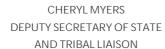
#### OFFICE OF THE SECRETARY OF STATE

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**

04/17/2024 10:06 AM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Adds CGM to formulary, adds STI prevention and short-acting opioid antagonists protocols, repeals pseudoephedrine

## LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 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: 05/22/2024 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: 392711816 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 May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

#### NEED FOR THE RULE(S)

Proposes to add continuous glucose monitors and related supplies to formulary. Proposes to repeal pseudoephedrine protocol from the protocol compendium. Proposes to amend the tobacco cessation, travel medications, and vaccine protocols in the protocol compendium. Vaccine protocols amended include Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway, Standard Protocol for All Vaccines: Managing Adverse Reactions, Coronavirus 2019, Haemophilus Influenza type b, Influenza - Inactivated Influenza Vaccines and Recombinant Influenza

Vaccines 2023-24, Japanese Encephalitis, Meningococcal containing vaccines, Measles Mumps & Rubella containing vaccines, Pneumococcal, Polio, Respiratory Syncytial Virus, Tetanus Diphtheria containing vaccines, Yellow fever, and Zoster. Proposes to add Sexually Transmitted Infections Post-exposure Prophylaxis protocol and Short-acting Opioid Antagonists protocol to the protocol compendium.

#### DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Pseudoephedrine: ORS 475.005(6),(17) Definitions- "Controlled substance", "Practitioner"; ORS 475.035 Authority to control sci Prescriptions Required; ORS 475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phe 855-080-0026 Schedule V

# Formulary Compendium:

Device and Supplies: Continuous Glucose Monitors & Associated Supplies https://www.oregon.gov/pharmacy/Documents/Formulary\_Devices\_Supplies\_4.2024.pdf

# Protocol Compendium:

Continuation of Therapy https://www.oregon.gov/pharmacy/Documents/Continuation\_Tx\_General\_4.2024.pdf Pseudoephedrine \*REPEAL https://www.oregon.gov/pharmacy/Documents/CoughColdSymptom\_PSE.pdf Tobacco Cessation https://www.oregon.gov/pharmacy/Documents/PrevCare\_Tobacco\_Cessation\_4.2024.pdf Travel Medications https://www.oregon.gov/pharmacy/Documents/PrevCare\_Travel\_Medications\_4.2024.pdf

## Vaccines:

Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway

https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Standard\_Protocol\_for\_All\_Vaccines\_Cover\_Page\_&\_Assessmen Standard Protocol for All Vaccines: Managing Adverse Reactions https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ Vaccines\_Managing\_Adverse\_Reactions\_4.2024.pdf

Coronavirus 19 https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Coronavirus\_19\_4.2024.pdf

Haemophilus Influenzae type b https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Haemophillus\_Influenza\_Type\_B Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024

Japanese Encephalitis https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Japanese\_Encephalitis\_4.2024.pdf

Meningococcal containing vaccines https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Meningococcal\_Containing\_

Pneumococcal https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Pneumococcal\_4.2024.pdf

Polio https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Polio\_4.2024.pdf

Respiratory Syncytial Virus https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Respiratory\_Syncytial\_Virus\_4.2024 Tetanus, Diphtheria containing vaccines https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Tetanus\_Diphtheria\_Co

Yellow Fever https://www.oregon.gov/pharmacy/Documents/PrevCare\_IMZ\_Yellow\_Fever\_4.2024.pdf

Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) https://www.oregon.gov/pharmacy/Documents/PrevCare\_Short-acting Opioid Antagonists https://www.oregon.gov/pharmacy/Documents/PrevCare\_SaOA\_4.2024.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:

Repealing the pseudoephedrine protocol might lead to higher out-of-pocket costs for patients because insurance cannot be billed without a prescription. No fiscal anticipated for the remaining proposed protocol amendments.

Licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the rulemaking 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 with 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 then the Public Health and Pharmacy Formulary Advisory Committee is responsible for recommending changes to the drafts or recommending the proposed protocols are sent to the board for consideration.

#### **RULES PROPOSED:**

855-115-0340, 855-115-0345

AMEND: 855-115-0340

RULE SUMMARY: Proposes to add continuous glucose monitors and related supplies to the formulary compendium.

CHANGES TO RULE:

#### 855-115-0340

Services: Prescribing - Formulary Compendium

A Pharmacist may prescribe, according to OAR 855-115-0330 and OAR 855-115-0335, a FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented. Devices and supplies:¶

- (1) Diabetic blood sugar testing supplies; ¶
- (2) Injection supplies; ¶
- (3) Nebulizers and associated supplies;¶
- (4) Inhalation spacers; ¶
- (5) Peak flow meters;¶
- (6) International Normalized Ratio (INR) testing supplies; ¶
- (7) Enteral nutrition supplies; ¶
- (8) Ostomy products and supplies; and ¶
- (9) Non-invasive blood pressure monitors; and ¶
- (10) Continuous glucose monitors and associated supplies.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-115-0345

RULE SUMMARY: Proposes to repeal pseudoephedrine protocol from the protocol compendium. ORS 475.005(6),(17) and ORS 475.185 prohibit a pharmacist from prescribing a controlled substance. Controlled substances include those scheduled by the board under ORS 475.035. Pseudoephedrine is scheduled by the board as a schedule V controlled substance under ORS 475.035 in OAR 855-080-0026 in accordance with ORS 475.973.

Proposes to amend the tobacco cessation, travel medications, and vaccine protocols in the protocol compendium. Vaccine protocols amended include Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway, Standard Protocol for All Vaccines: Managing Adverse Reactions, Coronavirus 2019, Haemophilus Influenza type b, Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24, Japanese Encephalitis, Meningococcal containing vaccines, Measles Mumps & Rubella containing vaccines, Pneumococcal, Polio, Respiratory Syncytial Virus, Tetanus Diphtheria containing vaccines, Yellow fever, and Zoster.

Proposes to add Sexually Transmitted Infections Post-exposure Prophylaxis protocol and Short-acting Opioid Antagonists protocol to the protocol compendium.

#### **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.  $\P$ 

- (1) Continuation of therapy including emergency refills of insulin (v. 06/20234)¶
- (2) Conditions¶
- (a) Cough and cold symptom management¶
- (A) Pseudoephedrine (v. 06/2021);¶
- (B) Benzonatate (v. 06/2021);¶
- $(\underline{\leftarrow}\underline{B})$  Short-acting beta agonists (v. 06/2021);¶
- (ĐC) Intranasal corticosteroids (v. 06/2021);¶
- (b) Vulvovaginal candidiasis (VVC) (v. 06/2021);¶
- (c) COVID-19 Antigen Self-Test (v. 12/2021);¶
- (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. 06/20224);¶
- (d) Travel Medications (v. 06/20234);¶
- (e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);¶
- (f) HIV Pre-exposure Prophylaxis (PrEP) (v.06/2023); and ¶
- (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 ¶
- (j) 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. 2/2024); ¶
- (D) Coronavirus 2019 (v. 06/2024); ¶
- (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

Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689