FILED

Department of Business and Professional Regulation

AGENCY CLERK

LERK

Ronda L. Bryan 3/23/2020 2020-02375

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

EMERGENCY ORDER 2020-02

WHEREAS, Novel Coronavirus Disease 2019 (COVID-19) is a severe acute respiratory illness that can spread among humans through respiratory transmission and presents with symptoms similar to those of influenza; and

WHEREAS, the Governor issued Executive Order 20-52 on March 9, 2020, pursuant to the authority vested in him by Article IV, Section 1(a) of the Florida Constitution, the State Emergency Management Act, s. 252.31, Florida Statutes, *et al.*, as amended, and all other applicable laws, and declared a state of emergency for the State of Florida; and

WHEREAS, the Governor, in Executive Order Number 20-52, authorized each State agency to suspend the provisions of any regulatory statute of that agency, if strict compliance with that statute would in any way prevent, hinder, or delay necessary action in coping with this emergency;

WHEREAS, the Secretary of the United States Department of Health and Human Services (HHS) declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak;

WHEREAS, the United States Food and Drug Administration thereafter issued an Emergency Use Authorization (EUA) for emergency use of certain disposable filtering facepiece respirators (FFRs) approved by the National Institute for Occupational Safety and Health (NIOSH) that have passed the manufacturers' recommended shelf-life, for use in healthcare settings by healthcare personnel to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak;

WHEREAS, Personal protective equipment (or "PPE") is equipment worn to minimize exposure to hazards that cause serious workplace injuries or illnesses. Such equipment includes FFRs such as N-95 respirators and surgical masks.

WHEREAS, PPE for which the expiration date has passed is ordinarily considered an adulterated device. § 499.006(9), Fla. Stat. (2019). Such an adulterated device is barred from distribution, sale, or delivery. §§ 499.005(1) & (3), Fla. Stat. (2019).

WHEREAS, Given the ongoing state of emergency and the dangers posed by the outbreak of COVID-19, it is reasonable to believe that the known and potential benefits of PPE, when used consistently with the EUA issued by the Food and Drug Administration, outweigh the known and potential risks of such a product even when the expiration date has passed.

NOW, THEREFORE, I, HALSEY BESHEARS, Secretary of Florida's Department of Business and Professional Regulation, pursuant to the authority granted by Executive Order No. 20-52, find the timely execution of the mitigation, response, and recovery aspects of the State's emergency management plan, as it relates to COVID-19, is negatively impacted by the application of certain regulatory statutes related to the Department of Business and Professional Regulation ("the Department"). Therefore, I order the following:

1. Accordingly, the provisions of section 499.006(9), Florida Statutes, as they relate to PPE are hereby SUSPENDED for the duration of the declaration of a state of emergency as described in Executive Order 20-52.

Executed this 23rd day of March, 2020, in Tallahassee, Leon County, Florida.

FLORIDA DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Halsey Beshears, Secretary 2601 Blair Stone Road Tallahassee, Florida 32399

Filed on this date, with the designated Agency Clerk, receipt of which is hereby acknowledged.

Agency Clerk's Office

Date: March 23, 2020