American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

March 30, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals (CMS-1516-ANPRM), Jan. 29, 2026

Dear Administrator Oz:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers, and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) advance notice of proposed rulemaking (ANPRM) on potential options to foster a more resilient supply chain for American-made personal protective equipment (PPE) and essential medicines.

The ANPRM outlines several ideas for incentivizing hospitals to increase procurement of domestically-made PPE and essential medicines. Specifically, CMS is exploring the potential establishment of a "Secure American Medical Supplies" designation for hospitals that procure a minimum percentage of American-made PPE and essential medicines. CMS also seeks input on a potential separate Medicare payment to hospitals that achieve the designation and a structural measure for the Hospital Inpatient Quality Reporting (IQR) Program, asking hospitals to attest to procuring minimum percentages of domestically-made PPE and essential medicines.

The AHA supports and shares the administration's long-term goal of strengthening American manufacturing of PPE and essential medicines while reducing our nation's reliance on sometimes volatile international sources. We also agree that appropriately designed incentives for hospitals and health systems to purchase domestically made PPE and medicines could advance progress towards this goal. **The AHA believes**

such incentives should be accessible to as broad a range of hospitals as possible, recognize the cost differential for domestically manufactured goods and be implemented without excessive administrative burden. While some of the policy ideas in the ANPRM align with these principles, others could prove less achievable and effective and entail administrative burdens that outweigh their benefits. At a high level, the AHA recommends that CMS:

- Make a public designation based on domestic procurement percentages voluntary.
- Implement separate Medicare payments in a non-budget-neutral manner.
- Deprioritize the development of a structural measure in the IQR Program.

Our detailed comments on CMS' policy ideas in the ANPRM follow.

"SECURE AMERICAN MEDICAL SUPPLIES" DESIGNATION

America's hospitals and health systems rely on a complex domestic and global supply chain to deliver safe, timely and effective care to patients every day. The availability of PPE and essential medicines is critical to hospitals' ability to care for patients and their communities. When the supply chain is strained or disrupted, hospitals expend clinical and operational resources to manage shortages, implement workarounds and adjust care delivery — often at significant cost to hospitals — to minimize disruptions to patient care. Recent public health emergencies, extreme weather events and geopolitical instability have underscored the fragility of existing supply chains and the need to make them more resilient.[1,2,3,4,5]

CMS is considering the establishment of a public designation of hospitals that procure sufficient amounts of PPE and essential medicines made in America. The designation could be obtained by meeting a minimum American-made percentage of all PPE or all essential medicines, or it could be obtained by meeting a minimum American-made

---

[1] Premier Inc. (2024, Jan. 23). *New year, ongoing challenges: The state of healthcare supply chain disruptions in 2024*. https://www.premierinc.com/newsroom/blog/new-year-ongoing-challenges-the-state-of-healthcare-supply-chain-disruptions-in-2024.

[2] U.S. Food and Drug Administration. (n.d.). *Supply chain news, reports and publications*. https://www.fda.gov/emergency-preparedness-and-response/supply-chain/supply-chain-news-reports-and-publications.

[3] Stein, R. (2023, July 27). *Tornado damage at a Pfizer factory could worsen drug shortages*. NPR. https://www.npr.org/sections/health-shots/2023/07/27/1190507719/tornado-pfizer-factory-drug-shortages

[4] United Nations Conference on Trade and Development. (n.d.). *Navigating troubled waters: The impact of global trade disruption from shipping routes in the Red Sea and Black Sea*. https://unctad.org/publication/navigating-troubled-waters-impact-global-trade-disruption-shipping-routes-red-sea-black.

[5] American Hospital Association. (2024, Sept. 30). *North Carolina under PHE following Hurricane Helene as IV solutions plant closes*. https://www.aha.org/news/headline/2024-09-30-north-carolina-under-phe-following-hurricane-helene-iv-solutions-plant-closed.

percentage of each subcategory (e.g., masks or anti-microbial medicines) for which the Department of Health and Human Services (HHS) determines there is sufficient domestic supply. CMS could, in turn, use the designation in determining whether hospitals could qualify for additional Medicare payments.

The AHA believes that strengthening the domestic supply chain is an important step toward making the supply chain more resilient, and we appreciate CMS' desire to recognize hospitals for their efforts to procure domestically-made medicines and PPE. However, substantial barriers would limit hospitals' ability to meet the requirements of a designation like the one proposed in the ANPRM, raising questions about the feasibility and overall usefulness of a hospital-based designation. **If CMS is intent on pursuing such a designation, we recommend that the agency make it voluntary.**

First, the AHA is concerned that the substantial administrative burden and operational challenges associated with meeting and maintaining a potential designation may outweigh any associated benefit to hospitals. As CMS acknowledges, prior payment adjustments implemented under the inpatient and outpatient prospective payment systems (PPS) intended to support a more resilient and reliable domestic supply of certain PPE have been underutilized, due in large part to the substantial administrative burden involved. The designation suggested in the ANRPM would require similar tracking, reporting and verification, which would raise many of the same challenges and could continue to serve to limit hospital participation.

These administrative challenges are compounded by hospitals' limited visibility into critical aspects of the supply chain. Hospitals rely on distributors, group purchasing organizations and manufacturers to source PPE and essential medicines and often do not have access to more detailed information, such as the specific location of a particular manufacturer. Even when this type of information is available through contractual arrangements or voluntary disclosures, hospitals lack the resources and technical expertise needed to independently verify its accuracy. As a result, hospitals are not well-positioned to independently determine where a particular item, or the various components of a particular item, are made.

Second, current domestic production capacity for PPE and essential medicines remains insufficient to consistently meet patient and provider needs. Limited supply, higher costs and other market constraints outside of hospitals' control continue to restrict their ability to procure domestically produced PPE and essential medicines in the volumes needed to support even routine patient care. For example, Chinese manufacturers supply the majority of N95 and other respirators used in health care. Additionally, China was the source for one-third of disposable face masks, two-thirds of non-disposable face masks and 94% of the plastic gloves used in health care settings.[6] The U.S. also relies heavily on international sourcing for essential medicines. For

[6] AdvaMed presentation, 2023

example, the U.S. gets nearly 30% of its active pharmaceutical ingredients (APIs) from China. Furthermore, according to a 2023 HHS estimate, over 90% of generic sterile injectable drugs — such as certain chemotherapy treatments and antibiotics — depend on key starting materials from either India or China. A recent US Pharmacopeia analysis also found that over 50% of the APIs for non-intravenous (IV) drugs come from either India or the European Union.

In light of these data, we foresee challenges for CMS to determine what domestic procurement percentages would be achievable and appropriate for hospitals. Indeed, conditioning a designation on a hospital's ability to obtain domestic PPE and supplies, especially if CMS were to set percentage thresholds at levels exceeding current domestic manufacturing capabilities, could keep hospitals from meeting the requirements of such a designation despite good-faith efforts to comply. Until domestic manufacturing capacity is sufficiently developed to reliably meet demand across a broad range of PPE and essential medicines, a designation that relies on hospital-level procurement thresholds risks setting expectations that hospitals cannot meet.

These same limitations also raise concerns about how hospitals would be treated in the event of a supply chain disruption or shortage. Even well-intentioned efforts to secure domestic PPE and essential medicines can be undermined by factors outside hospitals' control, such as public health emergencies, natural disasters or other disruptions to manufacturing or transportation. Recent events affecting domestic IV fluids and other supplies underscore the risks associated with overreliance on any single source of PPE or an essential medicine. **If CMS were to pursue a designation, we urge the agency to consider how a designation would be maintained during periods of disruption and to develop an extraordinary circumstance exception process.** CMS has used such processes in its quality reporting and value programs.

Finally, while CMS suggests that a "Secure American Medical Supplies" designation could potentially allow Medicare and other payers to recognize the additional costs associated with domestic procurement, it remains unclear whether such a designation would lead to higher payments from payers in amounts that would actually offset the higher costs of domestic PPE and essential medicines, as well as the administrative costs required to track and report data necessary to maintain such a designation. Without guarantees that associated payment adjustments would meaningfully offset higher procurement and administrative costs, hospitals may be unable to justify the added costs associated with the increased administrative activity required to obtain and maintain the designation.

SEPARATE MEDICARE PAYMENT TO "SECURE AMERICAN MEDICAL SUPPLIES" HOSPITALS

CMS seeks input on a potential separate payment to "Secure American Medical Supplies" hospitals for Medicare's share of the additional costs of these resources. For PPE supplies, CMS indicated that it could derive the separate payment using cost

report data on the number of Medicare fee-for-service (FFS) inpatient days, reasonable assumptions on PPE use per hospital day, and the additional unit costs of domestic PPE. For essential medicines, CMS indicated that it could derive the separate payment using cost report data on Medicare's share of the hospital's total drug costs, reasonable assumptions on what percentage of those costs are for essential medicines and the additional unit costs of domestically produced essential medicines. Furthermore, CMS indicated that for the inpatient PPS, the separate payment to "Secure American Medical Supplies" hospitals could potentially be made in a non-budget-neutral manner.

As the AHA has previously commented, we support CMS including in any such program a payment adjustment for a broad scope of domestically made PPE. This could include gowns, hairnets, beard covers, bouffant caps, shoe covers, face shields, American Society for Testing and Materials Level II and III surgical masks, powered air-purifying respirators, elastomeric respirators, syringes, needles, catheters and wound care dressings, among other items. These are all essential medical supplies largely manufactured in part or in whole in other nations and have experienced serious shortages in recent years. Including these other supplies could make the program more attractive to manufacturers considering expanding their domestic footprint and may improve hospital participation in the program, as this would be an opportunity to offset increased costs for additional high-volume, domestically-made supplies.

To best incentivize hospitals to procure domestically made supplies and medicines, we urge CMS to consider making payments for these medicines and supplies beyond just Medicare FFS patients. Hospitals and health systems do not make purchasing decisions and agreements that differ by payer. For example, when a hospital has a purchasing contract for nitrile gloves, gloves purchased under this contract are used to care for all patients, not just Medicare FFS patients. As such, any policy that only considers FFS days disregards the additional costs hospitals would incur for purchasing domestic supplies used to care for their other, non-Medicare FFS patients, such as Medicaid and uninsured patients. This also includes and is especially true for hospitals with Medicare Advantage (MA) patients. The proportion of Medicare beneficiaries in FFS is declining, while those in MA are growing. Therefore, a lever that focuses solely on FFS will become even less effective over time, weakening the goal of the proposal to increase and strengthen domestic manufacturing. **Minimally, we urge CMS to consider payments to include at least *all* Medicare patients, including not only FFS but also MA.**

In addition, a payment adjustment that only accounts for the Medicare *inpatient* FFS share of the additional costs of procuring domestically made supplies and medicines would likely not be sufficient to encourage hospitals to increase their purchasing of these products. **While we appreciate that CMS has indicated it would make separate payments in a non-budget-neutral manner under the *inpatient* PPS, we encourage the agency to also make non-budget-neutral payments under the *outpatient* PPS.** Indeed, if the administration believes that increasing the domestic manufacturing capacity of these products is an issue of national security, then we

encourage it to seek the authority to be able to make payments in this manner. Redistributing payments from an already underfunded system will not be of benefit to providers or patients. Further, making non-budget-neutral payments would be in alignment with the purposes of the president's executive order 13944 ''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) and other orders.

Also, the AHA continues to be concerned with any proposed policies that would require hospitals and health systems to separately report on new supplemental cost report forms the additional cost of procuring domestically manufactured supplies and drugs. These requirements add to the ever-increasing burden placed on hospitals and health systems, and if this program were to expand to add more supplies and drugs in the future, it would compound more and more burdensome reporting. **Therefore, we support the establishment of a national cost differential, as CMS has previously proposed, where it could utilize information already reported on hospitals' claims and cost reports to calculate a differential that is then used to determine payments.**

Finally, we also urge CMS to ensure that any new policies related to the supply chain are consistent across supplies and essential medicines. Specifically, these types of payments are already made for N95 respirators and buffer stocks. As such, it would be less burdensome and more cost-effective to procure and receive any similar new payment adjustment through a consistent type of process.

STRUCTURAL MEASURE

CMS seeks public input on the potential adoption of a structural measure into the IQR Program that would require hospitals to attest to meeting the domestic procurement minimum percentages for PPE and essential medicines. The structural measure would ask hospitals to attest (i.e., yes or no) to whether their procurements met a minimum percentage of American-made PPE and essential medications, as under the designation described above. CMS also suggests that the measure could be further broken down into specific categories for products and supplies — that is, asking hospitals to attest to whether they procured a certain percentage of masks or anti-microbial medicines from American manufacturers.

The AHA agrees that essential medicines and other supplies are critically important for supporting safe, effective care delivery. However, we believe a structural measure in the IQR Program would be redundant with the designation that CMS is considering, would not align well with the purpose and intent of the IQR Program and would add substantial compliance costs for hospitals. For these reasons, AHA does not support the development or inclusion of a structural measure into the IQR Program regarding procurement of minimum percentages of PPE and essential medicines.

CMS appropriately asks in the ANPRM for evidence demonstrating the connection between the use of domestically manufactured PPE and essential medicines and patient outcomes. The AHA is not aware of such evidence of minimum percentages of such supplies associated with marginal improvements in quality of care. In fact, it could prove infeasible to put together evidence-based literature and research demonstrating these connections for several reasons. Not every type of PPE or medicine is manufactured in the U.S., and the types of supplies under consideration are so varied and incomparable that a generalization about whether American-made supplies are superior would be hard to make. In other words, there is not enough domestic manufacturing of all types of PPE and essential medicines to come up with comparisons of American versus foreign-made supplies, and even if there were, the variation across the types of supplies would not enable meaningful comparisons.

When it comes to these medical supplies, the primary consideration for quality outcomes is availability rather than the location of origin. Disruptions in the supply chain certainly have implications for patient care, but as discussed above, disruptions are a result of several other factors besides the country of origin. Furthermore, imported and domestically manufactured supplies and drugs alike must meet the same Food and Drug Administration regulations. Differences in the quality of these supplies should be addressed before they are used in patient care, and thus, any changes to relevant regulatory oversight would be outside the scope of this ANPRM.

Furthermore, the AHA has long questioned the value of structural quality measures in federal programs. Such measures are generally structured as yes/no attestations and do not capture the complexity of clinical operations, administrative decision-making and the patient care environment. To meaningfully inform quality improvement, hospitals and providers analyze detailed breakdowns of data to pinpoint areas for progress, so a binary outcome (or multiple binary outcomes across individual categories) is unlikely to produce useful information to inform improvement efforts.

Structural measures are also difficult to update over time and thus quickly become “topped out.” In other words, as the hospital field advances, and more hospitals can positively attest to meeting the minimum percentage, the structural measure would no longer be able to distinguish performance variation. Increasing the minimum percentage to remain current may be a substantive change to the measure’s specifications, which would require renewed review by CMS and the Consensus-Based Entity. This time-consuming process could mean the measure is out of step with the current state of the field.

In addition, a structural measure requiring hospitals to attest to meeting the domestic procurement minimum percentages for PPE and essential medicines would be inconsistent with the purposes of the IQR Program. According to CMS’ QualityNet overview, the program “is intended to encourage hospitals and clinicians to improve the quality of inpatient care provided to all patients” through public transparency and

performance benchmarking. However, for such a structural measure, there is no "benchmark" against which providers can compare their performance to inform quality improvement initiatives — the measure would reflect a binary attestation. Furthermore, as described in the previous section, it is unclear whether CMS could set minimum percentages of domestically procured medicines and PPE that would be appropriate and achievable for hospitals. An equally important aim of the IQR Program is "to equip consumers with quality of care information to make more informed decisions about healthcare options." The AHA is unaware of any evidence suggesting that consumers have preferences about the country of origin of supplies used in a hospital where they will receive care, or whether consumers can or do use this information to make decisions about where to receive care.

Lastly, CMS has rightly focused on identifying ways to reduce administrative burden as part of its efforts to make health care more affordable, including by streamlining its quality reporting and value programs. Considering the issues described above, we believe the administrative costs of a structural measure focused on domestic procurement of PPE and essential medicines would outweigh its value to hospitals and patients. Choosing not to adopt this measure would align well with CMS' continued focus on burden reduction.

The AHA thanks CMS for the opportunity to provide input on policies aimed at strengthening the health care supply chain and looks forward to working with the administration to advance solutions that improve reliability and resilience while preserving hospitals' ability to care for the patients and communities they serve. Please contact me if you have questions, or feel free to have a member of your team contact Akin Demehin, vice president of quality and safety policy, at ademehin@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development