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 hospitals enrolled in the 340B federal drug discount program, the American Hospital Association, the Association of American Medical Colleges, the Catholic Health Association of the United States, America's Essential Hospitals, the Children's Hospital Association, and 340B Health respectfully submit 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 interest in addressing the problem of high drug prices and the opportunity to comment on this important matter. We share the Administration's concern about unsustainable increases in drug prices. Rising drug prices pose a threat to providers, patients, and federal and state budgets. If left unaddressed, the trend is only bound to continue, with prescription drug spending growth projected to outpace overall health care spending growth through 2026, mainly due to rapid growth in drug prices.[2]

The RFI posed a series of questions about existing policies that may play a role in driving high drug costs, including whether the 340B Program is causing manufacturers to increase their prices. As you evaluate your options for moving forward to address this critical issue, we ask you to consider the strong evidence demonstrating the 340B program does not contribute to high drug prices. To the contrary, for the past 25 years, the 340B program has successfully expanded access to care for vulnerable populations by helping covered entities manage their drug spend at no cost to taxpayers. We strongly urge the Administration to promote and protect this vital program.

Congress created the 340B program to allow hospitals and other covered entities to access drugs at a more affordable price so that they can reach more patients and furnish more comprehensive services.[3] Hospitals cannot access these discounts unless they meet strict eligibility criteria proving that they serve a high level of low-income patients or patients in remote rural areas. In 2015 alone, 340B hospitals provided $23.8 billion in uncompensated care[4]

---

[1] HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22,008 (May 7, 2018).
[2] Cuckler, Gigi A., et al., Health Affairs, National Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth (Feb. 14, 2018), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.1655.
[3] H.R. Rep. 102-384, 102d Cong., pt.2, at 12 (2d Sess. 1992).
[4] AHA 2015 Annual Survey Data.

and $51.7 billion[5] in total benefits to their communities. Hospitals were able to provide these benefits despite significant fiscal pressures.

The RFI asks whether discounts provided under the 340B program increase the list prices of drugs. While the Health Resources and Services Administration estimates the value of the 340B program at 3.6 percent of the total U.S. drug market, that figure examines what 340B entities paid for drugs, not the size of 340B discounts. The fact is, when examining the discounts, the figure drops to less than two percent of overall manufacturer revenue.[6] List prices for drugs are set by drug manufacturers. For many drugs, these prices are rising faster than inflation. For example, unit costs for Medicare Part D brand-name drugs rose nearly six times faster than inflation from 2011 to 2015.[7] These prices put needed medications out of reach for many Americans. Such a dramatic increase in list prices is clearly not due to 340B given the small size of the program compared to total spending.

Moreover, there would be significant consequences to vulnerable communities if the Administration reduced the number of eligible hospitals or otherwise limited the number of drugs purchased through the 340B program. Such actions would simply increase drug manufacturer revenue without any requirement that they treat low-income individuals, something that is required today of 340B entities.

Considering the tremendous importance of the program and the fact that it does not contribute to high list prices for drugs, we ask that you protect the 340B program. Thank you again for seeking to address the issue of high drug prices. If you have any questions or need additional information, please do not hesitate to reach out to our organizations.

Sincerely,

American Hospital Association
Association of American Medical Colleges
Catholic Health Association of the United States
America's Essential Hospitals
Children's Hospital Association
340B Health

---

[5] AHA 340B Community Benefit Analysis (Mar, 2018), https://www.aha.org/system/files/2018-03/340b-community-benefit-analysis.pdf.

[6] 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.

[7] HHS Office of the Inspector General, Increases in Reimbursement for Brand-Name Drugs in Part D 5, (June 4, 2018), https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf.