January 2020

340B DRUG DISCOUNT PROGRAM

Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement

GAO Highlights

Highlights of GAO-20-212, a report to congressional requesters

Why GAO Did This Study

Covered entities can receive substantial discounts on outpatient drugs through the 340B Program, an estimated 25 to 50 percent of the cost of the drugs, according to HRSA. Additionally, Medicaid drug rebates are an important source of savings for states and the federal government, saving more than $36 billion in fiscal year 2018. However, ensuring that manufacturers are not subject to both discounts requires coordination within HHS, and between covered entities and states. GAO was asked to provide information on the prevention of duplicate discounts. Among other things, this report examines HHS's efforts to ensure compliance with the prohibition on duplicate discounts. GAO reviewed documentation, including federal policies and those from all 50 states and Washington, D.C. on preventing duplicate discounts. GAO also interviewed officials from CMS, HRSA, and 16 covered entities from four states selected to obtain variation in the types of entities and other factors.

What GAO Recommends

GAO is making three recommendations, namely that: 1) CMS ensure that state Medicaid programs have written policies and procedures that are designed to prevent duplicate discounts and forgone rebates; and that HRSA 2) incorporate covered entities' compliance with state policies into its audits, and 3) require covered entities to work with manufacturers regarding repayment of identified duplicate discounts in managed care. HHS agreed with the recommendation to CMS, but disagreed with those to HRSA. GAO continues to believe these are needed to improve oversight and the integrity of the 340B Program, as explained in the report.

View GAO-20-212. For more information, contact Debra A. Draper at (202) 512-7114 or DraperD@gao.gov

What GAO Found

The 340B Drug Pricing Program (340B Program) and the Medicaid Drug Rebate Program require manufacturers to provide discounts on outpatient drugs in order to have their drugs covered by Medicaid. These discounts take the form of reduced sales prices for covered entities participating in the 340B Program—eligible hospitals and federal grantees—and rebates on drugs dispensed to Medicaid beneficiaries, shared by states and the federal government. However, federal law prohibits subjecting manufacturers to "duplicate discounts" in which drugs provided to Medicaid beneficiaries are subject to both 340B Program discounted prices (i.e., are 340B drugs) and Medicaid rebates. To prevent duplicate discounts, state Medicaid programs must know when covered entities dispense 340B drugs to Medicaid beneficiaries, so the state programs can exclude those drugs from their Medicaid rebate requests.

GAO found that limitations in the Department of Health and Human Services's (HHS) oversight of the 340B and Medicaid Drug Rebate Programs may increase the risk that duplicate discounts occur.

- HHS's Centers for Medicare & Medicaid Services (CMS) conducts limited oversight of state Medicaid programs' efforts to prevent duplicate discounts. CMS does not track or review states' policies or procedures for preventing duplicate discounts, and GAO found that the procedures states used to exclude 340B drugs are not always documented or effective at identifying these drugs. As a result, CMS does not have the information needed to effectively ensure that states exclude 340B drugs from Medicaid rebate requests. CMS also does not have a reasonable assurance that states are seeking rebates for all eligible drugs, potentially increasing costs to state and federal governments due to forgone rebates.
- HHS's Health Resources and Services Administration's (HRSA) audits of covered entities do not include reviews of states' policies and procedures for the use and identification of 340B drugs. As a result, the audits are unable to determine whether covered entities are following state requirements, and taking the necessary steps to comply with the prohibition on subjecting manufacturers to duplicate discounts.
- GAO reported in 2018 that HRSA had not issued guidance on, and did not audit for, duplicate discounts in Medicaid managed care and recommended the agency do so as the majority of Medicaid enrollees, prescriptions, and spending for drugs are in managed care. HRSA is working to determine next steps to address these recommendations. In this report, GAO found that, unlike Medicaid fee-for-service, when duplicate discounts in Medicaid managed care claims are identified, HRSA does not require covered entities to address them or work with manufacturers to repay them. As a result, manufacturers may be subject to duplicate discounts for drugs provided under managed care.

Given these limitations in federal oversight, HHS does not have reasonable assurance that states and covered entities are complying with the prohibition on duplicate discounts.