United States Government Accountability Office

GAO

Report to Congressional Requesters

February 2005

MEDICAID DRUG REBATE PROGRAM

Inadequate Oversight Raises Concerns about Rebates Paid to States

GAO-05-102

February 2005

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Highlights

Highlights of GAO-05-102, a report to congressional requesters

MEDICAID DRUG REBATE PROGRAM

Inadequate Oversight Raises Concerns about Rebates Paid to States

Why GAO Did This Study

To help control Medicaid spending on drugs, states receive rebates from pharmaceutical manufacturers through the Medicaid drug rebate program. Rebates are based on two prices–best price and average manufacturer price (AMP)–reported by manufacturers. Both reflect manufacturers' prices to various entities, accounting for certain financial concessions like discounts.

Concerns have been raised about rising Medicaid drug spending. GAO studied (1) federal oversight of manufacturer-reported best prices and AMPs and the methods used to determine them, (2) how manufacturers' determinations of those prices could have affected rebates, and (3) how the rebate program reflects financial concessions in the private market.

What GAO Recommends

GAO recommends that CMS issue clear, updated guidance on manufacturer price determination methods and price definitions. It also recommends that CMS implement systematic oversight of manufacturer methods and a plan to ensure the accuracy of reported prices and rebates to states.

HHS agreed with the importance of guidance to manufacturers but did not agree that the program had received inadequate oversight. GAO acknowledges HHS oversight actions but does not believe they ensure accurate rebates to states.

www.gao.gov/cgi-bin/getrpt?GAO-05-102.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marjorie Kanof at (202) 512-7114.

What GAO Found

Current rebate program oversight does not ensure that manufacturer-reported prices or price determination methods are consistent with program criteria specified in the rebate statute, rebate agreement, and Centers for Medicare & Medicaid Services (CMS) program memoranda. In administering the program, CMS conducts only limited checks for reporting errors in manufacturer-reported drug prices. In addition, CMS only reviews the price determination methods when manufacturers request recalculations of prior rebates. In four reports issued from 1992 to 2001, the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) identified several factors that limited its ability to verify the accuracy of drug prices reported by manufacturers, including a lack of clear guidance on how AMP should be calculated. In some cases, OIG found problems with manufacturers' price determination methods and reported prices. However, CMS has not followed up with manufacturers to make sure that the identified problems with prices and methods have been resolved.

There was considerable variation in the methods that manufacturers used to determine best price and AMP, and some methods could have reduced the rebates state Medicaid programs received. Manufacturers are allowed to make assumptions when determining best price and AMP, as long as they are consistent with the law and the rebate agreement. The assumptions often involve the treatment of discounts and other price reductions in best price and AMP. Some manufacturers combined price reductions associated with particular sales in their price determination methods, while others accounted for the reductions separately. Separate treatment of the reductions resulted in rebates to states that in some cases were lower than they would have been had the reductions been considered together. Some manufacturers made assumptions that diverged from the rebate agreement and CMS program memoranda that could have raised rebates. States could have to repay any excess rebates if manufacturers revise their assumptions and request recalculations of prior rebates.

The rebates that manufacturers pay to states are based on prices and financial concessions manufacturers make available to entities that purchase their drugs but may not reflect certain financial concessions they offer to other entities. In particular, the rebate program does not clearly address certain manufacturer payments that are negotiated by pharmacy benefit managers (PBM) on behalf of third-party payers such as employer-sponsored health plans and other health insurers. These types of financial arrangements are relatively new to the market. CMS's guidance to manufacturers has not clearly stated how manufacturers should treat these payments in their determinations of best price and AMP. Within the current structure of the rebate formula, additional guidance on how to account for these payments to PBMs could affect the rebates paid to states, although whether rebates would increase or decrease as a result, and by how much, is uncertain.

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Abbreviations

AMP	average manufacturer price
CMS	Centers for Medicare & Medicaid Services
DOJ	Department of Justice
HHS	Department of Health and Human Services
HMO	health maintenance organization
OIG	Office of Inspector General
PBM	pharmacy benefit manager

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Accountability * Integrity * Reliability
United States Government Accountability Office
Washington, DC 20548

February 4, 2005

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
House of Representatives

The Honorable Charles E. Grassley
Chairman
Committee on Finance
United States Senate

Prescription drug spending accounts for a substantial and growing share of state Medicaid program outlays.[1] The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program[2] to help control Medicaid drug spending. Under the rebate program, pharmaceutical manufacturers pay rebates to states as a condition for the federal contribution to Medicaid spending for the manufacturers' outpatient prescription drugs. In fiscal year 2002, Medicaid drug expenditures were $29.3 billion out of $258.2 billion in total Medicaid spending;[3] under the rebate program, manufacturers paid rebates to states of about $5.6 billion for covered outpatient drugs.[4] In recent years, concerns have been raised about increasing Medicaid spending on prescription drugs. Medicaid drug spending increased at an annual average rate of 19 percent from fiscal year

[1]Medicaid is a jointly funded federal-state health care program that covers certain low-income families and low-income individuals who are aged or disabled. States have latitude within federal guidelines to design their individual Medicaid programs with respect to eligibility, services, and payment. Although prescription drug coverage is included at states' discretion, all state Medicaid programs include drug coverage.

[2]Pub. L. No. 101-508, §4401, 104 Stat. 1388, 1388-143-161 (codified at 42 U.S.C. §1396r-8 (2000)). All states and the District of Columbia participate in the Medicaid drug rebate program, except for Arizona.

[3]State Medicaid programs do not purchase drugs directly but rather reimburse pharmacies when they dispense covered outpatient drugs to Medicaid beneficiaries. These payments, which include an amount to cover the cost of acquiring the drug as well as a dispensing fee, are calculated using state-specific payment formulas.

[4]This rebate amount includes the three types of rebates included in the Medicaid drug rebate program: the "basic" rebate for brand name drugs, the "additional" rebate for brand name drugs, and the rebate for generic drugs.

2000 to 2002, while Medicaid spending as a whole grew 12 percent annually during that period.[5]

Medicaid rebates for brand name outpatient drugs are calculated with two prices that participating manufacturers must report to the federal government for each drug: the "best price" and the "average manufacturer price" (AMP). Best price and AMP represent prices that are available from manufacturers to entities that purchase their drugs. Best price for a drug is the lowest price available from the manufacturer to any purchaser, with some exceptions. AMP for a drug is the average price paid to a manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade. Both best price and AMP must reflect certain financial concessions, such as discounts, that are available to drug purchasers. The basic Medicaid rebate for a brand name drug equals the number of units of the drug paid for by the state Medicaid program multiplied by the basic "unit rebate amount" for the drug, which is either the difference between best price and AMP, or 15.1 percent of AMP, whichever is greater.[6] The closer best price is to AMP, the more likely the rebate will be based on 15.1 percent of AMP—the minimum rebate amount.

The Centers for Medicare & Medicaid Services (CMS),[7] an agency of the Department of Health and Human Services (HHS), administers and oversees the rebate program, entering into rebate agreements with manufacturers,[8] collecting and reviewing manufacturer-reported best prices and AMPs, and providing ongoing guidance to manufacturers and states on the program. The Secretary of Health and Human Services, by law, may verify manufacturer-reported prices and has delegated that authority to HHS's Office of Inspector General (OIG). OIG regularly

[5]Since fiscal year 1995, the amount that manufacturers have paid in rebates has risen along with the increase in Medicaid drug spending; rebates, as a percentage of Medicaid drug spending, fluctuated from about 17 percent to just over 19 percent of spending between fiscal years 1995 and 2002.

[6]This report focuses on the basic rebate for brand name drugs, not the additional rebate for brand name drugs—which occurs when a brand name drug's AMP rises faster than inflation, as measured by changes in the consumer price index—or the rebate for generics. The total unit rebate amount for a brand name drug includes the basic rebate and any additional rebate.

[7]CMS was known as the Health Care Financing Administration until July 1, 2001. In this report, we refer to the agency as CMS when discussing agency actions.

[8]The rebate agreement is a standard contract between CMS and each manufacturer that governs manufacturers' participation in the rebate program, providing, among other things, definitions of key terms.

conducts audits, evaluations, and investigations pertaining to HHS programs.

Recent litigation has highlighted the importance of the accuracy of prices manufacturers report to CMS and the rebates they pay to states. Since 2002, several manufacturers have agreed to make payments to settle allegations that they underpaid rebates to states by reporting inaccurate prices.[9]

You asked us to study the Medicaid drug rebate program. We are reporting on (1) federal oversight of manufacturer-reported best prices and AMPs and the methods manufacturers used to determine those prices, (2) how manufacturers' methods of determining best price and AMP could have affected the rebates they paid to state Medicaid programs, and (3) how the rebate program reflects financial concessions available in the private market.

To report on the oversight of manufacturer-reported prices and methods, we reviewed the rebate statute, the standard rebate agreement, CMS program memoranda, and OIG reports on the rebate program. We also interviewed officials from CMS and OIG. To assess how manufacturers' price determination methods could have affected rebate amounts, we reviewed the pricing methodologies for the 13 manufacturers that accounted for the highest Medicaid expenditures in the last two quarters of 2000. We compared manufacturers' methods of determining best price and AMP to the rebate statute, rebate agreement, and relevant CMS program memoranda. In addition, we examined sales transaction data provided by these manufacturers. We received data for the 10 brand name drugs that produced the highest Medicaid expenditures for the last two quarters of 2000 for each manufacturer, as well as data for 5 additional frequently prescribed brand name drugs—135 drugs in total. We examined the sales transaction data to understand how manufacturers implemented their price determination methods and to calculate the impact of manufacturer practices on rebates. Because we purposely selected manufacturers and drugs that accounted for a large share of Medicaid drug

[9]For example, according to the Department of Justice (DOJ), in 2003 one manufacturer agreed to pay $88 million to settle allegations raised by DOJ under the False Claims Act that it had underpaid Medicaid rebates due to states by reporting inaccurate best price information for two of its drugs. In 2004, another manufacturer agreed to pay $345 million in connection with allegations that it had underpaid rebates for one of its drugs by failing to properly report best price.

spending, the results of our analysis cannot be generalized. To examine how the rebate program reflects financial concessions available in the private market, we reviewed the rebate statute, the standard rebate agreement, and CMS program memoranda; market literature; and recent financial statements of three large pharmacy benefit managers (PBM), which manage prescription drug benefits for third-party payers.

We determined that the manufacturers' sales transaction data were sufficiently reliable for the purposes of this report. To assess the reliability of the data, we (1) confirmed that the data included the elements we requested and were consistent with provided documentation; (2) reviewed related documentation, including each manufacturer's price determination methods; and (3) worked with individual manufacturers' Medicaid drug rebate program personnel to identify any data problems. We also compared the prices we calculated from the sales transaction data to the prices manufacturers reported to CMS for the relevant quarter. It was not feasible to compare the reported sales transaction data with their source documentation, such as invoices, because of the large volume of sales transactions associated with the drugs in our sample. We do not report data in a manner that would allow the identification of a specific manufacturer or drug. We performed our work from December 2003 through January 2005, in accordance with generally accepted government auditing standards.

Results in Brief

Current rebate program oversight does not ensure that manufacturer-reported prices or price determination methods are consistent with program criteria as specified in the rebate statute, rebate agreement, and CMS program memoranda. CMS conducts only limited checks for reporting errors in manufacturer-reported drug prices. Furthermore, the agency does not generally review the methods and underlying assumptions that manufacturers use to determine best price and AMP. Rather, CMS reviews manufacturers' price determination methods only when they request recalculations of prior rebates. In four reports issued from 1992 to 2001, OIG stated that its review efforts were hampered by unclear CMS guidance on how manufacturers were to determine AMP, by a lack of manufacturer documentation, or by both. In some cases, OIG found problems with manufacturers' price determination methods and reported prices. However, CMS has not followed up with manufacturers to make sure that the identified problems with prices and price determination methods have been resolved.

There was considerable variation in the methods that manufacturers used to determine best price and AMP, and some methods could have reduced rebates to state Medicaid programs. Manufacturers are allowed to make reasonable assumptions when determining best price and AMP, as long as those assumptions are consistent with the law and the rebate agreement. The assumptions often pertain to the transactions, including discounts and other price reductions, that are considered when determining best price and AMP. In determining best price and AMP, some manufacturers did not combine the price reductions associated with certain transactions involving prompt payment discounts. This resulted in rebates to states that in some cases were lower than they would have been had these manufacturers combined such price reductions as other manufacturers did. In addition, some manufacturers made assumptions that diverged from the rebate agreement and CMS program memoranda that could have raised rebates. States may have to repay any excess rebates if manufacturers later revise their assumptions and request recalculations of prior rebates.

The rebates that manufacturers pay to states are based on a range of prices and financial concessions that they make available to entities that purchase their drugs but may not reflect certain financial concessions they offer to other entities in today's complex market. In particular, the rebate program does not clearly address certain manufacturer payments that are negotiated by PBMs on behalf of third-party payers such as employer-sponsored health plans and other health insurers. These types of financial arrangements are a relatively new development in the market. CMS's guidance to manufacturers has not clearly stated how manufacturers should treat these payments in their determinations of best price and AMP. Within the current structure of the rebate formula, additional CMS guidance on how to account for these payments to PBMs could affect the rebates paid to states, although whether rebates would increase or decrease as a result, and by how much, is uncertain.

To help ensure that the Medicaid drug rebate program is achieving its objective of controlling states' Medicaid drug spending, we recommend that the Administrator of CMS issue clear guidance on manufacturer price determination methods and the definitions of best price and AMP, and update such guidance as additional issues arise. We also recommend that the Administrator implement, in consultation with OIG, systematic oversight of the price determination methods employed by pharmaceutical manufacturers and a plan to ensure the accuracy of manufacturer-reported prices and rebates to states.

In its comments on a draft of this report, HHS agreed with the importance of guidance to manufacturers, but disagreed with our conclusion that there has been inadequate program oversight. While the draft report cited oversight activities HHS has undertaken, we believe that its oversight does not adequately ensure the accuracy of manufacturer-reported prices and rebates paid to states. The manufacturers that supplied data for this report reviewed sections of the draft report and provided oral comments. Some of the manufacturers raised concerns about our discussion of certain methods they used to determine rebates. In response to the manufacturers' concerns, we clarified our discussion of manufacturers' price determination methods.

Background

The Medicaid drug rebate program provides savings to state Medicaid programs through rebates for outpatient prescription drugs that are based on two prices per drug that manufacturers report to CMS: best price and AMP. These manufacturer-reported prices are based on the prices that manufacturers receive for their drugs in the private market and are required to reflect certain financial concessions such as discounts.

Features of the Private Pharmaceutical Market

Pharmaceutical manufacturers sell their products directly to a variety of purchasers, including wholesalers, retailers such as chain pharmacies, and health care providers such as hospitals that dispense drugs directly to patients. The prices that manufacturers charge vary across purchasers. The private market also includes PBMs, which manage prescription drug benefits for third-party payers such as employer-sponsored health plans and other health insurers.[10] PBMs may negotiate payments from manufacturers to help reduce third-party payers' costs for prescription drugs; those payments may be based on the volume of drugs purchased by the payers' enrollees. PBMs also may operate mail-order pharmacies, purchasing drugs from manufacturers and delivering them to their clients' enrollees.

The amount a manufacturer actually realizes for a drug is not always the same as the price that is paid to the manufacturer at the time of sale. Manufacturers may offer purchasers rebates or discounts that may be

[10] *See* GAO, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies,* GAO-03-196 (Washington, D.C.: Jan. 10, 2003).

realized after the initial sale, such as those based on the volume of drugs the purchasers buy during a specified period or the timeliness of their payment. In some cases, purchasers negotiate a price with the manufacturer that is below what a wholesaler pays the manufacturer for a given drug. In such a circumstance, a wholesaler may sell the drug to the purchaser at the lower negotiated price and then request from the manufacturer a "chargeback"—the difference between the price the wholesaler paid for the drug and the purchaser's negotiated price.

The Medicaid Drug Rebate Program

The statute governing the Medicaid drug rebate program and the standard rebate agreement that CMS signs with each manufacturer define best price and AMP and specify how those prices are to be used to determine the rebates due to states. In the absence of program regulations,[11] CMS has issued program memoranda[12] in order to provide further guidance to manufacturers regarding how to determine best price and AMP, some of which were in response to questions that arose regarding the methods that manufacturers were using to determine those prices.[13] The rebate agreement states that in the absence of specific guidance on the determination of best price and AMP, manufacturers may make "reasonable assumptions" as long as those assumptions are consistent with the "intent" of the law, regulations, and the rebate agreement.[14] As a result, price determination methods may vary across manufacturers, particularly with respect to which transactions they consider when determining best price and AMP.

[11]In 1995, CMS issued a proposed rule for implementation of the drug rebate program, which included provisions regarding best price, AMP, and manufacturer reporting requirements. *See* 60 *Fed. Reg.* 48442 (1995). Only a portion of that rule—concerning the length of time manufacturers are able to report price adjustments to CMS and how long they must retain documentation of their reported prices—has been issued in final form. *See* 68 *Fed. Reg.* 51912 (2003).

[12]As of October 2004, CMS had issued a total of 65 program memoranda—also called "program releases"—to manufacturers to provide guidance on a range of issues relating to the rebate program.

[13]Several memoranda address whether prices to certain types of health care providers should be considered in determining best price or AMP, for example. CMS also responds to questions from individual manufacturers on a case-by-case basis. In addition, the agency provides an operational training guide and training for manufacturers and states on resolving disputes over state-reported drug utilization information used to calculate rebate amounts.

[14]The rebate agreement also requires manufacturers to maintain records of their assumptions.

Under the rebate statute, best price is the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization (HMO), or nonprofit or government entity, with some exceptions.[15] Best price is required to be reduced to account for cash discounts, free goods that are contingent on purchase requirements, volume discounts and rebates (other than rebates under this program), as well as—according to the rebate agreement and a CMS program memorandum—cumulative discounts and any other arrangements that subsequently adjust the price actually realized. Prices charged to certain federal purchasers,[16] eligible state pharmaceutical assistance programs and state-run nursing homes for veterans, and certain health care facilities—including those in underserved areas or serving poorer populations—are not considered when determining best price. Prices available under endorsed Medicare discount card programs, as well as those negotiated by Medicare prescription drug plans or certain retiree prescription drug plans, are similarly excluded from best price. Nominal prices—prices that are less than 10 percent of AMP—also are excluded from best price.

AMP is defined by statute as the average price paid to a manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade.[17] The transactions used to calculate AMP are to reflect cash discounts and other reductions in the actual price paid, as well as any other price adjustments that affect the price actually realized, according to the rebate agreement and a CMS program memorandum.[18] Under the rebate agreement, AMP does not include prices to government purchasers based on the Federal Supply Schedule, prices from direct sales to hospitals or HMOs, or prices to wholesalers when they relabel drugs they purchase under their own label.

[15]*See* 42 U.S.C. §1396r-8(c)(1)(C). The rebate agreement further defines best price as the lowest price at which the manufacturer sells the drug to any purchaser in any pricing structure, including capitated payments, with some exceptions.

[16]Sales made through the Federal Supply Schedule are not considered in determining best price, nor are single-award contract prices of any federal agency, federal depot prices, and prices charged to the Department of Defense, Department of Veterans Affairs, Indian Health Service, and Public Health Service.

[17]*See* 42 U.S.C. §1396r-8(k)(1). The statute states that customary prompt payment discounts are to be subtracted from prices used to calculate AMP. There is no definition in the statute for "retail pharmacy class of trade."

[18]Under the rebate agreement, AMP is calculated as net sales divided by units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements).

The relationship between best price and AMP determines the unit rebate amount and, thus, the size of the rebate that states receive for a brand name drug. The basic unit rebate amount is the larger of two values: the difference between best price and AMP, or 15.1 percent of AMP.[19] The closer best price is to AMP, the more likely the rebate for a drug will be based on the minimum amount—15.1 percent of AMP—rather than the difference between the two values. A state's rebate for a drug is the product of the unit rebate amount and the number of units of the drug paid for by the state's Medicaid program. In 2000, rebates were based on the minimum amount for about half of the brand name drugs covered under the rebate program; for the remaining drugs, rebates were based on the difference between best price and AMP.

Manufacturers pay rebates to states on a quarterly basis. They are required to report best price and AMP for each drug to CMS within 30 days of the end of each calendar quarter. Once CMS receives this information, the agency uses the rebate formula to calculate the unit rebate amount for the smallest unit of each drug, such as a tablet, capsule, or ounce of liquid. CMS then provides the unit rebate amount to the states. Each state determines its Medicaid utilization for each covered drug—as measured by the total number of the smallest units of each dosage form, strength, and package size the state paid for in the quarter—and reports this information to the manufacturer within 60 days of the end of the quarter. The manufacturer then must compute and pay the rebate amount to each state within 30 days of receiving the utilization information.

Manufacturers are required to report price adjustments to CMS when there is a change in the prices they reported for a prior quarter. These adjustments may result from rebates, discounts, or other price changes that occur after the manufacturers submit prices to CMS. Manufacturers also may request that CMS recalculate the unit rebate amounts using revised prices if they determine that their initially reported prices were incorrect due to, for example, improper inclusion or exclusion of certain transactions. In 2003, CMS issued a final rule that, effective January 1,

[19]*See* 42 U.S.C. §1396r-8(c)(1).

2004, limits the time for manufacturers to report any price adjustments to 3 years after the quarter for which the original price was reported.[20]

Current Program Oversight Does Not Ensure That Manufacturer-Reported Prices or Price Determination Methods Are Consistent with Program Criteria

The minimal oversight by CMS and OIG of manufacturer-reported prices and price determination methods does not ensure that those prices or methods are consistent with program criteria, as specified in the rebate statute, rebate agreement, and CMS program memoranda. CMS conducts limited reviews of prices and only reviews price determination methods when manufacturers request recalculations of prior rebates. OIG has issued four reports on audits of manufacturer-reported prices since the program's inception in 1991. OIG reported that, in the course of its work, its efforts were hampered both by unclear CMS guidance on determining AMP and by a lack of manufacturer documentation. In some instances, OIG found problems with manufacturers' price determination methods and reported prices. However, CMS has not followed up with manufacturers to make sure that the identified problems with prices and price determination methods have been resolved.

CMS's Review of Manufacturer-Reported Prices Is Limited

As part of the agency's administration of the Medicaid drug rebate program, CMS reviews drug prices submitted by approximately 550 manufacturers that participate in the program. Each quarter, CMS conducts automated data edit checks on the best prices and AMPs for about 25,000 drugs to identify reporting errors. These checks are intended to allow CMS to make sure all drugs for which manufacturers report prices are in its database of Medicaid-covered drugs and to ensure that those prices are submitted in the correct format. The agency's automated data checks also are intended to ensure that the correct price is used when there are multiple prices for the same drug. When data checks indicate a

[20]The 2003 final rule, which covered only two issues raised in the 1995 proposed rule, addressed the time frame for reporting price adjustments to CMS and the time frame for retaining documentation of reported prices. *See* 60 *Fed. Reg.* 48442 (1995), 68 *Fed. Reg.* 51912 (2003), 68 *Fed. Reg.* 55527 (2003). In this final rule, CMS required that a manufacturer retain written or electronic records documenting reported prices for 3 years after those prices are submitted to CMS or for a longer period if the records are the subject of an audit or a government investigation, of which the manufacturer is aware, relating to best price or AMP. However, just after the final rule became effective in January 2004, CMS issued an interim final rule that replaced the 3-year recordkeeping requirement with a 10-year recordkeeping requirement for calendar year 2004; manufacturers still are required to retain records for a longer period if the records are the subject of an audit or government investigation. 69 *Fed. Reg.* 508 (2004). At the same time, CMS issued a proposed rule that would make the 10-year requirement permanent. 69 *Fed. Reg.* 565 (2004).

potential reporting error, CMS sends an edit report to the manufacturer asking for corrected drug prices. However, CMS does not have a mechanism in place to track whether, in fact, manufacturers submit corrected prices.

CMS sometimes identifies other price reporting errors when it calculates the unit rebate amount for a drug, but the agency does not follow up with manufacturers to verify that errors have been corrected. CMS will notify a manufacturer of any missing price data for drugs in its database or any large deviations from previous unit rebate amounts. For example, CMS would send a report to a manufacturer that had a unit rebate amount for a drug that deviated from that of the prior quarter by more than 50 percent. It would be up to that manufacturer to indicate whether or not the underlying reported prices were, in fact, correct. If a manufacturer determined that there were problems with the reported price for a drug—such as incorrect unit pricing or typographical errors like misplaced decimals—it would send corrected data to CMS prior to or with future price submissions. In this situation, the manufacturer also would recalculate the unit rebate amount and, once invoiced by the states with total utilization for the drug paid for by Medicaid, would send the rebate payment to those states based on the recalculated unit rebate amount. If a manufacturer did not send revised pricing data to CMS, then the unit rebate amount would remain the same. In 2000, CMS generated approximately 150 reports detailing these 50 percent deviations, according to an agency official. The agency did not track how many unit rebate amounts were changed as a result or any effect on rebates.

Price Determination Methods Are Reviewed Only When Manufacturers Request Recalculations

CMS does not generally review the methods and underlying assumptions that manufacturers use to determine best price and AMP, even though these methods and assumptions can have a substantial effect on rebates. While the rebate agreement requires manufacturers to maintain documentation of the assumptions underlying their price determination methods, CMS does not verify that such documentation is kept and rarely requests it. Furthermore, CMS does not generally check to ensure that manufacturers' assumptions and price determination methods are consistent with the rebate statute and rebate agreement.

CMS reviews the methodologies employed to determine best price and AMP only when manufacturers request recalculations of prior rebates. A manufacturer may request a recalculation of a prior rebate any time it changes the methods it uses to determine best price or AMP.[21] CMS requires the manufacturer to submit both its original and its revised methods for determining those prices when requesting a recalculation of prior rebates, so that it can evaluate whether the revised methods are consistent with the rebate statute, rebate agreement, and program memoranda. Six approved recalculations, for which we could obtain data,[22] reduced prior rebates to states by a total of more than $220 million.[23] An additional approved recalculation required the manufacturer to pay states an additional $388,000.

OIG Reports That Its Efforts Have Been Limited by Unclear Program Guidance

OIG has issued four reports on audits of manufacturer-reported prices since the program's inception in 1991. Three of the four OIG reports documented limitations to OIG's ability to verify drug prices. OIG reported that its efforts were hampered by unclear CMS guidance on determining AMP, by a lack of manufacturer documentation, or by both. In particular, OIG found that a lack of specificity on how the "retail pharmacy class of trade" was defined limited its efforts to verify AMP. Both the rebate statute and rebate agreement define AMP as the average price paid by wholesalers for drugs distributed to the retail pharmacy class of trade, with some exceptions. OIG officials told us that program memoranda issued by CMS have not provided sufficient guidance on AMP to allow OIG to audit manufacturers' methods for determining AMP. Despite these limitations, in some instances OIG was able to identify some problems with the accuracy of manufacturers' reported prices; however, CMS has not followed up with manufacturers to make sure that these problems with prices and price determination methods have been resolved.

[21]Manufacturers may request a rebate recalculation, for example, after a merger, if the merging manufacturers need to reconcile different price determination methods.

[22]We asked CMS officials to provide information on all recalculation requests since the program's inception in 1991. CMS officials told us that they do not have data on all of the recalculation requests prior to September 2000.

[23]States refund rebate payments to manufacturers by having the future rebate payments they receive from manufacturers reduced.

In its first review of manufacturer-reported prices in 1992, OIG found that it could not verify the AMPs reported by the four manufacturers it reviewed.[24] OIG found it could not evaluate the methods these manufacturers used to determine AMP because neither the rebate statute nor CMS had provided sufficiently detailed instructions on methods for calculating AMP. OIG therefore advised CMS that it planned no future AMP data audits until CMS developed a specific written policy on how AMP was to be calculated. CMS disagreed, saying that the rebate statute and rebate agreement had already established a methodology for computing AMP, and stressed that this methodology was clarified, at manufacturer request, on an as-needed basis through conversations with individual manufacturers.[25]

In its second review of manufacturer-reported prices, OIG, in 1995, attempted to verify one manufacturer's recalculation request. While the OIG reported that it could not complete its analysis because of inadequate manufacturer documentation,[26] it was able to identify some manufacturer errors in determining AMP. In its review, OIG found that the manufacturer had miscalculated its revised AMP because it included "free goods" specifically excluded in the rebate agreement, miscalculated cash discounts, and improperly included sales rebates applicable to a period other than the quarter being audited. OIG recommended that CMS have the manufacturer revise its AMP data. Although CMS agreed with OIG's recommendations, as of October 2004, it had not required any such revision of the audited manufacturer's AMP determinations.

In its third review, conducted in 1997, OIG attempted to review a manufacturer's recalculation request but again reported that it was unable to complete its evaluation because of a lack of specific guidance on determining AMP and a lack of manufacturer documentation supporting its revised AMP. In the absence of guidance from CMS, OIG defined retail

[24]See Department of Health and Human Services, Office of Inspector General, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program*, A-06-91-00092 (Washington, D.C.: November 1992).

[25]Although CMS disagreed with OIG, it said it would further clarify AMP calculation in a forthcoming drug rebate program regulation. As of October 2004, the regulation had not been issued and CMS officials told us that the agency had no plans to promulgate any such regulation in the near future. Instead, the agency has issued several program memoranda intended to provide guidance on how manufacturers should calculate AMP.

[26]OIG reports on individual manufacturers are not publicly available.

pharmacy class of trade for this audit to include only independent and chain pharmacies that sold drugs directly to the public. Therefore, OIG recommended that CMS ask the manufacturer to exclude from the calculation of AMP transactions that OIG determined were to nonretail entities such as mail-order pharmacies, nursing home pharmacies, independent practice associations, and clinics. OIG also found that the manufacturer used a flawed methodology to identify certain sales that it had included in the retail class of trade, and thus AMP. As a result, OIG recommended that CMS ask the manufacturer to exclude those sales from AMP unless the manufacturer could provide additional documentation to support the inclusion of those sales in AMP. Although CMS did not agree with OIG's definition of retail pharmacy class of trade, CMS concurred with OIG's recommendation to ask the manufacturer to recalculate AMP.[27] As of October 2004, CMS had not required any revision of this manufacturer's AMP determinations.

In its fourth review of manufacturer-reported prices issued in 2001, OIG investigated how manufacturers were treating repackagers—entities such as HMOs that repackage or relabel drugs under their own names—in their best price determinations. The work followed up on previous work OIG conducted in response to a congressional inquiry in 1999. The rebate statute states that HMO sales are required to be included in best price determinations. CMS's June 1997 program memorandum stated that sales to other manufacturers that repackage the drugs are to be excluded from best price determinations. However, the rebate statute, rebate agreement, and CMS program memoranda did not address how HMOs should be treated when they act as repackagers. In a letter issued in response to the 1999 congressional request, OIG reported that excluding drug sales to two HMOs that acted as repackagers from best price determinations lowered state rebate amounts by $27.8 million in fiscal year 1998.[28] In July 2000, CMS issued an additional program memorandum to manufacturers stating that sales to an HMO should be considered in best price determinations

[27]In response to OIG recommendations, CMS said it would provide the manufacturer with a copy of recent guidance on AMP: Medicaid Drug Rebate Program Release No. 29, June 1997. This document, released to all manufacturers at the time OIG was conducting the 1997 review, in some cases differed from OIG's definition of retail pharmacy class of trade. It stated, for example, that sales to nursing home and mail-order pharmacies are to be included in AMP, while OIG's definition excluded these entities.

[28]Letter from OIG to Ranking Minority Member, Committee on Government Reform, House of Representatives, November 22, 1999.

regardless of whether the HMO was a repackager.[29] In 2001, OIG issued its fourth review, reporting that states lost $80.7 million in rebates in fiscal year 1999 due to improperly excluded drug sales to HMO repackagers.[30] In September 2004, a CMS official told us that CMS planned to release a program memorandum instructing manufacturers to revise prior rebates for which they had excluded sales to HMOs from best price. However, CMS does not have a mechanism in place to track that manufacturers have made these rebate adjustments and therefore cannot verify that manufacturers have made or will make these adjustments.

OIG officials told us that, despite the program releases issued by CMS, they remain unable to evaluate AMP because of the lack of clear CMS guidance, particularly related to the retail pharmacy class of trade and treatment of PBM transactions. In October 2004, OIG officials told us that they were working with CMS to review four manufacturers' recalculation requests and as part of this work were evaluating the methods manufacturers have used to determine prices. OIG officials also told us that they may conduct additional audits because of the number of recent manufacturer recalculation requests—18 requests received between September and December of 2003—and the significant financial impact the potential rebate adjustments would have on state Medicaid programs. However, in light of OIG's remaining concerns about CMS guidance, OIG officials told us that their current audits—and any future audits—likely would be limited to descriptions of how inclusion and exclusion of certain sales in price determinations would affect rebates.

Manufacturer Price Determination Methods Varied: Some Could Have Led to Lower Rebates

We found considerable variation in the methods that manufacturers used to determine best price and AMP. Manufacturers are allowed to make reasonable assumptions when determining best price and AMP, as long as those assumptions are consistent with the law and the rebate agreement. The assumptions often pertain to the transactions, including discounts or other price reductions, that are considered in determining best price and AMP. We found that in some cases manufacturers' assumptions could have led to lower rebates and in other cases to higher rebates. Manufacturers

[29]Medicaid Drug Rebate Program Release No. 47, July 2000.

[30]See Department of Health and Human Services, Office of Inspector General, *Medicaid Drug Rebates: Sales to Repackagers Excluded from Best Price Determinations*, A-06-00-00056 (Washington, D.C.: March 2001).

can later revise their assumptions and request recalculations of previously paid rebates, which can result in states repaying any excess rebates.

We found that manufacturers made varying assumptions about which sales to include and exclude from their calculations of AMP. For example, some included sales to a broad range of facilities in AMP, excluding only transactions involving facilities explicitly excluded by the law, rebate agreement, or CMS program memoranda. In contrast, others included sales to a narrower range of purchasers—only those purchasers explicitly included in AMP by the law, rebate agreement, or CMS program memoranda. Manufacturers also differed in how they treated certain types of health care providers that are not explicitly addressed by the law, rebate agreement, or CMS program memoranda. For example, some manufacturers included sales to physician groups in AMP, while others did not. These assumptions can affect the reported prices and, in turn, the size of rebates paid to states.

Some manufacturers did not account for certain "administrative fees" paid to PBMs when determining best price or AMP. The statute and rebate agreement require that best price incorporate volume-based discounts. Further, according to the rebate agreement and a CMS program memorandum, both best price and AMP are to account for cumulative discounts or other arrangements that subsequently adjust the prices actually realized.[31] While CMS has acknowledged that not all PBM arrangements will affect best price and AMP, the agency has advised manufacturers that administrative fees, incentives, promotional fees and chargebacks, as well as all discounts and rebates provided to purchasers, should be considered in determinations of best price and AMP when they are associated with sales that are to be considered in those prices.[32] When a PBM acts as a mail-order pharmacy and takes possession of drugs, it is a purchaser. We found that while the basis for the administrative fees paid to PBMs varied among the manufacturers we reviewed, the fees often were based on a utilization measure, such as the sales volume of drugs used by the enrollees of the PBM's clients. To the extent that PBMs' purchases for their mail-order pharmacies contributed to the utilization measures used to determine their administrative fees, the fees for the mail-

[31]Medicaid Drug Rebate Program Release No. 2, August 1991.

[32]See Medicaid Drug Rebate Program Release No. 14, December 1994, regarding administrative fees, and Medicaid Drug Rebate Program Releases No. 28, April 1997, and No. 29, June 1997, regarding PBM arrangements.

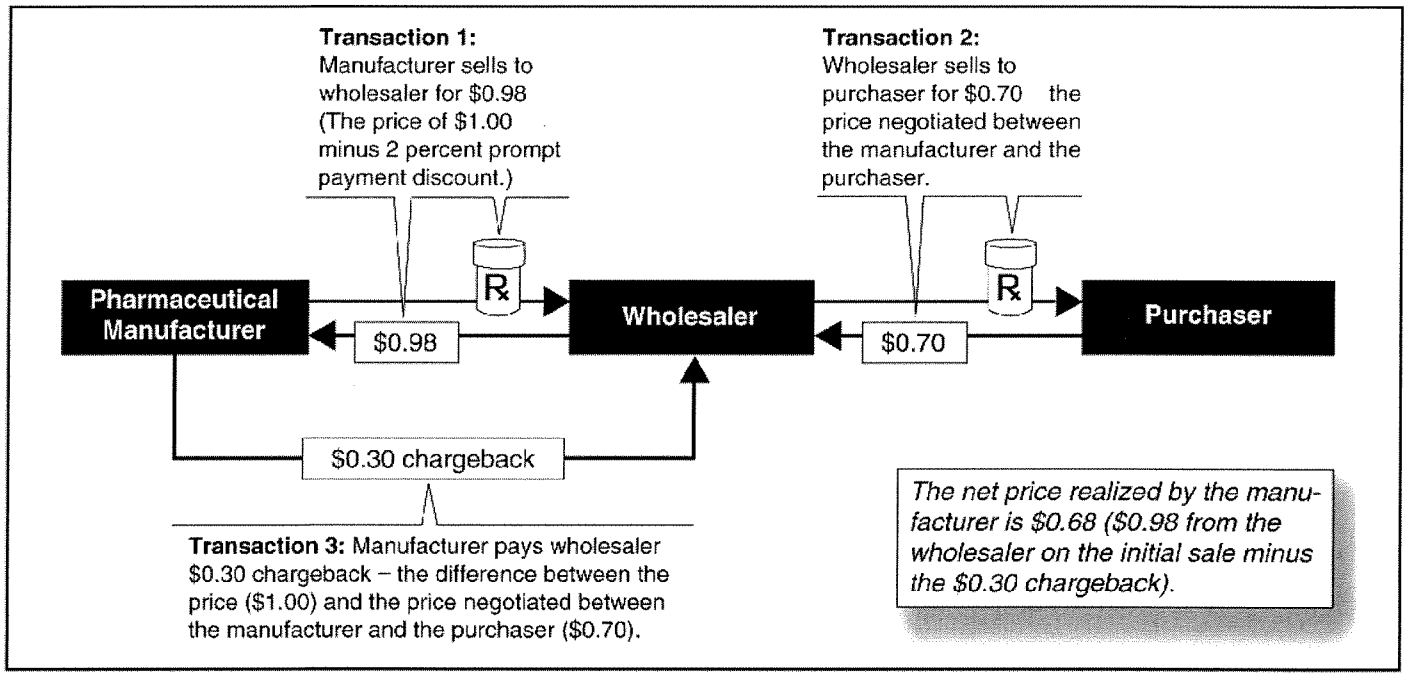
order portion of their business resemble a volume-based discount that adjusts the price actually realized. Some manufacturers told us that they accounted for the portion of administrative fees paid to PBMs associated with the PBMs' mail-order pharmacies in their determinations of best price or AMP. In contrast, others said they did not incorporate this portion of any administrative fees paid to PBMs in either best price or AMP. Some of those manufacturers characterized these fees as payments for services rather than adjustments to prices.

Excluding administrative fees from the determination of best price or AMP could have reduced rebates below what they would have been had the manufacturers included them when determining those prices. For one manufacturer, for example, if administrative fees paid to PBMs associated with their mail-order pharmacy purchases had been included in the manufacturer's determination of best price and AMP, rebates for 11 drugs would have been up to 16 percent higher in the third quarter of 2000 and up to 12 percent higher in the fourth quarter of 2000. The ultimate impact on rebates to states depends on how many manufacturers excluded these fees from reported prices, the volume of those manufacturers' sales to PBM mail-order pharmacies, as well as the prices and utilization of the relevant drugs.

Manufacturers also differed in how they accounted for certain transactions involving prompt payment discounts. Both the rebate agreement and an applicable CMS program memorandum specify that best price and AMP are to reflect cumulative discounts or other arrangements that subsequently adjust the prices actually realized. In examining manufacturers' practices, we found that they generally provided a prompt payment discount of 2 percent of the purchase price to wholesalers and others that purchased drugs from them directly, when they paid within a specified period. In most cases, when the manufacturers we reviewed sold a drug directly to a purchaser, they reduced the purchaser's price by any applicable prompt payment discount when determining best price and AMP. When the transaction also involved a chargeback arrangement, manufacturers' methods differed. A chargeback involves one drug passing from a manufacturer through a wholesaler to a purchaser, so the chargeback amount and the prompt payment discount together affect the amount the manufacturer actually realizes for the drug. (See fig. 1.) Some manufacturers calculated the net price as their price to the wholesaler, reduced by both the prompt payment discount and the chargeback amount for those drugs, when determining best price and AMP. Other manufacturers, however, considered any prompt payment discount given to the wholesaler separately from any chargeback amount and thus did not

incorporate the effect of both price reductions when determining best price and AMP. Some of these manufacturers indicated that they did not combine these price reductions because the price reductions occurred in two unrelated transactions to two separate purchasers.

Figure 1: Example of How Prompt Payment Discounts in Chargeback Situations Affect the Net Amount Realized by a Manufacturer



Source: GAO.

In some cases, not accounting for the effect of both price reductions—the prompt payment discount and the chargeback—in the determination of best price and AMP reduced rebates below what they otherwise would have been. For example, rebates for three drugs in our sample would have been 3 to 5 percent higher had the manufacturers considered the effects of both price reductions when determining the best prices and AMPs; for seven other drugs, rebates would not have changed. The ultimate impact on rebates to states depends on how many manufacturers adopted this approach as well as the sales prices and utilization of the relevant drugs.

When determining best price and AMP, some manufacturers adopted methods that could have raised rebates. For example, although the rebate agreement excludes from AMP sales through the Federal Supply Schedule and direct sales to hospitals and HMOs, which often involve relatively low prices, one manufacturer included these sales in its calculations. However, the manufacturer used list prices in the calculation of AMP instead of the actual prices associated with the sales that were to be excluded from the calculation.[33] This approach, which diverged from the rebate agreement and applicable CMS program memoranda, could have resulted in artificially high AMPs, which in turn could have raised rebates.

In addition, some manufacturers included in the determination of best price the contract prices they had negotiated with purchasers, even if they made no sales at those prices during the reporting quarter. This practice resulted in a lower best price in some cases, which may have increased rebates to states. One manufacturer, however, indicated that it later might revise this practice and request recalculations to recoup any excess rebates it had already paid. Manufacturers have up to 3 years to make such revisions.

Rebate Program Does Not Clearly Address Certain Financial Concessions Negotiated by PBMs

The rebates that manufacturers pay to states are based on a range of prices and financial concessions that manufacturers make available to entities that purchase their drugs, but may not reflect certain financial concessions manufacturers offer to other entities in today's complex market. In particular, the rebate program does not clearly address certain concessions that are negotiated by PBMs on behalf of third-party payers. The rebate program did not initially address these types of concessions, which are relatively new to the market. CMS's subsequent guidance to manufacturers has not clearly stated how manufacturers should treat these concessions in their determinations of best price and AMP.

Certain manufacturer financial concessions that are negotiated by PBMs on behalf of their third-party payer clients, such as employer-sponsored health plans and other health insurers, are not clearly reflected in best price or AMP. PBMs, in one of the roles they play in the market, may negotiate payments from manufacturers to help reduce their third-party

[33]Citing limitations in its data systems, this manufacturer used the wholesale acquisition cost, which is the manufacturer's list price for wholesalers or other direct purchasers before any rebates, discounts, allowances, or other price concessions.

payer clients' costs for prescription drugs.[34] (In these circumstances, the third-party payer does not purchase drugs directly from the manufacturer but instead covers a portion of the cost when its enrollees purchase drugs from pharmacies.[35]) The basis of these PBM-negotiated manufacturer payments varies.[36] For example, manufacturers may make a payment for each unit of a drug that is purchased by third-party payer enrollees or may vary payment depending on a PBM's ability to increase the utilization, or expand the market share, of a drug.[37] The payment may be related to a specific drug or a range of drugs offered by the manufacturer.

The amount of financial gain PBMs receive from these negotiated payments also varies. A PBM may pass on part or all of a manufacturer's payment to a client, depending on the terms of their contractual relationship. When a PBM passes on the entire manufacturer payment, the manufacturer may pay the PBM a fee to cover the costs of administering the program under which the payments are made. A PBM also may negotiate a manufacturer payment for each unit of the drug purchased that includes a fee, and the PBM may retain a part of that payment as compensation. Some PBM clients may receive smaller discounts on drug prices at the pharmacy in exchange for receiving all or a larger share of the manufacturer payments, while other clients may receive greater discounts on drug prices in exchange for the PBM retaining a larger share of the manufacturer payment. Manufacturers may not be parties to the contracts that PBMs have with their clients and so may not know the financial arrangements between the PBMs and their clients.

[34]GAO-03-196.

[35]PBMs often manage the transactions that take place between third-party payers and pharmacies. For example, in some cases, when an enrollee purchases a drug at a retail pharmacy, the pharmacy collects from the enrollee the appropriate cost sharing amount and then submits a claim to the PBM for reimbursement. The PBM pays the pharmacy and collects reimbursement from its third-party payer client.

[36]Some PBMs operate mail-order pharmacies and, when doing so, may separately negotiate rebates or discounts with manufacturers for the drugs they purchase for that component of their business.

[37]In managing pharmacy benefit plans for their clients, PBMs can influence the utilization of drugs using several approaches, such as formularies—lists of drugs that are approved for reimbursement by the PBM's clients—and tiered copayment systems that use financial incentives to encourage enrollees to select certain drugs.

These types of financial arrangements between manufacturers and PBMs are a relatively new development in the market. When the program began in 1991, PBMs played a smaller role in the market, managing fewer covered lives and providing a more limited range of services—such as claims processing—for their clients. Since then, PBMs' role has grown substantially,[38] contributing to a market that is much more complex, particularly with respect to the types of financial arrangements involving manufacturers. PBMs now commonly negotiate with manufacturers for payments on behalf of their clients, in addition to providing other services.[39] Although complete data on the prevalence and magnitude of PBM-negotiated manufacturer payments are not readily available, PBM officials and industry experts have said that these and other manufacturer payments to PBMs are a large portion of PBMs' earnings;[40] further, recent public financial information suggests that manufacturer payments to PBMs as a whole are substantial and key to PBMs' profitability.[41]

CMS has acknowledged the complexity that arrangements between manufacturers and PBMs introduce into the rebate program but has not clearly addressed how these arrangements should be reflected in manufacturer-reported prices. In 1997, CMS issued program memoranda that noted new types of arrangements involving manufacturer payments to PBMs and attempted to clarify whether those arrangements should be

[38]In 2004, according to a study prepared for a national association representing PBMs, an estimated 200 million people, or about 68 percent of the U.S. population, were in private plans that used PBMs. See PricewaterhouseCoopers, *The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation* (July 2004), http://www.pcmanet.org/research.asp (downloaded January 18, 2005).

[39]For example, PBMs now design pharmacy benefit plans—working with clients on issues such as which drugs to cover and how much of a drug's cost will be paid by enrollees—and provide clinical support such as disease management programs for enrollees with specific illnesses.

[40]GAO-03-196.

[41]For example, according to financial reports filed with the Securities and Exchange Commission, three large PBMs together received over $4.3 billion in total fiscal year 2002 payments from manufacturers. These payments can include payments related to PBM negotiations on behalf of clients as well as other payments such as fees. For one of the PBMs we reviewed, manufacturer payments totaled 7 percent of its revenue. (Comparable information on manufacturer payments was not available from the other PBMs' financial reports.) All three PBMs stated in their financial reports that manufacturer payments were important to their profitability.

reflected in best price and AMP.[42] However, in a program memorandum issued shortly thereafter, CMS stated that there had been confusion concerning the intent of the previous program memoranda and that the agency had "intended no change" to program requirements.[43] At the time, CMS said that staff were reexamining the issue and planned to shortly clarify the agency's position. As of January 2005, CMS had not issued such clarifying guidance. When we asked how PBM-negotiated manufacturer payments should be reflected in best price and AMP when PBMs have negotiated on behalf of third parties, CMS officials with responsibility for issuing program memoranda advised us that they could comment only on specific situations. They stated that financial arrangements among entities in the market are complex and always changing; in their view, the market is too complicated for them to issue general policy guidance that could cover all possible cases. Rather, these officials told us that they make determinations about PBM payments on a case-by-case basis, but only when manufacturers contact them regarding this issue.

Within the current structure of the rebate formula, additional guidance on how to account for manufacturer payments to PBMs could affect the rebates paid to states, although whether rebates would increase or decrease as a result, and by how much, is uncertain. Because of the structure of the rebate formula, any change in the determination of best price and AMP could raise or lower rebates for any given drug, depending on how the change affects the relationship between those prices. Incorporating PBM-negotiated manufacturer payments into the rebate determination could decrease the unit rebate amount for a drug if, for example, it reduced AMP but had no effect on best price.[44] Alternatively, if such a change increased the difference between AMP and best price for a drug, the unit rebate amount could increase.[45]

[42]Medicaid Drug Rebate Program Release No. 28, April 1997, and Medicaid Drug Rebate Program Release No. 29, June 1997.

[43]Medicaid Drug Rebate Program Release No. 30, September 1997.

[44]A change in guidance regarding how PBM payments should be reflected in best price would not necessarily affect the best price for every drug because best price can be determined by a transaction that is not related to PBM payments.

[45]A greater difference between best price and AMP would not always yield a larger rebate. For example, if the difference between the two prices increased but remained less than 15.1 percent of AMP, the unit rebate amount would still be based on the 15.1 percent of AMP minimum.

Conclusions

The importance of Medicaid rebates to states has grown as Medicaid spending on prescription drugs has risen. To determine the level of rebates that manufacturers pay to states, the rebate program relies on manufacturer-reported prices, which are based on the prices and financial concessions available in the private pharmaceutical market. CMS, however, has not provided clear program guidance for manufacturers to follow when determining those prices. This has hampered OIG's efforts to audit manufacturers' methods and reported prices. Furthermore, as the private market has continued to evolve, the rebate program has not adequately addressed how more recent financial arrangements, such as those between manufacturers and PBMs, should be accounted for in manufacturers' reported prices. In addition, oversight by CMS and OIG has been inadequate to ensure that manufacturer-reported prices and methods are consistent with the law, rebate agreement, and CMS program memoranda. Because rebates rely on manufacturer-reported prices, adequate program oversight is particularly important to ensure that states receive the rebates to which they are entitled.

Recommendations for Executive Action

To help ensure that the Medicaid drug rebate program is achieving its objective of controlling states' Medicaid drug spending, we recommend that the Administrator of CMS take the following two actions:

- Issue clear guidance on manufacturer price determination methods and the definitions of best price and AMP, and update such guidance as additional issues arise.
- Implement, in consultation with OIG, systematic oversight of the price determination methods employed by pharmaceutical manufacturers and a plan to ensure the accuracy of manufacturer-reported prices and rebates paid to states.

Agency and Industry Comments and Our Response

We received written comments on a draft of this report from HHS, which incorporated comments from CMS and OIG. (See app. I.) HHS concurred, in part, with our recommendation that CMS issue clear guidance on price determination methods, noting agreement that such guidance would help manufacturers, particularly with regard to accounting for sales to PBMs. HHS stated that those issues would be examined and an assessment made about where more guidance was needed. HHS noted that effort had been devoted to providing guidance and that CMS would examine the resources allocated to its review capabilities. In responding to our discussion of the changing pharmaceutical market, however, the comments noted that guidance could not address all current and potential arrangements in the

pharmaceutical market and therefore case-by-case guidance would continue to be necessary to address specific situations. In responding to our discussion of manufacturers' price determination methods, the comments stated that a response to our conclusion that some manufacturers' practices could lower or raise rebates was not possible because we did not provide sufficient information on manufacturers' practices. We believe that accurate and timely guidance could reduce the need for case-by-case determinations. Although we cannot present the detailed assumptions that various manufacturers made in interpreting and implementing program guidance, because that information is proprietary, we did provide examples of the different price determination methods and assumptions that can affect best price and AMP and, therefore, rebates.

HHS concurred, in part, with our recommendation that CMS should implement systematic oversight of manufacturers' price determination methods and a plan to ensure the accuracy of reported prices and rebates. While the comments noted that requests from manufacturers to revise their price determination methods were reviewed for adherence to current policies, the comments disagreed with our conclusion that current oversight does not ensure that prices or methods are consistent with program criteria. The comments stated that CMS subjects manufacturer-supplied data to systematic edits, that CMS has increased its referrals to OIG to examine recalculation requests, and that a regulation limiting the time frames for recalculations and recordkeeping has been published. The comments also referred to previous OIG reviews of manufacturer practices and the plans to continue such reviews. In our draft, we noted the data edits that CMS conducts, which help ensure the completeness of the data. The systematic edits, however, do not ensure the accuracy of the data. Specifically, while the edits address, for example, whether price data are submitted in the correct format, they do not ensure that prices are consistent with program criteria or that corrected prices are submitted when necessary. We also noted OIG's ongoing work on the Medicaid drug rebate program. However, CMS's referrals to OIG are made only when a manufacturer requests that its rebates be recalculated, so there is no ongoing review of the methods used by manufacturers. Finally, we also noted in the draft the recently issued regulation, which did not address all aspects of the program, such as determinations of best price and AMP. The actions cited in the HHS comments do not constitute adequate oversight of a program that relies on manufacturer-submitted data to determine substantial rebates owed to state Medicaid programs.

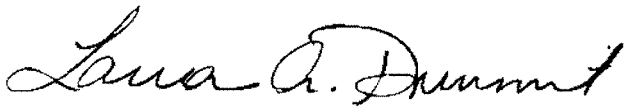
Representatives from all the manufacturers that supplied us data were invited to review and provide oral comments on portions of the draft report, including the background and our discussion of manufacturers' price determination methods. Representatives from five of the manufacturers indicated that administrative fees that manufacturers pay to PBMs do not necessarily need to be considered in the determination of best price and AMP. Some argued that the fee is a payment for services rendered and not a discount or rebate that would affect prices. Some manufacturers also noted that we did not address payments to PBMs when they are not acting as mail-order pharmacies. Others noted that CMS's guidance with respect to payments to PBMs is particularly unclear and that CMS's guidance has not addressed recent changes in the pharmaceutical market. Six of the manufacturers took issue with our discussion of the treatment of prompt payment discounts involving a chargeback arrangement. Several stated that CMS has not indicated that the prompt payment discount must be accounted for in the manner we described. Some manufacturers noted that they treat the situation we highlighted as two unrelated transactions to two separate purchasers, so they do not need to combine both price reductions when determining best price and AMP. Finally, six commented on the lack of clear guidance on various aspects of determining best price and AMP. Some manufacturers stated that program memoranda, which are a common CMS method of issuing guidance for the rebate program, do not have to be followed because they are not regulations.

In response to manufacturers' comments, we clarified our discussion of administrative fees paid to PBMs when they act as a mail-order pharmacies. We state that administrative fees may resemble volume-based discounts when PBMs take possession of drugs. The manufacturers did not have the opportunity to review our discussion of the changing pharmaceutical market, which addresses the broader role of PBMs in negotiating for third-party payers. With respect to our discussion of prompt payment discounts involving a chargeback arrangement, we observed in the draft that manufacturers differed in how they accounted for price reductions when determining best price and AMP, and we have clarified and expanded that discussion based on the comments we received.

Both HHS and the manufacturers also provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its date. We will then send copies of this report to the Secretary of Health and Human Services, the Administrator of CMS, the Acting Inspector General of Health and Human Services, and other interested parties. We will also provide copies to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please call Marjorie Kanof at (202) 512-7114. Major contributors to this report are listed in appendix II.



Laura A. Dummit
Director, Health Care—Medicare Payment Issues

Appendix I: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

[redacted] 5 [redacted]

Ms. Laura A. Dummit
Director, Health Care—Medicare Payment Issues
U.S. Government Accountability Office
Washington, DC 20548

Dear Ms. Dummit:

Enclosed are the Department's comments on your draft report entitled, "Medicaid Drug Rebate Program Inadequate Oversight Raises Concerns About Rebates Paid to States" (GAO-05-102). The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided several technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

Daniel R. Levinson

Daniel R. Levinson
Acting Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for Government Accountability Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT, "MEDICAID DRUG REBATE PROGRAM—INADEQUATE OVERSIGHT RAISES CONCERNS ABOUT REBATES PAID TO STATES" (GAO-05-102)

The Department of Health and Human Services (HHS) appreciates the opportunity to review the U.S. Government Accountability Office's (GAO's) draft report. This report looks at the Medicaid drug rebate program that requires participating drug manufacturers to submit to the Centers for Medicare & Medicaid Services (CMS) the "average manufacturer price" (AMP) and for brand name drugs, the "best price" (BP) of drugs on a quarterly basis. Specifically, the report examines: (1) Federal oversight of manufacturer-reported AMPs and BPs; (2) how manufacturers' methods of determining AMP and BP could have affected the rebates they paid to State Medicaid programs; and (3) how the rebate program reflects financial concessions available in the private market.

As discussed in the report, section 4401 of the Omnibus Budget Reconciliation Act of 1990 added section 1927 to the Social Security Act under which drug manufacturers must sign rebate agreements for their outpatient drugs to be covered under the Medicaid Program.

The national rebate agreement requires manufacturers to provide certain pricing information to CMS, and in turn, CMS reports a unit rebate amount to the States. The manufacturers receive information from the States on the total number of dosage units of each covered outpatient drug paid by the State under the Medicaid State plan during the quarter. The manufacturers then remit to the State a rebate payment based on the number of units paid for and the unit rebate amount.

GAO Recommendation 1

To help ensure that the Medicaid drug rebate program is achieving its objective of controlling States' Medicaid drug spending, we recommend that the Administrator of CMS take the following two actions:

- ***Issue clear guidance on manufacturer price determination methods and the definitions of BP and AMP, and update such guidance as additional issues arise.***

HHS Response 1

We concur in part. While substantial time and effort have gone into providing accurate and timely policy guidance, CMS agrees that clarifying existing guidance, including addressing sales to Pharmacy Benefit Managers (PBMs) in calculating AMP and BP, will be helpful to manufacturers. Going forward, we will be examining these issues in greater

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detail. We will work to assess where more guidance is needed by examining those instances where manufacturers did not follow the current guidance.

GAO Recommendation 2

- ***Implement, in consultation with OIG, systematic oversight of the price determination methods employed by pharmaceutical manufacturers and a plan to ensure the accuracy of manufacturer-reported prices and rebates paid to States.***

HHS Response 2

We concur in part. As the GAO report notes, the Office of the Inspector General (OIG) has ongoing responsibility for audits for the Medicaid program. While we currently review requests from manufacturers to revise their methodologies for determining AMP and BP, this is a review of adherence to the current policy. We continue to work with OIG to provide policy guidance to them to conduct audits of manufacturers' calculations of AMP and BP. We defer to OIG concerning the number and level of audits that are possible given their resources. CMS will also examine its own current allocation of resources pertaining to verifying the accuracy of AMPs and BPs for drugs. It would be of assistance to CMS in examining its internal resource allocation if GAO could provide additional detail in the final report information about the time it took it to review records on 135 drugs, and the additional time it believes it would have taken to conduct a review detailed enough to draw conclusions about the accuracy of the AMPs and BPs reported for these drugs.

We note, however, that GAO did not develop firm conclusions about the accuracy of AMPs and BPs of the 135 drugs for the 13 manufacturers for the last two quarters of 2000. GAO neither reviewed nor provided an estimate of the resources that would be needed to review the full compliment of Medicaid drugs on an ongoing basis.

The following are HHS's responses to the GAO Findings in the draft report:

GAO Finding*: *Current Program Oversight does not ensure that manufacturer-reported prices or price determination methods are consistent with program criteria.

GAO concludes that CMS's and OIG's oversight of manufacturer-reported price determination methods does not ensure that those prices or methods are consistent with program criteria. CMS disagrees with this conclusion. CMS applies systematic edits to data received from manufacturers and seeks correction of data that fail these edits.

As a growing number of manufacturers have proposed to modify their methodologies for calculating the AMP and BP in recent years, CMS has increased the number of manufacturers referred to OIG for potential onsite reviews. We also published a regulation to impose a 3-year time limitation for manufacturers to recalculate and report

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data to CMS on AMP and BP and to establish a 10-year recordkeeping requirement for manufacturers to retain pricing records under the Medicaid drug rebate program.

***GAO Finding:* Manufacturer price determination methods varied: Some could have lead to lower rebates.**

GAO concludes that there is considerable variation in the methods that manufacturers use to determine AMP and BP. The GAO draft report does not provide specific discussion regarding the varying assumptions that were made by manufacturers or whether the manufacturers requested a clarification of their assumptions from CMS. Without more information from GAO, it is impossible for CMS to respond to this finding.

GAO also noted that in some cases manufacturers made assumptions that could have caused manufacturers to overstate their rebate liability. However, absent sufficient and specific information to review such assumptions, we find that there is insufficient information to question the reasonableness of these assumptions.

***GAO Finding:* The rebate program does not clearly address certain financial concessions negotiated by PBMs.**

The report notes that pharmacy benefit manager (PBM) price concessions are a recent development in drug pricing and concludes that the current program instructions do not clearly address certain financial concessions by PBMs. In particular, the report states that the rebate program does not clearly address certain concessions that are negotiated by PBMs on behalf of third parties. As noted in the GAO report, CMS has issued program releases and guidance regarding the appropriate treatment of PBMs.

As stated above in our response to GAO's first recommendation, we agree that further guidance would be helpful. In fact, we are developing such guidance. We are concerned, however, that even the best general guidance cannot address all current and potential arrangements and that it will continue to be necessary for us to look at situations on a case-by-case basis.

GAO Conclusion

In addition, oversight by CMS and OIG has been inadequate to ensure that manufacturer-reported prices and methods are consistent with the law, rebate agreement and program guidance. Because rebates rely on manufacturer-reported prices, adequate program oversight is particularly important to ensure that states receive the rebates to which they are entitled.

OIG has done a great deal of work on the Medicaid drug rebate program, with a particular emphasis on manufacturer-reported data and methods. Recommendations were made accordingly. Our fiscal year 2005 work plan shows that work continues on this topic with a number of reviews planned and underway. We note, too, that OIG does not exercise program-operating responsibilities with respect to securing consistent

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manufacturer-reported prices and methods, so it would be misleading to imply that OIG can "ensure" such program compliance.

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Appendix II: GAO Contact and Staff Acknowledgments

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Acknowledgments

Major contributors to this report were Robin Burke, Martha Kelly, Ann Tynan, Helen Desaulniers, Julian Klazkin, and Jennie Apter.

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