

June 6, 2024

The Honorable Ron Wyden Chairman Committee on Finance United States Senate 219 Dirksen Senate Office Building Washington, D.C. 20510 The Honorable Mike Crapo Ranking Member Committee on Finance United States Senate 219 Dirksen Senate Office Building Washington, D.C. 20510

Dear Chairman Wyden and Ranking Member Crapo,

On behalf of the American College of Emergency Physicians (ACEP) and our nearly 40,000 members, thank you for the opportunity to provide our comments on the Committee's Prescription Drug Shortage Discussion Draft. As we have previously shared with you, shortages of everyday, lifesaving emergency medications remain a persistent and significant problem for emergency physicians and for our patients in need of emergency care. We are grateful for your efforts to examine and find policy solutions to address this critical patient safety issue.

The discussion draft seeks to stabilize the supply chain for drugs particularly at risk for shortages, including generic sterile injectables that emergency physicians rely on each and every day in providing lifesaving emergency care. We applaud the Committee for taking concrete steps to address this longstanding crisis and glaring patient safety issue. As you continue these efforts, we would like to reemphasize the need for prioritization of the production of essential emergency medications (EEMs), and that without specific focus on the unique needs of the emergency department (ED) and Emergency Medical Services (EMS) agencies, there remain gaps in terms of the supply and availability of these critical drugs throughout the emergency care spectrum that could be unintentionally exacerbated by new payment systems.

Emergency physicians have unique concerns and practice considerations that do not fit neatly within the payment system envisioned in this proposal. To be clear, this is not an oversight by the discussion draft but rather a more fundamental challenge built into our nation's health care system. As you know, emergency physicians may be either directly employed by a hospital or facility, or more often, work for a group or practice that contracts with a hospital to provide emergency services and 24/7/365 coverage for the ED. Regardless of either direct or indirect employment with a hospital, emergency physician practices do not purchase or maintain inventories of drugs as hospitals or other non-hospital-based physician specialties do, meaning that emergency physicians would not be able to be direct participants under this new model. The hospital or health system is the responsible entity for purchasing and maintaining an adequate supply of drugs used in the ED.

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As a result, despite our direct reliance upon a stable supply of EEMs, emergency physicians are largely indirect influences the decision-making processes regarding drug acquisition and stocking. At best, an emergency physician may be involved in an administrative role within a hospital, such as a medical director or as a member of the hospital's pharmacy and therapeutics (P&T) committee, and able to influence the process via such channels, but this is not always the case. It is more commonly an ad hoc effort where ultimately emergency physicians are essentially beholden to whatever a hospital or system prioritizes. And even in cases where a hospital technically has adequate stock of a specific medication needed in the ED, it may only be available in the central pharmacy and not in the ED pharmacy. The central pharmacy may be more reticent to provide the drug for a variety of reasons, including cost of the drug, which can lead to either unnecessary delays in getting a patient a necessary medication or requiring the emergency physician to substitute another drug (if any) which may not be as effective and can introduce greater risk of dosing errors depending on what substitutes and concentrations are available. Additionally, emergency departments (and EMS) frequently rely upon different concentrations of the same medications that may be used in other settings, once again highlighting the need for specific attention and incentives focused on EEMs. As your Committee continues its work to address drug shortages and refine this legislative proposal, we strongly urge you to develop measures that would prioritize EEMs necessary for both prehospital and emergency care, such as establishing criteria for participating hospitals or health systems to prioritize EEMs.

ACEP appreciates the Committee's efforts to ensure appropriate buffer stocks of medications, as stability and predictability in the supply chain are critical. But without broader systemwide reforms to the pharmaceutical manufacturing and distribution process, we are concerned that the incentive structures in the draft could widen the gap between hospitals and EMS agencies, where large hospital systems are able to command the majority of available drug supplies and under-resourced EMS agencies would be unable to compete. EMS systems that are hospitaloperated would be the most well-positioned to benefit under this system, while other EMS systems (private, municipal, city, etc.) could struggle. We thank you for including provisions to prevent hoarding of medications with respect to buffer stock, and would encourage the Committee to consider additional measures either discourage hoarding and incentivize any participants with excess stock to distribute or reallocate drugs that may be needed in emergency care settings. We also urge you to consider how EMS agencies could be more effectively incorporated into this framework, potentially under a separate incentive structure that would not place them in competition with large hospital systems or other organizations with significantly greater resources.

Once again, we thank you for the opportunity to respond to the thoughtful discussion draft you have shared with stakeholders. Persistent shortages of everyday, lifesaving emergency medications remain one of the greatest threats to the health care safety net and to the health and well-being of our patients. We look forward to continuing to work with you and your staff as you advance these critical efforts. Should you have any questions, please do not hesitate to reach out to Ryan McBride, ACEP Congressional Affairs Director, at rmcbride@acep.org.

Sincerely,

Aisha T. Terry, MD, MPH, FACEP

ACEP President