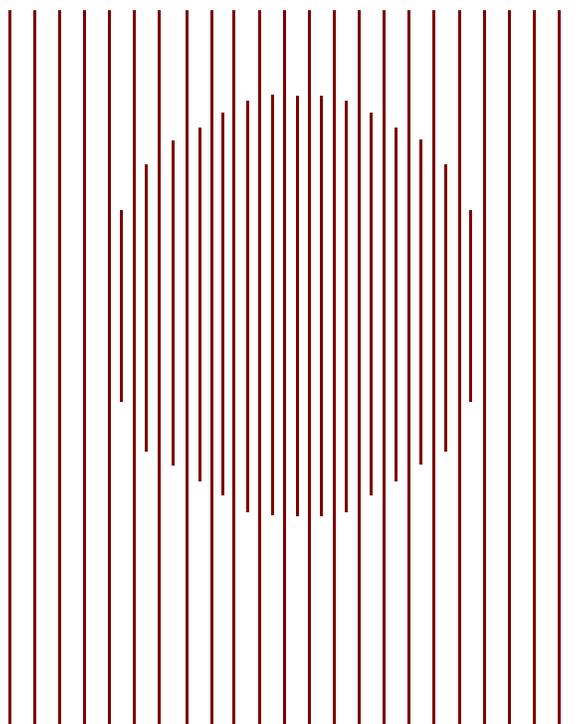


CBO PAPERS

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

January 1996



CONGRESSIONAL BUDGET OFFICE

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**CONGRESSIONAL BUDGET OFFICE
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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.

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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

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

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

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

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

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

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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.