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MEDICAID DRUG REBATE PROGRAM

Inadequate Oversight Raises Concerns about Rebates Paid to States

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Highlights

Highlights of GAO-05-850T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

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. GAO was asked to discuss issues relating to the rebate program and in February 2005 issued a report, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States* (GAO-05-102). For that report, GAO reviewed program guidance and OIG reports and conducted an analysis of rebates for brand name drugs. This testimony is based on the February 2005 report.

What GAO Recommends

In its February 2005 report, GAO recommended that CMS issue clear, updated guidance on manufacturer price determination methods and price definitions. It also recommended 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 acknowledged HHS oversight actions but did not believe they ensured accurate rebates to states.

www.gao.gov/cgi-bin/getrpt?GAO-05-850T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Kathleen King at (202) 512-7118.

What GAO Found

As noted in the February 2005 report, GAO found that 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 and only reviews price determination methods when manufacturers request recalculations of prior rebates. In several reports, 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 manufacturer-reported prices, including a lack of clear guidance on how AMP should be calculated. GAO noted that although in some cases OIG found problems with manufacturers' price determination methods and prices, CMS had not followed up with manufacturers to make sure that problems had been resolved.

GAO also found considerable variation in the methods that manufacturers used to determine best price and AMP. In some cases, manufacturers' assumptions could have lowered rebates; in other cases, their assumptions could have raised rebates. 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. GAO found that manufacturers made varying assumptions about which sales and prices to include and exclude from their determinations of best price and AMP. Manufacturers also differed in how they accounted for certain price reductions, fees, and other transactions when determining best price and AMP.

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 negotiated by pharmacy benefit managers (PBM) on behalf of third-party payers. 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 when determining best price and AMP. Additional guidance on how to account for these payments could affect rebates, although whether rebates would increase or decrease as a result, and by how much, is uncertain.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss our report entitled *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, which we issued in February 2005.[1] Prescription drug spending accounts for a substantial and growing share of state Medicaid program outlays. 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 recent years, the importance of Medicaid rebates to states has grown as Medicaid spending on prescription drugs has risen. From fiscal year 2000 to 2003, Medicaid drug spending increased at an annual average rate of 18 percent, while Medicaid spending as a whole grew 10 percent annually during that period. In fiscal year 2003, Medicaid drug expenditures were $33.8 billion out of $273.6 billion in total Medicaid spending; under the rebate program, manufacturers paid rebates to states of about $6.5 billion for covered outpatient drugs.[3,4]

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

[1]See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005).

[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.

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.[5] 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) administers and oversees the rebate program, entering into rebate agreements with manufacturers,[6] 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 the Department of Health and Human Services' (HHS) Office of Inspector General (OIG).

In this testimony, I will discuss our February 2005 report, in which we addressed (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.

In carrying out our work, we reviewed the rebate statute, the standard rebate agreement between CMS and participating manufacturers, CMS program memoranda, OIG reports on the rebate program, and market literature; interviewed officials from CMS and OIG; and conducted an analysis of rebates for brand name drugs, for which 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

[5]This testimony 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.

[6]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.

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 spending, the results of our analysis cannot be generalized. We performed our work from December 2003 through January 2005 in accordance with generally accepted government auditing standards.

In brief, we reported in February 2005 that 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. We found that CMS conducts only limited checks for reporting errors in manufacturer-reported drug prices and only reviews price determination methods when manufacturers request recalculations of prior rebates. In addition, OIG reported that its review efforts were hampered by unclear CMS guidance on how manufacturers are to determine AMP and by a lack of manufacturer documentation. Although OIG in some cases identified problems with manufacturers' price determination methods and reported prices, CMS had not followed up with manufacturers to make sure that those problems had been resolved. We also found considerable variation in the methods that the manufacturers we reviewed used to determine best price and AMP. In some cases, manufacturers' assumptions could have lowered rebates; in other cases, their assumptions could have raised rebates. 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. We found that manufacturers made varying assumptions about which sales and prices to include and exclude from their determinations of best price and AMP. We also found that manufacturers differed in how they accounted for certain price reductions, fees, and other transactions when determining best price and AMP. Finally, we found that the rebates that manufacturers pay to states are based on prices and financial concessions that manufacturers 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 concessions that are negotiated by pharmacy benefit

managers (PBM) on behalf of third-party payers—concessions that are a relatively new development in the market.

We concluded that although the rebate program relies on manufacturer-reported prices to determine the level of rebates that manufacturers pay to states, CMS has not provided clear program guidance for manufacturers to follow when determining those 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. We recommended that CMS take several steps to improve program guidance and oversight, namely, to issue clear guidance on manufacturer price determination methods and the definitions of best price and AMP; update such guidance as additional issues arise; and 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. HHS agreed with the importance of guidance to manufacturers, but disagreed with our conclusion that there has been inadequate program oversight. We acknowledged HHS's oversight actions, but stated that HHS oversight does not adequately ensure the accuracy of manufacturer-reported prices and rebates paid to states. Some of the manufacturers that supplied data for the report raised concerns about our discussion of certain methods they used to determine rebates, and 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.

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 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 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. The private market also includes PBMs, which manage

prescription drug benefits for third-party payers and may also operate mail-order pharmacies.[7]

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,[8] CMS has issued program memoranda[9] in order to provide further guidance to manufacturers regarding how to determine best price and AMP.[10] 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.[11] As a result, price determination methods may vary across manufacturers, particularly with respect to which transactions they consider when determining best price and AMP.

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.[12] Best price is required to be reduced to account for cash

[7]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).

[8]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* 69 *Fed. Reg.* 68815 (2004), 68 *Fed. Reg.* 51912 (2003).

[9]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.

[10]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.

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

[12]*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.

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,[13] 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.[14] 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.[15] 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.

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.[16] The

[13]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.

[14]*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."

[15]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).

[16]*See* 42 U.S.C. §1396r-8(c)(1).

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.

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 because of, for example, improper inclusion or exclusion of certain transactions. In 2003, CMS issued a final rule that, effective January 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.[17]

[17]The 2003 final rule addressed the time frame for reporting price adjustments to CMS and the time frame for retaining documentation of reported prices. *See* 68 *Fed. Reg.* 51912, 55527 (2003).

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

As we reported in February 2005, 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. In addition, OIG reported that its review efforts had been hampered by unclear CMS guidance on how to determine AMP and by a lack of manufacturer documentation. Although OIG in some cases identified problems with manufacturers' price determination methods and reported prices, CMS had not followed up with manufacturers to make sure that those problems were resolved.

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 ensure that, for example, prices are submitted in the correct format and that the reported prices are for drugs covered by Medicaid. When data checks indicate a potential reporting error, CMS asks the manufacturer for corrected drug prices, but CMS does not have a mechanism in place to track whether the manufacturer submits 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. For example, CMS notifies a manufacturer if the unit rebate amount for a drug deviates from that of the prior quarter by more than 50 percent. It would be up to that manufacturer to indicate whether the underlying reported prices were correct. If the manufacturer determined that there were problems with the reported price—for example, typographical errors such as misplaced decimals—it would send corrected data to CMS.[18] If the manufacturer did not send revised pricing data to CMS, then the unit rebate amount would remain the same.

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.

[18]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.

Furthermore, CMS does not generally check to ensure that manufacturers' methods are consistent with the rebate statute and rebate agreement, but rather reviews the methods 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. CMS requires the manufacturer to submit both its original and its revised methods when requesting a recalculation of prior rebates so that the agency can evaluate whether the revised methods are consistent with the rebate statute, rebate agreement, and program memoranda. Recalculations can involve substantial amounts of money; for example, six approved recalculations we examined reduced prior rebates to states by a total of more than $220 million.

In reports on its audits of manufacturer-reported prices, OIG stated that its efforts were hampered by unclear CMS guidance on determining AMP and by a lack of manufacturer documentation. 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.[19] OIG could not evaluate manufacturers' methods for determining 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.[20]

In its second review of manufacturer-reported prices, in 1995 OIG attempted to verify one manufacturer's recalculation request. While OIG reported that it could not complete its analysis because of inadequate

[19]See HHS OIG, *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).

[20]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; as we reported, CMS officials told us that the agency had no plans to promulgate any such regulation in the near future. Instead, CMS has issued several program memoranda intended to provide guidance on how manufacturers should calculate AMP.

manufacturer documentation,[21] 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 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.[22] 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 like HMOs that repackage or relabel drugs under their own names—in their

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

[22]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.

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.[23] In July 2000, CMS issued an additional program memorandum to manufacturers stating that sales to an HMO should be considered in best price determinations regardless of whether the HMO was a repackager.[24] In 2001, OIG reported that states lost $80.7 million in rebates in fiscal year 1999 because of improperly excluded drug sales to HMO repackagers.[25] 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.

As we reported, 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.

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

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

[25]See HHS OIG, *Medicaid Drug Rebates: Sales to Repackagers Excluded from Best Price Determinations*, A-06-00-00056 (Washington, D.C.: March 2001).

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

As we reported, we found considerable variation in the methods that the manufacturers we reviewed 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 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 and prices to include and exclude from their determinations of best price and 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.

We also found that manufacturers also differed in how they accounted for certain price reductions, fees, and other transactions when determining best price and AMP. For example, manufacturers differed in how they accounted for certain transactions involving prompt payment discounts. In some cases, manufacturers' assumptions could have reduced rebates below what they otherwise would have been. In other cases, manufacturers' methods could have raised rebates. For example, 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 could have increased rebates to states.[26]

[26]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

As we reported, 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 they 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, such as employer-sponsored health plans and other health insurers. 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. 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.

Certain manufacturer financial concessions that are negotiated by PBMs on behalf of their third-party payer clients 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 payer clients' costs for prescription drugs.[27] (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.) The basis of these PBM-negotiated manufacturer payments varies. 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. 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. 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.

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

[27] GAO-03-196.

covered lives and providing a more limited range of services—such as claims processing—for their clients. Since then, PBMs' role has grown substantially, 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. 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;[28] further, recent public financial information suggests that manufacturer payments to PBMs as a whole are substantial and key to PBMs' profitability.

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 reflected in best price and AMP.[29] 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.[30] 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 on 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.

[28]GAO-03-196.

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

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

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.[31] Alternatively, if such a change increased the difference between AMP and best price for a drug, the unit rebate amount could increase.[32]

Concluding Observations

As we stated in our report, because the rebate program relies on manufacturer-reported prices, adequate program oversight is important to ensure that states receive the rebates to which they are entitled. However, CMS has not provided clear program guidance for manufacturers to follow when determining prices, and this has hampered OIG's efforts to audit manufacturers' methods and 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. As a result, we recommended that CMS take several steps to improve program guidance and oversight, namely, to issue clear guidance on manufacturer price determination methods and the definitions of best price and AMP; update such guidance as additional issues arise; and 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. We believe that these actions could help ensure that the Medicaid drug rebate program achieves its objective of controlling states' Medicaid drug spending. HHS agreed with the importance of guidance to manufacturers, but disagreed with our conclusion that there has been inadequate program oversight. We

[31]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.

[32]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.

acknowledged HHS's oversight actions, but stated that HHS oversight does not adequately ensure the accuracy of manufacturer-reported prices and rebates paid to states. Some of the manufacturers that supplied data for the report raised concerns about our discussion of certain methods they used to determine rebates, and we clarified our discussion of manufacturers' price determination methods.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions you or other Members of the Subcommittee may have.

Contact and Staff Acknowledgments

For further information about this testimony, please contact Kathleen King at (202) 512-7118. Debra Draper, Robin Burke, and Ann Tynan also made key contributions to this statement.

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