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Advancing Health in America

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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

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

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including our nearly 2,000 member hospitals that participate in the 340B Drug Pricing Program (340B program), the American Hospital Association (AHA) welcomes the opportunity to comment on this bipartisan request for information on the critically important 340B Drug Pricing Program. **For over 30 years, the 340B program has successfully allowed health care providers to stretch scarce federal resources to better serve their patients and communities, consistent with Congress' objectives.** The savings 340B hospitals achieve through purchasing certain outpatient drugs at a discount allow them to provide a range of programs and services that directly benefit their patients. Examples include services like medication therapy management, diabetes education and counseling, behavioral health services, opioid treatment services, and the provision of free or discounted drugs. The recent Supreme Court 340B decision underscored this key tenant of the program, noting that it enables hospitals and health care systems to "perform valuable services for low-income and rural communities." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. ___ (2022) (slip op., at 13).

The 340B program has been especially important in the face of rising drug prices and chronic underpayments from Medicare and Medicaid. A recent report by the Department of Health and Human Services (HHS) found that between July 2021 and July 2022 drug prices increased by an average of 31.6% for over 1,200 drugs — many of which are used to treat cancer and other chronic conditions.[1] These staggering drug price increases have led to higher expenses for hospitals, compounding an already precarious financial situation and critical workforce shortages.

In fact, compared to pre-pandemic levels in 2019, hospitals have experienced a nearly 20% increase in their drug expenses.[2] This reality underscores the critical need for the 340B program. These drug price increases — which are at the sole discretion of drug manufacturers — crowd out the resources hospitals have available to care for their communities.

The AHA welcomes this opportunity to address how the 340B program continues to be of immense value to communities across the nation. Our comments primarily focus on how Congress can ensure that the 340B program continues to benefit patients and communities, while acting to prevent any cuts to the program that would jeopardize patient access to care.

Our detailed responses to your questions follow.

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) currently has ample authority, provided by Congress, to oversee the program and ensure program integrity. In fact, Congress, in the Affordable Care Act, provided HRSA with a key oversight tool through the Administrative Dispute Resolution (ADR) process. As required by federal law, the ADR process establishes a formal way for the agency to resolve disputed claims by 340B providers and drug manufacturers. Unfortunately, this ADR process has been challenged in court and has never been implemented in the way Congress intended. The AHA believes that HRSA should be given a chance to implement this

[1] https://aspe.hhs.gov/reports/prescription-drug-price-increases
[2] https://www.aha.org/system/files/media/file/2023/04/Cost-of-Caring-2023-The-Financial-Stability-of-Americas-Hospitals-and-Health-Systems-Is-at-Risk.pdf

ADR process before any new enforcement authorities are considered.

Among other things, the ADR process is intended to adjudicate disputes that arise when a drug manufacturer overcharges a 340B provider for covered 340B drugs. There is no more egregious example of this than the actions drug manufacturers have taken to limit or deny 340B pricing through arrangements with community and specialty pharmacies. For the last three years, in clear violation of the law and with no abatement on the horizon, several of the largest drug manufacturers have restricted, and in many instances denied, 340B hospitals' access to the statutorily required 340B prices for drugs purchased through established arrangements with community and specialty pharmacies. By intentionally denying or limiting access to the 340B price, these drug manufacturers are forcing hospitals to pay a higher price to acquire these drugs (e.g., wholesale acquisition cost price), representing an overcharge by these drug manufacturers for these covered drugs. According to AHA survey data, these unlawful actions by drug manufacturers have resulted in 340B Critical Access Hospitals experiencing average annualized losses of over $500,000 and 340B Disproportionate Share Hospitals (DSH) experiencing annualized losses of nearly $3 million, though the amount an individual hospital experiences can be much greater.[3] These overcharges jeopardize the ability of 340B hospitals to improve patient access by allowing both hospitals and pharmacies to coordinate care and ensure that drugs needed by the patients cared for by 340B hospitals are available to them at their local pharmacies. In addition, the loss of savings as a result of these actions, as noted above, reduces the resources that hospitals have to fulfill the intent of the program of increasing access to care.

The only beneficiaries of these restrictions are drug manufacturers who simply pocket the additional revenue to add to their already sky-high profits. Indeed, in 2021, 19 of the companies that introduced these restrictions made more than $660 million in profits. Unsurprisingly, these companies are *not* using their additional earnings to expand access to care or lower drug prices. As more restrictions on contract pharmacies have been put in place, drug manufacturers have only *increased* both the launch prices of new drugs and the prices of existing drugs. These drug manufacturers must be held accountable to the legal requirements in the 340B statute, which the ADR process was created to enforce.

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[3] https://www.aha.org/2022-11-14-survey-brief-drug-companies-reduce-patients-access-care-limiting-340b-community-pharmacies

Regrettably, for 13 years, the ADR process has not been fully implemented by the agency. It is imperative that HRSA finalize its most recent 340B ADR proposed rule and allow 340B hospitals and other participating covered entities the ability to bring forth disputed claims for administrative review before the panel. Drug companies should not be allowed to circumvent the law and indefinitely delay the implementation of this rule. **The AHA strongly urges HRSA to finalize the ADR rule and has recommended to the agency that HRSA explicitly state in its final rule that the ADR process is an available forum for affected 340B hospitals to seek redress from the restrictions targeted to community and specialty pharmacies.**

At the same time, the AHA continues to vigorously support the agency's efforts *outside* of the ADR process, including those by the Office of Inspector General (OIG), to enforce the law and penalize drug manufacturers who intentionally break the law. In particular, the AHA supports HRSA's actions to enforce drug companies' compliance with section 340B(a)(1) of the Public Health Service Act, which requires those companies to sell, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements. To that end, the AHA, along with other national hospital organizations, filed numerous *amici* briefs at the district and appellate court levels where the drug companies have challenged these enforcement efforts. Specifically, the AHA argued that the drug manufacturers "...understate the impact of [their] unlawful polic[ies] on 340B providers and their patients and overstate how reasonable it is to limit access to 340B discounts and to impose conditions found nowhere in the statute."[4] Ultimately, given the scope of drug manufacturers' wrongdoing with respect to contract and specialty pharmacy arrangements, a whole-of-agency effort is needed. Congress has afforded HRSA, OIG *and the ADR process* the authority necessary to preserve the integrity of the 340B program.

However, while HRSA has the *authority* to oversee the program, we recommend ensuring that it also has *the tools* that it needs to conduct that oversight. HRSA currently audits over 200 340B hospitals annually to ensure program integrity. In stark contrast, HRSA's conducts *only six* audits of drug manufacturers. As the contract pharmacy issue underscores, greater oversight of drug manufactures is needed. HRSA should be provided the resources necessary to conduct audits of drug manufacturers to ensure greater oversight of manufactures and audit parity.

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[4]Amicus Brief: Hospital Groups Urge Appeals Court to Uphold 340B Requirements In Contract Pharmacy Case, *AstraZeneca Pharmaceuticals LP v. United States Department of Health and Human Services,* June 29, 2022, https://www.aha.org/amicus-brief/2022-06-29-amicus-brief-hospital-groups-urge-appeals-court-uphold-340b-requirements

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

Contract pharmacies are an integral part of the 340B program that has been recognized by HRSA since 1996. These arrangements with community and specialty pharmacies are critical to ensuring patients can access the drugs they need when and where they need them. Dispensing drugs at contract pharmacies allows America's 340B providers to meet their patients where they are, rather than forcing them to travel long and costly distances to pick up prescriptions. In addition, the ability of 340B hospitals to contract with community and specialty pharmacies allows hospitals to get their patients drugs otherwise not available. For example, a drug in shortage may be placed in limited distribution and be available through only a select pharmacy, but the drug company restrictions keep these drugs out of the hands of those who need them. Patients further benefit from contract pharmacy arrangements either by having to pay less for their medicine (many hospitals pass the 340B discount directly to patients) or by the increased services the 340B savings make possible.

The actions by over twenty of the largest drug companies in the country since 2020 to restrict, condition or outright deny 340B pricing for drugs dispensed through these arrangements violates the law and undermines the purpose of the 340B program as specified by Congress. 340B DSH hospitals report that these restrictions are costing them on average nearly $3 million per year in reduced 340B savings; for rural hospitals, the average loss is approximately $500,000. These reductions in savings means hospitals are less able to provide the patients and communities they serve with critical programs and services that are supported by the 340B program. Examples of these services include medication therapy management services, behavioral health and opioid treatment services. Rural 340B hospitals rely on these savings to expand access to mobile treatment clinics and oncology services. Some hospitals, such as Ozarks Community Hospital and St. Bernards CrossRidge Community Hospital in Arkansas, report that drug manufacturers' refusal to provide 340B discounts on drugs dispensed through contract pharmacies threatens their ability to keep their doors open.

HRSA should continue to enforce the law and hold drug companies accountable by using its existing enforcement authority to impose civil monetary penalties against drug companies violating the law. Unfortunately, several drug companies filed lawsuits across the country challenging HRSA's authority to protect these contract

pharmacy arrangements. At least one court of appeals has sided with the drug companies, holding that HRSA lacks the needed authority to penalize drug companies for restricting access to 340B drugs sold at contract pharmacies. *See Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 700 (3d Cir. 2023). To address this misinterpretation of existing law and to prevent other courts from making the same mistake, Congress should clarify and codify protections for contract pharmacy arrangements in the federal 340B statute.

Question: What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

The AHA is increasingly concerned about the role that insurers and pharmacy benefit managers (PBMs) are playing in managing access to outpatient prescription drugs for patients. Rather than supporting 340B hospitals and their patients, PBMs have engaged in a number of harmful tactics to reduce the scope and benefits of the program.[5] Most importantly, PBMs have created terms and policies that discriminate against 340B hospitals by paying them less than non-340B hospitals for certain outpatient drugs in order to protect their rebate revenue from drug manufacturers. PBMs require 340B hospitals to accept unfair terms and policies to participate in their pharmacy networks, which are needed to give hospital patients greater access to those drugs.[6] This practice, widely referred to as "discriminatory 340B pricing," forces hospitals to accept lower and discriminatory reimbursement rates that threaten hospitals' ability to provide more comprehensive services to their patients as the law intends to ensure patient access to drugs through PBM pharmacy networks. Some of the tactics of concern entail PBMs establishing barriers for pharmacies that contract with 340B hospitals to participate in their networks, disallowing PBM members from using 340B pharmacies, and even wholly excluding certain hospital-based pharmacies from their networks. While some states have explicitly prohibited 340B discriminatory pricing by PBMs,[7] this practice as well as their other harmful policies remain prevalent in many parts of the country and continue to enrich PBMs at the expense of 340B hospitals.[8]

Congress should hold PBMs accountable as they continue to engage in policies that siphon 340B savings away from 340B hospitals and into their pockets. Specifically,

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[5] aha-to-ftc-re-request-for-public-comment-on-the-impact-of-pharmacy-benefit-managers-practice-letter-5-24-22.pdf
[6] https://340breport.com/16-states-have-passed-laws-since-2019-targeting-pbms-340b-payment-cuts/
[7] https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx
[8] https://www.jdsupra.com/legalnews/new-supreme-court-ruling-affirms-state-2371638

Congress should:

- Prohibit nationwide PBM policies that provide differential reimbursement to 340B providers and non-340B providers (discriminatory pricing).
- Prohibit PBMs from steering patients away from 340B pharmacies to pharmacies that they own, denying the ability of 340B entities to earn any savings.
- Prohibit PBMs from engaging in "whitebagging" or "brownbagging" policies that jeopardize patient safety and undermine access to 340B discounts for providers and their patients.[9]

We urge Congress to eliminate any possibility for drug companies to try to circumvent their responsibility and obligations under the 340B law by codifying the use of contract pharmacies as a lawful and critical part of the 340B program. The law should ensure that drug companies cannot condition, restrict or deny 340B pricing for drugs regardless of the manner in which those drugs are dispensed or administered to patients.

Questions: What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

The AHA supports a national data claims clearinghouse as proposed by the bipartisan legislation introduced by House Representatives Abigail Spanberger, D-Va., and Dusty Johnson, R-S.D.[10] Their 340B Protect Act (H.R. 2534) represents long-needed legislation that would prevent PBMs and health insurance companies from siphoning off savings from the 340B program that were meant to help health care organizations that care for many uninsured and low-income patients. In addition, the legislation would authorize the Secretary of Health and Human Services to contract with a third-party entity to collect and review data from state Medicaid agencies and covered entities to prevent Medicaid duplicate discounts. It is vitally important that any national data claims clearinghouse, such as the one created by the Protect 340B Act, should:

- Be free of any conflicts of interest;

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[9] https://www.aha.org/system/files/media/file/2022/05/aha-white-bagging-infographic.pdf
[10] https://www.aha.org/system/files/media/file/2023/07/aha-letter-in-support-of-the-preserving-rules-ordered-for-the-entities-covered-through-protect-340b-act-of-2023.pdf

- Limit data collection to Medicaid claims to mitigate against the prohibition of duplicative 340B discounts and Medicaid drug rebates on the same drug;
- Limit any burden on 340B covered entities to collect such data and allow sufficient time for providers to setup the necessary processes and programs to report claims data; and
- Ensure data security in accordance with HIPAA standards so that claims information or personal identifiable information are not compromised.

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?

HRSA has ample authority it uses to oversee the 340B program and ensure program integrity. Specifically, HRSA conducts over 200 audits of 340B covered entities every year, a majority of which are for hospitals. Since 2012, HRSA has conducted 1,720 audits of covered entities. These audits are rigorous and require hospitals to maintain several years of auditable records, as well as policies and procedures to mitigate against issues like diversion of drugs to ineligible patients and duplicate discounts. Further, should there be any finding of noncompliance, hospitals work in good faith with the agency to take corrective action and rectify issues to be compliant with program rules. In addition, 340B hospitals take program integrity seriously and invest significant resources in conducting regular self-audits of their programs to ensure they are staying compliant with all program rules and requirements.

Drug manufacturers are also permitted to conduct audits of 340B hospitals in certain instances in coordination with HRSA, but hospitals have no ability to audit drug manufacturers. There are many instances when drug companies have violated program rules and requirements such as overcharging hospitals, denying 340B pricing for certain drugs and arbitrarily placing drugs in limited distribution. **Congress should mandate that HRSA provide hospitals and other covered entities the same ability to audit drug manufacturers.**

As noted above, while HRSA performs over 200 audits of 340B covered entities each year, they only perform on average less than six audits annually for drug manufacturers. Since FY 2015, HRSA has conducted only 31 audits of drug manufacturers, which is a meager 4% of all drug manufacturers participating in the program. The obvious disparity between the oversight that HRSA exercises over covered entities and drug manufacturers

is concerning.[11] Therefore, **Congress should mandate that the agency bring more parity to their oversight of the 340B program, by increasing the number of annual audits of drug companies.**

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?

340B hospitals report a variety of information to demonstrate their commitment to providing care to underserved populations. Hospitals report uncompensated care, charity care and other benefits provided to the communities they serve through both the Medicare cost reports and the IRS 990 form required for tax-exempt organizations. In fact, the most recently available IRS 990 data show that 340B hospitals alone provided nearly $68 billion in community benefits.[12] HRSA requires separate reporting during its annual 340B hospital certification process including Medicare cost report information. And many 340B hospitals are voluntarily committing to the AHA Good Stewardship Principles that focus on 340B hospitals sharing how 340B savings benefit their patients and communities.[13]

At the same time, drug companies are not required to report *any* information about how they set their prices, by how much and when they decide to increase their prices, or when they have implemented a policy that restricts covered entities' access to 340B pricing. That type of information would be important in understanding drug companies' pricing decisions and how we can mitigate arbitrary and egregious price increases for drugs that are critical and lifesaving for patients, as well as ensure the government is aware of drug manufacturer actions that may unilaterally (and illegally) shrink the program. We urge Congress to increase oversight of drug companies to ensure they do not continue to obfuscate their pricing practices, undermining the law and their obligations to provide 340B discounts.

In conclusion, the AHA appreciates this opportunity to share our comments with key Senate leadership on the value of the 340B program and look forward to working with you to ensure that the 340B program continues to provide access to needed services for

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[11] https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2023.pdf
[12] https://www.aha.org/2022-06-07-2022-340b-hospital-community-benefit-analysis
[13] https://www.aha.org/initiativescampaigns/2018-09-13-340b-hospital-commitment-good-stewardship-principles

patients in our community and communities across the country.

Please contact me if you have questions or feel free to have a member of your team contact, Aimee Kuhlman, AHA's vice president for advocacy and grassroots, at akuhlman@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President