



U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

July 14, 2017

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “Examining HRSA’s Oversight of the 340B Drug Pricing Program.”

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, July 18, 2017, at 10:15 a.m. in 2322 Rayburn House Office Building. The hearing is entitled “Examining HRSA’s Oversight of the 340B Drug Pricing Program.” An agency within the U.S. Department of Health and Human Services (HHS), the Health Resources and Services Administration (HRSA), oversees the program. The purpose of the hearing is to review HRSA’s oversight of the 340B Drug Pricing Program, as well as how the program is impacting patients, providers, manufacturers, and other stakeholders. Further, the hearing will examine potential areas for improvement within the program to ensure program integrity.

I. WITNESSES

- Krista M. Pedley, PharmD, MS, CDR, USPHS, Director, Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services;
- Debbie Draper, Director, Health Care, Government Accountability Office; and,
- Erin Bliss, Assistant Inspector General, Office of Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services.

II. BACKGROUND

a. Overview of the 340B Program

The 340B drug discount program was created by Congress in 1992. The 340B program mandates that drug manufacturers provide outpatient drugs to eligible health care organizations (also known as “covered entities”) at reduced prices in order to remain eligible for reimbursements through entitlement programs such as Medicaid and Medicare. Covered entities include hospitals owned or operated by state or local governments that serve a higher percentage of Medicaid beneficiaries, as well as federal grantees such as federally qualified health centers (FQHC), FQHC look-alikes, family planning clinics, state-operated AIDS drug assistance programs, Ryan White CARE Act grantees, family planning and sexually transmitted disease

clinics, and others, as identified in the Public Health Services Act (PHSA). The Health Resources and Services Administration, under HHS, is tasked with accepting applications and overseeing covered entities.

Citing a Committee report from the time the authorizing legislation passed, HRSA states that the purpose of the 340B program is to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹

Participation in the 340B program is voluntary for covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities are eligible to receive discounts on outpatient prescription drugs from participating manufacturers. Covered entities report saving between 25 and 50 percent of the average wholesale price for covered outpatient drugs.² HRSA estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in fiscal year (FY) 2013,³ and \$4.5 billion in FY 2014.⁴ As of October 2016, 12,148 covered entities were participating in the program⁵ and roughly 1,200 pharmaceutical manufacturers participate in the program.⁶

Covered entities do not receive discounts on *inpatient* drugs under the 340B program, but can realize substantial savings through 340B price discounts and generate 340B revenue by selling 340B drugs at a higher price than the discounted price at which the covered entity obtained the drug. Moreover, while covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA’s current definition of a patient,⁷ these entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.

The 340B price for a drug paid by covered entities—sometimes referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug

¹ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program*, available at <https://www.hrsa.gov/opa/>.

² 340B Prime Vendor Program, *340B Price/Covered Outpatient Drugs*, available at <https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/>.

³ *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong. (March 24, 2015) (statement of Diana Espinosa, Deputy Administrator, Health Resources and Services Administration).

⁴ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2017*, available at <https://www.hrsa.gov/about/budget/budgetjustification2017.pdf>.

⁵ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

⁶ There are 1204 manufacturers are listed by HRSA, 706 of which are deemed “active.” See Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *Office of Pharmacy Affairs 340B Database*, available at <https://opanel.hrsa.gov/OPA/Manufacturers.aspx>.

⁷ For current definition of a patient, see HRSA’s website. Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *Eligibility & Registration*, available at <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

manufacturer may charge covered entities.⁸ Manufacturers are permitted to audit covered entity records if they suspect product diversion or multiple discounts are taking place. Occasionally, the formula results in a negative price for a 340B drug. In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA’s penny pricing policy.

In March 2010, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies, referred to as contract pharmacies. Prior to 2010, covered entities were allowed to contract with only one pharmacy – either an in-house pharmacy, or an individual contract pharmacy.⁹ The growth and oversight of contract pharmacies since 2010 has been identified as an issue of concern by the Office of Inspector General of the U.S. Department of Health and Human Services (HHS OIG), and the U.S. Government Accountability Office (GAO) is planning an upcoming report examining that issue.

Many 340B program covered entity parent organizations have multiple associated “child sites.” Child sites can include satellite clinics or facilities, hospital departments, outpatient treatment units, and other facilities. Child sites are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on a hospital’s most recently filed Medicare cost report. As of July 5, 2017, 40,745 covered entity sites were participating in the 340B Program, including 17,965 disproportionate share hospital (DSH) sites.¹⁰

Hospitals’ participation in the 340B program has grown markedly in recent years – faster than that of federal grantees, increasing almost three-fold in the number of participants from 2005 to 2011.¹¹ According to a 2011 report by the GAO, a third of all hospitals participated in the program, and DSH hospitals alone represented about 75 percent of all 340B drug purchases.¹² Currently, approximately 40 percent of all U.S. hospitals participate in the 340B program. According to HRSA’s database on covered entities, as of July 5, 2017, DSH hospitals accounted for 44 percent of covered entities sites.¹³

⁸ Manufacturers may sell a drug at a price that is lower than the ceiling price, so covered entities may negotiate prices below the ceiling price. The discount is determined by dividing the average total Medicaid rebate percentage of 15.1% for single source and innovator multiple source drugs, and 11% for non-innovator multiple source drugs by the average manufacturer price (AMP) for each dose and strength. The Medicaid statute defines AMP as the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers are required to report AMP and their best price to the Secretary, but subject to verification, manufacturers calculate the maximum price (“ceiling price”) they may charge 340B entities.

⁹ 75 Fed. Reg. 10272, 10274–10278 (March 5, 2010).

¹⁰ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://datawarehouse.hrsa.gov/topics/HealthcareSystems/CE340BDataExplorer.aspx>.

¹¹ U.S. Gov’t Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).

¹² *Id.*

¹³ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://datawarehouse.hrsa.gov/topics/HealthcareSystems/CE340BDataExplorer.aspx>.

b. Changes PPACA Made to the 340B Program

Enacted in 2010, the Patient Protection and Affordable Care Act (PPACA) made a number of notable changes to the 340B program, some of which have yet to be fully implemented.

- *Expanded Participation in 340B Program:*¹⁴ PPACA added the following to the list of covered entities entitled to discounted drug prices under the 340B program: (1) certain children's and free-standing cancer hospitals excluded from the Medicare prospective payment system; (2) critical access hospitals; and (3) certain rural referral centers and sole community hospitals. These 340B-eligible facilities also must meet other specified 340B participation requirements.
- *Changes to 340B Program Integrity:* PPACA required the Secretary of HHS to develop systems to improve manufacturer and covered entity compliance and program integrity activities, as well as administrative procedures to resolve disputes. The compliance and program integrity systems were to include a number of specifications to increase transparency and strengthen monitoring, oversight, and investigation of the prices that manufacturers charge covered entities, as well as additional improvements to ensure covered entities do not divert drugs or obtain multiple discounts. The Secretary was required to establish a new administrative dispute resolution process to mediate and resolve covered entity overpayment claims and manufacturer claims against covered entities for drug diversion or multiple discounts. Civil money penalty (CMP) sanctions up to \$5,000 per instance for manufacturer overcharges were authorized. The Secretary was required to establish standards and issue regulations for assessing CMPs on drug manufacturers for overcharge violations and was required to issue regulations to implement a dispute resolution process by which covered entities can report instances where they suspect they have been overcharged.
- *Required Manufacturers Communicate Prices to HHS:* PPACA required that pricing agreements stipulate that drug makers will report to the Secretary the quarterly ceiling prices for each covered drug and to offer these drugs to covered entities at or below these prices.

c. GAO and HHS OIG Findings

- *2011 GAO Findings:* In 2011, GAO issued a report, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement."¹⁵ GAO found that the 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services. However, GAO cautioned that HRSA's then-current approach to oversight did not ensure 340B program integrity, and raised concerns that this

¹⁴ Section 7101, as amended by HCERA Sec. 2302, amended PHS Act Sec. 340B.

¹⁵ U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).

vulnerability may be exacerbated by changes within the program. Among GAO's key findings:

- According to HRSA, the agency largely relies on participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers.
- HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements, so participants may be interpreting guidance in ways that are inconsistent with the agency's intent.
- Participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance.
- With the program's expansion, program integrity issues may take on even greater significance unless effective mechanisms to monitor and address program violations, as well as more specific guidance, are put in place.
- PPACA outlined a number of provisions that, if fully implemented, would help improve many of the 340B program integrity issues identified.
- GAO identified other program integrity issues that HRSA should also address: (1) HRSA is not required to audit covered entities or further specify the agency's definition of a 340B patient; (2) HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance; (3) HRSA guidance may allow some ineligible entities to be eligible for the program.
- Finally, GAO noted that while HRSA would benefit from more resources, limited resources could be prioritized to address areas of greatest risk to the program.

HRSA has addressed some of the concerns raised by GAO. For example, HRSA began conducting audits of covered entities and issued more specific nondiscrimination guidance for cases in which distribution of drugs is restricted.

- *2014 HHS OIG Findings:* Covered entities participating in the 340B Program may contract with pharmacies to dispense drugs purchased through the program on their behalf.¹⁶ Such pharmacies are referred to as "contract pharmacies." In a 2014 report examining "Contract Pharmacy Arrangements in the 340B program," HHS OIG noted that in 2010, the percentage of all covered entities that use contract pharmacies had risen

¹⁶ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Contract Pharmacy Services*, available at <http://www.hrsa.gov/opa/implementation/contract/index.html>.

from 10 percent to 22 percent.¹⁷ Moreover, the number of unique pharmacies serving as 340B contract pharmacies has grown by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent. Some of HHS OIG's key findings were:

- HHS OIG found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways.
- In some cases, HHS OIG explained that different methods lead to differing determinations of 340B eligibility across covered entities. That is, two covered entities may categorize similar types of prescriptions differently. As a result, HHS OIG concluded "there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible."
- Several covered entities did not offer the discounted 340B price to uninsured patients at their contract pharmacies.
- Most covered entities examined did not conduct all of the oversight activities recommended by HRSA. Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance.
- Contract pharmacy administrators reported difficulties in identifying beneficiaries covered by managed care organization Medicaid, and some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts.

In June 2011, HHS OIG published a review of states' reimbursement policies and oversight related to 340B-purchased drugs. At the time, HHS OIG found that states lacked pricing information needed for oversight and that nearly half of states did not have written 340B policies.¹⁸

- *2015 GAO Findings:* In 2015, GAO issued a report, "Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals."¹⁹ The report identified the characteristics of 340B DSH hospitals as compared to non-340B hospitals, and found that hospitals participating in the 340B program have a financial incentive to prescribe

¹⁷ Office of Inspector General, U.S. Dep't of Health and Human Services, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 4, 2014), available at <http://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

¹⁸ Office of Inspector General, U.S. Dep't of Health and Human Services, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321 (June 2011), available at <http://oig.hhs.gov/oei/reports/oei-05-09-00321.pdf>.

¹⁹ U.S. Gov't Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), available at <https://www.gao.gov/products/GAO-15-442>.

more drugs, and more expensive drugs to Medicare beneficiaries. Among GAO's key findings:

- 340B DSH hospitals tended to be larger in terms of facility revenues, and were more likely to be major teaching hospitals compared to non-340B hospitals.
- 340B DSH hospitals generally provided more charity care, and generally had DSH median adjustment percentages between two and three times larger than non-340B DSH hospitals, depending on teaching status.
- While most 340B DSH hospitals provided more charity care than non-340B hospitals, GAO found that 12 percent of 340B DSH hospitals studied were among those that provided the lowest amount of charity care.
- 340B DSH hospitals had higher Medicare margins, had substantially higher Medicare Part B spending per beneficiary (by 240 percent and 232 percent compared to non-340B DSH and non-340B institutions), and these differences were not attributable to differences in the health of the populations they served.
- The Centers for Medicare and Medicaid Services (CMS) uses a statutorily defined formula to pay hospitals for drugs, regardless of the cost to the hospital in purchasing those drugs.
- The 340B statute does not prohibit 340B entities from prescribing 340B discounted drugs to Medicare Part B beneficiaries, so HRSA and CMS have limited ability to hinder the 340B DSH hospitals' incentive to prescribe more, and more expensive drugs to Medicare beneficiaries.

III. CURRENT ISSUES

a. Program Growth Exceeds HRSA's Oversight Capabilities

For most of its existence, the 340B Program has not been subject to rigorous oversight. HRSA had 24 full-time employees (FTEs) for the 340B program in FY 2016, which it reduced to 22 FTEs for FY 2017 and 2018.²⁰ After GAO issued a 2011 report critical of the program's oversight, HRSA received additional funding of \$6 million in FY 2014 to increase its oversight efforts.²¹ However, the PPACA dramatically increased the size and scope of this program by expanding eligibility to more categories of hospitals, so the periodic audits conducted by the

²⁰ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²¹ In FY 2016 and FY 2017 HRSA budget was \$10.543 billion and \$10.401 billion respectively. For FY 2018, HRSA has requested \$9.9 billion. Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

GAO and HHS OIG, and HRSA's own limited oversight may not be sufficient to conduct adequate oversight of this program.

The number of participating unique covered entities has grown from 3,200 in 2011,²² to 11,180 in February 2015, to 12,148 covered entities in October 2016.²³ The number of hospitals in particular has grown significantly, from 591 in 2005, to 1,673 in 2011, to 2,871 as of July 2017. The number of child sites has also grown dramatically. In 2011, GAO reported that the number of child sites had nearly doubled over the previous decade, reaching just over 16,500 registered sites.²⁴ According to HRSA, that number had reached 37,496 in October 2016,²⁵ and 40,745 registered sites by July 2017.²⁶

In addition to an increase in child sites, the number of contract pharmacies has grown greatly since HRSA issued its 2010 guidance on contract pharmacies. In 2011, GAO reported that while HRSA did not track individual contract pharmacies in use, there were more than 7,000 contract pharmacy arrangements through the program.²⁷ In its 2018 Budget Justification, HRSA reported that twenty-seven percent of covered entity sites have contract pharmacy arrangements, resulting in approximately 18,078 unique pharmacy locations.²⁸ The GAO has ongoing work that will examine the growth of contract pharmacy arrangements.

Finally, the amount that covered entities save on 340B drugs has also increased. In FY 2013, HRSA estimated that covered entities saved \$3.8 billion on drug expenditures.²⁹ In FY 2014, that estimate rose to \$4.5 billion in savings.³⁰

Despite the rapid growth of the program, HRSA's auditing has remained at or below 200 annual audits of covered entities since 2012, when HRSA's practice of auditing covered entities began. The next section covers the results of those audits.

²² U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011), <http://gao.gov/assets/330/323702.pdf>.

²³ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²⁴ U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011), <http://gao.gov/assets/330/323702.pdf>.

²⁵ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²⁶ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://datawarehouse.hrsa.gov/topics/HealthcareSystems/CE340BDataExplorer.aspx>.

²⁷ U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011), <http://gao.gov/assets/330/323702.pdf>.

²⁸ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²⁹ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2016*, available at <https://www.hrsa.gov/about/budget/budgetjustification2016.pdf>.

³⁰ *Id.*

b. HRSA’s Oversight Reveals High Levels of Non-compliance

HRSA’s annual audits uncover a high level of non-compliance by covered entities. The HRSA audits from FY 2012 to FY 2016 demonstrate that non-complying entities violate program requirements in at least one of three ways: duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting.³¹

Figure 1: Program Requirement Violations:

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Duplicate Discounts	18	24	23	47	42
Drug Diversion	16	51	54	94	78
Incorrect Database	15	46	51	100	57
No Adverse Findings	19	20	18	43	59
Total Audits	*51	*94	*99	*200	*175

***Note:** numbers do not sum because several entities had more than one type of violation.

c. Duplicate Discounts

Covered entities are prohibited from receiving duplicate discounts.³² A duplicate discount occurs when a covered entity receives a 340B discount on drugs provided to Medicaid patients *and* the state Medicaid agency also receives a rebate for the drug dispensed to the Medicaid beneficiary through the Medicaid Drug Rebate Program. When an entity enrolls in the 340B Program, it must determine whether it will “carve-in” or “carve-out” for Medicaid prescriptions. Entities that “carve-in” agree to buy Medicaid drugs through the 340B program without seeking a Medicaid rebate, while entities that “carve-out” agree to buy Medicaid drugs through the Medicaid Drug Rebate Program or otherwise. Duplicate discounts occur because there is overlap in eligibility for the Medicaid rebate and 340B programs. While Medicaid rebates benefit state Medicaid programs and 340B programs benefit 340B-covered entities, both of these programs target the same safety-net population.³³ The significant overlap in prescription eligibility makes discount errors likely, and HRSA’s audits found duplicate discounts to be quite common. Further, 340B discounts are often determined retrospectively, which can also increase the rate of discount errors. At least 23 percent of 340B-covered entities audited had duplicate discount errors each year, as shown above in Figure 1.

In 2013, HRSA created the 340B Medicaid Exclusion File (MEF) as a strategy to prevent duplicate discounts for drugs subject to both Medicaid rebates and 340B prices for Fee-For-

³¹ Duplicate discounts, diversion, and incorrect reporting will be discussed later in this section.

³² Public Health Service Act, 42 U.S.C. 256b(a)(5)(A)(i).

³³ Jason Hardaway, *340B Program Puts Manufacturers At Risk of Duplicate Drug Discounts*, 41 PHARMACY AND THERAPEUTICS 1, 38 (2016).

Service claims.³⁴ The MEF is a list of Medicaid provider number or national provider numbers (NPI) of each entity that has agreed to purchase all drugs billed to Medicaid through the 340B program. The MEF is intended to prevent duplicate discounts by notifying states and manufacturers which drugs are not eligible for Medicaid rebates. This measure counts on the integrity and continued participation of covered entities to disclose accurate and current information.

HRSA lacks a centralized mechanism similar to the MEF to prevent duplicate discounts for Medicaid Managed Care Organizations (MCOs).³⁵ This is a significant problem because an increasing number of Medicaid programs rely on Managed Care. In 2014, 76 percent of Medicaid enrollees were in some type of managed care.³⁶ The HHS OIG released a report in June 2016, finding that duplicate discounts are a severe issue for Medicaid MCOs. The data that most states collect for MCO drugs is not granular enough to detect all individual drug claims. Many states still used the MEF for MCO drugs, despite HRSA's guidance to develop alternate strategies, since the MEF only works for Fee-For-Service drugs. Duplicate discounts for MCOs participating in the Medicaid Drug Rebate Program is a relatively new problem. Prior to the PPACA, only Medicaid Fee-For-Service (FFS) claims were eligible for rebates. Unfortunately, the PPACA did not anticipate the issues involved with reconciling duplicate discounts for MCOs, which notoriously under-report Medicaid data to the states.

d. Diversion

HRSA prohibits the resale or transfer of 340B drugs to ineligible patients, known as diversion. Only individuals who are patients of 340B-covered entities are eligible for drug pricing discounts.³⁷ To be considered a patient of a covered entity, the individual must maintain his or her records with the covered entity, and receive health care services from providers employed by the covered entity.³⁸

In FY 2012, FY 2015, and FY 2016, close to half of HRSA's audited entities diverted benefits to ineligible patients – 31 percent of covered entities in FY 2012, 47 percent of covered entities in FY 2015, and 44 percent of covered entities in FY 2016 were found to have diverted drugs. Diversion violations reached a 54 percent high in FY 2014 and FY 2015, when over 50 audited entities offered drug pricing benefits to ineligible patients.

³⁴ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File*, Release No. 2014-1, 3 (Dec. 2014).

³⁵ 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300, 52309 (Aug. 2015); See Office of Inspector General, U.S. Dep't of Health and Human Services, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016).

³⁶ *Medicaid Managed Care Enrollment and Program Characteristics, 2014*, Centers for Medicare and Medicaid Services, available at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/medicaid-managed-care/downloads/2014-medicaid-managed-care-enrollment-report.pdf>.

³⁷ There is one exception: individuals registered in state-operated or funded AIDS Drug Assistance Program who are automatically eligible for 340B benefits. See 340B Prime Vender Program, *Patient Definition*, available at <https://www.340bpvp.com/resource-center/faqs/patient-definition/>.

³⁸ See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207 (Oct. 24, 1996).

The lack of a clear definition of “patient” sheds light on the high number of covered entities who committed diversion violations. HRSA’s definition of “patient” has been criticized widely for its vagueness. The HHS OIG has stated that “[there is] a lack of clarity on how HRSA’s patient definition should be applied in contract pharmacy arrangements.”³⁹ The GAO has also offered criticism, explaining that “HRSA’s current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B.”⁴⁰

To identify which 340B-eligible patients received prescriptions, contract pharmacies⁴¹ often match information from the 340B providers, such as patient and prescriber lists, to their dispensing data. In its 2014 report, HHS OIG found wide variation in these eligibility determinations. Depending on the interpretation of HRSA’s patient definition, some 340B provider eligibility determinations would be considered diversion and others would not.⁴²

e. Incorrect Reporting

The administration of the 340B program depends on accurate database information. HRSA audits reveal that many covered entities are not fulfilling their obligations of maintaining current database information. With the exception of FY 2012, at least half of the audited entities kept incorrect records all other years, as shown above in Figure 1. The audits show that many times, records include clinic locations or outpatient facilities that are no longer in service. Another common error is that entities include unauthorized facilities in their database.

HHS OIG investigators have warned that incorrect reporting is one way to hide intentional abuses of government programs. Entities seeking reimbursement from Medicaid and Medicare sometimes practice poor bookkeeping to prevent auditors from noticing trends and practices that may alert the auditor to wrongdoing. As a result, it is imperative for program integrity that the covered entities be required to keep detailed records.

f. Unclear Program Requirements and Lack of Transparency Hamper HRSA’s Oversight Capabilities

In addition to significant growth, unclear program requirements and lack of transparency surrounding the program hamper HRSA’s ability to conduct sufficient oversight. According to a committee report from the time the authorizing legislation was passed, the purpose of the 340B program is to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”⁴³ However, neither the 340B statute nor

³⁹ Office of Inspector General, U.S. Dep’t of Health and Human Services, *Memorandum report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014).

⁴⁰ Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

⁴¹ Covered entities may contract with pharmacies to dispense drugs purchased through the program on their behalf. Such pharmacies are referred to as contract pharmacies.

⁴² Office of Inspector General, U.S. Dep’t of Health and Human Services, *Memorandum report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014).

⁴³ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program*, available at <https://www.hrsa.gov/opa/>.

HRSA guidance explain how 340B providers must use savings from the program. Notably, there is no requirement that the discounted 340B price be passed on to uninsured patients who seek treatment at 340B entities. As a result, the 340B entity will acquire the drug at a discounted price, but the uninsured patient may pay the full list price for the drug. While some 340B entities pass savings on to uninsured patients, many use savings from the 340B program to pay for the operations of the covered entity, such as marketing.

In 2011, GAO issued a report on the savings generated by covered entities through the program.⁴⁴ While covered entities reported that 340B savings were used to expand access and services, GAO told Committee staff that all but one entity audited was unable to tell GAO the exact number of funds generated from the 340B program and how 340B funds were used. HRSA does not require covered entities to report the amount of funds generated from the 340B program, or how the entity spends those funds.

Further, there is little transparency surrounding the ceiling prices set by manufacturers in accordance with a statutory formula. Consistent with an HHS OIG recommendation, the ACA mandated that HRSA share ceiling prices with covered entities through a secure website. HRSA has since testified that it was unable to do so due to a lack of resources, but would undertake that project in 2015. However, covered entities still do not have access to that data. Without that data, covered entities are unable to ensure they are paying an appropriate price for 340B drugs. While HRSA has authority to establish a mechanism to share ceiling prices with 340B providers, HRSA does not have the authority to share ceiling prices with the states in order to enable state Medicaid agencies to ensure that they too are paying appropriate prices.

g. HRSA's Authority is Limited

HRSA has limited authority to regulate and enforce requirements for the 340B program. The three areas in which HRSA has explicit regulatory authority are calculation of 340B drug ceiling prices, imposition of manufacturer CMPs, and implementation of a dispute resolution process. As described above, lack of clarity on program requirements creates confusion as to what constitutes compliance, and further, HRSA lacks the authority to issue regulations clarifying those requirements.

In 2014, HRSA was preparing an omnibus regulation, which the agency said would have addressed a wide range of policy issues related to the program, including the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities. However, before the omnibus 340B regulation was released, HRSA found itself in litigation over a separate orphan drug regulation.⁴⁵ In May 2014, a ruling by the United States District Court for the District of

⁴⁴ Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

⁴⁵ The orphan drug rule HRSA issued allowed 340B covered entities affected by the orphan drug exclusion (critical access hospitals, freestanding cancer hospitals, sole community hospitals and rural referral centers) to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation.

Columbia vacated HRSA's orphan drug regulation in the 340B program on the grounds that HRSA lacks the statutory authority to engage in that form of rulemaking.⁴⁶

In June 2014, HHS/HRSA announced it continued to stand by its interpretation described in its published final rule, and in July, HRSA issued an interpretive guidance pertaining to the statutory requirement for inclusion of drugs with orphan drug designations in the 340B drug pricing program.⁴⁷ These agency actions were met with further litigation. In November 2014, with the ongoing litigation on the orphan drug regulation, HRSA withdrew its omnibus 340B regulation. The District Court's ruling vacating the regulation was affirmed in October 2015, and hampers HRSA's ability to issue regulations and to enforce provisions of the 340B program.

After HRSA withdrew its omnibus regulation, it subsequently released its proposed 340B Drug Pricing Program Omnibus Guidance, commonly referred to as the "Mega-Guidance" in August 2015.⁴⁸ However, HRSA withdrew the Mega-Guidance on January 30, 2017, shortly after the Trump Administration issued a regulatory freeze requiring agencies to retract any regulations currently under review.

In light of these issues, the Committee hopes to explore the challenges HRSA faces in conducting oversight of the 340B program, and the impact of the program on patients, providers, manufacturers, and other stakeholders.

IV. ISSUES

The following issues may be examined at the hearing:

- How has HRSA's oversight changed to reflect the growth of the 340B program in recent years?
- How effective is HRSA's oversight in detecting and resolving non-compliance with 340B program regulations?
- Does HRSA currently have the regulatory authority it needs to successfully oversee the 340B program?
- How has the 340B program affected patient care?

⁴⁶ *Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services*, Civil Action No. 2013-1501 (D.C. 2014).

⁴⁷ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Program Requirements*, available at <http://www.hrsa.gov/opa/programrequirements/interpretiverule/>.

⁴⁸ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Omnibus Guidance*, available at <https://www.federalregister.gov/documents/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance>.

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Brighton Haslett or Brittany Havens of the Committee staff at (202) 225-2927.