PUBLIC MEMORANDUM

May 31, 2024

TO: Members of the Subcommittee on Oversight and Investigations

FROM: Majority Committee Staff

RE: Hearing titled "Oversight of 340B Drug Pricing Program."

On Tuesday, June 4, 2024, at 10:30 a.m. (ET) in 2322 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing titled "Oversight of 340B Drug Pricing Program."

I. WITNESSES

- Anthony DiGiorgio, D.O., MHA, Neurosurgeon, University of California San Francisco (UCSF) Health
- Sue Veer, President and CEO, Carolina Health Center
- William (Bill) Smith, PhD, Senior Fellow and Director of Pioneer Life Sciences Initiative, Pioneer Institute
- Matthew Perry, President and CEO, Genesis Healthcare System

II. OVERVIEW

The 340B Drug Discount Program ("340B Program") "is now unambiguously the second-largest government pharmaceutical program, based on net drug spending," behind only Medicare Part D. [1] In 2023, sales on covered outpatient drugs under the 340B Program exceeded $124 billion in wholesale acquisition cost (WAC) dollars, while total net rebates in the program exceeded $53 billion.[2] Since 2017, when this Committee last conducted an oversight hearing on

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[1] Adam J. Fein, *EXCLUSIVE: The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html.
[2] Rory Martin & Harish Karne, IQVIA, The 340B Drug Discount Program Grew to $124B in 2023 (2024), https://www.iqvia.com/locations/united-states/library/white-papers/the-340b-drug-discount-program-grew-to-$124b-in-2023.

the Program, the total value of net rebates from the 340B Program has increased by more than $34 billion.[3]

Operating through a complex network of drug manufacturers and health providers (covered entities), the 340B Program was created to "stretch scarce federal resources" and support covered entities in providing low-income and uninsured patients with increased access to care and life saving drugs. Today, the program is indispensable to many covered entities – including community health centers, rural hospitals, and disproportionate share hospitals with significant Medicare and Medicaid patient mixes. However, the program has longstanding challenges, due to a lack of regulatory infrastructure, administrative controls, and legislative guidance, which have led to an exploitation of the program by bad actors and unintended consequences across consolidation and prescribing practices by physicians and hospital systems that have led to overall higher costs for patients.

III. BACKGROUND

In 1992, Congress created the 340B Drug Discount Program ("340B Program") through the Veteran's Health Care Act to provide low-income and uninsured patients increased access to life saving drugs.[4] The authorizing statute—Section 340B of the Public Health Service Act (42 U.S.C. 256b)—requires drug manufacturers to provide outpatient drugs to eligible health care organizations ("covered entities") at steep, discounted prices in order to remain eligible for reimbursements through Medicaid.[5] Covered entities include federal grantees (e.g., Federally Qualified Health Centers and Ryan White grantees) and eligible hospitals, including children's hospitals, critical access hospitals (CAHs), disproportionate share (DSH) hospitals that meet a minimum Medicare and Medicaid patient mix requirement, rural referral centers, sole community hospitals, freestanding cancer hospitals, specialized clinics and other providers that care for rural and underserved populations.[6]

While the 340B Program dictates the ceiling price at which drugs must be sold to covered entities at, it does not specify the amounts that covered entities may, in turn, charge patients for the same drug. As such, covered entities are able to sell drugs at prices that significantly exceed the otherwise low acquisition cost, in order to collect significant savings that can be used for any array of needs by the covered entity. In 2022 alone, sales of 340B covered drugs generated as much as $54 billion and accounted for 7.2 percent of all sales in the U.S. drug market.[7]

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[3] *Id.*; *see also* Adam J. Fein, *ECLUSIVE: The 340B Program Reached $19.3 Billion in 2017 – As Hospitals' Charity Care Has Dropped*, Drug Channels (May 7, 2018), https://www.drugchannels.net/2018/05/exclusive-340b-program-reached-193.html.
[4] Hannah-Alise Rogers, Cong. Research Serv., IF12232, Overview of the 340B Drug Discount Program (2022), https://crsreports.congress.gov/product/pdf/IF/IF12232.
[5] *Id.*
[6] *Id.*
[7] Health Resources Serv. Admin., *2022 340B Covered Entity Purchases*, https://www.hrsa.gov/opa/updates/2022-340b-covered-entity-purchases (last accessed May 31, 2024); Hannah-Alise Rogers, Cong. Research Serv., IF12232, Overview of the 340B Drug Discount Program, *supra* note 4.

The value that the savings generated from the Program provide to covered entities for day-to-day operations cannot be overstated. Covered entities report using the savings from the Program to offer increased access to mental health treatments, extend clinical hours, and to hire additional medical and support staff. Many safety-net providers report concerns about their ability to maintain operations without the program.

To participate in the 340B Program, a covered entity must register with the Health Resources and Services Administration (HRSA,) be approved by the agency, and follow program requirements, including meeting the statutory definition of a covered entity, limiting the prescribing of 340B-acquired drugs to only patients of the covered entity, and not charging the manufacturer for rebates in the Medicaid program. Nonetheless, covered entities routinely fail to meet these basic requirements. In 2018, the Committee found "[a]t least 17 percent of 340B-covered entities audited had duplicate discounts errors each year since 2012," where manufacturers were charged for both 340B rebates and Medicaid rebates, while the rate of diversion, where drugs were prescribed to individuals who were not patients of the covered entity, hovered around 50 percent.[8] Additional work by the GAO has found continued concerns with covered entities' ability to comply with these requirements.[9]

Beyond these basic program integrity concerns, further questions have been raised about the Program's overall size and what it means for the Program's potential to distort markets and actually provide meaningful ways to lower health care costs for Americans. As noted, the 340B Program has grown considerably in recent years, reaching an estimated $54 billion in total net savings in 2022 alone.[10]

A single covered entity may have multiple sites ("child sites") that participate in the program. Participating child sites may include satellite clinics or facilities, hospital departments, outpatient treatment units, and other facilities. As of January 1, 2019, there were 24,651 hospital child sites and 8,165 consolidated health center child sites participating in the 340B Program.[11]

Hospitals' participation in the 340B Program has increased dramatically in recent years, and hospitals are now the primary beneficiaries of the 340B Program with 86.5 percent of total 340B purchases.[12] Participating hospitals must have a minimum disproportionate share (DSH) adjustment percentage (except for critical access hospitals), which is based on the share of a hospital's inpatients who are Medicaid and low-income Medicare patients. As of 2022, DSH

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[8] Staff of H. Comm. on Energy & Commerce, 115th Cong., Review of the 340B Drug Pricing Program 36, 38 (Comm. Print 2018).
[9] *See* U.S. Gov't Accountability Office, GAO-20-108, 340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements (2020), https://www.gao.gov/products/gao-20-108; U.S. Gov't Accountability Office, GAO-20-212, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement (2020), https://www.gao.gov/products/gao-20-212.
[10] Health Resources Serv. Admin., *2022 340B Covered Entity Purchases*, https://www.hrsa.gov/opa/updates/2022-340b-covered-entity-purchases (last accessed May 31, 2024).
[11] Memorandum from Cong. Research Serv. (on file with Committee).
[12] *See* Adam J. Fein, *supra* note 1.

hospitals accounted for 78 percent of total 340B purchases, totaling over $41 billion of 2022 purchases at 340B discounted prices.[13]

The use of contract pharmacies has also increased in recent years, with most covered entities, including those with in-house pharmacies, contracting with retail pharmacies to sell drugs to patients.[14] In 2020, some drug manufacturers announced restrictions on 340B covered entities that use contract pharmacies. These restrictions attempted to limit the number of distributing pharmacies to one contract pharmacy. Manufacturers claimed the restrictions were placed to limit duplicate discounting and the practice of diversion—where a covered entity may unlawfully distribute 340B drugs to nonpatients—while covered entities argued the restrictions prevented them from generating 340B savings. When HRSA issued violation letters to the manufacturers in response to the restrictions, the manufacturers sued HRSA before several federal courts in the country.[15] Many of the resulting judicial opinions looked to Congress to provide clarification on the appropriate role of contract pharmacies in the 340B Program, without which interpretations are likely to split based on decisions from courts and state legislatures.[16]

The 340B Program's explosive growth has resulted in concerns about abuses caused by the lack of regulatory infrastructure, administrative controls, and legislative guidance. Reports suggest that the 340B Program has expanded beyond its legislative purpose and does not benefit low-income patients either through lower drug costs or providing hospitals with additional resources to treat them. Instead, the 340B Program has resulted in additional profits for hospitals and health systems operating in affluent areas, through its network of rural referral centers and child sites.

In 2022, a *Wall Street Journal* analysis of HRSA data "found that 88 out of the 111 rural referral centers in the 340B Program weren't located in areas deemed rural by HRSA."[17] While participating hospitals realized millions of dollars in savings on drugs, there is no transparency on what these hospitals do with their discounts, given that the 340B Program neither requires hospitals to pass on drug discounts to patients, insurers, or Medicare, nor does the program require hospitals to disclose how much they make from drug sales.[18]

A 2023 Government Accountability Office (GAO) report found nearly half of surveyed hospitals that requested an exception to the 340B DSH adjustment percentage eligibility requirement during the COVID-19 pandemic, and that were subsequently approved, did not

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[13] *Id.*
[14] Hannah-Alise Rogers, Cong. Research Serv., LSB11163, Litigation Continues Over Use of Contract Pharmacies in 340B Drug Discount Program (2024), https://crsreports.congress.gov/product/pdf/LSB/LSB11163.
[15] *Id.*
[16] *Id.*
[17] Anna Wilde Mathews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients.*, Wall St. J. (Dec. 20, 2022), https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899?st=6jkq1vg3z6f1698&reflink=desktopwebshare_permalink.
[18] *Id.*

provide discounts to low-income, uninsured patients at contract pharmacies.[19] The percentage of hospital revenue dedicated to charity care or assistance to needy patients is nearly identical among 340B (2.6 percent) and non-340B hospitals (2.7 percent), and some 340B hospitals have been found to have among the lowest charity-care rates.[20] Commentators have described these changes to the 340B Program, as showing that hospitals have "made a major shift from being mission-oriented to being unashamedly, unabashedly profit-oriented."[21]

The growth of the 340B Program has occurred in part because HRSA has limited oversight authority and capacity. In 2018, the GAO found weaknesses in HRSA's oversight impeded the agency's ability to ensure compliance with 340B requirements at participating contract pharmacies.[22] Specifically, GAO found HRSA audits did not "fully assess compliance with the 340B Program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries"; that "because HRSA does not require all the covered entities to explain the methodology they used for determining the extent of the noncompliance, [the agency] does not know the scope of the assessments and whether they are effective at identifying the full extent of noncompliance"; and that HRSA "does not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing the audit."[23]

An earlier, 2014 Office of Inspector General (OIG) report found contract pharmacies used different methodologies to prevent diversion and duplicate discounts under the 340B Program that resulted in a complicated, inconsistent structure.[24] Remarkably, some covered entities did not offer discounted 340B pricing to uninsured patients at their contract pharmacies, resulting in these patients paying the full non-340B price for prescription drugs.[25]

Given the 340B Program's triple digit growth of 129.4 percent since 2018, and potential trajectory for accelerated growth in the coming years, Congressional oversight of the 340B Program, including successes and challenges, is both timely and necessary.

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[19] U.S. Gov't Accountability Office, GAO-23-106095, 340B Drug Discount Program: Information about Hospitals That Received an Eligibility Exception as a Result of COVID-19 (2023), https://www.gao.gov/products/gao-23-106095.
[20] Anna Wilde Mathews, *supra* note 20.
[21] Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N. Y. Times (Sept. 24, 2022), https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html.
[22] U.S. Gov't Accountability Office, GAO-18-480, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (2018), https://www.gao.gov/products/gao-18-480.
[23] *Id.*
[24] Office of Inspector General, U.S. Dep't of Health & Human Serv., OEI-05-13-00431, Contract Pharmacy Arrangements in the 340B Program (2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.
[25] *Id.*

IV. KEY QUESTIONS

The hearing may include discussion around the following key questions:

- What is the current status of the 340B Program?
- What are some of the current challenges affecting the 340B Program and what are some possible solutions for reform?
- What is the definition of a "patient" under the 340B Program?
- What is the appropriate role of contract pharmacies in the 340B Program?
- Should Congress prescribe how 340B cost savings can be used by covered entities? If so, how?

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact John Strom or Joanne Thomas of the Committee staff at (202) 225-3641.