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March 30, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20001

Submitted electronically at www.regulations.gov

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) (RIN 0938-AV72)

Dear Administrator Oz,

The Association for Clinical Oncology (ASCO) appreciates the opportunity to provide comments on the Administration's advanced notice of proposed rulemaking *Medicare Program; Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals* which was published in the Federal Register on January 29, 2026.

ASCO is a national organization representing more than 50,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

The medical community is facing persistent, and in some cases worsening, shortages of critical medications. Shortages of essential cancer drugs are forcing physicians to make difficult decisions about which patients receive recommended therapies and which patients must

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endure delayed care or rely on less effective alternatives. In recent years, the United States (U.S.) has experienced a growing number of shortages of essential medications, including at least 15 cancer drugs that have been in limited supply. These shortages affect both pediatric and adult patients. The unpredictability of the generic cancer drug supply chain further compounds the problem, disrupting treatment schedules and delaying care. Such interruptions can have serious consequences, including irreversible disease progression.

ASCO and a robust group of stakeholders formulated both long-term and short-term policy recommendations[1] to mitigate existing and prevent future drug shortages. In this response we highlight some recommendations of particular importance but encourage broad consideration of all our recommendations.

We are pleased to offer our comments on select questions below:

- ***"Since most essential medicine APIs are produced abroad and may take time to reshore, how can we encourage domestic final dosage form production without diminishing long-term demand signals for domestic API manufacturing?"***

To strengthen the reliability of the U.S. drug supply, dependable domestic manufacturing should be rewarded through price stabilization measures and investments in continuous or other advanced manufacturing technologies for critical and supportive drugs, as well as active pharmaceutical ingredients (APIs). Addressing the economic pressures that drive generic manufacturers out of the market is essential, including consideration of long term contracts and guaranteed pricing to promote market stability. Federal grants to support advanced manufacturing technologies could help facilities upgrade plants and more efficiently switch between production lines, enabling them to respond quickly to potential shortages. Additionally, the FDA should establish incentives, or streamline regulations, to encourage manufacturers to produce drugs during shortages, as companies are often reluctant to increase or initiate production under such conditions; these incentives should extend to 503B outsourcing facilities that compound shortage drugs under the Federal Food, Drug, and Cosmetic Act.

Building a resilient medical supply chain requires maintaining a diversified network of both domestic and international suppliers, as relying too heavily on any single source increases vulnerability during demand surges, natural disasters, or other disruptions. While expanding domestic manufacturing is an important long-term goal, focusing primarily or exclusively on

[1] https://www.usp.org/sites/default/files/usp/document/drug-shortage-task-force/call-to-action-on-drug-shortages.pdf

U.S.-based production could unintentionally heighten shortage risks, especially for essential medicines and PPE categories that currently depend on foreign APIs or lack sufficient domestic capacity to meet hospital needs. Hospitals must therefore retain the flexibility to procure high quality products from trusted international partners when domestic supplies are unavailable, delayed, or inadequate in volume, quality, or delivery timelines. Policies that encourage domestic procurement should reinforce, not replace, the global supply chains that ensure continuity of patient care and workforce safety. Restrictive measures that limit access to reliable foreign sources, such as imposing higher tariffs, could have an unintended consequence of increasing drug shortages.

- ***"What is the most appropriate definition of domestic for PPE and essential medicines, respectively?"; "What methods could we use to audit statements from hospitals or manufacturers that PPE and essential medicines are made in the USA using ingredients and components produced in the USA?"; "How can manufacturers designate if their product is wholly domestically made?"***

Any policy approach should minimize additional administrative burden for physicians and hospitals already managing complex operational demands. The priority must remain ensuring uninterrupted patient access to essential treatments and supplies. Where shortages exist or are emerging, policies should allow sufficient flexibility to use domestic or ally-friendly foreign products so providers can source safe, high-quality items from the most reliable and readily available suppliers. This balanced approach protects patient care while avoiding unnecessary strain on physicians and hospitals.

- ***Would having a specific list of items be preferable to a general rule for determining whether products are domestic?***

We caution that a fixed list may quickly become outdated as new PPE and essential medicines enter the market. If created, we encourage HHS to update the federal essential medicines list through a transparent stakeholder process. Regular updates will ensure the list reflects current clinical priorities and evolving supply chain vulnerabilities.

- ***If we were to use a designation standard that hospitals procure a sufficient amount of their PPE and essential medicines domestically, what would be a sufficient amount? Should this amount be expressed as a percentage of the PPE and essential medicines procured by the hospital? If so, what percentage would be appropriate? Should this amount vary by the type of PPE and subcategory of essential medicines? How should***

we measure this activity (by volume, dollar amount, etc.)? What would be the least burdensome effective method to audit the procurements, as feasible?

When considering a designation standard requiring hospitals to procure a "sufficient amount" of PPE and essential medicines domestically, any threshold should be informed by an analysis of current and historical data. U.S. manufacturing capability and capacity for critical products to determine whether gaps pose national security risks. Rather than establishing a fixed percentage, hospitals should retain flexibility to adjust procurement based on supply availability, patient needs, and operational realities, as domestic capacity varies significantly across different types of PPE and categories of essential medicines. Thresholds, if used, may need to differ by product type to reflect these variations. Any approach taken should minimize additional administrative burden for hospitals and physicians and prevent inequitable procurement between larger and smaller sized entities.

- ***In determining the amount of any additional payment, should essential medicines be subcategorized under our potential approach rather than treated as a single cost category? If so, what subcategories should be used? For essential medicines (or each subcategory of essential medicines), do commenters agree with the assumption for purposes of the illustrative example that essential medicines are generally 1 percent of drug costs? What is the breakdown of essential medicine spending between inpatient and outpatient? What would be an appropriate estimate for the higher costs of domestically produced essential medicines compared to non-domestic essential medicines?***

Any assumptions about essential medicine subcategories or spending levels should remain flexible, as hospital drug costs vary widely by patient mix, service lines, and region. A single estimate, such as essential medicines equaling 1% of drug costs or a fixed cost differential for domestic products, may not accurately reflect real-world variation across inpatient and outpatient settings.

- ***Would it be appropriate to expand a potential payment policy beyond IPPS and OPPS hospitals to other entities that receive Medicare payments? How could such an expansion be structured? For example, physicians and other Medicare suppliers do not file cost reports. What alternatives to a cost-report-based approach (for example, a claims-based approach) might be appropriate, including for hospitals? How might such alternatives be structured?***

Expanding a potential payment policy beyond IPPS and OPPS hospitals should include similar incentives for physicians and other Medicare participating entities, particularly because many practices, especially rural and other smaller clinics, lack the purchasing power of large health systems and are much less likely to have a reserve in place, acquiring only what is needed immediately. These practices experience drug shortages more quickly and more severely, underscoring the value of supporting them in maintaining an adequate reserve supply.

- ***What methods should be used to assess longer-term benefits with respect to patient safety that may result from more resilient domestic supply chains for critical PPE and essential medicines?***

Assessing the long-term patient safety benefits of a more resilient domestic supply chain should involve federal government authorities with jurisdiction over national security conducting an analysis of U.S. manufacturing capacity for critical drugs and medical devices to determine whether vulnerabilities pose systemic risks. FDA should establish a manufacturing rating system where higher-quality manufacturing receives the higher rating. High-quality manufacturing includes maintaining rigorous analytical testing and manufacturing consistency and requires a "diversified" supply chain so that a single quality failure at one plant doesn't collapse the entire global supply. The FDA should consider incentives for manufacturers to participate in the program. The rating system should include factors such as whether the company has a contingency plan for interruptions/disasters and whether the company has a plan for redundancy in production.

- ***How have supply chain disruptions due to the lack of domestically manufactured PPE and essential medicines impacted the quality of care at hospitals?***

Supply chain disruptions driven by limited domestic manufacturing of PPE and essential medicines have directly affected hospital care quality by creating inequitable access to critical drugs and forcing shifts in where and how patients receive treatment. Larger, well-resourced systems often have greater purchasing power and can secure medications at risk of shortage, leaving smaller or less resourced hospitals with constrained supplies and prompting a shuffling of patients between care settings. Although panic buying triggered by shortage anticipation can further strain availability, transparent and timely communication remains essential. The 2023 shortages of cisplatin and carboplatin illustrate the disproportionate impact: while some institutions maintained planned treatment schedules, others saw significant drops in administered doses, contributing to delays in cancer care. In 2025 ASCO estimated that cisplatin

and carboplatin shortages risk affected nearly 500,000 adult patients with cancer in the U.S. Other drugs that are used routinely in cancer treatment—such as 5-fluorouracil and methotrexate—are also in shortage, impacting pediatric oncology patients. The persistent and worsening shortage of important cancer therapies is a life-threatening issue for patients of all ages. These disruptions are exacerbated by limited visibility into the pharmaceutical supply chain, inconsistent manufacturer reporting to the FDA, and the agency's outdated data infrastructure, which hinder timely identification and mitigation of shortages. Once a shortage occurs, it is difficult for alternative manufacturers to fill the void because it can take weeks to pivot manufacturing lines—especially when the drug is a sterile generic injectable.

- ***"Should such a policy be phased in over time to increase hospital adoption and prevent shortages, and if so, how? Should the designation have "tiers" or a potential phase-in that can be adjusted as more PPE and essential medicine are domestically manufactured? For example, should such a policy be phased in such that at least 25 percent, 50 percent, and eventually 75 percent of a hospital's total procurement across contracts for PPE and essential medicine is domestically manufactured?" "When and how should we provide flexibilities under such a policy in the event of supply chain disruptions like natural disasters and demand surges?"***

A phased implementation with tiered thresholds would allow hospitals to adjust procurement practices gradually as domestic manufacturing capacity expands, helping avoid disruptions in care. Tiering could begin with a lower percentage of required domestic sourcing and progress to higher levels over time as production capabilities grow and hospitals gain experience with new procurement workflows. Flexibility must remain central to the policy so hospitals can respond effectively to natural disasters, demand surges, or other supply chain disruptions. Policies should permit ongoing access to products from ally-friendly partners when domestic options are unavailable or insufficient, while using incentives or tiered designations to encourage increased domestic procurement where feasible. This combination of phased adoption and built-in flexibility supports both the growth of domestic production and the resilience of the broader health care supply chain.

Conclusion

ASCO's recommended approaches to mitigation of drug shortages complement CMS's goals of ensuring reliable access to essential medicines and PPE, and we recommend several strategies to strengthen supply chain resilience. For example, increasing FDA visibility into the pharmaceutical supply chain is critical for predicting and addressing shortages, which includes addressing the economic pressures that drive generic manufacturers out of the market,

stabilizing production through long term contracts and guaranteed pricing, and rewarding reliable U.S. manufacturing with price stabilization and investment in continuous or advanced manufacturing technologies. Earlier identification of potential shortages and timely communication to health systems would allow providers to prepare and mitigate emerging supply challenges. Hospitals and any other health care entity purchasing drugs should establish multidisciplinary committees to monitor and manage limited drug supply and implement ASCO's recommendations for optimizing drug use during shortages, including: reprioritizing nonessential use, adjusting dosing schedules, minimizing waste through vial optimization and dose rounding, identifying alternative evidence-based regimens, and providing patient counseling. Together, these strategies highlight the importance of flexible procurement policies, gradually introducing domestic sourcing goals, and practical approaches that let clinicians provide uninterrupted care as we work to strengthen domestic supply chains.

Additional ASCO strategies for regulatory actions to address drug shortages can be found here. Comprehensive ASCO resources on drug shortages may be found here.

Please contact Shimere Sherwood at shimere.sherwood@asco.org or Gina Hoxie at gina.hoxie@asco.org for questions or additional information. We appreciate the opportunity to comment and look forward to collaborating with CMS on this and other efforts to ensure every patient with cancer has the best chance of a successful outcome.

Sincerely,

Lynn Schuchter, MD, FASCO
Chair of the Board
Association for Clinical Oncology