Published on *The National Law Review* https://natlawreview.com

A Broad Emergency Use Authorization for Face Masks

Article By:

Leah G. Brownlee

Nicole E. Bothwell

Jennifer Tharp

On April 18, 2020, FDA issued a new Emergency Use Authorization ("EUA") relating to non-surgical face masks with broad coverage and implications for recent industry participants manufacturing face masks. The EUA applies to the broad class of non-surgical face masks used to cover a person's nose and mouth. Please see our prior blog post for summaries of previously issued enforcement guidance and other EUAs related to respirators.

The EUA describes this type of mask as follows: "a device, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It includes cloth face coverings. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as 'face masks' that offer a range of protection against potential health hazards." FDA, *Letter of Authorization for Face Masks (non-surgical)* (April 18, 2020), available here.

Generally, these types of masks are regulated as Class I devices that are exempt from premarket notification requirements. Note that surgical masks, which are Class II devices that provide fluid barrier protection and are not exempt from premarket notification requirements, are *not* covered under this EUA.

Scope of Authorization:

The EUA is limited to the use of face masks by members of the general public, including health care personnel ("HCP") in healthcare settings as personal protective equipment ("PPE"), "to cover their noses and mouths, in accordance with CDC recommendations, to prevent the spread of SARS-CoV-2 during the COVID-19 pandemic." Authorized masks are those masks that are intended for this purpose and meet the following requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);

2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection, and includes recommendations that would reduce the risk of such use; for example, the labeling might include recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; or as an alternative example,recommendations for use only by the general public; and

3. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling should not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction, nor should it be used for particulate filtration.

Authorized face masks must also comply with the Conditions of Use described in the EUA. Manufacturers of authorized face masks that comply with the Conditions of Use do not need to take any additional action under the EUA.

Waiver of Requirements:

Face masks authorized under this EUA are not required to meet the quality system requirements under 21 CFR 820, the registration and listing requirements under 21 CFR Part 807, and the reports of corrections and removals under 21 CFR Part 806. They are also exempt from labeling requirements, except that they must include the labeling elements specified in the Conditions of Authorization. Manufacturers are not exempt from medical device reporting requirements, including specifically the requirement to report adverse events of which they become aware.

Conditions of Use:

The EUA sets forth specific labeling requirements that align with the elements described under the Scope of Authorization. Manufacturers are also required to include instructions for recommended cleaning and/or disinfection processes, if applicable. As noted above, manufacturers must comply with medical device reporting requirements and have a process in place for reporting adverse events of which they become aware. Manufacturers must also maintain records of entities to which they distribute the face masks and the numbers of each product distributed. Finally, the EUA sets forth conditions related to advertising and promotion, which are intended to prevent representations that authorized face masks are safe or effective for the "prevention or treatment of patients during the COVID-19 pandemic."

Prep Act Implications:

As background, the PREP Act, codified at 42 USC §§ 247d-6d and 247d-6e, authorizes the Secretary of HHS to issue a declaration that provides immunity from liability associated with the use of medical countermeasures. Specifically, "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure" within the Secretary's specified period of emergency.

A PREP Act declaration is specifically for the purpose of providing immunity from liability, and the Secretary will issue a unique declaration delineating the scope of immunity according to the nature of the public health emergency. For example, the Secretary has previously issued PREP Act declarations related to the Ebola virus, the Zika virus, anthrax, and smallpox. The Secretary issued a PREP Act declaration relating to COVID-19 on March 17, 2020, with retroactive application effective from February 4, 2020. The COVID-19 declaration applies to defined Covered Persons and Covered Countermeasures.

The immunity covers recommended activities including “the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.” The scope of the immunity is expansive and covers a broad array of claims, though it should be noted it is not available for willful misconduct. The population of individuals for whom manufacturers are provided immunity include “any individual who uses or is administered the Covered Countermeasures **in accordance with this Declaration**.” However, the liability immunity “is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population.” In other words, if the Covered Countermeasures under the Declaration reach additional unintended recipients, the immunity would still apply.

This new EUA opens additional opportunities for coverage under the PREP Act’s immunity from liability since devices authorized for emergency use qualify as a Covered Countermeasure. This means that face masks that meet the terms of the EUA outlined above would be Covered Countermeasures under the Act. The coverage **still only would apply if one of the covered methods of distribution are used**. The distribution pathways include (1) activities connected to a federal agreement or contract or (2) activities otherwise authorized in accordance with the public health and medical response of a specified governmental or health organization with authority to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure.

For more information on how the PREP Act applies in the current COVID-19 emergency, see our blog post.

National Law Review, Volume X, Number 113