American Society of Hematology
Helping hematologists conquer blood diseases worldwide

2026
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March 30, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: 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 Dr. Oz:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to submit these comments on the advanced notice of proposed rulemaking (ANPRM) for *Ensuring Safety Through Domestic Security with Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals*. We support the Centers for Medicare & Medicaid Services' (CMS) efforts to explore policy approaches that strengthen supply chain resilience while maintaining access to affordable medications to ensure patients with hematologic diseases and disorders have reliable access to the drugs they require.

ASH represents more than 18,000 clinicians and scientists committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematology (non-malignant) conditions like sickle cell disease. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the fields of stem cell biology, transfusion medicine, and gene and cell therapies. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients.

Domestic Procurement Designation and Payment Adjustment

The agency requested comments on the development of a special designation for hospitals that procure American-made essential medicines. This designation, "Secure American Medical Supplies," would create a streamlined way to recognize hospitals that procure domestically manufactured supplies and medicines. However, we recommend that this special designation be obtainable by all providers, and not just hospitals. In the healthcare ecosystem small and rural hospitals, group practices, and small, independently owned and operated physician offices are all entities that are purchasers of essential medicines and should benefit from the special designation if one were created.

CMS states that the agency will make payment adjustments and provide incentives to support the additional costs, if any, of obtaining and maintaining a supply of American-made essential medicines for entities with this designation.

If hospitals and other entities are expected to preferentially purchase domestically manufactured essential medicines, we agree that Medicare policy should recognize the potential financial impact of those procurement decisions. ASH believes that these financial incentives are critical to the success of this program.

Many of the drugs our members use to treat their patients are generic, sterile injectable drugs which are produced overseas where the cost of producing the drug or active pharmaceutical ingredient (API) is considerably lower than producing that same API in the United States. Providing an additional payment to healthcare entities that meet domestic sourcing thresholds would help offset the incremental costs associated with purchasing domestically produced medications and would support the broader goal of strengthening the domestic medical supply chain.

As recently as 2023, CMS considered policy options that encouraged the stockpiling of essential medicines, including the provision of a separate payment under the Inpatient Prospective Payment System for those hospitals that maintain a buffer stock of essential medicines. In response to that proposal, we agreed that a policy like this would help to mitigate shortages of essential medicines and safeguard and improve the care hospitals are able to provide to patients. However, as we stated previously, we believe that payment incentives or adjustments should be made to all healthcare entities, not just hospitals, that meet the designation.

Support for Strengthening the Essential Medicines Supply Chain

We share CMS's goal of improving the resilience and reliability of the supply chain for essential medicines. The agency proposes to rely on the list of 86 medicines identified in the Department of Health and Human Services' (HHS) Essential Medicines Supply Chain and Manufacturing Resilience Assessment as a starting point for defining essential medicines. This list identifies drugs that are critical for hospital care and national preparedness. However, CMS should ensure that the list remains responsive to evolving clinical needs and reflects the areas of medicine most affected by supply disruptions, including hematology.

Notably lacking from the essential medicines list are chemotherapeutic agents, except for one, cyclophosphamide. This drug alone is not enough to ensure that patients with blood cancers and other cancers have access to the treatment they need. We recognize that this may be most appropriate for care delivered in the hospital, however, there are many other chemotherapeutic agents and medications that are critical for patients with hematologic cancers and conditions that are administered in hospital outpatient settings and physician offices. These medications are essential to support positive patient outcomes.

ASH strongly recommends that CMS consider expanding the list of essential medicines to include additional chemotherapeutics and other non-chemotherapy drugs that are commonly used for the treatment of hematologic conditions, including blood cancers and classical (nonmalignant) conditions. Blood cancers such as leukemias, lymphomas, and multiple myeloma often rely on chemotherapy drugs as the backbone for treatment.

Non-chemotherapy drugs that are commonly used for blood cancers include tyrosine kinase inhibitors (such as dasatinib and asciminib for chronic myeloid leukemia), BCL-2 inhibitors (such as venetoclax for acute myeloid leukemia and chronic lymphocytic leukemia), and Bruton's tyrosine kinase inhibitors (such as acalabrutinib and zanubrutinib for chronic lymphocytic leukemia and some lymphomas).

Examples of additional drugs used in hematology that are vital to successful treatment and outcomes include antibody-based drugs, such as rituximab for non-Hodgkin lymphoma (NHL), caplacizumab for thrombotic thrombocytopenic purpura (TTP), and eculizumab for paroxysmal nocturnal hemoglobinuria (PNH). Antibody-drug conjugates, such as gemtuzumab ozogamicin for acute myeloid leukemia and inotuzumab ozogamicin for acute lymphoblastic leukemia, are also important cancer-fighting tools in the armamentarium.

Recent chemotherapeutic drug shortages have become a persistent challenge for hematology providers across the country. Many of the medications that have recently been in shortage have been used safely and effectively for decades and remain first-line or standard-of-care treatments for many hematologic cancers and conditions. Often, certain chemotherapy agents are not easily substitutable, meaning that shortages can force hematologists to delay treatment, modify treatment regimens, or use less effective or more toxic alternatives. When shortages do occur, providers must spend significant time managing drug allocations and identifying alternative treatment strategies, which can create additional burdens on the healthcare system and may ultimately affect patient outcomes.

We understand that essential medicines will not automatically be immune from shortages; however, we believe that the essential medicine designation may provide some protections from shortages. Drugs included on an essential medicines list are often prioritized for manufacturing, procurement, and supply chain monitoring, which can help stabilize production and reduce the risk of disruptions. The essential medicine designation may also support policies that ensure multiple manufacturers are producing the drug, support strategic stockpiling, or create targeted incentives for manufacturers and purchasers, all of which strengthen supply reliability. As a result, these medicines are generally less vulnerable to shortages compared with non-designated products.

Including chemotherapy and other hematology and oncology drugs on the essential medicines list would help ensure that efforts to strengthen the supply chain focus on medications that are critical to patient survival and that have historically been vulnerable to shortages.

Domestically Produced Medicines

While policies aimed at strengthening domestic manufacturing capacity are important, CMS should recognize the global nature of the pharmaceutical supply chain, particularly for generic medicines. Many generic drugs, including numerous chemotherapy and supportive care agents used in hematology, rely on APIs and finished dosage forms that are manufactured outside of the United States. Certain chemotherapy drugs are generic, sterile injectable products that are produced by a limited number of manufacturers worldwide. To be successful, incentives would need to be high enough to encourage such a significant investment in domestic manufacturing.

Because manufacturing capacity is often concentrated in a small number of facilities, even a single manufacturing disruption or quality issue can lead to nationwide shortages. For this reason, chemotherapy and other hematology drugs represent a particularly important category of medicines for CMS to consider within the essential medicines framework.

Perhaps most importantly, we recommend that CMS retain some flexibility should this policy be finalized. Strict domestic manufacturing requirements would likely reduce the number of available suppliers, increase acquisition costs for hospitals and other entities, and potentially exacerbate existing drug shortages while domestic production capacity is expanded. Generic drug markets often operate on very thin margins, and manufacturing shifts may take years to implement. As CMS considers policies designed to encourage domestic production, it will be important to recognize that onshoring pharmaceutical manufacturing is a complex and long-term process.

We encourage the agency to explore the policy options we have addressed when crafting the proposed rule. Should you have any questions or if you would like to discuss our comments, please contact ASH Manager for Policy & Practice, Myra Masood, at mmasood@hematology.org.

Sincerely,

Robert Negrin, MD
President