United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510–6400
(202) 224–5364

March 25, 2026

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

Dear Administrator Oz:

I write in strong support of the Centers for Medicare & Medicaid Services' (CMS) proposed rule to strengthen the domestic supply chain for personal protective equipment (PPE) and essential medicines, and to urge the agency to adopt the most robust policy options available under its statutory authority.

As Chairman of the U.S. Senate Special Committee on Aging, I have made the reshoring of critical medical supply chains one of my top legislative priorities. America's dangerous overreliance on foreign-manufactured drugs and medical supplies threatens the health and safety of every patient CMS serves, especially the most vulnerable patients like our seniors.

The COVID-19 pandemic exposed the catastrophic consequences of offshoring our medical supply chains. Hospitals across the country were unable to obtain adequate PPE to protect their patients and staff. Drug shortages that were already chronic became acute emergencies. Families were left desperate to get the essential medicines and supplies they and their loved ones needed to stay alive. The underlying cause was not a mystery: over decades, we allowed critical pharmaceutical and medical manufacturing to migrate overseas, primarily to China and India, in pursuit of lower short-term costs.

The result was a fragile, geopolitically exposed supply chain that failed American patients when they needed it most.

This is not merely a public health issue — it is a national security one. Communist China's dominance in the production of active pharmaceutical ingredients (APIs), key starting materials (KSMs), medical devices, and PPE gives the Chinese Communist Party extraordinary leverage over American healthcare. Any disruption, whether deliberate or otherwise, to that supply could leave American hospitals unable to treat patients across every disease category. The Special Committee on Aging's findings on pharmaceutical supply chain security have made clear that the United

States cannot afford to remain dependent on adversarial nations for the basic inputs of modern medicine.

I commend the Trump administration and CMS for taking meaningful steps to address this threat. The proposed "Secure American Medicine Supplies" (SAMS) designation, the potential for separate Medicare payment to incentivize domestic procurement, and the proposed Hospital Inpatient Quality Reporting (IQR) structural measure are all constructive tools. I offer the following comments urging CMS to adopt the strongest versions of these policies and to close any gaps that could undermine their effectiveness.

I. CMS Should Adopt a Robust SAMS Designation with Clear, Verifiable, Domestic Content Standards

The proposed "Secure American Medicine Supplies" designation is a sound mechanism, but its value depends entirely on the rigor of domestic content standards that underpin it. A designation that can be earned through nominal commitments or that relies on unverified self-attestation will not achieve the policy's goals.

Domestic Content Standards for Essential Medicines

CMS proposes that qualifying essential medicines must have over 50 percent of their API and their entire final dosage form manufactured in the United States. I support this as a floor, but I urge CMS to develop a clear, time-bound roadmap toward higher API thresholds. The 50 percent API threshold, while a meaningful step, does not eliminate our dependence on Chinese and Indian API suppliers for the remaining half of a hospital's essential medicine needs. CMS should establish a phased schedule, for example, progressing from 50 percent API domestic sourcing to 75 percent within five years, to create durable demand signals for domestic API investment.

For the final dosage form, the 100 percent domestic requirement is appropriate and should be maintained. CMS should resist pressure to accept foreign final dosage form manufacturing as a pathway to the designation, as this approach does nothing to rebuild domestic manufacturing infrastructure at the stages of production most critical to supply chain resilience.

Domestic Content Standards for PPE

CMS should adopt the full domestic content requirements of the Make PPE in America Act (Infrastructure Investment and Jobs Act, Pub. L. 117-58, sec. 70953) as the framework for the SAMS designation. This standard, which requires that PPE and its materials and components be grown, reprocessed, reused, or produced in the United States, is already familiar to manufacturers and provides a clear, legally grounded benchmark. Adopting a weaker standard for the SAMS designation would send contradictory signals to the market and would undermine the investment case for domestic PPE manufacturing.

Tiered Phase-In

I support the concept of a phased threshold structure, for example, beginning at 25 percent of total PPE and essential medicine procurement being domestic, rising to 50 percent and ultimately 75 percent over time. This approach acknowledges current market realities while creating stable, multi-year demand signals that will incentivize manufacturers to invest in domestic capacity. CMS should publish the full phase-in schedule at the time of final rulemaking so that hospitals, suppliers, and manufacturers can plan accordingly.

II. Attestation Alone Is Insufficient: CMS Must Establish Meaningful Verification Mechanisms

The ANPRM acknowledges that the SAMS designation might initially be based on hospital self-attestation. I urge CMS to move beyond self-attestation and explore alternative, independently verified verification mechanisms. The history of voluntary quality and procurement programs in healthcare demonstrates that attestation-only regimes are prone to drift and, in some cases, to fraud. The national security stakes of this program demand greater rigor.

I recommend that CMS explore the following verification mechanisms:

- **Manufacturer registration and product listing.** CMS should work with the Food and Drug Administration (FDA) and the Department of Commerce to maintain a publicly accessible list of PPE and essential medicine products that qualify as domestic under the SAMS designation criteria. Hospitals should be required to procure from registered products on this list, rather than making independent determinations of domestic status. This approach would reduce compliance burden on hospitals while creating a verifiable, auditable record.
- **Third-party audit pathway.** CMS should develop a pathway for accrediting bodies, group purchasing organizations (GPOs), and independent auditors to verify hospital compliance with SAMS designation requirements. This is consistent with how quality designation programs function across other areas of healthcare and would provide a stronger assurance framework than self-attestation alone.
- **Chain of custody documentation.** For essential medicines, CMS should require that hospitals maintain documentation provided by manufacturers tracing the API and final dosage form to domestic manufacturers. This documentation should be subject to Medicare Administrative Contractor (MAC) review at cost report settlement and should be available for CMS audit.

CMS should also note that the low adoption rates observed under the existing N95 FFR payment adjustment, where fewer than 100 hospitals reported qualifying data for FY 2024, are in part attributable to documentation complexity. A standardized, national product list would address this barrier directly while also strengthening verification.

III. The Hospital IQR Structural Measure Should Be Adopted and Aligned with SAMS Designation Thresholds

I support the inclusion of a structural attestation measure in the Hospital IQR Program. Pay-for-reporting requirements are one of the most effective tools CMS has to create uniform data collection and promote transparency in hospital behavior. Requiring hospitals to attest to their domestic procurement percentages would generate nationally consistent data on the current state of medical supply localization, identify gaps in domestic supply, and create a public accountability mechanism that complements the SAMS designation's positive incentive structure.

The IQR measure thresholds should be aligned with the SAMS designation thresholds to avoid creating a forked compliance system that imposes duplicative administrative burden on hospitals. A hospital that meets the SAMS designation criteria should automatically satisfy the IQR attestation requirement for the relevant reporting period. CMS should design the data elements for both programs in parallel to ensure that a single data submission satisfies both requirements.

The IQR measure should also capture whether a hospital experienced supply chain disruptions during the reporting period that necessitated procurement from non-domestic sources. This data would allow CMS to identify ongoing gaps in domestic manufacturing capacity and target future policy interventions, including the flexibility provisions the agency is appropriately considering for shortage scenarios.

IV. CMS Should Exclude Chinese-Origin Products from the SAMS Designation Framework

One significant gap in the ANPRM is the absence of explicitly exclusionary criteria for products with Chinese-origin components or APIs. The policy's goal is not merely to increase domestic production but to reduce our strategic vulnerability to supply chain disruption by adversarial nations. A policy that creates a domestic final dosage form requirement while leaving the API supply chain predominantly in Chinese hands will not achieve that goal.

I urge CMS to align the SAMS designation framework with the "Qualifying Country" definitions used in the Department of War's defense procurement regulations, with modifications appropriate to the healthcare context. Specifically, CMS should work with the Department of Commerce and the Office of the U.S. Trade Representative to develop a list of countries from which API and PPE component sourcing would disqualify a product from the SAMS designation. At a minimum, this should include countries designated as foreign adversaries under the Department of Commerce's regulations at 15 CFR 7.4. This would align the CMS program with broader national security policy and send a clear signal to the market that supply chain diversification away from adversarial suppliers, not merely to American shores, is the program's goal.

V. Legislative Complementarity: The *CLEAR LABELS Act*

The administrative policy framework CMS is building will be significantly strengthened by complementary legislation. The United States Senate Special Committee on Aging has been developing legislation directly relevant to this ANPRM: the *Consumer Labeling for Enhanced API Reporting and Legitimate Accountability for Base Entity Listings (CLEAR LABELS) Act*, which would require country-of-origin labeling on prescription drugs sold in the United States.

Country-of-origin labeling for prescription drugs would directly support the hospital verification challenge CMS faces under this ANPRM. If drug labels are required to disclose the country of manufacture of the API and final dosage form, hospitals and their group purchasing organizations would have a straightforward mechanism to verify the domestic status of their essential medicine procurement without relying solely on manufacturer representations or third-party audits. I urge CMS to note this gap in its final rule and to coordinate with the FDA and Congress to ensure that drug labeling requirements are aligned with the needs of the SAMS program.

VI. The Stakes for Older Americans are Particularly High

As Chairman of the U.S. Senate Special Committee on Aging, I want to be clear about the patient population most directly affected by the failures this ANPRM seeks to address. Older Americans are the heaviest users of both hospital services and the essential medicines that are the focus of this rulemaking. They are disproportionately harmed by drug shortages, by supply chain disruptions to antibiotics and crash cart medications, and by delays in receiving critical treatments. They are also the population whose trust in the Medicare program creates the greatest federal obligation to ensure the program's purchasing power is used to build a safe and resilient healthcare system.

The average drug shortage lasting approximately 1.5 years, as noted in the ANPRM, is not an abstract statistic. For a senior managing multiple chronic conditions, a shortage of an essential medicine can mean disease progression, hospitalization, or death. CMS has both the authority and responsibility to use Medicare's enormous market power to reduce the frequency and severity of these events. This ANPRM is a meaningful step in that direction, and I urge the agency to finalize the strongest possible version of these policies.

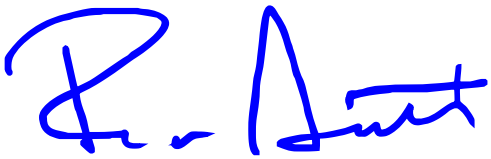
Conclusion

I strongly support CMS's initiative to establish the "Secure American Medical Supplies" designation, to create a meaningful separate Medicare payment for hospitals that commit to domestic procurement, and to incorporate a structural measure of domestic procurement into the Hospital IQR Program. I urge CMS to adopt robust domestic content thresholds, move beyond self-attestation to verifiable compliance mechanisms, align payment with full cost differential faced by participating hospitals, exclude adversarial-nation supply chains from the qualifying

framework, and coordinate with the FDA and Congress to address complementary policy gaps, including country-of-origin labeling.

Rebuilding America's domestic medical manufacturing base will require sustained commitment from Congress, the Executive Branch, hospitals, and the private sector. The policy choices CMS makes in finalizing this rulemaking will send a durable signal about the federal government's seriousness of purpose. I am confident that CMS shares the commitment to getting this right, and I look forward to working with the agency as it moves forward.

Sincerely,



Rick Scott
Chairman
Senate Special Committee on Aging