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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
Minority (202) 225-3641

MEMORANDUM

July 14, 2017

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining HRSA's Oversight of the 340B Drug Pricing Program"

On **Tuesday, July 18, 2017, at 10:15 a.m. in room 2322 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Examining HRSA's Oversight of the 340B Drug Pricing Program."

I. BACKGROUND

The 340B Drug Pricing Program requires drug manufacturers to provide discounts on outpatient prescription drugs to certain safety net health care providers, known as covered entities.[1] Covered entities include, but are not limited to, some disproportionate share hospitals ("DSH" hospitals), Federally Qualified Health Centers, family planning clinics, Black Lung clinics, hemophilia clinics, and AIDS Drug Assistance Programs.[2] Drug manufacturers must provide these discounts in order to have their drugs covered by state Medicaid programs.

The 340B program sets a price ceiling on covered prescription drug prices. Covered entities realize an estimated 20 percent savings off the cost of these drugs as a result.[3] These savings represent a very small percentage, however, of the overall U.S. drug market.[4]

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[1] Pub. L. 102-585.

[2] U.S. Government Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* (Sept. 2011) (GAO-11-836).

[3] U.S. Department of Health and Human Services, *Health Resources and Services Administration FY 2016 Justification of Estimates for Appropriations Committees* (www.hrsa.gov/about/budget/budgetjustification2016.pdf).

[4] *Id.*

As of January 2017, there were approximately 12,000 unique 340B covered entities participating in the 340B program, and approximately 19,000 unique contract pharmacies in the 340B database.[5]

II. PURPOSE OF THE 340B PROGRAM

Congress passed bipartisan legislation establishing the 340B program in 1992. A primary purpose of the program is to help "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[6] 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. The savings also enable covered providers to offer access to care to newly insureds, underinsureds, and the uninsured.

340B discounts enable hospitals and providers to offer high levels of care to low-income patients. For example, a recent study commissioned by an organization that represents 340B covered entities found that in 2012, 340B DSH hospitals provided $24.6 billion in uncompensated charity care.[7] These care levels represent approximately 60 percent of all charity care across the country, despite the fact that DSHs make up only 35 percent of hospitals.[8] More Medicaid and low-income Medicare patients receive treatment at 340B- than at non-340B hospitals. And, 340B hospitals are more likely than non-340B hospitals to provide specialized services, such as trauma, HIV/AIDS, and maternity and obstetrics services.[9] Accordingly, 340B providers depend on these savings to provide quality health care service to more patients, including low-income patients.[10]

In addition, 340B providers often form arrangements with pharmacies to provide services. These arrangements enable 340B entities who lack access to available "in-house" pharmacy services, or who need to supplement their "in-house" services, to take advantage of the 340B program. These "contract pharmacy" services are essential to rural hospitals. A recent survey of rural providers showed that 87 percent rely on such an arrangement to help them keep their doors open.[11] Likewise, 89 percent of 340B DSH hospitals reported maintaining or

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[5] Briefing by GAO staff to House Committee on Energy and Commerce Staff (July 10, 2017).

[6] *Pharm. Research & Mfrs. Of Am. v. United States HHS*, 2015 U.S. Dist. LEXIS 139617 at *8 (D.D.C. Oct. 14, 2015) (citing H.R. Rep. No. l102-384, pt.2, at 12 (1992)); *see* Pub. L. No. 102-585, 106 Stat. 4943, 4967.

[7] Dobson DaVanzo & Associates, *Analysis of 340B DSH Hospital Services Delivered to Vulnerable Patient Populations* (2015).

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] 340B Health, *340B Hospitals Use Their Contract Pharmacy Benefit to Treat Low-Income and Rural Patients* (2017).

providing more uncompensated care through their 340B contract pharmacy arrangements, and 71 percent reported using these arrangements to provide free or discounted drugs to low-income and rural patients.[12]

On July 13, 2017, the Centers for Medicare & Medicaid Services issued a proposed rule 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, effective for 2018.[13] If finalized, this proposed rule would result in a significant reduction in revenues, particularly for those in the program that are safety net providers.

III. GAO AND OIG REVIEWS OF THE 340B PROGRAM

The U.S. Government Accountability Office (GAO) reviewed the 340B program in 2011 and 2015. These reviews culminated in four recommendations to the Health Resources and Service Administration (HRSA), which oversees the 340B program, including that HRSA should: (1) conduct selective audits of 340B entities; (2) finalize new guidance on the definition of a 340B patient; (3) refine its 340B nondiscrimination guidance for manufacturer distribution of drugs; and (4) issue guidance on the definition of eligible hospitals.[14] Recommendations two and four are currently outstanding.

In 2014 and 2016, the U.S. Department of Health and Human Services Office of Inspector General (OIG) released reports on covered entities' contract pharmacy arrangements and their oversight of those arrangements. The 2014 report found that covered entities categorize similar prescriptions differently, leading to inconsistency within the 340B program as to which prescriptions are treated as 340B-eligible. That report also found that covered entities may have difficulty preventing diversion of 340B drugs to non-340B patients, in preventing duplicate discounts, and in complying with the oversight activities recommended by HRSA.[15]

The 2016 OIG report found that most State Medicaid agencies use methods that identify providers using 340B-purchased drugs; however, these provider-level methods may not accurately identify all individual 340B drug claims. These findings hold importance as inaccurate or incomplete identifications of these drug claims creates a risk of duplicate discounts.[16]

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[12] *Id.*

[13] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs* (July 13, 2017) (proposed rule).

[14] *See* note 2.

[15] U.S. Department of Health and Human Services, Office of Inspector General, *Contract Pharmacy Arrangements in the 340B Program* (Feb. 4, 2014) (OEI-05-13-00431).

[16] U.S. Department of Health and Human Services, Office of Inspector General, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates* (June 2016) (OEI-05-14-00430).

As a result of these reports, HRSA has started to undertake a greater number of audits, which have helped 340B entities to develop and implement corrective action plans to fix 340B compliance issues. HRSA has also started to audit manufacturer compliance, though its authority to provide oversight of issues, such as manufacture compliance with ceiling prices, is limited in the absence of specific regulations granting it enforcement authority.

IV. WITNESSES

Krista M. Pedley, PharmD, MS, Captain, USPHS
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
U.S. Department of Health and Human Services

Debra Draper
Director, Health Care
U.S. Government Accountability Office

Erin Bliss
Assistant Inspector General
Office of Evaluation and Inspections
Office of Inspector General
U.S. Department of Health and Human Services