



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-10, 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 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 Instructions for PPE and Device Manufacturers

On March 24, 2020, the FDA issued [instructions](#) to manufacturers importing PPE and other devices to increase U.S. supplies to support the U.S. response to COVID-19. These instructions to importers clarify the types of PPE that can be imported without engaging with FDA. They also include information about the type of information importers can submit to facilitate their entries. The agency has adjusted its import screening to further expedite imports of legitimate products and will continually monitor import systems to prevent and mitigate any potential issues.

FDA EUA Relating to Ventilators

On March 24, 2020, the FDA issued an [EUA](#) for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators, ventilator tubing connectors, and ventilator accessories. The products that are eligible for inclusion under this EUA are those that are not currently marketed in the U.S., or that are currently marketed in the U.S. but a modification is made to the device that would trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA. Manufacturers and other stakeholders may submit a request to FDA under the process outlined in the EUA to have their device(s) added to the EUA.

FDA Enforcement Policy for Face Masks and Respirators

On March 25, 2020, the FDA issued [guidance](#) to provide a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for health care professionals during the pandemic.

FDA recognizes that, when alternatives, such as FDA-cleared masks or respirators, are unavailable, individuals, including health care professionals, might improvise PPE. FDA does not intend to object to individuals' distribution and use of improvised PPE when no alternatives, such as FDA-cleared masks or respirators, are available.

To ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, for the duration of the public health emergency FDA does not intend to object to the distribution and use of face masks (not including respirators) that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face mask does not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, reports or corrections and removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830.

FDA does not intend to object where, for the duration of the declared public health emergency, surgical masks are distributed and used without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, and the surgical masks do not create an undue risk in light of the public health emergency.

To facilitate the safe reuse and conservation of PPE for the duration of the public health emergency, FDA is interested in interacting with manufacturers on the reprocessing of otherwise disposable N95 particulate filtering facepiece respirators (and other Filtering Facepiece Respirators) to facilitate marketing authorization through an EUA for reprocessed devices. FDA recommends that firms contact FDA and provide the following information to CDRH-COVID19- SurgicalMasks@fda.hhs.gov, if available. FDA will work with reprocessors through its EUA process to facilitate expedited evaluation of the request.

For devices that do not fall within the scope of the March 2, 2020 or March 24, 2020 EUAs, FDA is interested in interacting with manufacturers on additional device-specific EUAs. This may include manufacturers of masks and

respirators that are not currently legally marketed in the US as well as manufacturers who have not previously manufactured masks or respirators with capabilities to increase supply of these devices.

CDC PPE Burn Rate Calculator

The CDC has created a spreadsheet-based [model](#) that provides information for health care facilities to plan and optimize the use of PPE for response to COVID-19. Similarly, non-healthcare facilities may find this tool useful for planning and optimizing PPE use as part of the response to COVID-19. This tool can also be used for planning PPE use outside the context of COVID-19, where PPE shortages may also occur due to supply chain issues related to the COVID-19 response.

FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers

On March 29, 2020, the FDA issued [guidance](#) to provide a policy to help expand the availability and capability of sterilizers, disinfectant devices, and air purifiers during this public health emergency.

To help ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, during the declared public health emergency, FDA does not intend to object to limited modifications to the indications or functionality of FDA-cleared or FDA-approved sterilizers, disinfectant devices and air purifiers pertaining to a device's virucidal effectiveness against SARS-CoV-2, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.8112 or submission of a Premarket Approval Application (PMA) Supplement under section 515 of the FD&C Act and 21 CFR 814.3913, Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR 830 and 21 CFR 801.20.

In addition, during the declared public health emergency, FDA does not intend to object to the distribution and use of sterilizers, disinfectant devices, and air purifiers that are intended to be effective at killing the SARS-CoV-2 virus but do not already have FDA marketing authorization, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81 or submission of a PMA Supplement under section 515 of the FD&C Act and 21 CFR 814.39, Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR 830 and 21 CFR 801.20.

The guidance gives recommendations regarding design, evaluation, and validation of performance relevant to the enforcement policies. FDA encourages firms to discuss any alternatives to these recommendations with FDA. FDA also recommends that the devices described in the guidance include labeling that helps users better understand device modifications.

FDA EUA for the Battelle Decontamination System

On March 29, 2020, the FDA issued an [EUA](#) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ at the Battelle Memorial Institute, for use in decontaminating compatible N95 or N95-equivalent respirators for reuse by health care personnel to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic. Upon issuance of the EUA, Secretary Azar released the following statement: "Getting PPE to the heroic health care workers on the frontlines of the pandemic is one of President Trump's top priorities. FDA's quick action in authorizing Battelle's technology will help hospitals get the maximum use out of their N95 respirators, while we work on multiple fronts to expand supplies available to them. FDA worked closely with the company and responded rapidly to each of their requests, as the agency has done with all emergency use authorizations during this crisis. If you're

a company who wants to help get our healthcare workers what they need to stay safe—or help fight the pandemic in any other way—our door is open to you."

FDA Enforcement Policy for Gowns, Other Apparel, and Gloves

On March 30, 2020, the FDA issued [guidance](#) to provide a policy to help expand the availability of surgical apparel for health care professionals, including gowns (togas), hoods, and surgeon's and patient examination gloves during this pandemic.

To help foster the availability of gowns and apparel during the COVID-19 public health emergency, FDA does not intend to object to the distribution and use of gowns not intended for use as "surgical gowns" and other low-to-minimal barrier protection surgical apparel that does not comply with the following regulatory requirements where the gowns and apparel do not create an undue risk in light of the public health emergency: Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, reports of corrections and removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR Part 801.20. FDA does not intend to object to the distribution and use of ANSI/AAMI PB70 Level 3 moderate-to-high barrier protection surgical gowns that do not comply with the following regulatory requirements, where such surgical gowns do not create an undue risk in light of the public health emergency: Prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,20 Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.

Additionally, FDA does not intend to object to the distribution and use of patient examination gloves that do not comply with the following regulatory requirements, where the gloves do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,26 Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, reports of corrections and removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. Finally, FDA does not intend to object to the distribution and use of surgeon's gloves that do not comply with the following regulatory requirements where the surgeon's gloves do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,31 Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.