

GAO Highlights

Highlights of [GAO-18-480](#), a report to congressional requesters

Why GAO Did This Study

Covered entities can provide 340B drugs to eligible patients and generate revenue by receiving reimbursement from patients' insurance. The number of pharmacies covered entities have contracted with has increased from about 1,300 in 2010 to nearly 20,000 in 2017. GAO was asked to provide information on the use of contract pharmacies. Among other things, this report: 1) describes financial arrangements selected covered entities have with contract pharmacies; 2) describes the extent that selected covered entities provide discounts on 340B drugs dispensed by contract pharmacies to low-income, uninsured patients; and 3) examines HRSA's efforts to ensure compliance with 340B Program requirements at contract pharmacies. GAO selected and reviewed a nongeneralizable sample of 30 contracts between covered entities and pharmacies, 20 HRSA audit files, and 55 covered entities to obtain variation in the types of entities and other factors. GAO also interviewed officials from HRSA and 10 covered entities.

What GAO Recommends

GAO is making seven recommendations, including that HRSA's audits assess for duplicate discounts in Medicaid managed care, and HRSA require information on how entities determined the scope of noncompliance and evidence of corrective action prior to closing audits. HHS agreed with four of the recommendations, but disagreed with three recommendations, which GAO continues to believe are warranted to improve HRSA's oversight as explained in the report.

View [GAO-18-480](#). For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

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DRUG DISCOUNT PROGRAM

Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement

What GAO Found

The 340B Drug Pricing Program (340B Program), which is administered by the U.S. Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA), requires drug manufacturers to sell outpatient drugs at a discount to covered entities so that their drugs can be covered by Medicaid. Covered entities include certain hospitals and federal grantees (such as federally qualified health centers). About one-third of the more than 12,000 covered entities contract with outside pharmacies—contract pharmacies—to dispense drugs on their behalf. GAO's review of 30 contracts found that all but one contract included provisions for the covered entity to pay the contract pharmacy a flat fee for each eligible prescription. The flat fees generally ranged from \$6 to \$15 per prescription, but varied by several factors, including the type of drug or patient's insurance status. Some covered entities also agreed to pay pharmacies a percentage of revenue generated by each prescription.

Thirty of the 55 covered entities GAO reviewed reported providing low-income, uninsured patients discounts on 340B drugs at some or all of their contract pharmacies. Of the 30 covered entities that provided discounts, 23 indicated that they pass on the full 340B discount to patients, resulting in patients paying the 340B price or less for drugs. Additionally, 14 of the 30 covered entities said they determined patients' eligibility for discounts based on whether their income was below a specified level, 11 reported providing discounts to all patients, and 5 determined eligibility for discounts on a case-by-case basis.

GAO found weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements at contract pharmacies, such as:

- HRSA audits do not fully assess compliance with the 340B Program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries. Specifically, manufacturers cannot be required to provide both the 340B discount and a rebate through the Medicaid Drug Rebate Program. However, HRSA only assesses the potential for duplicate discounts in Medicaid fee-for-service and not Medicaid managed care. As a result, it cannot ensure compliance with this requirement for the majority of Medicaid prescriptions, which occur under managed care.
- HRSA requires covered entities that have noncompliance issues identified during an audit to assess the full extent of noncompliance. However, because HRSA does not require all the covered entities to explain the methodology they used for determining the extent of the noncompliance, it does not know the scope of the assessments and whether they are effective at identifying the full extent of noncompliance.
- HRSA does not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing the audit. Instead, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed and that the entity came into compliance with 340B Program requirements.

Given these weaknesses, HRSA does not have a reasonable assurance that covered entities have adequately identified and addressed noncompliance with 340B Program requirements.