

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 Ben Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Dear Sens. Thune, Stabenow, Capito, Baldwin, Moran, and Cardin,

Thank you for the opportunity to respond to your June 16 [request for information](#) on the 340B program. We greatly appreciate your continued support as champions of the 340B program, and we look forward to collaborating with you to ensure that the program continues to benefit covered entities and the patients and communities they serve.

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the [Liaison Committee on Medical Education](#); 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

The 340B Drug Pricing Program is Critical to the Missions of Academic Medicine and AAMC Members

Established in 1992, the 340B Drug Pricing Program allows certain safety-net health care providers, referred to as "covered entities," purchase covered outpatient drugs at a discount from manufacturers.¹ Covered entities leverage savings generated through their participation in the program to "stretch scarce federal resources as far as possible, reaching more eligible patients

¹ Health Resources and Services Administration (HRSA), "340B Drug Pricing Program," accessed July 16, 2023, <https://www.hrsa.gov/opa>.

and providing more comprehensive services.”² AAMC-member 340B hospitals use their savings to care for low-income and under-resourced communities by financing uncompensated care, providing free or discounted medications, and investing in community health programs.³ It is important to note that 340B supports these programs and services at no cost to taxpayers.

Academic Medical Centers Maintain an Important Role in the Health Care Safety Net

Academic medical centers are a critical component of the nation’s health care infrastructure, leveraging cutting-edge technology, research, and expertise to care for the nation’s most medically and socially complex patients. AAMC-member institutions provide highly specialized health care services that are often unavailable in other settings, including oncology services, transplant surgery, trauma care, and treatment for rare and complex conditions. Although they account for just five percent of all short-term, non-federal hospitals nationwide, AAMC members comprise 100 percent of all National Cancer Institute (NCI)-designated comprehensive cancer centers, 74 percent of all burn unit beds, and 64 percent of all level-one trauma centers.⁴ Because of the invaluable services they provide, AAMC-member institutions fundamentally serve as quaternary and tertiary care facilities, attracting patients seeking advanced levels of specialized care.

Not only do AAMC-member institutions provide life-saving health care services to the most medically complex patients, but they also serve as a safety net to other health care providers across their community, state, and region. Due to their unique capabilities, academic medical centers often receive transfers of seriously ill patients from other health care facilities, including non-teaching, community hospitals. Some researchers have hypothesized that this safety net function has positive spillover effects for patients across a given health care market, regardless of whether they are treated at an academic medical center or another setting. One recent study found that the presence of an academic medical center is associated with improved mortality outcomes and more healthy days at home for patients treated at community hospitals.⁵ Because of their important contributions to the broader health care delivery system, although AAMC members make up a small percentage of all hospitals, they play an outsized role in improving the health of people everywhere.

In addition to the life-saving services they provide, AAMC members share a common mission to care for the underserved. Not only do academic medical centers care for the nation’s most medically complex patients, but they also account for a disproportionate percentage of hospital-

² 102nd Congress, Second Session, H.R. Rept. No. 102-384(II), (1992).

³ Association of American Medical Colleges (AAMC), “Securing Our Safety-Net: The 340B Drug Pricing Program,” accessed July 16, 2023, <https://www.aamc.org/media/66471/download?attachment>.

⁴ AAMC analysis of FY2021 American Hospital Association data, American College of Surgeons Level 1 Trauma Center designations, 2023, and the National Cancer Institute’s Office of Cancer Centers, 2022. AAMC membership data, December 2022.

⁵ Burke LG, Burke RC, Orav EJ, Duggan CE, Figueroa JF, Jha AK. Association of Academic Medical Center Presence With Clinical Outcomes at Neighboring Community Hospitals Among Medicare Beneficiaries. *JAMA Netw Open*. 2023;6(2):e2254559. doi:10.1001/jamanetworkopen.2022.54559

based charity care and Medicaid inpatient days.⁶ This commitment to care, regardless of a patient’s ability to pay, can create significant financial challenges, as reimbursement from public payers is often insufficient to cover the total cost of care.

The 340B Program Supports AAMC-Members’ Ability to Care for Low-Income Patients and Communities

Consistent with congressional intent, the 340B program helps teaching hospitals “stretch scarce federal resources” by offsetting uncompensated costs incurred in caring for low-income patients, including underpayments from Medicare and Medicaid. The program ensures that AAMC members can continue to provide low-income patients with access to high-quality, specialized health care services. The 340B program advances health equity by ensuring that all patients, not just the commercially insured, have access to the innovative treatments, therapies, and cures available through teaching hospitals. Given the mounting financial challenges facing teaching hospitals and health systems, absent the 340B program, many AAMC members would be forced to consider difficult decisions related to the volume of care they can responsibly provide to uninsured and underinsured patients.

The 340B program also enables teaching hospitals to “provide more comprehensive services” through prescription drug assistance programs and community collaborations. The program helps patients manage the costs associated with expensive drug regimens used to treat complex medical conditions, such as HIV/AIDS, hepatitis C, and certain forms of cancer. AAMC-member 340B hospitals use their savings to provide free and discounted prescriptions, bedside medication delivery, and medication management services.⁷ In addition, the 340B program supports crucial collaborations between academic medical centers and local community-based organizations. Many AAMC-member 340B hospitals use their savings to invest in community health programs, such as mobile health clinics, immunizations, nutrition supports, and supportive housing.⁸ These partnerships, which are made possible by the 340B program, help to keep people healthy, thereby improving population-level health outcomes and decreasing hospital utilization rates.

Contract Pharmacy Partnerships Benefit 340B Covered Entities and the Patients They Serve

Contract Pharmacies Support Access to Care for Rural, Low-Income, and Under-Resourced Patients

Since the inception of the 340B program, AAMC members have partnered with community-based pharmacies (also known as “community pharmacies” or “contract pharmacies”) to distribute discounted drugs. Even those hospitals that enjoy access to an in-house pharmacy may choose to partner with contract pharmacies to expand access to care for patients, as Congress intended. Oftentimes, payers, including insurers and pharmacy benefit managers, will direct

⁶ AAMC analysis of FY2021 American Hospital Association data, American College of Surgeons Level 1 Trauma Center designations, 2023, and the National Cancer Institute’s Office of Cancer Centers, 2022. AAMC membership data, December 2022.

⁷ Association of American Medical Colleges (AAMC), “Securing Our Safety-Net: The 340B Drug Pricing Program,” accessed July 16, 2023, <https://www.aamc.org/media/66471/download?attachment>.

⁸ Ibid.

patients to certain in-network pharmacies for their medications (especially in the case of specialty pharmacies). Because these networks often exclude hospital-operated retail and specialty pharmacies, it is necessary for covered entities to contract with outside pharmacies to dispense medications to 340B patients. In addition, as previously noted, academic medical centers serve as quaternary and tertiary care facilities, attracting patients from across their state and region. Because these patients can reside miles away from the academic medical center where they receive care, absent contract pharmacy arrangements, they may be forced to travel many miles to pick up their prescription medications. This is especially true for patients living in rural areas, or who otherwise face transportation barriers. The low-income and historically under-resourced patients that the 340B program is intended to serve often face significant barriers to care, including inadequate transportation, a lack of reliable childcare, and inflexible working hours. Contract pharmacy arrangements allow these patients to pick up their prescriptions at a pharmacy that is most convenient to them, thereby lessening some of these challenges. In addition, some AAMC-member institutions contract with mail-order pharmacies to deliver medications straight to patients' homes. This strategy has proven to be particularly effective at improving medication adherence for 340B patients, particularly during the COVID-19 public health emergency, which prevented many patients from traveling to their local pharmacies.

Contract pharmacy arrangements ensure access to needed medications for 340B patients. Pharmaceutical manufacturers' unfair and unlawful restrictions on contract pharmacy arrangements place an undue burden on these patients, imposing yet another obstacle in their path to care.

Question 2: What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

Beginning in the summer of 2020, six pharmaceutical manufacturers implemented policies intended to limit covered entities' use of contract pharmacies to distribute discounted medications. These policies prompted concerns from the covered entity community that these restrictions would significantly limit access to 340B savings and, consequently, programs and services available to 340B patients. In response to these actions, in December 2020, the U.S. Department of Health and Human Services (HHS) issued an advisory opinion informing drug manufacturers that they are required to offer covered outpatient drugs at no more than the 340B ceiling price, even if said drugs are distributed via a contract pharmacy.⁹ Despite this guidance from the federal government, the six manufacturers persisted in their restrictions and did not adhere to the HHS advisory opinion. In May 2021, the Health Resources and Services Administration (HRSA) issued violation letters to these companies notifying them that their practices violate the law, and they may be charged civil monetary penalties for overcharges.¹⁰

⁹ U.S. Department of Health and Human Services, Office of General Counsel. *Advisory Opinion 20-6 on Contract Pharmacies Under the 340B Program*. Washington, DC: HHS, 2020.

https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf (Accessed July 16, 2023)

¹⁰ Health Resources and Services Administration. "Program Integrity, HRSA Correspondence to Stakeholders." Accessed July 16, 2023. <https://www.hrsa.gov/opa/program-integrity>.

The manufacturers subsequently challenged the enforcement action in court, igniting a legal battle. The AAMC has joined other hospital groups, including the American Hospital Association, 340B Health, and America's Essential Hospitals, as *amici* in support of the federal government's enforcement of the 340B statute, as it requires manufacturers to provide discounted drugs to covered entities, regardless of how they are delivered.¹¹

Contract Pharmacy Restrictions Pose a Profound Threat to the 340B Program

In the intervening years since HHS first published its advisory opinion, the number of pharmaceutical manufacturers restricting contract pharmacy arrangements has grown to over 20. These restrictions have a tangible impact on 340B hospitals' ability to care for patients and communities. According to 340B Health's 2022 annual survey, 43 percent of disproportionate share (DSH), rural referral center (RRC) and freestanding children's hospitals reported a decline in 340B savings resulting from these restrictions.¹² Given the mounting financial pressures facing teaching hospitals, including rising labor and supply costs, workforce shortages, insufficient reimbursement from payers, and increasing administrative burden, these restrictions may limit the programs and services that 340B hospitals can offer low-income and under-resourced patients.

The AAMC recommends that Congress clarify and codify protections for contract pharmacy arrangements in federal 340B statute. We support legislation clarifying that Section 340B of the Public Health Service Act (42 U.S.C. 256b) requires pharmaceutical manufacturers to deliver discounted drugs to covered entities, irrespective of the method through which these drugs are dispensed. We support specifically prohibiting pharmaceutical manufacturers from imposing conditions on covered entities' use of contract pharmacies, such as by requiring covered entities to submit additional claims data or other information for these dispenses. The AAMC supports efforts to address pharmaceutical companies' increasing proclivity to restrict 340B hospitals' use of contract pharmacies, thereby ensuring that the program can continue to benefit covered entities and the patients they serve.

Question 3: 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?

As the AAMC has continually emphasized, the intended beneficiaries of the 340B program are covered entities themselves, which leverage their 340B savings to provide comprehensive health care services to low-income patients and communities. Increasingly, for-profit entities, including insurers and pharmacy benefit managers (PBMs), have begun to siphon off savings intended for covered entities and the patients they serve. The AAMC is deeply concerned by these practices, which undermine the program's mission to support covered entities in caring for low-income and

¹¹ Brief of the American Hospital Association, 340B Health, America's Essential Hospitals, Association of American Medical Colleges, and Children's Hospital Association as Amici Curiae, *Eli Lilly & Co. v. Becerra*. Available online at: <https://www.aamc.org/media/62356/download?attachment>.

¹² 340B Health, 340B Health Annual Survey 2022: Vital 340B-Supported Patient Services Threatened as Manufacturer Restrictions Cut Into Savings, (Washington, D.C.: 340B Health, 2022), https://www.340bhealth.org/files/340B_Health_Survey_Report_2022_FINAL.pdf.

under-resourced patients and communities. By capturing savings intended for covered entities, insurers and PBMs not only threaten the financial viability of covered entities, but also, the continued availability of the programs and services they provide. To address this challenge, we urge Congress to pass the Preserving Rules Ordered for the Entities Covered Through 340B Act of 2023 (PROTECT 340B Act of 2023, [H.R. 2534](#)).¹³ This bipartisan legislation would prohibit payers, including insurers and PBMs, from imposing discriminatory reimbursement policies on 340B covered entities, such as reimbursing 340B providers at systematically lower rates than non-340B providers. It would authorize civil monetary penalties for insurers and PBMs found to be in violation of these protections. This commonsense legislation represents an important first step in ensuring that 340B savings benefit the intended beneficiaries of the program, rather than for-profit entities that do not provide care to patients.

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 health care stakeholders greater confidence in its oversight?

The AAMC and our members have serious concerns about pharmaceutical manufacturers' non-compliance with 340B program requirements and resistance to enforcement actions by federal oversight agencies, particularly as it relates to the issue of contract pharmacy. The AAMC is concerned that existing program integrity measures are imbalanced. For example, HRSA, the agency responsible for overseeing and administering the program, audits 200 covered entities per year, as compared to just five pharmaceutical manufacturers. We believe that additional audits of pharmaceutical manufacturers are needed to achieve audit parity and strengthen confidence in HRSA's oversight of the program.

The administrative dispute resolution (ADR) process is an important avenue for covered entities to resolve disputes with pharmaceutical manufacturers. However, to instill trust in the process, specific improvements are needed. In our comments on a recent proposed rule to strengthen the ADR process, the AAMC outlined our recommendations to ensure that the process is more accessible, administratively feasible, and timely.¹⁴ In particular, we support removing the \$25,000 minimum threshold necessary for covered entities to submit an ADR claim.¹⁵ In addition, to provide covered entities with greater certainty, we recommend that HRSA establish a timeframe for the ADR decision-making process.¹⁶

Question 6: 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?

¹³ Danielle Turnipseed to Reps. Abigail Spanberger and Dusty Johnson, April 26, 2023, AAMC Endorsement Letter for the Preserving Rules Ordered for the Entities Covered Through 340B Act of 2023 (PROTECT 340B Act of 2023), <https://www.aamc.org/media/66586/download>.

¹⁴ Jonathan Jaffrey, "AAMC Comment on 340B Drug Pricing Program; Administrative Dispute Resolution (HHS Docket No. HRSA-2021-0004) (RIN 0906-AB28)" (Washington, D.C.: AAMC, 2023), <https://www.aamc.org/media/64796/download?attachment>.

¹⁵ *Ibid*, 2.

¹⁶ *Ibid*, 4.

The AAMC appreciates the interest in promoting transparency and accountability in the 340B program. Given that hospitals are already subject to numerous regulatory requirements, we urge consideration of what constitutes *meaningful* transparency in the 340B program. The AAMC does not support any proposal that would duplicate existing regulatory requirements or otherwise require covered entities to collect and report data that does not appropriately capture the value of the program to patients and communities.

The AAMC Supports Meaningful, Voluntary Transparency in the 340B Program

We share your goal of illustrating the benefit of the program by informing stakeholders how covered entities use their savings to benefit patients and communities. In support of this objective, the AAMC has endorsed *voluntary* transparency measures, such as the American Hospital Association’s “340B Good Stewardship Principles,” which provide a framework for interested hospitals to communicate the value of the program to the community.¹⁷ These principles encourage hospitals to calculate, in a standardized manner, the savings they achieve from the program, as well as outline the many programs and services 340B makes possible. In addition to these principles, some AAMC-member institutions have found other ways to effectively convey the value of the 340B program to their community, such as by maintaining a webpage dedicated to the 340B program at their institution, or by filling out a 340B Health “Impact Profile.” The AAMC supports these voluntary transparency measures, which are highly individualized to meet the unique needs of each institution.

Existing Legislative Proposals Intended to Promote Program Integrity Are Poorly Constructed

Although the AAMC supports *voluntary* transparency efforts, we are concerned that certain legislative proposals intended to promote program integrity and accountability are poorly constructed and fail to capture the true value of the program to patients and communities. One such proposal is [H.R. 3290](#), which would authorize the HHS Secretary to audit how covered entities use their savings, as well as require 340B hospitals to report comprehensive financial data related to their participation in the program. The AAMC opposes this legislation, which would impose a significant administrative burden on 340B hospitals and would not provide accurate information on the value of the program for patients and communities.

To comply with these requirements, 340B hospitals would be required to report financial data for each of their child site locations, thereby necessitating the development of entirely new software systems. This requirement implies that 340B savings accrued to a specific child site should be used to finance programs and services at that site. In reality, hospitals use their savings in a manner that will best serve patients and communities, regardless of where they receive care. Moreover, the legislation’s intense focus on hospitals’ charity and uncompensated care costs presupposes that the 340B program’s purpose is to finance said costs, which is not the case. The 340B program is designed to help covered entities “stretch scarce federal resources” to provide “more comprehensive services” to patients and communities. As such, 340B covered entities are

¹⁷ American Hospital Association. “340B Hospital Commitment to Good Stewardship Principles.” Accessed July 16, 2023. <https://www.aha.org/initiativescampaigns/2018-09-13-340b-hospital-commitment-good-stewardship-principles>.

Senators Thune, Stabenow, Capito, Baldwin, Moran, and Cardin

July 26, 2023

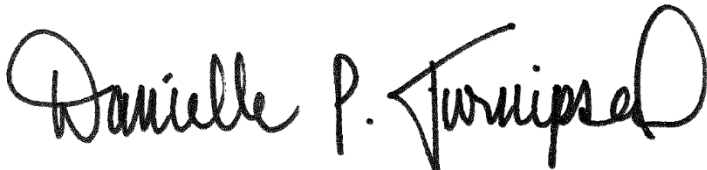
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afforded latitude to determine how they will use their savings to best serve patients and communities.

To summarize, as currently written, H.R. 3290 would impose onerous administrative and reporting requirements on 340B hospitals, while failing to adequately capture the value of the program to both covered entities and the communities they serve.

We look forward to working with you and your staff on potential solutions. Please contact me, Len Marquez (lmarquez@aamc.org), Senior Director of Government Relations and Legislative Advocacy, or Sinead Hunt, Legislative Analyst (sihunt@aamc.org) if you have any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Danielle P. Turnipseed". The signature is written in a cursive, flowing style with a large, looped initial 'D'.

Danielle P. Turnipseed, JD, MHSA, MPP
Chief Public Policy Officer
Association of American Medical Colleges

CC: David J. Skorton, MD
President and CEO
Association of American Medical Colleges

CC: Jonathan Jaffery, MD
Chief Health Care Officer
Association of American Medical Colleges