



A Passionate Voice for Compassionate Care

July 28, 2023

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, D.C. 20515

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 the Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,200 Catholic healthcare systems, hospitals, long-term care facilities, and service providers. I am writing in response to your request for information on the 340B program and to express our strong support for continuing to strengthen and protect this important program.

As a health care ministry guided by the teaching of the Catholic church, CHA, and its members are committed to respecting the human dignity of each person, promoting the common good, having special concern for low-income and other vulnerable persons, and being responsible stewards of resources. These foundational beliefs drive our long-standing commitment to ensuring that every patient has access to quality care regardless of ability to pay and that all persons in our communities reach their highest potential for health possible. The 340B program plays a vital role in supporting the work of more than 350 Catholic 340B providers as they work to meet these commitments to their communities.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers that participate in the Medicaid program to provide covered outpatient drugs at a discounted rate to nonprofit safety-net and other healthcare facilities serving low-income, vulnerable communities or remote rural areas. The significant pharmacy discounts available under the program allow hospitals to continue to provide and expand needed services that otherwise would not be available in these communities. To be eligible, a hospital must be nonprofit, owned or operated by or under contract with state or local governments and provide a significant level of care to low-income patients or serve rural communities.

The 340B discount drug program plays a critical role in allowing safety net and rural hospitals to continue to meet the needs of their patients and communities with the goal of stretching “scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹ Savings from 340B allows providers, for example, to run free and low-cost clinics; to provide services in remote or low-income areas; offer generous financial aid policies; provide low-cost or free prescriptions; maintain critical services that operate at a loss; and support community programs meeting the identified needs of their service areas.

As a result, 340B disproportionate share hospitals (DSHs) continue to serve a greater share of patients with low incomes and other characteristics indicative of their safety-net roles.² These hospitals provided 67% of all such care while representing only 44% of hospitals. Despite the many financial challenges facing hospitals, 340B hospitals continue to be much more likely than non-340B hospitals to offer vital healthcare services for [low-income and vulnerable people](#) including those with disabilities, those who are eligible for both Medicare and Medicaid, and patients who identify as Black or African American.

CHA welcomes this opportunity to provide suggestions on how to strengthen the 340B program so that it remains consistent with its original intent - assisting safety net and rural hospitals to stretch resources as far as possible, reaching more patients and providing more services.

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?

Under existing law, the Health Resources and Services Administration (HRSA) has ample authority to oversee and implement the 340B program. Under its authority, HRSA has the ability to set the rules for the program, monitor implementation and ensure compliance through ongoing audits of both hospitals and manufacturers.

However, despite this authority, drug manufacturers continue to take unlawful unilateral actions to restrict access to 340B drugs purchased through established arrangements with community and specialty pharmacies. As a result, drug manufacturers are restricting access to patients and forcing hospitals to pay higher prices to acquire these drugs. These restrictions have dramatically limited the availability of the 340B program to patients who rely on pharmacies that are accessible. In rural communities, these restrictions mean patients are forced to travel many miles to access a pharmacy for their medications. In order to address this abuse of the 340B program, CHA supports HRSA’s effort to implement an Alternative Dispute Resolution mechanism so that providers can seek redress from the unilateral restrictions currently being imposed by drug manufacturers. In addition, CHA continues to support the efforts by the Office of the Inspector General (OIG) and HRSA’s actions

¹ "340B Drug Pricing Program - Official website of the U.S. Health Resources & Services Administration". *Hrsa.gov*. retrieved 20 October 2020. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992); *See also* Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4967-4971 (1992).

² 340B Health. State Level Reports: 340B DSH Hospitals Serve a Greater Share of Patients with Low-Incomes and Other Characteristics Indicative of Their Safety-Net Roles. <https://www.340bhealth.org/members/research/state-level-reports/> .

to enforce drug companies to comply with the requirements of section 340B(a)(1) of the Public Health Service Act, requiring drug manufacturers to sell 340B covered drugs to covered entities with contract pharmacy arrangement.

Finally, CHA also urges Congress to continue to ensure that HRSA has funding to ensure compliance with the 340B program requirements. Currently, HRSA conducts audits of over 200 340B hospitals annually to ensure program integrity. However, HRSA only conducts around five to six audits of drug manufacturers in a given year. More resources are needed so that HRSA is able to conduct audits of drug manufacturers to ensure greater oversight and audit parity.

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

Contract pharmacies are critical for promoting patient access to drugs they need. These arrangements with 340B providers and community and specialty pharmacies have been recognized by HRSA since 1996 and are a crucial tool for allowing patients to receive drugs rather than travel long distances to pick up prescriptions. These contract pharmacies also promote patient access by allowing hospitals to get patients access to drugs that may be in limited distribution or supply. These contract pharmacy arrangements are particularly critical for rural health providers where access to pharmacies is more limited and where 340B providers already face significant financial hurdles in maintaining and expanding lines of services.

Despite the success of the 340B contract pharmacy arrangements in expanding access to necessary medications, drug manufacturers continue to litigate and restrict access to 340B contract pharmacies. As a result, providers and patients face significant financial and logistical challenges. We would urge Congress to support HRSA's efforts to protect these contract pharmacy arrangements by further clarifying 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 the patients they serve, not other parties?

The 340B program was created to help covered entities "stretch scarce federal resources, reaching more eligible patients and providing more comprehensive services." Through this benefit, hospitals and other covered entities are able to use these savings to serve low-income patients and meet the varied health needs of the communities they serve.

In order to further support 340B providers and the patients they serve, Congress should address the role that insurers and pharmacy benefit managers (PBMs) play in restricting access to contract pharmacies or working to siphon 340B savings away from 340B hospitals. For example, some PBMs require 340B hospitals to accept discriminatory terms and pricing and/or limit network access for pharmacies. To address this, Congress should prohibit discriminatory PBM and insurer conditions on participation or pricing while at the same time clearly stating in law that contract pharmacies are a lawful and crucial part of the 340B program.

Question 4: What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

Current law already prohibits duplicate discounts, and manufacturers are not required to provide a discounted 340B price and Medicaid drug rebate for the same drug (see 42 USC 256b(a)(5)(A)(i)). As a result, providers have significant requirements for ensuring that claims are accurate and duplicate discounts do not occur. For example, hospitals and other covered entities must inform HRSA whether a site will use its 340B drugs for its Medicaid fee-for-service patients (carve-in) or whether it will purchase drugs for its Medicaid fee-for-service patients (carve-out) through other mechanisms. Those 340B providers who elect to carve-in are required to list each Medicaid state in which it plans to bill and the corresponding billing numbers and maintain an auditable record of their compliance with these requirements.

In addition to enforcing the current standards, *The Protect 340B Act* (H.R. 2534) would further strengthen the 340B program. This act would create a national data claims clearinghouse for 340B claims while at the same time preventing PBMs and health insurance companies from appropriating 340B savings that were meant to support health care providers and other covered entities. This clearinghouse would be established in a way that mitigates against unintentional duplicated 340B and Medicaid drug rebates on the same drug while at the same time limiting further burdens and expenses on 340B hospitals and other covered entities.

Question 5: 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 healthcare stakeholders greater confidence in its oversight?

HRSA currently has significant authority to oversee the 340B program's implementation and integrity. For 340B covered entities, these program integrity requirements include an annual recertification for 340B providers and an ongoing process for covered entities to evaluate and correct aspects of their 340B program. In addition, covered entities, such as hospitals, are subject to audits of their 340B program by HRSA and drug manufacturers. As a result of these requirements, HRSA has conducted audits of 1,720 340B healthcare providers since 2012.

However, drug manufacturers and Pharmacy Benefit Managers face far less scrutiny and oversight of their 340B practices. Providing greater transparency and accountability for all stakeholders in the 340B program would be one way to significantly strengthen the program's integrity. For example, HRSA only audits around five to six drug manufacturers per year to ensure compliance with 340B requirements (31 audits since 2015). This lack of accountability by drug manufacturers continues despite their continuing disregard for HRSA's letters of noncompliance for failing to provide 340B prices to covered entities utilizing contract pharmacies. In addition, hospitals and other 340B covered entities have no ability to audit drug manufacturers' compliance with 340B requirements. As a result, health care providers receive significant scrutiny for program compliance, while drug manufacturers and other participants in the 340B program such as Pharmacy Benefit Managers (PBMS) receive little scrutiny or oversight.

To address this imbalance and promote greater trust and integrity in the 340B program, CHA recommends that Congress mandate that HRSA provide greater parity in audits by increasing the number of annual audits of drug companies. In addition, we recommend that 340B covered entities have the same ability to request an audit of the drug manufacturer's program that these manufacturers currently have of covered entities. Through increased audits and greater fairness in

the program, Congress could build greater trust and confidence in the oversight of the 340B program.

Question 6: What specific policies should be considered to ensure transparency to show how 340B healthcare providers' savings are used to support services that benefit patients' health?

As previously stated, the goal of the 340B program is to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”³ This means that the benefits of the 340B program go well beyond just reducing drug costs or individual services but rather helping to ensure that providers facing significant financial challenges remain open or are able to provide service lines that are critical for community needs. This is particularly critical at a time when hospitals are facing significant financial challenges and more than three hundred rural hospitals are at risk of closing.⁴

Hospitals are already one of the most regulated aspects of the health care system, with requirements to report prices, uncompensated care, charity care, and community benefit spending through Medicare cost reports and the IRS 990 form Schedule H for tax-exempt hospitals. These hospitals also regularly report financial and patient information through quarterly financial disclosure requirements. In addition, many Catholic health providers have also voluntarily committed to the AHA Good Stewardship Principles that focus on showing how 340B savings benefit their patients and communities. Requiring additional reporting requirements or limiting the use of the 340B savings to particular programs would exacerbate the challenges that hospitals are facing. This would also further restrict the value of the 340B program as a lifeline for supplementing federal government efforts to support patients who rely on rural hospitals and those serving low-income and uninsured patients.

In conclusion, CHA welcomes this opportunity to share our perspective on the critical importance of the 340B program to Catholic healthcare providers and their patients. We look forward to working with you to ensure that 340B continues to serve its critical role in supporting the healthcare safety net.

If you have any questions, please feel free to reach out to me or to our Senior Director for Government Relations, Lucas Swanepoel, at Lswanepoel@chausa.org.

Sincerely,



Lisa Smith, MPH
Vice-President, Advocacy & Public Policy
Catholic Health Association of the United States

³ "340B Drug Pricing Program - Official web site of the U.S. Health Resources & Services Administration". *Hrsa.gov*. retrieved 20 October 2020. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992); *See also* Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4967-4971 (1992).

⁴ Center for Healthcare Quality and Payment Reform, “Rural Hospitals at Risk of Closing,” January 2022, retrieved July 27, 2023. Available at http://ruralhospitals.chqpr.org/downloads/Rural_Hospitals_at_Risk_of_Closing.pdf