

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

September 8, 2017

Dr. A. Eugene Washington
President and Chief Executive Officer
Duke University Health System
2301 Erwin Road
Durham, NC 27710

Dear Dr. Washington:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee continues to examine implementation of the 340B Drug Pricing Program. As part of this oversight, the Committee is seeking information from your organization, Duke University Health System, because of its participation in this important program.

Established by Congress in 1992, the 340B Drug Pricing Program mandates that pharmaceutical manufacturers provide outpatient drugs to eligible health care organizations (referred to as “covered entities”) at discounted prices in order to have their drugs covered by Medicaid. The discounts are substantial—participating covered entities report savings between 25 to 50 percent of the average wholesale price for covered outpatient drugs.¹ Indeed, the federal agency responsible for managing and overseeing the program, the Health Services and Resources Administration (HRSA), estimated that covered entities saved a collective \$6 billion in 2015 by participating in the program.² Moreover, covered entities can purchase 340B drugs for all eligible patients regardless of the patient’s income or insurance status and therefore can generate revenue if the reimbursement for the drug exceeds the reduced price the hospital paid for the 340B drug.³

¹ Apexus, *340B Price/Covered Outpatient Drugs*, 340B Prime Vendor Program (last visited Aug. 17, 2017), available at <https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/>; See also U.S. Gov’t Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, at 2 (Sept. 2011).

² 82 Fed. Reg. 1210, 1227 (Jan. 5, 2017).

³ U.S. Gov’t Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, at 2 (Sept. 2011); See also Medicare Payment Advisory Commission (MedPAC), *Report to Congress: Overview of the 340B Drug Pricing Program*, at viii (May 2015).

While there is not an officially-stated purpose for the program in federal statute, HRSA has stated that Congress intended for covered entities to use the savings generated from the program to help the nation's most vulnerable patients gain better access to health care and "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."⁴ Covered entities include certain Ryan White clinics and State AIDS Drug Assistance Programs, children's hospitals, Medicare/Medicaid Disproportionate Share Hospitals, and other safety net providers as defined in the Public Health Services Act.⁵ Congress did not, however, restrict how covered entities use 340B program savings, nor did Congress provide HRSA with any authority to oversee how covered entities use program savings. In fact, during the Committee's July 2017 hearing examining HRSA's oversight of the program, HRSA testified that "the statute is silent regarding how covered entities have to use their savings" and "HRSA doesn't have authority to require what these entities are doing with their savings."⁶

Consequently, Congress has only had limited visibility into how covered entities use program savings. A recent survey conducted by an association of hospitals participating in the program—340B Health⁷—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.⁸ Furthermore, the survey revealed that some hospitals consider program savings to be essential to the continued operation of the hospital.⁹ According to the President and Chief Executive Officer of 340B Health, the program "gives hospitals the ability to address the most critical treatment needs for their community and customize programs that have the greatest potential to reach the most vulnerable patients."¹⁰

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.¹¹ For example, a 2014 *Health Affairs* study found that some hospitals use

⁴ H.R. Rep. 102-384, Pt. 2 (1992).

⁵ Health Resources & Services Administration (HRSA), *340B Drug Pricing Program* (last reviewed May 2017) <https://www.hrsa.gov/opa/>.

⁶ *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).

⁷ According to its website, "340B Health is a membership organization of more than 1,300 public and private nonprofit hospitals and health systems in the federal 340B drug pricing program." See 340BHealth, *About 340B Health* (last visited Aug. 16, 2017), <http://www.340bhealth.org/about/>.

⁸ 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients: Results from a Survey of 340B Health Members*, at 4-7 (May 2016), http://www.340bhealth.org/files/Savings_Survey_Report.pdf.

⁹ 340B Health, *340B Program Helps Hospitals Provide Services to Vulnerable Patients: Results from a Survey of 340B Health Members*, at 13-17 (May 2016), http://www.340bhealth.org/files/Savings_Survey_Report.pdf.

¹⁰ Ted Slafsky, *A Drug Discount Program that Punches Above its Weight*, THE HILL (July 17, 2017), <http://thehill.com/blogs/pundits-blog/healthcare/342363-340b-a-small-drug-discount-program-with-a-powerful-impact>.

¹¹ Susan Moore, *Hospitals Oppose Cuts to 340B Drug Program, but Oncology Group Says They're Abusing the Discount Program*, HEALTH CARE FINANCE NEWS (Jul. 17, 2017); See also Thair Phillips, *Hospital Abuse of Drug Discount Program Leaves Seniors in the Lurch*, THE HILL (Jul. 13, 2017); See also Scott Gottlieb, *How ObamaCare Hurts Patients*, THE WALL STREET JOURNAL (July 30, 2013), <https://www.wsj.com/articles/SB10001424127887324110404578630522319113676>.

the program to increase profits rather than helping extend services to low-income populations.¹² Additionally, a 2014 study by the Office of Inspector General at the U.S. Department of Health and Human Services found that not all covered entities ensure that uninsured patients benefit from the discounted 340B prices at their contract pharmacies.¹³ During the Committee's recent hearing, HRSA testified that HRSA does not know whether 340B entities pass program savings on to patients who need a reduction in the price of their medicine because the statute is silent and hospitals are not required under the law to pass the savings on to patients.¹⁴

Therefore, to assist the Committee in its oversight of the 340B Drug Pricing Program and help the Committee better understand the different ways in which covered entities use program savings, please provide Committee staff with a briefing no later than September 22, 2017. Please also provide the following information by September 22, 2017:

1. In a chart or similar format, please list each of the following items for 2012, 2013, 2014, 2015, and 2016:
 - a. The number of 340B drugs your organization, and all associated sites and off-site outpatient facilities registered as child sites, purchased for that year. Please provide a breakdown of the number of these drugs that were purchased by the covered entity's child sites and the number directly purchased by the covered entity;
 - b. The percentage of 340B drugs purchased and dispensed that fall into each of the following categories:
 - i. Analgesics
 - ii. Antidepressants
 - iii. Oncology treatment drugs
 - iv. Antidiabetic agents
 - v. Antihyperlipidemic agents
 - c. The number of 340B drugs your organization purchased that were dispensed to insured patients, including:
 - i. Medicare beneficiaries
 - ii. Medicaid beneficiaries
 - iii. Commercially-insured individuals;
 - d. The number of 340B drugs your organization purchased that were dispensed to uninsured patients;

¹² Rena M. Conti and Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities*, HEALTH AFFAIRS Vol. 33 No. 10 (2013).

¹³ U.S. Dep't of Health and Human Services, Office of Inspector General, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 4, 2014).

¹⁴ *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 & 54-55 (Jul. 18, 2017).

- e. The amount of savings (in dollars), as compared to the GPO price for the same drug, that your organization generated through participation in the 340B Drug Pricing Program; and
 - f. The amount of charity care (in dollars) that your organization provided; and
 - g. The number of patients that received charity care from your organization.
2. How does your organization calculate the amount of savings it generates through participation in the 340B Drug Pricing program? How does your organization track the amount of money your organization receives when an insured patients' insurance reimbursement exceeds the 340B price paid for the drug?
3. How does your organization use program savings to care for vulnerable populations? Are program savings used for any other purposes?
- a. Does your organization provide any additional charity care to uninsured and underinsured patients with funds derived from sources other than the 340B Drug Pricing Program? If so, please elaborate.
 - b. What percentage of total health care services provided by your organization is charity care?
4. Does your organization have any policies to help ensure that uninsured and underinsured patients directly benefit from the program by receiving discounts on 340B drugs? If so, please elaborate.
5. How many child-sites does your organization have registered to participate in the 340B Drug Pricing Program? Please provide a list of all child-sites, including the location of the child-site and the date it began participating in the program.
6. How many pharmacies has your organization contracted with to dispense drugs purchased through the 340B Drug Pricing Program on your behalf?
- a. Do your contracts with these pharmacies require that program savings be passed on to the intended beneficiaries, including requiring that uninsured or underinsured patients receive discounts on 340B drugs?
 - b. Does your organization share any program savings with these contract pharmacies? If so, please elaborate.

Thank you for your prompt attention to this matter. If you have any questions regarding this request, please contact Brighton Haslett, Brittany Havens, or Natalie Turner with the Majority Committee staff at (202) 225-2927.

Sincerely,



Greg Walden
Chairman
Committee on Energy and Commerce



Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations

cc: The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations