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July 16, 2018

Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Ave., SW, Room 600E
Washington, DC 20201

RE: RIN 0991-ZA49; HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs – (Section on the 340B Drug Pricing Program)

Dear Secretary Azar:

On behalf of our nearly 5,000 member hospitals, health systems, other health care organizations, including more than 1,900 hospitals that participate in the 340B Drug Pricing Program, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – the American Hospital Association (AHA) appreciates the opportunity to submit comments on the 340B section of the Department of Health and Human Services' (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

For more than 25 years, the 340B program has been critical in expanding access to lifesaving prescription drugs and comprehensive health care services in vulnerable communities across the country, including to low-income and uninsured individuals. Congress established the 340B program in response to the pressure high-drug costs were putting on providers serving communities with the stated objective: “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” At that time, high-drug costs were already straining providers' budgets and challenging their ability to invest in a wide array of services to meet the health care needs of their communities. The 340B program provided the critical relief to address this challenge 25 years ago as it continues to do so today.

Drug manufacturers, however, inappropriately suggest that the 340B program leads to higher drug prices. This is a blatant attempt to divert attention away from their decisions to set and raise drug prices at higher and higher levels, contributing to double-digit margins. For example, in the last 18 months, 20 prescription drugs had price increases of more than



200 percent.¹ Drug manufacturers are solely responsible for setting list prices as well as determining subsequent price increases, and the 340B program represents a very small portion of drug spending nationally. Only some outpatient drugs are subject to 340B discounts; all inpatient drugs, many other outpatient drugs and all retail drugs are not eligible. **According to the most recent data from the Health Resources and Services Administration (HRSA), the 340B program accounted for only 3.6 percent of the total drug market in the U.S. in 2016. Despite this discount program, drug manufacturers were still able to achieve double-digit margins.**

In 2015, 340B hospitals provided \$23.8 billion in uncompensated² care and \$51.7 billion³ in total benefits to their communities. Hospitals were able to provide these benefits despite significant fiscal pressures. Also in 2015, one out of every four 340B hospitals had a negative operating margin, and one in three 340B critical access hospitals (CAHs) had a negative operating margin.⁴

Any focus on the 340B program as part of a plan to lower drug prices is misplaced. Efforts to scale back the program would have devastating consequences for the communities served by 340B hospitals while only driving more revenue to drug manufacturers.

The following comments respond to the specific issues raised in the HHS Blueprint regarding the 340B program.

GROWTH IN THE 340B PROGRAM

HHS asked how growth in the 340B program has affected list prices. Drug manufacturers inaccurately claim that programs such as 340B have driven them to raise prices to unsustainable levels, largely as a result of growth in the program. While the 340B program did expand because of congressional extension of the program to support more vulnerable communities, much of the program growth can be attributed to drug manufacturers' dramatic price increases for outpatient drugs coupled with medical advances that have enabled more care to be provided in the outpatient setting.

Growth in the 340B program can primarily be attributed to three factors:

- **Growth in drug list prices.** Drug manufacturers have significantly increased drug prices, which creates the appearance that the 340B program has grown. As the cost of drugs increases, the value of the discounts correspondingly increase; therefore, the “growth” in the program is generated by the drug manufacturers. For example,

¹ Herman, B. “Drug prices are still going through the roof,” Axios, Mar. 21, 2018. <https://www.axios.com/drug-prices-exploding-2017-1521564090-aa025591-9e50-491d-b3e2-c981e85adb60.html>

² AHA 2015 Annual Survey Data

³ AHA 340B Community Benefit Analysis, March 2018 <https://www.aha.org/system/files/2018-03/340b-community-benefit-analysis.pdf>

⁴ AHA 2015 Annual Survey Data

cancer medication approved in 2000 costs an average of \$1,869 per month compared to \$11,325 for those approved in 2014. The 340B discount for an \$11,325 drug is going to be greater than the discount off a \$1,869 drug. Many stakeholders have questioned the rationale and validity of these drug price increases. Such dramatic increases underscore the importance of the 340B program in preserving access to care.

- **Expansion of the program by Congress.** In 2010, Congress expanded the benefits of the 340B program to additional safety-net hospitals to improve health care access for a greater number of low-income and uninsured patients. Those hospitals included CAHs, rural referral centers (RRCs), sole community hospitals (SCHs) and free-standing cancer hospitals. These hospitals now account for 54 percent of 340B-eligible hospitals. Many of these hospitals are the lifelines of their community, and the discounts they receive through the 340B program play an important role in allowing these organizations to care for patients.
- **Increase in services delivered in outpatient setting.** The last two decades has seen a significant shift in the site of care from the inpatient to the outpatient setting.⁵ As technology and medical knowledge improves, more services can safely and effectively be delivered in the outpatient setting, making the drug therapies used in these services eligible for a 340B discount. Therefore, the underlying trends in health care delivery of the last two decades is a contributing factor behind a portion of the 340B program's growth.

PRIME VENDOR PROGRAM AND GPO PROHIBITION

HRSA established the 340B Prime Vendor Program (PVP) to assist the agency in providing tools and resources for 340B covered entities. For example, the PVP helps promote program integrity and compliance by providing technical resources to 340B-covered entities, sharing best practices and negotiating lower prices on branded and generic pharmaceuticals that are below the 340B drug price. In particular, the PVP has provided 340B-covered entities with educational management and compliance resources. As such, **the AHA believes the PVP provides benefit for 340B-covered entities.**

In 2013, HRSA issued guidance related to Group Purchasing Organization (GPO) prohibition that required hospitals to revise their inventory management practices. This new policy was a departure from previous guidance regarding the statutory GPO prohibition. Our 340B members affected by the prohibition suggest that the 2013 guidance has added burden and cost without enhancing program oversight.

To address some of the issues with HRSA's implementation of the GPO prohibition, the AHA supports HRSA's previously proposed exceptions to its policy. We encourage the agency to move forward with finalizing the proposed exceptions for:

- Hospital off-site outpatient facilities not registered in the 340B program;

⁵American Hospital Association: TrendWatch Chartbook 2018 - Chapter 3: Utilization and Volume
https://www.aha.org/system/files/2018-05/20180302_Chartbook-2018_Chapter-3-Horizontal-Charts.pdf

- Inpatients reclassified as outpatients by a third-party insurer, Medicare Recovery Audit Contractor or hospital review, as long as the patients' status is documented; and
- Situations where patient care would be disrupted if the hospital could not access a drug at 340B prices or wholesale acquisition cost.

In addition, the AHA recommends HRSA allow clinics within the four walls of a hospital to opt-out of the 340B program with appropriate documentation to ensure no 340B drugs are utilized. We also recommend that HRSA implement a monetary "materiality standard" (threshold) that any GPO violation would be required to meet before program expulsion would be considered. HRSA should look to the materiality standards it uses in its 340B hospital recertification process; in the case that erroneous GPO purchases do not exceed the materiality threshold, HRSA should permit a corrective action, such as a credit or payment adjustment of GPO purchases, instead of expulsion from the program.

PROGRAM ELIGIBILITY

HHS asked whether several changes to the program, including the definition of a "patient," are needed to "refocus the program toward its intended purposes." The current 340B patient definition is based on the relationship the eligible patient has with his or her hospital. It includes patients who receive health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity. **Changing the definition of patient in the requirements governing covered entities would do significant harm to patients served by 340B hospitals. The AHA urges HHS to not alter the definition of patient as it applies to the 340B program.**

For example, previous proposals to narrow the definition of "patient" would have significantly reduced the volume of drugs eligible for 340B drug discount pricing, and jeopardized hospitals' ability to serve the most disadvantaged patients in their communities, including low-income patients, uninsured patients and patients receiving cancer treatments. These past proposals to narrow the definition of "patient" have included requiring that a prescription must be the result of a billable outpatient event in order to qualify for 340B drug discount pricing, or specifically exclude patients who receive infusion services only. Limiting the patient definition to a billable outpatient event could apply, for example, to discharge prescriptions intended for outpatient use. Many 340B hospitals have relied on HRSA's current policy to permit discharge prescriptions as they develop programs to reduce avoidable readmissions, particularly for their low-income patients. The ability to use 340B drug pricing for these discharge prescriptions is consistent with the objectives of the 340B program to provide access to pharmaceuticals to low-income populations.⁶ It also is consistent with the national health care objective to reduce avoidable readmissions.

⁶ U.S. House, Committee on Veterans Affairs, "Establishment of Limits on Prices of Drugs Procured by the Department of Veterans Affairs (to accompany H.R. 2890)," H. Rept. 102-384, Pt. 2, 1992.

In addition, past proposals to exclude patients receiving “only” infusion services from the definition of eligible 340B patient could also harm patients’ access to needed care. For example, critical oncology drugs have undergone extraordinary price increases. One study found that the average launch price of oncology drugs, adjusted for inflation and health benefits, *increased by 10 percent annually, or an average of \$8,500 per year, for almost 20 consecutive years* – from 1995 to 2013.⁷ 340B hospitals that provide cancer and other costly infusion services for underserved communities depend on 340B drug discount pricing to provide these vital services. Without the availability of such pricing, patients may lose access to these critical services. Patients in rural areas may be unable, due to their medical condition, age, or other factors, to travel to urban areas to receive these services; availability near their home vastly improves their quality of care and quality of life. About half of 340B hospitals are located in rural areas, and almost half of them offer vital chemotherapy services to their patient populations⁸ – this access point would be severely endangered under such a limitation in the patient definition.

DUPLICATE DISCOUNTS

The 340B statute prohibits a drug manufacturer from providing a Medicaid rebate and a 340B discounted price for the same drug provided to a Medicaid patient. This prohibition of duplicate discounts applies, by statute, to only the Medicaid program and to no other government or commercial payer. To extend the concept of duplicate discount beyond the Medicaid program, as suggested by the Blueprint, would subvert the purpose of 340B. Current efforts to prevent duplicate discounts have placed the burden on the hospitals. State Medicaid agencies and Medicaid managed care plans, in particular, should bear a larger share of the responsibility for preventing duplicate discounts. **The AHA recommends that HRSA engage with state Medicaid programs and Medicaid managed care plans to find ways to identify more easily Medicaid managed care patients to avoid a duplicate discount scenario.**

FY 2019 BUDGET PROPOSAL REGARDING MEDICARE OUTPATIENT PAYMENTS FOR 340B HOSPITALS

In its fiscal year (FY) 2019 budget proposals, the Administration recommends basing Medicare outpatient prospective payment system (OPPS) payments for 340B hospitals, in part, on the hospital providing a minimum amount of uncompensated care. Consistent with our ongoing legal challenge to similar actions taken by the Centers for Medicare & Medicaid Services (CMS) in 2018, we continue to contend that the agency lacks the statutory authority to cut OPPS payments to 340B hospitals in this way. Our assessment of the OPPS statute also finds that CMS does not have the authority to redistribute savings generated by 340B hospital OPPS payments, as proposed in the Administration’s FY 2019 budget. By cutting Medicare OPPS payments, CMS has eviscerated a significant portion of savings that would be used to meet the program intent to “stretch scarce federal resources.” The intent of the 340B program since its inception, is to allow covered entities to leverage their lower acquisition costs to generate “[a]dditional program resources” that will enable

⁷ David Howard, Peter Bach, Ernst Berndt, and Rena Conti, “Pricing in the Market for Anticancer Drugs,” *Journal of Economic Perspectives*, vol. 29, no. 1 (Winter 2015): 139-162.

⁸ American Hospital Association 2017 Annual Survey.

them to provide more access to, and more comprehensive, health care services.⁹ In short, without savings, there are no resources to stretch.

PROGRAM INTEGRITY EFFORTS TO STRENGTHEN 340B

The AHA remains committed to ensuring the long-term sustainability of the 340B program. Over the past few years, HRSA has made significant progress in improving compliance and program integrity. Since 2011, HRSA has implemented a multitude of integrity efforts, including an annual entity recertification process that requires covered entities to attest that they meet eligibility requirements and maintain compliance with program rules and guidance. In addition, HRSA has established risk-based audits based on covered entities length of time in the program, number of outpatient facilities, number of contract pharmacies, complexity of the program, and the volume of purchases.

Despite the increased effort to improve transparency on the part of covered entities, much remains to be done to increase manufacturer transparency. For more than seven years, a provision passed by Congress requiring a 340B ceiling price calculation methodology and application of civil monetary penalties for manufacturers' violations of the ceiling price has remained unenforced. These rules were intended to shine needed light on drug manufacturer price increases and hold drug manufacturers accountable for price overcharging. As a result of these continued delays, covered entities are unable to challenge drug manufacturers when these manufacturers sell drugs above the 340B ceiling price. In fact, a HHS Office of Inspector General (OIG) report found that manufacturers overcharged for more than half of the drugs subject to the current program's pricing policy (designed to rein in drug pricing) with incorrect charges ranging "anywhere from \$1.65 to \$1,931 per purchase over the ceiling price."¹⁰

Unfortunately, HHS recently decided once again to delay implementing the final rule on 340B drug ceiling prices and civil monetary penalties for manufacturers until July 1, 2019. We continue to be disappointed in the delays – including five times since the beginning of last year alone – of the final rule and in the short shrift given to the review of the latest public comments. As a result, vulnerable communities could be harmed and implementation costs could increase for the federal government.

PROGRAM WORKING AS CONGRESS INTENDED

The 340B program is working as Congress intended to help hospitals and other covered entities expand access to lifesaving prescription drugs and comprehensive health care services in vulnerable communities across the country, including to low-income and uninsured individuals. Added regulatory requirements to curtail the 340B program,

⁹ See, e.g., HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Services Act*, at Part 1.G (July 2005), available at <https://www.hrsa.gov/hemophiliatreat/emnt/340manual.htm#21> (last accessed Aug. 22, 2017). See also U.S. Gov't Accountability Off., GAO-11-836, *Manufacturer Discount in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* (Sept. 2011), at 17-18 (finding that studied covered entities generated revenue from the 340B Program and used the revenue in ways consistent with the program's purposes, e.g., by providing additional services at more locations, patient education programs, and translation and transportation services that the entities otherwise could not afford).

¹⁰ Dept. of Health and Human Services., *OIG, Review of 340B Prices* (July 2006), <https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf>

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particularly for hospitals, would only benefit drug manufacturers, who could drive up already sky-high margins by forcing hospitals to pay higher prices for a portion of their drugs. In the end, it is the patients and the communities served by the 340B hospitals that would ultimately pay the price through limited access to needed services.

Thank you for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Molly Collins Offner, director of policy, at mcollins@aha.org or (202) 626-2326.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations & Public Policy