



## COLLEGE of AMERICAN PATHOLOGISTS

March 30, 2026

Dr. Mehmet Oz  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals [Docket No. CMS-1516-ANPRM]**

Dear Dr. Oz,

The College of American Pathologists (CAP) appreciates the opportunity to submit comments on *Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals*. We look forward to continuing engagement with the Centers for Medicare and Medicaid Services (CMS) on multiple aspects of diagnostics to ensure sensible guidance for pathologists and the safety of patients. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, healthcare providers, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

Overall, the CAP is very supportive of expanding potential options for domestically made PPE products beyond N95 masks. We agree with the comments from others that CMS noted that additional important PPE items to consider including are (but are not limited to) face shields, goggles, respirators, gloves, isolation gowns, shoe coverings, hair nets, beard covers, and bouffant caps. We also strongly encourage CMS to include laboratory supplies in its consideration of "critical medical supplies" as a vital part of emergency public health preparedness for the American people. The CAP applauds and thanks CMS for the new potential options they may consider to expand the types of products that would be recognized within the Medicare program and increase payments for healthcare organizations that purchase from US manufacturers. The CAP also urges CMS to incorporate critical laboratory supplies. Many types of PPE and critical laboratory supplies are essential to ensuring safe, high-quality patient diagnosis, care, and pathology practice, particularly during a public health emergency. As mentioned in the advance notice of proposed rulemaking (ANPRM), CMS believes "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." The CAP agrees with this statement and believes it also applies to clinical laboratories, as well as critical laboratory supplies.

Pathologists know firsthand the implications of supply shortages during public health emergencies. During the COVID-19 pandemic, the CAP appreciated working collaboratively with CMS to address supply chain issues using bilateral communication, and the CAP believes in fostering a more resilient domestic supply chain to ensure clinical laboratories have the necessary supplies throughout any future public health emergency. Though the ANPRM does not specifically address laboratory supplies for emergency public health preparedness, the CAP urges CMS to add laboratory supplies to this initiative. During the COVID

pandemic, clinical laboratories experienced shortages of the following supplies: pipettes, glass slides, “blue-top” test tubes, specimen acquisition swabs, and transport media. Of note, any items purchased must be of the quality required to perform the specific laboratory function. Including clinical laboratory-related PPE and critical laboratory supplies in the initiative will likely lead to more hospitals participating.

The CAP also strongly encourages CMS to consider including in this initiative all types of clinical laboratories, not only clinical laboratories that operate as hospital departments. Through research done by the CAP, about 11% of pathologists work in independent laboratories, which signifies a large quantity of laboratories that could help strengthen the supply chain. Clinical laboratories are a crucial component of emergency public health preparedness for the testing of many viruses, bacteria, and fungi regardless of the type of pandemic. Including all types of clinical laboratories in eligibility for the potential options under consideration is the best way to ensure preparedness and further the development of domestically made PPE and critical laboratory supplies.

For CMS to facilitate this program, we believe that attestation would be sufficient, and CMS could audit selected laboratories to ensure compliance. This would be the easiest way for hospitals and laboratories to participate with the least burdensome requirements and encourage wider participation in the program. Once CMS has identified the list of items that will be included in this program, they should work collaboratively with stakeholders to develop what threshold must be met and the additional funding that will be provided when a facility exceeds the target threshold. The CAP would be pleased to work with the CMS on implementation in clinical laboratory settings.

It is important for hospitals and laboratories to be able to easily discern which products will be labeled as “domestically made”. Thankfully, there is already a process that exists to help with this. The Buy American Act (BAA) is the primary law requiring the federal government to prefer domestic goods and manufactured products when making purchasing decisions. The BAA and regulations in the Federal Acquisition Regulation (FAR) provide a two-part test for determining if a product qualifies as a domestic end product. First, the item must be manufactured in the United States, and second, more than 65 percent of the cost of all the component parts must be manufactured in the United States. With this in mind, CMS could implement similar or the same rule to signify a product as “domestically made”. Using already in place rules for labeling products would help hospitals and laboratories more easily find this information and ensure they are adhering to the policies.

We also appreciate that CMS recognizes the burden that reporting could place on hospitals and laboratories and is looking to use processes already in place. In this regard, the ANPRM discusses potential use of the Hospital Inpatient Quality Reporting (IQR) Program and the Hospital Outpatient Quality Reporting Program (OQR) for submission of documentation for domestically made products. As noted, the IQR and OQR already have quality measurements, as well as mechanisms to collect information from hospitals. Pathology practices outside of hospitals also already have a mechanism to report to CMS on quality improvement activities<sup>1</sup>e.g. the Quality Payment Program (QPP)<sup>2</sup>. Regardless of the program that the measures would be created for, there would need to be a clearly defined measure that explains the specific items that are eligible, the percentage of total supplies needed to qualify, and the additional funding per item that is eligible. Again, this should be developed with stakeholders to

---

<sup>1</sup>Pathology Quality Registry (PQR), The CAP currently owns and maintains Qualified Clinical Data Registry (QCDR) measures and has worked with CMS in the past to develop measures. The CAP would be willing to work with CMS to help develop a process for clinical laboratories to report domestically made products to ensure the least burdensome process.



## COLLEGE of AMERICAN PATHOLOGISTS

ensure that the specific items, percentages of items bought, and funding per item is sufficient for stakeholders to participate.

Overall, the CAP is very supportive of strengthening the supply chain of domestically made products since pathologists were on the frontlines of the supply shortages during the COVID pandemic and believe that laboratory supplies should be added. Adding critical laboratory supplies not only helps build the domestic supply chain more but will benefit the country during the next public health emergency since pathologists will be the first physicians to test to identify the pathogens. Extending the initiative to all clinical laboratories – not only those that operate as hospital departments – will help strengthen our public health preparedness and add to the potential value of domestic PPE production.

\* \* \* \* \*

The CAP appreciates the opportunity to comment and provide pathologists' perspective regarding the strengthening of the domestic supply chain. We are eager to be involved with CMS in shaping this important initiative. Please contact Andrew Jackson, CAP Senior Policy Analyst, Scientific Regulatory Affairs Policy, at [ajackso@cap.org](mailto:ajackso@cap.org) if you have any questions on these comments.