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Report to Congressional Requesters

January 2020

340B DRUG DISCOUNT PROGRAM

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

GAO-20-212

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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.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
FFS	fee-for-service
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
MEF	Medicaid Exclusion File

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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January 21, 2020

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Greg Walden
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Michael C. Burgess
Republican Leader
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable Brett Guthrie
Republican Leader
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

The 340B Drug Pricing Program (340B Program) and the Medicaid Drug Rebate Program require drug manufacturers to provide discounts on outpatient drugs in order to have their drugs covered by Medicaid.[1] For the 340B Program, administered by the U.S. Department of Health and Human Services's (HHS) Health Resources and Services Administration (HRSA), these discounts take the form of reduced sales prices for participating covered entities—eligible hospitals and federal grantees. The discounts, which HRSA estimates to be 25 to 50 percent of the cost of the drugs, are comparable to the rebates made available to state Medicaid programs through the Medicaid Drug Rebate Program, overseen by HHS's Centers for Medicare & Medicaid Services (CMS). While both covered entities and state Medicaid programs are eligible for

[1]42 U.S.C. §§ 256b, 1396r-8. Medicaid is a joint federal-state program that finances health care, including prescription drugs, for certain low-income and medically needy populations. Outpatient prescription drug coverage is an optional benefit in Medicaid but all states have elected to cover it.

these discounts, federal law prohibits subjecting drug manufacturers to duplicate discounts in which drugs provided to Medicaid beneficiaries are subject to both the 340B Program discounted price and a Medicaid rebate.[2]

To prevent duplicate discounts, covered entities and states must work together to identify when covered entities provide drugs purchased at discounted prices through the 340B Program to Medicaid beneficiaries so states can exclude those purchases from rebate requests sent to drug manufacturers. (In this report, we refer to the discounted price through the 340B Program as the 340B price, and to drugs purchased by covered entities at that price as 340B drugs.) States also need to know when the drugs provided to Medicaid beneficiaries by covered entities were not purchased at 340B prices, so they do not forgo rebates for which they are legally entitled, which may increase their costs, as well as that of federal taxpayers.

In recent years, the potential for duplicate discounts has increased due to substantial growth in the 340B Program and the expansion of the Medicaid Drug Rebate Program. Specifically, from 2010 to 2019, the number of covered entities participating in the 340B Program increased from nearly 9,700 to nearly 13,000. In addition, since a change in HRSA guidance allowed covered entities to have an unlimited number of contract pharmacies, there also has been a large increase in the number of contract pharmacies—outside pharmacies that covered entities contract with and pay to dispense 340B drugs on their behalf.[3] Specifically, the number of contract pharmacies increased from about 1,300 at the beginning of 2010 to around 23,000 in 2019. Furthermore, while the Medicaid Drug Rebate Program had historically been limited to drugs provided under Medicaid fee-for-service (FFS), in 2010, the Patient Protection and Affordable Care Act expanded the program by also requiring drug manufacturers to provide rebates for drugs provided under

[2]42 U.S.C. §§ 256b(a)(5)(A), 1396r-8(j)(1).

[3]The adoption and use of contract pharmacies in the 340B Program is governed by HRSA guidance, and in March 2010, HRSA issued final guidance allowing covered entities to have an unlimited number of contract pharmacies. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).

Medicaid managed care.[4] Since that time, total Medicaid drug rebates more than doubled from about $15 billion in fiscal year 2011 to more than $36 billion in fiscal year 2018.

In recent years, the HHS Office of Inspector General and others have identified challenges covered entities and states face in identifying 340B drugs provided to Medicaid beneficiaries, and thus in preventing duplicate discounts.[5] In addition, in a June 2018 report, we identified weaknesses in HRSA's oversight that impede its ability to ensure compliance with 340B Program requirements, including the prohibition on duplicate discounts.[6] We reported that HRSA had not issued guidance as to how covered entities should prevent duplicate discounts in Medicaid managed care and thus, did not include reviews of covered entities' processes to prevent duplicate discounts for drugs dispensed through Medicaid managed care in its audits of the entities. As a result, we found that drug manufacturers were at risk of providing duplicate discounts. We recommended that HRSA address these issues. HRSA concurred with our recommendations, and as of October 2019, reported that it was continuing to work to determine next steps to address them.

You asked us to examine stakeholders' efforts to prevent duplicate discounts under the 340B and Medicaid Drug Rebate Programs. In this report, we

[4]Pub. L. No. 111-148, § 2501(c), 124 Stat. 119, 308 (2010) (codified at 42 U.S.C. §§ 1396b(m)(2)(A)(xiii), 1396r-8(b)(1)). States provide Medicaid services through either FFS or managed care. Under FFS, states reimburse providers directly for each service delivered. Under managed care, states typically contract with managed care plans using a capitated payment model to provide a specific set of services to Medicaid beneficiaries (which could include drugs) and prospectively pays each plan a set amount per beneficiary per month to provide or arrange those services.

[5]See, for example, Department of Health and Human Services, Office of Inspector General, *State Efforts To Exclude 340B Drugs From Medicaid Managed Care Rebates*, Report Number OEI-05-14-00430 (Washington, D.C.: June 2016); National Association of Medicaid Directors, NAMD Working Paper Series, *Medicaid and the 340B Program: Alignment and Modernization Opportunities*, (Washington, D.C.: May 13, 2015); and Medicaid and CHIP Payment and Access Commission, Issue Brief, *The 340B Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact,* (Washington, D.C.: May 2018).

[6]GAO, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement,* GAO-18-480 (Washington, D.C.: June 21, 2018).

1. describe state Medicaid programs' policies on the use and identification of 340B drugs provided to their beneficiaries to prevent duplicate discounts; and
2. examine HHS's efforts, specifically those of CMS and HRSA, to ensure compliance with the prohibition on duplicate discounts in the Medicaid Drug Rebate and 340B Programs.

To describe state Medicaid programs' policies on the use and identification of 340B drugs provided to their beneficiaries to prevent duplicate discounts, we collected information from states and covered entities. Specifically, in January 2019, we sent a data collection instrument to all 50 states and the District of Columbia requesting documentation of, and information about, their policies related to 340B drugs.[7] The data collection instrument requested the states' policies related to the use and identification of 340B drugs in both Medicaid FFS and managed care for three different methods in which outpatient drugs can be dispensed to Medicaid beneficiaries.[8] We received responses from all states, and reviewed their available policies to determine whether they allowed covered entities to provide 340B drugs to beneficiaries covered under Medicaid FFS or managed care for each dispensing method, and how the state identified and excluded 340B drugs provided to such beneficiaries from rebate requests sent to drug manufacturers. For states that indicated they did not have written policies or procedures for using or identifying 340B drugs, we asked for a description of how they prevented duplicate discounts in practice.

In order to gain a more in-depth understanding of how states worked with covered entities to implement policies and procedures to prevent duplicate discounts, we also interviewed Medicaid officials from a nongeneralizable sample of four states. We selected the four states—Michigan, Oregon, Pennsylvania, and Texas—to obtain variation in factors such as the amount of Medicaid expenditures and rebates on outpatient drugs under both Medicaid FFS and managed care, and geographic location. In addition, we interviewed officials from a nongeneralizable sample of four covered entities located in each of the

[7]In this report, the term states refers to the 50 states and the District of Columbia.

[8]The three methods for dispensing outpatient drugs for which we requested information are (1) covered entities' in-house pharmacies, (2) contract pharmacies, and (3) provider-administered drugs—drugs that doctors and nurses administer to patients directly, such as during office visits.

four selected states (for a total of 16 covered entities) about their understanding of their individual states' policies and the covered entities' actions to prevent duplicate discounts.[9] We selected covered entities of various types that had either high quantities or dollar amounts of 340B drug purchases and that varied as to whether or not they were providing these drugs to Medicaid FFS beneficiaries.[10]

To examine HHS's efforts, specifically those of CMS and HRSA, to ensure compliance with the prohibition on duplicate discounts in the Medicaid Drug Rebate and 340B Programs, we reviewed relevant laws, policies, procedures, and guidance, including HRSA's audit procedures. In addition, we interviewed CMS and HRSA officials responsible for overseeing and administering the Medicaid Drug Rebate and 340B Programs, respectively, about their oversight of duplicate discounts, and any potential actions or initiatives the agencies were undertaking, such as updating or clarifying guidance for covered entities, states, and manufacturers. Additionally, as part of the interviews with the states and covered entities described earlier, we asked officials for their perspectives on federal guidance related to preventing duplicate discounts, and whether they believed any clarifications were needed. We also contacted and obtained information about federal oversight, including CMS's and HRSA's efforts to resolve disputes about duplicate discounts, from three drug manufacturers that had high 340B Program participation based on either total 340B drug sales in dollars or in units sold, as well as consultants that research duplicate discount issues on behalf of manufacturers, and a trade organization that represents drug manufacturers. (Appendix I provides information on manufacturers' efforts to detect and avoid duplicate discounts.) Finally, we evaluated CMS's and HRSA's guidance and oversight against federal internal control standards related to information and communication and monitoring.[11]

[9]Thirteen of the 16 covered entities we interviewed also provided us with their policy and procedure manuals on the use and identification of 340B drugs for Medicaid beneficiaries, and we reviewed these manuals to gain a better understanding of the entities' efforts to comply with state policies.

[10]HRSA has information on whether covered entities report using 340B drugs for Medicaid FFS beneficiaries, but does not have similar information related to Medicaid managed care.

[11]See GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

We conducted this performance audit from July 2018 to January 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The Medicaid Drug Rebate Program was established through the Omnibus Budget Reconciliation Act of 1990 and requires drug manufacturers to pay rebates to states on outpatient drugs as a condition of having their drugs covered by Medicaid.[12] The 340B Program, named for the statutory provision authorizing it in the Public Health Service Act, was created in 1992 following the enactment of the Medicaid Drug Rebate Program and allows covered entities to purchase outpatient drugs at discounted prices.[13] HRSA and CMS both have roles in overseeing compliance with the prohibition on duplicate discounts.

The Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries. Under the rebate program, drug manufacturers pay rebates to states as a condition for the federal contribution to Medicaid spending for the manufacturers' outpatient drugs. State Medicaid programs generally must cover all of the drugs of manufacturers that participate in the rebate program. Originally, rebates were available only for drugs paid for by the state on a FFS basis, but the Patient Protection and Affordable Care Act extended the program to outpatient drugs paid for under Medicaid managed care; there are more Medicaid enrollees, prescriptions, and spending for drugs under managed care than FFS.[14] The rebates received for both FFS and managed care are shared by the federal government and states.

[12]See Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (1990) (codified, as amended, at 42 U.S.C. § 1396r-8).

[13]42 U.S.C. § 256b.

[14]According to analysis from the Medicaid and CHIP Payment and Access Commission, in fiscal year 2018, 61 percent of Medicaid gross spending for drugs and 71 percent of Medicaid drug prescriptions were in managed care. Additionally, as of July 2017, about 69 percent of Medicaid enrollees received their medical care services through managed care.

The amount of Medicaid rebates for a drug is based on a statutory formula.[15] Using that formula CMS calculates a unit rebate amount for each drug and provides that amount to states so they can determine the amount of rebates to request.[16] Every quarter, each state multiplies the number of units of each drug it either paid for on a FFS basis or provided through its managed care plans by the CMS-provided unit rebate amount. For drugs provided under FFS, the state calculates the number of units based on drug claims it reimbursed, while states use drug utilization data provided by managed care plans to determine the number of units of each drug that were provided by the plans to Medicaid beneficiaries. Each state then sends rebate requests to each manufacturer reflecting the total quarterly amount of rebates owed for each of the manufacturer's drugs.[17] States are to exclude claims for 340B drugs from their rebate requests.

340B Program

Participation in the 340B Program is voluntary for both covered entities and drug manufacturers, but there are strong incentives for both to do so. Covered entities can realize substantial savings through the program's price discounts. In addition, covered entities can generate revenue to the extent that they can purchase 340B drugs for eligible patients whose insurance reimbursement exceeds the price paid. Incentives for participation by drug manufacturers are strong because they must participate in the 340B Program to receive Medicaid reimbursement for their drugs.

Covered entities generally become eligible for the 340B Program by qualifying as certain federal grantees or as one of six specified types of hospitals. Eligible federal grantees include federally qualified health centers, which provide comprehensive community-based primary and preventive care services to medically underserved populations, as well as certain other federal grantees, such as family planning clinics and Ryan

[15]See 42 U.S.C. § 1396r-8(c). See also 42 C.F.R. § 447.509 (2018).

[16]CMS uses drug pricing data provided by drug manufacturers to calculate the unit rebate amount for each drug.

[17]For each drug, the rebate request specifies, among other things, the unit rebate amount, the number of units Medicaid paid for, the amount of rebates claimed, and the number of prescriptions. The request does not have to separately list each prescription or drug claim for which the state is seeking a rebate.

White HIV/AIDS program grantees, among others.[18] Eligible hospitals include critical access hospitals—small, rural hospitals with no more than 25 inpatient beds; disproportionate share hospitals—general acute care hospitals that serve a disproportionate number of low-income patients; and four other types of hospitals.[19]

To participate in the 340B Program, covered entities must register with HRSA and annually recertify their continuing eligibility. Once their eligibility is approved by HRSA, covered entities can begin purchasing drugs from manufacturers at the 340B discounted prices. Covered entities may provide drugs, including 340B drugs, to patients through one or more dispensing methods. Specifically, covered entities may dispense these drugs through pharmacies—either through in-house pharmacies they own; through the use of contract pharmacy arrangements, in which they contract with outside pharmacies and pay them to dispense drugs on their behalf; or both. In addition, providers who work at covered entities, such as doctors and nurses, may administer 340B drugs to patients directly, such as during office visits. These are known as provider-administered drugs.

As a condition of participating in the 340B Program, covered entities must follow certain requirements. For example, they are prohibited from diverting a 340B drug to an individual who is not a patient of the covered entity. Covered entities are also prohibited from subjecting manufacturers to duplicate discounts.

Preventing Duplicate Discounts and Forgone Rebates

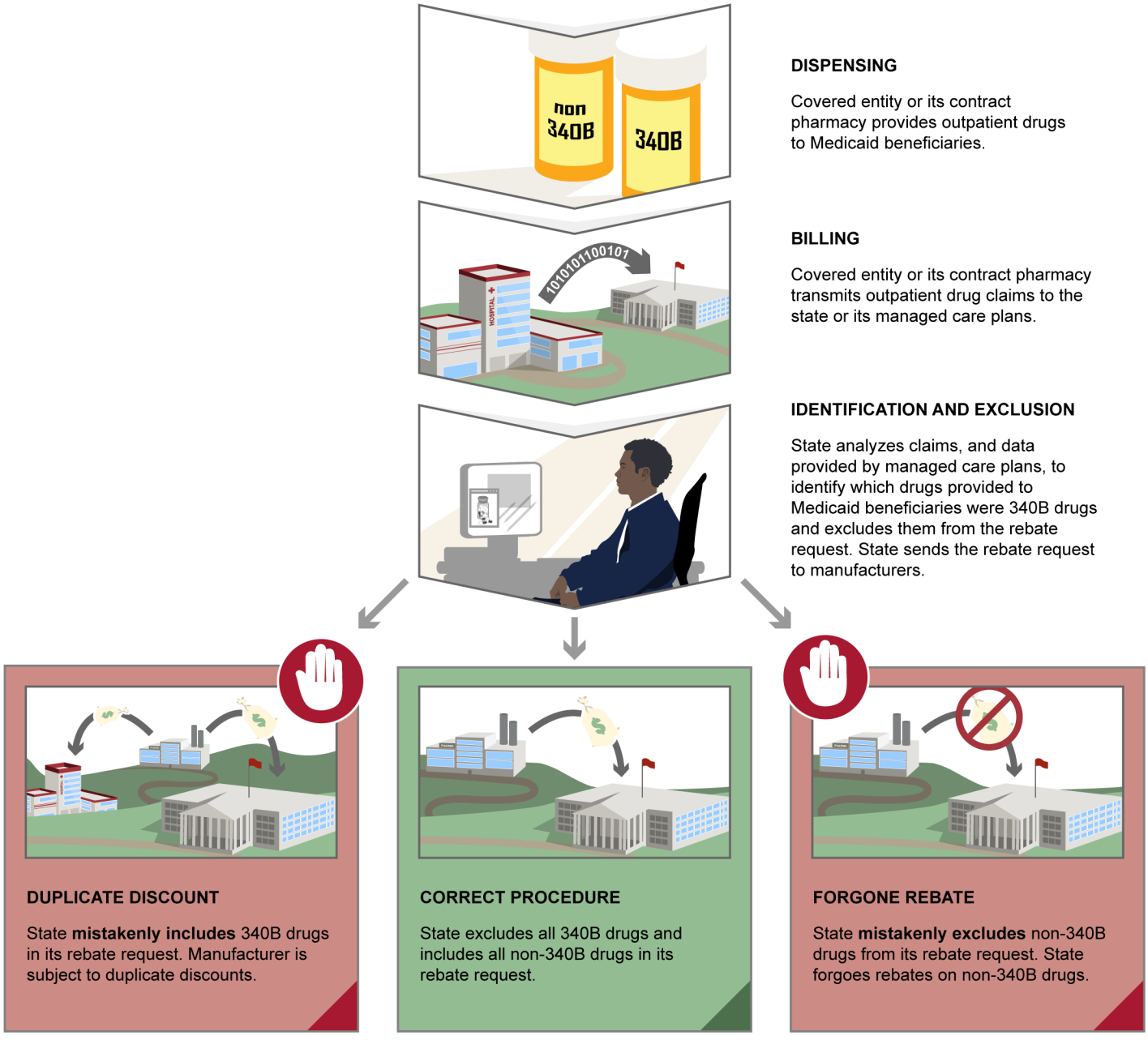
Both states and covered entities play key roles in preventing duplicate discounts and forgone rebates. States must know whether covered entities provided 340B drugs to Medicaid beneficiaries in order to exclude those drugs from the rebate requests they submit to manufacturers. When covered entities provide 340B drugs to Medicaid beneficiaries, it is known as “carving in;” if covered entities do not dispense these drugs to Medicaid beneficiaries, it is known as “carving out.” As shown in figure 1, if a state is not aware that a covered entity provided 340B drugs to Medicaid beneficiaries, it would not know to exclude those drugs from its

[18]The other types of federal grantees are Black Lung clinics, hemophilia treatment centers, Native Hawaiian health centers, sexually transmitted diseases grantees, tuberculosis grantees, and Urban Indian organizations.

[19]The other types of hospitals are children’s hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals.

rebate requests, which could lead to duplicate discounts. In contrast, if a state mistakenly believes the entity used 340B drugs when it did not, it might exclude those drugs from its rebate requests and would forgo eligible rebates.

Figure 1: Example of How Covered Entities and State Medicaid Programs Must Work Together to Prevent Duplicate Discounts and Forgone Rebates



Source: GAO. | GAO-20-212

Note: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program.

To help prevent duplicate discounts, in 1993, HRSA and CMS collaborated to establish the Medicaid Exclusion File (MEF) as a mechanism to assist in the identification of 340B drugs provided to Medicaid FFS beneficiaries. The MEF lists the covered entities that reported to HRSA that they choose to use or "carve in" 340B drugs for their Medicaid FFS patients. Specifically, HRSA requires that covered entities that decide to carve in these drugs for Medicaid provide the agency with the provider number or numbers that the entities use to bill the state for those drugs.[20] The entity and the provider number or numbers it specifies are then listed on the MEF. HRSA guidance specifies that all drugs billed with the provider numbers listed on the MEF should be 340B drugs so a state that choses to use the MEF knows the drugs should be excluded from rebate requests; there is no requirement for states to use the MEF to identify 340B drugs. If a covered entity wants its contract pharmacy to dispense 340B drugs to patients covered under Medicaid FFS, HRSA guidance requires the covered entity, the contract pharmacy, and the state Medicaid program to have an arrangement to prevent duplicate discounts; any such arrangement must be reported to HRSA.[21]

When the MEF was created, Medicaid drug rebates were only required for drugs provided under FFS. As such, in a 2014 policy release, HRSA clarified that the MEF is only intended for use for Medicaid FFS, that is, only covered entities that elect to carve in 340B drugs for Medicaid FFS are required to provide the provider numbers used for billing Medicaid FFS for inclusion on the MEF.[22] The MEF is not intended to capture whether covered entities have decided to carve in 340B drugs for Medicaid managed care and, if so, what provider numbers they use for billing for those drugs. HRSA has not created a mechanism for covered entities to use to identify 340B drugs provided to Medicaid managed care beneficiaries, but encourages covered entities to work with states to develop strategies to prevent duplicate discounts for drugs reimbursed through managed care.

[20]The provider number can either be a national provider identifier for the covered entity or for a provider at the covered entity, such as a pharmacy or doctor. In addition, it could be a Medicaid billing number that the covered entity uses when submitting claims for 340B drugs to a state.

[21]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services , 75 Fed. Reg. at 10278.

[22]See *Clarification on Use of the Medicaid Exclusion File* (Dec. 12, 2014).

While HRSA requires covered entities to use the MEF, there is no similar requirement for state Medicaid programs. CMS provides states the flexibility to determine procedures for identifying and excluding 340B drugs from their Medicaid rebate requests. Under a May 2016 final rule, states' contracts with Medicaid managed care plans that provide coverage of outpatient drugs must require the plans to provide the states with drug utilization data that is necessary for the states to claim Medicaid rebates.[23] In addition, the contracts must require the plans to establish procedures for excluding 340B drugs from the drug utilization data provided to states for purposes of rebate collection.[24]

Federal Oversight

To oversee covered entities' compliance with 340B Program requirements, in fiscal year 2012, HRSA implemented a systematic approach to conducting audits of a small sample of covered entities, and began conducting audits of 200 entities per year in fiscal year 2015.[25] HRSA audits include covered entities that are randomly selected based on risk-based criteria (approximately 90 percent of all audits conducted each year), or targeted based on information from stakeholders such as drug manufacturers about potential noncompliance (10 percent of the audits conducted). HRSA's criteria for risk-based audits include a covered entity's volume of 340B drug purchases, number of contract pharmacies, time in the program, and complexity of its program.

Among other things, HRSA's audits include reviews of each covered entity's policies and procedures, an assessment of the entity's compliance with respect to 340B Program requirements, including the prevention of duplicate discounts in Medicaid FFS, and reviews of a

[23]The rule specifies that the utilization data must, at a minimum, include the number of units of each outpatient drug dispensed by, or covered by, the managed care plan.

[24]Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability; Final Rule, 81 Fed. Reg. 27498, 27857 (May 6, 2016) (codified at 42 C.F.R. § 438.3(s)(3)). This requirement does not apply to states that require submission of managed care claims data from covered entities directly.

[25]HRSA began conducting audits in response to a recommendation we made in September 2011 for the agency to conduct selective audits of covered entities to deter the diversion of 340B drugs to individuals who are not patients of the entities. See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement,* GAO-11-836 (Washington, D.C.: Sep 23, 2011). In addition to audits, HRSA also has a self-disclosure process, whereby entities can report any material compliance breaches, and steps to address the breach, to HRSA.

sample of prescriptions filled during a 6-month period to identify any instances of noncompliance. Under HRSA's audit procedures, a covered entity with audit findings is required to 1) submit a corrective action plan to HRSA that indicates it will determine the full scope of any noncompliance (beyond the sample of prescriptions reviewed during an audit) and 2) outline the steps it plans to take to correct findings of noncompliance, including any necessary repayments to manufacturers, among other things. If the HRSA audit shows that duplicate discounts may have occurred, the covered entity must, as part of its corrective action plan, contact the state Medicaid program to determine whether duplicate discounts actually occurred—namely, whether the state requested a rebate on the claims in question, and if so, contact the drug manufacturer to offer repayment. HRSA closes the audit when a covered entity submits a letter attesting that its corrective action plan, including its assessment of the full scope of noncompliance, has been implemented and any necessary repayments to manufacturers have been resolved. In addition, HRSA may re-audit a covered entity (i.e. subject it to a targeted audit) to determine whether it has implemented its corrective action plan.

To oversee the Medicaid Drug Rebate Program, CMS receives copies of states' Medicaid rebate requests each quarter. States are required to submit this data to manufacturers for FFS and managed care drugs, which should not include drugs purchased through the 340B Program, within 60 days of the end of the quarterly rebate period. Specifically, states provide drug utilization data that includes the drug name, national drug code (a unique identifier for each drug), the unit rebate amount, the number of units reimbursed, the rebate amount claimed, and the number of prescriptions, among other things. CMS has a system that reviews this information for errors, such as the inclusion of drugs from manufacturers that no longer participate in the Medicaid Drug Rebate Program, and generates a discrepancy report for the state. CMS also has a system in place to identify, for state review, cases in which the utilization data reflect a substantial increase or decrease in the number of FFS records submitted compared to prior quarters; such a review is not currently performed for managed care. In addition, CMS reviews state Medicaid programs' contracts with managed care plans using a checklist to ensure that the contracts include elements required by statute or regulation.

State Medicaid Programs' Policies on the Use and Identification of 340B Drugs Vary, Are Not Always Documented, and May Not Prevent Duplicate Discounts

State Medicaid Programs' Policies for Use and Identification of 340B Drugs Vary

State Medicaid programs' policies varied in whether they allowed covered entities to use 340B Program drugs for Medicaid beneficiaries. Most states allowed covered entities to decide whether to use, or "carve in," 340B drugs for Medicaid beneficiaries at their in-house pharmacies and for provider-administered drugs. Fewer states allowed covered entities to dispense these drugs to Medicaid beneficiaries at contract pharmacies, particularly beneficiaries whose drugs were covered under FFS. Table 1 below summarizes states' policies on covered entities' use of 340B drugs for Medicaid beneficiaries for both FFS and managed care by dispensing method.

Table 1: Count of State Medicaid Programs' Policies Regarding Covered Entities' Use of 340B Drugs for Fee-for-Service and Managed Care by Dispensing Method, 2019

Policy on use of 340B drugs	Fee-for-Service			Managed Care		
	In-house pharmacies n=51	Provider-administered drugs n=51	Contract pharmacies n=51	In-house pharmacies n=36	Provider-administered drugs n=38	Contract pharmacies n=36
Covered entity decision	45	45	12	25	27	11
Carve out[a]	2	1	37	1	1	19
Carve in[b]	2	2	0	2	2	0
Other[c]	2	2	2	8	8	6
No policy	0	1	0	0	0	0

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: Not all state Medicaid programs covered outpatient drugs through managed care. Specifically, 38 of 51 states covered at least some outpatient drugs through managed care; managed care plans in two of the 38 states covered only provider-administered drugs. The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program.

[a]States that required covered entities to "carve out" 340B drugs did not allow covered entities to provide these drugs to Medicaid beneficiaries. This also includes states that allowed 340B drugs to

be dispensed to Medicaid beneficiaries at contract pharmacies if there was an established arrangement to prevent duplicate discounts between the state, the covered entity, and the contract pharmacy, but no such arrangements existed at the time of our review.

[b]States that required covered entities to "carve in" required covered entities to provide 340B drugs to eligible Medicaid beneficiaries.

[c]Other includes, for example, states that required covered entities to seek approval to provide 340B drugs, did not allow covered entities to bill the state for these drugs provided to Medicaid beneficiaries, or states in which policies regarding use were made by the managed care plans.

In addition to varying by state, policies on the use of 340B drugs sometimes varied within a state; that is, some states had different policies depending on whether the drugs were provided to Medicaid FFS or managed care beneficiaries, the dispensing method used, or both. For example, Oregon allowed covered entities to decide whether to dispense 340B drugs at contract pharmacies to Medicaid managed care beneficiaries, but required covered entities to carve out (not use) these drugs at contract pharmacies under Medicaid FFS. Illinois required covered entities to carve in 340B provider-administered drugs and those dispensed at in-house pharmacies for Medicaid beneficiaries in both FFS and managed care, but prohibited their use for Medicaid beneficiaries at contract pharmacies. See appendix II for information on each state Medicaid program's policies regarding covered entities' use of 340B drugs.

The states that allowed or required covered entities to carve in 340B drugs for Medicaid beneficiaries used several different procedures to identify and exclude those drugs from Medicaid rebate requests. These procedures included relying on the MEF, requiring covered entities to use a 340B claim identifier—a code on the claim that indicates that the drug used was purchased at the 340B discounted price, or using other state-developed procedures to identify and exclude 340B drugs from rebate requests.[26] The procedures states used varied between Medicaid FFS and managed care, and among dispensing methods. For example, states were more likely to use HRSA's MEF to identify and exclude provider-administered drugs in both Medicaid FFS and Medicaid managed care and to use a 340B claim identifier to identify and exclude drugs dispensed

[26]There are industry-accepted transaction standards that states can direct covered entities to use on their drug claims to identify them as 340B drugs. For pharmacy drugs, the National Council on Prescription Drug Programs has created a "submission clarification code" field that can be populated with a value of "20" to identify a 340B drug. For provider-administered drugs, the American National Standards Institute has created a "UD" modifier value that can be added to identify a relevant claim.

at in-house pharmacies. Some states used a combination of procedures or created their own state-specific procedures. For example,

- 11 states required that covered entities inform them of their decisions to carve in 340B drugs for Medicaid beneficiaries. The states then maintained a list of these covered entities or their providers, which they used to exclude 340B drugs from rebate requests.[27]
- Oregon required covered entities to provide the state with a list of each 340B drug dispensed to a Medicaid managed care beneficiary at a contract pharmacy so that the state could exclude those drugs from its rebate requests.
- Vermont required covered entities, on a monthly basis, to send the state a file listing each 340B drug provided to a Medicaid beneficiary; the state used this information to exclude those drugs from rebate requests.

See table 2 for a summary of the procedures used by states to identify 340B drugs provided to Medicaid beneficiaries, and appendix III for a listing of the procedures by state.

Table 2: Number of State Medicaid Programs That Allow Covered Entities to Use 340B Drugs, by Procedure for Identifying Those Drugs, Medicaid Fee-for-Service or Managed Care, and Dispensing Method, 2019

Procedure	Fee-for Service			Managed care		
	In-house pharmacies n=49	Provider-administered drugs n=50	Contract pharmacies n=14	In-house pharmacies n=35	Provider-administered drugs n=37	Contract pharmacies n=17
Medicaid Exclusion File[a]	13	18	2	8	13	1
340B claim identifiers	17	12	9	15	11	11
Medicaid Exclusion File and 340B claim identifiers	7	5	0	6	5	1
Other[b]	10	14	2	5	7	3
None[c]	1	1	0	0	1	0
Not applicable[d]	1	0	1	1	0	1

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: This table only includes state Medicaid programs that covered outpatient drugs through the specified delivery system and allowed covered entities to provide 340B drugs to Medicaid beneficiaries for the specified dispensing method. In other words, for each dispensing method, the table excludes states that required covered entities to “carve out” or not use 340B drugs for Medicaid

[27]Six of these 11 states used their state-developed provider list to exclude 340B drugs from rebate requests in conjunction with another procedure, usually the MEF.

beneficiaries. Additionally, states are not included in the managed care columns if they did not cover outpatient drugs under managed care. The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program.

[a]The Medicaid Exclusion File is a list of provider numbers of covered entities that elected to use, or carve in, 340B drugs for Medicaid fee-for-service beneficiaries; the list is maintained by the Health Resources and Services Administration.

[b]Other procedures used by states include, for example, state-developed lists of providers that provide 340B drugs to Medicaid beneficiaries and a covered entity-provided list of relevant claims. We also included states that delegate the identification of 340B drugs to managed care plans as other.

[c]None represents states that allowed covered entities to provide 340B drugs to Medicaid beneficiaries but did not have any procedures to identify those drugs.

[d]Not applicable represents a state which allows covered entities to dispense 340B drugs at in-house and contract pharmacies but prohibits them from billing the state for such drugs.

State Medicaid Programs' Policies on the Use and Identification of 340B Drugs Are Not Always Documented and May Not Prevent Duplicate Discounts

State Medicaid programs' policies related to 340B drugs were not always documented and some states' policies may not prevent duplicate discounts. Some states had written policies for the use of 340B drugs, and procedures to identify them, for some dispensing methods, but not for others, such as states that had documented policies for in-house pharmacies but not contract pharmacies. Without written policies, covered entities in those states may not be aware of requirements for dispensing and identifying 340B drugs, increasing the risk of duplicate discounts. Specifically, we found that nine states did not have written policies or procedures on the use or identification of 340B drugs for all dispensing methods. Seven of the nine states had policies or procedures regarding the use and identification of 340B drugs that were used in practice, but these policies and procedures were not always documented. For example:

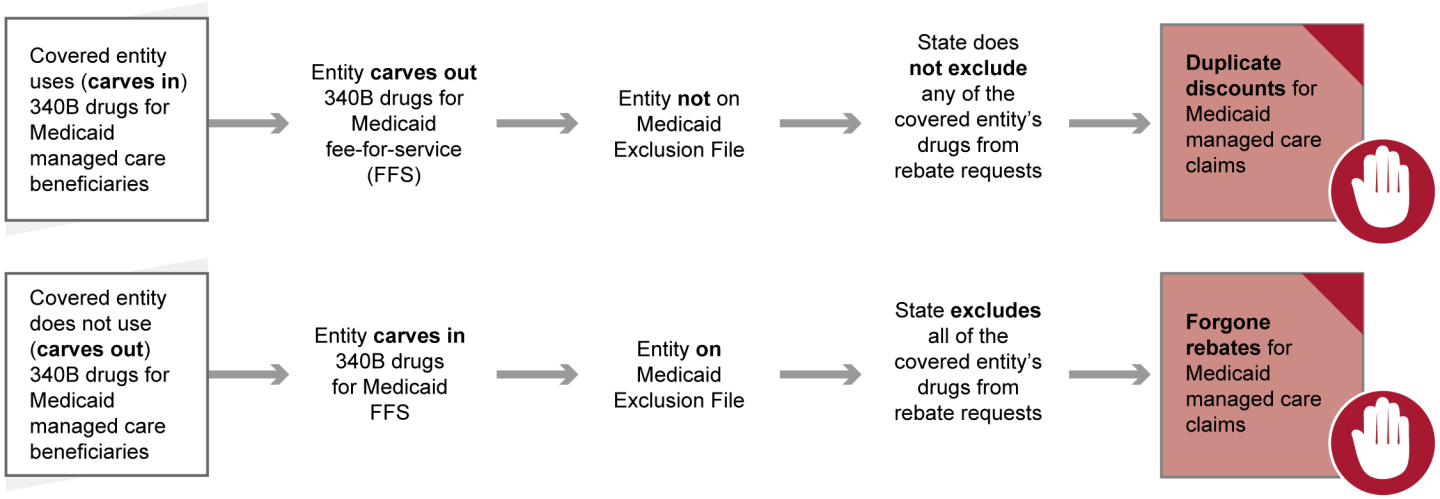
- Connecticut did not have documented policies on the use and identification of 340B drugs, but officials from the state reported that it allowed covered entities to provide these drugs to Medicaid beneficiaries and relied on the MEF to identify and exclude them from rebate requests.
- While Pennsylvania and Ohio had written policies regarding the use of 340B drugs in Medicaid FFS and for some dispensing methods under managed care, the states' policies requiring covered entities to carve out these drugs for Medicaid managed care beneficiaries at contract pharmacies were not documented.

The remaining two states did not have policies or procedures, documented or otherwise, for all dispensing methods:

- Officials from Washington, D.C. reported that D.C. did not have a policy regarding the use of provider-administered 340B drugs nor did it have procedures to identify and exclude those drugs from its Medicaid drug rebate requests.
- A Rhode Island Medicaid official told us that the state did not have written policies regarding the identification of 340B drugs dispensed to Medicaid FFS beneficiaries at in-house pharmacies, and that the state did not have procedures, written or otherwise, by which to exclude such drugs from rebate requests. Additionally, while the state had a written policy for identifying and excluding 340B drugs administered by providers at hospitals, officials told us that they had no policy or exclusion procedures for drugs administered by providers at other types of covered entities.

In addition, we found that states' policies may not prevent duplicate discounts. For example, some states used the MEF to identify and exclude 340B drugs from their rebate requests in a manner contrary to the MEF's purpose as set forth by HRSA. As noted previously, HRSA guidance specifies that the MEF is not intended to be used to identify and exclude 340B drugs provided to Medicaid managed care beneficiaries from Medicaid drug rebate requests. Covered entities are only required to be listed on the MEF if they carve in 340B drugs for Medicaid FFS. Since the MEF may not accurately reflect covered entities' use of 340B drugs for Medicaid managed care, states' use of the MEF in this instance may increase the risk of duplicate discounts or forgone rebates unless states require covered entities to make the same decisions on the use of 340B drugs for FFS and managed care. For example, as shown in figure 2, a state's use of the MEF for managed care would likely result in a duplicate discount if covered entities carve out 340B drugs for Medicaid FFS, but carve in these drugs for managed care, as those entities would not be listed on the MEF. Consequently, the state would not know to exclude drugs provided by those entities from the managed care plans' utilization data that are used for requesting rebates. If covered entities did the opposite—carved in for FFS and carved out for Medicaid managed care—then the state would likely forgo Medicaid rebates as it would exclude drugs from its rebate request that were not purchased through the 340B Program.

Figure 2: Depiction of How the Use of the Medicaid Exclusion File for Medicaid Managed Care Could Result in Duplicate Discounts or Forgone Rebates



Source: GAO. | GAO-20-212

Note: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program.

Seven of the 13 states that used the MEF exclusively to identify and exclude Medicaid managed care drugs from rebate requests for at least one dispensing method did not require covered entities to make the same carve-in decisions for both FFS and managed care. Additionally, while the six remaining states required covered entities to make the same decision regarding use of 340B drugs in FFS and managed care, that requirement was not always clearly explained in the states' policies. For example, an official from Arkansas, which used the MEF for identifying and excluding 340B drugs from rebate requests, told us that covered entities are required to make the same carve-in decisions for both Medicaid FFS and managed care. However, it is unclear how covered entities would be aware of that requirement, as it was not documented in the state's policy manuals at the time of our information request.

Finally, states that rely on the MEF or state-developed lists of providers carving in 340B drugs for Medicaid beneficiaries may not be able to identify instances where covered entities are unable to purchase drugs at the 340B Program discounted price, and instead need to purchase drugs outside of the 340B Program. For example, orphan drugs are excluded

from the discounted 340B Program price for some covered entities.[28] In these situations, states that rely on the MEF or other state-developed lists of providers may be forgoing rebates. For example, if covered entities do not have a separate provider number for billing Medicaid for these non-340B drugs, the states would be excluding both 340B and non-340B drugs from their rebate requests. State Medicaid officials in Oregon and Pennsylvania acknowledged that their states were likely forgoing rebates when covered entities listed on the MEF were unable to purchase drugs at the 340B Program price. While these state officials indicated that they did not consider the lost rebates financially significant, the loss of these rebates would also increase federal Medicaid expenditures, since rebates are shared between the state and the federal government.

Limitations in HHS Oversight Increase the Risk of Duplicate Discounts

CMS Oversight of State Medicaid Programs' Efforts to Prevent Duplicate Discounts Is Limited

CMS oversight of state Medicaid programs' efforts to prevent duplicate discounts is limited. States have the flexibility to select the procedures used for identifying and excluding 340B drugs from rebate requests. Although CMS collaborated with HRSA to establish the MEF as a tool for identifying 340B drugs in Medicaid FFS, CMS does not require states to use the MEF in their duplicate discount prevention efforts. Instead, CMS has provided states with options of procedures they could consider for identifying and excluding 340B drugs from rebate requests. For example, CMS's February 2016 final rule on covered outpatient drugs, which detailed requirements for Medicaid reimbursement of covered outpatient drugs, included in its preamble examples of procedures that states could use to identify and exclude 340B drugs in FFS without prescribing any specific required procedure.[29] Additionally, as noted earlier, the final rule CMS issued in May 2016 on Medicaid managed care included a provision relating to duplicate discounts for Medicaid managed care drugs. Specifically, it mandated that state Medicaid programs' contracts with

[28]42 U.S.C. § 256b(e). Orphan drugs are drugs designated by the Secretary of HHS as treating a rare disease or condition.

[29]See Medicaid Program; Covered Outpatient Drugs, Final Rule, 81 Fed. Reg. 5170, 5320 (Feb. 1, 2016).

managed care plans that provide outpatient drugs require the plans to establish procedures for excluding 340B drugs from utilization data provided to states for use in seeking rebates, but did not specify what procedures plans should use.[30] Most recently, in January 2020, CMS released a bulletin to state Medicaid programs on best practices for preventing duplicate discounts.

CMS has some visibility into state Medicaid programs' 340B-related policies and procedures through its oversight activities, but these activities are not intended to, and do not enable CMS to, assess compliance with the duplicate discount prohibition. For example, CMS has a system in place that reviews copies of states' quarterly Medicaid drug rebate requests; however, CMS officials told us that these requests do not contain detailed, claim-level information that could be used to determine if specific drugs purchased through the 340B Program were incorrectly included. Additionally, CMS reviews states' contracts with Medicaid managed care plans to ensure that they include language requiring the plans to have procedures to exclude 340B drugs from Medicaid rebate data provided to states, but CMS officials told us that the contract language does not have to specify or describe those mechanisms, limiting the information available regarding duplicate discount prevention efforts. CMS also required states to submit their plans for reimbursing covered entities for 340B drugs provided under Medicaid FFS to ensure that the states' payment methodologies complied with federal requirements, but these reviews were not focused on ensuring that such drugs were excluded from rebate requests.[31]

CMS officials told us that they do not track which procedures states use to prevent duplicate discounts; review states' policies or procedures for identifying and excluding 340B drugs from rebate requests for deficiencies or to ensure effectiveness; or audit states' compliance with the prohibition on duplicate discounts. This is problematic because, as

[30]Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care; CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. at 27,857 (codified at 42 C.F.R. § 438.3(s)).

[31]Federal regulations generally require states to pay for drugs covered under their FFS programs, including 340B drugs, at actual acquisition costs plus a professional dispensing fee. See 42 CFR § 447.512(b) (2018). According to CMS officials, states that require covered entities to carve out 340B drugs provided under Medicaid FFS would need to include this in the plans submitted to CMS describing their payment methodologies for outpatient drugs.

noted previously, we found that not all state Medicaid programs have written policies and procedures that specify the extent to which covered entities can use 340B drugs for Medicaid beneficiaries, or how they are to identify these drugs so the state can exclude them from Medicaid rebate requests. If states do not have written policies, covered entities may not be aware of whether, or under what circumstances, they are permitted to provide 340B drugs to Medicaid beneficiaries or how to properly inform the state of their use, which could result in errors that lead to duplicate discounts and forgone rebates. We found some evidence of confusion from covered entities about state policies. For example, officials from Apexus, which manages HRSA's 340B Prime Vendor Program, told us that Apexus's call center, which fields questions from covered entities and other stakeholders about the 340B Program, most frequently receives questions related to clarifying states' duplicate discount-related policies.[32] These inquiries about state requirements indicate that there is currently confusion among covered entities.[33]

CMS's limited oversight of state Medicaid programs' efforts to prevent duplicate discounts is also problematic because we found that states' policies and procedures were not always effective at preventing duplicate discounts, or in line with federal guidance. For example, the MEF is only intended to be used for Medicaid FFS. CMS officials told us that, while the agency was not aware of any states using the MEF for Medicaid managed care, such use would be concerning because it is not an accurate tool for that purpose. However, as previously shown in table 2, we found that eight states relied on the MEF to identify and exclude Medicaid managed care drugs dispensed at in-house pharmacies from rebate requests and 13 states used the MEF to identify and exclude managed care drugs administered by providers.

The lack of CMS oversight of state Medicaid programs' policies and procedures related to duplicate discount prevention is inconsistent with federal standards for internal control for information and communication, which state that management should obtain relevant data from reliable internal and external sources in a timely manner based on the identified information requirements so that data can be used for effective

[32]HRSA awarded a contract to Apexus to manage its Prime Vendor Program. As the prime vendor, Apexus provides 340B Program education to stakeholders, and helps support program integrity through technical assistance, among other things.

[33]Apexus officials told us that these questions include: "Does my state require carve in/out?" and "What are the Medicaid billing requirements for my state?"

monitoring.[34] Without reviewing states' policies and procedures, CMS does not have the information needed to effectively oversee states' compliance with the Medicaid drug rebate statute, which exempts 340B drugs from Medicaid rebate requirements, and ensure that states have effective policies and procedures for preventing duplicate discounts. The lack of oversight of states' policies and procedures also results in CMS not having reasonable assurance that states are seeking rebates for all eligible drugs, and since Medicaid rebates are shared by the states and the federal government, forgoing rebates increases Medicaid costs for both states and the federal government.

Oversight Weaknesses Impede HRSA's Ability to Ensure That Duplicate Discounts Are Prevented or Remedied

We identified several areas of weaknesses in HRSA's oversight processes that impede its ability to ensure that duplicate discounts are prevented or remedied:

Covered entities' compliance with state policies and procedures is not assessed. HRSA's auditors are instructed to look for the potential for duplicate discounts in Medicaid FFS by assessing whether the covered entity's information on the MEF is correct; whether the entity is following its policies and procedures to prevent duplicate discounts; and whether a sample of claims reveals any noncompliance.[35] Auditors are also instructed to use information provided by the covered entity to determine if the covered entity is following state policies. However, HRSA officials told us that its auditors are not expected to independently identify or verify state Medicaid programs' policies to determine whether the covered entity is actually following what the state requires. Instead, HRSA officials stated that it is a best practice for covered entities to include a description of state Medicaid programs' policies related to the 340B Program, such as how relevant drugs are to be identified, in their policy and procedure

[34]See GAO, *Standards for Internal Control in the Federal Government,* GAO-14-704G (Washington, D.C.: September 2014).

[35]If covered entities carve out Medicaid FFS, auditors are to review the sample of claims to make sure that no drugs purchased through the 340B Program were dispensed to Medicaid FFS beneficiaries. If covered entities carve in, auditors are to look to see that the covered entities are listed on the MEF and review a sample of claims to see that covered entities are following their outlined policies and procedures.

manuals.[36] In addition, HRSA told us that its auditors interview covered entity staff about the controls in place to prevent duplicate discounts, and may discuss state requirements during these interviews. The auditor is then required to use this information to determine whether the covered entity is following state policy. For example, if the covered entity says that the state requires a 340B claim identifier, the auditor is to look to see if the covered entity used that identifier in the sample of claims that are reviewed. However, the auditor is not expected to determine if the state actually requires a claim identifier, or allows covered entities to use 340B drugs.

The fact that HRSA does not assess whether covered entities are actually following state policies and procedures regarding the use and identification of 340B drugs for Medicaid beneficiaries is inconsistent with federal standards for internal control related to information and communication. Those standards state that management should obtain relevant data from reliable internal and external sources in a timely manner based on the identified information requirements and evaluate both internal and external sources of data for reliability so that it can be used for effective monitoring.[37]

This lack of HRSA oversight is especially concerning because we found that the covered entities we interviewed did not always have a correct understanding of their states' policies. For example, officials from two of the four Pennsylvania covered entities we spoke with told us they were dispensing 340B drugs to Medicaid managed care beneficiaries at contract pharmacies, despite state officials telling us the state does not allow that practice. As a result of this confusion, duplicate discounts may have occurred as the state was not excluding drugs dispensed by contract pharmacies from its Medicaid rebate requests. Additionally, of the 13 covered entity policy and procedure manuals we reviewed, only four had descriptions of their states' policies and two of those descriptions were incorrect. If HRSA were to audit the majority of those 13 covered entities, its auditors would likely be unable to appropriately assess the entities' compliance with state requirements. Without fully assessing

[36]Covered entities are expected to have policy and procedure manuals that, among other things, specify their procedures for preventing duplicate discounts. HRSA officials also told us that covered entities' policy and procedure manuals should, among other things, address whether the covered entity uses 340B drugs for Medicaid patients, and how the covered entity's billing information is reflected on the MEF.

[37]GAO-14-704G.

compliance with state policy, HRSA's audits do not provide the agency with reasonable assurance that covered entities are taking the necessary steps to prevent duplicate discounts. As a result, drug manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid drugs.

Not all identified duplicate discounts are repaid. HRSA officials told us that covered entities' obligations for preventing duplicate discounts are the same for Medicaid FFS and managed care. However, as we reported in 2018, HRSA audits do not assess for the potential for duplicate discounts in Medicaid managed care despite the fact that the potential for duplicate discounts related to Medicaid managed care has existed since 2010, when manufacturers were required to begin paying Medicaid rebates under managed care in addition to FFS. As we noted in 2018, HRSA indicated that it does not audit for duplicate discounts in managed care because the agency has not issued guidance on how covered entities should prevent this.[38] As a result, we recommended that HRSA issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care and incorporate into its audit process an assessment of covered entities' compliance with the prohibition on duplicate discounts as it relates to Medicaid managed care claims. HHS concurred with these recommendations and, as of October 2019, HRSA reported that it was working to determine next steps related to these recommendations. However, HRSA has noted that the agency lacks explicit general regulatory authority to issue regulations on most aspects of the 340B Program, and also told us, in October 2019, that guidance does not provide the agency with appropriate enforcement capability.[39] As a result, HRSA requested authority in the President's

[38]GAO-18-480. Although HRSA audits do not include assessments of potential duplicate discounts in Medicaid managed care, in April 2018, HRSA updated its audit process to require its auditors to determine if a covered entity has policies and procedures related to the prevention of duplicate discounts in managed care if, during the audit, the auditor learns that the covered entity is carving in Medicaid managed care claims. If such a check determines that the covered entity does not have policies and procedures related to the prevention of duplicate discounts in managed care, then the audit report is to include an area for improvement for the covered entity to develop these policies and procedures. According to HRSA officials, from April 2018 to August 2019, the agency identified this area for improvement for 37 audits.

[39]A May 2014 federal district court decision found that Congress granted HRSA limited rulemaking authority to carry out the 340B Program. See *Pharm. Research & Mfrs. of Am. v. United States HHS*, 43 F. Supp. 3d 28, 45 (D.D.C. 2014). Notably, however, in a subsequent decision, the court acknowledged the agency's authority to issue guidance documents interpreting the statute. See *Pharm. Research & Mfrs. of Am. v. United States HHS*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015).

budget request for fiscal year 2020 to issue regulations on all aspects of the 340B Program, as the agency believes that binding and enforceable regulations would provide it with the ability to more clearly define and enforce policy. In addition, the agency is not pursuing additional guidance under the 340B Program at this time. We note, however, that the law prohibits the payment of duplicate discounts and requires HRSA to issue guidance to covered entities describing methodologies and options for avoiding duplicate discounts.[40] In the absence of federal guidance, HRSA instructs covered entities to work with their states on duplicate discount prevention.

HRSA requires covered entities to work with affected drug manufacturers regarding the repayment of duplicate discounts in FFS that are identified through HRSA or manufacturer audits. However, HRSA officials told us that the agency does not require covered entities to take the same actions to address duplicate discounts for managed care claims that HRSA learns about through its audits or other means. For example, HRSA officials told us that they did not follow up on a letter from a state that confirmed a duplicate discount occurred on a Medicaid managed care claim, because the agency did not yet have guidance for covered entities related to Medicaid managed care claims. Additionally, HRSA officials told us they would not require a covered entity to develop a corrective action plan or make offers of repayment to a manufacturer if a drug manufacturer's audit of that covered entity identified a duplicate discount in managed care. Although HRSA officials told us that they expect covered entities to work in good faith with all parties involved to resolve potential duplicate discounts in managed care, HRSA does not require these actions if a duplicate discount is identified in managed care, as it does in FFS. This is particularly problematic as the majority of Medicaid enrollees, prescriptions, and spending for drugs are in managed care, and the drug manufacturers we contacted believe that duplicate discounts are more prevalent in Medicaid managed care than FFS.

HRSA expecting but not requiring covered entities to address identified duplicate discounts related to Medicaid managed care is contrary to federal law, which provides that covered entities are liable to drug manufacturers for duplicate discounts that are identified through HRSA or manufacturer audits.[41] It is also inconsistent with federal internal control

[40]42 U.S.C. § 256b(d)(2)(B)(iii).

[41]42 U.S.C. § 256b(a)(5)(D).

standards related to monitoring, which state that management should oversee the prompt remediation of deficiencies and the audit resolution process, which begins when the results of an audit or other review are reported to management, and is completed only after action has been taken that corrects identified deficiencies. Without HRSA requiring covered entities to address identified duplicate discounts in Medicaid managed care as they would duplicate discounts in FFS, drug manufacturers may erroneously provide both 340B discounts and Medicaid rebates on the same drug claim.

Conclusions

The prevention of duplicate discounts in the 340B and Medicaid Drug Rebate Programs requires extensive coordination between state Medicaid programs and covered entities, and among agencies within HHS. Similar levels of coordination are required to ensure that states are not forgoing rebates on drugs not purchased at the 340B price, which would result in increased costs for both state and federal governments.

Limitations in federal oversight impede CMS's and HRSA's ability to ensure compliance with the prohibition on duplicate discounts. CMS does not assess whether states have 340B policies and procedures and, if so, whether they are documented, effective, and accessible to stakeholders. As a result, it is unable to proactively identify and correct problematic policies and procedures, and prevent duplicate discounts and forgone rebates. Additionally, without knowing state Medicaid programs' 340B policies, HRSA is unable to perform a comprehensive review of whether covered entities are taking the necessary actions to prevent duplicate discounts. In addition, HRSA's audits are not assessing compliance with the prohibition against duplicate discounts in managed care because the agency has yet to put forth guidance on this issue. While HRSA is not currently pursuing 340B-related guidance, the agency continues to work on determining next steps to respond to our 2018 recommendations on the issue. In the meantime, however, HRSA still must ensure that covered entities are complying with 340B Program requirements, including the prohibition on duplicate discounts in managed care. Failure to do so not only puts drug manufacturers at risk of providing duplicate discounts, but also compromises the integrity of the 340B Program.

Recommendations for Executive Action

We are making a total of three recommendations, including one to CMS and two to HRSA. Specifically:

- The Administrator of CMS should ensure that state Medicaid programs have written policies and procedures that specify the extent to which covered entities can use 340B drugs for Medicaid beneficiaries, are designed to effectively identify if 340B drugs were used, and if so, how they should be excluded from Medicaid rebate requests. The policies and procedures should be made publically available and cover FFS, managed care, and all of the dispensing methods for outpatient drugs. (Recommendation 1)
- The Administrator of HRSA should incorporate assessments of covered entities' compliance with state Medicaid programs' policies and procedures regarding the use and identification of 340B drugs into its audit process, working with CMS as needed to obtain states' policies and procedures. (Recommendation 2)
- The Administrator of HRSA should require covered entities to work with affected drug manufacturers regarding repayment of identified duplicate discounts in Medicaid managed care. (Recommendation 3)

Agency Comments and Our Evaluation

HHS provided written comments, which are reproduced in app. IV, and technical comments, which we have incorporated as appropriate. In its written comments, HHS concurred with one of our three recommendations and did not concur with the remaining two recommendations.

HHS concurred with our recommendation that CMS ensure that state Medicaid programs have written policies and procedures for identifying 340B drugs and excluding them from Medicaid rebate requests and stated that it will work with states to strengthen policies and procedures related to 340B drugs for Medicaid beneficiaries.

HHS did not concur with our recommendation that HRSA incorporate assessments of covered entities' compliance with state Medicaid programs' policies and procedures into its audit process. HHS stated that HRSA does not have authority to determine whether state Medicaid policies and procedures are "accurate and appropriate." We agree that HRSA is not the appropriate party for reviewing and assessing state Medicaid programs' policies and procedures, which is why we recommended that CMS, not HRSA, strengthen its oversight of states' 340B-related policies and procedures, a recommendation with which HHS

concurred. We recommended that HRSA update its 340B Program audits to include assessments of whether covered entities are following state Medicaid programs' policies and procedures regarding the use and identification of 340B drugs. HHS stated that HRSA does not have authority to enforce covered entities' compliance with state Medicaid programs' policies and procedures and that doing so would be "beyond the scope of the 340B Program" and would require additional training for HRSA auditors, who currently "do not have this level of expertise." While we understand that HRSA does not have authority to enforce compliance with state Medicaid programs' policies and procedures, covered entities' compliance with state Medicaid programs' policies and procedures is fundamental to preventing duplicate discounts and assessing compliance with state policies and procedures is essential to ensuring covered entities' compliance with the 340B Program's prohibition on duplicate discounts.

Further, HRSA already audits for compliance with certain aspects of states' 340B-related Medicaid policies for preventing duplicate discounts. Specifically, HHS states that covered entities are expected to include a description of state policy in their policy and procedure manuals. If such descriptions exist, HRSA auditors are required to review those descriptions and determine if covered entities are following them. Thus, HRSA auditors already interpret state Medicaid policies and procedures when performing audits and the agency already enforces compliance with state policies by issuing audit findings when covered entities are not following them. However, as noted in our report, HRSA does not require its auditors to review state Medicaid programs' actual policies and procedures. Instead, the auditors currently rely on covered entities' descriptions of those policies and procedures, which we found were not always accurate. Additionally, knowledge of state policies would allow HRSA to incorporate an assessment of compliance into all audits as opposed to only those of covered entities that have such descriptions in their manuals. Finally, without considering states' actual policies and procedures and ensuring that covered entities are following them, HRSA's audits cannot effectively identify the potential for duplicate discounts. For example, simply checking covered entities' actions against information on the MEF does not provide useful information if the covered entities are in one of the many states that do not use the MEF and instead direct entities to identify 340B drugs dispensed to Medicaid beneficiaries via a different mechanism, such as 340B identifiers.

HHS states that implementing this recommendation would be burdensome and difficult to operationalize because HRSA would need to

be notified of any changes to states' policies and procedures. We understand that the lack of knowledge of state Medicaid programs' policies related to duplicate discount prevention at the federal level complicates the ability of HRSA and its auditors to determine what state-level requirements exist and to apply them to audits. This is, in part, why we recommended that CMS ensure that state Medicaid programs' policies are publicly available—a recommendation that, as noted above, HHS concurred with—and that HRSA work with CMS to obtain these policies as needed. Though we understand that this creates an additional step in HRSA's audit process, we continue to believe that including an assessment of covered entities' compliance with state Medicaid programs' policies and procedures related to 340B drugs is necessary to identify potential duplicate discounts and to ensure covered entities' compliance with 340B Program requirements.

HHS also did not concur with our recommendation that HRSA should require covered entities to work with affected drug manufacturers regarding repayment of identified duplicate discounts in Medicaid managed care. In its response, HHS noted that because HRSA does not have guidance related to preventing duplicate discounts in Medicaid managed care, "it is difficult to assess compliance in this area." However, our recommendation is not asking HRSA to assess compliance related to duplicate discounts in Medicaid managed care; instead, we are recommending that, when actual duplicate discounts have been identified, HRSA require covered entities to remedy those duplicate discounts. As noted in the report, actual duplicate discounts may be identified and confirmed by state Medicaid agencies through audits or other means. Given that HRSA officials told us that covered entities' obligations for preventing duplicate discounts are the same for Medicaid FFS and managed care, the steps for addressing identified noncompliance should be similar, and thus, the agency should require and not just "encourage" covered entities to work with manufacturers to remedy any duplicate discounts related to managed care as they do for those related to FFS.

Additionally, the potential for duplicate discounts related to Medicaid managed care has existed since 2010, when manufacturers were required to begin paying Medicaid rebates under managed care in addition to FFS. Ten years later, HRSA still has not issued guidance on how covered entities should prevent duplicate discounts in Medicaid managed care and has indicated that it is not pursuing new guidance at this time. This inaction continues to leave the 340B Program vulnerable to noncompliance with federal law. HHS concurred with our 2018

recommendations that HRSA issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care and incorporate into its audit process an assessment of covered entities' compliance with the prohibition on duplicate discounts as it relates to Medicaid managed care claims.[42] Until these recommendations are implemented, HRSA must, at a minimum, ensure that covered entities work with manufacturers regarding any identified duplicate discounts in managed care to help ensure compliance with 340B Program requirements.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, the Administrator of HRSA, the Administrator of CMS, and other interested parties. In addition, the report will be available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at DraperD@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix V.

Debra A. Draper
Director, Health Care

[42]GAO-18-480.

Appendix I: Drug Manufacturers' Efforts to Prevent and Detect Duplicate Discounts

Officials from all three drug manufacturers and the organizations that work on their behalf that we contacted reported challenges preventing and detecting duplicate discounts due to a lack of information. For example, officials from drug manufacturers told us that state Medicaid programs do not always provide data on the individual claims for which they were requesting rebates. Specifically, to obtain rebates, states submit requests to participating manufacturers for all drug purchases made that quarter; these requests contain the total quarterly amount owed for each of the manufacturers' drugs, but not information detailing each claim for which rebates are being sought. Although the Centers for Medicare & Medicaid Services (CMS) encourages states to respond to reasonable manufacturer requests for claim-level data, the provision of such data is not required.[1] Without this claim-level data, manufacturers reported that it is difficult to determine if rebate requests include claims for drugs purchased at the 340B discounted price. Additionally, manufacturers lack complete information on the extent to which covered entities use 340B drugs for Medicaid beneficiaries. This is because the Medicaid Exclusion File (MEF), a list maintained by the Health Resources and Services Administration (HRSA) to assist in the prevention of duplicate discounts, is only required to reflect the provider numbers used by covered entities that choose to use (carve in) 340B drugs provided directly by the covered entity to Medicaid fee-for-service (FFS) beneficiaries. The MEF does not include information on whether covered entities are using 340B drugs for Medicaid managed care beneficiaries and may not include information on contract pharmacies that are dispensing these drugs to Medicaid beneficiaries on covered entities' behalf.

Despite these limitations, the drug manufacturers we contacted reported that when claim-level data is available they review that data to detect potential duplicate discounts before they issue rebate payments. For example, officials from one drug manufacturer told us that they compare the provider numbers on the claim-level data obtained from states with the information on the MEF and dispute rebate requests for any claims from a provider number listed on the MEF. However, officials from some drug manufacturers told us that this approach is ineffective for preventing duplicate discounts for drugs dispensed at contract pharmacies because, as noted above, the MEF may not include information on contract

[1]See Medicaid Drug Rebate Program Notice Release No. 173.

pharmacies, and the claim-level data may only list the provider number for the dispensing pharmacy, not the prescribing covered entity.

The drug manufacturers we contacted also reported trying to identify duplicate discounts after rebates have been paid by looking at 340B purchasing patterns. For example, officials from one drug manufacturer told us they look at covered entities' purchases and assess whether the proportion of 340B purchases is consistent with their carve-in status. Specifically, these officials explained that if a covered entity is not listed on the MEF, then the entity should not be using 340B drugs for Medicaid FFS patients. Therefore, if all or nearly all of the purchases made by that covered entity were at the discounted price, it could indicate the presence of duplicate discounts. While the MEF is only intended to indicate covered entities that are using 340B drugs for Medicaid FFS beneficiaries, officials reported that drug manufacturers also rely on the MEF as a proxy for covered entities' carve-in practices for Medicaid managed care since there is no equivalent data source.

If there are concerns that duplicate discounts occurred, officials from the drug manufacturers we contacted indicated that they may conduct what is referred to as a "good faith inquiry," in which the manufacturer, or a consultant working on the manufacturer's behalf, requests data from covered entities on a specific set of drug claims for which they have paid rebates to determine if those claims involved 340B drugs.[2] If drug manufacturers confirm that a duplicate discount did occur, officials reported that they may work to negotiate a repayment from the state or covered entity, depending on which party was responsible for the error. Additionally, one official who works on behalf of manufacturers told us that manufacturers also will work with covered entities to remedy the cause of the duplicate discount to prevent future occurrences. Drug manufacturers told us that it is not always clear whether states or covered entities are responsible for duplicate discounts, and thus, which party should be contacted regarding repayment. Additionally, drug manufacturers reported that some states refer them directly to covered entities to resolve all inquiries. Medicaid program officials in Michigan and Texas, for example, said that their states refer manufacturers to the covered entities because they believe that the covered entities would

[2]Officials from nine of the 16 covered entities we spoke with said that they had been contacted by drug manufacturers or their representatives regarding their use of 340B drugs and, in one case, these inquiries determined that duplicate discounts had occurred, and resulted in the covered entity repaying a manufacturer.

most likely be responsible for any duplicate discounts that occurred due to a failure to correctly apply the required claim identifiers.

If drug manufacturers need assistance resolving their concerns or obtaining repayment for duplicate discounts, they can access options made available by HRSA and CMS. Specifically, drug manufacturers can request approval from HRSA to audit a covered entity to investigate suspicions of duplicate discounts in both Medicaid FFS and managed care. To receive approval from HRSA to conduct an audit, a drug manufacturer must document reasonable cause and provide an audit plan. In addition, HRSA requires the drug manufacturer to use an independent auditor who follows government auditing standards.[3] According to HRSA, from October 2011 through August 2019, 45 audits were requested by drug manufacturers and 26 requests were approved. Of the 26 audits approved by HRSA, the agency received 13 final audit reports, six of which had duplicate discount-related findings.[4] However, while audits can be a tool for identifying duplicate discounts and obtaining repayment, some drug manufacturers we spoke with indicated that the cost of audits may outweigh the benefits received in the form of repayments. Additionally, as noted previously, HRSA does not require covered entities to repay manufacturers for duplicate discounts that occur in managed care. Drug manufacturers also may use the state hearing process or pursue a dispute resolution in conjunction with states through CMS if their issues with state Medicaid programs cannot be resolved through inquires. According to CMS officials, through the dispute resolution process, the agency provides drug manufacturers and states with guidance to assist in determining responsibilities and identifying next steps to work through conflicts. CMS officials said that, in general, they have received five to 10 Medicaid drug rebate disputes per year, about half of which are related to 340B duplicate discount issues.

[3]See Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65406, 65409 (Dec. 12, 1996). Although HRSA requires manufacturer's audits of covered entities to be conducted in accordance with government auditing standards, HRSA's audits of covered entities do not follow such standards.

[4]Not all of the audits may have been specifically focused on, or included, a review related to duplicate discounts.

Appendix II: State Medicaid Programs' Policies on Covered Entities' Use of 340B Drugs, by Dispensing Method

Table 3: State Medicaid Programs' Policies Regarding Covered Entities' Use of 340B Drugs in Medicaid Fee-For-Service, by Dispensing Method, 2019

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Alabama	Covered entity decision	Covered entity decision	Covered entity decision
Alaska	Covered entity decision	Covered entity decision	Carve out
Arizona	Covered entity decision	Covered entity decision	Carve out
Arkansas	Covered entity decision	Covered entity decision	Carve out
California	Carve in	Carve in	[a]
Colorado	Covered entity decision	Covered entity decision	Carve out
Connecticut	Covered entity decision	Covered entity decision	Covered entity decision
Delaware	Covered entity must obtain approval from state to dispense 340B drugs	Covered entity must obtain approval from state to dispense 340B drugs	Carve out
District of Columbia	Covered entity decision	No policy	Carve out
Florida	Covered entity decision	Covered entity decision	Covered entity decision
Georgia	Covered entity decision	Covered entity decision	Carve out
Hawaii	Covered entity decision	Covered entity decision	Covered entity decision
Idaho	Covered entity decision	Covered entity decision	Carve out
Illinois	Carve in	Carve in	Carve out
Indiana	Covered entity decision	Covered entity decision	Carve out
Iowa	Covered entity decision	Covered entity decision	Carve out
Kansas	Covered entity decision	Covered entity decision	Carve out
Kentucky	Covered entity decision	Covered entity decision	Carve out
Louisiana	Covered entity decision	Covered entity decision	Carve out
Maine	Carve out	Covered entity decision	Carve out
Maryland	Covered entity decision	Covered entity decision	Covered entity decision
Massachusetts	Covered entity decision	Covered entity decision	Covered entity decision
Michigan	Covered entity decision	Covered entity decision	Covered entity decision
Minnesota	Covered entity decision	Covered entity decision	Carve out
Mississippi	Covered entity decision	Covered entity decision	Carve out
Missouri	Covered entity decision	Covered entity decision	Carve out
Montana	Covered entity decision	Covered entity decision	Carve out[b]
Nebraska	Covered entity decision	Covered entity decision	Carve out
Nevada	Covered entity decision	Covered entity decision	Carve out
New Hampshire	[c]	[c]	[c]
New Jersey	Covered entity decision	Covered entity decision	Carve out
New Mexico	Covered entity decision	Covered entity decision	Covered entity decision
New York	Covered entity decision	Covered entity decision	Covered entity decision

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
North Carolina	Covered entity decision	Covered entity decision	Covered entity decision
North Dakota	Covered entity decision	Covered entity decision	Carve out
Ohio	Covered entity decision	Covered entity decision	Carve out[b]
Oklahoma	Covered entity decision	Covered entity decision	Carve out[b]
Oregon	Covered entity decision	Covered entity decision	Carve out
Pennsylvania	Covered entity decision	Covered entity decision	Carve out
Rhode Island	Covered entity decision	Covered entity decision	Carve out
South Carolina	Covered entity decision	Covered entity decision	Covered entity decision
South Dakota	Carve out	Carve out	Carve out
Tennessee	Covered entity decision	Covered entity decision	Carve out
Texas	Covered entity decision	Covered entity decision	Covered entity decision
Utah	Covered entity decision	Covered entity decision	Carve out[b]
Vermont	Covered entity decision	Covered entity decision	Carve out
Virginia	Covered entity decision	Covered entity decision	Carve out
Washington	Covered entity decision	Covered entity decision	Carve out
West Virginia	Covered entity decision	Covered entity decision	Carve out
Wisconsin	Covered entity decision	Covered entity decision	Carve out
Wyoming	Covered entity decision	Covered entity decision	Carve out

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. Carve out means that the state does not allow covered entities to provide 340B drugs to Medicaid beneficiaries. Carve in means that the state requires covered entities to provide 340B drugs to eligible Medicaid beneficiaries.

[a]California allows covered entities to dispense 340B drugs at contract pharmacies if there is an approved arrangement between the state, the covered entity, and the contract pharmacy. At the time of our information request, California officials indicated that they only had approved arrangements for certain hemophilia centers and had no approved arrangements with other types of covered entities.

[b]State allows covered entities to dispense 340B drugs at contract pharmacies if there is an approved arrangement between the state, the covered entity, and the contract pharmacy. At the time of our information request, the state had no such arrangements, and thus covered entities would have to carve out 340B drugs.

[c]New Hampshire allows covered entities to provide 340B drugs to Medicaid beneficiaries, but generally does not allow them to bill Medicaid for these drugs. The one exception is that the state does allow covered entities that are approved family planning clinics to bill Medicaid for 340B drugs administered by providers to Medicaid beneficiaries.

Table 4: State Medicaid Programs' Policies Regarding Covered Entities' Use of 340B Drugs in Medicaid Managed Care, by Dispensing Method, 2019

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Arizona	Covered entity decision	Covered entity decision	Carve out
Arkansas	Covered entity decision	Covered entity decision	Carve out
California	Carve in	Carve in	Covered entity decision
Colorado	Covered entity decision	Covered entity decision	Carve out
Delaware	Covered entity must obtain approval from state to dispense 340B drugs	Covered entity must obtain approval from state to dispense 340B drugs	Carve out
District of Columbia	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
Florida	Covered entity decision	Covered entity decision	Covered entity decision
Georgia	Covered entity decision	Covered entity decision	Carve out
Hawaii	Covered entity decision	Covered entity decision	Covered entity decision
Illinois	Carve in	Carve in	Carve out
Indiana	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
Iowa	Covered entity decision	Covered entity decision	Carve out
Kansas	Covered entity decision	Covered entity decision	Carve out
Kentucky	Covered entity decision	Covered entity decision	Carve out
Louisiana	Covered entity decision	Covered entity decision	Carve out
Maryland	Covered entity decision	Covered entity decision	Covered entity decision
Massachusetts	Covered entity decision[a]	Covered entity decision	Covered entity decision[a]
Michigan	Covered entity decision	Covered entity decision	Covered entity decision
Minnesota	Covered entity decision	Covered entity decision	Carve out
Mississippi	Covered entity decision	Covered entity decision	Carve out
Nebraska	Policies determined by each managed care plan	Policies determined by each managed care plan	Carve out
Nevada	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
New Hampshire	[b]	[b]	[b]
New Jersey	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
New Mexico	Covered entity decision	Covered entity decision	Covered entity decision
New York	Covered entity decision	Covered entity decision	Covered entity decision
North Dakota	Carve out	Carve out	Carve out
Ohio	Covered entity decision	Covered entity decision	Carve out[c]
Oregon	Covered entity decision	Covered entity decision	Covered entity decision
Pennsylvania	Covered entity decision	Covered entity decision	Carve out

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Rhode Island	Covered entity decision	Covered entity decision	Covered entity decision
South Carolina	Policies determined by each managed care plan	Policies determined by each managed care plan	Policies determined by each managed care plan
Tennessee	[d]	Covered entity decision	[d]
Texas	Covered entity decision	Covered entity decision	Covered entity decision
Utah	Covered entity decision	Covered entity decision	Carve out[c]
Virginia	Covered entity decision	Covered entity decision	Carve out
Washington	Covered entity decision	Covered entity decision	Carve out
West Virginia	[d]	Covered entity decision	[d]

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: Not all state Medicaid programs covered outpatient drugs through managed care. As such, this table only includes the 38 states that covered at least some outpatient drugs through managed care.

The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. Carve out means that the state did not allow covered entities to provide 340B drugs to Medicaid beneficiaries. Carve in means that the state required covered entities to provide 340B drugs to eligible Medicaid beneficiaries.

[a]While Massachusetts allows most types of covered entities to decide whether or not to dispense 340B drugs to Medicaid managed care beneficiaries at in-house or contract pharmacies, the state requires federally qualified health centers to carve out these drugs for Medicaid managed care for these dispensing methods.

[b]New Hampshire allows covered entities to provide 340B drugs to Medicaid beneficiaries, but generally does not allow them to bill Medicaid for these drugs. The one exception is that the state does allow covered entities that are approved family planning clinics to bill Medicaid for 340B drugs administered by providers to Medicaid beneficiaries.

[c]State allows covered entities to dispense 340B drugs at contract pharmacies if there is an approved arrangement between the state, the covered entity, and the contract pharmacy. At the time of our information request, the state had no such arrangements, and thus covered entities would have to carve out 340B drugs.

[d]Managed care plans in this state do not cover outpatient drugs dispensed at pharmacies; they only cover provider-administered drugs.

Appendix III: State Medicaid Programs' Procedures for Identifying 340B Drugs, by Dispensing Method

Table 5: State Medicaid Programs' Procedures for Identifying 340B Drugs Dispensed to Medicaid Fee-For-Service Beneficiaries, by Dispensing Method, 2019

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Alabama	Medicaid Exclusion File	Medicaid Exclusion File	Medicaid Exclusion File
Alaska	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Arizona	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	[a]
Arkansas	340B claim identifiers	Medicaid Exclusion File	[a]
California	340B claim identifiers	340B claim identifiers	340B claim identifiers
Colorado	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Connecticut	Medicaid Exclusion File	Medicaid Exclusion File	Medicaid Exclusion File
Delaware	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	[a]
District of Columbia	340B claim identifiers	No procedure	[a]
Florida	340B claim identifiers	Medicaid Exclusion File	340B claim identifiers
Georgia	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File	[a]
Hawaii	State-developed exclusion process[b]	State-developed exclusion process[b]	340B claim identifiers
Idaho	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Illinois	340B claim identifiers	340B claim identifiers	[a]
Indiana	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Iowa	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Kansas	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Kentucky	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Louisiana	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Maine	[a]	State-developed list of providers using 340B drugs	[a]
Maryland	340B claim identifiers	State-developed list of providers using 340B drugs	340B claim identifiers
Massachusetts	State-developed list of providers using 340B drugs	State-developed list of providers using 340B drugs	[c]
Michigan	340B claim identifiers	340B claim identifiers	340B claim identifiers
Minnesota	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Mississippi	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Missouri	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	[a]
Montana	State-developed list of providers using 340B drugs	State-developed list of providers using 340B drugs	[a]
Nebraska	Medicaid Exclusion File and 340B claims identifiers	Medicaid Exclusion File	[a]
Nevada	Medicaid Exclusion File	Medicaid Exclusion File	[a]
New Hampshire	[d]	State-developed list of providers using 340B drugs	[d]
New Jersey	340B claim identifiers	Medicaid Exclusion File	[a]
New Mexico	340B claim identifiers	340B claim identifiers	340B claim identifiers
New York	340B claim identifiers	340B claim identifiers	340B claim identifiers
North Carolina	340B claim identifiers	340B claim identifiers	340B claim identifiers
North Dakota	340B claim identifiers	340B claim identifiers	[a]
Ohio	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Oklahoma	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	[a]
Oregon	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Pennsylvania	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Rhode Island	No procedure	[e]	[a]
South Carolina	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs
South Dakota	[a]	[a]	[a]
Tennessee	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Texas	340B claim identifiers	340B claim identifiers	340B claim identifiers
Utah	340B claim identifiers	340B claim identifiers	[a]
Vermont	State-developed exclusion process[f]	State-developed exclusion process[f]	[a]
Virginia	340B claim identifiers	340B claim identifiers	[a]
Washington	Medicaid Exclusion File	Medicaid Exclusion File	[a]
West Virginia	340B claim identifiers	340B claim identifiers	[a]
Wisconsin	340B claim identifiers	340B claim identifiers	[a]
Wyoming	Medicaid Exclusion File and State-developed list of providers using 340B drugs	Medicaid Exclusion File and State-developed list of providers using 340B drugs	[a]

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. The Medicaid Exclusion File is a list of provider numbers used to bill Medicaid for covered entities that elected to use, or carve in, 340B drugs for Medicaid fee-for-service beneficiaries. The list is maintained by the Health Resources and Services Administration.

[a]State does not allow covered entities to use 340B drugs for Medicaid fee-for-service beneficiaries for this dispensing method, and thus does not need a procedure to identify these drugs.

[b]Hawaii requires covered entities, on a quarterly basis, to identify for the state drugs provided to Medicaid beneficiaries that were not purchased under the 340B Program.

[c]Massachusetts requires contract pharmacies to include the covered entities' National Provider Identifier on claims using 340B drugs, which the state then uses to exclude those claims from its rebate request.

[d]New Hampshire allows covered entities to provide 340B drugs through this dispensing method, but does not allow them to bill Medicaid for these drugs.

[e]Rhode Island uses a 340B claim identifier to identify and exclude associated drugs administered by providers at hospitals, but does not have any procedures to identify these drugs administered by providers at other types of covered entities.

[f]Vermont requires covered entities, on a monthly basis, to identify for the state 340B drugs provided to Medicaid beneficiaries so they may be excluded from the state's rebate request.

Table 6: State Medicaid Programs' Procedures for Identifying 340B Drugs Dispensed to Medicaid Managed Care Beneficiaries, by Dispensing Method, 2019

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
Arizona	Medicaid Exclusion File and State-developed list of providers using 340B drugs	Medicaid Exclusion File and State-developed list of providers using 340B drugs	[a]
Arkansas	340B claim identifiers	Medicaid Exclusion File	[a]
California	340B claim identifiers	340B claim identifiers	340B claim identifiers
Colorado	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Delaware	Medicaid Exclusion File and State-developed list of providers using 340B drugs	Medicaid Exclusion File and State-developed list of providers using 340B drugs	[a]
District of Columbia	340B claim identifiers	No procedure	340B claim identifiers
Florida	340B claim identifiers	Medicaid Exclusion File	340B claim identifiers
Georgia	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File	[a]
Hawaii	State-developed exclusion process[b]	State-developed exclusion process[b]	340B claim identifiers
Illinois	340B claim identifiers	340B claim identifiers	[a]
Indiana	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers
Iowa	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Kansas	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Kentucky	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Louisiana	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Maryland	340B claim identifiers	State-developed list of providers using 340B drugs	340B claim identifiers
Massachusetts	340B claim identifiers	340B claim identifiers	340B claim identifiers
Michigan	340B claim identifiers	340B claim identifiers	340B claim identifiers
Minnesota	340B claim identifiers	340B claim identifiers	[a]
Mississippi	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Nebraska	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Nevada	Medicaid Exclusion File	Medicaid Exclusion File	Medicaid Exclusion File
New Hampshire	[c]	State-developed list of providers using 340B drugs	[c]
New Jersey	340B claim identifiers	Medicaid Exclusion File	340B claim identifiers
New Mexico	340B claim identifiers	340B claim identifiers	340B claim identifiers
New York	340B claim identifiers	340B claim identifiers	340B claim identifiers

State	In-house pharmacies	Provider-administered drugs	Contract pharmacies
North Dakota	[a]	[a]	[a]
Ohio	Medicaid Exclusion File and 340B claim identifiers	Medicaid Exclusion File and 340B claim identifiers	[a]
Oregon	Medicaid Exclusion File	Medicaid Exclusion File	State-developed exclusion process[d]
Pennsylvania	Medicaid Exclusion File	Medicaid Exclusion File	[a]
Rhode Island	Managed care plans are responsible for excluding 340B drugs from data they send to the state	Managed care plans are responsible for excluding 340B drugs from data they send to the state	Managed care plans are responsible for excluding 340B drugs from data they send to the state
South Carolina	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs	Medicaid Exclusion File and state-developed list of providers using 340B drugs
Tennessee	[e]	Medicaid Exclusion File	[e]
Texas	340B claim identifiers	340B claim identifiers	340B claim identifiers
Utah	340B claim identifiers	340B claim identifiers	[a]
Virginia	340B claim identifiers	340B claim identifiers	[a]
Washington	Medicaid Exclusion File	Medicaid Exclusion File	[a]
West Virginia	[e]	340B claim identifiers	[e]

Source: GAO analysis of state policies and communication with state officials. | GAO-20-212

Notes: Not all state Medicaid programs covered outpatient drugs through managed care. As such, this table only includes the 38 states that covered at least some outpatient drugs through managed care. The term 340B drugs refers to drugs purchased by covered entities at a discounted price through the 340B Program. The Medicaid Exclusion File is a list of provider numbers used to bill Medicaid for covered entities that elected to use, or carve in, 340B drugs for Medicaid fee-for-service beneficiaries. The list is maintained by the Health Resources and Services Administration.

[a]State does not allow covered entities to use 340B drugs for Medicaid managed care beneficiaries for this dispensing method and thus does not need a procedure to identify these drugs.

[b]Hawaii requires covered entities, on a quarterly basis, to identify for the state drugs provided to Medicaid beneficiaries that were not purchased under the 340B Program. The state also requires managed care plans to submit to the state, on a monthly basis, data that identifies 340B drugs at the claim level.

[c]New Hampshire allows covered entities to provide 340B drugs through this dispensing method, but does not allow them to bill Medicaid for these drugs.

[d]Oregon requires covered entities, on at least a quarterly basis, to identify for the state 340B drugs provided to Medicaid beneficiaries so they may be excluded from the state's rebate request.

[e]Managed care plans in this state do not cover outpatient drugs dispensed at pharmacies; they only cover provider-administered drugs.

Appendix IV: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

Debra Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*340B DRUG DISCOUNT PROGRAM: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*" (GAO-20-212).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Sarah Arbes
Acting Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED- 340 B DRUG DISCOUNT PROGRAM: OVERSIGHT OF THE INTERSECTION WITH THE MEDICAID DRUG REBATE PROGRAM NEEDS IMPROVEMENT (GAO-20-212)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

The Medicaid Drug Rebate Program was established by the Omnibus Budget Reconciliation Act of 1990 to help offset the Federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. It requires that, for covered outpatient drugs to be eligible for Federal financial participation through Medicaid, manufacturers must pay rebates to states on these drugs when dispensed to Medicaid beneficiaries and paid for by Medicaid. States are responsible for determining the amount of rebates owed and send invoices to manufacturers for each quarter. In addition, the 340B Drug Pricing Program, established by the Veterans Health Care Act of 1992, requires drug manufacturers to provide outpatient drugs to eligible health care providers, known as covered entities, at significantly reduced prices if those drugs are to be eligible for Federal financial participation through Medicaid. The covered entities generally bill their patients' insurance for 340B purchased drugs. Together, these programs serve as an increasingly important source of savings for both states and the Federal government. HHS places the highest priority on the integrity of these programs and continually works to strengthen oversight of the programs within its limited authority.

HHS appreciates the GAO's work in this area as it informs HHS' program integrity efforts. In its report, the GAO examines stakeholders' efforts to prevent duplicate discounts under the 340B and Medicaid Drug Rebate Programs. HHS recognizes the importance of avoiding duplicate discounts and has processes in place to ensure that duplicate discounts do not occur under these two programs. HHS regulations require that Medicaid Managed Care Organizations (MCOs) include an identifier on a prescription claim filled with a 340B-purchased drug so that these claims are excluded from the state quarterly rebate billings. The Health Resources and Services Administration provides the "Medicaid Exclusion File", which identifies covered entities that participate in the 340B Program specifically for fee-for-service drugs. States are also required to submit copies of their Medicaid rebate requests to HHS within 60 days of the end of each quarter. These data should exclude drugs that have been filled with drugs purchased through the 340B Program.

In addition, states are required to submit Medicaid State Plan Amendments (SPAs) to HHS when they change their Medicaid 340B drug program coverage policies. A SPA must be submitted to HHS if the state requires covered entities and/or contract pharmacies to "carve out" 340B drugs, meaning these entities will not use drugs purchased under the 340B Program for Medicaid patients. Rather, these drugs will be subject to Medicaid drug rebates. States may decide to carve-out 340B drugs as a mechanism to prevent duplicate discounts from occurring. If the covered entity or contract pharmacy is not able to use 340B drugs for Medicaid beneficiaries, the pharmacy can remain a Medicaid provider and drugs can be purchased outside of the 340B Program and dispensed to Medicaid patients.

As the GAO notes, states play a key logistic role in preventing duplicate discounts because they invoice manufacturers for rebates. The states rely on the information provided by covered entities and the MCOs to exclude prescription claims filled with 340B drugs before sending manufacturers' a rebate invoice. States use both provider-level and/or claim-level methods to exclude 340B drugs from invoices and have significant flexibility to use a variety of methods to prevent duplicate discounts. In some cases, states may place certain requirements on covered entities regarding the prevention of duplicate discounts. HHS will continue to work with the states to make sure that utilization data excludes any claims for 340B drugs and address any issues, if necessary.

The GAO's first recommendation for HRSA is related to HRSA's covered entity audit process. HRSA is currently evaluating its covered entity audit process and other program integrity efforts as they relate to HRSA's ability to enforce and require corrective action in the 340B Program, which is primarily administered by guidance. Guidance does not provide HRSA appropriate enforcement capability; therefore, HRSA is not pursuing new guidance under the program at this time. HRSA notes that it does not have regulatory authority related to the prevention of duplicate discounts for covered entities. The agency has requested regulatory authority in every President's Budget since fiscal year (FY) 2017 and has again requested this in FY 2020. Binding and enforceable regulations for all aspects of the 340B Program would provide HRSA the ability to more clearly define and enforce policy and would significantly strengthen HRSA's oversight of the program.

As discussed in more detail below, HHS has concerns with how the GAO characterizes its findings in the report. Specifically, the GAO asserts "covered entities' compliance with state policies and procedures is not assessed." HRSA notes that its audits of covered entities focus on ensuring that covered entities' 340B Program operations are meeting all 340B Program requirements. The program audits also help HRSA and covered entities identify and mitigate program risks, as well as identify best practices regarding 340B Program compliance. As such, these program audits emphasize having strong controls and involve an in-depth review of auditable records, system compliance, and the covered entities' policies and procedures to prevent diversion and duplicate discounts. While HRSA does not have the statutory authority to require covered entities to comply with state laws and requirements aimed at preventing duplicate discounts, it is HRSA's expectation that covered entities comply with all applicable laws and requirements and include a description of any applicable state Medicaid policies related to the 340B Drug Pricing Program in their 340B policies and procedures manual. HRSA auditors are expected to review the covered entities' policies and procedures for information related to state requirements to prevent a duplicate discount.

In addition, the GAO asserts that "not all identified duplicate discounts are repaid" and that HRSA does "not require a covered entity to develop a corrective action plan or make offers of repayment to a manufacturer" regarding identified duplicate discounts in Medicaid managed care organizations (MCOs). As the GAO explains, HRSA does not yet have guidance for covered entities related to Medicaid managed care claims; therefore, it is difficult to assess compliance in

this area absent policy on the issue. As noted in a 2014 policy release,[1] however, HRSA provides examples of best practices related to ways covered entities working with MCOs and state partners can develop models for the prevention of duplicate discounts. Some covered entities report using a variety of methods including, but not limited to, Bank Identification Numbers and/or Processor Control Numbers to identify patients of MCOs, National Council for Prescription Drug Programs codes at the individual claim level for claims submitted through a point of sale system at a retail or clinic pharmacy (contract pharmacy), and UD Modifiers for physician administered claims or drug costs submitted as part of a bundled or capitated rate. States may place certain requirements on covered entities regarding the prevention of duplicate discounts. HRSA encourages 340B covered entities to work with their states to develop strategies to prevent duplicate discounts on drugs reimbursed through MCOs. HRSA also encourages parties to work in good faith to resolve any issues.

Recommendation 1

The Administrator of CMS should ensure that state Medicaid programs have written policies and procedures that specify the extent to which covered entities can use 340B drugs for Medicaid beneficiaries, are designed to effectively identify if 340B drugs were used, and if so, how they should be excluded from Medicaid rebate requests. The policies and procedures should be made publically available and cover FFS, managed care, and all of the dispensing methods for outpatient drugs.

HHS Response

HHS concurs with this recommendation. HHS will continue to partner with states to ensure Medicaid drug rebates that are applied do not coincide with 340B discounts. HHS will work with states to strengthen policies and procedures related to 340B drugs for Medicaid beneficiaries. In addition, HHS plans to provide guidance to states on best practices for preventing duplicate discounts, especially in Medicaid managed care.

Recommendation 2

The Administrator of HRSA should incorporate assessments of covered entities' compliance with state Medicaid policies and procedures regarding the use and identification of 340B drugs into its audit process, working with CMS as needed to obtain states' policies and procedures.

HHS Response

HHS non-concurs with the GAO's recommendation.

HRSA does not have the authority to determine if state Medicaid policies and procedures are adequate or appropriate to prevent duplicate discounts. It also does not have the authority to enforce covered entities' compliance with those policies and procedures. However, as previously stated, HRSA does expect that covered entities include a description of their states' Medicaid policies related to 340B in their 340B policies and procedures manual. In addition, HRSA coordinates with CMS on any issues that may surface regarding state policy matters.

[1] See: https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/clarification-medicaid-exclusion.pdf

Although it is HRSA's view that interpreting state policies and billing requirements for the purpose of assessing covered entity compliance with state mandates is beyond the scope of the 340B Program, we note that even if this legal obstacle could be addressed, implementing this recommendation would still present significant challenges. For example, to incorporate an assessment of covered entities' compliance with state policies and procedures in its audit process, HRSA would first need to verify and interpret 50 varying state policies and procedures with respect to the identification of 340B drugs. HRSA notes that this degree of analysis would add tremendous burden and complexity to the audit process. HRSA auditors do not currently have this level of expertise and would need extensive training to be able to do so. To the extent that this recommendation is implemented, it would be further difficult to operationalize, as it is unclear how often state policies and procedures are updated. In addition, states would need to notify HRSA of any changes to policies and procedures, and covered entity audits would need to consider the policy at the time the 340B drug was purchased and dispensed, which would be extremely difficult to operationalize.

Recommendation 3
The Administrator of HRSA should require covered entities to work with affected drug manufacturers regarding repayment of identified duplicate discounts in Medicaid managed care.

HHS Response
HHS non-concurs with the GAO's recommendation.

As previously stated, HRSA does not have guidance for covered entities related to Medicaid managed care claims; therefore, it is difficult to assess compliance in this area absent policy on the issue. For any issues that arise, HRSA encourages parties to work in good faith to resolve issues.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, Michelle Rosenberg (Assistant Director), David Lichtenfeld (Analyst-in-Charge), Amanda Cherrin, and Sarah Tempel made key contributions to this report. Also contributing were Jennie Apter, Ethiene Salgado-Rodriguez, and Jennifer Whitworth.

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