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March 24, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-1850

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

Dear Dr. Oz:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to comment on the potential options to foster a more resilient supply chain by incentivizing hospital use of American-made personal protective equipment (PPE). APIC is a nonprofit, multidisciplinary organization representing 15,000 infection preventionists (IPs) whose mission is to create a safer world through the prevention of infection. Our comments will only address the PPE supply chain.

While APIC commends CMS for its commitment to strengthening the domestic medical supply chain, we write to express significant concerns regarding the policy paths suggested in the ANPRM. As currently drafted, this measure places an inequitable burden on healthcare facilities, especially small and rural hospitals, without addressing the systemic market forces that dictate hospital procurement.

Misalignment of Quality Reporting and Manufacturing Policy

The Inpatient Quality Reporting (IQR) and other quality and payment programs are designed to improve clinical outcomes and the quality of care delivered to patients. While domestic PPE production is a critical national security priority, it is fundamentally a manufacturing and supply chain issue, not a clinical quality metric.



Hospitals are currently facing unprecedented staffing shortages and financial strain. Requiring facilities to dedicate limited resources to track and report manufacturing origins detracts from direct patient care. In larger quality initiatives, administrative costs are typically offset by improved patient outcomes; however, this measure offers no such clinical offset.

Domestic Capacity and the Failure of Past Incentives

APIC acknowledges that a robust domestic PPE market would improve emergency preparedness. However, current domestic capacity is insufficient to meet the total demand of the American healthcare workforce. Despite federal investments during the COVID-19 pandemic, many domestic manufacturers have since shuttered because they could not compete with foreign pricing.

A more appropriate federal government focus would be to prioritize direct incentives for manufacturers to produce PPE domestically. Hospitals cannot be held accountable for a "Secure American Medical Supplies" designation if the market cannot reliably provide those supplies at scale. Imposing reporting requirements or Conditions of Participation requiring domestically produced PPE would unfairly penalize hospitals for their inability to obtain unavailable PPE. Establishing a special domestic procurement designation or payment provides no incentive to hospitals if the supply does not exist.

The Role of Group Purchasing Organizations (GPOs)

The most significant barrier to domestic sourcing is not hospital preference, but the structural dominance of GPOs. The current proposal fails to address how GPO contracts restrict hospital flexibility, including:

- **Market Power:** Over 95% of U.S. hospitals rely on a small number of national GPOs.¹ Exclusive contracts and volume-tier requirements make shifting to domestic suppliers operationally impossible for many facilities without violating binding agreements.
- **Misaligned Incentives:** The GPO "Safe Harbor" under the Anti-Kickback Statute [42 U.S.C. §1320a-7b(b)] allows GPOs to collect administrative fees from vendors. This financially incentivizes GPOs to prioritize large-scale international suppliers who offer lower costs and higher fee volumes, undermining domestic resilience.
- **Compliance Burdens on the Vulnerable:** Small and rural hospitals lack the negotiating leverage to bypass GPO contracts. Under the ANPRM proposals, these hospitals could face compliance penalties for market conditions they have no power to change.

APIC Recommendations

To ensure meaningful progress toward a resilient supply chain without compromising hospital stability, APIC recommends that CMS:



- Shift Accountability to GPOs: Require GPO transparency regarding product origin and administrative fee structures. CMS should align GPO participation in Medicare-serving networks with domestic sourcing benchmarks.
- Re-evaluate Regulatory Protections: Review the GPO Safe Harbor provisions to determine if they currently inhibit supply chain domesticity.
- Provide Hospital Flexibility: Implement waivers, extended transition periods, and safe harbor protections for hospitals forced into "off-contract" purchasing to meet domestic goals.
- Incentivize, Don't Penalize: Focus on supply-side incentives for manufacturers rather than demand-side reporting requirements for providers.
- Consider increasing Administration for Strategic Preparedness and Response funding for the Strategic National Stockpile to expand its inventory to better respond to future pandemic events. The Office of Industrial Base Management and Supply Chain could play a further role in supporting the investment in domestic PPE production.

Domestic PPE production is a vital priority, but it cannot be achieved by placing the burden solely on the healthcare facilities. The focus must be on incentivizing manufacturers to produce PPE domestically. In addition, without addressing the central role of GPOs in the purchasing ecosystem, this proposal will create obligations that hospitals simply cannot meet. APIC urges CMS to incorporate GPO-focused reforms to ensure a practical, achievable path toward a resilient U.S. medical supply chain.

APIC thanks CMS for the opportunity to provide input and recommendations on incentivizing the supply of American-made PPE for use in U.S. hospitals. We look forward to continuing to work with the agency to protect healthcare personnel, patients, and visitors from transmission of infection by improving the PPE supply chain.

Sincerely,

A handwritten signature in black ink that reads "Kathy Ward". The signature is written in a cursive, flowing style.

Kathy Ward, RN, BSN, MPH, FAPIC, CIC
2026 APIC President

¹ Dean EB, Reekarl P, et. al. Role of supply chain intermediaries in steering hospital product choice: Group Purchasing Organizations and biosimilars. Health Aff Sch. 2024 May 15;2(6):qxae067. doi: [10.1093/haschl/qxae067](https://doi.org/10.1093/haschl/qxae067). Accessed 3/20/26 from National Library of Medicine, PubMed Central <https://pmc.ncbi.nlm.nih.gov/articles/PMC11152204/>.