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BEV CLARNO  
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JEFF MORGAN  
INTERIM DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION  
STEPHANIE CLARK  
DIRECTOR  
800 SUMMER STREET NE  
SALEM, OR 97310  
503-373-0701

**TEMPORARY ADMINISTRATIVE ORDER**  
INCLUDING STATEMENT OF NEED & JUSTIFICATION

**BP 89-2020**  
CHAPTER 855  
BOARD OF PHARMACY

**FILED**  
09/21/2020 3:33 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE  
& LEGISLATIVE COUNSEL

FILING CAPTION: Temporary rule for Oregon Distilleries (COVID-19)

EFFECTIVE DATE: 09/21/2020 THROUGH 03/19/2021

AGENCY APPROVED DATE: 09/21/2020

CONTACT: Rachel Melvin  
971-673-0001  
pharmacy.rulemaking@oregon.gov

800 NE Oregon St., Suite 150  
Portland, OR 97232

Filed By:  
Rachel Melvin  
Rules Coordinator

**NEED FOR THE RULE(S):**

On March 8, 2020 Governor Brown declared a public health emergency in Oregon related to the coronavirus pandemic (COVID-19); On September 1st, 2020 Governor Brown issued Executive Order No. 20-38 extending the public health emergency a third time, through November 3rd, 2020.

**JUSTIFICATION OF TEMPORARY FILING:**

Due to a shortage of alcohol-based hand sanitizer, the FDA has issued temporary guidance: "Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)". In order for distilleries to prepare alcohol-based hand sanitizer pursuant to this guidance, they need to be licensed with the Board of Pharmacy as a manufacturer. The Board of Pharmacy is issuing a manufacturer's license that is valid through December 31, 2020 to allow distilleries to prepare hand sanitizer through that date."

**DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:**

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-temporary-policy-preparation-certain-alcohol-based-hand-sanitizer-products-during>

ADOPT: 855-007-0087

**RULE SUMMARY:** Whereas, during a declared emergency, the Board (or the Executive Director acting on behalf of the Board pursuant to OAR 855-007-0040) may adopt a temporary emergency rule as a way to address regulations impacting the health, safety and welfare of Oregonians. Whereas, in accordance with the nature of this COVID-19 pandemic, the need for alcohol-based hand sanitizers. This temporary rule permits Distilleries in Oregon who are licensed by OLCC, registered with the Board of Pharmacy as well as the FDA as a manufacturer, may prepare certain alcohol-based hand sanitizer products during the declared public health emergency through December 31, 2020.

**CHANGES TO RULE:**

855-007-0087

Preparation of Alcohol-Based Hand Sanitizer

Distilleries located in Oregon with a license issued by the Oregon Liquor Control Commission, and registered with the Board of Pharmacy and the US Food and Drug Administration (FDA) as a manufacturer may prepare certain alcohol-based hand sanitizer products pursuant to Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) issued by the FDA. The manufacturer registration issued by the Board of Pharmacy to distilleries for the purpose of preparing alcohol-based hand sanitizer pursuant to the temporary FDA policy is fee-waived and expires on December 31, 2020.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: