

## **Sen. Brown Plan to Mobilize American Manufacturing to Fight Coronavirus**

The current public health emergency has revealed significant gaps in our ability to provide health care workers with the personal protective equipment (PPE), medical devices, and other health care supplies they need to protect themselves and their patients as they provide treatment critical to stopping the spread of and preventing deaths from the coronavirus. We will not stop this pandemic unless we take immediate steps to address the shortfalls and expand and sustain a domestic supply chain for these items going forward. Our country has the workers, the expertise, and the resources, and we must immediately mobilize America's vast manufacturing capacity to meet this challenge.

### **Urgent Administrative Actions**

First and foremost, the Administration must quickly distribute any military stockpiles of PPE, medical devices, and health care supplies that have not already been deployed to communities around the country. No health care worker should have to ration masks or gowns while those items sit in government storage.

Even if existing stockpiles are deployed immediately, experts have made it clear that will not be enough. The coronavirus pandemic will demand a greater and ongoing supply of PPE, medical devices, and medical devices. Domestic manufacturers are interested in helping to resolve these shortages, but they need assistance with understanding the technical specifications for the materials, expanding their capacity, securing the equipment, and maintaining a safe workforce to produce the items. We must take the following steps now to help U.S. manufacturers respond to the PPE and medical device shortfall.

- 1) PPE and Medical Device Point Person: The Administration must designate a government official to be the point person responsible for acquiring and developing production of PPE, medical devices, and other critical supplies necessary to fight the coronavirus pandemic. This point person will make it easier and more efficient for health care providers, state and local governments, domestic producers, and wholesale and logistics companies to get the information they need regarding PPE and medical device supply and demand.
- 2) PPE and Medical Device Assessment and Database: The Administration must immediately complete a national assessment of the supply and anticipated needs for PPE, ventilators, diagnostic test kits, and other needed medical supplies to respond to the coronavirus pandemic. This assessment should be used to establish and maintain a PPE and medical device database to ensure this information is available during the current and any future public health emergency.
- 3) List of PPE and Medical Device Needs: The Administration must publish online a list of all PPE and medical devices needed to respond to the coronavirus pandemic. The list should identify the volumes needed for each item, locations where shortages are greatest, technical specifications or standards the items must meet, any government efforts currently in place to increase the supply of the item, and any other critical information.
- 4) Hotline: The Administration must establish a hotline capable of handling significant call capacity that will provide U.S. producers centralized information about the results of the national assessment and the current need for PPE, devices, and other health care supplies.

The hotline should provide further information about technical specifications, contracting requirements, and federal approval processes for relevant products.

- 5) Immediate Funding to Manufacturers: The Administration must immediately provide funding to manufacturers to purchase equipment, retool machinery, hire additional workers, and cover any other expenses needed to increase PPE and medical device production.
- 6) Streamlined Contract and Certification Procedures: The contracting process for all public health emergency materials must be streamlined and centralized to ensure production and delivery of materials are not delayed due to paperwork constraints. In addition, the Administration must ensure that federal agency product approvals for PPE and medical devices are expedited and streamlined wherever possible.
- 7) Provide Critical Protections For Workers: Allow companies who are making PPE, medical devices, and necessary supplies to receive a waiver from any shelter-in-place requirements to allow workers to volunteer to go to work in these critical industries. Provide immediate company-specific OSHA consultations about the precautions companies should take to protect workers who volunteer to work to prevent the further spread of coronavirus among this critical workforce.
- 8) Purchase Guarantees and Delivery Assistance: The Administration must provide purchase guarantees and delivery of product to the communities and health care facilities that need the products most. Companies who ramp up production, particularly those who do so at their own expense, should have commitments from the government to purchase their product and help them get it to market. In addition, the Administration should create a centralized mechanism for facilities and providers to order product and track delivery. The Administration should require cooperation from wholesalers, distributors, and other supply chain partners to coordinate timely shipments of products.
- 9) Support for Sterilizing Companies: In addition to producing additional PPE, it is critical that the Administration provide assistance to companies who have the capacity to sterilize reusable equipment to alleviate the existing PPE shortage. The Administration should conduct explicit outreach to companies with these capabilities and provide any additional resources necessary to enable them coordinate with health care providers, PPE suppliers and health care suppliers to increase equipment sterilization capacity.

### **Critical Legislative Actions:**

Policy changes are necessary to prevent PPE, medical device, and health care supply shortfalls throughout the protracted coronavirus response and to ensure proper preparedness in the future. These policies must improve the way we stockpile and distribute these items during a public health emergency and must create long-term incentives for U.S. manufacturers to produce these essential materials.

- 1) Expanded Strategic National Stockpile Authority: The Strategic National Stockpile is best suited to understand the gaps in PPE supplies, the technical specifications for those products, and the supply chains required to make and deliver them. The Strategic National Stockpile should be given authority that would authorize the Assistant Secretary for Preparedness and Response, following a declaration of a Public Health Emergency by HHS, to provide resources to domestic manufacturers to build and sustain a domestic pipeline of PPE, medical devices, and health care supplies, including equipment

purchases and purchase guarantees. This authority would build off of the Stockpile's existing authority to purchase materials and ensure the Stockpile maintains the authority and flexibility to replenish materials during a global public health crisis when supplies are strained.

- 2) Domestic Supply Chain Mapping: The Strategic National Stockpile must complete and maintain a comprehensive map of the U.S.-based supply chain for PPE, medical devices, health care supplies, and medicines. Producers designated as part of the domestic Stockpile supply chain must be obligated to report when they close or stop making a certain item to inform the Stockpile whether additional domestic production capacity must be added.
- 3) Substantially Increase Defense Production Act (DPA) Funding: Additional DPA funding is critical to bolster domestic production of urgently-needed medical supplies to address critical shortages.
- 4) Strengthen Domestic Preferences: To maintain domestic supply chain continuity, all government purchases of textile- and fabric-based PPE materials, medical supplies, and their components must be subject to existing domestic preferences under the Berry Amendment (10 USC 2533a). In addition, the Berry Amendment should be detached from the simplified acquisition threshold (SAT) given the low price points for many PPE items, which may not exceed the \$250,000 SAT threshold.
- 5) Input and Component Stockpile: Certain inputs and components for PPE, medical devices, and medical supplies are not currently made in the U.S. in any capacity, but they are necessary to produce the finished products. U.S.-based manufacturers should be compensated by the government for stockpiling those inputs to meet increased PPE, medical device, and health care supplies demand during a public health emergency.

The current PPE, medical device, and health care supplies shortage is threatening the lives of our health care workers and patients, and global supply chains have proven to be insufficient during global pandemics. American manufacturers are ready to serve our country during this public health emergency, but the federal government must provide the resources to produce these life-saving materials. The actions and policy changes outlined above will help to address the current shortfall, prevent it from occurring in the future, and save lives.