Personal Protective Equipment

The health care workers who are on the frontlines of responding to the coronavirus disease (COVID-19) outbreak are currently grappling with severe shortages of personal protective equipment (PPE). Such equipment includes eye protection, isolation gowns, facemasks, and N95 respirators. These products are critical to protecting the individuals caring for, testing, and screening patients with COVID-19. Many providers have taken proactive steps themselves to procure more supplies, taking to social media seeking donations of PPE. Politico and other news outlets are currently tracking hospital capacity, patient surge, and providers’ ability to obtain PPE, and collecting stories about how COVID-19 is impacting providers’ own health.

Public Health Emergency Determination and Personal Respiratory Device EUA

On February 4, 2020, U.S. Department of Health and Human Services Secretary Alex Azar determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the HHS Secretary declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak. Health care personnel can access a list of authorized respirators here.

PREP Act Declaration

On March 10, 2020, Secretary Azar took further action by issuing a declaration pursuant to the Public Readiness and Emergency Preparedness (PREP) Act, which authorizes the Secretary to provide liability immunity for activities related to medical countermeasures against COVID-19.

DPA Invocation

On March 18, 2020, President Trump invoked the Defense Production Act (DPA), which allows the federal government to compel companies through loans, loan guarantees, purchases and purchase commitments to prioritize and expedite the manufacture of medical supplies that are in short supply. The President delegated the key authority for implementing the DPA to Secretary Azar.

Separately, General Motors Co. Chief Executive Officer Mary Barra offered to manufacture hospital ventilators in auto factories closed because of the coronavirus outbreak, according to top White House economic adviser Larry Kudlow.

FDA Recommendations Regarding Gowns and Surgical Masks

On March 11, 2020, the Food and Drug Administration (FDA) issued a letter to health care providers intended to aid in the management of gowns and surgical masks. The letter outlines recommended conservation strategies for use by health care organizations and personnel. For surgical masks and gowns, the FDA recommends that health care providers follow these strategies based on the supply needs of their health care organization. Gowns that are ANSI/AAMI PB70 Level 1 and 2 barrier protection are considered non-surgical isolation gowns. Gowns that have ANSI/AAMI PB70 Level 3 and 4 barrier protection and/or can be used for a sterile procedure are considered surgical gowns or surgical isolation gowns.
The FDA notes that it is collaborating with manufacturers of surgical masks and gowns to better understand the current supply chain issues related to the COVID-19 outbreak, and to avoid any widespread shortages of these products. According to an FAQ issued by the FDA on shortages of surgical masks and gowns, the agency is also collaborating with manufacturers of PPE to help facilitate mitigation strategies related to the COVID-19 outbreak. Medical device manufacturers are not required to notify the FDA when they become aware of a circumstance that could lead to a device shortage or meaningful disruption in the supply of that device in the United States.

For potential or actual supply issues, email information to the FDA at deviceshortages@fda.hhs.gov. Anyone – user, patient, manufacturer, or organization within the supply chain – who is aware of a delay in distribution of a product, and/or anticipates a potential or actual shortage, can notify the agency.

FDA Recommendations Regarding Gloves

On March 20, 2020, the FDA issued a letter to health care providers intended to aid in the management of surgeons' gloves and patient examination gloves. The conservation strategies for use by health care organizations and personnel are categorized for a range of needs and supply levels and are intended to assist health care organizations as they determine procedures during the COVID-19 pandemic.

The conservation strategies described in the letter are intended to augment, and not intended to replace, specific controls and procedures developed by health care organizations, the Centers for Disease Control and Prevention (CDC), or the CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC) to aid in infection prevention and control. These strategies are not limited to use in the care of patients infected with COVID-19. Health care organizations may find additional useful information in guidelines on modifications to medical standards of care during a crisis.

CDC COVID-19 Interim Infection Prevention and Control Recommendations

The CDC has issued guidance for health care personnel caring for patients with confirmed or possible COVID-19 infection. Based on the current COVID-19 situation and availability of PPE, CDC has issued specific recommendations. CDC instructs health care personnel to adhere to Standard, Contact, and Airborne Precautions when caring for patients with COVID-19 infection. These precautions include the use of PPE.

PPE Availability

CDC communicates regularly with health care industry partners, as well as PPE manufacturers and distributors, to assess availability of PPE. Given decreases in exports from select countries and increases in demand due to the global outbreak, manufacturers of select types of PPE are reporting increased volume of orders and challenges in meeting order demands. Specific challenges are being reported for N95 respirators and facemasks. Orders received are up to 10-fold normal demand for these items. The CDC states that plans for surge manufacturing globally are underway.

Distributors of select types of PPE are also reporting an increased volume of orders from customers and challenges in meeting order demands for PPE, specifically for N95 respirators and facemasks. Due to decreased exports from overseas by manufacturers, distributors are reporting that these items are being placed on allocation, and orders are being filled based on historical demands for existing customers. At present, shortfalls may be anticipated to continue for the next 3–4 months.

The CDC has stated that U.S. health care systems are reporting higher than normal use for N95 respirators, due to fit testing and stockpiling, to prepare for possible widespread COVID-19 transmission. Orders are being placed in higher volumes to meet these needs. Some health care systems have begun reporting that orders for N95 respirators and facemasks are not being filled or are only being partially filled by distributors. In addition, major
pharmacy chains have reported stock outs of N95 respirators and facemasks with delays in replenishment of inventory.

CDC is encouraging health care systems to implement the following strategies to conserve supplies:

- Strategies for Optimizing the Supply of Eye Protection
- Strategies for Optimizing the Supply of Isolation Gowns
- Strategies for Optimizing the Supply of Face Masks
- Strategies for Optimizing the Supply of N95 Respirators

In addition to the CDC’s Interim Infection Prevention and Control Recommendations for COVID-19, the agency has issued and FAQ on Infection Control and an FAQ About PPE.

**FDA Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices**

On March 22, 2020, the FDA issued an immediately in effect guidance outlining a policy intended to help increase availability of ventilators and their accessories as well as other respiratory devices during the COVID-19 pandemic.

First, the guidance describes the agency’s intention to exercise enforcement discretion for certain modifications to these FDA-cleared devices. Normally, any time a manufacturer or user makes a modification to a ventilator device, those modifications can often trigger an FDA premarket review, which can delay the time it takes to get these devices to the bedside. The guidance also helps manufacturers ramp up their manufacturing by adding production lines or alternative sites to start manufacturing ventilator parts. In recognition of the current pandemic situation, and to ease regulatory burden on manufacturers, the FDA is being flexible in not enforcing the premarket review requirement for these modifications. Second, hospitals and health care professionals may use ventilators intended for other environments. The FDA also provides recommendations for other alternatives that should be considered such as devices for treating sleep apnea, continuous positive airway pressure (CPAP), devices. The FDA’s policy also applies to health care facilities that use ventilators beyond their indicated shelf life, which should increase ventilator capacity. Finally, the agency encourages manufacturers, whether foreign or domestic, to talk to FDA about pursuing an EUA, which would allow them to distribute their ventilators in the United States. This includes U.S.-based manufacturers that were previously engaged in making medical devices, but which have capabilities to increase supply of these devices.

**FDA Recommendations Regarding Ventilators and Accessories and Other Respiratory Devices**

The FDA also issued a letter to health care providers and facilities providing recommendations based on the recently issued guidance, regarding the use of devices with patients who develop respiratory compromise from COVID-19 or other respiratory disorders.

The FDA notes that it is collaborating with manufacturers of ventilators, ventilator accessories, and other respiratory devices to better understand the current supply chain issues related to the COVID-19 outbreak and to avoid any widespread shortages of these devices.

For potential or actual supply issues, email information to the FDA at device shortages@fda.hhs.gov. Anyone — user, patient, manufacturer, or organization within the supply chain – who is aware of a delay in distribution of a product, and/or anticipates a potential or actual shortage, can notify the agency.