

June 17, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1991-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Support for IPPS and OPSS Payment Adjustments for Wholly Domestically Made NIOSH-Approved Surgical N95 Respirators

Dear Administrator Brooks-LaSure:

On behalf of our American companies dedicated to the domestic manufacturing of medical supplies, we are pleased to express support for the Centers for Medicare & Medicaid Services' (CMS) Fiscal Year (FY) 2023 Hospital Inpatient Prospective Payment System (IPPS) proposed rule¹ ("Proposed Rule"). We would specifically like to highlight CMS's Proposed Rule that is considering increasing payments to hospitals that use American-made N95 masks. We applaud CMS for recognizing that Medicare payment policy is an essential component to maintaining a strong domestic industrial base for medical supplies. We also support implementing similar policies for other types of American-made medical and pharmaceutical products.

Support for an expansion of this type of increased payment aligns with President Biden's commitment to reward American-made products, a concept we all endorse and promote. As seen with the establishment of the Made in America office², there is a belief that spending American taxpayers' dollars should support American workers and businesses. The President has additionally signed a series of executive orders, where he has directed his Administration to implement policies that foster a robust American manufacturing sector and resilient domestic supply chains.³ We appreciate these efforts and believe that continued efforts should be made to prefer American-made pharmaceutical and medical supplies.

We applaud CMS for taking bold and decisive action to support American manufacturing and ensure that the United States is prepared for the next pandemic. In the Proposed Rule, CMS announced that it is considering increasing payments to hospitals that purchase American-made N95 respirators to maintain a sufficient level of domestic production for N95 respirators. As CMS

¹ 87 Fed. Reg. 28108 (May 10, 2022), available at <https://www.federalregister.gov/documents/2022/05/10/2022-08268/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>.

² <https://www.whitehouse.gov/omb/management/made-in-america/>

³ See, e.g., Executive Order 14001, *A Sustainable Public Health Supply Chain*, January 21, 2021; Executive Order 14005, *Ensuring the Future is Made in All of America by All of America's Workers*, January 25, 2021; Executive Order 14017, *America's Supply Chains*, February 24, 2021; Executive Order 14036, *Promoting Competition in the American Economy*, July 9, 2021.

observed in the Proposed Rule, hospitals are the largest purchaser of N95 respirators. Medicare is by far the largest purchaser of health care in the country; as such, a reimbursement policy agnostic to domestic production is a policy against it. Through this proposal, CMS recognizes that Medicare payment policy is an essential lever in maintaining a strong domestic industrial base for medical supplies. CMS has the opportunity to apply similar rules to other American-made medical products, and this would show that CMS is dedicated to encouraging American manufacturing and strengthening our domestic supply chain.

Similar policies that look to reward American-made medical products are being promoted in Congress, as well. The American Made Pharmaceuticals Act of 2022 and the Manufacturing API, Drugs, and Excipients (MADE) in America Act are two bills our companies support to ensure a resilient U.S. supply chain. The American Made Pharmaceuticals Act requires the U.S. Department of Health and Human Services to establish an innovative demonstration to test the impact of rewarding or providing lower out-of-pocket costs for domestically manufactured prescription drugs and biologics under public health insurance programs. The MADE in America Act incentivizes the domestic manufacturing of drugs, API, personal protective equipment (PPE), and diagnostics. Both bills further support the work of the administration to increase American-made companies and products.

We encourage CMS to utilize American-made policies beyond N95 respirators and personal protective equipment (PPE) to ensure domestic healthcare security for U.S. patients. As companies dedicated to American manufacturing, we are ready to work together to make these goals a reality. We ask that you consider expanding rules like the Proposed Rule to other products where the domestic supply chain is vulnerable, such as generics, biosimilars, medical devices, and active pharmaceutical ingredients (API) so that we can all work together to secure American production of medical products and pharmaceuticals.

Sincerely,

Securing America's Medicines and Supply Coalition (SAMS)

American Mask Manufacturer's Association (AMMA)

ALG Health

Amneal Pharmaceuticals

fluidIQ Inc.

Mallinckrodt Pharmaceuticals

Teva Pharmaceuticals

Coherus BioSciences

iRemedy Healthcare

Premium-PPE

United Safety Technology

Dentec Safety Specialists

Lutema

Safe Source Direct

U.S BIOLOGIC