Drug Shortage Task Force Comments on the CY 2027 OPPS and ASC Proposed Rule

August 31, 2026

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

Re: Calendar Year 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Proposed Rule (CMS-1850-P)

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 & Medicaid Services' (CMS) proposed rule regarding the "*Calendar Year 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System for CY 2027*." Our comments are specific to the proposed IPPS payment approach for Domestic Procurement of Essential Medicines.

Persistent drug shortages continue to disrupt patient care, resulting in treatment delays, use of less effective therapies, missed doses of critical medications, and increased burdens on healthcare providers and health systems. Drug shortages are a longstanding and systemic challenge that threaten patient access to lifesaving and life-sustaining therapies. The Task Force therefore commends CMS for exploring how Medicare payment policy can support a more reliable, resilient, and secure medicine supply chain.

The Task Force has consistently emphasized that the underlying causes of persistent drug shortages are rooted in market dynamics, which often fail to reward supply chain resilience, manufacturing quality, and reliable production. The proposed payment adjustment for domestically manufactured essential medicines represents an important opportunity to begin aligning incentives with the investments necessary to strengthen the long-term stability of the pharmaceutical supply chain.

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

As CMS advances this important work, the Task Force provides four recommendations for the agency to consider that reinforce and operationalize the principles outlined in our Call to Action[2]:

1. **Prioritize Vulnerable and High-Risk Medicines**
2. **Encourage Procurement Policies That Reward Resilience and Supply Continuity**
3. **Incorporate Resilience, Reliability, and Quality Measures**
4. **Adopt a Comprehensive Definition of Domestic Manufacturing**

1. Prioritize Vulnerable and High-Risk Medicines

The Task Force encourages CMS to prioritize patient impact as a fundamental element of any criteria for identifying medicines that qualify for the proposed payment adjustments. As currently proposed, these medicines have been identified using the Essential Medicines Supply Chain and Manufacturing Resilience Assessment list developed between various federal agencies.[3] This list focuses on essential medicines needed for acute, not chronic, patient care. Ultimately, CMS should seek to implement a transparent, evidence-based methodology for determining which drugs to prioritize. The methodology should leverage comprehensive supply chain vulnerability data and account for clinical importance, and patient impact. When considering patient impact, CMS should evaluate the extent to which a shortage would disrupt patient access to necessary, life-sustaining, or life-saving therapies including, but not limited to, medication substitution, treatment delays, and interruptions in care. Additionally, therapeutic importance, shortage history, manufacturing concentration, and dependence on foreign sources of active pharmaceutical ingredients (APIs) and key starting materials (KSMs) should also be considered as measurable indicators of patient impact for both chronic and acute conditions when determining eligibility.

Not all essential medicines face the same degree of supply chain risk. CMS can maximize the impact of limited resources by targeting incentives to those medicines where intervention is most likely to improve resilience, prevent shortages and protect continued patient access to needed treatments. A data-driven methodology, such as a Vulnerable

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[2] Drug Shortage Task Force. "Drug Shortages: A Call to Action" https://www.usp.org/sites/default/files/usp/document/drug-shortage-task-force/call-to-action-on-drug-shortages.pdf

[3] U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, Advanced Regenerative Manufacturing Institute (ARMI) / the Next Foundry for American Biotechnology (NextFAB). Essential Medicines Supply Chain and Manufacturing Resilience Assessment

Medicines List[4] that evaluates essentiality, population use, and shortage risk, can help ensure that incentives are focused on medicines at greatest risk of disruption and where policy intervention can provide the most meaningful benefit to patients' access. Such an approach would also provide predictability and transparency for hospitals, manufacturers, and policymakers.

2. **Incentivize Procurement Policies That Reward Resilience and Supply and Care Continuity**

The Task Force strongly supports efforts to move beyond procurement models that prioritize the lowest acquisition cost without recognizing supply chain reliability and resilience.

Unsustainable price erosion in the generic drug market has contributed to persistent vulnerabilities throughout the supply chain. These market dynamics discourage investments in manufacturing quality, redundancy, supplier diversification, and domestic production capacity. In some cases, they have driven manufacturers to reduce production, move production overseas, or exit the market on a product altogether.

The Task Force's Call to Action emphasizes the need for payment and purchasing models that value and reward resilience, reliability, and manufacturing quality. CMS's proposal represents an important opportunity to begin correcting these market signals. Aligning incentives with resilient purchasing practices can help establish a more stable market environment that supports long-term investment and improves continuity of patient care. Ultimately, the success of domestic or ally-shoring manufacturing initiatives will depend on whether markets for essential medicines remain sustainable over the long term.

3. **Incorporate Resilience, Reliability, and Quality Measures**

The Task Force encourages CMS to incorporate objective measures of resilience, reliability, and quality into program design.

Domestic production alone does not guarantee a resilient or reliable supply chain. Supply continuity depends on multiple factors, including manufacturing quality performance, supplier diversification, inventory management practices, production flexibility, reserve capacity, and operational reliability.

By incorporating objective indicators of resilience into future iterations of the proposed IPPS payment approach for Domestic Procurement of Essential Medicines,[5] CMS can

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[4] U.S. Pharmacopeia: 2025 Vulnerable Medicine List: Addressing Strategic Constraints to Strengthen the U.S. Medicine Supply Chain

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

better align incentives with outcomes that matter most to patients and providers uninterrupted access to essential medicines. Such measures would also encourage suppliers to make investments that strengthen the overall reliability of the supply chain, including growing domestic manufacturing capacity.

4. **Adopt a Comprehensive Definition of Domestic Manufacturing**

The Task Force, respectfully, urges CMS to consider its criteria and implementation carefully, so as to avoid major interruptions in treatment. Many medicines for which both the API and finished dosage form are manufactured in the United States continue to depend upon highly concentrated foreign sources of KSMs and other critical inputs.[6] As a result, domestic production of the finished product does not necessarily eliminate supply chain risk.

The Task Force supports efforts to expand domestic manufacturing capacity as an important element in creating a more resilient U.S. supply chain overall. Over time, CMS should also consider how payment and procurement incentives could further improve resilience across manufacturing networks, including APIs, KSMs, and other critical inputs. Incentives that promote diversification, redundancy, and visibility into these upstream dependencies can help reduce vulnerabilities and strengthen long-term supply security.

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The Drug Shortage Task Force appreciates CMS's leadership in advancing policies that strengthen pharmaceutical manufacturing, improve supply chain resilience, and help ensure uninterrupted patient access to essential medicines.

The Task Force believes that reducing shortages will ultimately require a fundamental shift in the market for essential medicines so that purchasers, payers, and policymakers reward reliability, resilience, and manufacturing quality, rather than focusing exclusively on the lowest cost. Actions should address both short-term and long-term needs and include cost-effective mitigation strategies, public-private partnerships, sustained investment, and payment reforms that support resilient and high-quality manufacturing.

CMS's proposal for an IPPS payment approach for Domestic Procurement of Essential Medicines represents an important step toward these objectives. 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,

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[6] U.S. Pharmacopeia: 2025 Annual Drug Shortage Report - Behind Fewer Drug Shortages: Longer Durations, Rising Discontinuations, and Hidden Upstream Risk

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)

American Cancer Society Cancer Action Network
American Society of Anesthesiologists
American Society of Health-System Pharmacists (ASHP)
Angels for Change
Arthritis Foundation
Association for Clinical Oncology (ASCO)
Center for Medicine in the Public Interest
Consumer Action
Generics Access Project
National Consumers League
National Psoriasis Foundation
National Rural Health Association
U.S. Pharmacopeia