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**Vizient Office of Public Policy and Government Relations**

# 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

**February 2, 2026**

## Background & Key Takeaways

On January 26, 2026, the Centers for Medicare & Medicaid Services (CMS) issued an 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 (hereinafter, "ANPRM"). Under the ANPRM, CMS seeks stakeholder comments regarding policy concepts that aim to shape hospital procurement of PPE and essential medicines to encourage domestic purchasing. One policy concept is a domestic procurement designation to be earned by hospitals and a payment adjustment to hospitals earning this designation. The other policy concept is adding a structural measure to the Hospital Inpatient Quality Reporting (IQR) Program where hospitals would attest to meeting minimum percentages of domestic procurement for PPE and essential medicines.

Comments must be submitted by March 30, 2026. Vizient looks forward to working with clients to inform our letter to the agency.

## Summary

CMS is interested in strengthening the American-made supply chain for PPE and essential medicines while reducing reliance on foreign-made medical supplies. Through the ANPRM, CMS seeks feedback on potential approaches to encourage hospitals to procure domestically manufactured PPE and essential medicines.

## Domestic Procurement Designation to be Earned by Hospitals and Payment Adjustment to Hospitals Earning the Designation

CMS is considering potential establishment of a publicly reported hospital designation reflecting Medicare-participating hospitals' commitment to procuring domestic PPE and essential medicines. Building from this designation ("Secure American Medical Supplies" friendly hospitals), CMS is also considering a separate Medicare payment to those receiving the designation.

### Potential Establishment of a Publicly Reported Hospital Designation Reflecting Medicare Participating Hospitals' Commitment to Procuring Domestic PPE and Essential Medicines

CMS believes this new designation would potentially allow Medicare and other payers a streamlined way to recognize the additional costs these hospitals incur in procuring domestic PPE and essential medicines. Hospitals could potentially earn this designation if they meet a minimum American-made

percentage of all PPE[1] and all essential medicines[2], or it could be obtained by meeting a minimum American-made percentage of each subcategory (e.g., masks or anti-microbial medicines) for which HHS determines that sufficient domestic producers exist. Initially, the new designation could be based on attestations by hospitals based on their cost report, but this may change over time.

Among other questions, CMS seeks feedback regarding:

- Would a "Secure American Medical Supplies" friendly hospital designation be an appropriate way to facilitate the creation of streamlined payment policies to bolster the domestic supply chain through the recognition of the additional resource costs hospitals incur when procuring domestically manufactured items? Where would it be most helpful for this designation to appear? What would be the most appropriate entity to grant this designation? What other ways might be effective?
- What is the most appropriate definition of domestic for PPE[3]? Also, what is the most appropriate definition for fully domestic for essential medicines[4]?
- Would having a specific list of items be preferable to a general rule for determining whether products are domestic?
- Should such a policy be phased-in 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 medicines 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?

## Potential Separate Medicare Payment to "Secure American Medical Supplies" Friendly Hospitals

CMS is considering establishing a separate payment to "Secure American Medical Supplies" friendly hospitals for Medicare's inpatient prospective payment system (IPPS) share of the costs of these additional resources. For IPPS, separate payments could potentially be made in a non-budget neutral manner. Payment could be given as a lump sum or interim[5] bi-weekly lump-sum payments that would be reconciled at cost report settlement. These payment amounts would be determined by the Medicare Administrative Contractor (MAC) consistent with existing policies and procedures.

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[1] For the ANPRM discussion, CMS defines "PPE" in a manner consistent with section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58) (see pg. 885 of the law) as surgical masks, respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease.

[2] CMS defines "essential medicines" as the 86 medicines prioritized in the report Essential Medicines Supply Chain and Manufacturing Resilience Assessment developed by the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response (formally known as the Office of the Assistant Secretary for Preparedness and Response) and published in May 2022, and any subsequent revisions to that list of medicines.

[3] For all types of PPE (including those covered by the Berry Amendment), whether the Make PPE in America domestic content requirements outlined in section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58) would be an appropriate framework for determining if these types of PPE are wholly made in the U.S.?

[4] Regarding the definition of fully domestic essential medicines, in the ANPRM, CMS indicates the agency's belief that over 50% of the API and entire final dosage form (not including components such as syringes or IV bags) must be manufactured in America.

[5] In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into 26 equal biweekly payments. The estimated amount would be based on the most current cost data available, which will be reviewed and, if necessary, adjusted at least twice during the reporting period. (See CMS Pub 15– 1 section 2405.2 for additional information). The MACs would determine the interim lump-sum payments based on the data the hospital may provide that reflects the information that would be needed to determine the additional cost for PPE and essential medicines to maintain the "Secure American Medical Supplies" friendly hospital criteria and the amount of any separate payment. In future years, the MACs could determine the interim biweekly lump-sum payments utilizing information from the prior year's cost report, which may be adjusted based on the most current data available.

For PPE, CMS is considering deriving the separate payment for a hospital using cost report data on the number of days the hospital treated Medicare fee-for-service (FFS) patients, reasonable assumptions on PPE use per hospital day and the additional domestic PPE unit costs.[6] For essential medicines, CMS is considering deriving the payments for a hospital using cost report data on Medicare's IPPS share of the hospital's total drug costs and reasonable assumptions on what percentage of those costs are for essential medicines and the higher costs of domestically produced essential medicines.[7]

Among other questions, CMS seeks feedback regarding:

- What additional costs or burdens would be incurred by a health care facility or system to achieve such a designation? How would medical facilities or systems cover this cost? What resources could CMS provide to help Medicare participating hospitals address intangible barriers to earning the "Secure American Medical Supplies" designation?
- What suggestions do stakeholders have for CMS regarding facilities' contracts with domestic manufacturers and/or suppliers of PPE and essential medicine through the "Secure American Medical Supplies" designation? Should there be contracting principles and elements that should be encouraged as part of this designation?
- For each type of PPE, would Medicare FFS inpatient days be an appropriate basis for deriving the Medicare IPPS utilization of the PPE? If not, what would be an appropriate basis for deriving the Medicare IPPS utilization?
- Under the potential approach for domestic essential medicines, would total drug costs as reported on the hospital cost report be an appropriate starting point for deriving Medicare's IPPS share of the additional costs to procure domestic essential medicines? If not, what would be an alternative basis for deriving Medicare's IPPS share of those costs?
- Would a payment adjustment to account for the Medicare FFS share of these additional costs be sufficient to encourage hospitals to increase their purchasing of domestically made PPE and essential medicines?
- 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?

### Hospital IQR Program[8] Measure

CMS seeks input on the potential adoption of a structural measure (attestation-based) that would require hospitals to attest to meeting the domestic procurement minimum percentages for PPE and essential medicines as part of the Hospital IQR Program. CMS provides that hospitals could be required to attest "yes" or "no" as to whether they met a minimum percentage of American-made PPE and essential medicines, as well as whether they met minimum percentages of relevant or applicable products and supplies in each category (that is, for example, masks under PPE or anti-microbial medicines for essential medicines) if sufficient domestic producers exist.

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[6] As an illustrative example for N95 FFRs, assume General Hospital is a "Secure American Medical Supplies" friendly hospital. If (a) General Hospital billed 10,000 Medicare patient days in a year, (b) the assumed average number of N95 FFRs used per day per patient nationally is 5, and (c) a domestically produced N95 FFR is assumed to cost $0.20 more than a non-domestic one, then General Hospital would receive a Medicare payment of $10,000 (=10,000 days x 5 FFR per day x $0.20 per FFR additional cost).

[7] As an illustrative example, if (a) Medicare's IPPS share of General Hospital's total drug costs as reported on its cost report are $2 million13, (b) essential medicines are assumed to represent 1 percent of those costs, and (c) domestic essential medicines are assumed to be 12 times more costly, then General Hospital would receive a Medicare payment of $240,000 (=$2 million x 1 percent for essential medicines x 12 for the domestic cost differential).

[8] The IQR program is a pay for reporting program. Hospitals that do not meet reporting requirements have a negative adjustment to their market basket update (it is reduced by 25%) for the applicable fiscal year.

Among other questions, CMS seeks feedback regarding:

- Would a structural attestation measure in the Hospital IQR Program be an appropriate way to bring transparency as to hospital procurement of domestically manufactured items and incentivize hospitals to prioritize resources for increasing procurement through domestic supply?
- If the measure attestations were to ask hospitals whether they met a minimum American-made percentage of all PPE and all essential medicines, as well as whether they met minimum American-made percentages of each subcategory (e.g., masks or anti-microbial medicines) if sufficient domestic producers exist, what would be a sufficient minimum percentage?
- What would be the least burdensome effective method to audit or validate hospitals' attestation responses, as feasible?
- What are potentially useful alternative measures to an attestation measure? How could hospitals measure care processes or outcomes related to impacts of purchasing from domestic suppliers? How could hospitals be asked to provide proof that they purchased from domestic suppliers? Could hospital accreditors, GPOs or some other entity be better positioned to track or measure hospitals' domestic procurement activities?

### Additional Comments

CMS also requests comments regarding economic impacts, timing, potential statutory authorities and a discussion of trade-offs in the context of potential approaches to bolster domestic supply chains through hospital purchasing.

## What's Next?

Comments on the ANPRM are due March 30, 2026.

Vizient's Office of Public Policy and Government Relations looks forward to hearing client feedback on this ANPRM. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed ANPRM – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, Vice President, Regulatory Affairs and Public Policy, in Vizient's Washington, D.C. office.