

Manisha Juthani, MD Commissioner



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## **Public Health Preparedness and Local Health Section**

DATE: June 22, 2022 OPHPR- 2022-005

TO: Department of Public Health Stakeholders and Partners

FROM: Erin McDermott, Health Program Supervisor

Office of Public Health Preparedness and Response

RE: FDA Extension of PPE

On April 18, 2020, in response to concerns relating to insufficient personal protective equipment (PPE) supply and availability of face masks, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA). The EUA was announced for authorizing the use of facemasks by members of the public, including health care personnel (HCP) in healthcare settings to cover their noses and mouths, in accordance with the Centers for Disease Control and Prevention (CDC) recommendations to prevent the spread of COVID-19. More recently, In May of 2021, the FDA modified this EUA as the availability of product returned to normal, declaring that non-medical and expired products can be used by the general public as well as HCP in healthcare settings as source control to help prevent the spread of COVID-19.

The authorized masks are recommended for source control to cover one's mouth and nose to prevent spread of respiratory secretions when they are talking, sneezing, or coughing. When used for this purpose, facemasks may be used until they become soiled, damaged, or hard to breathe through. They should be immediately discarded after removal. The authorized facemask products are not 1) a surgical mask, to provide liquid barrier protection; 2) for use in a clinical setting where the infection risk level through inhalation exposure is high; 3) for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses; 4) as a respiratory protective device; or 5) for high-risk aerosol-generating procedures.

Similarly, the FDA has allowed the extension of gowns under the same premise. Gowns and other apparel are authorized under this EUA specifically when they are intended for use by the public or HCPs in healthcare settings in to protect HCP and patients in low or minimal risk level situations. When used for this purpose, gowns may be used until they become soiled or damaged. They should be immediately discarded after removal. These non-surgical gowns are not intended for 1) for antimicrobial or antiviral protection, infection prevention, or infection reduction; 2) as



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a surgical gown or be labeled as having ANSI/AAMI PB70 Level 3 or Level 4 liquid barrier protection.

For more information regarding the extended and alternative use of expired surgical masks, non-medical masks, expired gowns, and non-surgical gowns, please visit the FDA links below:

CDC PPE Optimization: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html</a>

Gowns: https://www.fda.gov/media/138326/download

Masks: <a href="https://www.fda.gov/media/137121/download">https://www.fda.gov/media/137121/download</a>

Please reach out to <a href="PHAD.dph@ct.gov">PHAD.dph@ct.gov</a> with any questions.

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