

June 4, 2024

The Honorable Ron Wyden
Chair, Committee on Finance
United States Senate
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member, Committee on Finance
United States Senate
239 Dirksen Senate Office Building
Washington, DC 20510

Dear Chair Wyden and Ranking Member Crapo,

On behalf of the Association of American Medical Colleges (AAMC), I thank you for your recent discussion draft legislation to address drug shortages and ensure patients' reliable access to life-saving medications. Drug shortages are a serious challenge impacting our member institutions and the patients and communities they serve. We appreciate your commitment to addressing this problem and bipartisan approach to this discussion draft. We look forward to working with you and your staff on developing long-term, consensus-driven policy solutions to this pressing challenge.

The AAMC 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 158 U.S. medical schools accredited by the [Liaison Committee on Medical Education](#); 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, 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, academic health systems 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 participation in the AAMC by U.S. and international academic health centers.

We appreciate the committee's continued attention to the issue of drug shortages, which pose a serious challenge to AAMC-member teaching health systems and hospitals, their physician faculty, and the patients and communities they care for. According to data reported by the American Society of Health System Pharmacists (ASHP) and the University of Utah, the U.S. reported a record-high 323 active drug shortages in the first quarter of 2024.¹ These shortages have complex and cascading impacts on our health care system. When faced with a shortage of an essential medication, hospital staff must quickly adapt to identify and procure an alternative drug. This process can impose significant costs on health systems and hospitals: A recent study showed that hospitals spend an estimated \$360 million and 8.6 million personnel hours per year navigating drug shortages.² Although hospitals strive to mitigate the negative effects of shortages on patient care, this is not always feasible. Drug shortages can result in treatment delays and, in

¹ <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics?loginreturnUrl=SSOCheckOnly>

² <https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129>

the most extreme cases, care rationing. They can also lead to harmful clinical consequences for patients. For these reasons, it is crucial that lawmakers identify and address the root causes of these shortages.

The underlying drivers of generic drug shortages are complex and multi-faceted. Shortages occur when supply chains cannot nimbly adjust to disruptions to supply or demand. These interruptions can result from natural disasters, biologic events, quality issues, logistical challenges, geopolitical conflicts, and other forces. When a manufacturer is unable to quickly ramp up production and meet demand for a given medicine, it can result in a shortage. While some of these phenomena are beyond the control of the generic drug industry, critical decisions made by manufacturers have exacerbated the risk that these disruptions lead to shortages. These decisions include a reliance on “just-in-time” manufacturing practices, the offshoring of production overseas, and disinvestment in supply chain quality, redundancy, and resiliency. To address the root causes of drug shortages, policymakers must appropriately incentivize manufacturers to remedy these vulnerabilities by bolstering and diversifying their supply chains.

As purchasers of generic drugs, health systems and hospitals can and should implement evidence-based practices to mitigate their risk of experiencing drug shortages. As we have noted in previous comment letters, the opaque nature of the pharmaceutical supply chain means that purchasers sometimes lack information about the quality, resiliency, and maturity of the supply chains employed by manufacturers, and therefore, are unable to evaluate and prioritize these factors in their purchasing decisions. We support policies that provide health systems and hospitals with the tools and information they need to become informed purchasers of generic drugs, such as by increasing visibility into pharmaceutical supply chains. **However, it is important to note that as purchasers of generic drugs, health systems and hospitals have little to no influence upon manufacturers’ production decisions or the larger pharmaceutical supply chain.** Therefore, to effectively address this problem, it is necessary for policymakers to adopt a multi-pronged approach that both minimizes the risk of manufacturing disruptions and helps health systems and hospitals mitigate the impact of said disruptions on clinical operations and patient care. In other words, policymakers must acknowledge and comprehensively address both the supply- and demand-side factors that contribute to shortages.

With this in mind, we offer the following comments on this discussion draft:

Medicare Drug Shortage Prevention and Mitigation Program

The AAMC appreciates the time and care that your staff have invested into this proposed program, and we share your goal of mitigating the negative impacts of drug shortages on health systems and hospitals and the patients they serve. We greatly appreciate the voluntary nature of the proposed program, which would maximize flexibility for health systems and hospitals while supporting their ability to navigate shortages. However, we are concerned that this proposal is disproportionately focused on demand-side incentives. **As noted above, hospitals and other purchasers have limited control over the supply-side factors that ultimately result in drug shortages, and therefore, must not be held solely accountable for this problem.** To address the challenge of drug shortages, it is imperative that policymakers strengthen supply chains by increasing manufacturing redundancy, diversifying where raw materials are sourced and where drugs are manufactured, and investing in resilience and sustainability.

Increasing Supply Chain Visibility and Transparency

As purchasers of generic drugs, health systems and hospitals have little visibility into the supply chains employed by pharmaceutical manufacturers, and therefore, struggle to prioritize supply chain quality and resilience in their purchasing decisions. To do business in the U.S., all manufacturers must meet the regulatory requirements set forth in the Food and Drug Administration's Current Good Manufacturing Practices (CGMP). While this system has created a baseline set of quality management metrics that all manufacturers must meet, manufacturers are not incentivized to make investments in quality management processes above and beyond these standards. Moreover, while the CGMP help regulators to identify and address deficiencies in manufacturers' quality management systems, these standards are not helpful to health systems and hospitals, which lack information about the quality and reliance of the manufacturers they are purchasing from. Under this system, manufacturers compete on cost alone and are not incentivized to invest in the quality, diversity, and resiliency of their supply chains.

Considering these challenges, the AAMC supports the provisions contained in paragraph 4 of the legislative discussion draft requiring generic manufacturers participating in the program to enter into Manufacturer Reliability Agreements, which would include relevant supply chain quality and reliability information. As we previously noted in our [response](#) to a request for information issued by the Federal Trade Commission (FTC) and Department of Health and Human Services (HHS), providing health systems and hospitals with additional visibility into the supply chains employed by manufacturers can empower them to purchase from more reliable manufacturers. This provision represents an important first step in equipping health systems and hospitals and other purchasers to evaluate the quality and dependability of the generic manufacturers they purchase from.

There are other policies the committee should consider to increase transparency in the pharmaceutical supply chain. For example, we recommend that you work with the FDA and the Centers for Medicare and Medicaid Services (CMS) to fully execute the Quality Management Maturity (QMM) program, which aims to encourage drug manufacturers to implement quality management practices that go beyond current CGMP requirements. One advantage of the QMM is its use of a five-level rating system to inform purchasers about the maturity and robustness of manufacturers' supply chains. Unlike existing transparency measures, which simply inform purchasers of deficiencies in manufacturers' supply processes, the QMM allows health systems and hospitals to evaluate and compare manufacturers' quality management systems. Working with the FDA to further develop and disseminate quality ratings for generic manufacturers would empower health systems and hospitals to choose high-quality manufacturers with proven reliability.

Incentivizing Buffer Inventory

While supply chain shocks can be mitigated, they cannot be eradicated. Natural disasters, biologic events, and other factors unavoidably disrupt pharmaceutical supply chains, and therefore, it is imperative that health systems and hospitals are prepared and able to serve patients and communities. Maintaining a buffer stock of medications most susceptible to shortages is an evidence-based strategy to reduce the negative consequences of supply chain shocks on patients and providers. Encouraging health systems and hospitals to hold additional inventory of essential medications can help to cushion the impact of supply chain disruptions and prevent interruptions in patient care. Unfortunately, given the acute financial

challenges facing health systems and hospitals, including historic workforce shortages, rising costs, and insufficient reimbursement from payers, it is not always financially or logistically feasible for health systems and hospitals to maintain a buffer stock. As previously noted in our [comments](#) on the calendar year (CY) 2024 Hospital Outpatient Prospective Payment System proposed rule, the AAMC supports an additional add-on payment for health systems and hospitals to maintain a buffer stock of essential medicines. We support provisions contained in paragraph 3 of the discussion draft legislation, which would provide an additional lump-sum payment to support health systems and hospitals in maintaining a buffer inventory of certain generic medicines.

While the AAMC supports this proposal, we encourage the committee to consider additional safeguards to protect against unintended demand shocks and hospital hoarding. For example, the fiscal year (FY) 2025 Inpatient Prospective Payment System's buffer stock proposal includes a measure that would prevent a hospital from receiving additional payment for establishing a new buffer stock of a medicine that is currently experiencing a shortage. Additionally, the proposed rule includes a proposal for a phased-in approach that would allow hospitals to slowly build their buffer stocks. The AAMC supports these policies, which would help to mitigate the unintended consequences of a buffer stock payment and reduce the risk of demand shocks.

Reducing Health System and Hospital Burden

The AAMC has concerns about the administrative burden this program would impose on participating health systems and hospitals. As noted above, hospitals and other purchasers are not responsible for drug shortages, and therefore, it is unfair to place the onus of this problem solely on them. For example, under the proposed program, hospitals would be eligible for supplemental payments if they meet certain core and advanced standards. For example, to qualify for payments, hospitals must commit to a minimum purchase volume, a minimum contract term, a prohibition against off-contract purchasing, and a pricing stability provision that would require them to forgo 340B discounts and additional rebates. While we recognize that these provisions are intended to inject stability into the market, participating hospitals would be required to assume a significant degree of risk and administrative burden to participate. We are concerned that these barriers represent a disincentive for hospitals to participate and would limit the utility of the program.

Medicaid Shortage Provisions

The AAMC has significant concerns with this section of the discussion draft, which would limit the Medicaid Drug Rebate Program's (MDRP) inflationary rebates for certain generic medicines, as well as empower the HHS Secretary to reduce or waive inflationary rebates for generic medicines under specific circumstances. As we have previously [emphasized to lawmakers](#), the MDRP's inflationary penalty helps to support prescription drug affordability by discouraging manufacturers from rapidly raising the price of medications. 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 health systems and hospitals will ultimately be forced to shoulder. Given the persistent challenge of prescription drug unaffordability, the AAMC opposes efforts to weaken policies designed to keep prices low for patients and providers.

Furthermore, we would like to highlight the potential implications of this policy for hospitals participating in the 340B Drug Pricing Program. The 340B ceiling price, or the maximum amount that a manufacturer may charge covered entities for a drug, is calculated as the average manufacturer price (AMP) minus the unit rebate amount (URA). The URA for generic drugs is currently set to a statutory minimum of 13% but can increase due to the inflationary rebate. As a result, the 340B ceiling price is directly impacted by the MDRP's inflationary rebates; proposed limitations on these rebates would necessarily reduce the URA and increase the 340B ceiling price for 340B hospitals. Therefore, this policy would likely reduce hospitals' 340B savings and consequently, the financial resources available to support access to care for low-income patients and communities. The AAMC urges the committee to reconsider this provision.

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 (lm Marquez@aamc.org), Senior Director of Government Relations and Legislative Advocacy, or Sinead Hunt, Senior 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.

Danielle 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