



March 30, 2020

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, with an additional 12,700 ventilators as part of the Strategic National Stockpile \(SNS\)](#).
- 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.
- On March 17, the Pentagon [announced](#) it would supplement the SNS with an additional 2,000 ventilators, noting these devices are [different from civilian equivalent requiring special training](#) and may have [single-use limitations](#).
- 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. GM estimates it will be able to deploy its first ventilators in April, and will eventually have the ability to produce up to 10,000 ventilators per month.
- After GM's announcement, the Trump Administration [ordered](#) the company to accept, perform, and prioritize federal contracts under the Defense Production Act (DPA) for the production of such ventilators.
- Other manufacturers, including [Ford](#) and [Tesla](#), have announced they will begin production of ventilators, though it is not clear how soon ventilators will be available to be deployed.
- The Trump Administration has formed a Supply Chain Stabilization Task Force within the Federal Emergency Management Agency (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 is unclear). **Rear Admiral Polowczyk shared on March 27 that he is actively working to procure up to 100,000 more ventilators.**

- U.S. Department of Health and Human Services (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 INFORMATION PROVIDED FROM THE 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](#).