

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

June 1, 2017

Mr. George Sigounas
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Administrator Sigounas:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is conducting oversight into the implementation of the 340B Drug Pricing Program. Under the purview of the Health Resources and Services Administration (HRSA), the 340B program mandates that drug manufacturers provide outpatient drugs to eligible hospitals and health care centers (“covered entities”) at reduced prices. Drug manufacturers must provide these drugs at reduced prices in order to remain eligible for reimbursements through Medicare and Medicaid. Citing a Committee report from the time the legislation was passed, HRSA states that the purpose of the 340B program is to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹ Through the program, covered entities report saving between 24 and 50 percent of the average wholesale price for covered outpatient drugs.²

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,”³ which has increased program enrollment substantially.⁴ 340B drug sales

¹ HRSA, 340B Drug Pricing Program, <https://www.hrsa.gov/opa/>.

² Health Affairs, Health Policy Brief, *The 340B Drug Discount Program*, Nov. 17, 2014, available at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_130.pdf.

³ HemOnc, “Growth of 340B program triggers ‘battle over big money’” HEMONC (Aug. 25, 2014).

⁴ Rena M. Conti & Peter B. Bach, *Cost Consequences of the 340B Drug Discount Program*, JAMA, (May 15, 2013).

more than doubled between 2010 and 2015 and expanded by 66 percent between 2013 and 2015 alone.⁵ As of 2011, nearly a third of all U.S. hospitals participated in the program.⁶

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. About half of covered entities interviewed by the Government Accountability Office (GAO) in 2011 stated that they “generated revenue through the 340B program that exceeded drug-regulated costs.”⁷ That same report indicated, “covered entities generally reported using the 340B program to support or expand access to services.” 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.

Additionally, HRSA’s audits commonly find that covered entities bill for duplicate discounts on the same drug, and divert 340B drugs to ineligible patients. A duplicate discount occurs when a covered entity purchases a drug with an up-front 340B discount and is credited with a back-end Medicaid rebate. HRSA found that around 23 percent of covered entities audited had duplicate discounts each year from 2012 to 2016. The Department of Health and Human Services Office of the Inspector General is also concerned about the prevalence of duplicate discounts, and released a report last June finding that duplicate discounts are particularly common with Medicaid Managed Care Organizations.⁸

HRSA’s audits also revealed that covered entities have violated program requirements by reselling or transferring 340B drugs to ineligible patients. In FY 2012, FY 2015, and FY 2016, close to half of HRSA’s audited entities diverted benefits to ineligible patients. Just as the rate of duplicate discount violations has remained steady, incidents of diversion have not decreased with the implementation of the audit process.

According to an Office of Pharmacy Affairs Update issued on July 3, 2014, HRSA indicated that covered entities whose findings involve potential reimbursement to affected manufacturers or wholesalers would be subject to an audit in the following year.⁹ However, none of the audited entities that received duplicate discounts for drugs in FY 2015, a year after the release of the OPA Update, were audited in FY 2016. Only one of 81 non-complying entities in FY 2014 was audited again the next year. While the non-complying entity was found to have committed the same violation two years in a row, HRSA did not conduct an additional

⁵ Aaron Vandervelde & Eleanor Blalock, 340B PROGRAM SALES FORECAST: 2016-2021, Berkeley Research Group I (Dec. 2016).

⁶ Government Accountability Office (GAO), *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

⁷ GAO, *Manufacturer Discounts in the 340B Program Offer Benefits*.

⁸ See, Office of Inspector General (OIG), *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016).

⁹ Office of Pharmacy Affairs (OPA), *340B Audit Process* (July 3, 2014)

<https://www.hrsa.gov/opa/updates/july2014.html> (explaining timeline and materials of auditing process).

investigation in FY 2016. HRSA's lack of follow-up audits when it finds violations is troubling, and combined with the high rate of noncompliance, indicates a need for additional oversight of this program.

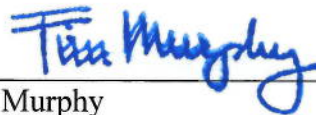
To assist with the Committee's oversight of the 340B program, please provide all documents collected by HRSA referring or relating to covered entity audits conducted during FY 2015 and FY 2016, including but not limited to items #1, #2, and #3 in the Covered Entity Data Request document provided to the Committee by June 15, 2017.

Thank you for your prompt attention to this matter. An attachment to this letter provides additional information about how to respond to the committee's request. If you have any questions regarding this request, please contact Brighton Haslett or Jennifer Barblan with the majority committee staff at (202) 225-2927.

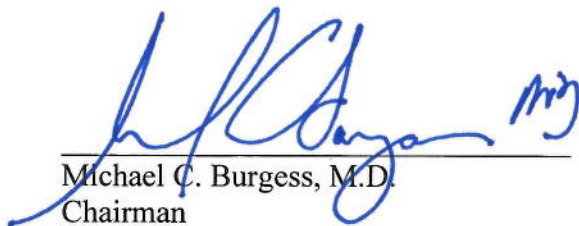
Sincerely,



Greg Walden
Chairman
Committee on Energy and Commerce



Tim Murphy
Chairman
Subcommittee on Oversight and
Investigations



Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

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

Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

Gene Green, Ranking Member
Subcommittee on Health

Attachment