



Highlights of [GAO-05-102](#), a report to congressional requesters

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.

MEDICAID DRUG REBATE PROGRAM

Inadequate Oversight Raises Concerns about Rebates Paid to States

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.