PURPOSE

This document addresses issues related to personal protective equipment (PPE) and medical supplies needed to respond to COVID-19. The information in this document is based on information provided by the Trump Administration. This document is intended to provide Members with the latest reported information during this unprecedented pandemic. The Committee continues to receive updates from Administration officials and will update Members as new information becomes available.

LATEST DEVELOPMENTS

- The Administration has noted that the Strategic National Stockpile (SNS) has deployed all remaining COVID-19 related PPE in its inventory to areas in greatest need. According to data from the Federal Emergency Management Agency (FEMA), as of April 12, FEMA and the Department of Health and Human Services (HHS) have shipped or are currently shipping the following supplies: 38 million N95 respirators, 32.6 million surgical masks, 5.5 million face shields, 4.7 million surgical gowns, 30.3 million gloves, 212,000 coveralls, 10,448 ventilators, and 8,600 federal medical station beds.

- The White House initiated “Project Airbridge,” in partnership with large U.S. health care distributors such as McKesson Corp., Cardinal, Owens & Minor, Medline, and Henry Schein Inc., to expedite air delivery of PPE to high-risk areas across the country over the next 30 days. FEMA covers the cost of flying these supplies into the country, and then directs 50 percent of the supplies to areas of greatest need, and the remaining 50 percent are sent into the distributors’ regular supply chains. As of April 13, 37 cargo planes of medical supplies have been delivered, with an additional 43 scheduled for a total of 80 flights. Products are being delivered to private medical supply companies, rather than states and hospitals. From March 29 through April 12, Project Airbridge has delivered the following supplies: 550,000 N95 masks, 377.2 million gloves, 25.1 million surgical masks, 4.9 million surgical gowns, and 24,000 face shields.

- FEMA also announced on April 13 that shipments of approximately 10 million FEMA-procured N95 masks from 3M have begun and will continue over the next month. The first flight carrying approximately 600,000 masks arrived on April 12.

- On April 12, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) to Advanced Sterilization Products for the STERRAD Sterilization Cycles, which can be used to decontaminate N95 or N95-equivalent respirators. It is estimated that this technology has the potential to decontaminate up to four million respirators per day in the U.S. This is in addition to the EUA granted to STERIS
Corporation for their sterilization systems on April 10. The STERIS technology will support the decontamination of up to 750,000 N95 or N95-equivalent respirators per day in the U.S.

- On April 8, HHS announced an agreement with DuPont to supply 450,000 Tyvek suits to the U.S. with an additional 2.25 million being supplied over the next five weeks.

HHS ACTIONS RELATED TO PPE

- On April 2, HHS and the Department of Justice (DOJ) announced the forthcoming distribution in New York and New Jersey of hoarded PPE and medical supplies confiscated from price gougers during an enforcement operation conducted by DOJ’s COVID-19 Hoarding and Price Gouging Task Force on March 30. Approximately 192,000 N95 respirator masks, 598,000 medical grade gloves and 130,000 surgical masks, procedure masks, N100 masks, surgical gowns, disinfectant towels, particulate filters, bottles of hand sanitizer, and bottles of spray disinfectant were confiscated and will be distributed.

- To address the shortages of masks, FDA has worked with the Centers for Disease Control and Prevention (CDC) to allow health care workers and first responders to use similar respirator masks approved by the National Institute for Occupational Safety and Health (NIOSH)—not currently regulated by the FDA, and typically used in construction and manufacturing—during the COVID-19 outbreak.

- In response to potential shortages, CDC has issued Interim Infection and Prevention Control Recommendations indicating that “alternatives to N95s should be considered.” These alternatives include other classes of filtering facepiece respirators (FFRs), elastomeric half-mask and full facepiece air purifying respirators, and powered air purifying respirators (PAPRs) where feasible.

- The Pentagon announced on March 17 that they will provide five million masks from Department of Defense stockpiles to the SNS with the first one million being made available to HHS immediately.

FOOD AND DRUG ADMINISTRATION ACTIONS RELATED TO PPE

- An EUA issued by FDA allowed for the importation of non-NIOSH-approved respirators that have been designed, evaluated, and validated to meet a performance standard for use in health care settings by health care personnel in accordance with recommendations from CDC. FDA also issued a new EUA that will allow for non-NIOSH approved respirators made in China to be used in response to COVID-19.

- FDA has provided information to health care providers on how to address shortages of diagnostic testing supplies, such as where test components, including swabs, can be substituted with alternative products. For individuals who have questions or would like to report shortages of testing supplies, FDA has a 24-hour toll-free line: 1-888-INFO-FDA, choose option *. Current CDC recommendations on optimizing respirator use are available at: Strategies for Optimizing the Supply of N95 Respirators.
FEMA EFFORTS RELATED TO PPE PROCUREMENT AND DISTRIBUTION

- The Trump Administration has formed a Supply Chain Stabilization Task Force led by Rear Admiral John Polowczyk that is tasked with identifying the medical supply and PPE needs in the United States, and then working daily with global manufacturers to procure supplies. Supplies are now being transported by air from both Asia and Europe into the United States.

- Supplies procured by the Task Force are being distributed in the United States by commercial distributors in communities identified by the Administration as most in need. This will include masks, gloves, gowns, hand sanitizer, and surgical caps.

WAYS FOR PROVIDERS AND FIRST RESPONDERS TO ACCESS SUPPLIES

- FEMA has requested all private industry companies interested in selling medical supplies or equipment to the federal government to submit information to FEMA here. If private companies are interested in donating medical supplies or equipment, further details should be provided to FEMA here. Private companies that want to produce a product related to the COVID-19 response should send an email to: nbeoc@max.gov. Private companies interested in doing business with FEMA and supporting the response to COVID-19 with their company’s non-medical goods and/or services should submit inquiries to the Department of Homeland Security (DHS) Procurement Action Innovative Response Team (PAIR) team at DHSIndustryLiaison@hq.dhs.gov.

- FDA has issued letters to health care providers to share conservation strategies, such as the use of alternatives or when supplies can be used beyond the manufacturer-designated shelf life for surgical masks and gowns and medical gloves.

- FDA has also provided contact information for manufacturers interested in importing PPE and other devices.

- Local providers and responders looking for supplies should be directed to your state health department. Some state health departments keep their own stockpiles of PPE and other devices for emergency purposes. If your state health department does not have additional PPE or other devices available for distribution, state governments are able to request federal assistance from the SNS. State governors or their designees are responsible for requesting deployment of SNS assets.

- The HHS Office of the Assistant Secretary of Preparedness and Response (ASPR) will work with state officials and other responding federal agencies to evaluate the request and situation. Ultimately, HHS/ASPR determines a prompt course of action of where and when to release those assets that are most appropriate.

- Each state has established plans to receive and distribute SNS assets to their local jurisdictions as soon as possible after receipt of the deployment. SNS assets are delivered to one predesignated location in the state. State personnel are then responsible for distributing the materials within the state to health care providers. To request items, governors or their designees should send their requests to: HHS.SOC@HHS.gov.