



April 15, 2020

UPDATED - COVID-19: PPE and Medical Supplies

COMMITTEE ON ENERGY & COMMERCE

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 pre-designated 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.



April 15, 2020

UPDATED - COVID-19: Issues Related to Ventilators

COMMITTEE ON ENERGY & COMMERCE

PURPOSE

- This document addresses issues related to ventilators needed to treat COVID-19 patients. 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.

UPDATE ON VENTILATOR SHORTAGES AND RESPONSE EFFORTS

- When the COVID-19 outbreak began, there were [approximately 160,000 ventilators in health care settings nationwide](#). Latest numbers from the Federal Emergency Management Agency (FEMA) reveal that the federal government has an additional 6,924 total ventilators available, including 6,724 in the Strategic National Stockpile (SNS) and 200 available from the Department of Defense (DoD). DoD has deployed 70 ventilators with USNS Mercy, 52 ventilators with USNS Comfort, and 36 ventilators with three Army field hospital personnel supporting Seattle and New York City.
- According to FEMA data, as of April 12, FEMA and the U.S. Department of Health and Human Services (HHS) have delivered or are currently shipping 10,888 ventilators from the SNS and DoD to the following locations: Alaska (60), Arizona (100), California (170), Colorado (100) Connecticut (350), Delaware (50), Florida (200), Georgia (150), Guam (30) Illinois (600), Indiana (100), Louisiana (350), Maryland (470), Massachusetts (400), Michigan (700), the Navajo Nation (50), Nevada (150), New Jersey (1,558), New York (4,400), Oregon (140), Rhode Island (100), Washington State (500), and the Federal Bureau of Prisons (20).
- FEMA and HHS are working to respond to state requests for ventilators; however, FEMA has stated that states should not expect shipments of ventilators until they are needed to sustain life within a 72-hour period.
- On April 8, HHS [announced](#) the first contract for ventilator production rated under the Defense Production Act (DPA) to General Motors. The contract is for \$489.4 million for the production of 30,000 ventilators to be delivered to the SNS by the end of August 2020. Of this amount, 6,132 ventilators are due by June 1, 2020. On March 27, [General Motors \(GM\) announced it was partnering with Ventec Life Systems](#), a ventilator manufacturer, to produce ventilators at GM's plant in Kokomo, Indiana.
- HHS also [announced](#) on April 8 a second contract for ventilator production rated under the DPA to Phillips. This contract is for \$646.7 million for the production of 2,500 ventilators to

be delivered to the SNS by the end of May 2020, and for a total of 43,000 ventilators to be delivered by the end of December 2020.

FEDERAL ACTIONS RELATED TO VENTILATORS

- For weeks, U.S. governors, mayors, and medical professionals have reported a widespread lack of ventilators to address the epidemic, a shortage far greater than what is available in the SNS.
- The Trump Administration has formed a Supply Chain Stabilization Task Force within FEMA, led by Rear Admiral John Polowczyk, tasked with identifying the medical supply needs in the United States, and working daily with global manufacturers to procure supplies. The Administration has stated that supplies are now being transported by air from both Asia and Europe into the United States (though quantities and a breakdown of which supplies are unclear). Rear Admiral Polowczyk shared on March 27 that he is actively working to procure up to 100,000 more ventilators.
- [Ford Motor Company](#) has announced a partnership with GE Healthcare to produce ventilators. Ford and GE have said the partnership expects to produce its first ventilators in April 2020, and will produce 50,000 ventilators within 100 days, and will have the capacity to produce 30,000 ventilators per month thereafter.
- On April 2, the President [ordered](#) HHS Secretary Alex Azar, in consultation with Acting Homeland Security Secretary Chad Wolf, to use authorities within the DPA to facilitate the supply of materials for the production of ventilators from the following manufacturers: General Electric Company; Hill-Rom Holdings, Inc.; Medtronic Public Limited Company; ResMed Inc.; Royal Philips N.V.; and Vyaire Medical, Inc.
- HHS Secretary Azar has also been tasked through [President Trump's executive order \(EO\) on hoarding prevention and price gouging](#) to take action as necessary to ensure continued access to medical supplies and equipment. Ventilators have been [designated](#) as medical resources needed to respond to the spread of COVID-19 and may be subject to action under this EO.
- Also, on March 27, the President issued an [EO delegating additional authority under the DPA](#), which, in addition to guaranteeing private loans and provisions to enable domestic production capabilities, also established [Peter Navarro](#), the Assistant to the President for Trade and Manufacturing Policy, as the National Defense Production Act Policy Coordinator.
- As part of the CARES Act, signed into law on March 27, Congress provided \$127 billion for emergency medical response efforts, including the purchase of ventilators and other medical equipment.

FOOD AND DRUG ADMINISTRATION (FDA) EFFORTS TO IMPROVE VENTILATOR ACCESS

- On March 22, FDA released [guidance](#) regarding ventilators and other respiratory devices. This guidance provides information for manufacturers about the modifications that manufacturers,

hospitals and health care professionals may make to existing ventilators; how manufacturers may increase production; how health care entities may safely utilize other types of ventilators and allows for the use of ventilators beyond their intended shelf life.

- The industry guidance allows health facilities to modify ventilators, anesthesia gas machines and other respiratory devices, and their accessories, to address the COVID-19 public health emergency.
- Such modifications can include: the use of powered emergency ventilators and anesthesia gas machines for patients needing mechanical ventilation; the use of ventilators intended for home use or during transport in medical facilities; the use of sleep apnea devices, such as CPAP machines; and the use of oxygen concentrators when medically necessary and clinically appropriate.
- On March 24, HHS Secretary Azar authorized [emergency use of medical devices](#). FDA has stated that it is seeking input from foreign and domestic manufacturers about pursuing an Emergency Use Authorization (EUA) to allow the distribution of their not-yet-approved ventilators within the United States. This can include manufacturers who have not previously engaged in medical device manufacturing. Manufacturers can reach out to FDA at CDRH-COVID19-Ventilators@fda.hhs.gov to begin a conversation with FDA about pursuing an EUA.

HOW STATES CAN OPTIMIZE CURRENT SUPPLIES AND ACCESS ADDITIONAL SUPPLIES, ACCORDING TO ADMINISTRATION

- The Centers for Disease Control and Prevention (CDC) has provided [strategies to health care professionals](#) on how hospitals and health systems can optimize ventilator allocations and deployment.
- States in need of additional ventilators for response efforts to COVID-19 should contact FEMA, which is coordinating procurement and DPA strategies for personal protective equipment (PPE) and medical equipment.
- If your state health department does not have ventilators or other devices available for distribution, state governments are also able to request federal assistance from the [SNS](#). State governors or their designees are responsible for requesting deployment of SNS assets.
- To request items, governors or their designees should send their requests to HHS.SOC@HHS.gov.

HOW INDIVIDUALS AND BUSINESSES CAN HELP THE EFFORT

- FEMA has [provided links](#) for individuals and private sector businesses interested in donating or selling medical equipment to respond to the COVID-19 emergency.
 - Businesses that have medical supplies or equipment to donate are asked to provide details of the offer through their online medical supplies and equipment [form](#).

- Businesses that want to sell medical supplies or equipment to the federal government should email specifics to covidsupplies@fema.dhs.gov.
- FDA has provided [contact information](#) for manufacturers interested in importing medical devices, including ventilators.
- Medtronic, one of the leading U.S. manufacturers of ventilators, [announced March 30](#) that it will make available the design, plans, and specs for a less complicated ventilator model to manufacture. According to the company, this new open sourcing program will let others access the information needed to develop more ventilators that can be used in hospitals and home settings. To access the specifications, businesses can register [here](#).



April 15, 2020

UPDATED - Overview of COVID-19 Testing Efforts

COMMITTEE ON ENERGY & COMMERCE

PURPOSE

- This document addresses issues related to COVID-19 testing. 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

- To date, Centers for Disease Control and Prevention (CDC), public, and commercial laboratories have tested over 2.39 million samples.
- On average, between 110,000–130,000 diagnostic tests are now conducted each day. The Administration has stated that it anticipates scaling up testing over the next four to six weeks, and that it eventually expects increasing the number of tests run each day to four to five times the current average.
- Serological tests, which detect the body's immune response to infections, such as COVID-19, rather than diagnostic tests, which detect the virus itself, can be used to help determine whether a person has previously contracted COVID-19 and developed antibodies. Because serological tests are believed to be less complex than diagnostic tests, the Food and Drug Administration (FDA) has said it will not object to these tests being developed and distributed for use in laboratories or by health care workers at point of care, as long as the test has been validated, the manufacturer has notified FDA, and the test includes warnings, including one noting that the test has not been reviewed by FDA. Nevertheless, FDA has encouraged serological test manufacturers to request an emergency use authorization (EUA) for their tests and [has granted one such serology test EUA](#). A list of tests that have received an EUA is available [here](#) and a list of manufacturers who have notified FDA that they intend to market a test without FDA authorization is available [here](#).
- The scientific community is working hard to determine parameters of use for serological tests; we currently know that the presence of specific antibodies means an individual has been exposed to the COVID-19 virus, but it is not fully understood how much protective immunity this confers to an individual. The Administration has stated that it expects to have approximately 20 million serological tests available each month in the future.
- The Federal Emergency Management Agency (FEMA) announced that the 41 Community-Based Testing Sites (CBTS) would be transitioned to state and local oversight on April 10, later [issuing an advisory](#) to clarify that states needed to confirm whether they would seek to

transition to full state control with federal supply assistance, or to continue under current operations. Those states that have requested continued FEMA presence at their CBTS have been asked to notify FEMA by May 30 if they are still not ready to transition.

- On March 27, FDA issued an EUA of a [point-of-care \(POC\) test by Abbott](#) that can reportedly deliver positive results in as little as five minutes and negative results in 13 minutes. Abbott currently has 18,000 machines in place across the country in different health facilities producing 50,000 tests per day in prioritized high-risk areas and is working to increase production to 100,000 tests per day. The Department of Health and Human Services (HHS) announced on April 6 that it has purchased 1,200 Abbott POC tests for distribution to state, territorial, and tribal public health labs. This is in addition to the authorization of two rapid POC tests, by Cepheid and Mesa, that can be used in laboratories and certain patient settings, providing results in up to 45 minutes. Cepheid is working to eventually produce up to ten million tests per month.
- Most COVID-19 diagnostic tests rely on a nasopharyngeal or oropharyngeal swab to collect a sample from a patient. On April 13, FDA issued an EUA to Rutgers RUDCR Infinite Biologics for a test that uses saliva, the first such authorization for COVID-19. While this test will still need to be conducted in a health care setting, this development is promising because health care providers will not be required to directly handle swabs and risk further exposure to coronavirus.
- CDC also partnered with Apple to release an app and [website](#) that helps guide individuals through a series of questions to determine if they should seek care for COVID-19.
- Ongoing limitations in testing capability may be due to testing supply access, including personal protective equipment (PPE) supply. For instance, some areas are preserving their test kits for high-priority patients or limiting tests at certain sites to ensure they do not run out of testing supplies or PPE. Laboratories also have different platforms that are not interchangeable, so not all tests can be performed everywhere, and some continue to experience shortages of testing supplies, including swabs and reagents. There are also reports of lack of plastic materials for use by manufacturers for their test kits, harming capacity of making these kits. Lab workforce capacity may be another reason for limitations in testing capabilities.

PRIORITIES FOR WHO SHOULD BE TESTED FOR COVID-19

- CDC has noted that health care providers should use their best judgment on which patients should be tested. On March 24, [CDC issued an additional revision to its testing priorities criteria](#). These [include](#):
 - Priority 1: Hospitalized patients with symptoms compatible with COVID-19 and symptomatic health care workers;
 - Priority 2: Symptomatic individuals who are at highest risk, which includes patients in long-term care facilities, older adults, individuals with chronic medical conditions and/or an immunocompromised state that may put them at higher risk, and first responders; and

- Priority 3: As resources allow, testing of individuals in communities with rapidly increasing hospital cases, including symptomatic critical infrastructure workers, symptomatic individuals not in priority 1 or priority 2, health care workers and first responders, and individuals with mild symptoms in communities experiencing high COVID-19 hospitalizations.
- If someone is experiencing symptoms of COVID-19 (fever, cough, shortness of breath), and may have had contact with a person with COVID-19, they should call a health care provider first before seeking medical care.
- CDC has compiled a [one pager](#) with links to all state and territorial health department websites. In addition, some states have put forward a list of available sites for where an individual can be tested.

PUBLIC HEALTH LAB TESTING

- For public health labs, [CDC provides the necessary test kits](#). Clinicians looking to access these tests should work with either their public health laboratory or the laboratories they routinely work with to see how best to access validated tests for COVID-19.
- According to [CDC](#), 98 public health labs currently have the capacity to administer a COVID-19 test. This includes at least one public health lab in each of the 50 states, Washington, D.C., Guam, and Puerto Rico.
- Additional information can be found at [APHL's website](#). State and local questions can be directed to the Emergency Operations Center at eoc@aphl.org.

FDA OVERSEES DIAGNOSTIC TESTING

- FDA has regulatory authority over in vitro diagnostics that are used to diagnose a disease or condition, including COVID-19. FDA states that it has actively been working with CDC, interested states, labs, and commercial developers to [provide guidance](#) on how to expand access to diagnostic tests, while also ensuring accurate tests.
- To assist labs and test developers, FDA has released [templates](#) detailing the information FDA will need in order to authorize a lab test under an EUA.
- FDA has released a [frequently asked questions page](#) to assist labs and developers pursuing an EUA. If labs and developers have additional questions, they can reach FDA 24 hours a day, seven days a week by calling 1-888-INFO-FDA (1-888-463-6332) and pressing *, or email CDRH-EUA-Templates@fda.hhs.gov.
- FDA has [issued guidance](#) to allow laboratory test kit manufacturers and laboratories certified to perform high complexity testing to begin testing individuals following a notification to FDA, and submission of an EUA application and demonstration of validation within 15 days. A [new FDA](#)

[policy](#) also allows states to work with the agency to set up a system in which the state takes responsibility for authorizing lab tests.

- **As of April 13, in addition to the test offered by CDC, FDA has [issued EUAs](#) for 34 in vitro diagnostic products, including two rapid POC tests. [Seven states are authorizing the use of tests conducted by labs within their state boundaries, and FDA has authorized nearly 90 laboratory-developed tests.](#)**
- To help mitigate shortages of testing supplies, FDA has [issued guidance](#) for laboratories to consider using an alternative foam swab. A senior official has reported to the Committee that there are currently six-to-seven million of these swabs in the supply chain. This foam swab is also useful because it does not require health care providers to change their PPE after each sample is taken, helping to administer more widespread testing without utilizing additional PPE.
- On March 24, FEMA announced it would be [utilizing the Defense Production Act \(DPA\) to allocate 60,000 test kits](#) where they are needed, though later stated the agency was able to secure the test kits without evoking the DPA.
- For laboratories experiencing difficulty in accessing the necessary materials to run diagnostic tests for COVID-19, [FDA has identified acceptable alternatives that can be used.](#)