


RULES UPDATE  
PHPFAC 5/8/2024

# RULEMAKING HEARING 5/22/2024 9:30AM

- Division 115 - Pharmacists - Services: Prescribing - Formulary & Protocol Compendium
  - Formulary Devices and Supplies
  - Continuation of Therapy (v. 06/2024)
  - Pseudoephedrine (v. 06/2021) \*REPEAL 
  - Tobacco Cessation (v. 06/2024)
  - Travel Medications (v. 06/2024)
  - Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) (v. 06/2024)
  - Short-acting Opioid Antagonists (v. 06/2024)
  - Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 06/2024)
  - Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 06/2024)
  - Coronavirus 19 (v. 06/2024)
  - Haemophilus Influenzae type b (v. 06/2024)
  - Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024 (v. 06/2024)
  - Japanese Encephalitis (v. 06/2024)
  - Meningococcal containing vaccines (v. 06/2024)
  - Pneumococcal (v. 06/2024)
  - Polio (v. 06/2024)
  - Respiratory Syncytial Virus (v. 06/2024)
  - Tetanus, Diphtheria containing vaccines (v. 06/2024)
  - Yellow Fever (v. 06/2024)

# HISTORY OF PSEUDOEPHEDRINE (PSE) PROTOCOL 3

- 06/2005- ORS 475.973 amended to require PSE to be in schedule III
- 06/2007- Board adopts PSE as a schedule III controlled substance
- 02/2018- PSE protocol recommended by PHPFAC to Board
- 10/2018- Board adopted PSE protocol by rule
- 02/2021- Biennial review of all protocols- standardization
- 06/2021- Board adopted revisions to PSE protocol by rule
- 09/2021- PHPFAC discussed if retaining the PSE protocol was necessary as 2021 HB 2648 allows transfer of PSE to a person who is  $\geq$  18 years old
  - PHPFAC decided to retain protocol at this time
- 12/2021- Board adopted rules to move PSE from schedule III to schedule V effective 1/1/2022
- 02/2023- PHPFAC biennial review of all protocols- no changes to PSE protocol
- 05/2024- Board sent PSE protocol to rulemaking for repeal

# ORS 475.005

## (6) “Controlled substance”:

(a) Means a drug or its immediate precursor classified in Schedules I through V under the federal Controlled Substances Act, 21 U.S.C. 811 to 812, **as modified under ORS 475.035**. The use of the term “precursor” in this paragraph does not control and is not controlled by the use of the term “precursor” in ORS 475.752 to 475.980.

# ORS 475.035

- (1) In arriving at any decision on changes in or addition to classification when changes or additions are proposed by the federal Drug Enforcement Administration or by any other reliable source, the State Board of Pharmacy shall review the scientific knowledge available regarding the substance, its pharmacological effects, patterns of use and misuse, and potential consequences of abuse, and consider the judgment of individuals with training and experience with the substance.
- (2) Whenever the board determines that a change in or an addition to the schedule of a controlled substance is justified, the board by rule may order the change and fix the effective date thereof.
- (3) If a substance is an ingredient of a controlled substance, the ingredient shall be considered to be in the same schedule as that controlled substance. Substances which are precursors of the ingredient shall not be subject to control solely because they are precursors of the ingredient. The use of the term “precursor” in this subsection does not control and is not controlled by the use of the term “precursor” in ORS 475.752 to 475.980.
- (4) The board shall administer ORS 475.005 to 475.285 and 475.752 to 475.980 in accordance with ORS chapter 183.
- (5) Authority to control under this section does not extend to tobacco or to alcoholic beverages as defined in ORS 471.001.

## ORS 475.973

- (1)(a) The State Board of Pharmacy may not adopt rules that exempt a product containing ephedrine or pseudoephedrine from classification as a controlled substance. Except as otherwise provided in this paragraph, the State Board of Pharmacy shall adopt rules to classify ephedrine, pseudoephedrine and phenylpropanolamine as Schedule III controlled substances. The Schedule III classification may be modified by the State Board of Pharmacy if the State Board of Pharmacy finds that restrictions on products containing ephedrine, pseudoephedrine or phenylpropanolamine under a Schedule III designation do not significantly reduce the number of methamphetamine laboratories within the state.

# ORS 475.005

(17) “Practitioner” means physician, dentist, veterinarian, scientific investigator, licensed nurse practitioner, physician assistant or other person licensed, registered or otherwise permitted by law to dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state but does not include a pharmacist or a pharmacy.

# ORS 475.185

(3) Except when dispensed directly by a practitioner to an ultimate user, a controlled substance included in Schedule V that is a prescription drug may not be dispensed without a written, oral or electronically transmitted prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date on which it was issued and a prescription authorized to be refilled may not be refilled more than five times. Additional quantities of the controlled substances listed in Schedule V may be authorized by a practitioner only through issuance of a new prescription.

# 2024 SB 1506

**SECTION 4. (1) Consistent with the protocols adopted by the State Board of Pharmacy by rule, as recommended by the Public Health and Pharmacy Formulary Advisory Committee, a pharmacist may test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and prescribe, dispense and administer treatment, including drug therapy, for SARS-CoV-2.**

**(2) When testing for SARS-CoV-2, a pharmacist may use:**

**(a) A screening procedure that can be safely performed by a pharmacist; and**

**(b) A test that:**

**(A) Guides the pharmacist's clinical decision-making;**

**(B) Is determined by the Centers for Medicare and Medicaid Services to qualify as a waived test under the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578, 42 U.S.C. 201 and 263a) or federal regulations adopted pursuant to the Clinical Laboratory Improvement Amendments of 1988 or is approved by the United States Food and Drug Administration; and**

**(C) Is approved by the board by rule for use under this section.**

**(3) A pharmacist may delegate to a pharmacy technician or an intern under the pharmacist's supervision the administrative and technical tasks of performing a task described in subsection (2) of this section.**

**(4) The board may adopt rules as necessary to carry out this section.**

**(p) The testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the prescribing, dispensing and administering of treatment for SARS-CoV-2 pursuant to section 4 of this 2024 Act and rules adopted by the board pursuant to section 4 of this 2024 Act.**

# HISTORY OF SARS-COV2 ANTIVIRAL PROTOCOL

- 12/2021- FDA issued Emergency Use Authorization of Paxlovid™
- 10/2022- Temporary adoption of COVID-19 Antiviral protocol
- 12/2022- Permanent adoption of COVID-19 Antiviral protocol – effective 2/1/2023
- 2/1/2023- FDA revises EUA for Paxlovid™ to require a diagnosis to prescribe
- 02/2023- Temporary repeal of COVID-19 Antiviral protocol
- 06/2023- Permanent repeal of COVID-19 Antiviral protocol
- 3/8/2024- EUA labeled Paxlovid™ no longer authorized
- 3/2024- 2024 SB 1506 signed into law. Effective 6/6/2024, operative 10/1/2024, will be repealed 6/30/2026



FORMULARY  
DISCUSSION

# ORS 689.645

- (1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205:
  - (d) A pharmacist may prescribe and dispense a drug or device included on the **formulary** established under subsection (6) of this section if the prescription and dispensation is **pursuant to a diagnosis by a health care practitioner who has prescriptive authority and is qualified to make the diagnosis.**
- (6)(a) The board shall establish by rule a **formulary** of drugs and devices, as recommended by the committee, that a pharmacist may prescribe and dispense to a patient **pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis.**
  - (b) The formulary may include post-diagnostic drugs and devices such as diabetic testing supplies, emergency refills of insulin, albuterol inhalers, epinephrine autoinjectors, smoking cessation aids, discharge medications for transitions of care, rapid strep tests and spacers.

# POTENTIAL ADDITIONS TO FORMULARY?

Are there any:

- Drugs authorized by statute to prescribe that should be considered for placement on the formulary?
- Drugs authorized by protocol to prescribe that should be considered for placement on the formulary?
- In general, drugs that are post-diagnostic that should be considered for placement on the formulary?

THANK  
YOU

