

March 20, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically to www.regulations.gov

RE: Medicare Program; Ensuring Safety through Domestic Security with Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals

Dear Administrator Oz,

The American Nurses Association (ANA) appreciates the opportunity to provide input to the Centers for Medicare and Medicaid Services (CMS) on the advanced notice of proposed rulemaking (ANPRM) regarding domestically produced personal protective equipment (PPE) and essential medicines within the Medicare Program.

ANA applauds the Administration's continued focus on strengthening PPE supply chains to ensure the safety of healthcare workers throughout the country. A strong domestically produced PPE supply chain is vital for keeping nurses safe every day, not just during major outbreaks or times of crisis. CMS must carry out its domestic-made PPE supply chain initiatives in ways that consider how nurses use PPE and the responsibility that a hospital has to protect the nurses that work there. More specifically CMS should:

- consider how PPE shortages impact nurses' ability to both keep themselves safe and care for patients,
- include nursing-specific PPE needs in any lists of domestic-made PPE,
- take steps to prevent PPE or essential medicine shortages during any program roll out, and
- acknowledge the role of the nurse in PPE usage and conservation.

ANA represents the interests of the nation's over 5 million registered nurses (RNs) through its state and constituent member associations, organizational affiliates, and individual members. ANA advances the nursing profession by championing nurses, fostering rigorous standards of nursing practice, promoting safe and ethical work environments, bolstering nurses' health and wellness, and advocating on the healthcare issues that impact both nurses and their patients. ANA seeks to ensure that nurses' voices, interests, and perspectives are represented and heard in policymaking discussions. Our membership consists of both registered nurses (RNs) and Advanced Practice

Registered Nurses (APRNs)—nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs).

Nurses form the backbone of the American healthcare system, and RNs serve across full spectrum of healthcare settings in multiple direct care, care coordination, research, and administrative leadership roles. Nurses provide and coordinate patient care, educate patients and the public about self-care and various health conditions, and offer counsel and emotional support to patients and their family members. As the most trusted profession, nurses play a critical role in treating patients and influencing health behaviors.¹ As such, we urge CMS to consider the nursing perspective in its PPE initiatives.

1. CMS should consider the impact of PPE shortages on nursing care while assessing the adoption of PPE-related structural measures to the Hospital Inpatient Quality Reporting Program.

CMS seeks input on adopting a structural measure as part of the Hospital Inpatient Quality Reporting (IQR) Program that would require hospitals participating in Medicare to attest “yes” or “no” to meeting minimum percentages for domestic PPE procurement. These hospitals would be required to further attest whether they meet minimum percentages of domestic procurement on the basis of applicable products under different PPE categories, such as masks, when CMS deems sufficient domestic production capacity exists. Since PPE shortages can impact quality of care that nurses and healthcare workers are able to provide, adding a domestic PPE procurement attestation to the IQR program would help hold hospitals accountable for stocking sufficient, reliable, and high-quality PPE.

Specifically, CMS requests public input on how supply chain disruptions impact quality of care. **PPE shortages impact nurses’ ability to protect themselves and care for their patients.** This was especially evident during the COVID-19 Public Health Emergency (PHE), where there were widespread PPE shortages and providers were often forced to reuse PPE equipment.

In the Summer of 2020, 78% of nurses were either required or encouraged to reuse single use PPE items, while 62% of nurses felt unsafe with their healthcare facility’s approach to reusing PPE.² Additionally, 24% of nurses reported that they were given N95 respirators that did not fit appropriately, even though correct fit is vital in ensuring respirator effectiveness and safety.^{3, 4} Healthcare providers must feel safe and be protected while treating patients; nurses deserve to

¹ American Nurses Association. (2026, January 12). *Nurses ranked most trusted profession for 24th consecutive year* [Press release]. <https://www.nursingworld.org/news/news-releases/2025/nurses-ranked-most-trusted-professionals-for-24th-consecutive-year/>

² American Nurses Foundation. (2020, December 8). *Pulse on the Nation’s Nurses COVID-19 survey series: Personal protective equipment survey 2*. <https://www.nursingworld.org/practice-policy/work-environment/health-safety/disaster-preparedness/coronavirus/what-you-need-to-know/ppe-survey-2/>

³ *Ibid.*,

⁴ Occupational Safety and Health Administration. (n.d.). *Personal protective equipment*. U.S. Department of Labor. <https://www.osha.gov/personal-protective-equipment>

have PPE supplies and policies that they are confident in. It becomes difficult for healthcare workers to provide the highest quality of care when they do not feel safe.

When PPE is not consistently available, nurses may be forced to limit room entries, consolidate tasks, or delay non-urgent care activities in ways that can directly affect the delivery of care. For example, disrupted access to appropriate PPE can impede timely assessments, medication administration, wound care, mobility and turning, patient education, and safe admissions, transfers, or discharges.^{5,6} Even when these changes are made with the intent of conservation, they can contribute to missed or delayed nursing care and make it more difficult to identify clinical deterioration early.

PPE shortages also affect nursing care coordination and the hospital operations that nurses routinely support, including interdisciplinary rounds, handoffs, transport to diagnostic testing or procedures, and timely implementation of infection prevention measures. When PPE supplies are unreliable or difficult to access at the point of care, nurses and other staff may spend valuable time searching for equipment or seeking substitutions, which can slow patient throughput and reduce time available for direct patient care.

Additionally, research has shown that inadequate PPE greatly contributed to nurse burnout rates during the COVID-19 pandemic and that working with limited PPE made nurses feel scared, afraid, isolated, angry, betrayed, and helpless.^{7,8,9} There is a negative association between nurse burnout rates and patient safety, quality of care, and patient satisfaction.¹⁰ Having a strong PPE supply chain and supporting nurse wellbeing in general would help better protect nurses during a major outbreak and enable them to give the fullest quality of care during times of crisis.

⁵ Ranasinghe, I., Perera, Y., Turner, P., & Dent, D. (2022). Implications of lack of available personal protective equipment on surgical trainees: Lessons learned from the COVID-19 pandemic. *The American Journal of Surgery*, 224(6), 1492–1493. <https://doi.org/10.1016/j.amjsurg.2022.08.014>

⁶ Centers for Disease Control and Prevention. (2024, October 22). *Strategies for conserving the supply of all personal protective equipment in healthcare*. <https://www.cdc.gov/niosh/healthcare/hcp/pandemic/conserving-PPE.html> (Accessed March 13, 2026)

⁷ McPhaul, K., & Lipscomb, J. (2023, October). Perceptions of the availability of personal protective equipment during the early phase of COVID-19 pandemic. *Journal of Occupational & Environmental Medicine*, 65(1), e1–e6. <https://doi.org/10.1097/JOM.0000000000002926>

⁸ de Cordova, P. B., Johansen, M. L., Grafova, I. B., Crincoli, S., Prado, J., & Pogorzelska-Maziarz, M. (2022). Burnout and intent to leave during COVID-19: A cross-sectional study of New Jersey hospital nurses. *Journal of nursing management*, 30(6), 1913–1921. <https://doi.org/10.1111/jonm.13647>

⁹ Iheduru-Anderson, K. C. (2021). Reflections on the lived experience of working with limited personal protective equipment during the COVID-19 crisis. *Nursing Inquiry*, 28(1), Article e12382. <https://doi.org/10.1111/nin.12382>

¹⁰ Li, L. Z., Yang, P., Singer, S. J., Pfeffer, J., Mathur, M. B., & Shanafelt, T. (2024). *Nurse burnout and patient safety, satisfaction, and quality of care: A systematic review and meta-analysis*. *JAMA Network Open*, 7(11), e2443059. <https://doi.org/10.1001/jamanetworkopen.2024.43059>

The care impacts of PPE shortages are not limited to hospitals that accept Medicare.¹¹ **ANA is greatly appreciative of CMS’ efforts to strengthen the PPE supply chain in hospitals that accept Medicare, and we also urge CMS to take steps to encourage domestically made PPE procurement for other facilities that accept Medicare patients.**

2. CMS must consider nursing-specific PPE needs and take steps to avoid potential domestic supply shortages should it establish a “Secure American Medical Supplies” Hospital Designation.

CMS proposes the creation of a Secure American Medical Supplies (SAMS) friendly designation that hospitals could earn by demonstrating commitment to procuring a certain percentage of domestically made PPE and essential medicines. This designation could be beneficial in providing transparency and informing nurses about a hospital’s reliability regarding PPE procurement methods prior to beginning employment, and the recognition could encourage more hospitals to procure more domestically produced PPE and essential medicines. **If CMS creates a SAMS designation, they must consider nursing-specific PPE needs, anticipate the impact of potential essential medicine and PPE supply shortages, and take steps to avoid potential shortages during a program roll out.**

- a. CMS must consider nursing-specific PPE needs when determining which PPE should be included in domestic procurement criteria.*

The ANPRM seeks comment on whether to use a list of “critical components of critical items” or to issue guidance every four years for all PPE items that hospitals would have to procure domestically to receive SAMS designation. **Should CMS pursue the SAMS friendly designation, they must consider nursing-specific PPE needs when developing the list of “critical components and critical items,” or while issuing guidance on which PPE supplies will be included under this potential designation.** The ANPRM defines *PPE* 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.”¹² The aforementioned items are all critical kinds of PPE that nurses use and must be included on any PPE requirements for SAMS designation. However, more detail is needed in any kind of list or rulemaking to make sure hospitals are procuring sufficient PPE to ensure nurses are protected. The kinds of PPE that nurses use include, but are *not limited to*:

- Body Protection, including protective clothing, gowns, aprons, and coveralls;

¹¹ American Nurses Association. (2020). *Personal protective equipment survey: Respondent snapshot* [Infographic]. <https://www.nursingworld.org/globalassets/covid19/ppe-infographic-june-5-2020.pdf>

¹² Centers for Medicare & Medicaid Services. (2026, January 29). *Medicare program; ensuring safety through domestic security with made in America personal protective equipment (PPE) and essential medicine procurement by Medicare participating hospitals*. *Federal Register*, 91, 3851–3856. <https://www.federalregister.gov/d/2026-01730/p-39>

- Hand and Foot Protection, including exam gloves, surgical gloves, and shoe covers;
- Face Protection, including face shields, goggles, safety glasses, surgical masks, and hoods; and
- Respiratory Protection, including filters and NIOSH approved respirators like N95s, Powered Air-Purifying Respirators (PAPRs), and elastomeric respirators.^{13, 14, 15, 16, 17}

CMS should make sure this list applies to a variety of sizes of PPE, when applicable, to protect nurses and other healthcare workers. Correct fit is essential in ensuring the effectiveness of certain PPE, like respirators, which is why healthcare workers are fit tested for respirators annually.¹⁸ The Occupational Safety and Health Administration (OSHA) already requires employers to have enough models and sizes of respirators available, yet 24% of nurses reported being given inappropriately fitting N95s during PPE shortages in Summer 2020.^{19, 20} This signals the importance of strengthening the supply chain for multiple fits of PPE, and this must be accounted for in any PPE lists or guidance for hospitals to achieve SAMS designation. Procurement approaches should support the entire healthcare workforce by ensuring that PPE fits a diverse range of healthcare workers and does not place certain staff at higher risk due to limited sizing or poorly fitting models.

In addition to specifying categories of PPE in any potential guidance on domestic procurement criteria, CMS should consider expectations that reflect how PPE is used in clinical practice, including product usability and staff competency. Domestic procurement criteria should promote PPE that supports safe performance of nursing tasks (e.g., adequate range of motion, minimal tearing or seam failure, appropriate barrier protection, and compatibility with clinical workflows) and should account for the need for training and competency on appropriate donning or doffing, seal checks, and the use of alternative respiratory protection (e.g., PAPRs or elastomeric respirators) when indicated. Further, PPE “availability” should mean reliable access at the point of

¹³ American Nurses Association. (2020). *Personal protective equipment survey: Respondent snapshot* [Infographic]. <https://www.nursingworld.org/globalassets/covid19/ppe-infographic-june-5-2020.pdf>

¹⁴ American Nurses Foundation. (2020, December 8). *Pulse on the Nation's Nurses COVID-19 survey series: Personal protective equipment survey 2*. <https://www.nursingworld.org/practice-policy/work-environment/health-safety/disaster-preparedness/coronavirus/what-you-need-to-know/ppe-survey-2/>

¹⁵ American Nurses Association. (n.d.). *Project Firstline: Personal protective equipment (PPE) resources*. <https://www.nursingworld.org/practice-policy/project-firstline/on-the-go-resource/ppe/>

¹⁶ Lee, Y. A., Salahuddin, M., Gibson-Young, L., & Oliver, G. D. (2021). Assessing personal protective equipment needs for healthcare workers. *Health science reports*, 4(3), e370. <https://doi.org/10.1002/hsr2.370>

¹⁷ Kenning, S., & Groen, K. (2023). *Personal protective equipment*. In *StatPearls*. StatPearls Publishing. <https://www.ncbi.nlm.nih.gov/books/NBK589639/>

¹⁸ Centers for Disease Control and Prevention. (2015). Hospital Respiratory Protection Toolkit (Publication No. 2015-117, Rev. 2022). U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health (NIOSH). <https://www.cdc.gov/niosh/docs/2015-117/pdfs/2015-117revised042022.pdf>

¹⁹ *Ibid.*,

²⁰ American Nurses Foundation. (2020, December 8). *Pulse on the Nation's Nurses COVID-19 survey series: Personal protective equipment survey 2*. <https://www.nursingworld.org/practice-policy/work-environment/health-safety/disaster-preparedness/coronavirus/what-you-need-to-know/ppe-survey-2/>

care, such that nurses can readily obtain appropriate PPE when initiating or escalating isolation precautions or responding to changes in patient condition.

CMS should also consider how PPE procurement and policies affect patient-centered care and communication. In many settings, PPE can create barriers to communication for patients and families, particularly for individuals with hearing impairment, limited English proficiency, cognitive impairment, or behavioral health needs. Ensuring reliable access to appropriate PPE and selecting options that support clear communication and safe interaction can help nurses provide education, obtain informed consent, and deliver compassionate care, including during end-of-life situations.

b. CMS needs to consider potential domestic PPE and essential medicine shortages should it establish a SAMS designation.

Nurses use and rely on PPE every day, not just during public health emergencies or pandemics. Any threat to the PPE supply chain, not just increased demand during major outbreaks, would pose risks to nurses. American manufacturing capability of PPE and essential medicines must be sufficient to withstand the increased demand if CMS initiates any of its proposals to encourage domestic procurement. **Therefore, if CMS or any federal agency determines that there is even a slight chance that introducing a SAMS designation could cause temporary supply chain shortages for PPE or essential medicines, then CMS must phase its initiatives over a time frame that would ensure there are enough domestic resources available when hospitals switch from international manufacturers to domestic.** Hospitals should be encouraged to procure domestic PPE and essential medicines and be discouraged from reliance on international manufacturers. However, in instances where procuring American-made PPE or essential medicines is near impossible, hospitals must still stock all necessary PPE and essential medicines to protect their employees and patients.

Because the proposed SAMS designation would also address essential medicines, CMS should recognize the downstream implications that medicine shortages and substitutions can have for bedside care. When facilities face shortages of commonly used medications, nurses may need to implement substitutions that require different preparation, administration, monitoring, titration, or patient education, which can increase risk for medication errors and adverse events and add to clinical workload. Any SAMS approach that includes essential medicines should be designed to support safe medication administration and monitoring at the point of care, particularly during periods of constrained supply.

CMS should also encourage hospitals to maintain clear, evidence-informed contingency plans that protect staff and patients if supply disruptions occur during implementation. This includes transparent triggers for PPE conservation strategies (e.g., extended use or limited reuse), defined safeguards to prevent unsafe workarounds, and clear criteria for returning to conventional practices when supply stabilizes. Such planning is essential to ensure nurses can continue to deliver timely, safe care while maintaining infection prevention and control practices during periods of constrained supply.

3. CMS should proceed with a Medicare payment option to encourage American-made PPE procurement.

CMS predicts that hospitals would face higher purchasing costs for domestically manufactured PPE versus internationally produced PPE. Therefore, CMS is also considering a separate Medicare payment option for hospitals that achieve SAMS designation to incentivize hospitals to acquire domestically produced PPE and offset some of the costs. This option could encourage hospitals to acquire domestically made PPE and therefore ensure a better supply chain to better protect nurses and healthcare workers. **ANA appreciates CMS' intent of encouraging hospitals to procure domestically made PPE, and we urge CMS to proceed with a reasonable payment that encourages hospitals to procure American-made PPE but discourages unnecessary PPE hoarding.**

- a. CMS must design the proposed Medicare payment option for American-made PPE procurement so that it discourages PPE hoarding*

ANA supported payment adjustments for domestically made, NIOSH approved N95 respirators during the COVID-19 PHE, but we emphasized the need for limits on the incentive payments to discourage facilities from hoarding excessive amounts of PPE.²¹ A hospital acquiring PPE but limiting staff's access in order to hoard it is a very different situation than hospitals acquiring PPE and having the necessary PPE going into the hands of nurses who need it. **ANA continues to maintain that any sort of incentive payments must be designed so that hospitals are not rewarded for hoarding PPE; incentive payments must be based on the ability of nurses to reliably obtain PPE at their hospital.**

To operationalize this principle while developing a Medicare payment option, CMS should consider safeguards that distinguish between what qualifies as appropriate preparedness and when stockpiling does not translate to frontline access. For example, CMS could require hospitals seeking payment incentives to demonstrate that PPE is available and accessible at the unit level (including nights, weekends, and surge staffing) and to attest to processes that prevent rationing that limits clinical care. CMS could also consider incorporating workforce-facing indicators, such as staff reporting mechanisms or audit processes that verify nurses can reliably obtain appropriate PPE when needed.

- b. In any PPE usage calculations for a SAMS Medicare payment, CMS should consider the role of the nurse in PPE usage and conservation.*

For the proposed SAMS hospital payment option, CMS proposes the following calculation for a hospital's usage of a given type of PPE. CMS suggests deriving the separate payment for a hospital

²¹ American Nurses Association. (2022, June 3). *Comments to CMS on the Inpatient Prospective Payment System (IPPS) proposed rule for FY 2023* [Comment letter]. <https://www.nursingworld.org/globalassets/docs/ana/comment-letters/ana-comments-to-cms-ipps-2022-06-03.pdf>

using cost report data on, among other variables “reasonable assumptions on PPE use per hospital day.” CMS must first study how much PPE nurses use per day before making any assumptions on PPE usage. Nurses in direct care roles, also known as bedside nursing, are on the frontlines treating patients. The roles and tasks of a direct care nurse in a hospital typically differ from those of a physician. Patients spend more time with nurses, and nurses provide more continuous monitoring and hands-on assessments.²² This means that the PPE usage of bedside nurses could fundamentally differ from other health roles. Nurses can use a large amount of PPE across a 12-hour shift. For example, gown usage in continuous care. Every time a nurse goes into the room of a patient who is under contact precautions, every entry to that room requires the use of a new gown. That gown must be changed upon exiting that room, and this will happen at every entry for 12 hours and is multiplied by several patients. **If CMS proceeds with this Medicare payment option, they must evaluate the amount and type of PPE all types of health care providers use, and account for this in any PPE calculations required for a SAMS payment.**

4. Changes to the Medicare Conditions of Participation (COP) is not the correct avenue for strengthening the PPE supply-chain.

Lastly, ANA rejects CMS’ alternative proposal to establish a new COP for Medicare hospitals regarding domestically made PPE and essential medicines. As CMS acknowledges, the only statutorily available penalty for noncompliance would be termination from the Medicare program. Although ANA strongly supports a strengthened PPE supply chain, this harsh penalty would make it harder for Medicare patients to access the care they need, especially in rural areas where there are limited care options. ANA fears that changing the COP could result in patients losing access to care and providers being unable to be reimbursed for their services should there be a domestically made PPE requirement under the Medicare COP. **CMS should pursue rulemaking that strengthens the PPE supply chain through the creation of the SAMS designation with a related Medicare payment option, and/or the addition of a domestic PPE procurement attestation to the IQR program, instead of through changes to the Medicare COP.**

ANA supports CMS’ intent to protect healthcare workers and their patients by encouraging hospitals to procure domestically made PPE. We encourage CMS to consider the PPE needs and usage of nurses while designing and issuing its rulemaking.

²² Butler, R., Monsalve, M., Thomas, G. W., Herman, T., Segre, A. M., Polgreen, P. M., & Suneja, M. (2018). Estimating time physicians and other health care workers spend with patients in an intensive care unit using a sensor network. *The American Journal of Medicine*, 131(8), 972.e9–972.e15. <https://doi.org/10.1016/j.amjmed.2018.03.015>

We appreciate the opportunity to submit these comments and look forward to continued engagement with CMS. Please contact Tim Nanof, Vice President, Policy and Government Affairs at ANA, at (301) 628-5166 or Tim.Nanof@ana.org, with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'B Goettl', written in a cursive style.

Bradley Goettl, DNP, DHA, RN, FAAN, FACHE
Chief Nursing Officer

cc: Jennifer Mensik Kennedy, PhD, RN, NEA-BC, FAAN, ANA President
Angela Beddoe, ANA Chief Executive Officer