



A Passionate Voice for Compassionate Care®

The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee
United States House Representatives
Washington, D.C.

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
United States House of Representatives
Washington, D.C.

The Honorable Morgan Griffith
Chairman
House Energy and Commerce Committee
Oversight and Investigations Subcommittee
United States House of Representatives
Washington, D.C.

The Honorable Kathy Castor
Ranking Member
House Energy and Commerce Committee
Oversight and Investigations Subcommittee
United States House of Representatives
Washington, D.C.

Dear Chair McMorris Rodgers, Chairman Griffith, Ranking Member Pallone, and Ranking Member Castor;

On behalf of the Catholic Health Association of the United States (CHA), the national leadership organization of the Catholic health ministry, representing more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations across the continuum of care, I would like to take this opportunity to express our views for the House Ways and Means Committee Oversight and Investigations Subcommittee hearing on “Oversight of the 340B Drug Pricing Program.”

As health care facilities 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 ensure 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 an important role in enabling nearly 350 Catholic safety net hospitals to meet these commitments in serving 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 safety net and other health care facilities serving low-income, vulnerable communities or remote rural areas. Congress created the program as a response to the high pharmaceutical costs faced by safety net hospitals. The intent was “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹ The significant pharmacy discounts available under the program allow hospitals to continue to provide and expand community services that otherwise would not be available to these populations.

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 \(1992\).](#)



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To participate in the 340B program, hospitals must provide a significant level of care to low-income patients or serve rural communities. These hospitals disproportionately treat an underserved and low-income population and consistently provide more uncompensated and unreimbursed care than non-340B hospitals.²³ They provided 67% of all such care while representing only 44% of hospitals. Despite the many financial challenges facing them, 340B hospitals continue to be much more likely than non-340B hospitals to offer vital health care 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. Savings from 340B, for example, allow providers to run free and low-cost clinics, 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.

Oversight and Compliance

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. 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). 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.

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. These 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

² DaVanzo, J., Dobson, Arzaluz, "340B Hospitals Prescribe Retail and Specialty Drugs to a Greater Share of Historically Underserved Populations," May 2024, https://www.340bhealth.org/files/340B_Part_D_Drug_Demographic_Study_2024_FINAL.pdf

³ Tomai, Lisa, "A Comparison of Characteristics of Patients Treated by 340B and on-340B Providers," April 8, 2019. https://www.340bhealth.org/files/340B_Patient_Characteristics_Report_04-10-19.pdf



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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.

We support measures to strengthen the 340B program consistent with its original intent: to allow safety net and rural hospitals to serve more people and provide more comprehensive services by giving these hospitals access to lower-cost outpatient drugs. CHA supports improvements such as:

- Full implementation of HRSA's Alternative Dispute Resolution mechanism so that providers can seek redress from the unilateral restrictions currently being imposed by drug manufacturers.
- Continued support for the efforts by the Office of the Inspector General (OIG) and HRSA to ensure that drug companies 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.
- Ensuring that HRSA has sufficient 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 each year. More resources are needed so that HRSA can conduct audits of drug manufacturers to ensure greater oversight and audit parity.

In addition to the oversight related to the 340B program, hospitals have a number of reports and financial disclosure obligations that go above and beyond in providing transparency to their financial situations. Catholic health care providers have not only worked to meet these requirements but also to go above and beyond the mandated requirements by participating voluntarily in the AHA Good Stewardship Principles and show how 340B savings benefit their patients and communities.

Thank you again for the Subcommittee's attention to this essential program. As you move forward, please always bear in mind the communities and individuals that rely on 340B for continued access to the health care they need. If you have any questions, please feel free to reach out to me or Lucas Swanepoel (Lswanepoel@chausa.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa Smith". The signature is fluid and cursive, with a large initial "L" and "S".

Lisa Smith, MPH
Vice-President, Advocacy & Public Policy