American Medical Manufacturers Association

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August 31, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1850-P

Re: Comments on the CY 2027 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule (CMS-1850-P), Section XXII: Consideration of Potential Approaches for Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines

Dear Administrator Oz:

The American Medical Manufacturers Association (AMMA) is the leading national trade association representing domestic manufacturers of personal protective equipment (PPE) and essential medical supplies. Our members' products include the gloves, masks, gowns, respirators, needles, syringes, and blood collection devices American hospitals and healthcare workers rely on every day. We appreciate the opportunity to comment on the domestic procurement provisions of the Proposed Rule[1], which build on the framework CMS raised in its Advance Notice of Proposed Rulemaking[2] and on which AMMA commented in March 2026.

AMMA strongly supports this policy and wants it to succeed. In addition, AMMA is encouraged that Section XXII moves substantially in the direction AMMA recommended: a national standardized cost differential rather than hospital-by-hospital pricing, a manufacturer attestation framework feeding a public product list, inclusion of non-surgical respirators and nitrile gloves. We appreciate CMS's recognition that domestic glove production depends on an input that the United States does not yet make. Each of these elements of Section XXII represent previous recommendations from AMMA.

We recognize that Section XXII seeks input on approaches CMS is considering for a future rulemaking, rather than proposing those approaches for adoption in this rule. Accordingly, we urge CMS to incorporate our proposals into that future rulemaking and to finalize them promptly. Doing so would

[1] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Proposed Rule, 91 Fed. Reg. 41734 (July 7, 2026), § XXII. Docket: https://www.regulations.gov/docket/CMS-2026-2344

[2] Medicare Program; Ensuring Safety Through Domestic Security with Made in America Personal Protective Equipment and Essential Medicine Procurement by Medicare Participating Hospitals, Advance Notice of Proposed Rulemaking, 91 Fed. Reg. 3851.

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enable manufacturers and hospitals to begin planning and preparing for the policy framework CMS ultimately intends to adopt.

AMMA's principal concern is whether the proposed policy will materially influence hospital purchasing decisions. CMS should calculate the domestic price premium using hospitals' full acquisition costs. Published import prices frequently reflect factory-gate, FOB, or port of entry costs and exclude freight, tariffs, duties, insurance, customs charges, importer and distributor margins, GPO fees, warehousing, and other costs incurred before delivery. Even prices described as landed may not include all downstream costs ultimately paid by the hospital. As a result, hospital acquisition costs for imported products may be closer to domestic costs than headline price comparisons suggest.

Even an accurate and narrower price differential may not, standing alone, alter purchasing behavior. Reimbursement that merely equalizes prices leaves hospitals economically indifferent while they continue to incur the costs associated with changing suppliers, qualifying products, modifying contracts, transitioning inventory, tracking purchases, and administering CMS payments. CMS should therefore supplement the base differential with a tiered procurement-conversion incentive designed to make domestic procurement economically preferable and reward substantial, long-term commitments to eligible domestic products.

1. Payment Calibrations

All-In Acquisition Cost Methodology

AMMA supports standardized, category specific payments based on an accurate comparison of hospitals' actual acquisition costs rather than requiring each hospital to calculate its own differential.

CMS should compare the domestic product's delivered acquisition cost with the imported product's all-in cost, inclusive of delivery and all associated charges. Reported foreign prices may exclude freight, tariffs, duties, insurance, customs charges, importer and distributor margins, GPO fees, warehousing, and other downstream costs. Including these costs may materially narrow the apparent difference between imported and domestic products.

This all-in acquisition cost methodology should apply across every covered PPE and critical medical supply category, including gloves, gowns, respirators, masks, needles, syringes, blood collection devices, and other eligible products. No single product category should serve as a proxy for the others.

The methodology should be consistent across categories, but CMS should calculate a separate differential for each category using evidence specific to that product. Product categories have different manufacturing inputs, labor requirements, regulatory costs, distribution channels, foreign pricing structures, and intermediary markups. CMS should rely on actual hospital invoice data, manufacturer data, distributor and GPO information, federal procurement data, and other reliable market evidence. A quoted foreign unit price is the tip of the iceberg. The bulk of the true cost, from tariffs to warehousing, sits below the waterline and is invisible in most price comparisons.

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Tiered Procurement Conversion Incentive

After determining the applicable differential, CMS should supplement the base differential with a tiered procurement conversion incentive. The base differential would address the recurring domestic price premium. The additional incentive would recognize the separate costs and risks hospitals incur when changing suppliers, qualifying products, modifying contracts and purchasing systems, transitioning inventory, training staff, tracking eligible purchases, and administering the CMS payment.

CMS should structure the incentive so that larger and longer domestic purchasing commitments receive greater support. Relevant factors should include:

- The percentage of annual purchases in the applicable category converted to eligible domestic products;
- The duration of the hospital's purchasing commitment;
- The hospital's size or purchasing volume; and
- Whether the contract reserves domestic production capacity or emergency surge capacity.

For example, CMS could establish progressively higher incentive tiers for hospitals committing to 25%, 50%, 75%, or 100% domestic purchasing over one, two, or three-year periods. The highest incentive tier should be available to hospitals making the most substantial and longest duration commitments.

The procurement conversion incentive should be paid in addition to the base differential. The differential would address the recurring product cost, while the additional incentive would provide an economic basis for changing purchasing behavior and support the dependable demand necessary for domestic manufacturers to maintain production.

Hospitals should also receive credit when their contracts reserve domestic production capacity, provide priority allocation during an emergency, or support documented surge readiness. The value of domestic manufacturing includes both routine production and the capacity to respond when foreign supply chains are disrupted.

CMS should ensure that allocation limits, proxies, or other administrative mechanisms do not reduce the differential or procurement conversion incentive to an amount insufficient to achieve the policy's objectives.

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2. Payment Mechanism and Allocation

Approach 1 Versus Approach 2

CMS is considering a claims-based approach (Approach 1) and a cost report approach (Approach 2), with two allocation options under Approach 2 (2a and 2b) for hospitals that cannot track PPE use at the patient level.

AMMA also recommends that CMS adopt Approach 2b as the primary payment methodology for PPE, subject to the correction to its per-category limit described below. Additionally, AMMA recommends that CMS allow hospitals that can track domestic PPE at the patient level to elect Approach 1 while keeping the elective claims-based process simple.

Approach 2b should be the primary methodology because it provides a larger payment under CMS's own illustration: a $114,000 domestic cost differential produces $33,250 under 2b, compared with $11,400 under 2a. The payment must be large enough to create a meaningful purchasing incentive.

The cost-report approach also need not delay payment. CMS states that hospitals could receive interim biweekly payments under Approach 2, reconciled at cost-report settlement (91 Fed. Reg. at 41994–95). The issue is therefore payment certainty, not payment timing.

AMMA also supports making Approach 1 available as an election for hospitals that can track domestic PPE at the patient level. This would preserve the advantages of claims-based payment by tying payment to a specific domestic product and claim without imposing its administrative burden on hospitals that cannot readily identify PPE at the patient level. Hospitals that cannot or do not wish to track individual units could use Approach 2b instead.

For the elective Approach 1, AMMA asks CMS to keep the process narrow and straightforward: limit it to the three billing codes, require no documentation beyond the listed product identifier, and publish the coding guidance and product file well before the performance year.

Approach 2b

AMMA recommends Approach 2b as the **primary payment method** because it would provide a more meaningful payment without requiring every hospital to track individual PPE items at the patient level.

When a hospital can document actual inpatient consumption, CMS should not impose an estimated inpatient use percentage as an absolute ceiling. Instead, CMS should replace Fraction 2 with documented inpatient consumption while retaining Fraction 3, the Medicare inpatient share. This approach would improve payment accuracy without extending the underlying IPPS differential to outpatient or non-Medicare use.

Hospitals that can identify domestic products furnished to individual Medicare inpatients should also be permitted to elect the claims-based approach. The payment process should remain voluntary and

administratively feasible, using existing hospital purchasing and materials management information to the greatest extent practicable and avoiding unnecessary new tracking requirements.

The tiered procurement conversion incentive should be available under either payment approach. Eligibility should be based on verified domestic purchasing commitments and should not require the hospital to associate each individual product with a particular patient.

Application Across Medicare Payment Settings

Hospitals and health systems do not purchase PPE and critical medical supplies separately for each Medicare payment system. They enter enterprise-wide contracts covering inpatient units, outpatient departments, emergency departments, ambulatory surgical centers, clinics, and other care settings. A policy limited to a narrow IPPS share may therefore be insufficient to influence systemwide purchasing decisions.

AMMA urges CMS to establish corresponding domestic procurement incentives under the OPPS and ASC Payment System and to develop a mechanism for recognizing domestic procurement in Medicare Advantage payment and contracting arrangements.

CMS should use its existing authority wherever possible and clearly identify any additional statutory authority required to provide incentives that are not budget neutral in payment settings where current law limits the agency's authority. CMS should work with Congress to obtain any necessary authority rather than allow distinctions among Medicare payment systems to prevent implementation of an effective, systemwide policy.

At a minimum, CMS should permit enterprise-wide domestic purchasing commitments to qualify a hospital or health system for the procurement conversion incentive. A contract covering IPPS, OPPS, Medicare Advantage, ASC, and other patients would create the dependable demand signal the policy is intended to produce, even if CMS must calculate the underlying differential separately under each payment system.

Worksheet G-2 Revenue Proxy

CMS asks whether hospital revenue reported on Worksheet G-2, Part I should be used to estimate the share of each PPE category attributable to inpatient care (91 Fed. Reg. at 41995). **AMMA recommends against using revenue as the proxy.**

PPE consumption is driven by patient care and staff contacts, not the dollar value of services. Using revenue could therefore understate the share of PPE used for inpatient care and further reduce the payment under the proposed allocation methodology. AMMA urges CMS to test this against its own utilization data before adopting a revenue-based proxy.

AMMA recommends the following alternatives, in order of preference:

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1. **Actual consumption:** Allow hospitals to use documented PPE consumption where their materials management systems allocate PPE by cost center.
2. **Utilization based proxy:** If CMS requires a uniform proxy, use inpatient days and outpatient visit equivalents rather than revenue. These measures more directly reflect PPE use, and CMS already collects inpatient days on Worksheet S-3.
3. **Rebuttable presumption:** If CMS retains the revenue proxy, treat the resulting allocation as a rebuttable presumption rather than a hard ceiling.

Finally, CMS should publish the median values and distributions it used for Fractions 1, 2, and 3 across IPPS hospitals. This would allow hospitals and other stakeholders to assess how the proposed limit would operate at different levels of domestic adoption.

3. Annual Aggregate Cap

CMS is considering a $500 million or $1 billion annual aggregate cap across all IPPS hospitals, allocated based on Medicare inpatient days and reconciled at settlement.

AMMA recommends that CMS eliminate the fixed cap or set it high enough that it does not bind, with annual review based on actual program uptake. A binding cap would create uncertainty for hospitals placing orders and could undermine the domestic production capacity the policy is intended to develop. Given the scale of the U.S. hospital market, a $500 million or $1 billion cap is also small relative to the market CMS seeks to influence.

If CMS retains a cap, AMMA recommends:

- A minimum allocation for each hospital;
- Rollover of unused allocations;
- Automatic increases as eligible domestic capacity expands; and
- Regular publication of program utilization.

The proposed aggregate cap of $500 million to $1 billion should be judged against the purpose of the policy, which is to grow domestic purchasing over time. Because the payment rises with domestic volume, a fixed cap allocated in advance will increasingly bind as adoption grows, and high-volume categories such as nitrile gloves could absorb a substantial share of the aggregate on their own. AMMA recommends that CMS set the aggregate amount high enough that it does not constrain participation in practice, or forgo a fixed cap, and in either case revisit the amount annually against actual uptake so the demand signal is not throttled.

Finally, Medicare inpatient days are a reasonable starting point for allocating the aggregate amount, but they do not capture PPE use associated with outpatient and procedural care. A blended allocation based on inpatient days and outpatient volume would better reflect actual PPE consumption.

4. Definition of "Domestic"

AMMA supports CMS's proposal to define "domestic" consistent with the Make PPE in America Act (Subtitle C, Title IX, Division G, Pub. L. 117-58), which requires PPE and its components to be domestically grown, reprocessed, reused, or produced. Anchoring to this existing statutory standard, rather than a new test, minimizes compliance burden for manufacturers already operating under it.

However, AMMA urges CMS to apply the FAR domestic content standard, based on substantial transformation and the percentage of domestic component cost, specifically to products relying on nitrile butadiene rubber (NBR), since NBR is not commercially produced domestically and U.S. manufacturers must import this feedstock regardless of where finished good manufacturing occurs. Without this carve out, NBR based PPE (e.g., nitrile gloves) could never qualify as "domestic," undermining the policy's intent.

More broadly, AMMA reiterates its hope that the "domestic" definition stay aligned with existing trade-compliance frameworks (Buy American Act/FAR, Trade Agreements Act, Make PPE in America Act) rather than introduce a new, freestanding standard requiring separate tracking and attestation. CMS should also clarify that "domestically manufactured" status applies only to components directly incorporated into the finished product, not to upstream inputs, materials, or services in a supplier's own manufacturing process. This is consistent with how domestic content determinations are made under the FAR and provides a clear, administrable standard for manufacturer attestations.

5. Scope of Covered Products

A. Personal protective equipment

AMMA supports the proposed inclusion of NIOSH-approved respirators, FDA/ASTM-conforming gloves, and FDA/AAMI-conforming gowns.

AMMA also urges CMS to **include four excluded categories:** surgical masks, face shields, protective eyewear, and head and foot coverings, as well as consider including needles, syringes, and blood collections devices.

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First, the exclusions are inconsistent with CMS's proposed definitional source. The Make PPE in America Act, CMS's definitional anchor, expressly identifies all four excluded categories.[3] If the Act supplies the content standard, it should also supply the scope.

Second, the exclusions are not supported by domestic capacity. AMMA members already have substantial U.S. production capacity in several excluded categories[4]:

Category	Est. U.S. hospital demand/yr	Current AMMA capacity	Current as % of demand	Status in rule
N95 respirators	~450 million	435 million	97%	Included
Surgical masks	~7 billion	2.1 billion	30%	Excluded
Head and foot coverings	~750 million	112 million	15%	Excluded
Nitrile exam gloves	~60 billion	4.8 billion	8%	Included
Medical gowns	~1.6 billion	93 million	6%	Included

Domestic manufacturers already supply roughly 30 percent of surgical mask demand, compared with 8 percent for gloves and 6 percent for gowns, both of which CMS proposes to include. They can also scale surgical mask production beyond 5 billion units annually. Head and foot coverings show a similar level of domestic capacity. The exclusions therefore cannot be attributed to a lack of domestic supply.

B. Essential Medical Supplies

The essential medicines track covers pharmaceuticals but not critical medical supplies such as needles, syringes, and blood collection devices. These are high volume, single use products that face the same import dependence and shortage history as PPE, and are backed by a domestic manufacturing base built on federal investment. Because they fall between CMS's two existing tracks, **AMMA recommends CMS establish a parallel category for essential medical supplies**. Since neither the Berry Amendment nor the Make PPE in America Act reaches medical devices, eligibility would need to rest on the FAR framework.

[3] Make PPE in America Act, § 70953 of Pub. L. 117-58 (definition of personal protective equipment).

[4] AMMA, Comments on CMS-1516-ANPRM (Mar. 30, 2026), § III (Domestic Manufacturing Capacity). Figures reflect confidential member submissions and are being refreshed for this submission.

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C. Essential Medicines

AMMA's members are concentrated in PPE rather than pharmaceuticals, so we comment on the medicines track only where it raises issues relevant across the policy. We support excluding repackaging from the substantial transformation test and addressing precursors and key starting materials. AMMA also recommends applying the same substantial transformation test, foreign adversary screen, and content standard across the PPE, medical supplies, and medicines tracks to avoid inconsistent standards and simplify compliance.

CMS's proposed two-tier medicines differential also supports a graduated approach for PPE. CMS would provide a higher differential when both the finished dosage form and active ingredient are domestic and a lower, non-zero differential when only the finished dosage form is domestic (91 Fed. Reg. at 41994). **AMMA recommends applying the same principle to PPE and medical supplies: provide a higher differential for wholly domestic products and a lower but non-zero differential when a documented unavailable input must be sourced from an allied country.** This would recognize the realities of domestic manufacturing without creating a binary domestic or foreign test.

6. Manufacturer Attestation

AMMA strongly supports CMS's proposed voluntary manufacturer attestation and annual public file of eligible products by NDC or UDI, consistent with the phased framework AMMA recommended in March 2026.

AMMA is prepared to help populate the file and can provide CMS with a list of member manufacturers ready to supply hospitals. AMMA's Verified Domestic™ seal is a market facing identifier and should remain distinct from CMS's official eligibility file. The CMS file should be the authoritative source for payment eligibility.

AMMA recommends seven refinements:

- **Make the file machine-readable.** Use a stable schema keyed to UDI or NDC where available and always include manufacturer name and part number so hospitals and GPOs can integrate the file into purchasing systems.
- **Update the file more frequently.** Use rolling or quarterly updates with a defined turnaround time because products cannot receive payment until they are listed.
- **Strengthen verification and enforcement.** Establish penalties for false attestations, audit authority, documentation requirements, and a process for challenging listings.
- **Conduct random compliance audits.** CMS should have authority to select a sample of attested products for audit each year, independent of any complaint or challenge, requiring manufacturers to produce supporting documentation on request. Random audits, backed by

defined penalties for false attestations, would deter noncompliance and give hospitals and CMS confidence in the integrity of the file without requiring CMS to verify every listing individually.

- **Protect hospitals acting in good faith.** Hospitals that rely on a listed product should not face liability or recoupment if the manufacturer's attestation later proves incorrect, including where that determination results from a random audit. Recovery should be directed to the attesting manufacturer.
- **Address packaging and filing errors.** Ensure the file can accommodate multi-item packages and kits and provide a correction period with retroactive eligibility for good-faith errors.
- **Require suppliers to pass through attestations.** Distributors and GPOs should provide manufacturer attestations to hospital purchasers because hospitals often purchase through intermediaries.

Finally, CMS should clarify the diligence required to support an attestation and confirm that hospitals may reasonably rely on supplier certifications. Clear rules will reduce uncertainty and encourage participation.

7. Cost Differentials

AMMA recommends category specific standardized differentials based on hospitals' actual delivered acquisition costs. Domestic and imported prices should be measured at the same point in the supply chain and should include comparable cost components.

CMS should consider the full amount paid before delivery to the hospital, including freight, tariffs, duties, insurance, customs charges, importer and distributor margins, GPO fees, warehousing, and other delivery costs. Factory-gate, FOB, landed, and port of entry prices may exclude costs added later in the supply chain and therefore may not reflect the hospital's actual acquisition cost.

CMS should apply this all-in acquisition cost methodology across every covered PPE and critical medical supply category, including gloves, gowns, respirators, masks, needles, syringes, blood collection devices, and other eligible products. No single product category should be treated as representative of the broader domestic medical manufacturing industry.

The methodology should be uniform, but each differential should be based on category specific evidence. Product categories have different materials, labor requirements, regulatory costs, distribution channels, foreign pricing structures, and intermediary markups. CMS should collect actual hospital invoice data, manufacturer data, distributor and GPO information, federal procurement data, and other reliable market evidence for each category.

AMMA does not recommend that CMS use an overstated price gap. CMS should determine the actual all-in differential for each category and supplement that differential with a tiered procurement conversion incentive sufficient to influence purchasing behavior. The differential would address the recurring domestic price premium, while the additional incentive would address conversion costs, administrative requirements, and the need to establish a clear economic rationale for selecting domestic products.

CMS should update differentials and procurement conversion incentives annually through a transparent, category specific, and consistent process. CMS should provide advance notice of material changes so hospitals and manufacturers can plan purchasing, contracting, and production.

8. Domestic Capacity

CMS has asked for information on domestic production capacity, expansion ability, timelines, and barriers to scaling. AMMA's answer is that the capacity exists or can be built. The figures below reflect capacity information reported by AMMA's members[5]. AMMA will update these figures as additional member information becomes available. Where the underlying data permit, AMMA distinguishes among current production capacity, installed but unused capacity, emergency surge capacity, and longer-term planned expansion; the table below reflects that distinction to the extent members' reporting currently supports it.

Category	Current capacity/yr	Surge or planned capacity/yr	Surge as % of U.S. hospital demand
Nitrile examination gloves	4.8 billion	28–34 billion	~52%
Surgical and procedure masks	2.1 billion	More than 5 billion	~72%
N95 respirators (incl. undeployed on-site lines)	435 million	More than 1.5 billion	Exceeds routine demand
Isolation and surgical gowns	93 million	~720 million within 3 years	~45%
Head and foot coverings	112 million	~500 million	~67%

These are a conservative baseline. Member facilities are actively expanding lines and training workforces. One member operates a 215 acre campus designed for 72 production lines with capacity approaching 20 billion gloves annually. Hundreds of millions of dollars have been invested in domestic

[5] AMMA, Comments on CMS-1516-ANPRM (Mar. 30, 2026), § III (Domestic Manufacturing Capacity).

needle, syringe, and blood collection manufacturing. These are operating businesses, not pilot programs.

Respirators are the clearest case: members report current and near-term domestic capacity equal to approximately 97 percent of routine U.S. hospital demand. This supports AMMA's request to remove the 8.75 percent domestic-share ceiling. The constraint is the payment methodology, not manufacturing capacity. AMMA is not asking CMS to expand the inpatient-share proxy or pay the inpatient differential on outpatient or non-Medicare volume.

The greater constraint is **demand certainty**. Members report that domestic production remains below capacity because import competition has not provided a sufficiently durable incentive to justify further investment. Upstream inputs such as domestic NBR latex and polypropylene filtration media remain gaps but can be addressed if demand is reliable. A well calibrated payment, without an artificial volume ceiling, would provide that signal.

9. Hospital Recognition and Quality Reporting

CMS states that it is no longer considering a "Secure American Medical Supplies" designation or a new IQR structural measure, based on commenter support for voluntary payment approaches that are not budget neutral (91 Fed. Reg. at 41996). AMMA supported both mechanisms in its ANPRM comments[6] but accepts CMS's decision and does not ask it to revisit them here.

AMMA asks only that CMS preserve the option of recognizing domestic sourcing through a future voluntary mechanism. The recommendations in AMMA's ANPRM comments, including category specific thresholds, phased targets, an emergency waiver, and credit for multiyear domestic contracts, can be considered in that context.

For this rule, AMMA asks CMS to recognize multi-year domestic supply commitments within the payment framework. For example, CMS could treat volumes covered by a multi-year domestic supply agreement as documented inpatient use under the Section II election or give those hospitals priority in any per-hospital allocation of the aggregate amount.

[6] AMMA, Comments on CMS-1516-ANPRM (Mar. 30, 2026), §§ VII, XI (Secure American Medical Supplies designation; Hospital IQR structural measure).

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10. Program Continuity and Reach

Because section 1833(t)(2)(E) requires outpatient payments to be budget neutral, CMS is considering sunsetting the existing OPPS surgical N95 policy while it explores alternatives[7]. **AMMA asks CMS to maintain the current policy until a replacement is in place and to establish a timeline for developing that replacement.** The proposed new payment applies only under inpatient authority, so ending the outpatient policy first would eliminate the incentive for outpatient departments and ambulatory surgical centers, where substantial PPE use occurs. Low participation in the existing policy should not be viewed as indifference to domestic sourcing; the payment was too small and delivered through the cost report, as discussed in Sections I and II. More broadly, AMMA supports extending domestic procurement incentives to ambulatory surgical centers, long-term care facilities, federally qualified health centers, and physician offices and asks CMS to identify any statutory barriers in the final rule.

11. Timing and Statutory Authority

Timing

CMS should establish the payment in the CY 2027 OPPS/ASC final rule rather than defer it to another rulemaking cycle. Domestic manufacturers need lead time to restart or expand production, hire and train workers, and complete quality system requirements. A payment announced after the performance year begins will not provide the demand signal needed to support that investment.

AMMA therefore asks CMS to state the effective date expressly and publish the initial differentials, product file specifications, and coding guidance at least one full purchasing cycle before payments begin. CMS should also confirm the availability of interim biweekly payments under Approach 2.

Statutory Authority

AMMA supports CMS's use of section 1886(d)(5)(I) to establish the proposed inpatient adjustment and urges CMS to make the adjustment non-budget-neutral, consistent with the existing N95 policy. A budget-neutral adjustment would reduce other IPPS payments to fund the incentive and weaken its effect.

The principal authority gap is outpatient payment. As discussed in Section X, section 1833(t)(2)(E) requires outpatient adjustments to be budget neutral. AMMA asks CMS to identify in the final rule

[7] 91 Fed. Reg. at 41986; see CY 2023 OPPS/ASC Final Rule, 87 Fed. Reg. 72037, 72042, 72268-69 (Nov. 23, 2022), https://www.federalregister.gov/documents/2022/11/23/2022-23896

what additional authority would be needed to provide a non-budget-neutral outpatient incentive and to maintain the existing outpatient N95 policy until a replacement is available.

For eligibility, CMS can rely on existing frameworks rather than create a new standard. AMMA supports the Make PPE in America Act framework where applicable and the graduated FAR domestic content standard described in Section IV for medical supplies not covered by those authorities.

Conclusion

AMMA commends CMS's thoughtful approach to the proposed domestic procurement provisions in Section XXII of the proposed rule. Our Association strongly supports strengthening domestic manufacturing across the health sector and is eager to continue working with the agency.

We appreciate the recommendations made in section XXII, and its basic framework is sound. However, to meaningfully change hospital purchasing behavior the payment needs to be substantial, broadly applicable, and easy to administer. In short, the framework needs better calibration. We urge CMS to incorporate the following recommendations into this rulemaking and to finalize them promptly.

Calibrate the cost differential accurately. Calculate each category's payment differential by comparing the domestic product's full delivered cost against the imported product's full delivered cost, including freight, tariffs, duties, insurance, margins, and GPO fees, using category specific evidence rather than one national number. Pair this with a tiered incentive that grows as a hospital converts more of its purchasing to domestic product and commits for a longer period.

Choose a workable payment methodology. Adopt Approach 2b as the primary methodology, but let hospitals use documented inpatient consumption instead of the Fractions 2 and 3 proxy, while keeping Approach 1 available as an option. Replace the Worksheet G-2 revenue proxy with a consumption based or patient day based measure, or let hospitals rebut the proxy with documented actual use. Adopt the graduated FAR content standard, along with a general exception for foreign inputs limited to allied sources and set to expire on its own terms.

Build in transparency and predictability. Publish a machine readable eligible product file, keyed to product identifier, manufacturer, and part number. Protect hospitals that rely on the file in good faith, and commit to an annual update process with a multi-year floor and advance notice before reductions.

Broaden the program's reach. Add the four excluded PPE categories, plus needles, syringes, and blood collection devices. Extend comparable domestic procurement incentives to the OPPS and ASC payment systems and to Medicare Advantage, using existing authority where possible and flagging where new authority is needed. Because hospitals buy PPE and supplies across their whole operation, enterprise wide purchasing commitments should qualify for the incentive even when payment is calculated separately across different Medicare systems.

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Update the program's structure and timing. Eliminate or substantially raise the aggregate payment ceiling, confirm the inpatient adjustment will not be budget neutral, keep the current outpatient policy in place until a replacement exists, and finalize this payment in the CY 2027 OPPS/ASC final rule.

Support hospital awareness and adoption. The program can only be effective if hospitals are aware of the program and understand how to utilize its benefits. CMS should prioritize clear guidance and proactive education for hospitals alongside the payment policy itself. Awareness is no less important than underlying calibration in driving the program's success.

Together, an accurate cost comparison, a tiered incentive, broader application across Medicare payment settings, an administrable process, and strong hospital awareness would give hospitals a meaningful economic incentive to buy American made products, and give domestic manufacturers the dependable demand needed to maintain and grow production.

AMMA and its members are ready to provide the capacity, cost, and timing data CMS has requested, and to work with the agency on implementation. Thank you for considering these comments.

Sincerely,

Eric Axel

Executive Director

American Medical Manufacturers Association