THE 340B COALITION

July 16, 2018

Secretary Alex Azar
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: RIN 0991-ZA49 – Comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (submitted via Federal eRulemaking Portal: http://regulations.gov)

Dear Secretary Azar:

On behalf of the thousands of safety-net providers enrolled in the 340B federal drug discount program, the 340B Coalition respectfully submits these comments in response to the Request for Information (RFI) published in the Federal Register on May 16, 2018.[1] We appreciate the Administration's desire to address high drug prices and the opportunity to comment on this important issue. The RFI asked whether current policies might be contributing to high drug costs, including whether 340B might be causing pharmaceutical manufacturers to raise their prices. As you evaluate different strategies for addressing the problem of high drug costs, we request that you consider the strong evidence that 340B does not play a role in high drug prices because of the program's small size compared to the total drug market. We also ask you to consider the importance of 340B to the U.S. healthcare safety net for both providers and patients, particularly those who are low-income, vulnerable, and live in rural areas. Lastly, we suggest steps that the Administration could take to strengthen the program and lower the prices charged by manufacturers, including imposing civil monetary penalties (CMP) on manufacturers that knowingly and intentionally overcharge 340B covered entities, enforcing the penny pricing policy, and releasing the 340B ceiling price database for covered entities.

I. Given 340B's Small Share of the Total Drug Market, the Program Cannot Be a Driver of High Drug Prices

The RFI asks whether 340B discounts increase manufacturers' list prices for drugs. There is strong evidence supporting 340B not being a driver of high drug prices. 340B discounts account for less than two percent of overall manufacturer revenues.[2] Medicare Part D brand-name drugs' unit costs increased nearly six times more quickly than the inflation rate from 2011 to

[1] HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22,008 (May 7, 2018).
[2] Coukell A, Dickson S, "Reforming the 340B Drug Pricing Program: Tradeoffs Between Hospital and Manufacturer Revenue," JAMA Internal Medicine (May 21, 2018), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2681652?redirect=true.

2015.[3] Such steep rise in list prices cannot be caused by 340B given the program's small size relative to total spending. We also note that the total volume of 340B discounts is significantly smaller than the total volume of rebates that manufacturers pay to health plans and pharmacy benefit managers (PBMs). In 2015, 340B discounts totaled $6.1 billion, while health plan and PBM rebates totaled $57.7 billion.[4]

II. 340B Plays a Vital Role in the U.S. Healthcare Safety Net, Enabling Covered Entities to Better Serve Their Patients

The congressional purpose behind the 340B program is to help safety-net providers "reach[] more . . . patients" and furnish "more comprehensive services" by allowing them to purchase drugs at affordable prices.[5] Covered entities fulfill this purpose in a wide variety of ways.

As explained below, multiple reports and national data demonstrate that the 340B program is used by hospitals that provide a high level of care to low-income patients. 340B DSH hospitals treat 64 percent more Medicaid and low-income Medicare patients than non-340B hospitals.[6] Although 340B DSH hospitals account for only 38 percent of all Medicare acute care hospitals, they provide nearly 60 percent of all uncompensated care.[7] 340B DSH hospitals are also significantly more likely than non-340B hospitals to offer vital health care services that are often unreimbursed, including trauma centers, HIV/AIDS services, and immunizations.[8] Compared to non-340B providers, 340B DSH hospitals treat many more Medicare Part B beneficiaries who are low-income cancer patients, dually eligible for Medicaid, disabled, have end stage renal disease, or are racial or ethnic minorities.[9] Children's hospitals similarly rely on 340B to provide care to the low-income patients they serve: On average, more than half of the patients treated in children's hospitals are covered by Medicaid. Rural hospitals also rely on

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[3] Increases in Reimbursement for Brand-Name Drugs in Part D, HHS Office of the Inspector General, OEI-03-15-00080, June 4, 2018.

[4] Dobson DaVanzo, Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers 5 (July 2017), https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf.

[5] H.R. Rep. 102-384, 102d Cong., pt.2, at 12 (2d Sess. 1992).

[6] Dobson DaVanzo, Analysis of Patient Characteristics among Medicare Recipients of Separately Billable Part B Drugs from 340B DSH Hospitals and Non-340B Hospitals and Physician Offices (Nov. 15, 2016), http://www.340bhealth.org/files/Demographics_Report_FINAL_11.15.2016.pdf.

[7] L&M Policy Research, Analysis of 340B Disproportionate Share Hospital Services to Low-income Patients (Mar. 12, 2018) https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf.

[8] *Id.*

[9] Dobson DaVanzo, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017), http://www.340bhealth.org/files/LowIncomeOncology.pdf; Dobson DaVanzo, Analysis of Patient Characteristics among Medicare Recipients of Separately Billable Part B Drugs from 340B DSH Hospitals and Non-340B Hospitals and Physician Offices (Nov. 15, 2016), http://www.340bhealth.org/files/Demographics_Report_FINAL_11.15.2016.pdf.

340B savings, given the financial struggles they face. 86 rural hospitals have closed since 2010 and more are squeezed by reduced reimbursements and rising healthcare costs.[10]

Many covered entities rely on their 340B program savings to meet the needs of their low-income patients. For example, one 340B hospital participant uses 340B savings to fund financial navigators who assist newly diagnosed cancer patients in locating and applying for resources such as grants and Medicaid. The navigators collaborate with patients to address their financial concerns so they can focus on their health and well-being. We know of another covered entity that uses 340B savings to provide free outreach clinics to the Amish community, which is uninsured and geographically and culturally isolated. Another covered entity uses 340B savings to employ a Patient Assistance/Indigent Coordinator who helps ensure that indigent cancer patients are able to achieve their life-saving chemotherapy regimens. Savings from the 340B program also support a comprehensive Language Access and Communication Service Center, the first of its kind in the nation, that assists patients with hearing or sight impairment, literacy issues, or limited English proficiency to navigate the healthcare system.

340B discounts also support a discharge counseling program that integrates a pharmacist into patients' discharge planning to augment the transition of care. Yet another example is an antimicrobial stewardship program that allows a pharmacist to review antibiotic regimens for appropriateness and safety to prevent the unnecessary use of antibiotics to stem the incidence of antibiotic-resistant microbes. The program enables covered entities to provide take-home medication packages for patients in rural areas to provide them with treatment until pharmacies are open. Savings from the program support underfunded home infusion and anticoagulation services.

340B savings are equally important to non-hospital covered entities that are often small and operate on modest budgets. Ryan White grantees use 340B savings to hire additional clinical staff, provide access to substance use and mental health services, and support other critical services that otherwise would not be provided. One Ryan White grantee uses the savings to meet the goals of the National HIV/AIDS Strategy 2020[11] by providing specialized and primary medical services, dental care and other services to people living with HIV/AIDS. Another Ryan White grantee uses lower 340B drug costs to enable a program for children and families that provides tutoring, mentoring, life skills, child and family advocacy, and other support services to children, youth, and parents living with HIV. Many of these services are not reimbursed by payers and would not be available without the savings offered by the 340B program. A Ryan White clinic uses the savings to assist patients with overcoming barriers to maintaining access to treatment, including transportation and housing.

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[10] NC Rural Health Research Program, 85 Rural Hospital Closures: January 2010 – Present, http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

[11] National HIV/AIDS Strategy for the United States: Update to 2020 (July 2015), https://files.hiv.gov/s3fs-public/nhas-update.pdf.

Federally Qualified Health Centers use the savings from the 340B program to provide free or heavily discounted medications to indigent, underinsured or uninsured patients under 200% of the federal poverty level. Savings from the 340B program support a wide range of services in their communities, including but not limited to opioid treatment services, clinical pharmacy services, increased access to dental services, home visits, and expanded hours.

Comprehensive hemophilia treatment centers use 340B program savings to maintain and expand clinical services for all bleeding disorders patients seen at their centers. These services include non-reimbursable services like coordination of care with primary care physicians, social work services and physical therapy assessments. Hemophilia treatment centers also use savings to provide patients with clinics where the centers bring care to patients who are otherwise unable to travel to the clinic.

III. HHS Should Use Its Existing 340B Authority to Strengthen the Program, Which Would Help Lower Drug Prices

Manufacturer overcharges have long plagued the program. The Department of Health and Human and Human Services (HHS) Office of Inspector General (OIG) has repeatedly reported on manufacturer overcharges. In 2003, the OIG reviewed sales of eleven prescription drugs by five manufacturers during the one-year period ending September 30, 1999 to determine whether the manufacturers overcharged 340B covered entities.[12] The OIG determined all five manufacturers overcharged 340B covered entities for all eleven drugs, and one of the drugs should have had a 340B ceiling price of a penny.[13] The Health Resources and Services Administration's (HRSA) penny pricing policy, which requires manufacturers to sell covered outpatient drugs to covered entities for a penny when the ceiling price calculation results in a price of $0.00, disincentivizes manufacturers from increasing drug prices much more quickly than the rate of inflation. The overcharges totaled $6.1 million, which was 45 percent of the amount paid by covered entities during the one-year period.[14]

In 2005, the OIG issued another report that focused on "Deficiencies in the Oversight of the 340B Drug Pricing Program."[15] One of the OIG's key findings was that "HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price."[16] The OIG reported that, in 2001, HRSA analyzed the drug prices charged to six hospitals and "found that 37 of the 50 drug prices exceeded the ceiling price."[17] HRSA "did not

[12] Dep't of Health & Human Servs. (HHS) Office of Inspector Gen. (OIG), A-06-01-00060, Pharmaceutical Manufacturers Overcharged 340B-Covered Entities 3 (2003), https://oig.hhs.gov/oas/reports/region6/60100060.pdf.
[13] *Id.*
[14] *Id*. at 3-4.
[15] HHS OIG, OEI-05-02-00072, Deficiencies in the Oversight of the 340B Drug Pricing Program (2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.
[16] *Id*. at ii-iii, 15-17.
[17] *Id.* at 17.

pursue the issue further, citing insufficient authority."[18] The OIG viewed HRSA's limited options for enforcing manufacturer compliance as significant shortcomings in the 340B program. Thus, the OIG recommended that "HRSA should seek authority to establish penalties for [340B] violations."[19] Also in 2005, an OIG Deputy Inspector General testified before the House Committee on Energy and Commerce that "HRSA should seek legislative authority to impose civil monetary penalties for situations of noncompliance."[20] CMPs were necessary "because the current penalty of kicking manufacturers out of Medicaid and the 340B program is so draconian that it's not likely to be utilized."[21]

In 2006, the OIG issued a report titled "Review of 340B Prices," which found that 14 percent of the sampled purchases made by 340B covered entities exceeded the 340B ceiling price.[22] The largest overcharges were due to manufacturers' failure to comply with HRSA's penny pricing policy.[23] OIG restated in the report its recommendation that HRSA establish penalties for 340B violations by manufacturers: "it is important that HRSA have sufficient penalty authority."[24]

Following these reports and hearings, Congress added the CMP provisions to the 340B statute in 2010. A year later, the Supreme Court noted that manufacturers overcharge covered entities, and the Court emphasized the importance of the CMP provisions:

> Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers. 124 Stat. 823–827, 42 U.S.C.A. § 256b(d). Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaining of 'overcharges and other violations of the discounted pricing requirements,' . . . .[25]

HRSA published a final regulation on January 5, 2017 to implement CMPs and to address ceiling price calculations, including codification of HRSA's penny pricing policy.[26] The agency

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[18] *Id.*
[19] *Id*. at iv, 22.
[20] Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce, 109th Cong. 20 (2006) (testimony of Stuart Wright, Deputy Inspector General for Evaluation & Inspections, HHS OIG), http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf.
[21] *Id.*
[22] HHS OIG, OEI-05-02-00073, Review of 340B Prices i, 10 (2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.
[23] *Id.*
[24] *Id.* at ii, 20-21.
[25] *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 121-22 (2011).
[26] Final Rule, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (Jan. 5, 2017).

initially planned to enforce the final rule on April 1, 2017, but HHS has delayed enforcement of the final rule on five occasions, most recently until July 1, 2019.[27]

In the meantime, concerns about manufacturer overcharges continue. For example, the pharmaceutical manufacturer Mylan recently entered a settlement with the federal government, under which Mylan agreed to pay $19.3 million plus interest to 340B covered entities to resolve allegations that the company overcharged entities for the drug EpiPen.[28] In addition, HRSA recently acknowledged that "manufacturers have informed HHS over the last several years that they charged more than $0.01 for a drug with a ceiling price below $0.01.[29]

We encourage HHS to immediately implement the final rule, including enforcing the penny pricing policy. The final rule will not only strengthen 340B program compliance, but also further the Administration's goal of controlling drug costs. It will give HHS an effective penalty to impose on manufacturers that overcharge covered entities and to deter other manufacturers from doing so. The final rule will codify and reinforce HRSA's penny pricing policy that discourages manufacturers from increasing drug prices far in excess of the rate of inflation. The policy may motivate manufacturers to stem the rate of increase of certain drug prices in order to prevent a 340B price of a penny, thus benefiting all drug purchasers nationwide.

We also recommend that HHS release the 340B ceiling price database for covered entities. A major deficiency in the 340B program from the beginning has been the lack of information on 340B ceiling prices. The program cannot function as intended if covered entities cannot determine whether manufacturers charge prices in compliance with the law. HHS has long recognized this problem. The OIG found that covered entities cannot independently verify that they receive the correct 340B discount.[30] The OIG recommended that CMS and HRSA work together to ensure accurate and timely pricing data for the government's official record of 340B ceiling prices.[31] The Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce held a hearing on the 340B program in which the Chairman, Ed Whitfield, stated, "It is nonsensical to me that the entities entitled to the 340B discount . . . do not have access to the ceiling prices."[32] To address this deficiency in the program, Congress mandated in 2010 that HHS publish on its website a database of ceiling prices that is accessible

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[27] Final Rule; Further Delay of Effective Date, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 25953 (June 5, 2018).
[28] Settlement Agreement between United States of America and Mylan Inc. & Mylan Specialty L.P. 3 (2017), https://www.justice.gov/opa/press-release/file/990736/download.
[29] Notice of Proposed Rulemaking; Further Delay of Effective Date, 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 20008, 20009 (May 7, 2018).
[30] HHS OIG, OEI-05-02-00072, Deficiencies in the Oversight of the 340B Drug Pricing Program iii, 18 (2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.
[31] *Id*. at iii, 21.
[32] Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce, 109th Cong., 2 (2006) (testimony of Stuart Wright, Deputy Inspector General for Evaluation & Inspections, HHS OIG), http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf.

to covered entities.[33] As of the date of these comments, the required database is still not operational and is long overdue. At a recent Senate Health, Education, Labor and Pensions Committee hearing, the OIG repeated its call for increased 340B ceiling price transparency, so covered entities can ensure they are paying the correct amount for 340B drugs.[34]

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Thank you again for the opportunity to comment on the important issue of high drug prices. If you have any questions or need additional information, please do not hesitate to reach out to any of the individuals in the attached list of organizational contacts.

Sincerely,

The 340B Coalition

[33] 42 U.S.C. § 256b(d)(1)(B)(iii).

[34] Examining Oversight Reports on the 340B Drug Pricing Program Hearing Before the Senate Committee on Health, Education, Labor, and Pensions, 115th Cong., 1 (2018) (testimony of Ann Maxwell, Assistant Inspector General for Evaluation & Inspections, HHS OIG), https://www.help.senate.gov/imo/media/doc/Maxwell.pdf.

Organizational Contacts

Joe Pugliese
President and Chief Executive Officer
The Hemophilia Alliance
215-439-7173; joe@hemoalliance.org

Ann Lefert
Senior Director, Policy and Legislative Affairs
National Alliance of State & Territorial AIDS Directors
202-434-7138; alefert@nastad.org

Stephanie Arnold Pang
Director, Policy and Government Relations
National Coalition of STD Directors
202-715-42865; sarnold@ncsddc.org

Andrea Weddle
Executive Director
HIV Medicine Association
703-299-0915; aweddle@idsociety.org

Diane Calmus
Regulatory Counsel
National Rural Health Association
202-639-0550 ext. 2075; dcalmus@nrharural.org

Steven Chen
Manager, Policy Analysis
Children's Hospital Association
202-753-5392; steven.chen@childrenshospitals.org

Beth Feldpush
Senior Vice President of Policy and Advocacy
America's Essential Hospitals
202-585-0111; bfeldpush@essentialhospitals.org

Maureen Testoni
Interim President and Chief Executive Officer
340B Health
202-552-5860; maureen.testoni@340bhealth.org