



August 23, 2023

The Honorable Cathy McMorris Rodgers  
Chair, Committee on Energy and Commerce  
United States House of Representatives  
2188 Rayburn House Office Building  
Washington, D.C.  
20515

Dear Chair Rodgers,

Thank you for the opportunity to provide comments on your recent [discussion draft legislation](#) to address the root causes of drug shortages and ensure patients' continued access to life-saving medications. Drug shortages are a significant issue facing AAMC-member teaching hospitals, health systems, and the patients and communities they serve. We appreciate your interest in addressing this problem and look forward to working with you and your staff on long-term policy solutions.

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.

We appreciate your attention to the issue of drug shortages, which significantly impact our members and the patients and communities they serve. In our [response](#) to your [June 12 request for information](#), the AAMC outlined which types of drugs are especially susceptible to shortages, along with their impact on clinical operations and patients' access to care. To summarize, while shortages affect a wide array of drugs, they disproportionately impact generic injectable drugs. Drug shortages can have cascading effects on patient care, resulting in treatment delays, a shift towards alternative (and sometimes, less effective) treatments, and in the most extreme cases, care rationing. This can be seen most acutely in cancer care, as chemotherapy drugs are among the top five drug classes impacted by shortages. A recent survey of 27 cancer centers found that shortages of carboplatin, a chemotherapy drug commonly used to treat breast, ovarian, and other types of cancers, have seriously impeded patients' access to care, with 36 percent of respondents reporting that they are unable to treat all patients requiring this particular treatment regimen.<sup>1</sup>

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<sup>1</sup> National Comprehensive Cancer Network, *NCCN Best Practices Committee Carboplatin and Cisplatin Shortage Survey Results* (Washington, D.C.: NCCN, 2023), <https://www.nccn.org/docs/default-source/oncology-policyprogram/NCCN-Drug->

This is just one example of how chronic drug shortages strain AAMC-member institutions and the patients and communities they serve.

Although we appreciate your interest in exploring this pressing challenge, we are concerned about certain provisions of your recently unveiled discussion draft, which proposes to curtail the 340B Drug Pricing Program. As we have previously emphasized, the AAMC categorically rejects the notion that the 340B Program is responsible for drug shortages. The AAMC firmly believes that the 340B program, which allows certain safety-net providers, referred to as “340B covered entities,” to purchase covered outpatient drugs at a discount, enhances prescription drug access. 340B covered entities use the savings generated by their participation in the program to invest in a wide array of programs and services benefiting low-income patients and communities.<sup>2</sup> Rather than driving shortages, the 340B program supports access to life-saving drugs through free and discounted prescriptions, bedside medication delivery, and medication management services.

The root causes of drug shortages are complex and multi-factorial. Research by policymakers, industry groups, governmental bodies, and academics has coalesced around several main causes of drug shortages, including vulnerabilities in the pharmaceutical supply chain and economic factors. In their landmark 2019 report, “Drug Shortage: Root Causes and Potential Solutions,” the FDA-led interagency Drug Shortage Task Force identified three main causes for shortages: (1) the lack of financial incentives to produce narrow-margin drugs, (2) challenges in quality management, and (3) vulnerabilities in the pharmaceutical supply chain.<sup>3</sup> **Notably, this report did not identify the 340B program as a contributor to drug shortages.**

There is no reliable evidence linking the 340B Drug Pricing Program to drug shortages. Rather, the program helps hospitals and health systems contend with the operational challenges generated by shortages. For example, when there is a shortage of a drug, a hospital must identify an alternative drug (where possible). In some cases, the alternative drug is more expensive than the original, creating unexpected costs for the hospital and patients. In these cases, the 340B program helps to defray the financial and operational consequences of drug shortages by allowing the hospital to purchase the alternative drug at a discount. The 340B program enables hospitals to nimbly respond to drug shortages, helping to avoid potential disruptions in care.

## **Title II, Sec. 201: Exempting Generic, Sterile Injectable Drugs from the 340B Drug Pricing Program**

The AAMC has significant concerns with Title II, Sec. 201 of the discussion draft, which would exempt certain generic, sterile injectable drugs from 340B pricing. As previously emphasized, the 340B program does not contribute to drug shortages, and as such, this policy would have little to no effect on the prevalence or severity of shortages. If passed, this legislation would set a worrying precedent by exempting certain drugs from 340B pricing. We are concerned that certain stakeholders, including pharmaceutical manufacturers, might exploit this precedent to carve out all types of drugs from the

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ShortageSurvey.pdf?utm\_campaign=pharmalittle&utm\_medium=email&\_hsmi=261813870&\_hsenc=p2ANqtz-R325mbaVCoHt23zb9zYdLNlJ5O2SU9K9cRIdb\_ge5XQqr2le1zJuSKNu5UDmj96mYfpHV\_upSdRE2bpHSYYN uD8yQEw&utm\_content=261813870&utm\_source=hs\_email.

<sup>2</sup> AAMC, *Securing Our Safety-Net: The 340B Drug Pricing Program* (Washington, D.C.: AAMC), <https://www.aamc.org/media/66471/download?attachment>

<sup>3</sup> Food and Drug Administration, *Drug Shortages: Root Causes and Potential Solutions*, Washington, D.C.: GPO, 2019, <https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions> (Accessed August 21, 2023)

program, thereby reducing covered entities' savings, and, consequently, low-income patients' access to care. Furthermore, the legislation does not require drug manufacturers to use the additional revenue they would receive to address the issue of drug shortages. As such, this policy would cause significant harm to health care providers participating in the 340B program and the patients and communities they care for, while neglecting the true drivers of drug shortages.

## **Title II, Sec. 202: Study on Penny Pricing**

While the AAMC appreciates your efforts to understand and address the root causes of drug shortages, we oppose any effort to ascribe blame for drug shortages to the 340B program or its beneficiaries. This provision would direct the Government Accountability Office (GAO) to develop a report analyzing the number of drugs subject to 340B "penny pricing" (or available for \$1 or less) that have experienced shortages over the past ten years. By commissioning this study, the discussion draft legislation would lend credibility to the argument that the 340B program is responsible for shortages. To be absolutely clear, a 340B drug can only be "penny priced" if a manufacturer chooses to raise its price faster than the rate of inflation. Drug pricing decisions are solely up to pharmaceutical manufacturers, which can avoid penny pricing by refraining from rapidly increasing the price of their products.

We believe that this proposed study would redirect blame for drug shortages to the 340B program, and, by extension, covered entities. Instead, the AAMC recommends you explore the role that drug manufacturers and other factors play in contributing to drug shortages, while empowering hospitals and health care providers to effectively navigate these challenges.

**While we support efforts to strengthen the pharmaceutical supply chain and address drug shortages, we firmly believe that this policy objective should not come at the expense of our nation's health care safety net institutions.** Considering the profound financial challenges facing teaching hospitals and health systems, now more than ever, it is imperative that policymakers protect the 340B program. 340B enables safety-net hospitals, many of which are teaching hospitals to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The program achieves this goal by offsetting uncompensated care costs, including underpayments from Medicare and Medicaid; financing essential programs and services (like substance use disorder treatment); and strengthening community collaborations. Absent the 340B program, many AAMC members would be forced to consider difficult decisions regarding the volume of care and array of services they can responsibly provide to uninsured and underinsured patients.

In addition to the challenges facing safety-net providers, the 340B program itself faces serious threats, including pharmaceutical manufacturers' increasing illegal restrictions on covered entities' use of contract pharmacy arrangements. Over the past three years, over 20 pharmaceutical manufacturers have chosen to impose unfair and unlawful restrictions upon covered entities' use of contract pharmacy arrangements. These restrictions not only deplete covered entities' savings, but also place an undue burden on patients, imposing yet another obstacle in their path to care. To address this challenge, the AAMC supports clarifying and codifying protections for contract pharmacy arrangements in federal statute.

In addition, the AAMC would like to provide comment on the following provisions:

### **Title I, Sec. 101: Exempting Certain Drugs from Rebates Under the Medicaid Program**

Under the Medicaid Drug Rebate Program (MDRP), generic drugs are currently subject to a rebate of 13 percent off the average manufacturer price (AMP).<sup>4</sup> The MDRP also includes an inflationary penalty, which is an additional rebate that manufacturers must pay if they choose to raise the price of their drug faster than the rate of inflation. The MDRP helps to support prescription drug affordability by discouraging manufacturers from rapidly raising the price of medications. In addition, the program provides essential savings that allow state Medicaid agencies to balance their budgets while ensuring access to life-saving medications for low-income and historically underserved patients.

This provision proposes to eliminate and/or cap the inflationary rebate for certain sterile injectable drugs that are either (a) used to treat patients with serious health conditions, or (b) experiencing or at risk of shortage. The AAMC opposes this proposal, which would result in significant drug price increases while doing little to address the root causes of drug shortages. It is unclear how this proposal would address drug shortages, as the bill would not require manufacturers to use their rebate savings to improve the supply chain for drugs in short supply. In addition, the AAMC believes that removing the inflationary penalty for certain generic drugs will result in significant drug price increases, which states, the federal government, and hospitals will ultimately be forced to shoulder. This policy would also set a concerning precedent, opening the possibility that other types of drugs could be exempted from inflationary penalties. Given the persistent challenge of prescription drug unaffordability, the AAMC opposes efforts to weaken policies designed to keep prices low for patients and providers.

### **Title III, Sec. 305: Hospital Reporting of Group Purchasing Organization (GPO) Remuneration under Medicare**

If enacted, this provision would require hospitals to report the remuneration they receive from group purchasing organizations (GPOs) on their Medicare Cost Report as a Medicare Conditions of Participation (CoP). The AAMC opposes this measure, which is both administratively burdensome and duplicative of existing reporting requirements. Hospitals are already required to report fee distribution from GPOs on their Medicare Cost Report, and as such, this proposal is both redundant and unnecessary.

Furthermore, we are concerned that the term “remuneration” is overly broad and ill-defined in this context. Given the complex relationships that exist between hospitals and GPOs, it is unclear what type of payments (beyond fee distribution) this requirement encompasses. We oppose linking this requirement to the CoP, which involves issues that have a direct impact on clinical quality and patient care. If a hospital were unable to meet this requirement, it could be excluded from both Medicare and Medicaid, effectively eliminating its ability to remain open and serve patients.

### **Title III, Sec. 307: Clarification of Medicare ASP Payment Methodology**

This measure would redefine “bona fide service fees” to exclude administrative fees paid to GPOs. The AAMC opposes this policy, which may dissuade pharmaceutical manufacturers from working with GPOs, as they would have to include GPO administrative fees in their products, thereby decreasing the average sales price (ASP) of drugs. GPOs perform many valuable services for hospitals, such as evaluating the clinical efficacy of drugs, clinician preferences, and the pharmaceutical supply chain. We

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<sup>4</sup> Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program* (San Francisco, C.A.: KFF, 2019), <https://www.kff.org/medicaid/issue-brief/understanding-the-medicare-prescription-drug-rebate-program/#:~:text=For%20generic%20drugs%2C%20the%20rebate,is%20no%20best%20price%20provision.&text=The%20rebate%20calculation%20also%20includes,rising%20drug%20prices%20over%20time>

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are concerned that shifting these responsibilities from the GPO to manufacturers would reduce the efficacy of the drug supply chain and lead to increased costs. Furthermore, we are concerned that this policy could reduce hospitals' reimbursement for provider-administered drugs, which are currently paid at a rate of ASP plus 6 percent under Medicare Part B.

Again, the AAMC appreciates your efforts to better understand and address the pervasive drug shortages facing our health care system and their impact on patients. We look forward to working with you and your staff on potential policy solutions to improve patients' access to care and improve lives. Please contact me, Len Marquez ([lmarquez@aamc.org](mailto:lmarquez@aamc.org)), Senior Director of Government Relations and Legislative Advocacy, or Sinead Hunt, Legislative Analyst ([sihunt@aamc.org](mailto: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.

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