



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

October 9, 2017

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “Examining How Covered Entities Utilize the 340B Drug Pricing Program”

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, October 11, 2017, at 10:00 a.m. in 2123 Rayburn House Office Building, entitled “Examining How Covered Entities Utilize the 340B Drug Pricing Program.”

I. WITNESSES

- Sue Veer, MBA, CMPE, President and Chief Executive Officer, Carolina Health Centers;
- Michael J. Gifford, President and Chief Executive Officer, AIDS Resource Center of Wisconsin;
- Ronald A. Paulus, M.D., President and Chief Executive Officer, Mission Health;
- Charles Reuland, MHS, Sc.D., Executive Vice President and Chief Operating Officer, Johns Hopkins Hospital; and
- Shannon A. Banna, Director of Finance and System Controller, Northside Hospital, Inc.

II. BACKGROUND

a. Overview of the 340B Drug Pricing Program

Established by Congress in 1992, the 340B Drug Pricing Program mandates that drug manufacturers provide outpatient drugs to eligible health care organizations (also known as “covered entities”) at reduced prices to remain eligible for reimbursements through entitlement programs such as Medicaid and Medicare. Covered entities are eligible to receive discounts on outpatient prescription drugs from participating manufacturers and report saving between 25 and 50 percent of the average wholesale price for covered outpatient drugs.¹ The Health Resources

¹ 340B Prime Vendor Program, *340B Price/Covered Outpatient Drugs*, available at <https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/>.

and Services Administration (HRSA) estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in fiscal year (FY) 2013,² and \$4.5 billion in FY 2014.³ As of October 2016, 12,148 covered entities are actively participating in the program⁴ and roughly 722 pharmaceutical manufacturers are actively participating in the program.⁵

Covered entities do not receive discounts on *inpatient* drugs under the 340B program. Covered entities can realize substantial savings on *outpatient* drugs 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,⁶ these entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, regardless of whether 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 manufacturer may charge covered entities.⁷ 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

² *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).

³ 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>.

⁴ 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>.

⁵ There are 1204 manufacturers are listed by HRSA, 706 of which are deemed “active.” Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, at 245-46, available at <https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf>.

⁶ 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. 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>.

⁷ 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 percent for single source and innovator multiple source drugs, and 11 percent 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.

contract pharmacies. Prior to 2010, covered entities were only allowed to contract with one pharmacy – either an in-house pharmacy, or an individual contract pharmacy.⁸ 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 currently examining this 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 October 2, 2017, 42,025 covered entity sites were participating in the 340B Program, including 18,737 disproportionate share hospital (DSH) sites.⁹

b. Types of Covered Entities

HRSA is tasked with accepting applications for participation in the 340B Program, determining program eligibility, and overseeing covered entities. Covered entities must recertify their eligibility for the 340B program annually. Eligibility is statutorily defined and is limited to certain qualifying hospitals and federal grantees.¹⁰ Congress has expanded program eligibility over time, most recently through the Patient Protection and Affordable Care Act (PPACA).¹¹

Federal grantees include various types of health centers, HIV/AIDS program grantees, and specialized clinics, including Federally Qualified Health Centers (FQHC), Federally Qualified Health Center Look-Alikes, Native Hawaiian Health Centers, Tribal/Urban Indian Health Centers, Ryan White HIV/AIDS Program Grantees, Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Sexually Transmitted Disease Clinics, Tuberculosis Clinics, and Title X Family Planning Clinics.¹² These entities typically are subjected to additional requirements and federal oversight because of their status as federal grantees. For example, HRSA (which oversees the Ryan White HIV/AIDS Program) has established that any revenue a Ryan White grantee generates through participation in the 340B program is Ryan White program income and therefore subject to HRSA restrictions on how Ryan White program income can be spent.¹³

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

⁹ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://340bopais.hrsa.gov/coveredentitysearch>.

¹⁰ 42 U.S.C. § 256b.

¹¹ 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.

¹² Health Resources and Services Administration, Eligibility & Registration (last visited Sept. 18, 2017), available at <https://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

¹³ Health Resources and Services Administration, 15-03 Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income, Policy Clarification Notice (PCN) #15-03, Relates to Policy #15-04 (last visited Sept. 19, 2017), https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf.

Hospitals that are eligible to participate in the 340B Drug Pricing Program include certain disproportionate share hospitals, children’s hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. Eligible hospitals must meet certain additional requirements to participate in the program. First, an eligible hospital typically must have a minimum disproportionate share adjustment percentage to qualify for program participation (which is based on the share of a hospital’s inpatients who are Medicaid and low-income Medicare patients). Furthermore, each eligible hospital must be (1) owned and operated by a state or local government, (2) a public or private nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare. Additionally, as shown in Figure 1 below, certain eligible hospitals must certify that they will not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement.

Figure 1: Hospital Eligibility¹⁴

Hospital Type	Nonprofit/Government Contract Requirement	DSH %	Subject to GPO Prohibition
Disproportionate Share Hospital	Yes	> 11.75%	Yes
Children’s Hospital	Yes	> 11.75%	Yes
Free-Standing Cancer Hospital	Yes	> 11.75%	Yes
Critical Access Hospital	Yes	N/A	No
Rural Referral Center	Yes	≥ 8%	No
Sole Community Hospital	Yes	≥ 8%	No

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 2011.¹⁵ According to a 2011 report by the GAO, one third of hospitals participated in the program, and DSH hospitals alone represented about 75 percent of all 340B drug purchases.¹⁶ 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.¹⁷

¹⁴ Apexus, 340B University, *340B Hospital Eligibility Criteria* (2015), available at https://docs.340bpvp.com/documents/public/resourcecenter/Hospital_Eligibility_Criteria.pdf.

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).

¹⁶ *Id.*

¹⁷ 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>.

c. HRSA's Oversight of the 340B Drug Pricing Program

i. Unclear Program Requirements and Lack of Transparency Hamper HRSA's Oversight Capabilities

According to a committee report from the time the authorizing legislation was adopted, 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.”¹⁸ Neither the 340B statute nor HRSA guidance, however, explain how 340B entities 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, it has been reported that some 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.¹⁹ 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. As discussed during the committee's July 2017 hearing, HRSA does not have the authority to 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, PPACA 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. Covered entities, however, 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 entities, HRSA does not have the authority to share ceiling prices with states to enable state Medicaid agencies to ensure that they too are paying appropriate prices.

ii. Program Growth Exceeds HRSA's Oversight Capabilities

For most of its existence, the 340B Drug Pricing Program has not been subject to rigorous oversight. After GAO issued a 2011 report critical of the program's oversight, HRSA

¹⁸ 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/>.

¹⁹ Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

received additional funding of \$6 million in FY 2014 to increase its oversight efforts.²⁰ HRSA had 24 full-time employees (FTEs) for the 340B program in FY 2016, which it reduced to 22 FTEs for FY 2017 and 2018.²¹

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 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 27 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.

The amount that covered entities save on 340B drugs has also increased. In FY 2013,

²⁰ 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>.

²¹ 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>.

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>.

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.

iii. HRSA’s Oversight Reveals High Levels of Non-Compliance

HRSA’s annual audits show 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.

Figure 2: 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.

1. Duplicate Discounts

Covered entities are prohibited from receiving duplicate discounts.³¹ 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

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.*

³¹ Public Health Service Act, 42 U.S.C. 256b(a)(5)(A)(i).

target the same safety-net population.³² 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 2.

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-Service claims.³³ The MEF is a list of Medicaid provider number or national provider numbers (NPN) 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).³⁴ This is a significant problem because an increasing number of Medicaid programs rely on managed care.³⁵ 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 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.³⁶

2. 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

³² Jason Hardaway, *340B Program Puts Manufacturers At Risk of Duplicate Drug Discounts*, 41 PHARMACY AND THERAPEUTICS 1, 38 (2016).

³³ 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).

³⁴ 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).

³⁵ *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>.

³⁶ See e.g., Office of Inspector General, U.S. Dep't of Health and Human Services, *Not All States Reported Medicaid Managed Care Encounter Data as Required*, OEI-07-13-00120 (July 2015).

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 Vendor Program, *Patient Definition*, available at <https://www.340bpvp.com/resource-center/faqs/patient-definition/>.

his or her records with the covered entity, and receive health care services from providers employed by the covered entity.³⁸ As shown in Figure 2, a large percentage of HRSA's audited entities diverted drugs to ineligible patients in FY 2012 through FY 2016.

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

3. 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.

d. Medicare Part B and the 340B Drug Pricing Program

Medicare Part B covers services and supplies considered medically necessary to treat a

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).

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).

disease or condition, including a limited number of outpatient prescription drugs.⁴³ Medicare generally pays 106 percent of the Average Sales Price (ASP) for most Part B drugs, regardless of the amount the hospital paid to purchase the Part B drug from the pharmaceutical manufacturer.⁴⁴ Medicare therefore pays the same amount for Part B drugs to both 340B hospitals and non-340B hospitals even though 340B hospitals can purchase outpatient drugs at reduced prices through the 340B Program.

In November 2015, HHS OIG issued a report finding that Medicare Part B payments to covered entities for 340B-purchased drugs substantially exceeded the covered entities' costs to obtain the drugs.⁴⁵ OIG found that "[i]n the aggregate, Part B payment amounts were 58 percent more than the statutorily based 340B ceiling prices [in 2013], which allowed covered entities to retain approximately \$1.3 billion."⁴⁶ The Agency also noted that Medicare beneficiary cost-sharing obligations are not reduced to reflect the discounted 340B prices (Part B beneficiaries typically are responsible for 20 percent of the Part B payments in coinsurance), and Medicare Part B does not share in any of the 340B program savings realized by hospitals.⁴⁷ Moreover, in 2015, GAO issued a report indicating that the financial incentive for 340B hospitals to prescribe more drugs, or more expensive drugs, to Medicare beneficiaries, might be impacting prescribing behavior. More specifically, GAO found that "per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals."⁴⁸

On July 13, 2017, CMS proposed changing how Medicare Part B pays hospitals for drugs that are acquired under the 340B Drug Discount Program. Rather than continue to reimburse 340B entities for certain Part B drugs purchased through the 340B program at ASP plus 6 percent, CMS proposes reducing reimbursement for certain Part B drugs purchased through the 340B program to ASP minus 22.5 percent.⁴⁹ CMS stated its goal is to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs."⁵⁰ The change in reimbursement for certain 340B drugs is limited to separately payable drugs under the outpatient prospective payment system (OPPS), with other additional exclusions.⁵¹

CMS justified its proposed changes by referring to a May 2015 report to Congress issued by the Medicare Payment Advisory Committee (MedPAC). In the report, MedPAC estimated

⁴³ CMS, *What Part B Covers*, Medicare.gov (last visited Sept. 19, 2017), available at <https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html>.

⁴⁴ 82 Fed. Reg. 33558, 33633 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

⁴⁵ U.S. Dep't of Health and Human Services, *Office of Inspector General, Part B Payments for 340B-Purchased Drugs*, OEI-12-14-00030 (Nov. 2015).

⁴⁶ *Id.* at 8.

⁴⁷ *Id.* at 4.

⁴⁸ U.S. Gov't Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-1442 (Jun. 5, 2015), available at <http://www.gao.gov/products/GAO-15-442>.

⁴⁹ 82 Fed. Reg. 33558, 33634 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

⁵⁰ 82 Fed. Reg. 33558, 33633 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

⁵¹ 82 Fed. Reg. 33558, 33633 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

that “hospitals in the 340B program receive a minimum discount of 22.5 percent of the average sales price for drugs paid under the outpatient prospective payment system.”⁵² CMS stated that the agency “believe[s] that the MedPAC Analysis that found the average minimum discount of 22.5 percent of ASP adequately reflects the average minimum discount that 340B hospitals paid under the OPSS receive.”⁵³ CMS estimates that with the proposed changes, OPSS payments for separately payable drugs, including beneficiary copayment amounts, may decrease by as much as \$900 million.⁵⁴

e. The Committee’s July 18, 2017 Hearing Examining the 340B Drug Pricing Program

On July 18, 2017, the Committee held a hearing examining HRSA’s oversight of the 340B Drug Pricing Program. Witnesses from HRSA, GAO, and HHS OIG answered questions about the size and scope of the program as well as HRSA’s annual program audits.

At the hearing, HRSA testified that the 340B statute does not require that entities report their savings or how those savings are used. Thus, HRSA has no data on how much each entity saves through program participation and how the savings are used, and lacks authority to require that entities use their savings in a specific way. HRSA could not testify as to the amount of charity care provided by covered entities, whether savings are used to serve insured or uninsured patients, whether covered entities used a sliding fee scale to discount drugs based on a patient’s ability to pay, or whether savings were passed along to any patients in the form of discounted prices.

f. The Committee’s September 8, 2017 Letter

Other than media reports, the Committee has limited information about how most covered entities utilize the 340B drug pricing program and the savings generated from the program. In order to better understand the ways in which different entities utilize the program, the Committee sent a letter on September 8, 2017, to a diverse group of covered entities requesting information about purchases made through the program, how the entities track and use program savings, and how patients benefit from the entities’ participation in the program.

III. ISSUES

The following issues may be examined at the hearing:

- How do covered entities track savings from the 340B drug pricing program?
- How do covered entities utilize savings from the 340B drug pricing program?

⁵² Medicare Payment Advisory Commission, *Report to the Congress: Overview of the 340B Drug Pricing Program* (May 2015), <http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0>.

⁵³ 82 Fed. Reg. 33558, 33634 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

⁵⁴ 82 Fed. Reg. 33558, 33711 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

- What requirements must different types of covered entities meet in order to receive reduced prices through the 340B drug pricing program?
- How do covered entities utilize contract pharmacy arrangements?
- How do covered entities utilize child sites?
- How do covered entities interact with HRSA?

IV. STAFF CONTACTS

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