

GAO

Report to Congressional Committees
and the Administrator of General
Services

June 1997

DRUG PRICES

**Effects of Opening
Federal Supply
Schedule for
Pharmaceuticals Are
Uncertain**



**Health, Education, and
Human Services Division**

B-276585

June 11, 1997

The Honorable Fred Thompson, Chairman
The Honorable John Glenn
Ranking Minority Member
Committee on Governmental Affairs
United States Senate

The Honorable Strom Thurmond, Chairman
The Honorable Carl Levin
Ranking Minority Member
Committee on Armed Services
United States Senate

The Honorable Dan Burton, Chairman
The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform and Oversight
House of Representatives

The Honorable Floyd Spence, Chairman
The Honorable Ronald V. Dellums
Ranking Minority Member
Committee on National Security
House of Representatives

The Honorable David J. Barram
Administrator
General Services Administration

The federal government purchased almost \$1.3 billion worth of pharmaceuticals during fiscal year 1996 from a catalog of prices referred to as a federal supply schedule. Schedule prices, which are often considerably lower than retail prices, are currently available primarily to federal purchasers. In 1994, the Congress sought to extend these lower prices to other government purchasers by authorizing the General Services Administration (GSA) to establish a cooperative purchasing program that would allow state, local, and Indian tribal governments and the Commonwealth of Puerto Rico to purchase pharmaceuticals and other goods and services from federal supply schedules.¹ In administering the

¹See the Federal Acquisition Streamlining Act of 1994, P.L. 103-355, sec. 1555. The Senate-passed version of a pending appropriation bill would repeal sec. 1555. The House version does not contain the repeal. As of June 2, 1997, the bill was in conference.

program, GSA indicated that it did not plan to open any schedule to nonfederal entities that could result in increased prices for products on the schedule.²

The Department of Veterans Affairs (VA), to which GSA has delegated administration of the pharmaceutical schedule, raised concerns that drug manufacturers would seek to increase schedule drug prices if a larger group of purchasers was given access to those prices. As a result, GSA proposed that the pharmaceutical schedule be excluded from the cooperative purchasing program because opening it would have the unintended effect of increasing federal agencies' drug costs.

Because of concerns about the potential effects of opening more than 140 federal supply schedules to state and local governments, the Congress directed GSA to delay opening the schedules, including the pharmaceutical schedule, pending completion of our assessment of the possible impact.³ This report focuses on the factors that can affect negotiations for schedule drug prices and the potential effects of opening the pharmaceutical schedule⁴ on schedule prices available to federal, state, and local government purchasers.⁵

To address the report's objectives, we interviewed representatives of federal agencies that purchase the most products from the pharmaceutical schedule: VA, the Department of Defense (DOD), and the largest Public Health Service drug purchaser, the Indian Health Service. In addition, we interviewed representatives of the Public Hospital Pharmacy Coalition,⁶ the Health Industry Group Purchasing Association (HIGPA),⁷ and two group

²See Cooperative Purchasing: Effects Are Likely to Vary Among Governments and Businesses (GAO/GGD-97-33, Feb. 10, 1997), pp. 19-21.

³See the National Defense Authorization Act for Fiscal Year 1996, P.L. 104-106, sec. 4309 (1996), and accompanying conference report, H.R. Conf. Rep. No. 104-450, at 970 (1996). The act requires that we submit our report to the Administrator of General Services and to the Congress.

⁴The implications of opening other schedules are discussed in GAO/GGD-97-33, Feb. 10, 1997.

⁵For the purposes of this report, Indian tribal governments were considered with federal purchasers because the pharmaceutical and other federal supply schedules are available to them under separate authority (see GAO/GGD-97-33, Feb. 10, 1997). Potential effects on the Commonwealth of Puerto Rico were considered with state and local governments.

⁶The Coalition represents 70 public hospitals that are owned or controlled by state and local governments and serve a disproportionate share of Medicaid and indigent patients.

⁷HIGPA is a national trade association that represents 84 organizations and vendors that purchase pharmaceuticals and other medical products.

purchasing organizations that represent public hospitals and clinics.⁸ We also interviewed representatives of the National Association of Chain Drug Stores, the Pharmaceutical Research and Manufacturers of America (PhRMA), and several drug manufacturers.⁹ We analyzed pharmaceutical schedule prices obtained from VA and reviewed assessments made by VA, HIGPA, and the Public Hospital Pharmacy Coalition of how opening the schedule could affect schedule and other drug prices. Although we reviewed economic and other assumptions used in these assessments, we did not validate the supporting data, such as drug prices and expenditures. We also reviewed public comments on GSA's proposed regulations and discussed the potential effects of opening the federal supply schedule with officials of the Congressional Budget Office (CBO).

We did our work between October 1996 and April 1997 in accordance with generally accepted government auditing standards.

Results in Brief

The effects of opening the federal supply schedule for pharmaceuticals on schedule prices ultimately depend on the outcome of negotiations between VA and drug manufacturers. Because of the uncertainties related to these negotiations, it is not possible to predict how schedule drug prices would change or what the ultimate impact on federal, state, and local purchasers would be.

Although many factors would influence the negotiations between VA and drug manufacturers, two primary ones are VA's negotiating ability and manufacturers' pricing strategies. Both of these factors would be influenced by the size of the market represented by combined federal, state, and local purchasers that would have access to schedule prices. Moreover, the size of this market could affect the size of any resulting price changes. The larger the market, the greater the economic incentive would be for a manufacturer to raise schedule prices to limit the impact of giving low prices to more purchasers.

At present, federal purchases from the schedule represent about 1.5 percent of the total dollar value of domestic pharmaceutical sales. Estimates of the size of a combined federal, state, and local market, however, vary widely because of uncertainty about which state and local entities would be eligible for schedule prices. If eligibility is not narrowed,

⁸Some group purchasing organizations represent hundreds of hospitals and have been able to negotiate significant price discounts for them.

⁹The manufacturers we contacted were Eli Lilly and Company; Johnson & Johnson; Merck & Co., Inc.; Pfizer Inc.; and SmithKline Beecham Corporation.

VA, PhRMA, drug manufacturers, and the Public Hospital Pharmacy Coalition agree that the size of the combined market could be significantly larger than the current federal market. Although the Coalition estimates that limiting eligibility as it suggests could keep state and local purchases from the schedule at between 0.5 and 4.4 percent of domestic pharmaceutical sales, this would result in a combined market about 33 to 300 percent larger than the federal market.

Federal efforts to lower Medicaid drug prices suggest how opening the pharmaceutical schedule could put upward pressure on schedule prices. In 1990, the Congress required drug manufacturers to give state Medicaid programs rebates for outpatient drugs based on the lowest prices they charged other purchasers. Because of the size of the Medicaid market, however, many drug manufacturers sought to minimize the impact of the rebates on their business by raising outpatient drug prices to some private sector purchasers.

If the pharmaceutical schedule were opened to state and local governments and drug manufacturers succeeded in raising their schedule prices in response, the impact on different government purchasers would vary. VA, DOD, the Public Health Service, and the Coast Guard would be somewhat protected from price increases because the Veterans Health Care Act of 1992 sets maximum prices for these agencies for over one-quarter of the drugs on the schedule. Other federal purchasers would not have that protection. State and local government purchasers, meanwhile, would benefit to the extent that schedule prices were lower than the prices they or their representatives could negotiate with drug manufacturers.

Background

The federal supply schedule (FSS) for pharmaceuticals is a price catalog currently containing almost 23,000 pharmaceutical products¹⁰ available to federal agencies and institutions and several other purchasers, such as the District of Columbia, U.S. territorial governments, and many Indian tribal governments. VA, to which GSA has given responsibility for administering the pharmaceutical schedule, negotiates prices with drug manufacturers. It is also the largest purchaser from the schedule; in fiscal year 1996 it made purchases of about \$922 million—or about 71 percent of the government's purchases from the pharmaceutical FSS.

¹⁰The FSS may list the same drug in different dosage amounts and package sizes. Each listing is considered an individual item or product in counting the total number of products on the FSS.

While the pharmaceutical FSS, like other supply schedules, is meant to provide eligible entities an efficient and economical option for purchasing, other options exist. For example, although VA depends on the FSS for most of its drug purchases, it has awarded several national contracts on a competitive basis for specific drugs it considered to be therapeutically interchangeable. VA spent about \$1.2 billion on pharmaceuticals in fiscal year 1996 through both FSS and national contract purchases.

Under the Veterans Health Care Act, drug manufacturers must make their brand-name drugs available through the FSS in order to receive reimbursements for drugs covered by Medicaid.¹¹ The act also requires drug manufacturers to sell drugs covered by the act to four agencies—VA, DOD, the Public Health Service, and the Coast Guard—at no more than 76 percent of the nonfederal average manufacturer's price,¹² a level referred to as the federal ceiling price. The FSS price may be higher or lower than the ceiling. If it is higher, the protected purchasers pay no more than the ceiling price, while purchasers not protected by the act—such as the Bureau of Prisons and institutions in the District of Columbia like Howard University and St. Elizabeths Hospital—pay the full FSS price.

Although state and local government entities have not had access to FSS drug prices, they have been able to purchase drugs at significantly discounted prices. For example, the Veterans Health Care Act gave certain hospitals that serve a disproportionate share of Medicaid recipients and certain categories of federally funded clinics access to discounted prices on outpatient drugs similar to those given state Medicaid programs.¹³ In addition, public hospitals have obtained significant discounts off retail and wholesale prices for both outpatient and inpatient drugs by using large group purchasing organizations to negotiate with drug manufacturers.

GSA published its proposed plan for implementing the Federal Acquisition Streamlining Act as it related to opening the federal supply schedules to

¹¹See P.L. 102-585, sec. 603. The act covers innovator multiple-source drugs, single-source drugs, insulin, and biological products such as vaccines and antitoxins. Innovator multiple-source drugs are ones that were approved by the Food and Drug Administration as original new drugs but that now have competing drugs, including generic versions, that have the same combination of active ingredients. Conversely, single-source drugs are original drugs that have a unique combination of active ingredients unavailable in other drugs. The act does not cover noninnovator multiple-source or generic drugs.

¹²The nonfederal average manufacturer price is the weighted average price of each single form and dosage unit of a drug that is paid by wholesalers in the United States to a manufacturer, taking into account any cash discounts or similar price reductions. Prices paid by the federal government are excluded from this calculation.

¹³See P.L. 102-585, sec. 602.

state and local governments in the Federal Register on April 7, 1995. The plan proposed excluding from cooperative purchasing the schedule for drugs and pharmaceutical products¹⁴ and one medical equipment and supplies schedule.¹⁵ In the plan, GSA specified that unique statutory requirements in the Veterans Health Care Act affect the pricing and availability of products on both schedules and that when combined with the cooperative purchasing provisions, would have the unintended effect of increasing costs to federal users of the schedules. The plan also proposed that participation in the cooperative purchasing program be optional for both sellers and purchasers of goods and services. In comments GSA received on the plan, PhRMA, VA, and about 30 drug manufacturers supported GSA's proposal to keep the pharmaceutical FSS closed to state and local governments, while the Public Hospital Pharmacy Coalition and over 60 public hospitals supported opening the schedule.

Impact of Opening the FSS Depends Largely on Price Negotiations

Price negotiations between VA and drug manufacturers would ultimately determine the extent to which opening the pharmaceutical FSS affects the schedule drug prices available to federal, state, and local governments. VA's negotiating ability and drug manufacturers' pricing strategies are two primary factors that would influence the outcome of those negotiations. Moreover, the size of the market that could gain access to FSS prices could affect the size of any resulting price changes. That is, the larger the market, the greater the incentive would be for drug manufacturers to raise FSS prices to limit the impact of giving low prices to more purchasers.

FSS Negotiations and Manufacturer Pricing Strategies Are Driving Forces

In its role as administrator of the pharmaceutical FSS, VA negotiates prices for the nearly 23,000 drug products listed on the schedule. Under GSA procurement regulations, VA contract officers are required to seek an FSS price that represents the same discount off a drug's list price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions.¹⁶ To help VA determine the "most-favored customer" discount, manufacturers provide VA information on price discounts and rebates offered different domestic customers and on the terms and conditions involved, such as length of contract periods and ordering and delivery practices.

¹⁴Federal Supply Classification Group 65, part I, sec. B.

¹⁵Federal Supply Classification Group 65, part VII. The implications of opening this schedule (in vitro diagnostic substances, reagents, test kits, and sets) are covered in GAO/GGD-97-33, Feb. 10, 1997.

¹⁶See 48 C.F.R. sec. 538.270.

GSA regulations recognize, however, that the terms and conditions of commercial sales vary and that there may be legitimate reasons why VA does not always obtain the most-favored customer discount. Hence, the regulations also allow VA's contract officers to accept a less favorable price if an officer determines that (1) the price offered to the government is fair and reasonable, even though a comparable discount was not negotiated, and (2) awarding the contract is otherwise in the best interest of the government.

Opening the pharmaceutical schedule to state and local purchasers could change the dynamics of negotiating FSS prices for both VA and drug manufacturers. Up to now, VA has been able to obtain significant discounts from drug manufacturers by seeking the most-favored customer price. Many FSS prices are more than 50 percent below nonfederal average manufacturer prices.¹⁷

Representatives of several drug manufacturers explained that their companies have been willing to give federal purchasers such low prices because they consider the FSS to be a special, limited category of pricing that affects no more than about 2 to 3 percent of total dollars in domestic pharmaceutical sales. Two representatives also told us that their companies gave VA favorable FSS discounts to help ensure that their drugs were widely used in VA hospitals where many of the nation's physicians receive part of their training. But some drug manufacturers have indicated an unwillingness to offer the same low prices to an expanded group of government purchasers as well as an unwillingness to combine different types of purchasers that the manufacturers are accustomed to treating as separate markets.

Opening the pharmaceutical and other schedules is intended to help government purchasers take advantage of the total volume represented by federal, state, and local sales to negotiate lower prices with sellers. But while volume of sales is integral to pharmaceutical price negotiations between purchasers and drug manufacturers, it is not the only important consideration. Drug manufacturers have historically offered different prices for the same product to different purchasers based largely on the purchasers' ability to influence drug utilization (sometimes referred to as the ability to move market share).¹⁸ A common technique used by

¹⁷Drugs covered by the Veterans Health Care Act that had FSS prices below federal ceiling prices as of Sept. 30, 1996, were, on average, 52 percent below the nonfederal average manufacturer price.

¹⁸See CBO Papers: How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry (Washington, D.C.: CBO, Jan. 1996).

large-volume purchasers to influence utilization is to establish a formulary. A formulary is a list of drugs that a health plan prefers its physicians to prescribe for patients. Drugs are included on a formulary not only for their medical value but also for their favorable prices. Both inclusion of a drug on a formulary and its cost can affect how much it is prescribed and purchased and, therefore, can affect its market share. Because formularies have the potential to significantly affect the sales of drugs, large purchasers that use them have greater leverage in negotiating discounts or rebates with manufacturers that want their drugs listed as preferred drugs. But because the FSS is a catalog of prices, not a formulary, VA lacks that kind of leverage. Access to FSS prices by state and local entities that use formularies, such as public hospitals, would not change the status of the FSS as a catalog.¹⁹ Therefore, although VA would be negotiating on behalf of a larger market if FSS prices were made available to state and local governments, the increased size of the market may not in and of itself improve VA's leverage to negotiate lower prices.

If drug manufacturers are unwilling to extend low FSS prices to state and local purchasers, VA contract officials expect a "showdown" with manufacturers over price increases that they have not experienced before. The potential for such a change in the dynamics of setting FSS prices was emphasized by several manufacturers' representatives. For example, they told us they consider drug sales to public hospitals a large enough market segment to influence current pricing decisions, even without having to give them and other state and local purchasers low FSS prices.

Because of their unwillingness to give state and local purchasers FSS prices, drug manufacturers could respond to the opening of the schedule in several ways. First, drug manufacturers could simply refuse to offer their products to state and local purchasers at FSS prices, an option that is permitted under GSA's current proposal. Representatives of several manufacturers told us, however, that they do not consider this option realistic because some competing manufacturers would be likely to offer FSS prices to state and local purchasers, a market too important to their companies' sales to ignore. Second, drug manufacturers could try to increase FSS prices by raising prices to most-favored customers to change the base on which prices are negotiated with VA. Several manufacturers have acknowledged that depending on the size of the market represented by all government purchasers, this could be an option. Third, drug manufacturers could attempt to negotiate higher FSS prices without linking

¹⁹PhRMA contends that opening the pharmaceutical schedule would actually negate the ability of state and local purchasers to influence drug utilization and, therefore, to move market share because they would be considered part of an FSS market in drug price negotiations with manufacturers.

them to most-favored customer prices. VA contract officials believe that this strategy could result in lengthy and difficult negotiations that they have not experienced before with manufacturers. Ultimately, VA officials could choose not to list those drugs on the FSS for which they were unable to reach agreement on price with manufacturers. VA contract officials, however, believe that incentives would exist for manufacturers to reach agreement with VA on price because drugs covered by the Veterans Health Care Act must be included on the pharmaceutical FSS for drug manufacturers to receive reimbursement for drugs covered by Medicaid.

Size of Market Eligible for FSS Prices Would Be Key Factor

The size of the market eligible to buy drugs at FSS prices if the schedule is opened to state and local governments would be a key factor in determining what would happen to drug prices. The size of the market involved would affect both VA's ability to negotiate and manufacturers' pricing strategies. The larger the market, the greater the incentive would be for manufacturers to raise FSS prices to limit the impact on their business of giving low prices to more purchasers.

Representatives of VA, PhRMA, drug manufacturers, HIGPA, and the Public Hospital Pharmacy Coalition agree that unless the definition of which state and local entities are to have access to the schedule is narrowed, the FSS market could expand significantly from its current size of about 1.5 percent of domestic pharmaceutical sales.²⁰

GSA's proposed implementation plan for opening the FSS would make any state and any department, agency, or political subdivision of a state, including local governments eligible to participate.²¹ Because GSA proposed that each state verify participants' eligibility, it is possible that states would interpret the definition in different ways. Both purchasers and sellers, including retail pharmacies, believe that the proposed definition could allow a large number of entities to qualify for FSS prices. For example, PhRMA and the Coalition note that if entities that do not actually purchase and take possession of pharmaceuticals themselves, such as home health agencies and board and care homes are eligible, the

²⁰According to IMS America, a private vendor of pharmaceutical information, in 1996 the U.S. pharmaceutical market totaled about \$85.4 billion in sales, including sales to federal, state, and local government entities. FSS drug sales of about \$1.3 billion for fiscal year 1996 represent about 1.5 percent of U.S. pharmaceutical sales.

²¹See GSA's Federal Register notice, Apr. 7, 1995, and the Federal Acquisition Streamlining Act of 1994, P.L. 103-355, sec. 1555.

number of organizations that could purchase drugs at FSS prices could be substantial.²²

PhRMA, several drug manufacturers, and the National Association of Chain Drug Stores expressed concern that a broad definition of eligibility could also increase the potential for drugs purchased at FSS prices to be diverted to individuals or groups not meant to benefit from the program.²³ For example, they believe that if eligibility is loosely defined, an organization that does not take possession of drugs or purchase drugs for its own use could buy drugs at FSS prices and attempt to resell them to individuals or groups that may not be state or local entities. In addition to being concerned about diversion, retail pharmacies are also concerned that opening the FSS would give state and local government entities access to drug prices that could be considerably lower than those retail pharmacies pay. Since publishing its proposed implementation plan for opening the FSS, GSA has considered several modifications. These include more specifically defining which entities would be eligible to participate in cooperative purchasing, requiring GSA—rather than states—to determine entities' eligibility, and prohibiting the resale of products purchased off the schedule.

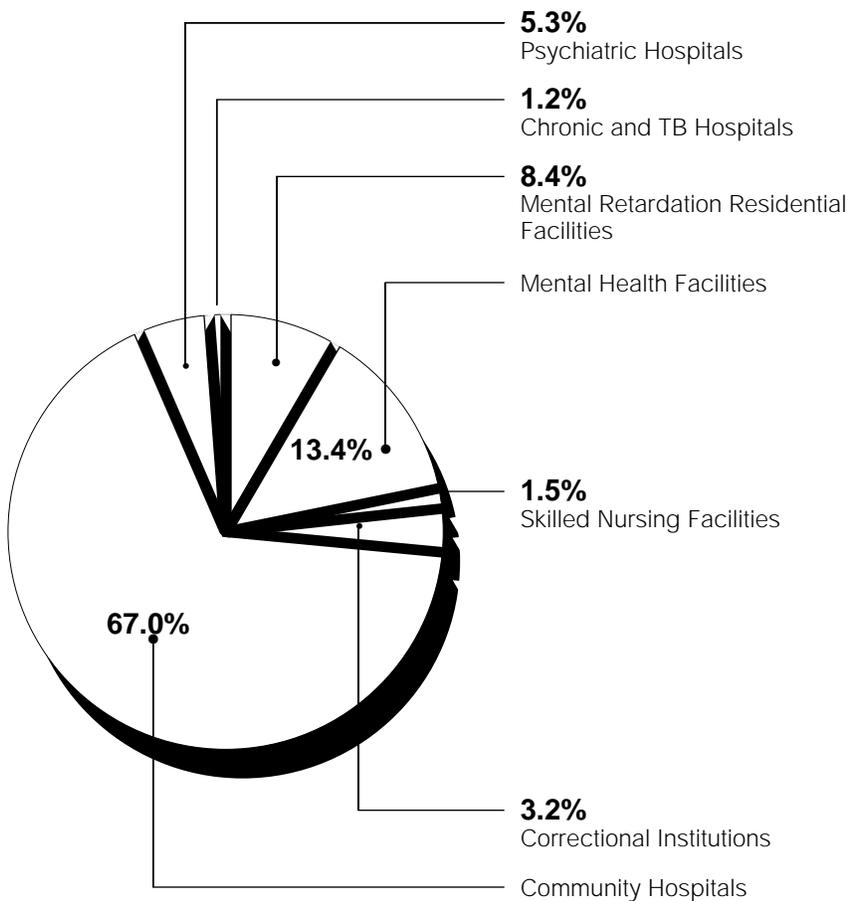
The Public Hospital Pharmacy Coalition has suggested that GSA's definition be narrowed to limit access to FSS prices to state and local government entities that purchase drugs for their own use and dispense drugs in their own facilities. The Coalition estimated that defining eligibility that way would result in a state and local FSS market of about 4.4 percent of total dollars in domestic pharmaceutical sales.²⁴ Figure 1 shows the potential composition of the state and local market for FSS sales based on the Coalition's proposal.

²²Coalition estimates indicate that these types of facilities could represent over 30 percent of about 7,900 potential eligible state and local entities.

²³PhRMA noted that the Congress acknowledged the potential for diversion of discounted products in the Veterans Health Care Act. Sec. 602 provided safeguards to ensure that entities receiving discounted outpatient drugs under the program would not resell those drugs to other entities.

²⁴See PRIME Institute, College of Pharmacy, University of Minnesota, Section 1555 of the Federal Acquisition Streamlining Act: Impact of Cooperative Purchasing on the Pharmaceutical Market, prepared for the Public Hospital Pharmacy Coalition (Washington, D.C.: Jan. 15, 1997).

Figure 1: Composition of the State and Local Market for FSS Sales Based on the Public Hospital Pharmacy Coalition's Proposal



Note: Percentage estimates are based almost exclusively on 1993 drug expenditures for approximately 5,760 entities.

Source: The Public Hospital Pharmacy Coalition.

But the market might actually be considerably smaller, according to the Coalition, for two reasons. First, some state and local purchasers are subject to procurement laws or regulations that would restrict their participation in the cooperative purchasing program. Second, eligible state

and local purchasers that choose to participate probably would not buy all their drugs through the program because some FSS prices would be higher than the drug prices they or their representatives could negotiate with manufacturers. If these two assumptions are considered, the Coalition estimated that state and local FSS purchasers would represent about 0.5 percent of the total drug market. The Coalition's estimates mean that the total FSS market would expand by between about 33 and 300 percent if state and local governments are given access to FSS prices.

As for the impact of procurement laws or regulations on state and local participation, 27 of 50 respondents²⁵ reported in a September 1996 survey we conducted that current state competitive-bidding and other laws would limit their use of federal supply schedules.²⁶ But most state and local government purchasing officials we contacted indicated that they want the option of purchasing items from the schedules. How many states and localities would change purchasing laws and regulations so that they could participate in the cooperative purchasing program is uncertain. It is also uncertain how many and to what extent eligible state and local entities would choose to buy drugs through the FSS rather than rely on the prices they negotiate themselves with manufacturers.

Although the size of the combined federal, state, and local market that could have access to FSS prices if the schedule is opened is unclear, past federal efforts to lower drug prices for a significant market segment caused many manufacturers to raise prices. Before the Medicaid rebate program was enacted in 1990, state Medicaid programs, which represent about 11 percent of the domestic pharmaceutical market,²⁷ paid close to retail prices for outpatient drugs. Other purchasers, such as hospitals and health maintenance organizations, paid considerably less. Under the program, the Congress required drug manufacturers to give state Medicaid programs rebates for outpatient drugs based on the lowest prices they charged other purchasers.

After the rebate program's enactment, the prices many large private purchasers paid for outpatient drugs increased substantially. In particular, prices paid by health maintenance organizations rose, on average, more

²⁵Respondents represented 48 states and 2 territories.

²⁶See GAO/GGD-97-33, Feb. 10, 1997.

²⁷According to IMS America, in 1995 total sales for the U.S. pharmaceutical market were about \$77.1 billion. According to the Health Care Financing Administration, Medicaid drug expenditures for fiscal year 1995 totaled about \$8.4 billion, including rebates.

than twice as fast as the year before the program.²⁸ Moreover, the lowest outpatient drug prices in the market increased faster than the drugs' average prices²⁹ as drug manufacturers significantly reduced the price discounts they offered private purchasers.³⁰ On the basis of its analysis of these price changes for outpatient drugs, the Congressional Budget Office concluded that because of the size of the market represented by Medicaid, "pharmaceutical manufacturers are much less willing to give large private purchasers steep discounts off the wholesale price when they also have to give Medicaid access to the same low price."³¹

FSS Price Changes Would Affect Government Purchasers Differently

How FSS prices would change if the pharmaceutical FSS is opened cannot be predicted given the uncertainties about the outcome of negotiations between VA and drug manufacturers. The factors involved in these negotiations and the subsequent outcomes could vary for different drugs. For example, the factors involved in negotiating FSS prices for unique, single-source drugs may differ greatly from those involved in negotiating FSS prices for drugs that have competing, generic versions. At a minimum, federal, state, and local purchasers have options for the sources they can use to purchase generics.

If the pharmaceutical schedule is opened, however, the factors involved in negotiations between VA and drug manufacturers could produce, in general, an upward pressure on FSS prices. As described earlier in this report, such factors include a change in the dynamics of negotiations between VA and drug manufacturers, continued limitations on VA's leverage to negotiate, and uncertainties about the size of the overall market that would be represented by sales to federal, state, and local purchasers. If FSS prices were to rise, the impact on federal purchasers would vary between those that are protected by ceiling prices for drugs covered by the Veterans Health Care Act and other federal purchasers that are not. The

²⁸See Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions (GAO/HRD-93-43, Jan. 15, 1993).

²⁹See Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals (GAO/HEHS-94-194FS, Aug. 5, 1994).

³⁰A study conducted for HIGPA contended that opening the pharmaceutical FSS could result in similar reductions in drug price discounts to private purchasers. See Muse & Associates, The Federal Acquisition Streamlining Act of 1994: The Effect of Federal Supply Schedule Expansion on Expenditures for Health Care Products (Washington, D.C.: Oct. 1996).

³¹See CBO Papers: How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry. 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.

effects of FSS price increases on state and local purchasers would depend on whether FSS prices are lower than the prices they can negotiate independently with drug manufacturers.

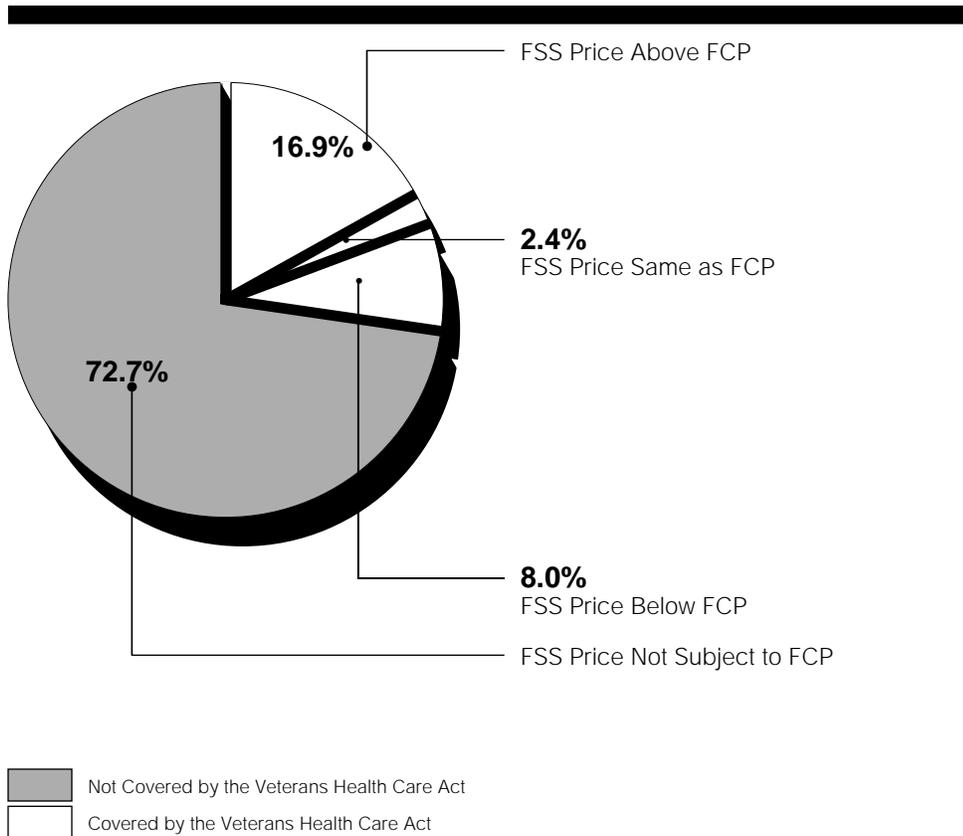
**For Federal Purchasers,
Impact of Any FSS Price
Increases Would Vary**

If FSS prices rise after the schedule is opened, all federal purchasers could pay higher FSS prices for drugs not covered by the Veterans Health Care Act. As seen in figure 2, about 73 percent of the roughly 22,800 drugs on the FSS are not covered by the act.³² The noncovered drugs, however, are generally generic drugs, and though they constitute most of the drugs on the FSS, they represent a smaller portion of federal expenditures because of the lower prices charged for generics. A VA official estimated that about three-quarters of VA's total drug expenditures are for covered drugs.³³

³²As of Sept. 30, 1996, the FSS included 22,828 products—6,243 were covered drugs and 16,585 were not covered.

³³Expenditure data were not readily available for products on the pharmaceutical FSS.

Figure 2: FSS Price Relative to FCP for Schedule Drugs as of September 30, 1996



Note: Percentages are based on the number of FSS products, rather than FSS expenditures.

Source: VA data.

For drugs that the act covers, VA and the three other protected federal agencies would not have to pay FSS prices that are higher than the federal ceiling prices (FCP). But as figure 2 shows, they may have to pay more for the 8 percent of all FSS drugs that currently have FSS prices below the ceiling prices if manufacturers succeed in raising those prices to or above the ceilings. The increases could be substantial given that, on average, the FSS prices for these drugs are about 28 percent below the ceiling price. Hence, VA and the other protected agencies could experience price increases for almost 81 percent of all the drugs on the FSS.

In February 1995, VA presented to GSA its analysis of the potential effects of opening the pharmaceutical schedule on FSS prices and VA drug costs taking into consideration the protection the Veterans Health Care Act gives VA against drug price increases. On the basis of discussions with representatives of numerous drug manufacturers, VA made two key assumptions in its analysis about the potential effects of opening the pharmaceutical FSS: (1) drug manufacturers would eliminate FSS pricing for all drugs not covered by the Veterans Health Care Act, forcing federal purchasers to buy these generic drugs at higher wholesale prices, and (2) FSS prices for all drugs covered by the act would rise to their ceiling prices.³⁴

VA applied those two assumptions to drug purchases it made during the first 6 months of 1994.³⁵ According to VA, it spent about \$37.8 million on 4,877 generic drugs not covered by the act. If it had purchased the same drugs at wholesale rather than FSS prices, VA estimated that it would have paid over \$79.7 million, about 111 percent more. In the same period, VA spent about \$118.3 million on 911 brand-name drugs that were covered by the act and that had FSS prices below their federal ceiling prices. Had the manufacturers of those drugs raised the FSS prices to the ceilings, VA estimated that it would have paid over \$152.9 million, roughly 29 percent more. Thus, VA calculated that on an annualized basis, the impact of giving state and local governments access to the FSS would have been a \$153.1 million increase in its own yearly drug expenditures because it would have to pay about 49 percent more overall for the drugs included in its analysis.

Those federal purchasers that, unlike VA, have no protection from the ceiling prices established by the Veterans Health Care Act would pay full FSS prices on all drugs they buy from the schedule.³⁶ Currently, however, most manufacturers' FSS prices do not exceed the ceiling prices. In fact, as of November 1996, only 25 of 162 drug manufacturers had FSS prices that were above the federal ceiling prices. But manufacturers can offer

³⁴DOD and Indian Health Service officials agreed with VA's assumptions about the potential effects of opening the schedule.

³⁵According to VA, calculations were based on actual contract purchase prices from VA's prime vendor network from Jan. 1 through June 30, 1994.

³⁶Any federal purchaser may contact drug manufacturers and attempt to obtain FSS price reductions on specific products before placing orders from the schedule. Manufacturers are allowed to provide such reductions without passing them on to other federal purchasers or changing a product's listed FSS price. According to a VA official, however, drug manufacturers typically do not provide FSS price reductions without providing them to all federal purchasers.

purchasers not protected by the act prices above the ceilings.³⁷ Officials representing several drug manufacturers told us manufacturers would consider this option attractive if the pharmaceutical schedule is opened because they could then offer these higher prices to state and local purchasers. The federal purchasers that are not protected by the ceiling prices would then also pay the full price increases when purchasing from the schedule.

The potential impact of FSS price increases on different government purchasers when purchasing from the pharmaceutical schedule is summarized in table 1.

Table 1: Potential Effects of FSS Price Increases on FSS Prices Paid by Government Purchasers

Purchaser	FSS price paid		Implications
	Before FSS opened	After FSS opened	
VA, DOD, Public Health Service, Coast Guard	Lower of FSS or federal ceiling price for covered drugs; FSS for drugs not covered	Lower of FSS or federal ceiling price for covered drugs; FSS for drugs not covered	FSS price for 8% of drugs could increase up to federal ceiling price; FSS price could increase for many drugs not covered
Other federal government entities	FSS	FSS	FSS prices could increase for many covered and uncovered drugs
State and local government entities	Not applicable— negotiated prices	FSS	FSS prices, even if they increase, could be lower than prior negotiated prices; if they are not, purchasers could try to negotiate lower prices

Note: For the purpose of this table, federal purchasers are considered to be dependent on purchasing many of their drugs from the FSS rather than from alternative sources.

State and Local Purchasers Could Choose Between FSS or Other Drug Prices

Opening the pharmaceutical schedule would give state and local purchasers the choice of buying drugs from the FSS or from other sources. If a drug’s FSS price rises, public hospitals, for instance, could choose to buy it at the FSS price or continue to use group purchasing organizations,

³⁷About 72 percent of the drugs with FSS prices above FCP as of Sept. 30, 1996, had FSS prices that were less than 1 percent above FCP. According to a VA representative, many of these drugs’ prices probably would be at FCP if not for a minimal fee included in the price that covers VA’s administration of the FSS.

formularies, and other cost-control tools to attempt to negotiate a better price with drug manufacturers.³⁸ The incentive for a drug manufacturer to negotiate a price below the FSS price would be limited, however, because the negotiated price could become the most-favored customer price and, thus, potentially affect the manufacturer's FSS price negotiations with VA.

The Public Hospital Pharmacy Coalition believes opening the schedule will benefit state and local purchasers because FSS prices will continue to represent a significant discount. The Coalition contends that drug manufacturers would have little incentive to raise FSS or other drug prices if the pharmaceutical schedule is opened because

- a manufacturer's participation in the cooperative purchasing program is voluntary, thus allowing a company to opt out of the program if it anticipates any adverse economic consequences;
- if a manufacturer concludes that it must participate in the program for competitive reasons, the same competitive forces will keep prices from rising;
- the potential size of the state and local market will be small based on the Coalition's proposal for determining eligibility to access FSS drug prices; and
- market size is but one of many factors drug manufacturers consider in developing drug pricing strategies.

Therefore, the Coalition believes that any adverse effects on FSS or other drug prices would be negligible and state and local purchasers would have access to many FSS prices that would be lower than the drug prices they currently pay.

A Coalition analysis of the differences between FSS prices and the prices nine public hospitals paid for drugs showed that, on average, FSS prices were considerably lower than the hospitals' purchase prices.³⁹ The analysis compared the prices for the 100 drugs each hospital spent the most on during a recent fiscal year.⁴⁰ The Coalition concluded that FSS prices, on average, were lower than the hospitals' purchase prices for about 83 percent of the drugs. The FSS price, on average, was about 17 percent lower than the price the hospitals paid.

³⁸In addition to group purchasing organizations that represent hospitals, state and local agencies in more than 25 states have joined together to purchase drugs as a single group purchasing organization.

³⁹The analysis was based on FSS and hospital purchase prices as of Oct. 1, 1996.

⁴⁰Hospitals ranged in size from 140 to over 900 beds and included some that received price discounts on outpatient drugs because they serve a disproportionate share of Medicaid patients.

Had those hospitals been able to buy their top 100 drugs at FSS prices whenever the FSS price was below the hospitals' regular purchase price, they would have saved, on average, about 21 percent on drug expenditures, the Coalition concluded.⁴¹ For those drugs with FSS prices below hospital purchase prices, the average savings on total purchases of a drug would have been about 25 percent.

If the pharmaceutical schedule is opened and FSS prices rise, the extent to which state and local government purchasers could benefit is unclear. The drug prices paid by the hospitals in the Coalition's analysis show that many FSS prices could rise and still be lower than what the hospitals have paid. The extent to which FSS prices would increase, however, is uncertain. In addition, if FSS prices increase because drug manufacturers raise prices for their most-favored customers, the impact on state and local purchasers could vary, depending on whether a state or local purchaser was a most-favored customer. For each drug manufacturer, the most-favored customer can vary by drug and by type of purchaser, such as a hospital, health maintenance organization, or government purchaser. Therefore, in those instances in which the state and local purchaser was a most-favored customer, the negotiated price could rise. While an increase in most-favored customer prices could affect state or local purchasers differently, they would retain the freedom to try to negotiate better prices for themselves. The result for federal purchasers, however, would be an increase in FSS prices.

Agency Comments and Our Response

We received both written and oral comments on a draft of this report from GSA, VA, PhRMA, and the Public Hospital Pharmacy Coalition.

In general, GSA, VA, and PhRMA agreed that the report accurately reflected the difficulty and complexity of assessing the potential effects of opening the pharmaceutical FSS on schedule drug prices. PhRMA also commented that the report provided important insights into characteristics of the market that could be affected by such a change. However, PhRMA said that in its view the report placed unnecessary emphasis on the Coalition's study and did not sufficiently analyze its flaws and limitations. We did not provide a point-by-point analysis of each study mentioned in the report because the purpose of this report was to provide an overall assessment of the potential effects of opening the pharmaceutical FSS.

⁴¹Total expenditures for each hospital for the top 100 drugs at the lowest prices ranged from about \$345,000 to about \$7.3 million.

The Coalition's primary concern was that it believed the report overemphasized the potential adverse effects of opening the schedule and ignored potential competitive benefits. For example, the Coalition believed that opening the schedule would create downward pressure on FSS prices. The Coalition also said that drug manufacturers could absorb any potential losses from providing lower drug prices to state and local government entities. Moreover, the Coalition was concerned that the report offered no real analysis of why FSS prices could increase and did not emphasize that federal purchasers were not limited to purchasing pharmaceuticals from the FSS. The Coalition contended that the Medicaid rebate experience had minimal relevance to opening the FSS because the FSS market would be much smaller than the Medicaid market and participation in the cooperative purchasing program would be optional for drug manufacturers. The Coalition also contended that because overall drug prices did not increase after enactment of the Veteran's Health Care Act—which set price ceilings on certain drugs for VA and other agencies—opening the pharmaceutical schedule would have little or no impact on FSS prices. In addition, the Coalition recommended that we delete any reference to diversion from the report because the diversion of pharmaceuticals is already prohibited by the Robinson-Patman Price Discrimination Act⁴² and the Non-Profit Institutions Act.⁴³ The Coalition also requested that we clarify GSA's reasoning for proposing that the pharmaceutical schedule be excluded from the cooperative purchasing program. The Coalition strongly rejected GSA's implication that a unique relationship between the Veterans Health Care Act and the cooperative purchasing program would cause an increase in FSS drug prices.

Throughout the report we emphasize that it is not possible to predict how pharmaceutical FSS prices would change if the schedule is opened. In response to the Coalition's comments, we modified the report to underscore this point. While we recognize that opening the FSS could enable state and local government entities to purchase drugs at lower prices, we focused on the potential for FSS drug prices to rise because it was most relevant to GSA in determining whether to exclude the schedule from the cooperative purchasing program. GSA has indicated that it is not the intent of the cooperative purchasing program to increase schedule prices. The report discusses the types of pressures that could potentially result in increased FSS prices. We agree that federal purchasers can purchase pharmaceuticals from sources other than the FSS and that the extent to which federal purchasers buy products from other sources could

⁴²June 19, 1936, ch. 592 (15 U.S.C. sec. 3-13c, 21a).

⁴³May 26, 1938, ch. 283 (15 U.S.C. sec. 13c).

have an impact on schedule prices. Nevertheless, VA, which spends the most federal dollars on pharmaceuticals, currently depends on the FSS for most of its pharmaceutical purchases.

In our view, the Medicaid rebate experience provides a useful example of how drug manufacturers have responded to requirements that they provide lower prices to a significant share of the market and how FSS prices could be affected if the size of the combined market represented by federal, state, and local purchasers was also significant. The report recognizes the uncertainty that exists about the size of this potential market as well as the economic reasons why drug manufacturers would not be likely to opt out of cooperative purchasing. While we agree that overall pharmaceutical price changes following the Veterans Health Care Act may be relevant in assessing the potential impact of opening the pharmaceutical schedule, a better indicator would be changes in pharmaceutical FSS prices following the act's enactment. According to VA's fiscal year 1998 budget submission about 70 percent of all covered drugs' prices have increased since then. Some VA officials believed that the increase in FSS prices was the result, in part, of drug manufacturers responding to the act's drug pricing provisions, particularly those that set price ceilings on certain drugs for VA and other agencies. These officials also indicated, however, that the increase in FSS prices could be related to other factors as well. In addition, we agree with the Coalition that federal law already places restrictions on the resale or diversion of discounted commodities purchased from the FSS. We included the issue in the report because of the concerns raised by PhRMA and others. Moreover, the Congress was sufficiently concerned about the diversion of outpatient drugs to include specific safeguards against it in the Veterans Health Care Act.⁴⁴

In response to the Coalition's comments, we added to the report GSA's specific justification for proposing that the pharmaceutical schedule be excluded from cooperative purchasing. We agree that drug pricing provisions in the Veterans Health Care Act alone or in combination with other factors would not necessarily result in increased FSS drug prices. But the federal price ceilings set in the act would be a factor in FSS negotiations between VA and drug manufacturers and would be relevant to the ultimate FSS prices different government purchasers could pay if the pharmaceutical schedule were opened.

⁴⁴See P.L. 102-585, sec. 602.

Each of the organizations provided a number of suggested technical changes that we incorporated into the final report where appropriate.

We will make copies of this report available upon request. This report was prepared by John Hansen, Assistant Director, Joel Hamilton, Leslie Albin, and Toni Navarro. Please call me at (202) 512-7119 or Mr. Hansen at (202) 512-7105 if you or your staff have any questions about this report.

A handwritten signature in black ink that reads "Bernice Steinhardt". The signature is written in a cursive style with a large, stylized initial 'B'.

Bernice Steinhardt
Director, Health Services Quality
and Public Health Issues

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