CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Douglas Holtz-Eakin, Director

June 21, 2005

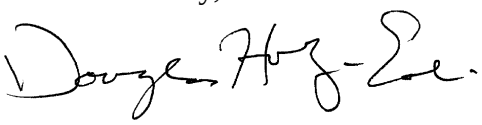
Honorable Charles E. Grassley
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

In response to your request, the Congressional Budget Office (CBO) has prepared the attached analysis, which discusses the Medicaid Drug Rebate Program and provides estimates of the average rebate received by Medicaid for brand-name prescription drugs. In keeping with CBO's mandate to provide objective, impartial analysis, the document contains no recommendations.

If you have any questions about the analysis, please feel free to call me at (202) 226-2700. The staff contact for this work is Colin Baker, who is available at (202) 225-2593.

Sincerely,



Douglas Holtz-Eakin

Attachment

Identical letter sent to the Honorable Max Baucus

cc: Honorable Joe Barton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives

The Rebate Medicaid Receives on Brand-Name Prescription Drugs

June 21, 2005

Congress of the United States
Congressional Budget Office

Spending on prescription drugs in the Medicaid program has increased rapidly in recent years. Federal drug expenditures in the fee-for-service component of the program grew at a real (inflation-adjusted) average annual rate of 15.5 percent between fiscal years 1998 and 2004, reaching $18.4 billion in 2004. State spending stood at $12.2 billion in 2004—for a combined spending level of $30.6 billion that year.[1] Medicaid spending on prescription drugs will undergo a onetime drop with the introduction of the Medicare drug benefit in 2006 as dually eligible beneficiaries switch their coverage to Medicare. Nonetheless, upward pressure on prescription-drug spending will continue to pose budgetary challenges for Medicaid, and the Congress is currently examining Medicaid's payment policies for prescription drugs.

This Congressional Budget Office (CBO) analysis focuses on one aspect of Medicaid drug spending: the rebate that Medicaid receives from drug manufacturers for brand-name prescription drugs furnished in the fee-for-service component of the program.[2,3] CBO estimates that as of 2003, the latest year for which data are available, Medicaid received unit rebate payments amounting to approximately 31 percent of the average manufacturer price (AMP) for brand-name prescription drugs as a result of the various provisions of the rebate.

The Medicaid Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990 created the Medicaid Drug Rebate Program, under which drug manufacturers must enter into a rebate agreement with the Centers for Medicare and Medicaid Services (CMS) in order to have their products covered by the Medicaid program. Drugmakers are not obligated to take part in the program; however, if they choose not to, states will receive no federal Medicaid payment for those companies' drugs. In turn, state Medicaid programs generally must cover prescription-drug products made by manufacturers that have entered into a rebate agreement with CMS.[4]

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1. The Federal Medical Assistance Percentage was temporarily raised for the last two quarters of fiscal year 2003 and for the first three quarters of fiscal year 2004 because of a provision in the Jobs and Growth Tax Relief Reconciliation Act of 2003. As a result, federal Medicaid spending (and the federal share of total Medicaid spending) was somewhat higher than it otherwise would have been.

2. See Congressional Budget Office, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, CBO Paper (January 1996).

3. Prescription drugs furnished through managed care arrangements (and for which managed care organizations negotiate with manufacturers for discounts) are not subject to the pricing mechanisms that are discussed in this analysis.

4. Forty-nine states and the District of Columbia participate in the Medicaid Drug Rebate Program. Although Arizona does not participate, it does offer prescription drugs through managed care plans.

The program works in the following way: A Medicaid beneficiary obtains a prescription drug from a participating pharmacy, which has purchased the drug in the marketplace from a manufacturer or wholesaler. The pharmacist receives payment from the state Medicaid agency based on the state's formula for the cost of acquiring and dispensing the drug.[5] Drugmakers pay a rebate directly to the state Medicaid agency, which also receives matching payments from the federal government through CMS (see Figure 1). Because the federal share is computed after the rebate, the states and the federal government both share in the savings from the rebate.

As a condition of participation, drugmakers must report two prices to CMS within 30 days of the end of each calendar quarter. The first is the AMP, which is the average price that a drugmaker receives in a given quarter for sales to wholesalers of a drug distributed in the retail class of trade. The second is the lowest transaction price, or "best price," charged to any buyer in the private market (and reflecting all rebates or discounts) during that quarter. The AMP and the best price must be reported for each respective dosage form and strength of all prescription drugs purchased on behalf of Medicaid beneficiaries.[6] Those prices, which remain confidential, serve as reference points in determining drugmakers' rebate obligations.

For brand-name prescription drugs, the amount that drugmakers are obliged to rebate to Medicaid has two components: the basic rebate and the additional rebate.[7]

Basic Rebate for Brand-Name Drugs

Under the basic rebate formula, drugmakers must remit to the states a payment for each brand-name drug bought in the fee-for-service sector on behalf of Medicaid beneficiaries. The required payment, made on a quarterly basis, is the larger of either a "flat rebate" amount—currently 15.1 percent of the AMP—or the difference between the AMP and the best price extended to any private buyer. For

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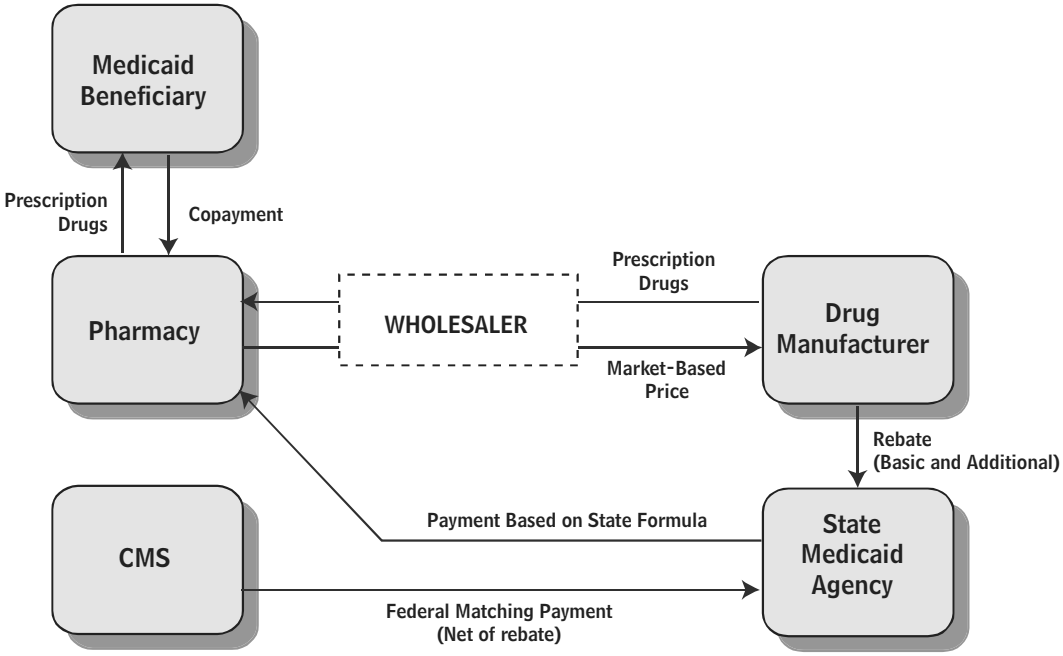
5. Federal regulations permit states broad discretion in setting payment rates. For brand-name drugs with no generic substitutes, payment is equal to the lower of the pharmacy's usual-and-customary charge or the pharmacist's estimated acquisition cost plus a dispensing fee, both of which are set by the state. See Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs* (December 2004).

6. The Secretary of Health and Human Services has the legal authority to verify manufacturer-reported prices, but the Government Accountability Office recently concluded that CMS conducts only limited checks of those prices. See Government Accountability Office, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States*, GAO-05-102 (February 2005).

7. For generic and over-the-counter drugs, the rebate is 11 percent of the AMP, with no additional rebate or best-price provisions.

Figure 1.

Medicaid's System for Purchasing Brand-Name Prescription Drugs



Source: Congressional Budget Office.

Note: CMS = Centers for Medicare and Medicaid Services.

example, suppose that the AMP for a given drug is $2 per unit, and the reported best price in the private market is $1 per unit. The best-price discount in this case will be $1, or 50 percent of the AMP. Because the percentage discount exceeds the flat rebate of 15.1 percent, the rebate in this case (for all units of the drug purchased on behalf of Medicaid beneficiaries) will be 50 percent of the AMP. If the AMP was $2 and the best price was $1.80, then the best-price discount would reflect only a 10 percent discount relative to the AMP, and the appropriate rebate percentage would be 15.1 percent of the AMP.

The parameters used in calculating the basic rebate have changed since the program's inception. In 1991, the flat rebate was 12.5 percent of the AMP, and a cap limited the maximum rebate that could result from the best-price provision (see Table 1). The Veteran's Health Care Act of 1992 increased the flat rebate to 15.7 percent of the AMP and removed the cap on the maximum best-price rebate. The current flat rebate of 15.1 percent has remained unchanged since 1996.

Table 1.

Changes in the Basic Rebate Rules for Brand-Name Prescription Drugs, 1991 to 2003

(As a percentage of average manufacturer price)

	Flat Rebate	Maximum Best-Price Rebate
1996 to 2003	15.1	No maximum
1995	15.2	No maximum
1994	15.4	No maximum
1993	15.7	No maximum
1992[a]	12.5	50
1991	12.5	25

Source: Congressional Budget Office.

a. In the fourth quarter of 1992, the flat rebate was 15.7 percent of the AMP.

Additional Rebate for Brand-Name Drugs

Depending on how much they raise the prices they charge private purchasers, manufacturers may have to pay an additional rebate to Medicaid beyond the basic rebate. Every drug covered by Medicaid has a base-period AMP that is determined by the drug's original market date and that serves as a reference point for calculating the additional rebate.[8] For a given quarter, no additional rebate is owed if the drug's current AMP does not exceed its inflation-adjusted base-period level, as measured using the consumer price index for urban consumers (CPI-U). If the AMP does exceed the allowed (inflation-adjusted) level, then an additional rebate is owed that is equal to the excess amount.

Suppose, for example, that a brand-name drug's base-period AMP is $1.00 per unit and several years after that base quarter the quarterly CPI-U had increased by a cumulative 14 percent. That means that in the current quarter the manufacturer could have an AMP of up to $1.14 per unit without owing any additional rebate. If the current-quarter AMP was $1.25, however, then the difference of $0.11 per unit would be owed as an additional rebate. If the basic rebate for that same drug reflected the flat rebate percentage, then the total rebate for each unit of the drug would be $0.30: $0.19 (15.1 percent of $1.25) plus the $0.11 additional rebate.

8. For prescription drugs introduced on or before September 30, 1990, the AMP for the third quarter of 1990 serves as the base-period amount; for drugs introduced subsequently, the base-period amount is the AMP for the first quarter after the market date. In the case of drugs introduced after September 30, 1990, and before October 1, 1993, a slightly different definition of base-period AMP applied for calculating the rebate values representing January 1991 through March 1993.

Expressed as a percentage of the current AMP, the total rebate would amount to about 24 percent in that example.

Estimated Average Rebates Received by Medicaid

CBO estimates that in 2003, the average rebate received by Medicaid for brand-name prescription drugs was 31.4 percent of the AMP.[9] The average basic rebate was 19.6 percent of the AMP, or slightly less than two-thirds of the total rebate percentage. The remainder, 11.7 percent, is attributable to the additional rebate (see Table 2).

The average basic rebate percentage has remained fairly stable in recent years, at about 20 percent of the AMP (see Figure 2). The additional rebate percentage, however, has risen somewhat—a not unexpected development during periods when average manufacturer prices are increasing relatively rapidly compared with overall inflation. The slight growth in the total unit rebate from the mid-1990s to 2003 is attributable to a higher additional rebate.

For most brand-name prescription drugs purchased by Medicaid, manufacturers' basic rebate obligation equals the flat amount of 15.1 percent of the AMP. In 2003, for example, those drugs made up about 64 percent of Medicaid's reimbursements for brand-name prescription drugs. The remaining drugs had a larger basic rebate because they had best-price discounts greater than 15.1 percent of the AMP. For a large majority of Medicaid-reimbursed brand-name drugs, manufacturers owed an additional rebate. In 2003, the drugs for which some additional rebate was owed represented about 84 percent of Medicaid's reimbursements for brand-name prescription drugs.

One option for budgetary savings would be to increase the flat rebate percentage in the basic rebate rules. In CBO's estimation, boosting the flat rebate from 15.1 percent to 20 percent would increase Medicaid's average basic rebate (relative to the AMP) to 23 percent, thus reducing mandatory federal spending by an estimated $0.6 billion in 2006 and by $3.2 billion through 2010.

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9. The figures reported here are for brand-name drugs in capsule and tablet form only, although estimated rebates are similar when the sample is not limited to those categories. Average rebate percentages for each quarter are weighted by that quarter's volume of sales to Medicaid. The annual figures shown in Table 2 are four-quarter averages for each year, except as noted. All estimates are based on manufacturer-reported prices from CMS; as indicated earlier, the Government Accountability Office has reported that CMS conducts only limited checks of those prices.

Table 2.

Estimated Average Unit Rebate Received by Medicaid for Brand-Name Prescription Drugs, 1991 to 2003

(As a percentage of average manufacturer price)

	Basic Rebate	Additional Rebate	Total[a]
2003	19.6	11.7	31.4
2002	19.9	10.5	30.4
2001	20.3	9.1	29.3
2000	20.2	8.8	28.9
1999	20.0	9.0	29.0
1998	19.9	8.3	28.2
1997	19.9	8.6	28.6
1996	20.5	7.6	28.0
1995	21.5[b]	8.3	29.9
1994	22.6	*	*
1993	24.2	*	*
1992	25.4	*	*
1991	20.3	*	*

Source: Congressional Budget Office.

Notes: Average rebate percentages for each quarter are weighted by that quarter's volume of sales to Medicaid. The annual figures shown are four-quarter averages for each year, except as noted. All estimates are based on manufacturer-reported prices from the Centers for Medicare and Medicaid Services.

* = estimate not available.

a. Basic and additional rebate estimates may not sum to totals because of rounding.

b. Represents the first two quarters only.

Trends in Reported Best Prices

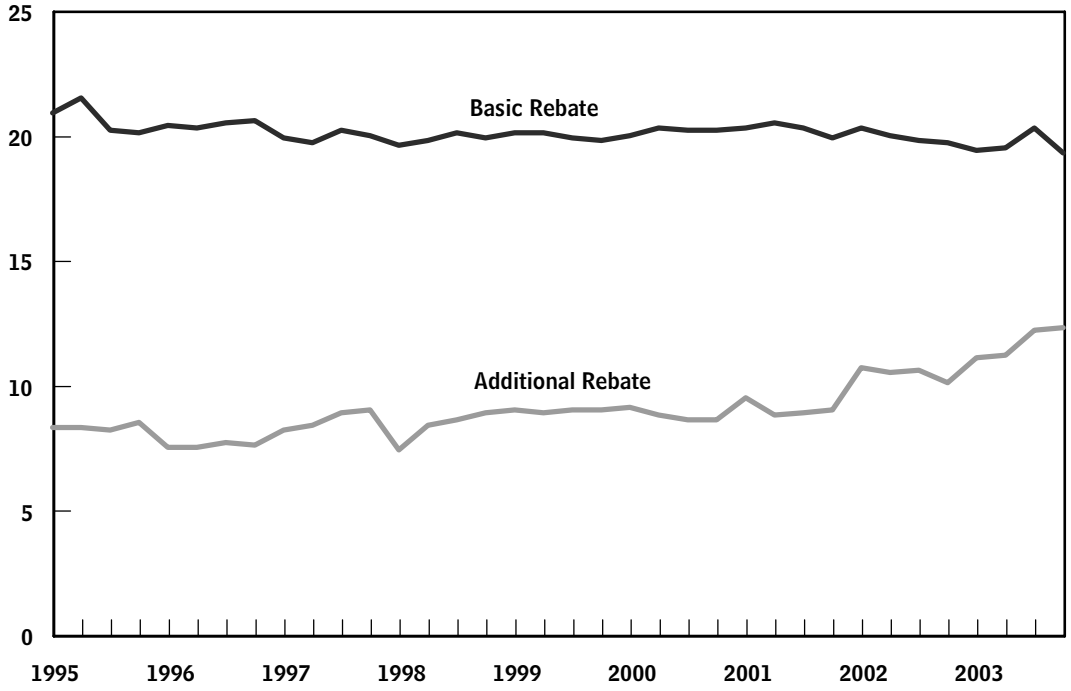
One concern that has arisen over time is that although the rebate program has lowered Medicaid's expenditures, it may also have increased the prices paid by other purchasers. Medicaid's drug rebate rules make it more costly for drug manufacturers to offer price concessions to other purchasers if those concessions trigger the best-price provision. Sales to Medicaid constitute a significant proportion of the outpatient prescription drug market (currently about 10 percent to 15 percent, although that fraction will decline with the new Medicare benefit). As a result, pharmaceutical manufacturers are less willing to give private purchasers steep discounts since doing so increases the rebate they owe to Medicaid.[10] At least partly as a consequence, the largest discounts offered by manufacturers have fallen

10. Congressional Budget Office, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*.

Figure 2.

Estimated Medicaid Unit Rebate for Brand-Name Prescription Drugs, 1995 to 2003

(As a percentage of average manufacturer price)



Source: Congressional Budget Office.

Note: Figures are weighted by volume of sales to Medicaid.

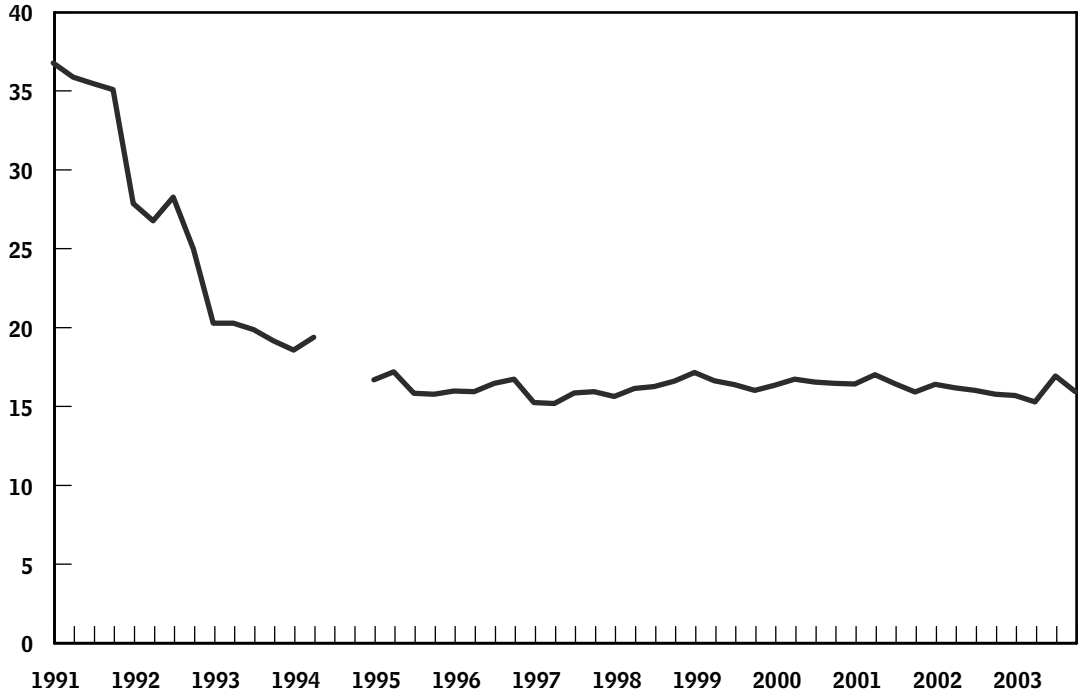
substantially since the drug rebate program began. Elimination of the best-price provision would probably increase the discounts received by some purchasers.

Figure 3 shows changes in the average reported best-price discounts for brand-name prescription drugs between 1991, the first year of the Medicaid drug rebate program, and 2003. (The averages shown are weighted by the volume of sales to Medicaid for each specific drug.) The reported best-price discount fell from an average of about 36 percent in 1991 to about 20 percent in the first two years of the program. Since 1996, the average best-price discount has remained at slightly more than 15 percent, a level close to the threshold of 15.1 percent that triggers the best-price provision.

Figure 3.

Average Reported Best-Price Discount Relative to AMP, 1991 to 2003

(As a percentage of average manufacturer price)



Source: Congressional Budget Office.

Notes: Figures are weighted by volume of sales to Medicaid.

Figures representing the third and fourth quarters of 1994 were not available.