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**STATEMENT
of the
Federation of American Hospitals
to the
United States Senate Committee on Finance**

**Re: “DRAFT Medicare Drug Shortage Prevention and Mitigation Program”
June 6, 2024**

The Federation of American Hospitals (FAH) submits the following feedback to the Senate Committee on Finance discussion draft entitled “Medicare Drug Shortage Prevention and Mitigation Program.” As the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States, FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. We applaud the Committee’s bipartisan efforts to tackle drug shortages and thank you for the opportunity to provide input on this proposal.

Program Participant Eligibility

First, we appreciate the Committee’s responsiveness in revising the original proposal to include Group Purchasing Organizations (GPOs) and wholesalers as eligible program participants. This inclusion recognizes the critical role these entities play in ensuring the continuous and efficient supply of essential medications and medical supplies for patient care.

Manufacturer Reliability Agreements

We also fully support the outlined terms and conditions of Manufacturer Reliability Agreements, which require a comprehensive description and supporting evidence of the manufacturer's capabilities to meet program requirements, relevant supply chain reliability and quality information, an attestation of compliance with the Food and Drug Administration’s (FDA) rules related to quality and shortages, and an agreement to provide timely information to program participants and submit to audits. We agree that the Secretary should consult with the FDA and stakeholders to develop standards for the specific supply chain, compliance, and quality information that must be submitted under these agreements. These measures will significantly enhance the transparency, reliability, and quality of the supply chain.

Provider Incentives

FAH remains concerned that the proposal incentivizing payment-eligible providers, including hospitals, physician practices, and other providers, to maintain a buffer inventory standard of up to a six-month supply of generic drugs may lead to unintended consequences. While we understand the intent to ensure an adequate supply of essential medications, the creation of a large buffer inventory could result in significant disadvantages for providers, potentially diverting resources from other critical areas of patient care.

First, working with a distributor to maintain and account for buffer stock, ensuring those drugs are used before their expiration, and accounting for systems and storage costs would create significant challenges. Second, the logistics of managing and storing large quantities of buffer inventory could place an additional burden on health care providers. Many facilities may lack the necessary storage space or resources to handle these increased inventory levels, potentially compromising the quality and safety of the stored medications. Third, this approach may inadvertently favor larger providers who have more capacity and resources to meet the buffer inventory standards, thus creating disparities between different types and sizes of health care facilities. Smaller practices or rural providers might struggle to comply, leading to inequities in the healthcare system. Lastly, the focus on maintaining buffer inventories could divert attention and resources away from other critical areas of patient care and operational efficiency.

Additionally, managing and maintaining such extensive inventories could introduce logistical challenges, increasing the risk of medication wastage, and complicating inventory management processes. We believe it is essential to explore alternative strategies that balance the need for buffer inventories with these concerns, ensuring that incentives align with broader healthcare objectives and do not inadvertently create inefficiencies or inequities in the system.

For these reasons, FAH urges the committee to exclude such provider incentives from future iterations of this proposal. We encourage further consideration and dialogue with stakeholders to develop a more sustainable and balanced approach to achieving the program's goals.

Thank you for your focus on addressing drug shortages and look forward to working with the Committee on these critical issues.