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# **REVIEW OF THE 340B DRUG PRICING PROGRAM**

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## I. Executive Summary

The 340B Drug Pricing Program (340B program) was established by Congress in 1992, and mandates that, to remain eligible for participation in the Medicaid program, drug manufacturers must provide outpatient drugs to eligible health care providers—also known as covered entities—at reduced prices. Covered entities include certain nonprofit organizations such as qualifying hospitals and federal grantees identified in the Public Health Services Act (PHSA). The Health Resources and Services Administration (HRSA) is the Operating Division within the U.S. Department of Health and Human Services (HHS) that administers and oversees the 340B program.

The 340B program is an important program that enjoys strong bipartisan support in Congress. The program helps reduce the prices of covered drugs for certain participating entities who, in turn, provide care for patients. Numerous covered entities have stated the 340B program has helped ensure that underserved and indigent patients have access to affordable medicines and health care. On numerous occasions, including during the Energy and Commerce Committee’s (the committee’s) most recent hearing in October 2017, the committee has emphasized the importance of the 340B program in providing care to vulnerable Americans.<sup>1</sup>

Over the past 25 years, the nation’s health care system has changed in some significant ways. For example, in 1992, there were roughly 29 million people enrolled in Medicaid and the program spent \$120 billion that year. Comparatively, in 2016, there were more than 72 million people enrolled in Medicaid and the program cost more than \$575 billion.<sup>2</sup> In that same period, the 340B program has also grown substantially—not only in the number of covered entities and contract pharmacies, but also in the amount of money saved by covered entities. HRSA estimates that covered entities saved approximately \$6 billion on approximately \$12 billion in discounted purchases in Calendar Year (CY) 2015 by participating in the 340B program.<sup>3</sup> It is estimated that discounted drug purchases made by covered entities under the 340B program totaled more than \$16 billion in 2016—a more than 30 percent increase in 340B program purchases in just one year.<sup>4</sup>

The committee has been examining the operation and oversight of the 340B program over the past two years. Through stakeholder meetings, hearings, and document requests, the committee has identified several weaknesses in program administration and oversight.

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<sup>1</sup> *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., Preliminary Transcript, at 84 (Oct. 11, 2017).

<sup>2</sup> Medicaid and CHIP Payment and Access Commission, *MACStats: Medicaid and CHIP Data Book, Exhibit 10* (Dec. 2017), available at [https://www.macpac.gov/wp-content/uploads/2017/12/MACStats-Medicaid-and-CHIP-Data-Book\\_December-2017.pdf](https://www.macpac.gov/wp-content/uploads/2017/12/MACStats-Medicaid-and-CHIP-Data-Book_December-2017.pdf).

<sup>3</sup> 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).

<sup>4</sup> Aaron Vandervelde and Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2012-2017*, BERKELEY RESEARCH GROUP (July 2017), available at [https://www.thinkbrg.com/media/publication/928\\_Vandervelde\\_Measuring340Bsize-July-2017\\_WEB\\_FINAL.pdf](https://www.thinkbrg.com/media/publication/928_Vandervelde_Measuring340Bsize-July-2017_WEB_FINAL.pdf).

Congress did not clearly identify the intent of the program and did not identify clear parameters, leaving the statute silent on many important program requirements. According to the 1992 House Report accompanying the legislation, the 340B program was intended “to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>5</sup> It is unclear whether Congress intended low-income and uninsured individuals to directly benefit from the reduced drug prices offered under the 340B program. Congress should clarify the intent of the 340B program and, in doing so, evaluate how developments in the health care landscape over the past 25 years have affected, if at all, the structure and goals of the 340B program.

HRSA lacks sufficient regulatory authority to adequately oversee the program and clarify program requirements. In 2014, a federal court ruled that HRSA’s regulatory authority is limited to three specific areas, including (1) establishing and implementing a binding Administrative Dispute Resolution (ADR) process for the resolution of certain disputes relating to compliance with 340B program requirements, (2) providing for the imposition of civil monetary penalties (CMPs) against manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug, and (3) issuing precisely defined standards of methodology for calculation of 340B ceiling prices. As a result, HRSA is unable to issue rules that would clarify certain program requirements. In addition, HRSA has not fully implemented guidance or regulations in the three areas where the agency has regulatory authority, nor has HRSA issued guidance on fundamental aspects of the program such as the definition of an eligible patient. Consequently, important aspects of the program have remained vague, as the statute is silent on many key aspects of the program, resulting in variation in the way covered entities use the program. HRSA should finalize regulations in the areas in which it has regulatory authority, and Congress should provide HRSA with more regulatory authority to adequately administer and oversee the 340B program, including the ability to improve program integrity, clarify program requirements, monitor and track program use, and ensure that low-income and uninsured patients directly benefit from the 340B program.

HRSA’s primary compliance mechanism is the agency’s annual audit process. HRSA began auditing covered entities in 2012. HRSA conducted 51, 94, and 99 audits in the first three years of auditing, and since 2015 has conducted approximately 200 audits annually. HRSA’s annual audits uncovered a high level of non-compliance by covered entities. Given HRSA’s limited authority, HRSA only conducts a limited review of the covered entity’s use of the program during the audit process. Specifically, HRSA audits entities only for program eligibility, duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting. HRSA also conducts audits of manufacturers to determine whether they are offering drugs at prices no higher than the 340B ceiling price.

The Patient Protection and Affordable Care Act (PPACA) dramatically increased the size and scope of this program by expanding eligibility to more types of hospitals, such as critical access hospitals and sole community hospitals, and expanded Medicaid eligibility. Program participation has more than quadrupled over the past decade. While HRSA’s authorities and resources have increased over the same period, they do not appear sufficient to meet the demands of this program. Although HRSA has increased the number of covered entity audits it conducts

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<sup>5</sup> H.R. Rep. 102-384, Pt. 2 (1992).

per year, the percentage of covered entities audited in 2016 was below two percent of total entities participating in the program. Program growth has outpaced HRSA's ability to effectively oversee the program. Congress should equip HRSA with the resources and staff necessary to conduct more rigorous oversight of the program. In addition, Congress should consider whether the permissible scope of HRSA's audits should be expanded, and HRSA should work toward auditing covered entities and manufacturers at approximately the same rate. To further aid HRSA in its administration of the program, Congress should require certain covered entities to conduct independent audits of program compliance, including of any contract pharmacies.

The 340B statute does not require covered entities to track or report program savings or how they are used. As a result, covered entities use program savings in a variety of ways. While some covered entities (*i.e.*, federal grantees) are restricted in the way they can use program funds due to other federal grant requirements, most entities are not required to use program savings in any specific way. Further, the 340B statute does not require covered entities to report the level of charity care that they provide to patients. The absence of reporting requirements in the 340B statute has resulted in a lack of data and transparency on how covered entities use the program and the value of the program, both to entities themselves and to the patients these entities serve.

The term "340B savings" refers to the cost saved by the covered entity by purchasing a drug at a reduced price. Because covered entities can purchase medicines at 340B prices for patients that have insurance, entities can also use the program to generate "340B revenue" by collecting insurance payments that exceed the acquisition price paid by the covered entity under the 340B program. Examples of ways a covered entity may maximize its 340B revenue include prescribing expensive drugs purchased at a significantly discounted 340B price and then receiving a higher insurance reimbursement rate for the drug, or hospitals acquiring private oncology clinics that prescribe expensive oncology drugs and then increasing the cost of care for the patient through facility fees, even though the treatment that the patient receives has not changed. Committee staff also heard directly from doctors and administrators about how some unintended consequences of the 340B program may negatively impact the quality of patient care.

In the committee's opinion, increasing transparency in the 340B program would allow for an accurate accounting of the full scope of the program's use and benefits. Congress, or HRSA where HRSA already has authority to make such changes, should promote transparency in the 340B program, including by ensuring that covered entities and other relevant stakeholders have access to ceiling prices and requiring covered entities to disclose information about annual 340B program savings and/or revenue. Congress should also establish a mechanism to monitor the level of charity care provided by covered entities. This should include a clear definition of charity care such that the data can be used to fairly compare care provided across entities.

While the 340B program only applies to certain *outpatient* drugs, eligibility is determined by using an *inpatient* metric. The current metric used to determine hospital eligibility for the 340B program does not necessarily reflect the amount of charity care offered by the hospital or the 340B patient population for the hospital. Congress should consider whether an inpatient metric remains an appropriate measure for program eligibility, or whether another metric is more appropriate.

The report concludes with a series of recommendations that, in the opinion of the committee, would improve the administration of the 340B program, primarily through changes in HRSA's regulatory authority and requiring transparency and accountability from covered entities. If implemented, these changes would strengthen the 340B program.

## II. Table of Acronyms

<b>Acronym</b>	<b>Description</b>
ADR	Administrative Dispute Resolution
AMP	Average Manufacturer Price
ANPRM	Advanced Notice of Proposed Rulemaking
CAP	Corrective Action Plan
CAHS	Cook Area Health Services
CMP	Civil Monetary Penalty
CMS	Centers for Medicare and Medicaid Services
COA	Community Oncology Alliance
CY	Calendar Year
DSH	Disproportionate Share Hospital
EPI	Erlanger Pharmacies Inc.
EHS	Erlanger Health System
FFS	Fee-For-Service
FTE	Full Time Employees
FQHC	Federally Qualified Health Centers
FY	Fiscal Year
GAO	U.S. Government Accountability Office
GPO	Group Purchasing Organization
HHS	U.S. Department of Health and Human Services
HHS OIG	Office of Inspector General. U.S. Department of Health and Human Services
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HRSA	Health Resources and Services Administration, U.S. Department of Health and Human Services
IT	Information Technology
JHH	Johns Hopkins Hospital
LPN	Licensed Practical Nurses
MCO	Managed Care Organization
MedPAC	Medicare Payment Advisory Commission
MEF	Medicaid Exclusion File
NPI	National Provider Identifier
NPRM	Notice of Proposed Rulemaking
NYULH	NYU Langone Health
OPA	Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services
OPAIS	Office of Pharmacy Affairs Information System
PPA	Pharmaceutical Pricing Agreement
PHSA	Public Health Services Act
PPACA	Patient Protection and Affordable Care Act
RN	Registered Nurse
SSI	Supplemental Security Income
URA	Unit Rebate Amount
WAC	Wholesale Acquisition Cost

### III. Findings

- HRSA has started, but after several years not completed, the process to issue and enforce regulations pertaining to the Administrative Dispute Resolution Process, the calculation of ceiling prices, and manufacturer civil monetary penalties. HRSA has not fully implemented these regulations in a timely manner.
- HRSA lacks sufficient authority to adequately oversee the program and clarify program requirements. HRSA needs more regulatory authority to promote compliance and ensure program integrity. Key aspects of the program have remained vague, resulting in variation in the way covered entities use the 340B program.
- Although HRSA has increased the number of covered entity audits it conducts per year, the audit process still needs improvement. Given HRSA's limited regulatory authority over the 340B program, HRSA only conducts a limited review of the covered entity's use of the program during the audit process. Covered entities would benefit from clearer guidance on the audit process.
- HRSA's annual audits uncovered 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 a variety of different ways, including duplicate discounts, diversion to ineligible patients and facilities, incorrect database reporting, and violation of the Group Purchasing Organization (GPO) prohibition (if applicable).
- HRSA audits manufacturers and in their audits to date found no manufacturers out of compliance with the statute. However, without access to ceiling prices, covered entities may not know that they should report to HRSA that they are not getting an accurate price.
- The PPACA significantly increased the scope of the Medicaid program by expanding eligibility to certain low-income, non-disabled, non-elderly, non-pregnant adults. Medicaid expansion under the PPACA has likely increased the number of hospitals eligible for the 340B program because some hospitals' eligibility is based, in part, on the number of the hospital's inpatients who are Medicaid and low-income Medicare patients by virtue of their DSH (disproportionate share hospital) percentage. Overall, program participation has more than quadrupled over the past decade. HRSA's limited oversight ability does not appear to be sufficient to conduct adequate oversight of this program.
- Congress did not clearly identify its intent for the program and did not clearly identify the program's parameters, leaving the statute silent on many important program requirements. Moreover, given the vastly changed health care landscape and 340B program environment, it is unclear whether, and to what degree, the program's original structure is still relevant.
- Congress did not establish any mechanisms to monitor or calculate program savings or specify how they are used. As a result, covered entities use program savings in a variety of different ways. Some covered entities are restricted in the way they can use program funds due to other federal grant requirements.



- The 340B statute does not require covered entities to report the level of charity care provided. As a result, there is a lack of data on how much charity care is provided by covered entities. Further, because there is no universally accepted definition of charity care, drawing a fair comparison of charity care provided across covered entities is difficult, if not impossible. Finally, while charity care spending often exceeds program savings, charity care levels have been on the decline at some hospitals, even as program savings increase.
- There is a financial incentive for 340B hospitals to prescribe more, and/or more expensive drugs to Medicare Part B beneficiaries, and prescribing trends indicate that 340B hospitals do prescribe more and more expensive drugs to Medicare Part B beneficiaries as compared to non-340B hospitals.
- There has been a marked increase in consolidation of private oncology practices, which, in some instances, negatively impacts the quality of patient care and can result in increased patient cost.
- The current metric used to determine hospital eligibility for the 340B program does not necessarily reflect the amount of charity care offered by the hospital or the outpatient population for the hospital. Hospitals have a financial incentive to open child sites in areas that do not reflect the DSH percentage of the parent entity, thus enabling the hospital to gain access to a higher number of commercially insured patients.

## IV. Background

### A. Overview of the 340B Program's Development and Growth

Congress established the 340B Drug Pricing Program (340B program) through the Veterans Health Care Act of 1992.<sup>6</sup> The 340B program mandates that, to remain eligible for participation in the Medicaid program, drug manufacturers provide covered outpatient drugs to eligible health care providers at reduced prices.<sup>7</sup> More specifically, the statute requires that, as a condition of participation in the Medicaid program, drug manufacturers enter into pharmaceutical pricing agreements (PPAs) that require those manufacturers to sell their product at a discount to certain health care providers, known as covered entities.<sup>8</sup> Covered entities include certain nonprofit organizations such as qualifying hospitals and federal grantees identified in the Public Health Services Act (PHSA).<sup>9</sup>

According to the 1992 House Report accompanying the original legislation, the 340B program was established, in part, to respond to the increase in prescription drug prices for the Department of Veterans Affairs and some federally-funded clinics and public hospitals following the enactment of the 1990 Medicaid Drug Rebate Program (created through the Omnibus Budget Reconciliation Act of 1990 (OBRA)).<sup>10</sup> Before the enactment OBRA, many drug manufacturers voluntarily sold medicines to the Veterans Health Administration and other federal entities (including public health service grantees) at significant discounts and drug manufacturers also bargained with large purchasers.<sup>11</sup> Because the Medicaid Drug Rebate Program requires that pharmaceutical manufacturers provide Medicaid with the manufacturers' lowest or "best price" for outpatient drugs, some stakeholders were concerned that after the program was implemented, manufacturers might limit discounts to federal, non-Medicaid purchasers. The 1992 House Report indicated that, "[i]n giving these 'covered entities' access to price reductions the committee intends to enable these entities to stretch scarce [f]ederal resources as far as possible, reaching more eligible patients and providing more comprehensive services."<sup>12</sup> Beyond these statements in the 1992 House Report, it is unclear exactly how Congress intended covered entities to use the 340B program. Congress remained silent in the statute on many important questions regarding the structure and scope of the 340B program.

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<sup>6</sup> Veterans Health Care Act of 1992 (VHCA), P.L. 102-585.

<sup>7</sup> The definition of a covered outpatient drug is set forth in section 1927(k) of the Social Security Act. According to Apexus, the 340B program generally includes the following outpatient drugs: (1) FDA-approved prescription drugs; (2) Over-the-counter (OTC) drugs written on a prescription; (3) biological products that can be dispensed only by a prescription (other than vaccines); or (4) FDA-approved insulin. Apexus, *340B Price/Covered Outpatient Drugs* (last accessed Jan. 3, 2018), <https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs>.

<sup>8</sup> Public Health Service Act, 42 U.S.C. 256b. A sample 340B program Pharmaceutical Pricing Agreement is available on HRSA's website. See U.S. Dep't of Health and Human Services, Health Services and Resources Administration, *General Instructions for Completing the Pharmaceutical Pricing Agreement (PPA)* (last accessed Jan. 3, 2018), <https://www.hrsa.gov/sites/default/files/opa/manufacturers/pharmaceuticalpricingagreement.pdf>.

<sup>9</sup> See Health Resources and Services Administration, *340B Eligibility & Registration* (last accessed Dec. 1, 2017), <https://www.hrsa.gov/opa/eligibility-and-registration/index.html>.

<sup>10</sup> H.R. Rep. 102-384, Pt. 2 (1992).

<sup>11</sup> U.S. Senate, Committee on Labor and Human Resources, *Hearing on Public Health Clinic Prudent Pharmaceutical Purchasing Act (S. 1729)* (Oct. 16, 1991) (statement of Stephen Schondelmeyer, Pharm.D., Ph.D.).

<sup>12</sup> H.R. Rep. 102-384, Pt. 2 (1992).

The 340B program is an important program that helps reduce the prices of covered drugs for certain participating entities who, in turn, provide care for patients. On numerous occasions, including during the committee's most recent hearing in October 2017, the committee has emphasized the importance of the 340B program in further enabling covered entities to provide care to vulnerable Americans.<sup>13</sup>

The Health Resources and Services Administration (HRSA) is the Operating Division within the U.S. Department of Health and Human Services (HHS) that administers and oversees the 340B program. According to HRSA's Fiscal Year (FY) 2018 Budget Justification, HRSA budgeted \$10.2 million and 22 Full Time Employees (FTEs) to administer the 340B program in FY 2017.<sup>14</sup> HRSA and manufacturers have had the authority to audit covered entities since the 340B program was established in 1992.<sup>15</sup> Initially, however, HRSA primarily relied on covered entities to self-monitor and ensure compliance with 340B program requirements.<sup>16</sup> In 2012, following a 2011 Government Accountability Office (GAO) report recommending HRSA begin auditing covered entities to monitor for program violations, provide additional program oversight, and prevent diversion and duplicate discounts, HRSA began conducting selective audits of covered entities.<sup>17</sup> HRSA also conducts audits of manufacturers to ensure compliance with program requirements.<sup>18</sup>

Participation in the 340B program is voluntary for covered entities and drug manufacturers, but there are incentives to participate. Participating manufacturers remain eligible for the Medicaid program, meaning that their pharmaceuticals are covered by Medicaid. Covered entities are eligible to receive discounts on certain outpatient prescription drugs from participating manufacturers and save between 25 and 50 percent of the average wholesale price for covered outpatient drugs.<sup>19</sup> 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.<sup>20</sup> HRSA calculates the ceiling price for each 340B drug as the difference between the drug's average manufacturer price (AMP) and its unit rebate amount (URA), obtaining both the AMP and URA from the Centers for Medicare and Medicaid Services (CMS) as part of quarterly reporting for the Medicaid Drug Rebate

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<sup>13</sup> *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Oct. 11, 2017).

<sup>14</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees*, at 244 (2018).

<sup>15</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *340B Drug Pricing Program Notice: Clarification of HRSA Audits of 340B Covered Entities*, Release No. 2012-1 (Mar. 5, 2012), <https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/auditclarification030512.pdf>.

<sup>16</sup> *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 114th Cong., at 19 (Mar. 24, 2015).

<sup>17</sup> *Id.*

<sup>18</sup> U.S. Dep't of Health and Human Services, *Health Resources and Services Administration, FY 2017 Manufacturer Audit Results* (last updated Dec. 12, 2017), <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-17-manufacturer-audit-results.html>.

<sup>19</sup> 340B Prime Vendor Program, *340B Price/Covered Outpatient Drugs* (last accessed Dec. 1, 2017), available at <https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/>.

<sup>20</sup> 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.

Program.<sup>21</sup> AMP is defined as the average price paid to manufacturers by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.<sup>22</sup> The URA is based on the formula used to calculate Medicaid drug rebates as specified in Section 1927 of the Social Security Act.<sup>23</sup> Currently, the Medicaid Drug Rebate Program rebate is 23.1 percent for single-source and innovator drugs and 13 percent for generic drugs. 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.<sup>24</sup>

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 eligible outpatient 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,<sup>25</sup> 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. Both the Office of Inspector General at the U.S. Department of Health and Human Services (HHS OIG) and GAO have criticized HRSA’s failure to provide adequate clarity on the definition of a patient.<sup>26</sup> HRSA does not have regulatory authority to clarify the definition of an eligible patient, and after a decision by a federal court limiting HRSA’s regulatory authority, HRSA withdrew their guidance on this topic.<sup>27</sup> HRSA could issue guidance clarifying important program requirements and providing information about best practices for program participants, but to date, the agency has not released such guidance.

Recent years have seen significant changes and expansions to the program (see Appendix A for a complete list of major legislation affecting the 340B program). HRSA estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in FY 2013,<sup>28</sup> \$4.5

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<sup>21</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *340B Ceiling Price Calculation* (last reviewed April 2017), <https://www.hrsa.gov/opa/updates/2015/may.html>; Medicare Payment Advisory Commission, *Report to Congress: Overview of the 340B Drug Pricing Program*, at 6 (May 2015).

<sup>22</sup> See Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (Feb. 1, 2016).

<sup>23</sup> Medicare Payment Advisory Commission, *Report to Congress: Overview of the 340B Drug Pricing Program*, at 6 (May 2015).

<sup>24</sup> Medicaid and CHIP Payment and Access Commission, *Issue Brief: Medicaid Payment for Outpatient Prescription Drugs* (March 2017), available at <https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf>.

<sup>25</sup> For current definition of a patient, see HRSA’s website. U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Eligibility & Registration* (last accessed Dec. 1, 2017), available at <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

<sup>26</sup> See, e.g., *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017).

<sup>27</sup> See, e.g., *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Capt. Krista M. Pedley, Director, Office of Pharmacy Affairs, Healthcare Systems Bureau, Health Resources and Services Administration, U.S. Dep’t of Health and Human Services).

<sup>28</sup> *Examining the 340B Drug Discount Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 114th Cong. (March 24, 2015) (statement of Diana Espinosa, Deputy Administrator, Health Resources and Services Administration).

billion in FY 2014,<sup>29</sup> and approximately \$6 billion in Calendar Year (CY) 2015.<sup>30</sup> In CY 2015, approximately \$12 billion in discounted purchases were made by covered entities.<sup>31</sup> It is estimated that discounted drug purchases made by covered entities under the 340B program totaled more than \$16 billion in 2016—a more than 30 percent increase in 340B program purchases in just one year.<sup>32</sup> As of October 1, 2017, 12,722 covered entities are participating in the program and, as of January 2, 2018, 743 pharmaceutical manufacturers are participating in the program.<sup>33</sup>

While many covered entities contract with multiple external pharmacies in operating their 340B programs, this structure is a relatively recent arrangement born out of administrative guidance, not the statute. The statute itself is silent on pharmacy arrangements for covered entities. 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 could contract with only one pharmacy if they did not have an in-house pharmacy.<sup>34</sup> The growth and oversight of contract pharmacies since 2010 has been identified as an issue of concern by HHS OIG, and GAO is planning an upcoming report examining that issue. According to HRSA’s FY 2018 Budget Justification, 27 percent of covered entity sites have contract pharmacy arrangements, and there are about 18,078 unique pharmacy locations in the 340B Office of Pharmacy Affairs Information System (OPAIS).<sup>35</sup> Contract pharmacies may have arrangements to dispense drugs for more than one entity. HRSA data indicates that there were 46,174 contract pharmacy arrangements—arrangements between a covered entity site and a pharmacy—as of January 1, 2017.<sup>36</sup> As GAO noted, however, “the total number of contract pharmacy arrangements is likely higher, as HRSA does not require entities to report all arrangements to the agency.”<sup>37</sup>

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<sup>29</sup> Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2017* (2016), available at <https://www.hrsa.gov/about/budget/budgetjustification2017.pdf>.

<sup>30</sup> 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).

<sup>31</sup> *Id.*

<sup>32</sup> Aaron Vandervelde and Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2012-2017*, BERKELEY RESEARCH GROUP (July 2017), available at [https://www.thinkbrg.com/media/publication/928\\_Vandervelde\\_Measuring340Bsize-July-2017\\_WEB\\_FINAL.pdf](https://www.thinkbrg.com/media/publication/928_Vandervelde_Measuring340Bsize-July-2017_WEB_FINAL.pdf).

<sup>33</sup> U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Email from U.S. Department of Health and Human Services Staff to Committee Staff (Dec. 21, 2017); U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *340B Drug Pricing Program Manufacturers* (last accessed Dec. 13, 2017), <https://340bopais.hrsa.gov/manufacturersearch>.

<sup>34</sup> Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,274-10,278 (March 5, 2010).

<sup>35</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, at 245-46 (2017), available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

<sup>36</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., at footnote 19 (Jul. 18, 2017) (statement of Debra Draper, Director, Health Care, Government Accountability Office).

<sup>37</sup> *Id.* HRSA does not require covered entities to report contract pharmacy arrangements by entity sites. Instead, covered entities may just report the contract pharmacy arrangements for the main parent site even if some, or all, of the child sites also have an arrangement with the same pharmacy. If entities were required to report all arrangements, the percent of sites with contract pharmacy arrangements could be higher.

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 1, 2017, 42,029 registered covered entity sites were participating in the 340B program, including 12,722 covered entity (parent) sites and 29,307 associated (child) sites participating in the program.<sup>38</sup>

Over the past 25 years, the health care landscape has changed dramatically. According to HHS’s National Health Interview Survey, over 35 million Americans under the age of 65 did not have health insurance in 1992.<sup>39</sup> In 2016, about 28 million Americans under the age of 65 were uninsured.<sup>40</sup> Moreover, in 1992, there were about 29 million people enrolled in Medicaid and the program spent \$120 billion that year, whereas in 2016, there were more than 72 million people enrolled and the program cost more than \$575 billion.<sup>41</sup> In addition to changes in coverage, the structure of hospitals has also evolved dramatically. In a recent report, the National Academies Press indicated that nonprofit hospitals are increasingly displaying characteristics of for-profit hospitals.<sup>42</sup> Indeed, a recent press article highlighted how some, particularly large non-profit hospitals, have become quite profitable and “now resemble and act like Fortune 500 companies instead of the charities they were often built as.”<sup>43</sup>

## **B. Types of Covered Entities**

HRSA is tasked with reviewing 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.<sup>44</sup> Congress has expanded program eligibility over time, most recently through the PPACA.<sup>45</sup>

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<sup>38</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *340B Drug Pricing Program Covered Entities* (last accessed Dec. 1, 2017), <https://340bopais.hrsa.gov/coveredentitysearch>; U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Email from U.S. Dep’t of Health and Human Services Staff to Committee Staff (Dec. 21, 2017).

<sup>39</sup> U.S. Dep’t of Health and Human Services, Centers for Disease Control and Prevention, *National Health Interview Survey: Long-term Trends in Health Insurance Coverage* (Oct. 2017), available at [https://www.cdc.gov/nchs/data/nhis/health\\_insurance/TrendHealthInsurance1968\\_2016.pdf](https://www.cdc.gov/nchs/data/nhis/health_insurance/TrendHealthInsurance1968_2016.pdf).

<sup>40</sup> *Id.*

<sup>41</sup> Medicaid and CHIP Payment and Access Commission, *MACStats: Medicaid and CHIP Data Book, Exhibit 10* (Dec. 2017), available at [https://www.macpac.gov/wp-content/uploads/2017/12/MACStats-Medicaid-and-CHIP-Data-Book\\_December-2017.pdf](https://www.macpac.gov/wp-content/uploads/2017/12/MACStats-Medicaid-and-CHIP-Data-Book_December-2017.pdf).

<sup>42</sup> National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 6 (Nov. 2017).

<sup>43</sup> Bob Herman, *Hospitals are making a fortune on Wall Street*, AXIOS (Dec. 7, 2017), available at <https://www.axios.com/hospitals-are-making-a-fortune-on-wall-street-2513530266.html>.

<sup>44</sup> 42 U.S.C. § 256b.

<sup>45</sup> The 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, including but not limited to, having a minimum disproportionate share adjustment percentage to qualify for program participation (Critical

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,<sup>46</sup> 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.<sup>47</sup> 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 may be spent.<sup>48</sup>

Hospitals that are eligible to participate in the 340B program include certain disproportionate share hospitals (DSH 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).<sup>49</sup> 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.<sup>50</sup>

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 arrangements (referred to as the "GPO prohibition").<sup>51</sup>

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Access Hospitals are not required to have a minimum disproportionate share adjustment percentage to participate in the 340B program). See Figure 1: Hospital Eligibility for additional details regarding hospital eligibility requirements in the 340B program.

<sup>46</sup> "Federally Qualified Health Center Look-Alikes are community-based health care providers that meet the requirements of the HRSA Health Center Program, but do not receive Health Center Program funding. They provide primary care services in underserved areas, provide care on a sliding fee scale based on ability to pay and operate under a governing board that includes patients. The defining legislation for Federally Qualified Health Center Look-Alikes (under the Consolidated Health Center Program) is Section 1905(l)(2)(B) of the Social Security Act." See U.S. Department of Health and Human Services, Health Resources and Services Administration, *Federally Qualified Health Center Look-Alike* (last accessed Jan. 2, 2018), available at <https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc-look-alikes/index.html>.

<sup>47</sup> Health Resources and Services Administration, Eligibility & Registration (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

<sup>48</sup> 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 accessed Dec. 1, 2017), [https://hab.hrsa.gov/sites/default/files/hab/Global/pcn\\_15-03\\_program\\_income.pdf](https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf).

<sup>49</sup> Public Health Service Act, 42 U.S.C. 256b(a)(4)(L)(ii).

<sup>50</sup> Public Health Service Act, 42 U.S.C. 256b(a)(4)(L)(i).

<sup>51</sup> Public Health Service Act, 42 U.S.C. 256b(a)(4)(L)(iii).

**Figure 1: Hospital Eligibility<sup>52</sup>**

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

Participation by hospitals 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.<sup>53</sup> According to a 2011 report by GAO, one third of all hospitals participated in the program, and DSH hospitals alone represented about 75 percent of all spending by covered entities on 340B drugs.<sup>54</sup> Similarly, in 2015, GAO found that about 40 percent of all U.S. hospitals participate in the 340B program and that the majority of 340B drugs are sold to hospitals.<sup>55</sup> Indeed, according to the Medicare Payment Advisory Commission (MedPAC), as of the first quarter of 2015, DSH hospitals represented about 78 percent of all 340B drug purchases.<sup>56</sup>

### C. Background on the Committee’s Investigation

The committee has been examining the operation and oversight of the 340B program for over two years. During this review, committee staff have interviewed more than 50 stakeholders including but not limited to HRSA, CMS, GAO, HHS OIG, covered entities, drug manufacturers, pharmacies, third party administrators, and physicians. The committee has held three hearings examining the 340B program and sent letters to HRSA and covered entities requesting documents and information about the program. The committee has also requested that GAO examine certain aspects of the 340B program. The findings in this report are primarily grounded in the committee’s work over the past two years.

The first two hearings—on March 24, 2015<sup>57</sup> and July 18, 2017<sup>58</sup>—included federal

<sup>52</sup> Apexus, 340B University, *340B Hospital Eligibility Criteria* (2015), available at [https://docs.340bpvp.com/documents/public/resourcecenter/Hospital\\_Eligibility\\_Criteria.pdf](https://docs.340bpvp.com/documents/public/resourcecenter/Hospital_Eligibility_Criteria.pdf).

<sup>53</sup> 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).

<sup>54</sup> *Id.*

<sup>55</sup> 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 (Jun. 2015).

<sup>56</sup> Medicare Payment Advisory Commission, *Report to Congress: Overview of the 340B Drug Pricing Program*, at 12 (May 2015).

<sup>57</sup> *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong. (Mar. 24, 2015).

<sup>58</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017).



witnesses from GAO, HHS OIG, and HRSA. During the 2015 hearing, the witnesses testified that while HRSA had taken some steps to strengthen the agency's oversight of the 340B program, there were additional opportunities for enhanced program integrity that were restricted by HRSA's limited authority over the program.<sup>59</sup> HRSA noted that the agency's regulatory authority was limited to three specific topics (as discussed in more detail in Section V.A-B, these three areas include calculation of the 340B ceiling price, imposition of manufacturer civil monetary penalties, and implementing an administrative dispute resolution process), and since HRSA does not have regulatory authority over many aspects of the program, they cannot be as clear or definitive on the program requirements given the different enforcement authority associated with guidance documents.<sup>60</sup> Similarly, during the 2017 hearing, GAO and HHS OIG testified that while HRSA has strengthened their oversight of the 340B program, several weaknesses in program oversight remain. HRSA testified that their limited regulatory authority over the 340B program hinders their ability to oversee program integrity, and that regulatory authority would allow HRSA to provide greater clarity and specificity of program requirements.<sup>61</sup> For example, the 340B statute does not require that entities report their savings or how those savings are used. HRSA therefore does not have data on how much each entity saves through program participation and how the savings are used. In addition, HRSA lacks the authority to promote transparency or direct how covered entities use program savings.

The third hearing was held on October 11, 2017, and included representatives from different types of covered entities participating in the 340B program, including DSH hospitals, a FQHC, a Ryan White grantee, and critical access hospitals.<sup>62</sup> The witnesses provided information about how they use the 340B program to serve vulnerable populations, including whether the program savings are passed directly on to the most vulnerable patients. During the hearing, covered entities discussed the importance of program flexibility. While some covered entities track their program savings regularly to determine how those funds should be used, others testified that they do not track their savings on a regular basis.<sup>63</sup> Moreover, the covered entities did not track program savings in a consistent manner, thereby making it hard to compare the value of the program across different entities.<sup>64</sup> Similarly, the covered entities had varying ways in which they calculated the charity care that they provided to vulnerable populations thereby making it difficult to compare the amount of charity care provided by an entity to examine how savings are being used to improve patient care.<sup>65</sup>

The committee sent a letter to HRSA on June 1, 2017, requesting documents and information about the agency's audits of covered entities. The committee explained the basis of the request:

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<sup>59</sup> *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong., at 51 (Mar. 24, 2015).

<sup>60</sup> *Id.* at 53.

<sup>61</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., at 26 (Jul. 18, 2017).

<sup>62</sup> *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Oct. 11, 2017).

<sup>63</sup> *Id.* at 50-54.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 59-64.

The Committee is concerned about the 340B program's rapid growth without additional and proportional oversight. Provisions in the Patient Protection and Affordable Care Act (PPACA) expanded the definition of eligible entities to include 'free-standing cancer, community and critical access hospitals on the basis of their disproportionate share hospital (DSH) percentage,' which has increased program enrollment substantially. 340B drug sales more than doubled between 2010 and 2015 and expanded by 66 percent between 2013 and 2015 alone. As of 2011, nearly a third of all U.S. hospitals participated in the program.

Although HRSA began auditing covered entities and publishing its findings in 2012, the lack of reporting requirements presents additional challenges. HRSA does not track how much covered entities make through [the] 340B program, nor how they use program savings. Further, there is no legislative requirement that requires hospitals to use 340B savings in a specific way.... Given the program's ability to generate revenue for covered entities, HRSA has a vested interest in ensuring that those funds are used to benefit patients. The Committee is concerned about reports that uninsured and underinsured patients at 340B hospitals often pay the full list price for a drug while the hospital receives that same drug at a severely discounted price.<sup>66</sup>

After negotiations with committee staff, HRSA produced a sample of 20 audits, selected by HRSA, from different types of covered entities with different characteristics. Committee staff received the entire audit file for these sample audits, including, but not limited to, the audit findings, the covered entity's policies and procedures relating to the 340B program, and contract agreements between pharmacies and covered entities. HRSA subsequently provided an additional 12 audit files to the committee.

In light of the limited information that HRSA was able to provide about the ways in which different covered entities utilize the program, the committee sent a letter on September 8, 2017, to a diverse group of covered entities, 19 in total, requesting information about the entity's participation in the 340B program.<sup>67</sup> Given how differently each covered entity approaches the

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<sup>66</sup> Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, and Hon. Michael C. Burgess, M.D., Chairman, Subcomm. on Health of the H. Comm. on Energy and Commerce, to Mr. George Sigounas, Administrator, Health Resources and Services Administration, U.S. Dep't of Health and Human Services (June 1, 2017).

<sup>67</sup> Information provided by these covered entities is discussed throughout the report. The covered entities that received the committee's September 8, 2017 letter and are discussed in this report include: ARcare (P.O. Box 497, August, Arkansas 72006), Cedars-Sinai Medical Center (8700 Beverly Boulevard, Los Angeles, California 90048), Cook Area Health Services, Inc. (20 Fifth Street SE, Cook, Minnesota 55723), Duke University Health System (14209 red zone, Duke South, Durham, NC 27710), Emory University Hospital Midtown (550 Peachtree Street NE, Atlanta, Georgia 30308), Erlanger Health System (975 East Third Street, Chattanooga, Tennessee 37403), Grady Health System (80 Jesse Hill Drive SE, Atlanta, Georgia 30303), Hudson Headwaters Health Network (9 Carey Road, Queensbury, New York 12804), Primary Children's Hospital (owned and operated by Intermountain Healthcare) (100 North Mario Capecchi Drive, Salt Lake City, Utah 84113), Johns Hopkins Hospital (600 North Wolfe Street, Baltimore, Maryland 21287), Massachusetts General Physicians Organization (Hemophilia Treatment Center Designation) and Massachusetts General Hospital (55 Fruit Street, Boston, Massachusetts 02114), Mission Health (509 Biltmore Avenue, Asheville, North Carolina 28801), Northern Nevada HOPES (580 West 5th Street,

340B program, the committee wanted to hear from a variety of covered entities across the country. The committee explained:

Congress has only limited visibility into how covered entities use program savings. A recent survey conducted by an association of hospitals participating in the program – 340B Health – indicates that many covered entities use program savings in ways that include but are not limited to, using savings to increase services to uninsured or underinsured patients, improve pharmacy services by funding patient assistance programs and patient counseling, and help fund community service initiatives.... Over the years, however, the program has grown substantially and reports indicate that some hospitals may be abusing the program and may be failing to pass program savings on to the intended beneficiaries.<sup>68</sup>

Information sought by the committee included estimated amount of savings each entity generates through 340B program participation, how each entity calculates, tracks, and spends the program savings, drugs purchased through the program, number of registered child sites, number of contract pharmacy arrangements, patient population served, and how patients benefit from the entities' participation in the program. In addition to requesting information in the letter, committee staff was briefed by each entity, during which staff asked detailed follow-up questions about how each entity uses the program.

#### **D. GAO and HHS OIG Reports on the 340B Program**

HHS OIG and GAO have both closely examined various aspects of the 340B program and identified weaknesses in program oversight. In response to Congressional requests, GAO issued reports in 2011<sup>69</sup> and 2015<sup>70</sup> regarding the 340B program. Recently, during the

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Reno, Nevada 89503), Northland Cares (3112 Clearwater Drive Suite A, Prescott, Arizona 86305), Northside Hospital (1000 Johnson Ferry Road NE, Atlanta, Georgia 30342), NYU Langone Health (One Park Avenue 3rd Floor, New York, New York 10016), Parkland Health and Hospital System (5200 Harry Hines Boulevard, Dallas, Texas 75235), UC San Francisco (UCSF) Medical Center (500 Parnassus Avenue, San Francisco, California 94143), and the University of Washington Medicine (Box 356340, Seattle, Washington 98195-6340). Copies of the letters and recipient responses are available on the committee's website. *See* Committee on Energy and Commerce, U.S. House of Representatives, *Letters to a Series of Covered Entities Participating in the 340B Drug Pricing Program* (Sept. 8, 2017), available at <https://energycommerce.house.gov/news/letter/letters-series-covered-entities-participating-340b-drug-pricing-program/>.

<sup>68</sup> *See, e.g.*, Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, to Mr. Thomas A. Priselac, President and Chief Executive Officer, Cedars-Sinai Medical Center (Sept. 8, 2017).

<sup>69</sup> In 2011, GAO issued a report entitled, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*. 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 vulnerability may be exacerbated by changes within the program. 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).

<sup>70</sup> In 2015, GAO issued a report entitled, *Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*. 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 more drugs, and more expensive drugs to Medicare beneficiaries. U.S. Gov't Accountability Office, *Medicare Part B*

committee’s July 2017 hearing, GAO testified that HRSA has implemented some, but not all, of the recommendations to improve program integrity.<sup>71</sup> Similarly, HHS OIG issued reports examining different aspects of the 340B program in 2011<sup>72</sup> and 2014.<sup>73</sup> At the July 2017 hearing before the committee, HHS OIG testified that some of the weaknesses they identified have been addressed through legislation or by HRSA directly. HHS OIG also noted, however, that long-standing fundamental vulnerabilities continue to exist, including: (1) a lack of transparency that prevents accurate payments by 340B providers, state Medicaid programs, and pharmaceutical manufacturers; and (2) a lack of clarity regarding program rules that creates uncertainty and results in uneven program implementation and limited accountability.<sup>74</sup> Moreover, HHS OIG testified that HRSA needed additional authority to increase transparency and clarity around program rules.<sup>75</sup>

GAO is currently reviewing issues related to contract pharmacies and characteristics of 340B covered entities at the request of the committee. The committee will determine whether to undertake additional work with respect to these issues upon receiving the GAO’s reports.

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*Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015).

<sup>71</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript* (Jul. 18, 2017) (statement of Debra Draper, Director, Health Care, Government Accountability Office).

<sup>72</sup> In 2011, HHS OIG issued a report entitled, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*. HHS OIG found that states lacked pricing information needed for oversight and that nearly half of states did not have written 340B program policies. 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).

<sup>73</sup> In 2014, HHS OIG issued a report entitled, *Contract Pharmacy Arrangements in the 340B program*. HHS OIG found that contract pharmacy arrangements create complications in preventing diversion and duplicate discounts. HHS OIG also found that “some covered entities in [their] study [did] not offer the discounted 340B price to uninsured patients in their contract pharmacy arrangements.” In the report, HHS OIG noted that 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. 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).

<sup>74</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, Assistant Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services).

<sup>75</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 50 (Jul. 18, 2017).

## V. HRSA Administration and Oversight of the 340B Program

### A. HRSA's Implementation of 340B Regulations

***Finding: HRSA has started, but after several years not completed, the process to issue and enforce regulations pertaining to the Administrative Dispute Resolution Process, the calculation of ceiling prices, and manufacturer civil monetary penalties. HRSA has not fully implemented these regulations in a timely manner.***

HRSA is the Operating Division within HHS that administers and oversees the 340B program. HRSA is the principal federal agency responsible for increasing access to effective and efficient basic health care for individuals who are medically underserved or face barriers (*e.g.*, economic, geographic, linguistic, and cultural) to health care.<sup>76</sup> In addition to administering the 340B program, HRSA supports other programs and services including the Health Center Program, and the Ryan White HIV/AIDS Program, among others.<sup>77</sup> The President's FY 2018 Budget Proposal requested \$9.9 billion, including \$4.4 billion in mandatory funding, for HRSA to invest in programs that provide these health care services.<sup>78</sup>

According to HRSA's FY 2018 Budget Justification, HRSA budgeted \$10.2 million and 22 FTEs to administer the 340B program in FY 2017.<sup>79</sup> HRSA testified in July 2017 that there were currently 16 FTEs overseeing the 340B program and that the amount requested in the agency's budget proposal was necessary to maintain their current level of oversight of the 340B program.<sup>80</sup> The amount of funding for the 340B program has stayed relatively constant since 2014 despite the significant amount of program growth over the past few years.

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<sup>76</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees* (2018).

<sup>77</sup> U.S. Dep't of Health and Human Services (HRSA), *HRSA Program Areas* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov>.

<sup>78</sup> *Id.*

<sup>79</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees*, at 244 (2018).

<sup>80</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 56 (Jul. 18, 2017).

**Figure 2: HRSA Funding for the 340B Program**

Year	Funding History (in millions)	FTEs
2010 <sup>81</sup>	\$2.22 million ( <i>actual</i> )	--
2011 <sup>82</sup>	\$4.48 million ( <i>enacted</i> )	1
2012 <sup>83</sup>	\$4.47 million ( <i>enacted</i> )	3
2013 <sup>84</sup>	\$4.19 million ( <i>final</i> )	3
2014 <sup>85</sup>	\$10.21 million ( <i>final</i> )	4
2015 <sup>86</sup>	\$10.24 million ( <i>final</i> )	11
2016 <sup>87</sup>	\$10.24 million ( <i>enacted</i> )	24
2017 <sup>88</sup>	\$10.22 million ( <i>annualized CR</i> )	22
2018 <sup>89</sup>	\$10.22 million ( <i>requested</i> )	22

In 2014, Congress increased HRSA’s budget for the 340B program by \$6 million to expand the agency’s oversight of the program. HRSA used the funding to support program integrity efforts and to develop information technology (IT) systems supporting program compliance.<sup>90</sup> To ensure that both covered entities and pharmaceutical manufacturers are in compliance with program requirements, HRSA, among other things: (1) conducts initial eligibility checks of all entities seeking to register with the program; (2) recertifies covered entities on an annual basis; (3) performs audits of covered entities and manufacturers; and (4) provides additional compliance support.

HRSA has prioritized rulemaking in the three specific areas where the D.C. Circuit has clearly recognized the agency’s regulatory authority<sup>91</sup>: (1) the ‘regulatory issuance’ of precisely defined standards of methodology for calculation of ceiling prices; (2) imposition of manufacturer civil monetary penalties; and (3) establishment of an administrative dispute resolution process.<sup>92</sup> However, HRSA has not yet fully implemented regulations addressing any of these issues. The limits established by the D.C. Circuit on HRSA’s regulatory authority, and

<sup>81</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2012 Justification of Estimates for Appropriations Committees* (2012).

<sup>82</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2013 Justification of Estimates for Appropriations Committees* (2013).

<sup>83</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2014 Justification of Estimates for Appropriations Committees* (2014).

<sup>84</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2015 Justification of Estimates for Appropriations Committees* (2015).

<sup>85</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2016 Justification of Estimates for Appropriations Committees* (2016).

<sup>86</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2017 Justification of Estimates for Appropriations Committees* (2017).

<sup>87</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees* (2018).

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 114th Cong. (Mar. 24, 2015).

<sup>91</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 26 (Jul. 18, 2017).

<sup>92</sup> *Id.* at 81.

the impact this has on HRSA's ability to oversee the 340B Program, are discussed in Section V.B.

To resolve disputes between covered entities and manufacturers regarding the 340B program in an expeditious manner, in 1996, HRSA established a voluntary administrative dispute resolution (ADR) process for resolving these claims.<sup>93</sup> In 2010, the PPACA required HHS to promulgate regulations to establish and implement a binding ADR process for resolution of certain disputes concerning compliance with the 340B program.<sup>94</sup> The purpose of the ADR process is to resolve assertions by covered entities that they have been overcharged for 340B drugs and claims by manufacturers that a covered entity has violated the prohibitions on duplicate discounts and diversion. In 2010, HHS issued an advanced notice of proposed rulemaking (ANPRM) requesting comments on the development of the ADR process.<sup>95</sup> After being under development for a number of years,<sup>96</sup> during which time HRSA considered the 14 comments the agency received regarding the ANPRM, HHS issued a notice of proposed rulemaking (NPRM) on the ADR process on August 12, 2016.<sup>97</sup> The comment period for the NPRM closed on October 11, 2016.<sup>98</sup> On August 1, 2017, HHS withdrew the NPRM.<sup>99</sup> Accordingly, HRSA has not yet developed an ADR process, some seven years after the law requiring them to do so was enacted.

The PPACA required HHS to provide for the imposition of civil monetary penalties (CMPs) against manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug.<sup>100</sup> Because HHS had never had CMP authority to address overcharging by manufacturers in the 340B program, HHS issued an ANPRM entitled *340B Drug Pricing Program Manufacturer Civil Monetary Penalties* in 2010 to solicit public feedback on this requirement.<sup>101</sup> After considering the 15 comments on the ANPRM regarding the imposition of CMPs for manufacturers that knowingly and intentionally overcharge covered entities under the 340B program, on June 17, 2015, HHS issued a NPRM on the calculation of ceiling prices, the imposition of manufacturer CMPs, and to establish the requirement that a manufacturer charge a \$0.01 (penny pricing policy) for 340B drugs if the ceiling price equals zero.<sup>102</sup>

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<sup>93</sup> Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406 (Dec. 12, 1996).

<sup>94</sup> 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233 (Sept. 20, 2010).

<sup>95</sup> *Id.*

<sup>96</sup> *See, e.g.*, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583 (stating that "The administrative dispute resolution process remains under development and is not included in this notice of proposed rulemaking.").

<sup>97</sup> 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016).

<sup>98</sup> *See* Docket for 340B Drug Pricing Program; Administrative Dispute Resolution, 81 Fed. Reg. 53,381 (Aug. 12, 2016), available at <https://www.regulations.gov/document?D=HRSA-2016-0002-0001>.

<sup>99</sup> *See* Office of Management and Budget, *340B Drug Pricing Program; Administrative Dispute Resolution Process* (last accessed Dec. 12, 2017), available at <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90>.

<sup>100</sup> 340B Drug Pricing Program Manufacturer Civil Monetary Penalties, 75 Fed. Reg. 57,230 (Sept. 20, 2010).

<sup>101</sup> *Id.*

<sup>102</sup> 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties Regulation, 80 Fed. Reg. 34,583 (Jun. 17, 2015).

On January 5, 2017, HHS finalized this rule and established an effective date of October 1, 2017.<sup>103</sup> The final rule requires that manufacturers calculate the 340B ceiling price on a quarterly basis, requires that manufacturers charge \$0.01 per unit of measure if the 340B ceiling price calculation results in a ceiling price that equals zero, establishes the methodology manufacturers must use when estimating the ceiling price for a new 340B drug, establishes how a CMP will be imposed on a manufacturer that knowingly and intentionally overcharges a covered entity, and establishes what constitutes an instance of overcharging that triggers a CMP.<sup>104</sup> On August 21, 2017, however, HRSA published a NPRM to further delay the effective date of the final rule.<sup>105</sup> Shortly thereafter, on September 29, 2017, HRSA formally delayed the effective date and the enforcement date of the final rule to July 1, 2018, and expressed their intent to engage in further rulemaking.<sup>106</sup> Thus, HRSA has not yet effectuated their regulation on this issue, some seven years after the law requiring them to do so was enacted.

Consistent with HHS OIG's recommendation for HRSA to improve program transparency surrounding the ceiling prices set by manufacturers in accordance with the statutory formula, the PPACA authorized HRSA to share confidential ceiling price information with covered entities.<sup>107</sup> HRSA used part of the increased funding it received in 2014 to develop an IT system to share ceiling prices with covered entities, and has since testified that it is continuing to work on the development of that system.<sup>108</sup> While HRSA testified that they were "getting very close to the release of [this] system," covered entities still do not have access to ceiling price information.<sup>109</sup> As discussed in Section V.D., without this data, covered entities are unable to ensure they are paying an appropriate price for 340B drugs.<sup>110</sup> Accordingly, they may not know that they should report to HRSA that they are not receiving an accurate price from a manufacturer.

HHS OIG also has recommended that state Medicaid programs have access to information about ceiling prices for 340B drugs to help ensure state Medicaid programs can effectively enforce Medicaid payment policies for 340B drugs.<sup>111</sup> While the PPACA provided HRSA with the authority to share ceiling prices with covered entities, HRSA does not have the authority to share ceiling prices with the state Medicaid programs. HRSA testified in July 2017

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<sup>103</sup> 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1,210 (Jan. 5, 2017).

<sup>104</sup> Health Resources and Services Administration, *Office of Pharmacy Affairs Update* (Jan. 2017), available at <https://www.hrsa.gov/sites/default/files/opa/updates/2017/170106monthlyupdate.pdf>.

<sup>105</sup> 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 39,553 (Aug. 21, 2017).

<sup>106</sup> See 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 45,511 (Sept. 29, 2017).

<sup>107</sup> See *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, U.S. Dep't of Health and Human Services, Office of Inspector General).

<sup>108</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 86 & 101 (Jul. 18, 2017).

<sup>109</sup> *Id.* at 102.

<sup>110</sup> *Id.* at 31.

<sup>111</sup> See *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, U.S. Dep't of Health and Human Services, Office of Inspector General).



that while providing access to ceiling prices would not address any issues relating to duplicate discounts, state Medicaid agencies could use this information to ensure compliance with CMS reimbursement requirements:

Q: Do you have sufficient statutory authority to carry out that recommendation of providing ceiling prices to state Medicaid agencies?

A: The statute is very specific to allow HRSA to provide ceiling prices to covered entities. Therefore, we would need a legislative change to provide that information to the states. We are currently in discussion with CMS regarding some possible administrative options. But we would need up front a legislative –

Q: Okay. So let us talk about that for a second. Let us assume that state Medicaid agencies have the ability to learn of the ceiling prices. Can you share for this subcommittee how that would positively impact program integrity?

A: So in terms of providing the ceiling to states, it would not address any issues around duplicate discounts under the 340B statute. The ceiling prices would be in place to help inform the prices being paid for those drugs so that the states could reimburse the covered entity according to CMS rules.<sup>112</sup>

According to a February 2016 final rule, CMS requires that states adopt a Medicaid reimbursement methodology based on Actual Acquisition Cost that reflects the actual price that a provider paid to acquire the medicine.<sup>113</sup> In a February 11, 2016 letter to State Medicaid Directors, CMS explained that “[f]or drugs purchased through the 340B program, reimbursement should not exceed the 340B ceiling price.”<sup>114</sup> However, many State agencies are unable to effectively enforce their Medicaid payment policies for 340B drugs because they do not have access to ceiling prices.<sup>115</sup>

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<sup>112</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 107 (Jul. 18, 2017).

<sup>113</sup> Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (Feb. 1, 2016).

<sup>114</sup> Letter from Vikki Wachino, Director, Centers for Medicare and Medicaid Services, to State Medicaid Directors re Implementation of the Covered Outpatient Drug Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program (Feb. 11, 2016).

<sup>115</sup> *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce, 114th Cong.* (Mar. 24, 2015) (statement of Ann Maxwell, Assistant Inspector General, Office of Evaluation and Inspections, Office of Inspector General, U.S. Dep’t of Health and Human Services).

## B. HRSA's Authority to Clarify Program Requirements

***Finding: HRSA lacks sufficient authority to adequately oversee the program and clarify program requirements. HRSA needs more regulatory authority to promote compliance and ensure program integrity. Key aspects of the program have remained vague, resulting in variation in the way covered entities use the 340B program.***

HRSA continues to face challenges in overseeing the 340B program, primarily because the agency has limited regulatory authority over the 340B program. HRSA has encountered numerous oversight hurdles since a federal court established limits on HRSA's rulemaking authority in 2014, ruling that the 340B statute provides HRSA with explicit regulatory authority in only three specific areas: (1) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices; (2) imposition of manufacturer civil monetary penalties; and (3) establishment of an administrative dispute resolution process.<sup>116</sup>

The federal court decision limiting HRSA's regulatory authority regarded a 2013 final rule relating to the circumstances in which an orphan drug must be offered at a discounted price under the 340B program.<sup>117</sup> In a suit brought by the Pharmaceutical Research and Manufacturers of America, the D.C. District Court concluded that HRSA lacked the statutory authority to promulgate the orphan drug regulations and vacated the rule.<sup>118</sup> The court reasoned that Congress provided HRSA with limited explicit regulatory authority in three specific areas and the agency therefore could not promulgate regulations regarding other provisions in the 340B program statute.<sup>119</sup> The court noted "[t]he rulemaking authority granted HHS by Congress under the 340B program has thus been specifically limited, and HHS has not been granted broad rulemaking authority to carry out all provisions of the 340B program."<sup>120</sup> Shortly thereafter, in June 2014, HRSA announced they continued to stand by their interpretation described in the published final rule, and in July 2014, HRSA issued an interpretive rule pertaining to the statutory requirement for inclusion of drugs with orphan drug designations in the 340B drug pricing program.<sup>121</sup> These agency actions were also challenged, and, in October 2015, the D.C. District Court held that the interpretive rule was contrary to the language of the 340B statute.<sup>122</sup>

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<sup>116</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 81 (Jul. 18, 2017).

<sup>117</sup> 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. Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, 78 Fed. Reg. 44,016 (Jul. 23, 2013).

<sup>118</sup> *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health and Human Serv.*, 43 F. Supp. 3d 28, 42-5 (D.D.C. 2014).

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Covered Entities Under the 340B Program* (Jul. 23, 2014), available at <https://www.hrsa.gov/sites/default/files/opa/programrequirements/interpretiverule/interpretiverule.pdf>.

<sup>122</sup> *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health and Human Serv.*, case no. 14-1685 (D.D.C. 2015).

Consequently, HRSA has struggled to provide stakeholders with specific information about program requirements.<sup>123</sup>

In 2014, HRSA had planned to issue an omnibus regulation for the 340B program to strengthen the agency's oversight of covered entities and manufacturers and establish additional policies, including clarifying the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities. Because of the May 2014 federal court decision invalidating the orphan drug regulation, however, HRSA withdrew the omnibus 340B regulation from Office of Management and Budget (OMB) review in November 2014 to re-evaluate the proposed omnibus regulation given the court's ruling.<sup>124</sup> HRSA subsequently released a proposed 340B Drug Pricing Program Omnibus Guidance, commonly referred to as the "Mega-Guidance," in August 2015.<sup>125</sup> HRSA ultimately 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.<sup>126</sup> In July 2017, HRSA testified that they were "working on next steps to address these policy issues."<sup>127</sup>

HRSA has requested additional regulatory authority for the 340B program under both President Obama and President Trump.<sup>128</sup> For example, in the overview of President Obama's FY 2017 Budget, the administration proposed a user fee to be imposed on covered entities to support operation of the program, and noted it was "committed to program integrity in the 340B program, and the FY 2017 Budget [sought] new rulemaking authority to ensure adherence to the program's principles, compliance with the law, and the most effective use of this critical safety-net program."<sup>129</sup> The Obama administration also proposed the use of fees to support the program in the FY 2015 and FY 2016 budgets.<sup>130</sup> Similarly, in HRSA's congressional budget justification

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<sup>123</sup> See, e.g., *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong. (Mar. 24, 2015).

<sup>124</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, U.S. Dep't of Health and Human Services, Office of Inspector General).

<sup>125</sup> *340B Drug Pricing Program Omnibus Guidance* 80 Fed. Reg. 52,300 (Aug. 28, 2015).

<sup>126</sup> Executive Office of the President, Office of Management and Budget, Office of Information and Regulatory Affairs, *340B Program Omnibus Guidance*, RIN 0906-AB08 (last accessed Dec. 1, 2017), available at <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AB08>.

<sup>127</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 26 (Jul. 18, 2017).

<sup>128</sup> U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Committee Staff Phone Briefing with U.S. Dep't of Health and Human Services, Health Resources and Services Administration (Jul. 13, 2017); See also U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees* (2018).

<sup>129</sup> See U.S. Dep't of Health and Human Services, *HHS FY 2017 Budget in Brief – HRSA* (last accessed Dec. 19, 2017), available at <https://www.hhs.gov/about/budget/fy2017/budget-in-brief/hrsa/index.html>.

<sup>130</sup> See U.S. Dep't of Health and Human Services, *HHS FY 2015 Budget in Brief – HRSA*, <https://www.hhs.gov/about/budget/fy2015/budget-in-brief/hrsa/index.html> ("The Budget includes \$17 million for the 340B program, an increase of \$7 million above FY 2014, through a new cost recovery fee, which will help improve the program's operations, oversight and integrity.") (last accessed Dec. 19, 2017); U.S. Dep't of Health and Human Services, *HHS 2016 Budget in Brief – HRSA*, <https://www.hhs.gov/about/budget/fy2016/budget-in->

for President Trump’s FY 2018 Budget, HRSA stated: “HHS will work with Congress to develop a legislative proposal to improve 340B Program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations. This proposal would provide regulatory authority.”<sup>131</sup>

In July 2017, HRSA testified “[s]pecific legislative authority to conduct rule making for all provisions in the 340B statute would be more effective for facilitating HRSA’s oversight and management of the program. Specifically, regulatory authority would also allow HRSA to provide greater clarity and specificity of program requirements.”<sup>132</sup> HRSA also noted that the agency has struggled to clarify some of the program requirements since they lack explicit regulatory authority for other provisions of the 340B statute:

Q: So let me ask you then what you think then are the key – Captain Pedley, the key areas that we ought to be looking at to support your work in making sure that your audits are as effective as they can be and that this program is as effective as it can be.

A: As proposed in the – in the fiscal year ‘18 president’s budget, HRSA only, again, has regulatory authority in three specific areas and we have proposed guidance in all other areas. The regulatory authority across the program is critical for us to be able to provide clarity in our program requirements and assist HRSA in our oversight efforts to be able to then enforce those requirements. So regulatory authority is key.<sup>133</sup>

Similarly, in March 2015, HRSA testified that if the agency had additional tools to clarify program requirements, they would certainly use those tools.<sup>134</sup> Moreover, HRSA said that rulemaking authority would allow the agency to provide more specificity about program requirements:

Q: And then what about the difficulties, other difficulties with enforcing guidance in the absence of rule-making authority?

A: Generally rule making allows an agency to be more specific about its requirements and that is clearly something that has been identified by both the GAO and IG. So greater specific, clarity on the requirements. It also

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brief/index.html (“In addition, it proposes a new user fee totaling \$7.5 million as a long-term financing strategy to support the program’s activities) (last accessed Dec. 19, 2017).

<sup>131</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees*, at 246 (2018).

<sup>132</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 26 (Jul. 18, 2017).

<sup>133</sup> *Id.* at 90.

<sup>134</sup> *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 114th Cong., at 60 (Mar. 24, 2015).

has a stronger enforcement ability than guidance. So yes, overall, rule making is a stronger enforcement tool than guidance.<sup>135</sup>

Likewise, HHS OIG testified during the committee's July 2017 hearing that HRSA needs additional regulatory authority to effectively administer and oversee the 340B program:

Q: And Ms. Bliss, I just wanted to ask you quickly what tools or authorities do you believe HRSA needs in order to efficiently administer the 340B program?

A: Thank you. We believe that increasing transparency and clarity around the program rules is very important, and while I can't offer a legal opinion on HRSA's authority, our understanding is they may need additional authority from Congress to do this.<sup>136</sup>

GAO has also identified vulnerabilities in HRSA's oversight of the 340B program in some of their work. For example, in 2011, GAO issued a report entitled *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*.<sup>137</sup> In the report, GAO found that HRSA's oversight of the 340B program was inadequate to ensure compliance with program rules, and GAO made recommendations for HRSA to improve program integrity. HRSA has addressed two of GAO's four recommendations in the report by beginning to conduct audits of covered entities and providing more specific non-discrimination guidance for manufacturers on handling cases in which distribution of drugs is restricted.<sup>138</sup> HRSA, however, has not clarified guidance on the definition of an eligible patient and hospital eligibility criteria for program participation as recommended in GAO's report.<sup>139</sup> The committee therefore asked GAO about these findings during the July 2017 hearing, and asked whether there were any remaining concerns about program integrity:

Q: Now, so, Dr. Draper, I understand that in the GAO audits you found some weaknesses in HRSA's ability to oversee the program and also you found that the agency needs to issue guidance that defines a 340B patient and clarity the standard for hospital eligibility. Are those in general your concerns?

A: Well, to give you an example, the definition of a patient is very ambiguous. It is that the patient has an established relationship with the entity and the

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<sup>135</sup> See, e.g., *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 114th Cong., at 26 & 62 (Mar. 24, 2015).

<sup>136</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 50 (Jul. 18, 2017).

<sup>137</sup> 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).

<sup>138</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Debra Draper, Director, Health Care, Government Accountability Office).

<sup>139</sup> *Id.*

entity maintains the medical records and that the entity – the provider of services for that entity is either employed or under contract arrangement or some other type of arrangement. So we had concerns about the language about like some other type of arrangement –

Q: Right.

A: -- what specifically does that mean, and I think it has been interpreted very broadly.

Q: So let me ask you, do you think the agency has authority under the current statutory language to tighten those definitions up or do you think that we need to do something with the statute?

A: Well, since 1992 the agency has issued program guidance to try and clarify the rules of the program. So we are not – we are a little confused about why. I think there is some concern that they need some regulatory authority versus having guidance and –

Q: Okay. So we might have to – we might have to go and look at the statute.

A: Perhaps.<sup>140</sup>

Despite these limitations on HRSA’s regulatory authority, the agency has attempted to clarify program requirements in a variety of ways. This process, however, oftentimes has been inadequate and made it difficult for some covered entities to comply with the program. In the Questions for the Record for the October 2017 hearing, one covered entity, Mission Health, told the committee that HRSA’s inability to issue clear guidance on program requirements has resulted in varying interpretations of program requirements:

[Over the last 25 years], HRSA has, due to the state of the applicable statutes, at times, dictated or ushered compliance through the issuance of ‘frequently asked questions’ posed on the 340B website and/or through audit findings (instead of issuing regulations and/or through rulemaking), leading to varying interpretations of permissible/impermissible use across the 340B program. This process has made it more difficult to optimally achieve compliance in an already complex program.

By way of example, 340B providers have asked the question as to whether, in owned or contracted community pharmacies, a Medicaid Managed Care patient is eligible for 340B-priced medications. In multiple forums, the verbal answer from HRSA has been that only fee-for-service Medicaid duplicate discounts are prohibited, and a Medicaid Managed Care patient, is therefore, 340B eligible. The Apexus website ‘frequently asked question’ does not include an answer to this

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<sup>140</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcommittee on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 50 (Jul. 18, 2017).

question. The ‘eligible patient definition’ in this situation is not clear, and accordingly, hospitals must make a decision that could ultimately result in audit findings. Situations like this example are what Mission references as a lack of regulatory clarity, and it is a clear opportunity for improvement.<sup>141</sup>

Mission Health continued: “The issuance of clear, statutory language supported by a formal and consistent regulatory and/or rule-making process regarding the ‘patient’ definition would strengthen the 340B Program and help 340B hospitals meet program requirements in consistent manner.”<sup>142</sup>

HHS OIG has also highlighted concerns with the current lack of clarity in program requirements and commented on how covered entities might interpret program requirements in different ways. For example, in 2015, HHS OIG testified that health care providers use different definitions of eligible patient:

Let’s imagine a doctor sees a patient at a community health center. Later that same doctor sees the same patient at her private practice. If that doctor prescribes a drug to that patient at her private practice, is that prescription eligible for the 340B discount? One provider we talked to in our study said yes. Another provider in our study said no. And yet another said maybe. So who is right? We couldn’t tell based on current guidance.<sup>143</sup>

Likewise, at the same hearing in 2015, GAO testified that “[b]ecause of the complex nature of and significant growth in the program, it is also critical that program requirements are clearly and explicitly laid out in guidance or regulations. Otherwise, much is left to interpretation, increasing the risk of misuse of the 340B Program.”<sup>144</sup>

### C. HRSA’s Audits of Covered Entities

***Finding: Although HRSA has increased the number of covered entity audits it conducts per year, the audit process still needs improvement. Given HRSA’s limited regulatory authority over the 340B program, HRSA only conducts a limited review of the covered entity’s use of the program during the audit process. Covered entities would benefit from clear guidance on the audit process.***

Under 42 USC 256b(a)(5)(C), HRSA has the authority to audit covered entities for compliance with 340B program requirements. The relevant provision in the PHSA provides:

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<sup>141</sup> Letter from Ronald A. Paulus, M.D., President and Chief Executive Officer, Mission Health System, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, *Additional Questions for the Record* (Nov. 21, 2017).

<sup>142</sup> *Id.*

<sup>143</sup> *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 114th Cong., at 36-37 (Mar. 24, 2015).*

<sup>144</sup> *Id.* at 19.

(C) AUDITING. ---A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

Subparagraph (A) under 42 USC 256(b)(a)(5) prohibits requiring manufacturers to pay discounts or rebates under both the 340B program and the Medicaid Drug Rebate Program (*i.e.*, duplicate discounts). Subparagraph (B) under 42 USC 256(b)(a)(5) prohibits the resale of 340B drugs to a person who is not a patient of the entity (*i.e.*, diversion).

HRSA and manufacturers have had the authority to audit covered entities since the 340B program was established in 1992.<sup>145</sup> Until 2012, however, HRSA primarily relied on covered entities to self-monitor and ensure compliance with 340B program requirements. In response to a 2011 GAO report recommending HRSA begin auditing covered entities to monitor for program violations, provide additional program oversight, and prevent diversion and duplicate discounts, HRSA began conducting selective audits of covered entities in 2012.<sup>146</sup> Since FY 2012, HRSA has slowly increased the number of audits it conducts each year of covered entities—conducting 51 audits in 2012,<sup>147</sup> 94 in 2013,<sup>148</sup> 99 in 2014,<sup>149</sup> 200 in 2015,<sup>150</sup> 200 in 2016,<sup>151</sup> and 132 in 2017 (as of December 12, 2017).<sup>152</sup>

As of October 2016, there were 12,148 covered entities participating in the 340B program.<sup>153</sup> HRSA therefore audited fewer than 2 percent of covered entities participating in the

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<sup>145</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *340B Drug Pricing Program Notice: Clarification of HRSA Audits of 340B Covered Entities*, Release No. 2012-1 (Mar. 5, 2012), <https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/auditclarification030512.pdf>.

<sup>146</sup> *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 114th Cong., at 19 (Mar. 24, 2015).

<sup>147</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY12 Results* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-12-results.html>.

<sup>148</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY13 Results* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-13-results.html>.

<sup>149</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY14 Results* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-14-audit-results.html>.

<sup>150</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY15 Results* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-15-audit-results.html>.

<sup>151</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY16 Results* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-16-results.html>.

<sup>152</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity: FY17 Results* (last updated Dec. 12, 2017) (last accessed Jan. 3, 2018), available at <https://www.hrsa.gov/opa/program-integrity/audit-results/fy-17-results.html>.

<sup>153</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Fiscal Year (FY) 2018 Justification of Estimates for Appropriations Committees* (2018).



program in 2016. HRSA conducts selective and targeted audits of covered entities. For the first selective model, HRSA selects covered entities through a risk-based approach whereby the agency factors in certain risk factors and then randomly selects covered entities to audit based on those factors.<sup>154</sup> In the targeted model, HRSA specifically targets certain covered entities to audit based on either specific allegations HRSA has received about compliance issues with the covered entities or information HRSA has indicating that a covered entity is not in compliance with program requirements.<sup>155</sup> For example, HRSA considers if a previous audit had findings, and may consider re-auditing the covered entity once the Corrective Action Plan (CAP) is fully processed so the agency can assess whether the covered entity fully implemented the CAP.<sup>156</sup>

During audits of covered entities, HRSA reviews covered entity compliance with respect to eligibility status and program requirements, including compliance with the GPO prohibition as applicable, incorrect database, duplicate discounts, and diversion. In certain instances, HRSA also will make non-binding recommendations to the covered entity in an “Area for Improvement” section in the final audit report issued to the covered entity.<sup>157</sup> When HRSA is auditing for duplicate discounts and diversion, HRSA follows a standard auditing process whereby the agency only audits a sample of the 340B drugs purchased by the covered entity rather than all 340B drugs purchased by that entity.<sup>158</sup> To ensure the entire program is in compliance with program requirements, HRSA also reviews all other aspects of the program including looking at their policies and procedures, interviewing staff, reviewing software systems, and examining any other relevant documents and information.<sup>159</sup>

HRSA also examines the covered entity’s off-site facilities and contract pharmacies participating in the program. During the committee’s July 2017 hearing, HRSA testified that the more than 800 covered entity audits conducted by the agency since 2012 included reviews of nearly 11,000 offsite facilities and 18,000 contract pharmacy locations.<sup>160</sup>

Q: But why the great expansion in the number of contract pharmacies? Is it just because we lifted the cap of one or how did that happen?

A: The 340B statute is silent on how these covered entities dispense and get these drugs to their patients. We had understood that through state law entities were contracting with pharmacies. So in recognition of that, we did

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<sup>154</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 88 (Jul. 18, 2017).

<sup>155</sup> *Id.*

<sup>156</sup> U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Committee Staff Phone Briefing with U.S. Dep’t of Health and Human Services, Health Resources and Services Administration (Jul. 13, 2017).

<sup>157</sup> *See* HRSA audit records on file with the Committee.

<sup>158</sup> U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Committee Staff Phone Briefing with U.S. Dep’t of Health and Human Services, Health Resources and Services Administration (Jul. 13, 2017).

<sup>159</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 89-90 (Jul. 18, 2017).

<sup>160</sup> *Id.* at 27. HRSA’s review of contract pharmacies is limited due to HRSA’s narrow authority.

develop guidance in 2010 that stated if they were going to have these contract pharmacies they needed to ensure they were also complying with the statutory requirements of diversion and duplicate discounts and we audit that information on those contract pharmacies when we go in to audit a covered entity.

Q: All right.... But I have also heard that the contract pharmacies are not only allowed to charge a dispensing fee but some of them ask for part of the savings on the drug. Is that correct or is that incorrect?

A: I don't have the information on that. That's a business matter between the parties and their contract.

Q: But it is not prohibited?

A: It is – it is not prohibited.

Q: Okay. Now let us get back to the audits.... Do you suspend the pharmacy or do you suspend the entity if they are not doing the proper oversight of the contracting pharmacies?

A: So we have audited now over 800 covered entities but it doesn't stop there. We also do conduct the audits within those of their contract pharmacies. So we have audited over 18,000 contract pharmacy arrangements related to those audits. We do ensure the covered entity is providing oversight. We sample 340B drugs dispensed from those pharmacies to ensure that they have not been diverted or have a duplicate discount, and if we do find the entity is not providing oversight of those contracts pharmacies we will remove the pharmacies from the program.

Q: All right. Now, that raises an interesting issue. If you have done the audits, and you touched on 18,000 contract pharmacies, those audits didn't reveal to you if some of them were getting a split of the savings with the entity?

A: That is a matter outside of our authority so we don't review it when we – when we audit them.<sup>161</sup>

Typically, if there is a finding during HRSA's audit process such as diversion or duplicate discounts, the covered entity is required to submit a CAP to HRSA. HRSA will review and approve the CAP, and then HRSA will continue to monitor the covered entity to ensure the CAP is properly implemented. The covered entity also may be required to offer the manufacturers repayment if there are certain findings and HRSA may remove the covered entity from the 340B program. HRSA posts summaries of the audit findings for each covered entity on their website

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<sup>161</sup> *Id.* at 116-118.

and information about whether the covered entity is under a CAP.<sup>162</sup> HRSA rarely terminates covered entities from the 340B program through the audit process. In July 2017, the agency testified that they had terminated one covered entity for not submitting a corrective action plan following an audit.

Q: Have you ever terminated an entity?

A: We have terminated one covered entity for not submitting a corrective action plan. We were able to terminate them through that mechanism. We have terminated contract pharmacies through the program where a covered entity was not providing oversight and there were a few cases where we terminated a child or offsite clinic of a hospital because they were not eligible for the program. But that is just through the audit process. We also terminate through our recertification process and some other quarterly integrity checks that we do to ensure compliance.<sup>163</sup>

HRSA can terminate an entity from the 340B program through the audit process if HRSA finds that the GPO prohibition is applicable to that entity and the covered entity is not complying with the GPO prohibition.<sup>164</sup>

While HRSA examines a covered entity's policies and procedures and interviews staff during an audit, audits are limited in scope as HRSA does not audit any information that is not within their explicit statutory authority.<sup>165</sup> For example, as previously noted, HRSA does not examine whether a covered entity is sharing program revenue with its contract pharmacy. Similarly, HRSA does not examine how covered entities use program savings:

Q: Do we or do we not know or audit how the savings are spent? That seems to be one of the issues. We all believe that everybody is a good actor and the money is going to the people most in need, as well as savings. But I

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<sup>162</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/program-integrity/index.html>.

<sup>163</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 72-73 (Jul. 18, 2017).

<sup>164</sup> Section 340B(a)(4)(L)(iii) of the PHSA provides that, to be eligible for the 340B program, certain covered entities may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." HRSA's long-standing policy is that if a covered entity subject to this prohibition participates in a GPO or other group purchasing arrangement, the covered entity "will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices." 340B Drug Pricing Program Omnibus Guidance, 59 Fed. Reg. 25,110 at 25,113 (May 13, 1994). See Health Resources and Services Administration, *340B Drug Pricing Program Notice: Statutory Prohibition on Group Purchasing Organization Participation*, Release No. 2013-1 (February 7, 2013) (indicating that "[s]ince the GPO prohibition is an eligibility requirement, covered entities found in violation will be considered ineligible and immediately removed from the 340B Program. Covered entities may also be subject to repayment to manufacturers for the time period for which the violation occurred.").

<sup>165</sup> See, e.g., *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 44 (Jul. 18, 2017).

also am not clear that HRSA actually – that there is a clear definition of how the money should be spent or that we track the money. Is that correct?

A: So the statute is silent as to how savings are used. Therefore, HRSA does not audit or have access to that information.<sup>166</sup>

If HRSA audits beyond the scope of their authority, the findings can easily be challenged by the covered entity.<sup>167</sup> If a covered entity disagrees with HRSA’s audit findings, the entity has 30 days in which to notify HRSA of their disagreement and provide supporting documentation.<sup>168</sup> OPA then reviews the entity’s response and may reissue the audit Final Report if appropriate.<sup>169</sup>

### i. Audit Findings

***Finding: HRSA’s annual audits uncovered 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 a variety of different ways, including duplicate discounts, diversion to ineligible patients and facilities, incorrect database reporting, and violation of the Group Purchasing Organization (GPO) prohibition (if applicable).<sup>170</sup>***

**Figure 3: Program Requirement Violations\*:<sup>171</sup>**

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
<b>Duplicate Discounts</b>	18	16	18	36	48
<b>Drug Diversion</b>	16	54	54	95	94
<b>Incorrect Database</b>	15	46	51	96	60
<b>GPO Prohibition</b>	0	1	9	18	9
<b>No Adverse Findings</b>	19	22	19	45	62
<b>Total Audits</b>	51**	94**	99**	200**	200**

\*Numbers provided represent the number of entities that committed this type of violation. In some cases, an entity may have committed one type of violation multiple times.

\*\*Numbers do not sum because several entities had more than one type of violation.

<sup>166</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript* (Jul. 18, 2017).

<sup>167</sup> U.S. House of Representatives, Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 115th Cong., Committee Staff Phone Briefing with U.S. Dep’t of Health and Human Services, Health Resources and Services Administration (Jul. 13, 2017).

<sup>168</sup> U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *340B Audit Process* (last accessed Dec. 14, 2017), available at <https://www.hrsa.gov/opa/updates/july-2014.html>.

<sup>169</sup> *Id.*

<sup>170</sup> Duplicate discounts, diversion, and incorrect reporting will be discussed later in this section.

<sup>171</sup> See U.S. Dep’t of Health and Human Services, Health Resources and Services Administration, *Program Integrity* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/program-integrity/index.html>.

## ii. Duplicate Discounts

Covered entities are prohibited from receiving duplicate discounts.<sup>172</sup> 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 Drug Rebate Program and the 340B program. While Medicaid rebates benefit state Medicaid programs and 340B discounts benefit 340B-covered entities, both of these programs target the same safety-net population.<sup>173</sup> 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 17 percent of 340B-covered entities audited had duplicate discount errors each year since 2012, when HRSA began conducting audits, as shown above in Figure 3.

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 (FFS) claims.<sup>174</sup> The MEF is a list of Medicaid provider numbers or national provider identifiers (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 drug claims 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).<sup>175</sup> This is a very significant and growing problem because an increasing number of Medicaid programs rely on MCOs to deliver Medicaid benefits. In 2014, 76 percent of Medicaid enrollees were in some type of managed care.<sup>176</sup> HHS OIG released a report in June 2016 finding that duplicate discounts are a severe issue for Medicaid MCOs.<sup>177</sup> 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

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<sup>172</sup> Public Health Service Act, 42 U.S.C. 256b(a)(5)(A)(i).

<sup>173</sup> Jason Hardaway, *340B Program Puts Manufacturers At Risk of Duplicate Drug Discounts*, 41 PHARMACY AND THERAPEUTICS 1, 38 (2016).

<sup>174</sup> 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).

<sup>175</sup> 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).

<sup>176</sup> *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>.

<sup>177</sup> U.S. Dep’t of Health and Human Services, *Office of Inspector General, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016).

HRSA's guidance to develop alternate strategies, since the MEF only works for FFS drugs.<sup>178</sup> Overall, this dynamic results in the risk of duplicate discounts for a majority of Medicaid patients, since a majority of Medicaid beneficiaries receive their benefits through MCOs.

Duplicate discounts for MCOs participating in the Medicaid Drug Rebate Program is a growing problem. Prior to the PPACA, only Medicaid FFS claims were eligible for rebates. The PPACA extended the Medicaid Drug Rebate program to expenditures made for drugs under managed care but did not create a centralized mechanism to help prevent duplicate discounts for MCOs.

The volume of duplicate discounts likely occurring in the Medicaid and 340B programs due to this dynamic may be far greater than has been previously realized. That is because the majority of Medicaid beneficiaries are enrolled in MCOs. According to MACPAC, the percentage of Medicaid enrollees in comprehensive managed care as of July 1, 2015 was about 65 percent—a number that has likely only increased as more states adopt managed care delivery systems.<sup>179</sup> Additionally, most Medicaid expenditures for covered outpatient drugs currently occur under managed care.<sup>180</sup> While there are some safeguards in place to prevent duplicate discounts in Medicaid FFS, HRSA audits do not include the same review of Medicaid managed care. This problem will only grow over time to the degree states increasingly rely on MCOs to deliver Medicaid benefits.

The committee's review of HRSA's audit files revealed that, while there are some safeguards in place to prevent duplicate discounts in FFS Medicaid, some covered entities fail to adequately protect against the risk of duplicate discounts.<sup>181</sup> For example, in one final audit report for a covered entity audited by HRSA, HRSA indicated that the covered entity and its off-site outpatient facilities did not accurately appear on the 340B MEF at the time of the audit.<sup>182</sup> Similarly, in a final audit report for a different covered entity, HRSA found that the covered entity was billing Medicaid contrary to the information contained in the 340B MEF.<sup>183</sup> In the final report, HRSA noted that:

Duplicate discounts are prohibited by section 340B(a)(5)(A) of the of the PHSA; that is, a drug purchase shall not be subject to both a discount under section 340B and a Medicaid rebate under section 1927 of the Social Security Act. HRSA has created the 340B Medicaid Exclusion File as a mechanism for covered entities to

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<sup>178</sup> To remedy this issue, some stakeholders have suggested the inclusion of 340B-specific claims identifiers, the provision of claims-level identifiers, and the provision of claims level data by covered entities to states as well as manufacturers sufficient to identify claims. Since the Centers for Medicare and Medicaid Services (CMS) provides oversight of State Medicaid programs, separate regulations pertaining to this issue may need to be issued by CMS. However, since 340B drugs are determined retrospectively, stakeholders have informed the committee that the IT infrastructure is not currently equipped to resolve the issue of identifying Medicaid managed care claims under 340B.

<sup>179</sup> See Medicaid and CHIP Payment and Access Commission, *MACStats: Medicaid and CHIP Data Book* (December 2017) at 83, available at <https://www.macpac.gov/wp-content/uploads/2015/12/MACStats-Medicaid-CHIP-Data-Book-December-2017.pdf>.

<sup>180</sup> See *id.* at 80.

<sup>181</sup> See HRSA audit records on file with the committee.

<sup>182</sup> See HRSA audit records on file with the committee.

<sup>183</sup> See HRSA audit records on file with the committee.

comply with the duplicate discount prohibition. [The covered entity] must ensure it is appropriately listed on the 340B Medicaid Exclusion File and follow any additional state Medicaid laws. [The covered entity] responded “no” to the question “Will you bill Medicaid for drugs purchased at the 340B price?” which was contrary to the entity’s practice at the time of the audit. Since [the covered entity] failed to appear on the 340B Medicaid Exclusion File, this action may have resulted in duplicate discounts, prohibited under 340B(a)(5)(A) of the PHSA.<sup>184</sup>

### iii. Diversion

HRSA prohibits the resale or transfer of 340B drugs to ineligible patients, known as diversion. Only individuals who are patients of covered entities are eligible to receive 340B drugs.<sup>185</sup> 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.<sup>186</sup> As shown in Figure 3, a large percentage of HRSA’s audited entities diverted drugs to ineligible patients in FY 2012 through FY 2016.

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 47 percent of covered entities in FY 2016 were found to have diverted drugs. Diversion violations reached 54 percent in FY 2014 and a 57 percent high in FY 2013, when more than 50 audited entities offered drug pricing benefits to ineligible patients.

The lack of a clear definition of “patient” may be directly connected to the high number of covered entities who committed diversion violations, since HRSA’s definition of “patient” has been criticized widely for its vagueness. HHS OIG has stated that “[there is] a lack of clarity on how HRSA’s patient definition should be applied in contract pharmacy arrangements.”<sup>187</sup> 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.”<sup>188</sup>

To identify which 340B-eligible patients received prescriptions, contract pharmacies often match information from the 340B providers, such as patient and prescriber lists, to their dispensing data. In their 2014 report, HHS OIG found wide variation in these eligibility

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<sup>184</sup> See HRSA audit records on file with the committee.

<sup>185</sup> 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* (last accessed Jan. 8, 2018), available at <https://www.340bpvp.com/resource-center/faqs/patient-definition/>.

<sup>186</sup> See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207 (Oct. 24, 1996).

<sup>187</sup> 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).

<sup>188</sup> Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

determinations. Depending on the interpretation of HRSA’s patient definition, some 340B provider eligibility determinations would be considered diversion and others would not.<sup>189</sup>

The committee’s review of HRSA’s audit files revealed that many entities have engaged in diversion by dispensing a 340B drug to an ineligible individual. Moreover, in at least eight of the 32 audit files reviewed by committee staff, HRSA recommended that the covered entity improve its oversight of each contract pharmacy arrangement to prevent diversion of 340B drugs at the contract pharmacy.<sup>190</sup> For example, in the “Areas for Improvement” section of one final audit report for a covered entity, HRSA wrote:

Covered entities are required to oversee each contract pharmacy arrangement used to dispense 340B drugs (75 Fed. Reg. 10272 (Mar. 5, 2010)).

While [the covered entity] has written 340B Program policies and procedures for contract pharmacy arrangements, such policies and procedures do not currently reflect all of the actions that [the covered entity] is taking to ensure 340B Program compliance and oversight activities of their contract pharmacies. More specifically, current 340B Program policies and procedures do not include all controls to verify 340B-eligibility or prevent diversion of 340B drugs at the contract pharmacy. [The covered entity’s] 340B Program policies and procedures should describe monitoring procedures to include effective procedures for eligibility determination process used at contract pharmacies and reconciliation of dispensing and purchasing records to ensure that diversion has not occurred.

Covered entities must ensure 340B Program compliance at the entity, off-site outpatient facilities, and contract pharmacies. [Covered entity] remains responsible for ensuring their contract pharmacies meet statutory obligations to ensure against diversion or duplicate discounts of [covered entity’s] 340B drugs. At the time of the audit [covered entity] relied on [third party vendors] to monitor contract pharmacies’ 340B dispenses. HRSA expects that all covered entities perform annual independent audits (or more frequent as necessary) of all their contract pharmacies to ensure 340B Program compliance, although the exact method of ensuring compliance is left up to the entity.<sup>191</sup>

HRSA’s suggestions in the “Areas for Improvement” section of audit documents, however, are not binding and thus do not require the covered entity to take the recommended course of action. As is alluded to above, the exact method of ensuring compliance is left up to the entity.

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<sup>189</sup> 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).

<sup>190</sup> See HRSA audit records on file with the Committee.

<sup>191</sup> *Id.*



#### iv. 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 3. The audits show that many times, records include clinic locations or outpatient facilities that are no longer in service. During the committee’s review of HRSA’s audit files, the committee found that covered entities also did not always register all off-site outpatient facilities in the 340B database that used 340B drugs.<sup>192</sup> HHS OIG investigators have warned that incorrect reporting could hide program violations.<sup>193</sup>

#### v. GPO Prohibition and Program Termination

Certain eligible hospitals must certify that they will not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement (referred to as the “GPO prohibition”).<sup>194</sup> HRSA can terminate an entity from the 340B program through the audit process if HRSA finds that the GPO prohibition is applicable to that covered entity and the entity is not complying with the GPO prohibition.<sup>195</sup> In one of the audit files produced to the committee, HRSA found that the entity did not comply with the GPO prohibition as the entity obtained covered outpatient drugs through a GPO during a certain period of time.<sup>196</sup> HRSA did not, however, terminate the covered entity from the 340B program “based upon the information provided to HRSA that [covered entity] is currently in compliance with the GPO prohibition.” In the final audit report, HRSA wrote:

A DSH hospital must meet the requirement in section 340B(a)(4)(L)(iii) of the PHSA to be eligible for the 340B Program, which states the entity may not “obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.” HRSA’s longstanding policy is that if a covered entity subject to this prohibition participates in a GPO, the covered entity “will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices.” 59 Fed. Reg. 25110 at 25113 (May 13, 1994). HRSA published 340B Drug Pricing Program Notice (Release No. 2013-1) on February 7, 2013 to clarify HRSA’s position on violations of the prohibition against

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<sup>192</sup> See HRSA audit records on file with the committee.

<sup>193</sup> U.S. Dep’t of Health and Human Services, Office of Inspector General, *State Efforts to Exclude 340B Drugs From Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016) <https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf>.

<sup>194</sup> Public Health Service Act, 42 U.S.C. 256b(a)(4)(L)(iii).

<sup>195</sup> 340B Drug Pricing Program Omnibus Guidance, 59 Fed. Reg. 25,110 at 25,113 (May 13, 1994). See Health Resources and Services Administration, *340B Drug Pricing Program Notice: Statutory Prohibition on Group Purchasing Organization Participation*, Release No. 2013-1 (February 7, 2013) (indicating that [s]ince the GPO prohibition is an eligibility requirement, covered entities found in violation will be considered ineligible and immediately removed from the 340B Program. Covered entities may also be subject to repayment to manufacturers for the time period for which the violation occurred.”).

<sup>196</sup> See HRSA audit records on file with the committee.

purchasing covered outpatient drugs through a GPO and gave covered entities until August 7, 2013, to come into compliance with the prohibition.

Based upon the information provided by [the covered entity], [the covered entity] began purchasing covered outpatient drugs through a GPO on [Date]. [The covered entity's] use of a GPO to purchase covered outpatient drugs violates section 340B(a)(4)(L)(iii) of the PHSA. Violation of the GPO prohibition is grounds for removal from the 340B Program. However, based upon the information provided to HRSA that [covered entity] is currently in compliance with the GPO prohibition, OPA will not remove [the covered entity] from the 340B Program at this time. [The covered entity] may be required to repay impacted manufacturers for 340B purchases made while [the covered entity] was in violation of the GPO prohibition. [The covered entity] may be liable to manufacturers for any purchases or transfers of covered outpatient drugs under the 340B Program during the period of ineligibility from [Date] until [Date].<sup>197</sup>

Similarly, the committee heard from one covered entity that expressed concerns with the lack of guidance and information available regarding HRSA's audit process, especially with respect to a finding of non-compliance with the GPO prohibition. This covered entity was found to be non-compliant with the GPO prohibition during an audit. While the finding of non-compliance was ultimately reversed, the covered entity expressed concerns that they were not given an opportunity to respond to HRSA's finding before they received a letter from HRSA recommending that they stop purchasing outpatient drugs through the 340B program. Instead, according to the covered entity, HRSA conducted an on-site audit and then over three months later HRSA sent a "Final Report" to the covered entity indicating the agency had found that the covered entity, its off-site outpatient facilities, and its contract pharmacies were no longer eligible to participate in the 340B program and were required to make any necessary repayments to affected manufacturers. At the time HRSA conducted the audit of the entity, the entity believed, based upon discussions with auditors, that the audit went well. In the "Final Report" HRSA sent to the covered entity, HRSA provided the covered entity 30 days to dispute the findings and demonstrate to HRSA that the covered entity was in compliance with the GPO prohibition. HRSA did not, however, provide the covered entity with any information about why the agency believed that the covered entity was not in compliance with the GPO prohibition. HRSA also recommended the entity immediately stop purchasing 340B drugs. After multiple exchanges, the covered entity ultimately resolved the issue by presenting evidence to HRSA that it was in compliance with the GPO prohibition and HRSA ultimately reversed their findings, leaving the covered entity with no findings regarding eligibility, duplicate discounts, or diversion.

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<sup>197</sup> *Id.*

## D. HRSA's Audits of Manufacturers

***Finding: HRSA audits manufacturers and in their audits to date found no manufacturers out of compliance with the statute. However, without access to ceiling prices, covered entities may not know that they should report to HRSA that they are not getting an accurate price.***

Under Section 340B(a)(1) of the PHSA, manufacturers of covered outpatient drugs that participate in the 340B program must offer all covered outpatient drugs at no more than the 340B ceiling price to a covered entity listed on HRSA's public 340B database if such drug is made available to any other purchaser at any price. Under 340B(d)(1)(B)(v), HRSA has the authority to audit manufacturers to ensure compliance with program requirements. HRSA does not appear to audit manufacturers at the same rate as covered entities. According to HRSA's website, HRSA has audited 10 manufacturers since FY 2015 and has not had any adverse findings.<sup>198</sup> If a manufacturer fails to comply with 340B pricing requirements, the manufacturer may be liable to covered entities for refunds of overpriced 340B drugs.<sup>199</sup>

In 2015, HRSA testified that they have efforts in place for manufacturer compliance, but the requirements for manufacturers under the law are much narrower as they only have to offer the ceiling price.<sup>200</sup> HRSA made similar comments in 2017:

Q: What have the audits found so far?

A: Thus far, we do post the audits on our website and we have not had any findings whereby the manufacturers are not in compliance with the statute. The manufacturers only have – they have a more narrow focus than the 340B-covered [entities] and that is to provide the drug at or below the ceiling price and that is what we audit. But that is only one tool we use for manufacture[r] compliance. We also ensure that once they are in the Medicaid program that they appropriately sign an agreement with HRSA to provide the drugs at or below the ceiling price. We also issue regulation and guidance in the program related to manufacturer compliance. We also review all allegations that we receive if a covered entity is not receiving a price at or below the ceiling price and we investigate each of those situations.<sup>201</sup>

As previously mentioned in Section V.A, HRSA is working on, but has not yet released, an information system that will allow covered entities to view ceiling prices. In July 2017,

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<sup>198</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/program-integrity/index.html>.

<sup>199</sup> U.S. Dep't of Health and Human Services, Health Resources and Services Administration, *Program Integrity* (last accessed Dec. 1, 2017), available at <https://www.hrsa.gov/opa/program-integrity/index.html>.

<sup>200</sup> *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 114th Cong., *Preliminary Transcript*, at 99 (Mar. 24, 2015).

<sup>201</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 67 (Jul. 18, 2017).

HRSA indicated the system would be released in the “coming months.”<sup>202</sup> Since covered entities do not yet have access to ceiling prices, they do not necessarily know whether they are getting a fair ceiling price on the 340B drugs.<sup>203</sup> A covered entity therefore may not know they should report to HRSA that they are not getting an accurate price. HHS OIG testified in July 2017 that “[a]lthough Congress authorized HRSA to share confidential ceiling prices with 340B providers in 2010, HRSA has not yet done so” and “340B providers need to know the 340B ceiling prices to determine whether they are paying the accurate price.”<sup>204</sup> The committee has previously expressed concern about this lack of transparency. For example, during the committee’s 2005 hearing entitled *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency*, the then-Chairman of the Subcommittee on Oversight and Investigations noted it was “nonsensical” that covered entities did not have access to the ceiling prices:

[T]he common theme of all of the subcommittee’s drug pricing work, has been transparency. The 340B program certainly fits that mold. It is nonsensical to me that the entities entitled to the 340B discount, the 340B institutions and the prime vendor, do not have access to ceiling prices. Imagine going to a grocery store which advertises a special discounted price, only to find that when you go to the register to check out, no one can tell you what that discount is.<sup>205</sup>

## E. Program Growth and HRSA’s Ability to Keep Up

***Finding: The PPACA significantly increased the scope of the Medicaid program by expanding eligibility to certain low-income, non-disabled, non-elderly, non-pregnant adults. Medicaid expansion under the PPACA has likely increased the number of hospitals eligible for the 340B program because some hospitals’ eligibility is based, in part, on the number of the hospital’s inpatients who are Medicaid and low-income Medicare patient by virtue of their DSH (disproportionate share hospital) percentage. Overall, program participation has more than quadrupled over the past decade. HRSA’s limited oversight ability does not appear to be sufficient to conduct adequate oversight of this program.***

The 340B program has grown drastically since its inception, particularly after the PPACA expanded the list of eligible entities in 2010 and expanded Medicaid eligibility. The 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. As discussed above, these 340B-eligible facilities

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<sup>202</sup> *Id.* at 102.

<sup>203</sup> *Id.* at 102.

<sup>204</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong. (Jul. 18, 2017) (statement of Erin Bliss, Assistant Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Dep’t of Health and Human Services).

<sup>205</sup> *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 109th Cong., at 2 (Dec. 15, 2005).

also must meet other specified 340B participation requirements.<sup>206</sup>

Historically, Medicaid was only available for certain low-income children, pregnant women, parents of dependent children, the elderly, and individuals with disabilities.<sup>207</sup> The PPACA expanded Medicaid eligibility in 2014 by giving states the option to extend Medicaid coverage to all adults under age 65 (including adults without dependent children) with incomes below 138 percent of the federal poverty level.<sup>208</sup> The largest growth in Medicaid enrollment between July/September 2013 and September 2017 has been in states that expanded Medicaid to include the newly eligible adult group.<sup>209</sup> Since 2013, enrollment in Medicaid expansion states has increased by 37.6 percent, with 13.9 million new enrollees in these states.<sup>210</sup> Because certain hospitals qualify based in part on their DSH percentage, which accounts for the number of the hospital's inpatients who are Medicaid and low-income Medicare patients, more hospitals have likely become eligible to participate in the 340B program over the past few years.<sup>211</sup>

In the wake of these expansions, the number of participating unique covered entities has grown from 3,200 in 2011, to 11,180 in February 2015, to 12,148 in October 2016, to 12,722 in October 2017.<sup>212</sup> Notably, the number of hospitals has grown significantly, from 591 in 2005, to 1,673 in 2011, to 2,479 as of October 2017.<sup>213</sup>

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.<sup>214</sup> According to HRSA, that number has now reached 29,307.<sup>215</sup>

Part of the apparent growth in child sites can be attributed to a 2012 HRSA rule which changed how child sites must be registered. The rule provided that each hospital department administering 340B drugs must be registered as a child site, even if multiple separate

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<sup>206</sup> Section 7101, as amended by HCERA Sec. 2302, amended PHSA Sec. 340B.

<sup>207</sup> Julia Paradise et al., *Medicaid at 50: Low-Income Pregnant Women, Children, and Families, and Childless Adults*, THE HENRY J. KAISER FAMILY FOUNDATION (May 6, 2015), <https://www.kff.org/report-section/medicaid-at-50-low-income-pregnant-women-children-and-families-and-childless-adults/>.

<sup>208</sup> Medicaid and CHIP Payment and Access Commission, *Medicaid expansion to the new adult group* (last accessed Dec. 19, 2017), <https://www.macpac.gov/subtopic/medicaid-expansion/>.

<sup>209</sup> Medicaid and CHIP Payment and Access Commission, *Medicaid enrollment changes following the ACA* (last accessed Dec. 19, 2017), <https://www.macpac.gov/subtopic/medicaid-enrollment-changes-following-the-aca/>.

<sup>210</sup> *Id.*

<sup>211</sup> Alliance for Integrity and Reform of 340B, *Benefiting Hospitals, Not Patients: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program* (Spring 2016), available at <http://340breform.org/userfiles/May%202016%20AIR340B%20Avalere%20Charity%20Care%20Study.pdf>.

<sup>212</sup> 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>; 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).

<sup>213</sup> Email from U.S. Dep't of Health and Human Services Staff to Committee Staff (Dec. 21, 2017); 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).

<sup>214</sup> 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).

<sup>215</sup> Email from U.S. Dep't of Health and Human Services Staff to Committee Staff (Dec. 21, 2017).

departments are housed within one building.<sup>216</sup> Thus, part of the growth may be artificial because many hospitals began newly registering as child sites facilities that had previously been in operation. For example, Erlanger Health System noted in their letter to the committee, “[w]e would note again that you will see a dramatic increase in the number of child sites following our audit and HRSA’s direction to register hospital departments as child sites.”<sup>217</sup> Johns Hopkins Hospital (JHH) echoes Erlanger’s statement:

In accordance with new child site registration requirements (updated in April 2014), JHH has registered all individual outpatient departments and clinics (221). This does not reflect an effort by JHH to expand its 340B program by constructing or acquiring new clinics.... Most have been critical components of patients’ care since the start of JHH’s participation in the 340B program, well prior to the requirement to enroll each separately.<sup>218</sup>

This rule change alone, however, cannot account for the increase in child sites. After the rule was last updated in 2014, the number of child sites grew from 25,348 registered sites in October 2016,<sup>219</sup> and reached 29,307 sites by October 2017.<sup>220</sup>

In addition to an increase in child sites, the number of contract pharmacies has grown greatly since HRSA issued their 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.<sup>221</sup> In their 2018 Budget Justification, HRSA reported that 27 percent of covered entity sites have contract pharmacy arrangements, resulting in approximately 18,078 unique pharmacy locations.<sup>222</sup> GAO is currently examining the growth of contract pharmacy arrangements at the committee’s request.

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

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<sup>216</sup> Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Hot Topics*, available at <https://www.hrsa.gov/opa/updates/august-2014.html>.

<sup>217</sup> Letter from Kevin M. Spiegel, FACHE, President & CEO Erlanger Health System, Assistant Professor University of Tennessee College of Medicine, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 20, 2017).

<sup>218</sup> Letter from Redonda G. Miller, MD, MBA, President, The Johns Hopkins Hospital, to the Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, and Hon. Diana DeGette, Ranking Member, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 14 (Sept. 29, 2017).

<sup>219</sup> 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>.

<sup>220</sup> Email from U.S. Dep’t of Health and Human Services Staff to Committee Staff (Dec. 21, 2017).

<sup>221</sup> 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).

<sup>222</sup> 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.<sup>223</sup> In FY 2014, that estimate rose to \$4.5 billion in savings.<sup>224</sup> In CY 2015, covered entities saved approximately \$6 billion.<sup>225</sup> According to the responses the committee received to its September 2017 letter to select covered entities, one covered entity saw its program savings increase by over 529 percent in three years.

**Figure 4: Estimated 340B Program Savings: 2013 versus 2016\*, \*\*, \*\*\***

Covered Entity	2013	2016	% Increase
Erlanger Health System (TN)	\$3,010,079	\$18,938,111	529.1 %
Cedars-Sinai Medical Center (CA)	\$21,100,000	\$55,700,000	164 %
Johns Hopkins Hospital (MD)	\$41,398,000	\$109,100,000	164 %
UC San Francisco (CA)	\$36,652,522	\$82,931,835	126.3%
Mission Health System, Inc. (NC)	\$18,014,353	\$37,440,073	107.8 %
Cook Area Health Services (MN)	\$100,409	\$207,808	107 %
University of Washington Medical Center (WA)	\$16,650,039	\$31,091,454	86.8%
Intermountain Primary Children’s Hospital (UT)	\$3,376,012	\$6,217,754	84.2 %
Grady Memorial Hospital (GA)	\$28,139,538	\$48,183,675	71.2%
Harborview Medical Center (WA)	\$24,282,264	\$41,219,791	69.8%
Hudson Headwaters Health Network (NY)	\$4,876,405	\$6,625,533	35.9 %
Northern Nevada HOPES (NV)	\$1,413,969	\$1,915,809	35.4 %
Emory University Hospital Midtown (GA)	\$38,907,913	\$44,072,375	13.3 %
Parkland Health and Hospital System (TX)	\$147,325,149	\$129,523,015	-12.1%****
Duke University Hospital (NC)	N/A	\$103,674,873	N/A
NYU Langone Health (NY)	N/A	\$66,894,274	N/A
Northside Hospital (GA)	N/A	\$52,949,357	N/A

\* Program savings for different covered entities cannot be compared in this chart as some of these covered entities calculated program savings using different methods.

\*\* The estimated savings provided to the committee oftentimes included numerous disclaimers as to why they were only approximate estimates and therefore actual program savings, program revenue, and/or percent increase may be higher or lower than the amount of savings listed in the above table.

\*\*\* Some covered entities reported by fiscal year and some reported by calendar year.

\*\*\*\* Although Parkland Health and Hospital System’s program savings are reflected as decreasing between 2013 and 2016 in this chart, Parkland explained to committee staff that, due to the way Parkland calculated program savings, years 2012-2015 are likely represented as higher than actual savings.

Covered entities cited a variety of different factors for this increase in 340B program savings, including, but not limited to, an increase in insured patients, an increase in the cost and number of medicines prescribed, and an increase in pharmacy access for patients in areas that otherwise did not have access through expanded contract pharmacy arrangements. In addition, numerous third-party consultants offer services to covered entities to help maximize program savings.<sup>226</sup> For example, one wholesale distributor, McKesson, published an article on

<sup>223</sup> 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>.

<sup>224</sup> *Id.*

<sup>225</sup> 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).

<sup>226</sup> See, e.g., McKesson, *340B Consulting* (last accessed Dec. 5, 2017), available at <http://www.mckesson.com/pharmacies/growth-and-expansion/340b-consulting/>; RxStrategies, Inc., *RxStrategies’ Integrated 340B Solutions* (Mar. 3, 2017), <http://rxstrategies.com/rxstrategies-integrated-340b-solutions/>; Vizient,

December 4, 2017, entitled *How Hospital Pharmacies Can Maximize on 340B Drug Savings*.<sup>227</sup> In the article, McKesson describes “how carving Medicaid into 340B can save money on outpatient drug purchases, and the steps hospital pharmacies can take to maximize their 340B savings.”<sup>228</sup> McKesson estimates that for “each Medicaid prescription charged through 340B, the hospital would save more than \$7. For a large hospital or health system that bills for 500,000 Medicaid prescriptions a year, that’s an annual savings of \$3.6 million.”<sup>229</sup>

The rapid growth of the 340B program shows no signs of stopping, and poses challenges to HRSA’s ability to effectively oversee 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. As mentioned above, in 2016, HRSA audited fewer than two percent all of covered entities.

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*Minimizing risk and maximizing opportunity for pharmacy operations and 340B programs* (last accessed Dec. 5, 2017), <https://www.vizientinc.com/Members/Case-studies/Minimizing-risk-and-maximizing-opportunity-for-pharmacy-operations-and-340B-programs>.

<sup>227</sup> McKesson, *How Hospital Pharmacies Can Maximize on 340B Drug Savings* (Dec. 4, 2017), available at <http://www.mckesson.com/blog/how-hospital-pharmacies-can-maximize-on-340b-drug-savings/>.

<sup>228</sup> *Id.*

<sup>229</sup> *Id.*



## VI. Covered Entity Use of the 340B Program

### A. Congressional Intent of the 340B Program

*Finding: Congress did not clearly identify its intent for the program and did not clearly identify the program’s parameters, leaving the statute silent on many important program requirements. Moreover, given the vastly changed health care landscape and 340B program environment, it is unclear whether, and to what degree, the program’s original structure is still relevant.*

Congress established the Medicaid Drug Rebate Program through the Omnibus Budget Reconciliation Act of 1990 (OBRA 90). Before the Medicaid Drug Rebate Program was implemented in 1991, drug manufacturers often provided substantial discounts on their medicines to certain types of safety-net providers. Because the Medicaid Drug Rebate Program requires that pharmaceutical manufacturers provide Medicaid with the manufacturers’ lowest or “best price” for outpatient drugs, some stakeholders were concerned that after the program was implemented, manufacturers might limit discounts to some of these safety-net providers.

Congress therefore established the 340B program through the Veterans Health Care Act of 1992.<sup>230</sup> According to the House Report accompanying the legislation, the program was established, in part, to respond to the increase in prescription drug prices for the Department of Veterans Affairs and some federally-funded clinics and public hospitals following the enactment of the 1990 Medicaid prescription drug rebate program.<sup>231</sup> The report indicated the legislation was intended to “stretch scarce Federal resources as far as possible:”

Hard evidence on the effect of OBRA 90 on prescription drug prices is still being compiled. The testimony received by the subcommittee is not dispositive as to the impact of the OBRA 90 Medicaid rebate program. There is still uncertainty as to the extent to which manufacturers have raised prices to purchasers other than Medicaid, and the extent to which such increases were due to the provisions of OBRA 90. But two points seem clear. Prices paid for outpatient drugs by the [U.S. Department of Veterans Affairs] and some Federally-funded clinics and public hospitals, have increased substantially over the last two years. Those price increases have in turn reduced the level of services and the number of individuals that these hospitals and clinics are able to provide with the same level of resources....

In giving these “covered entities” access to price reductions the committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.<sup>232</sup>

Beyond these statements in the House Report, it is unclear exactly how Congress intended covered entities to use the 340B program. Congress remained silent in the statute on

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<sup>230</sup> PL 102-585 (Nov. 4, 1992).

<sup>231</sup> H.R. Rep. 102-384, Pt. 2 (1992).

<sup>232</sup> *Id.*

many important questions regarding the structure and oversight of the program. During the committee’s July 2017 hearing, HRSA responded the “statute is silent,” or in a similar manner, over a dozen times when asked questions about program requirements.<sup>233</sup> Although covered entities significantly benefit from revenue that is generated through the program when a patient’s insurer reimburses the product at a higher price than the covered entity paid for the prescription drug, the statute is silent on how covered entities must use these funds. Moreover, as HRSA testified at the July 2017 hearing, HRSA does not have any authority to track the amount of revenue covered entities generate through participation in the program or how they use the money:

Q: There is a lack of clarity in how the intent of the program is, which you outlined in your testimony in your documents there. The absence of reporting requirements and specific mandates on how savings must be spent – can you elaborate a little bit more on what that impact is?

A: So the statute is silent regarding how covered entities have to use their savings. Therefore, HRSA doesn’t have authority to require what these entities are doing with their savings.<sup>234</sup>

Notably, there is no requirement that the discounted 340B price be passed on to uninsured patients who seek treatment at 340B covered entities. As a result, the covered entity may acquire the drug at a discounted price, but the uninsured patient may still pay the full list price for the drug at the pharmacy. In 2015, HRSA testified “the law does not...specify the status of any of the patients that could potentially benefit from the program.”<sup>235</sup> Similarly, in 2017, HRSA testified “[s]o the amount that [covered entities] charge the patient after they receive that discount, again, is a decision made at the hospital. The price that they charge is outside of the 340B statute.”<sup>236</sup>

The committee’s investigation found that some covered entities pass 340B program savings on to uninsured or underinsured patients, while others do not. For example:

- One Community Health Center, Cook Area Health Services (CAHS), said “CAHS passes the full 340B savings directly to all uninsured and underinsured patients, who are charged only the 340B price for their drugs.”<sup>237</sup>

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<sup>233</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript* (Jul. 18, 2017).

<sup>234</sup> *Id.* at 41.

<sup>235</sup> *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 114th Cong., Preliminary Transcript*, at 71 (Mar. 24, 2015).

<sup>236</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 43 (Jul. 18, 2017).

<sup>237</sup> Letter from Cook Area Health Services, Inc. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

- One FQHC, ARcare, said “ARcare has a 340B ‘Cash Card’ that is provided to eligible patients who lack sufficient drug benefit coverage. The ‘Cash Card’ ensures that patients possessing the card are able to directly benefit from the 340B program by paying the discounted 340B cost of their medication.”<sup>238</sup>
- One DSH hospital, NYU Langone Health (NYULH), said “NYULH does not have any specific policies to help ensure that uninsured and underinsured patients directly benefit from the Program by receiving discounts on 340B drugs, since this is not the way in which the Program is structured.”<sup>239</sup>

In 2017, GAO testified that Congress should clarify the intent of the program to improve program integrity.

Q: I wanted to ask Dr. Draper what are the most important actions out of GAO’s recommendations to improve program integrity in 340B and how should Congress prioritize?

A: Well, I think one of the key pieces is really clarifying the intent of the program. The intent was set up 25 years ago and, you know, there is a – I think there is a misperception [what] it does. It doesn’t explicitly talk about uninsured or under insured patients being treated by the – by the – to receive benefits through the program. That is implied, depending on – you know, depending on the types of covered entities.<sup>240</sup>

Moreover, the intent and purpose of the program are even less clear given the changing landscape in the health care sector. According to GAO: “HRSA has undertaken efforts to improve oversight of the 340B program. However, there are a number of critical issues that remain unresolved including whether the intent of the program, which was established nearly 25 years ago, is still relevant today, given the vastly changed healthcare landscape and 340B program environment.”<sup>241</sup>

Similarly, in its recent report entitled *Making Medicines Affordable*, the National Academies Press commented on how much the health care landscape has changed since the program’s inception, especially in relation to hospitals:

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<sup>238</sup> Letter from Steven F. Collier, MD, FACHE, Chief Executive Officer, ARcare, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 21, 2017).

<sup>239</sup> Letter from Gilda Ventresca Ecroyd, Vice President, Office of Government and Community Affairs, NYU Langone Health, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

<sup>240</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 59-60 (Jul. 18, 2017).

<sup>241</sup> *Id.* at 39.

However, in the years since the program’s inception, the structure of hospitals in the United States has dramatically changed, with nonprofit hospitals increasingly displaying characteristics of for-profit hospitals ... and standalone hospitals pursuing mergers and affiliations with other hospitals and hospital systems and outpatient provider groups.<sup>242</sup>

## **B. 340B Program Savings**

***Finding: Congress did not establish any mechanisms to monitor or calculate program savings or specify how they are used. As a result, covered entities use program savings in a variety of different ways. Some covered entities are restricted in the way they can use program funds due to other federal grant requirements.***

The 340B program generates savings for covered entities by allowing them to purchase certain outpatient medications for less than they otherwise would pay—saving approximately 25 to 50 percent.<sup>243</sup> Moreover, because covered entities can purchase 340B drugs for all eligible patients regardless of their insurance status, including for patients enrolled in private insurance or the Medicare program, a covered entity can generate revenue if the reimbursements from payers exceeds the discounted price that the covered entity paid for the drug.<sup>244</sup>

### **i. Restrictions on the Use of Program Savings by Covered Entities**

The 340B statute does not restrict how covered entities use 340B savings. It also does not provide HRSA any authority to require or even explain how covered entities use 340B program savings or track how covered entities use these savings. HRSA testified about the absence of reporting requirements and lack of requirements on how program savings must be used by covered entities at the committee’s July 2017 hearing. HRSA noted that the statute is silent on these issues and HRSA therefore does not have authority to provide guidance or clarity on either issue. HRSA testified:

Q: There is a lack of clarity in how the intent of the program is, which you outlined in your testimony in your documents there. The absence of reporting requirements and specific mandates on how savings must be spent – can you elaborate a little bit more on what that impact is?

A: So the statute is silent regarding how covered entities use their savings. Therefore, HRSA doesn’t have authority to require what these entities are doing with their savings.<sup>245</sup>

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<sup>242</sup> National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 6 (Nov. 2017).

<sup>243</sup> 340B Prime Vendor Program, *340B Price/Covered Outpatient Drugs* (last accessed Dec. 1, 2017), available at <https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/>.

<sup>244</sup> See, e.g., Medicare Payment Advisory Commission, *Report to the Congress: Overview of the 340B Drug Pricing Program*, at viii (May 2015).

<sup>245</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 41 (Jul. 18, 2017).

In the same hearing, HRSA reiterated this point and further stated that the agency does not have access to information about program savings or how savings are used by covered entities. HRSA testified:

Q: Do we or do we not know or audit how the savings are spent? That seems to be one of the issues. We all believe that everybody is a good actor and the money is going to the people most in need, as well as savings. But I also am not clear that HRSA – that there is a clear definition of how the money should be spent or that we track the money. Is that correct?

A: So the statute is silent as to how savings are used. Therefore, HRSA does not audit or have access to that information.

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Q: Do we know if those savings get passed specifically back to people who need reduction in prices on the drugs?

A: The statute is silent in that area. So HRSA does not have that information.

Q: Okay. So we don't know that. And those savings, could the 340B hospitals take that money and use it for good things but not necessarily back to the same person that is buying the drugs?

A: So that – because the statute is silent --<sup>246</sup>

In addition, both HHS OIG and GAO have raised concerns in testimony before the committee about the lack of transparency regarding the amount of program savings generated by participation in the 340B program and how covered entities use those savings. In 2015, HHS OIG testified, “I do believe we have concerns about program integrity that then compromise the ability of the program to achieve its goals. So more clarity around how the savings are used would allow us to understand the benefits of the program.”<sup>247</sup> In 2017, GAO testified that there are no requirements regarding whether covered entities track their savings or how covered entities use their 340B program savings and, as a result, neither the federal government nor most covered entities have access to that information.<sup>248</sup> GAO indicated that it is possible that the discounts are not passed on to low-income patients and stated that, given the lack of transparency, there is oftentimes no way of knowing how much low-income patients pay for 340B drugs.<sup>249</sup> GAO’s testimony echoed their 2011 report, *Manufacturer Discounts in the 340B*

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<sup>246</sup> *Id.* at 52-53.

<sup>247</sup> *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. On Health of the H. Comm. on Energy and Commerce*, 114th Cong., at 51 (Mar. 24, 2015).

<sup>248</sup> *Examining HRSA’s Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., *Preliminary Transcript*, at 47 & 53 & 77 (Jul. 18, 2017).

<sup>249</sup> *Id.* at 53-54 & 63-64.

*Program Offer Benefits, but Federal Oversight Needs Improvement.*<sup>250</sup> GAO found that covered entities have generally reported using the 340B program to support or expand access to services, but that HRSA’s oversight, which primarily relied on covered entities self-policing, was inadequate.<sup>251</sup>

## ii. Calculation and Tracking of 340B Savings

Currently, there is no consistent methodology that covered entities use to estimate their program savings from participation in the 340B program. Some covered entities do not track this information at all. In the course of its investigation, the committee found numerous ways in which covered entities may track 340B program savings. Some entities reported to the committee an estimate most accurately characterized as program revenue (e.g. Cook Area Health Services, below) while others reported program savings (e.g. NYU Langone, below). For example:

- “ARcare tracks its 340B revenues by comparing its gross pharmaceutical reimbursements (reimbursement and copays less contracted pharmacy dispense fees and third-party administration fees) and 340B cost of goods sold (the amount ARcare paid for the medications dispensed or administered). With the assistance of its third-party administrator, ARcare receives and reviews reports that track the revenue. Those figures overstate 340B savings, but ARcare does not have access to the non-340B pricing data . . . that would allow it to compare the 340B cost of goods sold to what it might have paid for the drugs absent the 340B program.”<sup>252</sup>
- “[Cook Area Health Services] only records the net between 340B program revenue less 340B acquisition cost and dispensing fees in its financial statements” and “[t]he organization receives semi-monthly statements from [their] 340B Drug Pricing program contract administrator Rx Strategies. These statements identify direct purchase costs as well as the amount of money the organization receives when the insured patients’ insurance reimbursements exceed the total of the 340B price and dispensing fees.”<sup>253</sup>
- “[Erlanger Health System (EHS)] calculates the amount of savings it generates through participation in the Program in three different ways. (a) Covered Entity Savings- derived by analyzing all 340B and [Wholesale Acquisition Cost (WAC)] purchases and comparing to GPO pricing. Savings is derived as the amount saved as opposed to making all purchases at GPO pricing (which would be the case without 340B in place). This is

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<sup>250</sup> 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).

<sup>251</sup> *Id.* at 13.

<sup>252</sup> Letter from Steven F. Collier, MD, FACHE, Chief Executive Officer, ARcare, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 21, 2017).

<sup>253</sup> Letter from Cook Area Health Services, Inc. to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

represented as ‘net savings.’ ... (b) Erlanger Pharmacies Inc. (EPI) Savings- EPI is a wholly-owned subsidiary of ContinCare Health Services, Inc. (A wholly-owned subsidiary of EHS) and a contracted pharmacy to the covered entities. This saving is calculated by analyzing all purchases at 340B compared to retail pricing (comparable to WAC). These savings are recognized on the EPI income statement and subsequently recognized in the EHS consolidated financials. (c) Contract Pharmacy savings- derived by analyzing the reimbursement less the dispensing fee, actual administrative fees and actual 340B replenishment purchases for each contract pharmacy.”<sup>254</sup>

- “[Grady Health System] does not routinely calculate the amount of savings it generates each year through participation in the 340B Drug Pricing Program, though Grady does periodically (as needed for informational purposes) develop[] working estimates of its 340B savings ... Tabulating 340B savings annually would require the establishment of separate and time intensive data capture and accounting processes to inventory and compare various drug prices (e.g., GPO, WAC, and 340B) and document cost differences. We are not set up to do this presently and would need to redirect scarce resources to do so.”<sup>255</sup>
- NYU Langone’s “savings from the 340B program are calculated by subtracting the 340B price from the GPO price for Gross Savings and further subtracting the cost of purchasing medications at WAC price due to 340B requirements and Program administration costs to arrive at Net Savings. We do not track the money received from insurer reimbursement due to the fact that payor reimbursement methodologies vary. For example, medication reimbursement may be grouped with other services and not itemized as a stand-alone; in other instances reimbursement mechanisms do not provide sufficient detail to infer specific medication payments. For contract pharmacies, we utilize the Sentry software platform to calculate savings using the formula of Reimbursement minus Cost of Medication minus Dispensing Fee.”<sup>256</sup>
- “Hudson Headwaters purchases 340B drugs and dispenses them to patients through contract pharmacy arrangements. The calculation of the 340B program benefit can be shown as: (insurance payment + co-pay or other patient payment) – (340B drug cost + dispensing fees and admin expenses).”<sup>257</sup>

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<sup>254</sup> Letter from Kevin M. Spiegel, FACHE, President & CEO Erlanger Health System, Assistant Professor University of Tennessee College of Medicine, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 20, 2017).

<sup>255</sup> Letter from John Haupt, FACHE, Chief Executive Officer, Grady Health System, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

<sup>256</sup> Letter from Gilda Ventresca Ecroyd, Vice President, Office of Government and Community Affairs, NYU Langone Health, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

<sup>257</sup> Letter from Tucker Slingerland, M.D., Hudson Headwaters Health Network, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

During briefings with committee staff, many covered entities indicated that the committee's request that they calculate program savings caused them to calculate savings for the first time. For example, one covered entity told the committee that it generated over \$72 million in savings from 340B program participation in 2016, and that, until the committee requested the information, they had never calculated their program savings nor had any entity requested information about their program savings.

In addition to calculating savings in various ways, covered entities also differ in how program savings are allocated within their budgets. For example, at the October 2017 hearing, witnesses provided the following answers regarding whether and how program savings are allocated in their budgets:<sup>258</sup>

Northside: They aren't earmarked. They are tracked and monitored and then our growth is tracked and monitored. And we do ensure that our growth far exceeds the savings.

Johns Hopkins: One way to think about it, perhaps, is that there is not really a check that comes back, if you will. This is a lower price paid. So there isn't a check that comes back that then you have the opportunity to say where it goes. This is a reflection of paying less for a drug than you otherwise would pay. So there is not really a budgeted amount that you could say that is what you are going to put in each of these buckets.

Mission Health: To directly answer the question, there is not a dollar-for-dollar tracking no more than there would be an earmark for a tax dollar that I might pay in income tax. But on the other hand, we track very closely our savings. We know those savings and when we prepare our budget for each year, we include those dollars in the charity care allocations in all of these programs. So I would say that yes, they are targeted but not literally dollar-for-dollar.

ARCW: In our budgeting process, we identify the savings that we anticipate in the coming year and we direct it to the pharmacy, health, and social services that I discussed in my testimony.

Carolina Health Centers: I would have to echo my colleagues to some degree. It is not an exact line item transfer dollar-for-dollar from one cost center to another center, but at the beginning of the year, as part of both the budgeting and the strategic planning process, we estimate what we anticipate in those savings to be and then look at what programs they can fund, what otherwise unfunded programs they can fund. Then at the end of the year, we do an annual report to our Board of Directors linking those two together.

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<sup>258</sup> *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., at 52-54 (Oct. 11, 2017).*



### iii. Requirements for HRSA Grantees

Covered entities benefit from program flexibility as it enables them to use the program savings in ways that are tailored to serve their specific community and patient population.<sup>259</sup> Each covered entity provides unique services, serves a unique population, and faces unique challenges in their community.<sup>260</sup>

While the 340B statute does not impose any requirements on recipients regarding how they use the program savings, federal grantees often have restrictions on their use of 340B program savings due to their grant requirements. Likewise, federal grantees, including FQHCs and Ryan White Grantees, are subject to additional HRSA oversight because of their status as a federal grantee. For example:

- At the October 2017 hearing, a FQHC, Carolina Health Centers, testified that their federal grant requirements mandate that FQHCs use 340B program savings “for purposes that advance their HRSA-approved scope of project.”<sup>261</sup> The FQHC testified, “one of our grant conditions is that we are required to use all program incoming, including what is generated outside of the grant, for the purposes of advancing our HRSA scope projects.”<sup>262</sup>
- At the October 2017 hearing, the Ryan White Program grantee, Aids Resource Center of Wisconsin, testified that the entity is limited on how it uses its 340B savings since, under its grant requirements and HRSA guidance, 340B savings are considered Ryan White HIV/AIDS program income and program income must be used for the purposes and under the conditions of the federal award.<sup>263</sup>
- Hudson Headwaters told the committee, “[a]s an FQHC, Hudson Headwaters is subject to intensive oversight by HRSA to ensure our on-going compliance with the 18 Program Requirements. This oversight takes many forms, including: site visits; mandatory annual reporting on budget, patient, and quality measures (Which are posted publicly on the HRSA website); frequent contact with our Project Officers; and regular re-competitions for grant funding. In addition, we are required by statute to reinvest all 340B savings into activities that are approved by HRSA and advance our mission of expanding access to quality care to medically underserved populations.”<sup>264</sup>

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<sup>259</sup> See, e.g., *id.* at 84.

<sup>260</sup> The use of program funds by covered entities is discussed below in Section VI.B.

<sup>261</sup> *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., Preliminary Transcript, at 24 (Oct. 11, 2017).

<sup>262</sup> *Id.* at 83.

<sup>263</sup> *Id.* at 29.

<sup>264</sup> Letter from Tucker Slingerland, M.D., Hudson Headwaters Health Network, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 22, 2017).

- ARcare, another FQHC, said it was “required by law to use any reimbursement or public funding for purposes that further the objective of the project.”<sup>265</sup>

Numerous HRSA grantees such as FQHCs and Ryan White Grantees told the committee that they found the additional program requirements manageable.

### C. Charity Care Provided by Covered Entities

***Finding: The 340B statute does not require covered entities to report the level of charity care provided. As a result, there is a lack of data on how much charity care is provided by covered entities. Further, because there is no universally accepted definition of charity care, drawing a fair comparison of charity care provided across covered entities is difficult, if not impossible. Finally, while charity care spending often exceeds program savings, charity care levels have been on the decline at some hospitals, even as program savings increase.***

As previously mentioned, Congress did not clearly identify the intent of the program when it stated that the program was intended to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>266</sup> Because there is not a requirement that program savings be spent in a specific way, or that entities provide a certain level or type of charity care, covered entities use program savings in a variety of different ways. For example:

- Cedars-Sinai Medical Center, a DSH hospital, said that “in [FY] 2016, it spent “\$695,634,000 on community benefit activities,” which included “two mobile medical clinics staffed by bilingual nurse practitioners, registered nurses, social workers, and other healthcare professionals .... [that] provide a range of preventative services, including well-child and immunization clinics for children, treatment for minor illnesses, dental screenings, blood pressure screenings for adults, and linkages to additional health services at family homeless shelters, public housing developments, ... [schools], and community based organizations,” and a “Healthy Habits program [that] provides nutrition education and obesity prevention programs and elementary and middle schools.”<sup>267</sup>
- Erlanger Health System, a DSH hospital, said its “uncompensated care costs exceed[ed] \$100 million for [FY] 2017.” Erlanger said the 340B savings in part fund a “free prescription home delivery service,” “a clinical pharmacist at the FQHC child site [who] provides education and assistance to help patients gain a greater understanding of their medications and disease state,” and allow Erlanger

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<sup>265</sup> Letter from Steven F. Collier, MD, FACHE, Chief Executive Officer, ARcare, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce (Sept. 21, 2017).

<sup>266</sup> 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/>.

<sup>267</sup> Letter from Thomas M. Priselac, President & Chief Executive Officer, Cedars-Sinai Medical Center, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 29, 2017).

to provide many generic prescriptions to patients for as low as four dollars at some contract pharmacies.<sup>268</sup>

- Mission Health, a DSH and Critical Access Hospital, said that “67 percent of Mission Health’s hospitalized patients are uninsured or covered by Medicare and Medicaid. In 2016, Mission Health’s total value of charity and unreimbursed care was nearly \$105 million and total 2016 community investments were more than \$183 million.” Mission Health’s community investment activities included “two ... mobile oral care programs that provide free preventative and restorative oral care to school-aged children[,]” a Mountain Area Medical Airlift program with “two helicopters available 24 hours a day [that] provides air medical services [over] roughly 10,000 square miles ... and has transported more than 21,000 patients,” and Sexual Assault Nurse Examiners “that are specially trained, registered nurses who provide comprehensive care for victims of sexual assault, domestic violence, and child, elder, and dependent-adult abuse and neglect, and other violence crimes,” among other community services.<sup>269</sup>
- Parkland, a DSH hospital, said that its “DSH percentage is 49.2 percent” and “payor mix is 38 percent charity, 28 percent Medicaid, 16 percent Medicare, 10 percent self-pay, and 8 percent commercial insurance.” Parkland’s “outreach to the community includes care in 12 Community Oriented Primary Care health centers, 12 Youth & Family centers, 10 women’s health centers, acute response clinics, homeless outreach mobile units and nursing homes, [and] to inmates in the Dallas County Jail.” Parkland further said that “[i]n FY 2016, [Parkland] provided \$871 million in uncompensated care” and “97,200 unique patients received charity care.”<sup>270</sup>

However, entities use different methodologies to calculate the amount of charity care that they provide to patients. As a result, it can be difficult to fairly and accurately compare charity care levels of various entities.

Indeed, the covered entities that received the committee’s September 8, 2017 letter defined charity care in numerous ways. The three primary differences in how entities calculated charity care were whether to include bad debt,<sup>271</sup> whether to include community benefit

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<sup>268</sup> Letter from Kevin M. Spiegel, FACHE, President & CEO Erlanger Health System, Assistant Professor University of Tennessee College of Medicine, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 1, 5-6 (Sept. 20, 2017).

<sup>269</sup> Letter from Ronald A. Paulus, M.D., President and Chief Executive Officer, Mission Health System, Inc., Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 2, 16-17 (Sept. 22, 2017).

<sup>270</sup> Letter from Fred Cerise, MD, MPH, President & CEO, Parkland Health & Hospital System, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 1, 3 (Sept. 22, 2017).

<sup>271</sup> The committee heard from several entities and advocacy groups that include bad debt in their measure of charity care. While bad debt may reflect an entity’s services to low-income and vulnerable individuals and provide a fuller understanding of an entity’s financial burden, it is crucial that—if bad debt is included in uncompensated and

activities, and how to calculate the percentage of health care services that are provided as charity care. Further, as Parkland Health and Hospital System noted, “[w]hile some organizations will report charity care as the amount of charges the institution generates for charity care, that representation overstates the actual costs. We are reporting actual costs to Parkland.”<sup>272</sup>

Entities varied on what activities were considered appropriate to include in charity care estimates. Some entities included “community benefit activities,” while others included only uncompensated care costs as a measure of charity care. For example, Johns Hopkins Hospital (JHH) stated in its response to the committee that “[c]ommunity benefit is a more appropriate indicator, than charity care alone, of JHH’s overall commitment to its community and free or discounted care to vulnerable patients.”<sup>273</sup> Using such a metric, JHH reported that its spending on community benefit activities for FY 2016 was nearly \$200 million dollars, which the hospital described as including: “charity care or funding for free or discounted medically necessary care for patients, plus community health improvement programs and health screenings, accredited training of doctors, nurses and allied professionals, financial and in-kind contributions to community groups, and other community building activities.”<sup>274</sup>

Further, when asked what percentage of total health care services provided by each organization is charity care, entities did not agree on what metric should be used to as an indicator of “total health care services.” Covered entities provided that “total health care services” could be measured by examining hospital operating expenses,<sup>275</sup> net patient service revenue,<sup>276</sup> total patient care operating costs,<sup>277</sup> and operating revenues.<sup>278</sup> During the committee’s October 2017 hearing, the committee asked covered entities what they thought was the best measure to estimate an entity’s commitment to serving low-income and uninsured individuals:

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charity care estimates—the entity ensures that any amounts later collected through the collections process are not included in the entity’s charity care calculations.

<sup>272</sup> Letter from Fred Cerise, MD, MPH, President & CEO, Parkland Health & Hospital System, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 3 (Sept. 22, 2017).

<sup>273</sup> Letter from Redonda G. Miller, MD, MBA, President, The Johns Hopkins Hospital, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, and Hon. Diana DeGette, Ranking Member, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 8 (Sept. 29, 2017).

<sup>274</sup> *Id.*

<sup>275</sup> Letter from Daniel S. Owens, Chief Executive Officer, Emory University Hospital Midtown, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 11 (Sept. 29, 2017).

<sup>276</sup> Letter from Steven F. Collier, MD, FACHE, Chief Executive Officer, ARcare, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 5 (Sept. 21, 2017).

<sup>277</sup> Letter from Thomas M. Priselac, President & Chief Executive Officer, Cedars-Sinai Medical Center, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 29, 2017).

<sup>278</sup> Letter from Kevin M. Spiegel, FACHE, President & CEO Erlanger Health System, Assistant Professor University of Tennessee College of Medicine, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 7 (Sept. 20, 2017).

Question: We have had a lot of different ways we have heard about how the money you get out of this program is tracked to do charity care....This makes it a little hard to do apples to apples comparison of whether covered entities are truly using 340B savings to improve patient care. So to each of you, what do you think is the best measure to estimate an entity's commitment to serving low-income and uninsured individuals? Do community benefit programs serve only low-income and uninsured patients or the entire community, including those with commercial insurance? Would a patient receive one element of care for free, at a reduced cost, be counted as one of those patients? I mean how do we track this?

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Northside: I do think industry standard is not to reflect the provision of care to the vulnerable population of the percent of just operating expenses, which is what was done in the AJC article. I would say that is inaccurate or at least incomplete. When comparing to expenses, you are including things like overhead, and telephone, and depreciation on your buildings. So we would emphasize other more commonly quoted mechanisms, which would be the provision of charity and indigent in terms of total patient revenues or distinct patient served and those are the ways that we quoted in our submissions.

Mission Health: I would point you, perhaps, to the idea behind Schedule H for the IRS filing and the community benefit. I think there might be opportunities there to define and identify a specific reporting. I would think about total unreimbursed care because that is really what we are talking about here.

Carolina Health Centers: I think the term or concept of charity care is one that is not terribly familiar for community health centers or in the community health center world, not because we don't understand that concept, but because we operate under a set of statutory requirements that essentially mean we are on the hook for taking care of everyone, regardless of their ability to pay, and for providing a full range of services, regardless of their ability to pay, and have been for decades. So my health center, the \$4.2 million that is listed as charity care really represents the cost of all care provided to patients for which we receive no compensation.... So the health centers do have a very concrete way of measuring that.<sup>279</sup>

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<sup>279</sup> *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. On Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript, at 60-62 (Oct. 11, 2017).*

Further, because the 340B statute does not include any reporting requirements, HRSA is unable to provide any information on the level of charity care provided by covered entities. In July 2017, HRSA testified that they did not have the authority to request information about how covered entities used program savings:

Q: Okay. But is there any data which would show the level of charity care they are providing? Anything that they are required to show you?

A: They do not share anything with HRSA. They may report charity care information on their cost reports that is submitted to CMS.

Q: And we don't know if that charity care money came from the 340B or came from something else?

A: Yes, HRSA would not know that.

Q: So as I understand it so far with the vague guidelines of eligibility for patients, the intent of the program, of course, to help the indigent population -- good. The idea that other people who may not fit that definition may still have the hospital or clinic purchasing at a discount and can use that money in any way, shape, or form and you have no way of finding out and they are not required to keep data and the books aren't kept in such a way that anybody could trace it if they wanted to?

A: Yes. The statute, again, does not in any way mention what covered entities do with that savings or that they have to report it to HRSA.<sup>280</sup>

The committee analyzed data from Worksheet S-10 of the Medicare cost reports, as available in the CMS Healthcare Cost Report Information System (HCRIS), to identify how much charity care and unreimbursed care and uncompensated care was reported by DSH hospitals that received the committee's September 8, 2017 letter. The amount of charity care and unreimbursed and uncompensated care differed greatly across the covered entities:

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<sup>280</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 45-46 (Jul. 18, 2017).

**Figure 5: Select Data for Select Hospitals from Medicare Cost Report Submissions for 2015<sup>281</sup>**

	Total Operating Expenses*	Cost of Charity Care-Total**	Cost of Unreimbursed and Uncompensated Care***	Estimated Savings as Calculated by Entities****
Dallas County Hospital District	\$1,530,686,240	\$396,051,781	\$454,708,458	\$163,607,998
UCSF Medical Center (CA)	\$3,100,587,242	\$9,105,327	\$297,028,036	\$48,969,427
Grady Memorial Hospital (GA)	\$894,292,825	\$128,000,025	\$174,022,464	\$41,610,167
NYU Hospitals Center (NY)	\$3,241,048,237	\$30,798,905	\$100,477,229	--
Duke University Hospital (NC)	\$1,922,256,226	\$88,631,398	\$97,981,838	--
Cedars-Sinai Medical Center (CA)	\$2,865,868,438	\$34,321,412	\$93,019,056	\$42,100,000
Harborview Medical Center (WA)	\$915,048,238	\$22,149,698	\$67,670,987	\$33,913,794
Erlanger Medical Center (TN)	\$743,398,577	\$30,663,444	\$51,376,071	--
Northside Hospital (GA)	\$1,603,727,959	\$13,278,505	\$45,277,244	\$51,811,078
Mission Health <sup>282</sup> (NC)	\$1,205,110,197	\$29,155,329	\$43,817,407	\$35,350,752
Emory University Hospital Midtown (GA)	\$698,888,484	\$16,840,662	\$37,432,007	\$39,618,918
The Johns Hopkins Hospital (MD)	\$2,152,342,294	\$14,462,788	\$34,346,128	\$69,749,000
University of Washington Medical Center (WA)	\$1,126,648,993	\$8,826,587	\$21,954,392	\$21,774,743
Intermountain Primary Children's Hospital (UT)	\$433,768,433	\$5,474,127	\$11,060,789	\$4,938,455

\* Total Operating Expenses: Operating expenses incurred that arise during the ordinary course of operating the hospital complex less any deductions from operating expenses that the hospital specifies on the cost report.

\*\* Cost of Charity Care-Total: Charity care costs for both insured and uninsured patients. This figure may be negative (-) if payments received from patients for amounts previously written off as charity care exceed the cost of patients approved for charity care and uninsured discounts.

\*\*\* Cost of Unreimbursed and Uncompensated Care: Total unreimbursed costs of: 1) Medicaid, CHIP, state/local indigent care programs; 2) charity care; 3) non-Medicare and non-reimbursable Medicare bad debt.

\*\*\*\* Program savings for different covered entities cannot be compared in this chart as some of these covered entities calculated program savings using different methods. The estimated savings included numerous disclaimers as to why they were only approximate estimates and therefore actual program savings, program revenue, and/or percent increase may be higher or lower than the amount of savings listed in the above table. See the covered entity's response in the October 2017 hearing record for information on how the covered entity calculated this estimate. Moreover, while the Medicare cost report data is for FY 2015, some covered entities submitted program savings by Calendar Year. The 2015 estimated savings for certain covered entities are not included in this chart either because the covered entity did not participate in the program at that time or the estimated savings were not provided to the committee in a format enabling it to be included.

<sup>281</sup> Information in the table is from: U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services, *Hospital 2552-10 Cost Report Data files* (last updated Nov. 4, 2014), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Hospital-2010-form.html>; U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services, *The Provider Reimbursement Manual - Part 2, Chapter 40-Hospital and Hospital Health Care Complex Report* (last accessed Dec. 14, 2017), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.html>.

<sup>282</sup> The information for Mission Health includes the sum of Mission Hospital (NC), The McDowell Hospital (NC), Transylvania Community Hospital (NC), Angel Medical Center (NC), Highlands-Cashiers Hospital (NC), and Blue Ridge Regional Hospital (NC).

In addition to the vagueness surrounding how entities define and measure charity care, the recent report issued by the National Academies Press revealed that some 340B hospitals with the highest operating margins also provide the least amount of uncompensated care.

Evidence about the impact of 340B revenue on safety net and community need engagement among qualifying hospitals is largely anecdotal...GAO conducted a cross-sectional comparison of 340-B qualified Medicare disproportionate share hospitals with non-340B hospitals in 2012 using publicly available data from Medicare hospital cost reports (GAO, 2015). The report found that 340B hospitals provided more uncompensated care than did non-340B hospitals and also had lower profit margins than non-340B hospitals, in part because they provided more uncompensated and charity care. A more recent report found that hospitals participating in 340B in 2014 exhibited widely varying financial stability and safety net care provision....Some 340B disproportionate share hospital (DSH) program participants operated at a substantial loss, but at least one-quarter of participants operated with a comfortable margin. Many of the hospitals with the highest operating margins were also those that provided the least uncompensated care, while the hospitals that provided the most uncompensated care had the lowest operating margins.<sup>283</sup>

Similarly, in March 2016, the Medicare Payment Advisory Commission (MedPAC) found that hospitals' "total (all-payer) profitability reached a 30-year high in 2014 and that total margins for hospitals increased to 7.3 percent."<sup>284</sup> Moreover, MedPAC determined that the 340B program is not "targeted to hospitals with high levels of uncompensated care or to hospitals with financial difficulties."<sup>285</sup> In the report, MedPAC stated:

Currently, the 340B program is not well targeted to hospitals with high levels of uncompensated care or to hospitals with financial difficulties. We find that 40 percent of 340B hospitals provide less than the median level of uncompensated care (3.6 percent) as reported on Worksheet S-10 of the Medicare cost reports. While the median all-payer margin is 3.8 percent for 340B hospitals compared with 5.3 percent at non-340B hospitals, there is wide variation in profitability among 340B hospitals: 25 percent of 340B hospitals reported all-payer margins of over 8 percent in 2014. Because of variation in the uncompensated care provided by 340B hospitals and variation in the profit margins of 340B hospitals, we are suggesting that a portion of the 340B discounts be redirected toward the hospitals providing the most uncompensated care.<sup>286</sup>

Furthermore, information provided to the committee reveals that at some hospitals, charity care has been on the decline, even as 340B savings and other revenue grow at those

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<sup>283</sup> National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 106 (Nov. 2017).

<sup>284</sup> Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy – Chapter 3: Hospital inpatient and outpatient services* (March 2016).

<sup>285</sup> *Id.*

<sup>286</sup> *Id.*



hospitals.<sup>287</sup> Several entities pointed to the passage of the PPACA to explain the decrease in charity care. For example, Cedars Sinai Hospital reported that the number of patients that received charity care dropped from 150,672 in 2012 to 126,968 in 2016.<sup>288</sup> Cedars Sinai wrote “[p]lease note that the number of uninsured patients in California and the U.S. began dropping significantly starting in 2013 with the implementation of the Affordable Care Act.”<sup>289</sup> Similarly, Johns Hopkins Hospital (JHH) reported to the committee that its charity care spending “decreased from FY2015 to FY2016 consistent with national trends in states that expanded Medicaid.”<sup>290</sup> Specifically, JHH reported that its charity care spending in 2012 was \$36,281,442, and had fallen to \$28,302,449 in 2016.<sup>291</sup>

In the case of JHH, the decline in charity care may be offset by an increase in community benefit activities, which, as described above, JHH believes is a more appropriate measure.<sup>292</sup> JHH’s “total net community benefit,” which includes charity care, rose from \$173,015,061, to \$191,099,530 in that same time frame.<sup>293</sup> Media reports, however, have suggested that there has not been a consistent increase in community benefit spending as charity care declines and revenues rise:

[I]n many cases, top hospitals’ community benefit spending has remained flat or declined since the ACA took effect, too. For example, Massachusetts General Hospital in Boston, which has been ranked as the best hospital in the world, spent \$53.8 million on community benefits in 2015, down from \$62.1 million in 2013, even as its total annual revenue went up by more than \$200 million.<sup>294</sup>

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<sup>287</sup> Hospitals that Politico reported had experienced increased revenues while decreasing their charity care between 2013 and 2015 included UCLA, UCSF, Massachusetts General, and Johns Hopkins, each of which are 340B covered entities and received the committee’s September 8<sup>th</sup> letter. Dan Diamond, *How Hospitals got richer off Obamacare*, POLITICO (July 17, 2017) available at <https://www.politico.com/interactives/2017/obamacare-non-profit-hospital-taxes/>.

<sup>288</sup> Letter from Thomas M. Priselac, President & Chief Executive Officer, Cedars-Sinai Medical Center, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, and Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 29, 2017).

<sup>289</sup> *Id.*

<sup>290</sup> Letter from Redonda G. Miller, MD, MBA, President, The Johns Hopkins Hospital, to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, Hon. Tim Murphy, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, Hon. Frank Pallone, Jr., Ranking Member, H. Comm. on Energy and Commerce, and Hon. Diana DeGette, Ranking Member, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, at 9 (Sept. 29, 2017).

<sup>291</sup> *Id.*

<sup>292</sup> *Id.*

<sup>293</sup> *Id.*

<sup>294</sup> Dan Diamond, *How hospitals got richer off Obamacare*, POLITICO (Jul. 17, 2017), available at <https://www.politico.com/interactives/2017/obamacare-non-profit-hospital-taxes/>.

## D. Medicare Part B and the 340B Program

***Finding: There is a financial incentive for 340B hospitals to prescribe more, and/or more expensive drugs to Medicare Part B beneficiaries, and prescribing trends indicate that 340B hospitals do prescribe more and more expensive drugs to Medicare Part B beneficiaries as compared to non-340B hospitals.***

Medicare Part B covers services and supplies considered medically necessary to treat a disease or condition, including a limited number of outpatient prescription drugs.<sup>295</sup> 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.<sup>296</sup> 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.<sup>297</sup> 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.”<sup>298</sup> 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.<sup>299</sup>

Similarly in 2015, GAO issued a report finding that “per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at 340B DSH hospitals than at non-340B hospitals.”<sup>300</sup> This indicated that on average, those patients were prescribed either more, or more expensive drugs by 340B hospitals than by other hospitals.<sup>301</sup> The trend could not be explained by patient or hospital characteristics.<sup>302</sup> According to GAO, this trend seemed to be driven by the fact that CMS pays hospitals for drugs according to a statutorily defined formula—a set rate—regardless of the cost at which the hospital acquired the drugs, and therefore, there is a financial incentive at 340B hospitals to prescribe more drugs or more expensive drugs to Medicare beneficiaries “in order to maximize the revenue generated by the difference between the cost of the drug and Medicare’s reimbursement.”<sup>303</sup> In other words, because hospitals were able to buy 340B drugs at discounted prices and still collect Medicare

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<sup>295</sup> CMS, *What Part B Covers*, Medicare.gov (last accessed Sept. 19, 2017), available at <https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html>.

<sup>296</sup> 82 Fed. Reg. 33558, 33633 (Jul. 20, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-07-20/pdf/2017-14883.pdf>.

<sup>297</sup> 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).

<sup>298</sup> *Id.* at 8.

<sup>299</sup> *Id.* at 4.

<sup>300</sup> 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).

<sup>301</sup> *Id.* at 21.

<sup>302</sup> *Id.* at 24-26.

<sup>303</sup> *Id.* at 29.

reimbursements at a set rate, prescribing more, or more expensive drugs to Medicare beneficiaries allowed hospitals to increase their 340B program savings. GAO noted in conclusion that this trend raises concerns about “the appropriateness of the health care provided to Medicare beneficiaries if it is overly influenced by financial incentives to prescribe outpatient drugs.”<sup>304</sup>

### **E. Consolidation of Oncology Clinics**

***Finding: There has been a marked increase in consolidation of private oncology practices, which, in some instances, negatively impacts the quality of patient care and can result in increased patient cost.***

The dramatic growth in 340B child sites can be attributed in part to the issue of consolidation, or the practice of 340B hospitals acquiring private practices and registering those practices as child sites. The committee explored this issue with particular focus on the acquisition of oncology practices. A 2016 report from the Community Oncology Alliance (COA) showed that there has been a 172 percent increase in the consolidation of community oncology practices into hospitals since 2008.<sup>305</sup> A 2017 report from COA showed that from 2008 to 2016, the percentage of Medicare Part B oncology drug reimbursements has more than tripled at 340B hospitals, while at private practices the percentage of reimbursements fell from 72 to 49 percent.<sup>306</sup> According to a GAO report issued in 2015, the average number of oncology patients grew for all hospitals between 2008 and 2012, but grew the most at 340B DSH hospitals.<sup>307</sup> For non-340B hospitals, the growth in oncology patients treated was one to two percent; for 340B hospitals, the growth in oncology patients treated was five percent.<sup>308</sup>

According to the 2017 report by the National Academies Press, this trend is driven by profit motive. Acquiring an oncology practice can be quite lucrative for a hospital. Oncology drugs are very expensive, so a 340B hospital that is able to purchase those drugs at a discount can realize a significant profit margin if it chooses not to pass those savings on to the patient. According to the National Academies Press report:

For example, hospital-affiliated outpatient practices that qualify for 340B discounts can purchase drugs at reduced cost while still receiving full reimbursement for them in addition to their ability to charge facility fees. Conversely, community oncology practices that do not qualify for 340B discounts operate on lower per person-per treatment margins derived from the administration of the drugs they purchase, including the revenue generated off buy and bill reimbursements and the ability to

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<sup>304</sup> *Id.*

<sup>305</sup> Community Oncology Alliance (COA), *2016 Community Oncology Practice Impact Report: Tracking the Changing Landscape of Cancer Care* (Oct. 4, 2016), available at <https://www.communityoncology.org/wp-content/uploads/2016/09/PracticeImpactReport-2016-Report.pdf>.

<sup>306</sup> Berkeley Research Group, *The Oncology Drug Marketplace: Trends in Discounting and Site of Care* (Dec. 2017), available at [https://www.communityoncology.org/wp-content/uploads/2017/12/BRG\\_COA-340B-Study\\_NOT\\_EMBARGOED.pdf](https://www.communityoncology.org/wp-content/uploads/2017/12/BRG_COA-340B-Study_NOT_EMBARGOED.pdf).

<sup>307</sup> 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, at 27 (June 2015).

<sup>308</sup> *Id.* at 28-29.

charge facility fees (Polite et al., 2014). These disparities in revenue-generating incentives may act to encourage the consolidation of health care providers (Baker et al., 2014; Cutler and ScottMorgan, 2013). For example, there has been significant growth in 340B eligibility among outpatient clinics affiliated with 340B participating hospitals preceding and following [PPACA] implementation. As a result, GAO estimates that 340B discounts apply to 50 percent of cancer drugs sold and paid for by Medicare part B (GAO, 2015).<sup>309</sup>

A 2017 report from COA noted that the profit margin realized by 340B hospitals on oncology drugs after Medicare reimbursement was 49 percent in 2015, up from 39.5 percent in 2010.<sup>310</sup> The margin realized by non-340B hospitals in 2015 was 6 percent.<sup>311</sup>

Some hospitals explained to the committee that because the cost of oncology drugs is high, operating an oncology practice can be very expensive, and as a result, it is not uncommon for such a practice to approach a hospital for purchase in order to achieve financial stability. For example, in the committee's October 2017 hearing, one covered entity testified that they were approached by an oncology clinic that wanted to be acquired by the hospital:

Q: ...Northside did, however, acquire two oncology practices in 2013, did it not?

A: Those discussions began in 2011 and completed in 2012.

Q: Okay. So Ms. Banna, can you explain why Northside acquired these sites?

A: Absolutely. We were approached by a large oncology practice that was seeking integration with the hospital system, as were several other hospital systems in the Atlanta area. We worked with them throughout 2011 and 2012 to determine the model that would provide the right kind of clinically-integrated care that both parties were looking for and completed that transaction in 2012.<sup>312</sup>

The committee was unable to determine the frequency of such solicitations.

Regardless of the motivation for such consolidation, these acquisitions often result in higher cost of care to patients due to additional costs imposed by the hospital, such as facility fees. Hospitals charge patients an average of 189 percent more than for infusions than what a

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<sup>309</sup> National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 113 (Nov. 2017).

<sup>310</sup> Berkeley Research Group, *The Oncology Drug Marketplace: Trends in Discounting and Site of Care* (Dec. 2017), available at [https://www.communityoncology.org/wp-content/uploads/2017/12/BRG\\_COA-340B-Study\\_NOT\\_EMBARGOED.pdf](https://www.communityoncology.org/wp-content/uploads/2017/12/BRG_COA-340B-Study_NOT_EMBARGOED.pdf).

<sup>311</sup> *Id.*

<sup>312</sup> *Examining How Covered Entities Utilize the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 115th Cong., Preliminary Transcript, at 95-96 (Oct. 11, 2017).

private oncology practice would charge, according to a 2014 study by IMS Institute for Healthcare Informatics.<sup>313</sup> The National Academies Press noted that:

For drugs dispensed or used by clinicians at a hospital-affiliated clinic or an outpatient infusion center affiliated with a hospital, these providers also charge payers facility fees, which may amount to 50 percent or more of the drug's acquisition cost. As the site of care for outpatient infusion services has increasingly shifted toward hospital-owned or affiliated practices in recent years, spending associated with this form of care has grown (MedPAC, 2017b).<sup>314</sup>

In the case of Northside specifically, the *Atlanta Journal-Constitution* reported that after Northside acquired Atlanta Cancer Care in 2013, the out of pocket cost of treatment for one patient rose from \$20 to \$212, a more than 1000 percent increase.<sup>315</sup> The cost to his insurer rose from \$2,735 to \$5,661, a more than 200 percent increase.<sup>316</sup> The *Journal* spoke with at least three other patients whose cost of care had increased, despite no change in the care they received.<sup>317</sup>

Not only do these acquisitions often result in higher cost of care for patients, GAO found that for Medicare Part B beneficiaries in particular, 340B DSH hospitals “prescribed more oncology drugs, or prescribed more expensive oncology drugs,” than did non 340B hospitals treating Medicare Part B oncology patients.<sup>318</sup> As explained in an earlier section of this report, this reflects the financial incentive of 340B hospitals maximize revenue generated by Medicare reimbursements, and calls into question the appropriateness of care provided.<sup>319</sup>

In addition to increasing a patient's out of pocket costs, consolidation can result in a decline in quality of care. The committee had confidential conversations with several physicians and administrators with experience treating oncology patients before, during, and after such an acquisition by a hospital.

- One doctor who spoke to the committee detailed a troubling decline in patient care after the doctor's private oncology practice was acquired by a large hospital. The doctor also noted that while the treatment regime patients received did not change, costs rose “markedly.” The doctor noted one patient in particular who shared his bills for a bone marrow biopsy showing the increase in cost of care over a three-year period. Two years before the practice was acquired, the patient's biopsy cost \$1,000 when performed at the

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<sup>313</sup> Roni Caryn Rabin, *Chemo Costs in U.S. Driven Higher By Shift to Hospital Outpatient Facilities*, KAISER HEALTH NEWS (May 6, 2014), available at <https://khn.org/news/chemo-costs-in-u-s-driven-higher-by-shift-to-hospital-outpatient-facilities/>.

<sup>314</sup> National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 113 (Nov. 2017).

<sup>315</sup> Carrie Teegardin, *When doctors sell out, hospitals cash in*, THE ATLANTA JOURNAL-CONSTITUTION (Jul. 6, 2013), available at <http://www.myajc.com/news/when-doctors-sell-out-hospitals-cash/AtShGSUuv3kmN6sBKL2nvM/>.

<sup>316</sup> *Id.*

<sup>317</sup> *Id.*

<sup>318</sup> 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, at 28 (June 2015).

<sup>319</sup> *Id.* at 29.

private practice. A year later, one year before the practice was acquired, the practice could no longer afford to perform the biopsy, and referred the patient to the hospital that would eventually acquire the practice. When the same procedure was performed by the hospital, the patient was billed \$7,000. The next year, after the practice was acquired by the hospital, the patient was billed \$14,000 for the procedure that had cost him only \$1,000 two years prior. The doctor further stated that the kit needed for the procedure cost the practice \$125. The practice first referred the patient to the hospital because the reimbursement for the kit had dropped to \$100, and the practice could no longer afford to perform the procedure. The doctor stated that despite the higher costs, no services were added that improved patient experience, and in fact quality of care and patient satisfaction declined.

The doctor stated that prior to the acquisition, overall patient support was superior. The practice employed registered nurses (RNs) and there were eight staff members devoted to optimizing the quality of patient care. Within roughly a month of the acquisition, the hospital removed the RNs from the practice and replaced them with licensed practical nurses (LPNs). According to the doctor, an LPN's salary is about half of that of an RN, and the hospital explained to the oncology practice that it needed to cut costs wherever it could. LPNs, however, have less experience than RNs, and are unable to provide the same services. The doctor noted that RNs are able to keep patients out of the emergency room by providing symptom management by phone, whereas calls with LPNs often resulted in patients being referred to the emergency room. Emergency room visits can be very expensive, so not only does this lead to increased cost for patients, but it also leads to higher income for the hospital. Similarly, the hospital also decided to discontinue the practice's research project, because the project was not lucrative.

Finally, the doctor stated that immediately following the acquisition, the hospital asked if the doctor could change the patients' infusion regime such that after a certain drug was administered at the physician clinic, the patient would then be moved to the hospital to receive a subsequent drug. The doctor noted that this would require patients to be moved during a period in which the patient would be experiencing severe nausea. The doctor noted that this was medically unnecessary, as both drugs had previously been provided in one location, and the doctor could identify no other reason for the shift than profit incentive. The hospital did not ultimately require that the doctor change the infusion regime.

- An administrator of a community oncology center that was acquired by a 340B hospital stated that although the treatment regime did not change at all after the acquisition, patient prices rose by as much as 530 percent for some services after the acquisition. The administrator noted that several patients contemplated leaving the practice, but the administrator was unsure if any patients ultimately left, noting that in that area, there were not many alternative treatment centers available. The administrator also stated that patient satisfaction decreased after the acquisition, particularly because of a different software and additional forms used by the hospital that slowed down treatment and which the administrator found to be inefficient.

- More troubling, one doctor told the committee that the doctor had seen 16 patients put on a waiting list for patients without insurance. The doctor noted that the wait list was not a capacity issue, but a decision by the hospital to cap the number of uninsured patients that it will treat within a set period of time. Due to the nature of the cancer with which those patients had been diagnosed, several of those patients' conditions worsened during the time they waited for treatment.
- Finally, one doctor told the committee that after a local hospital began acquiring oncology clinics, private clinics could no longer compete, because the hospital refused to refer patients to those clinics, even if it would have been in the best interest of the patient. The doctor explained that the hospital was short staffed on oncology doctors, but refused to hire more doctors or refer patients to other treatment centers that were not within that hospital's 340B system, even though such a referral would mean the patient got treatment sooner. The doctor also noted that the treatment regime and procedures performed in the hospital were the same as they would be in a private clinic, but the hospital charged higher prices for those services. Finally, the doctor stated that the hospital refused to treat uninsured patients outside of an emergent setting. If such a patient came to the emergency room, the hospital would stabilize the patient, and refuse further treatment because the patient could not pay.

The committee has been unable to determine at this time how frequent or widespread such dynamics may be. However, the sincere concerns expressed by numerous health care providers who have witnessed these challenges suggest there may be at least some negative consequences of market dynamics associated with the 340B program. Given the widespread agreement between all covered entities that the aim of the 340B program is to assist these entities in providing care to patients, first-person reports of negative patient impacts or patient harm should be concerning to everyone focused on improving patient care.

## **F. Disproportionate Share Hospital Metric and Covered Entity Eligibility**

***Finding: The current metric used to determine hospital eligibility for the 340B program does not necessarily reflect the amount of charity care offered by the hospital or the outpatient population for the hospital. Hospitals have a financial incentive to open child sites in areas that do not reflect the DSH percentage of the parent entity, thus enabling the hospital to gain access to a higher number of commercially insured patients.***

As shown in Figure 1, one of the requirements for hospitals to qualify as covered entities and participate in the 340B program is that they must be a DSH hospital and have a minimum disproportionate share adjustment percentage to qualify for program participation. The requirement that certain hospitals have a disproportionate share adjustment percentage above 11.75 percent (or greater than or equal to 8 percent for some hospitals) to qualify as a covered entity is a statutory requirement.<sup>320</sup> Congress referred to Section 1886 of the Social Security Act for the definition of a disproportionate share hospital for purposes of the 340B program, which only addresses Medicare payment for hospital inpatient services.<sup>321</sup> According to Section 1886

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<sup>320</sup> PHSA § 340B(a)(4)(L)(ii).

<sup>321</sup> See *id.*

of the Act, there are two ways that a hospital can qualify for the Medicare DSH adjustment: (1) the primary method; and (2) the alternate special exemption method.<sup>322</sup> Under the primary method, the DSH patient percentage is determined by calculating the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI) and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.<sup>323</sup> The alternate special exemption is for large urban hospitals that can show that more than 30 percent of their total net inpatient care revenues are from state and local governments for indigent care.<sup>324</sup>

Therefore, although the 340B program is an outpatient program, hospital eligibility for the 340B program is calculated by analyzing inpatient care. The only requirement for an outpatient facility to be eligible as a child site of a 340B hospital is that the facility be listed on the hospital's Medicare cost report; the child site need not be independently eligible for program participation.<sup>325</sup> This raises concerns about whether the patient population served by a child site is reflective of the patient population served by the parent entity. If a DSH hospital were to open a child site in an affluent area in which a large percentage of the patient population has commercial health insurance, it is possible the hospital could profit significantly from prescribing discounted 340B drugs to patients that are charged the full price for those drugs and for which the hospital receives a larger payment than it would from a Medicaid/Medicare patient. Because covered entities are not required to track or report program savings, and many choose not to, there is currently no available data on which child sites generate the most savings and revenue for covered entities. Many covered entities told committee staff that they track drug purchases and savings in the aggregate and are unable to identify program savings generated by each child site.

While this practice is not prohibited, it does not seem to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>326</sup> Although the program's specific purpose may be unclear, as previously discussed, the DSH eligibility requirement makes clear that hospitals are eligible based on serving vulnerable and underserved populations. Given the changing health care landscape, especially regarding consolidation and the growth in child sites, it is unclear whether Congress intended for this outcome. In 2015, when asked about the use of the DSH metric, GAO testified that because the health care landscape has changed so dramatically, it is especially important for Congress to clearly define the intent of the program. GAO testified:

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<sup>322</sup> U.S. Dep't of Health and Human Services, Centers for Medicare & Medicaid Services, *Disproportionate Share Hospital (DSH)* (last modified Sept. 29, 2017), available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>.

<sup>323</sup> U.S. Dep't of Health and Human Services, Centers for Medicare & Medicaid Services, *Disproportionate Share Hospital (DSH)* (last modified Sept. 29, 2017), available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>.

<sup>324</sup> *Id.*

<sup>325</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 98 (Jul. 18, 2017).

<sup>326</sup> 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/>.



Q: In your report, you noted that using the DSH adjustment percentage as part of the 340B eligibility criteria for hospitals has the effect of making eligibility for 340B expand as more people become insured due to broader Medicaid coverage. Since your report was written, we have seen the uninsured rates decline at hospitals in states that have expanded Medicaid. The question is, do you think it makes sense for hospitals in those states to gain full access to 340B just as their charity care burden is decreasing due to patients gaining Medicaid or do you think there might be another metric for 340B eligibility that could work better than the DSH metric to help ensure the program reaches the hospitals that are truly serving a disproportionate share of uninsured and vulnerable patients?

A: Well, it is probably best if I first explain what DSH is. It is actually an inpatient indicator. The 340B Program is an outpatient program. DSH is actually the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and Supplemental Security Income and the percentage of total inpatient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A. So it is really an inpatient indicator and it is sometimes used as a proxy for uncompensated care or the amount of low-income clients a particular facility serves. So the question is an interesting one. And part of the issue is that it is a difficult question to answer because much has changed in the healthcare landscape over the last several years since the 340B Program was created in 1992. One of the big things, of course, is the healthcare reform that was recently enacted which provided coverage for more people than originally was the case when the program was initially established. However, I think the bigger question is, what is the intent of the 340B Program. And there is a lot of uncertainty or lack of clarity around what is this program intended to do. In our prior work when we issued our 2011 report, there was a lot of varying interpretations of what the 340B Program was. HRSA talks about the program. And the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more patients and provide more comprehensive services.... Others believe that this is a program to assist low-income individuals in need of medications. And while it does that, there is no criteria in terms of patient eligibility, no criteria related to level of income. So it could benefit anyone, any level of income as long as they meet the other criteria for an eligible patient. And I can just tell you that when we conducted our work in 2011, we found a range of payer mixes in the hospitals that we interviewed. We asked them about their Medicaid and uninsured payer mix and it ranged anywhere from 15 percent to 85 percent. So it is really all over the board, and I think it is just really being able to add more clarity. It is important to add more clarity and more specificity to what is the intent of the program, what is it intended to do.<sup>327</sup>

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<sup>327</sup> *Examining the 340B Drug Pricing Program: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 114th Cong., at 47-48 (Mar. 24, 2015).*

Moreover, it is unclear whether the DSH metric ensures that the program is available for hospitals that are truly serving a disproportionate share of uninsured and vulnerable patients. According to the recent report issued by the National Academies Press, there is “little correlation between county-level uninsured rates and the adjusted DSH patient percentage” of a hospital.<sup>328</sup>

Evidence about the impact of 340B revenue on safety net and community need engagement among qualifying hospitals is largely anecdotal.... GAO conducted a cross-sectional comparison of 340B-qualified Medicare disproportionate share hospitals with non-340B hospitals in 2012 using publicly available data from Medicare hospital cost reports.... The report found that 340B hospitals provided more uncompensated care than did non-340B hospitals and also had lower profit margins than non-340B hospitals, in part because they provided more uncompensated and charity care. A more recent report found that hospitals participating in 340B in 2015 exhibited widely varying financial stability and safety net care provision....Some 340B disproportionate share hospital (DSH) program participants operated at a substantial loss, but at least one-quarter of participants operated with a comfortable margin. Many of the hospitals with the highest operating margins were also those that provided the least uncompensated care, while the hospitals that provided the most uncompensated care had the lowest operating margins. Furthermore, there was little correlation between county-level uninsured rates and the adjusted DSH patient percentage.<sup>329</sup>

On the other hand, in its response to the Questions for the Record following the October 2017 hearing, Mission Health recently defended the use of the DSH metric to determine 340B eligibility by arguing that the DSH metric provides direct insight into the culture of the hospital and its commitment to caring for vulnerable, uninsured, and underinsured patients:

Even though the metric measures inpatient care, the Disproportionate Share Hospital (DSH) metric is appropriate for use in the 340B program, especially with respect to urban DSH and safety net hospitals.

The DSH metric identifies hospitals that provide inpatient services to a larger number of Medicaid and low-income Medicare/SSI patients than other hospitals (as opposed, for example, to hospitals that more routinely provide stabilizing treatment and then transfer or refer those patients to other medical centers for acute care). In other words, the DSH metric percentage identifies hospitals that provide a disproportionate share of inpatient care that is reimbursed below the actual cost of providing that care and correspondingly, identifies those hospitals that consistently serve a larger number of the most vulnerable patients in the community.

These vulnerable patients are often in need of complex care, require more resources, and are almost universally unable to afford the care that they need. The DSH metric, while imperfect, provides direct insight into the culture of the hospital

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<sup>328</sup> National Academies Press, *Making Medicines Affordable: A National Imperative*, Pre-publication Copy at 106 (Nov. 2017).

<sup>329</sup> *Id.*

and its commitment to caring for vulnerable, uninsured, and underinsured patients; that culture and philosophy of caring is unlikely to differ between inpatient and outpatient services. Importantly, those unique outpatient settings that are similarly dedicated to providing care to the most vulnerable (e.g., Rural Health Centers) separately qualify for the program.

There is no perfect metric, and perfect is often the enemy of the good. The DSH metric effectively identifies those hospitals providing higher amounts of care to inherently vulnerable populations, as is consistent with the goals of the 340B Program. The data used to support the calculation is readily available to the Health Resources and Services Administration (HRSA) and results in a reliable and clear metric for determining access to the 340B Program.<sup>330</sup>

In recent years, there have been fewer uninsured patients and charity care has declined. At the same time, because Medicaid enrollment has increased and the DSH metric measures Medicare and Medicaid inpatient stays, an increased number of entities are eligible to participate in the program. In 2017, GAO testified that another weakness with the DSH metric is that it is based on patients with health care coverage:

Q: This metric for qualifying DSH hospitals is an inpatient measure yet 340B is for outpatient drugs. So does it make sense for us to use an inpatient metric for an outpatient program?

A: Well, we do believe that that is a – that is one of the weaknesses of the DSH measure. The other is that it really – the formula is based on covered patients and that would be those covered by Medicare and Medicaid. So, you know, there are weaknesses inherent in that measure.<sup>331</sup>

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<sup>330</sup> Letter from Ronald A. Paulus, M.D., President and Chief Executive Officer, Mission Health System, Inc., to Hon. Greg Walden, Chairman, H. Comm. on Energy and Commerce, *Additional Questions for the Record* (Nov. 21, 2017).

<sup>331</sup> *Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 115th Cong., Preliminary Transcript*, at 114 (Jul. 18, 2017).

## VII. Conclusion

The 340B program is a vital lifeline to health care providers that allows them to purchase certain outpatient medications at reduced rates. For some covered entities, the 340B program and related savings are critical to the entity's financial viability and their ability to keep their doors open. For others, the program allows them to invest more dollars to extend care to underserved populations, to create programs that serve specific community needs, and to provide life-saving drugs at discounted prices to the populations that need them the most.

In recent years, however, concerns have been raised about how some entities use the program and how HRSA administers and oversees the program. Over the past two years, the committee has examined the 340B program by holding three hearings, meeting with more than 50 shareholder and advocacy groups, and reviewing documents from both HRSA and covered entities about how the 340B program is used. The committee's investigation has uncovered several weaknesses in program administration and oversight.

Program participation has more than quadrupled over the past 10 years, yet HRSA has remained largely the same size. This explosion in program growth has raised concerns about HRSA's ability to effectively oversee the program with their limited resources. Per a 2014 federal court ruling, HRSA's authority to oversee the program and enforce program requirements is limited. HRSA needs more regulatory authority to promote compliance, clarify requirements, and ensure program integrity.

Further, the intent and parameters of the program are unclear. Covered entities are not required to use program savings in any specific way, which has led to concerns about whether the money is truly devoted to improving patient care. Clarifying the intent of the program will better enable HRSA to oversee the program in a way that is consistent with that intent, as well as provide further guidance to participating covered entities on how best to utilize the program to improve patient care.

Finally, a lack of reporting requirements has resulted in a lack of reliable data. The little data that are available are self-reported by entities that measure savings, charity care, and program value in differing ways. There are dueling claims among program participants and stakeholders about whether the program is working to best serve indigent and vulnerable patients and whether, given program growth, the lack of clear Congressional purpose, and the changing health care landscape, the program's original structure is still appropriate. Reforming the program to promote transparency and accountability will allow for an accurate accounting of the full scope of the program's use and will help promote program integrity and oversight.

The 340B program is an important piece of our nation's health care system. Reforming the 340B statute is an important step toward providing quality health care to our most vulnerable populations. As the program continues to expand, additional program examination is likely to be warranted.

## VIII. Recommendations

- HRSA should soon finalize and begin enforcing regulations in each of the three areas in which it currently has regulatory authority, including the 340B Alternative Dispute Resolution process, the imposition of civil monetary penalties against manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug, and the calculation of ceiling prices.
- Congress should give HRSA sufficient regulatory authority to adequately administer and oversee the 340B program, including the ability to improve program integrity, clarify program requirements, monitor and track program use, and ensure that low-income and uninsured patients directly benefit from the 340B program.
- Congress should require certain covered entities to conduct independent audits of program compliance, and should determine what such audits should assess and evaluate.
- All covered entities should perform independent audits of their contract pharmacies at regular intervals to ensure 340B program compliance.
- Congress should equip HRSA with more resources and staff to conduct more rigorous oversight and more effective management of the 340B program.
- Congress (and HHS to the degree possible) should take steps to identify and reduce duplicate discounts for drugs paid for under Medicaid managed care.
- Congress should evaluate whether the permissible scope of HRSA's audits should be expanded to cover other features of the program.
- HRSA should work toward ensuring that it audits covered entities and manufacturers at the same rate.
- Congress should clarify the intent of the 340B program to ensure that HRSA administers and oversees the 340B program in a way that is consistent with that intent. In doing so, Congress also should evaluate how developments in the health care landscape over the past 25 years have affected, if at all, the structure and goals of the 340B program.
- Congress (or HRSA where HRSA already has authority to make such changes) should promote transparency in the 340B program, including ensuring that covered entities and other relevant stakeholders have access to ceiling prices and requiring covered entities to disclose information about annual 340B program savings and/or revenue.

- Congress should establish a mechanism to monitor the level of charity care provided by covered entities. This should include a clear definition of charity care such that the data can be used to fairly compare care provided across entities.
- Congress should reassess whether DSH is an appropriate measure for program eligibility, or whether a metric based on outpatient population would be more appropriate.

## IX. Appendix

Year	Legislative Changes	Program Change Summary
1992	Veterans Health Care Act of 1992 (VHCA, P.L. 102-585); § 602	340B program authorizing legislation
1993	National Institutes of Health Revitalization Act of 1993 (NIHRA, P.L. 103-43), § 2008	NIHRA made a technical change to the directory language of VHCA.
2003	The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173), § 101, § 103, § 303, § 1002	MMA amended the Social Security Act (SSA) by changing the Disproportionate Patient Percentage (DPP) hospitals needed to qualify as Disproportionate Share Hospitals (DSHs). As a result, approximately 800 new small urban and rural hospitals became eligible for the 340B program.
2006	Deficit Reduction Act of 2005 (DRA, P.L. 109-171), § 6001, § 6004	<p>DRA revised the Medicaid definition of Average Manufacturer Price (AMP) and made other technical changes. As a result of the AMP definition change, drug manufacturers were reluctant to extend 340B program prices to university health clinics and certain health center lookalikes, because under the new AMP definition, drug manufacturers were required to consider sales to university clinics and lookalikes as being included in the calculation of each covered drug's AMP. If the university clinic and lookalike sales were included in AMP, those transactions would increase drug manufacturer rebates. Prior to the AMP definition change in DRA, sales to university health clinics and lookalikes were considered sales at nominal price and as a result were excluded from the AMP calculation.</p> <p>DRA also amended the SSA to include children's hospitals as 340B covered entities. Covered entities under the 340B program are identified in the Public Health Service Act (PHSA) [PHSA §§ 340B (a)(4)(A)-(N), Covered Entity, Defined], and not the SSA. As a result, there may have been some uncertainty about whether children's hospitals were eligible for the 340B program. HRSA published children's hospital participation guidance in 2007, but final guidance was not issued until September 2009. Some children's hospitals enrolled in the 340B program in 2009, but most enrolled after the ACA amended the PHSA [PHSA § 340(a)(4)(M)] by adding children's and other hospital types to the list of covered entities eligible to participate in the 340B program.</p>
2009	Omnibus Appropriations Act, 2009, (OAA, P.L. 111-8) §§ 221(a)-(b)	OAA amended the SSA [SSA § 1927(c)(1)(D), Limitation on Sales at Nominal Price] to specify that covered drug sales to certain 340B program covered entity types – lookalikes and university health clinics were to be considered sales at nominal price and would therefore drug manufacturers could exclude the amount of those sales from the calculation of AMP for each affected drug. The 340B covered entity sales that were to be considered nominal price sales were to nonprofit entities that have the same functions as federal PHS grantees, but don't receive grants and entities based at institutions of higher learning whose primary purpose was to provide health services to students of the institution.

Year	Legislative Changes	Program Change Summary
2010	Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) §§ 7101-7103, § 2501 and Health Care and Education Reconciliation Act of 2010 (HCERA, P.L. 111-152), § 2302	<p>ACA added four new hospital covered entities that were eligible to participate in the 340B program (1) critical access hospitals, (2) freestanding cancer hospitals, (3) sole community hospitals, and (4) rural referral centers. ACA also clarified that children’s hospitals were eligible to participate in the 340B program.</p> <p>ACA extended 340B program discounted ceiling prices to inpatient drugs, but the inpatient drug extension was repealed [HCERA § 2302].</p> <p>ACA required the Secretary to establish an administrative dispute resolution process and to promulgate regulations implementing civil monetary penalties on manufacturers and covered entities.</p> <p>ACA required drug manufacturers to have non-discrimination policy when there are drug shortages so that 340B covered entities have the same access to drugs at ceiling prices as do non-340B drug purchasers.</p> <p>ACA required drug manufacturers to report ceiling prices to the Secretary [PHSA § 340B(a)(1)].</p> <p>ACA increased Medicaid rebates from 17.1% on single source drugs to 23.1% and on multiple source drugs from 11% to 13%. For Medicaid, the federal government received the entire amount of the rebate increase. The ACA Medicaid rebate increase resulted in increased discounts (lower ceiling prices) for 340B covered entities (increases of 17.1% to 23.1% for single source drugs and 11% to 13% for multiple source drugs. The amount of the ACA increased drug discount was available to 340B program covered entities.</p> <p>ACA limited the total rebate (Medicaid)/discount (340B) to a maximum of 100% of AMP.</p> <p>ACA required the Government Accounting Office (GAO) to conduct a study and issue a report on the 340B drug pricing program.</p> <p>ACA/HCERA stipulated that for the new hospital covered entities added by ACA, including children’s hospitals, orphan drugs (as defined in the Food Drug and Cosmetic Act, § 526, for the treatment of a rare disease or condition) were not included in definition of covered outpatient drugs. The hospital covered entities that were not entitled to the 340B ceiling price discount were children’s hospitals, critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals. DSHs were entitled to the 340B ceiling prices for orphan drugs.</p>
2010	Medicare and Medicaid Extenders Act of 2010 (MMEA, P.L. 111-309), § 204	MMEA amended the PHSA to exempt children’s hospitals from the requirement that orphan drugs were not subject to the 340B ceiling price discounts for the newly added ACA hospital covered entities (critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals). Other covered entities, including DSHs and children’s hospitals are entitled to the 340B ceiling price discount on orphan drugs.

**Source:** Review of Public Laws, legislation, and guidance.