impact on profits, manufacturers would need to assess how much of their revenue they would lose by charging retail pharmacies the lower HMO prices, versus any losses in sales due to raising the prices to HMOs and other large private purchasers. Manufacturers would recognize that raising prices to these large purchasers could result in decreased sales. Manufacturers would likely temper their price changes depending on how price sensitive large purchasers were. If large purchasers were very price sensitive, sharply restricting their purchases as prices rose, manufacturers might restrain their price increases. If large purchasers were less price sensitive, manufacturers could raise prices more while experiencing the loss of fewer sales. The net result of requiring that retail pharmacies and large purchasers pay the same prices would likely be higher prices for those who had previously benefited from lower prices and lower prices for those who had not.

Extending federal prices to a large group of purchasers, such as Medicare beneficiaries, could have similar pricing implications. Large groups of purchasers that pay very different prices based on their price sensitivity would be combined and manufacturers would be required to charge everyone in the enlarged combined group the same price. The magnitude of the price effects would depend considerably on which federal price was provided and the number of beneficiaries that would now purchase drugs at that federal price.³² For example, if the FSS price were extended to Medicare beneficiaries, the market segments that included FSS purchasers and cash-paying retail Medicare customers would be combined. In this case, the federal price would be based on prices paid by manufacturers' most-favored customers, and the volume of sales at the FSS price would be significantly larger than at present. Depending on the number of Medicare beneficiaries that would purchase their drugs at FSS prices, sales at FSS

³² For further discussion of the potential effects of extending FSS prices to nonfederal purchasers, see GAO/HEHS-97-60 (June 11, 1997).

prices could be between 6 and 20 times larger than the current level.³³ How much manufacturers might charge would vary by product, depending considerably on whether there were competing products, as well as the price sensitivity of the manufacturers' other customers. However, for those products whose retail and most-favored customer prices were considerably different, manufacturers would have the incentive to charge a new price that would likely fall somewhere between the two to offset any reduction in revenues. In these cases, extending the FSS price to Medicare beneficiaries could result in important out-of-pocket savings, particularly for cash-paying beneficiaries.³⁴ However, it could also raise the prices paid by private and federal purchasers, as increases in the prices manufacturers charged their best customers would, in turn, increase FSS prices.

Medicaid Rebate Experience

Federal efforts to provide state Medicaid programs discounts on prescription drugs demonstrate the potential price effects of mandating a federal price or discount that, in effect, combines purchasers from different market segments. Before the Medicaid rebate program was enacted, state Medicaid programs were paying near-retail prices for outpatient drugs, although collectively they were the largest single purchaser of prescription drugs. OBRA required that manufacturers provide rebates to state Medicaid programs on outpatient drugs based on the lowest prices they charged other purchasers. After the rebate program's enactment, the discounts that large private purchasers, such as HMOs and hospitals,

³³ In 1996, Medicare beneficiaries with drug coverage spent an average of \$769 on prescription drugs; beneficiaries without coverage spent an average of \$463. If the approximate 12 million beneficiaries that lacked drug coverage had access to FSS prices and those prices were lower than the prices they would pay otherwise, it could increase the volume of drugs they would purchase. Therefore, if their drug spending at FSS prices increased to about the same amount as those with coverage, sales at FSS prices would be about \$9.2 billion, or over six times greater than total FSS sales in fiscal year 1999. If all 39 million beneficiaries had access to FSS prices and spent an annual average of \$769 on drugs, FSS sales would be about \$30 billion or about 20 times greater than total FSS sales in fiscal year 1999. Based on data from the 1996 Medicare Current Beneficiary Survey. See J.A. Poisal and G.S. Chulis, "Medicare Beneficiaries And Drug Coverage," *Health Affairs* (Mar./Apr. 2000), p. 252.

³⁴ Other beneficiaries with drug coverage, such as those enrolled in Medicare HMOs, may already receive drugs at discounted prices.

received for many outpatient drugs dropped substantially.³⁵ Within 2 years, we found that the average best-price discount for the drugs they purchased was no greater than 15.3 percent of AMP—about the mandated minimum rebate for Medicaid programs.³⁶ This was confirmed by a CBO analysis that concluded that manufacturers were much less willing to give steep discounts to large purchasers when they had to give the same discounts to Medicaid.³⁷

Summary

By using its purchasing power, principally derived from the large purchases covered by the Medicaid program, the federal government obtains significantly discounted prices for prescription drugs from drug manufacturers for both federal and select nonfederal entities. Extending federal prices to Medicare beneficiaries could result in their paying less for drugs. However, these lower prices could come with a trade-off—federal and nonfederal purchasers might pay more if drug manufacturers raise prices to them to offset revenue losses resulting from extending federal prices to Medicare beneficiaries. The extent to which prices would change would vary by drug and would depend on many factors, including the number of Medicare beneficiaries affected, whether a drug had competition, and the price sensitivity of private purchasers. The decrease in price discounts following enactment of the Medicaid rebate program demonstrated the potential effects of reducing manufacturers' ability to differentiate among purchasers and charge some purchasers higher prices than others.

³⁵ See *Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals* (GAO/HEHS-94-194FS, Aug. 5, 1994). Also, see *Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions* (GAO/HRD-93-43, Jan. 15, 1993).

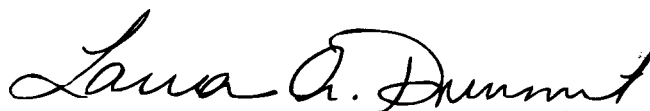
³⁶ This is average percentage that the best price was below the AMP. The average best price discount decreased because the average best price increased faster than the AMP during the 2-year period.

³⁷ See *CBO Papers: How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry* (Washington, D.C., Jan. 1996). CBO also noted that many FSS prices increased significantly, perhaps because FSS prices were initially considered with private-sector prices in calculating rebates. In 1992, in the Veterans Health Care Act, the Congress exempted all drug prices paid by federal entities from rebate calculations.

Agency and Other Comments

We obtained comments on the draft report from VA officials associated with pharmaceutical purchasing and pharmacy benefit management, including the Executive Director and Chief Operating Officer of the National Acquisition Center and the Chief Consultant for the Pharmacy Benefits Management Strategic Healthcare Group. We also obtained comments from two nationally known researchers on pharmaceutical pricing issues. The reviewers agreed with our findings and provided technical comments, which we have incorporated where appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that point, we will send copies to interested congressional committees and Members and agency officials, and will make copies available to others on request. If you or your staffs have any questions about this report, please call me at (202) 512-7114, or John Hansen at (202) 512-7105. Others who made major contributions to this report include Joel Hamilton, Elsie Picyk, and George Bogart.



Laura A. Dummit
Associate Director, Health Financing
and Public Health Issues

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