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To: EMS Clinicians
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From: Timothy Chizmar, MD, FACEP
State EMS Medical Director

Date: August 13, 2020

RE: **KN-95 and Non-NIOSH-Approved Respirators – Removal of FDA Emergency Use Authorization**

The FDA has revised and reissued the emergency use authorizations (EUAs) for Non-NIOSH-Approved Filtering Facepiece Respirators several times (April 3, 2020; May 7, 2020; June 6, 2020; with most recent update on August 11, 2020). The emergency use authorization for respirators primarily pertains to KN-95 and similar model respirators imported from China.

Specifically, the FDA is concerned that some of these respirators may not provide consistent and adequate respiratory protection to health care personnel exposed to COVID-19 based on additional filtration performance testing conducted by the National Institute for Occupational Safety and Health (NIOSH). **The respirators that failed testing should not be used in clinical situations that call for a NIOSH-tested N-95 respirator. However, the KN-95 (or similar model) respirators that have been removed from the EUA may be used as simple face masks**.

Prior to the revision of these EUAs by the FDA, you may have purchased KN-95 or Non-NIOSH-Approved Filtering Facepiece Respirators or received them from MIEMSS. All agencies that received these masks from MIEMSS have been notified. I would strongly encourage you to check your supply of respirators to ensure that any non-FDA-approved products are either removed from stock or re-labeled for use as simple face masks. Guidance for re-labeling the affected respirators may be found on page 5 in the Face Mask Umbrella EUA (https://www.fda.gov/media/140894/download).

A complete listing of authorized and non-authorized Non-NIOSH approved respirators is available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas.