

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 | <u>10</u> | <u>10</u> |
| 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

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

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.

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 .

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

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.

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.

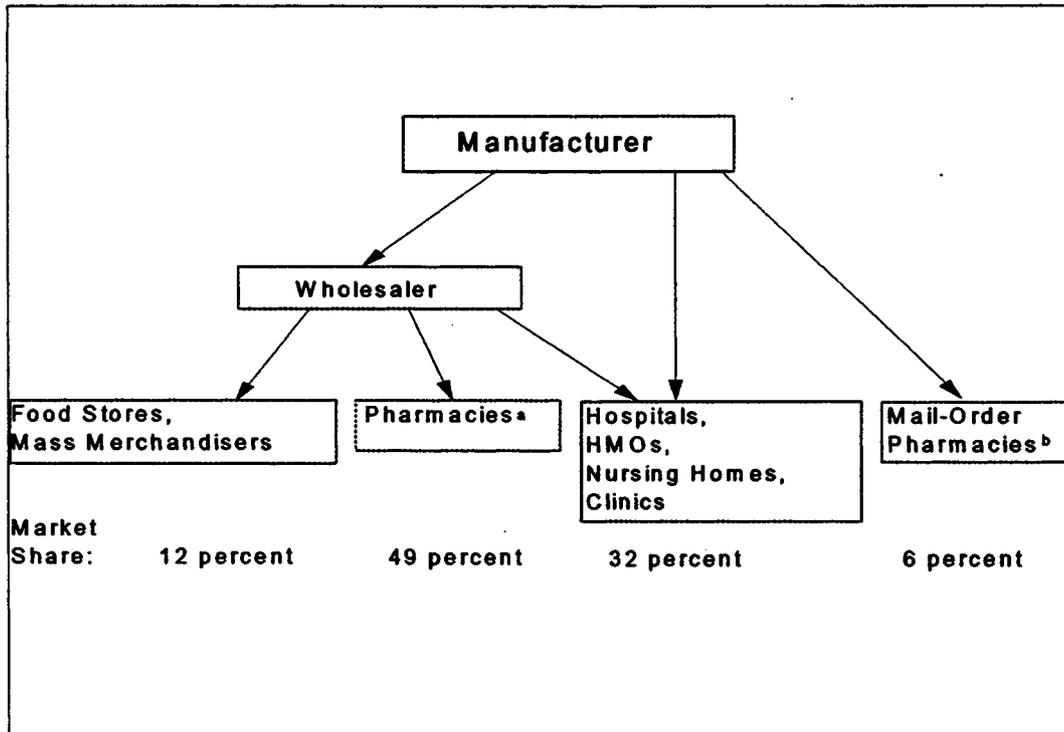
The Medicaid rebate program should not affect the AMP very much for drugs on the market by 1990.¹ Although the minimum rebate encourages firms to raise the AMP, the additional rebate penalizes them for raising the AMP faster than the inflation rate. On balance, the Medicaid rebate slightly discourages 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 purchasers are used exclusively in an inpatient setting and are therefore not

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 effect. 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.

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

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

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.

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.

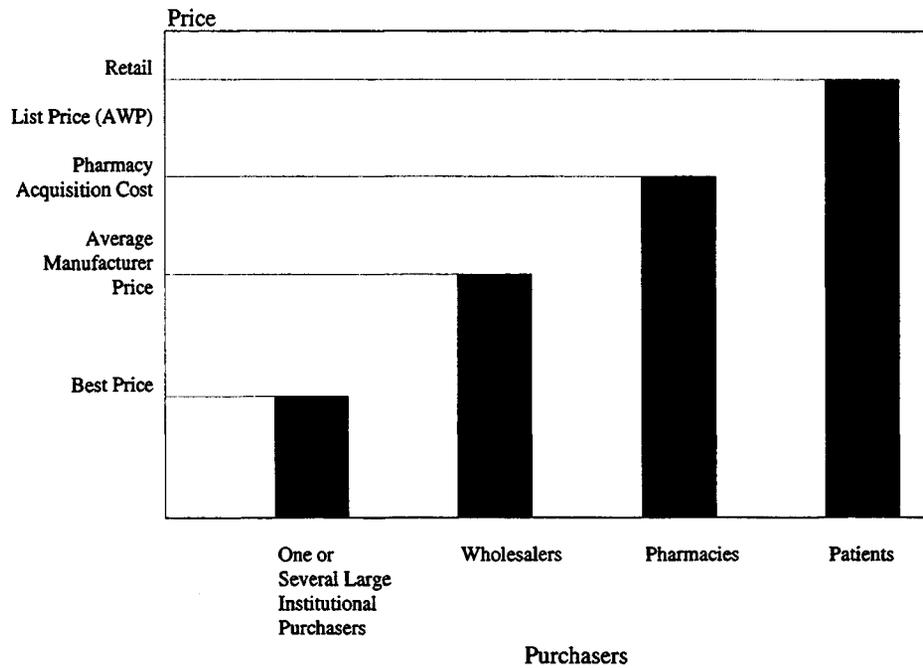
When Are Big Discounts Still Profitable?

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.

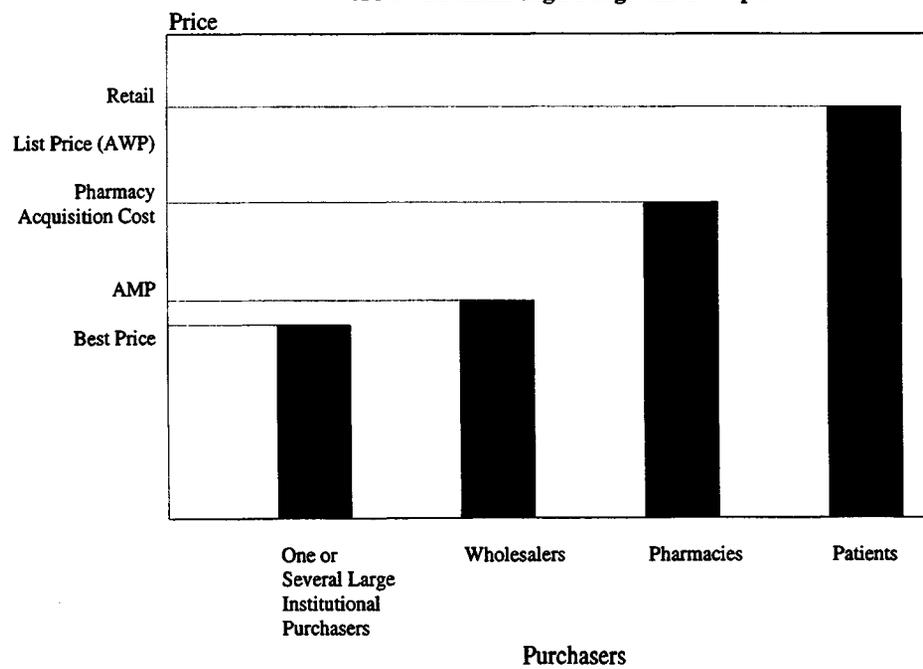
The best-price provision can greatly increase the costs of offering a discount in excess of 15.1 percent. Before the Medicaid rebate provision, a manufacturer would offer a discount to some purchasers in excess of 15.1 percent of the AMP if the profits from the new sales generated by the higher discount 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

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,

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

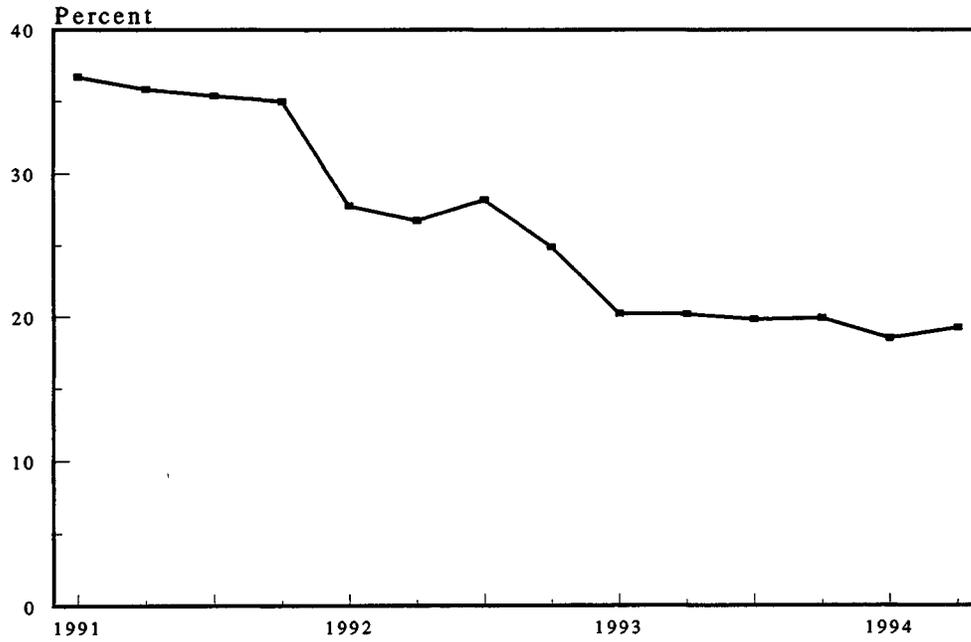
The average best-price discount, weighted by total Medicaid payments for each drug, declined from over 36 percent in the first quarter of 1991 to 20 percent in the second quarter of 1994 (see Figure 3). (This weighting places greater emphasis on the best-price discounts of those drugs with the highest 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.

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