OFFICE OF THE SECRETARY OF STATE

TOBIAS READ SECRETARY OF STATE

MICHAEL KAPLAN
DEPUTY 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

06/26/2025 9:23 AM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Standard Vaccination Protocols

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 07/22/2025 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.

CONTACT: Rachel Melvin

pharmacy.rulemaking@bop.oregon.gov

971-673-0001

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: 07/22/2025 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: 429564160
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/

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 July 22, 2025. Email written comments to

pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes amending current rules by removing "compendia and compendium", incorporates new streamlined standard vaccination protocols and proposes repealing existing individual vaccine protocols.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

April 9-11, 2025 DRAFT Board Meeting Summary

https://www.oregon.gov/pharmacy/Documents/April_2025_DRAFT_Bd_Meeting_Summary.pdf

April 11, 2025 Teams video part #2 0:20:35 for board discussion https://www.youtube.com/watch?v=FI_Oznvj-9g PHPFAC Draft 4.23.2025 Meeting Summary

https://www.oregon.gov/pharmacy/Documents/PHPFAC_4.23.2025_DRAFT_Mtg_Summary.pdf

Teams video part #4 1:09:53 for committee discussion https://www.youtube.com/watch?v=pSY7qWs6s_o

Draft Vaccination Protocol for Ages 6 months - 2 yrs

 $https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_6_months_through_2_Years_7.22.2025.pdf$

Draft Vaccination Protocol for Ages 6 months - 2 yrs - Assessment Treatment Care Pathway

https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_6_months_through_2_Years_A ssessment_Treatment_Care_Pathway_7.22.2025.pdf

Draft Vaccination Protocol for Ages 3-6 yrs

https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_3_through_6_Years_7.22.202 5 DRAFT.pdf

Draft Vaccination Protocol for Ages 3-6 yrs - Assessment Treatment Care Pathway

 $https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_3_through_6_Years_Assessment_Treatment_Care_Pathway_7.22.2025.pdf$

Draft Vaccination Protocol for Ages 7-17 yrs

https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_7_through_17_Years_7.22.20 25.pdf

Draft Vaccination Protocol for Ages 7-17 yrs - Assessment Treatment Care Pathway

https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Ages_7_through_17_Years_Assessment_Treatment_Care_Pathway_7.22.2025.pdf

Draft Vaccination Protocol for Adults 18 yrs of age and older

https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Adults_18_Years_of_Age_and_Older _7.22.2025.pdf

Draft Vaccination Protocol for Adults 18 yrs of age and older - Assessment Treatment Care Pathway

https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Adults_18_Years_of_Age_and_Older _Assessment_Treatment_Care_Pathway_7.22.2025.pdf

Draft Vaccination Protocol for Managing Adverse Reactions

 $https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Managing_Adverse_Reactions_7.22. \\ 2025.pdf$

Draft Vaccination Protocol for Managing Adverse Reactions - Assessment Treatment Care Pathway

 $https://www.oregon.gov/pharmacy/Documents/DRAFT_Vaccination_Protocol_for_Managing_Adverse_Reactions_Assessment_and_Treatment_Care_Pathway_7.22.2025.pdf$

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 interested parties 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 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.

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.

RULES PROPOSED:

855-104-0055, 855-115-0330, 855-115-0335, 855-115-0340, 855-115-0345

AMEND: 855-104-0055

RULE SUMMARY: Proposes removing "compendia" and "for 6 years" from (B) to provide clarity to licensees.

CHANGES TO RULE:

855-104-0055

Record and Document Retention

- (1) Each licensee and registrant must create documents and retain records required by ORS 475, ORS 689, and OAR 855. Documents and records:¶
- (a) May be in written or electronic format; ¶
- (b) Must be stored securely;¶
- (c) Must be made available to the board upon request; and ¶
- (d) Must be retained for 3 years except that: ¶
- (A) Clinical pharmacy records must be retained for 7 years; and ¶
- (B) Training records for immunization administration and protocol and formulary compendia prescribing, must be retained for 6 years or uploaded into the licensee's electronic licensing record with the board;¶
- (2) Records generated by a registrant:¶
- (a) Must be stored on-site by the registrant for at least 12 months and must be provided to the board immediately upon request at the time of inspection; ¶
- (b) May be stored in a secured off-site location after 12 months of storage at the registrant and must be provided to the board upon request within 3 business days;¶
- (3) Records generated in the practice of pharmacy that do not belong to a registrant must be stored by a Pharmacist in a secure manner and provided to the board upon request within 3 business days; and \P
- (4) Records must be retained for longer periods of time than required under this rule if: ¶
- (a) Federal law provides for a longer retention schedule; or ¶
- (b) Licensee or registrant has received notice of a Board investigation to which the records would be relevant; ¶
- (c) Licensee or registrant has received a Board request to retain the records for a longer period of time.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.508

RULE SUMMARY: Proposes removing "compendia" and adds "pursuant to a statewide drug therapy protocol" in (1) to provide clarity to licensees and adds (9) pharmacist requirements related to reporting prescription and administration of vaccines to a patient's primary healthcare provider and the Oregon Health Authority pursuant to ORS 689.654(4). Proposes differentiating prescribing requirements for protocols and formulary.

CHANGES TO RULE:

855-115-0330

Services: Prescribing - Formulary or Protocol Compendia

- (1) A Pharmacist located and licensed in Oregon may prescribe and dispense an FDA-approved drug and device included on either the Formulary or Protocol Compendia pursuant to a statewide drug therapy protocol (Protocol), set forth in this Division. ¶
- (2) A Pharmacist may submit a concept, on a form prescribed by the board to the Public Health and Pharmacy Formulary Advisory Committee for consideration, for the addition of a drug or device to the Formulary Compendia or for the development of a protocol for the Protocol Compendia Protocol. A Pharmacist may provide feedback on the Formulary or Protocol-Compendias on a board prescribed form and located on the board website.¶
- (3) A Pharmacist must only prescribe a drug or device consistent with the parameters of the Formulary and or Protocol Compendia, and in accordance with federal and state regulations.
- (4) The Pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.¶
- (5) For each drug or device the Pharmacist prescribes via the Formulary or Protocol Compendia Protocol, the Pharmacist must:¶
- (a) Ensure training and education requirements have been met prior to engaging in prescribing activities. A copy of all required training and education must be retained according to OAR 855-104-0055; ¶
- (b) Collect subjective and objective information about the patient's health history and clinical status. If prescribing pursuant to the Formulary Compendia in OAR 855-115-0340, a diagnosis from the patient's health_care provider is required. ¶
- (c) Assess the information collected in (b). Any physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means.¶
- (d) Create an individualized patient-centered care plan that utilizes information obtained in the assessment to evaluate and develop a care plan; ¶
- (e) Implement the care plan, to include: ¶
- (A) Addressing medication and health-related problems and engaging in preventive care strategies;¶
- (B) Initiating, modifying, discontinuing, or administering medication therapy as permitted by the Formulary or Protocol-Compendia; \P
- (C) Providing education and self-management training to the patient or caregiver; ¶
- (D) Contributing to coordination of care, including the referral or transition of the patient to another health care professional; and \P
- (E) Scheduling follow-up care as needed to achieve goals of therapy: and ¶
- (f) Monitor and evaluate the effectiveness of the care plan and make modifications to the plan; and \P
- (6) For each drug or device the Pharmacist prescribes via Formulary, the Pharmacist must: ¶
- (a) Ensure training and education requirements have been met prior to engaging in prescribing activities. A copy of all required training and education must be retained according to OAR 855-104-0055; and ¶
- (b) Ensure prescribing is pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis.¶
- (7) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a Formulary or Protocol Compendia drug or device.¶
- (68) If consultation is provided through an electronic means, the Oregon licensed All records and documents must be retained according to OAR 855-104-0055 and must be made available to the patient and provider upon request.¶
- (9) Pharmacists must use report the prescription and audiovisual communication system to conduct the consultation.¶
- (7) All dministration of vaccines to a patient's primary health care provider and to the Oregon Health Authority pursuant to ORS 689.645(4). The respords and documents must be retained according to OAR 855-104-0055 and must be made available to the patient and provider upon request ting of the prescription and administration of

vaccines to a patient's primary health care provider and to the Oregon Health Authority can be accomplished by reporting to the ALERT Immunization Information System (ALERT-IIS) per ORS 433.090, ORS 433.092, ORS 433.094, ORS 433.095, ORS 433.096, ORS 433.098, ORS 433.100, ORS 433.102, ORS 433.103, and ORS 433.104.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645, ORS 689.649

RULE SUMMARY: Proposes adding "Formulary or Protocol" to (1)(b) and removes "compendia" to provide clarity to licensees.

CHANGES TO RULE:

855-115-0335

Services: Prescribing - Prohibited Practices

- (1) A Pharmacist must not prescribe a drug or device via the Formulary or Protocol Compendia: ¶
- (a) To self; or ¶
- (b) When the compendia Formulary or Protocol requires referral to a non-Pharmacist provider. ¶
- (2) A Pharmacist must not require, but may allow, a patient to schedule an appointment with the Pharmacist for the prescribing or administering of an injectable hormonal contraceptive or the prescribing or dispensing of a self-administered hormonal contraceptive.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645, ORS 689.649

RULE SUMMARY: Proposes removing "compendium" and adds "Formulary" to provide clarity to licensees.

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, an FDA-approved drug and device listed in the following compendium Formulary, 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.

- DFormulary 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

RULE SUMMARY: Proposes removing "compendium", adds that protocols in their entirety are adopted by the board by specific effective dates referenced can be found on the board website to provide clarity and a path to resources licensees can utilize. Adds "protocol" to (1), (2), (3), (4) and proposes adding new vaccination protocols in (4)(a),(b),(c),(d) and (e) per board and Public Health and Pharmacy Formulary Advisory Committee directives to simplify and streamline vaccine protocols. Proposes repealing (A) through (V) individual existing vaccine protocols which would be relocated and incorporated into the new vaccination protocols in (4) (a) through (e).

CHANGES TO RULE:

855-115-0345

Services: Prescribing Pursuant to - 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, pursuant to a Protocol. Protocols in their entirety are adopted by the board by this rule pursuant to the respective effective date referenced and can be found on the board website at https://www.oregon.gov/pharmacy/Pages/PFAC.aspx.

- (1) Continuation of therapy <u>Protocol</u> including emergency refills of insulin and early refills of opioid use disorder medications (v. 08/2024)¶
- (2) Conditions Protocols: ¶
- (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) COVID-19 Antigen Self-Test (v. 12/2021);¶
- (c) SARS-CoV-2 Antiviral (v. 08/2024)¶
- (3) Preventative €Care Protocols:¶
- (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. 06/2025);¶
- (h) Sexually Transmitted Infections Post-exposure Prophylaxis (STI PEP) (v. 06/2024);¶
- (i) Short-acting Opioid Antagonists (v. 06/2024); and ¶
- (j4) Vaccine Protocols:¶
- (Aa) Standard Vaccination Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathwaydults 18 Years of Age and Older (v. 068/20245);-¶
- (Bb) Standard Vaccination Protocol for All Vaccines: Managing Adverse Reactions (v. 06/2024); ¶
- (C) Cholera (v. 02/2024); ¶
- (D) Coronavirus 2019 (v. 06/2025); ¶
- (E) Haemophilus Influenza type bges 7 through 17 Years (v. 068/20245);¶
- (Fc) Hepatitis A containing vaccines (v. 02/2024); ¶
- (G) Hepatitis B containing vaccines (v. 06/2025); ¶
- (H) Human Papillomavirus (v. 02/2024); ¶
- (I) Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2024-2025 Vaccination

Protocol for Ages 3 through 6 Years (v. 1208/20245); ¶

- (J) Influenza Live Attenuated Influenza Vaccine 2024-2025 (v. 12/2024); ¶
- (K) Japanese Encephalitis (v. 06/2024); ¶
- (L) Meningococcal containing vaccines (v. 06/2025); ¶
- (M) Measles Mumps & Rubella containing vaccines (v. 02/2024); ¶
- (N) Pneumococcald) Vaccination Protocol for Ages 6 months through 2 Years (v. 068/2025); and ¶
- (Oe) Polio (v. 06/2024);¶
- (P) Rabies (v. 02/2024); ¶
- (Q) Respiratory Syncytial Virus (v. 06/2025);¶
- (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 Vaccination Protocol for Managing Adverse Reactions (v. 028/20245).¶

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

Statutory/Other Authority: ORS 689.205, ORS 689.005

Statutes/Other Implemented: ORS 689.645, ORS 689.649, ORS 689.689, ORS 689.005