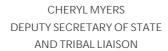
#### OFFICE OF THE SECRETARY OF STATE

LAVONNE GRIFFIN-VALADE SECRETARY OF STATE





#### **ARCHIVES DIVISION**

STEPHANIE CLARK DIRECTOR

800 SUMMER STREET NE SALEM, OR 97310 503-373-0701

# NOTICE OF PROPOSED RULEMAKING INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855 BOARD OF PHARMACY

# **FILED**

06/20/2024 11:34 AM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Amends Continuation of Therapy and Coronavirus 2019 protocols, adds new SARS-CoV-2 Antiviral protocol

### LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/23/2024 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin

971-673-0001

pharmacy.rulemaking@bop.oregon.gov

800 NE Oregon St., Suite 150

Portland, OR 97232

Filed By:

Rachel Melvin

**Rules Coordinator** 

## HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 07/23/2024 TIME: 9:30 AM

OFFICER: Rachel Melvin

## REMOTE HEARING DETAILS

MEETING URL: Click here to join the meeting

PHONE NUMBER: 503-446-4951 CONFERENCE ID: 836629590 SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony virtually during this hearing, sign up on our website at

www.oregon.gov/pharmacy/pages/

rulemaking-information or email your first and last name and email address to

pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.

You must submit written comments before 4:30PM on July 23, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

## NEED FOR THE RULE(S)

Proposes amending Continuation of Therapy protocol by adding early refills of non-controlled opioid use disorder medications to pursuant to 2024 HB 4002 Sections 6, 7 and 9 and proposes adding new SARS-CoV-2 Antiviral protocol pursuant to 2024 SB 1506. Proposed to amend current version of the Coronavirus 19 protocol.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2024 SB 1506 https://olis.oregonlegislature.gov/liz/2024R1/Downloads/MeasureDocument/SB1506/Enrolled 2024 HB 4002 https://olis.oregonlegislature.gov/liz/2024R1/Downloads/MeasureDocument/HB4002/Enrolled

## **Protocol Compendium:**

Proposed Continuation of Therapy https://www.oregon.gov/pharmacy/Documents/Continuation\_Tx-v.08\_2024.pdf

Proposed SARS-CoV-2 Antiviral https://www.oregon.gov/pharmacy/Documents/Conditions\_SARS-CoV-2 Antiviral\_v.08.2024.pdf

Vaccines:

Proposed Coronavirus 19

https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Coronavirus\_19\_v.08.2024.pdf

## STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The proposed rule amendments are not expected to affect racial equity in this state.

#### FISCAL AND ECONOMIC IMPACT:

No fiscal anticipated. Licensees, registrants and stakeholders will have an opportunity to provide fiscal and economic impact statements during the open comment period.

#### COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

The proposed rule amendments will have no additional economic impact on state agencies, units of local government, the public or registrants or licensees who identify as a small business.

## DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

### WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO. IF NOT, WHY NOT?

Subject Matter Experts (SME) are responsible for drafting proposed protocols and the Public Health and Pharmacy Formulary Advisory Committee is responsible for recommending proposed or amended protocols sent to the board for consideration.

## AMEND: 855-115-0345

RULE SUMMARY: Proposes to amend the Continuation of Therapy protocol by adding early refills of non-controlled opioid use disorder medications pursuant to directives of 2024 HB 4002 Sections 6,7, and 9, proposes adding new protocol SARS-CoV-2 Antiviral pursuant to 2024 SB 1506 to the protocol compendium and proposes to amend current vaccine protocol for Coronavirus 2019.

# **CHANGES TO RULE:**

#### 855-115-0345

Services: Prescribing - Protocol Compendium

A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, FDA-approved drugs and devices listed in the following compendium, pursuant to a statewide drug therapy management protocol. ¶

- (1) Continuation of therapy including emergency refills of insulin and early refills of opioid use disorder medications (v. 068/2024)¶
- (2) Conditions¶
- (a) Cough and cold symptom management¶
- (A) Benzonatate (v. 06/2021);¶
- (B) Short-acting beta agonists (v. 06/2021);¶
- (C) Intranasal corticosteroids (v. 06/2021):¶
- (b) Vulvovaginal candidiasis (VVC) (v. 06/2021);¶
- (c) COVID-19 Antigen Self-Test (v. 12/2021);¶
- (d) SARS-CoV-2 Antiviral (v. 08/2024)¶
- (3) Preventative care¶
- (a) Emergency Contraception (v. 06/2021);¶
- (b) Male and female condoms (v. 06/2021);¶
- (c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT (v. 06/2024);¶
- (d) Travel Medications (v. 06/2024);¶
- (e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);¶
- (f) HIV Pre-exposure Prophylaxis (PrEP) (v.06/2023); ¶
- (g) Contraception (v. 06/2023);¶
- (h) Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) (v. 06/2024);¶
- (i) Short-acting Opioid Antagonists (v. 06/2024); and ¶
- (i) Vaccines:¶
- (A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 06/2024); ¶
- (B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 06/2024); ¶
- (C) Cholera (v. 02/2024); ¶
- (D) Coronavirus 2019 (v. 068/2024); ¶
- (E) Haemophilus Influenza type b (v. 06/2024);¶
- (F) Hepatitis A containing vaccines (v. 02/2024); ¶
- (G) Hepatitis B containing vaccines (v. 02/2024); ¶
- (H) Human Papillomavirus (v. 02/2024); ¶
- (I) Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 06/2024); ¶
- (J) Influenza Live Attenuated Influenza Vaccine 2023-24 (v. 02/2024); ¶
- (K) Japanese Encephalitis (v. 06/2024); ¶
- (L) Meningococcal containing vaccines (v. 06/2024); ¶
- (M) Measles Mumps & Rubella containing vaccines (v. 02/2024); ¶
- (N) Pneumococcal (v. 06/2024); ¶
- (O) Polio (v. 06/2024);¶
- ¶.
- (P) Rabies (v. 02/2024); ¶
- (Q) Respiratory Syncytial Virus (v. 06/2024);¶
- (R) Tetanus Diphtheria containing vaccines (v. 06/2024);¶
- (S) Typhoid (v. 02/2024); ¶
- (T) Varicella containing vaccines (v. 02/2024);¶
- (U) Yellow fever (v. 06/2024); and ¶
- (V) Zoster (v. 02/2024).¶

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689.205, 2024 HB 4002, 2024 SB 1506

Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689, 2024 HB 4002, 2024 SB 1506