Dated: January 20, 2026.

Kevin McOmber,

Regional Administrator, Region 4.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 482

[CMS–1516–ANPRM]

RIN 0938–AV72

Medicare Program; Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This advance notice of proposed rulemaking solicits public comment on potential options we may consider for Medicare participating hospitals to help foster a more resilient supply chain for American-made personal protective equipment and essential medicines to secure our nation's health and safety and to reflect the additional resource costs incurred when procuring these domestically manufactured items. We seek input on a possible new ''Secure American Medical Supplies'' friendly designation that could be earned by hospitals that demonstrate their commitment to domestic procurement. In addition, we seek input on potential ways such a designation could facilitate the creation of new, streamlined payment policies to support hospitals in their efforts. We are also seeking input on a potential new structural quality measure as part of the Hospital Inpatient Quality Reporting (IQR) Program that could promote hospital commitments to invest in domestic procurement to secure our nation's health and safety.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than March 30, 2026.

ADDRESSES: In commenting, please refer to file code CMS–1516–ANPRM.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1516–ANPRM, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1516–ANPRM, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Ted Oja, (410) 786–4487 or *DAC@cms.hhs.gov.*

Made in America Office, *MadeInAmerica@omb.eop.gov*.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Sufficient domestic availability of personal protective equipment (PPE) and essential medicines in the health care sector is a critical component of emergency public health preparedness. In spring of 2020, supply chains for PPE faced severe disruptions due to lockdowns that limited production and unprecedented demand spikes across multiple industries. Supply of National Institute for Occupational Safety and Health (NIOSH)-approved® surgical N95® respirators — a specific type of filtering facepiece respirator (FFR) that is a subset of N95 respirators used in some clinical settings under conditions requiring respiratory protection from airborne pathogens and splash protection from exposure to fluids — was one type of PPE that experienced significant supply chain disruptions. So-called ''just-in-time'' supply chains that minimize stockpiling, in addition to reliance on overseas production, left U.S. hospitals unable to obtain enough PPE to protect health care workers. Similarly, shortages for critical medical products have persisted, with a recent report authored by the Senate Committee on Homeland Security and Government Affairs noting that the average drug shortage lasts about 1.5 years.[1] For pharmaceuticals, nearly two-thirds of hospitals reported more than 20 drug shortages at any one time—from antibiotics used to treat severe bacterial infections to crash cart drugs necessary to stabilize and resuscitate critically ill adults.[2] Shortages of both essential medicines and reliable PPE jeopardize patient safety and health care quality.

In recent years, we have solicited comment and, based on feedback from interested parties, implemented payment adjustments to Medicare participating hospitals to reflect the additional costs of procuring domestically made surgical N95 FFRs and creating buffer stocks of certain essential medicines. In the Calendar Year (CY) 2023 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period (87 FR 72037 through 72047), we implemented payment adjustments under the OPPS and Inpatient Prospective Payment System (IPPS) to support a resilient and reliable domestic supply of NIOSH-approved surgical N95 respirators.. This payment adjustment is based on the IPPS and OPPS shares of the difference in cost between domestic and non-domestic NIOSH-approved surgical N95 FFRs and is available where those costs are separately tracked, reported and

[1] Senate Committee on Homeland Security & Governmental Affairs, Short Supply: The Health and National Security Risks of Drug Shortages, March 2023: *https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.*

[2] Vizient, Drug Shortages and Labor Costs: Measuring the Hidden Costs of Drug Shortages on U.S. Hospitals, June 2019: *https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129.*

appropriately claimed by the hospital on its cost report submitted to Medicare. As discussed in the CY 2023 OPPS/ASC final rule with comment period, the payment adjustment is intended to account for the marginal costs that hospitals face in procuring domestically -made NIOSH-approved and FDA-certified surgical N95 FFRs. These marginal costs are due to higher per-unit acquisition prices that stem from higher costs of inputs and labor in the U.S., as compared to international suppliers, which make many N95 and other FFRs, as well as a demonstrated record of more consistent high -quality for domestically -made products. Usage of the payment adjustments has been limited, and HHS has conducted stakeholder outreach to better understand barriers to awareness and uptake and seek feedback on potential modifications that could increase effectiveness. For FY 2024, less than 100 hospitals reported the information necessary to determine the payment adjustment on their cost reports. This low adoption rate may be partially attributable to administrative reporting burden concerns raised by stakeholders.

As noted in the CY 2023 OPPS/ASC final rule with comment period, we received many comments urging us to expand this policy to cover other forms of PPE and critical medical supplies. A few commenters stated that other forms of PPE are susceptible to shortages similar to surgical N95 FFRs, and therefore investing in domestic production for these products was also important for future emergency preparedness. We stated that we would consider these comments, and other modifications to the payment adjustment, for future rulemaking as we gained more experience with our policy.

In addition to PPE, essential medicines are another critical component of preparedness. In the Fiscal Year (FY) 2025 IPPS/Long-Term Care Hospital (LTCH) PPS final rule (89 FR 69387 through 69400), we finalized a separate payment under the IPPS to small (100 beds or fewer), independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to a 6 -month buffer stock of one or more essential medicines.[3] Under this policy, essential medicines are defined as the medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* developed by the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response (formally known as the Office of the Assistant Secretary for Strategic Preparedness and Response) and published in May 2022, and any subsequent revisions to that list of medicines.[4] As required by Executive Order (E.O.) 14336,[5] the list is currently under review and is scheduled to be updated in 2026.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59396 through 59399), we solicited feedback and comments on potential modifications to the surgical N95 FFR policy to increase hospital uptake, reduce reporting burden, and achieve the policy goal to maintain a baseline domestic production capacity of PPE to ensure that quality PPE is readily available to health care personnel when needed.

As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94290 through 94295), commenters were supportive of a variety of modifications to the established policy, including modifications to the payment adjustment methodology calculation that would provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 FFRs, stating that such a modification would minimize reporting burden for hospitals and ensure payments to hospitals are equitable. We note that some commenters differed in their view as to how the cost differential should be calculated. Commenters also stated that expanding the payment adjustment to more products would increase uptake of the payment adjustment by hospitals, strengthen the existing U.S. manufacturing base, incentivize other manufacturers to prioritize domestic production, and protect access to high-quality products. Commenters requested that CMS work with the Congress to give CMS authority to offset all the marginal costs incurred by the hospital in procuring domestically manufactured surgical N95 FFRs rather than just the Medicare share of these costs. Some commenters also indicated that hospitals have had difficulty ascertaining which products meet the definition of domestic under the surgical N95 FFR policy and were supportive of making publicly available a list of products eligible under the surgical N95 FFR policy.

As also discussed in the CY 2025 OPPS/ASC final rule with comment period, several commenters urged CMS to expand the payment adjustment to include other PPE types and medical devices. Examples from commenters included gowns, hair nets, beard covers, bouffant caps, shoe covers, face shields, The American Society for Testing Materials (ASTM) level II and III surgical masks, powered air purifying respirators, elastomeric respirators, syringes, needles, catheters, and wound care dressings. Commenters indicated that many of these products are currently being purchased from non-domestic manufacturers and have been prone to shortages and quality issues (89 FR 94295). For example, a commenter cited safety concerns regarding the quality of imported syringes and needles which they stated have had issues ranging from leaks to breakages that compromise patient safety.

When finalizing the essential medicines and surgical N95 FFR policies, we stated that we may consider comments regarding domestic manufacturing requirements of essential medicines and other forms of PPE in future rulemaking, and as domestic manufacturing capacity increases (89 FR 69395 and 87 FR 72039, respectively). We continue to believe that hospitals' procurement preferences directly influence upstream intermediary and manufacturer behavior and can be leveraged to help foster a more resilient supply chain for domestically manufactured goods, which is foundational to safeguarding timely access and continuity of care for patients. Therefore, we are seeking public input on the following policy paths.

1. *Domestic Procurement Designation and Payment Adjustment:* The creation of a designation that could be earned by hospitals with a demonstrated commitment to procuring domestic PPE and domestic essential medicines. We are also seeking input on a separate Medicare payment to hospitals that earn the designation to recognize the additional resource costs they incur when procuring these domestically manufactured items.

2. *Hospital IQR Program:* A structural measure requiring hospitals to attest to meeting the domestic procurement designation minimum percentages for PPE and essential medicines as part of the Hospital IQR Program.

3. *Additional Options:* We also seek additional ideas on other policy paths within CMS's statutory authority to help foster a more resilient supply chain for domestically manufactured PPE and essential medicines.

[3] Hereafter referred to as the ''essential medicines policy.''

[4] The list is available at *https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf* and there have been no subsequent revisions to the list.

[5] *https://www.federalregister.gov/documents/2025/08/19/2025-15823/ensuring-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active.*

II. Provisions of the Advance Notice of Proposed Rulemaking

Hospitals, as major purchasers and users in the U.S. of PPE and essential medicines, can help to improve safety through domestic security in the health care sector by procuring PPE and essential medicines that are made in America. In section III. of this ANPRM, we seek input on a possible new ''Secure American Medical Supplies'' friendly designation that could be earned by hospitals that demonstrate their commitment to procuring domestic PPE and essential medicines. In section IV. of this ANPRM, we seek input on potential ways such a designation could facilitate the creation of new, streamlined payment policies to support hospitals in their efforts. These streamlined payment policies could bolster the domestic supply chain through the recognition of the additional resource costs hospitals incur when procuring domestically manufactured items. In section V. of this ANPRM, we seek input on a potential structural measure requiring hospitals to attest to meeting the domestic procurement minimum percentages for PPE and essential medicines as part of the Hospital IQR Program. In section VI. of this ANPRM, we discuss alternatives we considered but are not pursuing at this time. In section VII. of this ANPRM, we seek input on additional options to improve safety through domestic security in the health care sector.

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

In alignment with the President's E.O. 13944 entitled ''Combating Public Health Emergencies and Strengthening National Security By Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made In The United States,'' (85 FR 49929) as bolstered by E.O.s 14293,[6] 14257,[7] and 14336,[8] we are considering establishing a ''Secure American Medical Supplies'' friendly hospital designation to be reported on a public website. We believe adding this designation to a public website would potentially allow Medicare and other payers a streamlined way to recognize the additional costs that these hospitals incur to procure domestic PPE and essential medicines as opposed to non-domestic.

One potential way hospitals could earn this ''Secure American Medical Supplies'' friendly designation is if they procure sufficient amounts of PPE and essential medicines that are made in America. This designation could be obtained by meeting a minimum American-made percentage of all PPE and all essential medicines, or it could be obtained by meeting a minimum American-made percentage of each subcategory (that is, masks or anti-microbial medicines) for which HHS determines that sufficient domestic producers exist.

For the purposes of this ANPRM discussion, we define ''PPE'' in a manner consistent with section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58) as surgical masks, respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease. We define ''essential medicines'' as the 86 medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* developed by the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response (formally known as the Office of the Assistant Secretary for Preparedness and Response) and published in May 2022, and any subsequent revisions to that list of medicines.[9]

For all types of PPE, including those covered by the Berry Amendment[10] (such as NIOSH-approved surgical N95 FFRs), we are requesting comment on whether the Make PPE in America domestic content requirements outlined in section 70953 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58) would be an appropriate framework for determining if these types of PPE are wholly made in the U.S. Those statutory requirements, which apply to procurement of PPE by the U.S. Departments of Health and Human Services, Veterans Affairs, and Homeland Security, require the procurement of PPE, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the U.S. These statutory requirements have become familiar to manufacturers of PPE.

We are considering the use of a list of ''critical components and critical items'' (as defined in FAR 25.003) rather than a general rule for which items of PPE and essential medicines would be included in this policy, likely employing the list in FAR section 25.105 (48 CFR 25.105), developed in accordance with E.O. 14005[11] and implemented via rulemaking (87 FR 12781 to 12782). While this list remains forthcoming at the time of the publishing of this ANPRM, it will be developed through rulemaking based on the government's quadrennial critical supply chain review, the National COVID Strategy, and Office of Management and Budget (OMB) review.

Alternatively, we could issue guidance every 4 years which lists all PPE items and essential medicines that are included for purposes of this potential designation, with specifications for how each item would count as domestic. Items might include, for example, 100 percent of the active pharmaceutical ingredient (API) and 50 percent of the key starting materials (KSMs) for a given essential medicine, or 100 percent of the materials necessary for the manufacture of N95 FFRs.

For essential medicines as defined previously in this ANPRM, we believe an appropriate standard to qualify as fully domestic for purposes of this potential designation would be that over 50 percent of the API and the entire final dosage form (not including components such as syringes or IV bags) must be manufactured in America, but we invite feedback on this definition.

Regarding the domestic manufacturing capabilities for the raw materials and components of PPE and essential medicines, we understand that certain key inputs may not currently be available domestically in sufficient quantity or quality to meet market needs. For example, in the case of nitrile gloves, there is currently one domestically manufactured source of nitrile butadiene rubber (NBR), an essential component of nitrile gloves.

[6] *https://www.whitehouse.gov/presidential-actions/2025/05/regulatory-relief-to-promote-domestic-production-of-critical-medicines/.*

[7] *https://www.whitehouse.gov/presidential-actions/2025/04/regulating-imports-with-a-reciprocal-tariff-to-rectify-trade-practices-that-contribute-to-large-and-persistent-annual-united-states-goods-trade-deficits/.*

[8] *https://www.whitehouse.gov/presidential-actions/2025/08/ensuring-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active-pharmaceutical-ingredients-reserve/.*

[9] See the discussion in section III. of this ANPRM.

[10] The Berry Amendment is a statutory requirement that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the United States. The Berry Amendment was originally passed by the 77th Congress and later made permanent via Section 8005 of Public Law 103–139.

[11] *https://www.federalregister.gov/documents/2021/01/28/2021-02038/ensuring-the-future-is-made-in-all-of-america-by-all-of-americas-workers.*

We expect the domestic manufacturing capacity of PPE and essential medicines to increase over time with a demand for domestically-made products. To this end, the Administration for Strategic Preparedness and Response (ASPR) has invested over $136 million to increase domestic production of nitrile gloves [12] and the Make PPE In America Act requires Federal procurement of domestic PPE with multi-year contracts.

The potential new ''Secure American Medical Supplies'' friendly hospital designation might initially be based on attestations by hospitals on their cost report. Hospitals that attest to meeting the standard could be designated ''Secure American Medical Supplies'' friendly hospitals. The criteria for qualifying for the designation might change over time as we gain experience with the program and additional domestic manufacturing capacity develops.

As outlined in this section, quality PPE and essential medicines are crucial to the safety of health care workers and patients. Overreliance on imports of PPE and essential medicines jeopardizes public health and the health and safety of health care workers and patients, especially in the case of supply chain crises or geopolitical conflicts. We solicit comment on the following questions:

- Would a ''Secure American Medical Supplies'' friendly hospital designation be an appropriate way to facilitate the creation of streamlined payment policies to bolster the domestic supply chain through the recognition of the additional resource costs hospitals incur when procuring domestically manufactured items? Where would it be most helpful for this designation to appear? What would be the most appropriate entity to grant this designation? What other ways might be effective?
- For administering the designation, what are potentially useful alternatives to self-attestation? How could hospitals be asked to provide proof that they purchased from domestic suppliers? Could hospital accreditors, group purchasing organizations (GPOs) or some other entity be better positioned to administer oversight of the designation?
- What is the most appropriate definition of domestic for PPE and essential medicines, respectively?
- If we were to use a designation standard that hospitals procure a sufficient amount of their PPE and essential medicines domestically, what would be a sufficient amount? Should this amount be expressed as a percentage of the PPE and essential medicines procured by the hospital? If so, what percentage would be appropriate? Should this amount vary by the type of PPE and subcategory of essential medicines? How should we measure this activity (by volume, dollar amount, etc.)? What would be the least burdensome effective method to audit the procurements, as feasible?
- What methods could we use to audit statements from hospitals or manufacturers that PPE and essential medicines are made in the USA using ingredients and components produced in the USA?
- What standards designation might be appropriate?
- Since most essential medicine APIs are produced abroad and may take time to reshore, how can we encourage domestic final dosage form production without diminishing long-term demand signals for domestic API manufacturing?
- Would having a specific list of items be preferable to a general rule for determining whether products are domestic?
- How can manufacturers designate if their product is wholly domestically made?
- As discussed in section III. of this ANPRM and in the CY 2025 OPPS/ASC final rule, in the past commenters indicated that hospitals have had difficulty ascertaining which products meet the definition of domestic under the surgical N95 FFR policy. How do purchasers currently identify domestic PPE and domestic essential medicines? How could this be improved? What is the role of third-party distributors vs. direct procurement from individual manufacturers?
- For hospitals purchasing PPE and essential medicines through GPOs or other third parties, what barriers would such hospitals face in meeting the requirements of a ''Secure American Medical Supplies'' friendly designation? How could these barriers be addressed?
- Should such a policy be phased in over time to increase hospital adoption and prevent shortages, and if so, how? Should the designation have ''tiers'' or a potential phase-in that can be adjusted as more PPE and essential medicine are domestically manufactured? For example, should such a policy be phased in such that at least 25 percent, 50 percent, and eventually 75 percent of a hospital's total procurement across contracts for PPE and essential medicine is domestically manufactured?
- When and how should we provide flexibilities under such a policy in the event of supply chain disruptions like natural disasters and demand surges?

[12] *https://aspr.hhs.gov/MCM/IBx/portfolio/Pages/Gloves-Nitrile-Health-Supply.aspx.*

IV. Potential Separate Medicare Payment To ''Secure American Medical Supplies'' Friendly Hospitals

We expect that the resource costs of domestically manufactured PPE and essential medicines will generally be higher than the resource costs of PPE and essential medicines made outside of the United States. Wholly domestically made, high-quality PPE and essential medicines are generally more expensive than foreign-made ones, especially those of lower quality. These higher prices primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in other countries, where most PPE and molecular precursors of pharmaceuticals are made. These higher prices mean higher marginal costs for hospitals for procuring domestically made PPE and essential medicines. For example, an ASPR review of publicly available individual and wholesale prices for both domestic and non-domestic nitrile gloves on manufacturer websites shows that the price of domestically manufactured nitrile gloves is approximately 1.5 to 3 times that of non-domestically manufactured nitrile gloves. A similar ASPR review of the publicly available prices of API from domestic and non-domestic sources reveals that domestic API are, on average, approximately 12 times as expensive as non-domestic alternatives. Therefore, we are considering establishing a separate payment to ''Secure American Medical Supplies'' friendly hospitals for Medicare's IPPS share of the costs of these additional resources.

For a given type of PPE, one possible approach could be that we could derive the separate payment for a hospital using cost report data on the number of days the hospital treated Medicare fee-for-service (FFS) patients, reasonable assumptions on PPE use per hospital day, and the additional domestic PPE unit costs. As an illustrative example for N95 FFRs, assume General Hospital is a ''Secure American Medical Supplies'' friendly hospital. If (a) General Hospital billed 10,000 Medicare patient days in a year, (b) the assumed average number of N95 FFRs used per day per patient nationally is 5, and (c) a domestically produced N95 FFR is assumed to cost $0.20 more than a non-domestic one, then General Hospital would receive a Medicare payment of $10,000 (= 10,000 days × 5 FFR per day × $0.20 per FFR additional cost).

For essential medicines, one possible approach could be that we could derive the payments for a hospital using cost report data on Medicare's IPPS share of

the hospital's total drug costs and reasonable assumptions on what percentage of those costs are for essential medicines and the higher costs of domestically produced essential medicines. As an illustrative example, if (a) Medicare's IPPS share of General Hospital's total drug costs as reported on its cost report are $2 million [13], (b) essential medicines are assumed to represent 1 percent of those costs, and (c) domestic essential medicines are assumed to be 12 times more costly, then General Hospital would receive a Medicare payment of $240,000 (= $2 million × 1 percent for essential medicines × 12 for the domestic cost differential).

For the IPPS, the separate payment to ''Secure American Medical Supplies'' friendly hospitals could potentially be made in a non-budget neutral manner under section 1886(d)(5)(I) of the Social Security Act (the Act). Payment could be provided as a lump sum at cost report settlement or biweekly as interim lump-sum payments to the hospital, which would be reconciled at cost report settlement. Specifically, in accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9, Medicare could make a lump-sum payment for Medicare's IPPS share of these additional inpatient costs at cost report settlement. Alternatively, a hospital could make a request for biweekly interim lump sum payments for an applicable cost reporting period, as provided under 42 CFR 413.64 (Payments to providers: Specific rules) and 42 CFR 412.116(c) (Special interim payments for certain costs). These payment amounts would be determined by the Medicare Administrative Contractor (MAC) consistent with existing policies and procedures.

In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into 26 equal biweekly payments. The estimated amount would be based on the most current cost data available, which will be reviewed and, if necessary, adjusted at least twice during the reporting period. (See CMS Pub 15–1 section 2405.2 for additional information). The MACs would determine the interim lump-sum payments based on the data the hospital may provide that reflects the information that would be needed to determine the additional cost for PPE and essential medicines to maintain the ''Secure American Medical Supplies'' friendly hospital criteria and the amount of any separate payment. In future years, the MACs could determine the interim biweekly lump-sum payments utilizing information from the prior year's cost report, which may be adjusted based on the most current data available. This is consistent with the current policies for medical education costs, and bad debts for uncollectible deductibles and coinsurance paid on an interim biweekly basis as noted in CMS Pub 15–1 section 12405.2. It is also consistent with the payment adjustment for domestically sourced NIOSH-approved surgical N95 FFRs (87 FR 72037) and the separate IPPS payment for the additional resource costs of establishing and maintaining access to buffer stocks of essential medicines (89 FR 69387) discussed in section I. of this ANPRM.

As discussed in this section, we are considering establishing a separate payment to hospitals that earn the ''Secure American Medical Supplies'' friendly hospital designation to recognize the additional resource costs of procuring domestically manufactured PPE and essential medicines. We solicit comment on the following questions:

- What additional costs or burdens would be incurred by a health care facility or system to achieve such a designation? How would medical facilities or systems cover this cost? What resources could we provide to help Medicare participating hospitals address intangible barriers to earning the ''Secure American Medical Supplies'' designation?
- What suggestions do stakeholders have for CMS regarding facilities' contracts with domestic manufacturers and/or suppliers of PPE and essential medicine through the ''Secure American Medical Supplies'' designation? Should there be contracting principles and elements that should be encouraged as part of this designation?
- Under the potential approach for domestic PPE, what types of PPE should be included? [14]
- For each type of PPE, would Medicare FFS inpatient days be an appropriate basis for deriving the Medicare IPPS utilization of the PPE? If not, what would be an appropriate basis for deriving the Medicare IPPS utilization?
- For each type of PPE, what assumptions regarding how many items of PPE are used per inpatient day (or another basis) would be appropriate for deriving the Medicare IPPS utilization?
- For each type of PPE, what would be an appropriate estimate for the additional domestic PPE unit costs compared to non-domestic PPE? Please provide supporting evidence.
- As an alternative to a cost reporting-based approach, how might a claims-based approach to the payments be structured?
- Under the potential approach for domestic essential medicines, would total drug costs as reported on the hospital cost report be an appropriate starting point for deriving Medicare's IPPS share of the additional costs to procure domestic essential medicines? If not, what would be an alternative basis for deriving Medicare's IPPS share of those costs?
- In determining the amount of any additional payment, should essential medicines be subcategorized under our potential approach rather than treated as a single cost category? If so, what subcategories should be used?
- On average, what percentage of a hospital's total drug costs are for essential medicines (or each subcategory of essential medicines)?
- For essential medicines (or each subcategory of essential medicines), do commenters agree with the assumption for purposes of the illustrative example that essential medicines are generally 1 percent of drug costs? What is the breakdown of essential medicine spending between inpatient and outpatient? What would be an appropriate estimate for the higher costs of domestically produced essential medicines compared to non-domestic essential medicines?
- Should any new IPPS supply chain policy replace existing IPPS supply chain policies for N95 FFRs and buffer stocks?
- For PPE, in addition to separate payment for the higher inpatient hospital costs, should Medicare also consider making separate payment for the higher outpatient hospital costs? Under our current policy for domestically produced surgical N95 FFRs [15] we used our authority under section 1833(t)(2)(E) of the Act to make separate payment for the higher outpatient hospital costs, which authorizes the Secretary to establish, in

[13] Sum of Drugs Charged to Patients and Medical Supplies Charged to Patients cost centers (column 5, lines 71 and 73 of Worksheet D Part II of Form CMS–2552–10.

[14] As noted in section III. of this ANPRM and as summarized in the CY 2025 OPPS/ASC final rule, in the past commenters recommended that the payment adjustment be expanded to additional types of PPE, including 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.

[15] Discussed in section III. of this ANPRM.

a budget-neutral manner, other adjustments as determined to be necessary to ensure equitable payments.

- Would a payment adjustment to account for the Medicare FFS share of these additional costs be sufficient to encourage hospitals to increase their purchasing of domestically made PPE and essential medicines?
- Would it be appropriate to expand a potential payment policy beyond IPPS and OPPS hospitals to other entities that receive Medicare payments? How could such an expansion be structured? For example, physicians and other Medicare suppliers do not file cost reports. What alternatives to a cost-report-based approach (for example, a claims-based approach) might be appropriate, including for hospitals? How might such alternatives be structured?
- What methods should be used to assess longer-term benefits with respect to patient safety that may result from more resilient domestic supply chains for critical PPE and essential medicines?

V. Hospital IQR Program Measure

This section discusses the background and history of the Hospital IQR Program and a request for information on a structural measure of domestic procurement.

A. Background and History of the Hospital IQR Program

The Hospital IQR Program is a pay-for-reporting program intended to measure the quality of hospital inpatient services, improve the quality of care provided to Medicare beneficiaries, and facilitate public transparency. Section 1886(b)(3)(B)(viii) of the Act states that subsection (d) hospitals participating in the Hospital IQR Program that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a reduction to their annual payment update for the applicable fiscal year of one-quarter of the market basket update. We refer readers to our previous IPPS final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set. We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

B. Request for Information on a Structural Measure of Domestic Procurement

We seek public input on the potential adoption of a structural measure that would require hospitals to attest to meeting the domestic procurement minimum percentages for PPE and essential medicines as part of the Hospital IQR Program. Similar to how hospitals could potentially earn a ''Secure American Medical Supplies'' friendly designation as described earlier, hospitals could be required to attest ''yes'' or ''no'' as to whether they met a minimum percentage of American-made PPE and essential medicines, as well as whether they met minimum percentages of relevant or applicable products and supplies in each category (that is, for example, masks under PPE or anti-microbial medicines for essential medicines)if sufficient domestic producers exist. We solicit comment on this attestation measure and the following questions:

- Would a structural attestation measure in the Hospital IQR Program be an appropriate way to bring transparency as to hospital procurement of domestically manufactured items and incentivize hospitals to prioritize resources for increasing procurement through domestic supply?
- If the measure attestations were to ask hospitals whether they met a minimum American-made percentage of all PPE and all essential medicines, as well as whether they met minimum American-made percentages of each subcategory (that is, masks or anti-microbial medicines) if sufficient domestic producers exist, what would be a sufficient minimum percentage?
- Should the structural measure attestations, including minimum percentages, be aligned with the attestations and minimum percentages for the ''Secure American Medical Supplies'' friendly hospital designation, or should the structural quality measure seek different information about hospitals' domestic procurement activities (and if so, what types of activities or attestations would be appropriate for a measure in the Hospital IQR Program)?
- What would be the least burdensome effective method to audit or validate hospitals' attestation responses, as feasible?
- What are potentially useful alternative measures to an attestation measure? How could hospitals measure care processes or outcomes related to impacts of purchasing from domestic suppliers? How could hospitals be asked to provide proof that they purchased from domestic suppliers? Could hospital accreditors, GPOs, or some other entity be better positioned to track or measure hospitals' domestic procurement activities?
- Are hospitals aware of evidence-based literature and independent research that demonstrates the use and availability of domestically manufactured health care supplies and drugs to improve health care, health outcome, and safety?
- How have supply chain disruptions due to the lack of domestically manufactured PPE and essential medicines impacted the quality of care at hospitals?

VI. Alternatives Considered: Conditions of Participation for Domestic PPE and Essential Medicines

In developing these options, CMS considered alternative policy approaches, including establishing a new Condition of Participation (CoP) at 42 CFR part 482 for hospitals that participate in Medicare. Under that approach, hospitals would be required to demonstrate a commitment to procuring PPE and essential medicines that are made in America to help secure our nation's health and safety. However, because the only statutorily available penalty for noncompliance with hospital CoPs is termination from the Medicare program, we believe this would be overly burdensome on hospitals and could result in very high additional costs.

VII. Solicitation of Additional Options: Domestic PPE and Essential Medicines

In addition to the proposals described earlier, we solicit general input on additional options from the public. Comments that include detailed information on economic impacts, timing, potential statutory authorities, and a discussion of trade-offs are especially useful to CMS. Include references to research and data in comments where appropriate.

VIII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the relevant comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on January 22, 2026.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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