

VIA ELECTRONIC SUBMISSION

March 30, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Medicare Program; Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals (CMS-1516-ANPRM)

Dear Administrator Oz,

The Drug Shortage Task Force (Task Force),¹ a multi-stakeholder collaborative committed to preventing and mitigating drug shortages in the United States, appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) advanced notice of proposed rulemaking (ANPRM) '*Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals*'.

We commend CMS for recognizing the foundational role that Medicare payment and procurement policies can play in improving the reliability, resilience, and security of the U.S. medicine supply chain and mitigating the impacts of drug shortages. Persistent drug shortages continue to affect care quality and patient outcomes, leading to treatment delays, use of less effective treatments, or missed doses of therapies and – in too many cases – life threatening consequences. This ANPRM represents a meaningful step to realign market incentives with the needs of patients, health systems, and manufacturers by targeting those drugs most often facing shortages and focusing on sustainability, quality, and resilience. As CMS advances this important work, the Task Force provides six recommendations for the agency to consider that reinforce and operationalize the principles outlined in our Call to Action²:

- 1. Encourage Procurement Policies That Reward Reliability, Not Just Lowest Price**
- 2. Center CMS Policy on Supply Chain Resilience, Reliability, and Quality**
- 3. Use a Data-Driven Vulnerable Medicines List to Guide Prioritization**
- 4. Ensure Goals for Domestic Production Informed by Upstream Supply Chain Data**
- 5. Support Modernized Domestic Manufacturing and Advanced Manufacturing Technologies**
- 6. Promote Interagency Coordination and Sustain Cross Sector Collaboration**

1. Encourage Procurement Policies That Reward Reliability, Not Just Lowest Price

The Task Force appreciates CMS's recognition that price pressures have created market dynamics that can undermine domestic and quality producers. CMS's proposal offers a valuable opportunity to align incentives toward rewarding manufacturers that maintain consistent, quality supply. Prioritizing reliability over lowest costs can help create a more predictable market that supports sustainable U.S. manufacturing and protects patients. For participating hospitals, the shift may also help

¹ Drug Shortage Task Force. <https://www.usp.org/supply-chain/drug-shortage-task-force>

² Drug Shortage Task Force. [Drug Shortages: A Call to Action](#)

to reduce the administrative burden of managing shortages and improving continuity of care by ensuring that essential medicines are consistently available when patients need them.

2. Center CMS Policy on Supply Chain Resilience, Reliability, and Quality

The Task Force supports integrating resilience measures into any procurement incentives and establishing a mechanism to differentiate manufacturers based on objective indicators of reliability. Drug shortages are systemic, longstanding, and rooted in economic structures that undervalue supply chain resilience and manufacturing quality.^{3,4} By embedding resilience, reliability, and quality into Medicare-related procurement expectations, CMS can shift incentives toward manufacturers that invest in dependable production practices and help the market function more predictably by supporting procurement decisions that prioritize stability alongside affordability.

Tools such as the Drug Supply Chain Resilience Initiative (DSCRI), proposed by the United States Pharmacopeia (USP),⁵ offer structured, data driven frameworks to assess manufacturer reliability at the molecule and formulation level. Incorporating resilience benchmarks—such as DSCRI—into the Secure American Medical Supplies (SAMS) qualification- would enable CMS to incentivize manufacturers that invest in modernized quality systems, surge capacity, diversified sourcing, and predictable, quality supply.

3. Use a Data Driven Vulnerable Medicines List to Guide Prioritization

The Task Force encourages CMS to utilize a Vulnerable Medicines List⁶ (VML) to provide predictability for hospitals and to help ensure procurement incentives target medicines where intervention will produce the greatest impact. A data-driven VML that evaluates essentiality, population use, and drug shortage risk is vital to ensure that limited resources and incentives focus on medicines at highest risk of shortage and most in need of intervention. Focusing efforts with the greatest potential for meaningful resiliency gains will help CMS anchor the list of qualifying products in a transparent, consistent methodology anchored in measurable risk factors.

4. Ensure Goals for Domestic Production Are Informed by Upstream Supply Chain Data

As CMS evaluates domestic content thresholds, it is essential to account for the geographic concentration of active pharmaceutical ingredients (APIs) and key starting materials (KSMs) – upstream components necessary to manufacture drug products - as these upstream factors drive vulnerability across drug classes. The use of available data resources and tools, such as USP's Medicine Supply Map,⁷ can identify concentrated dependencies such as APIs produced predominantly in a single country which allows CMS to tailor thresholds in ways that avoid unintentionally destabilizing already fragile supply chains.

Rigid or overly broad domestic sourcing thresholds risk unintended disruptions or shortages of highly vulnerable medicines and may not reduce or address the root causes of shortages. **The Task Force recommends a phased approach that uses real-world API and KSM data to set achievable domestic sourcing expectations and adjusts them as domestic capacity grows.**

5. Support Modernized Domestic Manufacturing and Advanced Manufacturing Technologies

The Task Force supports policies that would expand U.S. manufacturing capacity, promote diversification, and accelerate adoption of advanced manufacturing technologies (AMTs)—all needed to address the structural causes of shortages. AMTs can improve efficiency, enhance product

³ U.S. Pharmacopeia. [USP Annual Drug Shortages Report: Economic Factors underpin 2023 shortages. 2024.](#)

⁴ U.S. Pharmacopeia. [USP Annual Drug Shortages Report: Long-standing drug shortages persist in 2024](#)

⁵ U.S. Pharmacopeia. [A drug supply chain resilience initiative will better support patients.](#)

⁶ U.S. Pharmacopeia. [2024-2025 Vulnerable Medicines List for the United States: A data-based approach to identify risks and enable interventions to increase reliability of supply](#)

⁷ USP's Medicine Supply Map is a data intelligence platform that maps where 94% of U.S. pharmaceutical drug products and their ingredients are made, and identifies, characterizes, and predicts supply chain risk. www.usp.org/medicinesupplymap.

reliability, reduce environmental impact, and support more geographically distributed production networks. CMS can play a transformative role by encouraging procurement from manufacturers that adopt AMTs and by supporting policies that reward investments in modernized, resilient manufacturing infrastructure.

6. Promote Interagency Coordination and Sustain Cross Sector Collaboration

Drug shortages are multisector challenges requiring sustained coordination across federal agencies and the broader health care ecosystem. The Task Force encourages CMS to work closely with partners across the Department of Health and Human Services, the Food and Drug Administration, the Administration for Strategic Preparedness and Response, and other agencies to align policies, share insights, and harmonize data. Ongoing engagement with industry, providers, and patient groups will help ensure that emerging solutions are practical, scalable, and responsive to the real-world experiences of those directly impacted by shortages.

The Drug Shortage Task Force appreciates CMS's leadership in advancing policies that would strengthen the domestic manufacturing base, enhance supply chain resilience, and help ensure uninterrupted patient access to essential medicines. By grounding the proposal in objective resilience metrics, data driven prioritization, feasible domestic sourcing thresholds, and coordinated federal action, CMS can meaningfully accelerate progress toward a secure and reliable medicine supply for U.S. patients.

The Task Force thanks the CMS for its leadership on this issue and its commitment to improving patient care. We are committed to working on solutions to this urgent public health issue and look forward to working with you to seek solutions to drug shortages that will ensure patients have access to the therapies they need. In the meantime, if you have any questions or would like additional follow up, please contact Joe Patterson (joe.patterson@usp.org) and Nishith Pandya (Nishith.pandya@cancer.org), Co-Leads for the Drug Shortage Task Force.

Sincerely,

The Drug Shortage Task Force on Preventing and Mitigating Drug Shortages (Undersigned Organizations)

Alliance for Aging Research
American Association of Oral and Maxillofacial Surgeons (AAOMS)
American Cancer Society Cancer Action Network (ACS CAN)
American Pharmacists Association (APhA)
American Society of Anesthesiologists
American Society of Health-System Pharmacists (ASHP)
American Urological Association
Angels for Change
Arthritis Foundation
Association for Clinical Oncology (ASCO)
Cancer Support Community (CSC)
Center for Medicine in the Public Interest
Consumer Action
Friends of Cancer Research
Generics Access Project (GAP)
GO2 for Lung Cancer
Hemophilia Federation of America (HFA)
Howard University, College of Pharmacy
Lupus Foundation of America
National Association of Boards of Pharmacy

National Consumers League (NCL)
National Health Council
National Kidney Foundation
National Psoriasis Foundation
National Rural Health Association (NRHA)
Oley Foundation
Patient Empowerment Network
Susan G. Komen
U.S. Pharmacopeia