American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

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The Honorable Ron Wyden
Chairman
United States Senate
Committee on Finance
Washington, DC 20510

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

Dear Chairman Wyden and Ranking Member Crapo:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) thanks the Senate Committee on Finance for the opportunity to comment on its draft legislation, the "Drug Shortage Prevention and Mitigation Act."

America's hospitals and health systems have long been concerned about increasing shortages of essential drugs required to treat patients, particularly shortages of generic sterile injectable drugs (GSIs). Shortages can adversely affect patient care by causing delays in treatment, increasing the risk of medication errors and requiring the use of less effective alternative treatments.

When a drug is in shortage, hospitals must find an alternative drug to use in treating patients. This process of finding, procuring and safely administering an alternative drug can result in significant costs to the hospital. There are numerous complicated steps to manage changes in products, doses, concentrations and routes of administration. This includes just-in-time training for staff on how to use the new drug and what its side effects might be. It also requires changes in the hospital's electronic health record so that dosage, allergies and drug-drug interactions and other safety precautions are updated. One study estimated that drug shortages result in at least $359 million annually in additional labor costs to hospitals.[1]

[1] https://newsroom.vizientinc.com/en-US/releases/new-vizient-survey-finds-drug-shortages-cost-hospitals-just-under-360m-annually-in-labor-expenses

Due to the increased cost and necessity of treating patients in a timely manner, especially in cases of cancer and other serious illnesses, it is important to ensure the pharmaceutical supply chain is protected and priority drugs are identified and given special attention to protect uninterrupted patient access. It has become increasingly clear that our national pharmaceutical supply chain is fragile, and this fragility poses significant risk to the patients and communities served by America's hospitals and health systems. Various businesses make up the pharmaceutical supply chain, including suppliers, manufacturers, distributors and group purchasing organizations (GPOs). A disruption anywhere in the chain can create prolonged difficulties in pharmaceutical supply acquisition for providers, which can directly affect their ability to treat patients.

The AHA welcomes the committee's continued attention to the issue of generic drug shortages and its willingness to receive stakeholder input. We also appreciate that the committee, recognizing that a more reliable, resilient and sustainable drug supply chain is necessary, has drafted bipartisan legislation intended to provide Medicare incentive payments to hospitals that would support long-term contracting, financing for private sector buffer stock and transparency provisions that would provide hospitals and other providers with increased insight into the manufacturers' supply chains and quality management practices.

Below we review in greater detail aspects of the draft legislation that we support, as well as parts about which we have concerns or recommendations.

PROVISIONS AHA SUPPORTS

The AHA believes that the proposed Medicare Drug Shortage Prevention and Mitigation Program is a step in the right direction because it seeks to address core economic challenges associated with the increasing numbers of GSI shortages. In particular, the low prices for these products and the Food and Drug Administration's (FDA) limited authority to enforce manufacturing quality reduce drugmakers' incentive to adhere to good manufacturing practices. The resulting quality problems often lead to recalls, production stoppages and ultimately shortages.

The AHA appreciates the draft legislation's focus on resolving these shortcomings by requiring participating generic manufacturers to enter into Manufacturer Reliability Agreements with program participants (such as GPOs, wholesalers and hospitals). These agreements would include requirements that manufacturers provide supporting evidence on why they have the capabilities to meet program requirements, relevant supply chain reliability and quality information, an attestation of compliance with the FDA's rules related to quality and shortages, and an agreement to provide timely information to program participants and submit to audits.

The AHA strongly supports efforts to incentivize greater manufacturing reliability and quality for GSIs. We believe that these agreements, with stakeholder input into their components and proper oversight by CMS and FDA, could help spur drugmakers to improve their quality management systems and manufacture their products and source their active pharmaceutical ingredients (API) in a manner that would diversify and strengthen the pipeline for GSI manufacturing, with the goal of achieving a better balance between domestic and trusted international sources. Moreover, including this enhanced level of transparency into where and how GSIs are manufactured is something for which the AHA has long advocated. We are hopeful that these agreements will provide hospitals with an improved ability to determine which manufacturers can best guarantee a reliable and steady supply of high-quality GSIs.

In addition, we support the voluntary nature of the program, including both voluntary hospital participation and selection of applicable GSI(s) to be included. This will help ensure that the participants are fully committed to the program's intent to incentivize improvements in the supply, quality and resilience of GSIs. Moreover, we are also pleased that the program would not only include GPOs, wholesalers and nonprofits as coordinating entities on behalf of the payment-eligible providers, but also would permit providers to participate directly if they so choose. This differs from other recent drug shortage proposals which did not address the critical role of these intermediaries.

PROVISIONS ABOUT WHICH AHA HAS CONCERNS

340B Program Concerns

The AHA has two primary concerns as it relates to the bill's interaction with the 340B Drug Pricing Program. First, the inability for a 340B payment-eligible provider to access 340B pricing for units of a generic drug subject to the Medicare Drug Shortage Prevention and Mitigation Program undermines the very purpose of the 340B program. Second, the ability of the secretary to reduce or waive the inflationary rebate under the Medicaid Drug Rebate Program (MDRP) is likely to increase drug prices and has important consequences for the determination of the 340B ceiling price, which would impact all 340B providers. Below, we detail our specific concerns with these provisions, their potential impacts and suggestions to improve the bill language to mitigate any harm to 340B providers.

Subsection (b)(3)(G) of the draft requires that all program participants annually submit "pricing stability certifications" attesting to the fact that the provider did not seek or accept any discounts on units of applicable generics, including any 340B discounts. The inability of 340B providers who volunteer to participate in this program to receive 340B discounts on these drugs is counterproductive to the purpose of the program. As Congress has previously recognized, the purpose of the 340B program is to "stretch scarce Federal resources as far as possible, reaching more eligible patients and

providing more comprehensive services."[2] By prohibiting 340B providers from accessing these discounts, it would reduce their 340B savings and could jeopardize their ability to maintain, improve and expand access to care for the patients and communities they serve. In particular, many hospitals use their 340B savings to help offset the costs required to manage drug shortages and ensure patients are able to access their needed medications. Denying the ability of 340B providers to access these savings would contravene the goal of mitigating the impact of drug shortages.

Even if the program's incentive payments can help offset some of the 340B savings losses that are bound to occur, the fact that the hospital is unable to purchase the drug at the upfront 340B discounted price presents cash flow and budgetary concerns for the hospital. As a result, this provision alone could create a catch-22 scenario for 340B providers — the hospital wants to participate in the program to mitigate drug shortages and make those drugs available to patients but cannot participate because the inability to access 340B discounted pricing presents an insurmountable challenge to purchasing the drug. Ultimately, this provision alone could make it difficult for 340B providers to participate in the program, which would ultimately reduce the value and effectiveness of this program. **The AHA recommends that Congress remove the following language, "including discounts under section 340B of the Public Health Service Act," and preserve the ability of payment-eligible 340B providers to access 340B pricing for generic drugs under this program.**

Section 3 of the bill allows the secretary to reduce or waive inflationary rebates under the MDRP for applicable generic drugs in shortage. These inflationary rebates serve as important disincentives for drug companies to raise the prices of their drugs indiscriminately, particularly those in shortage. One example that highlights the value of the inflationary rebate is a provision of the American Rescue Plan Act that removed the previous cap for the inflationary rebate of 100% of the drug's average manufacturer price (AMP) and went into effect Jan. 1, 2024. In effect, this meant that if drug companies were particularly egregious in raising drug prices, the inflationary rebate could far exceed 100% of the drug's AMP. As a result of removing this cap, many drug companies have recently responded by *reducing* prices for insulin and other drugs because the threat of an uncapped inflationary rebate has acted as a successful disincentive against unrestrained price increases.[3] The inflationary rebate is also important because it is well-documented that drug companies increase the prices of their drugs consistently, with many drugs experiencing price increases well above inflation. A report by the Assistant Secretary of Planning and Evaluation found that between January 2022 and January 2023, over 4,000 drugs experienced price increases, of which approximately 2,000 experienced price increases that exceeded

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[2] H.R. Rep. 102384,102d Cong., pt. 2, at 12 (2d Sess. 1992). https://protect340b.org/wp-content/uploads/2018/05/HRReport-102-384-II-p-12.pdf.
[3] https://www.kff.org/policy-watch/what-are-the-implications-of-the-recent-elimination-of-the-medicaid-prescription-drug-rebate-cap/

inflation, with an average price increase of 15.2%.[4] Therefore, the almost certain result of any reduction or waiver of the inflationary rebate will be unfettered increases in drug prices — a cost that will be borne by patients, the government and hospitals — and far outweighs the marginal possibility that drug companies' lessened rebate obligations would result in more adequate supply of these drugs.

Of particular concern to the AHA is that the removal or waiver of this inflationary penalty will have serious implications for 340B pricing. The 340B ceiling price of a covered outpatient drug is determined based on two components: the AMP and a unit rebate amount (URA) as determined under the MDRP. Specifically, the 340B ceiling price is equal to the AMP minus the URA. The URA for generic drugs is set at a statutory minimum of 13% but can increase significantly due to the inflationary rebate. As a result, the 340B ceiling price, which is the minimum discounted price that any 340B provider can acquire a covered outpatient drug, is directly affected by the inflationary rebate under MDRP. Any waiver or reduction in the inflationary rebate for a generic drug under the drug shortage and mitigation program would reduce the URA and thereby increase the 340B ceiling price for *all* 340B providers, regardless of their participation in the voluntary program. In effect, the waiver or reduction of the inflationary rebate would penalize all 340B providers and reduce their 340B savings while incenting drug companies to increase drug prices. We believe the almost certain harmful effects of this provision for 340B providers far outweighs the marginal possibility that drug companies increase supply of generic drugs in shortage.

Therefore, the AHA strongly urges Congress to remove this provision or add specific language that: (1) ensures that any removal of the inflationary rebate will not apply for the purposes of determining the 340B ceiling price; and (2) that drug companies be required to use savings from any reduction or removal of the inflationary rebate for a given generic drug in or at risk of shortage to ensure that the drug is made available with adequate supply.

The 340B program is an important tool for participating hospitals to overcome the operational and financial impact of drug shortages. Reducing the program's benefit will harm 340B hospitals' ability to manage drug shortages and will endanger patients' access to the many programs and services that are supported by 340B savings. As a result, the AHA urges Congress to address the concerning provisions as we have outlined above and maintain its support of the 340B program.

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[4] https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs

Holding Hospitals Responsible for Standards and Measures Outside of Their Control

Hospitals should only be held accountable for meeting measures, including advanced standards and outcome measures, over which they have some control. The draft legislation includes several incentive and bonus payment measures which are outside of the hospital's control. **The AHA is concerned that including such standards and measures as a basis for rewarding hospitals will unnecessarily complicate the program and disincentivize provider participation, particularly as they attempt to calculate whether the risks and costs of participation (e.g., audits, administrative and reporting burden, loss of rebates, discounts or other price concessions, including 340B discounts) outweigh the potential benefits of the program's incentive payments and bonuses.**

For example, one of the program's outcome measures would hold hospitals accountable for the applicable generic manufacturer's failures to meet its program attestations, including legal and regulatory requirements related to redundancy risk management plans, current FDA Good Manufacturing Practices, and drug shortage notification requirements under the Federal Food, Drug, and Cosmetics Act. These are basic requirements all manufacturers are already required to meet and for which the FDA has established regulatory and legal remedies. As such, we strongly encourage the FDA to hold manufacturers responsible for these failures, not hospitals. To the extent that an applicable generic manufacturer's agreement to meet the terms of its Manufacturer Reliability Agreement is a legal and binding contract, the committee may consider creating an additional layer of accountability for generic manufacturers that fail to adhere to these terms.

In addition, under the program, a provider could be eligible for bonus payments where the provider's primary or secondary supplier for an applicable GSI uses an advanced manufacturing technology, as defined by the FDA, for a substantial portion of the manufacture of the GSI. While the AHA strongly supports the adoption of advanced manufacturing technologies by drugmakers, as appropriate, hospitals have no control over manufacturer decisions in this area and little ability to assess the appropriateness of different manufacturing techniques for a given drug. Moreover, many manufacturers use traditional manufacturing techniques and are still able to provide a stable supply of quality products. Therefore, we urge the committee to reconsider adding this as a program participant advanced standard, and instead, potentially add it as a separate incentive program for manufacturers via grants or tax credits.

Ultimately, we are concerned that some of the incentives included in the draft legislation are unlikely to work because they are too indirect and may not motivate manufacturers to improve or update their processes. Hospitals should not be held accountable for shortages induced by manufacturer action or inaction.

Repercussions Related to DEA Oversight of Quotas for Controlled Substances

It is likely that among the GSIs included in this program there will be Drug Enforcement Administration (DEA) regulated controlled substances, such as surgical anesthesia drugs, which are essential to hospital-level care. If many eligible hospitals suddenly begin to order larger volumes of such GSIs for purposes of creating a buffer stock, drug manufacturers could encounter quota problems with the DEA. **We urge the committee to add language to the discussion draft requiring CMS to consult with the DEA regarding the provisions of the program, particularly about the impact that the buffer stock requirements would have on manufacturers' quotas to reduce the likelihood of demand-driven shocks and resulting shortages of these critically important drugs.**

Other Considerations

We are hopeful that the final legislation will include provisions that appropriately incentivize hospitals and their GPO partners to participate and encourage manufacturers to take responsibility for developing better quality products and a more resilient supply. However, as noted above, we are concerned that such market-based proposals may inappropriately place the onus of preventing shortages on hospitals and other health care providers, rather than on the manufacturers that have the ability to make needed investments and quality improvements in the supply chain.

Therefore, the AHA also supports additional measures to mitigate shortages by improving the overall pharmaceutical supply chain, including:

- On-shoring and near-shoring domestic manufacturing capacity of essential drugs and diversifying, and where possible, on-shoring or near-shoring critical APIs and key starting materials (KSMs) production.

- Increasing inventories and incentivizing additional cushion across the supply chain.

- Requiring the development of quality ratings for drug manufacturers to enable hospitals and GPOs to choose to do business with more reliable manufacturers.

- Requiring drug manufacturers to disclose to the FDA the locations where their products are manufactured, including contract manufacturer locations, as well as the locations from which they source APIs and KSMs used in their finished products.

- Requiring drug manufacturers to notify the FDA regarding unusual spikes in demand for essential drugs, which would allow the agency to take steps to mitigate or prevent any impacts on availability and prevent potential shortages.

Finally, we note that in the past year, the AHA has supported multiple bills in the Senate that address drug shortages and shore up the pharmaceutical supply chain, including:

- **The MAPS Act (S. 2364)**, which would create a plan for the FDA and the Department of Defense to map the pharmaceutical supply chain.[5]

- **The Pharmaceutical Supply Chain Risk Assessment Act (S. 1961)** that would require an interagency risk assessment of the pharmaceutical supply chain.[6]

- **The RAPID Reserve Act (S. 2510)**, which would award contracts to eligible generic drug makers that require them to maintain a six-month reserve of critical generic drugs and their active ingredients to prepare for shortages.[7]

- **The Drug Shortage Prevention Act (S. 2362)** that would require manufacturers to notify the FDA of increased demand for critical drugs and disruptions in the supply chain.[8]

The AHA thanks you for the opportunity to submit comments to the Senate Committee on Finance regarding the "Drug Shortage Prevention and Mitigation Act." We look forward to continuing to work with you on this important issue.

Sincerely,

/s/

Stacey Hughes
Executive Vice President

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[5] https://www.aha.org/lettercomment/2023-08-10-aha-letter-support-mapping-americas-pharmaceutical-supply-chain-or-maps-act-2023
[6] https://www.aha.org/lettercomment/2023-08-10-aha-letter-support-pharmaceutical-supply-chain-risk-assessment-act-2023
[7] https://www.aha.org/lettercomment/2023-08-10-aha-letter-support-rolling-active-pharmaceutical-ingredient-and-drug-or-rapid-reserve-act-2023
[8] https://www.aha.org/lettercomment/2023-08-10-aha-letter-support-drug-shortage-prevention-act-2023.