

# Publications

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## A New “Made in America” Push for Hospitals: CMS Seeks Input on Domestic Sourcing for PPE and Essential Medicines

### Key Takeaways

- CMS is seeking input by March 30 on a proposed framework to promote U.S.-made PPE and essential medicines in Medicare-participating hospitals.
- The proposal could extend federal-style sourcing requirements to hospital systems outside traditional procurement channels.
- Hospitals, suppliers and distributors should evaluate current sourcing practices and prepare for enhanced documentation or compliance obligations.

The Centers for Medicare & Medicaid Services (CMS) recently issued an Advance Notice of Proposed Rulemaking (ANPRM) soliciting feedback on options to encourage Medicare-participating hospitals to procure U.S.-manufactured personal protective equipment (PPE) and essential medicines. In issuing its Jan. 29, 2026 notice, CMS has signaled that hospital purchasing may become the next major lever for the “Made in America” policy, with potential downstream impacts for suppliers, compliance representations and contracting strategies well beyond traditional federal procurement channels.

### CMS Seeks Early Input on ‘Made in America’ Framework for Hospitals

CMS’ decision to issue an ANPRM in lieu of a Notice of Proposed Rulemaking (NPRM) presents a unique opportunity for providers and other stakeholders to provide input that would help to inform and potentially shape CMS’ final policy and rulemaking. While an NPRM is an official part of the Administrative Procedures Act (APA) rulemaking process and proposes specific regulatory changes for public comment, an ANPRM instead provides an opportunity for CMS to gather stakeholder input *before* developing a detailed proposed rule. If CMS, after reviewing the comments from the ANPRM, decides to proceed with the proposal to push hospitals to procure domestically made PPE and medicines, CMS will need to issue an NPRM before issuing a final rule.

CMS describes three possible policy paths in the ANPRM:

1. A “Secure American Medical Supplies”-friendly hospital designation for hospitals that

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- meet specified domestic procurement thresholds for PPE and essential medicines;
2. Potential Medicare payment approaches to recognize incremental costs for hospitals that earn the designation (including concepts tied to IPPS/OPPS frameworks); and
  3. A potential Hospital Inpatient Quality Reporting (IQR) Program structural measure based on meeting domestic procurement minimum percentages, consistent with the Secure American Medical Supplies designation.

## **What CMS Means by “PPE,” “Essential Medicines” and “Made in America”**

CMS defines PPE with respect to the ANPRM consistent with section 70953 of the Infrastructure Investment and Jobs Act (IIJA). This includes items such as surgical masks, respirators and required filters, face shields/protective eyewear, gloves and disposable/reusable surgical and isolation gowns, as well as head and foot coverings and other gear or clothing used to protect an individual from the transmission of disease. In its ANPRM, CMS specifically asks whether the “Make PPE in America” domestic content requirements in IIJA section 70953 would be an appropriate framework for determining whether covered PPE is “wholly made” in the U.S., noting those statutory requirements already apply to PPE procurement by the U.S. Departments of Health and Human Services (HHS), Veterans Affairs (VA) and Homeland Security (DHS) and would require procuring PPE (including its materials and components) that is grown, reprocessed, reused or produced in the United States.

For essential medicines, CMS points to the 86 medicines prioritized in the HHS May 2022 Essential Medicines Supply Chain and Manufacturing Resilience Assessment (and any revisions to that list). CMS is also requesting comment on a potential domestic manufacturing standard — for example, treating a medicine as “fully domestic” if more than 50% of the active pharmaceutical ingredient (API) and the entire final dosage form (excluding certain components such as syringes or intravenous (IV) bags) are manufactured in the United States.

## **CMS Signals a Federal Procurement Lens for Hospital Sourcing**

CMS is signaling a potential shift toward using federal acquisition frameworks to define acceptable sourcing thresholds for PPE and essential medicines, even in contexts outside traditional government contracting. CMS is considering relying on a list of “critical components” and “critical items” as defined in the Federal Acquisition Regulation (FAR) at FAR 25.003 and is potentially using the list at FAR 25.105 (48 C.F.R. § 25.105), which is currently being developed pursuant to Executive Order 14005 and related rulemaking. CMS acknowledges the list is forthcoming at the time of the ANPRM but frames it as a potential way to define what PPE and essential medicines would be within its scope.

## **Suppliers Should Prepare for Compliance and Contracting Shifts**

For suppliers that sell into (or alongside) VA channels, CMS is evaluating “Made in America” concepts that look more like domestic content and manufacturing-location tests than the “country of origin” representations that suppliers may be used to making under other procurement regimes.

If CMS establishes final rules based on these concepts through public designation criteria, hospital systems, distributors and group purchasing organizations (GPOs) will be required to materially revise current contracting approaches with applicable product manufacturers to include detailed sourcing substantiation in commercial supply chains, certifications of compliance with country of origin requirements and audit-ready documentation that resemble (or are benchmarked to) familiar federal procurement standards. Consultants and third-party auditors will also need to develop significant new expertise to verify

certifications by manufacturers of compliance with any such requirements.

## **Medicare Reimbursement Considerations**

CMS acknowledges in the ANPRM that domestically manufactured PPE and essential medicines generally cost more than foreign-made equivalents. To help offset the additional resource costs that hospitals would incur, CMS contemplates a separate payment under the Inpatient Prospective Payment (IPPS) to hospitals that earn the “Secure American Medical Supplies” designation. Specifically, these hospitals could receive 1) a lump-sum payment at cost report settlement, in which Medicare could make a lump-sum payment for Medicare’s IPPS share of the additional cost using cost report data; or 2) biweekly interim lump-sum payments, in which CMS could make advance payments in 26 equal installments over the year, which would be reconciled at settlement with Medicare Administrative Contractor (MAC) review.

Both payment mechanisms would rely on reasonable cost principles and MAC determinations consistent with existing Medicare rules. CMS also discussed the potential for a non-budget neutral payment under Social Security Act Section 1886(d)(5)(I), in which CMS would explore providing additional funding for additional costs to the designated hospitals rather than redistributing existing IPPS dollars. Finally, CMS is considering adding a structural measure to the IQR Program that would require hospitals to attest to meeting minimum percentages of domestically manufactured PPE and essential medicines in their procurement. CMS is seeking comments on all of these proposals.

While CMS’ suggested separate payment may potentially generate additional revenue for designated hospitals, there are some operational and compliance implications that providers should consider. To receive proposed payment, hospitals would need to understand which products meet CMS’ definition of “domestic” and have a robust and efficient tracking system in place to identify and quantify procurement volumes for domestically manufactured PPE and essential medicines and unit costs per product, as well as how these costs map to the CMS cost report. In addition, with CMS signaling it would only reimburse the Medicare share of the IPPS payment, it is unclear whether the Medicare portion would account for all the additional cost to providers for procuring domestically. Finally, designated hospitals should anticipate continued validation of cost report submissions by the MACs and be prepared to address any potential overpayment or underpayment risks with supporting documentation during reconciliation at settlement.

## **Deadline to Weigh In on Domestic Procurement Rules Is March 30**

Comments on the ANPRM are due March 30, 2026. Hospitals, suppliers, group purchasing organizations and related stakeholders should consider weighing in on feasibility, compliance burden and unintended consequences before CMS codifies requirements into formal rulemaking.

CMS specifically solicits comments on the following questions:

1. Potential Establishment of a Publicly Reported Hospital Designation Reflecting Medicare Participating Hospitals’ Commitment To Procuring Domestic PPE and Essential Medicines
  1. 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?

2. For administering the designation, what are potentially useful alternatives to self-attestation? How could hospitals be asked to provide proof that they purchased from domestic suppliers? Could hospital accreditors, group purchasing organizations (GPOs) or some other entity be better positioned to administer oversight of the designation?
  3. What is the most appropriate definition of domestic for PPE and essential medicines, respectively?
  4. 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?
  5. 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?
  6. What standards designation might be appropriate?
  7. 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?
  8. Would having a specific list of items be preferable to a general rule for determining whether products are domestic?
  9. How can manufacturers designate if their product is wholly domestically made?
  10. As discussed in section III of this ANPRM and in the CY 2025 OPPS/ASC final rule, in the past commenters indicated that hospitals have had difficulty ascertaining which products meet the definition of domestic under the surgical N95 FFR policy. How do purchasers currently identify domestic PPE and domestic essential medicines? How could this be improved? What is the role of third-party distributors vs. direct procurement from individual manufacturers?
  11. For hospitals purchasing PPE and essential medicines through GPOs or other third parties, what barriers would such hospitals face in meeting the requirements of a “Secure American Medical Supplies” friendly designation? How could these barriers be addressed?
  12. 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?
  13. When and how should we provide flexibilities under such a policy in the event of supply chain disruptions like natural disasters and demand surges?
2. Potential Separate Medicare Payment To “Secure American Medical Supplies” Friendly Hospitals
1. 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 we provide to help Medicare participating hospitals address intangible barriers to earning the “Secure American Medical Supplies” designation?
  2. 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?

3. Under the potential approach for domestic PPE, what types of PPE should be included?
4. 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?
5. For each type of PPE, what assumptions regarding how many items of PPE are used per inpatient day (or another basis) would be appropriate for deriving the Medicare IPPS utilization?
6. For each type of PPE, what would be an appropriate estimate for the additional domestic PPE unit costs compared to non-domestic PPE? Please provide supporting evidence.
7. As an alternative to a cost reporting-based approach, how might a claims-based approach to the payments be structured?
8. 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?
9. 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?
10. On average, what percentage of a hospital's total drug costs are for essential medicines (or each subcategory of essential medicines)?
11. 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?
12. Should any new IPPS supply chain policy replace existing IPPS supply chain policies for N95 FFRs and buffer stocks?
13. For PPE, in addition to separate payment for the higher inpatient hospital costs, should Medicare also consider making separate payment for the higher outpatient hospital costs? Under our current policy for domestically produced surgical N95 FFRs we used our authority under section 1833(t)(2) (E) of the Act to make separate payment for the higher outpatient hospital costs, which authorizes the Secretary to establish, in a budget-neutral manner, other adjustments as determined to be necessary to ensure equitable payments.
14. 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?
15. Would it be appropriate to expand a potential payment policy beyond IPPS and OPSS 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?
16. 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?

### 3. Hospital IQR Program Measure

1. 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?
2. 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 (that is, masks or antimicrobial medicines) if sufficient domestic producers exist, what would be a sufficient minimum percentage?
3. Should the structural measure attestations, including minimum percentages, be aligned with the attestations and minimum percentages for the “Secure American Medical Supplies” friendly hospital designation, or should the structural quality measure seek different information about hospitals’ domestic procurement activities (and if so, what types of activities or attestations would be appropriate for a measure in the Hospital IQR Program)?
4. What would be the least burdensome effective method to audit or validate hospitals’ attestation responses, as feasible?
5. 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?
6. Are hospitals aware of evidence-based literature and independent research that demonstrates the use and availability of domestically manufactured health care supplies and drugs to improve health care, health outcome and safety?
7. How have supply chain disruptions due to the lack of domestically manufactured PPE and essential medicines impacted the quality of care at hospitals?