October 30, 2020

Via 340B@help.senate.gov and 340B@mail.house.gov

The Honorable Lamar Alexander
Chairman, Committee on Health, Education, Labor, Pensions
Washington, D.C. 20510

The Honorable Greg Walden
Ranking Member, Energy and Commerce Committee
Washington, D.C. 20515

Re: Request for Input on the 340B Drug Pricing Program

Dear Chairman Alexander and Ranking Member Walden:

On behalf of our members, more than 1,400 public and nonprofit hospitals that participate in the federal 340B drug pricing program, 340B Health is writing in response to your request for input on improvements to the 340B program.[1]

The 340B program plays an important role in financing healthcare services to low-income and rural patients. 340B hospitals use their program savings to support a variety of health care services for their patients, and the program is more critical than ever in light of the challenges faced by hospitals in response to the COVID-19 pandemic.

However, drug manufacturers have recently begun denying 340B pricing to covered entities, in violation of the 340B statute, and we understand manufacturers are considering other actions that could limit access to 340B pricing. To improve the 340B program, we request that Congress use its oversight powers to ensure that the Department of Health and Human Services (HHS) is enforcing the 340B statute and using its existing authority to penalize manufacturers that are not meeting their 340B obligations. We offer the following recommendations for actions that Congress should ensure HHS takes to enforce the statute:

1. HHS should notify manufacturers that they must offer 340B pricing for drugs ordered by covered entities to be dispensed through contract pharmacies and should impose civil monetary penalties against manufacturers that deny 340B pricing in such instances; and

[1] Walden and Alexander Ask for Input on Modernizing 340B Drug Pricing Program (Oct. 9, 2020), https://republicans-energycommerce.house.gov/news/walden-and-alexander-ask-for-input-on-modernizing-340b-drug-pricing-program/.

2. HHS should notify manufacturers that they may not adopt a rebate model to offer 340B pricing without HHS first issuing guidance through the notice-and-comment process allowing a rebate model and directing how it would work.

Below, we share examples of the value of the 340B program to hospitals and how hospitals use 340B savings to finance care for low-income and rural patients. We also outline in more detail steps that Congress can take to oversee HHS and ensure manufacturers are providing 340B pricing as required by the 340B statute.

I. The 340B Program is Working as Intended to Finance Care for Low-Income and Rural Patients

Our members encompass a broad spectrum of hospitals that participate in the 340B program, including academic medical centers, community hospitals, children's hospitals, and rural facilities. Congress created the 340B drug pricing program to allow safety-net providers "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2] Consistent with this purpose, hospitals use the financial benefit created by 340B drug pricing discounts to finance care for patients who are uninsured and underinsured or who live in isolated rural areas.

340B hospitals are a critical element of America's safety net. 340B hospitals report using their program savings to support patients in a variety of ways, including maintaining or providing more patient care services and supporting uncompensated and unreimbursed care.[3] Examples of specific uses of 340B include, but are not limited to, running a multi-disciplinary diabetes program, funding an HIV/hepatitis C specialty clinic, subsidizing chemotherapy and immunotherapy for Medicaid and uninsured patients, and dispensing free and low-cost medications.[4]

340B hospitals have a documented record of providing high levels of care to individuals with low incomes. 340B hospitals provide 60 percent of uncompensated care.[5] And, although 340B disproportionate share (DSH) hospitals represent 43 percent of hospitals, they provide 75 percent of all hospital care to Medicaid patients,[6] who have a higher burden of illness and have payment rates below cost, thus creating special challenges for these hospitals.[7]

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[2] H.R. Rep. 102-384(II) at 12 (1992).
[3] 2019 340B Health Annual Survey, https://www.340bhealth.org/files/340B-Health-Survey-Report-2019-FINAL.pdf.
[4] *Id.*
[5] L&M Policy Research, Analysis of Disproportionate Share Hospital Services to Low-income Patients (2018) https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf
[6] Dobson DaVanzo, The Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients (2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.
[7] Medicaid and CHIP Payment and Access Commission (MACPAC) and Medicare Payment Advisory Commission (MedPAC), Data Book: Beneficiaries Dually Eligible for Medicare and Medicaid. 2018, https://www.macpac.gov/wp-content/uploads/2020/07/Data-Book-Beneficiaries-Dually-Eligible-for-Medicare-andMedicaid-January-2018.pdf; American Hospital Association,. Underpayment by Medicare and Medicaid

The patient characteristics of 340B hospitals also reflect their vital role as safety-net providers. Medicare patients of 340B DSH hospitals are 43 percent more likely to be low income, 29% more likely to be disabled, and 66 percent more likely to be Black or African American than patients of non-340B hospitals.[8] 340B hospitals play a special role in the cancer care safety net, an area with large disparities in outcomes and very high drug costs. Medicare cancer patients of 340B DSH hospitals are 57 percent more likely to be low income, 36 percent more likely to be disabled, 78 percent more likely to be Black, and 92 percent more likely to be Hispanic than those of non-340B hospitals.[9]

Further, 340B DSH hospitals are much more likely than non-340B hospitals to provide essential health care services that are vital to low-income patients, but are often under-reimbursed, including HIV/AIDS services, trauma care, and outpatient alcohol/drug abuse services.[10] The crucial role of 340B DSH hospitals in the safety net is accompanied by substantially lower— negative on average—operating margins than those of non-340B hospitals.[11]

And finally, in addition to improving access to care for low-income and rural patients, 340B is linked to slower growth in drug prices for all Americans, according to independent research. Contrary to claims by drug companies that 340B raises drug prices, a recent study appearing in the Journal of the American Medical Association concluded the opposite: the 340B program helps constrain drug price growth, even for drugs not sold through 340B. The research found that the inflation penalties built into the 340B program to penalize manufacturers that increase drug prices faster than inflation are working to keep those price hikes in check.[12]

II. Congress Should Ensure that HHS is Enforcing the 340B Statute and Taking Action Against Non-Compliant Manufacturers

In your statement requesting input on improvements to the 340B program, you recognized that the Health Resources and Services Administration (HRSA) "must use its existing authorities to the fullest extent to make certain that the 340B program is serving health care providers and patients

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Factsheets, 2016-2020, https://www.aha.org/fact-sheets/2020-01-07-fact-sheet-underpayment-medicare-and-medicaid.

[8] L&M Policy Research. A Comparison of Characteristics of Patients Treated by 340B Hospitals (2019), https://www.340bhealth.org/files/340B_Patient_Characteristics_Report_FINAL_04-10-19.pdf

[9] Dobson DaVanzo. Characteristics of Cancer Patients Receiving Drugs at 340B DSH Hospitals, Non-340B Hospitals, and Physician Offices (2020), https://www.340bhealth.org/files/340B_Oncology_Demographics_Issue_Brief_Final.pdf

[10] Dobson DaVanzo, The Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients, supra.

[11] Dobson DaVanzo, The Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients, supra.

[12] Dickson S. Association Between the Percentage of US Drug Sales Subject to Inflation Penalties and the Extent of Drug Price Increases, *JAMA Netw Open.* 2020;3(9):e2016388, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770540

with integrity."[13] As we discuss below, HHS is not using its authority under the statute and regulations to address recent actions by drug manufactures that undermine the 340B program and are in violation of the 340B statute. Congress should ensure that HHS takes actions to address the below issues.

a. Recent Manufacturer Actions Requiring HHS Enforcement

Three manufacturers – Eli Lilly, AstraZeneca, and Sanofi – have announced that they will no longer offer 340B pricing to covered entities for drugs dispensed through community pharmacies under contract with a covered entity. Two other manufacturers – Merck and Novartis – have sent demands to 340B covered entities for millions of contract pharmacy claims, threatening to deny 340B discounts or take other burdensome actions if their demands are not met.

Meanwhile, manufacturer consultant Kalderos recently launched a product through which participating manufacturers would implement a process for payment of rebates, rather than providing upfront discounts, to covered entities for some or all of the manufacturers' drugs subject to 340B pricing. Such a rebate model has the potential to increase costs to covered entities, make it more difficult to access 340B pricing, and in some cases result in denials of 340B pricing.

In response to both manufacturer denials of 340B pricing and their consideration of a 340B rebate model, covered entities have called on HHS to take action to enforce the 340B statute and stop manufacturers from limiting access to 340B discounts. HHS has not taken enforcement actions. As such, Congress should use its oversight powers to ensure HHS is enforcing the 340B statute and holding manufacturers accountable.

Below, we provide more detail on the harm to patient care resulting from manufacturer denials of 340B pricing for drugs dispensed through contract pharmacy. We also outline the steps HHS should take to ensure manufacturers are providing 340B pricing consistent with the statute.

b. Denials of 340B Pricing for Drugs Dispensed Through Contract Pharmacy Undermine the 340B Benefit for Safety-Net Hospitals and the Patients They Serve

The ability to access the 340B financial benefit through contract pharmacy arrangements is critical to ensuring care low-income and rural patients. Based on survey data, about 25% of the 340B benefit for our member hospitals overall is provided through contract pharmacy arrangements, and that portion rises to 51% for rural sole community hospitals and to 57% for critical access hospitals.[14] Some rural hospitals have emphasized the importance of their 340B benefit, including

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[13] Walden and Alexander Ask for Input on Modernizing 340B Drug Pricing Program (Oct. 9, 2020), https://republicans-energycommerce.house.gov/news/walden-and-alexander-ask-for-input-on-modernizing-340b-drug-pricing-program/.

[14] 2019 340B Health Annual Survey: 340B Hospitals Use Benefits to Provide Services and Improve Outcomes for Low-income Rural Patients, 340B Health (April 2020), https://www.340bhealth.org/files/340B-Health-SurveyReport-2019-FINAL.pdf.

the benefit from contract pharmacy arrangements, as the difference between keeping the hospital open or shutting its doors.[15]

Manufacturer actions restricting 340B pricing undermine the benefit of the 340B program for covered entities. Refusing to offer 340B pricing for covered outpatient drugs dispensed through community pharmacies reduces the 340B benefit that covered entities use to finance needed health care in their communities. These actions will cause significant harm to safety-net providers participating in the 340B program and the millions of patients with low incomes and those living in rural areas who count on 340B covered entities for their care.

The financial harm to 340B hospitals from these manufacturer actions comes at a time when the resources and finances of these safety-net providers are already severely strained, as safety-net hospitals are on the frontlines of treating COVID-19 patients and ensuring access to care during the pandemic. As a result of COVID-19, hospitals are currently dealing with shortages of equipment and drugs and struggling to cope with massive decreases in revenue that necessitate reductions in expenses and staffing.

c. HHS Has the Authority to Stop Manufacturer Actions Restricting Covered Entities' Access to 340B Pricing

Manufacturer actions denying 340B pricing for drugs dispensed through contract pharmacy arrangements violate the 340B statute. The statute requires "that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[16] There is no provision under the statute that allows a manufacturer to deny 340B pricing to a covered entity based on where the entity elects to have 340B drugs shipped or based on the entity's arrangements for dispensing 340B drugs to its patients.

The 340B statute also calls for the imposition of civil monetary penalties (CMPs) for an instance of overcharging by a manufacturer.[17] Regulations promulgated by HRSA define an instance of overcharging as "any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price … for that covered outpatient drug."[18]

HHS clearly has authority under the statute and the civil monetary penalties regulation to take action to stop manufacturer actions that restrict covered entities' access to 340B pricing for covered outpatient drugs.

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[15] *Id.*
[16] 42 U.S.C. § 256b(a)(1).
[17] 42 U.S.C. § 256b(d)(1)(B)(vi).
[18] 42 C.F.R. §10.11(b).

d. HHS Must Determine Whether Manufacturers May Use a Rebate Model Under 340B and Must Provide for Public Notice and Comment Before Making That Determination

Drug manufacturer vendor Kalderos has indicated that under its product, 340B Pay, covered entities would be required to purchase the participating manufacturers' drugs at higher non-340B prices and submit requests for rebates that would be paid at a later date. We also understand that, under the rebate model, manufacturers would have the ability to deny 340B rebate requests, resulting in the covered entity not accessing 340B pricing and paying a higher price. We are concerned that manufacturers would be able to essentially audit individual rebate claims and unilaterally deny rebate payments for alleged "noncompliant" transactions. Denying 340B rebate requests could result in an overcharge in violation of the 340B statute.

The imposition of a rebate process would be a fundamental departure from the manner in which the 340B program has operated since its inception and would be contrary to longstanding program guidance providing for operation of 340B as a discount program. Guidance published in 1993 and 1994 made clear that a "discount must be made available" to covered entities through wholesalers.[19] The guidance specifically distinguished discounts from "rebates" and "retroactive discounts," permitting rebates only in the narrow case of making covered entities whole for purchases made prior to initial implementation of 340B.[20] 340B has been administered by HRSA exclusively as a discount program, with only one very narrow exception to accommodate one type of covered entity, which was implemented only after publishing notice in the federal register and providing the opportunity for public comment.[21]

The 340B statute does not permit manufacturers or their vendors to determine unilaterally how covered entities obtain 340B pricing. The statute requires that under each manufacturer's pharmaceutical pricing agreement with the Secretary, "the amount required to be paid (*taking into account any rebate or discount, as provided by the Secretary*) to the manufacturer" for a covered outpatient drug by a covered entity shall not exceed the 340B ceiling price for that drug.[22] Congress provided the Secretary with "the discretion to determine the mechanism (rebate, point-of-purchase discount, or otherwise) for assuring [the] price reduction" to covered entities and expected that the

[19] 1 Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994) (Final Notice on Entity Guidelines) (emphasis added); *see also* Guidance Regarding Section 602 of the Veterans Health Care Act of 1992; Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27291 (May 7, 1993) (Notice on Initial Guidance) ("discounts" must be passed through wholesalers to covered entities).

[20] Final Notice on Entity Guidelines, 59 Fed. Reg. 25112; Notice on Initial Guidance, 58 Fed. Reg. 27291, 27292. The 1993 initial program guidance stated that covered entities added to updated eligibility lists would be eligible for "drug discounts" only for purchases on or after their inclusion on the eligibility list and that HHS was "notifying each covered entity of its eligibility to purchase drugs at the discounted prices."

[21] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45823 (Aug. 29, 1997) (Notice on Proposed Rebate Option); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35239 (June 29, 1998) (Final Notice on Rebate Option).

[22] 42 U.S.C. § 256b(a)(1) (emphasis added).

Secretary would "use the mechanism that is the most effective and most efficient from the standpoint of each type of 'covered entity.'"[23]

Thus, the statute prohibits manufacturers from restricting access to 340B pricing through a mandatory rebate process unless the Secretary provides for a rebate model, after determining that doing so would be most effective for the covered entity. The Secretary should prevent manufacturers from implementing a rebate model until guidance has been issued, subject to notice and public comment, directing how a rebate model would work.

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Thank you for the opportunity to provide input regarding ways to improve the 340B program. We appreciate your support of safety-net providers and would be happy to discuss our recommendations in more detail. Please contact me if you have questions, or feel free to have a member of your team contact Kathryn DiBitetto (kathryn.dibitetto@340bhealth.org) or Kate Ilahi (kate.ilahi@340bhealth.org) in our government affairs department.

Sincerely,

/s/

Maureen Testoni

President and CEO, 340B Health

[23] H.R. Rep. No. 102–384, 102d Cong., 2d Sess., pt. 2, at 16 (1992).