COALITION for a PROSPEROUS AMERICA

ENSURING SAFETY THROUGH DOMESTIC SECURITY WITH MADE IN AMERICA PERSONAL PROTECTIVE EQUIPMENT & ESSENTIAL MEDICINE PROCUREMENT BY MEDICARE PARTICIPATING HOSPITALS

CPA Comments on the Advance Notice of Proposed Rulemaking Published by the Centers for Medicare & Medicaid Services

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Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Re: Medicare Program; Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals [CMS–1516–ANPRM; RIN 0938–AV72]

Dear Administrator Oz,

The Coalition for a Prosperous America (CPA) appreciates the opportunity to submit comments on the Advance Notice of Proposed Rulemaking (ANPRM) entitled "Medicare Program; Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals" (CMS–1516–ANPRM; RIN 0938–AV72), published by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on January 29, 2026 (91 FR 3851).

CPA is a bipartisan organization representing domestic manufacturers, farmers, ranchers, and workers. Our mission is to advance trade, tax, and growth policies that strengthen America's industrial base and reduce dependence on foreign supply chains for critical goods. We work closely with American PPE, medical device, and pharmaceutical manufacturers who would be directly affected by the policies proposed in this ANPRM. Our comments below reflect both CPA's policy expertise on domestic manufacturing and supply chain resilience, and the operational perspective of domestic producers.

We strongly support the objectives of this rulemaking. The COVID-19 pandemic exposed dangerous vulnerabilities in America's health care supply chain, and those vulnerabilities persist. In the spring of 2020, hospitals faced critical shortages of surgical masks, N95 respirators, isolation gowns, and other PPE because most of these products were manufactured overseas, primarily in China. Despite significant federal and private investment efforts since COVID-19, many new domestic PPE manufacturers have since ceased operations due to ultra-low-priced imports from subsidized foreign suppliers that have made it impossible to operate profitably.[1] U.S. purchasers have largely reverted to pre-pandemic reliance on foreign sources.[2]

The United States remains almost entirely import-dependent for key products such as nitrile medical gloves, with approximately 99% of supply sourced abroad based on market research and import data.[3], [4] The recent closure of SafeSource Direct in Louisiana—resulting in the loss of more than 500 U.S. manufacturing jobs—underscores how dumped imports continue to undermine viable domestic operations.[5] This failure reflects distorted market conditions—not a lack of U.S. manufacturing capability. Viable domestic capacity exists and continues to advance under more durable production models. For example, Health Supply US / Glove One has established a large-scale, vertically integrated nitrile glove manufacturing facility in Greenville, South Carolina, supported in part by federal investment through HHS. Unlike failed projects, this facility demonstrates a commercially viable path forward when stable demand and pricing conditions are in place.

The supply chain vulnerabilities exposed by the pandemic extend well beyond traditional PPE to encompass essential medical device commodities—syringes, IV catheters, prefilled flush syringes, blood collection devices—and essential medicines that hospitals rely on daily.

In total, the United States lacks domestic sources for more than 80% of APIs needed to produce critical medicines.[6] The result is a supply chain defined by systemic single points of failure, where the disruption of a single foreign facility can trigger nationwide shortages. At the same time, sustained price compression driven by subsidized foreign production has displaced U.S. manufacturers and made domestic production economically unviable, leaving the nation dependent on supply chains that are both economically unstable and strategically insecure.

These structural weaknesses now manifest in persistent shortages, declining quality assurance, and growing risks to patient safety. The United States regularly faces 200–320 active drug shortages at any given time,[7] with over 85% of hospital pharmacists reporting that shortages are critically or moderately impacting care.[8] Drug shortages drive up hospital error rates by 1—5%, create unsafe conditions in 60% of cases, and often force hospitals to pay 300—500% markups to obtain critical medicines.[9]

Our comments address both PPE and these broader essential medical supply categories, which face the same foreign-sourcing risks and deserve equal attention from CMS in this rulemaking. The ANPRM's proposals to establish a "Secure American Medical Supplies" friendly hospital designation, create a separate Medicare payment to offset higher domestic procurement costs, and introduce a structural quality measure in the Hospital Inpatient Quality Reporting (IQR) Program represent the kind of demand-side policy action that can reverse this trend. Our comments address each of these proposals.

1. Payment Adjustments Must Reflect Real Domestic Manufacturing Costs

Domestic PPE, essential medical supplies, and essential medicines are produced under higher labor, compliance, and materials standards than foreign alternatives. The ANPRM acknowledges this cost differential, citing a $0.20 per-unit premium for domestically produced NIOSH-approved surgical N95 filtering facepiece respirators (FFRs) over non-domestic alternatives, and a cost premium of approximately 12 times for domestic active pharmaceutical ingredients (APIs).[10]

These figures likely understate the full cost of domestic manufacturing. The $0.20 per-unit N95 differential reflects acquisition price differences but does not capture the upstream capital investment, workforce training, and regulatory compliance costs that domestic manufacturers absorb to maintain production lines in the United States. Domestic PPE manufacturers use specialized raw materials—melt-blown polypropylene for respirators, for example—that carry their own supply constraints and cost premiums. Any payment

enhancement model must incorporate verifiable domestic manufacturing cost structures, including labor, raw materials, regulatory compliance, and capital investment in domestic facilities.[11]

Structural cost disadvantages in manufacturing inputs compound these differentials. Index prices in North America for polypropylene resin and steel are significantly higher than in Northeast Asia. Between 2017 and 2022, 122 Chinese firms in the medical and industrial supply sectors saw their access to government subsidies increase approximately fivefold.[33] U.S. manufacturers of essential medical supplies compete against foreign producers whose input costs, labor costs, and regulatory burdens are all substantially lower, often reinforced by direct state support.

The cost structure of syringe imports illustrates the scale of the challenge. CPA analyzed U.S. Department of Commerce trade data for HTS 9018.31 (syringes, with or without needles) and found a stark two-tier pricing structure among import sources.[12] A cluster of low-cost producers—China, India, South Korea, Vietnam, Thailand, and Indonesia—supply syringes to the U.S. market at $0.05 to $0.07 per unit. Allied-nation producers such as Germany, Japan, Mexico, and Singapore supply syringes at $0.24 to $0.68 per unit. China alone accounts for 1.95 billion units at $0.06 per unit (see Figure 1).

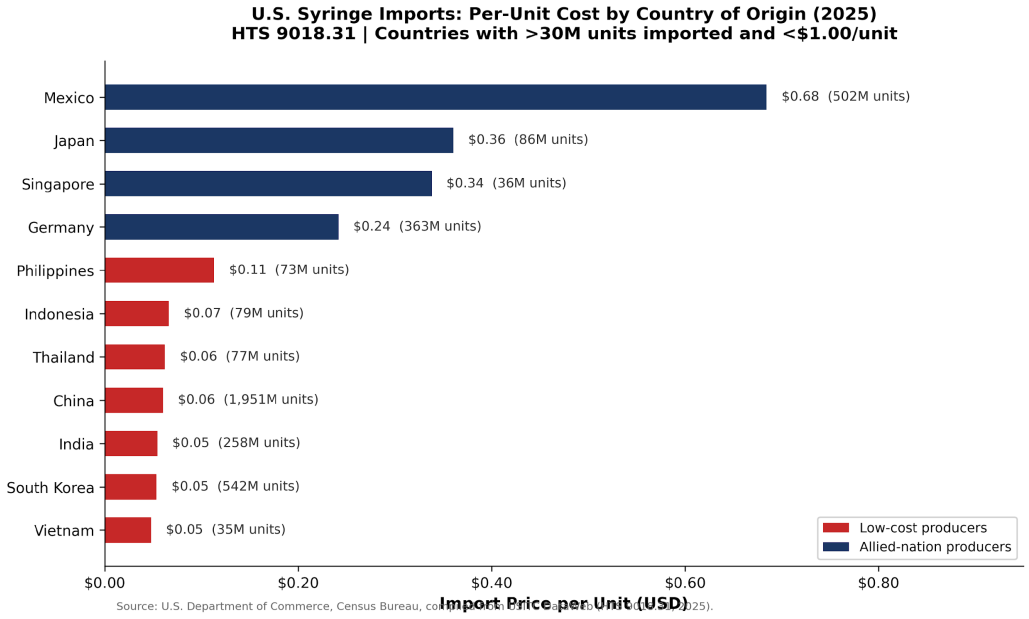


Figure 1: U.S. Syringe Imports: Per-Unit Cost by Country of Origin (2025)

This pricing structure has a critical policy implication: tariffs alone will not shift hospital purchasing toward domestic sources. Even with the 100% Section 301 tariff on Chinese syringes (effective September 2024), hospitals can redirect purchasing to India, South Korea, or Vietnam at comparable prices rather than to domestic manufacturers. A Medicare payment adjustment that offsets the cost differential between domestic and imported products is therefore essential to achieving the ANPRM's objectives.

The trade data reveal the scale of the cost gap domestic manufacturers face. Allied-nation imports from Germany ($0.24/unit), Japan ($0.36), and Mexico ($0.68) already cost 4 to 11 times more than the low-cost producer cluster. Domestically manufactured syringes

carry still higher costs, reflecting U.S. labor rates, stringent FDA quality system requirements, and the capital investment needed to maintain production facilities in the United States.

The same pattern holds for isolation gowns. CPA analyzed trade data for HTS 6210.10 (garments of nonwoven fabrics) and HTS 6211.43 (garments of man-made fibers), which together capture the primary import categories for disposable and reusable surgical and isolation gowns.[13] China dominates gown imports even more than syringes, supplying 766 million units in 2025—54.9% of total import volume—at $0.56 per gown. The next-cheapest major supplier, Myanmar, comes in at $0.57. From there, prices rise sharply: Cambodia at $1.19, Bangladesh at $0.94, and nearshore DR-CAFTA producers such as Honduras ($1.63) and the Dominican Republic ($1.85) at 3 to 3.3 times China's price. Mexico, the largest USMCA supplier, comes in at $3.57 per gown—6.4 times the Chinese price (see Figure 2).

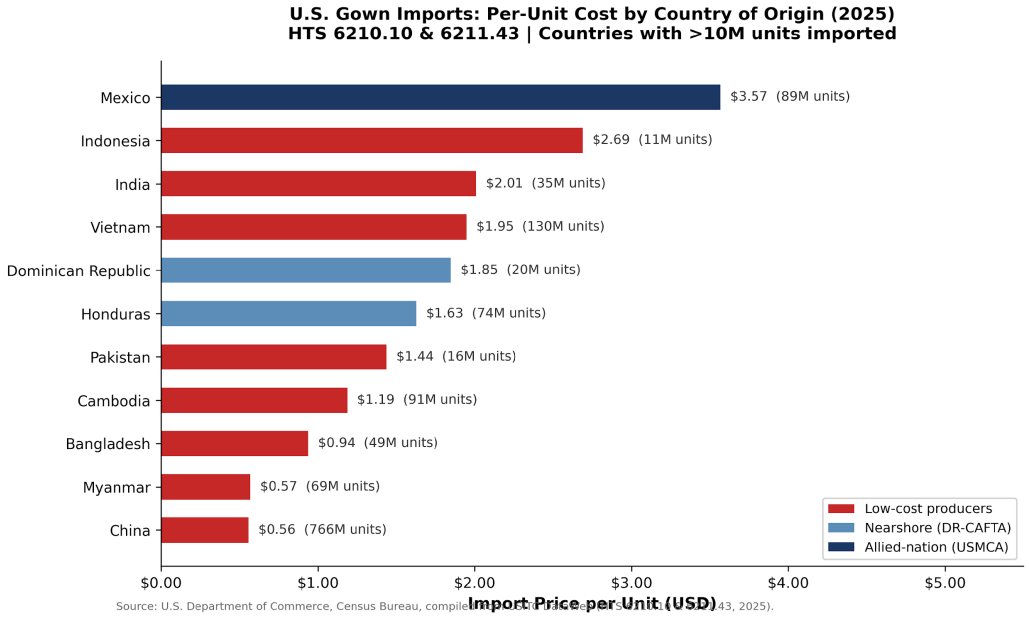
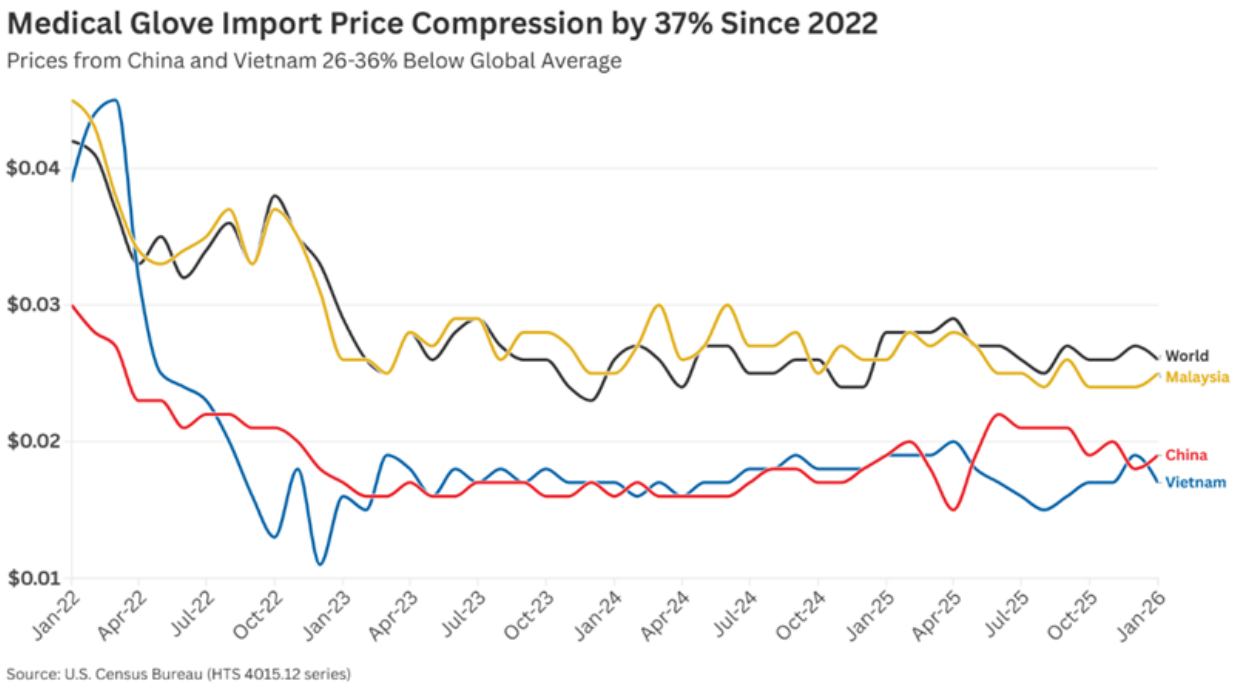


Figure 2: U.S. Isolation Gown Imports: Per-Unit Cost by Country of Origin (2025)

The gown data reinforce the syringe findings: across multiple PPE product categories, China's import prices are substantially below those of every other significant supplier. Domestic U.S. production costs are necessarily higher still. The ANPRM notes that CMS has observed domestic cost premiums of 1.5 to 3 times for nitrile gloves and approximately 12 times for active pharmaceutical ingredients. The cost differentials for syringes and gowns, while product-specific, operate within this broader pattern of significantly higher domestic production costs across medical product categories.

Medical gloves show the same pattern. Import prices have fallen by 37% since 2022, with Chinese and Vietnamese imports persistently priced 26–36% below the global average, reinforcing severe price distortion in the market. This price dynamic extends beyond finished goods to upstream inputs such as nitrile-butadiene rubber (NBR), where global supply is similarly concentrated and heavily influenced by Chinese production and pricing dynamics.[14], [15] During COVID-19, this structure contributed to severe shortages, rationing by hospitals, and the entry of counterfeit and substandard products into the U.S. market. Today, global overcapacity—driven in large part by state-supported expansion in China—has pushed prices to artificially low levels, further undermining the viability of domestic

manufacturing and reinforcing long-term dependence. The result is a supply chain with limited resilience and significant exposure to future supply disruptions, export restrictions, or geopolitical leverage.



The magnitude of the pricing distortion is both measurable and addressable. Current market data indicates that imported nitrile gloves—particularly from China and Southeast Asia—are priced approximately $0.04–$0.05 per glove below U.S. production costs. This gap reflects a combination of subsidized production, excess capacity, and non-market pricing behavior. A targeted procurement preference or tariff-rate adjustment calibrated to this pricing disparity would be sufficient to restore competitive balance. Closing this $0.04–$0.05 per glove price gap would allow domestic manufacturers to operate at scale while maintaining cost parity for purchasers.

Without reimbursement that reflects these real costs, hospitals will continue to default to the cheapest available imports regardless of any voluntary designation. CPA urges CMS to establish a payment methodology that fully closes the cost gap between domestic and foreign products, measured at the product category level. A payment that covers only the Medicare share of the differential would leave hospitals bearing the remaining cost and discourage adoption.

2. Demand-Side vs Production-Side Incentives

CMS's proposed approach appropriately recognizes that current procurement dynamics can prioritize the lowest upfront acquisition cost, even where that approach may not fully account for supply chain resilience, product quality, or long-term availability. Adjustments to these demand-side incentives can support greater consideration of domestically produced alternatives within hospital purchasing decisions.

At the same time, the constraints facing these markets extend beyond hospital procurement. The structure of medical supply chains places key economic pressures upstream, within the production base and intermediary contracting systems. While hospitals exert some influence, purchasing decisions are shaped by group purchasing organizations (GPOs), distributors, and reimbursement frameworks that aggregate demand and reinforce price-based competition. As a result, procurement outcomes do not fully reflect the pricing conditions required to sustain domestic manufacturing capacity.

Across PPE, medical devices, and essential medicines, domestic producers compete in markets where pricing is shaped by global supply conditions, including subsidization, excess capacity, and other non-market factors. These conditions can place sustained downward pressure on prices, making it difficult for domestic manufacturers to operate at scale or justify new investment, even where underlying production capability exists.

Within this structure, demand-side policies operate downstream of both intermediary contracting systems and production decisions. While payment adjustments and procurement-related incentives can influence purchasing behavior, hospitals must weigh additional administrative burden and contracting friction against often limited, delayed, or uncertain financial benefit. In practice, it often remains operationally easier to continue purchasing low-cost imports than to shift procurement toward domestic suppliers. As a result, these policies often do not directly change the cost structure facing manufacturers or provide the level of demand certainty required to support long-term capacity expansion, and may not be sufficient to generate the scale of domestic supply needed to meet policy objectives.

A more complete approach aligns demand-side incentives with the economic conditions required for production. Investors require clear price stability, predictable policy implementation, and long-term demand commitments to finance new production capacity. Absent these conditions, capital will remain on the sidelines, delaying investment and extending supply chain vulnerabilities.

In this context, demand-side and production-side considerations are complementary but not interchangeable. Effective policy must include production-side incentives that directly address the economics of domestic manufacturing. This includes manufacturer-directed rebates or production incentives that reduce the effective cost of domestic output, as well as federal procurement commitments that provide guaranteed offtake and alignment across Medicare, the Department of Defense, the Veterans Health Administration, and other federal purchasing to establish stable demand. Direct manufacturer rebates lower costs at the point of production, allowing domestic suppliers to offer competitive pricing without shifting the burden to hospitals. These mechanisms target the binding constraint in the current system: insufficient investment and scale. Demand-side policies can support the incorporation of domestically produced goods into procurement decisions, but production-side conditions ultimately determine whether that supply exists and can scale. Aligning these elements supports a more durable and resilient domestic supply base.

3. The Quality and Safety Case for Domestic Procurement

The case for domestic procurement extends beyond supply chain resilience to patient safety, and beyond PPE to essential medical device commodities used in routine hospital care. Procurement must not be solely concerned with cost. U.S.-based manufacturing has historically set the global standard for quality, safety, and regulatory compliance. In contrast, persistent quality failures, recalls, and compliance violations at foreign facilities demonstrate that lowest-cost sourcing often comes at the expense of reliability and patient safety.

Rebuilding domestic production is therefore not only an economic imperative but a return to a system in which quality, accountability, and trust define the supply chain. Continued reliance on artificially cheap imports shifts both economic value and safety risk offshore—undermining U.S. manufacturing while exposing patients to lower-quality supply.

Recent FDA enforcement actions against foreign syringe manufacturers underscore the quality risks associated with imported medical products. In 2023–2024, the FDA issued a Class I recall—its most serious category—of 12,477,300 Sanxin Medical disposable syringes distributed by Fresenius Medical Care after reports of blood leakage and contamination with black particulate material. The FDA separately identified quality failures in syringes manufactured by Jiangsu Shenli Medical Production Co. and Jiangsu Caina Medical Co., distributed by Medline Industries, for leakage, breakage, and debris risks in cardiac and epidural procedures.[16]

The scope of the problem proved far wider than initial reports suggested. The FDA received more than 4,000 Medical Device Reports regarding plastic syringes in 2023, prompting a broader investigation that revealed quality issues with Chinese-manufactured syringes were more widespread than originally known.[17] In March 2024, the FDA issued warning letters to Jiangsu Shenli (manufacturer), Medline Industries, and Sol-Millennium Medical (distributors), and import alerts against Zhejiang Longde Pharmaceutical and Shanghai Kindly Enterprise Development Group, with additional enforcement actions following later in 2024.[18]

China supplied nearly 2 billion syringes to the U.S. market in 2025, accounting for 46.5% of all syringe imports by volume.[19] The concentration of imports from a country whose manufacturers are the subject of repeated FDA enforcement actions represents a compounding risk: supply chain dependence and patient safety vulnerability reinforce each other. The ANPRM rightly notes that commenters have cited quality concerns with imported syringes, needles, and other products, including issues ranging from leaks to breakages that compromise patient safety (91 FR 3852). The FDA data confirm these concerns are well-founded.

Quality risks extend beyond syringes. Prefilled flush syringes deliver fluid directly into a patient's bloodstream, where any contamination or defect can have serious, even fatal, consequences. Peripheral IV catheters provide immediate access to the bloodstream for the delivery of medications, blood products, and contrast agents. Blood collection devices underpin diagnostic testing and clinical decision-making across virtually all areas of health care. For each of these product categories, the consequences of quality failures are immediate and clinical, reinforcing the case for domestic procurement as a patient safety measure.

These same quality risks are now translating directly into supply instability, as failures in foreign manufacturing can remove large portions of these critical products from the market with little warning. Repeated cases of data falsification, contamination, and substandard production abroad show that low-cost sourcing often undermines reliability, safety, and the stability of supply. At generic medicine manufacturer Glenmark Pharmaceuticals' plant in India, inspectors found repeated dissolution failures in potassium chloride capsules, poor cleaning, and inadequate investigations.[20] The company recalled more than 100 batches in 2024, and FDA records linked the product to at least eight U.S. patient deaths.[20] Similarly, in 2023, the FDA shut down an Indian plant producing 50% of the U.S. supply of cisplatin after uncovering serious quality failures, including falsified records.[21], [22] With no domestic capacity to replace it, the disruption triggered nationwide shortages and forced hospitals to ration cancer treatments.

This is a systemic failure directly linked to the current U.S. procurement and reimbursement framework that has consistently rewarded the lowest upfront price rather than resilience, supply chain security, or domestic capacity. Without correcting these underlying incentives, the United States will remain exposed to recurring shortages, safety risks, and supply disruptions across both PPE and essential medicines.

CPA urges CMS to frame the "Secure American Medical Supplies" designation and the associated payment adjustments as patient safety measures, consistent with the quality and safety evidence.

4. CMS Must Publish a Clear, Operational Definition of "Domestically Manufactured"

The ANPRM solicits comments on several possible approaches to defining "domestic" PPE and essential medicines, including percentage-of-U.S.-content standards, the Berry Amendment framework, and the Make PPE in America requirements in section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58). Manufacturers cannot redesign supply chains, adjust labeling, or invest in domestic capacity without a clear, stable rule.

CPA recommends that CMS adopt a product-category-specific approach to defining "domestic," drawing selectively from existing federal frameworks rather than relying on any single standard. The Berry Amendment and section 70953 already define "domestic" for federal procurement purposes and have been operationalized across the Departments of Health and Human Services, Veterans Affairs, Homeland Security, and Defense. These frameworks are well-suited to textile-based PPE—masks, gowns, hair nets, shoe covers—where the Berry Amendment's woven-materials provisions apply directly.

Other essential medical supplies, however, fall outside the Berry Amendment's scope. Syringes, needles, nitrile gloves, IV catheters, prefilled saline flush syringes, and blood collection devices are manufactured from non-woven materials—polypropylene resins, stainless steel, and medical-grade plastics—that the Berry Amendment was never designed to cover. CMS has acknowledged that the "Make PPE in America" domestic content requirements may be the most appropriate framework for determining if a nitrile glove is wholly made in the United States. While relevant, neither of these frameworks provides a comprehensive or scalable definition that can be applied consistently across the full range of essential medical supplies used in hospital care.

For non-textile essential medical supplies, CPA recommends that CMS anchor its definition of "domestic" to the "domestic end product" definition in the Buy American provisions of the Federal Acquisition Regulation (FAR), specifically 48 CFR § 25.003.[23] This framework is well established, familiar to manufacturers already serving federal markets such as the Department of Veterans Affairs, and adaptable across diverse medical supply categories. CMS could recognize the current 60% domestic content standard—where domestic components are reasonably available—as a baseline for evaluating U.S. manufacturing, while preserving access to critical medical supplies during the transition period. The FAR framework also provides a built-in trajectory: the domestic content threshold is scheduled to rise to 75% by 2029, which would align naturally with a phased approach to strengthening domestic procurement requirements over time.

CMS should avoid reliance on Commercially Available Off-the-Shelf (COTS) exemptions within any domestic content framework it adopts. COTS exemptions remove domestic content evaluation altogether and provide no graduated mechanism to encourage increased domestic production. For essential medical products, such exemptions would reduce supply chain visibility and weaken incentives for manufacturers to invest in U.S. manufacturing capacity, directly undermining the ANPRM's long-term objectives of supply chain resilience and domestic preparedness.

CMS should also clarify how the designation interacts with the Trade Agreements Act (TAA) and other existing trade obligations. Manufacturers operating under TAA-compliant supply chains need to understand whether TAA-qualifying products will count toward the designation thresholds or whether a stricter domestic-content standard will apply.

For manufacturer verification, CMS should rely on manufacturer-level attestation and certification using established federal definitions, supported by existing procurement and compliance documentation. CMS should avoid requiring hospitals to validate upstream component sourcing, which hospitals are not operationally positioned to assess.

For essential medicines, a tiered framework is necessary to reflect how medicines are produced. Drug manufacturing occurs in multiple stages and domestic designation should reflect that. Active pharmaceutical ingredients (APIs) are the core chemical compounds that create the therapeutic effect, while final dosage form (FDF) manufacturing involves converting those ingredients into finished products such as tablets, capsules, or injectables. A clear distinction should be made between fully domestic production (both API and FDF produced in the United States), partially domestic production (FDF produced in the United States using imported inputs), and minimal to no domestic processing. Without this distinction, policies risk recognizing limited domestic activity while leaving the most critical and supply-constrained stages of production offshore.

5. The Designation Should Be Phased and Tied to Verified Manufacturing Capacity

CPA supports the creation of a publicly reported hospital designation recognizing commitment to domestic procurement. The designation would serve as a market signal to manufacturers, investors, and the public that participating hospitals prioritize supply chain resilience. However, the designation thresholds must be calibrated to actual domestic manufacturing capacity. Setting procurement minimums that exceed available domestic supply would be counterproductive, potentially creating shortages or driving hospitals to game the system rather than make genuine procurement shifts.

Domestic manufacturers are investing in capacity expansion, but this takes time. Becton, Dickinson and Company (BD) has invested approximately $300 million in domestic manufacturing capacity for essential medical supplies since 2020, across its facilities in Columbus, Nebraska; North Canaan, Connecticut; and Sandy, Utah.[24] The Columbus and North Canaan facilities are the only remaining large-scale syringe manufacturing sites in the United States. The Sandy, Utah facility—which opened in 1956 and employs approximately 1,200 associates across 650,000 square feet—is the largest producer of IV catheter lines in the world. BD's investments include $110 million for pre-fillable syringe expansion in Nebraska, $35 million for prefilled flush syringe capacity, and additional investments in safety-engineered devices and conventional syringes.[25]

DeRoyal Industries has the capacity to produce approximately 25 million isolation gowns annually at its Powell, Tennessee facility, though current order volumes do not fully utilize this capacity.[26] The Administration for Strategic Preparedness and Response (ASPR) has invested over $136 million in domestic nitrile glove production.[27] These investments demonstrate that domestic capacity is growing, but CMS must set initial thresholds that reflect where capacity stands today.

In the medical glove sector, the U.S. hospital market consumes approximately 36–45 billion nitrile gloves annually, with Medicare and Medicaid accounting for roughly 40% of demand. A 60–70% procurement threshold would generate approximately 8.4–12.6 billion gloves of demand—sufficient to fully utilize existing domestic capacity and support planned expansion. At this scale, producers can reach efficient production levels and significantly narrow cost gaps. Existing U.S. capacity can already meet this demand. The Health Supply US / Glove One facility in Greenville, South Carolina has an initial production capacity of approximately 4.3 billion gloves per year, with an additional 8.6 billion gloves per year planned expansion on the same campus—consistent with capacity outlined in federal industrial base (IBx) expansion announcements. At full scale, a single manufacturing campus could supply the majority of U.S. medical glove demand.

CPA recommends that CMS consult the Industrial Base Medical Supply Chain (IBMSC) interagency body to conduct a comprehensive assessment of current domestic manufacturing capacity across each product category before setting initial thresholds. IBMSC maintains confidential capacity data across essential medical supply categories that would provide a more accurate and defensible basis for threshold-setting than publicly available estimates or individual manufacturer disclosures. Thresholds should be measured by dollar value rather than physical volume, as a dollar-based metric better reflects the diversity of costs across product categories and aligns more directly with the purchasing systems hospitals already use.

Based on available industry data, initial thresholds in the range of 60–70% of domestic procurement by dollar value would be supportable for several product categories, with the expectation that strong demand signals from a Medicare payment program would incentivize further capacity expansion and potentially attract new entrants into domestic manufacturing. CMS should establish a defined schedule for increasing thresholds over time as domestic capacity grows. Thresholds should also account for the variable levels of domestic manufacturing across product categories; a categorical approach that sets different initial thresholds for product groups at different stages of capacity development would be more practical than a single uniform percentage.

More fundamentally, procurement policy should focus less on rigid thresholds and more on correcting the underlying cost imbalance facing U.S. manufacturers. A meaningful price preference for domestically produced products—such as allowing them to be treated as cost-competitive even when priced above imports—would more directly align purchasing behavior with supply chain resilience objectives. This approach offsets the structural price disadvantage facing domestic producers and creates a clearer, more durable demand signal. It also removes the inherent ceiling of percentage-based thresholds, which by design cap the share of demand that hospitals are required or incentivized to shift toward domestic production. Unlike fixed percentage requirements, a procurement preference scales naturally across product categories and levels of domestic capacity, encouraging adoption where supply exists without imposing quotas that may be difficult to meet or verify. It also provides a more reliable foundation for investment, enabling manufacturers and investors to respond to a consistent pricing advantage rather than uncertain participation in threshold-based programs.

6. Reporting Requirements Must Be Streamlined to Encourage Adoption

The ANPRM's existing surgical N95 FFR payment adjustment offers a cautionary example. CMS notes that for fiscal year 2024, fewer than 100 hospitals reported the information necessary to determine the payment adjustment on their cost reports.[28] This low adoption rate is partially attributable to administrative reporting burden.

Hospital purchasing operates within layered contracting and distribution arrangements—particularly through group purchasing organizations (GPOs), distributors, and reimbursement frameworks—that consistently favor minimizing upfront cost. Because the designation is voluntary, hospitals must evaluate whether the added administrative requirements and contracting adjustments are justified by what may be an often limited or uncertain financial return. Overly complicated documentation requirements—such as multiparty attestations or chain-of-custody reporting—suppress hospital participation regardless of the financial incentive.

For example, payment adjustments for domestically produced N95 respirators have not resulted in meaningful increases in domestic procurement, suggesting that voluntary demand-side incentives do not consistently generate sufficient demand to support domestic production. In practice, maintaining existing sourcing relationships with lower-cost imports will often remain the path of least resistance compared to pursuing qualification under the designation. If expanded designation and payment programs replicate these

administrative and economic frictions, adoption may remain limited. However, a more streamlined and predictable framework could improve participation and strengthen the effectiveness of these incentives.

CPA urges CMS to adopt a single, standardized domestic-origin certification format that manufacturers can issue to all customers. Currently, when third-party verification is involved, each intermediary demands a separate format and content, multiplying the compliance burden on manufacturers. A standardized CMS certification template would allow manufacturers to certify domestic content once and have that certification recognized across all hospital customers and purchasing intermediaries.

For hospitals, the attestation process should be straightforward: a yes/no attestation on the cost report, supported by manufacturer-issued certifications maintained on file. CMS should also make publicly available a list of products eligible under the designation, as past commenters have recommended, to reduce the burden on hospitals of independently ascertaining which products qualify.

CMS should also explore leveraging existing hospital data and procurement systems to minimize new reporting requirements. Hospitals already capture aggregate supply spend data through finance systems, group purchasing organization (GPO) contracts, and enterprise resource platforms. Permitting hospitals to apply supplier- or GPO-provided information on country of manufacture at the vendor or product-category level would be far more practical than requiring product- or patient-level tracking. Hospitals do not procure or manage essential medical supplies based on patient payer status, and requiring segmentation of utilization for CMS-covered versus non-CMS-covered patients would be operationally infeasible.

7. Compliance Verification Should Rest with CMS, Not GPOs or Distributors

CMS asks which entity should administer the designation and verify compliance. CPA believes CMS should retain direct oversight. The three largest group purchasing organizations (GPOs)—Vizient, Premier, and HealthTrust—collectively control an estimated 60–80% of U.S. hospital purchasing volume.[29] While GPOs play a significant role in hospital procurement, relying on them or on distributors as primary compliance verification mechanisms raises structural concerns.

Several of the largest U.S. medical supply distributors are also manufacturers of competing products. Medline Industries holds approximately 60% of the medical-surgical distribution market while also manufacturing medical products. Cardinal Health manufactures exam gloves, surgical kits, IV catheters, and surgical apparel while distributing from over 1,200 suppliers. Owens & Minor manufactures gowns, gloves, and protective apparel while distributing over 180,000 products.[30] Assigning compliance verification to entities that compete with the domestic manufacturers whose products they would be verifying creates an inherent conflict of interest. GPOs also charge manufacturers administrative fees of 2–3% of contract revenues for access to their purchasing networks, with some national GPOs charging above the traditional 3% benchmark.[31] These fees create barriers for smaller domestic manufacturers, and adding a compliance verification role would likely generate additional charges passed on to the very producers the ANPRM is intended to support. The Medical Device Manufacturers Association has estimated that the supplier-funded GPO model costs the healthcare system over $35 billion annually.[32]

CPA recommends that CMS administer compliance verification directly, using the standardized manufacturer-issued domestic-origin certifications described in Section 5 above. CMS should adopt high-level, risk-based, and administratively simple verification approaches that prioritize program integrity without placing additional burden on hospitals. Audit activity should be targeted to product

categories with elevated supply vulnerability or significant offshore concentration. This approach would minimize costs, avoid conflicts of interest, and ensure consistent application of the designation criteria.

At the same time, CMS should support GPOs' efforts to establish domestic-preferred contract tiers and enhance transparency regarding product origin on purchasing platforms. These enhancements would allow hospitals to participate more effectively in a domestic procurement program without having to renegotiate entire contracting portfolios.

8. The Hospital IQR Structural Measure Should Be Phased Incrementally

CPA supports the inclusion of a structural quality measure in the Hospital IQR Program requiring hospitals to attest to meeting domestic procurement minimum percentages. Linking domestic procurement to the quality reporting framework reinforces the principle that supply chain resilience is a patient safety issue. Hospitals that fail to meet the threshold would face a reduction in their annual payment update, creating a meaningful financial incentive.

CPA recognizes industry concern that domestic sourcing reflects supply chain and payment-policy dynamics rather than clinical performance, and that introducing procurement-related measures within the IQR framework could blur the distinction between quality reporting and purchasing decisions. Any structural measure should therefore be designed carefully to avoid creating new standalone reporting constructs or data-collection requirements beyond what hospitals already submit through existing mechanisms. The measure should rely on information already captured through Medicare cost reports or comparable administrative processes.

The structural measure should be aligned with the "Secure American Medical Supplies" designation thresholds so that hospitals work toward a single, consistent standard. Any IQR structural measure should be phased in incrementally, with thresholds tied to validated industry capacity data. CMS should assess available domestic supply before establishing minimum percentages and adjust those percentages upward on a defined schedule as domestic capacity grows.

This phased approach is appropriate for hospital-based reporting and compliance measures but should be distinguished from broader procurement and pricing policies that operate at the production level. In key product categories such as medical gloves, domestic manufacturing capacity already exists but remains underutilized, reflecting sustained price distortion from low-cost imports rather than an absolute lack of supply. In this context, the primary constraint is the absence of a clear and durable pricing signal that supports domestic production and investment. Policies that adjust purchasing incentives—such as procurement preferences or other mechanisms that improve price competitiveness—do not impose rigid volume requirements and can be implemented immediately, allowing demand to scale with available capacity. Strengthening these demand signals would help activate existing production, support incremental capacity expansion, and provide the investment certainty needed to close remaining gaps in domestic supply.

CMS should also ensure that the attestation requirements and the designation criteria seek the same information from hospitals. Requiring one set of data for the IQR measure and a different set for the designation would create unnecessary duplication and further suppress adoption.

9. PPE and Essential Medicines Require Separate Procurement Metrics

The ANPRM covers both PPE and essential medicines under a single policy framework, but these product categories have fundamentally different supply chains. PPE manufacturers use specialized raw materials with global supply constraints and distinct production economics. Pharmaceutical supply chains involve different regulatory pathways (FDA drug approval vs. device clearance), different procurement channels, and different cost structures. The 12x cost differential for domestic APIs operates on entirely different economics than the per-unit differentials for PPE products.

These differences are further reinforced by the multi-layered structure of pharmaceutical supply chains. Final dosage form (FDF) manufacturing represents the downstream stage and offers the most immediate opportunity for capacity expansion, as existing U.S. facilities can scale more rapidly than upstream production. U.S.-based manufacturers such as PAI Pharma and Oxford Pharma operate FDA-approved facilities producing essential generic medicines and continue to invest in expanding domestic production.

However, policies that focus exclusively on FDF risk reinforcing structural dependence, as even domestically produced medicines often rely on imported active pharmaceutical ingredients (APIs). Expanding FDF capacity alone does not resolve this upstream dependence or address core supply vulnerabilities.

CMS should therefore differentiate procurement metrics and incentives based on production depth and capacity timelines, recognizing fully domestic production (API + FDF), partial domestic production (U.S. FDF with imported API), and minimal domestic processing. This approach supports near-term capacity expansion, preserves incentives to rebuild upstream production, and strengthens the supply chain as a whole.

CPA recommends that CMS establish separate procurement metrics, thresholds, and payment methodologies by product category and production inputs. A one-size-fits-all threshold would inevitably set unrealistic expectations for one category or the other. Subcategorizing essential medicines by type, as CMS proposes in the ANPRM, is a sound approach and should be mirrored by similar subcategorization within PPE—masks, respirators, gowns, gloves, syringes and needles, and wound care products each have distinct supply dynamics and should be evaluated independently.

10. Essential Generic Medicines Require Tiered Procurement Based on Supply Chain Depth

Because pharmaceutical supply chains are multi-layered and defined by upstream dependency, procurement policy must distinguish between production stages rather than treating all finished medicines equally.

CMS should establish a tiered procurement framework for essential medicines that assigns eligibility and preference based on supply chain depth, with primary emphasis on the origin of APIs and critical upstream inputs. Final dosage manufacturing location should determine the level of preference within each tier, but not the tier itself. This approach ensures that upstream production—the foundation of pharmaceutical supply chains—remains the primary determinant of supply chain security.

Tier 1 — Fully Domestic Supply Chains (U.S. API + U.S. FDF)

- APIs, key starting materials, intermediates, and precursors are predominantly produced in the United States
- Final dosage manufacturing occurs in the United States

- Represents the highest level of supply chain security and should receive the strongest procurement preference

Tier 2 — U.S.-Anchored Supply Chains

- APIs are produced in the United States or in trusted partner countries with equivalent regulatory standards (e.g., FDA MRA countries)
- Final dosage manufacturing occurs in the United States
- Supports domestic manufacturing capacity while maintaining secure upstream sourcing

Tier 3 — Trusted Partner Supply Chains

- APIs are produced in trusted partner countries with equivalent regulatory standards
- Final dosage manufacturing occurs in trusted partner countries (not the United States)
- Provides a secondary layer of supply chain security where domestic capacity is not yet sufficient

Tier 4 — Mixed or Non-Preferred Supply Chains (Non-MRA API with U.S. or Trusted Partner FDF)

- APIs are sourced from countries that do not meet trusted MRA partner criteria
- Final dosage manufacturing occurs in the United States or in trusted MRA partner countries
- Enables near-term supply continuity but reflects limited upstream security and should receive reduced preference

Tier 5 — Non-Preferred Foreign Supply Chains (Non-MRA API + Non-MRA FDF)

- Both API and final dosage manufacturing occur outside the United States and trusted MRA partner countries
- Represents the lowest level of supply chain security and should receive no procurement preference relative to higher tiers

Within each tier, procurement preference should increase with greater domestic production of final dosage forms, reflecting both near-term capacity expansion and long-term industrial development. However, upstream production must remain the determining factor for tier placement, as it governs the resilience and integrity of the entire supply chain.

To ensure durability and prevent circumvention, this framework should be paired with:

- Regular manufacturer certification of API sourcing and supply chain composition
- Automatic tier reassignment if sourcing conditions change
- Post-award compliance requirements to prevent offshoring of API or final drug production
- Procurement eligibility considerations tied to FDA inspection coverage, enforcement history, and manufacturing reliability

This structure ensures that procurement policy rewards movement up the supply chain rather than final-stage assembly alone. It supports immediate expansion of domestic manufacturing capacity while preserving clear incentives to rebuild upstream production over time.

Procurement policy that fails to distinguish between supply chain layers will subsidize dependence rather than eliminate it.

11. The Payment Adjustment Should Cover All Essential Medical Supply Categories

CMS asks whether the payment adjustment should extend beyond surgical N95 FFRs to additional types of PPE. CPA strongly urges CMS to expand the adjustment to cover all PPE categories and essential medical consumables from the outset, and to adopt a broader category of "essential medical supplies" that extends beyond the traditional notion of PPE. Past commenters have identified gowns, hair nets, beard covers, bouffant caps, shoe covers, face shields, ASTM level II and III surgical masks, powered air purifying respirators, elastomeric respirators, syringes, needles, catheters, and wound care dressings as products susceptible to the same foreign supply chain vulnerabilities.

CMS should specifically include the following high-volume medical consumables that are foundational to hospital operations and face the same import dependence and cost dynamics as the PPE categories already identified in the ANPRM:

Syringes and needles are used daily in hospitals for administration of life-saving medications, preparation of medications for IV infusion, fluid filtration, oral medication administration, sensitivity testing, anesthesia delivery, and wound irrigation. Beyond vaccine administration, these products support virtually every clinical workflow in a hospital. Despite both public and private investments to bolster domestic manufacturing capacity during the pandemic, two of the three major domestic manufacturers of syringes and needles have since closed their plants and now source exclusively from manufacturers in China. The United States is left with only one major domestic manufacturer, which has already consolidated from three production sites to two.

Medical gloves are among the highest-volume medical consumables used across all care settings, forming a basic layer of infection control and patient safety. The United States remains almost entirely import-dependent for nitrile gloves, with domestic production constrained by persistent price distortion from low-cost imports that has prevented new capacity from operating at scale.

Prefilled saline flush syringes are used in nearly every hospital across the country as part of catheter care and maintenance to help prevent catheter-related complications and support efficient, high-quality patient care. Quality in manufacturing is critical: these devices deliver fluid directly into a patient's bloodstream, where any contamination or defect can have serious, even fatal, consequences.

Peripheral intravenous (IV) catheters provide immediate, reliable access to a patient's bloodstream for the delivery of fluids, medications, blood products, and contrast agents. They are a foundational tool used across virtually all care settings. Peripheral IVs enable rapid treatment during trauma, sepsis, pandemics, natural disasters, and mass-casualty events.

Blood collection devices are used to safely obtain blood specimens for diagnostic testing, disease monitoring, transfusion preparation, and public health surveillance. They are foundational to clinical decision-making across nearly all areas of health care.

These products are high-volume and scale-driven, which makes them uniquely vulnerable to low-cost foreign competition from manufacturing systems optimized for mass commodity production. Unlike many higher-margin medical technologies, these categories operate with limited pricing flexibility and are therefore especially susceptible to competitive pressure from countries whose manufacturing costs are structurally lower. As a result, U.S. manufacturers face disadvantages that erode domestic capacity and heighten dependence on foreign suppliers, even as the broader U.S. medical device sector remains globally competitive.

The safety and quality evidence reinforces this recommendation. The FDA enforcement actions against imported syringes described in Section 2, along with commenter reports of quality issues with imported syringes, needles, and other products (91 FR 3852), demonstrate that the case for domestic procurement spans well beyond N95 respirators. Limiting the payment adjustment to a single product category would address only a narrow slice of the vulnerability this ANPRM seeks to remedy.

12. CMS Should Incentivize Long-Term Contracting

Domestic PPE and essential medicine manufacturers require predictable, multi-year procurement commitments to justify the capital investment needed to maintain and expand production capacity. The ANPRM's stated goal of strengthening the American-made supply chain requires sustained demand. The pattern during COVID-19 was instructive: domestic manufacturers scaled up production in response to emergency demand, then saw orders collapse as hospitals reverted to cheaper foreign suppliers once the crisis passed. Many of those domestic manufacturers subsequently went out of business.

CPA recommends that CMS's payment policy explicitly encourage multi-year contracting by hospitals that earn the "Secure American Medical Supplies" designation. Hospitals that enter into multi-year procurement agreements with domestic manufacturers should receive favorable treatment under the designation criteria or payment adjustments. This would provide manufacturers with the demand certainty needed to invest in capacity, hire workers, and maintain the resilient supply chains the ANPRM envisions.

13. CMS Should Provide Clear Flexibilities During Supply Disruptions

Any domestic procurement policy must account for the reality of supply disruptions. The current high-level of foreign reliance creates the substantial risk during supply disruptions–public health emergencies, natural disasters, and sudden demand surges–when foreign export controls, production shocks, or geopolitical actions can abruptly cut off access to critical goods. The COVID-19 experience demonstrated that dependence on foreign suppliers can leave hospitals without reliable access to essential products precisely when demand is highest.

Domestic procurement policy should reduce this structural exposure over the long-term while recognizing that temporary supply constraints can still arise. In those cases, hospitals must retain the ability to maintain continuity of care.

CMS should therefore establish clearly defined, limited flexibility mechanisms that allow temporary sourcing from non-domestic suppliers during verified shortages or declared emergencies. These flexibilities should be tightly scoped, time-bound, and tied to objective indicators such as product-level shortages or public health emergency declarations. Hospitals should be required to return to compliant domestic sourcing once conditions stabilize or when domestic supply is available.

This framework maintains pressure to rebuild domestic capacity while ensuring the system remains functional under stress.

14. CMS Should Consider Expanding Payment Incentives Beyond IPPS and OPPS Hospitals

For many essential medical supplies, particularly high-volume, low-margin products such as needles and syringes, medical gloves, and essential generic medicines, competitive dynamics are driven increasingly by non-hospital sites of care, including physician offices, ambulatory surgical centers, home health providers, and durable medical equipment suppliers. Limiting the domestic procurement policy to Inpatient Prospective Payment System (IPPS) and Outpatient Prospective Payment System (OPPS) hospitals alone may fail to address the full market exposure to low-cost, foreign-manufactured products.

CPA encourages CMS to explore mechanisms for extending domestic procurement incentives to non-hospital providers, while recognizing that these providers operate under fundamentally different administrative and procurement structures. CMS should avoid imposing hospital-style cost accounting requirements on non-hospital entities, as this would be operationally infeasible. Instead, CMS could apply modest payment adjustments or add-on payments tied to categories of services that rely on essential medical supplies, with eligibility linked to participation in domestic sourcing initiatives or supplier attestations. Aggregated distributor or GPO data on country of manufacture could inform national-level estimates of domestic versus foreign sourcing, minimizing provider burden while improving system-wide visibility.

15. Complementary Federal Policies Are Essential

A demand-side incentive through Medicare payments will be effective only if domestic manufacturers can scale production to meet increased demand. Demand-side incentives alone cannot resolve structural dependence if supply-side capacity does not scale in parallel. Domestic production requires a coordinated framework in which demand signals, production incentives, and federal procurement operate together. CPA encourages CMS to coordinate with other federal agencies to ensure that the supply-side conditions are in place for this policy to succeed.

Production and investment tax credits are essential to help U.S. manufacturers scale rapidly enough to meet the demand that domestic-purchasing requirements would create. These credits also serve as the primary mechanism to close the structural price gap created by subsidized foreign production. Without this cost correction, demand-side incentives will shift procurement at the margin but will not support sustained domestic scaling or new capacity investment.

CPA urges the Administration and Congress to pair the Medicare payment incentives proposed in this ANPRM with targeted tax credits for domestic PPE and essential medicine manufacturing, modeled on the successful 45X Advanced Manufacturing Production Credit in the Inflation Reduction Act. The investments by BD and DeRoyal described in Section 4 demonstrate that domestic manufacturers respond to market signals, but sustained scaling requires both demand-side pull (through Medicare payments) and supply-side support (through tax incentives and regulatory streamlining).[34]

Federal procurement must function as an anchor demand layer. Coordinated purchasing across CMS, ASPR, the Department of Defense, and the Veterans Health Administration can provide long-term offtake commitments that reduce demand uncertainty and support investment decisions. Without this baseline demand, manufacturers face a fragmented and unreliable market signal that limits their ability to scale even with tax incentives in place.

CMS should also coordinate across agencies to ensure that definitions of “domestic” are consistent across all federal health care procurement programs. Alignment with the FAR Buy American framework recommended in Section 3 would facilitate this coordination.

The policies in this ANPRM should complement existing domestic procurement requirements under Executive Order 14336, the Berry Amendment (for textile-based PPE), and the Make PPE in America Act. CPA also notes that while CMS has some authority to adjust payments within existing IPPS and OPPS frameworks, the creation of new dedicated payment add-on categories for domestic procurement may require Congressional authorization. CPA urges the Administration to work with Congress to ensure the necessary statutory authority is in place to support the payment incentive structures envisioned in this ANPRM.

Conclusion

The policies outlined in this ANPRM represent a critical step toward rebuilding America's capacity to produce the health care products its hospitals and patients depend on. The evidence is clear: the United States remains dangerously dependent on foreign suppliers, particularly China, for PPE, essential medical supplies, and essential medicines. That dependence carries both supply chain risk and patient safety risk, as FDA enforcement actions against imported medical products demonstrate. CMS has an opportunity to use Medicare's purchasing power to create durable, market-based incentives for domestic manufacturing.[35]

This opportunity requires a coordinated approach. Demand-side incentives must align with production-side cost structures and be reinforced by federal procurement commitments. Without this alignment, policy will shift purchasing at the margin but will not support sustained domestic capacity or supply chain resilience.

Payment adjustments must fully close the cost gap between domestic and foreign production, while complementary production incentives and coordinated federal procurement provide the demand certainty required for long-term investment. Together, these mechanisms establish a stable foundation for rebuilding domestic manufacturing capacity across PPE, essential medical supplies, and essential medicines.

CPA urges CMS to move forward with all three proposed policy paths: the "Secure American Medical Supplies" designation, the separate Medicare payment for domestically manufactured PPE and essential medicines, and the structural quality measure in the Hospital IQR Program.

We particularly urge CMS to ensure that payment adjustments reflect real domestic manufacturing costs; that definitions of "domestic" are tailored by product category, anchored to the FAR Buy American framework for non-textile medical supplies and the Berry Amendment for textile-based PPE; that COTS exemptions are excluded from any domestic content framework; that reporting requirements are streamlined through a single standardized certification format; that compliance verification remains with CMS rather than conflicted intermediaries; that procurement thresholds are informed by IBMSC capacity assessments and phased upward on a defined schedule; and that the policy is extended over time to cover essential medical supplies across all Medicare care settings.
Thank you for the opportunity to provide these comments. We welcome the chance to discuss our recommendations further.

Respectfully submitted,

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President

Coalition for a Prosperous America

Endnotes

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[10] CMS ANPRM, 91 FR 3851, 3854 (January 29, 2026).

[11] CMS ANPRM, 91 FR 3851, 3854. CMS notes that domestic API is approximately 12 times as expensive as non-domestic alternatives. An ASPR review of publicly available prices for domestic and non-domestic nitrile gloves shows a domestic cost premium of approximately 1.5 to 3 times.

[12] U.S. Department of Commerce, Census Bureau, compiled from USITC DataWeb, HTS 9018.31, 2025 annual data. All-country import data: total customs value $1,510,365,251 across 4,198,579,480 units from 49 countries. Low-cost producer cluster (China, India, South Korea, Vietnam, Thailand, Indonesia) ranges from $0.05–$0.07/unit. Allied-nation producers (Germany, Japan, Mexico, Singapore) range from $0.24–$0.68/unit. See Figure 1.

[13] U.S. Department of Commerce, Census Bureau, compiled from USITC DataWeb, HTS 6210.10 (garments of nonwoven fabrics) and HTS 6211.43 (women's/girls' garments of man-made fibers), 2025 annual data. Total imports: customs value $1,641,064,353 across approximately 1.39 billion units. China supplied 766 million units (54.9% of volume) at $0.56/unit. See Figure 2.

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[17] U.S. Food and Drug Administration, "Update: Evaluating Plastic Syringes Made in China for Potential Device Failures," FDA Safety Communication, March 18, 2024. FDA received more than 4,000 Medical Device Reports (MDRs) regarding plastic syringe quality issues in 2023.

[18] FDA issued import alerts against Zhejiang Longde Pharmaceutical Co. and Shanghai Kindly Enterprise Development Group Co., and warning letters to Jiangsu Shenli Medical Production Co. Ltd. (manufacturer), Medline Industries LP, and Sol-Millennium Medical Inc. (distributors), March 2024. Additional warning letters to two further Chinese manufacturers followed later in 2024.

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[23] 48 CFR § 25.003 defines a "domestic end product" as an end product manufactured in the United States if the cost of its components mined, produced, or manufactured in the United States exceeds a specified percentage of the cost of all its components. The current threshold under Executive Order 14005 (January 25, 2021) and subsequent FAR amendments is 60%, rising to 75% by 2029.

[24] Becton, Dickinson and Company (BD) press releases: "BD Boosts U.S. Manufacturing of Critical Medical Devices," January 15, 2025; "BD Announces $110 Million to Support U.S. Pharmaceutical Supply Chain for Biologic Drugs," January 13, 2026; "BD to Invest $35 Million in Nebraska Facility to Expand Prefilled Flush Syringe Manufacturing," August 4, 2025. BD's Columbus, Nebraska, North Canaan, Connecticut, and Sandy, Utah facilities represent the core of remaining large-scale essential medical supply manufacturing in the United States.

[25] BD investments include $10+ million for a 40% increase in safety-engineered devices and 50% increase in conventional syringes; $110 million for pre-fillable syringe expansion in Columbus, Nebraska (creating 120 new jobs); and $35 million for prefilled flush syringe capacity (creating 50 new jobs). BD's Sandy, Utah facility employs approximately 1,200 associates across 650,000 square feet and is the largest producer of IV catheter lines in the world. BD has committed approximately $300 million to U.S. manufacturing capacity for essential medical supplies since 2020.

[26] DeRoyal Industries has the capacity to produce approximately 25 million isolation gowns annually at its Powell, Tennessee facility through a partnership with Premier and 34 health systems, representing a $10.3 million domestic investment, though current order volumes do not fully utilize this capacity.

[27] Administration for Strategic Preparedness and Response (ASPR) has invested over $136 million in domestic nitrile glove production. CMS ANPRM, 91 FR 3851, 3854.

[28] CMS ANPRM, 91 FR 3851, 3852 (January 29, 2026). For FY 2024, fewer than 100 hospitals reported the information necessary to determine the payment adjustment on their cost reports.

[29] Definitive Healthcare, "Top 10 GPOs by Staffed Beds in U.S. Hospitals." The three largest GPOs—Vizient, Premier, and HealthTrust—collectively control an estimated 60–80% of U.S. hospital purchasing volume.

[30] Medline Industries holds approximately 60% of the U.S. medical-surgical distribution market and also manufactures competing medical products. Cardinal Health manufactures exam gloves, surgical kits, IV catheters, wound dressings, and surgical apparel while distributing products from over 1,200 suppliers. Owens & Minor manufactures gowns, gloves, and protective apparel while distributing over 180,000 products.

[31] GAO-02-690T, Group Purchasing Organizations: Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products. GPOs charge manufacturers administrative fees of 2–3% of contract revenues. See also Health Affairs Scholar (2024), noting that some national GPOs have increased fees beyond the traditional 3% benchmark.

[32] Medical Device Manufacturers Association (MDMA), Congressional testimony on GPO reform. MDMA estimates that eliminating the supplier-funded GPO model would save public and private healthcare organizations more than $35 billion annually.

[33] Merics, "How Chinese Companies Benefit from Government Subsidies," 2024. Between 2017 and 2022, 122 firms in China saw their access to government support increase approximately fivefold.

[34] Senate Committee on Homeland Security & Governmental Affairs, Short Supply: The Health and National Security Risks of Drug Shortages, March 2023.

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