Maryland
Hospital Association

July 28, 2023

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Benjamin L. Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Re: Bipartisan 340B RFI

Dear Senators Thune, Stabenow, Moore Capito, Baldwin, Moran and Cardin:

On behalf of the Maryland Hospital Association's (MHA) 60 member hospitals and health systems, we appreciate the opportunity to share comments on the 340B Drug Pricing Program. The 340B program allows hospitals to stretch scarce federal resources to serve their patients and communities. As drug prices continue to rise, it is important for Congress to protect the 340B program and help hospitals care for their communities.

Our responses to your questions are below.

Question: What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?

The Health Resources and Services Administration (HRSA) should implement its Administrative Dispute Resolution (ADR) authority as provided by the Affordable Care Act. ADR was intended to create a pathway for HRSA to resolve disputes between pharmaceutical manufacturers and 340B providers. HRSA should finalize the ADR rule and explicitly state in the final rule that the ADR process is available for affected 340B hospitals seeking compensation from pharmaceutical

manufacturers that are limiting or denying 340B pricing through contract pharmacy arrangements.

HRSA also needs sufficient resources to oversee the program. While HRSA audits over 200 340B providers annually, it conducts only six audits of pharmaceutical manufacturers. HRSA should have the necessary resources to conduct appropriate levels of pharmaceutical manufacturer audits to ensure program integrity.

Question: What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

Contract pharmacy arrangements are a vital part of the 340B program. Instead of forcing patients to travel long distances, contract pharmacies allow patients to pick up drugs from more accessible locations. Recent litigation filed by several pharmaceutical manufacturers, however, challenged HRSA's authority to regulate drug companies for restricting access to 340B drugs sold at contract pharmacies. Congress should clarify and codify protections for contract pharmacy arrangements in the federal 340B statute.

Question: What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?

As described above, HRSA already audits hundreds of 340B providers annually. When certain conditions are met, pharmaceutical manufacturers can also audit 340B providers. HRSA, on the other hand, averages less than six manufacturer audits per year, and hospitals cannot audit drug companies. 340B providers should be allowed to audit pharmaceutical manufacturers to reduce instances of manufacturer overcharging or denying of 340B pricing for certain drugs. HRSA should also increase the number of annual drug company audits to ensure adequate oversight of the program.

Question: What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?

Hospitals file Medicare cost reports and the IRS Form 990, which disclose uncompensated care, charity care, and other community benefits. HRSA also requires additional reporting during the annual 340B hospital certification process. Pharmaceutical companies, however, are not required to disclose any information about their launch prices, the amount or timing of any price increases, or when they implement a restrictive policy on the 340B program. Congress should increase oversight of the pharmaceutical companies to improve the transparency of their pricing practices and ensure they are fulfilling their obligations under the 340B program.

MHA appreciates the opportunity to comment on the 340B program, and we look forward to working with you to ensure its success. Please do not hesitate to contact me with any questions.

Sincerely,

Brian Frazee
Vice President, Government Affairs