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PRESCRIPTION DRUGS

Oversight of Drug Pricing in Federal Programs

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Highlights

Highlights of GAO-07-481T, a testimony before the Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

Several federal programs help pay for or reduce the costs of prescription drugs for eligible individuals and entities. Three examples are the Medicaid drug rebate program, part of the joint federal-state Medicaid program that finances medical services for certain low-income people; the 340B drug pricing program, which provides discounted drug prices to certain eligible entities such as community health centers; and the Medicare Part D program, which provides a Medicare drug benefit for the elderly and certain disabled people. The price information drug manufacturers report under these federal programs affects related federal spending. Spending is also affected by the extent to which federal oversight ensures the accuracy of this information.

GAO was asked to provide information related to the oversight of prescription drug pricing practices that affect these federal programs. This testimony focuses on the oversight of drug pricing related to the three programs and the implications for future congressional oversight. This testimony is based on recent GAO reports examining these programs and related work by the Department of Health and Human Services Office of Inspector General and others.

www.gao.gov/cgi-bin/getrpt?GAO-07-481T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact John Dicken at (202) 512-7119 or dickenj@gao.gov.

What GAO Found

Regarding the Medicaid drug rebate program, GAO and others have reported inadequacies in the Centers for Medicare & Medicaid Services' (CMS) oversight of the prices manufacturers report to CMS to determine the statutorily required rebates owed to states. For example, GAO and others have reported a lack of clarity in CMS's guidance to manufacturers for calculating these prices. Several recent legal settlements under which manufacturers agreed to pay hundreds of millions of dollars to states because they were alleged to report inaccurate prices to CMS highlight the potential for abuse under the program. CMS recently issued a proposed rule intended to provide more clarity to manufacturers in determining the prices they report.

GAO and others have reported inadequacies in the Health Resources and Services Administration's (HRSA) oversight of the 340B drug pricing program and problems related to the lack of transparency in the maximum prices, called 340B prices, charged to eligible entities. GAO reported that HRSA did not routinely compare the prices actually paid by certain eligible entities with the 340B prices and that many of these eligible entities paid prices higher than the 340B prices. Because these prices are not disclosed to the entities, the entities are unable to determine whether the prices they pay are at or below these prices. In addition, because 340B prices are based on information reported by drug manufacturers for the Medicaid drug rebate program, inaccuracies under that program affect these prices. HRSA has made changes to its oversight of the program intended to address some of these concerns.

The Medicare Part D program shares in common with other federal programs certain features that led to federal agency oversight challenges. For example, Part D relies on multiple private organizations to report to CMS certain price concessions from manufacturers, similar to the Medicaid drug rebate program. Also, Part D relies on CMS's oversight to ensure that price information reported to it by private organizations are accurate, similar to the Medicaid drug rebate and 340B drug pricing programs. Other features of Part D, such as its reliance on contracts with private insurers to provide drug coverage to beneficiaries through a complex set of relationships and transactions with private entities, also suggest potential oversight challenges.

Oversight inadequacies, inaccurate prices, lack of price transparency, and the potential for abuse suggest areas the Committee may wish to consider as it develops its oversight agenda. The Committee may wish to consider the extent to which CMS and HRSA will systematically take steps to ensure the accuracy of prices reported and charged by private organizations that participate in federal programs. The Committee may also wish to consider the extent to which federal agencies will effectively monitor for and detect abuses in the reporting of drug price information that affect these three federal programs.