



April 15, 2020

## UPDATED - COVID-19: Issues Related to Ventilators

### COMMITTEE ON ENERGY & COMMERCE

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#### 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](mailto: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](mailto: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](mailto: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](#).