

**Oregon Board of Pharmacy** 

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January 27, 2021

Oregon Legislative Assembly VIA Email

Re: ORS 183.403 Report from the Oregon Board of Pharmacy

## Dear Legislators:

The Oregon Board of Pharmacy is pleased to submit this executive summary and report as required pursuant to Chapter ORS 183. This report contains adopted, amended, and repealed rules filed during calendar year January 01, 2020 to December 31, 2020 for the Oregon Board of Pharmacy.

The Oregon Board of Pharmacy has taken the following rulemaking actions:

Rules Adopted, Amended, or Repealed [ORS 183.335(2) and (3)]

- Adopted 7
- Amended 14
- Repealed 2

Temporary Rules Adopted, Amended, or Suspended [ORS 183.335(5)]

- Adopted 6
- Amended 4
- Suspended 0

BP 1-2020 Filed: 03/23/2020 7:46 PM

855-006-0005 Amend

## Statement of Need

On March 8, 2020 Governor Brown declared a public health emergency in Oregon related to the coronavirus pandemic (COVID-19); On March 23, 2020 Governor Brown issued Executive Order No. 20-12 ("Stay home, save lives") describing updated social distancing requirements.

## Justification

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, ORS 689.225 directs the Board to adopt rules relating to the use of pharmacy technicians working under the supervision, direction and control of a pharmacist.

Whereas, in accordance with the nature of this COVID-19 pandemic, the focus remains on minimization of individuals in close contact with one another ("social distancing") to reduce transmission of the coronavirus. The Board expects pharmacies to continue to care for their patients in a manner that assures access and safety to citizens and pharmacy personnel. This temporary emergency rule permits a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location, during the declared public health emergency timeframe, for safe social distancing.

## BP 2-2020 Filed: 03/25/2020 10:51 AM 855-007-0085 Adopt

#### Statement of Need

On March 8, 2020 Governor Brown declared a public health emergency in Oregon related to the coronavirus pandemic (COVID-19). 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. Chloroquine is effective for malaria treatment and prophylaxis, and hydroxychloroquine is effective for treatment of rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. There are no data currently available to justify the use of chloroquine or hydroxychloroquine for prevention or treatment of sub-critical COVID-19 infection. There are no data currently available on the use, dosing, or duration of these medication for COVID-19 infection. Use of these agents for the presumptive treatment or prevention of COVID-19 infection threatens the supply for patients who depend on its availability.

## Justification

Use of these agents for the presumptive treatment or prevention of COVID-19 infection threatens the supply for patients who depend on its availability.

# BP 3-2020 Filed: 04/02/2020 5:06 PM 855-007-0085 Adopt

## Statement of Need

On March 8, 2020 Governor Brown declared a public health emergency in Oregon related to the coronavirus pandemic (COVID-19). 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. Chloroquine (CQ) is effective for malaria treatment and prophylaxis, and hydroxychloroquine (HCQ) is effective for treatment of rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. There are no data currently available to justify the use of chloroquine or hydroxychloroquine for prevention or treatment of sub-critical COVID-19 infection. There are no data currently available on the use, dosing, or duration of these medication for COVID-19 infection. Use of these agents for the presumptive treatment or prevention of COVID-19 infection threatens the supply for patients who depend on its availability.

Temporary emergency rule adopted 3/25/2020.

On April 2, 2020 the Board was notified of the challenges healthcare providers are facing related to COVID-19 testing capabilities and delayed turn-around times in Oregon This new language permits dispensing of chloroquine and hydroxychloroquine to patients with a clinical diagnosis of COVID-19 infection.

#### Justification

Use of these agents for the presumptive treatment or prevention of COVID-19 infection threatens the supply for patients who depend on its availability. On 3/31/2020, the FDA added hydroxychloroquine to its shortage list; the Board was notified that distributors are allocating this drug. Due to variations in COVID-19 testing availability and timeliness of results, pharmacists may dispense chloroquine and hydroxychloroquine to hospitalized patients with a positive test for or a clinical diagnosis of COVID-19 infection.

## BP 4-2020 Filed: 04/07/2020 4:25 PM 855-031-0026 Amend

### Statement of Need

Preceptor to intern ratio is temporarily suspended to permit students to complete non-direct patient care School-based Rotational Internships (SRIs) required for graduation purposes, via remote learning

#### Justification

Due to the COVID-19 public health emergency, certain SRI sites have limited personnel to host pharmacy interns. If ratio is not temporarily suspended, students will not be able to complete required number of hours necessary to graduate.

## BP 5-2020 Filed: 04/09/2020 11:24 AM 855-025-0010 Amend

#### Statement of Need

Due to COVID-19 public health emergency testing centers have closed or have limited testing capabilities and technicians are unable to take and pass the certification exam required to apply for a Certified Oregon Pharmacy Technician license.

#### Justification

Due to potential pharmacy staffing shortages this policy helps minimize disruptions to pharmacy work force.

## BP 7-2020 Filed: 06/15/2020 4:34 PM 855-007-0085 Adopt

### Statement of Need

On 6/15/2020, the FDA revoked the emergency use authorization (EUA) that allowed for chloroquine phosphate and hydroxychloroquine sulfate donated to the Strategic National Stockpile to be used to treat certain hospitalized patients with COVID-19 when a clinical trial was unavailable, or participation in a clinical trial was not feasible. The agency determined that the legal criteria for issuing an EUA are no longer met. Based on its ongoing analysis of the EUA and emerging scientific data, the FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events and other potential serious side effects, the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use. Furthermore, hydroxychloroquine continues to remain on the FDA's drug shortage list.

#### Justification

New clinical evidence has determined that there are potential serious patient health risks associated with the inappropriate use of these drugs.

BP 9-2020 Filed: 07/14/2020 2:58 PM 855-007-0085 Adopt

Statement of Need Drugs no longer in short supply

#### Justification

Repeal of a temporary rule set to expire on 9/20/2020. Oregon Board of Pharmacy voted today to repeal it, effective today 7/14/2020.

BP 10-2020 Filed: 07/16/2020 3:01 PM 855-007-0086 Adopt

## Statement of Need

Agency must have the ability to enforce licensee's compliance of Governor's Executive Orders during a declared public health emergency.

#### Justification

Pursuant to OAR 855-007-0040, Executive Director may issue temporary emergency rules during a declared emergency. The Board of Pharmacy may utilize this rule to enforce licensee's compliance.

BP 89-2020 Filed: 09/21/2020 3:33 PM 855-007-0087 Adopt

#### Statement of Need

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

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."

BP 93-2020 Filed: 12/22/2020 10:49 AM 855-007-0080 Amend

### Statement of Need

The intern to pharmacist preceptor ratio of 1:2 is temporarily suspended to permit meeting the high demand for COVID- 19 vaccination, which may exceed supply of pharmacist and intern vaccinators under the current ratio.

The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

Temporarily increasing the Intern:Preceptor ratio may improve the supply of vaccinators and facilitate increased vaccination capacity.

## Justification

Due to the COVID-19 public health emergency, there will be high demand for pharmacists to provide vaccinations with COVID-19 vaccine in the coming weeks and lasting for several months. Pharmacists may supervise interns for vaccine clinics to increase the number of persons who may be vaccinated with COVID-19 vaccine.

Sincerely,

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