AMERICAN MEDICAL MANUFACTURERS ASSOCIATION

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March 30, 2026

Dr. Mehmet Oz
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1516-ANPRM
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Comments on Advance 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 (CMS-1516-ANPRM)

Dear Dr. Oz:

The American Medical Manufacturers Association (AMMA) submits these comments in response to the Advance Notice of Proposed Rulemaking (ANPRM) published by the Centers for Medicare & Medicaid Services (CMS). AMMA is the leading national trade association representing domestic manufacturers of personal protective equipment (PPE) and essential medical supplies.

Our members are U.S.-based companies that manufacture the gloves, masks, gowns, respirators, needles, syringes, blood collection devices, and other essential medical products upon which American hospitals and healthcare workers depend every day. These essential supplies underpin the functioning and resilience of the U.S. healthcare system. They enable core hospital operations while supporting rapid emergency response and maintaining care capacity during pandemics, natural disasters, and other public health emergencies.

AMMA strongly supports the Administration's commitment to rebuilding and sustaining domestic supply chain resilience for PPE and critical medical supplies. Recent public health emergencies, natural disasters, and global supply chain disruptions have exposed the dangers of overreliance on foreign manufacturing and the indispensable role that domestic manufacturers played in protecting healthcare workers and patients when global supply chains collapsed.

It is critical that CMS create a durable demand signal through payment adjustments that support the long-term viability of the domestic manufacturing base, including the workforce, facilities, and capital investment needed to surge production during future emergencies. The additional proposed "Secure American Medical Supplies" (SAMS) designation and the Hospital IQR structural

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measure are also meaningful steps toward securing America's health and safety, and we are pleased to offer detailed input in support of this initiative.

Our comments below address the specific questions posed in the ANPRM that are most relevant to AMMA's membership and mission.

I. MEANINGFUL PAYMENT ADJUSTMENTS

American hospitals are the primary market for domestic PPE and critical medical supplies. Their procurement decisions directly shape the commercial viability of domestic manufacturing. Currently, hospitals face significant cost pressures that disadvantage domestic suppliers. Foreign competitors, particularly those based in China, benefit from low labor costs, government subsidies, and currency practices that allow them to flood U.S. markets with artificially underpriced goods. Without a meaningful financial incentive, even hospitals that wish to support American manufacturing find it difficult to do so within their operating budgets.

CMS is proposing to address this through a payment adjustment mechanism tied to the SAMS designation, under which hospitals that demonstrate a commitment to domestic procurement would receive Medicare payments calculated to offset the additional cost of domestically produced PPE and essential medical supplies relative to foreign alternatives. AMMA strongly supports this approach.

The critical question is calibration. AMMA recommends that the payment adjustment be set in the range of four to six times the difference between reference-based pricing for foreign-sourced items and the average domestic production cost, with the applicable multiplier determined on a per-product-category basis to reflect the distinct cost dynamics of each PPE and essential medical supply vertical. (For detailed cost differential data supporting this recommendation, see Section IV below.) This approach aims to better align payment levels with real production economics and sustain domestic manufacturing capacity.

This level of adjustment is necessary for several reasons. It provides a genuine financial incentive that offsets the true cost differential hospitals face, not just the nominal per-unit price difference. It accounts for supply chain markups applied by prime distributors, ensuring financial benefits reach hospitals rather than being absorbed by intermediaries. It creates a buffer against drastic temporary price reductions by foreign competitors during periods of artificially low import pricing. And it provides the stable, long-term demand signal that domestic manufacturers need to justify continued capital investment in U.S. production capacity.

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II. PROGRAM DEFINITIONS

Definition of "Domestic"

AMMA 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. This framework is well established, familiar to manufacturers serving federal markets (including Veterans Affairs suppliers), and is readily adaptable across diverse medical supply categories.

CMS should recognize the current 65 percent domestic content standard as the baseline for evaluating U.S. manufacturing content, where domestic components are reasonably available. This standard, updated from the original 60 percent threshold in 2024, provides a clear, auditable threshold that reflects meaningful domestic production without imposing an unworkable all-or-nothing requirement.

AMMA notes that the domestic content threshold under the Buy American Act will increase to 75 percent in 2029 and recommends that CMS build this escalation trajectory into the program's design from the outset, ensuring alignment with broader federal procurement policy as it evolves.

Critically, CMS should avoid applying the Commercially Available Off-the-Shelf (COTS) exemption to this program. The COTS exemption removes domestic content evaluation altogether and provides 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. This would directly undermine the long-term objectives of supply chain resilience and domestic preparedness that this ANPRM seeks to advance.

NBR Production & Phased Approach to Nitrile Gloves

AMMA urges CMS to build a phased escalation of domestic content requirements for nitrile gloves into the program structure from the outset. No meaningful domestic production capacity for Nitrile Butadiene Rubber (NBR) latex currently exists, which means domestic glove manufacturers must source this critical input from TAA-compliant foreign suppliers, primarily in South Korea and Italy. As a result, current U.S. glove production cannot yet achieve full domestic content compliance, through no fault of domestic manufacturers.

This is not a permanent condition as significant investment in onshore NBR capacity is underway. AMMA recommends that CMS's proposed program recognizes domestic assembly with TAA-

compliant materials as qualifying in the near term, with content requirements stepping up in phases as verified domestic NBR capacity reaches defined milestones.

The long-term objective should be full domestic content compliance for nitrile gloves, with phased requirements tied to verified availability of domestically produced NBR latex. This will send a clear signal to petrochemical investors while protecting today's domestic manufacturers from being penalized for an upstream gap beyond their control.

Scope of Products: PPE and Essential Medical Supplies

AMMA recommends that CMS consider the scope of the proposed policy to include both PPE and essential medical supplies that present similar supply chain risks but fall outside traditional PPE definitions. This two-track approach ensures comprehensive coverage of the products most critical to hospital operations and emergency preparedness while maintaining definitional clarity for each category.

Essential medical supplies warranting inclusion alongside PPE include needles, syringes, and blood collection devices. These high-volume consumables are heavily reliant on foreign manufacturing, have experienced shortages during prior emergencies, and can be supported by a growing domestic manufacturing base capable of scaling with appropriate demand signals. CMS should incorporate these products within the SAMS designation framework, either by broadening the definition of covered products or by establishing a parallel category for critical medical supplies.

Definition of "PPE"

Specifically for PPE, AMMA recommends that CMS adopt a clear and narrowly tailored definition of PPE limited to equipment used to protect against the transmission of disease.

- The definition established in the Make PPE in America Act provides an appropriate model: "surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, and head and foot coverings, or other gear or clothing used to protect an individual from the transmission of disease."
- This approach avoids ambiguity in broader formulations that could create compliance uncertainty, particularly where domestic sourcing requirements might otherwise be interpreted to apply to products not intended for medical use.
- The PPE definition should also expressly exclude categories that serve fundamentally different purposes, including Self-Contained Breathing Apparatus (SCBA), industrial-use PPE, and Chemical/Biological (ChemBio) protective equipment.

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Definition of "Sufficient Percentage"

AMMA supports a phased, category-specific approach regarding the appropriate domestic procurement threshold for hospitals to earn the SAMS designation. Rather than a single blended percentage across all PPE or essential medical supplies, thresholds should apply individually to each major product category and take into consideration current domestic capacity: gloves, surgical masks and respirators, gowns, and needles and syringes. This prevents hospitals from satisfying the overall threshold through selective purchasing in one category while ignoring domestic options in others and better reflects the different capacity realities across product lines.

AMMA recommends that initial domestic procurement thresholds reflect the current domestic manufacturing capacity within each product category. For product categories where domestic capacity is still building, such as nitrile gloves and isolation gowns, starting thresholds should be set at levels consistent with current domestic market share, with meaningful but achievable escalation targets over time.

For categories where domestic capacity is more established, such as N95 respirators, needles, and syringes, higher initial thresholds may be appropriate. AMMA recommends that CMS consult with the Industrial Base Management and Supply Chain (IBMSC) office and relevant interagency bodies to determine the specific capacity-based starting points for each category.

As a general framework, AMMA recommends the following illustrative phase-in trajectory:

- **Current baseline**: approximately 5% domestic capacity across major PPE categories, with variation by product line
- **Year 3 target**: 10% of hospital procurement from domestic sources per product category
- **Year 5 target**: 25% of hospital procurement from domestic sources per product category

AMMA is confident that, given secure long-term demand signals from hospitals and appropriate Medicare payment support, domestic manufacturers can scale to supply 25 percent of hospital demand within five years. We are confident that our members' existing facilities, trained workforce, and supply chains can be expanded with sufficient market certainty.

Procurement thresholds should be based on the number of units purchased, not the total dollar value. This will prevent agencies from meeting domestic sourcing targets by buying only a few low-cost U.S. items while still sourcing most high-volume products from foreign sources.

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III. DOMESTIC MANUFACTURING CAPACITY

AMMA's manufacturers of essential medical supplies and PPE have a long history of manufacturing in the U.S. dating back over 120 years. Domestic manufacturers are actively growing operations in the U.S. and are fully prepared to scale further to meet the demand this program will generate.

AMMA member manufacturers have invested hundreds of millions of dollars in building and sustaining the domestic manufacturing base from the ground up, creating American jobs, reducing dependence on foreign supply chains, and materially strengthening national security.

The U.S. already has a strong manufacturing base that needs protection, and the new facilities AMMA members are building and operating today mark a true revival of American industry.

Robust Domestic Industry Investments

Across every major product category, domestic manufacturers have made substantial private capital investments in U.S.-based manufacturing infrastructure. In the glove sector, large-scale production campuses have been constructed featuring dozens of automated dipping lines. One AMMA member alone is operating a 215-acre campus designed to house 72 production lines capable of supplying nearly 20 billion gloves annually.

Domestic mask and respirator manufacturers expanded capacity dramatically in response to public health emergencies and have maintained and grown that infrastructure since. During recent public health emergencies, U.S. N95 production expanded to more than 95 million units per month and U.S. N95 manufacturers retain that footprint today.

Investment has extended well beyond respiratory protection. Domestic textile PPE manufacturers have pivoted their operations to produce hospital-grade gowns and masks at scale. Hundreds of millions of dollars have been invested in domestic manufacturing of needles, syringes, and blood collection products. Those facilities now represent the backbone of the U.S. syringe supply.

These are not startup ventures or pilot programs. AMMA members are operating growing businesses that are producing essential medical supplies for the U.S. marketplace today, and they are positioned to scale further as demand signals strengthen.

Ready to Scale

AMMA's membership demonstrates both the strength of the existing domestic manufacturing base and the extraordinary scale-up potential that sustained demand would unlock. **For nitrile examination gloves, combined current domestic capacity among AMMA members is approximately 4.8 billion gloves per year, with credible expansion plans that could reach 28 to 34 billion gloves annually, approaching 50 percent of estimated U.S. hospital demand.** For surgical and procedure masks, current domestic capacity totals approximately 2.1 billion units per year, scalable to more than 5 billion annually. For N95 respirators, current domestic capacity including on-site undeployed lines stands at approximately 435 million units per year, approaching full coverage of estimated routine hospital demand, with surge capacity exceeding 1.5 billion units per year.

The gown sector tells a particularly compelling story. Combined AMMA member gown capacity currently stands at approximately 93 million units per year and can reach approximately 720 million units annually within three years given healthy demand signals, representing 45 percent of estimated U.S. hospital demand.

Across all categories, domestic manufacturers are not asking for market protection. They are asking for the market certainty that justifies deploying the capital they are ready and willing to invest.

Growing Industrial Base

Many AMMA member facilities are actively expanding. New production lines are coming online, plants are growing, and workforces are being trained and increased in scale. The domestic PPE manufacturing sector is a dynamic, growing industry. The capacity figures presented in this section represent a conservative baseline; actual domestic manufacturing capability will continue to grow throughout the period in which CMS is implementing this program. AMMA is confident that domestic manufacturers can meet the procurement thresholds proposed in Section II of these comments and exceed them over time.

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Examples of Domestic PPE and Critical Medical Supplies Manufacturing: Supply vs. U.S. Hospital Demand

Category	Est. U.S. Hospital Demand/yr	Current Capacity/yr	Current as % of Demand	Surge Capacity/yr	Surge as % of Demand
Nitrile exam gloves	~60 billion	4.8 billion	**8%**	31 billion	**52%**
Surgical masks	~7 billion	2.1 billion	**30%**	5.1 billion	**72%**
N95 respirators	~450 million	435 million	**97%**	1.5 billion	**333%**
Medical gowns	~1.6 billion	93 million	**6%**	725 million	**45%**
Shoe / head covers	~750 million	112 million	**15%**	500 million	**67%**

Consistent Demand

While AMMA members have demonstrated the willingness and ability to invest, build, and scale, one challenge remains common across the entire domestic PPE manufacturing sector: the need for consistent, predictable, long-term demand.

Recent reversion of the commercial healthcare sector to heavily subsidized imports for some critical PPE has left domestic manufacturers operating below their potential capacity. The market has not yet provided the durable signal required to justify full deployment of available capital.

AMMA members note that raw material availability, particularly domestic NBR latex for gloves and polypropylene filtration media for masks and respirators, remains an area where further upstream investment would strengthen the supply chain. However, even these upstream constraints are addressable with sufficient demand to justify the investment.

AMMA believes that a meaningful payment incentive is sufficient to create a sustained and growing market for domestically manufactured PPE. AMMA is confident that the payment

adjustments and procurement thresholds proposed in this response will provide the demand certainty to allow domestic manufacturers to scale to full potential.

IV. ESTIMATED COST DIFFERENTIALS

CMS has asked stakeholders to provide an appropriate estimate of the additional domestic PPE unit costs compared to non-domestic PPE, with supporting evidence. AMMA strongly cautions against reducing this question to a single multiplier. Input gathered from AMMA manufacturers reveals that the cost differential between foreign and domestic PPE is not a fixed number. Instead, it is a dynamic range that varies significantly depending on the product category, the measurement methodology employed, the supply chain depth of the specific manufacturer, and macroeconomic conditions including tariff levels and freight costs. Providing a single figure without this context risks either understating the true cost burden facing domestic producers or overstating it in a way that invites accusations of an inaccurate depiction of the marketplace.

Member input illustrates the complexity clearly. For nitrile examination gloves, multiple domestic manufacturers independently report foreign-sourced gloves from Malaysia and Thailand at a landed price of approximately $0.020 to $0.035 per glove, against domestic production costs of $0.060 to $0.080, a gross differential of roughly 2.0 to 3.0 times.

For surgical and procedure masks, the production-cost differential is similarly 2 to 3 times. One member producing ASTM Level 3 flat masks reports domestic costs of $0.05 to $0.07 per unit against Chinese import prices as low as $0.008 to $0.018, a differential of up to 5 times at the production level.

It is worth noting that the hospital end-user price for domestic masks ranges from $0.08 to $0.12 after distributor and GPO fees, and that comparing domestic delivered pricing against FOB China pricing, which excludes freight, customs, tariffs, and distributor markups, can make the apparent ratio appear as high as 4 to 9 times. For N95 respirators, domestic production costs of approximately $0.50 to $0.70 per unit compare to an imported price of approximately $0.25, a differential of roughly 2.0 to 2.8 times.

For textile PPE such as gowns and caps, reported differentials range from approximately 10 percent above foreign pricing for manufacturers sourcing some inputs internationally, to 5 to 10 times for those operating fully domestic supply chains.

One AMMA member offered a particularly instructive frame of this complexity. The raw unit cost differential between U.S. and foreign manufacturing is driven by several structural factors: labor costs in China and Southeast Asia of roughly $3 to $6 per hour compare to U.S. wages of $18 to

$25 per hour; foreign manufacturers benefit from government subsidies including below-market energy rates, export tax rebates, and state-backed financing; Asian PPE producers operate at a scale that drives down per-unit costs in ways domestic manufacturers cannot match without equivalent order volumes; and key raw material inputs such as nitrile, polypropylene, and latex are produced in closer proximity to Asian factories. These factors together produce a raw production cost gap that can appear large in isolation. **However, once Section 301 tariffs, ocean freight, customs duties, and quality-control losses are factored in, the effective landed differential narrows to approximately 10 to 30 percent above domestic pricing. That gap is continuing to shrink as tariff actions proceed through 2026.**

Another AMMA member made the important observation that distributor and GPO markups can reach 300 to 1,500 percent above import cost and are a primary driver of the price gap hospitals experience. A modest, direct reimbursement of $0.03 to $0.05 per mask could be sufficient to stimulate domestic sourcing by making it financially attractive to hospitals independent of distributor bundling practices.

AMMA therefore recommends that CMS adopt a category-specific, range-based approach to cost differential estimation rather than a single national figure. For payment adjustment purposes, CMS should use the midpoint of the documented domestic-to-foreign production cost range for each product category, updated periodically to reflect tariff and freight conditions.

AMMA further recommends that the payment adjustment methodology explicitly accounts for the full distribution chain, not just factory-gate prices. This will allow for the financial benefit to hospitals to be accurately reflected in the actual cost difference they encounter in the marketplace.

A payment adjustment benchmarked only against raw FOB foreign pricing will systematically undercompensate hospitals and fail to create the durable demand signal that domestic manufacturers need.

V. VERIFICATION AND AUDIT MECHANISMS

Audit Mechanisms

AMMA recommends that CMS implement verification and audit mechanisms in a phased manner that reflects the practical realities of standing up a new domestic procurement program while building toward a more robust and durable compliance infrastructure over time.

In the near term, AMMA recommends that CMS launch the program using a manufacturer attestation framework. Under this approach, manufacturers would submit signed attestations

affirming compliance with the applicable domestic content standard at the time their products are enrolled in any CMS-recognized domestic product registry.

Hospitals would rely on those attestations and registry status when claiming payment adjustment, shielding them from liability where they have acted in good faith on manufacturer representations. CMS would retain authority to conduct audits on a risk-based, complaint-driven, or random basis, providing meaningful oversight without imposing a mandatory audit requirement on every transaction.

Penalties for false attestation should be substantial and clearly communicated, ensuring strong deterrence without placing routine compliance costs on legitimate domestic producers. This structure mirrors established federal procurement mechanisms and can be operational quickly without requiring CMS to build new administrative infrastructure from the outset.

As the program matures, AMMA recommends that CMS transition toward a certified product and vendor list. This is an approach that CMS has considered in prior rulemaking cycles and that AMMA strongly supports. A formally maintained registry of products and manufacturers that have been verified as meeting the applicable domestic content standard would provide hospitals and distributors with a definitive, easy-to-use compliance tool, reduce the burden of independent verification at the point of purchase, and give CMS greater systemic visibility into the domestic supply base. AMMA is prepared to work with CMS to populate such a list from day one, drawing on AMMA's own membership roster and the AMMA Verified Domestic™ seal program as an existing market-recognized verification mechanism.

This phased approach, moving from attestation and progressing toward certification, will allow the program to launch expeditiously while building toward the kind of rigorous, institutionalized compliance framework that will sustain it over the long term.

Audit Standards Designation

Consistent with AMMA's recommendation on the definition of "domestic," we recommend that the applicable standard be anchored to the "domestic end product" definition in the Buy American provisions of the FAR (48 CFR § 25.003). This standard is widely understood by manufacturers serving federal markets, provides a clear and defensible threshold, and is already embedded in the compliance processes of many AMMA members.

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VI. HELPING HOSPITALS IDENTIFY DOMESTIC PRODUCTS

Product Lists vs. Broad Standards

AMMA supports CMS maintaining a publicly accessible registry of domestic PPE and medical supply products that have been certified as compliant with the applicable domestic content standard. This approach, combining a general rule with a specific registry, achieves the best of both frameworks: it maintains openness to new market entrants while giving hospitals and distributors a practical tool for compliance.

AMMA is prepared to provide CMS with a list of member manufacturers who are ready to supply hospitals with domestically manufactured PPE and critical medical supplies. AMMA also maintains the AMMA Verified Domestic™ certification seal program. This trademarked designation with established terms of use that cannot be applied by any manufacturer without meeting AMMA's verified domestic content standards.

A growing number of AMMA member companies have adopted this seal on their product packaging and labeling to signal verified domestic manufacture to hospital purchasers, GPOs, and distributors. While AMMA is not requesting that CMS formally incorporate the seal into the SAMS designation framework, CMS may reference the AMMA Verified Domestic™ seal as a marketplace indicator of domestically manufactured products, providing hospitals and procurement officers with a practical, ready-made tool for identifying qualified domestic products without creating new administrative infrastructure.

Additionally, the Association for Health Care Resource & Materials Management (AHRMM) has developed a directory of domestic manufacturers that is already in use by hospital supply chain professionals. CMS should consider formally recognizing and linking to this directory to maximize its reach and utility.

Regarding third-party distributors: AMMA acknowledges that hospitals often procure PPE through GPOs and prime distributors rather than directly from manufacturers. CMS should require that distributors pass through manufacturer domestic content attestations and make those attestations available to hospital purchasers. A CMS-managed product registry accessible to distributors would significantly reduce the burden on hospitals of independently verifying the domestic status of each product.

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VII. SAMS DESIGNATION AND PHASE-IN APPLICATION

SAMS Designation

AMMA strongly supports the establishment of the Secure American Medical Supplies designation. The designation represents a meaningful step toward aligning hospital purchasing behavior with national security objectives, and AMMA has long advocated for exactly this kind of market-based mechanism. By officially recognizing hospitals that demonstrate a commitment to domestic procurement, CMS would create both a reputational incentive and a financial one, sending a clear and durable demand signal to domestic manufacturers across every PPE and critical medical supply category.

The SAMS designation is, however, one piece of a larger picture. Excessive reliance on foreign-manufactured PPE represents a genuine national security vulnerability, as supply chain disruptions have repeatedly demonstrated. A hospital designation alone, without meaningful payment adjustments, enforceable procurement thresholds, and a credible product verification framework, will not be sufficient to shift the structural economics that currently favor imports. AMMA urges CMS to treat the SAMS designation not as a standalone recognition program, but as the anchor of a comprehensive domestic procurement strategy.

To be effective, the designation must be paired with financial incentives calibrated to the real cost differential hospitals face, category-specific procurement minimums that grow over time, and a clear path toward a certified domestic product registry. Taken together, these elements can transform hospital procurement behavior in a way that strengthens the domestic manufacturing base, reduces national security risk, and ensures that American healthcare workers have access to reliable, high-quality supplies when they need them most.

SAMS Phase-In & Tiers

AMMA strongly supports a phased, tiered approach to the SAMS designation. A phased approach is necessary for two reasons: first, to give hospitals time to update or change their procurement practices and contractual relationships; and second, to allow domestic manufacturers time to scale production to meet increased demand without creating interim shortages.

As outlined in Section II above, AMMA recommends that initial SAMS thresholds be differentiated by product category to reflect current domestic manufacturing capacity. For categories where domestic capacity is nascent, starting thresholds should be set at levels consistent with actual domestic market share, with scheduled escalation to 10 percent by Year 3 and 25 percent by Year 5.

For categories with more established domestic capacity, higher starting thresholds are warranted. We do not recommend that CMS adopt the 25%, 50%, and 75% phase-in structure suggested in the ANPRM, as these targets exceed current and near-term domestic manufacturing capacity and could cause hospitals to be unable to meet procurement thresholds, inadvertently discouraging adoption of the program rather than incentivizing it.

The SAMS designation tiers should be clearly defined and publicly reported, so that hospitals can track their progress and so that manufacturers can anticipate demand growth in each category.

VIII. SUPPLY CHAIN FLEXIBILITY

Program Flexibility During Supply Chain Disruptions

AMMA emphasizes that the core purpose of this program is to strengthen the domestic manufacturing base that hospitals and the nation rely upon during supply chain disruptions, natural disasters, and public health emergencies. History has demonstrated that when foreign supply chains fail, domestic manufacturers serve as the critical backstop. A stronger domestic manufacturing base sustained by consistent hospital demand and Medicare payment support is the most effective form of supply chain flexibility.

That said, AMMA recognizes that unforeseen events may make it impossible for hospitals to meet their domestic procurement thresholds in isolated periods. CMS should establish a clear waiver process that allows hospitals to temporarily suspend their SAMS designation requirements during declared public health emergencies or supply chain crises, without permanently losing their designation status. Any such waiver should require attestation that the hospital made good-faith efforts to procure domestic products and could not do so due to supply constraints beyond its control.

While AMMA acknowledges that isolated supply chain emergencies could occur, any waiver process must be strictly temporary and conditioned on attestation that domestic supply was demonstrably unavailable. A broad or routinely available waiver would undermine the program's demand signal and create a loophole that defeats its purpose.

IX. PPE CATEGORIES

AMMA recommends that CMS include the following PPE and essential medical supplies categories in the initial scope of the SAMS designation and associated payment adjustment:

- Gloves (nitrile and latex examination and surgical gloves)
- Surgical masks and N95 respirators

- Isolation and surgical gowns
- Needles and syringes
- Blood collection devices

These categories represent the highest volume of products purchased by hospitals and are the categories in which domestic manufacturing capacity is most developed and most capable of scaling to meet increased demand. AMMA is prepared to work with CMS to define appropriate product specifications for each category to ensure that the applicable domestic content standards are applied consistently.

We also recommend that CMS commit to a regular review process (at minimum every two years) to consider expanding the scope of included products as domestic manufacturing capacity grows in other PPE categories.

X. EXPANDING THE PROGRAM

Beyond IPPS/OPPS Hospitals

AMMA fully supports expansion of the domestic procurement payment policy beyond IPPS and OPPS hospitals to all entities receiving Medicare payments. Our members have the capacity to serve the full spectrum of healthcare facilities including ambulatory surgical centers, long-term care facilities, federally qualified health centers, and physician offices. Broader adoption of the SAMS framework would dramatically strengthen the demand signal for domestic manufacturing.

XI. HOSPITAL IQR PROGRAM STRUCTURAL MEASURE

Structural Attestation Measure

AMMA supports the inclusion of a domestic procurement structural attestation measure in the Hospital IQR Program. Public reporting of hospital domestic procurement performance would serve as an important transparency and accountability mechanism and would create positive reputational incentives for hospitals to prioritize domestic sourcing in addition to the financial incentives created by the payment adjustment.

The IQR attestation measure should be designed to complement, not duplicate, the SAMS designation framework. We recommend alignment between the two programs wherever possible to minimize administrative burden on hospitals.

Minimum Percentages

AMMA recommends that the IQR minimum percentage thresholds align with the SAMS designation thresholds. Consistency across programs reduces confusion, minimizes administrative burden, and creates a coherent policy signal to the market.

AMMA also recommends that CMS use the IQR program as a vehicle to encourage long-term supply contracts between hospitals and domestic manufacturers. Long-term contracts provide the demand certainty that domestic manufacturers need to justify capital investment in expanded production capacity. CMS could consider giving additional IQR credit to hospitals that have entered into multi-year domestic supply agreements, further reinforcing the program's supply chain resilience objectives.

XII. LESSONS FROM SUPPLY CHAIN DISRUPTIONS AND QUALITY CHALLENGES

AMMA members have witnessed firsthand the devastating consequences of over-reliance on foreign manufacturing. During recent public health emergencies, the near-total collapse of global PPE supply chains left American hospitals scrambling to protect healthcare workers with substandard, counterfeit, or wholly unavailable equipment. Domestic manufacturers, including AMMA members, stepped into the breach to ramp up production and supply hospitals, federal agencies, and state governments with critically needed products.

Beyond supply availability, the quality and safety of foreign-manufactured medical products remain a significant concern. The U.S. Food and Drug Administration has issued safety communications regarding quality deficiencies in imported medical supplies, including Chinese-manufactured syringes that presented risks to patient safety. These quality challenges underscore that domestic manufacturing is not solely about supply chain resilience; it is also about ensuring that American healthcare workers and patients have access to products that meet rigorous U.S. quality and safety standards.

The supply chain disruptions of 2020-2022 were not isolated events. They reflected a structural vulnerability in the U.S. healthcare supply chain that has been decades in the making. The concentration of global PPE manufacturing in a small number of countries creates systemic risk that cannot be mitigated by stockpiling alone. Only a robust, viable domestic manufacturing base can provide the surge capacity needed to protect American patients and healthcare workers in future crises.

The policies proposed in this ANPRM are exactly the kind of durable, market-based solutions needed to rebuild that manufacturing base. AMMA urges CMS to finalize these policies expeditiously and to implement them with the ambition and urgency that national security demands.

CONCLUSION

AMMA thanks CMS for the opportunity to comment on this important ANPRM and for the Administration's commitment to Made in America procurement in the healthcare sector.

We strongly support the proposed payment adjustments, the "Secure American Medical Supplies" designation and the Hospital IQR structural measure.

We urge CMS to finalize these policies in a manner that provides meaningful financial incentives for hospitals, establishes clear and workable domestic content standards, and supports the long-term viability of the domestic PPE and critical medical supply manufacturing industry.

AMMA and its members stand ready to serve as a resource to CMS as it develops these policies. We would welcome the opportunity to meet with CMS staff to discuss our recommendations in greater detail and to provide the product-specific data and manufacturer information that would support implementation.

Respectfully submitted,

Eric Axel

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APPENDIX: REFERENCES

Note: Capacity data and cost differential estimates cited in the body of these comments are drawn from confidential submissions by AMMA member manufacturers and are not attributed to specific companies herein. All other factual claims are supported by the publicly available sources listed below.

I. Regulatory and Statutory Authority

1. Centers for Medicare & Medicaid Services. (2022). Medicare Program; CY 2023 Revisions to Payment Policies under the Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (CY 2023 OPPS/ASC Final Rule). 87 FR 72037. Retrieved from https://www.federalregister.gov/documents/2022/11/23/2022-23896/medicare-program-cy-2023-revisions-to-payment-policies

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