



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.

MEDICAID DRUG REBATE PROGRAM

Inadequate Oversight Raises Concerns about Rebates Paid to States

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.