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Personal Protective Equipment (PPE) and COVID-19: FDA Regulation and Related Activities

The Coronavirus Disease 2019 (COVID-19) pandemic has affected the medical product supply chain globally and domestically. The impact of COVID-19 on the availability of personal protective equipment (PPE), such as gowns, gloves, respirators, and surgical masks, for health care personnel continues to be a concern.

PPE is generally worn by health care personnel to protect the wearer from infection or illness from blood, body fluids, or respiratory secretions. In the United States, PPE intended for use in the cure, mitigation, treatment, or prevention of disease meet the definition of a medical device (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). PPE that do not meet the FFDCA definition of device (i.e., not intended for medical use) are not regulated by FDA. This In Focus provides an overview of how FDA regulates PPE and summarizes the agency's response to mitigate reported PPE shortages related to COVID-19.

FDA Regulation of PPE

In general, any company interested in distributing medical PPE 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 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 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, a manufacturer must demonstrate that the device proposed to be marketed is *substantially equivalent* to a device already on the market.

In general, 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.

Regulatory requirements vary by type of PPE, which are generally class I or II devices.

Medical Gloves

Medical gloves are used to protect the wearer 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

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 minimal-to-low 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 certain 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 certain special controls.

Surgical Masks and Filtering Facepiece Respirators

Masks are a broad category of PPE that include surgical masks and filtering facepiece respirators (FFRs). FFRs intended for medical use (e.g., *surgical* N95 FFRs) are subject to both National Institute for Occupational Safety and Health (NIOSH) approval and FDA regulation as devices. Surgical masks and surgical N95 FFRs (21 C.F.R. §§878.4040 and 880.6260)—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.

Face masks intended for nonmedical or public use generally are not subject to FDA oversight. FFRs and other respirators for occupational use (e.g., N95s for industrial use) are subject to NIOSH approval but not FDA oversight.

FDA Response to Address PPE Shortage

FDA has taken various steps to prevent and mitigate shortages of critical PPE. FDA cannot compel firms to make PPE, although the agency 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 PPE that have not received agency clearance (21 U.S.C. §360bbb-3). For example, FDA has issued several EUAs allowing the distribution and use—as PPE in health care settings by health care personnel during the COVID-19 pandemic—of certain NIOSH-approved respirators typically not intended for medical use; certain imported respirators that are not FDA-cleared or NIOSH-approved; and systems for decontaminating respirators intended for single use. FDA also has issued umbrella EUAs covering surgical masks, face shields, and other protective barriers that meet certain performance standards. Because FDA modifies, revokes, and grants new EUAs as the agency deems appropriate, this In Focus is not intended to track all PPE EUAs.

To further expand availability of PPE, FDA also has issued enforcement policies through guidance documents that further describe conditions under which entities may manufacture and distribute PPE during the COVID-19 public health emergency without complying with certain FDA requirements, such as clearance or registration. Generally, distributing these devices without complying with such requirements would be a violation of the FFDCA 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).

While FDA's actions have allowed additional entities to produce PPE for the U.S. market, waiving or modifying regulatory requirements is not without risk and may affect the safety, effectiveness, and quality of PPE. Throughout the duration of the COVID-19 pandemic, FDA has amended and revoked EUAs for medical products as the agency has received new scientific information about them. For example, on April 3, 2020, FDA issued an EUA allowing certain non-NIOSH-approved and non-FDA-cleared respirators to be imported from China in order to address reported shortages. However, FDA subsequently amended the EUA to exclude certain previously authorized respirators because they failed to demonstrate adequate filtration performance in testing conducted by NIOSH. Similarly, on May 1, 2020, FDA issued an umbrella EUA for use of protective barrier enclosures, by health care personnel in health care settings, that would provide an extra layer of barrier protection in addition to PPE. Such barrier enclosures were authorized for use when caring for or performing medical procedures on patients with known or suspected COVID-19 to prevent exposure to pathogenic biological airborne particulates. On August 20, 2020, FDA revoked the umbrella EUA, determining that individual

consideration of each EUA request for protective barrier enclosures would better protect the public health.

Considerations for Congress

Availability of and access to PPE has been a concern throughout the COVID-19 pandemic. PPE shortages have presented challenges for both health care personnel treating patients in medical settings and expansion of COVID-19 testing. Looking forward, the federal government may encounter similar challenges if a COVID-19 vaccine becomes available in the near future.

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 had 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) expanded 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, which the agency did for the first time on August 14, 2020, specific to devices in shortage during the COVID-19 public health emergency. Congress could consider expanding reporting requirements in future legislation to include requiring manufacturers of medical devices 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).

As mentioned, FDA cannot require an entity to make or increase production of a device, and FDA alone likely cannot address ongoing supply chain concerns. However, other mechanisms in federal law may be used to increase domestic production of PPE and other medical devices. One example is the Defense Production Act (DPA), which is described in more detail in other CRS products. In addition, various legislative proposals have been introduced in the 116th Congress to address concerns about vulnerabilities in the medical product supply chain. These proposals include, among other things, commissioning studies; expanding manufacturer reporting requirements and information sharing across agencies; restricting federal health programs from purchasing foreign-made medical products; and expanding and incentivizing domestic manufacturing.

A more detailed discussion of FDA's role in the medical product supply chain can be found in CRS Report R46507, *FDA's Role in the Medical Product Supply Chain and Considerations During COVID-19*, by Victoria R. Green, Agata Dabrowska, and Kate M. Costin.

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