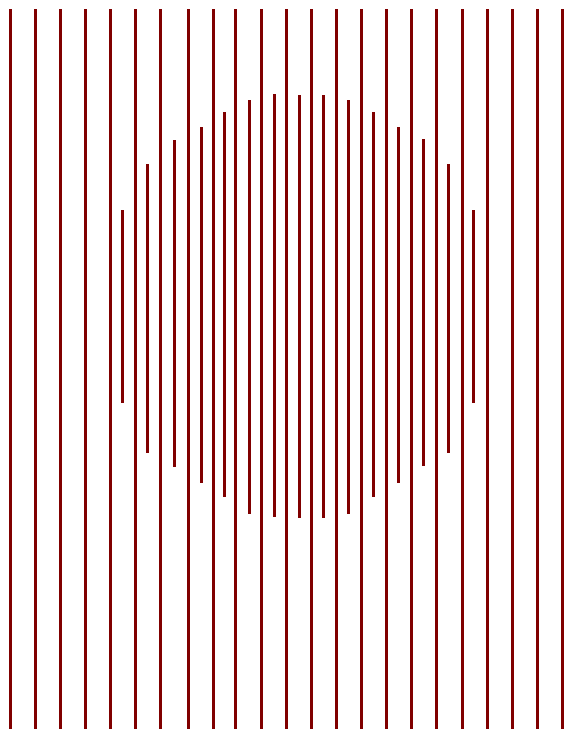# CBO
PAPERS

**HOW THE MEDICAID REBATE
ON PRESCRIPTION DRUGS
AFFECTS PRICING IN THE
PHARMACEUTICAL INDUSTRY**

January 1996

CONGRESSIONAL BUDGET OFFICE

CBO
PAPERS

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NOTES

Unless otherwise indicated, all years referred to in this paper are calendar years.

Numbers in the text and tables may not add up to totals because of rounding.

PREFACE

The Omnibus Budget Reconciliation Act of 1990 established the Medicaid rebate program for outpatient prescription drugs. That program requires pharmaceutical manufacturers to rebate to the federal and state governments a portion of their revenues from sales to Medicaid patients. In response to a request by the Senate Budget Committee, this Congressional Budget Office (CBO) paper examines both how much the Medicaid rebate program has saved federal and state governments and how it has affected pricing in the pharmaceutical industry. At the end of November, the Congress passed the Balanced Budget Act of 1995, which the President vetoed. The act would have shifted responsibility for the Medicaid program to the states, with continued federal support through block grants. The rebate program would have continued much as before.

<div align="right">
June E. O'Neill
Director
</div>

January 1996

CONTENTS

TABLES

FIGURES

BOXES

SUMMARY

The Medicaid rebate program, established by the Omnibus Budget Reconciliation Act of 1990, has succeeded in reducing government spending on outpatient prescription drugs. Under the basic rebate formula, pharmaceutical manufacturers rebate to the states at least 15.1 percent of the wholesale price of brand-name drugs that Medicaid beneficiaries purchase as outpatients. The basic rebate is often higher than that 15.1 percent minimum because of a "best-price" provision that gives Medicaid access to the lowest price paid by any other purchaser in the United States. In fiscal year 1994, Medicaid payments for outpatient prescription drugs totaled $9.5 billion. The total rebates paid came to $1.8 billion, thereby reducing net Medicaid payments for outpatient prescription drugs to $7.7 billion (see Summary Table).

Although the basic rebate has lowered Medicaid's expenditures on outpatient prescription drugs, spending on prescription drugs by non-Medicaid patients may have increased as a result of the Medicaid rebate program. In particular, the best-price provision has increased the prices paid by some purchasers in the private sector. Since Medicaid constitutes between 10 percent and 15 percent of the market for outpatient prescription drugs, 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. As a result, the largest discounts that pharmaceutical manufacturers give off the wholesale price—the best-price discounts—have fallen from an average of more than 36 percent in 1991 to 19 percent in 1994. Hence, although the Medicaid rebate appears on the surface to be attractive, it may have had unintended consequences for private purchasers. Rather than continuing to give Medicaid access to the lowest prices available in 1991, manufacturers often chose to increase their best prices.

Under the best-price provision, state Medicaid agencies obtain access to the lowest prices paid for prescription drugs by any purchaser in the United States without having to duplicate the efforts of large private purchasers to earn those discounts. Many large private purchasers use a formulary—a list of drugs that doctors are encouraged to prescribe for a given illness—to guide their patients toward the most cost-effective drugs. In return for being listed on the formulary, manufacturers are sometimes willing to offer a substantial discount. However, state Medicaid programs need not adopt those practices to obtain large discounts on brand-name drugs from manufacturers. One alternative to the Medicaid rebate would be for states to adopt the practices of private purchasers and negotiate their own discounts with manufacturers. Whether the states would be able to obtain discounts as large as those that they get under the Medicaid rebate program is unclear.

SUMMARY TABLE.   MEDICAID EXPENDITURES ON PRESCRIPTION DRUGS, 1984-1994
(By fiscal year, in billions of dollars)

Year	Total Expenditures	Total Rebates Collected	Net Medicaid Expenditures
1984	2.0	n.a.	2.0
1985	2.3	n.a.	2.3
1986	2.7	n.a.	2.7
1987	3.1	n.a.	3.1
1988	3.4	n.a.	3.4
1989	3.9	n.a.	3.9
1990	4.6	n.a.	4.6
1991	5.6	0.1	5.5
1992	7.1	0.9	6.2
1993	8.5	1.5	7.0
1994	9.5	1.8	7.7

SOURCE: Health Care Financing Administration, trend data based on Form 64.

NOTE: n.a. = not applicable.

The Congress is currently considering reforming the Medicaid program through block grants. Under the Balanced Budget Act of 1995, which was passed by the Congress in November but vetoed by the President, states would have had full responsibility for the Medicaid program, and federal funding would no longer have been directly linked to the level of state expenditures. The act would have preserved the Medicaid rebate program. However, the savings from the rebate program would no longer have been shared with the federal government, but rather would have belonged entirely to the states. As long as states continued to offer prescription drug benefits to their current Medicaid beneficiaries, they would probably have continued to participate in the rebate program under this reform.

HOW THE MEDICAID REBATE PROGRAM WORKS

Medicaid provides health care coverage primarily to low-income families with dependent children and low-income aged or disabled individuals. The federal government and the states share funding for the program. The federal share of Medicaid expenditures averages about 57 percent. The states administer the program under broad federal guidelines that allow each state to determine, within established limits, exactly who is covered, the extent of services offered, and the method of reimbursing providers. All states offer outpatient prescription drug coverage to most of their Medicaid beneficiaries, though they are not required to do so.

Pharmaceutical manufacturers must sign a rebate agreement with the Secretary of Health and Human Services in order for Medicaid to cover their products. If a manufacturer decides not to enter into a rebate agreement, then states do not receive federal Medicaid reimbursements for purchases of that company's drugs.

The manufacturer directly pays the Medicaid rebate on outpatient prescription drugs to each state Medicaid agency. All forms of the Medicaid rebate are based on the average manufacturer price (AMP) paid by wholesalers, inclusive of all discounts and price reductions "for drugs distributed to the retail pharmacy class of trade." The basic rebate ensures that Medicaid pays manufacturers no more--and sometimes less--than any private purchaser in the United States for outpatient prescription drugs.

If a brand-name drug's AMP rises faster than the inflation rate, an additional rebate is imposed so that manufacturers cannot offset the basic rebate by raising their AMP. The additional rebate is equal to the difference between the current AMP and a base-year AMP increased by the inflation rate as measured by the consumer price index.

Finally, manufacturers pay a rebate equal to 11 percent of the AMP on generic and over-the-counter drugs. To encourage states to promote substituting lower-cost generic drugs for brand-name ones, federal regulations set special reimbursement limits on 100 to 200 drugs that have generic substitutes.

HOW BEST-PRICE DISCOUNTS HAVE CHANGED

The Congressional Budget Office (CBO) analyzed the change in best-price discounts on more than 800 brand-name drugs purchased by Medicaid beneficiaries. In 1991, nearly one-third of the brand-name drugs still under patent (single-source drugs) had a best-price discount as high as 50 percent. But by 1994, only 9 percent of the single-source drugs had a best-price discount in that range. That change in pricing is particularly important since single-source drugs constitute over two-thirds of

Medicaid reimbursements and are a major component of total U.S. expenditures on prescription drugs. (The decline in the weighted average best-price discount appears to have leveled off by 1994 as firms finished adjusting to the incentives created by the best-price provision.)

The quantity of drugs sold at the best price is not known. Therefore, the magnitude of the effect of the change in pricing on private-sector purchasers is difficult to assess. The fall in the size of the best-price discounts between 1991 and 1994 suggests that purchasers with access to those discounts have been hurt by the best-price provision of the Medicaid rebate program. The reduction in the best-price discounts between 1991 and 1994 exceeded 30 percentage points for nearly one-quarter of the drugs in the sample analyzed by CBO. Such a large percentage-point change may have affected more purchasers than just those that received the best-price discount. Any purchaser that received a discount within 30 percentage points of the best-price discount would certainly have been affected by the change in best-price discounts on those drugs.

The best-price provision increases the Medicaid rebate when a manufacturer gives a discount off the AMP that exceeds the minimum rebate of 15.1 percent. Therefore, only those private purchasers that had access to discounts in excess of 15.1 percent of the AMP would pay more as a result of the best-price provision.

Since the AMP is not public information, purchasers may not know whether their discounts are in excess of the minimum rebate. CBO calculates that the AMP is, on average, equal to about 80 percent of the published list price (also known as the average wholesale price). Hence, purchasers would have to get a discount equivalent to one-third off the list price before possibly being affected by the best-price provision.

The General Accounting Office surveyed four health maintenance organizations (HMOs) and eight hospital purchasing groups in 1990 and 1991 and found that the discounts those purchasers obtained averaged between 29 percent and 34 percent off the list price. In other words, those purchasers were, on average, getting discounts right at the threshold where the best-price provision can take effect. Some drugs that they purchased would have had discounts above that average and hence could have been affected by the best-price provision.

Several types of purchasers can obtain steep discounts from manufacturers and therefore may have been affected by the best-price provision. Those purchasers include hospitals, HMOs, clinics, nursing homes, mail-order pharmacies, and third-party payers that manage their prescription drug benefits—often with the assistance of pharmaceutical benefit management companies.

HOW THE MEDICAID REBATE AFFECTS PRICING

The Medicaid rebate is based on a complex pricing structure in which firms practice price discrimination by charging different prices to different types of purchasers. Price discrimination occurs in markets in which purchasers are broken into groups that vary in their sensitivity to price and suppliers have some degree of market power. Under some circumstances, price discrimination can increase both profits and total benefits to consumers. In the pharmaceutical industry, the retail sector often pays higher prices than some large institutional purchasers.

Why Best-Price Discounts Decline

In negotiating discounts with private purchasers, the manufacturers balance the decline in price on current sales against the increase in profits from the new sales that a larger discount will bring. Because Medicaid must be given access to the best price negotiated with any U.S. purchaser, the size of the rebate that would be paid to Medicaid must also be calculated as part of the cost of offering that best price to private purchasers. Since the Medicaid market is so large, the best-price provision can more than double the cost of giving discounts in excess of the minimum rebate.

The size of the Medicaid market varies widely for different drugs. CBO calculated the Medicaid market share for 89 top-selling drugs. For 20 percent of those drugs, less than 5 percent of total sales went to Medicaid beneficiaries. For 16 percent of the drugs, Medicaid's market share exceeded 20 percent. The average Medicaid market share for all drugs in the sample was 12.2 percent. The larger Medicaid's market share, the greater should be the impact of the Medicaid rebate on the pricing of a drug. Those drugs with a small Medicaid market share are more insulated from the potential effects of the best-price provision.

The effect of the Medicaid rebate on discounting also depends on the magnitude of the difference between the AMP and the best price. The best-price provision affects the pricing only of those drugs that firms wish to discount significantly to some purchasers. If the manufacturer of a drug would not offer a discount in excess of 15 percent, even if there was no Medicaid rebate, then the best-price provision would not affect the pricing of that drug. Manufacturers appear to offer larger discounts to some purchasers when many substitutes are available. In 1991, the best-price discount of brand-name drugs with no generic substitutes in CBO's sample averaged 35 percent, whereas the best-price discount of brand-name drugs that had chemically equivalent drugs on the market (usually generic) averaged 51 percent. The best-price provision probably has less effect on the pricing of highly innovative new drugs that face little competition than on the pricing of drugs that have several close substitutes.

The Medicaid Rebate and the Retail Sector

The Medicaid rebate not only affects the lowest prices charged by the manufacturer for a drug, but it could also affect the price charged to wholesalers for the retail class of trade--namely, the average manufacturer price. The minimum rebate, which is based on the AMP, would by itself create an incentive for manufacturers to raise their prices to wholesalers. However, the additional rebate does exactly the opposite--it reduces revenues on Medicaid sales when a firm raises the AMP faster than the inflation rate. The basic rebate when combined with the additional rebate does not create an incentive for firms to increase their AMP in real terms (that is, faster than the inflation rate as measured by the consumer price index for all urban consumers).

However, new drugs may be launched at a slightly higher price because of the Medicaid rebate. The larger Medicaid's anticipated share in total sales of a drug, the more important that effect is. The additional rebate is based on the increase in a drug's AMP since its first quarter on the market. Consequently, the additional rebate penalizes a pricing strategy that consists of a low introductory price followed by increases over time as the drug becomes better known. Both the minimum rebate and the additional rebate create an incentive to charge a slightly higher launch price. All things being equal, that effect implies that a drug with a significant market share anticipated for Medicaid may be launched at a slightly higher price because of the Medicaid rebate program.

CHANGES IN THE AVERAGE MEDICAID REBATE

Because of reduced discounts to private purchasers, the Medicaid program has not benefited as fully from the 1990 policy change as it might have. If the best-price discounts had been as high in 1994 as they were in 1991, CBO calculates, the average basic rebate paid would have been 38.6 percent rather than just 22.8 percent. But the decline of best-price discounts between 1991 and 1994, in part because of the Medicaid rebate program, was hardly a surprise to policymakers. In fact, CBO assumed a decline in best-price discounts when it originally projected the savings from the Medicaid rebate program.

Although the basic rebate was capped at 25 percent in 1991 and not capped in 1994, the best-price provision increased the average basic rebate paid by 7 to 8 percentage points of AMP in both 1991 and 1994. The decline in best-price discounts since 1991 has limited the contribution of the best-price provision to the average basic rebate. Indeed, that contribution is no higher now than it was in 1991 under the cap.

ALTERNATIVES TO THE BEST-PRICE PROVISION

Rather than extending their best prices to the entire Medicaid market, firms more often have chosen to raise their best prices (that is, lower their discounts). However, when that occurs, both the government and some private-sector purchasers lose. Fortunately, some alternatives exist that would reduce the impact of the best-price provision on firms' incentive to offer steep discounts without reducing the savings obtained through the Medicaid rebate program.

Modifying the best-price provision could benefit purchasers that negotiate discounts with pharmaceutical manufacturers because manufacturers would not pay as large a penalty for offering generous discounts. CBO estimates that a repeal of the best-price provision would not affect the total rebate savings in 1996 if the minimum rebate was increased from 15.1 percent to 22.6 percent. Alternatively, a cap of 50 percent on the basic rebate would be budget neutral if the minimum rebate was increased from 15.1 percent to 16.7 percent.

Another alternative is to eliminate the Medicaid rebate program and fold Medicaid beneficiaries into managed care plans that can negotiate their own discounts on outpatient drugs from manufacturers. Of course, that policy has broad implications beyond the cost and use of prescription drugs by Medicaid beneficiaries. As of the end of 1994, eight states had obtained waivers from statutory requirements from the Health Care Financing Administration allowing them to move a large portion of their Medicaid beneficiaries into managed care organizations. Most of those states have forgone the Medicaid rebates for beneficiaries enrolled in managed care organizations (or plan to). This latter option could still benefit states if the managed care organizations cover outpatient prescription drugs at a very reasonable rate based in part on their ability to negotiate their own discounts.

CHAPTER I

INTRODUCTION

Pharmaceutical manufacturers often charge different types of purchasers different prices for the same product. Such price discrimination occurs in markets where suppliers have some degree of market power and purchasers can be separated into groups that vary in their sensitivity to price. In the pharmaceutical industry, that varying price sensitivity, when combined with patent protection and low production costs, can lead to a wide spectrum of prices for a single pharmaceutical product.

Consider, for example, that pharmaceutical manufacturers charge wholesalers more for the drugs they distribute to retail pharmacies than they charge some other types of large-scale purchasers, such as hospitals, nursing homes, and health maintenance organizations. Manufacturers are sometimes willing to give steep discounts to such institutional purchasers in return for being listed on a formulary—an established list of drugs that is used to guide the prescribing practices of doctors. Retail customers generally pay higher prices, in part because if they have health insurance coverage, frequently neither they nor their doctors take price into account. In 1970, only 18 percent of outpatient prescription drug expenditures were covered by third-party payers; by 1993, that amount had grown to 43 percent.[1] As one economist has pointed out, "The combination of physician decision-making, imperfect information, and third-party payment makes drug demand stronger and less price-elastic than it might otherwise be, conferring considerable monopoly power upon the sellers of well-accepted drugs."[2] Although that situation has begun to change as computer networks enable pharmacists to monitor formulary compliance for third-party payers, the retail sector remains one of the least price-sensitive segments of the pharmaceutical market.

Manufacturers can increase profits by categorizing purchasers and charging each group a distinct price that maximizes profits from sales to that group. Those purchasers that are more sensitive to price are better off under price discrimination. Conversely, those that are less sensitive to price pay more but are willing to do so. Manufacturers may find it profitable to offer some purchasers a very low price as long as that price exceeds production costs, which are markedly low in the pharmaceutical industry. Although the capitalized costs of research and development (R&D) for drugs marketed in the 1980s averaged close to $200 million per drug, production

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1. Katherine Levit, Arthur Sensenig, and others, National Health Expenditures, 1993, *Health Care Financing Review*, vol. 16, no. 1 (Fall 1994), p. 258.

2. F.M. Scherer, Pricing, Profits, and Technological Progress in the Pharmaceutical Industry, *Journal of Economic Perspectives*, vol. 7, no. 3 (Summer 1993), p. 99.

costs averaged about 25 percent of manufacturer sales.[3] On average, the price manufacturers charge must be high enough to generate a return on the large investment they have made in the R&D process. But charging very low prices to some purchasers can increase profits as long as those lower prices increase sales volume sufficiently while covering production costs.

The Medicaid rebate program is based on this complex pricing structure. Medicaid patients typically purchase their outpatient prescription drugs from retail pharmacies and account for 10 percent to 15 percent of the outpatient drug market. Thus, before the rebate program began in 1991, when Medicaid paid for outpatient drugs it paid retail prices despite its large market share. Partly in response to that situation, the Omnibus Budget Reconciliation Act of 1990 established the Medicaid rebate on outpatient prescription drugs to give the Medicaid program access to the same low prices that pharmaceutical manufacturers offer to other large purchasers.

The basic Medicaid rebate equals at least 15.1 percent of the average price paid by wholesalers. The basic rebate also contains a "best-price" provision that gives state Medicaid agencies access to the lowest price paid by any private purchaser in the United States. Moreover, state Medicaid agencies need not duplicate the efforts of private purchasers--such as negotiating with manufacturers and applying a strict formulary--to gain access to the lowest prices available.

The best-price provision appears on the surface to be attractive, but it may have had unintended consequences for both Medicaid and non-Medicaid purchasers. Many manufacturers have responded to the provision by raising the lowest prices previously offered to some private purchasers rather than giving Medicaid access to their lowest price. Hence, for many drugs, Medicaid did not succeed in getting the low prices obtained by some purchasers before 1991 because many of those prices increased substantially after the rebate program began.

At the end of November, the Congress passed the Balanced Budget Act of 1995, which the President vetoed. That act would have reformed the Medicaid program through block grants. States would have taken over the full responsibility for the Medicaid program, and the federal government would have continued to support Medicaid through fixed payments that would have no longer been tied directly to state expenditures. The Medicaid rebate formula for pharmaceuticals would have continued in its current form, and the Health Care Financing Administration would have continued to collect the necessary price data from manufacturers. States could have chosen whether they wished to participate in the rebate program. Since the revenues collected through the rebate program would have

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3. Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* (February 1993), pp. 91-93.

belonged entirely to the states, all states probably would have chosen to participate provided they continued to offer prescription drug benefits to Medicaid beneficiaries.

Under the block grant program, the states would have no longer shared with the federal government any savings resulting from cutbacks in Medicaid prescription drug coverage. Hence, although states are currently not required to offer prescription drug coverage, they would have had a greater incentive than now exists to reduce the number of people eligible for prescription drug coverage under Medicaid or to eliminate drug coverage entirely. A cutback in Medicaid drug coverage by the states would reduce the impact of the Medicaid rebate program on drug pricing. The Congress and the President are currently negotiating a revised version of that bill, and the outcome is unknown.

CHAPTER II

HOW MEDICAID AND THE REBATE PROGRAM WORK

The purpose of the Medicaid rebate program, established by the Omnibus Budget Reconciliation Act of 1990 (OBRA-90), is to reduce federal and state government spending on outpatient prescription drugs. In fiscal year 1994, the Medicaid rebate saved federal and state governments $1.8 billion. Total Medicaid expenditures on outpatient drugs in 1994, net of the rebate, were $7.7 billion.

MEDICAID

The Social Security Amendments of 1965 established the Medicaid program. Medicaid provides health care coverage primarily to low-income families with dependent children and to low-income aged or disabled individuals. The federal government funds 50 percent to 83 percent of Medicaid payments to health care providers in each state (state governments pay the remainder). The federal share is inversely related to the state's per capita income and equals about 57 percent on average.[1]

The states administer the Medicaid program under broad federal guidelines that allow each state to determine, within established limits, exactly who is covered, the extent of services offered, and the method for reimbursing health care providers. Although states are not required to cover outpatient prescription drugs for Medicaid beneficiaries, all states do offer such coverage to most of their beneficiaries.[2]

Eligibility

Under current rules, states have considerable discretion in determining who is eligible for Medicaid. They are required to offer Medicaid to all families that qualify for assistance under Aid to Families with Dependent Children (AFDC). (These are low-income families with children and usually one absent or unemployed parent.) But each state sets its own eligibility standards for AFDC based on its assessment of the cost of basic necessities such as food, clothing, and shelter in that state. Those

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1. Health Care Financing Administration, *Health Care Financing Review, Medicare and Medicaid Statistical Supplement 1995* (1995), pp. 118-127 and Table 103.

2. National Pharmaceutical Council, *Pharmaceutical Benefit Under State Medical Assistance Programs* (Reston, Va.: NPC, September 1994), pp. 251-559.

eligibility standards vary widely. In 1994, the income eligibility standard for AFDC ranged from 17 percent to 81 percent of the federal poverty level.[3]

The other major group that states are required to cover is recipients of Supplemental Security Income (SSI)--namely, low-income elderly, blind, or disabled people. Twelve states apply more restrictive standards for this group and therefore do not offer Medicaid to all recipients of SSI cash grants.[4] States can also elect to offer Medicaid to low-income institutionalized people who do not receive SSI.

Furthermore, states have the option to extend Medicaid coverage to the medically needy. Those are people who meet the nonfinancial criteria for categorical eligibility--specifically, members of single-parent families with dependent children and the aged, blind, or disabled--but who have incomes above the state's eligibility standards for welfare. Currently, 35 states and the District of Columbia offer Medicaid coverage to medically needy individuals.[5]

Recent federal legislation has extended Medicaid coverage to some groups that do not meet the general (nonfinancial) criteria for welfare eligibility. Medicaid now covers children under 6 and pregnant women in all families with incomes below 133 percent of the federal poverty level. Certain other low-income groups of pregnant women and children are also eligible for Medicaid.[6] In addition to those who are categorically eligible, Medicaid now assists all Medicare beneficiaries who have incomes below the poverty line by picking up Medicare premiums and cost-sharing requirements. However, that group of people, known as qualified Medicare beneficiaries, is not eligible for Medicaid's prescription drug benefits.

Prescription Drug Coverage

Coverage of outpatient prescription drugs is among the optional benefits left to each state's discretion. Inpatient drugs are covered as part of the medical services offered

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3. National Governors' Association, Health Policy Studies Division, "State Coverage of Pregnant Women and Children--February 1995," *MCH Update* (March 1995), Table 3. The unweighted average for the 50 states was 44.2 percent of the federal poverty level.

4. These are known as 209(b) states. States can use more restrictive standards only if the standards were part of a state's approved Medicaid plan before the SSI program began. See Congressional Budget Office, *Factors Contributing to the Growth of the Medicaid Program,* CBO Memorandum (May 1992), p. 4.

5. National Governors' Association, "State Coverage of Pregnant Women and Children," Table 5.

6. States are required to offer Medicaid to children under 18 born after September 30, 1983, with family incomes below the poverty level. States may choose to offer Medicaid to pregnant women and infants under age 1 with family incomes between 133 percent and 185 percent of the poverty level. Health Care Financing Administration, *Health Care Financing Review, Medicare and Medicaid Statistical Supplement 1995,* p. 118.

by a hospital or skilled nursing facility.[7] The majority of states choose to offer outpatient prescription drug coverage to all Medicaid recipients (30 states and the District of Columbia did so in 1993), and all states offer outpatient prescription drug coverage at least to those people receiving cash grants from AFDC or SSI.[8]

Medicaid's prescription drug coverage has relatively low cost-sharing requirements. Federal regulations place limits on the deductibles and copayments that states may charge. Federal regulations also prohibit states from imposing cost-sharing requirements on children, pregnant women, and institutionalized people. The deductibles for all health services cannot exceed $24 a year per family. The maximum copayment allowed on a prescription that costs from $25 to $50 is $2, and copayments for health services can never exceed $3.[9] In 1993, 27 states and the District of Columbia required some Medicaid beneficiaries to make copayments when purchasing a prescription drug.[10]

Reimbursement Rules for Outpatient Prescription Drugs

States pay health care providers directly for services rendered to Medicaid beneficiaries. However, providers that choose to participate in the Medicaid program must accept the state's reimbursements as full payment. For outpatient drug benefits, pharmacies are typically the direct provider. Wider participation by pharmacies enables more Medicaid beneficiaries to obtain prescriptions at convenient locations, but wider participation also costs more if reimbursement rates must rise to attract greater participation by providers. Thus, when setting reimbursement rates, states must balance their budgetary concerns against the need to provide sufficient incentives for providers to participate.

Each state Medicaid agency sets the reimbursement rate to pharmacies based on the federal regulations created by the Health Care Financing Administration (HCFA) within the Department of Health and Human Services. Those regulations leave the states with some discretion in setting reimbursement rates. For brand-name drugs that have no generic substitutes (single-source drugs), the reimbursement rate is equal to the lower of the pharmacy's usual and customary charge or the pharmacist's estimated acquisition cost plus a dispensing fee, both of which are set by the state.[11] The

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7. Pharmaceuticals used by patients in a nursing care facility are subject to the Medicaid rebate only if they are billed separately rather than as part of the per diem rate.

8. National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, pp. 251-559.

9. Code of Federal Regulations, title 42, section 447.54. The maximum copayment on a prescription that costs $25 or less is $1.

10. National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, p. 139.

dispensing fee is usually between $3 and $5. The estimated acquisition cost is frequently based on the published average wholesale price of the drug, which is the manufacturer's suggested price to the pharmacist. In most states, the estimated acquisition cost is set 5 percent to 11 percent below the published average wholesale price.[12] Researchers have found that state Medicaid payments to independent and chain-store pharmacies are roughly equal to the average cost of filling a prescription.[13]

To encourage states to promote lower-cost generic drugs, federal regulations set special reimbursement limits on 100 to 200 drugs that have generic substitutes. Those regulations limit the state expenses that are eligible for federal reimbursement to 150 percent of the lowest published generic price plus a reasonable dispensing fee. However, that lower federal reimbursement rate does not apply if the physician writes "brand necessary," "medically necessary," or just "necessary" on the prescription. In that case, the reimbursement formula for single-source drugs applies.[14]

The generic drug used as a basis for reimbursement must be widely available and rated as both bioequivalent and therapeutically equivalent to the original patented drug by the Food and Drug Administration (FDA). The price of this drug, increased by 50 percent, is referred to as the maximum allowable cost. That limit on reimbursement is not applied individually to each drug appearing on HCFA's list but rather to the state's total expenditures on all of the listed drugs. As long as the state pays on average no more than the maximum allowable cost for the listed drugs, it will receive its full share of federal funding. But the federal government will not pay its share of the state's expenditures that exceed the total spending limit set for those drugs.

The application of federal guidelines on generic substitution differ in each state. Some states choose to limit the reimbursement rate on multisource drugs to the maximum allowable cost set by HCFA plus a dispensing fee. Since the acquisition costs of brand-name drugs are much higher than the maximum allowable cost, that

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11. One exception exists in states that have allowed some Medicaid beneficiaries to enroll in health maintenance organizations. The state pays a fixed amount to the HMO that does not depend on the amount of services actually used by the Medicaid beneficiary.

12. National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, p. 139. One source for the average wholesale price is the *Red Book*, published by Medical Economics Data Production Company (Montvale, N.J.: Medical Economics Data, 1994).

13. E. Kathleen Adams, David H. Kreling, and Kathleen Gondek, "State Medicaid Pharmacy Payments and Their Relation to Estimated Costs," *Health Care Financing Review*, vol. 15, no. 3 (Spring 1994). Those states that have lower estimated acquisition costs tend to have higher dispensing fees. Hospital outpatient pharmacies may be able to purchase pharmaceuticals at a significantly lower price than other types of pharmacies. See General Accounting Office, *Medicaid: Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland*, GAO/HRD-93-55FS (March 1993).

14. Code of Federal Regulations, title 42, section 447.331.

difference creates an incentive for the pharmacist to dispense the generic drug--except when the brand-name drug is deemed "necessary." Overall, the Congressional Budget Office calculates that 52 percent of Medicaid prescriptions dispensed in 1993 were for a generic drug.[15]

Cost Containment Efforts by the States

Both in response to federal reimbursement limits on multisource drugs and to reduce Medicaid expenditures, many states have taken further measures to encourage generic substitution. Some states use formularies that indicate which drugs are generally covered by the state Medicaid program.[16] The state can subject nonformulary drugs to a prior-authorization procedure or even refuse coverage if the drug is therapeutically equivalent to another drug on the formulary.[17] In 1992, 22 states required pharmacists to dispense generic drugs when available, unless the doctor's prescription ruled out generic substitution.[18]

All but eight states have some type of limit on the quantity of drugs used, be it a limit on the number of prescriptions per month, on the number of refills, or on the quantity dispensed per prescription. Thirty-four states limit the quantity of any single prescription, and 20 states limit the number of refills.[19] Many use prior-authorization programs to enforce those limits on quantity.[20]

Prescription drugs can be divided into three categories: single-source innovator drugs, multiple-source innovator drugs, and generic drugs. All innovator drugs have been approved by the FDA under an original new-drug application, and most have also been patented. Single-source drugs have a unique combination of active

15.   Congressional Budget Office tabulation based on data collected by the Health Care Financing Administration for the Medicaid rebate program.

16.   Health Care Financing Administration, *Manufacturers' Prices and Pharmacists' Charges for Prescription Drugs Used by the Elderly* (June 1990), p. 36.

17.   The Omnibus Budget Reconciliation Act of 1990 prohibited states from refusing to cover the drugs of any manufacturer that had signed a rebate agreement. OBRA-93 modified that provision, however. Under the supervision of a committee made up of pharmacists and doctors, the states can exclude from their formulary any drug that "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary"; 42 U.S.C. 1396r-8 (d) (4) (c), 107 Stat 619.

18.   National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs* (September 1993), p. 111.

19.   National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs* (September 1994), p. 145. All states cover certain over-the-counter drugs through Medicaid's outpatient drug benefit.

20.   The Omnibus Budget Reconciliation Act of 1990 placed restrictions on the prior-authorization programs used by state Medicaid agencies. States are required to give prior authorization within 24 hours of a request and to waive prior approval in emergency situations.

ingredients that are not available in any other drug product. Multiple-source innovator drugs have been approved by the FDA as an original new drug, but other bioequivalent drugs are available with the same combination of active ingredients. That situation occurs either because more than one firm has the right to produce the innovator drug (perhaps through a licensing agreement) or because the patent of the innovator drug has expired and generic versions are being produced.

In 1993, approximately half of all Medicaid outpatient prescriptions were filled with a generic drug. Yet those drugs accounted for only 22 percent of the dollar value of reimbursements (see Table 1). The difference occurred because generic drugs are much cheaper than innovator drugs. That over half of all prescriptions dispensed to Medicaid beneficiaries were for a generic drug indicates a high level of generic substitution. Only 10 percent of the prescriptions were for innovator multiple-source drugs—in those instances, a brand-name drug was prescribed, although a generic drug was available.

Thirty-eight percent of prescriptions dispensed were for a single-source drug, and those drugs accounted for over two-thirds of total reimbursements. The higher prices of innovator single-source drugs cause their share in reimbursements to far exceed their share in total units dispensed.

TABLE 1.   MEDICAID EXPENDITURES ON GENERIC AND BRAND-NAME DRUGS, 1993
            (In percent)

Drug Type	Share of Outpatient Drug Reimbursements	Share of Prescriptions
Generic	22	52
Brand Name		
Single source	68	38
Innovator multiple source	10	10
Total	100	100

SOURCE: Congressional Budget Office tabulations based on data collected by the Health Care Financing Administration on the Medicaid rebate program.

THE MEDICAID REBATE PROGRAM

The manufacturer directly pays the Medicaid rebate on outpatient prescription drugs to each state Medicaid agency.[21] The basic rebate on brand-name drugs takes one of two forms. It either equals a flat percentage of the average price paid by wholesalers or is based on the lowest price charged to any U.S. purchaser, called the best price. An additional rebate is also imposed on brand-name drugs when their prices rise faster than the rate of inflation. That additional rebate makes it more difficult for manufacturers to offset the basic rebate by raising prices faster than inflation.

Manufacturers of generic and over-the-counter drugs also pay a Medicaid rebate. That rebate equals 11 percent of the average price that wholesalers pay.

Pharmaceutical manufacturers are required to sign a rebate agreement with the Secretary of Health and Human Services if they want to participate in the Medicaid reimbursement program. If a manufacturer chooses not to enter into a rebate agreement, states will not receive federal Medicaid reimbursements for purchases of that company's drugs.

The Basic Rebate

All forms of the Medicaid rebate are based on the average manufacturer price (AMP) paid by wholesalers, inclusive of all discounts and price reductions, "for drugs distributed to the retail pharmacy class of trade."[22] Manufacturers are required to report to the Health Care Financing Administration the AMP on every dosage form of each drug they distribute. The basic rebate must be paid on all single-source and innovator multiple-source drugs purchased by Medicaid beneficiaries. The basic rebate on these brand-name drugs is equal to the greater of 15.1 percent of the AMP or the difference between the AMP and the best price.[23] Thus, if any U.S. purchaser pays less than 84.8 percent of the AMP for a drug, the rebate is based on the best price. The purpose of the best-price provision is to ensure that Medicaid pays manufacturers no more for prescription drugs than any other U.S. purchaser does.

OBRA-90 established the basic rebate and limited it to 25 percent of AMP through the end of 1991. In 1992, the limit was set at 50 percent of AMP (see

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21. This section is based on section 1927 of the Social Security Act as amended by the Omnibus Budget Reconciliation Acts of 1990 and 1993 and the Veterans Health Care Act of 1992 (42 U.S.C. 1396r-8). It is also based on the Medicaid rebate agreement signed by manufacturers.

22. Ibid.

23. The best price is calculated for each dosage form of a drug. It is the lowest price charged for that dosage form in any package size.

Table 2). Since 1992, there has been no limit on the basic rebate; in fact, it exceeds 70 percent of AMP on a few drugs because of the best-price provision. The size of the minimum rebate has also increased from 12.5 percent in 1991 to its current level of 15.1 percent.

The best-price provision of the Medicaid rebate discourages manufacturers from giving large discounts on outpatient drugs to other purchasers. Medicaid's purchases constitute over 10 percent of the outpatient prescription drug market, whereas the largest private institutional purchasers together may represent a smaller portion of the market for outpatient drugs. Medicaid effectively obtains the best price from manufacturers, but the reimbursement mechanism allows for a markup by both the wholesaler and the pharmacy. Hence, Medicaid still pays more for prescription drugs than some institutional purchasers do. In negotiating discounts with private purchasers, the manufacturers balance the loss in revenues from lowering their price on current sales against the increase in market share that a larger discount brings. When Medicaid must be given access to the best price negotiated with any U.S.

TABLE 2.   CHANGES IN THE MEDICAID REBATE RULES BETWEEN 1991 AND 1996

Year	Quarter	Basic Rebate (In percent)		Are FSS Prices Exempted from Best-Price Calculation?
		Minimum	Upper Limit	
1991	1-4	12.5	25	no
1992	1-2	12.5	50	yes
	3	12.5	50	no
	4	15.7	50	yes
1993	1-4	15.7	none	yes
1994	1-4	15.4	none	yes
1995	1-4	15.2	none	yes
1996 and Beyond		15.1	none	yes

SOURCE: Congressional Budget Office.

NOTE: FSS = Federal Supply Schedule prices of the General Services Administration.

purchaser, the size of the rebate that would be paid to Medicaid must also be calculated as part of the cost of offering the best price to the largest private purchasers. Since the Medicaid market is so large, that requirement can more than double the cost of giving a discount in excess of the minimum rebate.

Manufacturers may sometimes hide a large discount on one drug by bundling its sales with another drug. A bundled sale "refers to the packaging of drugs of different types where the condition of the rebate or discount is that more than one drug type is purchased."[24] For example, suppose that drug A costs $4 per pill and drug B costs $2 per pill and that a manufacturer would like to give some purchaser a 50 percent discount off the price of drug A. The manufacturer could offer a purchaser the following arrangement: when one pill of drug A is purchased along with two pills of drug B, the buyer gets a $2 discount. The allocation of the discount for drugs under a bundled sale "is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement."[25]

In the above example, the $2 discount is split between the two drugs. Since half of the expenditures under that arrangement are on drug A and half are on drug B, the discount is split evenly. For the best-price calculation, drug A costs $3 and drug B costs $1.50 per pill. Both drugs sell at a 25 percent discount. If the discount had been given on drug A alone, the best price for drug A would be $2 (a 50 percent discount). In short, a large discount on one drug can be partially masked by bundling its sales with another drug for which the manufacturer intends to give a very low (or no) discount.

The Additional Rebate

If a drug's AMP rises faster than the inflation rate, an additional rebate is imposed to discourage price increases. The additional rebate equals the difference between the current quarter's AMP and the AMP in the quarter beginning July 1, 1990, after adjusting by the percentage increase in the consumer price index for all urban consumers.

For new drugs launched after October 1990, the additional rebate is based on the difference between the current quarter's AMP and the AMP in the first quarter that the drug is on the market. That provision may encourage manufacturers to launch new drugs at a higher price during their first quarter on the market. A higher launch

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24. From the definition of bundled sale in the Medicaid rebate agreement signed by manufacturers.

25. From the definition of best price in the Medicaid rebate agreement signed by manufacturers.

price in the first quarter would yield a higher base AMP from which to calculate the additional rebate in all subsequent quarters.

The additional rebate was intended to prevent manufacturers from circumventing the minimum rebate by raising prices. For example, the additional rebate actually lowers profits on Medicaid sales when the AMP rises faster than the inflation rate. Moreover, when combined with the best-price provision, the additional rebate can have a very strong effect on unit revenues from Medicaid sales. When the best-price provision applies, unit revenues equal the best price less the additional rebate. The best price is already the lowest price to any purchaser in the United States, and the additional rebate reduces the price paid by Medicaid even further (see Box 1).

Rebate on Generics

Manufacturers must pay a rebate equal to 11 percent of the AMP on noninnovator multiple-source drugs—that is, generic and over-the-counter drugs. Since the Drug Price Competition and Patent Term Restoration Act was passed in 1984, manufacturers of generic drugs have been allowed to use a shortened process to obtain FDA approval. Under that process, they need only demonstrate bioequivalence to a previously approved drug.

Calculating the Average Manufacturer Price

All forms of the Medicaid rebate increase as the reported AMP rises. The manufacturer must calculate an AMP for each dosage form of each drug distributed. The AMP is calculated by dividing sales revenues to the retail sector, net of all discounts and rebates to the retail class of trade, by the number of units sold. Sales to hospitals, nursing homes, and other institutional purchasers are not included in calculating the AMP.

Determining the Best Price

Federal government agencies not associated with Medicaid obtain some of the lowest prices on pharmaceuticals. Whether those prices are considered in the best-price calculation can affect the discounts that manufacturers are willing to give private purchasers.

Throughout 1991, most prices obtained by federal government agencies were eligible to be counted as a best price. The Department of Veterans Affairs (VA) is

BOX 1.
THE ADDITIONAL REBATE: SOME EXAMPLES

The additional rebate slightly lowers unit revenues on sales to Medicaid beneficiaries when the average manufacturer price (AMP) rises faster than the rate of inflation as measured by the consumer price index for all urban consumers. For example, if the base-year AMP inflated to current dollars is equal to $10, a manufacturer will on average net 15.1 percent less, or $8.49, when the current AMP is equal to $10.[1] If the manufacturer chooses to charge $12, average unit revenues on Medicaid sales decline to $8.19. That decline occurs because the additional rebate ($2) compensates for the AMP's rising faster than inflation and the minimum rebate increases (15.1 percent of $12 instead of $10).[2] When the AMP is increased to $12, unit revenues on sales to Medicaid beneficiaries drop by 30 cents.

The additional rebate applies even when the basic rebate is based on the best price. In that case, unit revenues on Medicaid sales are equal to the best price less the additional rebate. Suppose that the best price is equal to $7, the AMP is $12, and the base-year price adjusted for inflation is $10. Without the additional rebate, unit revenues on average would be equal to the best price ($7). The additional rebate would reduce unit revenues on Medicaid sales from $7 to $5. When the AMP rose to $12, unit revenues on Medicaid sales would decline by the full amount of the additional rebate--$2.

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1. Unit revenues are equal to the AMP less the minimum rebate. Calculation: $10 - 0.152 (10) = $8.48.

2. Unit revenues are equal to the AMP less the minimum rebate less the additional rebate. Calculation: $12 - 0.152 (12) - ($12 - $10) = $8.18.

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one of the largest federal direct purchasers of prescription drugs, spending more than $900 million in fiscal year 1995.[26] Medical centers belonging to the VA can purchase prescription drugs either through the department's depot system or directly from the manufacturer at the prices listed on the Federal Supply Schedule (FSS) for pharmaceuticals. Both the depot prices and the FSS prices are set by negotiations between the VA and pharmaceutical manufacturers. Although the department's depot prices have always been excluded from the best-price calculation, FSS prices originally were not excluded.

During 1991, many of the FSS prices increased significantly, perhaps because of the best-price provision in the Medicaid rebate agreement.[27] The Congress responded

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26. Personal communication with Jeff Ramirez, Pharmacy Services Department, Department of Veterans Affairs, December 12, 1995.

27. General Accounting Office, Medicaid: Changes in Drug Prices Paid by VA and DOD Since Enactment of Rebate Provisions, GAO/HRD-91-139 (September 1991).

by exempting FSS prices from the best-price calculation. The exemption was temporary at first, holding only for the first six months of 1992. However, the Congress permanently exempted all prices obtained by any federal agency from the best-price calculation in the Veterans Health Care Act of 1992.[28] Exempting federal prices from the best-price calculation means that the prices obtained by private purchasers are counted as the best price.

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28. This act took effect in the fourth quarter of 1992. The act also excluded prices obtained by state pharmaceutical assistance programs from the best-price calculation.

CHAPTER III
PRICING IN THE PHARMACEUTICAL INDUSTRY
AND THE MEDICAID REBATE

The effect of the best-price provision on the pricing of a specific drug depends on whether the difference between the average manufacturer price and the best price would exceed 15 percent if no Medicaid rebate existed. Hence, it depends in part on how great the difference in sensitivity to price is among the different purchasers of that drug.

The competitive conditions in the pharmaceutical market vary from drug to drug. Manufacturers are probably more likely to offer steep discounts off the AMP when a drug has close substitutes. Hence, the best-price provision may have a bigger impact on pricing in more competitive markets. In addition, the larger Medicaid's market share, the greater the impact of the best-price provision on the pricing of a drug should be.

The Medicaid rebate program should not affect the AMP very much for drugs on the market by 1990.[1] Although the minimum rebate encourages firms to raise the AMP, the additional rebate penalizes them for raising the AMP faster than the inflation rate. On balance, the Medicaid rebate slightly discourages firms from increasing the AMP faster than the rate of inflation as measured by the consumer price index for all urban consumers (CPI-U). New drugs, however, may be launched at a somewhat higher price because of the Medicaid rebate program. The analysis in this chapter is based on an economic model in which firms can maximize profits by charging different prices to different types of purchasers (for a full presentation of the model, see the appendix).

WHO GETS DISCOUNTS

Over 60 percent of prescription drugs are distributed through more than 60,000 pharmacies and other retail stores (see Figure 1). The retail sector is generally the least price-sensitive segment of the pharmaceutical market. Other segments include hospitals, health maintenance organizations (HMOs), nursing homes, and clinics, which together purchase 32 percent of all prescription drugs. Some drugs bought by those pruchasers are used exclusively in an inpatient setting and are therefore not

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1. The few instances in which the Medicaid rebate could have a very small effect on the AMP of drugs already on the market are discussed in the appendix.

FIGURE 1. CHANNELS OF PRESCRIPTION DRUG DISTRIBUTION
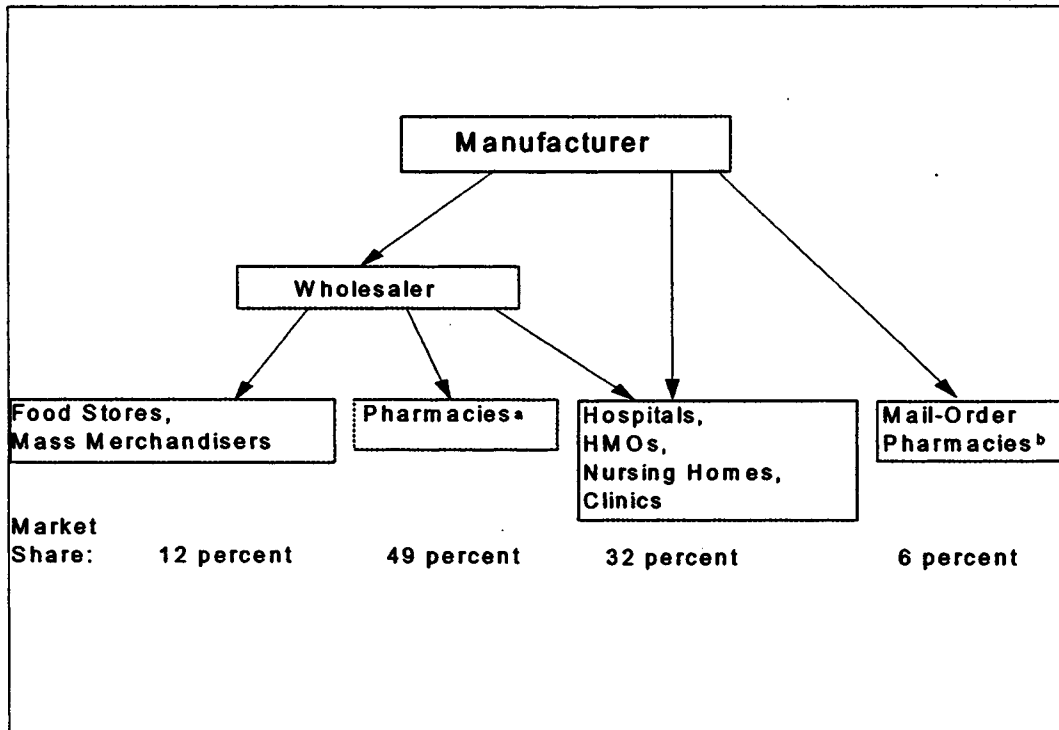
SOURCE: Market shares are from *The Pink Sheet*, vol. 54 (March 16, 1992) and are based on IMS America data. Distribution channels are based on Micky Smith, *Pharmaceutical Marketing Strategy and Cases* (New York: Pharmaceutical Products Press, 1991), Chapter 3; and Boston Consulting Group, *The Changing Environment for U.S. Pharmaceuticals* (April 1993).

NOTE: HMO = health maintenance organization.

a. Some chain-store pharmacies buy directly from the manufacturer.

b. Some mail-order pharmacies go through a wholesaler.

affected by the Medicaid rebate. Mail-order pharmacies distribute 6 percent of prescription drugs.[2]

Wholesalers distribute about three-quarters of all prescription drugs, largely to the retail sector. A single wholesaler purchases products from many different pharmaceutical manufacturers.[3] However, many large purchasers such as hospitals, nursing homes, HMOs, and mail-order pharmacies buy directly from the manufacturer rather than through a wholesaler.

Hospitals along with nursing homes, clinics, HMOs, mail-order pharmacies, and pharmaceutical benefit management companies (PBMs) are among the groups that may obtain discounts large enough to be affected by the best-price provision of the Medicaid rebate. More specifically, the best-price provision directly affects only those purchasers that could obtain discounts in excess of 15 percent off the AMP.

A recent General Accounting Office (GAO) survey found that four HMOs received an average discount off the published list price of 32 percent in 1990 and 34 percent in 1991 on their top 100 outpatient drugs.[4] Eight hospital group purchasing organizations included in the GAO survey received discounts that averaged 29 percent off the list price on the top 50 outpatient drugs that they purchased. The Congressional Budget Office calculated that a 32 percent discount off the list price would be equivalent to a discount off the AMP of about 15 percent. That calculation is based on the result that the AMP averages about 80 percent of the list price (see Box 2). Therefore, those purchasers obtained discounts that were right at the threshold where the best-price provision takes affect. Some drugs would have higher discounts than that average, and others would have lower discounts. The best-price provision could have affected the prices for those drugs with above-average discounts.

Manufacturers sometimes give significant discounts to hospitals, HMOs, nursing homes, and clinics because those institutions can exercise control over the choice of prescriptions for a large group of patients through a formulary. A formulary is a list of drugs that a hospital, HMO, or third-party payer encourages doctors to prescribe. Formularies can be used as a means to exclude expensive drugs when lower-priced substitutes are available. Not surprisingly, pharmaceutical manufacturers are sometimes willing to give discounts in order to be included on an institution's

2. Based on IMS America data for 1991 reported in F-D-C Reports, "Mail Order Grew, *The Pink Sheet*, March 16, 1992.

3. Mickey Smith, *Pharmaceutical Marketing Strategy and Cases* (New York: Pharmaceutical Products Press, 1991), Chapter 3; and Standard & Poor's, "Health Care Products & Services: Basic Analysis (New York: Standard & Poor's, September 9, 1993).

4. General Accounting Office, *Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions*, GAO/HRD-93-43 (January 1993).

BOX 2.
COMPARING THE AVERAGE MANUFACTURER PRICE
WITH THE LIST PRICE

The average wholesale price (AWP) is the published (list) price that manufacturers suggest wholesalers charge their customers. Wholesalers usually charge pharmacists a price that is lower than the AWP, which is the price that is most widely available in published form. In contrast, the average manufacturer price (AMP), used to calculate the Medicaid rebate, is not public information. The AMP is lower than the AWP since it is the average price paid by wholesalers. The Congressional Budget Office (CBO) has examined the relationship between the AMP and AWP to determine the equivalent discount off the AWP that a private purchaser must obtain before the Medicaid best-price provision applies.

CBO examined the relationship between the AWP and AMP for 224 drug products that were the top-selling Medicaid drugs in 1993 (based on data collected by the Health Care Financing Administration for the Medicaid rebate program and the AWPs reported in Redbook).[1] For that sample, the AMP averaged 80 percent of the AWP. Therefore, wholesalers paid on average 80 percent of the list price for those drugs. For 84 percent of the 224 drug products examined, the AMP fell between 75 percent and 85 percent of the AWP. For 94 percent of the 224 drug products, the AMP fell between 75 percent and 90 percent of the AWP. Given that the AMP is equal to 80 percent of the AWP on average, a discount of 32 percent off the AWP equals a discount of 15 percent off the AMP on average.

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1. Medical Economics Data, *1994 Redbook* (Montvale, N.J.: MED, 1994).

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formulary. Discounts can also be based on volume--for example, hospital purchasing groups can sometimes obtain such discounts.

Increasingly, third-party payers--be they unions, insurance companies, or large corporations--are also attempting to "manage" their outpatient drug benefits with formularies.[5] Many third-party payers are contracting with pharmaceutical benefit management companies to take on the management for them. For instance, a PBM contracts with a large group of pharmacies to sell prescription drugs to its customer base at previously negotiated prices. The PBM and participating pharmacies then use computer networks to help them both process claims automatically and apply a

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5. Stephen W. Schondelmeyer and Joseph Tomas, "Trends in Retail Prescription Expenditures," *Health Affairs* (Fall 1990); and Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* (February 1993), Chapter 10.

formulary to purchases made by the PBM's customers. After a patient presents his or her card, the pharmacist can determine immediately if the patient's prescription is on the PBM's formulary. The PBM may give the pharmacist incentives to dispense a generic drug when possible or to contact the physician and try to switch the prescription if it is not on the formulary. PBMs also negotiate with pharmaceutical manufacturers for a rebate in return for including their drugs on the formulary. The six largest PBMs handled about 36 percent of all retail prescriptions in 1993, and the largest company, PCS Health Systems, managed over half of those prescriptions.[6]

Mail-order companies can obtain discounts from manufacturers because they often call physicians and ask them to switch the prescription to the most cost-effective drug (a process called counterdetailing).[7] Counterdetailing is probably more cost-effective for mail-order pharmacies than for community pharmacies because a higher proportion of mail-order customers are long-term users of pharmaceutical products.[8]

PRICE DISCRIMINATION AND THE MEDICAID REBATE

The analysis in this section is based on an economic model with two groups of consumers—one representing the retail sector and the other representing purchasers that have access to the best prices. Each group is charged a different price by the manufacturer. Production costs are assumed to be constant no matter how much is produced.[9] The Medicaid rebate program is added to this simple, two-sector model. Thus, the model fully incorporates the various forms of the Medicaid rebate, including the best-price provision. Interested readers can refer to the appendix for a full explanation of the model and the mathematical results.

Both firms and some consumers can benefit from price discrimination. Firms can improve their profits by lowering prices selectively. Assuming fixed costs are already covered, offering a lower price to some consumers that still exceeds variable production costs will increase profits. Those consumers that obtain the lower price will be better off.

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6. F-D-C Reports, "PCS Manages 21% of Retail Dispensed Prescriptions, *The Pink Sheet*, March 14, 1994. See also Alex Barnum, McKesson Plans to Hold Onto PCS, *San Francisco Chronicle*, May 26, 1994, p. B1; and General Accounting Office, *Pharmacy Benefit Managers: Early Results on Ventures with Drug Manufacturers*, GAO/HEHS-96-45 (November 1995).

7. For example, Medco, the largest mail-order pharmacy, obtains discounts from the manufacturers whose drugs they favor (*Fortune*, February 24, 1992, p. 10).

8. Anita M. McGahan, "Industry Structure and Competitive Advantage, *Harvard Business Review* (November-December 1994), p.120.

9. This simplifying assumption does not affect the results as long as unit costs do not change much when production is increased beyond the level necessary to serve the retail sector alone.

How the Medicaid Rebate Affects Discounting

The results of the model imply that the effect of the Medicaid rebate on discounting will depend on the magnitude of the difference between the prices paid by the retail sector (the AMP) and the best price. Suppose that before the Medicaid rebate program was imposed, no purchasers received more than a 15 percent discount off the average price charged to wholesalers (see the bottom panel of Figure 2). In that case, the best-price provision would not affect the discounts obtained by large purchasers. If, in the absence of the Medicaid rebate, the manufacturer of a drug would not offer a discount in excess of 15 percent of the AMP, then applying the best-price provision would not affect the price of that drug. New innovative drugs with no close substitutes are more likely to have this pricing scheme. Because large purchasers cannot find substitutes for those drugs, manufacturers are under less pressure to offer discounts.

Manufacturers may tend to offer larger discounts off the wholesale price when close substitutes are available. For example, the average best-price discounts calculated by CBO were much lower for single-source drugs than for brand-name drugs that faced generic competition (35 percent versus 51 percent in 1991). Now suppose that in the absence of the Medicaid rebate the difference between the AMP and the best price exceeds 15 percent of the AMP (as shown in the top panel of Figure 2). In response to the best-price provision, firms are likely to either limit the best-price discount to 15.1 percent of the AMP or shrink the size of the best-price discount but still let it exceed 15.1 percent of the AMP. In either case, the best-price discounts are lower than they would be without the Medicaid rebate.

When Are Big Discounts Still Profitable?

Although manufacturers have less incentive to give discounts in excess of 15.1 percent of the AMP, they have continued to give deep discounts on some drugs. The larger Medicaid's market share for a given drug, the stronger the potential adverse effect of the best-price provision on discounting. The conditions under which a manufacturer finds it profitable to offer a higher discount than 15.1 percent off the AMP to some purchasers depend critically on the size of the Medicaid market.

The best-price provision can greatly increase the costs of offering a discount in excess of 15.1 percent. Before the Medicaid rebate provision, a manufacturer would offer a discount to some purchasers in excess of 15.1 percent of the AMP if the profits from the new sales generated by the higher discount offset the loss in revenues from lowering the price to those purchasers. Under the best-price provision, when the discount exceeds 15.1 percent, unit revenues decline on sales to Medicaid beneficiaries as well. If the volume of sales to Medicaid is as large as the volume purchased by those who can negotiate discounts in excess of 15.1 percent off the

FIGURE 2. ILLUSTRATIVE RELATIONSHIPS BETWEEN THE BEST PRICE AND THE
                    AVERAGE MANUFACTURER PRICE

A Drug With Several Close Substitutes: An Example
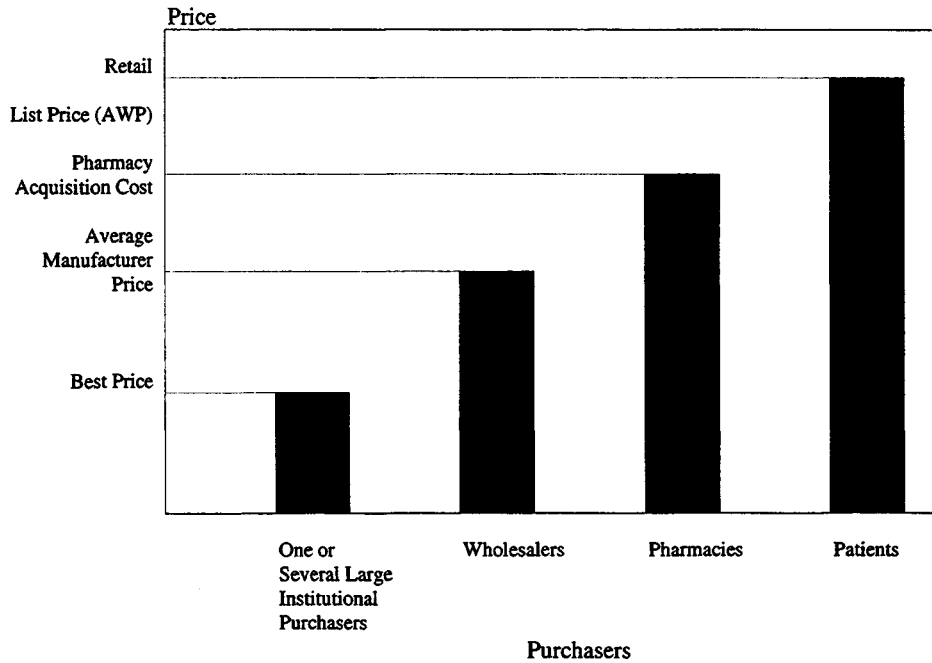
A New Breakthrough Drug: An Example
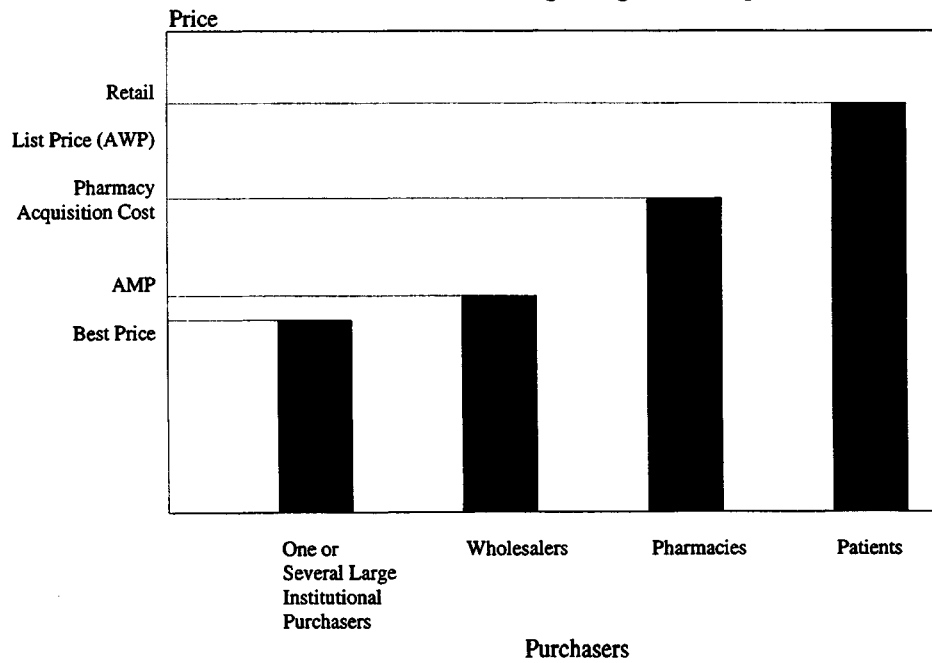
SOURCE: Congressional Budget Office.

NOTE: AWP = average wholesale price; AMP = average manufacturer price.

AMP, then the best-price provision doubles the cost of offering a discount in excess of 15.1 percent.

The proportion of sales to Medicaid beneficiaries varies greatly among drugs. CBO calculated the Medicaid market share for 89 top-selling drugs (see Table 3). For 20 percent of them, less than 5 percent of total sales went to Medicaid beneficiaries. For 16 percent of the drugs, Medicaid's market share exceeded 20 percent. On average, the Medicaid market share for those drugs was 12.2 percent. The types of drugs that had a Medicaid market share in excess of 20 percent included treatments for seizures, asthma, and infections. The variation in Medicaid market share among different drugs is another reason why the impact of the Medicaid rebate on pricing will vary from drug to drug. The best-price provision can have a strong adverse effect on discounting for those drugs with an average-size Medicaid market share or higher. But those drugs with a small Medicaid market share are more insulated from the effects of the Medicaid rebate on pricing.

How discounts as high as 50 percent off the AMP would still be profitable after the passage of the Medicaid rebate is difficult to explain unless a drug has a very small Medicaid market share. When variable production costs average 20 percent of the AMP, increasing a discount from 15.1 percent to 50 percent is profitable if the sales to the purchasers who get that higher discount are doubled as a result. Under the Medicaid rebate, if the volume of sales to those large purchasers is roughly equal to the volume of sales to Medicaid, the sales to those purchasers would have to triple to justify increasing the discount from 15.1 percent to 50 percent.[10] In 1994, only 17 percent of the drug products still had discounts above 50 percent.

Another reason why some drug products still have discounts in excess of 50 percent may be that the prices of different drug products are interlinked when all the drugs in a manufacturer's portfolio are negotiated simultaneously. Just as a supermarket may charge a very low price on a few products to attract consumers to the store, so a manufacturer may choose to set some of the prices in its portfolio very low in order to attract private purchasers to its product line. Moreover, in this case of interlinkage, manufacturers might lower the price of drugs that are not affected by the best-price provision in order to make up for increases in the price of drugs that are affected. Best-price discounts may also remain high for teaching hospitals and other institutions where the prescribing practices of new doctors can be affected.

The best-price provision of the Medicaid rebate should have had the biggest impact on those purchasers that were getting the lowest prices--often those that

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10. If incremental production costs were higher than 20 percent of the AMP, sales would have to increase more. The Office of Technology Assessment estimated that production, distribution, and depreciation costs average 25.5 percent of manufacturer sales. See OTA, *Pharmaceutical R&D*, p. 91. The figure for incremental production costs would be less than 25 percent since it does not include depreciation and other fixed costs.

TABLE 3.   SHARE OF THE MEDICAID MARKET FOR TOP-SELLING PRESCRIPTION
            DRUGS (In percent)

Market Share	Proportion of Drugs with This Share[a]
Less Than 5	20
5 to 9.9	28
10 to 14.9	19
15 to 19.9	17
20 to 24.9	8
25 to 29.9	2
30 and Higher	6

SOURCE: Congressional Budget Office tabulations based on data collected by the Health Care Financing Administration on
           the Medicaid rebate program. U.S. sales were obtained from *Med Ad News*, May 1994.

a.   Based on a sample of 89 prescription drugs that ranked in the top 100 drugs by 1993 U.S. sales. The average Medicaid market
     share for this sample was 12.2 percent.

strictly enforced a formulary and had a very large patient base. Yet the rebate program may have somewhat diminished the rewards available to large purchasers that undertake the cost of organizing their patient base and using a strict formulary.

The best-price provision of the Medicaid rebate program may also have strengthened the bargaining position of pharmaceutical manufacturers in their pricing negotiations with large purchasers. Manufacturers could credibly claim that deep discounts are no longer feasible since they are required to give the same discount to the entire Medicaid market. Institutional purchasers are at somewhat of a disadvantage because they cannot assess the size of their discounts relative to the AMP, since that price is known only by the manufacturer.

The Effect of the Medicaid Rebate on the Retail Sector

The Medicaid rebate may affect not only the lowest prices charged by the manufacturer for a drug but also the price charged to wholesalers for the retail class of trade (the AMP). The minimum rebate creates an incentive for manufacturers to raise the AMP. But the additional rebate does exactly the opposite--it reduces revenues on Medicaid sales when a firm raises the AMP faster than the inflation rate.

Overall, the results of the model imply that on balance the Medicaid rebate should have very little effect on the AMP for drugs on the market by 1990. Firms are likely to increase their AMP only if it is profitable to do so in the non-Medicaid retail sector.

The additional rebate does not, however, fully offset the effects of the minimum rebate for new drugs launched after October 1990. For new drugs, the additional rebate is based on the rate of increase in the AMP since the first quarter the drug was on the market. In anticipation of the Medicaid rebate, new drugs may be launched at a slightly higher price—in part, to offset revenue losses imposed by the minimum rebate and to avoid the additional rebate, which would penalize subsequent price increases. How great the effect of the Medicaid rebate on the pricing of new drugs will be depends on how large the expected Medicaid market share of the new drug is.

CHAPTER IV

HOW THE MEDICAID REBATE HAS AFFECTED PRICING

The Medicaid rebate discourages discounting in the pharmaceutical industry. Ironically, the size of best-price discounts has fallen in a market in which the price sensitivity of buyers may be increasing. Enrollment in health maintenance organizations and other managed care organizations is on the rise, and formularies are increasingly used to link price with prescription choice. Yet counter to this trend, manufacturers have reduced the size of their best-price discounts.

By reducing discounting in the pharmaceutical market, in some instances the Medicaid rebate may have reduced the cost advantage that a consumer can obtain by joining a plan in which the drug benefit is managed. The data indicate clearly that those purchasers that had access to the best-price discounts saw a decline in the size of their discounts. Less clear, however, is how broad the impact has been among all purchasers that obtain discounts from pharmaceutical manufacturers. Since the volume of sales made at the best-price discounts is not known, the size of the market that is affected by increases in the best price is also not known.

Nevertheless, for 24 percent of the drugs in the Congressional Budget Office's data set, the best-price discount fell by 30 percentage points or more. This swing in discounting affects all of those purchasers that obtained a discount within 30 percentage points of the best-price discount.

CHANGES IN THE BEST-PRICE DISCOUNTS BETWEEN 1991 AND 1994

Based on the prices reported by manufacturers to the Health Care Financing Administration under the Medicaid rebate agreement, CBO analyzed the change in best-price discounts. The data set that CBO obtained from HCFA consists of the average manufacturer price and the best price reported by pharmaceutical manufacturers for each quarter from January 1991 through June 1994. The data set also includes the total dollar value of state reimbursements to pharmacies in 1991 through 1994, as well as the quantity of prescriptions reimbursed by the states. All of that information is given for each dosage form of prescription drugs that Medicaid beneficiaries purchase on an outpatient basis. The data set used for CBO's analysis consisted of 1,886 different single-source and innovator multiple-source drug products.[1] However, many drugs come in more than one dosage form (tablet,

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1. Those drug products that did not have Medicaid reimbursements in excess of about $100,000 in 1991, 1992, 1993, or 1994 were dropped in order to improve the quality of the data. Although 2,755 out of 4,686 drug products were deleted by this step, they constituted less than 1 percent of total sales of the original data set. An additional 45

capsule, liquid) and in several strengths (amount of active ingredient). Consequently, closer to 800 different brand-name drugs are in the data set.[2]

The empirical evidence suggests that between 1991 and 1994, the Medicaid rebate program caused pharmaceutical manufacturers to reduce the size of their best-price discounts substantially. Thirty-two percent of single-source drugs had a best-price discount as high as 50 percent in 1991. By 1994, however, only 9 percent had best-price discounts in that range.

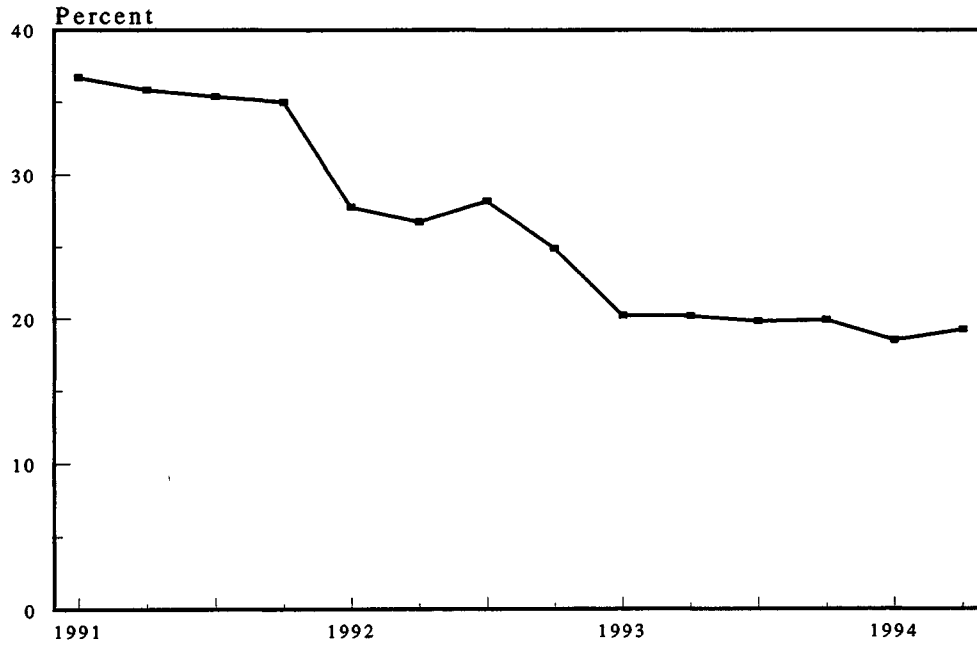## Changes in the Average Best-Price Discount

The average best-price discount, weighted by total Medicaid payments for each drug, declined from over 36 percent in the first quarter of 1991 to 20 percent in the second quarter of 1994 (see Figure 3). (This weighting places greater emphasis on the best-price discounts of those drugs with the highest sales to Medicaid, and more closely reflects how the decline in best-price discounts affects the average basic rebate paid.) Approximately 2 to 3 percentage points of the decline in the weighted average best-price discount over that period can be attributed to the exemption of federal government prices from the best-price provision (see Box 3). Since federal government agencies occasionally get the lowest prices of any U.S. purchaser, exempting them from the best-price provision will sometimes increase the reported best price. Much of the remaining decline in the weighted average best-price discount stems largely from firms' reacting to the best-price provision by lowering their best-price discounts on many drugs.

The links between the timing of the decline in the best-price discounts and the changes in the best-price provision indicate that it was indeed the Medicaid rebate program that was driving the decline in best-price discounts. In the first year, the weighted average best-price discount declined by less than 2 percentage points (see Table 4). The change was so small during the first year because a ceiling of 25 percent was placed on the size of the basic rebate. The best-price provision could only increase the basic rebate from 12.5 percent to 25 percent of the average manufacturer price in 1991 because of that ceiling. Hence, manufacturers could offer a 50 percent discount to some customers and still pay a rebate equal to just 25 percent of AMP on the units sold to Medicaid. The largest changes in the average best-price discount between consecutive quarters occurred at the beginning of 1992 and 1993 when the ceiling on the basic rebate changed.

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observations were deleted because of inconsistencies such as the best price exceeding the average manufacturer price in more than one quarter.

2. Keeping only the top-selling dosage strengths reduces the sample to just over 1,000 drug products. This smaller sample was used to calculate unweighted averages and to examine changes in the distribution of best-price discounts over time.

FIGURE 3. WEIGHTED AVERAGE BEST-PRICE DISCOUNT, 1991-1994

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the Medicaid
         rebate program.

BOX 3.
FEDERAL SUPPLY SCHEDULE PRICES
AND THE AVERAGE BEST-PRICE DISCOUNT

Between the first quarter of 1991 and the first quarter of 1992, the average best-price discount fell by 9 percentage points. Part of the decline was caused by a change in the reporting status of prices obtained by federal government agencies and therefore does not reflect an actual change in pricing. Specifically, in the first quarter of 1992, the low prices offered by pharmaceutical manufacturers to federal government agencies were no longer counted as a best price for the purpose of calculating best-price discounts for the Medicaid rebate. Thus, the part of the 9 percentage-point decline in best-price discounts caused by the change in reporting status should not be attributed to changes in pricing.

How much then of the decline in best-price discounts should be excluded because it reflects only a change in reporting status? The Congressional Budget Office estimates that the portion of the 9 percentage-point decline that resulted from the federal government price exemption is about 2 to 3 percentage points. That estimate can be made because in the third quarter of 1992 the Federal Supply Schedule (FSS) and other federal government prices were again eligible to be counted as best prices. As a result, the average best-price discount increased in the third quarter and then fell again in the fourth quarter when FSS prices were exempted permanently. That change in reporting status can be used to isolate the effect of FSS prices on the average best-price discount.

The calculation is based on the assumption that the weighted average discount in the third quarter would have fallen halfway between the second- and fourth-quarter values had the reporting rule not changed. This constructed average for the third quarter was more than 2 percentage points below the actual weighted average best-price discount in the third quarter. Therefore, the Congressional Budget Office concludes that the FSS price exemption in the first quarter of 1992 probably lowered the average

TABLE 4.   AVERAGE BEST-PRICE DISCOUNTS, 1991-1994 (In percent)

| Year | Quarter | All Drugs | | Top 100 Drugs, Unweighted |
		Weighted	Unweighted	
1991	1	36.7	42.1	35.1
	2	35.8	41.7	34.1
	3	35.4	41.1	33.6
	4	35.0	39.5	33.2
1992	1	27.8	37.7	27.8
	2	26.7	36.7	27.8
	3	28.2	36.9	27.8
	4	24.9	33.4	24.7
1993	1	20.2	29.2	18.8
	2	20.2	28.5	18.5
	3	19.8	26.3	18.5
	4	19.9	25.7	18.8
1994	1	18.5	25.0	18.8
	2	19.3	25.2	19.3

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the Medicaid rebate program.

The existence of a ceiling in the first year gave firms a grace period to adjust to the new rebate program. Firms in some instances could have been locked in to low price levels through contracts with private purchasers. The small change in discounts during the first year of the program is consistent with the results of a General Accounting Office report. That report found that the year after the Omnibus Budget Reconciliation Act was enacted, there was not a dramatic increase in the prices paid for outpatient drugs by the health maintenance organizations and hospital group purchasing organizations GAO surveyed.[3]

The decline in the average best-price discounts nearly leveled off in 1993 and 1994, and a slight upturn took place in the second quarter of 1994. Manufacturers appear to have finished responding to the incentives created by the best-price provision. The average best-price discount probably will not decline any further as a result of the current Medicaid rebate regulations. If Medicaid was reformed through

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3. General Accounting Office, Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions, GAO/HRD-93-43 (January 1993).

block grants, however, some states might choose to cut back on prescription drug benefits since the resulting savings would fully accrue to the states. If the share of purchases made by Medicaid in the prescription drug market was to decline, so would the impact of the rebate program on drug pricing.

The average best discount on the top-selling drugs for Medicaid is lower than the average best discount on all drugs. For example, in the first quarter of 1991 the average best discount (unweighted) on all drugs was 42 percent, whereas the average best discount on the top-selling drugs in the sample was 35 percent. The average discount on those top-selling drugs also declined substantially between 1991 and 1993, falling from 35 percent in the first quarter of 1991 to 19 percent in the first quarter of 1993. The impact of the Medicaid rebate on the discounts offered on the top-selling drugs is important because those drugs constitute a large portion of rebate payments as well as of private-sector expenditures.

The best-price discounts on both single-source and multiple-source innovator drugs declined substantially between 1991 and 1994. The average best discount for multiple-source innovator drugs in the first quarter of 1991 was 51 percent, whereas for single-source drugs the average was just 35 percent (see Figure 4). By the second quarter of 1994, the average best-price discount on multiple-source innovator drugs fell to 32 percent, a drop of 19 percentage points from its 1991 level. The average best discount on single-source drugs fell to 21 percent, a decline of 14 percentage points.
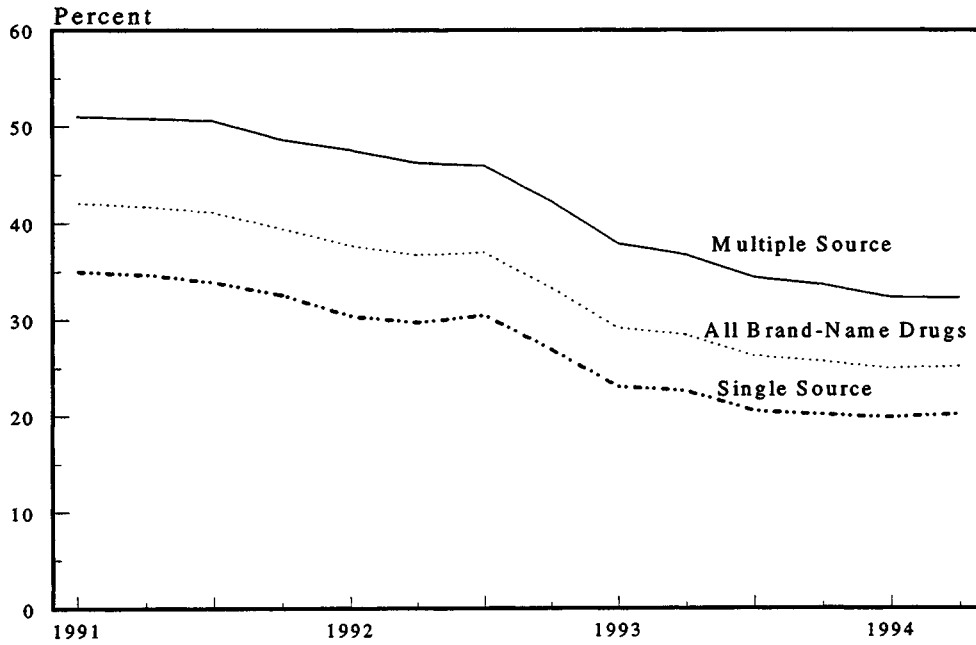
Change in the Distribution of Best-Price Discounts

The Medicaid rebate had a large impact on the pricing of those drugs that were most heavily discounted in 1991. For example, large discounts off the AMP became much less common. In the first quarter of 1991, 40 percent of the best discounts exceeded 50 percent off the AMP. By the second quarter of 1994, only 17 percent of the best discounts exceeded 50 percent off the AMP.

CBO examined how the distribution of best-price discounts changed between 1991 and 1994 (see Figure 5). In 1991, the best-price discounts were more evenly spread out, with as many drugs being discounted between 80 percent and 90 percent as were discounted between 10 percent and 20 percent. By 1994, a clear pattern emerged in which most of the best discounts were concentrated in the lower ranges. In the first quarter of 1991, only one-third of the best discounts were less than 20 percent off the AMP. Yet by 1994, 56 percent of the best discounts were less than 20 percent off the AMP.

The change in the distribution of best-price discounts on single-source drugs is even more dramatic (see Figure 6). In 1991, one-third of single-source drugs had

FIGURE 4.   UNWEIGHTED AVERAGE BEST-PRICE DISCOUNTS, 1991-1994

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the Medicaid
          rebate program.

FIGURE 5.   DISTRIBUTION OF BEST-PRICE DISCOUNTS FOR ALL BRAND-
                 NAME DRUGS
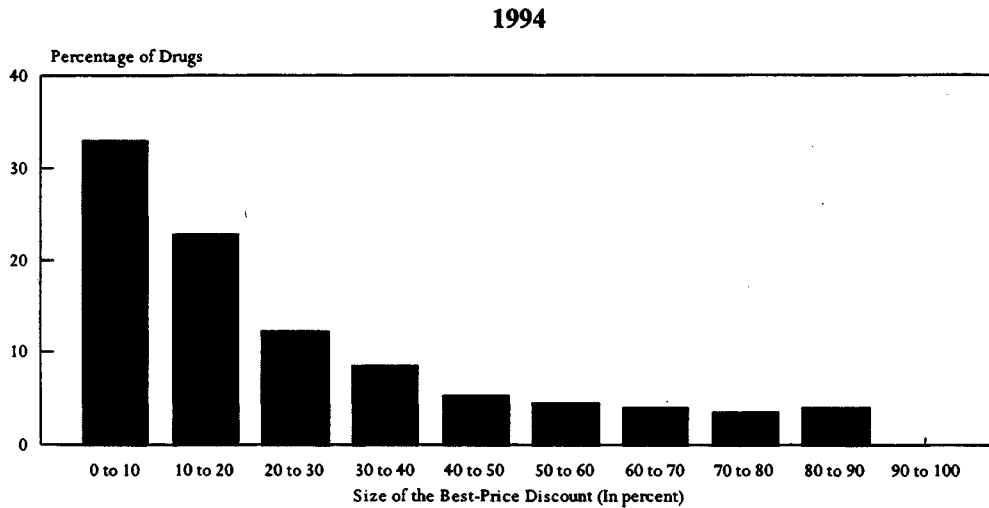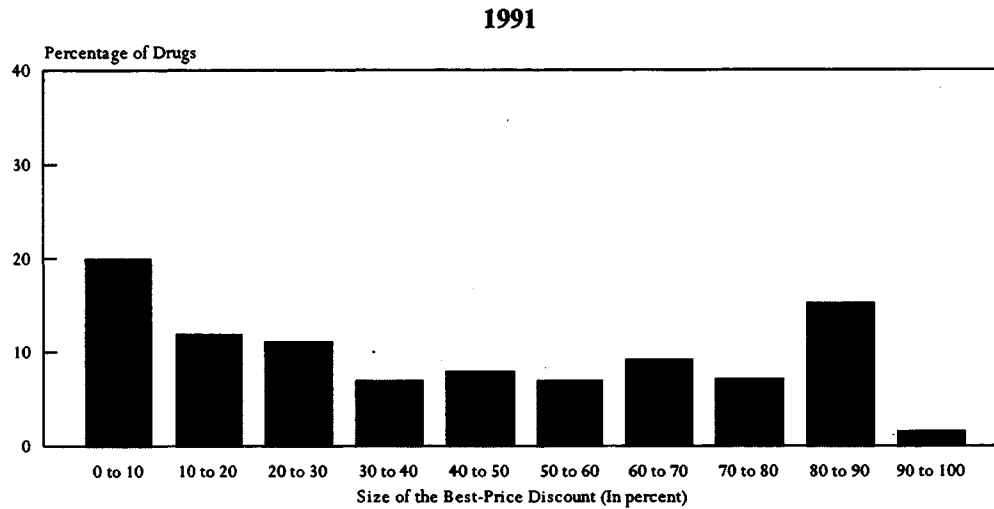
1991

Percentage of Drugs

Size of the Best-Price Discount (In percent)

1994

Percentage of Drugs

Size of the Best-Price Discount (In percent)

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the
         Medicaid rebate program.

NOTE: Manufacturers are not required to report those prices equal to or less than 10 percent of the average manufacturer
         price (AMP). Hence, best-price discounts as high as 90 percent off the AMP are rarely recorded.

FIGURE 6.   DISTRIBUTION OF BEST-PRICE DISCOUNTS FOR SINGLE-
                 SOURCE DRUGS

1991

1994

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the
           Medicaid rebate program.
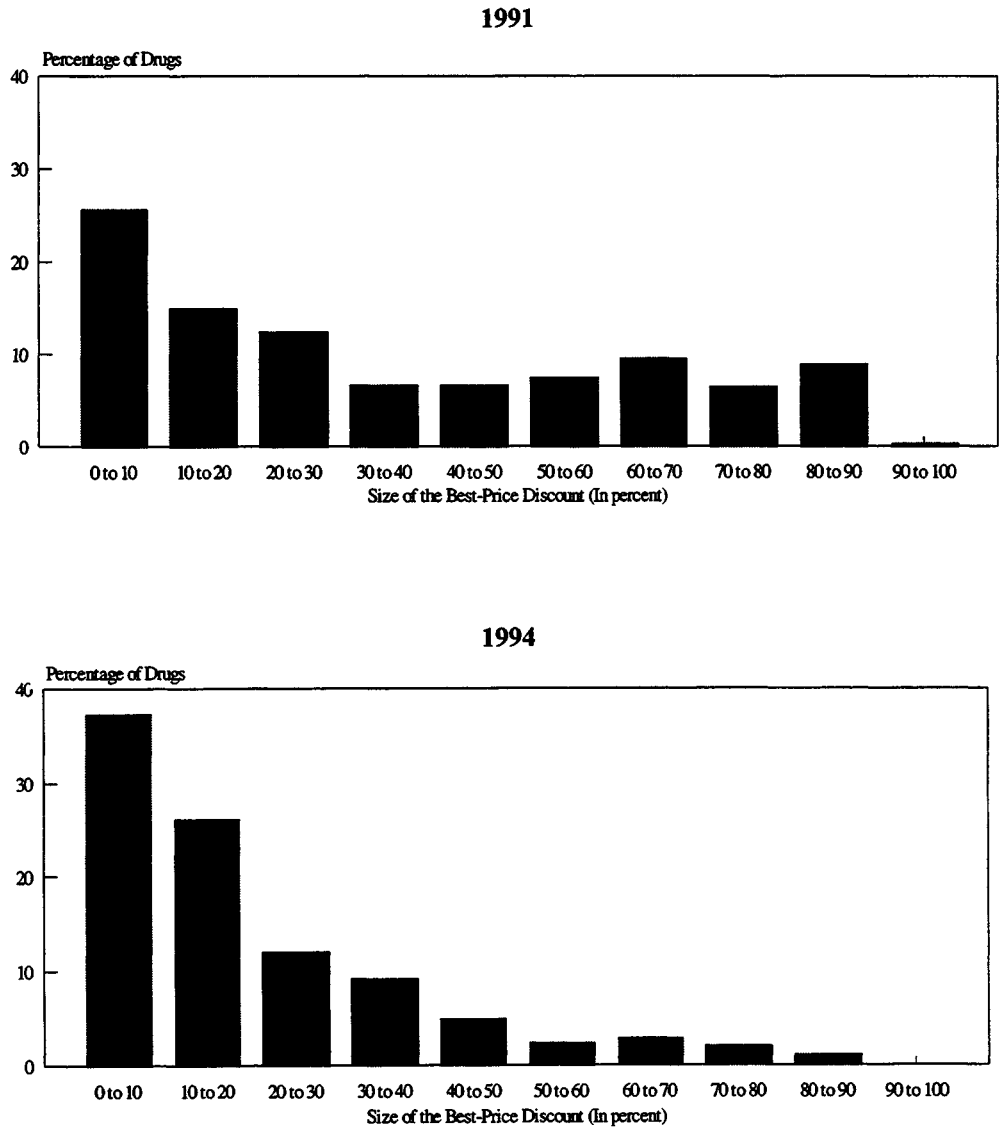
NOTE: Manufacturers are not required to report those prices equal to or less than 10 percent of the average manufacturer
           price (AMP). Hence, best-price discounts as high as 90 percent off the AMP are rarely recorded.

best-price discounts in excess of 50 percent. By 1994, best-price discounts were much more concentrated in the lower ranges with only 9 percent of single-source drugs having best discounts above 50 percent. In 1991, just over half of the single-source drugs had discounts of 30 percent or less. By 1994, three-quarters of the single-source drugs had discounts of 30 percent or less. Single-source drugs constitute two-thirds of Medicaid reimbursements. They also constitute roughly the same proportion of U.S. sales; most top-selling drugs are single-source drugs. Therefore, the changing best-price discounts on those drugs can have a large impact on both Medicaid rebate revenues and prescription drug expenditures of private purchasers that negotiate discounts.

Half of all innovator multiple-source drugs had discounts of over 50 percent in 1991. By 1994, only 28 percent of innovator multiple-source drugs had discounts in that range. As Figure 7 shows, a shift toward lower best-price discounts took place between 1991 and 1994 for multiple-source drugs as well, though it was much less pronounced than for single-source drugs. Innovator multiple-source drugs constitute just 10 percent of Medicaid reimbursements. The changes in the best prices of multiple-source drugs may have had a smaller effect on the expenditures of private purchasers because there is often an option to substitute a generic drug. In fact, manufacturers frequently offer higher discounts on innovator multiple-source drugs because those drugs face generic competition.

The best-price provision creates an incentive for firms to lower their best-price discounts to the level of the minimum rebate (15.1 percent in 1996). It does not, however, change the incentives to offer no discounts or to offer very low discounts. The proportion of single-source drugs with best-price discounts between 5 percent and 15 percent doubled between 1991 and 1994—by 1994, 30 percent of single-source drugs had best-price discounts in that range (see Figure 8). At the same time, the proportion of single-source drugs with discounts in excess of 20 percent declined from 59 percent in 1991 to 36 percent by 1994. That change in the distribution of discounts for single-source drugs, which constitute 68 percent of Medicaid expenditures on outpatient prescription drugs, is in part a response to the incentives created by the Medicaid rebate.

Surprisingly, for 30 percent of the drugs in the sample, the best-price discounts were higher in 1994 than in 1991 (see Table 5). However, for over two-thirds of those drugs, the best-price discount increased only because the AMP rose more rapidly than the best price, not because the best price itself declined. The average best-price discount for single-source drugs in this group rose from 17 percent in 1991 to 26 percent in 1994. That evidence suggests that the best-price provision has not eliminated the incentive for manufacturers to give discounts of more than 15 percent in order to increase market share.

FIGURE 7.   DISTRIBUTION OF BEST-PRICE DISCOUNTS FOR MULTIPLE-
                 SOURCE DRUGS
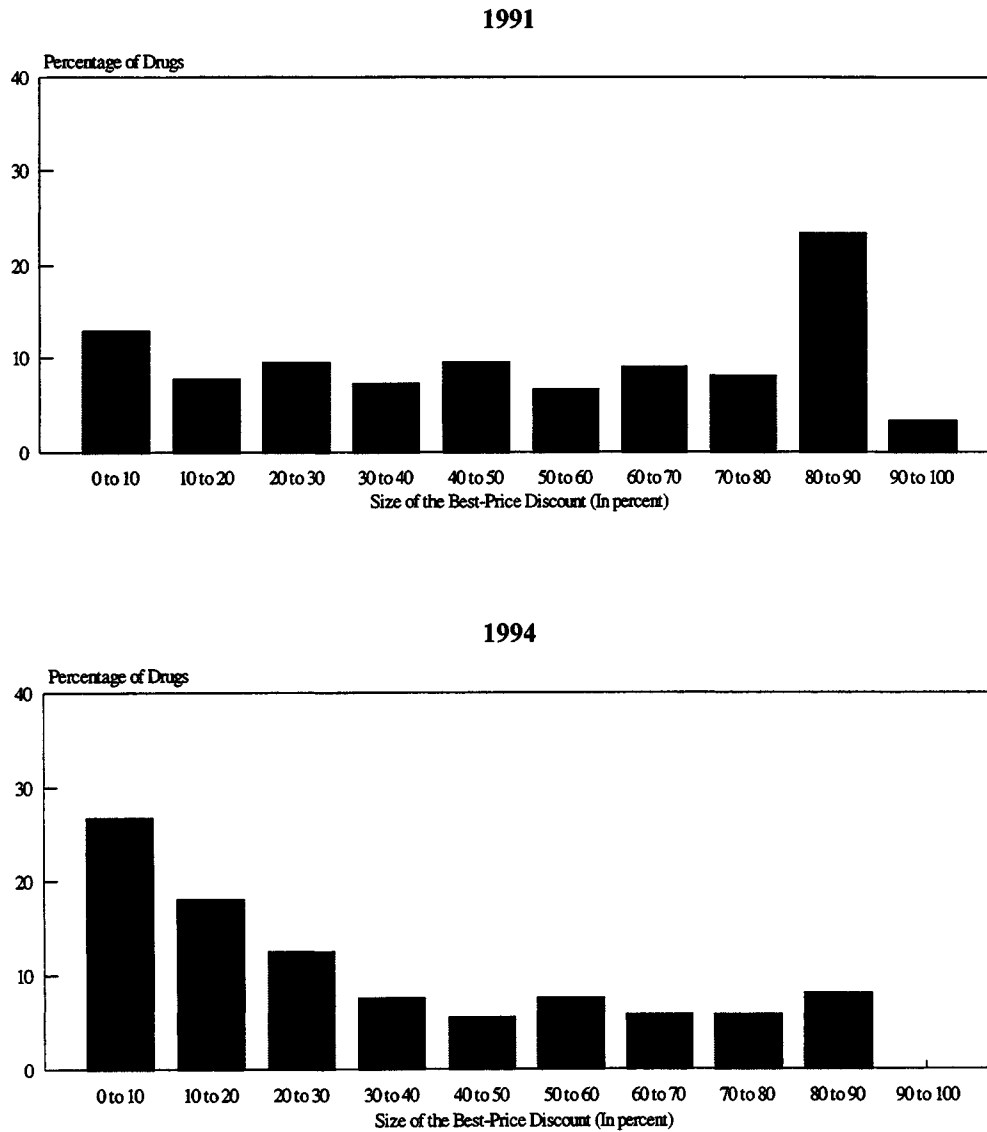
1991

1994

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the
         Medicaid rebate program.

NOTE: Manufacturers are not required to report those prices equal to or less than 10 percent of the average manufacturer
         price (AMP). Hence, best-price discounts as high as 90 percent off the AMP are rarely recorded.

FIGURE 8.   BEST-PRICE DISCOUNTS FOR SINGLE-SOURCE DRUGS
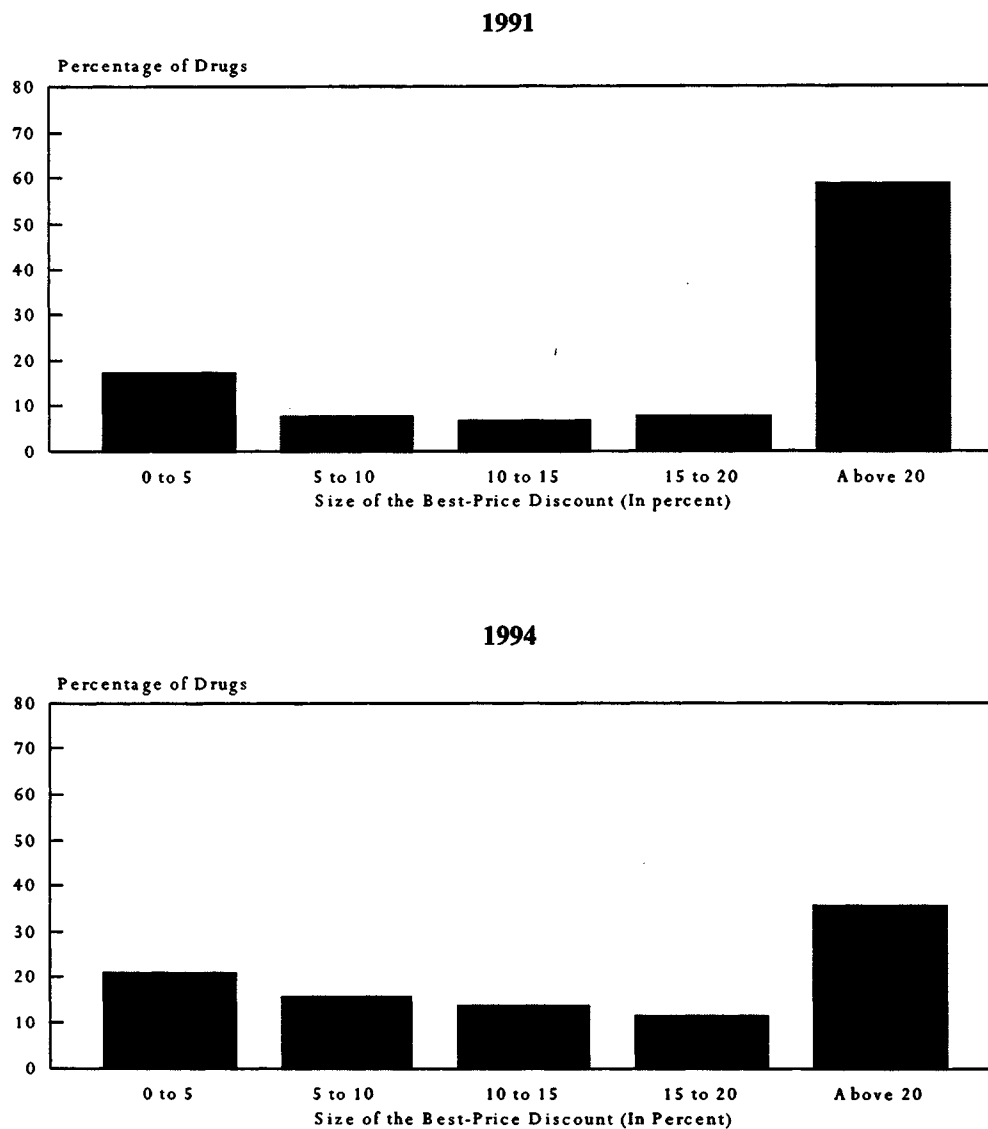
1991

Percentage of Drugs

Size of the Best-Price Discount (In percent)

1994

Percentage of Drugs

Size of the Best-Price Discount (In Percent)

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the Medicaid rebate program.

NOTE: Manufacturers are not required to report those prices equal to or less than 10 percent of the average manufacturer price (AMP). Hence, best-price discounts as high as 90 percent off the AMP are rarely recorded.

TABLE 5.   HOW BEST-PRICE DISCOUNTS CHANGED BETWEEN 1991 AND 1994

Percentage-Point Difference Between Best-Price Discounts in 1991 and 1994	Percentage of Brand-Name Drugs		
	All	Single Source	Multiple-Source Innovators
Lower in 1994 by			
0 to 10	25	26	23
10 to 20	14	14	13
20 to 30	8	7	9
Over 30	24	22	27
Greater in 1994	30	31	28

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the Medicaid rebate program.

The best-price discount is only an indicator of the level of discounting that occurs with a given drug. Purchasers that negotiate discounts with pharmaceutical companies can receive anything from a small discount off the AMP up to the best-price discount. If the best-price discount on a drug declines from 50 percent to 30 percent, any purchaser that received a discount in excess of 30 percent is affected.

The best-price discounts of 24 percent of all drugs in the sample declined by 30 percentage points or more between 1991 and 1994 (see Table 5). Moreover, such dramatic declines in best-price discounts were not confined to multiple-source drugs. The best-price discounts of 22 percent of the single-source drugs declined by at least 30 percentage points between 1991 and 1994. Although probably only a small number of purchasers have access to the best-price discounts, many more purchasers may obtain a discount within 30 percentage points of the best-price discount.

Price Changes

CBO created two price indices to assess the change in both the AMPs and the best prices (see Table 6). The drugs purchased in 1993 by Medicaid beneficiaries were used as the basket of goods to create the price indices. Despite the additional rebate, the AMP price index increased by 14.8 percent between 1991 and 1994; the rate of inflation over the same period, as measured by the consumer price index for all urban consumers (CPI-U), was 8.6 percent. During 1991, the percentage increase in the AMP index was more than twice that of the CPI-U (6.7 percent compared with 2.6 percent), which is roughly in line with the experience of the producer price index

TABLE 6.   PERCENTAGE CHANGE IN PRICE INDEXES, 1991-1994

Time Period[a]	Index for Best Prices[b]	Index for Average Manufacturer Prices[b]	Producer Price Index for Pharmaceuticals	Consumer Price Index
1991 to 1992	14.6	6.7	7.7	2.6
1992 to 1993	12.6	4.5	5.0	3.3
1993 to 1994	3.9	3.0	3.6	2.5
Total, 1991 to 1994	34.1	14.8	17.2	8.6

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the Medicaid rebate program. The fourth and fifth colums are from the Department of Commerce, Bureau of Labor Statistics.

a. Based on data from the first quarter of each year.

b. Based on the quantities of single-source and innovator multiple-source drugs purchased by Medicaid beneficiaries in 1993.

(PPI) for pharmaceuticals before the Medicaid rebate program (see Table 7). Between 1985 and 1991, the PPI for pharmaceuticals increased each year by at least 8 percent whereas the CPI-U never increased by more than 5.4 percent. Viewed in that context, the percentage increase in the AMP index in 1991 was not unusual. After 1991, the percentage increase in the AMP index was much closer to the percentage increase in the CPI-U.

The change in the best-price index far exceeded the change in the AMP index. Between 1991 and 1994, the best-price index rose by 34 percent--over twice the percentage change in the AMP price index (see Table 6). That result confirms that the difference between best prices and AMPs was narrowing over this period largely because the best prices were rising. Most of the increase in the best-price index occurred during the first two years that the Medicaid rebate program was in effect. During 1993, the percentage increase in the best-price index was very close to the percentage increase in the producer price index for pharmaceuticals. Evidently, by 1993 manufacturers had largely adjusted to the incentives created by the best-price provision.

CHAPTER IV

TABLE 7.   ANNUAL CHANGE IN THE PRODUCER PRICE AND CONSUMER PRICE
            INDEXES, 1974-1994 (In percent)

Year	PPI for Pharmaceuticals	PPI for All Products	Consumer Price Index
1971	-0.2	3.1	4.4
1972	0	3.2	3.2
1973	1.0	9.1	6.2
1974	4.2	15.4	11.0
1975	8.6	10.6	9.1
1976	6.4	4.5	5.8
1977	4.1	6.4	6.5
1978	5.2	7.9	7.6
1979	7.1	11.2	11.3
1980	8.9	13.4	13.5
1981	11.7	9.2	10.3
1982	11.1	4.1	6.2
1983	10.7	1.6	3.2
1984	9.2	2.1	4.3
1985	9.2	1.0	3.6
1986	8.8	-1.4	1.9
1987	9.1	2.1	3.6
1988	7.9	2.5	4.1
1989	9.1	5.2	4.8
1990	8.9	4.9	5.4
1991	8.3	2.1	4.2
1992	6.5	1.2	3.0
1993	4.5	1.2	3.0
1994	3.2	0.6	2.6

SOURCE: Bureau of Labor Statistics and the *Economic Report of the President, 1995.*

NOTE: PPI = producer price index.

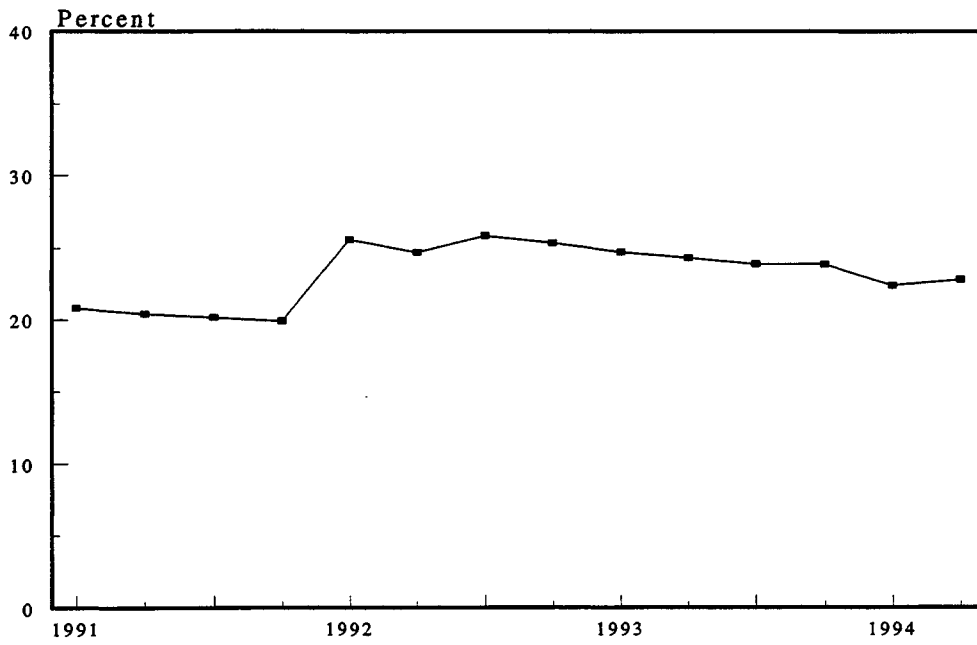## CHANGES IN THE AVERAGE BASIC REBATE BETWEEN 1991 AND 1994

Firms responded to the incentives created under the Medicaid rebate program by lowering their best-price discounts. As a result, the Medicaid rebates paid today are lower than they would be if firms had left their discounts at the higher 1991 levels (see Figure 9 for the average basic rebate, weighted by sales, in each quarter from 1991 to 1994). The basic rebate is equal to a flat percentage of the AMP (15.4 percent in 1994) or to the difference between the AMP and the best price, whichever is greater. The best-price provision increased the basic rebate from the flat 15.4 percent to 22.8 percent of AMP on average in 1994 (see Table 8). CBO estimates that if best-price discounts were still at 1991 levels, the weighted average basic rebate in 1994 would have been much higher—38.6 percent. Therefore, the decline in best-price discounts since 1991 lowered the average basic rebate by almost 16 percentage points in 1994. The decline in the average basic rebate appears to have leveled off in 1994.

Although no cap on the basic rebate existed in 1994, the amount by which the best-price provision increased the basic rebate was no larger in 1994 than in 1991, when there was a cap of 25 percent. The best-price provision increased the average basic rebate paid by 7 to 8 percentage points in both 1991 and 1994. Thus, the decline in best-price discounts since 1991 has limited the contribution of the best-price provision to the average basic rebate. In fact, by 1994 less than 30 percent of the average basic rebate could be attributed to the best-price provision.

The contribution of the best-price provision to the average rebate was highest in 1992 when the cap was increased from 25 percent to 50 percent. Similarly, the average basic rebate was highest in 1992. As a result of the 25 percent cap in 1991, the average basic rebate was just 20 percent to 21 percent of the AMP. In 1992, the ceiling was increased to 50 percent and as a result the average basic rebate rose to about 25 percent of the AMP.

In two instances, declining best-price discounts offset changes that would have increased the basic rebate. In the fourth quarter of 1992, the flat rebate increased by over 3 percentage points (from 12.5 percent to 15.7 percent), but the average basic rebate was less than 1 percentage point higher than in the second quarter. (The third quarter cannot be used as a comparison because of the temporary change in the rule regarding FSS prices.) The decline in best-price discounts had offset much of the increase in the flat rebate. In 1993, the ceiling on the basic rebate was lifted entirely. The flat rebate was still 15.7 percent, 3 percentage points higher than in early 1992. The average basic rebate, however, was no higher in 1993 than in early 1992. Manufacturers had lowered their best-price discounts enough in 1993 to offset the effect of the higher flat rebate and the repeal of the ceiling.

FIGURE 9.   WEIGHTED AVERAGE BASIC REBATE, 1991-1994

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the Medicaid
          rebate program.

TABLE 8.   CHANGES IN THE AVERAGE BEST-PRICE DISCOUNT AND BASIC REBATE
             BETWEEN 1991 AND 1994 (In percent)

| Year | Quarter | Weighted Average Best-Price Discount | Basic Rebate | | Average Contribution of Best-Price Provision to Basic Rebate |
			Weighted Average	Minimum	
1991	1	36.7	20.8	12.5	8.3
	2	35.8	20.4	12.5	7.9
	3	35.4	20.2	12.5	7.7
	4	35.0	19.9	12.5	7.4
1992	1	27.8	25.6	12.5	13.1
	2	26.7	24.7	12.5	12.2
	3	28.2	25.9	12.5	13.4
	4	24.9	25.4	15.7	9.7
1993	1	20.2	24.7	15.7	9.0
	2	20.2	24.3	15.7	8.6
	3	19.8	23.9	15.7	8.2
	4	19.9	23.8	15.7	8.1
1994	1	18.5	22.4	15.4	7.0
	2	19.3	22.8	15.4	7.4

SOURCE: Congressional Budget Office based on data collected by the Health Care Financing Administration on the Medicaid
          rebate program.

The decline of the best-price discounts between 1991 and 1994, in part because of the Medicaid rebate program, comes as no surprise to policymakers. Indeed, CBO accounted for a decline in best-price discounts when it estimated the anticipated savings from the Medicaid rebate program.

CHAPTER V

OPTIONS FOR CHANGING THE BEST-PRICE PROVISION

The Congressional Budget Office examined two alternatives that could reduce the interference of the Medicaid rebate with discounting, while having a very small impact on the total savings obtained under the Medicaid rebate. One alternative is to repeal the best-price provision and compensate for the loss in savings by raising the minimum rebate. A second option is to place a cap on the basic rebate.

For the first alternative, CBO estimates that repealing the best-price provision would be budget neutral in 1996 if at the same time the minimum rebate was increased from 15.1 percent to 22.6 percent. Whether such an increase could itself affect pricing is discussed below. The minimum basic rebate in 1996 and thereafter is 15.1 percent. CBO calculated that the weighted average basic rebate in 1994 would have been 22.6 percent if the minimum rebate at that time had been 15.1 percent. Any option that maintained an estimated weighted average basic rebate of 22.6 percent in 1996 and beyond would be approximately budget neutral. Those estimates do not account for any change in best-price discounts that might occur as manufacturers responded to changes in the best-price provision.

The second alternative—a cap combined with an increase in the minimum rebate—could also maintain budget neutrality. Since capping the basic rebate is a more gradual step than repealing the best-price provision, it would require a smaller compensating increase in the minimum rebate. A 50 percent cap on the basic rebate combined with an increase in the minimum rebate from 15.1 percent to 16.7 percent would be budget-neutral in 1996 (see Table 9).

The two options are designed to reduce the impact of the best-price provision on the incentive of firms to offer steep discounts without reducing the savings the federal government obtains through the Medicaid rebate. Eliminating the best-price provision would require more than a 7 percentage-point increase in the minimum rebate to maintain budget neutrality. Alternatively, capping the basic rebate would limit the impact of the best-price provision on discounting and require a smaller increase in the minimum rebate to maintain budget neutrality.

A cap would reduce the basic rebate only in those instances in which the best-price discount exceeded the cap. CBO calculates that a 50 percent cap would reduce the average basic rebate by about 1 percentage point, and a 40 percent cap would reduce the weighted average basic rebate by about 2 percentage points.

The lower the cap, the higher the required increase would be in the minimum rebate to maintain budget neutrality. For instance, a cap of 40 percent on the basic rebate would require an increase in the minimum rebate from 15.1 percent to 18 percent to maintain budget neutrality. A 70 percent cap would require less than a 0.5 percentage-point increase in the minimum rebate to maintain budget neutrality. Since few best-price discounts are as high as 70 percent, such a high cap would not have a big effect on rebate revenues or on discounting. Conversely, a cap as low as 30 percent would require a much larger increase in the minimum rebate to be budget neutral because many more best-price discounts exceed that amount.

When the cap is as low as 30 percent, the difference between the cap and the minimum rebate required for budget neutrality is small--just 10 percentage points. As the gap between the minimum rebate and the cap narrows, the option begins to resemble a repeal of the best-price provision accompanied by a higher minimum rebate of 22.6 percent.

In response to a cap on the basic rebate, firms could raise some of their best discounts that already exceeded the level of the cap. Firms could also increase the level of best discounts that were just under the cap. A cap limits the extent to which the Medicaid rebate increases the cost of giving some customers large discounts. That limit on the basic rebate would benefit a number of private-sector purchasers if firms were to raise some of their discounts as a result.

TABLE 9.   THE EFFECT OF COMBINING A CAP ON THE BASIC REBATE WITH A HIGHER
MINIMUM REBATE TO MAINTAIN BUDGET NEUTRALITY (In percent)

Cap on the Basic Rebate	Minimum Rebate Required for Budget Neutrality[a]
70	15.4
60	15.9
50	16.7
40	18.0
30	20.0

SOURCE: Congressional Budget Office calculations based on data collected by the Health Care Financing Administration
on the Medicaid rebate program.

a.   The minimum rebate in 1996 and thereafter is 15.1 percent. These options are budget neutral for 1996 and beyond.

A repeal of the best-price provision would require about a 7 percentage-point increase in the minimum rebate to maintain budget neutrality. Such a large increase in the minimum rebate could affect the average manufacturer price. However, the additional rebate would limit the extent to which manufacturers could compensate for an increase in the minimum rebate by raising the AMP.

Firms could partially offset an increase in the minimum rebate by charging higher launch prices for new drugs. However, for drugs already on the market, an increase in the minimum rebate could cause manufacturers to raise their AMP only in instances in which they were charging less than the price that maximizes profits. If firms were already charging the profit-maximizing AMP, then increasing the AMP further would not increase profits on non-Medicaid sales. Moreover, the additional rebate would prevent a price increase from raising unit revenues on Medicaid sales.

Hence, if firms were already charging the profit-maximizing AMP, they could not compensate for an increase in the minimum rebate by raising the AMP. However, there may be some markets, particularly for new and unique drugs, in which firms face no close competitors and could profitably charge higher prices, but do not. Public opinion may limit prices in those instances. If such markets exist, firms in them could compensate for an increase in the minimum rebate by slightly raising their prices.

Another alternative to the Medicaid rebate (though not examined by CBO) would be to encourage Medicaid beneficiaries to enroll in health maintenance or other managed care organizations that can negotiate their own discounts with manufac-turers. In a few states, that alternative is already happening. By the end of 1994, eight states had obtained demonstration waivers from statutory Medicaid require-ments from the Health Care Financing Administration to help them move many of their Medicaid beneficiaries into managed care organizations.[1] Most of those states have turned over the prescription drug benefit to the managed care organizations (or plan to), in which case the Medicaid rebate does not apply. But those organizations are free to negotiate their own discounts with manufacturers.[2]

Substantial reforms to the Medicaid program were included in the Balanced Budget Act passed by the Congress in November 1995. Although the President vetoed the act, subsequent budget legislation may include similar reforms to Medicaid. The act would turn full responsibility for Medicaid over to the states and continue federal support through block grants. In short, the direct link between state expen-

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1.   Those eight states are Arizona, Florida, Hawaii, Kentucky, Oregon, Rhode Island, South Carolina, and Tennessee. Seven additional states are seeking waivers for that purpose. See Mark Merlis, *Medicaid: Program and Demonstration Waivers*, 95-109 EPW (Congressional Research Service, December 23, 1994).

2.   Personal communication with Sidney Trieger, Office of Research Demonstrations, Health Care Financing Administration, August 21, 1995.

ditures and federal funding would be broken, but the Medicaid rebate program would be left intact. However, the rebate savings would no longer be shared by the federal government; instead, they would belong entirely to the states. Under such a reform of Medicaid, the options proposed above would be budget neutral for the states, since changes in the rebate formula would no longer affect the federal budget.

If the Medicaid program was reformed through block grants, the savings that could be obtained from reducing Medicaid prescription drug coverage would accrue entirely to the states. As a result, some states might choose to reduce the number of people eligible for drug benefits under Medicaid or eliminate those benefits entirely. If Medicaid's market share was to decline significantly, the impact of the rebate program on drug pricing would diminish.

APPENDIX
PRICE DISCRIMINATION
AND THE MEDICAID REBATE:
A MODEL

This appendix presents a basic mathematical (economic) model that explains the pricing behavior of a pharmaceutical manufacturer charging different prices to different groups of buyers. The model demonstrates the relationship between price and costs of production under differing degrees of price sensitivity that buyers may display and examines the impact of the Medicaid rebate program on that relationship.

A very basic model of third-degree price discrimination in which different groups of purchasers are charged different prices based on observable characteristics can be depicted as follows:

$$\Pi = (p_1 - c)q_1 + (p_2 - c)q_2$$

where:

p_1 = the price charged to group 1
p_2 = the price charged to group 2
q_1 = the quantity sold to group 1
q_2 = the quantity sold to group 2
c = unit production costs (marginal cost), which are constant

The first-order conditions yield:

$$\frac{p_1 - c}{p_1} = -\frac{1}{\epsilon_1}, \quad \frac{p_2 - c}{p_2} = -\frac{1}{\epsilon_2}$$

where ϵ_1 and ϵ_2 represent the elasticities of demand of the respective group of purchasers. Assuming that group 2 has a more elastic demand than group 1, it will obtain a lower price. This model assumes that marginal cost is constant. Nothing is lost by that assumption if production costs per unit do not change when group 2 is served in addition to group 1.

If the manufacturer is restricted to offering the same price to both groups (uniform pricing), the inverse of the price-cost margin will be a weighted average of the elasticities of demand of each group where the weights are the quantities demanded. Under uniform pricing, group 1 will pay less and group 2 will pay more than when the manufacturer practices price discrimination.[1]

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1. Jean Tirole, *The Theory of Industrial Organization* (Cambridge, Mass.: MIT Press, 1989), pp. 137-140.

Accounting for the Medicaid rebate complicates the model somewhat. The share of retail sales purchased by Medicaid beneficiaries is denoted by m. The new profit-maximizing equation (assuming the minimum rebate is equal to 15 percent) is:

$$\Pi = (p_1 - c)q_1 + (p_2 - c)q_2 - \max[0.15p_1, (p_1 - p_2)]mq_1 - \max[(p_1 - p_0), 0]mq_1$$

where:

$p_1 =$ the price manufacturers charge the retail sector (the average manufacturer price)

$p_2 =$ the lowest price to any purchaser in the United States (the best price)

$p_0 =$ the inflated base-year price (used to calculate the additional rebate)

$q_1 =$ the quantity sold to the retail sector

$q_2 =$ the quantity sold at p_2

$m =$ the proportion of retail-sector sales made to Medicaid beneficiaries

In reality, many purchasers pay manufacturers many different prices. The point here is to focus on the retail sector and those purchasers that have access to the lowest prices. The model also assumes that the proportion of retail sales made to Medicaid beneficiaries (m) does not change when p_1 changes.

Purchasers not included in the model are those that pay less than p_1 but more than p_2. Those purchasers can be divided into two groups: ones that pay more than 85 percent of p_1 and ones that pay less than 85 percent of p_1. The former group will not be affected by the best-price provision. The latter group may be affected by the best-price provision if p_2 rises by a sufficient amount. Hence, what happens to those purchasers can be assessed to some degree by examining what happens to p_2.

Three basic cases exist based on the difference between p_1 and p_2.

Case A: Without the Medicaid rebate, the difference between p_1 and p_2 would be less than 15 percent of p_1.

In this case, firms would not offer group 2 a discount over 15 percent off the price to group 1 (the retail sector), even if there was no Medicaid rebate. Whether the difference between p_1 and p_2 would be this small depends on the difference in price elasticities between the two groups of purchasers. The ratio (p_2/p_1) without the Medicaid rebate is equal to:

$$\frac{p_2}{p_1} = \frac{1 - \frac{1}{\epsilon_1}}{1 - \frac{1}{\epsilon_2}}$$

If this ratio is less than or equal to 0.85, then Case A holds. The profit-maximizing equation becomes:

$$\Pi = (p_1 - c)q_1 + (p_2 - c)q_2 - 0.15p_1 m q_1 - \max[(p_1 - p_0), 0]m q_1$$

The first-order conditions for p_2 do not change--the Medicaid rebate does not affect p_2 in this case. The first-order conditions for p_1 depend on whether p_1 exceeds the inflated base-year price p_0. In the case where p_1 does not exceed p_0 (the additional rebate is equal to zero), the first-order condition for p_1 implies:

$$\frac{p_1 - c}{p_1} = - \frac{1}{\epsilon_1} + 0.15m(1 + \frac{1}{\epsilon_1})$$

The second term is positive, indicating that p_1 (or the markup over cost) is higher because of the minimum rebate. When the effect of the additional rebate is considered, however, firms will be discouraged from raising p_1 above the inflated base-year price.

In one instance, the Medicaid rebate could slightly raise the average manufacturer price (AMP) of drugs already on the market. For drugs for which the AMP would have increased more slowly than the inflation rate, the minimum rebate pushes the AMP slightly upward. That increase occurs because firms respond to the minimum rebate by increasing prices and the additional rebate does not take effect until prices rise faster than the rate of inflation. The minimum rebate and additional rebate together push the AMP toward the inflation-adjusted base-year price.

Case B: Without the Medicaid rebate, the difference between p_1 and p_2 exceeds 15 percent of p_1. Firms respond to the Medicaid rebate by limiting p_2 to 85 percent of p_1.

Substituting for p_2, the profit maximization equation becomes:

$$\Pi = (p_1 - c)q_1 + (0.85p_1 - c)q_2 - 0.15p_1 m q_1$$

Noting that the derivative of q_2 with respect to p_1 is:

$$\frac{\partial q_2}{\partial p_1} = 0.85 \frac{\partial q_2}{\partial p_2}$$

The first-order conditions for p_1 imply:

$$\frac{p_1 - c}{p_1} = -\frac{1}{\epsilon_1} + 0.15m(1 + \frac{1}{\epsilon_1}) - 0.85\frac{q_2}{q_1}\frac{1}{\epsilon_1}(1 + \frac{p_2 - c}{p_2}\epsilon_2)$$

Just as in Case A, the second term indicates that the minimum rebate puts upward pressure on p_1. The third term in the equation is negative, indicating that p_1 is lower than in Case A. The third term reflects that fact that by lowering p_1 slightly, firms can charge group 2 a price that is closer to their true profit-maximizing price, while maintaining p_2 equal to 85 percent of p_1.

The third term implies that when firms choose to limit the best-price discount to 15 percent of the AMP, there is a small incentive to lower the AMP. However, since the size of the retail sector (group 2) is very large relative to the size of the market that previously obtained more than a 15 percent discount off the AMP (group 1), the effect has to be very small. That effect is also at least partially offset by the incentive to raise the AMP because of the minimum rebate. In Case B, the Medicaid rebate probably has a very small downward effect on the AMP, and the best price (p_2) has increased to 85 percent of p_1.

Case C: Without the Medicaid rebate, the difference between p_1 and p_2 exceeds 15 percent of p_1. Firms respond to the Medicaid rebate by raising p_2, but p_2 is still less than 85 percent of p_1.

The profit-maximizing equation becomes:

$$\Pi = (p_1 - c)q_1 + (p_2 - c)q_2 - (p_1 - p_2)mq_1$$

The first-order condition for p_2 implies:

$$\frac{p_2 - c}{p_2} = -\frac{1}{\epsilon_2}(1 + \frac{mq_1}{q_2})$$

In this case, the best-price provision increases p_2. The effect is greater as Medicaid's market share increases relative to the market share of those purchasers with access to the best price (q_2).

In sum, the best-price provision increases the price paid by group 2 in Cases B and C but has no effect on the price paid by group 2 in Case A. The Medicaid rebate does not have much effect on p_1. The additional rebate discourages firms from

raising p_1 faster than inflation to compensate for the minimum rebate. And when the best-price provision applies, there can be a very small incentive to lower p_1.