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President and CEO

March 30, 2026

Via electronic submission at <http://www.regulations.gov>

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

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

Dear Dr. Oz:

The Federation of American Hospitals (FAH) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Advance Notice of Proposed Rulemaking (ANPRM) titled *Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment and Essential Medicine Procurement by Medicare Participating Hospitals*. As the national representative of more than 1,000 tax paying hospitals and health systems throughout the United States, FAH supports the goal of strengthening the resilience of the health care supply chain and ensuring reliable access to essential medicines and medical supplies.

The COVID-19 pandemic demonstrated the importance of dependable supply chains for personal protective equipment and pharmaceuticals, and it highlighted vulnerabilities associated with overreliance on global manufacturingⁱ CMS appropriately recognizes that disruptions in the availability of these products can threaten patient safety and the ability of clinicians to deliver timely care.ⁱⁱ The Administration has also emphasized the importance of strengthening domestic manufacturing of critical medical products through federal policy initiatives focused on supply chain resilience. Taken together, these efforts appropriately reinforce that ensuring reliable access to essential medicines and medical supplies requires a strong and diversified manufacturing base.

Policies designed to strengthen domestic supply chains should build on the Administration's broader efforts to both expand domestic manufacturing of personal protective equipment and essential medicines and prevent future drug shortages. Achieving these goals requires addressing the root causes of supply disruptions and recognizing the roles of different stakeholders within the health care supply ecosystem. Extensive analysis from federal agencies, academic experts and health system stakeholders finds that shortages of pharmaceuticals and medical supplies are driven primarily by manufacturing disruptions, quality failures, shortages of raw materials and economic decisions by manufacturers regarding production.ⁱⁱⁱ

The National Academy of Medicine has similarly concluded that drug shortages are largely the result of structural vulnerabilities in pharmaceutical manufacturing markets, including limited manufacturing redundancy, economic pressures affecting generic drug production, and quality-related production disruptions.^{iv} These systemic issues occur upstream in the supply chain and are largely outside the control of hospitals and other providers. Pharmaceutical manufacturing markets are often highly concentrated, with a small number of facilities supplying large portions of global demand for certain generic medications. When disruptions occur at one of these facilities, hospitals across the country can experience shortages simultaneously despite having no ability to influence the manufacturing decisions that led to the disruption.

Decisions regarding the location of manufacturing facilities, the sourcing of active pharmaceutical ingredients and the capital investments required to build domestic production capacity are made upstream in the pharmaceutical and manufacturing supply chain. As a result, policies that focus on hospital procurement practices will have limited ability to influence the underlying factors that determine product availability.

For these reasons, FAH urges CMS to ensure that policies intended to strengthen domestic manufacturing focus on the upstream stakeholders that control production decisions while avoiding policies that impose additional operational or administrative burdens on hospitals.

Executive Summary

FAH supports federal efforts to strengthen domestic production of essential medicines and critical medical supplies. Ensuring the resilience of the health care supply chain is essential to protecting patients, clinicians, and communities. However, the policies outlined in the ANPRM risk placing a disproportionate responsibility for supply chain challenges on hospitals, missing an opportunity to target the root cause of the underlying drivers of shortages.

Evidence from federal agencies, academic research, and hospital system analyses demonstrate that shortages are overwhelmingly driven by supply side factors, including manufacturing disruptions, shortages of raw materials, regulatory actions affecting production facilities and economic decisions by manufacturers regarding which products to produce.

Hospitals bear the brunt of the impacts of drug shortages despite taking significant steps within their control to mitigate the impact. In doing so, hospitals devote substantial resources to managing drug shortages when they occur. For example, when a commonly used medication becomes unavailable, hospital pharmacists and clinicians must rapidly evaluate alternative therapies, update prescribing protocols, communicate changes to care teams and monitor patients for differences in dosing or clinical response.

National analyses of hospital operations indicate that hospitals collectively devote millions of staff hours annually to shortage management activities, including identifying substitute therapies, revising treatment protocols, coordinating with suppliers and adjusting inventory management practices to maintain patient care.^{v.vi} These operational burdens result in hundreds of millions of dollars in additional labor costs across the health care system each year.^{vii}

Because hospitals must address the operational consequences of supply disruptions, policies that place additional procurement reporting requirements or payment incentives on hospitals will not address the underlying causes of shortages. Instead, policies intended to strengthen domestic supply chains should focus on encouraging domestic manufacturing capacity, improving transparency regarding production disruptions and strengthening national preparedness for supply chain emergencies.

I. Domestic Procurement Designation

CMS seeks comment on establishing a “Secure American Medical Supplies” designation for hospitals that procure a certain percentage of personal protective equipment and essential medicines from domestic manufacturers.

FAH appreciates CMS’s interest in encouraging domestic manufacturing of critical medical products. However, the proposed designation framework does not reflect how hospitals actually procure pharmaceuticals and medical supplies and therefore, risk imposing administrative burdens without meaningfully strengthening supply chain resilience. Hospitals typically procure pharmaceuticals and medical supplies through complex purchasing arrangements that involve distributors, wholesalers, and purchasing networks that coordinate contracts across large groups of providers. These supply chain intermediaries negotiate contracts with manufacturers, monitor supply disruptions, evaluate manufacturing reliability and communicate shortages to manufacturers and hospitals when disruptions occur.

Because purchasing decisions are negotiated across networks of providers, individual hospitals generally do not have the ability to independently alter national supply chain dynamics through their procurement practices. Furthermore, domestic manufacturing capacity for many pharmaceutical products remains limited. The Food and Drug Administration (FDA) has reported that a significant portion of active pharmaceutical ingredient manufacturing occurs

outside the United States, particularly for generic drugs that represent a large share of medications used in hospitals.^{viii} Establishing procurement thresholds before domestic manufacturing capacity exists could create compliance challenges for hospitals without meaningfully increasing domestic production.

II. Role of Purchasing Intermediaries

CMS asks how hospitals that procure supplies through intermediaries may be affected by a domestic procurement designation and whether these entities could play a role in administering the program.

Hospitals rely on supply chain networks that include distributors, wholesalers, and purchasing cooperatives that negotiate contracts with manufacturers on behalf of hospitals. These intermediaries play a critical role in monitoring supply disruptions and coordinating responses across the health care system. Purchasing networks help hospitals identify supply risks, monitor manufacturing reliability, evaluate quality metrics for suppliers, and coordinate distribution of critical products during shortages.

Policies that attempt to measure procurement behavior at the individual hospital level may not accurately capture how supply chains actually operate. Hospitals frequently purchase pharmaceuticals and medical supplies through contracts negotiated across entire health systems or purchasing networks rather than through independent facility level procurement. As a result, hospitals may have limited ability to influence the geographic origin of products purchased through these arrangements.

III. Medicare Payment Adjustment

CMS seeks comment on establishing a Medicare payment adjustment for hospitals that obtain the proposed designation.

FAH appreciates CMS's continued focus on domestic supply chain resilience and shares the Agency's commitment to ensuring that hospitals have reliable access to essential medicines and PPE. However, FAH respectfully encourages CMS to consider whether a Medicare payment adjustment for hospitals will achieve the intended policy goals, particularly considering the experience with the existing surgical N95 Filtering Facepiece Respirator (FFR) payment adjustment. If the policy objective is to increase domestic manufacturing capacity, incentives should be directed toward manufacturers and supply chain stakeholders rather than hospitals. Hospitals do not control where pharmaceuticals or PPE are manufactured, where active pharmaceutical ingredients or raw material inputs are sourced or where manufacturers choose to locate production facilities.

The history of the surgical N95 FFR payment adjustment offers useful context here. Despite being in effect since CY 2023, fewer than 100 hospitals claimed the adjustment on their FY 2024 cost reports — a participation rate that CMS itself has acknowledged is very limited. FAH believes this outcome reflects not merely administrative burden, but a more fundamental challenge: as FAH noted in prior comments, domestic manufacturers have at times lacked the production capacity to meet hospital demand at scale, a constraint that hospital-facing payment adjustments are unlikely to resolve. Production capacity decisions are made by manufacturers and their investors. Payment incentives directed at hospitals are therefore unlikely to influence the manufacturing investment decisions necessary to meaningfully expand domestic production. FAH urges CMS to reconsider this approach.

Hospitals already incur significant operational costs associated with managing shortages. When shortages occur, pharmacists and clinicians must identify therapeutic alternatives, adjust treatment protocols and coordinate with suppliers to secure limited inventories. These activities require substantial staff time and resources and can affect patient care. Studies of hospital pharmacists have documented treatment delays, substitutions with less effective therapies and increased risk of medication errors when shortages occur.^{ix}

IV. Hospital IQR Structural Measure

CMS also seeks comment on incorporating domestic procurement requirements into the Hospital Inpatient Quality Reporting program through a structural measure.

FAH strongly opposes incorporating supply chain procurement policies into hospital quality reporting programs. The Hospital Inpatient Quality Reporting program was designed to measure and improve clinical quality and patient outcomes. Procurement practices related to medical supplies and pharmaceuticals are operational supply chain issues rather than indicators of clinical quality. Expanding the program to include procurement requirements would impose additional administrative burdens without improving patient outcomes.

V. Procurement Thresholds

CMS seeks comment on potential phased thresholds such as 25 percent, 50 percent, and 75 percent domestic sourcing.

Recent shortages illustrate why policies focused on hospital procurement behavior are unlikely to address the root causes of supply chain disruptions. For example, shortages of several oncology medications, including sterile injectable chemotherapy agents such as cisplatin and carboplatin, have disrupted cancer treatment across the United States in recent years. These shortages were associated with manufacturing disruptions and quality issues at production facilities that supply large portions of the global market.^x

Hospitals have also experienced shortages of sterile saline and intravenous fluids, which are essential for hydration, medication delivery, and surgical procedures. Manufacturing disruptions affecting a small number of facilities producing large volumes of saline have previously resulted in nationwide shortages of these products.^{xi} Shortages have also affected antibiotics and other medications commonly used in emergency and inpatient care. These shortages require hospitals to identify substitute therapies and adjust treatment protocols in order to maintain patient care.^{xii}

These examples illustrate an important policy reality. When shortages arise because of manufacturing disruptions or limited production capacity, hospitals cannot resolve the problem through procurement decisions alone. If procurement thresholds are established without corresponding increases in domestic manufacturing capacity, hospitals could face situations in which they are expected to meet procurement requirements even when domestic products are unavailable. These shortages occurred despite strong demand from hospitals and existing purchasing commitments, illustrating that availability is primarily determined by manufacturing capacity and facility reliability rather than hospital purchasing preferences.

FAH appreciates CMS's commitment to strengthening the resilience of the United States' health care supply chain and ensuring reliable access to essential medicines and personal protective equipment. However, policies intended to promote domestic production should focus primarily on supply side manufacturing incentives and supply chain transparency rather than imposing procurement mandates or reporting requirements on hospitals.

FAH looks forward to continuing to work with CMS and other federal partners to develop policies that promote domestic production and strengthen supply chain resilience while allowing hospitals to focus on their core mission of delivering high quality care to patients. If you have questions, please contact Tilithia McBride at tmcbride@fah.org.

Sincerely,

/s/

Charlene MacDonald
President and CEO



Endnotes

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- ⁱ Centers for Medicare and Medicaid Services. *Medicare Program, Ensuring Safety Through Domestic Security With Made in America PPE and Essential Medicine Procurement by Medicare Participating Hospitals*. Federal Register, 2026.
- ⁱⁱ Executive Order 13944. *Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines and Medical Countermeasures Are Made in the United States*.
- ⁱⁱⁱ U.S. Government Accountability Office. *Drug Shortages: FDA's Ability to Respond Should Be Strengthened*. GAO-23-105312. 2023.
- ^{iv} National Academy of Medicine. *Building Resilience into the Nation's Medical Product Supply Chains*. National Academies Press. 2022.
- ^v U.S. Government Accountability Office. *Drug Shortages: Certain Factors Are Strongly Associated With This Persistent Public Health Challenge*. GAO-16-595. Washington, DC: Government Accountability Office; 2016.
- ^{vi} Fox ER, Sweet BV, Jensen V. *Drug Shortages: A Complex Health Care Crisis*. Mayo Clinic Proceedings. 2014;89(3):361-373.
- ^{vii} American Society of Health-System Pharmacists. *Drug Shortages Statistics and Trends*. ASHP Drug Shortages Resource Center. Updated 2024.
- ^{viii} U.S. Food and Drug Administration. *Drug Shortages: Root Causes and Potential Solutions*. 2019.
- ^{ix} Fox ER et al. *Drug Shortages A Complex Health Care Crisis*. Mayo Clinic Proceedings. 2014.
- ^x U.S. Food and Drug Administration. *Cisplatin and Carboplatin Drug Shortage Communications*. 2023.
- ^{xi} U.S. Government Accountability Office. *Drug Shortages: Public Health Threat Continues Despite Efforts to Help Ensure Product Availability*. GAO-20-143. 2019.
- ^{xii} American Society of Health System Pharmacists. *Drug Shortages Statistics*. 2024.