

April 2, 2020

## Personal Protective Equipment and Ventilators for COVID-19: FDA Regulation and Related Activities

The Coronavirus Disease 2019 (COVID-19) pandemic has affected the medical product supply chain both globally and domestically. Perhaps most salient has been the impact of COVID-19 on the availability of personal protective equipment (PPE), such as gowns and masks, for health care personnel, and respiratory devices, including ventilators, for patients.

In the United States, respiratory devices and PPE used in the health care setting meet the definition of a medical *device* under the Federal Food, Drug, and Cosmetic Act (FFDCA) and are regulated by the U.S. Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS). This In Focus provides an overview of how these devices are regulated and summarizes the FDA response to mitigate reported PPE and ventilator shortages related to COVID-19.

### FDA Regulation of PPE and Ventilators

In general, any company interested in distributing medical PPE or ventilators—a type of respiratory device—in the United States would need permission from FDA. Pursuant to its authorities in the FFDCA, FDA regulates medical devices based on the risk they pose to consumers. There are three regulatory classes of medical devices with different applicable requirements: class I (low risk), class II (moderate risk), and class III (high risk). Class II devices are subject to special controls, and class III devices are subject to premarket approval (PMA). However, all devices regardless of regulatory class are subject to general controls (e.g., establishment registration, good manufacturing practices) unless exempt. Premarket notification, which requires a 510(k) submission, is a type of general control that applies to certain class I and most class II devices, and requires manufacturers to submit certain materials to FDA at least 90 days prior to marketing (21 U.S.C. §360(k)). To receive a 510(k) clearance, the manufacturer must demonstrate that the device proposed to be marketed is *substantially equivalent* to a device already on the market.

Generally, a 510(k) submission includes the regulatory class of the device, actions taken to comply with relevant performance standards, proposed labeling, and a statement describing how the device is similar to or different from a predicate device, among other things (21 C.F.R. §807.87). There are certain circumstances under which a change to an existing device would require a new 510(k) submission. According to FDA guidance, such changes include, among other things, labeling, technology, and/or materials used.

### Personal Protective Equipment (PPE)

PPE refers to single-use protective gowns, gloves, masks, and respirators intended to *block transmission* of infection

from blood, body fluids, or respiratory secretions. Regulatory requirements vary by type of PPE, which are generally class I or II devices.

**Medical gloves** are used to protect an individual from the spread of infection during medical procedures and examinations. Medical gloves are class I devices that require a 510(k) clearance, and include patient examination gloves (21 C.F.R. §880.6250) and surgical gloves (21 C.F.R. §878.4460).

**Medical gowns** (21 C.F.R. §878.4040) are a type of surgical apparel used to protect against infection or illness if contact with infectious liquid or solid material is likely. Manufacturers are encouraged to comply with national consensus standards so their gowns provide any one of four levels of protection: level 1 (minimal risk), level 2 (low risk), level 3 (moderate risk), and level 4 (high risk). While medical gown terminology is not standardized, FDA generally regulates medical gowns in three categories:

- *Nonsurgical gowns* are intended for use in low- or minimal-risk patient isolation situations (level 1-2) and are class I devices exempt from premarket review (i.e., 510(k) notification or PMA approval).
- *Surgical isolation gowns* are used in moderate- to high-risk situations (level 3-4) and are class II devices subject to 510(k) notification and special controls (e.g., performance standards).
- *Surgical gowns* are generally used during surgical procedures but can be used for any risk level (levels 1-4) and are class II devices subject to 510(k) notification and special controls.

**Face masks** are a broad category of PPE that include surgical masks and filtering facepiece respirators (FFRs). FFRs and other respirators for occupational use (e.g., N95 FFRs) are subject to certification and approval by the National Institute for Occupational Safety and Health (NIOSH). FFRs intended for nonmedical or general public use are not subject to FDA oversight.

FFRs intended for medical use (e.g., *surgical* N95 FFRs) are subject to both NIOSH approval and FDA regulation as devices. Surgical masks and surgical N95 FFRs (21 C.F.R. §§878.4040 and 878.6260)—both class II medical devices requiring 510(k) notification, unless exempt—provide a physical barrier to fluids and particulate matter by covering the nose or mouth. Both are tested for fluid resistance, filtration efficiency, flammability, and biocompatibility. Surgical masks are loose-fitting, while surgical N95 FFRs form a tight seal around the nose and mouth, providing very efficient filtration (i.e., 95%) of airborne particles.

## Ventilators

Ventilators and their accessories (21 C.F.R. Part 868, Subpart F) assist patients experiencing respiratory difficulties with breathing either manually or by mechanical control in a health care or home setting. In contrast to PPE, which are intended to be protective devices, ventilators and their accessories are intended to *mitigate respiratory symptoms* associated with COVID-19. Ventilators and their accessories are generally class II devices subject to 510(k) notification and certain special controls. Unlike PPE, ventilators and their accessories are generally reusable, subject to certain requirements.

## FDA Response to Address Shortages of PPE and Respiratory Devices

FDA and other agencies have taken various steps to prevent and mitigate shortages of critical PPE and respiratory devices, examples of which are provided in this section.

FDA cannot compel firms to make PPE or ventilators, although it may expedite review, enable access to unapproved devices, and exercise regulatory flexibility to reduce barriers to market entry. Through emergency use authorization (EUA), FDA has enabled access to respirators and ventilators that have not received agency clearance (21 U.S.C. §360bbb-3). As of the date of this In Focus, three EUAs are in effect for respirators and one for ventilators. Together, the three EUAs for respirators authorize the use—in health care settings by health care personnel during the COVID-19 outbreak—of (1) certain NIOSH-approved FFRs not regulated by FDA and those that have passed the recommended shelf life, as well as certain NIOSH-approved air purifying respirators; (2) certain imported FFRs that are not NIOSH-approved; and (3) the Battelle Decontamination System for compatible N95 or equivalent respirators. The EUA concerning ventilators authorizes use of ventilators; anesthesia gas machines and positive pressure breathing devices modified for use as ventilators; ventilator tubing connectors; and ventilator accessories not currently marketed in the United States or that are currently marketed in the United States, but have been modified in a way that would trigger a new 510(k) submission.

FDA has described in guidance the conditions under which entities may distribute nonrespirator face masks, gloves, gowns, and other apparel without 510(k) clearance or registering with the agency. Generally, distributing these devices without registration and FDA clearance would be a violation of the FFDCRA and FDA regulations, subject to enforcement action. However, FDA states it will not take enforcement action during the COVID-19 outbreak if the entity distributing the covered PPE complies with the criteria specified in guidance (e.g., fluid standards testing).

FDA also has sent letters to health care providers recommending strategies to conserve gowns and masks, as well as describing how they may consider alternative devices for patients requiring respiratory support if ventilators are in shortage. For example, subject to appropriate monitoring, emergency transport ventilators, anesthesia gas machines, and continuous positive airway pressure (CPAP) machines could be used.

FDA is working with other agencies on the federal response to increase availability of PPE and ventilators. For example, FDA is working with the Federal Emergency Management Agency (FEMA) on supply chain issues, including importation of medical products to support the U.S. response. FDA also has provided instructions to manufacturers interested in importing PPE and other devices, clarifying what information needs to be submitted to FDA and/or U.S. Customs and Border Protection (CBP).

## Considerations for Congress

Until recently, FDA's ability to monitor potential device shortages was limited, at least compared to drugs. For example, unlike drug manufacturers, medical device manufacturers have not been required to report to FDA interruptions in manufacturing or product discontinuances. The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136) expands FDA's authority to address shortages of PPE and other medical devices. Specifically, the law requires manufacturers of certain devices—those that are critical during a public health emergency or for which FDA determines that information on potential meaningful supply disruptions is needed during, or in advance of a public health emergency—to report to FDA interruptions and discontinuances in manufacturing. It also explicitly authorizes FDA to take certain actions to mitigate shortages and requires FDA to make public a list of devices that are in shortage. Congress could consider expanding reporting requirements in future legislation to include requiring manufacturers of medical devices (and drugs) to report to FDA actual or forecasted increases in demand that may lead to a shortage or actions taken by other regulatory authorities that could affect U.S. supply (e.g., export restrictions).

Congress also could further reduce barriers to market entry for devices. However, FDA has already waived various requirements, in some cases allowing for distribution and purchase of devices that have not been reviewed by the agency for safety or effectiveness. In addition, waiving regulatory requirements is not without risk and may affect the safety, effectiveness, or quality of PPE and ventilators. Furthermore, some recommendations issued by FDA may conflict with those of physician groups and other stakeholders. For example, the American Society of Anesthesiologists issued guidance in February 2020 discouraging the use of CPAP machines among COVID-19 patients, citing concerns that the devices may increase the spread of COVID-19 by pumping the virus into the air.

As mentioned, FDA cannot require an entity to make or increase production of a device. However, other mechanisms in federal law allow for required increases in production. One example is the Defense Production Act (DPA), which was invoked by President Trump on March 18, 2020 (see CRS Insight IN11231, *The Defense Production Act (DPA) and COVID-19: Key Authorities and Policy Considerations*).

---

**Agata Dabrowska**, Analyst in Health Policy  
**Victoria R. Green**, Analyst in Health Policy

## Disclaimer

This document was prepared by the Congressional Research Service (CRS). CRS serves as nonpartisan shared staff to congressional committees and Members of Congress. It operates solely at the behest of and under the direction of Congress. Information in a CRS Report should not be relied upon for purposes other than public understanding of information that has been provided by CRS to Members of Congress in connection with CRS's institutional role. CRS Reports, as a work of the United States Government, are not subject to copyright protection in the United States. Any CRS Report may be reproduced and distributed in its entirety without permission from CRS. However, as a CRS Report may include copyrighted images or material from a third party, you may need to obtain the permission of the copyright holder if you wish to copy or otherwise use copyrighted material.