



## **NOTICE OF PROPOSED RULEMAKING**

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855

**BOARD OF PHARMACY**

**FILED**

04/16/2025 11:52 AM

ARCHIVES DIVISION

SECRETARY OF STATE

**FILING CAPTION:** Amends protocols for Contraception, Coronavirus 19, Hepatitis B, Meningococcal, Pneumococcal and RSV; repeals VVC protocol

**LAST DAY AND TIME TO OFFER COMMENT TO AGENCY:** 05/22/2025 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.*

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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:** 05/22/2025

**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:** 421663659

### **SPECIAL INSTRUCTIONS:**

This hearing 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/](http://www.oregon.gov/pharmacy/pages/)

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

pharmacy.rulemaking@bop.oregon.gov. Please indicate which

rule(s) you would like to comment on.

You must submit written comments before 4:30PM on May 22, 2025. Email written comments to

pharmacy.rulemaking@bop.oregon.gov.

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

Proposes to permanently adopt revised protocol for Contraception and revises vaccine protocols for Coronavirus 19, Hepatitis B containing vaccines, Meningococcal containing vaccines, Pneumococcal, and Respiratory Syncytial Virus to align with the current Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations. Repeals the Vulvovaginal Candidiasis protocol.

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

Temporary Rule – OAR 855-115-0345 [https://www.oregon.gov/pharmacy/Documents/OAR-855-115-0345\\_BP\\_66-2024TrackedChanges.pdf](https://www.oregon.gov/pharmacy/Documents/OAR-855-115-0345_BP_66-2024TrackedChanges.pdf)

Protocol Compendium:

Conditions: Vulvovaginal Candidiasis (VVC) \*REPEAL [https://www.oregon.gov/pharmacy/Documents/Cg-VVC\\_Protocol\\_v.62021\\_REPEAL.pdf](https://www.oregon.gov/pharmacy/Documents/Cg-VVC_Protocol_v.62021_REPEAL.pdf)

Preventative Care: Contraception (v. 12/2024)

[https://www.oregon.gov/pharmacy/Documents/PrevCare\\_Contraception\\_Protocol\\_v.12.2024.pdf](https://www.oregon.gov/pharmacy/Documents/PrevCare_Contraception_Protocol_v.12.2024.pdf)

Vaccines:

Coronavirus 19 (v. 12.17.2024)

[https://www.oregon.gov/pharmacy/Documents/PrevCare\\_IMZ\\_Coronavirus\\_19\\_v.12.17.2024.pdf](https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Coronavirus_19_v.12.17.2024.pdf)

Hepatitis B containing vaccines

[https://www.oregon.gov/pharmacy/Documents/PrevCare\\_IMZ\\_Hepatitis\\_B\\_v.12.2024.pdf](https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Hepatitis_B_v.12.2024.pdf)

\*FDA announcement re: PreHevbrio® <https://www.fda.gov/vaccines-blood-biologics/prehevbrio>

Meningococcal containing vaccines

[https://www.oregon.gov/pharmacy/Documents/PrevCare\\_Meningococcal\\_v.12.2024.pdf](https://www.oregon.gov/pharmacy/Documents/PrevCare_Meningococcal_v.12.2024.pdf)

Pneumococcal [https://www.oregon.gov/pharmacy/Documents/PrevCare\\_IMZ\\_Pneumococcal\\_v.12.2024.pdf](https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Pneumococcal_v.12.2024.pdf)

Respiratory Syncytial Virus (v. 12.17.2024)

[https://www.oregon.gov/pharmacy/Documents/PrevCare\\_IMZ\\_Respiratory\\_Syncytial\\_Virus\\_v.12.17.2024.pdf](https://www.oregon.gov/pharmacy/Documents/PrevCare_IMZ_Respiratory_Syncytial_Virus_v.12.17.2024.pdf)

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#### 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.

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#### FISCAL AND ECONOMIC IMPACT:

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

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#### 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.

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

Registrants who identify as a small business and who have signed up to receive notices 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.

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

No. Subject Matter Experts (SME) are responsible for drafting proposed amendments or draft protocols and the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) is responsible for recommending proposed or amended protocols to the board for consideration.

**RULE SUMMARY:** Proposes to permanently adopt revisions to the Contraception protocol. Proposes to permanently adopt revisions to vaccine protocols for Coronavirus 2019, Hepatitis B containing vaccines, Meningococcal containing vaccines, Pneumococcal, and Respiratory Syncytial Virus to align with the most current Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations.

Per the FDA, PreHevbrio® has been voluntarily withdrawn from the market by the company, VBI Vaccines Inc., due to the bankruptcy of the company and the termination of its operations.

Proposes to permanently repeal the Vulvovaginal Candidiasis protocol as suggested by the Public Health & Pharmacy Formulary Advisory Committee.

**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. 08/2024)¶

(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);¶

(e) 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¶

(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. 02/2024);¶

(D) Coronavirus 2019 (v. 1206/2024);¶

(E) Haemophilus Influenza type b (v. 06/2024);¶

(F) Hepatitis A containing vaccines (v. 02/2024);¶

(G) Hepatitis B containing vaccines (v. 026/2024);¶

(H) Human Papillomavirus (v. 02/2024);¶

(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2024-2025 (v. 12/2024);¶

(J) Influenza - Live Attenuated Influenza Vaccine 2024-2025 (v. 12/2024);¶

(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. 1206/2024);¶

(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~~ORS 689.005

Statutes/Other Implemented: ~~ORS 689.645, ORS 689.649, ORS 689.689, 2024 HB 4002, 2024 SB 1506~~ORS 689.005