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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
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MEMORANDUM

October 9, 2017

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining How Covered Entities Utilize the 340B Drug Pricing Program"

On **Wednesday, October 11, 2017, at 10 a.m. in room 2123 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Examining How Covered Entities Utilize the 340B Drug Pricing Program."

I. BACKGROUND

Congress established the 340B drug discount program through bipartisan legislation passed in 1992.[1] Its goal was to generate savings for certain health care providers by making it possible for them to purchase outpatient drugs at discounted rates.[2]

Under the terms of the program, drug manufacturers provide discounts on outpatient prescription drugs to certain eligible health care providers, known as covered entities.[3] Covered entities include, but are not limited to, some disproportionate share hospitals ("DSH" hospitals), Federally Qualified Health Centers, Black Lung clinics, hemophilia clinics, and AIDS Drug Assistance Programs.[4] The discounts off the cost of covered drugs average between 25 and 50 percent.[5]

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[1] Veterans Health Care Act of 1992, H.R. Rep. No. 102-384 (1992); *see* 42 U.S.C. §256b.

[2] Veterans Health Care Act of 1992, H.R. Rep. No. 102-384, at 7-13.

[3] 42 U.S.C. § 256b(a)(1).

[4] 42 U.S.C. § 256b(a)(4).

[5] Health Resources and Service Administration, *FY 2018 Justification of Estimates for Appropriations Committees* (www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf). The exact discount is calculated based on a formula set out at 42 U.S.C. § 256b (a)(2)(A).

Over 600 manufacturers, 12,300 covered entities, and 26,000 associated sites participate in the 340B program.[6] Participation in the program is voluntary, but drug manufacturers must provide the discounts in order to participate in the Medicaid Drug Rebate Program. The Health Resources and Services Administration (HRSA), which administers the program, estimates that the program enabled covered entities to save $4.5 billion on drugs in 2014.[7] Still, 340B savings represent only a very small percentage of the overall U.S. drug market.[8]

II. PURPOSE OF THE 340B PROGRAM

The primary purpose of the 340B program is to help "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[9] This purpose is accomplished as covered entities pass on their 340B program savings to patients in the forms of more affordable medicine and expanded health care services. As a bipartisan group of Members has stated,

> [T]he 340B program allows hundreds of hospitals and other safety net providers across the country to do more with less – to expand community-based services to serve our most vulnerable. Thanks to 340B, our hospitals are able to expand services, increase the number of patients they serve, and offset losses from uncompensated care – all because of the 340B program.[10]

III. PROGRAM INTEGRITY

Several statutory provisions and regulations applicable to the 340B program are designed to ensure that the program works as intended.

First, covered entities may only dispense these drugs to eligible patients, meaning patients with whom the covered entity has an established relationship; who receive health care services from a professional employed by the covered entity or in a contractual relationship with that entity; and for whom the health care services provided are consistent with the range of

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[6] Health Resources and Service Administration, *Statement of Capt. Krista M. Pedley, PharmD, MS, Director, Office of Pharmacy Affairs, Healthcare Systems Bureau, Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives* (July 18, 2017).

[7] Health Resources and Service Administration, *FY 2017 Justification of Estimates for Appropriations Committees* (www.hrsa.gov/sites/default/files/about/budget/budgetjustification2017.pdf).

[8] *Id.*

[9] Veterans Health Care Act of 1992, H.R. Rep. No. 102-384, at 12 (1992).

[10] Letter from 77 Members to Chairman Upton and Ranking Member Waxman (July 25, 2014).

services for which the covered entity receives grant funding.[11] Diversion of drugs, or providing drugs to individuals who do not meet this definition, is prohibited.[12] Second, a covered entity may not obtain a Medicaid drug rebate for a drug that it purchases at a 340B discount price, a process known as duplicate discounts.[13] Covered entities are subject to audit by HRSA, and those that fail to comply with these requirements may be sanctioned.[14]

With respect to manufacturers, "HRSA has the authority to conduct audits of manufacturers with program requirements."[15] As part of these audits, "HRSA verifies manufacturers that participate in Medicaid have signed a pharmaceutical pricing agreement, reviews all allegations brought to its attention, and requires refunds and credits when a covered entity is overcharged."[16]

IV. RECENT DEVELOPMENTS

In July 2017, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule, set to take effect in 2018, that would reduce the Medicare Part B reimbursement amount for 340B-purchased drugs from 106 percent of the average sales price to 77.5 percent of the average sales price.[17] If finalized, the proposed rule would significantly reduce reimbursements for 340B safety net hospitals. On August 21, 2017, CMS's independent Advisory Panel on Hospital Outpatient Payment recommended that the Agency not implement this provision of the proposed regulation, instead recommending that the agency collect further data and conduct additional analysis on the policy.[18]

The subcommittee held a hearing examining oversight of the 340B program on July 18, 2017. Witnesses included Captain Krista Pedley, HRSA Director of the Office of Pharmacy

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[11] *See* 61 Fed. Reg. 55156, 55157-55178 (Oct. 24, 1996). Disproportionate share hospitals are exempt from the requirement that services provided be consistent with the range of services for which grant funding has been provided.

[12] 42 U.S.C. § 256b (a)(5)(B).

[13] 42 U.S.C. § 256b (a)(5)(A)(i).

[14] 42 U.S.C. § 256b (a)(5)(D).

[15] Health Resources and Service Administration, *Statement of Capt. Krista M. Pedley, PharmD, MS, Director, Office of Pharmacy Affairs, Healthcare Systems Bureau, Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives* (July 18, 2017).

[16] *Id*; *see* 42 U.S.C. § 256 (d).

[17] Centers for Medicare & Medicaid Services, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 33558 (July 20, 2017).

[18] Centers for Medicare & Medicaid Services, Advisory Panel on Hospital Outpatient Payment, *Recommendations: OPPS Payment for Drugs Acquired Under the 340B Program* (Aug. 21, 2017).

Affairs; Debra Draper, Director in the Government Accountability Office's Health Care division; and Erin Bliss, Assistant Inspector General for the Department of Health and Human Services Office of Inspector General.

On September 8, 2017, Republican Members of the Committee sent letters to 19 entities in the 340B program requesting information about the entities' savings from the program, charity care provided, and how entities use 340B savings.[19] We expect these subjects and issues to be discussed at the hearing, particularly the amount of savings generated and how those savings are used to further essential services.

V. WITNESSES

Michael Gifford
President and Chief Executive Officer
AIDS Resource Center of Wisconsin

Sue Veer, MBA, CMPE
President and Chief Executive Officer
Carolina Health Centers

Charles Reuland, MHS, Sc.D
Executive Vice President and Chief Operating Officer
Johns Hopkins Hospital

Ronald Paulus, MD
President and Chief Executive Officer
Mission Health

Shannon Banna
Director of Finance and System Controller
Northside Hospital

[19] Letter from Rep. Greg Walden, Chairman, Committee on Energy and Commerce, and Rep. Tim Murphy, Chairman, Subcommittee on Oversight and Investigations, to ARcare, et al. (Sept. 8, 2017).