Oregon Board of Pharmacy
*REVISED BOARD MEETING AGENDA
December 13-15, 2023

Public Attendance Options:

1. **In-person: 800 NE Oregon St. Conference Room 1A, Portland, OR**
2. **Virtually via Teams: Link**
3. **Audio only: (503) 446-4951 Phone Conference ID: 506 774 999#**
4. ***If you experience audio issues upon joining the virtual meeting, send an email to pharmacy.board@bop.oregon.gov for assistance***

The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

Wednesday, December 13, 2023 @ 8:30AM
Thursday, December 14, 2023 @ 8:30AM
Friday, December 15, 2023 @ 8:30AM

- All OBOP meetings, except Executive Sessions, are open to the public. Pursuant to ORS 192.660(1)(2)(f)(L), Executive Sessions are closed to the public, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the board will return to Open Session
- To sign up for Public Comment, email your request to pharmacy.board@bop.oregon.gov by **12:00PM on 12/15/2023**

If you need accommodations under the Americans with Disabilities Act (ADA), complete and submit the online OBOP Request for ADA Accommodations for Public Meetings form located on our website.

WEDNESDAY, DECEMBER 13, 2023

I. OPEN SESSION, Ian Doyle RPh, Presiding

***Please note that the board will meet in Executive Session for most of the day and anticipates resuming Open Session between 4:30-5:00PM.**

a. Roll Call
b. Agenda Review and Approval — *Action Necessary*
c. New Compliance Officer Introduction

II. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 192.660(1)(2)(f)(L), ORS 192.690(1) ORS 676.165, ORS 676.175.

a. Deliberation on Disciplinary Cases and Investigations
b. Contested Case Deliberation *if applicable

III. OPEN SESSION – PUBLIC MAY ATTEND – At the conclusion of Executive Session, the board may convene Open Session to review scheduled agenda items as time permits.

Adjourn — *Action Necessary*

Oregon Board of Pharmacy
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THURSDAY, DECEMBER 14, 2023

I. **OPEN SESSION, Ian Doyle RPh, Presiding**
***Please note that the board will meet in Executive Session starting at 10:45AM and anticipates resuming Open Session at 1:00PM.**
   a. Roll Call

II. **GENERAL ADMINISTRATION**
   a. Strategic Plan Update **#A, #A1**

II. **EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 192.660(1)(2)(f)(L), ORS 192.690(1) ORS 676.165, ORS 676.175.**
   a. Deliberation on Disciplinary Cases and Investigations
   b. Contested Case Deliberation *if applicable

III. **OPEN SESSION – PUBLIC MAY ATTEND** - At the conclusion of Executive Session, the board may convene Open Session to review scheduled agenda items as time permits.

IV. **GENERAL ADMINISTRATION CONTINUED**
   a. Rules
      i. Review Rulemaking Hearing Report & Comments **#B** *Action Necessary*
      ii. Consider Adoption of Temporary Rules
         1. **Div 041** – Short-acting Opioid Antagonist (2023 HB 2395, 2023 SB 450 & 2023 SB 1043) **#C** *Action Necessary*

      iii. Consider Adoption of Rules
         1. **Div 019/025/041/139** – RPH/COPT/PT Administration of Vaccines (2023 HB 2486 & 2023 HB 2278) **#D** *Action Necessary*
         2. **Div 020** – Vaccination Protocols – Protocol Compendium **#D1** *Action Necessary*
            a. Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 2/2024) **#D1a**
            b. Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 2/2024) **#D1b**
            c. Cholera (v. 2/2024) **#D1c**
            d. Coronavirus 19 (v. 2/2024) **#D1d**
            e. Haemophilus Influenzae type b (v. 2/2024) **#D1e**
            f. Hepatitis A containing vaccines (v. 2/2024) **#D1f**
            g. Hepatitis B containing vaccines (v. 2/2024) **#D1g**
            h. Human Papillomavirus (v. 2/2024) **#D1h**
            i. Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024 (v. 2/2024) **#D1i**
            j. Influenza Live Attenuated Influenza Vaccine 2023-2024 (v. 2/2024) **#D1j**
            k. Japanese Encephalitis (v. 2/2024) **#D1k**

l. Measles, Mumps & Rubella containing vaccines (v. 2/2024) **#D1l**
m. Meningococcal containing vaccines (v. 2/2024) **#D1m**
n. Pneumococcal (v. 2/2024) **#D1n**
o. Polio (v. 2/2024) **#D1o**
p. Rabies (v. 2/2024) **#D1p**
q. Respiratory Syncytial Virus (v. 2/2024) **#D1q**
r. Tetanus, Diphtheria containing vaccines (v. 2/2024) **#D1r**
s. Typhoid (v. 2/2024) **#D1s**
t. Varicella containing vaccines (v. 2/2024) **#D1t**
u. Yellow Fever (v. 2/2024) **#D1u**
v. Zoster (v. 2/2024) **#D1v**

3. **Div 041** – Drug Outlet Requirements **#D2** *Action Necessary*
4. **Div 080** – Schedule II Prescriptions **#D3** *Action Necessary*
5. **Div 115/125** – RPH/COPT/PT Administration of Vaccines **#D4** *Action Necessary*
6. **Div 115** – Pharmacist Applicability, Definitions, Supervision, Counseling, PIC: Qualifications & Limitations, and CPA & CDTM **#D5** *Action Necessary*
7. **Div 125** – Pharmacy Technician Prohibited Practices **#D6** *Action Necessary*

iv. Rules in Development
v. Rulemaking Policy Discussion Items

1. **Div 041** – Short-acting Opioid Antagonist **#E** *Action Necessary*
2. **Div 001** – Procedural Rules (Repeal) **#E1** *Action Necessary*
3. **Div 010** – Board Administration and Policies (Repeal) **#E2** *Action Necessary*
4. **Div 019** – Pharmacists (Repeal) **#E3** *Action Necessary*
5. **Div 020** – Pharmacist Prescribing (Repeal) **#E4** *Action Necessary*
6. **Div 025** – Certified Oregon Pharmacy Technician/Pharmacy Technician (Repeal) **#E5** *Action Necessary*
7. **Div 031** – Interns (Repeal) **#E6** *Action Necessary*
8. **Div 041/110** – Pharmacies- Consulting Drugless **#E7** *Action Necessary*
9. **Div 115** – Pharmacist Applicability **#E8** *Action Necessary*
10. **Div 120** – Preceptor Renewal/Reinstatement **#E9** *Action Necessary*
11. **Div 041/043/183** - Drug Compounding **#E10** *Action Necessary*
12. **Div 006** – Definitions **#E11** *Action Necessary*

Adjourn *Action Necessary*

FRIDAY, DECEMBER 15, 2023

I. OPEN SESSION, Ian Doyle RPh, Presiding
a. Roll Call

II. MOTIONS RELATED TO DISCIPLINARY ACTIONS *Action Necessary*
**At this time the board will vote on cases, including proposed disciplinary actions against licensees/registrants.*

Oregon Board of Pharmacy
***REVISED BOARD MEETING AGENDA**
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III. GENERAL ADMINISTRATION

b. Rules Policy Discussion Continued
c. Recognition of outgoing Executive Director Schnabel
d. Rules Policy Discussion Continued
e. Discussion Items
   i. Petition Request (OAR 137-001-0070) **#F** *Action Necessary*
   ii. Requests
      1. SBAR – Albertsons Companies, Inc. **#G** *Action Necessary*
   iii. Safe Pharmacy Practice Conditions
   iv. NABP Member Forum Report **#H**

IV. ISSUES AND ACTIVITIES* (*Items in this section may occur at any time during the meeting as time permits*)

2024 Board Meeting Dates

- February 7-9, 2024 Portland
- April 10-12, 2024 Portland
- June 12-14, 2024 Portland
- August 7-9, 2024 Portland
- October 9-11, 2024 Portland
- November 7, 2024 Portland (Strategic Planning)
- December 11-13, 2024 Portland

Proposed Rulemaking Hearing Dates

(The following dates are reserved for potential rulemaking hearings & identified only for planning purposes and approved by the board. Actual rulemaking activities will be noticed as required by law and may deviate from this schedule as needed.)

- January 24, 2024
- May 22, 2024
- November 26, 2024

Conferences/Meetings

- N/A

V. APPROVE CONSENT AGENDA* *Action Necessary*

**Items listed under the consent agenda are considered routine agency matters and will be approved by a single motion of the Board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.*

a. License/Registration Ratification 9/26/2023 – 11/27/2032 - **# CONSENT-1**
b. Board Meeting Summary– October 2023 - **# CONSENT-2**
c. Strategic Planning Meeting Summary – November 2023 - **#CONSENT-3**

VI. PUBLIC COMMENT

VII. MATTERS TO BE DISCUSSED BY THE BOARD

Adjourn *Action Necessary*

Date: December 8, 2023

Strategic Planning Session November 8-10, 2023

Checklist of Board Direction Item and Draft Goals and Actions

Licensees

Addressed in Draft?*	Board Meeting Item/Guidance
√	Monitor and respond to impact of updated rules as they go into effect
√	Support professional fulfillment (i.e., fight box checking) – Box checking in Regulation and Compliance
√ (in part)	Staffing Capacity - Quotas and performance metrics? (Regulation) - What are reasonable ratios? (Regulation) - PBM reimbursement – *Not in scope for OBOP??* - Look through SPPC process. [Registrants]
√	Pipeline- attract, recruit and develop new/future pharmacy professionals. (Communication)

Registrants

Addressed in Draft?	Board Meeting Item/Guidance
√	Continue SPPC effort and process to ensure diverse representation in addressing safe practice challenges. Ensure access is a priority/goal (i.e., look at closures)
√	Focus on assessing and enhancing access by underserved individuals and groups
√	Review, and update rules with focus on clarity, administrative burden, reduce
√	Investigate and identify ways to improve efficiency for registrants (i.e., revise apps online (In Operations)
√	Refine self-inspection forms (In Operations)

Innovation

Addressed in Draft?	Board Meeting Item/Guidance
√	Consider who may be left out and brought in by technology (consider access, capability)
√	Explore impact of the use of AI (positive/negative)
√	Leverage other agency/enterprise technology
√	Increase access through multiple languages and vision and hearing impairment priorities
√	Data use/value of technology
	Clarify Governor's guidance on Board role

* "Addressed" means either as a Goal, Key Action or both. (May not include exact language from the planning meeting.)

Operations

Addressed in Draft?	Board Meeting Item/Guidance
√	Clarification and updates of behavioral and mental health questions for all licensees and be a resource for licensees. [added to Licensees]
√	Review and revise agenda process and Board knowledge of past decisions
√	Procure Appropriate software to ensure better communications and function
√	Investigate the possibilities and needs surrounding additional staff
√	Increase access to PIC classes.
	Clarify Governor's guidance on customer service; Diversity, Equity, and Inclusion; and Agency reporting Expectations

Regulation and Compliance

Addressed in Draft?	Board Meeting Item/Guidance
√	Review options for case data gathering and reporting (what, when, and why) tied to the system
√	Continue analyzing causes for growth in number of cases/complaints- look for opportunities to address
√	Continue approach to organize case information and review to make it easier and more effective for Board
√	Explore ways to enhance communication of new rules. (Communication)
√	Assess effectiveness of rule deployment
√	Standing committees/resources for input on rules. Diverse input to be included at the beginning of rule writing
√	Restore opportunities for "Interim" discussion on rule priorities, rationale, scoping between Board and Staff
	Clarify Governor's guidance on Board role in legislation (i.e., contradicting statues)
√	Evaluate rules and their impact: kiosks and lockers. (Innovation)

Communications

Addressed in Draft?	Board Meeting Item/Guidance
√	Engage in activities that will foster a culture of professionalism, accountability, transparency and empathy
√	Develop Trust (i.e., among board members; board members and staff; board, staff, and external partners)
√	Increase clarity and ability of comprehension of public facing documents

√	Explore opportunities for PR to support board and licensees collaboration with other groups. (Did not mention PR specifically; may use other methods/resources)
√	Explore pathways to outreach and communications to the broader community to increase board visibility and influence
	Clarify Governor's guidance on customer service

Oregon Board of Pharmacy: Strategic Plan Draft Goals and Actions

This document outlines draft Goals and Key Actions for each of the Board of Pharmacy's strategic Pillars following the Board's 2023 Strategic Planning Meeting held November 8th-9th, 2023.

LICENSEES

Goals

A. Promote deployment and effective implementation of new Licensee rules to ensure they achieve intended outcomes.

Key Actions:

1. Monitor questions, concerns and impacts of updated rules to assess their effectiveness and identify any unintended consequences and/or need for clarification.
2. Take action as needed to amend and refine rules, to ensure clarity and achieve the intended results.

B. Enhance and/or support factors that can positively impact the well-being and ability of Licensees to safely and equitably serve patients.

Key Actions:

1. Collect and analyze data to gain insights into trends, challenges and opportunities related to Licensee diversity, job competence and satisfaction.
2. Collaborate with and learn from professional associations, other agencies and employers to build and sustain Licensee competency and promote their ability to effectively serve patients.
3. Support Licensee access to and prompt utilization of resources to address behavioral and mental health service needs.

REGISTRANTS

Goals

A. Amend existing rules for pharmacy Registrants to clarify categories and operating standards, support safe and equitable access, and avoid unnecessary administrative effort.

Key Actions:

1. Establish clear goals, priorities and a high-level plan for the pharmacy Registrant rule revision process.
2. Evaluate and refine each proposed rule change to minimize compliance challenges while prioritizing public safety and access to medication.

B. Update rules for non-pharmacy Registrants—manufacturers, wholesalers, third-party logistics providers, drug distribution agents and non-prescription drug outlets—to address changes in federal regulations.

Key Actions:

1. Harmonize existing rules with updated Federal regulations to ensure consistency and alignment.
2. Identify and address gaps in state rules to mitigate risks to patients, support efficient drug distribution and provide clear operating guidelines for non-pharmacy Registrants.

C. Utilize the Board's platform and expertise to help address Registrant-related obstacles to equitable access and potential patient safety risks.

Key Actions:

1. Engage with public and other interested parties to identify individuals, groups and locations facing obstacles to accessing pharmacy services.
2. Continue the Safe Pharmacy Practice Conditions (SPPC) initiative, considering enhancements to promote diverse representation and more effectively address safe practice challenges.

INNOVATION

Goals

A. Proactively assess and manage the impact of emerging technologies on pharmacy practice and patient safety.

Key Actions:

1. Monitor the adoption of innovative technologies in the pharmacy industry, evaluating their potential benefits and challenges in terms of pharmacy access, service and patient safety risks.
2. Identify areas where the Board can act to facilitate the safe and effective implementation of innovative technology solutions, including potential modifications to statutes and rules.
3. Examine potential applications and implications of Artificial Intelligence (AI) in the context of the Board's work and the overall practice of pharmacy, highlighting both advantages and concerns.

B. Explore and adopt innovative approaches to enhance access to Board rules, information and services.

Key Actions:

1. Continue progress in providing on-line informational resources and interactive tools to foster engagement with our customers, patients, and communities.
2. Collaborate with state enterprise and/or other agencies to leverage technology solutions and improve access to, and quality of, Board services and information. (E.g., translation services for non-English speakers, ADA access guidelines, etc.)

OPERATIONS

Goals

A. Address opportunities to promote efficiency and access to Board-provided services and support.

Key Actions:

1. Continuously enhance the online information and tools provided to Licensees, Registrants, and the public prioritizing user-friendliness and accessibility.
    a) Regularly evaluate the effectiveness of Registrant self-inspection forms and other guidance documents to ensure they remain relevant, informative, and easy to understand.
    b) Expand access to Pharmacist-in-Charge training and other high-demand training programs. Ensure adequate tracking mechanisms are in place to keep accurate records of participation and completion.

B. Ensure agency capacity, diversity, and capability to achieve operational and strategic priorities, deliver effective service to customers and optimize resource utilization.

Key Actions:

1. Conduct a comprehensive analysis of staff roles, diversity, skill levels, budgets and organizational culture in relation to workload, priorities and values.
2. Implement realignments to staffing levels, roles and responsibilities as needed to achieve Key Performance Measures-KPMs), promote staff diversity, foster strong morale and deliver on key goals.
3. Evaluate existing processes, procedures and systems/software tools to identify and take action to streamline operations and ensure high quality performance.
4. Support the Governor's strategic initiatives and fulfill all agency requirements within the assigned timeframes.

C. Improve support for Board member engagement and participation.

Key Actions:

1. Strengthen and reinforce the Board Member and staff onboarding and orientation process, ensuring a regular review of procedures and responsibilities.
2. Review the agenda-build process to broaden input and provide flexibility in addressing emerging priorities.

3. Develop and provide training on new board rules and procedures for meeting decorum, using Roberts Rules of Order.

REGULATION & COMPLIANCE

Goals

A. Continue and refine rule review and revision efforts, balancing patient safety goals with speed of progress, volume of changes and Board/constituent capacity.

Key Actions:

1. Proceed with planned overhaul of rules governing Registrants and implementation of recent Licensee rule updates and reorganization.
2. Expand opportunities for Board review, discussion and input on rule priorities, rationale and scoping.
3. Review current rule-writing process and implement measures to ensure early, diverse and thoughtful input from various interested parties, such as through outreach efforts, standing Rule Advisory Committees, Board standing committees and other approaches.
4. Continuously monitor the impact of new rules on safe practice of pharmacy and gather feedback from Licensees and Registrants. Take action as needed to refine rule writing and format.

B. Address causes and impact of significant growth in case and complaint volume.

Key Actions:

1. Conduct thorough, fact-based review and analysis of cases submitted for Board adjudication. Identify patterns and root causes by source of case or complaint.
2. Based on analysis and ongoing review of case trends, take appropriate mitigating action. This may include providing information for Licensees and Registrants to avoid violations, adding resources and/or adapting processes to manage case volumes.
3. Continue steps to improve organization of case information for effective Board review.
4. Design and implement an enhanced case tracking process to improve monitoring and response to trends and compliance issues.

COMMUNICATION

Goals

A. Enhance communication and understanding across the practice of pharmacy to promote safe access to medications, equitable treatment, trust and professionalism.

Key Actions:

1. Share and promote the Board and Governor's Vision and Goals as a foundation for alignment and collaboration with customers and partners.
2. Expand outreach and networking with diverse organizations, agencies and individuals to gain a deeper understanding of shared needs, identify opportunities for collaboration, and develop joint actions to achieve mutual goals.
3. Evaluate the effectiveness of current communications methods and channels and identify approaches to boost the impact of our messaging.
4. Review clarity and usability of frequently used public-facing documents and revise/improve them as needed to enhance accessibility and understanding.

B. Promote awareness and knowledge of rule changes and other Board actions to support understanding and compliance.

Key Actions:

1. Implement comprehensive pre- and post-launch communication strategies for rule updates, targeting Licensees, Registrants and other affected or interested parties.
2. Establish accessible "inbound" communication channels to facilitate feedback and address questions on rule amendments.
3. Explore and implement more diverse and effective methods to strengthen communication and interaction between Board and staff, ensuring clarity of goals, challenges, and decisions.

C. Develop a more responsive, service-oriented approach to providing timely and useful information to customers and the public.

Key Actions:

1. Investigate and evaluate approaches and options for handling Licensee and Registrant questions while maintaining a clear distinction between providing information and offering legal advice.
2. Identify and test various methods to enhance the handling of inquiries and evaluate their impact on customer/inquiry understanding and satisfaction.
3. Adopt effective response strategies while continuously evaluating their impact on compliance with regulations, service quality and perception of the Board of Pharmacy.

Oregon
Tina Kotek, Governor

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Date: November 22, 2023

To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: November 21, 2023

Hearing Location: Virtual Hearing via Teams

Proposed Rules:

- Divisions 019/025/041/139 related to Pharmacist/COPT/PT Administration of Vaccines
- Division 020 related to Vaccination Protocols - Protocol Compendium
    - Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 10/2023)
    - Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 10/2023)
    - Cholera (v. 10/2023)
    - Coronavirus 19 (v. 10/2023)
    - Haemophilus Influenzae type b (v. 10/2023)
    - Hepatitis A containing vaccines (v. 10/2023)
    - Hepatitis B containing vaccines (v. 10/2023)
    - Human Papillomavirus (v. 10/2023)
    - Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024 (v. 10/2023)
    - Influenza Live Attenuated Influenza Vaccine 2023-2024 (v. 10/2023)
    - Japanese Encephalitis (v. 10/2023)
    - Measles, Mumps & Rubella containing vaccines (v. 10/2023)
    - Meningococcal containing vaccines (v. 10/2023)
    - Pneumococcal (v. 10/2023)
    - Polio (v. 10/2023)
    - Rabies (v. 10/2023)
    - Respiratory Syncytial Virus (v. 10/2023)
    - Tetanus, Diphtheria containing vaccines (v. 10/2023)
    - Typhoid (v. 10/2023)
    - Varicella containing vaccines (v. 10/2023)
    - Yellow Fever (v. 10/2023)
    - Zoster (v. 10/2023)

- Division 041 related to Drug Outlet Requirements
- Division 080 related to Schedule II Prescriptions
- Divisions 115/125 related to Pharmacist/COPT/PT Administration of Vaccines

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- Division 115 related to Pharmacist Applicability, Definitions, Supervision, Counseling, PIC: Qualifications & Limitations, and CPA & CDTM
- Division 125 related to Pharmacy Technician Prohibited Practices

On October 20, 2023, the November 21, 2023 Rulemaking Hearing public notice was sent out via GovDelivery to 4,131 rulemaking/adopted rules subscribers and 23,179 licensees/registrants (27,310 total).

Stakeholders/public were invited to sign up to provide oral testimony during the virtual hearing, encouraged to email written comments to pharmacy.rulemaking@bop.oregon.gov and had an opportunity to call in to listen to the hearing.

The rulemaking hearing convened at 9:31AM and adjourned at 9:39AM. #13 people joined the public call to listen to the hearing. #1 person signed up to provide oral testimony, and #1 person provided testimony during the hearing. #18 written comments were received during the open comment period from 10/20/2023 through 4:30PM on 11/21/2023. The hearing was recorded, and the notice of proposed rulemaking filings were available on our website.

The following board and staff members participated:

Board Vice President Chinn
Board Member Joyce
Staff Member Davis
Staff Member Efremoff
Executive Director Fox
Staff Member Hennigan
Staff Member Melvin
Staff Member Runyon

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Pharmacist/Certified Oregon Pharmacy Technician/Pharmacy Technician Administration of Vaccines
ADOPT: OAR 855-025-0024

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AMEND: OAR 855-019-0270, OAR 855-019-0280, OAR 855-019-0290, OAR 855-041-1040, OAR 855-139-0600

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Vaccination Protocols – Protocol Compendium

AMEND: OAR 855-020-0300

Protocols:

- Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 10/2023)
- Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 10/2023)
- Cholera (v. 10/2023)
- Coronavirus 19 (v. 10/2023)
- Haemophilus Influenzae type b (v. 10/2023)
- Hepatitis A containing vaccines (v. 10/2023)
- Hepatitis B containing vaccines (v. 10/2023)
- Human Papillomavirus (v. 10/2023)
- Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024 (v. 10/2023)
- Influenza Live Attenuated Influenza Vaccine 2023-2024 (v. 10/2023)
- Japanese Encephalitis (v. 10/2023)
- Measles, Mumps & Rubella containing vaccines (v. 10/2023)
- Meningococcal containing vaccines (v. 10/2023)
- Pneumococcal (v. 10/2023)
- Polio (v. 10/2023)
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- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Drug Outlet Requirements
ADOPT: OAR 855-041-1019, OAR 855-041-1190

AMEND: OAR 855-041-1010, OAR 855-041-1018, OAR 855-041-1060, OAR 855-041-1105, OAR 855-041-1115, OAR 855-041-2115

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Schedule II Prescriptions

AMEND: OAR 855-080-0085

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Pharmacist/Certified Oregon Pharmacy Technician/Pharmacy Technician Administration of Vaccines

ADOPT: OAR 855-115-0305, OAR 855-125-0305

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Pharmacist Applicability, Definitions, Supervision, Counseling, PIC: Qualifications & Limitations, and CPA & CDTM

ADOPT: OAR 855-115-0001, OAR 855-115-0005, OAR 855-115-0122, OAR 855-115-0145,

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OAR 855-115-0205, OAR 855-115-0315

- Michele Koder, Pharmacy Director - Multnomah County Health Department
  - Was on CPA/CDTM workgroup
  - States CPA rules are counter to workgroup recommendation
  - Disagrees with economic and racial equity assessments for rule as referred to in prior testimony
  - May decrease fiscal sustainability of pharmacy programs provision of high quality care
  - May shift healthcare costs to more expensive providers such as emergency departments and hospitals
  - May adversely impact Medicaid and BIPOC communities across the state

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Pharmacy Technician Prohibited Practices

ADOPT: OAR 855-125-0150

- No oral testimony was provided.

All written comments received by the public comment deadline date of 11/21/2023 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 10/20/2023 Notice of Proposed Rulemaking.

OBOP Rulemaking Hearing Notification - November 21, 2023

Oregon Board of Pharmacy sent this bulletin at 10/20/2023 05:10 PM PDT

Oregon Board of Pharmacy

Proposed Oregon Administrative Rules

Rulemaking Hearing

November 21, 2023

Public Notice

The Oregon Board of Pharmacy is proposing to adopt the following rules:

November 21, 2023 Rulemaking Hearing

- Divisions 019/025/041/139 related to Pharmacist/COPT/PT Administration of Vaccines
- Division 020 related to Vaccination Protocols - Protocol Compendium
    - Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 10/2023)
    - Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 10/2023)
    - Cholera (v. 10/2023)
    - Coronavirus 19 (v. 10/2023)
    - Haemophilus Influenzae type b (v. 10/2023)
    - Hepatitis A containing vaccines (v. 10/2023)
    - Hepatitis B containing vaccines (v. 10/2023)
    - Human Papillomavirus (v. 10/2023)
    - Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024 (v. 10/2023)
    - Influenza Live Attenuated Influenza Vaccine 2023-2024 (v. 10/2023)
    - Japanese Encephalitis (v. 10/2023)
    - Measles, Mumps & Rubella containing vaccines (v. 10/2023)
    - Meningococcal containing vaccines (v. 10/2023)
    - Pneumococcal (v. 10/2023)
    - Polio (v. 10/2023)
    - Rabies (v. 10/2023)
    - Respiratory Syncytial Virus (v. 10/2023)
    - Tetanus, Diphtheria containing vaccines (v. 10/2023)
    - Typhoid (v. 10/2023)
    - Varicella containing vaccines (v. 10/2023)
    - Yellow Fever (v. 10/2023)
    - Zoster (v. 10/2023)

- Division 041 related to Drug Outlet Requirements
- Division 080 related to Schedule II Prescriptions
- Divisions 115/125 related to Pharmacist/COPT/PT Administration of Vaccines
- Division 115 related to Pharmacist Applicability, Definitions, Supervision, Counseling, PIC: Qualifications & Limitations, and CPA & CDTM
- Division 125 related to Pharmacy Technician Prohibited Practices

November 21, 2023 Rulemaking Hearing Information

Please review and provide comment on proposed draft rule language including the Fiscal Impact statement and Racial Equity statement. You can find the filing notices and rule text on our website.

The November 21, 2023 rulemaking hearing will be held virtually via Microsoft Teams and begins at 9:30AM. If you wish to present oral testimony virtually during this hearing, please complete and submit the sign up form on our website.

You may also sign up by submitting your first and last name, email address and which rule(s) you would like to comment on to pharmacy.rulemaking@bop.oregon.gov no later than 9:00AM on November 21, 2023. You will receive a confirmation email and a separate calendar invitation to join the virtual hearing.

You may submit written comments by 4:30PM on November 21, 2023 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov.

If you want to listen to the rulemaking hearing, call:

(503) 446-4951 Phone Conference ID: 343 868 791#

Questions?

Email all rulemaking inquiries to pharmacy.rulemaking@bop.oregon.gov.

NOVEMBER 21, 2023 RULEMAKING HEARING

The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

oregon.gov/pharmacy

The Oregon Board of Pharmacy is an equal opportunity, affirmative action employer committed to a diverse work force.
We respect, reflect and respond to the diverse people we serve.

From: Adam A
To: PHARMACY RULEMAKING * BOP
Subject: Commentary // Pharmacy Rules
Date: Tuesday, November 21, 2023 4:30:15 PM

To whom it may concern:

I am providing written commentary expressing concern regarding the proposed amendment to OAR 855-041-1105, which is summarized as follows:
“Amends rule by adding dispensing requirements for a Drug Outlet and relocates and revises existing language from OAR 855-019-0210(4)-(7) pertaining to required information for a prescription. Requires Pharmacist to clarify discrepancies or uncertainties regarding a prescription. Requires read back of an oral prescription. Clarifies prescriber authority to request no substitution for the manufacturer of a drug.”
The major concern is how this rule affects the capacity of Pharmacists to exercise professional judgment, discretion, and assessment in fulfilling prescription orders. Secondarily, the documents relied upon to generate the amendment are both informal and out of date, coming from a 2017 reader’s survey. And thirdly, Cost of Compliance statements of “no impact” are false when the very nature of the rule is requiring additional documentation, labor, and administration resources.
The amendment of OAR 855-041-1105 to require readback of oral prescriptions, and repeat listening of voicemail prescriptions undermines professionalism by dictating a requirement best left to professional discretion, and adds unnecessary burden to already overburdened pharmacy staff, regardless of practice setting. The task of ensuring proper delivery of medication requires a range of practices and should not be reduced to prescriptive rules such as “...Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription.” This is an unnecessary redundancy as OAR 855-019-0210 Duties of the Pharmacist Receiving a Prescription already contains language to impart the responsibility to ensure prescriptions, refills, and drug orders are correctly dispensed. The rule to require pharmacists to document transcription in a singular way parses out one method from a range of skills that practitioners of this profession use to carry out Pharmacy work. In doing so, the rule creates a myopia that restricts the professional capacity of pharmacists and could be detrimental to patient care.
In the notice’s section for Documents Relied Upon, an informal and dated web article is cited which seems like a poor basis for creating legislation that would dictate the practice of all Licensees in the state. The article “Despite Technology, Verbal Orders Persist, Read Back is Not Widespread, and Errors Continue” is not an organized study and evaluation of best practices for handling oral prescriptions but rather a web survey of the site’s own constituents, from 2017. Even within the article itself, many different practices are presented besides “read back” to reduce error; however none of those are presented in the amendment to OAR 855-041-1105. The scope of this article’s recommendations lay within an individual organization's practice, not a regulatory body.
The Cost of Compliance section of the notice incorrectly states there is “no additional mandatory reporting, recordkeeping, or other administrative requirements,” and “imposes no additional ...labor or administration.” The exact language of the amendment demands additional time and documentation to perform, and would certainly require additional administrative resources to maintain. The exact wording is as follows: “Reading back the prescription as transcribed to the person transmitting it; or¶ ¶ (ii) Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription.¶”
Thank you for taking the time to address my concerns before moving further with the Proposed Rule Making,

November 6, 2023

Jamal T. Fox
Executive Director
Oregon State Board of Pharmacy
800 N.E. Oregon Street, Suite 150
Portland, OR 97232

Re: Proposed Rules: Divisions 019/025/041/139 related to Pharmacist/COPT/PT Administration of Vaccines; Division 041 related to Drug Outlet Requirements; Division 080 related to Schedule II Prescriptions; Divisions 115/125 related to Pharmacist/COPT/PT Administration of Vaccines; Division 115 related to Pharmacist Applicability, Definitions, Supervision, Counseling, PIC Qualifications & Limitations, CPA & CDTM; Division 125 related to Pharmacy Technician Prohibited Practices

Dear Executive Director Fox:

Albertsons Companies Inc. ("ACI") family of pharmacies is one of the largest pharmacy providers in the state of Oregon. We currently operate 106 locations in the state under both the Albertsons and Safeway banners. Nationwide, ACI operates 1728 pharmacies across 34 states including the District of Columbia.

Divisions 019/025/041/139 related to Pharmacist/COPT/PT Administration of Vaccines

During the COVID-19 pandemic, pharmacies became a destination of choice for the administration of vaccines. This was due, in part, to the very accessible nature of pharmacies being located near a majority of Oregon residents. ACI appreciates the board promulgating rules to implement legislative bills that recently passed during the Oregon legislative session. Lowering the age for administering influenza vaccines to six months old and older as well as permanently allowing pharmacy technicians to administer vaccines under the supervision of a qualified and trained pharmacist will benefit the public. Lowering the age increases access to the influenza vaccine for many patients in the state, which will further support increased vaccination rates. The permanent allowance for pharmacy technicians to administer vaccines will support pharmacists by allowing the delegation of vaccinations to well-trained individuals who can assist in increasing capacity for administering vaccines in community pharmacies.

Division 041 related to Drug Outlet Requirements

ACI appreciates the board members listening to feedback provided during previous rulemaking hearings relative to several aspects including increasing the amount of time pharmacies have for notifying the Board of PIC changes to within 15 days of the change. While this helps from an administrative perspective, it does not ease the burden of the drug outlet to immediately replace a PIC when there is a vacancy. Without a grace period to find the most qualified individual for the position of PIC, outlets are forced to identify someone to assume this significant position immediately. While outlets are constantly identifying candidates as part of succession plans, there is still turnover that occurs unexpectedly or in areas where available and qualified candidates are scarce. This leaves outlets selecting candidates who are either inexperienced or do not want to assume the responsibility of being a PIC. **We strongly encourage the Board Members to consider instituting a grace period to allow an outlet additional time to search for and select the most qualified individuals to become the PIC.** During the grace period, an outlet can designate a point of contact who will be available for the day-to-day maintenance and operation of the pharmacy while a permanent PIC is found. We believe permitting a reasonable grace period will ultimately yield more compliant pharmacies in the state by improving the quality of the PIC and allowing for selection of individuals who are prepared, experienced, and willing to serve as PIC.

<u>855-041-1060: Out-of-State Pharmacies:</u>

This section was significantly amended during the most recent Board of Pharmacy Meeting in October. We are concerned that some of the amendments have the potential for reducing access to lifesaving essential medications. Removal of the 90-day grace period to replace an outgoing PIC will require an Out-of-State pharmacy to replace the PIC immediately or "cease dispensing, delivery, distribution, and provision of pharmacy services into Oregon." Many Out-of-State pharmacies, including our specialty pharmacy based in Michigan, distribute limited distribution drugs (LDD) into Oregon. Our specialty pharmacy, and other pharmacies like ours, are accredited or certified by manufacturers to distribute drugs that a traditional community pharmacy cannot. If there is a disruption in dispensing these medications to Oregon residents due to an unexpected departure of the Oregon licensed PIC, these patients will be forced to find another specialty pharmacy or go without their medication. **We request the board consider adding the stricken language back to allow Out-of-State pharmacies a 90-day grace period to either find and hire an Oregon licensed pharmacist or to allow time for an existing pharmacist on staff to become licensed in Oregon.** We believe that maintaining this grace period will uphold the mission of the Board to protect public safety. We believe the intent of the Board in removing the grace period was to provide equal treatment to pharmacies within the state as compared to those located outside the state. An alternative approach to preserving this intent would be to instead allow instate pharmacies to benefit from the same grace period historically given to pharmacies located out of state. It is also important to note that an Oregon licensed out-of-state pharmacy is dually subject

to the laws and regulations of their resident state, which requires a pharmacist to be designated in charge. When there is an absence of a pharmacist licensed in Oregon as PIC, that doesn't inherently mean these facilities are without supervision.

855-041-1105 Prescriptions: General Requirements

This section is unnecessarily prescriptive in nature as it outlines very specifically in subpart (2)(g) how a prescriber must sign and send a prescription. Leaving it at a prescription must have a valid signature would be sufficient and would also allow for innovation within the marketplace. The specificity of this requirement will undoubtedly result in many clarifying phone calls to prescribers to validate the type of signature on a prescription. Additionally, we foresee this additional specificity requirement as an auditing tool that Pharmacy Benefit Managers will be able to use to unnecessarily claw back reimbursements for prescriptions that would otherwise be valid and legitimate prescriptions.

Additionally, the newly added requirements in subpart (4) (a) and (b) of this section are more akin to standard operating procedures that are most likely already addressed by most companies' policies and procedures. Dictating the specific process for receiving verbal orders live or on voice mail removes all remnants of a pharmacist using professional judgment in how they practice pharmacy. **We request the Board remove this new language and allow the profession to continue operating without such nuanced oversight into standard operating procedures.** We understand there are mistakes that can be avoided by following the Board's proffered best practices, and we recommend the board consider using these specific procedures when crafting medication error related corrective action plans for pharmacies that struggle to operationalize their own best practices. However, this level of prescriptive regulation does not belong in state regulations. We suggest the Board instead use their experience related to these cases to publish a guidance document for pharmacies that outlines best practices for preventing medication errors rather than writing them into regulations. Collaborative outreach would have a better effect than creating onerous regulations that only increase the administrative burden on the profession.

Lastly, the same theme continues with subparts (7) (a) through (b). These sections are overly prescriptive with how a prescriber must designate how a prescription is to be dispensed as written without substitution. These are better served to be dictated by the Board of Medicine if they felt it would improve the safety of the way their profession issues prescriptions. **We recommend striking this language.**

Division 080 related to Schedule II Prescriptions

ACI appreciates the Board's efforts to align its regulations with previously available DEA guidance on what can be updated on Schedule II prescriptions. This has often been an area of the practice of pharmacy that is confusing for pharmacists. We believe this alignment will help

pharmacists practice with confidence when needing to clarify elements of a Schedule II prescription.

Divisions 115/125 related to Pharmacist/COPT/PT Administration of Vaccines

As we already stated at the beginning of these comments, we appreciate the Board aligning its regulations with the bills recently passed in the latest legislative session. We agree with the content of these proposed regulations and look forward to our trained pharmacy technicians being able to assist pharmacists in administering vaccines to the public.

Division 115 related to Pharmacist Applicability, Definitions, Supervision, Counseling, PIC Qualifications & Limitations, CPA & CDTM

855-115-0001 Applicability

During the September rulemaking hearing, we were very happy with how the Board left subpart (3) in this section. We believe it served the purpose and intent of the Board Members desire to allow pharmacists and other personnel working in an out-of-state pharmacy to support pharmacies and patients within the state of Oregon without requiring licensure in Oregon, with the exception of the PIC of that out-of-state facility. We believe the addition of the following phrase at the end of this section is unnecessary and creates ambiguity that was not there previously:

"This exception applies only when a pharmacist is dispensing, delivering, or distributing drugs into Oregon from a registered drug outlet. A pharmacist who is providing other pharmacy services must be licensed in Oregon."

Oregon allows a pharmacy to have a designation added to their facility license for purposes of providing centralized shared support of pharmacies located in Oregon. There are two designations -- one for central fill and a second for remote/central processing. The latter designation allows for a shared service relationship between two pharmacies under common ownership or as part of a contractual agreement. The permissible shared services include interpretation, evaluation, DUR, counseling and verification of prescriptions. In a central processing arrangement where the supporting pharmacy is located out-of-state, the prescription is received by the local Oregon pharmacy and then pharmacists from the Oregon licensed out-of-state pharmacy assist in processing the prescription on behalf of the staff located in the local Oregon pharmacy. However, the local pharmacy ultimately fulfill and dispense the prescription to the patient located in Oregon. By stating the "exception applies only when a pharmacist is dispensing, delivering or distributing drugs into Oregon" suggests that where an individual is providing only processing services, but not "dispensing, delivering or distributing," that individual will be required to hold an Oregon license. The Board's proposed "exception to the exception" language, in our opinion, effectively requires all individuals who assist in prescription processing to hold an Oregon license. This is

contrary to the beginning of subpart (3) that allows for this relationship and specific activities to be carried out as long as the facility has a responsible PIC who is licensed in Oregon. Given the expressed intent by Board members in the August and October meetings that this support of Oregon pharmacies can continue without added licensure requirements, **we request the Board members remove the contradictory language that was added during the October board meeting.** The centralized support pharmacy does not ship medication into Oregon, but rather supports the pharmacies electronically to allow for safer working environments in local pharmacies. Considering they don't ship medication into the state even though they are appropriately licensed to do so, this exception would become problematic to continue supporting our pharmacies in Oregon.

855-115-0005 Definitions

ACI supports the revised and clarified definition of counseling in this section. We believe it hearkens back to the way counseling has been defined historically in the state and does not create any unnecessary conflict that could limit patient access. Thank you for reacting to the feedback provided in previous public comment periods.

855-115-0145 Counseling

ACI supports the changes and added language to this section that will allow flexibility in who can extend the offer to a patient for a pharmacist to counsel them on the safe and effective use of their medication. We believe this will simplify the operation of a pharmacy and interactions that naturally occur in a pharmacy at the point of sale. The additional allowance in subpart (6) for written materials to be used to convey important information when prescriptions are either mailed or delivered to a patient's home will allow for patients who are homebound or otherwise unavailable to visit a pharmacy during normal operating hours to receive their medications in a timely manner. This serves the purpose of protecting public health by preserving access to pharmacy services.

855-115-0205 Pharmacist-in-Charge: Qualifications and Limitations

We have commented several times on this section as it relates to potential conflicts with a pharmacy's ability to appoint a PIC. Earlier in these comments, we outlined the need for a grace period between an outgoing PIC and the incoming PIC to allow pharmacies an adequate opportunity to identify an appropriate candidate. The requirements in this section are one of the contributing factors to our opinion that this grace period is critical. While we appreciate the delay in effective date for the requirement that a PIC with less than 1500 hours of experience has to take the PIC training course prior to being appointed as PIC, we still see challenges arising from this requirement in 2025. While this rule allows flexibility for pharmacies to choose a PIC who has less than 1500 hours of experience, thus increasing the potential candidate pool, this less

experienced pharmacist will not be qualified to accept a PIC position unless they have previously taken the PIC training course. In the event of an unforeseen departure of a PIC in a rural area, it's not unreasonable that a pharmacy'swhere only option will be to appoint less tenured pharmacist as PIC. However, there will invariably be a gap between the outgoing PIC and the incoming PIC while the pharmacist schedules and completes the PIC training course. Under currently proposed regulations, this gap will mandate that the drug outlet close temporarily while the training requirement is fulfilled. The alternative is that every new pharmacist working in Oregon will need to proactively take the course whether they are interested in being a PIC or not. We believe this will result in undue burden on Board staff to either increase the frequency of this training or increase class sizes. A clear alternative would be to allow for a grace period between outgoing and incoming PICs to allow for both the right person being appointed and time sufficient to complete any training necessary prior to becoming the PIC. **ACI recommends the board take the approach of creating a grace period between PICs to ease what has historically been a very difficult to comply with requirement to immediately replace a PIC.**

Division 125 related to Pharmacy Technician Prohibited Practices

ACI agrees with the modifications made to this section. Primarily the items that were removed to allow licensed technicians to better assist the pharmacist with administrative work associated with the practice of pharmacy. We are excited for our technicians to begin supporting the pharmacist with tasks such as facilitating transfers between pharmacies for non-controlled substances, clarifying information with a prescriber that does not require judgment, taking new verbal prescriptions over the phone or on voicemail, and most impactfully, administering vaccines.

We observed the discussion during the Board meeting in October very closely related to technicians being prohibited from supervising, directing, or controlling a licensee in activities that constitute the practice of pharmacy. We believe the addition of (n) as a prohibited practice will create confusion in the industry both in health systems and community pharmacies. In standard practice of pharmacy Technicians often support each other to ensure they are appropriately trained to assist the pharmacist in the practice of pharmacy. This often involves more experienced technicians supporting and supervising lesser experienced technicians while they are learning to assist the pharmacist in the practice of pharmacy. We are concerned that pharmacists or technicians will interpret (n) to prohibit that relationship to occur, ultimately requiring pharmacists being required to directly train new technicians. This could create more patient safety concerns as it would overburden the pharmacist and pull them away from their professional duties. The Board members might consider using a little "s" to allow technicians to supervise each other and a big "S" to indicate the supervision required by a pharmacist. The big "P" and little "p" references to pharmacists have never confused anyone.

We appreciate this opportunity to provide feedback on these regulations and their significance to patient access to pharmacy care in Oregon. Should you have any questions or if you would like to

discuss this matter in further detail, please do not hesitate to contact me. I can be reached by email at Rob.Geddes@albertsons.com or on my mobile phone at (208) 513-3470.

Sincerely,

Rob Geddes, PharmD, MBA
Director, Pharmacy Legislative and Regulatory Affairs

From:	Rob Geddes
To:	PHARMACY RULEMAKING * BOP
Cc:	Kasia Kujawski
Subject:	November Rule Making Comments
Date:	Tuesday, November 7, 2023 12:39:56 PM
Attachments:	November 2023 Rulemaking Comments Final 11-6-23.pdf

Rachel,

Here are our comments on the current rule packages up for public comment. Have a great day.

Rob Geddes, PharmD, MBA
Director, Pharmacy Legislative and Regulatory Affairs
Albertsons Companies, Inc.
(M) 208.513.3470
(O) 208.395.3987
(F) 623.869.1568
Rob.Geddes@albertsons.com

From: Anthony Tran
To: PHARMACY RULEMAKING * BOP
Subject: Comment on Rulemaking for OAR 855-041-1105
Date: Tuesday, November 21, 2023 3:28:20 PM

Tuesday Nov 21, 2023

To: Ian Doyle
President Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Dear Ian and Board of Pharmacy members,

I am providing written commentary expressing concern regarding the proposed amendment to OAR 855-041-1105, which is summarized as follows:

"Amends rule by adding dispensing requirements for a Drug Outlet and relocates and revises existing language from OAR 855-019-0210(4)-(7) pertaining to required information for a prescription. Requires Pharmacist to clarify discrepancies or uncertainties regarding a prescription. Requires read back of an oral prescription. Clarifies prescriber authority to request no substitution for the manufacturer of a drug."

The major concern is how this rule affects the capacity of Pharmacists to exercise professional judgment, discretion, and assessment in fulfilling prescription orders. Secondarily, the documents relied upon to generate the amendment are both informal and out of date, coming from a 2017 reader's survey. And thirdly, Cost of Compliance statements of "no impact" are false when the very nature of the rule is requiring additional documentation, labor, and administration resources.

The amendment of OAR 855-041-1105 to require readback of oral prescriptions, and repeat listening of voicemail prescriptions undermines professionalism by dictating a requirement best left to professional discretion, and adds unnecessary burden to already overburdened pharmacy staff, regardless of practice setting. The task of ensuring proper delivery of medication requires a range of practices and should not be reduced to prescriptive rules such as *"...Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription."* This is an unnecessary redundancy as OAR 855-019-0210 Duties of the Pharmacist Receiving a Prescription already contains language to impart the responsibility to ensure prescriptions, refills, and drug orders are correctly dispensed. The rule to require pharmacists to document transcription in a singular way parses out one method from a range of skills that

practitioners of this profession use to carry out Pharmacy work. In doing so, the rule creates a myopia that restricts the professional capacity of pharmacists and could be detrimental to patient care.

In the notice's section for *Documents Relied Upon*, an informal and dated web article is cited which seems like a poor basis for creating legislation that would dictate the practice of all Licensees in the state. The article *"Despite Technology, Verbal Orders Persist, Read Back is Not Widespread, and Errors Continue"* is not an organized study and evaluation of best practices for handling oral prescriptions but rather a web survey of the site's own constituents, from 2017. Even within the article itself, many different practices are presented besides "read back" to reduce error; however none of those are presented in the amendment to OAR 855-041-1105. The scope of this article's recommendations lay within an individual organization's practice, not a regulatory body.

The *Cost of Compliance* section of the notice incorrectly states there is "no additional mandatory reporting, recordkeeping, or other administrative requirements," and "imposes no additional …labor or administration." The exact language of the amendment demands additional time and documentation to perform, and would certainly require additional administrative resources to maintain. The exact wording is as follows: *"Reading back the prescription as transcribed to the person transmitting it; or¶ ¶ (ii) Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription.¶"*

Thank you for taking the time to address my concerns before moving further with the Proposed Rulemaking,

Anthony Tran

Oregon Board of Pharmacy

800 NE Oregon St., Suite 150

Portland, OR 97232

Executive Director Fox and Distinguished Members of the Board,

First, we would like to thank the Board for considering our previous comments and updating the proposed rule to allow licensed personnel to accept the declination for counseling and documentation of the attempt to consult.

Today we would like to submit written comments opposing rule change 855-125-0150 regarding prohibited practices for Pharmacy Technicians including:

> (n) Supervise, direct, or control a licensee in activities that constitute the practice of pharmacy as defined in ORS 689.005 or assisting in the practice of pharmacy;
> (o) Delegate tasks to healthcare providers.

We are in alignment with the Board's position that a pharmacist must be responsible for control of each aspect of the practice of pharmacy, (OAR 855-019-0200(4)(b)), and that each technician must know at all times the pharmacist that is supervising, directing, and controlling them (OAR 855-025-0023(2)(c)). We believe the spirit of these rules allows a Pharmacy Technician to serve as a trainer, department lead, or direct daily workflow with authorization from, and under the direction and supervision of a pharmacist, and with a pharmacist responsible for all actions taken by licensed personnel that constitute assisting in the practice of pharmacy.

Specialty pharmacy requires a high touch model to ensure that we can meet each patient's unique needs. This form of pharmacy necessitates a higher number of licensed staff to support all aspects of a patient's healthcare journey including securing financial support and increased patient and provider outreach, interaction, and follow-up. **Allowing a Pharmacy Technician to direct these day-to-day activities, and provide delegated supervision, enables the pharmacist to focus on clinical tasks and responsibilities that require professional judgement, without the distraction of directing each daily task of staff.** In addition, it is standard practice for a pharmacist to delegate to a lead or senior technician authority to direct the team and assign priorities for tasks that need to be completed each day as part of normal pharmacy workflow. **The rule, as written, could interpret this standard pharmacy practice as delegating tasks to other healthcare providers, and could therefore be prohibited.**

While we understand that a financial impact statement will be requested at a later date, it is important to note at this time that this will have a fiscal and economic impact. **Pharmacies will be required to employ more pharmacists to act as trainers, supervisors, and directors of day-to-day pharmacy activities.**

Recommendations:

We recommend that the Board does not make supervision and direction, or delegation of tasks by a Pharmacy Technician a prohibited practice. **We suggest that the Board remove this language from the proposed rule 855-125-0150, or that a caveat is added to state:**

> (n) Supervise, direct, or control a licensee in activities that constitute the practice of pharmacy as defined in ORS 689.005 or assisting in the practice of pharmacy, ***without authorization and ultimate supervision, direction, or control by a pharmacist.***
> (o) Delegate tasks to healthcare providers, ***without authorization and ultimate supervision, direction, or control by a pharmacist.***

We want to thank you for the opportunity to comment on these proposed rule changes. If the Board requires additional information, please feel free to contact us.

Respectfully,

Valerie Ott, PharmD

Ardon Health

Pharmacist-In-Charge & Director of Pharmacy Operations

ardon

From: Valerie Ott
To: PHARMACY RULEMAKING * BOP
Subject: Rulemaking Written Comment
Date: Tuesday, November 21, 2023 9:22:08 AM
Attachments: image002.png
image003.png
855-125-0150 Prohibited Practices for Pharmacy Technicians.pdf

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> You don't often get email from valerie.ott@ardonhealth.com. Learn why this is important

Good Morning,

Thank you for the opportunity to provide a comment in relation to proposed rules.

Please see attachment for written comment.

Regards,

Valerie Ott, PharmD, CSP, MSCS (she/her)
Director of Pharmacy Operations, Pharmacist-In-Charge, Ardon Health
office 503-444-6532 | ardonhealth.com

Inspiring people and improving lives

From:	Emily Colborn
To:	PHARMACY RULEMAKING * BOP
Cc:	Daniel Luce; Thomas Menighan; Carmen Catizone
Subject:	Comments to Oregon Board of Pharmacy Advisors
Date:	Tuesday, November 21, 2023 7:01:13 AM
Attachments:	Comments to Oregon Board 21November2023.pdf

Hello,

Please see the attached comments for the Oregon Board of Pharmacy Advisors.

Best,
Emily Colborn

Lauren Paul, RPh, PharmD, MS
Executive Director, Pharmacy Regulatory Affairs
CVS Pharmacy

One CVS Drive
Woonsocket, RI 02895

c 540-604-3661

lauren.paul@cvshealth.com

November 20, 2023

Jamal Fox, MPA
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Amendments to Divisions 020, 041 and 115

Dear Executive Director Fox and Members of the Oregon State Board of Pharmacy,

I am writing to you in my role as Executive Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide care with diverse access points to patients in the state of Oregon through our integrated offerings across the spectrum of pharmacy care. We appreciate the opportunity to comment on proposed rules.

OAR 855-020-0300 Protocol Compendium – Related to Vaccination Protocols

CVS Health is supportive of the vaccine protocols moving from Oregon Health Authority oversight into Division 20 protocol compendium. However, to provide clarity and streamline practice in Oregon, we request the Board consider not adopting individual vaccine protocols as standards adopted by reference, but instead adopt one protocol to cover all vaccines. Most recently, the Virginia Board of Pharmacy was granted statutory authority to develop statewide protocols for various treatments, including vaccines.[1] The Board then adopted simple statewide protocols, one for ages 3 to 17 and one for ages 18+. We request the Oregon Board of Pharmacy review this method and consider adoption of a simplified protocol for all vaccines, which includes pharmacist's shared clinical decision making.

OAR 855-041-1060 Out of State Pharmacies

CVS Health has grave concerns with the proposed language which removes the four-month window to designate PIC upon initial registration, allows for a 90 day window for change of PIC, requires an out of state PIC to follow requirements in OAR 855-115-0210(1)(a-h) and (2), and requires pharmacies to follow Oregon standards of practice of pharmacy in OAR 855-155. An out of state pharmacy, by the nature of being located outside of the state of Oregon, would have a limited number of Oregon licensed pharmacists as compared to pharmacies within Oregon. Therefore, when an out of state pharmacy experiences the turnover of the Oregon nonresident PIC, the pharmacy may have to cease dispensing to the residents of the state of until the PIC is replaced. The ensuing delay of identifying a successor could cause an immediate impact to patient safety with the potential resultant lapse in therapy. We ask the Board to weigh the benefit of out of state change in PIC timeframe decrease compared to the potential negative effect on the residents of the state of Oregon.

Additionally, it is questionable as to whether the Board has the statutory authority to require an out of state pharmacy comply with the practice standards for the practice of pharmacy in OAR 855-115. An out of state pharmacy, located outside of the state of Oregon, is required to comply with the pharmacy laws and rules as mandated by their home state's legislature or regulatory agency. As a result, these proposed rules create the risk of creating a conflict of laws issue where an out of state pharmacy is placed in a position to choose which state law to comply with. Furthermore, this requirement may be viewed as an undue burden on interstate commerce without an overriding patient safety reason behind the proposed rule.

Therefore, to avoid the potential disruption in service to patients in Oregon and the potential conflict of resident state compliance, we urge the Board NOT to adopt the amended rules as proposed.

OAR 855-115-0001 Applicability

Over the past year, Board members and staff engaged in numerous discussions on the applicability section, which has led to various iterations of proposed amendments for which the Board has received public comment. Each time the rule has been discussed; it is mentioned that the goal is to provide clarity. However, with each iteration, there seems to be less clarity. CVS Health is unsure of the goal with the current proposed language, which added two sentences referencing dispensing, delivering or distribution. We request the Board consider not adopting the proposed rule as noticed and consider a version that is more like current language in OAR 855-019-0100.

> Suggested Language:
>
> 855-115-0001 Applicability
>
> (3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a pharmacist ~~located in another state who is~~ working for an out-of-state registered Drug Outlet Pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification is not required to be licensed by the board unless they are the Pharmacist-in-charge (PIC). ~~This exception applies only when a pharmacist is dispensing, delivering, or distributing drugs into Oregon from a registered drug outlet. A pharmacist who is providing other pharmacy services into Oregon must be licensed in Oregon.~~

OAR 855-115-0005 Definitions

The concept of collaborative pharmacist practice to address public health needs has strong public support from the American Medical Association (AMA), Centers for Disease Control and Prevention (CDC), Center for Medicaid and Chip Services (CMCS), and National Governors Association (NGA), among others.[2-5] In 2015, the Collaborative Practice Workgroup, convened by the National Alliance of State Pharmacy Associations (NASPA), developed recommendations addressing elements of pharmacist collaborative practice authority that should appropriately be defined under state law or regulation and which elements are best left to be determined between pharmacists and other practitioners when developing their specific collaborative practice arrangement.[6] Following these recommendations, the American Pharmacists Association (APhA) adopted the following policy statement:[7]

Collaborative Practice Agreements

1. APhA supports the establishment of collaborative practice agreements between pharmacists and other health care professionals designed to optimize patient care outcomes.

2. APhA shall promote the establishment and dissemination of guidelines and information to pharmacists and other health care professionals to facilitate the development of collaborative practice agreements.

3. APhA supports the establishment of collaborative practice agreements between one or multiple pharmacists and one or multiple prescribers.

4. APhA supports collaborative practice laws that are inclusive of patients lacking a primary care provider.

5. APhA opposes state laws that limit collaborative practice agreements to specific patients.

6. APhA supports state laws that allow for delegated pharmacist prescriptive authority.

7. APhA supports state collaborative practice laws that allow all licensed pharmacists, in all practice settings, to establish collaborative practice agreements with other healthcare professionals.

Community pharmacists throughout the country are partnering with physicians through collaborative drug therapy management. For example, pharmacists in Washington State have been entering into collaborative drug therapy agreements (CDTAs) that include the ability to initiate, dispense, and administer not only prescription drugs but also controlled substances for *four* decades. The trend is to implement proven measures, such as CDTAs, that safely increase patient access to pharmacist provided care to help address community health care needs, especially in rural America. Therefore, we request the Board amend the definition of collaborative drug therapy management to remove the initiation for an individual patient to enter a CDTA on the prescription of a participating provider, allowing pharmacists to manage drug therapy of a broader set of patients, while following requirements set forth in the written protocol with a health care provider who is acting within their scope.

Suggested Language

855-115-0005 Definitions

(2) "Collaborative Drug Therapy Management" means the process in which a Pharmacist or pharmacy and a health care provider or group of health care providers agree to a pre-specified drug therapy management protocol that ~~is initiated for an individual patient on the prescription or prescription drug order of a participating provider~~ provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient.

OAR 855-115-0145 Counseling

CVS Health appreciates the Board's consideration of comments submitted on previous proposed amendments to these sections of the rules. As currently proposed, CVS supports the proposed language which allows a pharmacist to determine the manner and appropriate amount of counseling that is reasonable and necessary to promote the safe and effective use of or administration of the drug or device in addition to allowing a licensee to make the offer and also accept the patient or patient's request not to be counseled.

OAR 855-115-0205 Pharmacist-in-Charge; Qualifications and Limitations

CVS Health asks the Board to reconsider the Pharmacist-in-Charge requirements proposed in this section to become operative on July 1, 2025. On June 15, 2022, the New Hampshire Board of Pharmacy repealed rule Ph704.11 addressing practice requirements prior to becoming a PIC which included a practice requirement of 2 years as a pharmacist, obtaining an 80% passing score on an exam designed by the Board as well as hours requirements to be present and practicing within the pharmacy.[8] We also are not aware of any other state that requires additional PIC training at regular cadence after the appointment and acceptance of the position and are concerned this may continue to drive interest away from the responsibility. CVS Health requests the Board not move forward with the requirements outlined (3) of the proposed new rule and only adopt language in OAR 855-115-0205(1) and (2).

Suggested Language:
855-115-0205 Pharmacist-in-Charge: Qualifications and Limitations
(1) ~~Effective March 1, 2024, i~~In order to be a Pharmacist-in-Charge (PIC), a Pharmacist must have:
(a) Completed at least one year of pharmacy practice; or
(b) Completed a board provided PIC training course either before the appointment or within 90 days after the appointment; and
(c) Be employed by the outlet.
(2) A Pharmacist must not be designated PIC of more than three pharmacies. The following drug outlet types do not count towards this limit:
(a) Pharmacy Prescription Kiosks in OAR 855-141; and
(b) Pharmacy Prescription Lockers in OAR 855-143.
~~(3) Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must: (a) Complete a board-provided PIC training course as described below:~~
~~(A) A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90 days after appointment.~~
~~(B) A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to the appointment.~~
~~(b) Complete a board provided PIC training course at least every five years.~~
~~(c) Be employed by the outlet.~~
~~(d) Not be designated PIC of more than three pharmacies.~~
~~The following drug outlet types do not count towards this limit:~~

~~(A) Pharmacy Prescription Kiosk in OAR 855-141; and~~
~~(B) Pharmacy Prescription Locker in OAR 855-143~~

CVS Health appreciates the opportunity to provide feedback and submit comments on the proposed rules. Should the Board have any questions, please do not hesitate to contact me.

Sincerely,

Lauren Paul, PharmD, RPh, MS

Lauren Paul, PharmD, RPh, MS
Executive Director, CVS Health

References

1. Virginia Board of Pharmacy, Statewide Protocols. Available from: https://www.dhp.virginia.gov/Boards/Pharmacy/PractitionerResources/StatewideProtocols/ (Accessed November 9, 2023)
2. American Medical Association. 2017. Embedding Pharmacists Into the Practice Collaborate with pharmacists to improve patient outcomes. Available from: https://www.stepsforward.org/modules/embedded-pharmacists (Accessed November 9, 2023).
3. CDC. 2018. Increasing the Use of Collaborative Practice Agreements Between Prescribers and Pharmacists A Brief for Decision Makers, Public Health Practitioners, and Prescribers. Available from: https://www.cdc.gov/dhdsp/pubs/docs/CPA-Translation-Guide.pdf (Accessed November 9, 2023).
4. National Governors Association. The Expanding Role of Pharmacists in a Transformed Health Care System. Available from: http://www.nga.org/files/live/sites/NGA/files/pdf/2015/1501TheExpandingRoleOfPharmacists.pdf. (Accessed November 9, 2023).
5. Center for Medicaid and Chip Services. CMCS Informational Bulletin. January 17, 2017. Available from: https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf (Accessed November 9, 2023).
6. NASPA. 2015. Collaborative Practice Agreements: Key Elements of Legislative and Regulatory Change. Available from: https://naspa.us/wp-content/uploads/2017/01/CPA-Workgroup-Report-FINAL.pdf (Accessed November 9, 2023).
7. American Pharmacists Association. 2019. APhA House of Delegates Policy Manual. Available from: https://www.pharmacist.com/apha-house-delegates?is_sso_called=1 (November 1, 2019).
8. New Hampshire Board of Pharmacy, ph 700 Adopted Text 6/15/2022. Available from: https://www.oplc.nh.gov/sites/g/files/ehbemt441/files/inline-documents/sonh/ph-700-adopted-text-20220615.pdf (Accessed November 9, 2023).

From:	Paul, Lauren N.
To:	PHARMACY RULEMAKING * BOP
Cc:	Paul, Lauren N.
Subject:	CVS Health Comments on Various Divisions
Date:	Monday, November 20, 2023 11:04:51 AM
Attachments:	image001.png CVS Health Comments Various Divisions Oregon Board of Pharmacy November 2023.pdf

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Hello,

Please find attached comments from CVS Health on various proposed rules. Should the Board have questions, please do not hesitate to contact me.

Thanks,

Lauren

Lauren Paul PharmD, MS | Executive Director, Pharmacy Regulatory Affairs
c 540-604-3661
1 CVS Drive, Mail Code 2325, Woonsocket, RI 02895

Planned Business Travel: November 28-29th, December 5-6th, December 12-14th , December 19-20th

PTO: November 22nd - 24th

From: Anteneh, Geta M
To: PHARMACY RULEMAKING * BOP
Subject: Propose Rule amendment
Date: Tuesday, November 21, 2023 3:43:05 PM

To: Ian Doyle President Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
Dear Ian and Board of Pharmacy members,

I am providing written commentary expressing concern regarding the proposed amendment to OAR 855-041-1105, which is summarized as follows: “Amends rule by adding dispensing requirements for a Drug Outlet and relocates and revises existing language from OAR 855-019-0210(4)-(7) pertaining to required information for a prescription. Requires Pharmacist to clarify discrepancies or uncertainties regarding a prescription. Requires read back of an oral prescription. Clarifies prescriber authority to request no substitution for the manufacturer of a drug.”

The major concern is how this rule affects the capacity of Pharmacists to exercise professional judgment, discretion, and assessment in fulfilling prescription orders. Secondarily, the documents relied upon to generate the amendment are both informal and out of date, coming from a 2017 reader’s survey. And thirdly, Cost of Compliance statements of “no impact” are false when the very nature of the rule requires additional documentation, labor, and administration resources.

The amendment of OAR 855-041-1105 to require readback of oral prescriptions, and repeat listening of voicemail prescriptions undermines professionalism by dictating a requirement best left to professional discretion, and adds unnecessary burden to already overburdened pharmacy staff, regardless of practice setting. The task of ensuring proper delivery of medication requires a range of practices and should not be reduced to prescriptive rules such as “…Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription.” This is an unnecessary redundancy as OAR 855-019-0210 Duties of the Pharmacist Receiving a Prescription already contains language to impart the responsibility to ensure prescriptions, refills, and drug orders are correctly dispensed. The rule to require pharmacists to document transcription in a singular way parses out one method from a range of skills that practitioners of this profession use to carry out Pharmacy work. In doing so, the rule creates a myopia that restricts the professional capacity of pharmacists and could be detrimental to patient care.

In the notice's section for Documents Relied Upon, an informal and dated web article is cited which seems like a poor basis for creating legislation that would dictate the practice of all Licensees in the state. The article "Despite Technology, Verbal Orders Persist, Read Back is Not Widespread, and Errors Continue" is not an organized study and evaluation of best practices for handling oral prescriptions but rather a web survey of the site's own constituents, from 2017. Even within the article itself, many different practices are presented besides "read back" to reduce error; however none of those are presented in the amendment to OAR 855-041-1105. The scope of this article's recommendations lay within an individual organization's practice, not a regulatory body.

The Cost of Compliance section of the notice incorrectly states there is "no additional mandatory reporting, recordkeeping, or other administrative requirements," and "imposes no additional …labor or administration." The exact language of the amendment demands additional time and documentation to perform, and would certainly require additional administrative resources to maintain. The exact wording is as follows: "Reading back the prescription as transcribed to the person transmitting it; or¶ ¶ (ii) Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription.¶"

Thank you for taking the time to address my concerns before moving further with the Proposed Rule Making.

Geta Anteneh, Supv Retail Pharmacy Credena

Credena Health Pharmacy PPMC Plaza
5050 NE Hoyt st Suite 142 Portland, OR 97213
P:503-215-6296; F: 503-215-6459

Catizone, Luce, Menighan, LLC

2323 Glen Eagles Lane
Riverwoods, IL 60015

Comments to Oregon Board of Pharmacy Advisors
RE: Proposed Rulemaking - Division 115 and 141

CLM Pharmacy Advisors (CLM) is requesting clarification of certain provisions of the proposed rulemaking to eliminate any ambiguity and assist with compliance. The specific provisions are:

Division 115 - 855-115-0001 Applicability
Division 041 - 855-041-1019 Drug Procurement

855-115-0001 Applicability (pg. 4)

The particular provision notes:

855-115-01 (3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a pharmacist located in another state who is working for an out-of-state registered Drug Outlet Pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification is not required to be licensed by the board unless they are Pharmacist-in-charge (PIC). This exception applies only when a pharmacist is dispensing, delivering or distributing drugs into Oregon from a registered drug outlet. A pharmacist who is providing other pharmacy services into Oregon must be licensed in Oregon.

The proposed revision defines the conditions that require the licensure of pharmacists located in another state and performing professional and dispensing tasks into Oregon and raises a critical question. Is the interpretation correct that a pharmacist working for an out-of-state Oregon registered Drug Outlet Pharmacy and engaged in the tasks noted in the provision (interpretation, evaluation, DUR, counseling and verification) would be exempt from licensure if the pharmacist is also engaged in dispensing, delivery, or distributing drugs into Oregon? Further, if that interpretation is accurate then a pharmacist providing the tasks noted in the proposed rule but not dispensing, delivering, or distributing drugs into Oregon would be required to license. The immediate and critical question that we respectfully seek clarification for is "If that pharmacist is employed by an Oregon registered Drug Outlet Pharmacy, including an Oregon licensed PIC, is the pharmacist required to also obtain licensure if he or she performs professional tasks for a medication that has not been dispensed by the pharmacist?" Continuing, is the interpretation directing that the pharmacist not answer the patient's concern and refer them back to the dispensing pharmacist not affiliated with the non-resident, Oregon registered Drug Outlet Pharmacy?

An example may better illustrate the question:

> Patient A is a long-time patient of an out-of-state Oregon registered Drug Outlet Pharmacy and routinely receives monthly medications from the pharmacy. Patient A gets sick and has to pick up an acute medication from a local community pharmacy (independent or chain). Patient A calls the out-of-state Oregon registered Drug Outlet Pharmacy to ask about harmful interactions with their routine medications dispensed by the out-of-state Oregon registered Drug Outlet Pharmacy. Can the out-of-state Oregon registered Drug Outlet Pharmacy respond (counsel) Patient A without being in violation of the proposed provision?

If the answer is that the pharmacist must be separately licensed in order to counsel the patient, we would opine that the proposed rule would be overly burdensome and actually prohibit patients from receiving necessary and appropriate care from an Oregon registered Drug Outlet Pharmacy. In fact, it would stand contrary to the Oregon Board of Pharmacy Strategic Plan 2022-2026. Specifically:

> *"Regulatory trends: The move to remote practice and telework has impacted pharmacy service models and regulation. Improvements in technology and the need to assure equitable access to pharmacy services for all Oregonians has necessitated new regulatory approaches. The board supports such rule changes when they result in improved access, efficiency, and protection of the public health, safety and welfare."*

The required licensure of the Drug Outlet Pharmacy and Pharmacist-in-Charge (PIC) provides the regulatory foundation for the Board to appropriately ensure the safety of Oregon's patients and ability to enact discipline, if needed. Additional licensure requirements would not enhance the Board's regulatory oversight and actions. It would deny a patient's equitable access to care and disregard new regulatory approaches advocated in the Board's Strategic Plan by imposing burdensome, duplicative, and unnecessary requirements. More importantly, it could result in negative patient safety outcomes, per the example highlighted above where the patient picked up a drug from a different pharmacy, and there are restrictions on providing care to the patent even though there is a nexus to the patient, history of dispensing, and appropriate regulation.

Relatedly, what other pharmacy services, as noted in the proposed rules, provided into Oregon would require licensure?

Division 041 Drug Procurement

855-041-1019 Drug Procurement (pg. 5)

- A Drug Outlet Pharmacy **may only receive drugs from an Oregon Registered Drug Outlet** (i.e. Wholesaler, Manufacturer or Pharmacy).

The provision seems to indicate that a pharmacy (non-resident or resident) may only dispense medications that have been received from an Oregon Registered Drug Outlet. If this is the intended purpose of the proposed rulemaking, the new requirement will result in registered Oregon Drug Outlet Pharmacies not being able to provide medications to patients in Oregon. This would occur in the circumstance where a registered Oregon Drug Outlet Pharmacy purchases medications from a wholesaler not licensed with Oregon.

In these situations, the Drug Outlet Pharmacy would still bear full responsibility for the integrity of the medication and be required to perform all of the necessary due diligence upon receipt and dispensing of the medication to patients in Oregon. In order for a wholesaler to conduct operations, it must be licensed by its state of residence and other states into which it distributes products. Similarly, the soon-to-be-implemented requirements of the Drug Quality and Security Act (DSCSA) will also address the integrity of the medications and further obviate the need for additional licensure.

CLM respectfully requests that the Board clarify the proposed rule to allow non-resident, registered Oregon Drug Outlet Pharmacies to utilize appropriately licensed wholesalers and, if such a wholesaler is not distributing directly into Oregon, to exempt the wholesalers from licensure with Oregon.

Respectfully submitted,

Daniel Luce

Daniel Luce, President
CLM Pharmacy Advisors

From:	Emily Colborn
To:	PHARMACY RULEMAKING * BOP
Cc:	Daniel Luce; Thomas Menighan; Carmen Catizone
Subject:	Comments to Oregon Board of Pharmacy Advisors
Date:	Tuesday, November 21, 2023 7:01:13 AM
Attachments:	Comments to Oregon Board 21November2023.pdf

Hello,

Please see the attached comments for the Oregon Board of Pharmacy Advisors.

Best,
Emily Colborn

From: Huglyn Balase
To: PHARMACY RULEMAKING * BOP
Subject: Commentary
Date: Tuesday, November 21, 2023 3:40:33 PM

To Oregon Board of Pharmacy
pharmacy.rulemaking@bop.oregon.gov
Tuesday Nov21,2023
To: Ian Doyle
President Oregon Board of Pharmacy 800 NE Oregon St., Suite 150 Portland, OR 97232

Dear Ian and Board of Pharmacy members,
I am providing written commentary expressing concern regarding the proposed amendment to OAR 855-041-1105, which is summarized as follows:
“Amends rule by adding dispensing requirements for a Drug Outlet and relocates and revises existing language from OAR 855-019-0210(4)-(7) pertaining to required information for a prescription. Requires Pharmacist to clarify discrepancies or uncertainties regarding a prescription. Requires read back of an oral prescription. Clarifies prescriber authority to request no substitution for the manufacturer of a drug.”
The major concern is how this rule affects the capacity of Pharmacists to exercise professional judgment, discretion, and assessment in fulfilling prescription orders. Secondarily, the documents relied upon to generate the amendment are both informal and out of date, coming from a 2017 reader’s survey. And thirdly, Cost of Compliance statements of “no impact” are false when the very nature of the rule is requiring additional documentation, labor, and administration resources.
The amendment of OAR 855-041-1105 to require readback of oral prescriptions, and repeat listening of voicemail prescriptions undermines professionalism by dictating a requirement best left to professional discretion, and adds unnecessary burden to already overburdened pharmacy staff, regardless of practice setting. The task of ensuring proper delivery of medication requires a range of practices and should not be reduced to prescriptive rules such as “...Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription.” This is an unnecessary redundancy as OAR 855-019-0210 Duties of the Pharmacist Receiving a Prescription already contains language to impart the responsibility to ensure prescriptions, refills, and drug orders are correctly dispensed. The rule to require pharmacists to document transcription in a singular way parses out one method from a range of skills that practitioners of this profession use to carry out Pharmacy work. In doing so, the rule creates a myopia that restricts the professional capacity of

pharmacists and could be detrimental to patient care.
In the notice’s section for Documents Relied Upon, an informal and dated web article is cited which seems like a poor basis for creating legislation that would dictate the practice of all Licensees in the state. The article “Despite Technology, Verbal Orders Persist, Read Back is Not Widespread, and Errors Continue” is not an organized study and evaluation of best practices for handling oral prescriptions but rather a web survey of the site’s own constituents, from 2017. Even within the article itself, many different practices are presented besides “read back” to reduce error; however none of those are presented in the amendment to OAR 855-041-1105. The scope of this article’s recommendations lay within an individual organization's practice, not a regulatory body.
The Cost of Compliance section of the notice incorrectly states there is “no additional mandatory reporting, recordkeeping, or other administrative requirements,” and “imposes no additional ...labor or administration.” The exact language of the amendment demands additional time and documentation to perform, and would certainly require additional administrative resources to maintain. The exact wording is as follows: “Reading back the prescription as transcribed to the person transmitting it; or¶ ¶ (ii) Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription.¶”
Thank you for taking the time to address my concerns before moving further with the Proposed Rule Making,
Huglyn D Balase

Sent from my iPhone

November 14, 2023

Oregon Board of Pharmacy

800 NE Oregon St., Suite 150
Portland, OR 97232
Phone: 971-673-0001
Fax: 971-673-0002

pharmacy.rulemaking@bop.oregon.gov.

Dear Members of the Oregon Board of Pharmacy,

Thank you for the opportunity to comment on the proposed rule amendment which will permit a Pharmacist, Certified Oregon Pharmacy Technician or Pharmacy Technician to administer influenza vaccine to patients age 6 months of age or older. I write to you as a full time retail pharmacist with Costco Wholesale in Central Point, Oregon.

As a retail pharmacist, I can sum up this new proposed amendment in one word…. TRAUMA.

First, very young children sometimes carry trauma for the rest of their lives. My personal experience involves my caring parents enrolling me in a "drown-proofing" experience in the late 1960s. If you are unaware of the technique, it would sometimes involve life-guard supervision of pushing a child into deep water and supervising them attempting to get to the side of the pool. I was a two-year old and clearly recall a woman lifeguard taking me out on the diving board and pushing me in. In my flailing, I aspirated a significant amount of water. It was terrifying. I now spend the rest of my life with a deep fear of water.

Pediatricians are excellent with children and their parents. This is why they chose children for their delivery of medical service. They have a rapport with the child and the parent. Their setting is clean, tranquil, often has soft, plush animals and decoration specific to children's comfort. By contrast, the retail pharmacy is loud, hurried, crowded, sterile and there is no built-in rapport with the child. Usually, the youngest vaccine recipients must be restrained. The immunizer is terrified that

the needle may miss the proper location and land elsewhere in the child, adult, or the immunizer. Overall, the result could be lifetime vaccine trauma for the child, the parent, the immunizer (and collateral customers and pharmacy staff).

For now, let's set aside potential trauma. The Notice of Proposed Rulemaking suggests no anticipated fiscal or economic impact of the proposed rule. However, based on recent walkouts at a few major retail chain outlets, including Walgreens and CVS, we may soon see many more pharmacists suddenly leave the profession permanently due to excessive physical and mental distress. Are we beginning to see pharmacy school admissions plummet? What will we (as a nation) do if we have a sudden, intractable shortage of pharmacists?

Insurance companies and retail chain pharmacies continue to use expanded services as financial opportunity. I have sympathy with retail pharmacies. As a retail pharmacist, I see the real economic devastation that Insurance companies and their Pharmacy Benefit Managers (PBMs) cause. Insurance companies and their PBMs will always choose to do what is cheapest (and by no means what is best for the patient). It wouldn't be a stretch to imagine pharmacy being charged with all pediatric vaccinations soon.

In closing, I have invested time and energy into writing this comment in hopes that a sympathetic board will hear issues directly from the ones delivering the service.

In my greater than fifty years of life and with great interest in economic theory, I have observed that the cheap and simple solution to a complex market problem is indeed low cost at the front end but tends to be very, very costly at the back end. Please do not let insurance companies short-change pediatricians, children and their families my using the cheap, simple solution.

Thank you kindly for your consideration and thoughtful deliberation in this matter.

Sincerely,

Jeffrey Scott Gerschler, Rph.

Staff Pharmacist, Costco Wholesale

Central Point, Oregon

Phone: 541-734-2482

From: Jeffrey Gerschler
To: PHARMACY RULEMAKING * BOP; Jeffrey Gerschler
Subject: Re: Comment regarding Proposed Rule Change - Immunization of 6 month old Children
Date: Tuesday, November 14, 2023 9:00:20 AM
Attachments: Immunizing6montholdComment.docx

Good morning,

Attached is a comment regarding the proposed rule change for pharmacists to vaccinate 6 month old and older children with influenza vaccine.

Please consider this letter in the upcoming hearing.

Thank you.

Jeff Gerschler, Rph
Costco Wholesale
Central Point Oregon

Work Phone: 541 734-2482
Home Phone: 541 601-1580

November 16, 2023

To: Oregon Board of Pharmacy

From: Kevin Russell RPh, MBA, BCACP

Re: Rulemaking comments for 855-041-1105 and 855-041-1115 Requirements for Prescriptions

In light of predatory PBM auditing practices, I am concerned that desired elements of a prescription are becoming required elements of a prescription. For example, is it really necessary to document a prescriber's address on a prescription if it is already on file, or to document the reading back of a prescription? More concerning is that adding section 855-041-1115 makes a prescription not valid if any of the 15-20 required elements are missing. The validity of a prescription should be about the legitimacy of the prescription, not about if every clerical element is present.

Oregon law protects pharmacies from predatory PBM auditing for clerical errors. However, if Board of Pharmacy rule invalidates a prescription for a clerical error, then a PBM could declare that the claim is also invalid and even perhaps fraudulent. This could result in substantial financial penalties or exclusion from insurance networks. I suggest that section 2 should be struck from proposed rules as those requirements are already present elsewhere.

855-041-1115

Verification of Prescription Authenticity Validity
Each Drug Outlet Pharmacy must ensure that:
(1) Prior to dispensing a prescription, a Pharmacist has verified its validity. In order for a prescription drug to be valid it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing of the prescription drug is upon the prescribing practitioner, in any manner constitutes an invalid order unless verified with the prescriber, and a corresponding responsibility rests with the pharmacist who dispenses the prescription.
~~(2) A prescription is considered not valid if:~~
~~(a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it;~~
~~(b) The prescription does not contain the required information as provided in OAR 855-041-1105;~~
~~(c) The prescription is expired per OAR 855-041-1125; or~~
~~(d) The prescription is for a controlled substance and does not comply with the requirements of OAR 855-080-0085.~~

Re: 855-041-1190 Operation of a Laboratory in Drug Outlet Pharmacy

I suggest that (2)(a) be struck: *~~Display the laboratory license in a prominent place in view of the pubic~~*

There are already 6 documents which are required to be prominently displayed to the public. I submit that the public does not know or care about CLIA waivers. Showing the license on request should be adequate. Every piece of prominent wall space with required signs comes at the expense of healthcare information or health products. The public is better served by the latter.

Re: 855-080-0085 Prescription Requirements

I suggest that date and time be removed from documentation requirements amending a prescription by a pharmacist. This is not a current requirement of documentation, and I don't see a compelling problem that this solves. Again, it gives PBM auditors one more thing to penalize pharmacies for.

(4)(B)(d) For (b) and (c), the Pharmacist must document on the prescription the ~~date and time of the~~ prescriber's authorization, the amendment or addition authorized, and the Pharmacist's identity.

Thank you for your consideration.

Kevin Russell, RPh, MBA, BCACP
205 SW Meadow Lakes Dr.
Prineville, OR 97754
541-609-0306

From: Kevin Russell
To: PHARMACY RULEMAKING * BOP
Subject: Rulemaking comments
Date: Thursday, November 16, 2023 12:26:11 PM
Attachments: BOP rulemaking comments 11-16-23.docx

To: Oregon Board of Pharmacy

I am submitting the attached rulemaking comments for the November 21, 2023 hearing on behalf of myself.

Kevin Russell RPh, MBA, BCACP

Subject: Comments on proposed rule changes in division 41 and 125

Dear Board of Pharmacy,

I wanted to submit comments on the following sections of the proposed rule changes in Division 41 and 125.

Thank you for your consideration,
Natalie Gustafson, PharmD

Director of Pharmacy
Lloyd Central Compounding Pharmacy
2606 NE Broadway St Suite B
Portland, OR 97232

Comments

855-041-1105 Prescriptions: General Requirements
Section (2)(b) and (2)(e)- Clarification requested on whether this information would be required on the hard copy of the prescription, or if the electronic dispensing record would be sufficient.

- For non-controlled prescriptions, would this new wording require that the address of the practitioner prescribing be on the hard copy of the prescription?

Recommendation: For non-controlled substances, allow doctor address to be recorded in the electronic dispensing record. It is logistically burdensome to add addresses to all non-controlled hard copies.

Section (4)(b):
(4) An oral prescription must: (b) After the prescription has been transcribed, the licensee must verify accuracy by: (i) Reading back the prescription as transcribed to the person transmitting it; or (ii) Listening to the voicemail a second time; and (c) The confirmation of accuracy in (b) must be documented on the prescription.

Recommendation: Remove these requirements to always double verify prescriptions received orally and document it. This requirement falls under general pharmacist duties and does not need to be that specific. It adds further burdens and requirements that may not be necessary in many scenarios. This requirement should fall under professional judgment of the pharmacist if they were confused at all in the voicemail or the phone conversation. Pharmacists communicate all day long and are able to exert professional judgment when double checks are needed.

In addition, it seems unusual that in this instance OBoP is requiring a very detailed method to complete a task that is a regular part of pharmacy. Other rules are not this specific and allow for professional judgment to dictate what is best given the specific context. There are many workflow considerations to take into consideration, and while in the abstract it may seem like

requiring a double check and documentation and readback is always the best practice, in reality context matters a lot.

It would seem this requirement was added due to expanded rights given to technicians to receive oral prescriptions. While we don't agree that technicians should have expanded rights for receiving oral prescriptions beyond accepting simple refill authorizations (receiving oral prescriptions requires professional/clinical judgment), we would support the additional checks added in 4(b) only if it applies to technicians.

855-041-1115 Prescription Validity

Proposed Language: (1) Prior to dispensing a prescription, a Pharmacist has verified its validity. In order for a prescription drug to be valid it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing of the prescription drug is upon the prescribing practitioner, and a corresponding responsibility rests with the pharmacist who dispenses the prescription.

Recommendation: Remove the requirement for a pharmacist to verify the validity of all prescriptions prior to dispensing.

This language greatly expands the current rule, which solely discusses alterations of prescriptions. The wording of this proposed rule could imply that a pharmacist must contact the prescriber for each prescription, even if there is no suspicion of fraud. For a pharmacist to "verify its validity," it seems the contacting of the prescriber would be a required new step in verification. This requirement is cumbersome, unnecessary for most prescriptions, would lead to delays in therapy while waiting to speak with the prescriber, and cause significant confusion for the prescribers when there is no indication of alteration or suspicion of fraud. A pharmacist uses professional judgment to determine when a prescription's validity must be verified with the prescriber.

In addition, we recommend removing the "his or her" language and replace it with a non-binary term such as "their."

855-125-0150 Prohibited Practices
Section (1) (m) Receive or transfer a prescription for a controlled substance orally;

Recommendation: Remove wording "for a controlled substance"

We don't recommend that technicians receive any prescription orally. They do not receive the proper training to do so. There is inherently professional judgment used when receiving oral prescriptions, which falls under the practice of pharmacy, thus requiring a pharmacist. We support technicians accepting simple non-controlled refill authorizations orally, but do not support expanding that role.

From:	Pharmacist Lloyd Central Pharmacy
To:	PHARMACY RULEMAKING * BOP
Subject:	Comments for Divisions 41 and 125 Rulemaking Hearing 11.21.23
Date:	Tuesday, November 21, 2023 4:17:47 PM
Attachments:	LCRX Comments OBOP Divisions 41 and 125 Rulemaking 11.21.23.pdf

Hello Oregon Board of Pharmacy,

Please see attached comments for Divisions 41 and 125 for the rulemaking hearing.

Thank you for your consideration,
Natalie Gustafson, PharmD

--
Lloyd Central Compounding Pharmacy
2606 NE Broadway St, Suite B, Portland OR 97232
Phone: 503-281-4161
Fax: 503-281-1990

From: Mallory Kempton-Hein
To: PHARMACY RULEMAKING * BOP
Subject: OBOP Commentary on 855-041-1105
Date: Tuesday, November 21, 2023 4:22:03 PM

Tuesday Nov 21, 2023

To: Ian Doyle
President Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Dear Ian and Board of Pharmacy members,

I am providing written commentary expressing concern regarding the proposed amendment to OAR 855-041-1105, which is summarized as follows:

"Amends rule by adding dispensing requirements for a Drug Outlet and relocates and revises existing language from OAR 855-019-0210(4)-(7) pertaining to required information for a prescription. Requires Pharmacist to clarify discrepancies or uncertainties regarding a prescription. Requires read back of an oral prescription. Clarifies prescriber authority to request no substitution for the manufacturer of a drug."

The major concern is how this rule affects the capacity of Pharmacists to exercise professional judgment, discretion, and assessment in fulfilling prescription orders. Secondarily, the documents relied upon to generate the amendment are both informal and out of date, coming from a 2017 reader's survey. And thirdly, Cost of Compliance statements of "no impact" are false when the very nature of the rule is requiring additional documentation, labor, and administration resources.

The amendment of OAR 855-041-1105 to require readback of oral prescriptions, and repeat listening of voicemail prescriptions undermines professionalism by dictating a requirement best left to professional discretion, and adds unnecessary burden to already overburdened pharmacy staff, regardless of practice setting. The task of ensuring proper delivery of medication requires a range of practices and should not be reduced to prescriptive rules such as *"...Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription."* This is an unnecessary redundancy as OAR 855-019-0210 Duties of the Pharmacist Receiving a Prescription already contains language to impart the responsibility to ensure prescriptions, refills, and drug orders are correctly dispensed. The rule to require pharmacists to document transcription in a singular way parses out one method from a range of skills that practitioners of this profession use to carry out Pharmacy work. In doing so, the rule creates

a myopia that restricts the professional capacity of pharmacists and could be detrimental to patient care.

In the notice's section for *Documents Relied Upon*, an informal and dated web article is cited which seems like a poor basis for creating legislation that would dictate the practice of all Licensees in the state. The article *"Despite Technology, Verbal Orders Persist, Read Back is Not Widespread, and Errors Continue"* is not an organized study and evaluation of best practices for handling oral prescriptions but rather a web survey of the site's own constituents, from 2017. Even within the article itself, many different practices are presented besides "read back" to reduce error; however none of those are presented in the amendment to OAR 855-041-1105. The scope of this article's recommendations lay within an individual organization's practice, not a regulatory body.

The *Cost of Compliance* section of the notice incorrectly states there is "no additional mandatory reporting, recordkeeping, or other administrative requirements," and "imposes no additional …labor or administration." The exact language of the amendment demands additional time and documentation to perform, and would certainly require additional administrative resources to maintain. The exact wording is as follows: *"Reading back the prescription as transcribed to the person transmitting it; or¶ ¶ (ii) Listening to the voicemail a second time; and¶ (c) The confirmation of accuracy in (b) must be documented on the prescription.¶"*

Thank you for taking the time to address my concerns before moving further with the Proposed Rule Making,

Regards,
--
Mallory Kempton-Hein
(She/Hers)
Pharmacist in Charge
Pharmacy

M: 907.738.8037
O: 503.941.3807
Website: zoomcare.com

OREGON STATE PHARMACY ASSOCIATION
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November 20, 2023

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Dear Board of Pharmacy members,

OSPA would like to commend and thank the board members and staff for their conversation at the recent strategic planning meeting. We were encouraged by the discussion and future path for the board.

Below you will find public comments that OSPA would like to submit for this rulemaking meeting. I've outlined the rules in bold and have included comments/questions. In some cases, I also include the rule text with highlights.

855-041-1010: Outlet (RP & IP): Personnel
Instead of using abbreviations of RP & IP, can you please write out the words?

855-080-0085: Prescription Requirements
(4) For a Schedule II controlled substance prescription, a Pharmacist may:

We would encourage you to use the rules that are in line with the DEA rather than making rules that are more restrictive. That will only lead to confusion and fines.

855-115-0001: Applicability
(3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a pharmacist located in another state who is working for an out-of-state registered Drug Outlet Pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification is not required to be licensed by the board unless they are the Pharmacist-in-charge (PIC). This exception applies only when a pharmacist is dispensing, delivering or distributing drugs into Oregon from a registered drug outlet. A pharmacist who is providing other pharmacy services into Oregon must be licensed in Oregon.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.255

In reference to the yellow highlighted portion above, would it mean that anyone at a call center or who works within a remote processing environment would need to hold an Oregon license? Does this include MTM? Out of state nurses and technicians are currently doing this, but it doesn't appear to be violating our rules. If so, OSPA opposes this rule. Pharmacists work in a number of areas outside of drug outlets, and the rules should take into account the variation in practice sites. If this is not a correct interpretation of the rule, recommend revising to provide additional clarity for the intent of the rule.

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855-115-0122: Responsibilities: Supervision
(a) No more than four Interns participating in direct patient care activities.

With the use of flu clinics, pandemic clinics, etc., this elicits concern about limiting a pharmacist's ability to supervise interns by creating an arbitrary limit. OSPA would like to express opposition to Board imposed restriction of a pharmacist's judgment for how many interns they may safely supervise.

855-115-0205: Pharmacist-in-Charge: Qualifications and Limitations
(1) Effective March 1, 2024, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must have:¶
(a) Completed at least one year of pharmacy practice; or¶
(b) Completed a board provided PIC training course either before the appointment or within 90 days after the appointment; and¶
(c) Be employed by the outlet. ¶
(2) A Pharmacist must not be designated PIC of more than three pharmacies. The following drug outlet types do not count towards this limit:¶
(a) Pharmacy Prescription Kiosks in OAR 855-141; and ¶
(b) Pharmacy Prescription Lockers in OAR 855-143.¶
(3) Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:¶
(a) Complete a board-provided PIC training course as described below:¶
(A) A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90 days after appointment.¶
(B) A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to appointment
(b) Complete a board provided PIC training course at least every five years. ¶

A Pharmacist-in-Charge is required to complete an annual Self-Inspection Form, as well as complete 30 hours of CPE biennially. We feel these requirements are sufficient enough to ensure these licensed professionals are aware of rule changes and are capable of being a PIC without a mandated training course every 5 years. If there are items of emphasis the Board feels are important enough for PICs to know, then these should be sent out in a bulletin, rather than waiting 5 years for a training course. Recommend removal of paren (3), as this is overly complicated and does not improve on the current rule to ensure quality of PIC knowledge.

855-125-0150: Prohibited Practices
Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:
(m) Receive or transfer a prescription for a controlled substance orally;

Can the board members please clarify the prohibited practices for technicians and the new proposed rules dealing with controlled substances? The DEA has made clarifications about controlled substances that include technicians in definition as pharmacists more than once. The rule allowing technicians to orally receive a prescription would be new for Oregon and we feel that it would be reasonable to take one step at a time and not include controlled substances. We believe some technicians might be

relieved by not having this responsibility. In addition, what are you defining as evaluate and interpret? We don't feel that transcription should fall under that, but want to confirm there isn't a time that it would be considered. The section around technicians seems redundant. Lastly, if a patient calls in and says "I'd like to speak to the pharmacist," can the technician ask clarifying questions to see if the patient just needs to refill a prescription rather than pulling the pharmacists away from other duties?

855-115-0305: Services: Administration of Vaccines, Drugs, or Devices
(a) Prior to administration of an injectable drug or device, receive practical training on the injection site and
administration technique that is utilized. For orally administered drugs, training is not required.¶

Is there a reason these rules need to stand alone? Can you define "practical" (highlighted above)?

855-115-0315 Services: Clinical Pharmacy Agreement & Collaborative Drug Therapy Management
(1) A Pharmacist or pharmacy may engage in the practice of clinical pharmacy under a written Clinical Pharmacy Agreement with health care organization, Physician or Naturopathic Physician.¶
(2) If the agreement in (1) is made with a health care organization, the organization is responsible for ensuring that each protocol utilized by a Pharmacist or pharmacy to provide clinical pharmacy services:¶
(a) Is developed and overseen by a Physician or Naturopathic Physician acting within their scope.¶
(b) Is reviewed by each participating health care provider.¶
(c) Does not allow any act that is prohibited by ORS 475, ORS 689 and OAR 855.¶
(3) Each protocol developed under the agreement in (1) must include:¶
(a) The name of the principal Pharmacist and principal Physician or Naturopathic Physician who is responsible for:¶
(A) Initial training and ongoing competency assessment for participating Pharmacists; if necessary;¶
(B) Development, quality assurance and updating or discontinuing each protocol;¶
(b) The identification, either by name or by description, of each participating Pharmacist;¶
(c) The identification, either by name or description, of each participating Physician, Naturopathic Physician or health care provider within a health care organization. These persons must have scope to independently treat patients.¶
(d) The disease state or patient panel for which the Pharmacist may provide clinical pharmacy services;¶
(e) Types of clinical pharmacy services provided;¶
(f) Circumstances that require communication from the participating Pharmacist to the patient's Physician, Naturopathic Physician or health care provider within the health care organization such as:¶
(A) Information collected;¶
(B) Patient assessment;¶
(C) Plan of care including follow-up;¶
(D) Services provided; and¶
(E) Circumstances requiring urgent communication with the patient's health care provider; and¶
(g) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary.¶
(4) A Pharmacist may engage in Collaborative Drug Therapy Management under a written protocol with a health care provider who is acting within their scope. ¶

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(5) Each protocol developed under the agreement in (4) must include:¶
(a) The name of the principal Pharmacist and health care provider who are responsible for:¶
(A) Initial training and ongoing competency assessment for participating Pharmacists, if necessary; and¶
(B) Development, quality assurance and updating or discontinuance of each protocol; ¶
(b) The identification, either by name or by description, of each participating Pharmacist;¶
(c) The identification, by name or description, of each participating health care provider or group of health care providers;¶
(d) A detailed description of the: ¶
(A) Indications;¶
(B) Drugs including dosage, frequency, duration and route of administration;¶
(C) Methods; ¶
(D) Procedures;¶
(E) Decision criteria; and ¶
(F) Plan the Pharmacist is to follow;¶
(e) Documentation the Pharmacist is to complete concerning actions taken and a plan or appropriate mechanism for communication, feedback, and reporting to the health care provider concerning specific actions taken.¶
(f) Circumstances which will cause the Pharmacist to initiate communication with the health care provider;¶
(g) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary;¶
(6) Each protocol developed in (1) and (4) must be reviewed and updated, or discontinued at least every two years;¶
(7) The Pharmacist must document the protocol version and all clinical pharmacy activities in the prescription record, patient profile, electronic health record or in some other appropriate system.¶
(8) Records and documents must be retained according to OAR 855-104-0055.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

This section is causing confusion. Our understanding was the workgroup recommended not combining CPA and CDTM. We feel the current rules are effective and there is no reason to change them. If you choose to adopt this set of rules, will you please define what a “principal pharmacist” (highlighted in yellow above) is?

In regards to the green highlights, our understanding is that you could identify a “group/position” and wouldn’t need to develop a new protocol for each staffing change. Is that a correct understanding?

Thank you for the opportunity to comment on these rules.

Sincerely,
Brian Mayo
Executive Director

From:	Brian Mayo
To:	PHARMACY RULEMAKING * BOP
Subject:	Written comments for proposed rules
Date:	Tuesday, November 21, 2023 2:27:04 PM
Attachments:	2023 November rulemaking letter.pdf

Hi Rachel,

I've attached our written comments for the proposed rules that will be discussed at the December meeting.

Have a great Thanksgiving!
Brian

Brian Mayo
Executive Director
Oregon State Pharmacy Association
Office: (503) 582-9055
brian@oregonpharmacy.org | www.oregonpharmacy.org
Leading Pharmacy, Advancing Healthcare!

November 20, 2023

Attn: Oregon Board of Pharmacy
800 NE Oregon St, Suite 150
Portland OR 97232
Phone (971) 673-0001
Fax: (971) 673-0002
pharmacy.rulemaking@bop.oregon.gov

Fellow Board Members,

Re: Proposed Rules – Division 125 Technician – Prohibited Practices

After reviewing the October meeting agenda, recordings, and documents, I see the decision was made to move the pharmacy tech rules back again to rulemaking with the change specifically around techs taking oral prescriptions for controlled substances.

Having been absent from the meeting, I am submitting this letter to provide more context to this topic and share my position.

At the August board meeting, we had robust discussion related to the current prohibition of pharmacy technicians' ability to take new oral and transferred prescriptions. Consensus of the Board was to remove these prohibitions and send the rule packet to September rulemaking. We received no negative comments or concerns related to this change. In fact, there were multiple letters commending us for moving this direction.

During the October board meeting, the following definition was shared and the basis to move taking oral prescriptions for controlled substances to the list of prohibited tasks for pharmacy technicians.

> § 1300.01 Definitions relating to controlled substances.
>
> *Pharmacist* means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

In the recently published document regarding C2 transfers[1], that included Q&A, the DEA responded to a commenter who inquired about adding, for instance, an intern or technician into the regulatory language. The DEA responded that no change was necessary, as their current definition of Pharmacist, that could include an intern, technician or any other person – supervised by a Pharmacist – is already allowed to perform duties where state laws allow.

[1] Federal Register :: Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling

Transfers Communicated Between Two Licensed Pharmacists

Comments. One commenter suggested that DEA allow the transfer of EPCS to be communicated between pharmacy personnel (*e.g.*, pharmacy technicians, pharmacist interns, etc.), as permitted by State laws, instead of requiring the communication to be between two licensed pharmacists.

DEA Response. Existing DEA regulations ". . . include any other person (*e.g.*, pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State" in the definition of a pharmacist.[24] As such, DEA does not believe any further clarification is needed, as the existing regulations include the allowance requested by the commenter. However, DEA emphasizes that a pharmacist continues to have a corresponding responsibility to fill only those prescriptions that conform in all respects with the requirements of DEA regulations.[25]

Taking this information into consideration, it is my opinion that pharmacy technicians are not excluded by federal regulation from taking a new oral or transferred prescription for controlled substances. This would be a policy decision for the Board Members to make.

It is also my opinion that we should not be including elements on the prohibited list of tasks a pharmacy technician can complete unless we can specifically point to something a legislative or other regulatory body has already prohibited or we are solving to a problem in Oregon that threatens patient safety.

We have spent a significant amount of time over the last few years building rules to empower Pharmacists. A pharmacist, not the Board, should make the decision whether they are comfortable with a technician performing this task, as the DEA has emphasized, they still have a corresponding responsibility.

Respectfully,

Rachael DeBarmore, RPh
Board Member
Oregon Board of Pharmacy
Email: trdebarmore@comcast.net

From: Tracy Rachael DeBarmore
To: PHARMACY RULEMAKING * BOP
Subject: Proposed Rules – Division 125 Technician – Prohibited Practices
Date: Monday, November 20, 2023 11:04:43 AM
Attachments: Division 125 - Technician Prohibited Practices_Rulemaking Comments.pdf

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My comments related to proposed rules in Division 125 are attached for Board Member and public review.
Thank you,
Rachael DeBarmore
Board Member
Oregon Board of Pharmacy

From: Shivani Patel
To: PHARMACY RULEMAKING * BOP
Subject: Proposed amendment concerns
Date: Tuesday, November 21, 2023 3:30:17 PM

Tuesday Nov 21,2023

To: Ian Doyle
President Oregon Board of Pharmacy 800 NE Oregon St., Suite 150 Portland, OR 97232

Dear Ian and Board of Pharmacy members,

I am providing written commentary expressing concern regarding the proposed amendment to OAR 855-041-1105, which is summarized as follows:
“Amends rule by adding dispensing requirements for a Drug Outlet and relocates and revises existing language from OAR 855-019-0210(4)-(7) pertaining to required information for a prescription. Requires Pharmacist to clarify discrepancies or uncertainties regarding a prescription. Requires read back of an oral prescription. Clarifies prescriber authority to request no substitution for the manufacturer of a drug.”

The major concern is how this rule affects the capacity of Pharmacists to exercise professional judgment, discretion, and assessment in fulfilling prescription orders. Secondarily, the documents relied upon to generate the amendment are both informal and out of date, coming from a 2017 reader’s survey. And thirdly, Cost of Compliance statements of “no impact” are false when the very nature of the rule is requiring additional documentation, labor, and administration resources.
The amendment of OAR 855-041-1105 to require readback of oral prescriptions, and repeat listening of voicemail prescriptions undermines professionalism by dictating a requirement best left to professional discretion, and adds unnecessary burden to already overburdened pharmacy staff, regardless of practice setting. The task of ensuring proper delivery of medication requires a range of practices and should not be reduced to prescriptive rules such as “...Listening to the voicemail a second time; and (c) The confirmation of accuracy in (b) must be documented on the prescription.” This is an unnecessary redundancy as OAR 855-019-0210 Duties of the Pharmacist Receiving a Prescription already contains language to impart the responsibility to ensure prescriptions, refills, and drug orders are correctly dispensed. The rule to require pharmacists to document transcription in a singular way parses out one method from a range of skills that practitioners of this profession use to carry out Pharmacy work. In doing so, the rule creates a myopia that restricts the professional capacity of
pharmacists and could be detrimental to patient care.

In the notice’s section for Documents Relied Upon, an informal and dated web article is cited which seems like a poor basis for creating legislation that would dictate the practice of all Licensees in the state. The article “Despite Technology, Verbal Orders Persist, Read Back is Not Widespread, and Errors Continue” is not an organized study and evaluation of best practices for handling oral prescriptions but rather a web survey of the site’s own constituents, from 2017. Even within the article itself, many different practices are presented besides “read back” to reduce error; however none of those are presented in the amendment to OAR 855-041-1105. The scope of this article’s recommendations lay within an individual organization's

practice, not a regulatory body.

The Cost of Compliance section of the notice incorrectly states there is “no additional mandatory reporting, recordkeeping, or other administrative requirements,” and “imposes no additional ...labor or administration.” The exact language of the amendment demands additional time and documentation to perform, and would certainly require additional administrative resources to maintain. The exact wording is as follows: “Reading back the prescription as transcribed to the person transmitting it; or(ii) Listening to the voicemail a second time; and (c) The confirmation of accuracy in (b) must be documented on the prescription.”

Thank you for taking the time to address my concerns before moving further with the Proposed Rule Making.

From:	Walmsley, Lorri
To:	PHARMACY RULEMAKING * BOP
Cc:	Kroeger, Victoria
Subject:	Comments on Proposed Regulations
Date:	Monday, November 20, 2023 12:23:58 PM
Attachments:	image001.png OR Comment Letter November 2023 DIV115.pdf OR Comment Letter November 2023 DIV 115 and 125 Vaccines.pdf OR Comment Letter November 2023 DIV 41.pdf

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Please see attached comments on behalf of Walgreens.

Warm Regards,

Lorri

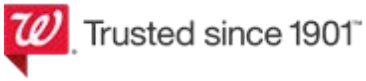
Lorri Walmsley, RPh, FAzPA

Director, Pharmacy Affairs

Walgreen Co.

She/Her why this matters

Mobile 602-214-6618



Lorri Walmsley, RPh., FAzPA
Director, Pharmacy Affairs
Walgreen Co.
5330 E. Washington St, Ste. 105
Phoenix, AZ 85034
p: 602-214-6618
lorri.walmsley@walgreens.com

November 20th, 2023
Oregon State Board of Pharmacy
Attention: Jamal Fox, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232

Via Email: pharmacy.rulemaking@bop.oregon.gov

RE: Division 041 – Outlets

Dear Executive Director Fox and members of the Oregon Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of Oregon, we thank the Board for the opportunity to comment on the proposed rules. We ask the board to review the comments below and suggested edits.

Throughout Division 041, the board has proposed language that requires an outlet to be responsible for the individual actions and professional judgment of the pharmacists working in their facilities. Outlets clearly do have a responsibility to ensure they have policies and procedures in place to ensure compliance with board rules. And the pharmacists working for the outlets must understand the policies and procedures in place. However, if an individual pharmacist utilizes poor judgment or deviates from the established practices of their facility the board and the outlet must take appropriate action upon that individual and ensure accountability for their personal actions and choices. An outlet cannot control every single decision, judgment, or choice of the individuals working in their facilities, but they can be asked to ensure a structure is in place to ensure compliance and patient safety. Walgreens asks the board to amend the language in OAR 855-041-1018(1), 855-041-1105 and 855-041-1115.

855-041-1018 Outlet: General Requirements
A drug outlet pharmacy must:
(1) Establish policies and procedures to ensure each :
(a) Prescription is dispensed in compliance with OAR 855-~~019, OAR 855-025, OAR 855-031 and OAR 855-041~~;41, OAR 855-115, OAR 855-120, OAR 855-125, OAR 855-139, OAR 855-141 and OAR 855-143;
(b) Controlled substance is dispensed in compliance with OAR 855-080;
(c) Compounded preparation is dispensed in compliance with OAR 855-045; and
(d) Radiopharmaceutical is dispensed in compliance with OAR 855-042.

855-041-1105 ~~Requirements for Prescriptions~~ Prescriptions: General Requirements
Each Drug Outlet Pharmacy must establish policies and procedures to ensure that:
(1) Prescriptions, prescription refills, and drug orders ~~must be correctly dispensed~~are dispensed:
(a) Accurately;
(b) To the correct party;
(c) Pursuant to a valid prescription;
(d) Pursuant to a valid patient-practitioner relationship;
(e) For a legitimate medical purpose; and
(f) In accordance with the prescribing practitioner's authorization

855-041-1115 Verification of Prescription Authenticity Validity
~~Alteration of a written prescription, other than by a pharmacist's or practitioner's authoriza~~
Each Drug Outlet Pharmacy must establish policies and procedures to ensure that:
(1) Prior to dispensing a prescription, a Pharmacist has verified its validity. In order for a prescription drug to be valid it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing of the prescription drug is upon the prescribing practition~~, in any manner constitutes an invalid order unless verified with the prescriber~~er, and a corresponding responsibility rests with the pharmacist who dispenses the prescription.

Additionally, Walgreens asks the board to discontinue its practice of establishing specific policies and procedures through rules for tasks completed by pharmacists. OAR 855-041-1105 (4)(B)(b) and (c), is an example of the boards attempt to write rules that eliminate and prohibit professional judgement by the pharmacist and acts as a standard operating procedure. We feel this approach is minimizing the professionalism required to be a pharmacist and is an overreach in rule writing. Also, when viewing the rule from an enforcement standpoint, does the board intend to take disciplinary action on a licensee for not listening to a lengthy voicemail twice or forgetting to document the confirmation of accuracy on the prescription even if the prescription is completely accurate and clinically appropriate? Will this rule as written substantially reduce the likelihood of transcription errors, will it increase the amount of work for pharmacy teams, or will it increase enforcement action on licensees who have not made an actual error on a prescription? As the board navigates writing rules to ensure the safety of patients in Oregon while balancing supporting pharmacist's workload, the additional administration burdens and unnecessary stress placed on licensees must also be considered. We respectfully request the following amendment:

855-041-1105 ~~Requirements for Prescriptions~~ Prescriptions: General Requirements

(4) An oral prescription must:

(a) Be promptly reduced to writing or entered into an electronic ~~prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.~~

~~(c) Such instructions shall not be default values on the prescription.~~

~~(4) A pharmacy or pharmacist filling a prescription or order for a biological product may not substitute a biosimilar product for the prescribed biological product unless~~:record system and must include:

(A) The name, initials or electronic identifier of the licensee receiving the prescription;

(B) The name of the person transmitting the prescription; ~~and~~

~~(b) After the prescription has been transcribed, the licensee must verify accuracy by:~~

~~(i) Reading back the prescription as transcribed to the person transmitting it; or~~

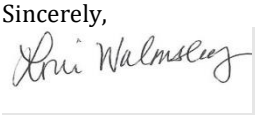
~~(ii) Listening to the voicemail a second time; and~~

~~(c) The confirmation of accuracy in (b) must be documented on the prescription.~~

Walgreens also has significant concerns with the requirement for Out-of-State pharmacies to have an Oregon-licensed PIC at all times as proposed in OAR 855-041-1060. Removing the 90-day timeframe to appoint a new PIC that is licensed in Oregon is problematic. It can be difficult to recruit and select an appropriate candidate for the role, particularly finding an out-of-state pharmacist who holds an Oregon license, which may result in the temporary cessation of operations to patients in Oregon if the requirements cannot be met potentially causing a lack of access for Oregon patients that non-resident pharmacies serve, especially for specialty pharmacies in which the patient cannot obtain medication locally. There is not a surplus of Oregon licensed pharmacists nationwide who also are interested in becoming a PIC, especially with the complex, confusing, and lengthy current board rules. If an Out-of-State Outlets does not already employ an Oregon-licensed pharmacist, it is necessary for an individual to reciprocate their license into Oregon, which is a process that takes time. This change will potentially cause harm to patients and reduce accessibility to pharmaceutical care for all Oregonians. Walgreens respectfully requests **not** to adopt the rules as proposed but retain current the regulation as it exists in OAR 855-041-1060 Non-Resident Pharmacies.

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,



Lorri Walmsley, RPh, FAzPA

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November 20th, 2023
Oregon State Board of Pharmacy
Attention: Jamal Fox, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232
Via Email: pharmacy.rulemaking@bop.oregon.gov

RE: Division 20 Related to vaccine protocols – protocol compendium

Dear Executive Director Fox and members of the Oregon Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of Oregon, we thank the Board for the opportunity to comment on the proposed rules. Walgreens thanks the board for its work on converting the Oregon Health Authority (OHA) vaccine protocols for pharmacists to the statewide protocols approved by the board. Walgreens also extends our gratitude for the tremendous effort by the subject matter experts for their dedication and time to creating comprehensive protocols.

Walgreens has significant concerns moving forward with individual protocols for each vaccine. Vaccine protocols rapidly change as new research develops and new vaccines are brought to market, when these protocols are so specific and require regulatory action for change there will be unnecessary delays for patient access. Pharmacies are the dominant healthcare facility that adults choose to receive their vaccinations and almost 90% of all insurance claims for adult vaccinations are submitted by pharmacies.[1] It is clear that patients depend on vaccination services by pharmacists and pharmacy technicians. Chaos, confusion, and frustration can be created when the public is aware of new vaccines or new indications and begin to request vaccinations that do not have an approved protocol in the state of Oregon. This was evident during the COVID vaccine rollout, where many patients were impacted by the minor delays in protocols published by OHA. The process that is now owned by the board will take much longer due to utilizing the formulary committee and requiring final board approval. Even more chaos, confusion, and frustration will occur in the pharmacies when there is even a minor delay in a protocol being updated to reflect new Advisory Committee on Immunization Practices (ACIP) or Centers for Disease Control and Prevention (CDC) recommendations and approvals. Additionally, board members will be required to quickly alter their personal and professional schedules to ensure the protocols are approved ultimately impacting and delaying public access to care.

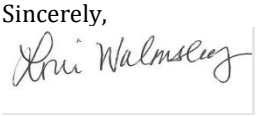
Walgreens requests the board to consider simplifying the process and adopting two statewide protocols. One for adults aged 18+ and one for individuals ages 3-17. The Virginia Board of Pharmacy[2] has adopted protocols in this manner, and we feel this will expedite the process for updated vaccines recommendations or approvals and reduce chaos, confusion, and frustration for patients who wish to receive the vaccine in the state of Oregon, while still maintaining patient safety. If pharmacists are issuing vaccine prescriptions consistent with the immunization schedule published by the CDC and recommended by ACIP, additional Oregon protocols are unnecessary, redundant, and inappropriately utilizes time and resources for all concerned, including the board staff and board members. We urge the board **not** to adopt all the protocols below as noticed, but recommend the board revisit the protocol compendium and create two simplified protocols based on age to ensure vaccine availability.

- Division 020 related to Vaccination Protocols - Protocol Compendium
  - Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 10/2023)
  - Cholera (v. 10/2023)
  - Coronavirus 19 (v. 10/2023)
  - Haemophilus Influenzae type b (v. 10/2023)
  - Hepatitis A containing vaccines (v. 10/2023)
  - Hepatitis B containing vaccines (v. 10/2023)
  - Human Papillomavirus (v. 10/2023)
  - Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024 (v. 10/2023)
  - Influenza Live Attenuated Influenza Vaccine 2023-2024 (v. 10/2023)
  - Japanese Encephalitis (v. 10/2023)

- Measles, Mumps & Rubella containing vaccines (v. 10/2023)
- Meningococcal containing vaccines (v. 10/2023)
- Pneumococcal (v. 10/2023)
- Polio (v. 10/2023)
- Rabies (v. 10/2023)
- Respiratory Syncytial Virus (v. 10/2023)
- Tetanus, Diphtheria containing vaccines (v. 10/2023)
- Typhoid (v. 10/2023)
- Varicella containing vaccines (v. 10/2023)
- Yellow Fever (v. 10/2023)
- Zoster (v. 10/2023)

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,



Lorri Walmsley, RPh, FAzPA

1. Trends in vaccine administration in the United States. IQVIA Institute. January 13, 2023. Accessed August 23, 2023. https://www.iqvia.com/insights/the-iqvia-institute/reports/trends-in-vaccineadministration-in-the-united-states
2. Virginia Board of Pharmacy Statewide Protocols. (n.d.) Accessed November, 16th 2023. https://www.dhp.virginia.gov/Boards/Pharmacy/PractitionerResources/StatewideProtocols/

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November 20th, 2023
Oregon State Board of Pharmacy
Attention: Jamal Fox, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232
Via Email: pharmacy.rulemaking@bop.oregon.gov

RE: Divisions 115, and 125 – Pharmacists and Pharmacy Technicians

Dear Executive Director Fox and members of the Oregon Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of Oregon, we thank the Board for the opportunity to comment on the proposed rules. The ability for licensees and registrants of the board, as well as the general public, to clearly understand the rules is paramount to ensuring public health and safety. We ask the board to review our comments, concerns, and suggested edits to the proposed rules.

Walgreens again commends the board for its discussion in its previous meetings regarding OAR 855-115-0001(3) 'Applicability'. However, with the most recent updates to the language, Walgreens has critical concerns that the proposed language could be interpreted to significantly limit the ability of licensed pharmacists working in a non-resident pharmacy to serve the patients in Oregon and will, as a result, increase the burden of the workload for in-state Pharmacists. There are qualified, licensed, and trained pharmacists nationwide providing specialized care to patients in Oregon, and without their expertise and availability, patients in Oregon will be left to navigate their complex disease states without them. Allowing licensed Oregon non-resident outlets with non-Oregon licensed pharmacists the ability to provide a patient's consultation and other remote pharmacy services whether they are part of the dispensing, delivering, or distribution process, is key to ensuring patients in Oregon continue to receive quality, safe, and timely pharmaceutical care. Additionally, there are licensed Oregon non-resident outlets that perform processing tasks (data entry, data review, DUR, and MTM services) without dispensing the final product to patients in Oregon. This rule is unclear if this process would be allowed without the pharmacists in these outlets holding an individual Oregon pharmacist license. The disallowance of this process or the requirement that all non-resident pharmacists hold an Oregon license would force massive amounts of work back into the Oregon-located pharmacies. Currently, many organizations, including community and health system pharmacies, have safely removed many aspects of prescription processing and patient care services to support the workload of in state pharmacy teams and consequently been able to increase access to local patient services like immunizations and health testing. Walgreens requests the board to review the stricken language below and ensure that there is no ambiguity on how this rule could be interpreted.

855-115-0001 Applicability
(1) This Division applies to any Pharmacist who engages in the practice of pharmacy.
(2) Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance with statutes and rules unless exempt under ORS 689.225.
(3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a pharmacist located in another state who is working for an out-of-state registered Drug Outlet Pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification is not required to be licensed by the board unless they are the Pharmacist-in-charge (PIC). ~~This exception applies only when a pharmacist is dispensing, delivering or distributing drugs into Oregon from a registered drug outlet. A pharmacist who is providing other pharmacy services into Oregon must be licensed in Oregon.~~

Walgreens supports and promotes the board's mission to ensure that a Pharmacist-in-Charge (PIC) is appropriately trained and qualified to ensure compliance in their pharmacy. However, in OAR 855-115-0205(3) the board has overcomplicated what is required to be a PIC, and what training is necessary, and when it is required. When an individual is interested in becoming a PIC, it is their responsibility, in partnership with the outlet, to ensure they have a sufficient understanding of the PIC role and an appropriate knowledge of pharmacy law and the expectations of the board. Also, flexibility is needed to ensure that outlets can choose the right candidate for a PIC role. Limiting the outlets' choice in candidates will have negative effects on the effective operation of pharmacies and may lead to

additional compliance issues. Furthermore, the time an individual has practiced pharmacy has no bearing on their ability to lead or ensure compliance with local state and federal rules governing pharmacy practice in the state of Oregon. Additionally, unless the board has the ability to track and publicly share the status of an individual who has taken the required board provided PIC course, the requirement to retake the PIC course every 5 years should be stricken. The board must consider the additional administrative burden placed on licensees and registrants when requiring additional training beyond the legal CE requirements. We respectfully request that the board consider the following amendment or retain OAR 855-019-0300 as currently written:

855-115-0205 Pharmacist-in-Charge: Qualifications and Limitations

(1) Effective March 1, 2024, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must have:

(a)Completed at least one year of pharmacy practice; or

(b)Completed a board provided PIC training course either before the appointment or within 90 days after the appointment; and

(c)Be employed by the outlet.

(2) A Pharmacist must not be designated PIC of more than three pharmacies. The following drug outlet types do not count towards this limit:

(a)Pharmacy Prescription Kiosks in OAR 855-141; and

(b) Pharmacy Prescription Lockers in OAR 855-143.

~~(3)Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:~~

~~(a)Complete a board-provided PIC training course as described below:~~

~~(A)A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90 days after appointment.~~

~~(B)A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to the appointment.~~

~~(b)Complete a board provided PIC training course at least every five years.~~

Walgreens supports and promotes professional judgment for pharmacists on duty and asks the board to clarify and simplify OAR 855-125-0150 and permit pharmacists to make the determination of what an appropriately trained technician can or can't do, based on their training level, experience, and professionalism. Technicians are allowed to assist in the practice of pharmacy as defined in ORS 689 and permitted in OAR 855-125-0105(4), but the language below causes significant confusion as currently written. The confusing nature of this language was evident in the board discussion at its previous meetings, as many questions were raised by board members. If the language and intent is not clear to the board, how can the public, licensees, and registrants be asked to understand and ensure compliance with these rules?

OAR 855-125-0150(1) seemingly restricts a pharmacist's ability to use professional judgment to determine how they utilize a pharmacy technician to assist in the practice of pharmacy or delegate tasks to another licensee when appropriate. We request the board to consider reviewing and revising the language to ensure that it is clear a technician is allowed to assist in the practice of pharmacy and play an important role in administering CLIA-waived tests, assisting with Medication Therapy Management, administering drugs or devices, and directing other licensees or delegating tasks when appropriate and when given permission from the pharmacist-in-charge or pharmacist on duty. We ask the board to review the proposed amendments and revisions as suggested to ensure clarity for all licensees as to what technicians can do when assisting in the practice of pharmacy.

855-125-0150 Prohibited Practices

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:

(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0105(4), including but not limited to the following tasks:

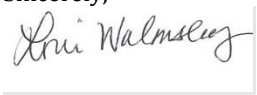
a. Evaluate and interpret a prescription;
b. Conduct a Drug Utilization Review or Drug Regimen Review;
c. Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription that requires judgment;
d. Counsel a patient or the patient's agent regarding a prescription;
e. Advise on therapeutic values, content, hazards and use of drugs and devices;
f. Interpret the clinical data in a patient record system or patient chart;
g. Conduct the clinical evaluations for Medication Therapy Management.
h. Practice pursuant to a Clinical Pharmacy Agreement or Collaborative Drug Therapy Management;
i. Practice pursuant to Statewide Drug Therapy Management Protocols;
j. Prescribe a vaccine, drug or device;
k. Administer a drug or device unless appropriately trained;

l. Order, interpret ~~or monitor~~ a laboratory test;
m. Receive or transfer a prescription for a controlled substance orally;
n. Supervise, direct, or control another licensee in activities that constitute the practice of pharmacy ad defined in ORS 6809.005 or assisting in the practice of pharmacy;
~~o. Delegate tasks to healthcare providers and~~
p. Deny the patient or the patient's agent request to speak to the Pharmacist.

(2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.
(3) Perform any task while assisting in the practice of pharmacy that requires judgment unless it is verified by a pharmacist.
(4) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace.
(5) Refuse a request from a patient, patient's agent, or practitioner to interact with a pharmacist.

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,



Lorri Walmsley, RPh, FAzPA

Division 041: Operation of Pharmacies (Short-acting Opioid Antagonist)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Institutional Drug Outlet Labeling Requirements for Short-acting Opioid Antagonist Temporary Rule

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Temporarily amends Emergency Department labeling requirements related to short-acting opioid antagonist for practitioners with prescriptive authority in Oregon. Incorporates legislative mandates of 2023 HB 2395, 2023 SB 450, 2023 SB 1043 related to short-acting opioid antagonist.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): Rule amendments are necessary by 1/1/2024 to comply with the legislative directives of 2023 SB 450, 2023 SB 1043 and 2023 HB 2395.

Optional: Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 SB 450, 2023 SB 1043, 2023 HB 2395

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-041-6410 – Temporarily amends (1)(d) and (e) by adding labeling exemptions pursuant to 2023 SB 450, effective 1/1/2024

OAR 855-041-6270 – Temporarily amends rule by adding (8) that states that nothing in the rule is intended to restrict or conflict with the directives of 2023 SB 450, 2023 SB 1043, or 2023 HB 2395, effective 1/1/2024

Division 041
OPERATION OF PHARMACIES

855-041-6410
Emergency Department Distribution

(1) A practitioner or associate practitioner with prescriptive authority in Oregon who is a member of the hospital's medical staff may dispense an emergency supply of drugs to a patient examined by them or by an associate practitioner subject to the following requirements:

(a) The prescriber ~~shall~~ **must** offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice;

(b) During consultation with the patient or the patient's caregiver, the prescriber ~~shall~~ **must** clearly explain the appropriate use of the drug supplied and the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice;

(c) The patient must be given instructions on the use and precautions for taking the drug;

(d) **Except as described in SB 450 (2023),** ~~T~~**t**he drug is in a manufacturer's unit-of-use container, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(B) Accessory cautionary information as required for patient safety;

(C) Product identification label if the drug is not in unit-of-use packaging;

(D) An expiration date after which the patient should not use the drug; and

(E) Name, address and phone number of the hospital pharmacy.

(e) **Except as described in SB 450 (2023),** ~~T~~**t**he following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

(D) Unique identifying number as determined by policy and procedure;

(E) Name of prescribing practitioner; and

(F) Initials of the dispensing nurse or practitioner.

(f) A prescription or record of the distribution must be completed by the practitioner or nurse. This record must contain:

(A) Name of patient;

(B) Date of issuance;

(C) Drug name and strength distributed;

(D) Units issued;

(E) Name of practitioner;

(F) Initials of the dispensing nurse or practitioner; and

(G) Instructions given to the patient as labeled.

(g) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient;

(h) The record must be reviewed and documented by a pharmacist for accuracy and completeness. The pharmacist ~~shall~~ **must** review the record of dispensing of drugs within 24 hours. However, if the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open but not to exceed 72 hours following the dispensing; and

(i) Errors and discrepancies will be included in hospital and pharmacy QA review process and available to the board.

(2) A controlled substance may only be distributed or dispensed to an outpatient by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined. Distribution of a controlled substance must comply with all applicable state and federal laws and regulations.

(3) The CPO or PIC and appropriate hospital committee will establish a limited selection and quantity of drugs to be included in the Emergency Department formulary and the amount contained in each prepak that may be distributed to meet only the acute care needs of a patient; for example, an emergency supply of drugs. The amount dispensed may not exceed a 48 hour supply except for:

(a) A drug in the manufacturer's unit-of-use packaging such as an inhalant or a topical drug;

(b) A full course of therapy that may be dispensed if in the professional judgment of the pharmacist or practitioner this would be in the patient's best interest such as an antibiotic;

(4) Any additional preparation for use of the medication must be completed prior to discharge; for example, reconstituting antibiotics;

(5) For the purpose of this rule an Automated Dispensing Machine (ADM) is a machine or contrivance which will prepare a completed and labeled prescription which is ready for dispensing to the patient or patient's representative.

(6) An Automated Dispensing Machine; may only be located within the Emergency Department in a secure environment that has no direct public access, and when used, must be part of the discharge procedure;

(7) When the patient or patient's representative receives the prescription from an ADM;

(a) A registered nurse or practitioner or pharmacist must be present at the time of dispensing; and

(b) A registered nurse or practitioner or pharmacist will grant access to the ADM for the release of the drugs to be dispensed using a password protected or biometric access; and

(c) The patient or patient's representative will obtain the drug using a specific patient access code.

(8) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may access the drug supply in the ADM.

(9) The CPO or PIC will establish policies and procedures for use of the ADM including, but not limited to emergency access and down time procedures for the ADM.

(10) Upon written request, the board may waive any of the requirements of this rule if a waiver will further public health or safety. A waiver granted under this section ~~shall~~ **must** only be effective when it is issued in writing and will be time limited.

(11) Nothing in this rule is intended to restrict or conflict with HB 2395 (2023), SB 450 (2023), SB 1043 (2023).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155**,** ~~&~~ ORS 689.505**, 2023 HB 2395, 2023 SB 450, 2023 SB 1043**

855-041-6270
Institutional Drug Outlet Pharmacy Prescription Labeling

(1) Each pharmacy record keeping system must identify all pharmacy personnel involved in the repackaging including the pharmacist who verified the repackaged drug.

(2) Each repackaged drug, prepared by the pharmacy and intended for use within the facility must be in an appropriate container with a label that meets the requirements of OAR 855-041-1135 and includes:

(a) The brand or generic name and expiration date;

(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;

(c) The strength of the drug.

(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:

(a) Name and location of patient;

(b) Name and strength of drug;

(c) Route of administration, when necessary for clarification;

(d) Manufacturer and lot number, or internal pharmacy code;

(e) Auxiliary labels as needed, and

(f) Expiration date.

(4) A drug that is provided for outpatient use must be dispensed by a retail drug outlet.

(5) When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.

(6) When a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that includes the:

(a) Name, quantity and concentration of the drug added and the primary solution;

(b) Date and time of addition;

(c) Expiration date;

(d) Scheduled time for administration;

(e) Infusion rate, when applicable;

(f) Name or initials of person performing admixture;

(g) Identification of the pharmacy where the admixture was performed; and

(h) Name or initials of the verifying pharmacist.

(7) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.

(8) Nothing in this rule is intended to restrict or conflict with HB 2395 (2023), SB 450 (2023), SB 1043 (2023).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155**, ~~&~~** ORS 689.505**, 2023 HB 2395, 2023 SB 450, 2023 SB 1043**

Divisions 019/025/041/139: Vaccinations

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Pharmacist, Certified Oregon Pharmacy Technician and Pharmacy Technician Administration of Vaccines

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Beginning 1/1/2024, proposed rule amendments will permit a Pharmacist to administer an influenza vaccine to persons who are six months of age or older pursuant to 2023 HB 2278 and permit a Certified Oregon Pharmacy Technician (COPT) or Pharmacy Technician (PT) to administer a vaccine under the supervision of a Pharmacist pursuant to 2023 HB 2486.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 HB 2278, 2023 HB 2486

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Part of the proposed amendments may favorably impact racial equity making it easier for Black, Indigenous, people of color, and American Indian/Alaska Native people (BIPOC-AI/AN) to access vaccines in a pharmacy. Permitting pharmacists to administer influenza vaccine to patients aged 6 months and older and pharmacy technicians to administer vaccines may contribute to closing disparities in vaccination rates between white persons and BIPOC-AI/AN. Pharmacies are often located in communities where BIPOC-AI/AN live and are more accessible than other healthcare settings. Pharmacists and pharmacy technicians are also trained to provide culturally competent care.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule amendments have no anticipated fiscal and economic impact as the rules do not require a Pharmacist, COPT or PT to provide vaccinations.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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).
(1) The proposed rule amendments will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule amendments apply to pharmacy registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not convened. Why? The board did not direct staff to convene a Rules Advisory Committee or Workgroup to advise on the proposed rule amendments. Recent legislation informed the proposed rule amendments. Pursuant to 2023 HB 2278, proposed amendments will permit a Pharmacist to administer an influenza vaccine to persons who are six months of age or older. Pursuant to 2023 HB 2486, proposed amendments will permit a Certified Oregon Pharmacy Technician (COPT) or Pharmacy Technician (PT) to administer a vaccine under the supervision of a Pharmacist.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Due to recently adopted legislation, 2023 HB 2486 and 2023 HB 2278 related to immunizations, it is necessary to amend and adopt rules for Pharmacists, COPTs and PTs, Drug Outlet Pharmacies and Remote Dispensing Site Pharmacies to comply with the directives of the legislation.

OAR 855-019-0270: Amends by relocating existing rules related to supervision of an immunizing Intern, protocols and to whom a pharmacist can administer vaccines to 855-019-0280.

OAR 855-019-0280: Amends by adding language relocated from OAR 855-019-0270; Adds that a Pharmacist may administer to a person who is six months of age or older if the vaccine administered is an influenza vaccine per 2023 HB 2278 beginning 1/1/2024; Moves requirements for a pharmacy to 855-041-1040; Adds rules related to the Pharmacist duties for administration or supervision of vaccination; Removes requirement for Pharmacist to 'give' Vaccine Information Statement (VIS) to patient and ensure it was read by/to patient and alternatively requires Pharmacist to 'ensure' patient receives VIS; Adds pharmacist requirements for supervising Interns, COPTs and PTs who administer a vaccine, which includes the Pharmacist being immediately available to the vaccinator.

OAR 855-019-0290: Adds the phrase "or supervises each administration of" to OAR 855-019-0290(1). Removes "former requirement" language from (2).

OAR 855-025-0024: Adopts new rule permitting an appropriately trained and qualified COPT and PT to perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist pursuant to 2023 HB 2486 beginning 1/1/2024.

OAR 855-041-1040: Amends (2)(i) by adding requirements for the outlet to have policies and procedures for COPT/PT vaccination; Adds (2)(l) "Disposal of drugs and/or devices including hazardous and pharmaceutical waste" which is relocated from OAR 855-019-0270.

OAR 855-139-0600: Amends (1) by revising language in (a) to match proposed language in OAR 855-125-0150 and adding (b) which prohibits a COPT/PT at a RDSP to "Administer a vaccine." as a pharmacist is not present to respond to an adverse reaction.

Division 019
PHARMACISTS

855-019-0270
Vaccination: Qualifications

A Pharmacist may administer vaccines if the Pharmacist:

(1) Has completed a course of training approved by the board and maintained competency that includes, injection site, and Cardiopulmonary Resuscitation (CPR) specific to the age and population of patients being vaccinated by the Pharmacist;

(2) Holds active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that contains a hands-on training component and is valid for not more than three years;

(3) Has access to the current edition of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."

Statutory/Other Authority: ORS 689.205, ORS 689.645
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645

855-019-0280
Vaccination: Protocols, Policies and Procedures

(1) Prior to prescribing, administering or dispensing a vaccine, a Pharmacist:

(a) Until January 31, 2024, must follow protocols written and approved by the Oregon Health Authority (OHA) for vaccines and the treatment of severe adverse events following administration of a vaccine.

(b) Effective February 1, 2024, must follow a statewide drug therapy management protocol per OAR 855-020-0300 or a collaborative drug therapy management agreement per OAR 855-019-0260.

(2) A Pharmacist may administer vaccines:

(a) To a person who is seven years of age or older;

(b) To a person who is six months of age or older if the vaccine administered is an influenza vaccine; and

(c) To a person who is at least three years of age when:

(A) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or

(B) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.

(3) A Pharmacist who administers or supervises administration of any vaccine must:

(a) Make vaccine recommendations;

(b) Select each vaccine to be administered;

(c) Ensure compliance with (1);

(d) Ensure the appropriate Vaccine Information Statement (VIS) is provided to the patient or legal representative prior to each dose of vaccine;

(e) Perform verification prior to administration that includes but is not limited to:

(A) Prescription order accuracy verification; and

(B) Vaccine product accuracy review;

(f) Advise or counsel on therapeutic values, content, hazards and use of each vaccine;

(g) Manage adverse events;

(h)Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient;

(i) Verify accuracy and completeness of documentation for vaccine administration; and

(j) Ensure all persons administering vaccines under their supervision are appropriately trained and qualified.

(4) An appropriately trained and qualified Pharmacist may permit an appropriately trained and qualified:

(a) Intern to perform the same duties as a Pharmacist except as prohibited in OAR 855-019-0200(6).

(b) Certified Oregon Pharmacy Technician or Pharmacy Technician to conduct the physical act of administering a vaccine in accordance with OAR 855-025-0024.

(5) The appropriately trained and qualified Pharmacist who is supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician in administering a vaccine must be immediately available to the vaccinator to respond to adverse reactions and any other issues that may arise.

Statutory/Other Authority: ORS 689.205, ORS 689.645, ORS 433.441, ORS 433.443, 2023 HB 2278, 2023 HB 2486
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645, 2023 HB 2278, 2023 HB 2486

855-019-0290

Vaccination: Record Keeping and Reporting

A Pharmacist who administers or supervises each administration of a vaccine to a patient must:

(1) Fully document the administration in the patient's permanent record.

(2) Report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration.

(a) The name, address, gender and date of birth of the patient;

(b) The date of administration of the vaccine;

(c) The NDC number of the vaccine, or other acceptable standardized vaccine code set;

(d) The address of the pharmacy where vaccine was administered unless automatically embedded in the electronic report provided to the OHA ALERT Immunization System;

(e) The phone number of the patient when available;

(f) The dose amount, manufacturer, site of administration, lot number and expiration date of the vaccine when available;

(3) Keep documentation of current CPR training. This documentation will be kept on site and available for inspection.

(4) Follow storage and handling guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC).

(5) For the purpose of participation in the Oregon Vaccines for Children program,

(a) The vaccine eligibility code for each dose must be reported to the ALERT Immunization Information System in the manner prescribed by OHA, and

(b) The Pharmacist is recognized as a prescriber.

(c) If providing state or federal vaccines during a pandemic as determined by the CDC, the event and priority code as specified by OHA must be provided upon request in the manner prescribed by OHA.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645, 2023 HB 2278, 2023 HB 2486

Division 025
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-025-0024
Services: Vaccine Administration

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist:

(a) To a person who is seven years of age or older;

(b) To a person who is at least three years of age when;

(A) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or

(B) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.

(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician must:

(a) Prior to administration of a vaccine, receive practical training that includes infection control, recognition of anatomical landmarks and competency in hands-on administration technique.

(b) Prior to administration of a vaccine, hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program that is specific to the age and population receiving the vaccine, contains a hands-on training component, and is valid for not more than three years.

(3) Document the vaccine administration including but not limited to the vaccine administered, dose, expiration date, lot number, and injection site.

(4) Notify the supervising Pharmacist immediately in the event of a suspected adverse reaction to a vaccine.

(5) The training required in (2) may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college or school of pharmacy, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board.

(6) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

Statutory/Other Authority: ORS 689.205, 2023 HB 2486
Statutes/Other Implemented: ORS 689.151, 2023 HB 2486

Division 041
OPERATION OF PHARMACIES

855-041-1040
Outlet: Policies and Procedures

(1) The drug outlet pharmacy and its Pharmacist in Charge is accountable for establishing, maintaining, and enforcing written policies and procedures for the drug outlet pharmacy in compliance with federal and state regulations. The written policies and procedures must be maintained at the drug outlet pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the responsibilities of the drug outlet pharmacy including;

(a) Security;

(b) Operation, testing and maintenance of pharmacy systems and equipment;

(c) Sanitation;

(d) Storage of drugs;

(e) Dispensing;

(f) Pharmacist supervision, direction and control of non-Pharmacists;

(g) Documenting the date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(h) Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians;

(i) Certified Oregon Pharmacy Technician or Pharmacy Technician final verification and/or vaccination, if utilized;

(j) Drug and/or device procurement;

(k) Receiving of drugs and/or devices;

(l) Disposal of drugs and/or devices including hazardous and pharmaceutical waste;

(m) Delivery of drugs and/or devices;

(n) Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling);

(o) Recordkeeping;

(p) Patient confidentiality;

(q) Continuous quality improvement;

(r) Plan for discontinuing and recovering services in the event of a pharmacy closure;

(s) Training: initial and ongoing; and

(t) Interpretation, translation and prescription reader services.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508 & 2022 HB 4034

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet RDSP must not:

(1) Allow a Certified Oregon Pharmacy Technician or Pharmacy Technician to:

(a) Refuse a request from a patient, patient's agent, or practitioner to interact with a Pharmacist; and

(b) Administer a vaccine.

(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the board pursuant to ORS 689.305;

(3) Compound sterile preparations; or

(4) Repackage drugs.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.700
Statutes/Other Implemented: ORS 689.155, ORS 689.315, ORS 689.700, 2023 HB 2486

Division 020: Pharmacists (Protocol Compendium- Vaccinations)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds Vaccination Protocols to Protocol Compendium

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Adds vaccination protocols to protocol compendium effective 2/1/2024 and adopts each protocol as a standard adopted by reference.

Documents Relied Upon per ORS 183.335(2)(b)(D):
Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 10/2023)
Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 10/2023)
Cholera (v. 10/2023)
Coronavirus 19 (v. 10/2023)
Haemophilus influenzae type b (v. 10/2023)
Hepatitis A containing vaccines (v. 10/2023)
Hepatitis B containing vaccines (v. 10/2023)
Human Papillomavirus (v. 10/2023)
Influenza Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-2024 (v.10/2023)
Influenza Live Attenuated Influenza Vaccine 2023-24 (v.10/2023)
Japanese Encephalitis (v. 10/2023)
Measles, Mumps & Rubella containing vaccines (v. 10/2023)
Meningococcal containing vaccines (v. 10/2023)
Pneumococcal (v. 10/2023)
Polio (v. 10/2023)
Rabies (v. 10/2023)
Respiratory Syncytial Virus (v. 10/2023)
Tetanus, Diphtheria containing vaccines (v. 10/2023)
Typhoid (v. 10/2023)
Varicella containing vaccines (v. 10/2023)
Yellow Fever (v. 10/2023)
Zoster (v. 10/2023)

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): 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 (OBOP/Other State Agencies/Units of Local Government/Public):
(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).
(1) The rule amendments will have no additional economic impact on state agencies, units of local government, or the public.
(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business
(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.
(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not convened. Why? Subject Matter Experts (SME) are responsible for drafting proposed protocols and the Public Health and Pharmacy Formulary Advisory Committee is responsible for recommending changes to the drafts or recommending the proposed protocols which are then sent to the board for consideration.
Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):
OAR 855-020-0300: Amended to add vaccination protocols to the compendium effective 2/1/2024.

Division 020
PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0300
Protocol Compendium

A Pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium:

(1) Continuation of therapy including emergency refills of insulin (v. 06/2023)

(2) Conditions

(a) Cough and cold symptom management

(A) Pseudoephedrine (v. 06/2021);

(B) Benzonatate (v. 06/2021);

(C) Short-acting beta agonists (v. 06/2021);

(D) 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, Nicotine Replacement Therapy (NRT) and Non-NRT (v. 06/2022);

(d) Travel Medications (v. 06/2023);

(e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);

(f) HIV Pre-exposure Prophylaxis (PrEP) (v. 06/2023); and

(g) Contraception (v. 06/2023); and

(h) Effective 2/1/2024, vaccinations:

(A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 2/2024);

(B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 2/2024);

(C) Cholera (v. 2/2024);

(D) Coronavirus 2019 (v. 2/2024);

(E) Haemophilus Influenza type b (v. 2/2024)

(F) Hepatitis A containing vaccines (v. 2/2024);

(G) Hepatitis B containing vaccines (v. 2/2024);

(H) Human Papillomavirus (v. 2/2024);

(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 2/2024);

(J) Influenza - Live Attenuated Influenza Vaccine 2023-24 (v. 2/2024);

(K) Japanese Encephalitis (v. 2/2024);

(L) Meningococcal containing vaccines (v. 2/2024);

(M) Measles Mumps & Rubella containing vaccines (v. 2/2024);

(N) Pneumococcal (v. 2/2024);

(O) Polio (v. 2/2024);

(P) Rabies (v. 2/2024);

(Q) Respiratory Syncytial Virus (v. 2/2024);

(R) Tetanus Diphtheria containing vaccines (v. 2/2024);

(S) Typhoid (v. 2/2024);

(T) Varicella containing vaccines (v. 2/2024);

(U) Yellow fever (v. 2/2024);

(V) Zoster (v. 2/2024).

[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, ORS 689.696

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Cover Page & Assessment and Treatment Care Pathway

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a Pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110 a Pharmacist licensed and located in Oregon may prescribe and administer routine and travel vaccines in adherence with current CDC ACIP recommendations, CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases and CDC Yellow Book: Health Information for International Travel information.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized All Vaccines Assessment and Treatment Care Pathway (pg. 2)
- Utilize the Protocol for each specific vaccine to be administered
- Utilize the Protocol for Managing Adverse Reactions when applicable

PHARMACIST TRAINING/EDUCATION:

- The Pharmacist has completed a course of training as outlined in OAR 855-019-0270.
- The Pharmacist maintains active CPR certification as outlined in OAR 855-019-0270.

RESOURCES

CDC ACIP: Vaccine Recommendations and Guidelines- https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases- https://www.cdc.gov/vaccines/pubs/pinkbook/index.html

CDC Yellow Book: Health Information for International Travel information- https://wwwnc.cdc.gov/travel/page/yellowbook-home-2020

Immunization Action Coalition (IAC) Screening Checklist for Contraindications to Vaccines for Adults- http://www.immunize.org/catg.d/p4065.pdf

Immunization Action Coalition (IAC) Screening Checklist for Contraindications to Vaccines for Children and Teens- http://www.immunize.org/catg.d/p4060.pdf

CDC Adult Immunization Schedule -https://www.cdc.gov/vaccines/schedules/hcp/adult.html

CDC Child and Adolescent immunization Schedule- https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

CDC Checklist for Determining Recommended Vaccines -http://www.cdc.gov/vaccines/hcp/adults/downloads/patient-intake-form.pdf

CDC Vaccine Information Statements - https://www.cdc.gov/vaccines/hcp/vis/current-vis.html

Administering Vaccines to Adults: Dose, Route, Site, and Needle Size-https://www.immunize.org/catg.d/p3084.pdf

Vaccine Adverse Event Reporting System (VAERS) - https://vaers.hhs.gov/index

National Vaccine Errors Reporting Program (VERP)- https://www.ismp.org/form/verp-form

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Cover Page & Assessment and Treatment Care Pathway

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: COLLECT

- Gather information to screen for indications including age, health conditions, occupation, travel, and lifestyle
- Check the ALERT Immunization Information System (IIS). If ALERT is unavailable, use documentation and patient statement.
- Check patient health records and other records
- Gather information to screen for precautions and contraindications including current health status, present & past medical history, allergies, medications, immunization history, and pregnancy status

STEP 2: ASSESS

- Assess routine and travel vaccinations in adherence with current CDC ACIP recommendations, CDC Pink Book: Epidemiology and Prevention of Vaccine-Preventable Diseases and CDC Yellow Book: Health Information for International Travel information and each specific vaccine protocol
- Assess immunization needs based on age, health conditions, occupation, travel, and lifestyle indications
- Assess immunization history using IIS records, patient health records, and other sources of records to determine whether the patient needs this vaccine and any other vaccines
- Assess precautions and contraindications to needed vaccine(s) based on responses to screening questionnaire

STEP 3: PLAN

- Strongly recommend needed vaccine(s)
- Offer to administer vaccine or refer the patient to another immunizing health care provider

STEP 4: IMPLEMENT

- Provide current patient education and Vaccine Information Statements (VIS) and answer questions
- Prescribe and administer needed vaccine(s)
  - Verify needle length for injection.
  - To avoid injury related to vaccine administration, immunizer must recognize the anatomic landmarks for identifying the deltoid muscle and use proper IM administration technique.
- Provide documentation to patient and record all required data elements in the patient's permanent health record
- Report to ALERT Immunization Information System (IIS)

STEP 5: FOLLOW-UP

- Monitor patient for 15 minutes after administration of vaccine(s) for signs and symptoms of syncope, localized and/or generalized reactions
- Adverse Events Reporting
  - Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html.
  - VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html.
- Schedule follow-up for subsequent doses of multidose vaccine series
- Refer patient for other health, wellness, or follow-up services to their identified primary care provider or another provider (provide patient with documentation of referral)

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110 a Pharmacist licensed and located in Oregon may prescribe and administer medications used in the management of adverse reactions following immunization in adherence with current CDC ACIP recommendations and Epidemiology, Prevention of Vaccine-Preventable Diseases (Pink Book), and CDC Yellow Book: Health Information for International Travel information.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Managing Adverse Events Assessment and Treatment Care Pathway (pg.2)
- Utilize Managing Adverse Events Protocol (pgs. 3-9)
- Utilize Adverse Event Record Tool (Appendix A) & Emergency Kit Medications & Equipment List (Appendix B)
- Refer to Recognizing & Responding to Anaphylaxis (Appendix C)

PHARMACIST TRAINING/EDUCATION:

- The Pharmacist has completed a course of training as outlined in OAR 855-019-0270
- The Pharmacist maintains active CPR certification as outlined in OAR 855-019-0270

RESOURCES

CDC ACIP General Best Practice Guidelines: Preventing and Managing Adverse Reactions- https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.pdf

Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book): Vaccine Administration- https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html

Medical Management of Vaccine Reactions in Adults in a Community Setting- https://www.immunize.org/catg.d/p3082.pdf

Medical Management of Vaccine Reactions in Children and Teens in a Community Setting- https://www.immunize.org/catg.d/p3082a.pdf

State of Oregon Trauma and EMS Systems. Treatment of severe allergic reaction; A Protocol for Training (2018). https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EMSTRAUMASYSTEMS/Documents/Training%20Material/Epinephrine-Training-Protocol.pdf

Vaccine Adverse Event Reporting System (VAERS) - https://vaers.hhs.gov/index

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

Assessment and Treatment Care Pathway

STEP 1: COLLECT

- Observe patient's signs and symptoms
- Obtain prepared Emergency Kit (E-Kit)

STEP 2: ASSESS

- Assess patient's blood pressure and vital signs
- Anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than one body system is involved) or are serious or life-threatening in nature, even if they involve a single body system (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips)
- Activate emergency response (Call 911) if signs and symptoms indicate progression towards anaphylaxis

STEP 3: PLAN

- Prepare treatment medications if indicated
- Prepare for CPR

STEP 4: IMPLEMENT

- Apply treatment plan and/or administer treatment medications per protocol
- If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately and apply AED if available

STEP 5: FOLLOW-UP

- Continue assessing vitals and monitor per protocol until Emergency Medical Services arrive
- Document actions using Adverse Event Record Tool
- Report anaphylaxis and vasovagal syncope to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html.
- VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html.

Event and Interval From Vaccination
A. Anaphylaxis or anaphylactic shock (7 days) B. Vasovagal syncope (7 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Any acute complication or sequelae (including death) of above events (interval – not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert)

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

1. What's New

A. N/A

2. Anaphylaxis Protocol (Generalized Symptoms)

A. If symptoms are generalized, call 9-1-1 immediately. This should be done by a second person if available, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Do not delay transport; DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.
B. Keep patient in recumbent position (flat on back) unless patient is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
C. Take and record the patients' blood pressure and vital signs (pulse, respirations) at the initial assessment, and at minimum – every 5 minutes, and following the administration of any medication.
D. The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
E. Administer 1mg/mL epinephrine intramuscularly (IM) into the anterolateral thigh (all ages), through clothing if necessary, with the correct needle length for the patient's age and size according to the dosage chart in Table 1.
F. If no improvement in condition, repeat epinephrine dose every 5–15 minutes for up to 3 doses, depending on patient's response.
G. Complete the Adverse Event Record Tool.
H. If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately. Apply AED if available.
I. Monitor until Emergency Medical Services arrive.
J. Any patient who develops signs and symptoms of anaphylaxis MUST be transported via a fully equipped emergency vehicle to an emergency department. Any refusal of transport must be handled by EMS personnel.
K. Give report and list of medications given to emergency medical personnel upon arrival.
L. Medication Schedule: *See Table 1 on next page*

Table 1: Anaphylaxis

Inject EPINEPHRINE (1mg/mL): 0.01 mg/kg of body weight up to 0.5mg maximum dose. May be repeated every 5–15 minutes for a total of 3 doses.
Give intramuscularly (IM) in the vastus lateralis muscle of the thigh, regardless of age, either by auto injector or by syringe and needle, through the clothing if necessary. [1]

Suggested dosing of Epinephrine for children[2] and adults: consider needle length

Age Group	Weight in lb[#]	Weight in kg[#]	Epinephrine injectable (1:1000 dilution); IM =(1mg/mL) [Minimum dose: 0.05mL]	Epinephrine auto–injector 0.1mg (7.5-14.5 kg), 0.15mg (15-29.5 kg) or 0.3 mg (≥30 kg)
6 months (use only for dosing by weight)	9-16 lb	4-7 kg	0.05 mL (or mg)	Off-Label
	16.5-19 lb	7.5-8.5 kg		0.1mg/dose[*]
7-36 months (use only for dosing by weight)	20-32 lb	9-14.5 kg	0.1 mL (or mg)	0.1mg/dose[*]
37-59 months	33-39 lb	15-17.5 kg	0.15 mL (or mg)	0.15mg/dose
5-7 years	40−56 lb	18−25.5 kg	0.25 mL (or mg)	0.15mg/dose
8–10 years	57−76 lb	26−34.5 kg	0.3 mL† (or mg)	0.15 mg/dose or 0.3mg/dose
11–12 years	77−99 lb	35−45.5 kg	0.4 mL (or mg)	0.3mg/dose
≥13 years	100+ lb	46+ kg	0.5 mL‡ (or mg)	0.3mg/dose

[#]Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months. Round kg to nearest 0.5 kg.

[*] The 0.15mg epinephrine autoinjector can also be used for children 7.5 kg (16.5 lb) to 14.5 kg (32 lb) when other alternatives are not available.

†Maximum dose for children (prepubertal)[1]

‡Maximum dose for adolescents and adults[1]

3. Urticaria Protocol (Localized Symptoms)

A. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
B. Apply ice to the site where the vaccine was administered. If more than one site is involved, apply ice to the sites that appear to be red, warm, or swelling.
C. Administer diphenhydramine intramuscularly (IM) with the correct needle length for the patient's age and size according to the dosage chart in Table 2.
D. Administer hydroxyzine hydrochloride orally if diphenhydramine unavailable according to patient's age and size in the dosage chart in Table 3.
E. Complete the Adverse Event Record Tool.
F. Take and record the patient's blood pressure and vital signs at the initial assessment, and at minimum - every 10 minutes, and following the administration of any additional medication.

G. Continue to monitor for and treat signs and symptoms progressing towards anaphylaxis when indicated. If signs and symptoms present, immediately initiate anaphylaxis protocol.

H. Medication Schedule:

Table 2: Urticaria

First-Line Treatment for Urticaria: Give Diphenhydramine IM as follows:			
Suggested dosing of Diphenhydramine for children[2] and adults			
Age Group Dose	**Weight in lbs[#]**	**Weight in kg[#]**	**Injectable: 50mg/mL IM[†]**
6 months (use only for dosing by weight)	9-19 lb	4-8.5 kg	5-10 mg (0.1 - 0.2 mL)
7-36 months (use only for dosing by weight)	20-32 lbs	9-14.5 kg	10-15 mg (0.2 - 0.3 mL)
37-59 months	33-39 lbs	15-17.5 kg	15-20 mg (0.3 - 0.4 mL)
5-7 years	40–56 lbs	18–25.5 kg	20–25 mg (0.4 - 0.5 mL)
8–12 years	57–99 lbs	26–45.5 kg	25–50 mg (0.5 - 1.0 mL)
≥13 years[‡]	100+ lbs	46+ kg	50 –100 mg (1 - 2 mL)[*]

[#] Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

[†] Pediatric dose is 1-2mg/kg

[‡] Maximum single dose is 100mg for persons ≥13 years[2-3]

[*] No more than 1 mL per injection site

Table 3: Optional Treatment: Hydroxyzine Hydrochloride

Hydroxyzine Hydrochloride for urticaria when Diphenhydramine is unavailable: Give PO as follows:			
Suggested dosing of Hydroxyzine Hydrochloride for children[2] and adults			
Age Group Dose	**Weight in lbs[#]**	**Weight in Kg[#]**	**Liquid: 10mg/5mL or 25mg/5mL[†]**
6 months (use only for dosing by weight)	9-19 lb	4-8.5 kg	2.5-5 mg/dose
7-36 months (use only for dosing by weight)	20-32 lbs	9-14.5 kg	5-7.5 mg/dose
37-59 months	33-39 lbs	15-17.5 kg	7.5-10 mg/dose
5-7 years	40–56 lbs	18–25.5 kg	10-12.5 mg/dose
8–10 years	57–76 lbs	26–34.5 kg	12.5–15 mg/dose
11–12 years	77–99 lbs	35–45.5 kg	15–25 mg/dose
≥13 years	≥100 lbs	≥46 kg	25 mg/dose

[#] Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

[†] Pediatric dose is 0.5-1 mg/kg

[*] Maximum single dose is 25mg for persons ≥13 years[2-3]

4. Loss of Consciousness/Syncope Protocol

A. If the individual "feels faint", ammonia ampules should be used if available. Crush and wave near patient's nose.
B. Have patient lie flat with feet elevated or sit with their head down for several minutes.
C. If the patient loses consciousness, place flat on back, with feet elevated.
D. Unconsciousness from fainting should only last seconds. In a vasovagal response, the pulse should be slow. A weak, thready or rapid pulse may indicate anaphylaxis. Continue to monitor for signs and symptoms progressing towards anaphylaxis. If signs and symptoms present, immediately initiate anaphylaxis protocol.
E. Have patient rest in a quiet area for 10 minutes after regaining consciousness. Slowly have patient move to a sitting position and then standing, checking to make sure no symptoms recur.
F. Complete the Adverse Event Record Tool.

5. Contraindications

A. There are **no** contraindications for the use of epinephrine to treat anaphylaxis
B. Previous hypersensitivity is a contraindication for diphenhydramine and hydroxyzine.
C. Do not administer epinephrine auto-injector to children weighing less than 16.5 lbs.

6. Other Considerations

A. Required Documentation:
- Current Healthcare Provider CPR Card as required by OAR 855-019-0270
- Completed Adverse Event Record Tool for each event (Appendix A).

B. Required Medications & Equipment: See Emergency Kit Medications & Equipment List (Appendix B)

7. Storage and Handling

A. Store medications according to OAR 855-041-1036.

8. Adverse Events Reporting

A. Anaphylaxis and vasovagal syncope must be reported to the Vaccine Adverse Events Reporting System (VAERS) online at: https://vaers.hhs.gov/reportevent.html.
B. VAERS Table of Reportable Events Following Vaccination: https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

9. References

1. CDC. Management of Anaphylaxis at a COVID-19 Vaccination Location. Last updated 11 February 2022. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html Accessed 23 August 2022.
2. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Children and Teens in a Community Setting. July 2019. Available at: https://www.immunize.org/catg.d/p3082a.pdf. Accessed 23 August 2022.
3. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Adults in a Community Setting. July 2019. Available at: https://www.immunize.org/catg.d/p3082.pdf. Accessed 23 August 2022.

10. Appendix

A. Adverse Event Record Tool
B. Emergency Kit Medications & Equipment
C. Recognizing & Responding to Anaphylaxis Reference

PREVENTIVE CARE

STANDARD PROTOCOL FOR All VACCINES

Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

APPENDIX A: Adverse Event Record Tool

Patient Name: _____ Allergies: _____
Date of Birth: _____ Vaccine(s) Given: _____
Date: _____ Site(s):_____
Pharmacist: _____ Route(s): _____
Patient is displaying signs of: Anaphylaxis – Urticaria – Syncope (Circle One)

VITALS							
Time	**Pulse**	**Respirations**	**Blood Pressure**	**Medication**	**Dose**	**Site–Route**	**Initials**

Notes:

APPENDIX B: Emergency Kit Medications & Equipment List

Required Medications & Equipment	**Quantity/Type**	**Expiration Date**	**Optional Medications & Equipment**	**Quantity/ Type**	**Expiration Date**
Epinephrine solutions	**1** multi-dose vial (MDV) of 1mg/mL Epinephrine **OR** Epinephrine auto-injectors; **3** doses each of adult and pediatric size units		Hydroxyzine Hydrochloride for use when Diphenhydramine is unavailable	Liquid: 10 mg/5 mL or 25 mg/5 mL Tablets: 10 mg or 25 mg Capsules: 25 mg	
Diphenhydramine 50 mg/mL injectable	**1** multi-dose vial (MDV) **OR 2** single-dose vials (SDV) vials		Bottle of water for swallowing oral antihistamines		
Blood Pressure Monitor (with pediatric cuff if applicable)	Automated devices must show current calibration and replace batteries as needed		Sphygmomanometer and Stethoscope (with pediatric cuff if applicable)		
Syringes/Needles	For Epinephrine injection only: 1-cc syringes with 22–25g, 1-1½" needles For Diphenhydramine injection only: 1-3-cc syringes with 22-25g, 1–1½" needles		Ammonia Ampules	**1** Box	
Standard injection supplies	N/A				

APPENDIX C:

Recognizing and Responding to Anaphylaxis

How to recognize anaphylaxis

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as **hives, serious or life-threatening symptoms** (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips), or **symptoms that involve more than one body system.**

Respiratory:
- sensation of throat closing
- stridor (high-pitched sound while breathing)
- shortness of breath
- wheeze, cough

Gastrointestinal:
- nausea
- vomiting
- diarrhea
- abdominal pain

Cardiovascular:
- dizziness
- fainting
- tachycardia (abnormally fast heart rate)
- hypotension (abnormally low blood pressure)

Skin/mucosal:
- generalized hives
- itching
- swelling of lips, face, or throat

Neurological:
- agitation
- convulsions
- acute change in mental status
- sense of impending doom (a feeling that something bad is about to happen)

What to do if you suspect anaphylaxis

Assess airway, breathing, and circulation

Administer epinephrine

Call Emergency Medical Services (EMS)

Place in supine position

Detailed information can be found in the Interim Considerations:
Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination

www.cdc.gov/COVID19

CS322867-A | 03/1/21

Protocol for Cholera Vaccine (VAXCHORA®)

1. What's New

A. Updated to include ACIP recommendation for children 7-17 years of age.
B. VAXCHORA® may be consumed within 30 minutes of reconstitution if sucrose/non-flavored stevia is added or within 4 hours of reconstitution if no flavoring is added.
C. VAXCHORA® is no longer stored in the freezer.

2. Immunization Protocol[2,3]

A. Administer a 100-mL dose, oral, of cholera vaccine to persons ≥7 years traveling to cholera-affected areas, as recommended in Section 5.
B. Stress to patients that **safe food** and **water** and **personal hygiene** measures are the key to prevention of cholera.

3. Vaccine Schedule

Cholera Vaccine (VAXCHORA)® Dose and Route – 100 mL (4×10^8 to 2×10^9 colony-forming units), oral		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	7-64 years	

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
VAXCHORA®[1,2]	Live, attenuated *Vibrio cholerae* O1 (CVD 103-HgR)	Single dose carton containing two packets: Buffer Component Packet Active Component Packet	2-64 years	None

5. Recommendations for Use[2,3]

A. Cholera vaccine is not routinely recommended for U.S. travelers.
B. Use in recipients 7–64 years of age ≥10 days before traveling to an area of active cholera transmission. An area of active cholera transmission is defined as a province, state, or other administrative subdivision within a country with endemic or epidemic cholera caused by toxigenic V. cholerae O1 and includes areas with cholera activity within the last year that are prone to recurrence of cholera epidemics; it does not include areas in which only rare imported or sporadic cases have been reported.
C. Persons at higher risk of exposure:
   a. Travelers visiting friends or relatives
   b. Health care personnel
   c. Cholera outbreak response workers
   d. Persons traveling to or living in a cholera-affected area for extended periods
D. Persons at higher risk of poor outcomes:
   a. Persons with type O blood

b. Persons with low gastric acidity from antacid therapy, partial gastrectomy, or other causes
c. Pregnant persons
d. Persons with cardiovascular disease or kidney disease
e. Travelers without ready access to medical services

6. Contraindications[2,3]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Contains
VAXCHORA®	Anhydrous lactose, Ascorbic acid, Sucrose

7. Warnings and Precautions

A. Persons with acute, moderate, or severe illness with or without fever may choose to delay immunization until symptoms have improved.[3]
B. VAXCHORA® may be shed in the stool of recipients for at least 7 days. There is a potential for transmission of the vaccine strain to non-vaccinated close contacts (e.g., household contacts). Use caution when considering whether to administer VAXCHORA® to individuals with immunocompromised close contacts.[2]

8. Other Considerations [2,3]

A. **Bottled water:** Buffer should be mixed with cold or room temperature purified, non-carbonated, non-flavored bottled or spring water. Do not use tap water, which can be chlorinated and affect vaccine potency.[3]
B. **Palatability:**[3]
   a. Vaccine may be mixed with ¼–1 tsp. (1–4 g) of table sugar or 1 packet (1 g) of stevia sweetener (e.g., Truvia, Splenda Naturals) to improve palatability.
   b. Do not mix with other food or drinks (e.g., applesauce, apple juice, milk).
   c. Do not mix with medicinal flavorings containing propylene glycol, which could inactivate the vaccine.
C. **Food and drink:** Avoid eating or drinking for 60 minutes before and after vaccine administration.[2,3]
D. **Antibiotics:** Do not administer cholera vaccine to patients who have received oral or parenteral antibiotics within the past 14 days.[2,3]
E. **Antimalarial prophylaxis:** Do not administer concomitantly with chloroquine. Administer cholera vaccine at least 10 days before beginning a chloroquine regimen.[2,3]
F. **Oral typhoid vaccine:** If a patient needs both cholera vaccine and oral typhoid vaccine (Vivotif), administer the cholera vaccine first, followed by the first dose of oral typhoid vaccine ≥8 hours later.[3] No data are available on concomitant administration with other vaccines.[2,3]
G. **Immunosuppression:** The safety and effectiveness of cholera vaccine in immunosuppressed patients has not been established. Cholera vaccine virus may be shed in the stool for at least 7 days. Use caution when considering whether to administer cholera vaccine to persons with immunocompromised close contacts.[2,3]

H. **Pregnancy and Breastfeeding:** Cholera vaccine is not absorbed systemically following oral administration thus, maternal exposure to the vaccine is not expected to result in exposure to the fetus or breastfed infant to the vaccine. Prospective travelers who are pregnant and their clinicians should consider the risks associated with traveling to areas with active cholera transmission. However, the vaccine strain might be shed in stool for ≥7 days after vaccination, and theoretically, the vaccine strain could be transmitted to an infant during vaginal delivery. A breastfed infant theoretically could receive benefit from maternally derived vaccine antibodies present in maternal milk. There is a pregnancy registry that monitors pregnancy outcomes in persons who receive cholera vaccine during pregnancy. To enroll in or to receive more information call 800-533-5899.[2,3]

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Fatigue, headache	Up to 32%*
Abdominal pain, nausea, vomiting, lack of appetite	Up to 19%*
Diarrhea	Up to 4%
Fever	Up to 0.6%*

*Similar rates in placebo recipients

10. Storage and Handling[1]

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
VAXCHORA®	36°F to 46°F (2° to 8°C) vaccine & diluent	Store buffer components and active components packets in the refrigerator protected from light and moisture. Packages may be stored at 48°F to 77°F (9°C to 25°C) for no more than 5 days prior to reconstitution.	Packets should not be out of refrigeration for more than 12 hours prior to reconstitution. Packets should not be exposed to temperatures above 80°F.

11. References

1. Cholera Vaccine Information. Centers for Disease Control and Prevention. Updated April 5, 2023. Accessed April 12, 2023. https://wwwnc.cdc.gov/travel/page/cholera-travel-information
2. Emergent Travel Health. VAXCHORA® (Dec 2022) package insert. Available at: https://www.fda.gov/media/128415/download. Accessed 12 April 2023.

3. Collins J, Ryan E, Wong K, et al. Cholera vaccine: recommendations of the Advisory Committee on Immunization Practices, 2022. MMWR Recommendations and Reports 2022; 71(2):1–8. Available at: https://www.cdc.gov/mmwr/volumes/71/rr/pdfs/rr7102a1-H.pdf. Accessed 12 April 2023.

12. Appendix

A. N/A

Protocol for Coronavirus 19 Vaccines
(Pfizer-BioNTech, Moderna, Novavax)

1. What's New

A. ACIP no longer categorizes Pfizer and Moderna as preferred Coronavirus 19 (COVID-19) vaccines for the 2023-2024 season. Individuals ages 12 years and older may receive either the 2023-2024 mRNA (Moderna of Pfizer) or the 2023-2024 adjuvanted (Novavax) vaccine, as appropriate.

2. Immunization Protocol

A. Administer a dose of updated 2023–2024 Pfizer, Moderna, or Novavax COVID-19 vaccine according to ACIP recommendations and the vaccine package insert. See section 3 for vaccine volume and spacing based on age and vaccine formulation.[1-5]

B. COVID-19 vaccine may be administered concomitantly with other vaccines. There is no need to separate COVID-19 vaccine from other vaccinations by 2 weeks.

3. Vaccine Schedule[1-3]

A. Any immunocompetent person 7-11 years of age who has received at least 1 dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine is currently up-to-date.[6]

B. Any immunocompetent person ≥12 years of age who has received at least 1 dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine OR who is previously vaccinated* and has received at least 1 dose of adjuvanted (Novavax) 2023-2024 COVID-19 vaccine is currently up-to-date.[5]

C. Any immunocompetent unvaccinated person 7-11 years of age may be brought up-to-date with a single dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine.[6]

D. Any Immunocompetent unvaccinated persons ≥12 years of age may be brought up-to-date with a single dose of updated mRNA (Pfizer or Moderna) 2023–2024 COVID-19 vaccine OR a two dose series of updated adjuvanted (Novavax) 2023-2024 COVID-19 vaccine.[5,6]

E. The PREP Act currently allows pharmacists to administer COVID-19 vaccines to persons aged 3-18 years old through 12/31/24.[2] Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.

*Previously vaccinated indicates the individual has received 1 or more doses of any mRNA vaccine; 1 or more doses of Novavax or Janssen, including in combination with any Original monovalent or bivalent COVID-19 vaccine doses.

PFIZER[1,3]

Pfizer[1] 2023-2024 pediatric mRNA vaccine Dose and Route – 0.3-mL, 3 mcg, IM (yellow cap and border). ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Unvaccinated children 3-4 years of age*		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	3-4 years of age (<5 years)	
2		3 weeks
3		8 weeks

*Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive all doses with Pfizer-BioNTech COVID-19 vaccine, supplied in vials with yellow caps and borders.[1]

Protocol for Coronavirus 19 Vaccines
(Pfizer-BioNTech, Moderna, Novavax)

Children 3-4 years of age previously vaccinated with Pfizer vaccine, any formulation ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Received	**Needs Now**	**Minimum Acceptable Spacing**
1 dose	2 doses 2023-2024 Pfizer	3 weeks after last dose
2 or more doses	1 dose 2023-2024 Pfizer	8 weeks after last dose

Pfizer[1] 2023-2024 pediatric mRNA vaccine Dose and Route – 0.3-mL, 10 mcg, IM (blue cap and border) ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Children 5-11 years of age		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1*	5-11 years of age	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Pfizer 2023-2024 mRNA vaccine (COMIRNATY®) Dose and Route – 0.3-mL, 30 mcg, IM (gray cap and border or pre-filled syringe)[3]		
Unvaccinated persons ≥ 12 years of age		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1*	≥ 12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

*Immunocompromised persons may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

MODERNA[2,4]

Moderna 2023-2024 pediatric mRNA vaccine Dose and Route – 0.25-mL, 25 mcg, IM (dark blue cap and green border)[2]		
Unvaccinated children 3-4 years of age ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	6 months-4 years (<5 years)	
2*		28 days

* Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Immunocompromised children may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

Children 3-4 years previously vaccinated with Moderna COVID-19 vaccine, any formulation[2] ***<u>For Informational Purposes Only</u>- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Received	**Needs Now**	**Minimum Spacing**
1 dose	1 dose 2023-2024 Moderna (0.25mL, dark blue cap and green border)	4 weeks after last dose*
2 or more doses	1 dose 2023-2024 Moderna (0.25 mL, dark blue cap, green border)	8 weeks after last dose*

* Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Moderna 2023-2024 pediatric mRNA vaccine Dose and Route – 0.25-mL, 25 mcg, IM (dark blue cap and green border) ***<u>For Informational Purposes Only</u>- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Unvaccinated children 5-11 years of age		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1*	5-11 years (<12 years)	

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Children 5-11 years of age previously vaccinated with Moderna COVID-19 vaccine, any formulation ***<u>For Informational Purposes Only</u>- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-019-0280.***		
Received	**Needs Now**	**Minimum Spacing**
1 or more doses	1 dose 2023-2024 Moderna* (0.25mL, dark blue cap and green border)	8 weeks after last dose

*Immunocompromised children ≤11 years of age should receive a 3-dose vaccine series. At least one dose should be the updated 2023–24 COVID-19 vaccine. Additional doses may be administered at the discretion of the healthcare provider based on individual patient circumstances.

Moderna 2023-2024 mRNA vaccine (SPIKEVAX®) Dose and Route – 0.5-mL, 50 mcg, IM (dark blue cap and border)[4]		
Unvaccinated persons ≥ 12 years of age		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1*	≥ 12 years	If previously vaccinated, at least 8 weeks after the last dose of a COVID-19 vaccine (original monovalent or bivalent)

* Immunocompromised persons may be administered additional doses at the discretion of the healthcare provider based on individual patient circumstances.

NOVAVAX[5]

Novavax 2023-2024 adjuvanted vaccine Dose and Route –0.5-mL, 5 mcg, IM (dark blue cap, light blue on label)		
Unvaccinated children ≥ 12 and adults		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥12 years	
2		21 days

Children ≥ 12 and adults previously vaccinated with COVID-19 vaccine		
Received	**Needs Now**	**Minimum Acceptable Spacing**
1 or more doses (any original monovalent or bivalent COVID-19 vaccine)	1 dose 2023–24 Novavax*	8 weeks after last dose

*Immunocompromised persons may receive an additional dose of Novavax COVID-19 vaccine at least two months following the last dose of 2023-2024 COVID-19 vaccine. Additional doses of 2023-2024 Novavax COVID-19 vaccine may be administered sat the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on the individual's clinical circumstances.

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Cap/Label Color**
Pfizer 2023-2024 formulation[1]	mRNA	0.9 mL, 3 dose vial 0.3 mL, single dose vial	3-4 years 5-11 years	Yellow Cap Blue Cap
Pfizer COMIRNATY®[3] 2023-2024 formulation	mRNA	0.3 mL, single dose vial 0.3 mL, prefilled syringe	≥ 12 years	Gray Cap
Moderna 2023-2024 formulation[2]	mRNA	0.25 mL, single dose vial	3-11 years	Blue Cap/Green Label
Moderna SPIKEVAX® 2023-2024 formulation[4]	mRNA	2.5 mL, 5 dose vial 0.5 mL, single dose vial 0.5 mL, prefilled syringe	≥ 12 years	Blue Cap/Blue Label
NVX-CoV2373[3] (NOVAVAX® 2023-2024 formulation)[5]	Protein subunit	2.5 mL, 5-dose vial	≥ 12 years	Royal Blue Cap

5. Recommendations for Use[1-7]

A. An updated, 2023–2024 mRNA COVID-19 vaccine dose should be offered to all persons aged ≥ 7 years. For adults and children ≥12 years of age, a 2023-2024 protein subunit (Novavax) vaccine may be used.

B. For a primary series, COVID-19 vaccines are not routinely interchangeable. When multiple doses are indicated (i.e. in unvaccinated children), the same vaccine brand should be used. In exceptional situations in which an mRNA vaccine series was begun, but the particular product administered for previous doses is not available, the other mRNA COVID-19 vaccine may be administered to complete the primary vaccine series.
C. Doses for adults and immunocompromised persons ≥7 years of age may be any authorized product.
D. Children ≤11 years of age with immune compromise require a 3-dose primary series. All three doses should be the same vaccine brand. At least one dose should be of the 2023–24 COVID-19 vaccine.[1,2]
E. For all persons with immune compromise, additional doses of vaccine may be administered at the discretion of the healthcare provider, based on the individual's clinical circumstances.[7]
F. Persons with immune compromise may self-attest to the need for additional doses. No other documentation is necessary.
G. Conditions causing moderate to severe immunodeficiency include:
- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of Chimeric antigen receptor (CAR)-T-cell or hematopoietic cell transplant (HCT) within 2 years of transplantation or taking immunosuppression therapy
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day)
- Alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1-5]

Vaccine	Contains
Pfizer 2023-2024 formulation[1] (yellow cap and border)[1]	Lipids (0.04 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]-N,N itetradecylacetamide, 0.01 mg 1,2-distearoyl-snglycero-3-phosphocholine, and 0.02 mg cholesterol), 9.4 mg sucrose, 0.02 mg tromethamine, and 0.12 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 1.88 mg sodium chloride per dose.
Pfizer 2023-2024 formulation[1] (blue cap and border)	Lipids (0.14 mg ((4- hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.03 mg 1,2- distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 31 mg

	sucrose, 0.06 mg tromethamine, and 0.4 mg tromethamine hydrochloride.
Pfizer COMIRNATY® 2023-2024 formulation[3] (gray cap and border)	Lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane6,1-diyl)bis(2-hexyldecanoate),0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose
Moderna 2023-2024 formulation[2] (dark blue cap and green border)	Total lipid content of 0.5 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC]), 0.13 mg tromethamine, 0.62 mg tromethamine hydrochloride, 0.011 mg acetic acid, 0.049 mg sodium acetate trihydrate, and 21.8 mg sucrose.
Moderna SPIKEVAX® 2023-2024 formulation[4] (dark blue cap and border)	Total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose.
NVA-CoV2373 (NOVAVAX® 2023-2024 formulation)[5]	Cholesterol, phosphatidylcholine, potassium dihydrogen phosphate (3.85 µg), potassium chloride (2.25 µg), disodium hydrogen phosphate dihydrate (14.7 µg), disodium hydrogen phosphate heptahydrate (2.465 mg), sodium dihydrogen phosphate monohydrate (0.445 mg), sodium chloride (8.766 mg) and polysorbate 80 (0.050 mg). The vaccine contains a recombinant form of the SARS-CoV-2 spike protein produced from baculovirus infected Sf9 (fall armyworm) insect cells and Matrix-M™ adjuvant is composed of Fraction-A (42.5 µg) and Fraction-C (7.5 µg) of saponin extracts from the soapbark tree, Quillaja saponaria Molina. The pH is adjusted with sodium hydroxide or hydrochloric acid.

7. Warnings and Precautions[7]

A. History of severe allergic reaction (e.g. anaphylaxis) to any other vaccine or injectable therapy (e.g. intravenous, intramuscular or subcutaneous).

B. Persons who have a contraindication to additional doses of mRNA COVID-19 vaccines are considered to have a precaution to the Novavax vaccine. A single dose may be given in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist. This additional dose could be considered after a minimum interval of 28 days after the mRNA COVID-19 vaccine dose. See Appendix A for additional information.

C. Moderate or severe acute illness.

8. Other Considerations[7]

A. Patients with known COVID-19 infection should wait until their symptoms have resolved and criteria have been met to discontinue isolation. Persons who have a history of COVID-19 disease should be vaccinated if otherwise indicated. If desired, persons with acute COVID-19 may wait up to 90 days to receive vaccination, as reinfection within 90 days is uncommon.

Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

B. Patients who received monoclonal antibodies or convalescent plasma during COVID-19 treatment may be vaccinated as soon as their symptoms have resolved.
C. Patients with a known community or outpatient setting COVID-19 exposure should wait until the end of their quarantine period before seeking vaccination to avoid potentially exposing healthcare personnel.
D. Patients who have been exposed to COVID-19 living in congregate settings, including long-term care, homeless shelters, or correctional institutions, where exposure or transmission can occur repeatedly over a long period of time may be vaccinated without completing a quarantine period.
E. Ask patient to remain seated in the clinic for 15 minutes after vaccination to decrease the risk of injury should they faint. Patients with a history of severe allergic reactions should be asked to remain for 30 minutes.
F. CDC recommends that vaccine for children aged 5–17 years of age with history of Multisystem Inflammatory Syndrome of Children (MIS-C) be delayed for 90 days after their diagnosis of MIS-C. Providers should inform patients that the risk of reinfection, and therefore the potential benefit from vaccination, may increase with time following initial infection.
G. COVID-19 vaccination is recommended for all people of childbearing age, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.
H. Persons who are trying to become pregnant do not need to avoid pregnancy after receiving COVID-19 vaccine. There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine.
I. Persons with underlying medical conditions who have no contraindications may receive COVID-19 vaccine.
J. Children 3 years through 4 years of age should complete a multi-dose initial series (2 doses of Moderna vaccine or 3 doses of Pfizer vaccine) with at least one dose of the 2023–2024 COVID-19 mRNA vaccines. Doses for adults and immunocompromised persons ≥5 years of age may receive any age-appropriate authorized product.

9. Side Effects and Adverse Reactions

A. COVID-19 vaccines appear to be more reactogenic than most. Inform patient that symptoms of immune system activation are normal (see Table) and should improve without intervention in 12-24 hours.

Pfizer[1,3] and Moderna[2,4] Adverse Events	**Frequency**
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 93%
Systemic events (fatigue, headache, muscle ache, joint pain)	Very common, up to 77%
Fever	Up to 16%
Lymphadenopathy*	Up to 20%
Serious adverse events	Uncommon, up to 1% (similar to placebo group)

Novavax[5] Adverse Events	Frequency
Injection site events (pain at the injection site, redness, swelling)	Very common, up to 82%
Systemic events (fatigue, muscle pain, headache, nausea)	Very common, up to 62%
Fever	Uncommon, up to 6%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. For Pfizer vaccine only: thaw, if needed. The yellow cap formulation requires reconstitution; the blue and gray cap formulations are ready to administer.[1,3]

C. For Moderna vaccine only: thaw vaccine prior to administration.[2,4]

Vaccine	Temp	Storage Issues	Notes
Pfizer[1,3]	-90° to -60° C (-130° to -76° F)	Vaccine may be stored until the expiration date.	
	2° to 8° C (36° to 46° F)	**Adolescent/adult bivalent formulation (blue or gray cap):** store in the refrigerator for up to 10 weeks	
		Pediatric formulation (yellow cap): before mixing, the vaccine may be stored in the refrigerator for up to 10 weeks.	
	Ambient temperatures	**Adolescent/adult bivalent formulation (blue or gray cap):** vaccine may be held at room temperature for up to 12 hours	Any unused vaccine should be discarded.
		Pediatric bivalent formulations (yellow cap): once mixed, vaccine may be held at room temperature for up to 12 hours	
Moderna[2,4]	-50° to -15° C (-58° to 5° F)	Vaccine is viable until the expiration date.	For multi-dose vials, once stopper has been punctured, all doses must be used within 12 hours. Do not refreeze once thawed. Protect vaccine from light.
	2° to 8° C (36° to 46° F)	Vaccine is viable under refrigeration for up to 30 days.	
	Ambient temperatures	Unpunctured vials of vaccine is viable for up to 24 hours at room temperature	
Novavax[5]	2°– 8°C (36° to 46° F)	No expiration date is printed on vial or carton. Lookup the expiration date of the batch/Lot number at www.novavaxcovidvaccine.com enter "United States" as the "country/region."	Once vial stopper has been punctured, store vial at 2° to 25° C (36° to 77° F) for use within 12 hours. Discard the vial 12 hours after first puncture. Do not freeze. Protect vaccine from light.

11. References

1. Pfizer-BioNTech COVID-19 Vaccine, 2023–2024 formulation. Emergency use authorization (EUA) fact sheet, 11 Sep 2023. Available at: https://www.fda.gov/media/167211/download. Accessed 14 Sep 2023.
2. Moderna COVID-19 vaccine, 2023–2024 formulation. Emergency use authorization (EUA) fact sheet and prescribing information, 11 Sep 2023. Available at: https://www.fda.gov/media/167208/download. Accessed 14 Sep 2023.
3. Pfizer-BioNTech Comirnaty, 2023–2024 formulation. Package insert, September 11, 2023. Available at: https://www.fda.gov/media/151707/download. Accessed 14 Sep 2023.
4. Moderna Spikevax, 2023–2024 formulation. Package insert, 11 Sep 2023. Available at: https://www.fda.gov/media/155675/download. Accessed 14 Sep 2023.
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6. Wallace M. Evidence to Recommendations Framework: 2023–2024 (Monovalent, XBB Containing) COVID-19 Vaccine. PowerPoint presentation, 12 Sep 2023. Available at: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-09-12/11-COVID-Wallace-508.pdf. Accessed 14 Sep 2023.
7. Interim clinical considerations for use of COVID-19 vaccines in the United States, May 12, 2023. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html. Accessed 14 Sep 2023.

12. Appendix

A. COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised by COVID-19 vaccination history, September 2023: https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-immunization-schedule-ages-6months-older.pdf

Protocol for Haemophilus influenzae type b Vaccines (ActHIB®, HIBERIX®, PedvaxHIB®)

1. What's New

A. Contraindications- Latex (Removed for ActHib®)[1]

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of Hib vaccine to persons ≥7 years of age according to high-risk group indication.

B. Hib vaccines can be given with all other routinely recommended vaccines.

3. Vaccine Schedule

A. Not routinely recommended. See recommendations for use for guidance for high-risk groups.

Hib Vaccine (ActHIB®, HIBERIX®, PedvaxHIB®)[1-3] Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
2		28 days
3		28 days

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
ActHIB®[1] (PRP-T)	Hib (tetanus toxoid conjugate)	0.5-mL lyophilized single-dose vials packaged with single-dose diluent	6 weeks – 5 years*	None
HIBERIX®[2] (PRP-T)	Hib (tetanus toxoid conjugate)		6 weeks – 4 years*	
PedvaxHIB®[3] (PRP-OMP)	Hib (meningococcal protein conjugate)	0.5-mL single-dose suspension	6 weeks – 5 years*	

*Any licensed product presentation may be used for Catch-Up for Persons at High Risk

5. Recommendations for Use

A. **Routinely Recommended Use**- N/A

B. **Catch-Up for Healthy Children**- N/A

C. **Catch-Up for Persons at High-Risk**[4]

High-Risk Group	Vaccine Guidance
Patients aged ≥7 years undergoing elective splenectomy	If unimmunized, 1 dose at least 14 days prior to procedure
Asplenic patients ≥7 years	If unimmunized, 1 dose
HIV-infected children 7-18 years	If unimmunized, 1 dose
HIV-infected persons ≥19 years	Hib immunization is not recommended
Hematopoietic stem cell transplantation (HSCT) ≥7 years	3 doses (4-week intervals) beginning 6–12 months after HSCT regardless of prior Hib vaccine history

6. Contraindications[5]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component, including latex (PedvaxHIB®[3]).

Vaccine	Contains
Hib (ActHIB®[1])	Sodium chloride, formaldehyde, sucrose
Hib (HIBERIX®[2])	Formaldehyde, sodium chloride, lactose
Hib (PedvaxHIB®[3])	Amorphous aluminum hydroxyphosphate sulfate, sodium chloride

7. Warnings and Precautions

A. N/A

8. Other Considerations [1-3]

A. In immunosuppressed persons, including those receiving immunosuppressive therapy, the expected antibody responses may not be obtained.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Any systemic reaction—Irritability, drowsiness, loss of appetite, fever	Very common, up to 70%
Any local reaction—pain, redness, induration or swelling at injection site	Very common, up to 49%
Severe (grade 3) systemic reactions—irritability, drowsiness	Uncommon, up to 6%
Severe pain, induration or swelling at injection site	Uncommon, up to 4%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
ActHIB®[1]	2°to 8°C (36° to 46°F) vaccine & diluent	Do not freeze.	
HIBERIX®[2]	2°to 8°C (36° to 46°F) vaccine 2°to 25°C (36° to 77°F) diluent	Protect from light. Do not freeze.	Discard if the diluent has been frozen.
PedvaxHIB®[3]	2°to 8°C (36° to 46°F) vaccine	Do not freeze.	

11. References

1. ActHIB® package insert. 2022. Available at https://www.fda.gov/media/74395/download. Accessed 22 August 2022.

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6. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/. Accessed 22 August 2022.

12. Appendix

A. N/A

Protocol for Hepatitis A Containing Vaccines (HAVRIX®, VAQTA®, TWINRIX®)

1. What's New

A. Warnings and Precautions-Latex (Removed for Twinrix®)

2. Immunization Protocol

A. Administer an IM dose of Hepatitis A vaccine appropriate for the person's age and the formulation being used.

B. Hepatitis A vaccines may be given with all routinely recommended vaccines.

3. Vaccine Schedule

Pediatric Hepatitis A Vaccine[1,2] (HAVRIX®, VAQTA®) Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	7-18 years	
2		6 months

Adult Hepatitis A Vaccine[1,2] (HAVRIX®, VAQTA®) Dose and Route – 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥19 years	
2		6 months

Adult Hepatitis A – Hepatitis B Combination Vaccine[3] (TWINRIX®) Dose and Route – 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		4 weeks
3		6 months

Adult Hepatitis A – Hepatitis B Combination Vaccine[3] (TWINRIX®) Dose and Route – 1.0-mL, IM		
Accelerated Schedule		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		7 days
3		21 days
4		12 months

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
HAVRIX®[1] pediatric	Hepatitis A 720 ELISA units	0.5-mL single-dose vials and prefilled syringes	1-18 years	None

HAVRIX®[1] adult	Hepatitis A 1440 ELISA units	1.0-mL single-dose vials and prefilled syringes	≥19 years	
VAQTA®[2] pediatric	Hepatitis A 25 units	0.5-mL single-dose vials and prefilled syringes	1-18 years	
VAQTA®[2] adult	Hepatitis A 50 units	1.0-mL single-dose vials and prefilled syringes	≥19 years	
TWINRIX®[3]	Hepatitis A 720 ELISA units Hepatitis B 20 mcg	1.0-mL prefilled syringes	≥18 years	

5. Recommendations for Use[4]

A. All children should routinely receive hepatitis A vaccine.
B. Persons at increased risk for hepatitis A virus (HAV) infection should be routinely vaccinated, including:
    a. Travelers to countries with high or intermediate hepatitis A endemicity.
        i. Persons traveling in less than 2 weeks, and other travelers who choose not to be vaccinated should receive immune globulin before travel. See the immunization protocol for immune globulin for more information.
    b. Men who have sex with men (MSM)
    c. Persons who use illegal drugs
    d. Persons in group settings for persons with developmental disabilities
    e. Persons who work with HAV-infected non-human primates or with clinical or nonclinical material containing HAV in a research laboratory
    f. Persons who anticipate close personal contact with an international adoptee from a high or intermediate endemicity country during the first 60 days after arrival of the adoptee in the U.S.
    g. Persons experiencing homelessness
    h. Persons in correctional facilities during outbreaks
C. Persons at increased risk for severe disease from HAV infection, including:
    a. Persons with immunocompromising conditions or chronic liver disease
    b. Persons who are HIV positive
D. Other persons recommended for vaccination:
    a. Pregnant women at risk for HAV infection
    b. Persons at risk during outbreaks
E. Any person who requests vaccination

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1-3]

Protocol for Hepatitis A Containing Vaccines (HAVRIX®, VAQTA®, TWINRIX®)

Vaccine	Contains
HAVRIX®	MRC-5 cellular proteins, formalin, aluminum hydroxide, amino acid supplement, phosphate-buffered saline solution, polysorbate 20, neomycin sulfate, aminoglycoside antibiotic
VAQTA®	Amorphous aluminum hydroxyphosphate sulfate, non-viral protein, DNA, bovine albumin, formaldehyde, neomycin, sodium borate, sodium chloride, other process chemical residuals
TWINRIX®	MRC-5 cellular proteins, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein

7. Warnings and Precautions[1-3]

A. Hypersensitivity to latex: HAVRIX®- tip caps of prefilled syringes contain latex. VAQTA® – vial stopper and the syringe plunger stopper and tip cap contain latex.
B. Altered immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response.
C. Limitation of vaccine effectiveness: Hepatitis A virus has a relatively long incubation period, 20-50 days. Hepatitis A vaccine may not prevent hepatitis A infection in individuals who have an unrecognized hepatitis A infection at the time of vaccination.
D. Syncope: Fainting can occur after vaccination.

8. Other Considerations[4]

A. Post-exposure prophylaxis: People ≥7 years of age who have been exposed to HAV should receive single-antigen hepatitis A vaccine within 2 weeks of exposure. Persons should complete the two-dose series for long-term protection. Immune globulin may also be indicated for some persons. See the immunization protocol for immune globulin.
B. Serologic testing: Postvaccination serologic testing for immunity is not necessary after routine vaccination. Testing for the presence of anti-HAV antibody at least one month after vaccination is recommended for persons whose subsequent clinical management depends on knowledge of their immune status and persons for whom revaccination might be indicated, such as persons with HIV infection and other immunocompromised persons (e.g., HCT and solid organ transplant recipients and persons receiving chemotherapy).
C. Revaccination: Revaccination is not necessary for healthy persons. Revaccination may be considered for immunosuppressed persons who fail to demonstrate an adequate immune response after the initial vaccination series.

9. Side Effects and Adverse Reactions[1-3]

Adverse Event	Frequency
Single-antigen Hepatitis A Vaccine	
Local reactions: soreness, redness, swelling	Up to 67% adults, 37% children
Systemic reactions: fever, headache, irritability, loss of appetite	Up to 14% adults, 9% children
Hepatitis A-Hepatitis B Vaccine	
Local reactions: soreness and redness	Up to 41%
Systemic reactions: headache and fatigue	Up to 22%

10. Storage and Handling

A. Upon storage, a fine white deposit with a clear colorless layer above may be present. Shake well before use to obtain a slightly opaque, white suspension.
B. Store medications according to OAR 855-041-1036.
C. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
All	Store at 2° to 8°C (36° to 46° F)	Do not use if vaccine has been frozen.	

11. References

1. HAVRIX®. [Package insert]. September 2022. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Havrix/pdf/HAVRIX.PDF. Accessed 11 July 2023.
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3. TWINRIX® [Package insert]. April 2023. Available at: https://www.fda.gov/media/119351/download. Accessed 11 July 2023.
4. Nelson NP, Weng MK, Hofmeister MG, et al. Prevention of hepatitis A infection in the United States: Recommendations of the ACIP. MMWR 2020;69(5);1-42. Available at: https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6905a1-H.pdf. Accessed 11 July 2023.

12. Appendix

A. N/A

Protocol for Hepatitis B Containing Vaccines
(ENGERIX-B®, HEPLISAV-B®, PREHEVBRIO®, RECOMBIVAX HB®, TWINRIX®)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer an IM dose of Hepatitis B vaccine appropriate for the person's age, risk group, and the formulation being used.

B. May be given with all ACIP-recommended child and adult vaccinations.

3. Vaccine Schedule

Pediatric Hepatitis B Vaccine[1,3,4] (Engerix-B®, Recombivax-HB®) Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	7-19 years	
2		4 weeks
3		8 weeks after dose 2 **and** 16 weeks after dose 1

Adult Hepatitis B Vaccine[2,3] (HEPLISAV-B®) Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		4 weeks
Adult Hepatitis B Vaccine[3] (PREHEVBRIO®) Dose and Route – 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		4 weeks
3		8 weeks after dose 2 **and** 16 weeks after dose 1
Adult Hepatitis A – Hepatitis B Combination Vaccine[3] (TWINRIX®) Dose and Route – 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		4 weeks
3		5 months after dose 2 **and** 6 months after dose 1
Adult Hepatitis B Vaccine[1,3,4] (Engerix-B®, Recombivax-HB®) Dose and Route – 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥20 years	
2		4 weeks
3		8 weeks after dose 2 **and** 16 weeks after dose 1

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Engerix-B®[1], pediatric formulation	Hepatitis B	0.5-mL single-dose vials and prefilled syringes	Birth-19 years	None
Recombivax HB®[4], pediatric formulation		0.5-mL single-dose vials and prefilled syringes	Birth-19 years	
HEPLISAV-B®[2]		0.5-mL prefilled syringes	≥18 years	
PREHEVBRIO®[3]		1.0-mL single-dose vials	≥18 years	

ENGERIX-B®, adult formulation[1]		1.0-mL single-dose vials and prefilled syringes	≥20 years	
RECOMBIVAX HB®[4], adult formulation		1.0-mL single-dose vials and prefilled syringes	≥20 years	
RECOMBIVAX HB®[4] Dialysis		1.0-mL single-dose vials	≥20 years	
TWINRIX®[5]	Hepatitis A Hepatitis B	1.0-mL prefilled syringes	≥18 years	None

5. Recommendations for Use

A. Additional schedules:

Catch-up Pediatric Hepatitis B Vaccine Schedule		
Dose	**Preferred Spacing**	**Minimum Spacing After Previous Dose**
1		
2	8 weeks after dose 1	4 weeks
3	4 months after dose 2 **and** 6 months after dose 1	8 weeks after dose 2 **and** 16 weeks after dose 1

Alternative Pediatric Hepatitis B Vaccine Schedules[1, 2]							
Vaccine and Formulation	**Dose Volume**	**Number of Doses in Series**	**Age at First Dose**	**Interval from 1 to 2**	**Interval from 2 to 3**	**Interval from 1 to 3**	**Interval from 1 to 4**
Engerix-B® (20 mcg/mL)	0.5 mL	4	1–10 years	4 weeks	4 weeks	8 weeks	12 months
		3	5-16 years	12 months	12 months	24 months	
	1.0 mL*	4	11-18 years	4 weeks	4 weeks	8 weeks	12 months
		3		4 weeks	8 weeks	6 months	
Recombivax HB® (10 mcg/mL)	1.0 mL	2	11-15 years◊	4 to 6 months			

* 1.0-mL dose recommended for persons who travel to endemic areas, sexual exposure, and children born to Hepatitis B surface antigen positive (HBsAg+) mothers.

◊ Both doses must be 1.0 mL of Recombivax HB®. Series must be completed prior to 16th birthday or an additional dose is required.

TWINRIX® Accelerated Schedule[5]		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		7 days after dose 1
3		14 days after dose 2
4		11 months after dose 3 **and** 12 months from dose 1
ENGERIX-B® Accelerated Schedule[1]		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥20 years	
2		4 weeks after dose 1

3		4 weeks after dose 2
4		10 months after dose 3 **and** 12 months from dose 1

ENGERIX-B® Dialysis Schedule[1]			
Dose	**Acceptable Age Range**	**Dose Volume**	**Minimum Acceptable Spacing**
1	≥20 years	One 2.0-mL dose or Two 1.0-mL doses	
2			4 weeks after dose 1
3			4 weeks after dose 2
4			4 months after dose 3
RECOMBIVAX HB® Dialysis Schedule[4]			
Dose	**Acceptable Age Range**	**Dose Volume**	**Minimum Acceptable Spacing**
1	≥20 years	1.0 mL (40-mcg formulation)	
2			4 weeks after dose 1
3			8 weeks after dose 2 **and** 16 weeks from dose 1

B. Hepatitis B vaccination is recommended for all adults 19–59 years of age.
C. Adults ≥60 years of age with risk factors for hepatitis B infection.
D. Persons at risk for infection through sexual exposure:
   a. Sexual partners of hepatitis B positive persons
   b. Persons seeking evaluation or treatment for a sexually transmitted infection
   c. Sexually active persons not in a long-term, mutually monogamous relationship
   d. Men who have sex with men (MSM)
E. Persons at risk for infection by percutaneous or mucosal exposure to blood[7]:
   a. Recent or current injection-drug use
   b. Household contacts of Hepatitis B surface antigen (HBsAg) positive persons
   c. Residents and staff of facilities for developmentally disabled persons
   d. Healthcare and public-safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
   e. Hemodialysis patients and pre-dialysis, peritoneal dialysis, and home dialysis patients
   f. Persons with diabetes mellitus aged <60 years; and persons with diabetes mellitus aged ≥60 years at the discretion of the treating clinician
F. Persons with[7]:
   a. Hepatitis C virus infection
   b. Human immunodeficiency virus
   c. Chronic liver disease (including, but not limited to, those with cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal)
G. Others[7]:
   a. Travelers to countries with high or intermediate levels of endemic hepatitis B virus (HBV) infection (HBsAg prevalence ≥2%)
   b. Incarcerated persons
   c. Immigrants, refugees, or adoptees from countries where HBV infection is endemic and their household members
   d. Other persons seeking protection from hepatitis B virus infection even without acknowledgment of a specific risk factor

6. Contraindications[5]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
B. Engerix-B®, Heplisav-B®, Recombivax HB®, Twinrix®: Hypersensitivity to yeast
C. Heplisav-B®: Pregnancy
D. Recombivax HB®: Hypersensitivity to soy peptones
E. Twinrix®: Hypersensitivity to neomycin, polysorbate 80, polymyxin B

Vaccine	Contains[8]
ENGERIX-B®	aluminum hydroxide, yeast protein, sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate
HEPLISAV- B®	yeast protein, yeast DNA, deoxycholate, phosphorothioate-linked oligodeoxynucleotide, sodium phosphate, dibasic dodecahydrate, sodium chloride monobasic dehydrate, polysorbate 80
PREHEVBRIO®	sodium chloride, potassium chloride, disodium hydrogen phosphate dodecahydrate, potassium dihydrogen phosphate anhydrous. Each dose may contain residual amounts of Chinese hamster ovary (CHO) cell proteins, CHO cell DNA, bovine serum albumin and formaldehyde.
RECOMBIVAX HB®	formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, yeast protein
TWINRIX®	MRC-5 cellular proteins, formalin, aluminum phosphate, aluminum hydroxide, amino acids, sodium chloride, phosphate buffer, polysorbate 20, neomycin sulfate, yeast protein

7. Warnings and Precautions

A. Engerix-B®[1], Recombivax HB®[4] - dry natural rubber latex is used in the vial stopper, the syringe plunger stopper and tip cap.

8. Other Considerations [1-3]

A. Vaccine Interchangeability:
   a. Heplisav-B®[2]: A 2-dose series only applies when both doses in the series consist of Heplisav-B®. Series consisting of a combination of 1 dose of Heplisav-B® and a different vaccine should consist of a total of 3 vaccine doses and should adhere to the 3-dose schedule minimum intervals. A series containing 2 doses of Heplisav-B® administered at least 4 weeks apart is valid, even if the patient received a single earlier dose from another manufacturer.
   b. Twinrix®[5]: Recommended for persons at risk for hepatitis A or hepatitis B. The hepatitis B component of Twinrix® is equivalent to a standard adult dose of hepatitis B vaccine, the hepatitis A component has 50% of the adult standard dose. A total of 3 Twinrix® doses are required to complete the series. If Twinrix® is unavailable or not used to complete the Twinrix® series, administer single-antigen vaccine as follows:
      i. If 1 dose of Twinrix® was given, complete the series with 2 adult doses of hepatitis B vaccine and 2 adult doses of hepatitis A vaccine
      ii. If 2 doses of Twinrix® were given, complete the schedule with 1 adult dose of hepatitis A vaccine and 1 adult dose of hepatitis B vaccine
B. Booster Doses

a. Hemodialysis patients: Post vaccination serology testing is recommended annually. Booster doses should be provided when anti-HBs levels decline to <10 milli-international units/mL.[7] Anti-HBs testing 1–2 months following the booster dose to assess response is not recommended.
b. Other immunocompromised persons: In HIV-infected persons, hematopoietic stem-cell transplant recipients, and persons receiving chemotherapy, the need for booster doses has not been determined. Annual anti-HBs testing and booster doses should be considered for persons with an ongoing risk for exposure.

C. Lactation and Pregnancy[7]
   a. Pregnant women who are identified as being at risk for HBV infection during pregnancy (e.g., having more than one sex partner during the previous 6 months, been evaluated or treated for an STI, recent or current injection-drug use, or having had an HBsAg-positive sex partner) should be vaccinated with Recombivax HB® or Engerix-B®. Do not use Heplisav-B®[2] or Prehevbrio®[3].
   b. Lactation: Breast feeding is not a contraindication to vaccination for mother or infant.
D. Adoptees born in Asia, the Pacific Islands, Africa, and other regions of high or intermediate hepatitis B endemicity should undergo serologic testing for HBsAg regardless of vaccination status. Adoptees born in countries other than those mentioned above whose records indicate receipt of ≥3 doses of vaccine can be considered protected if ≥1 dose was administered at age ≥6 months.
E. Pre-vaccination serological testing* is recommended for[7]:
   a. Persons born in countries of high and intermediate hepatitis B virus endemicity (HBsAg prevalence ≥2%)
   b. HIV positive persons
   c. Household, sex, and needle-sharing contacts of HBsAg-positive persons
   d. Men who have sex with men (MSM)
   e. Past or current injection drug users

*Hepatitis B vaccine should be administered immediately after collection of blood for testing. Serologic testing comprises testing for HBsAg, antibody to HBsAg (anti-HBs), and antibody to hepatitis B core antigen (anti-HBc).

F. Postvaccination serologic testing[7]
   a. Postvaccination serologic testing 1–2 months after the final dose of the complete vaccine series is recommended for:
      i. Hemodialysis patients and others who might require outpatient hemodialysis (e.g., pre-dialysis, peritoneal dialysis, and home dialysis)
      ii. HIV-infected and other immunocompromised persons
      iii. Other immunocompromised persons (e.g., hematopoietic stem-cell transplant recipients or persons receiving chemotherapy)
      iv. Health-care personnel and public-safety workers
      v. Sex partners of HBsAg-positive persons
   b. Postvaccination serologic testing should be performed using a method that allows determination of the protective level of anti-HBs (≥10 milli-international units/mL).
G. Revaccination for non-responders[7]:
   a. Persons with anti-HBs <10 milli-international units/mL following receipt of 2 doses of Heplisav-B® (HepB-CpG) should be revaccinated with a second complete Heplisav-B® series or any 3-dose hepatitis B series, followed by anti-HBs testing 1–2 months after the final dose.

b. Alternatively, revaccination may consist of administration of an additional single hepatitis B vaccine dose (challenge dose) followed by anti-HBs testing 1–2 months later.
c. If anti-HBs remains <10 milli-international units/mL, completion of a second hepatitis B vaccine series followed again by anti-HBs testing 1–2 months after the final dose.
d. Administration of more than two complete hepatitis B vaccine series is generally not recommended, except for hemodialysis, and potentially immunocompromised patients.
e. Heplisav-B® (HepB-CpG) may be used for revaccination following an initial hepatitis B vaccine series that consisted of doses of HepB-CpG or doses from a different manufacturer.
f. Healthcare personnel who do not respond to a challenge dose should complete revaccination and retesting for anti-HBs.

9. Side Effects and Adverse Reactions[1-5]

Adverse Events Adults	**Frequency**
Pain at the injection site	Up to 52%
Mild systemic complaints (fatigue, headache)	Up to 25%
Temperature up to 37.7 C (≤99.9°F)	Less than 2%
Any severe reaction	Rare
Adverse Events Children	**Frequency**
Pain at the injection site	Uncommon, up to 9%
Fatigue, headache, other mild systemic symptoms	Common, up to 20%
Temperature up to 37.7 °C (≤99.9°F)	Uncommon, up to 6%
Any severe reaction	Rare

10. Storage and Handling

A. Upon storage, a fine white deposit with a clear colorless layer above may be present. Shake well before use to obtain a slightly opaque, white suspension.
B. Store medications according to OAR 855-041-1036.
C. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	**Temp**	**Storage Issues**
Engerix-B®, Heplisav-B®, Prehevbrio®, Recombivax HB®, Twinrix®	Store at 2°to 8°C (36° to 46° F)	Do not use if vaccine has been frozen.

11. References

1. Engerix-B®. [Package insert]. June 2021. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Engerix-B/pdf/ENGERIX-B.PDF. Accessed 25 July 2023.
2. Heplisav-B®. [Package insert]. May 2023. Available at: www.fda.gov/media/108745/download. Accessed 14 July 2023.

3. Prehevbrio®. [Package insert]. November 2021. Available at: https://www.prehevbrio.com/wp-content/uploads/2021/11/PreHevbrio-Full-Prescribing-Information.pdf. Accessed 14 July 2023.
4. Recombivax® HB. [Package insert]. April 2023. Available at: https://www.merck.com/product/usa/pi_circulars/r/recombivax_hb/recombivax_pi.pdf. Accessed 14 July 2023.
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8. Centers for Disease Control and Prevention. Vaccine Excipient Summary. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-b.pdf. Accessed 14 July 2023.

12. Appendix

A. N/A

Protocol for Human Papillomavirus Vaccine (Gardasil® 9)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of HPV vaccine to persons ≥9 years of age.
B. HPV vaccine may be given simultaneously with all routine adolescent or adult vaccines.

3. Vaccine Schedule[1]

HPV Vaccine[1] (Gardasil® 9) Dose and Route – 0.5-mL, IM		
2 Dose Series		
Dose	Acceptable Age Range	Dose spacing
1	9-14 years	
2		5-12 months after dose 1
3 Dose Series*		
1	15-45 years◊	
2		4 weeks after dose 1
3		3 months after dose 2 and 5 months after dose 1

*Healthy persons who begin the HPV series before their 15th birthday may complete the series with 2 doses.[2] Immunocompromised persons and catch-up for persons beginning the series ≥15 years of age need 3 doses to complete series.[2]

◊ Shared clinical decision-making regarding HPV vaccination is recommended for some adults aged 27 through 45 years who are not adequately vaccinated.[3] See section 5 for guidance.

4. Licensed Vaccines[1]

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Gardasil® 9 [1]	Human Papillomavirus 9-valent Vaccine, Recombinant Suspension	0.5-mL single-dose vials 0.5-mL pre-filled syringes	9 – 45 years	None

5. Recommendations for Use[2]

A. Children and adults aged 9 through 26 years: HPV vaccination is routinely recommended at age 11 or 12 years; vaccination can be given starting at age 9 years. Catch-up HPV vaccination is recommended for all persons through age 26 years who are not adequately vaccinated.
B. Adults aged >26 years: Ideally, HPV vaccination should be given in early adolescence because vaccination is most effective before exposure to HPV through sexual activity. Catch-up HPV vaccination is not recommended for all adults aged >26 years. Instead, ACIP recommends HPV vaccination for persons aged 27–45 years on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine

recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian.

- Pharmacists can engage in shared clinical decision making to discuss HPV vaccination with persons aged 27-45 years who are not adequately vaccinated and are most likely to benefit. HPV vaccination does not need to be discussed with most adults aged >26 years. HPV vaccines are not licensed for use in adults aged >45 years.
- Pharmacists are authorized to administer HPV vaccine if one of the following risk factors is present:
  - At any age, having a new sex partner is a risk factor for acquiring a new HPV infection
  - Adults with few or no previous sex partners might not have been infected with HPV in the past, therefore they may have a higher chance of getting HPV infection from a new sex partner in the future

C. Special populations and medical conditions: These recommendations for children and adults aged 9 through 26 years and for adults aged >26 years apply to all persons, regardless of behavioral or medical risk factors for HPV infection or disease. For persons who are pregnant, HPV vaccination should be delayed until after pregnancy; however, pregnancy testing is not needed before vaccination. Persons who are breastfeeding or lactating can receive HPV vaccine.

6. Contraindications[1]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
B. Hypersensitivity to yeast
C. Pregnancy: HPV vaccines should not be administered during pregnancy. Exposure during pregnancy can be reported to the Merck Pregnancy Registry at 1-800-986-8999.

7. Warnings and Precautions[4]

A. Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves.
B. Syncope after immunization is common among adolescents. Have the client sit for 15 minutes after vaccination

8. Other Considerations

A. Individuals with altered immunocompetence may have reduced immune responses. [4]
B. Cervical cancer screening should be initiated at 21 years and continuing through age 65 years for both vaccinated and unvaccinated women. [6]
C. Women with an equivocal or abnormal pap test, positive Hybrid Capture II® high-risk test or genital warts can receive HPV vaccine. Recipients should be advised that the vaccine has no therapeutic value and will only provide protection against infection with HPV types not already acquired.[5]

9. Side Effects and Adverse Reactions[1]

Adverse Event	Frequency
Injection Site Reactions	
Pain, redness, or swelling at vaccination site	Up to 90%
Systemic Adverse Reactions	
Low-grade fever of up to 101°F	Up to 10%
Fever of 102°F or more	Up to 1.5%

10. Storage and Handling[1]

A. Store medications according to OAR 855-041-1036.
B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Gardasil® 9	Store at 2°to 8°C (36° to 46°F)	Do not freeze, protect from light	Administer as soon as possible after being removed from refrigeration

11. References

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Protocol for Human Papillomavirus Vaccine (Gardasil® 9)

12. Appendix

A. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making HPV Vaccination for Adults Aged 27-45 Years: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2019. https://www.cdc.gov/vaccines/hcp/admin/downloads/ISD-job-aid-SCDM-HPV-shared-clinical-decision-making-HPV.pdf

Protocol for Inactivated Influenza Vaccines and Recombinant Influenza Vaccines
Inactivated Influenza Vaccine (Afluria®, Fluarix®, FluLaval®, Fluzone®), Recombinant Influenza Vaccine (Flublok®), Cell Cultured Influenza Vaccine (Flucelvax®), Adjuvanted Inactivated Influenza Vaccine (Fluad®)

1. What's New

A. ACIP Recommended that all egg-based inactivated influenza vaccines for use in the 2023-2024 influenza season Northern Hemisphere[9] contain the following:
   a. A/Victoria/4897/2022 (H1N1) pdm09-like virus
   b. A/Darwin/9/2021 (H3N2)-like virus
   c. B/Austria/1359417/2021-like virus (B/Victoria lineage)
   d. B/Phuket/3073/2013-like virus (B/Yamagata lineage)

B. ACIP Recommended that all cell-culture-based inactivated or recombinant-based influenza vaccines for the 2023-2024 influenza season Northern Hemisphere[9] contain the following:
   a. A/Wisconsin/67/2022 (H1N1) pdm09-like virus
   b. A/Darwin/6/2021 (H3N2)-like virus
   c. B/Austria/1359417/2021-like virus (B/Victoria lineage)
   d. B/Phuket/3073/2013-like virus (B/Yamagata lineage)

C. ACIP recommends that adults aged ≥65 years preferentially receive any one of the following higher dose or adjuvanted influenza vaccines: quadrivalent high-dose inactivated influenza vaccine (HD-IIV4), quadrivalent recombinant influenza vaccine (RIV4), or quadrivalent adjuvanted inactivated influenza vaccine (aIIV4).[10]

D. All persons ages ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.[11]

2. Immunization Protocol

A. Administer a 0.25-mL, 0.5-mL, or 0.7-mL dose, IM, of an appropriate influenza vaccine, to persons ≥ 6 months of age based on the patient's age and the formulation being used.

B. May be given with all ACIP-recommended child and adult vaccinations, including COVID-19 vaccines.

C. When co-administering COVID-19 vaccines and adjuvanted or high-dose influenza vaccines that might be more likely to cause a local reaction, different limbs should be used, if possible.[10]

3. Vaccine Schedule

Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV) Schedule for the 2023–2024 Flu Season[1-8] Dose and Route – 0.25-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	6 months – 35 months	
2*	6 months – 35 months	28 days, *see flowchart in recommendations for use for determining 1 or 2 doses

Protocol for Inactivated Influenza Vaccines and Recombinant Influenza Vaccines
Inactivated Influenza Vaccine (Afluria®, Fluarix®, FluLaval®, Fluzone®),
Recombinant Influenza Vaccine (Flublok®),
Cell Cultured Influenza Vaccine (Flucelvax®),
Adjuvanted Inactivated Influenza Vaccine (Fluad®)

Inactivated Influenza Vaccine (IIV) and Recombinant Influenza Vaccine (RIV) Schedule for the 2023–2024 Flu Season[1-8] Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥ 36 months	
2*	36 months – 8 years of age	28 days, *see flowchart in recommendations for use for determining 1 or 2 doses

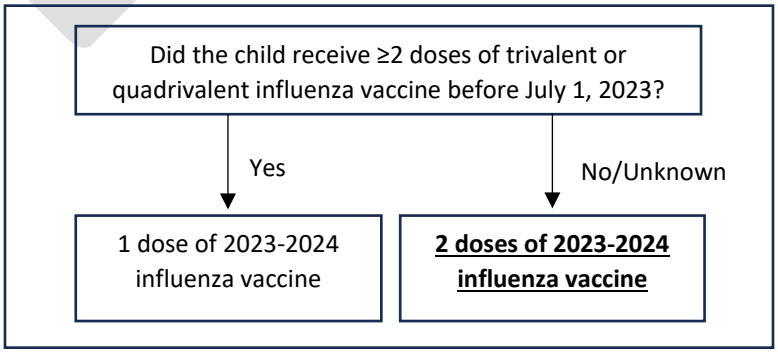
4. Licensed Vaccines

Product Name	Presentation	FDA Age Range	Thimerosal (mcg Hg)
Afluria® Quadrivalent[1]	0.5 mL prefilled syringes†	≥ 6 months	None
	5-mL multi-dose vial		24.5
Fluad® Quadrivalent[8]	0.5 mL prefilled syringes	≥ 65 years	None
Fluarix® Quadrivalent[2]	0.5 mL prefilled syringes†	≥ 6 months	None
Flublok® Quadrivalent[6]	0.5 mL prefilled syringes	≥ 18 years	None
Flucelvax® Quadrivalent[7]	0.5 mL prefilled syringes†	≥ 6 months	None
	5-mL multi-dose vial		25
FluLaval® Quadrivalent[3]	0.5 mL prefilled syringes†	≥ 6 months	None
Fluzone High Dose® Quadrivalent[4]	0.7 mL prefilled syringes	≥ 65 years	None
Fluzone® Quadrivalent[5]	0.5 mL prefilled syringes†	≥ 6 months	None
	0.5 mL single dose vial		None
	5 mL multi-dose vial		25

† FDA approved for ≥ 6 months; however, the approved dose is 0.25 mL for ages 6 months-35 months.

5. Recommendations for Use

A. All persons ≥ 6 months of age that do not have contraindications. Children < 9 years of age receiving flu vaccine for the first time need 2 doses, separated by at least 28 days. Children who receive the first dose at age 8 years and turn 9 during flu season should receive the 2nd dose in the same season.[10]



B. Persons who are pregnant may be vaccinated with inactivated influenza vaccine during any trimester.[10]
C. Persons with history of egg allergy may receive any vaccine (egg-based or non-egg-based) that is otherwise appropriate for their age and health status. Beginning with the 2023-2024 season, additional safety measures are no longer recommended for flu vaccination of people who are allergic to eggs beyond those recommended for receipt of any vaccine, regardless of the severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of allergic reactions are available, such as a pharmacy.[11]
D. For non-pregnant adults, vaccination in July or August should be avoided, even if vaccine is available, unless there is serious concern that later vaccination might not be possible.[10]
E. Providers should offer flu vaccination to unvaccinated persons by the end of October, if possible. Vaccination should continue to be offered as long as unexpired vaccine is available.[10]

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component. However, ACIP makes an exception for allergy to egg (see Persons with a History of Egg Allergy above).
   a. Most flu shots and the nasal spray flu vaccine are manufactured using egg-based technology. Because of this, they contain a small amount of egg proteins, such as ovalbumin. However, studies that have examined the use of both the nasal spray vaccine and flu shots in egg-allergic and non-egg-allergic patients indicate that severe allergic reactions in people with egg allergies are unlikely.[11]

Vaccine	Contains[14]
Afluria® Quadrivalent	Sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, ovalbumin, sucrose, neomycin sulfate, polymyxin B, beta-propiolactone, thimerosal (multidose vials)
Fluad® Quadrivalent	Squalene, polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, neomycin, kanamycin, barium, hydrocortisone, egg proteins, cetyltrimethylammonium bromide (CTAB), formaldehyde
Fluarix® Quadrivalent	Octoxynol-10 (TRITON X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sodium phosphate-buffered isotonic sodium chloride
Flublok® Quadrivalent	Sodium chloride, monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20 (Tween 20), baculovirus and Spodoptera frugiperda cell proteins, baculovirus and cellular DNA, Triton X-100

Flucelvax® Quadrivalent	Madin-Darby Canine Kidney (MDCK) cell protein, phosphate buffered saline, protein other than HA, MDCK cell DNA, polysorbate 80, cetyltrimethylammonium bromide, and βpropiolactone, Thimerosal (multi-dose vials)
FluLaval® Quadrivalent	Ovalbumin, formaldehyde, sodium deoxycholate, α-tocopheryl hydrogen succinate, polysorbate 80, thimerosal (multi-dose vials), phosphate-buffered saline solution.
Fluzone High Dose® and Fluzone® Quadrivalent	formaldehyde, egg protein, octylphenol ethoxylate (Triton X100), sodium phosphate-buffered isotonic sodium chloride solution, thimerosal (multi-dose vials)

7. Warnings and Precautions

A. **Persons with a history of Guillain-Barré Syndrome (GBS)** within 6 weeks following influenza vaccination have a substantially greater likelihood of subsequently developing GBS than persons without such a history. Whether influenza vaccination might be causally associated with this risk for recurrence is not known. Consult with an individual's health care provider and consider avoiding a subsequent influenza vaccination in persons known to have developed GBS within **6 weeks** of a previous influenza vaccination. Experts believe that the benefits of influenza vaccination justify yearly vaccination for most persons who have a history of GBS and who are at risk for severe complications from influenza.[10]

B. **History of severe allergic reaction to a previous dose of an egg-based influenza vaccine** is a precaution to both Flublok® and Flucelvax. ®[10]

8. Other Considerations

A. **Foreign travelers:** Travelers who want to reduce the risk for influenza infection should consider influenza vaccination, preferably at least 2 weeks before departure. In particular, persons who live in the United States and are at higher risk for complications of influenza and who were not vaccinated with influenza vaccine during the previous Northern Hemisphere fall or winter should consider receiving influenza vaccine before departure if they plan to travel to the tropics, with organized tourist groups or on cruise ships, or to the Southern Hemisphere during the Southern Hemisphere influenza season (April–September).[10]

B. **Lactation:** Inactivated and recombinant influenza vaccines are safe for breastfeeding mothers and their infants.[12]

C. **Immunocompromised:** Persons with immunocompromising conditions should receive an age appropriate IIV or RIV4. Immune response to influenza vaccines might be blunted in persons with some conditions, such as persons with congenital immune deficiencies, persons receiving cancer chemotherapy, and persons receiving immunosuppressive medications.[13]

D. **Novel adjuvants:** Because of the limited data on the safety of simultaneous administration of two or more vaccines containing novel adjuvants and the availability of nonadjuvanted

influenza vaccine options, selection of a nonadjuvanted influenza vaccine may be considered in situations in which influenza vaccine and another vaccine containing a novel adjuvant are to be administered concomitantly. However, vaccination should not be delayed if a specific product is not available.

E. **Antiviral agents for influenza:** consult CDC's most recent recommendations for guidance on clinical management of influenza using antiviral agents. Available at: www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm

F. **Hematopoietic Stem Cell Transplant (HSCT) recipients:** Influenza vaccine should be administered beginning at least 6 months after HSCT and annually thereafter for the life of the patient. A dose of vaccine can be given as soon as 4 months after the transplant, but a second dose should be considered in this situation. Do not use live influenza vaccine in this population.[13]

G. **Ocular and Respiratory Symptoms after Vaccination: Oculo-respiratory syndrome** (ORS) The cause of ORS has not been established; however, studies suggest that the reaction is not IgE-mediated. When assessing whether a patient who experienced ocular and respiratory symptoms should be revaccinated, providers should determine whether signs and symptoms concerning for IgE-mediated immediate hypersensitivity are present. Health care providers who are unsure whether symptoms reported represent an IgE-mediated hypersensitivity immune response should seek advice from an allergist/immunologist. See https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html

9. Side Effects and Adverse Reactions [1-8]

Adverse Event	Frequency
Local reactions: soreness, erythema, induration at injection site	Up to 60%
Fever, malaise, chills	10% -15%
Severe allergic reactions	1 per 3 million doses

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Latex	Storage Issues	Notes
Afluria® Quadrivalent [1]	Store at 2° to 8°C (36° to 46°F)	No	Store in original package to protect from light.	Discard opened multi-dose vials 28 days after opening.

Fluad® Quadrivalent[8]			Store multi-dose vials in recommended conditions.	Use opened multi-dose vials through the expiration date
Fluarix® Quadrivalent[2]				
Flublok® Quadrivalent[6]				
Flucelvax® Quadrivalent[7]				
FluLaval® Quadrivalent[3]				
Fluzone High Dose® and Fluzone® Quadrivalent[4,5]				

11. References

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3. FluLaval® Quadrivalent 2023–2024. [Package insert]. Available at: www.fda.gov/media/115785/download. Accessed 14 Jul 2023.
4. Fluzone® High-dose Quadrivalent 2023–2024. [Package insert]. Available at: www.fda.gov/media/139731/download. Accessed 14 Jul 2023.
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7. Flucelvax® IIV4 2023–2024. [Package insert]. Available at: www.fda.gov/media/115862/download. Accessed 14 Jul 2023.
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12. Appendix

A. N/A

Protocol for Live Attenuated Influenza Vaccine (FluMist® Quadrivalent)

1. What's New

A. The 2023-2024 season U.S. flu vaccines will contain an updated influenza A(H1N1) pdm09 component:[1]
   a. A/Victoria/4897/2022 (H1N1) pdm09-like virus for egg-based vaccines and
   b. A/Wisconsin/67/2022 (H1N1) pdm09-like virus for cell-based or recombinant vaccines.

B. All persons ages ≥6 months with egg allergy should receive influenza vaccine. Any influenza vaccine (egg based or non-egg based) that is otherwise appropriate for the recipient's age and health status can be used.[2]

2. Immunization Protocol[1,2]

A. Administer a 0.2-mL dose, Intranasally, to persons 7-49 years of age without contraindications. The number of doses indicated varies by age and vaccine history. See appendix for administration instructions.

B. May be given concomitantly with all ACIP-recommended child and adult vaccinations. Live vaccines not given on the same day must be separated by at least 28 days.

3. Vaccine Schedule

Live Attenuated Influenza Vaccine (LAIV) Schedule for the 2023-2024 Flu Season[1] Dose and Route – 0.2-mL, Intranasal		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	7-49 years	
2	7-8 years	28 days, see flowchart in recommendations for use for determining 1 or 2 doses

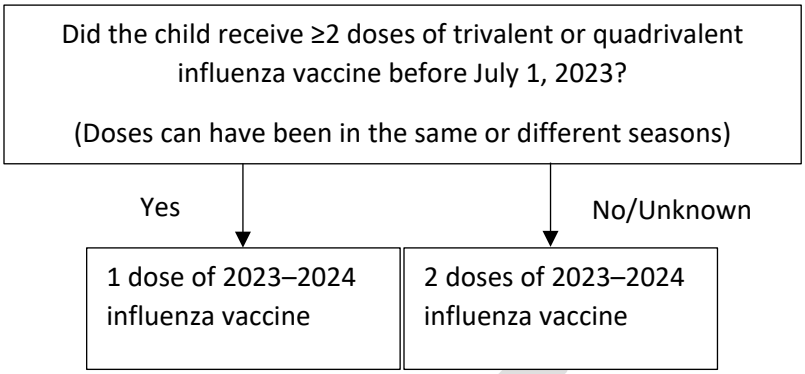
4. Licensed Vaccines

Product Name	Presentation	FDA Approved Age Range	Thimerosal
FluMist® Quadrivalent[1]	0.2 mL pre-filled intranasal sprayer	2-49 years	None

5. Recommendations for Use[1, 2]

A. All persons 7–49 years of age without contraindications.

B. Children <9 years of age receiving flu vaccine for the first time need 2 doses. Doses should be separated by 28 days. Children who receive the first dose at age 8 years and turn 9 during flu season should still receive the 2nd dose in the same season.



C. Do not use LAIV in pregnant women.
D. Persons with history of egg allergy may receive any vaccine (egg-based or non-egg-based) that is otherwise appropriate for their age and health status. Beginning with the 2023-2024 season, additional safety measures are no longer recommended for flu vaccination of people who are allergic to eggs beyond those recommended for receipt of any vaccine, regardless of the severity of previous reaction to egg. All vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of allergic reactions are available, such as a pharmacy.
E. Providers should offer flu vaccination to unvaccinated persons by the end of October, if possible. Vaccination should continue to be offered if unexpired vaccine is available.

6. Contraindications[1,2]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component. However, ACIP makes an exception for an allergy to egg (see Persons with a History of Egg Allergy above).
   a. Most flu shots and the nasal spray flu vaccine are manufactured using egg-based technology. Because of this, they contain a small amount of egg proteins, such as ovalbumin. However, studies that have examined the use of both the nasal spray vaccine and flu shots in egg-allergic and non-egg-allergic patients indicate that severe allergic reactions in people with egg allergies are unlikely.

Vaccine	Contains
FluMist® Quadrivalent[1]	Monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, ovalbumin, gentamicin sulfate, ethylenediaminetetraacetic acid (EDTA).

B. Concomitant aspirin or salicylate-containing therapy in children and adolescents through age 17 years of age.
C. Children and adults who are immunocompromised due to any cause, including but not limited to immunosuppression caused by medications, congenital or acquired immunodeficiency states, HIV infection, anatomic asplenia, or functional asplenia (such as that due to sickle cell anemia).

D. Close contacts and caregivers of severely immunosuppressed persons who require a protected environment.
E. Pregnancy.
F. Persons with active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, or ear or any other cranial CSF leak.
G. Persons with cochlear implants, because of the potential for CSF leak that might exist for a period after implantation (providers might consider consultation with a specialist concerning the risk for persistent CSF leak if an age-appropriate inactivated or recombinant vaccine cannot be used).
H. Receipt of influenza antiviral medication within the previous 48 hours for oseltamivir and zanamivir, previous 5 days for peramivir, and previous 17 days for baloxavir. The interval between influenza antiviral receipt and LAIV4 during which interference might potentially occur might be further prolonged in the presence of medical conditions that delay medication clearance (e.g., renal insufficiency).

Antiviral Drug	Potential Interference Interval
Baloxavir	17 days before- 2 weeks after
Peramivir	5 days before- 2 weeks after
Oseltamivir or Zanamivir	48 hours before- 2 weeks after

7. Warnings and Precautions[1,2]

A. Guillain-Barré Syndrome (GBS). If GBS has occurred within 6 weeks of any prior influenza vaccination, the decision to give FluMist® Quadrivalent should be based on careful consideration of the potential benefits and potential risks.
B. Asthma in persons aged ≥5 years.
C. Other underlying medical condition (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection (e.g., chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus]).

8. Other Considerations[1,2,4]

A. Lactation: FluMist® Quadrivalent is not absorbed systemically by the mother following intranasal administration and breastfeeding is not expected to result in exposure of the child to the vaccine components.

9. Side Effects and Adverse Reactions[1]

Adverse Event	Frequency
Nasal Congestion	Up to 58%
Low grade fever, headache, sore throat	5-20%
Allergic reactions	Less than 1%

10. Storage and Handling[1]

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
FluMist® Quadrivalent[1]	2°to 8°C (36° to 46° F)	Do not freeze. Keep enclosed in outer carton to protect from light.	A single temperature excursion up to 25°C (77°F) for 12 hours has been shown to have no adverse impact on the vaccine. No further excursions are allowed. Once administered or expired, the sprayer should be disposed of according to the standard procedures for medical waste (e.g., sharps container or biohazard container)

11. References

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12. Appendix

A. N/A

Protocol for Japanese Encephalitis Vaccine (IXIARO®)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer a 0.5- mL dose, IM, of Japanese Encephalitis (JE) vaccine to persons ≥7 years of age according to age and schedule if indicated.

B. IXIARO® can be given with all other ACIP-recommended vaccines.

3. Vaccine Schedule

JE Vaccine (IXIARO®) [1] Dose and Route – 0.5-mL IM				
Age	**Dose in Series**	**Acceptable Age Range**	**Dose Volume**	**Booster**
7-17 years	2 doses at 0 and 28 days	≥ 7 years	0.5 mL	≥ 1 year after primary series†
18-64 years	2 doses at 0 and 7-28 days*			
≥ 65 years	2 doses at 0 and 28 days			

* This is the only age group for which an accelerated schedule is approved.

† If ongoing exposure or re-exposure to JE virus is expected.[2]

4. Licensed Vaccine[3]

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
IXIARO®[1] (JE-VC)‡	6 antigen units purified, inactivated JEV proteins and 250 µg of aluminum hydroxide per 0.5-mL dose	0.5 mL suspension in a pre-filled single dose syringe	2 months – 65 years	None

‡JE-MB (JE-VAX) is no longer manufactured in the United States.

5. Recommendations for Use[2]

A. JE vaccination is recommended for the following:
   a. Persons moving to JE-endemic countries.
   b. Travelers who plan to spend a month or longer in endemic areas.
   c. Laboratory personnel who work with live, wild-type JE virus strains.[3]

B. Vaccine should also be considered for the following:
   a. Shorter-term travelers (e.g. less than 1 month) with an increased risk of exposure to JE based on planned travel duration, season, location, activities, and accommodations.[2]
   b. Travelers going to endemic areas, but who are uncertain of specific destinations, activities, or duration of travel.

C. Booster doses
   a. A booster dose should be given ≥1 year after completion of the primary JE-VC series if ongoing exposure or re-exposure to JE virus is expected.

b. The 2-dose primary series of JE-VC vaccine should be given to persons who received JE-MB (JE-VAX®) † and need a booster.
c. Vaccinated, at-risk laboratory personnel should receive appropriate booster doses of JE vaccine or be evaluated regularly for JE virus-specific neutralizing antibodies to assure adequate titers.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1]

Vaccine	Contains
IXIARO® (JE-VC)	Protamine sulfate, aluminum hydroxide and phosphate buffered saline (sodium chloride, potassium dihydrogen phosphate, disodium hydrogen phosphate)[1]

7. Warnings and Precautions

A. Hypersensitivity to protamine sulfate[1]
B. Other vaccines: Studies of concomitant administration of JE vaccine with hepatitis A vaccine and JE vaccine with rabies vaccine have showed noninferiority compared to administering each vaccine alone. An additional study of concomitant administration of JE vaccine, rabies vaccine and meningococcal conjugate vaccine showed protective responses to all administered vaccines.[3]
C. Pregnancy: No studies of JE-VC in pregnant women have been conducted. Pregnancy is a precaution for use of JE-VC and in most instances, its administration to pregnant women should be deferred. However, pregnant women who must travel to an area where risk for JE virus infection is high should be vaccinated when the theoretical risk of immunization is outweighed by the risk of infection.[2]
D. Newborns: JE vaccine has not been tested in individuals ≤2 months of age.[3] Older adults: In a post-licensure study, seroprotection and gross mean titers were substantially lower among adults ≥65 years of age compared to younger persons. No data exists on the safety or immunogenicity of an additional dose or early booster dose of JE vaccine for adults ≥65 years of age. [3]

8. Other Considerations [1-3]

A. Although ≤1% of JEV infections results in clinical disease, JE is a devastating illness that has a case-fatality rate of 20%–30% and neurologic or psychiatric sequelae in 30%–50% of survivors. No specific treatment exists.[3]
B. In all instances, travelers are advised to take personal precautions to reduce exposure to mosquito bites.[2]
C. The decision to use JE-VC should balance the risks for exposure to the virus and for developing illness, the availability and acceptability of repellents and other alternative measures, and the side effects of vaccination.[2]
D. Risk assessments should be interpreted cautiously because risk can vary within areas and from year to year.[2]

E. Risk of JE for travelers to highly endemic areas during the transmission season can reach 5 to 50 cases per 100,000; the risk for most short-term travelers may be 1 per million or less.[2]
F. Adverse Events: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[4]
G. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses. Immunosuppressive therapies may decrease the immune response to IXIARO®[1]
H. Lactation: Breastfeeding is not a contraindication or precaution to JE vaccine.[3]

9. Side Effects and Adverse Reactions[1]

Adverse Events	Frequency
Infants and Children	
Pain, itching, redness or swelling at the injection site	Up to 20%
Fever	Up to 10%
Allergic reactions	Rare
Adults	
Soreness, redness or itching at the injection site, headache, fatigue	Up to 30%
Vomiting, fever, chills, rash	Up to 5%
Allergic reactions	Rare

10. Storage and Handling

A. IXIARO® is a clear liquid with a white precipitate. Before administration, shake the syringe well to obtain a white, opaque, homogeneous suspension.
B. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
IXIARO®[1]	2°– 8°C (36˚F–46˚F)	Do not freeze. Store in original container. Protect from light.	No natural rubber latex. Do not use after manufacturer's expiration date on product label.

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2. Hills, Lindsey, & Fischer. (n.d.). Japanese Encephalitis - Chapter 4 - 2020 Yellow Book | Travelers' Health | CDC. Centers for Disease Control and Prevention. Available at: https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/japanese-encephalitis. Accessed 22 April 2023.
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12. References

A. N/A

Protocol for Measles, Mumps and Rubella Containing Vaccines (M-M-R®II, PRIORIX™ and ProQuad®)

1. What's New

A. Updated to allow intramuscular administration for M-M-R® II and ProQuad.® [1,2]

2. Immunization Protocol

A. Administer a 0.5-mL dose, SQ or IM, of M-M-R® II to persons ≥7 years of age; or
B. Administer a 0.5-mL dose, SQ, of PRIORIX™ to persons ≥7 years of age; or
C. Administer a 0.5-mL dose, SQ or IM, of ProQuad® to persons ages 7-12 years.
D. May be given simultaneously with all routinely recommended vaccines. Do not give simultaneously with immune globulin.

3. Vaccine Schedule[1-3]

M-M-R®II (MMR) Dose and Route –0.5-mL SQ or IM		
PRIORIX™ (MMR) Dose and Route –0.5-mL SQ Only		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
2		28 days
ProQuad® (MMRV) Dose and Route –0.5-mL SQ or IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	7-12 years	
2		3 months

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
M-M-R® II[1]	MMR	Single-dose lyophilized vaccine vials and 0.5-mL single-dose diluent vials	≥12 months	None
PRIORIX™[3]	MMR	Single-dose lyophilized vaccine vials and prefilled diluent syringes without needles. Dose after reconstitution is ~0.5- mL	≥ 12 months	
ProQuad®[2]	MMRV	Single-dose lyophilized vaccine vials and 0.5-mL single-dose diluent vials	12 months – 12 years	

5. Recommendations for Use[4,5]

A. Catch-up Vaccination: All children should routinely receive the second dose of MMR vaccine at 4–6 years of age. In Oregon, the second MMR dose is required for school attendance, beginning in kindergarten. Catch-up vaccination is recommended through age 18.
B. Students in Colleges and Universities, Healthcare Workers, International Travelers, and Household and Close Contacts of Immunocompromised Persons: Persons without evidence of immunity need two doses of MMR vaccine, at least 28 days apart.
C. Persons with HIV: Persons without evidence of current severe immunosuppression who are not immune need two doses of MMR vaccine, at least 28 days apart. MMRV is contraindicated for persons with HIV.

D. Pre- and Post-partum persons: Persons without immunity to rubella should receive MMR vaccine upon completion or termination of pregnancy.
E. All Other Adults: Persons born after 1956 without evidence of immunity need at least one dose of MMR vaccine.
F. Measles Post-Exposure Prophylaxis: MMR vaccine, if administered within 72 hours of initial exposure, might provide some protection or modify the clinical course of measles. For more information, see the Immune Globulin for the Prevention of Hepatitis A or Measles immunization protocol.
G. Community Measles Outbreaks: During community outbreaks of measles, any patient without two verified doses of MMR vaccine may receive an additional dose. Infants ≥6 months of age may receive a dose of MMR vaccine. Any doses given prior to 12 months of age do not count towards the two-dose series.
H. Mumps Outbreaks: Persons at increased risk for acquiring mumps due to prolonged or intense exposure who have received <3 doses of mumps virus-containing vaccine or have unknown vaccination status should receive 1 dose of MMR vaccine.

6. Contraindications[4,5]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Contains[6]
M-M-R® II	sorbitol, sucrose, hydrolyzed gelatin, recombinant human albumin, neomycin, fetal bovine serum, WI-38 human diploid lung fibroblasts
PRIORIX™	Anhydrous lactose, sorbitol, amino acids, mannitol, neomycin sulphate, ovalbumin, and bovine serum albumin[3]
ProQuad®	MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, recombinant human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride, potassium phosphate dibasic, neomycin, bovine calf serum, other buffer and media ingredients

B. Pregnancy: MMR vaccines should not be administered to women known to be pregnant or attempting to become pregnant[4]
C. Immunodeficiency: MMR and MMRV should not be administered to persons with primary or acquired Immunodeficiency.[4]
    a. Persons with HIV who are not currently severely immunosuppressed may receive MMR. MMRV is contraindicated in persons with HIV.
    b. Persons who have a family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings), should not receive MMR or MMRV unless the immune competence of the potential vaccine recipient has been substantiated clinically or verified by a laboratory.
    c. Persons receiving systemic immunosuppressive therapy, including corticosteroids ≥2 mg/kg of body weight or ≥20 mg/day of prednisone (or equivalent) for persons who weigh >10 kg, when administered for ≥2 weeks, should not receive MMR or MMRV.
D. Immune Globulin (IG): Do not administer MMR or MMRV simultaneously with immune globulin.[4]

7. Warnings and Precautions

A. Moderate or severe illness, with or without fever.[7]

B. Antibody-containing blood products: Receipt of antibody-containing blood products (e.g., IG, whole blood, or packed red blood cells) might interfere with the serologic response to measles and rubella vaccine for variable periods, depending on the dose of IG administered.[4]

   a. MMR vaccine should be administered to persons who have received an IG preparation only after the recommended intervals have elapsed. See Appendix for guidance.

   b. Do not delay postpartum administration of MMR to women who lack immunity to rubella due to administration of Rho(D) IG (human) or any other blood product received at delivery or during the last trimester of pregnancy. Vaccinate immediately and test for immunity to rubella and measles 3 months later.

C. Tuberculosis testing: TB skin tests may be administered simultaneously with MMR or MMRV vaccine. If not administered simultaneously, wait 4–6 weeks after vaccination to place the TB test.[4]

D. Personal or Family History of Seizures: A personal or family (i.e., sibling or parent) history of seizures of any etiology is a precaution for the first dose of MMRV but not MMR vaccination.[4]

E. History of thrombocytopenia or thrombocytopenic purpura: Persons who have a history of thrombocytopenia or thrombocytopenic purpura might be at increased risk for developing clinically significant thrombocytopenia after MMR or MMRV vaccination.[4]

F. Simultaneous and non-simultaneous vaccination with live vaccines: Two or more live vaccines may be administered on the same clinic day. Live vaccines not administered simultaneously need to be separated by 28 days. If not separated by at least 28 days, the vaccine administered second needs to be repeated at least 28 days later.[7]

G. Salicylate Therapy: Avoid the use of salicylates (aspirin) or salicylate-containing products in children aged 12 months to 12 years for six weeks following vaccination with MMRV due to the association of Reye Syndrome with salicylate therapy and wild-type varicella infection.

8. Other Considerations

Acceptable Evidence of Immunity[4]		
For routine purposes, persons who meet the criteria below are considered immune to Measles, Mumps, or Rubella, respectively.		
Population	**Measles or Mumps**	**Rubella**
Routine Vaccination	• Documentation of vaccination with a live measles or mumps virus-containing vaccine: o PreK: 1 dose o K–12: 2 doses o Adults at low risk: 1 dose • Laboratory evidence of immunity; • Laboratory confirmation of disease; • Birth before 1957	• Documentation of 1 dose of live rubella virus-containing vaccine; • Laboratory evidence of immunity; • Laboratory confirmation of disease; • Birth before 1957.
College or University Students	• Documentation of vaccination with 2 doses of live measles- or mumps-virus containing vaccine • Laboratory evidence of immunity; • Laboratory confirmation of disease • Birth before 1957.	
International Travelers, Healthcare Workers, HIV+ persons, Household and Close Contacts of Immunocompromised Persons	• Documentation of vaccination with a live measles or mumps virus-containing vaccine: o Infants 6–11 months (measles): 1 dose o ≥12 months: 2 doses • Laboratory evidence of immunity; • Laboratory confirmation of disease; • Birth before 1957.	

9. Side Effects and Adverse Reactions

Adverse Event	**Frequency[1-4]**
Pain, redness or swelling at the injection site	Up to 27%
Irritability	Up to 63%
Arthralgia, arthritis-like symptoms*[4]	10–30% in post-pubertal women
Fever	Up to 35%
Transient rashes	5%
Transient lymphadenopathy	5% children, 20% adults
Parotitis	<1%

*Symptoms typically begin 1–3 weeks after vaccination, usually are mild, last approximately 2 days and are not incapacitating.

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.
B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Protocol for Measles, Mumps and Rubella Containing Vaccines
(M-M-R®II, PRIORIX™ and ProQuad®)

Vaccine	Temp	Storage Issues	Notes
M-M-R® II[1]	-50° to 8°C (-58° to 46°F)	Vaccine may be stored frozen. Before reconstitution, refrigerate vaccine at 2°–8°C (36°– 46°F).	Protect from light. Use immediately after reconstitution. If not used, may be stored at 2°–8°C, protected from light, for up to 8 hours.
M-M-R® II (diluent)[1]	2°to 8°C (36° to 46°F)	Diluent may be stored refrigerated or at room temperature.	Do not freeze.
PRIORIX™ [3]	2° to 8°C (36° to 46°F)	Do not freeze.	Protect from light. Use immediately after reconstitution. If not used, may be stored at 2°–8°C, protected from light, for up to 8 hours.
PRIORIX™ (diluent)[3]	2°to 8°C (36° to 46°F)	Diluent may be stored refrigerated or at room temperature (up to 25°C or 77°F).	Do not freeze.
ProQuad® [2]	-50° to -15°C (-58° to 5°F)	Store frozen to maintain potency. Vaccine may be stored in the refrigerator for up to 72 hours before reconstitution.	Reconstituted vaccine may be stored at room temperature, protected from light, for up to 30 minutes. Do not freeze reconstituted vaccine.
ProQuad® (diluent)[2]	2°to 25°C (36° to 77°F)	Diluent may be stored refrigerated or at room temperature.	Do not freeze.

11. References

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12. Appendix

A. Recommended intervals between administration of antibody-containing products and measles or varicella virus-containing vaccine, by product or indication for vaccination. Revised February 2021: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/recommended-intervals-between-administration.pdf

Protocol for Meningococcal Containing Vaccines
MenQuadfi®, Menveo®, Bexsero®, and Trumenba®

1. What's New

A. Contraindications- Latex (Removed for Bexsero®[5])
B. Menveo® dosage and administration updated for 1 and 2 vial presentations.[4]
C. Menactra® has been removed from the market, all guidance related to Menactra® removed from protocol.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of meningococcal vaccine according to age-appropriate schedules and high-risk conditions.
B. Meningococcal ACWY vaccines are interchangeable when more than one brand is age-appropriate. [1]
C. Meningococcal B vaccines are not interchangeable. All doses of Meningococcal B must be of the same brand of vaccine.[1]
D. Meningococcal conjugate quadrivalent vaccine and Meningococcal B vaccine may be given simultaneously at different sites if indicated. [1]
E. Meningococcal vaccines can be given with all other routinely recommended vaccines.[2]

3. Vaccine Schedule

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	11-18 years	
Booster	16-18 years	8 weeks

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
2		8 weeks if 2 doses indicated
Boosters (if person remains at risk)	Aged <7 years at completion of primary series: Single dose at 3 years after primary vaccination and every 5 years thereafter Aged ≥7 years at completion of primary series: Single dose at 5 years after primary vaccination and every 5 years thereafter	

MenB Vaccines (Bexsero®, Trumenba®) Schedule for Healthy Persons*, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	16-23 years	
2		28 days for Bexsero®, 6 months for Trumenba®

*ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. See section 5 for guidance.

MenB Vaccines (Bexsero®, Trumenba®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥10 years	
2		28 days
3*		4 months after dose 2
Boosters (if person remains at risk)		Single dose at 1 year after completion of primary vaccination and every 2–3 years thereafter

*Dose 3 applies to Trumenba® only, not needed if dose 2 was administered at least 6 months after dose 1. If dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3.

4. Licensed Vaccines

Meningococcal ACWY Conjugate Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenACWY-TT[3] (MenQuadfi®)	Neisseria meningitidis serogroup A, C, W, and Y capsular polysaccharide antigens that are individually conjugated to tetanus toxoid protein	0.5-mL single-dose vials	≥2 years	None
MenACWY-CRM[4] (Menveo®)	Neisseria meningitidis serogroup A, C, Y, and W-135 oligosaccharides conjugated individually to Corynebacterium diphtheriae CRM protein	Single-dose 2 vial presentation (gray and orange caps) that requires reconstitution. 0.5-mL dose once reconstituted	2 months-55 years	None
		0.5-mL single-dose 1 vial presentation (pink cap) that does **not** require reconstitution	10-55 years	None

Meningococcal B Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenB-4C (Bexsero®)[5]	Recombinant proteins Neisserial adhesin A (NadA), Neisserial Heparin Binding Antigen (NHBA), and factor H binding protein (fHbp)	0.5-mL prefilled syringes	10-25 years	None
MenB-fHbp (Trumenba®)[6]	Two recombinant lipidated factor H binding protein (fHbp) variants from N. meningitidis serogroup B, one from fHbp subfamily A and one from subfamily B (A05 and B01, respectively)	0.5-mL prefilled syringes	10-25 years	None

5. Recommendations for Use

A. Routine use of Meningococcal ACWY vaccine[1]
   a. All adolescents 11–18 years of age without contraindications. Preferred age for dose one is 11-12 years with a booster dose at age 16 years. Catch-up vaccination age for dose one is 13–15 years with a booster dose at age 16–18 years. If series started at age 16 or older, no booster dose is indicated.
      i. Children who received MenACWY at age 10 years do not need an additional dose at age 11–12 years but should receive the booster dose at age 16 years. Children who received MenACWY before age 10 years and with no ongoing risk for meningococcal disease for which boosters are recommended should still receive MenACWY according to the recommended adolescent schedule.
   b. Unvaccinated or under vaccinated first-year college students living in residence halls. One dose may be administered to persons 19-21 years who have not received a dose after their 16th birthday. Boosters are not routinely recommended unless there is another indication.
   c. Military recruits 19-21 years of age who have not received a dose after their 16th birthday. Administer one dose with booster every 5 years based on assignment. Vaccine recommendations for military personnel are made by the U.S. Department of Defense.
   d. Booster doses for previously vaccinated persons who become or remain at increased risk. At 3 or 5 years after primary vaccination depending on age at last dose and every 5 years thereafter.

B. Use of Meningococcal ACWY vaccine in high-risk persons[1]
   a. Persons with complement component deficiency or who are taking complement inhibitor medications, with anatomical or functional asplenia, or with HIV should receive 2 doses 8 weeks apart.

b. Microbiologists routinely exposed to isolates of Neisseria meningitidis, persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men [MSM]), and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic, particularly the meningitis belt in sub-Saharan Africa, should receive 1 dose.
   i. Vaccination is required for entry for persons traveling to Saudi Arabia for the Hajj and Umrah pilgrimages.

C. Use of Meningococcal B vaccine in healthy persons[1]
   a. Vaccination of adolescents and young adults aged 16–23 years with a 2-dose MenB series on the basis of shared clinical decision-making. MenB vaccination is not routinely recommended for all adolescents. Instead, ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision making to discuss MenB vaccination with persons aged 16-23 years who are most likely to benefit.
      i. Pharmacists are authorized to administer MenB vaccine if the following risk factor is present: College students, especially those who are freshmen, attend a 4-year university, live in on-campus housing, or participate in sororities and fraternities

D. Use of Meningococcal B vaccine in high-risk persons[1]
   a. Persons with persistent complement component deficiencies or who are taking complement inhibitor medications, with anatomic or functional asplenia, and Microbiologists routinely exposed to isolates of *Neisseria meningitidis* should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.
      i. A single booster dose for previously vaccinated persons who remain at increased risk should be given at 1 year after completion of primary vaccination and every 2-3 years thereafter.
   b. Persons at increased risk during an outbreak (e.g., in community or organizational settings, and among MSM should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.
      i. A single booster dose for previously vaccinated persons and identified at increased risk during an outbreak should be given if ≥1 year after completion of primary series (a ≥ 6-month interval might also be considered by public health).

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[3-7]

Vaccine	Contains
MenACWY-TT – MenQuadfi®	sodium chloride, sodium acetate, formaldehyde, tetanus toxoid
MenACWY-CRM - Menveo®	formaldehyde, CRM197 protein
MenB-4C - Bexsero®	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
MenB-FHbp - Trumenba®	polysorbate 80, aluminum phosphate, histidine buffered saline

7. Warnings and Precautions[3-6]

A. N/A

8. Other Considerations

A. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses. [3-6]
B. Pregnant and lactating women should receive MenACWY vaccine if indicated. However, due to a lack of data, vaccination with MenB should be deferred unless the woman is at increased risk and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks. [1]
C. Lactation: It is not known whether meningococcal vaccines are excreted in human milk. Use with caution in nursing mothers.[1]
D. MenACWY meningococcal vaccines will stimulate protection only against infections caused by organisms from serogroups A, C, Y and W meningococci. They are not protective against serogroup B meningococci.[5,6]
E. Meningococcal vaccine is recommended 2 weeks before or ≥2 weeks after splenectomy surgery for persons ≥7years of age. [1]
F. Immunization with MenQuadfi® does not substitute for routine tetanus immunization.[3]

9. Side Effects and Adverse Reactions[3-6]

MenACWY Vaccines	
Adverse Event	**Frequency**
Low-grade fever, headache, redness at injection site, dizziness	Up to 40%
Grade 3 - fever, headache, redness at injection site, dizziness	Up to 3%
MenB Vaccines	
Adverse Event	**Frequency**
Headache, fatigue, redness at injection site	Up to 51%
Pain at injection site	Up to 26%
Chills, joint pain	Up to 20%
Fever	Up to 2.5%

10. Storage and Handling

A. Menveo® two-vial presentation reconstitution[4]:
   a. Use the MenCYW-135 liquid conjugate component (Vial 1, gray cap) to reconstitute the MenA lyophilized conjugate component (Vial 2, orange cap) to form Menveo®.
   b. Invert Vial 2 and shake well until the lyophilized conjugate component is dissolved.
   c. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine.
   d. Administer Menveo® immediately or store between 36°F and 77°F (2°C and 25°C) for up to 8 hours. Shake well before using. Discard reconstituted vaccine if it has been frozen or not used within 8 hours.
B. Store medications according to OAR 855-041-1036.
C. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
MenQuadfi®[3]	Store at 2°to 8°C (36° to 46°F)	Protect from light. Do not use if vaccine has been frozen.	
Menveo®[4] and diluent			See directions for Menveo 2 vial presentation reconstitution above
Bexsero®[5] and Trumenba®[6]			

11. References

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4. Menveo® package insert. Available at: https://www.fda.gov/media/78514/download. Accessed 12 June 2023.
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6. Trumenba® package insert. Available at: https://www.fda.gov/media/89936/download. Accessed 12 June 2023.
7. Centers for Disease Control and Prevention. Vaccine Excipient Summary. November 2021. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 12 June 2023.

12. Appendix

A. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making for Meningococcal B Vaccination in Adolescents and Adults: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/vaccines/hcp/admin/downloads/ISD-job-aid-SCDM-mening-b-shared-clinical-decision-making.pdf

Protocol for Pneumococcal Vaccines
PCV20 (Prevnar 20®), PCV15 (VAXNEUVANCE™), PCV13 (Prevnar 13®) and Pneumococcal Polysaccharide Vaccine: PPSV23 (Pneumovax®23)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of pneumococcal conjugate vaccine (PCV) to persons ≥7 years of age according to age-appropriate schedule or high-risk group indication **OR**

B. Administer a 0.5-mL dose, IM or SQ, of pneumococcal polysaccharide vaccine (PPSV) to persons ≥7 years of age according to age-appropriate schedule or high-risk group indication.

C. PCV and PPSV should not be given at the same time. Either vaccine type may be given simultaneously with influenza and most other ACIP-recommended child and adult vaccinations.[5]

3. Vaccine Schedule

Pneumococcal Vaccine (PCV13 or PCV15, PPSV23) for Persons 7-18 Years of Age with Underlying Conditions* Dose-0.5-mL, Route varies by product				
Acceptable Age Range	**Previous PCV13 Vaccination History**	**Previous PPSV23 Vaccination History**	**Due Now/Route** (≥ 8 weeks since last pneumococcal vaccine)	**Due Next**
7-18 years of age with high-risk conditions	Unvaccinated	Unvaccinated	PCV13 or PCV15 IM	PPSV23 in ≥8 weeks. Revaccinate with PPSV23 in 5 years.
		1 dose	PCV13 or PCV15 IM	Revaccinate with PPSV23 in 5 years.
	≥1 dose of PCV13	Unvaccinated	PPSV23 IM or SQ	Revaccinate with PPSV23 in 5 years.
		1 dose	Complete	
*CSF leak, cochlear implant, sickle cell disease and other hemoglobinopathies, asplenia, HIV infection, chronic renal failure, nephrotic syndrome, immunodeficiency, diseases treated with immunosuppressive therapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; generalized malignancy; solid organ transplantation; or multiple myeloma. Alcoholism and cigarette smoking are indications for PPSV23 only.				

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with Underlying Conditions* Dose-0.5-mL, Route varies by product		
Age	**Previous PCV or PPSV Vaccination History**	**Recommended Regimen/Route**
19-64 years	PPSV23 only	1 dose of PCV20 or PCV15 IM
	PCV13 only	PPSV23 IM or SQ, if indicated
	PCV13 and PPSV23	No additional doses
	Unknown Vaccination History	1 dose of PCV20 IM; or PCV15 IM followed by PPSV23 IM or SQ

*Alcoholism; chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy); cigarette smoking; diabetes mellitus; CSF leak; cochlear implant; sickle cell disease and other hemoglobinopathies; asplenia; HIV infection; chronic renal failure; nephrotic syndrome; immunodeficiency; diseases treated with immunosuppressive therapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; generalized malignancy; solid organ transplantation; or multiple myeloma

Routine Schedule* for PCV15 or PCV20, PPSV23 Dose and Route – 0.5-mL, Route varies by product			
Product/Route	**Preferred Age**	**Preferred Spacing**	**Minimum Spacing**
PCV20 or PCV15 IM	≥ 65		
PPSV23[+] IM or SQ		≥ 1 year after PCV15	≥ 8 weeks after PCV15
*See recommendations for use for specific guidance. [+]Indicated only for persons who received PCV15, and not for those who received PCV20. If PPSV23 is not available, one dose of PCV20 may be used.			

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
Pneumococcal Conjugate Vaccines (PCV)				
Prevnar 20™ [1]	Sterile suspension of mixture of saccharides of the capsular antigens of S. pneumoniae, individually linked to non-toxic diphtheria CRM197 protein	0.5 mL prefilled syringes	≥ 18 years	None
VAXNEUVANCE™ [2]		0.5 mL prefilled syringes	≥ 2 months	
Prevnar 13® [4]		0.5 mL prefilled syringes	≥ 6 weeks	
Pneumococcal Polysaccharide Vaccine (PPSV23)				
Pneumovax 23® [3]	Pneumococcal Vaccine Polyvalent is a sterile, liquid vaccine consisting of a mixture of purified capsular polysaccharides from Streptococcus pneumoniae	0.5 mL single dose vials	≥ 2 years	None
		0.5 mL prefilled syringes		

5. Recommendations for Use

A. Age 7-18 years:

a. Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:

i. Any incomplete series with PCV: no further PCV doses needed
ii. No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV doses)

b. Cerebrospinal fluid leak, cochlear implant:
   i. No history of either PCV or PPSV23: 1 dose PCV, 1 dose PPSV23 at least 8 weeks later
   ii. Any PCV but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV
   iii. PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent dose of PPSV23

c. Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:
   i. No history of either PCV or PPSV23: 1 dose PCV, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
   ii. Any PCV but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
   iii. PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent PPSV23 dose and a dose 2 of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV

B. Age 19–64 years:

a. Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV, Hodgkin disease, immunodeficiency, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplants, or sickle cell disease, or other hemoglobinopathies
   i. Not previously received a PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose.
      1. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak
      2. Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid

organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies

ii. Previously received only PCV7: follow the recommendation above

iii. Previously received only PCV13: 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

iv. Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23

v. Previously received both PCV13 and PPSV23 but have not completed the recommended series: 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

C. Age 65 years or older:

a. Not previously received a dose of PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose

i. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk of invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.

ii. Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies.

b. Previously received only PCV7: follow the recommendation above.

c. Previously received only PCV13: 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

d. Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.

e. Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older: 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

f. Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older: Adults aged 65 or older have the option to receive PCV20 if they previously completed the pneumococcal vaccine series with both PCV13 and PPSV23. This includes one dose of PCV13 at any age and all recommended doses of PPSV23, including one dose at or after age 65. PCV20 is not routinely recommended for these individuals as their risk of disease is lower due to prior vaccinations. Instead, ACIP recommends a

PCV20 vaccination for persons aged 65 or older who have received both PCV13 and PPSV23 on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision making to discuss PCV20 vaccination with persons aged 65 or older who are most likely to benefit. Pharmacists are authorized to administer PCV20 vaccine if one of the following risk factors is present AND at least 5 years has elapsed since last pneumococcal vaccination:

i. Persons living in nursing homes or other long-term care facilities
ii. The presence of underlying medical conditions or other risk factors that increase the risk of developing severe disease (refer to Section 5.B.a. for list).

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
B. PCV20[1], PCV15[2], or PCV13[4]: Persons who experienced an anaphylactic reaction to a previous dose of any diphtheria toxoid-containing vaccine.
C. PCV13[4]: Allergy to soy peptones.

7. Warnings and Precautions

A. PPSV23: Care should be exercised when administering to patients with severely compromised cardiovascular or pulmonary function in whom a systemic reaction would pose a significant risk.[3]

8. Other Considerations

A. Adults with previous PPSV23 only: Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23. [5]
B. Adults with previous PCV13: The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These adults should complete the previously recommended PPSV23 series. [5] One dose of PCV20 may replace the PPSV23 if PPSV23 is not available.
C. Lactation: It is not known whether pneumococcal vaccines are excreted in human milk. Use with caution in people who are nursing. [1-4]
D. Pregnancy: Pneumococcal vaccine should be considered for persons at increased risk.[10]
E. Simultaneous administration of PCV15 and PPSV23 is NOT recommended. See section 5, recommendations for use, for the necessary minimum interval between doses. [5,7]
F. Splenectomy, immunocompromising therapy, or cochlear implant: When elective splenectomy, immunocompromising therapy, or cochlear implant placement is being planned, age appropriate PCV vaccination should be completed at least 2 weeks before surgery or initiation of therapy. If vaccine is not administered before surgery, it should be administered ≥2 weeks after surgery. If the patient is unlikely to return, vaccine can be administered in the immediate postoperative period. [9]

G. Children who have experienced invasive pneumococcal disease should receive all recommended doses of a pneumococcal conjugate vaccine as appropriate for their age and underlying condition. The full series of scheduled doses should be completed even if the series is interrupted by an episode of invasive pneumococcal disease. [9]

H. Individuals with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.[1-4]

I. Recipients of Hematopoietic Cell Transplants (HCT): ACIP recommends that patients be revaccinated with three sequential doses of age appropriate PCV vaccine beginning 3–6 months after HCT transplant. A dose of PPSV should be administered ≥8 weeks after the last dose of PCV.[10]

9. Side Effects and Adverse Reactions

PCV13[4] Adverse Events	**Frequency**
Infants and children	
Irritability, soreness at the injection site	Up to 80%
Decreased appetite, decreased sleep, increased sleep	Up to 48%
Fever, erythema, induration at injection site	Up to 30%
Allergic reactions	Rare
PCV20[1], PCV15[2], PCV13[4] Adverse Events	**Frequency**
Adults	
Soreness at the injection site, fatigue	Up to 76%
Headache, muscle pain, joint pain, decreased appetite, local swelling, decreased arm movement	Up to 30%
Vomiting, fever, chills, rash	Up to 30%
Allergic reactions	Rare
PPSV23[3] Adverse Events	**Frequency**
Soreness, redness, swelling at the injection site	Up to 60%
Headache, muscle pain, fatigue	Up to 20%
Nausea, fever, chills	Rare, up to 2%
Allergic Reactions	Rare

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	**Temp**	**Storage Issues**	**Notes**
Prevnar 20™ [1]	Store at 2°– 8°C (36°- 46°F)	Store syringes horizontally to minimize re-suspension time; do not freeze	
VAXNEUVANCE™ [2]		Do not freeze. Protect from light.	

Prevnar® 13[3]		Vaccine is stable at temperatures up to 25 ° C for up to 4 days- not recommended for storage or shipping.	
Pneumovax® 23[4]		None	

11. References

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12. Appendix

A. Centers for Disease Control and Prevention (CDC). Pneumococcal Vaccine Timing. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
B. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making for Pneumococcal Conjugate Vaccine (PCV20) Vaccination in Adults Aged 19 Years or Older: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/vaccines/hcp/admin/downloads/job-aid-SCDM-PCV20-508.pdf

Protocol for Polio Vaccine (IPOL®)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer 0.5-mL dose, IM or SQ, of polio vaccines as recommended for age, vaccination status, and travel itinerary.

B. May be given with all ACIP-recommended child and adult vaccinations.

3. Vaccine Schedule

A. **Routine schedule for children <18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Recommended Spacing**
1	≥ 7 years	
2		4-8 weeks from previous dose
3		6-12 months from previous dose
4		A 4th dose is not necessary if 3rd dose administered at age 4 or older and at least 6 months after the previous dose. A 4th dose is indicated if all previous doses were administered at <4 years or if the 3rd dose was administered <6 months after the second dose. The minimum interval between the 3rd and 4th dose is 6 months.

B. **Accelerated schedule for children <18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥ 7 years	
2		≥4 weeks after dose 1
3		≥6 months after dose 2

C. **Unvaccinated, incompletely vaccinated, or unknown vaccine status for travelers ≥18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Recommended Spacing**
1	≥18 years	
2		4-8 weeks after dose 1
3		6-12 months after dose 2

D. **Accelerated schedule for unvaccinated, incompletely vaccinated, or unknown vaccine status for travelers ≥18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	
2		≥4 weeks after dose 1*
3		≥4 weeks after dose 2*

* If less than 8 weeks but more than 4 weeks is available before protection is needed, 2 doses of IPV should be administered at least 4 weeks apart. If less than 4 weeks is available before protection is needed, a single dose of IPV is recommended.[5]

E. **Fully vaccinated travelers ≥18 years of age**

Polio Vaccine (IPOL®) Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	≥12 months after last dose

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
IPOL®[1]*	Inactivated polio virus (IPV) serotypes 1,2 and 3	5-mL multi-dose vials	≥ 6 weeks	None

*Combination vaccines including polio may also be used according to approved age indication

5. Recommendations for Use

A. IPV is considered routine for children <18 years of age but is not routinely recommended for unvaccinated adults ≥18 years.

B. Adults who previously completed the full, routine polio vaccine series and are planning to travel to any country with circulating poliovirus should receive a onetime booster dose of polio vaccine IPV. Adults working in health care settings, refugee camps or other humanitarian aid settings in countries bordering a country with circulating poliovirus should also receive a one-time booster dose of IPV.[5] Countries where a booster of IPV is recommended before travel can be found at: https://wwwnc.cdc.gov/travel/notices/alert/global-polio

C. Unvaccinated adults who are traveling to countries with increased risk of exposure to poliovirus should receive a three-dose series of IPV vaccine. Adults who have received only one or two doses in the past should get the remaining doses of IPV vaccine administered at least 4 weeks apart.[3] If an adult cannot complete the series before departure, an accelerated schedule (doses administered at least 4 weeks apart) is recommended.[3]

D. Adults who continue to be at risk of exposure to poliovirus should complete the IPV 3 dose series when they return from travel.[3]

E. If a child cannot complete the accelerated schedule before departure, the remaining doses should be given in the visited country, or upon return home, at the intervals recommended in the accelerated schedule.[3]

F. Children completing the accelerated schedule should still receive a final dose of IPV at ≥4 years old, and at least 6 months after the previous dose.[3]

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1]

Protocol for Polio Vaccine
(IPOL®)

Vaccine	Contains[3]
IPOL®[1]	calf bovine serum albumin, 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B, M-199 medium

7. Warnings and Precautions

A. Moderate or severe acute illness with or without fever.[4]
B. Although no causal relationship between IPOL® vaccine and Guillain-Barré Syndrome (GBS) has been established, GBS has been temporally related to administration of another inactivated poliovirus vaccine.[1]

8. Other Considerations

A. IPOL® can also be given by the subcutaneous route.[1]
B. Polio vaccine given outside the United States is valid if written documentation indicates that all doses were given after 6 weeks of age and the vaccine received was IPV or trivalent oral poliovirus vaccine (tOPV). Recipients receiving both tOPV and IPV require a total of 4 doses.[5]
C. OPV given before April 1, 2016, can be assumed to be trivalent and valid.[5] OPV doses given in April of 2016, can only be counted as valid if the documentation indicates that it was trivalent.[5] OPV given after May 1, 2016 should not be counted as valid because it was a bivalent or monovalent vaccine.[5]
C. Persons <18 years of age with doses of OPV that do not count should receive IPV to complete the series.[5] Oral polio vaccine (OPV) has been unavailable in the United States since 1999.[5]
D. Travelers staying in a polio-infected country longer than 12 months may receive available poliovirus vaccine (IPV or OPV) in the infected country to meet the departure requirement.[3]
E. Immunodeficiency: IPV may be administered safely to immunocompromised travelers and their household contacts. Although a protective immune response cannot be ensured, IPV might confer some protection to the immunocompromised person.[4] People with certain primary immunodeficiency diseases should not be given live, attenuated OPV and should avoid contact with excreted OPV virus (such as exposure to a child vaccinated with OPV in the previous 6 weeks). Because OPV is no longer given in the United States, this situation would arise only if a child receives OPV overseas.[5] Revaccination with 3 doses of IPV is recommended 6–12 months after hematopoietic stem cell transplantation.
F. Mild Illness: IPV may be administered to people with diarrhea. Minor upper respiratory illnesses with or without fever, current antimicrobial therapy, and the convalescent phase of acute illness are not contraindications for vaccination.[6]
G. Pregnancy: If a pregnant woman is unvaccinated or incompletely vaccinated and requires immediate protection against polio because of planned travel to a country or area where polio cases are occurring, IPV can be administered as recommended for adults.[5]
H. Breastfeeding: Is not a contraindication to administration of polio vaccine to an infant or mother.[5] It is not known whether polio-containing vaccines are excreted in human milk. Use with caution in nursing mothers.[1]
I. After an interval of 15–40 years, 25%–40% of survivors of paralytic poliomyelitis may experience muscle pain and exacerbation of existing weakness or develop new weakness or paralysis. This disease entity, referred to as post-polio syndrome, has been reported only in

persons infected during the era of wild poliovirus circulation. This is not an infectious process.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Any local reaction – pain, redness, induration or swelling at the injection site	Up to 75%
Redness ≥50 mm at injection site	Up to 18%
Severe pain, induration or swelling at the injection site	Up to 9%
Any systemic reaction – fever, malaise, aches, persistent crying, drowsiness	Up to 50%
Severe (grade 3) systemic reactions including fever above 102° F	Up to 3%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
IPOL®[1]	Store at 2°to 8°C (36°to 46°F)	Do not use if vaccine has been frozen. Protect from light.	

11. References

1. IPOL®. Package insert. Swiftwater, PA: Sanofi Pasteur SA; Updated May 1, 2022. https://www.fda.gov/media/75695/download. Accessed April 14, 2023.
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12. Appendix

A. N/A

Protocol for Rabies Vaccines
(IMOVAX®, RabAvert®)

1. What's New

A. Updated pre-exposure prophylaxis to the currently recommended 2-dose regimen for adults.

2. Immunization Protocol

A. Administer a 1.0-mL dose, IM, of rabies vaccine according to the appropriate schedule and indication.

B. If administering post-exposure prophylaxis, assess patient's tetanus vaccination status and co-administer, if indicated.

3. Vaccine Schedule

A. **Pre-exposure prophylaxis[3]**

Rabies Vaccine (IMOVAX®, RabAvert®)[1,2] Dose and Route - 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥18 years	Day 0
2		Day 7
Booster		See section 5, recommendations for use.

Rabies Vaccine (IMOVAX®, RabAvert®)[1,2] Dose and Route - 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	7-17 years	Day 0
2		Day 7
3		Day 21-28
Booster		See section 5, recommendations for use.

B. **Post-exposure prophylaxis – unvaccinated person[3]**

Rabies Vaccine (IMOVAX®, RabAvert®)[1,2] Dose and Route - 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	Day 0
2		Day 3
3		Day 7
4		Day 14
5*		Day 28

* Necessary only for patients who are immunocompromised.

C. **Post-exposure prophylaxis – previously vaccinated person[3]**

Rabies Vaccine (IMOVAX®, RabAvert®)[1,2] Dose and Route - 1.0-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	Day 0
2		Day 3

Protocol for Rabies Vaccines
(IMOVAX®, RabAvert®)

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
IMOVAX®[1]	Rabies	Single-dose vial of freeze-dried vaccine and diluent in a prefilled syringe	Licensed for all ages	No
RabAvert®[2]				

5. Recommendations for Use

A. Pre-exposure for high-risk persons.[3]

Risk Category	Who This Typically Affects	Recommendations
Category 1 *Highest Risk*	Laboratory workers handling live or concentrated rabies virus	2-dose pre-exposure prophylaxis. Check titer every 6 months; booster if titer <0.5 units/mL
Category 2	People frequently handling bats, having contact with bats, or entering high-density bat environments. People performing animal necropsies.	2-dose pre-exposure prophylaxis. Check titer every 2 years; booster if titer <0.5 units/mL
Category 3	People who interact with animals that could be rabid (other than bats). Risk lasts longer than 3 years after receiving pre-exposure prophylaxis. This group includes most: - Veterinarians - Veterinary technicians - Animal control officers - Wildlife biologists - Wildlife rehabilitators - Trappers - Spelunkers (cave explorers)	2-dose pre-exposure prophylaxis, **plus**: Check titer once after 1 to 3 years After completion of 2 dose primary series of pre-exposure prophylaxis; booster if titer <0.5 units/mL **OR** 1 dose booster between 21 days and 3 years following completion of 2 dose primary series pre-exposure prophylaxis
Category 4	Same risk factors as category 3 but at risk for less than 3 years after receiving pre-exposure prophylaxis. This group includes International travelers to endemic or high-risk countries	2 dose pre-exposure prophylaxis. No titer recommended
Category 5 *Lowest Risk*	General U.S. population	None

B. Pre-exposure prophylaxis for persons with altered immunocompetence:[3] For persons with altered immunity, the same series is recommended, but a titer is needed after completion

of the vaccine series; a rabies antibody titer no sooner than 1 week after completion of the series (but ideally 2-3 weeks after it) should be ≥0.5 units/mL. If it is not, an additional dose should be administered followed by another titer check. If two such additional doses fail to achieve the minimum acceptable antibody titer, public health authorities should be consulted for case-specific guidance.

C. Routine serologic testing for rabies virus neutralizing antibody: Is not necessary for high-risk persons working in areas where rabies is uncommon to rare (infrequent exposure group). If these persons are subsequently exposed, they will require post-exposure prophylaxis for a previously vaccinated person.

D. Post-exposure treatment:[4] Bite from a dog, cat, or ferret. If healthy and available for observation, hold prophylaxis unless clinical signs of rabies develop. If animal is unavailable, consult with public health officials.

6. Contraindications

A. Pre-exposure Prophylaxis: Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[3]

Vaccine	Contains
IMOVAX®[1]	Human albumin, neomycin sulfate, phenol red, betapropiolactone.
RabAvert®[2]	Chicken protein, polygeline (processed bovine gelatin), human serum albumin, potassium glutamate, sodium EDTA, ovalbumin, neomycin, chlortetracycline, amphotericin B.

B. Post-exposure Prophylaxis: Since rabies is almost always fatal, there are no contraindications to vaccination for post-exposure prophylaxis, including pregnancy.[4]

7. Warnings and Precautions[3-5]

A. Immunosuppression: Persons with immunosuppression may be administered pre-exposure prophylaxis with the understanding that the immune response may be inadequate. Patients who are immunosuppressed by disease or medication should postpone pre-exposure prophylaxis and consider avoiding activities for which pre-exposure prophylaxis is indicated. When this is not possible, post-vaccination virus neutralizing antibodies should be checked. A patient who fails to seroconvert after the third dose should be managed in consultation with their physician and the Oregon Acute and Communicable Disease Section ohd.acdp@dhsoha.state.or.us.

B. Pregnancy: Pregnancy or breastfeeding is not a contraindication for postexposure prophylaxis. If the exposure risk is substantial, pre-exposure prophylaxis may be indicated during pregnancy. Certain studies have indicated no increased incidence of abortion, premature births, or fetal abnormalities associated with rabies vaccination. Rabies exposure or the diagnosis of rabies in the mother should not be regarded as reasons to terminate the pregnancy.

C. Allergies: Persons who have a history of serious hypersensitivity to components of rabies vaccine or to other vaccines with components that are also present in rabies vaccine should be revaccinated with caution.

a. RabAvert® is produced in chick embryo cell culture. Persons with a history of serious allergic reaction to egg ingestion should be vaccinated with IMOVAX® or if unavailable, RabAvert® should be used with caution.
b. IMOVAX® is produced in human diploid cells.

8. Other Considerations[5]

A. For most persons, routine serological testing after pre-exposure or postexposure prophylaxis to document seroconversion is not necessary unless:
   a. the person is immunosuppressed
   b. significant deviations of the prophylaxis schedule have occurred
   c. the patient received vaccination internationally with a product of questionable quality
   d. the person's antibody status is being monitored routinely due to occupational exposure to rabies virus

9. Side Effects and Adverse Reactions

A. Once initiated, rabies prophylaxis should not be interrupted or discontinued because of local or mild systemic adverse reactions to rabies vaccine. Usually, such reactions can be successfully managed with anti-inflammatory, antihistaminic, and antipyretic agents.[1]

Adverse Event	Frequency
Injection site events (pain)	Up to 84%
Injection site events (itching, redness, swelling)	Up to 45%
Systemic events (malaise, headache, dizziness, myalgia)	Up to 30%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temperature	Storage Issues	Notes
IMOVAX®[1] and RabAvert®[2]	2°to 8°C (36° to 46°F)	Do not freeze	Administer immediately after reconstitution.

11. References

1. IMOVAX®. Package insert. Swiftwater, PA: Sanofi Pasteur SA; Updated October 2019. https://www.fda.gov/media/75709/download. Accessed April 13, 2023.
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12. Appendix

A. N/A

Protocol for Respiratory Syncytial Virus Vaccine (ABRYSVO™, AREXVY™)

1. What's New

A. Added indication for Abrysvo™ seasonal administration during the final trimester of pregnancy between 32–36 weeks' gestation.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of respiratory syncytial virus (RSV) vaccine to persons ≥ 60 years of age, using shared clinical decision making, as described in Section 5.

B. May be given with all ACIP-recommended adult vaccinations.

3. Vaccine Schedule

RSV Vaccine (ABRYSVO™, AREXVY™) [1,2] Dose and Route – 0.5-mL IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥60 years	

RSV Vaccine (ABRYSVO™ only) [4] Dose and Route – 0.5-mL IM			
Dose	**Acceptable Age Range**	**Indication**	**Minimum Acceptable Spacing**
1	N/A	Pregnancy	Administer 32–36 weeks of pregnancy during or just prior to the start of the RSV season*.

*Vaccine should be administered to pregnant persons during September–January in most of the continental United States, including Oregon, to target vaccine to pregnant persons whose infants will be in their first months of life during the RSV season.

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
ABRYSVO™[1]	60 mcg RSV prefusion F A protein and 60 mcg RSV prefusion F B protein	0.5-mL single-dose diluent in prefilled syringe and vial with lyophilized antigen	≥60 years	No
AREXVY™[2]	120 mcg of the recombinant RSVPreF3 antigen, 25 mcg of MPL and 25 mcg of QS-21	0.5-mL single-dose vial of adjuvant suspension and single-dose vial of lyophilized antigen		

MPL: 3-O-desacyl-4'-monophosphoryl lipid A; QS-21: saponin purified from plant extract *Quillaja Saponaria* Molina

5. Recommendations for Use[3,4]

A. Shared clinical decision making for patients 60 years of age and older: until additional evidence becomes available from post-marketing surveillance clarifying the potential risk (e.g. neurologic inflammatory events, atrial fibrillation), RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease. Pharmacists can engage in shared clinical decision making to discuss RSV vaccination with persons aged 60 years or older who are most likely to benefit. Pharmacists are authorized to administer RSV vaccine if the patient provides information that one of the following risk factors is present:

Chronic underlying medical conditions
• Lung disease (such as chronic obstructive pulmonary disease and asthma) • Cardiovascular disease (such as congestive heart failure and coronary artery disease) • Moderate or severe immune compromise* • Diabetes mellitus • Neurologic or neuromuscular conditions • Kidney disorders • Liver disorders • Hematologic disorders • Other underlying conditions that a health care provider, including a pharmacist, determines may increase the risk for severe respiratory disease
Other factors
• Frailty† • Advanced age‡ • Residence in a nursing home or other long-term care facility • Other underlying factors that a health care provider, including a pharmacist, determines may increase the risk for severe respiratory disease

*A list of potentially immune compromising conditions is available at:
https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-who-are-immunocompromised.html

† Frailty is a multidimensional geriatric syndrome and reflects a state of increased vulnerability to adverse health outcomes. Although there is no consensus definition, one frequently used tool is the Fried frailty phenotype in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10 pounds or 4.5 kilograms in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity.

‡ Among adults aged ≥ 60 years, RSV incidence increases with advancing age. Although age may be considered in determining an older adult patient's risk for severe RSV-associated disease, there is no specific age threshold at which RSV vaccination is more strongly recommended within the age group of adults aged 60 years.

B. Pregnancy: Administer at 32–36 weeks' gestation during every pregnancy using seasonal administration (September–January in most of the continental United States, including Oregon) for prevention of RSV-associated LRTI in infants aged < 6 months.

6. Contraindications[1,2]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Contains
ABRYSVO™[1]	Tromethamine, tromethamine hydrochloride, sucrose, mannitol, polysorbate 80, sodium chloride, host cell protein and DNA
AREXVY™[2]	Trehalose, sodium chloride, potassium dihydrogen phosphate, dipotassium phosphate, polysorbate 80, disodium phosphate anhydrous, dioleoyl phosphatidylcholine (DOPC), host cell protein and DNA

7. Warnings and Precautions[1,2,4]

A. Individuals with acute, moderate, or severe illness with or without fever should delay immunization until symptoms have improved.

B. Individuals with an immunocompromising condition may experience a diminished immune response to the vaccine.

C. Potential risk of preterm birth. To avoid the potential risk of preterm birth (defined as birth before 37 weeks' gestation), administer Abrysvo™ as indicated only to pregnant individuals at 32 through 36 weeks' gestational age.

8. Other Considerations[1,2,4]

A. Coadministration with other vaccines: Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable. Available data on immunogenicity of coadministration of RSV vaccines and other vaccines is currently limited. Coadministration of RSV and influenza vaccines met noninferiority criteria for immunogenicity except for a lower antibody response to the influenza A Darwin H3N2 strain when ABREXVY™ was administered with an adjuvanted quadrivalent inactivated influenza vaccine. The clinical significance of this is unknown.

   Administering RSV vaccines with one or more other adult vaccines during the same visit may increase local or systemic reactogenicity. When determining whether to coadminister other vaccines with the RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preference.

B. Pregnancy and Breastfeeding: RSV vaccines are not approved for individuals <60 years of age. It is unknown if RSV vaccines are excreted in human milk.

C. Nirsevimab administration: Providers who care for pregnant persons should discuss the relative advantages and disadvantages of maternal RSV vaccination and nirsevimab and consider patient preferences when determining whether to vaccinate the pregnant person or to rely on administration of nirsevimab for prevention of RSV in the infant. Nirsevimab administration is recommended for infants aged < 8 months who are born during or are entering their first RSV season and whose mother did not receive a RSV vaccination or vaccination status is unknown; but administration of both products is not needed for most infants.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
ABRYSVO™[1]	
Fatigue	15.5%
Headache	12.8%
Injection site pain	10.5%
Myalgia	10.1%
Adults who are pregnant	
Preeclampsia	1.8% (95% CI 1.4, 2.3)
Gestational hypertension	1.1% (95% CI 0.8, 1.5)
AREXVY™[2]	
Injection site pain	60.9%
Fatigue	33.6%
Myalgia	28.9%
Headache	27.2%
Arthralgia	18.1%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
ABRYSVO™[1]	Store at 2°– 8°C (36°- 46°F)	Store in original carton and protect from light. Do not freeze. Discard if carton has been frozen.	Reconstituted vaccine may **only** be stored at room temperature, 15°– 30°C (59°- 86°F). Discard reconstituted vaccine if not used within 4 hours.
AREXVY™[2]			Reconstituted vaccine may be stored in the refrigerator between 2°– 8°C (36°- 46°F) or at room temperature up to 25°C (77°F). Discard reconstituted vaccine if not used within 4 hours.

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12. Appendix

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Protocol for Tetanus Diphtheria Containing Vaccines (Adacel®, Boostrix®, TENIVAC®, and TDVAX™)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of tetanus-containing vaccine, according to the age-appropriate schedule and vaccine history.

B. May be given with all ACIP-recommended child and adult vaccinations.

3. Vaccine Schedule

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM		
For unvaccinated persons ≥ 7 years of age[1]*		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥ 7 years	
2		4 weeks after dose 1
3		6 months after dose 2
The preferred schedule is 1 dose of Tdap, followed by either Td or Tdap for dose 2 & 3		
*See appendices for catch-up schedule for partially vaccinated children.		

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM		
Booster schedule for persons ≥ 10 years of age[2]		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
Adolescent booster	11-18 years	These persons should receive a single dose of Tdap, preferably at age 11–12 years. For persons aged 7–9 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap dose should be administered at age 11–12 years. If a Tdap dose is administered at age ≥10 years, the Tdap dose may count as the adolescent Tdap dose.
Routine booster	≥19 years	Regardless of the interval since their last tetanus or diphtheria toxoid–containing vaccine, persons aged ≥19 years who have never received a dose of Tdap should receive 1 dose of Tdap.
Additional boosters		To ensure continued protection against tetanus and diphtheria, 1 booster dose of either Td or Tdap should be administered every 10 years throughout life.

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM
For Pregnant Persons[2]
Tdap should be administered during **every** pregnancy, at 27-36 weeks' gestation, preferably during the earlier part of the third trimester. Vaccination during the third trimester provides the highest concentration of maternal antibodies to be transferred closer to birth.
Tdap can be given at any time during pregnancy if needed for catch-up or wound management.

Protocol for Tetanus Diphtheria Containing Vaccines
(Adacel®, Boostrix®, TENIVAC®, and TDVAX™)

Td or Tdap Vaccine (Adacel®, Boostrix®, Tenivac®, TDVAX™), Dose and Route – 0.5-mL, IM For Wound Management[2]				
History of absorbed tetanus toxoid doses	Clean, minor wounds		All other wounds*	
	Tdap or Td	TIG#	Tdap or Td	TIG#
Unknown or <3 doses	Yes	No	Yes	Yes
≥ 3 doses	Administer if ≥ 10 years since last dose	No	Administer if ≥ 5 years since last dose	No
*Wounds contaminated with dirt, feces, soil or saliva; puncture wounds; avulsions; or wounds from missiles, crushing, burns or frostbite. #Persons with HIV or severe immunodeficiency should receive Tetanus Immune Globulin (TIG), regardless of immunization history or wound severity.				

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range*	Thimerosal
Adacel®[3]	Tetanus, diphtheria, and acellular pertussis	Single-dose vials and prefilled syringes containing a 0.5- mL suspension for injection	10-64 years	None
Boostrix®[4]			≥10 years	
TENIVAC®[5]	Tetanus and diphtheria		≥7 years	
TDVAX™[6]		Single-dose vials containing a 0.5- mL suspension for injection		≤0.3 mcg (not as a preservative)
*Off-label use is approved by ACIP				

5. Recommendations for Use

A. Routine use: All persons ≥11 years of age who have not received a dose of Tdap should receive a single dose of Tdap at the first opportunity, regardless of when they last received a Td booster.[1]

B. Catch-up vaccination: Persons who do not have documentation of receiving a series of diphtheria/tetanus-containing vaccine in childhood need a single-dose of Tdap and two doses of either Td or Tdap vaccine.

C. Pregnant persons: No change has been made to the recommendations for routine Tdap immunization during pregnancy. Pregnant persons should receive 1 dose of Tdap during each pregnancy, irrespective of their history of receiving the vaccine. Tdap should be administered at 27–36 weeks' gestation, preferably during the earlier part of this period, although it may be administered at any time during pregnancy.

D. Wound management: Either Td or Tdap can be used for wound management. Tdap is preferred for persons who haven't previously received Tdap or whose history is unknown.[2]

6. Contraindications

A. Allergy: Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component, including latex (Adacel®, Boostrix®, Tenivac®)

Vaccine	Contains[7]
Adacel®	aluminum phosphate, formaldehyde, 2-phenoxyethanol, glutaraldehyde, tip caps of prefilled syringes may contain latex
Boostrix®	formaldehyde, aluminum hydroxide, sodium chloride, polysorbate 80, tip caps of prefilled syringes may contain latex
Tenivac®	aluminum phosphate, formaldehyde, sodium chloride, tip caps of prefilled syringes may contain latex
TDVAX™	aluminum phosphate, formaldehyde, thimerosal

B. Encephalopathy: (Tdap) Encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures) not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap. These persons should receive Td in place of Tdap.[5]

7. Warnings and Precautions

A. Neurological disorders: (Tdap) Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized; these precautions are for pertussis components.[1]

B. Guillain-Barré syndrome: Guillain-Barré syndrome <6 weeks after a previous dose of tetanus toxoid-containing vaccine.[1]

C. Arthus-type hypersensitivity: History of Arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid–containing vaccines; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid–containing vaccine.[1]

8. Other Considerations

A. Catch up schedules for 7 through 18 years of age:

i. If patients' vaccination status is unknown or incomplete, guidance for catch-up schedules can be found at https://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html

1. For children 7-9 years of age: https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-1.pdf
2. For children and adolescents 10-18 years of age: https://www.cdc.gov/vaccines/schedules/downloads/child/job-aids/tdap-2.pdf

B. History of disease:

i. Persons who have a history of pertussis should receive a booster dose of Tdap according to the routine recommendation. While pertussis disease likely confers some natural immunity, duration of protection is not long-term.[5]

ii. Tetanus or diphtheria disease does not confer immunity against re-infection. Persons who have a history of a primary series should receive a booster dose during convalescence. Persons without a history of vaccination should begin the 3-dose Tdap/Td series.[1]

C. Inadvertent administration of the incorrect formulation:[1]

i. DTaP is not indicated for persons aged ≥7 years. If DTaP is administered inadvertently to a fully vaccinated child aged 7–10 years, this dose should be counted as the adolescent Tdap dose.

ii. If DTaP is administered inadvertently to an under-vaccinated child aged 7– 10 years, this dose should count as the Tdap dose of the catch-up series, and the child should receive an adolescent booster dose of Tdap.

iii. If DTaP is administered inadvertently to a person aged ≥11 years, this dose should count as the Tdap dose, and the person should not receive an additional dose of Tdap.

iv. Children aged 7–10 years who are fully vaccinated. If Tdap is administered inadvertently, the Tdap dose should not be counted as valid. The adolescent Tdap dose should be administered as recommended when this child is aged 11–12 years.

9. Side Effects and Adverse Reactions

Tdap[3,4] Adverse Events	Frequency
Injection site pain	Very common, up to 78%
Other local reactions (redness, swelling)	Less Common, up to 21%
Fever >100. 4°F	Uncommon, up to 5%
Other systemic reactions (fatigue, headache, GI symptoms)	Common, up to 43%

Td[5,6] Adverse Events	Frequency
Injection site pain	Very common, up to 81%
Other local reactions (redness, swelling)	Less Common, up to 26%
Fever >100. 4°F	Uncommon, up to 2%
Other systemic reactions (fatigue, headache, GI symptoms)	Less Common, up to 25%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Adacel®[3] Boostrix®[4] Tenivac®[5]	Store at 2°– 8°C (36°- 46°F)	Do not freeze. Do not use if vaccine has been frozen.	
TDAVAX™[6]			No latex.

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12. Appendix

A. N/A

Protocol for Typhoid Vaccines (Typhim Vi®, Vivotif®)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of Typhim Vi® vaccine to persons ≥7 years of age if indicated **OR**

B. Dispense Vivotif® vaccine to persons ≥7 years of age if indicated and provide manufacturer's instructions and review with patient: https://vivotif.com/downloads/VIVOTIF_CLING-Z.pdf.

C. Typhoid-containing vaccines can be given with all other ACIP-recommended vaccines.

3. Vaccine Schedule

Typhoid (Typhim Vi®)[1] Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	≥ 7 years	
Booster		2 years since last dose

Typhoid (Vivotif®)[2] Dose and Route – 4 capsules, oral		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥ 7 years	
2		48 hours
3		48 hours
4		48 hours
Booster	Entire series may be repeated every 5 years, if needed	

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Typhim Vi®[1]	Salmonella Typhi Ty[2] strain: 25 mcg	Single-dose syringe, 0.5 mL Multi-dose vial, 20 Dose	≥2 years	None
Vivotif®[2]	Salmonella Typhi Ty21a: 2.0–10.0x10^9 colony-forming units Nonviable S. Typhi Ty21a: 5–50x10^9 bacterial cells	A single foil blister contains 4 doses of vaccine in a single package	≥6 years	N/A

5. Recommendations for Use

A. Immunization against typhoid fever[3] is indicated for the following groups:

a. Travelers to areas in which there is a recognized risk of exposure to S. Typhi, particularly those who will have prolonged exposure to potentially contaminated food and drink.

b. Persons with intimate exposure (e.g., continued household contact) to a documented S. Typhi carrier.

c. Microbiology laboratorians who frequently work with S. Typhi.

B. Use of Typhim Vi®:[1]

a. May be used in patients ≥7 years of age.
b. Booster doses may be given every 2 years if there is expected to be repeated or continued risk of exposure to S. Typhi.[1,3]
c. Immunization should occur at least two weeks prior to potential exposure to S. Typhi.[1]

C. Use of Vivotif®:[2]

a. May be used in patients ≥7 years of age.
b. Oral vaccines can be administered simultaneously or at any interval before or after other live vaccines (injectable or intranasal) if indicated. This includes live, attenuated yellow fever vaccine or immune globulin if indicated.[1]
c. When indicated: Oral cholera vaccine should be administered before the oral typhoid vaccine, and at least 8 hours should separate the cholera vaccine and the first dose of typhoid vaccine.[5]
d. Immunization (i.e., ingestion of all four doses) should be completed at least one week prior to potential exposure to S. Typhi.[1]
e. Instruct patient and review the following instructions:[2]
   i. Inspect blister pack to ensure that foil seal and capsule are intact.
   ii. Each capsule should be taken on an empty stomach, ≥ 2 hours after eating and at least 1 hour before the next meal. Swallow one capsule one hour before a meal with cold or lukewarm water (≤37°C or 98.6°F), on alternate days (days 1, 3, 5, 7)
   iii. Do not chew capsule.
   iv. Swallow as soon as possible after placing in mouth.
   v. Do not expose capsule to direct sunlight.
   vi. It is essential to replace unused vaccine in the refrigerator between doses.
   vii. Patient should call vaccine administrator if vaccine is taken incorrectly or mishandled.
f. Dispense vaccine with prescription label and provide client with adequate insulation for safe transport (e.g., provide sufficient ice on warm days to protect vaccine until client can get the vaccine into cold storage).
g. Re-immunization is recommended every five years for persons under conditions of repeated or continued exposure to S. Typhi.[1]

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1-2]

Vaccine	Contains[7]
Typhim Vi®	Formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, sodium chloride.
Vivotif®	Sucrose, ascorbic acid, amino acids, lactose, magnesium stearate, gelatin.

B. Vivotif®:

a. Do not give during an acute febrile illness. Postpone vaccination if persistent diarrhea or vomiting is occurring.
b. Do not use during pregnancy.[1]
c. Do not use in immunocompromised patients.[1]

d. Oral typhoid vaccine should not be given to people taking antibacterial agents, as these may inactivate the vaccine. Vivotif® should not be given until at least 3 days after the last dose of antimicrobial agent and, if possible, antimicrobial agents should not be started within 3 days of the last dose of Vivotif® vaccine. A longer interval should be considered for long-acting antimicrobials (e.g., azithromycin).[1]

7. Warnings and Precautions

A. Vivotif®: The antimalarial agents mefloquine and chloroquine and the combinations atovaquone/proguanil and pyrimethamine/sulfadoxine can, at doses used for prophylaxis, be administered together with Vivotif®; however, the manufacturer advises that other antimalarial agents only be administered ≥3 days after the last vaccine dose.[3]
When needed, administer higher doses of proguanil ≥10 days after the last dose of Vivotif®.[3]

B. Typhim Vi®:
   a. Acute or febrile illness may be reason for delaying use of this vaccine except when, in the opinion of the physician, withholding the vaccine entails a greater risk.[1]
   b. Vaccination of pregnant women should occur only if clearly needed.[1]
   c. Typhim Vi® should not be used to treat a patient with typhoid fever or a documented carrier.[3]

8. Other Considerations

A. Pregnancy: Typhim Vi® may be used during pregnancy only when clearly indicated. The manufacturer of Typhim Vi® recommends not vaccinating during the first trimester.[1]

B. Breastfeeding: Breastfeeding mothers should be vaccinated according to the recommended schedule. Administration of most live or inactivated vaccines does not affect breastfeeding, breast milk, or the process of lactation.[4]

C. Current CDC advisories should be consulted regarding areas with a risk of exposure to S. Typhi. Typhoid vaccines are 50–80% effective. Travelers should use caution in selecting food and water, even if vaccinated. Infections with drug resistant strains can be fatal.[4]

D. Typhoid vaccines will not protect against serotypes of *Salmonella* other than Typhi.[2,3]

9. Side Effects and Adverse Reactions

Typhim Vi®[1] Adverse Events	**Frequency**
Injection site reactions (pain at the injection site, redness, swelling)	Up to 97%
Systemic reactions (malaise, nausea, diarrhea)	Up to 8%
Headache	Up to 16%
Fever	Up to 3%
Vivotif®[2] Adverse Events	**Frequency**
Abdominal pain	Up to 6.5%
Nausea, diarrhea, vomiting	Up to 6%
Fever	Up to 3.3%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Protocol for Typhoid Vaccines
(Typhim Vi®, Vivotif®)

Vaccine	Temp	Storage Issues	Notes
Typhim Vi®[3]	2°to 8°C (36˚F to 46˚F)	Do not freeze	Not stable when exposed to ambient temperatures. Manufacturer expiration date is valid only if the cold chain has been maintained.
Vivotif®[2]	2° to 8°C (36˚F to 46˚F)		

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12. Appendix

A. N/A

Protocol for Varicella Containing Vaccines (ProQuad® and Varivax®)

1. What's New

A. Updated to allow intramuscular administration for Varivax® and ProQuad®.[1,2]

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM or SQ, of Varicella-containing vaccine to persons ≥7 years of age. MMRV may be used for persons 7-12 years of age.

B. May be given simultaneously with all routinely commended vaccines. Do not give simultaneously with immune globulin.

3. Vaccine Schedule

Varicella Vaccine[1] Dose and Route – 0.5-mL, IM or SQ		
Dose	**Acceptable age range**	**Minimum acceptable spacing**
1	≥ 7 years	
2		28 days*
MMRV Vaccine[2] Dose and Route – 0.5-mL, IM or SQ		
1	7-12 years	
2		3 months

* For children between the ages of 7-12 years of age, the minimal acceptable spacing between doses is 3 months. A dose inadvertently administered after at least 4 weeks may be counted as valid. At least 3 months should elapse between a dose of varicella-containing vaccine and MMRV.[2]

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Varivax®[1]	Varicella	0.5-mL single-dose vaccine vials and 0.5-mL single-dose diluent vials	≥ 7 years	No
ProQuad®[2]	MMRV		7 years-12 years	

5. Recommendations for Use[3]

A. Catch-up Vaccination: All healthy children should be routinely vaccinated with varicella-containing vaccine. A second dose of varicella-containing vaccines is recommended ≥ 3 months after dose 1.

B. Persons with immunodeficiency: Persons with impaired humoral immunity may be vaccinated. Persons receiving inhaled, nasal, or topical steroids may be vaccinated. Persons receiving systemic steroids who are not otherwise immunocompromised may receive varicella vaccine if they are receiving.

C. Children with HIV Infection: Because children infected with HIV are at increased risk for morbidity from varicella and herpes zoster compared with healthy children, ACIP recommends that, after weighing potential risks and benefits, single-antigen varicella vaccine should be considered for HIV infected children with CD4+ T-lymphocyte percentages >15%.

D. Household Contacts of Immunocompromised Persons: Children living with immunocompromised persons should be vaccinated routinely. Adults living with

immunocompromised persons should have their immunity assessed and be offered vaccination, if indicated.

E. Persons Aged ≥ 13 Years: Persons ≥ 13 years without acceptable evidence of varicella immunity should receive two doses of single-antigen varicella vaccine, 4-8 weeks apart.

F. Other Healthy Adults: All healthy adults should be assessed for varicella immunity, and those who do not have evidence of immunity should receive two doses of single-antigen varicella vaccine, 4–8 weeks apart.
Persons at increased risk of exposure, including students in post-secondary education, healthcare workers, people at occupational risk (e.g., teachers, daycare workers, corrections officers), non-pregnant women of childbearing age, international travelers, and household contacts of young children should receive special consideration for vaccination.

6. Contraindications[4]

A. Allergy: Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

Vaccine	Contains[3]
Varivax®	sucrose, hydrolyzed gelatin, sodium chloride, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, MRC-5 human diploid cells including DNA & protein, sodium phosphate monobasic, EDTA, neomycin, fetal bovine serum
ProQuad®	MRC-5 cells including DNA and protein, sucrose, hydrolyzed gelatin, sodium chloride, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, recombinant human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride, potassium phosphate dibasic, neomycin, bovine calf serum, other buffer and media ingredients

B. Pregnancy: Do not vaccinate pregnant persons with varicella or MMRV. Persons should be told to avoid pregnancy for one month after each vaccine dose. Nursing is not a contraindication to vaccination.

C. Immunodeficiency: Varicella and MMRV should not be administered to persons who have cancer, blood dyscrasias, or other malignant neoplasms affecting the blood marrow or lymphatic systems.
    a. MMRV should not be administered to persons with primary or acquired immunodeficiency, including persons with AIDS or other clinical manifestations of HIV infections.
    b. Persons with HIV who are not currently severely immunosuppressed may receive varicella vaccine. MMRV is contraindicated in persons with HIV.
    c. Persons who have a family history of congenital or hereditary immunodeficiency in first-degree relatives (e.g., parents and siblings), should not receive varicella or MMRV unless the immune competence of the potential vaccine recipient has been substantiated clinically or verified by a laboratory.
    d. Persons receiving systemic immunosuppressive therapy, including corticosteroids ≥2 mg/kg of body weight or ≥20 mg/day of prednisone (or equivalent) for persons who weigh >10 kg, when administered for ≥2 weeks, should not receive varicella or MMRV.

D. Immune Globulin (IG): Do not administer varicella or MMRV simultaneously with immune globulin.

Protocol for Varicella Containing Vaccines
(ProQuad® and Varivax®)

7. Warnings and Precautions

A. Moderate or severe illness, with or without fever.[5]

B. Antibody-containing blood products: Receipt of antibody-containing blood products (e.g., IG, whole blood, or packed red blood cells) might interfere with the serologic response to varicella vaccine for variable periods, depending on the dose of IG administered. Varicella vaccine should be administered to persons who have received an IG preparation only after the recommended intervals have elapsed.[4] See Appendix for guidance.

C. Tuberculosis testing: TB skin tests may be administered simultaneously with varicella or MMRV vaccine. If not administered simultaneously, wait 4-6 weeks after vaccination to place the TB test.[5]

D. Personal or Family History of Seizures: A personal or family (i.e., sibling or parent) history of seizures of any etiology is a precaution for the first dose of MMRV vaccine but not single-antigen varicella vaccine.[4]

A. History of thrombocytopenia or thrombocytopenic purpura: Thrombocytopenia is not a contraindication for single-antigen varicella vaccine.[4] Persons who have a history of thrombocytopenia or thrombocytopenic purpura might be at increased risk for developing clinically significant thrombocytopenia after MMRV vaccination.[4]

E. Simultaneous and non-simultaneous vaccination with live vaccines: Two or more live vaccines may be administered on the same clinic day. Live vaccines not administered simultaneously need to be separated by 28 days. If not separated by at least 28 days, the vaccine administered second needs to be repeated at least 28 days later.[4]

F. Salicylate Therapy: Avoid the use of salicylates (aspirin) or salicylate containing products in children aged 7 years to 12 years for six weeks following vaccination wit MMRV due to the association of Reye Syndrome with salicylate therapy and wild-type varicella infection.[4]

8. Other Considerations

A. Post-Exposure Prophylaxis: Single-antigen varicella vaccine may be effective in preventing illness or modifying varicella severity if administered to children within 3 days, and possibly up to 5 days, of exposure to rash.[4]

B. Evidence of Immunity:

Evidence of Immunity to Varicella[4]

• Documentation of vaccination with a live varicella-virus containing vaccine:
  o PreK: 1 dose
  o K-12: 2 doses
  o Adults: 2 doses
• Laboratory evidence of immunity;
• Laboratory confirmation of disease;
• Birth in the United States before 1980;
• Diagnosis or verification of a history of varicella disease by a health care provider;
• Diagnosis or verification of a history of herpes zoster by a health care provider.

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Varivax®[1]	
Children 7-12 years of age	
Fever ≥102°	Up to 15%
Local reactions: pain, swelling, redness, rash, itching	Up to 20%
Generalized varicella-like rash	Up to 4%
Children ≥13 years of age and adults	
Fever ≥100°	Up to 11%
Local reactions: pain, swelling, redness, rash, itching	Up to 33%
Generalized varicella-like rash	Up to 6%
ProQuad®[2]	
Children up to 3 years of age	
Fever	Up to 21%
Other systemic reactions: irritability, rash, diarrhea	Up to 6%
Injection site pain	Up to 22%
Other local reactions: swelling, redness, bruising	Up to 15%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Varivax®[1] and ProQuad®[2]	-50° to -15°C (-58° to 5°F)	Store frozen to maintain potency. Vaccine may be stored in the refrigerator for up to 72 hours before reconstitution.	Reconstituted vaccine may be stored at room temperature, protected from light, for up to 30 minutes. Do not freeze reconstituted vaccine.
Varivax®[1] and ProQuad® (diluent)[2]	2° to 25°C (36° to 77°F)	Diluent may be stored refrigerated or at room temperature.	Do not freeze.

11. References

1. Varivax® package insert. March 2020. Merck and Co. Available at: https://www.fda.gov/media/76008/download. Accessed on 5 June 2023.
2. ProQuad® package insert. Current as of April 2021. Merck and Co. Available at: https://www.fda.gov/media/147563/download. Accessed on 5 June 2023.
3. CDC. Vaccine Excipient Summary. February 2020. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 5 June 2023.
4. CDC. Prevention of Varicella: Recommendations of the ACIP. MMWR 2007; 56(4);1-48. Available at: https://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf. Accessed CDC. Accessed 5 June 2023.

5. Kroger AT, Duchin J, Vázquez M. General Best Practice Guidelines for Immunization. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 5 June 2023.

12. Appendix

A. Recommended intervals between administration of antibody-containing products and measles or varicella virus-containing vaccine, by product or indication for vaccination. Revised February 2021: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/recommended-intervals-between-administration.pdf

Protocol for Yellow Fever Vaccine (YF-VAX®)

1. What's New

A. YF-VAX® (yellow fever vaccine) is now available in the United States. As of May 6, 2021, Stamaril® is no longer available. Providers with a current Oregon Yellow Fever Vaccination Stamp may now order YF-VAX® from the manufacturer.[2]

2. Immunization Protocol

A. Administer a 0.5-mL dose, SQ, of yellow fever vaccine to persons ≥7 years of age if indicated.

B. YF-VAX®[3] may be given with all other ACIP-recommended vaccines.

C. **You must be an Oregon-certified Yellow Fever (YF) vaccine provider to administer this vaccine**. More information on Oregon's yellow fever certification can be found at: https://www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/yellfev.aspx

3. Vaccine Schedule

Yellow Fever Vaccine (YF-VAX®)[3] Dose and Route – 0.5-mL SQ		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
Booster[#]		10 years

[#]Not routinely recommended. See Recommendations for use.

4. Licensed Vaccine

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
YF-VAX®[1]	17D-204 strain of YF virus grown in chicken embryos with gelatin and sorbitol as a stabilizer	Vaccine vial, 1 Dose supplied in a package of 5 vials Diluent vial containing sodium chloride, 0.6 mL, supplied separately in a package of 5 vials Vaccine vial, 5 Dose supplied in a package of 1 vial Diluent vial, 3 mL supplied separately in a package of 1 vial	≥9 months	None

5. Recommendations for Use

A. Due to the risk of serious adverse events that can occur following YF vaccine administration, providers should carefully observe the contraindications and consider the precautions to vaccination prior to administration; and vaccinate only persons who are at risk of exposure to YF virus or who require proof of vaccination for country entry.[2]

B. YF vaccine is recommended for persons aged 7 years and older who are traveling to or living in areas at risk for yellow fever virus (YFV) transmission in Central and South America or Africa.[2]

C. Countries or areas with risk of yellow fever transmission are listed at: wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/yellow-fever-vaccine-and-malaria-prophylaxis-information-by-country. Vaccination is also recommended for travel outside the urban areas of countries that do not officially report the disease but that lie in a yellow fever-endemic zone.[2]

D. Yellow fever vaccination may be required for international travel. Some countries in Africa require evidence of YF vaccination from all entering travelers and some countries may waive the requirements for travelers arriving from areas where there is no current evidence of significant risk for contracting yellow fever and will be staying less than 2 weeks. Some countries require an individual, even if only in transit, to have a valid International Certificate of Vaccination if the individual has been in countries either known or thought to harbor yellow fever virus. The certificate becomes valid 10 days after vaccination with YF vaccine.[2]

E. Laboratory personnel who might be exposed to virulent yellow fever virus or to concentrated preparations of the yellow fever vaccine strain by direct or indirect contact or by aerosols should be vaccinated.[3]

F. Simultaneous Administration of Other Vaccines or Drugs: No evidence exists that inactivated vaccines and YF vaccine interfere with the immune response to the vaccine. Therefore, inactivated vaccines can be administered either simultaneously or at any time before or after YF vaccination. YF vaccine should be administered either simultaneously or 28 days apart from other live viral vaccines because the immune response to one live virus vaccine might be impaired if administered within 28 days of another live-virus vaccine.[6]

G. Booster Dose recommendations: As of July 11, 2016, International Health Regulations NO LONGER require revaccination at intervals of 10 years: a completed International Certificate of Vaccination or Prophylaxis is now valid for the lifetime of the vaccinee. Vaccine administrators should check national requirements.[4]

   a. High-Risk Travel: Travelers who received their last dose of yellow fever vaccine at least 10 years previously and who will be in a higher-risk setting based on season, location, activities, and duration of their travel. This would include travelers who plan to spend a prolonged period in endemic areas or those traveling to highly endemic areas such as rural West Africa during peak transmission season or an area with an ongoing outbreak.
   b. Hematopoietic stem cell transplant recipients: Persons who received a hematopoietic stem cell transplant after receiving a dose of yellow fever vaccine and who are sufficiently immunocompetent to be safely vaccinated should be revaccinated before their next travel that puts them at risk for yellow fever virus infection.
   c. HIV Infection: Persons who were infected with human immunodeficiency virus when they received their last dose of yellow fever vaccine should receive a dose every 10 years if they continue to be at risk for yellow fever virus infection.
   d. Pregnancy: Persons who were pregnant when they received their initial dose of vaccine should receive 1 additional dose before they are next at risk for YF.
   e. Laboratory workers: Individuals who routinely handle wild-type yellow fever virus should have yellow fever virus-specific neutralizing antibody titers measured at least every 10 years to determine if they should receive additional doses of the vaccine. For laboratory workers who are unable to have neutralizing antibody titers measured, yellow fever vaccine should be given every 10 years as long as they remain at risk.

6. Contraindications[1]

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
B. History of life-threatening allergic reaction to eating eggs or chicken.
C. History of thymus disorders associated with abnormal immune cell function, such as thymomas or myasthenia gravis.[3]
D. Symptomatic HIV infection.[3]
E. History of primary immunodeficiencies, malignant neoplasms, transplantation, immunosuppressive or immunomodulatory therapies. Persons receiving current or recent radiation therapy or immunosuppressive drugs.[1]
F. Postpone vaccination in case of an acute or febrile disease.[1]

Vaccine	Contains
YF-VAX®[1]	sorbitol, gelatin, sodium chloride, egg protein

7. Warnings and Precautions

WARNING

Yellow fever vaccine-associated viscerotropic disease (YEL–AVD)[1]
YEL-AVD is a severe illness similar to wild-type YF disease, with vaccine virus proliferating and disseminating throughout the host's tissues. To date, two specific risk factors for YEL-AVD have been identified: older age and a history of thymus disease or thymectomy. YEL-AVD has been reported to occur only after the first dose of YF vaccine.

Yellow fever vaccine-associated neurotropic disease (YEL–AND)[1]
YEL-AND is a serious but rarely fatal adverse event that occurs in first-time YF vaccine recipients. YEL-AND represents a conglomeration of clinical syndromes, including meningoencephalitis, Guillain-Barré syndrome, acute disseminated encephalomyelitis, and cranial nerve palsies.

Adults ≥60 years of age[1]
Age ≥60 years is a precaution to receiving YF vaccine, particularly a first-ever dose. The risks of YEL-AVD and YEL-AND are higher in this age group.

A. Avoid vaccinating breastfeeding women against YF. However, when travel of nursing mothers to YF–endemic areas cannot be avoided or postponed, these women should be vaccinated. Some experts recommend breastfeeding women who receive YF vaccine should temporarily suspend breastfeeding, pump, and discard pumped milk for at least 2 weeks after vaccination before resuming breastfeeding. Lactation is a precaution for vaccination, particularly if the breastfeeding infant is <9 months of age, because of the risk of encephalitis.[4]
B. Pregnancy is a precaution, and pregnant persons should avoid travel to a yellow fever-endemic area. If travel is unavoidable and the vaccination risks outweigh the risks of YFV exposure, pregnant persons should be excused and issued a medical waiver to fulfill health regulations. Pregnant persons who must travel to areas where YFV exposure is likely should be vaccinated.[1]

C. Persons ≥60 years of age maybe at increased risk for serious adverse events after vaccination, compared with younger persons. The rate of serious adverse events following vaccination is 1.5 times higher than the average rate for persons 60–69 years of age and 3 times higher for persons 70 years or older.
If travel is unavoidable, the decision to vaccinate travelers aged ≥60 years needs to be weighed against their destination-specific risk for exposure to YFV. Particular caution should be considered for older travelers receiving YF vaccine for the first time.[1]

D. Asymptomatic HIV infection with moderate immune suppression, i.e., CD4+ T-lymphocyte values of 200 to 499/mm^3 for persons aged ≥6 years old.[4]

8. Other Considerations

A. ACIP recommends that a woman wait 4 weeks after receiving the yellow fever vaccine before conceiving.[3]

B. Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.[5]

C. HIV-infected persons, because vaccination of asymptomatic HIV-infected persons might be less effective, measurement of their neutralizing antibody response to vaccination should be considered before travel. Contact CDC at 970-221-6400 to discuss serologic testing further.[6]

D. Allergic Reactions: less severe or localized manifestations of allergy to eggs or to feathers are not contraindications to vaccine administration and do not usually warrant vaccine skin testing.[1]

E. National YF vaccination requirements are mandatory and are primarily intended to prevent importation into and transmission of YF virus within a given country. Some countries require evidence of vaccination from all entering travelers. International Health Regulations stipulate that a Yellow Fever Stamp-Approved care provider may issue a waiver of yellow fever vaccination to a traveler, if the provider judges that yellow fever vaccination is medically contraindicated. The traveler also should be advised of the possibility that the medical waiver might not be accepted by the destination country. Failure to secure validations can cause a traveler to be quarantined, denied entry, or possibly revaccinated at the point of entry to a country.[4] Country requirements are subject to change at any time; therefore CDC encourages travelers to check with the appropriate embassy or consulate before departure. Because requirements may change, current information should be obtained from the CDC's Travelers' Health website: https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/yellow-fever-vaccine-and-malaria-prophylaxis-information-by-country.

F. All travelers to yellow fever endemic countries should be advised of the risks of the disease and available methods to prevent it, including personal protective measures and vaccine. All travelers should take precautions to avoid mosquito bites to reduce the risk of YF and other vector-borne infectious diseases. These precautions include using insect repellent, wearing permethrin-impregnated clothing, and staying in screened or air conditioned-rooms. Additional information on protection against mosquitoes and other arthropods can be found at: https://wwwnc.cdc.gov/travel/page/avoid-bug-bites

Protocol for Yellow Fever Vaccine
(YF-VAX®)

9. Side Effects and Adverse Reactions

Adverse Event	Frequency
Local injection site reactions like pain, redness, swelling, rash	Up to 71.9%
Systemic symptoms like fever, tiredness, headache, muscle pain	Up to 30%
Vaccinees over 60 years of age are at increased risk of systemic adverse events and at lower risk of local reactions.	
Yellow Fever Vaccine–Associated Neurologic Disease (YEL-AND) YEL-AND represents a conglomeration of clinical syndromes, including meningoencephalitis, Guillain-Barré syndrome, acute disseminated encephalomyelitis, and, rarely, cranial nerve palsies	0.8/100,000 doses **Age ≥ 60 years:** 2.2/100,000 doses
Yellow Fever Vaccine–Associated Viscerotropic Disease (YEL-AVD) YEL-AVD is a severe illness similar to wild-type YF disease, with vaccine virus proliferating in multiple organs and often leading to multiorgan dysfunction or failure and occasionally death	0.3/100,000 doses **Age ≥ 60 years:** 1.2/100,000 doses

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
YF-VAX®[1]	2° to 8°C (36˚F to 46˚F)	Do not use if vaccine has been frozen.	Use immediately. Reconstituted vaccine not used must be discarded after one hour. Discarded vaccine must be either sterilized or disposed in red hazardous waste containers.

11. References

1. YF-VAX® February 2019 package insert. Available at: https://www.fda.gov/media/76015/download Accessed 13 April 2023.
2. Yellow Fever. In: CDC Yellow Book 2020; Health Information for International Travel. Gershman, M, Staples, JE. Oxford University Press. June 2020. Chapter Four. Available at: https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/yellow-fever. Accessed 13 April 2023.
3. Yellow fever vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010. 59(RR07); P 1–32. Available at: www.cdc.gov/mmwr/pdf/rr/rr5907.pdf. Accessed 13 April 2023.
4. CDC. Yellow fever vaccine booster doses: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2015. MMWR 2015;64;647–50. Available at: https://www.cdc.gov/mmwr/pdf/wk/mm6423.pdf. Accessed 13 April 2023.
5. CDC. Notes from the field: Fatal yellow fever vaccine-associated viscerotropic disease–Oregon, September 2014. (2015). 64(10);279-81. Available at: https://www.cdc.gov/mmwr/pdf/wk/mm6410.pdf. Accessed 13 April 2023.
6. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP).

Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html. Updated 7 Apr 2023. Accessed 13 April 2023.

7. Yellow fever vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010. 59(RR07); P 1–32. Available at: www.cdc.gov/mmwr/pdf/rr/rr5907.pdf. Accessed 13 April 2023.
8. CDC. Transmission of yellow fever vaccine virus through breast-feeding— Brazil,2009. MMWR 2010;59(05);130-132. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/mm5905a2.htm. Accessed 21 March 2023.
9. World Health Organization. Vaccine-preventable diseases, Yellow Fever. Available at: https://www.who.int/teams/immunization-vaccines-and-biologicals/diseases/yellow-fever. Accessed 13 April 2023.

12. Appendix

A. N/A

Protocol for Zoster Vaccine (SHINGRIX®)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of zoster vaccine to persons ≥19 years of age according to age and high-risk condition.[1]

B. Zoster vaccine can be administered concomitantly, at different anatomic sites, with other adult vaccines.[2]

3. Vaccine Schedule

Shingrix®[1] Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	≥ 19* years	2 doses at 0 and 2-6 months[+]
2		

*Ages 19-49 for persons with selected immunocompromising conditions including: hematopoietic cell transplant (HCT) recipients, solid organ transplant recipients, patients with cancer, persons living with human immunodeficiency virus (HIV) and patients with autoimmune and inflammatory conditions.[2]

[+]For persons who are or will be immunodeficient or immunosuppressed and who would benefit from completing the series in a shorter period, the second dose can be administered 1–2 months after the first.[2]

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Shingrix®[1]	Varicella zoster virus	0.5-mL single- dose vials packaged with single-dose diluent	≥ 18 years	None

5. Recommendations for Use[1]

A. Recombinant Herpes Zoster Vaccine (RZV) is routinely recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged 50 years and older and does not require pre-screening for chickenpox (varicella).

B. Immunocompromised adults aged 19 years and older should receive a two-dose series of RZV.[2]

C. Persons previously vaccinated with live zoster vaccine (Zostavax) should be revaccinated with RZV. Studies evaluated safety and immunogenicity ≥ 5 years after receipt of live zoster vaccine. Per ACIP, RZV should not be given < 2 months after live zoster vaccine.

D. Persons with a history of herpes zoster should receive RZV. Patients experiencing an episode of zoster should wait to be vaccinated until the acute stage of the illness is over and symptoms have abated.

E. Persons with chronic medical conditions (e.g., diabetes mellitus, chronic renal failure, rheumatoid arthritis, and chronic pulmonary disease) should receive RZV.

F. ACIP recommends using RZV in persons taking low-dose immunosuppressive therapy (e.g., < 20 mg/day of prednisone or using inhaled or topical steroids), persons anticipating immunosuppression or people who have recovered from immunocompromising illness.

G. Persons known to VZV negative should receive varicella vaccine, not RZV. See the varicella immunization protocol for schedule information.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1]

Vaccine	Contains[3]
Shingrix®	Sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-O-desacl4'monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract Quillaja saponaria Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80, host cell protein and DNA.

7. Warnings and Precautions[1,4]

A. RZV is not a treatment for herpes zoster or postherpetic neuralgia and should not be administered during an acute episode of herpes zoster.
B. In a post marketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following RZV vaccination.

8. Other Considerations

A. Recombinant vaccines such as RZV may be given to breastfeeding women and pose no known risk to the mother or infant.[5]
B. Antiviral therapy, such as acyclovir, may be given concurrently with RZV.
C. The RZV adjuvant solution may contain up to 0.75 mL of liquid. The entire volume of the adjuvant solution should be withdrawn and used to reconstitute the lyophilized RZV vaccine. After mixing, withdraw the recommended dose of 0.5 mL. Any reconstituted vaccine left in the vial should be discarded.
D. The vaccine series does not need to be restarted if more than 6 months have elapsed since the first dose.[4]

9. Side Effects and Adverse Reactions[1]

Adverse Event	Frequency
Any local reaction—pain, redness, induration or swelling at injection site	Very common, up to 78%
Any systemic reaction—fatigue, headache, muscle ache, fever	Very common, up to 45%
Gastrointestinal	Uncommon, up to 17%
Severe (grade 3) systemic reactions—irritability, drowsiness	Uncommon, up to 2% (similar to placebo group)

*At least 17% of recipients will experience an adverse reaction that may disrupt activities of daily living and last up to 3 days.

Protocol for Zoster Vaccine
(SHINGRIX®)

10. Storage and Handling[1]

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
Shingrix®	2°to 8°C (36°to 46°F)	Protect vials from light. Do not freeze. Discard if the adjuvant suspension or antigen component has been frozen.	Discard reconstituted vaccine if not used within 6 hours.

11. References

1. Shingrix®. [Package insert]. May 2023. Available at: www.fda.gov/media/108597/download. Accessed 21 July 2023.
2. Centers for Disease Control and Prevention. (2022, January 20). Clinical considerations for use of recombinant zoster vaccine (RZV, Shingrix) in immunocompromised adults aged ≥19 years. https://www.cdc.gov/shingles/vaccination/immunocompromised-adults.html Accessed 21 July 2023
3. Vaccine Excipient Summary. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf Accessed 21 July 2023
4. Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for use of herpes zoster vaccines. MMWR 2018;67:103–8. Available at: www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6703a5-H.pdf. Accessed 21 July 2023
5. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). ACIP General Best Practice Guidelines for Immunization | CDC Accessed 21 July 2023

12. Appendix

A. N/A

Division 041: Drug Outlet Pharmacies (RP/IP Alignment with Divisions 102/104/115/120/125)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Drug Outlet Pharmacy requirements

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed new rules and proposed amendments for Division 041 include general requirements for an outlet and requirements for personnel, drug procurement, out of state pharmacies, prescription requirements, prescription validity, operating a laboratory and prescription transfer requirements for Drug Outlet pharmacies.

Documents Relied Upon per ORS 183.335(2)(b)(D): Institute for Safe Medication Practices. Despite Technology, Verbal Orders Persist, Read Back is Not Widespread, and Errors Continue. May 2017. Accessed September 29, 2023. https://www.ismp.org/resources/despite-technology-verbal-orders-persist-read-back-not-widespread-and-errors-continue

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): The proposed amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): Proposed amendments may financially impact out-of-state pharmacies if the Drug Outlet Pharmacy does not currently require the Oregon licensed PIC to be physically present in the pharmacy on a regular basis to ensure compliance. A Drug Outlet may be faced with ceasing dispensing, delivering or distributing drugs into Oregon immediately if they do not have a PIC. An out-of-state pharmacy may need to employ an additional Oregon licensed Pharmacist in order to ensure the outlet does not have to cease dispensing, delivering or distributing drugs into Oregon. When the board sends the proposed rules to a rulemaking hearing, licensees, registrants and stakeholders will have an opportunity to provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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).
(1) The proposed rule amendments have no additional economic impact on state agencies, units of local government, or the public.
(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.
(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.
(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No a RAC was not convened. Why? The resources involved in convening a RAC were not necessary to amend/develop these rules. Board members represent the interests of persons and communities likely to be affected by the proposed rules and were able to provide information necessary to amend the rules. The board believes that it is necessary for all pharmacies that serve Oregon residents to adhere to Oregon pharmacy laws and employs a PIC at all times, whether in-state or out-of-state.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):
OAR 855-041-1010 – Amends rule by adding Pharmacist in Charge personnel requirements for a Drug Outlet.

OAR 855-041-1018- Proposed amendments include adding rule references, compliance requirements for dispensing drugs including controlled substances, compounded preparations and radiopharmaceutical, adds licensed and non-licensed personnel requirements, and adds that drug outlet written procedures are to be established and maintained.

OAR 855-041-1019 – Adds new rule for drug procurement requirements for a Drug Outlet.

OAR 855-041-1060 – Amends rule by modifying PIC requirements for out of state pharmacies that dispense, deliver or distribute drugs into Oregon. Changes term "non-resident" to "out-of-state." Removes requirement for outlet to be in "good standing" in state where pharmacy is physically located. Removes four-month window to designate PIC upon initial registration and 90 day window for change in PIC. Requires pharmacies to follow Oregon standards for practice of pharmacy in OAR 855-115.

OAR 855-041-1105 – Amends rule by adding dispensing requirements for a Drug Outlet and relocates and revises existing language from OAR 855-019-0210(4)-(7) pertaining to required information for a prescription. Requires Pharmacist to clarify discrepancies or uncertainties regarding a prescription. Requires read back of an oral prescription. Clarifies prescriber authority to request no substitution for the manufacturer of a drug.

OAR 855-041-1115 – Amends rule by revising and relocating OAR 855-019-0210(2), and adding prescription validity requirements prior to dispensing for a Drug Outlet.

OAR 855-041-1190 – Adds new rule related to requirements for operating a laboratory in a Drug Outlet pharmacy.

OAR 855-041-2115 – Amends rule by adding requirements for prescription transfers, relocates and revises existing language from OAR 855-019-0210(8).

Highlights:

- Blue- minor corrections

Division 41
OPERATION OF PHARMACIES

855-041-1010
Outlet (~~RP & IP~~ **Both Retail and Institutional Drug Outlets**): Personnel

Each Drug Outlet Pharmacy must:

(1) At all times have one Pharmacist-in-Charge (PIC) who is normally present in the pharmacy on a regular basis for a sufficient amount of time as needed to ensure Drug Outlet Pharmacy compliance.

(2) Ensure the PIC is qualified per OAR 855-115-0205 and complies with OAR 855-115-0210.

(3) Report a change in PIC within 15 days of occurrence in the registrant's electronic licensing record with the board.

(4) Report terminating or allowing a board licensee to resign in lieu of termination to the board within 10 working days. The report must include the name of licensee, license number, the date, and the reason for the termination.

(5) Provide a working environment that protects the health, safety and welfare of a patient which includes but not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

(c) Adequate time for a Pharmacist to complete professional duties and responsibilities as specified in OAR 855-115;

(d) Ensure there is sufficient staff to provide services in a safe manner. The outlet must abide by the Pharmacist-on-duty's decision to temporarily shut down a service or services and must respond substantively to a Pharmacist who has identified staffing concerns.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.305

855-041-1018
Outlet: General Requirements

A Drug Outlet Pharmacy must:

(1) Ensure each:

(a) Prescription is dispensed in compliance with OAR 855-041, OAR 855-115, OAR 855-120, OAR 855-125, OAR 855-139, OAR 855-141 and OAR 855-143;

(b) Controlled substance is dispensed in compliance with OAR 855-080;
(c) Compounded preparation is dispensed in compliance with OAR 855-045; and

(d) Radiopharmaceutical is dispensed in compliance with OAR 855-042.

(2) Comply with all applicable federal and state laws and rules;

(3) Ensure all licensees are trained to appropriately perform their duties prior to engaging or assisting in the practice of pharmacy.

(4) Ensure each licensed and non-licensed individual only perform duties they are licensed and trained to perform.

(5) Be responsible for the actions of each licensed and non-licensed individual.

(6) Establish, maintain and enforce the drug outlet written procedures required in OAR 855-041-1040.

(7) Comply with the Pharmacist's determination in OAR 855-115-0120(1)(k);

(8) Develop, implement and enforce a continuous quality improvement program for dispensing services from a Drug Outlet Pharmacy designed to objectively and systematically:

(a) Monitor, evaluate, document the quality and appropriateness of patient care;

(b) Improve patient care; and

(c) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

855-041-1019
Drug: Procurement

A Drug Outlet Pharmacy may only receive drugs from an Oregon Registered Drug Outlet (i.e. Wholesaler, Manufacturer or Pharmacy).

Statutory/Other Authority: ORS 475.035 & ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-1060
Out-of-State Pharmacies

(1) An “out-of-state pharmacy” is any establishment located outside of Oregon that engages in the dispensing, delivery or distribution of drugs into Oregon.
(2) Every out-of-state pharmacy that provides drugs, devices or services to a person in Oregon must be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every out-of-state pharmacy must be registered with the Board of Pharmacy in the state where the pharmacy is physically located.

(4) Every out-of-state pharmacy must have, at all times when dispensing, delivering or distributing drugs into Oregon, an Oregon licensed PIC, who is physically present in the pharmacy on a regular basis for a sufficient amount of time as needed to ensure Drug Outlet pharmacy compliance and is responsible for ensuring compliance with all applicable Oregon laws and rules when dispensing, delivering or distributing drugs into Oregon. To qualify for this designation, the individual must:

(a) Hold a license to practice pharmacy in the state where the pharmacy is physically located;

(b) Comply with the PIC qualifications and limitations in OAR 855-115-0205; and

(c) Comply with the PIC requirements in OAR 855-115-0210(1)(a-h) and (2).

(5) An out-of-state pharmacy must cease drug dispensing, delivery, distribution and provision of pharmacy services into Oregon while there is not an Oregon licensed PIC.

(6) Each out-of-state pharmacy must ensure each prescription that is dispensed, delivered or distributed into Oregon complies with the standards for the practice of pharmacy in OAR 855-115.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.225

855-041-1105
Prescriptions: General Requirements

Each Drug Outlet Pharmacy must ensure that:

(1) Prescriptions, prescription refills, and drug orders are dispensed:

(a) Accurately;

(b) To the correct party;

(c) Pursuant to a valid prescription;

(d) Pursuant to a valid patient-practitioner relationship;

(e) For a legitimate medical purpose; and

(f) In accordance with the prescribing practitioner's authorization.

(2) The following information is required for each new or refilled prescription drug or device:

(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal. If for an animal, the name of the patient, name of the owner and the species of the animal;

(b) The full name~~, address,~~ and contact phone number **of the practitioner** and, in the case of controlled substances, the address and the Drug Enforcement Administration registration number of the practitioner;

(c) The name, strength, dosage form of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

(d) The directions for use;

(e) The date of issuance and, if different from the date of issuance, the date of filling;

(f) The total number of refills authorized by the prescribing practitioner;

(g) A valid signature:

(A) For non-controlled substances:

(i) Received by the pharmacy via a hard-copy written prescription, the prescribing practitioner or practitioner's agent manual signature.

(ii) Received by the pharmacy via facsimile, the prescribing practitioner or practitioner's agent manual or electronic signature.

(iii) Received by the pharmacy electronically, the prescribing practitioner's or practitioner's agent electronic signature.

(B) For controlled substances:

(i) Received by the pharmacy via hard-copy written prescription, the prescription must have an original manually-signed signature from the prescribing practitioner.

(ii) Received by the pharmacy via facsimile, the prescription must have an original manually-signed signature from the prescribing practitioner.

(iii) Received by the pharmacy electronically, the prescribing practitioner's digital signature that complies with the rules adopted by reference in OAR 855-080.

(C) In (g), manually-signed specifically excludes a signature stamp or any form of electronic or digital signature unless permitted under federal regulations; and

(h) Any other information required for controlled substances pursuant to federal regulations.

(3) If there are any discrepancies or uncertainties regarding the prescription, the Pharmacist promptly seek clarification from the prescribing practitioner or the practitioner's agent.

(4) An oral prescription must:

(a) Be promptly reduced to writing or entered into an electronic record system and must include:

(A) The name, initials or electronic identifier of the licensee receiving the prescription;

(B) The name of the person transmitting the prescription; and

(b) After the prescription has been transcribed, the licensee must verify accuracy by:

(i) Reading back the prescription as transcribed to the person transmitting it; or

(ii) Listening to the voicemail a second time; and

(c) The confirmation of accuracy in (b) must be documented on the prescription.

(5) The prescription originated from an authorized practitioner or practitioner's agent;

(6) The prescription contains all of the information specified in (2) and for controlled substances in OAR 855-080-0085.

(7) In accordance with ORS 689.515(3) and ORS 689.522, the pharmacy dispenses the prescription pursuant to the prescribing practitioner's request that there may be no substitution for the specified brand name or manufacturer of a drug.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, instruction may use any one of the following phrases or notations:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words with similar meaning.

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent must clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or

words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

(c) Such instructions must not be default values on the prescription.
(7) The written or electronic record of each prescription must be retained on file as required by OAR 855-041-1160, and in the case of controlled substances, under rules adopted by reference in OAR 855-080.

Statutory/Other Authority: ORS 689.205, ORS 689.522
Statutes/Other Implemented: ORS 689.505, 689.515, ORS 689.522

855-041-1115
Prescription Validity

Each Drug Outlet Pharmacy must ensure that:

(1) Prior to dispensing a prescription, a Pharmacist has verified its validity. In order for a prescription drug to be valid it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of ~~his or her~~ **their** professional practice. The responsibility for the proper prescribing of the prescription drug is upon the prescribing practitioner, and a corresponding responsibility rests with the pharmacist who dispenses the prescription.

(2) A prescription is considered not valid if:

(a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it;

(b) The prescription does not contain the required information as provided in OAR 855-041-1105;

(c) The prescription is expired per OAR 855-041-1125; or

(d) The prescription is for a controlled substance and does not comply with the requirements of OAR 855-080-0085.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.508

855-041-1190
Operation of a Laboratory in Drug Outlet Pharmacy

(1) A Drug Outlet pharmacy may perform a laboratory test when:

(a) The Drug Outlet pharmacy possesses a valid laboratory license, including a certificate of a 42 CFR 493.35 waiver;

(b) The laboratory test is permitted under the laboratory license; and
(c) Requested by a physician, dentist, pharmacist or other person authorized by law to use the findings of laboratory examinations or without a practitioner order as permitted in ORS 438.010, ORS 438.030, ORS 438.040, ORS 438.050, ORS 438.055, ORS 438.060, ORS 438.070, ORS 438.110, ORS 438.120, ORS 438.130, ORS 438.140, ORS 438.150, ORS 438.160, ORS 438.210, ORS 438.220, ORS 438.310, ORS 438.320, ORS 438.420, ORS 438.430, ORS 438.435, ORS 438.440, ORS 438.450, 438.510.

(2) The Drug Outlet pharmacy must:

(a) Display the laboratory license in a prominent place in view of the public; and

(b) Report, to the local health department or state, reportable conditions as required in OAR 333-018.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.661

855-041-2115
Prescription: Transfers

(1) Prescriptions may be transferred between pharmacies for the purpose of an initial or refill dispensing provided that:

(a) The prescription is invalidated at the sending pharmacy; and

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.

(2) Prescriptions for controlled substances can only be transferred one time unless otherwise permitted or forbidden by federal regulation.

(3) A pharmacy that transmits or receives prescription information to or from another pharmacy electronically must ensure as appropriate:

(a) The accurate transfer of prescription information between pharmacies;

(b) The creation of an original prescription or image of an original prescription containing all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability and that the pharmacist will use in verifying the prescription;

(c) The prescription is invalidated at the sending pharmacy; and

(d) For controlled substances, complies with the rules adopted by reference in OAR 855-080.

(4) An Oregon registered pharmacy must transfer a prescription:

(a) To a pharmacy requesting a transfer on behalf of the patient or patient's agent unless the transfer would compromise patient safety or violate state or federal laws or rules; and
(b) By the end of the next business day of the request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

Division 080: Controlled Substances (Changes to a Schedule II Prescription)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Changes a Pharmacist may make to a Schedule II Prescription

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments add items that a Pharmacist may change on a Schedule II prescription.

Documents Relied Upon per ORS 183.335(2)(b)(D): Drug Enforcement Administration (DEA) Frequently Asked Questions- What changes can be made to a schedule II paper prescription? Current 9/6/2023; Historical 8/19/2003, 7/30/2009, 10/3/2014

Other state regulations: IA Rule 657-10.30, IL Rule 3100.400

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule amendment is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule amendments have no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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).
(1) The proposed rule amendments have no additional economic impact on state agencies, units of local government, or the public.
(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.
(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.
(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not consulted. Why? The board did not direct staff to convene a Rules Advisory Committee or Workgroup to advise on the proposed rule amendments. Board members represent the interests of persons and communities likely to be affected by a proposed rule. Overall, board members are licensees of the Oregon Board of Pharmacy or public members who represent Oregon patients.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):
OAR 855-080-0085: Permits a Pharmacist to add the patient's address with appropriate verification to the schedule II prescription. Permits a Pharmacist to add the drug strength, dosage form, drug quantity, directions for use, prescriber's address, and prescriber's DEA registration number and to amend or correct the date the prescription was issued and the date the prescription can be filled after consultation and agreement of the prescriber to a schedule II prescription. Requires documentation of amendments or additions. Prohibits changing the patient's name, controlled substance prescribed (except for generic substitution) and the name or signature of the prescriber.

Division 080
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0085
Prescription Requirements

(1) Registrants, practitioners and Pharmacists as specified therein in the issuance, preparation, labeling, dispensing, recordkeeping and filing of prescriptions for controlled substances must comply with the provisions of 21 CFR 1306.01 (04/01/2022), 21 CFR 1306.02 (04/01/2022), 21 CFR 1306.03 (04/01/2022), 21 CFR 1306.04 (04/01/2022), 21 CFR 1306.05 (04/01/2022), 21 CFR 1306.06 (04/01/2022), 21 CFR 1306.07 (04/01/2022), 21 CFR 1306.08 (04/01/2022), 21 CFR 1306.09 (04/01/2022); 21 CFR 1306.11 (04/01/2022), 21 CFR 1306.12 (04/01/2022), 21 CFR 1306.13 (04/01/2022), 21 CFR 1306.14 (04/01/2022), 21 CFR 1306.15 (04/01/2022); 21 CFR 1306.21 (04/01/2022), 21 CFR 1306.22 (04/01/2022); 21 CFR 1306.23 (04/01/2022), 21 CFR 1306.24 (04/01/2022), 21 CFR 1306.25 (04/01/2022), 21 CFR 1306.27 (04/01/2022); and 21 CFR 1304.03(d) (04/01/2022).

(2) Controlled substances listed in 21 CFR 1308.15 (04/01/2022) as schedule V are prescription drugs.

(3) Pseudoephedrine and ephedrine may be:

(a) Provided to a patient without a prescription under ORS 475.230.

(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/2022), 21 CFR 1306.22 (04/01/2022); 21 CFR 1306.23 (04/01/2022), 21 CFR 1306.24 (04/01/2022), 21 CFR 1306.25 (04/01/2022), and 21 CFR 1306.27 (04/01/2022).

(4) For a Schedule II controlled substance prescription, a Pharmacist may:

(a) Add the patient's address based on information provided by the patient or patient's agent with appropriate verification;

(b) Amend or add the following information after consultation with and agreement of the prescriber:

(A) Drug strength;

(B) Dosage form;

(C) Drug quantity;

(D) Directions for use;

(E) Prescriber's address; and

(F) Prescriber’s DEA registration number.

(c) Amend the following information after consultation with and agreement of the prescriber, the:

(A) Date the prescription was issued; and

(B) Date the prescription can be filled.

(d) For (b) and (c), the Pharmacist must document on the prescription the date and time of the prescriber’s authorization, the amendment or addition authorized, and the Pharmacist’s identity.

(5) For a Schedule II controlled substance prescription, a Pharmacist must not change the patient's name, the controlled substance prescribed except for generic substitution, and the name or signature of the prescriber.

[Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.185 & ORS 475.188

Divisions 115/125: Vaccinations (RPH, COPT/PT Administration)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Pharmacist, Certified Oregon Pharmacy Technician and Pharmacy Technician Administration of Vaccines

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Beginning 1/1/2024, proposed rule amendments will permit a Pharmacist to administer an influenza vaccine to persons who are six months of age or older pursuant to 2023 HB 2278 and permit a Certified Oregon Pharmacy Technician (COPT) or Pharmacy Technician (PT) to administer a vaccine under the supervision of a Pharmacist pursuant to 2023 HB 2486.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 HB 2278, 2023 HB 2486

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Part of the proposed rules may favorably impact racial equity making it easier for Black, Indigenous, people of color, and American Indian/Alaska Native people (BIPOC-AI/AN) to access vaccines in a pharmacy. Permitting pharmacists to administer influenza vaccine to patients aged 6 months and older and pharmacy technicians to administer vaccines may contribute to closing disparities in vaccination rates between white persons and BIPOC-AI/AN. Pharmacies are often located in communities where BIPOC-AI/AN live and are more accessible than other healthcare settings. Pharmacists and pharmacy technicians are also trained to provide culturally competent care.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rules have no anticipated fiscal and economic impact as the rules do not require a Pharmacist, COPT or PT to provide vaccinations.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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).
(1) The proposed rules will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule amendments apply to pharmacy registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not convened. Why? The board did not direct staff to convene a Rules Advisory Committee or Workgroup to advise on the proposed rule amendments. Recent legislation informed the proposed rule amendments. Pursuant to 2023 HB 2278, proposed amendments will permit a Pharmacist to administer an influenza vaccine to persons who are six months of age or older. Pursuant to 2023 HB 2486, proposed amendments will permit a Certified Oregon Pharmacy Technician (COPT) or Pharmacy Technician (PT) to administer a vaccine under the supervision of a Pharmacist.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Due to recently adopted legislation, 2023 HB 2486 and 2023 HB 2278 related to immunizations, it is necessary to amend and adopt rules for Pharmacists, COPTs and PTs, Drug Outlet Pharmacies and Remote Dispensing Site Pharmacies to comply with the directives of the legislation.

OAR 855-115-0305: Revises and relocates OAR 855-019-0270, OAR 855-019-0280 and OAR 855-019-0290. Adds administration requirements for Pharmacists who provide administration of a drug, device or vaccine and/or supervise an Intern, COPT or PT in the administration of a vaccine, including training, verification and documentation requirements.

OAR 855-125-0305: Permits an appropriately trained and qualified COPT and PT to perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist pursuant to 2023 HB 2486 beginning 1/1/2024, adds training and certification requirements prior to administering vaccines, adds documentation requirements, adds notification and record retention requirements.

Division 115
PHARMACISTS

855-115-0305
Services: Administration of Vaccines, Drugs, or Devices

(1) In accordance with ORS 689.645 and ORS 689.655, a Pharmacist may administer a vaccine, drug or device as specified in this rule. The Pharmacist must be acting:

(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice; or

(b) In accordance with a statewide drug therapy management protocol per OAR 855-115-0345; or

(c) In accordance with a clinical pharmacy agreement or collaborative drug therapy management agreement per OAR 855-115-0315.

(2) A Pharmacist who administers a vaccine, drug or device must:

(a) Prior to administration of an injectable drug or device, receive practical training on the injection site and administration technique that is utilized. For orally administered drugs, training is not required.

(b) Hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that is specific to the age and population receiving the vaccine, drug or device, contains a hands-on training component, and is valid for not more than three years. The most current CPR certification record must be retained according to OAR 855-104-0055;

(c) Ensure that any drug administered to a patient was stored in accordance with the drug storage rules for pharmacies in ORS 855-041-1036;

(d) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the vaccine, drug or device;

(e) Ensure that vaccine, drug or device administration is documented in the patient's permanent record; and

(f) Ensure records and documents are retained according to OAR 855-104-0055. Records of administration must include but are not limited to:

(A) Patient identifier;

(B) Vaccine, drug or device and strength;

(C) Route and site of administration;

(D) Date and time of administration; and

(E) Pharmacist identifier.

(3) For vaccines only, the requirements in (2) and the following apply, and the Pharmacist who administers or supervises each administration of a vaccine to a patient must:

(a) Complete training that includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. The training may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college or school of pharmacy, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board; and

(b) Make vaccine recommendations;

(c) Select each vaccine to be administered;

(d) Ensure compliance with (1);

(e) Ensure the appropriate Vaccine Information Statement (VIS) is provided to the patient or patient's agent prior to each dose of vaccine.

(f) Perform verification prior to administration that includes but is not limited to:

(A) Prescription order accuracy verification; and

(B) Vaccine product accuracy review;

(g) Advise or counsel on therapeutic values, content, hazards and use of each vaccine;

(h) Manage adverse events;

(i) Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient;

(j) Verify accuracy and completeness of documentation for vaccine administration;

(k) Ensure all persons administering vaccines under their supervision are appropriately trained and qualified;

(l) Follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022); and

(m) Have access to a current edition of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);

(5) The Pharmacist may administer a drug or device in conjunction with training the patient or the patient's agent on how to administer or self-administer the drug or device.

(6) Records and documents must be retained according to OAR 855-104-0055.

(7) An appropriately trained and qualified Pharmacist may permit an appropriately trained and qualified:

(a) Intern to perform the same duties as a Pharmacist except as prohibited in OAR 855-120-0150.

(b) Certified Oregon Pharmacy Technician or Pharmacy Technician to conduct the physical act of administering a vaccine in accordance with OAR 855-125-0305.

(8) The appropriately trained and qualified Pharmacist who is supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician in administering a vaccine must be immediately available to the vaccinator to respond in the case of an adverse reaction and any other issue that may arise.

Statutory/Other Authority: ORS 689.205, 2023 HB 2486, 2023 HB 2278
Statutes/Other Implemented: ORS 689.655, 2023 HB 2486, 2023 HB 2278

Division 125
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-125-0305

Services: Vaccine Administration

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist:

(a) To a person who is seven years of age or older;

(b) To a person who is at least three years of age when;

(A) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or

(B) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.

(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician must:

(a) Prior to administration of a vaccine, receive practical training that includes infection control, recognition of anatomical landmarks and competency in hands-on administration technique.

(b) Prior to administration of a vaccine, hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program that is specific to the age and population receiving the vaccine, contains a hands-on training component, and is valid for not more than three years.

(3) Document the vaccine administration including but not limited to the vaccine administered, dose, expiration date, lot number, and injection site.

(4) Notify the supervising Pharmacist immediately in the event of a suspected adverse reaction to a vaccine.

(5) The training required in (2) may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college or school of pharmacy or state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board.

(6) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.

Statutory/Other Authority: ORS 689.205, 2023 HB 2486

Statutes/Other Implemented: ORS 689.151, 2023 HB 2486

Division 115: Pharmacists (Applicability, Definitions, Supervision, Counseling, PIC Qualifications & Limitations, CPA & CDTM)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Pharmacists; Applicability, Definitions, Supervision, Counseling, PIC Qualifications & Limitations, CPA & CDTM

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule):

855-115-0001 Applicability - Proposed rule adds new language related to applicability. Relocates and revises OAR 855-019-0001 related to applicability. Removes waiver authority and reference to Interns.

855-115-0005 Definitions - Relocates and reorganizes existing rules from Division 006 and 019 related to definitions of CPA, CDTM, Counseling and DUR. Board staff are reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

855-115-0122 - Adds proposed new rule to clarify required ratios for supervision of Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians. For direct patient care activities, rule allows a pharmacist to supervise up to 4 interns regardless of learning setting (e.g., school rotation or paid experience). For non-direct patient care activities, rule allows a pharmacist to supervise as many Interns they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare.

855-115-0145 Counseling - Relocates and reorganizes existing pharmacist rules from Division 019 related to counseling. Board staff are reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

855-115-0205 PIC: Qualifications and Limitations - In August 2023, the board adopted OAR 855-115-0200 effective 3/1/2024. The new rule that was adopted in August 2023 does not currently include requirements for a PIC between the effective date of the rule, 3/1/2024, and 7/1/2025. The current rule adopted also does not include limitations for a PIC. Proposed rule amendments add PIC qualification and limitation requirements. Having these requirements for a PIC will ensure public protection.

855-115-0315 Services: Clinical Pharmacy Agreement & Collaborative Drug Therapy Management - Relocates and revises existing CDTM rules from Division 019 into Division 115. Adds rules for CPA to Division 115.

Documents Relied Upon per ORS 183.335(2)(b)(D):

855-115-0001 Applicability- OBOP 2022-2026 Strategic Plan
https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

855-115-0005 Definitions - OBOP 2022-2026 Strategic Plan
https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

855-115-0122 Responsibilities: Supervision - OAR 855-120-1122 Responsibilities: Supervision - Preceptor, effective 3/1/2024 https://www.oregon.gov/pharmacy/Documents/Div_115_Pharmacists_BP_16-2023TrackedChanges.pdf, OBOP 2022-2026 Strategic Plan
https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

855-115-0145 Counseling - OBOP 2022-2026 Strategic Plan
https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

855-115-0205 PIC: Qualifications and Limitations - OAR 855-115-0200, effective 3/1/2024 (pg. 21)
https://www.oregon.gov/pharmacy/Documents/Div_115_Pharmacists_BP_16-2023TrackedChanges.pdf

OBOP 2022-2026 Strategic Plan
https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

855-115-0315 Services: CPA & CDTM – 5/4/2023 CDTM - CPA Workgroup Meeting Minutes
https://www.oregon.gov/pharmacy/Documents/May_CDTM_CPA_Workgroup_Meeting_Minutes.pdf

OBOP 2022-2026 Strategic Plan
https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) 855-115-0001 Applicability, 855-115-0005 Definitions , 855-115-0122 Responsibilities: Supervision, 855-115-0145 Counseling, 855-115-0205 PIC: Qualifications and Limitations and 855-115-0315 Services: CPA & CDTM – The proposed rules are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E):

855-115-0001 Applicability – Pharmacists who are not working for a drug outlet and not included in the exemption would be required to obtain licensure in Oregon which depending on the method of licensure (e.g., reciprocity, score transfer, examination) costs between $346.25 – $396.25 (including fees) initially. In addition, pharmacists may need to pay an application fee to apply to transfer the North American Pharmacist Licensure Examination ($85-$185 per exam) score and/or pay an application fee ($100 per exam) and take the Oregon Multistate Pharmacy Jurisprudence Examination ($200). If the pharmacist chooses to renew their license, the biannual fee costs between $324-374.

855-115-0005 Definitions - No anticipated fiscal and economic impact.

855-115-0122 Responsibilities: Supervision - Rule clarifies number of pharmacy Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians that can safely be supervised by a pharmacist. These licensees may increase the efficiency of a pharmacist by allowing them to direct their efforts to professional activities, therefore may positively impact an organizations bottom line.

855-115-0145 Counseling – An offer for the pharmacist to counsel must be made by a licensee. Pharmacies that utilize non-licensed personnel (i.e., clerks) may experience an increase in labor costs to ensure compliance with the rule. Per indeed.com, on average an Oregon Pharmacy clerk base salary is $18.39/hr, Pharmacy Technician $24.97/hr and Certified Pharmacy Technician $29.96/hr. Acceptance of declination of counseling by a non-Pharmacist licensee may result in a decrease in labor costs. Per indeed.com, on average an Oregon Pharmacist base salary is $63.07/hr.

855-115-0205 PIC: Qualifications and Limitations – Rule requires PIC to be an employee of the Drug Outlet. There may be an additional cost or savings to the Drug Outlet when employing a PIC instead of

contracting with a PIC who is not an employee. These costs or savings are uncertain as this information is not currently available.

855-115-0315 Services: CPA & CDTM - No anticipated fiscal and economic impact.

Licensees, registrants and stakeholders may provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): (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).

855-115-0001 Applicability, 855-115-0005 Definitions, 855-115-0122 Responsibilities, 855-115-0145 Counseling, 855-115-0205 PIC: Qualifications and Limitations, and 855-115-0315 Services: CPA and CDTM:

(1) The proposed new rule has no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy.

Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on

small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): 855-115-0001 Applicability, 855-115-0005 Definitions, 855-115-0122 Responsibilities: Supervision, 855-115-0145 Counseling, and 855-1115-0205 PIC: Qualifications and Limitations - No. The board did not direct staff to convene a RAC or Workgroup to advise on the proposed rules. Board members represent the interests of persons and communities likely to be affected by the proposed rules and were able to provide expertise when drafting the proposed rules.

855-115-0315 Services: CPA & CDTM - No. The board directed staff to convene a CDTM – CPA Workgroup consisting of Subject Matter Experts with expertise related to CDTMs/CPAs to assist with the development of proposed rules/amendments. The CDTM/CPA workgroup held a meeting on 5/4/2023 and reviewed and provided input on all proposed rules/amendments related to CDTM and CPAs. The board reviewed and discussed the proposed rules at the October 2023 board meeting. Board members represent the interests of persons and communities likely to be affected by a proposed rule. Overall, board members are licensees of the Oregon Board of Pharmacy or public members who represent Oregon.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-115-0001: Proposed new rule relocates and revises existing rule language from OAR 855-019-0100 to OAR 855-115-0001 related to applicability. Removes provision for Interns that is now included in OAR 855-120-0135 and removes board waiver of rule. Clarifies which pharmacists working for out-of-state must be licensed by the board.

OAR 855-115-0005: : Rule relocates and revises existing definitions from OAR 855-006-0005, OAR 855-019-0110, OAR 855-019-0260 to OAR 855-115-0005 related to definitions.

OAR 855-115-0122: : New rule that applies to all Pharmacists and aligns with previously adopted rule in OAR 855-120-1122 Responsibilities: Supervision- Preceptor. Permits a Pharmacist to supervise up to four Interns for direct patient care activities and supervise a suitable number for non-direct care activities. Clarifies in rule that the limit for supervision, direction and control of a COPT/PT is as determined by Pharmacist.

OAR 855-115-0145: Proposed rule relocates and revises existing rule from OAR 855-019-0230 to OAR 855-115-0145 related to counseling. Clarifies circumstances that require a Pharmacist to provide counseling, removes reference to Intern provided counseling that is now included in OAR 855-120-0135, introduces provisions for written counseling, requires supplemental information when required by federal law, permits any board licensee to offer for a pharmacist to provide counseling or accept declination of offer for pharmacist counseling and adds requirements for documentation of the licensees identity for counseling, attempts to counsel or declination of counseling.

OAR 855-115-0205: Proposed new rule adds PIC qualifications and limitations currently in rule from OAR 855-019-0300 to be effective 3/1/2024 to 6/30/2025. Utilizes PIC qualifications adopted by the board in OAR 855-115-0200 and adds limitations currently in rule from OAR 855-019-0300 effective 7/1/2025. Adds additional requirement that PIC must be employed by the outlet.

OAR 855-115-0315: Adds requirements for Pharmacists who provide Clinical Pharmacy Agreement services under a written protocol and modifies requirements from OAR 855-019-0260 for Pharmacists who provide Collaborative Drug Therapy Management services under a written protocol; relocates and revises existing language from OAR 855-019-0260. Requires protocol version to be documented.

Division 115
PHARMACISTS

855-115-0001
Applicability

(1) This Division applies to any Pharmacist who engages in the practice of pharmacy.

(2) Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance with statutes and rules unless exempt under ORS 689.225.

(3) A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the board in accordance with the following rules, except that a pharmacist located in another state who is working for an out-of-state registered Drug Outlet Pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification is not required to be licensed by the board unless they are the Pharmacist-in-charge (PIC). This exception applies only when a pharmacist is dispensing, delivering or distributing drugs into Oregon from a registered drug outlet. A pharmacist who is providing other pharmacy services into Oregon must be licensed in Oregon.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.255

855-115-0005
Definitions

(1) “Clinical Pharmacy Agreement” means an agreement between a Pharmacist or pharmacy and a health care organization, or a Physician as defined in ORS 677.010 or a Naturopathic Physician as defined in ORS 685.010 that permits the Pharmacist to engage in the practice of clinical pharmacy as defined in ORS 689.005 for the benefit of the patients of the health care organization, or Physician or Naturopathic Physician.

(2) "Collaborative Drug Therapy Management" means the process in which a Pharmacist or pharmacy and a health care provider or group of health care providers agree to a pre-specified drug therapy management protocol that is initiated for an individual patient on the prescription or prescription drug order of a participating provider.

(3) "Counseling" or “Counsel” means an oral, electronic or written communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

(4) "Drug utilization review" or "DUR" means evaluation of a prescription to identify and resolve potential problems through the review of information provided to the Pharmacist by the patient, patient's agent, prescriber and the patient's record.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

855-115-0122

Responsibilities: Supervision

(1) When supervising a Certified Oregon Pharmacy Technician or Pharmacy Technician, each Pharmacist may supervise as many Certified Oregon Pharmacy Technicians or Pharmacy Technicians as they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare.

(2) When supervising an Intern, each Pharmacist may supervise:

(a) No more than four Interns participating in direct patient care activities.

(b) As many Interns as they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare for Interns participating in non-direct patient care activities such as informational health fairs that provide general information, but not patient-specific information.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

855-115-0145

Counseling

(1) For each prescription, the pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(2) Counseling must be provided or offered to be provided to the patient or patient's agent on the use of a drug or device:

(a) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;

(b) When there has been a change in the dose, formulation, or directions;

(c) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or

(d) For any refill that the pharmacist deems counseling is necessary.

(3) An offer for the pharmacist to counsel under (1) and (2) must be made by a licensee.

(4) The pharmacist must counsel the patient or patient’s agent on the use of a drug or device upon request.

(5) When communicating (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the pharmacist is proficient in the patient's preferred language.

(6) For a prescription where counseling has only been provided in writing, the pharmacist must provide drug information in a format accessible by the patient, including information on when the pharmacist is available and how the patient or patient's agent may contact the pharmacist.

(7) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused:

(a) Only a licensee can accept a patient's or patient's agent's request not to be counseled, when counseling is required.

(b) The pharmacist may choose not to release the prescription until counseling has been completed.

(8) Counseling must be provided under conditions that maintain patient privacy and confidentiality.

(9) Counseling, offers to counsel or declinations of counseling regarding prescriptions must be documented with the licensee's identity.

(10) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

855-115-0205
Pharmacist-in-Charge: Qualifications and Limitations

(1) Effective March 1, 2024, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must have:

(a) Completed at least one year of pharmacy practice; or

(b) Completed a board provided PIC training course either before the appointment or within 90 days after the appointment; and

(c) Be employed by the outlet.

(2) A Pharmacist must not be designated PIC of more than three pharmacies. The following drug outlet types do not count towards this limit:

(a) Pharmacy Prescription Kiosks in OAR 855-141; and

(b) Pharmacy Prescription Lockers in OAR 855-143.

(3) Effective July 1, 2025, in order to be a Pharmacist-in-Charge (PIC), a Pharmacist must:

(a) Complete a board-provided PIC training course as described below:

(A) A Pharmacist with 1500 hours or more of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training course within two years prior to appointment as PIC or within 90 days after appointment.

(B) A Pharmacist with less than 1500 hours of pharmacy practice as a Pharmacist within the last three years in a US state or jurisdiction must complete the board-provided PIC training prior to the appointment.

(b) Complete a board provided PIC training course at least every five years.

(c) Be employed by the outlet.

(d) Not be designated PIC of more than three pharmacies. The following drug outlet types do not count towards this limit:

(A) Pharmacy Prescription Kiosk in OAR 855-141; and

(B) Pharmacy Prescription Locker in OAR 855-143.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

855-115-0315
Services: Clinical Pharmacy Agreement & Collaborative Drug Therapy Management

(1) A Pharmacist or pharmacy may engage in the practice of clinical pharmacy under a written Clinical Pharmacy Agreement with health care organization, Physician or Naturopathic Physician.

(2) If the agreement in (1) is made with a health care organization, the organization is responsible for ensuring that each protocol utilized by a Pharmacist or pharmacy to provide clinical pharmacy services:

(a) Is developed and overseen by a Physician or Naturopathic Physician acting within their scope.

(b) Is reviewed by each participating health care provider.

(c) Does not allow any act that is prohibited by ORS 475, ORS 689 and OAR 855.

(3) Each protocol developed under the agreement in (1) must include:

(a) The name of the principal Pharmacist and principal Physician or Naturopathic Physician who is responsible for:

(A) Initial training and ongoing competency assessment for participating Pharmacists; if necessary;

(B) Development, quality assurance and updating or discontinuing each protocol;

(b) The identification, either by name or by description, of each participating Pharmacist;

(c) The identification, either by name or description, of each participating Physician, Naturopathic Physician or health care provider within a health care organization. These persons must have scope to independently treat patients.

(d) The disease state or patient panel for which the Pharmacist may provide clinical pharmacy services;

(e) Types of clinical pharmacy services provided;

(f) Circumstances that require communication from the participating Pharmacist to the patient's Physician, Naturopathic Physician or health care provider within the health care organization such as:

(A) Information collected;

(B) Patient assessment;

(C) Plan of care including follow-up;

(D) Services provided; and

(E) Circumstances requiring urgent communication with the patient's health care provider; and

(g) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary.

(4) A Pharmacist may engage in Collaborative Drug Therapy Management under a written protocol with a health care provider who is acting within their scope.

(5) Each protocol developed under the agreement in (4) must include:

(a) The name of the principal Pharmacist and health care provider who are responsible for:

(A) Initial training and ongoing competency assessment for participating Pharmacists, if necessary; and

(B) Development, quality assurance and updating or discontinuance of each protocol;

(b) The identification, either by name or by description, of each participating Pharmacist;

(c) The identification, by name or description, of each participating health care provider or group of health care providers;

(d) A detailed description of the:

(A) Indications;

(B) Drugs including dosage, frequency, duration and route of administration;

(C) Methods;

(D) Procedures;

(E) Decision criteria; and

(F) Plan the Pharmacist is to follow;

(e) Documentation the Pharmacist is to complete concerning actions taken and a plan or appropriate mechanism for communication, feedback, and reporting to the health care provider concerning specific actions taken.

(f) Circumstances which will cause the Pharmacist to initiate communication with the health care provider;

(g) Training requirement for Pharmacist participation and ongoing assessment of competency, if necessary;

(6) Each protocol developed in (1) and (4) must be reviewed and updated, or discontinued at least every two years;

(7) The Pharmacist must document the protocol version and all clinical pharmacy activities in the prescription record, patient profile, electronic health record or in some other appropriate system.

(8) Records and documents must be retained according to OAR 855-104-0055.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

Division 125: Pharmacy Technicians (Prohibited Practices)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Pharmacy Technician Prohibited Practices

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Adds prohibited practices for Certified Oregon Pharmacy Technicians and Pharmacy Technicians. The rules are needed for transparency and clarity for licensees pursuant to the board's 2022- 2026 Strategic Plan.

Documents Relied Upon per ORS 183.335(2)(b)(D):

21 CFR 1300.01 Definitions relating to controlled substances. (Pharmacist)
21 CFR 1306.03 Persons entitled to issue prescriptions.
21 CFR 1306.21 Requirement of prescription.
21 CFR 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): 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 (OBOP/Other State Agencies/Units of Local Government/Public): (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).
(1) The proposed rule will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule applies to registrants of the Oregon Board of Pharmacy. Approximately 30 % of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No a RAC was not convened. Why? The resources involved in convening a RAC were not necessary to amend this rule. Board members represent the interests of persons and communities likely to be affected by a proposed rule and were able to provide information necessary to amend the rule.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-125-0150: Proposed new rule adds prohibited practices for Certified Oregon Pharmacy Technicians and Pharmacy Technicians. Language is adapted from current rule OAR 855-019-0200(3) concerning activities only a pharmacist can do.

Division 125
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-125-0150
Prohibited Practices

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:

(1) Engage in the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0105(4), including but not limited to the following tasks:

(a) Evaluate and interpret a prescription;

(b) Conduct a Drug Utilization Review or Drug Regimen Review;

(c) Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription that requires judgment;

(d) Counsel a patient or the patient's agent regarding a prescription;

(e) Advise on therapeutic values, content, hazards and use of drugs and devices;

(f) Interpret the clinical data in a patient record system or patient chart;

(g) Conduct Medication Therapy Management;

(h) Practice pursuant to a Clinical Pharmacy Agreement or Collaborative Drug Therapy Management;

(i) Practice pursuant to Statewide Drug Therapy Management Protocols;

(j) Prescribe a vaccine, drug or device;

(k) Administer a drug or device;

(l) Order, interpret or monitor a laboratory test;

(m) Receive or transfer a prescription for a controlled substance orally;

(n) Supervise, direct, or control a licensee in activities that constitute the practice of pharmacy as defined in ORS 689.005 or assisting in the practice of pharmacy;

(o) Delegate tasks to healthcare providers; and

(p) Deny the patient or the patient's agent request to speak to the Pharmacist.

(2) Assist in the practice of pharmacy unless permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.

(3) Perform any task while assisting in the practice of pharmacy that requires judgment unless it is verified by a Pharmacist.

(4) Engage in any form of discrimination, harassment, intimidation, or assault in the workplace.

(5) Refuse a request from a patient, patient's agent, or practitioner to interact with a Pharmacist.

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.155

Division 041: Operation of Pharmacies (Short-acting Opioid Antagonist)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Institutional Drug Outlet Labeling Requirements for Short-acting Opioid Antagonists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes to amend Emergency Department labeling requirements related to short-acting opioid antagonist for practitioners with prescriptive authority in Oregon. Incorporates legislative mandates of 2023 HB 2395, 2023 SB 450, 2023 SB 1043 related to short-acting opioid antagonist.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 SB 450, 2023 SB 1043, 2023 HB 2395

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): 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 (OBOP/Other State Agencies/Units of Local Government/Public): (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).
(1) The proposed rule amendments will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule amendments apply to registrants of the Oregon Board of Pharmacy. Approximately 30 % of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: Licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No a RAC was not convened. Why? The resources involved in convening a RAC were not necessary to amend this rule. This rule enacts the mandates of 2023 SB 450, 2023 SB 1043, or 2023 HB 2395 and does not contain further decisions or requirements by the Board beyond what is in the legislation itself.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-041-6410 – Proposes amending (1)(d) and (e) by adding exemptions and incorporates a reference to 2023 SB450, effective upon filing

OAR 855-041-6270 – Proposes to amend rule by adding (8) that states that nothing in the rule is intended to restrict or conflict with the directives of 2023 SB 450, 2023 SB 1043, or 2023 HB 2395, effective upon filing

Division 041
OPERATION OF PHARMACIES

855-041-6410
Emergency Department Distribution

(1) A practitioner or associate practitioner with prescriptive authority in Oregon who is a member of the hospital's medical staff may dispense an emergency supply of drugs to a patient examined by them or by an associate practitioner subject to the following requirements:

(a) The prescriber ~~shall~~ **must** offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice;

(b) During consultation with the patient or the patient's caregiver, the prescriber ~~shall~~ **must** clearly explain the appropriate use of the drug supplied and the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice;

(c) The patient must be given instructions on the use and precautions for taking the drug;

(d) **Except as described in SB 450 (2023),** ~~T~~the drug is in a manufacturer's unit-of-use container, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(B) Accessory cautionary information as required for patient safety;

(C) Product identification label if the drug is not in unit-of-use packaging;

(D) An expiration date after which the patient should not use the drug; and

(E) Name, address and phone number of the hospital pharmacy.

(e) **Except as described in SB 450 (2023),** ~~T~~the following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

(D) Unique identifying number as determined by policy and procedure;

(E) Name of prescribing practitioner; and

(F) Initials of the dispensing nurse or practitioner.

(f) A prescription or record of the distribution must be completed by the practitioner or nurse. This record must contain:

(A) Name of patient;

(B) Date of issuance;

(C) Drug name and strength distributed;

(D) Units issued;

(E) Name of practitioner;

(F) Initials of the dispensing nurse or practitioner; and

(G) Instructions given to the patient as labeled.

(g) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient;

(h) The record must be reviewed and documented by a pharmacist for accuracy and completeness. The pharmacist ~~shall~~ **must** review the record of dispensing of drugs within 24 hours. However, if the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open but not to exceed 72 hours following the dispensing; and

(i) Errors and discrepancies will be included in hospital and pharmacy QA review process and available to the board.

(2) A controlled substance may only be distributed or dispensed to an outpatient by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined. Distribution of a controlled substance must comply with all applicable state and federal laws and regulations.

(3) The CPO or PIC and appropriate hospital committee will establish a limited selection and quantity of drugs to be included in the Emergency Department formulary and the amount contained in each prepak that may be distributed to meet only the acute care needs of a patient; for example, an emergency supply of drugs. The amount dispensed may not exceed a 48 hour supply except for:

(a) A drug in the manufacturer's unit-of-use packaging such as an inhalant or a topical drug;

(b) A full course of therapy that may be dispensed if in the professional judgment of the pharmacist or practitioner this would be in the patient's best interest such as an antibiotic;

(4) Any additional preparation for use of the medication must be completed prior to discharge; for example, reconstituting antibiotics;

(5) For the purpose of this rule an Automated Dispensing Machine (ADM) is a machine or contrivance which will prepare a completed and labeled prescription which is ready for dispensing to the patient or patient's representative.

(6) An Automated Dispensing Machine; may only be located within the Emergency Department in a secure environment that has no direct public access, and when used, must be part of the discharge procedure;

(7) When the patient or patient's representative receives the prescription from an ADM;

(a) A registered nurse or practitioner or pharmacist must be present at the time of dispensing; and

(b) A registered nurse or practitioner or pharmacist will grant access to the ADM for the release of the drugs to be dispensed using a password protected or biometric access; and

(c) The patient or patient's representative will obtain the drug using a specific patient access code.

(8) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may access the drug supply in the ADM.

(9) The CPO or PIC will establish policies and procedures for use of the ADM including, but not limited to emergency access and down time procedures for the ADM.

(10) Upon written request, the board may waive any of the requirements of this rule if a waiver will further public health or safety. A waiver granted under this section ~~shall~~ **must** only be effective when it is issued in writing and will be time limited.

(11) Nothing in this rule is intended to restrict or conflict with HB 2395 (2023), SB 450 (2023), SB 1043 (2023).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155**,** ~~&~~ ORS 689.505**, 2023 HB 2395, 2023 SB 450, 2023 SB 1043**

855-041-6270
Institutional Drug Outlet Pharmacy Prescription Labeling

(1) Each pharmacy record keeping system must identify all pharmacy personnel involved in the repackaging including the pharmacist who verified the repackaged drug.

(2) Each repackaged drug, prepared by the pharmacy and intended for use within the facility must be in an appropriate container with a label that meets the requirements of OAR 855-041-1135 and includes:

(a) The brand or generic name and expiration date;

(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;

(c) The strength of the drug.

(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:

(a) Name and location of patient;

(b) Name and strength of drug;

(c) Route of administration, when necessary for clarification;

(d) Manufacturer and lot number, or internal pharmacy code;

(e) Auxiliary labels as needed, and

(f) Expiration date.

(4) A drug that is provided for outpatient use must be dispensed by a retail drug outlet.

(5) When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.

(6) When a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that includes the:

(a) Name, quantity and concentration of the drug added and the primary solution;

(b) Date and time of addition;

(c) Expiration date;

(d) Scheduled time for administration;

(e) Infusion rate, when applicable;

(f) Name or initials of person performing admixture;

(g) Identification of the pharmacy where the admixture was performed; and

(h) Name or initials of the verifying pharmacist.

(7) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.

(8) Nothing in this rule is intended to restrict or conflict with HB 2395 (2023), SB 450 (2023), SB 1043 (2023).

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155**, ~~&~~** ORS 689.505**, 2023 HB 2395, 2023 SB 450, 2023 SB 1043**

Division 001: Procedural Rules (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 001; Procedural Rules

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 001 Procedural Rules in its entirety, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Div 104 Universal Rules Permanent Administrative Order

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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 repeal 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 the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 104 Universal rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 001 Procedural Rules in its entirety. The board adopted Division 104 Universal Rules in August 2023, which replaces Division 001. Division 001 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 104 rules to become effective at 12:00AM on 3/1/2024.

~~Division 1~~
~~PROCEDURAL RULES~~

~~855-001-0000~~
~~Notice of Proposed Rule~~

~~Prior to the permanent adoption, amendment, or repeal of any rule, the State Board of Pharmacy must give notice of its intended action as required in ORS 183.335:~~

~~(1) In a manner established by rule adopted by the board under ORS183.341(4), which provides a reasonable opportunity for interested persons to be notified of the agency's proposed action;~~

~~(2) In the bulletin referred to in ORS 183.360 at least 21 days prior to the effective date;~~

~~(3) To persons who have requested notice pursuant to ORS183.335(8) at least 28 days before the effective date; and~~

~~(4) To persons specified in ORS 183.335(15) at least 49 days before the effective date; and~~

~~(5) To persons or organizations the Board's Executive Director determines, pursuant to ORS 183.335, are interested persons in the subject matter of the proposed rule, or would be likely to notify interested persons of the proposal; and~~

~~(a) Oregon State Pharmacy Association;~~

~~(b) Oregon Society of Health System Pharmacists;~~

~~(6) To the Associated Press and the Capitol Press Room.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 183.335~~

~~855-001-0005~~
~~Model Rules of Procedure~~

~~Pursuant to the provisions of ORS 183.341, the Board of Pharmacy adopts the Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act effective 07/2019. These rules must be controlling except as otherwise required by statute or rule.~~

~~[ED. NOTE: The full text of the Attorney General's Model Rules of Procedure is available from the office of the Attorney General or Board of Pharmacy.]~~

~~Statutory/Other Authority: ORS 183.341 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 183.341~~

~~855-001-0012~~
~~Time for Requesting a Contested Case Hearing~~

~~A request for a contested case hearing must be in writing and must be received by the board within 21 days from the date the contested case notice was served. When the board has issued a denial of a~~

~~license, a request for a contested case hearing must be in writing and must be received by the board within 60 days from the date the licensure denial was served.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & ORS 183.435~~

~~855-001-0016~~
~~Filing Exceptions and Argument to the Board~~

~~After a proposed order has been served on a party, the board must notify the party when written exceptions must be filed to be considered by the board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-001-0017~~
~~Petition for Reconsideration or Rehearing as Condition for Judicial Review~~

~~All parties, including limited parties, must file a petition for reconsideration or rehearing with the board as a condition for obtaining judicial review of any order of the board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-001-0035~~
~~Duty to Cooperate~~

~~(1) Applicants, licensees, and registrants must comply with all board requests, including responding fully and truthfully to inquiries and providing requested materials within the time allowed by the board and complying with a subpoena.~~

~~(2) Applicants, licensees, and registrants must comply with the terms of board orders and agreements.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 676.612~~

~~855-001-0040~~
~~Inspections~~

~~(1) A Compliance Officer is a board authorized representative and must be permitted entry to any drug outlet to conduct inspections at all reasonable hours.~~

~~(2) The Compliance Officer is authorized and must be permitted to perform the following to determine compliance with ORS 475, ORS 689, and OAR 855 and board orders including but not limited to:~~

~~(a) Inspecting conditions, structures, equipment, materials, and methods for compliance;~~

~~(b) Inspecting all drugs and devices;~~

~~(c) Taking photographs, recording video and audio; and~~

~~(d) Reviewing, verifying and making copies of records and documents.~~

~~(3) All records and documents required by ORS 475, ORS 689, and OAR 855:~~

~~(a) Must be stored on-site for 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 on-site storage and must be provided to the board upon request within three business days; and~~

~~(c) May be in written or electronic format.~~

~~(4) All licensees and employees must fully comply and cooperate with all questions and requests made by the Compliance Officer at the time of inspection.~~

~~(5) Refusal to allow inspection is grounds for discipline.~~

~~Statutory/Other Authority: ORS 475.125 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

Division 010: Board Administration and Policies (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 010; Board Administration and Policies

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 010 Board Administration and Policies rules in its entirety, effective at 11:59PM on 2/29/20024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 102 Board Administration Rules Permanent Administrative Order

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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 repeal 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 the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 102 Board Administration rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 010 Board Administration and Policies rules in its entirety. The board adopted Division 102 Board Administration rules in August 2023, which replaces Division 010. Division 010 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 102 rules to become effective at 12:00AM on 3/1/2024.

~~Division 10~~
~~BOARD ADMINISTRATION AND POLICIES~~

~~855-010-0005~~
~~Meetings~~

~~(1) The board meetings must be held not less than once every three months as designated by the board.~~

~~(2) The President of the board must have the power to call special meetings, subject to ORS 689.185, when it may be deemed necessary or upon request of a majority of members.~~

~~(3) The board must hold an annual meeting each year for the election of officers, the reorganization of the board and the transaction of other business, which may include but is not limited to:~~

~~(a) Approval of providers of continuing pharmacy education accredited by the Accreditation Council for Pharmacy Education (ACPE);~~

~~(b) Approval of schools and colleges of pharmacy accredited, accredited with probation, pre-candidate or candidate status by ACPE; and~~

~~(c) Review and adopt standards by reference.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.135, ORS 689.151, ORS 689.185 & ORS 689.255~~

~~855-010-0015~~
~~Individual Commitments~~

~~(1) Board members must be governed by board action and must make no individual commitments or promises on matters of board policies.~~

~~(2) No declaration must be made or vote taken on any question, except at board meetings.~~

~~Statutory/Other Authority: ORS 689 & ORS 183~~
~~Statutes/Other Implemented: ORS 183~~

~~855-010-0016~~
~~Pharmacy Board Member and Public Health and Pharmacy Formulary Advisory Committee Member Compensation~~

~~(1) A board member and Public Health and Pharmacy Formulary Advisory Committee member of the Oregon Board of Pharmacy who is entitled to compensation under ORS 292.495 is eligible to receive an amount equal to the per diem amount paid to members of the Legislative Assembly under ORS 171.072 when engaged in the performance of official duties for each day or portion thereof.~~

~~(2) For the purpose of compensation, a board member or member of the Public Health and Pharmacy Formulary Advisory Committee is considered engaged in the performance of official duties when:~~

~~(a) The activity furthers the board's mission, such as attending a board meeting;~~

~~(b) Engaged in an activity at the request of the board chair or authorized by a vote of the board in advance of the activity; or~~
~~(c) Attending an authorized meeting.~~

~~(3) Except as otherwise provided by law, all members, including those employed in full-time public service, may receive actual and necessary travel or other expenses actually incurred in the performance of their official duties within the limits provided by law or by the Oregon Department of Administrative services under ORS 292.210, ORS 292.220, ORS 292.230, and ORS 292.250.~~

~~(4) A board member or Public Health and Pharmacy Formulary Advisory Committee member is not required to accept compensation or reimbursement of travel expenses while performing their official duties as a board or appointed committee member.~~

~~Statutory/Other Authority: ORS 689.115 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.115, ORS 292.495, ORS 689.175, ORS 689.645, ORS 689.649 & ORS 171.072~~

~~855-010-0018~~
~~Public Health and Pharmacy Formulary Advisory Committee~~

~~(1) The Public Health and Pharmacy Formulary Advisory Committee must consist of:~~

~~(a) Two physicians licensed to practice medicine under ORS 677.100 to 677.228;~~

~~(b) Two advanced practice registered nurses who have prescriptive authority and who are licensed by the Oregon State Board of Nursing; and~~

~~(c) Three Pharmacists licensed by the State Board of Pharmacy, at least one of whom is employed as a community Pharmacist and one of whom is employed as a health system Pharmacist.~~

~~(2) A Pharmacist may submit a concept, on a form prescribed by the board to the committee for consideration, for the development of a protocol or the addition of a drug or device to the formulary.~~

~~(3) The committee must recommend to the board, for adoption by rule, a protocol or formulary of drugs and devices from which a Pharmacist can prescribe and dispense to a patient pursuant to a diagnosis by a qualified healthcare practitioner.~~

~~(4) The committee must periodically review the formulary and protocol compendium and recommend the revisions to the board for adoption by rule.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.645, ORS 689.649 & ORS 689.155~~

~~855-010-0021~~
~~Adoption by Reference~~

~~(1) The board adopts standards and other publications by reference, as necessary, through administrative rule. When a matter is included in a referenced publication that is in conflict with Oregon Revised Statutes or Oregon Administrative Rules, the statute or rule applies and the standard provision does not. All remaining parts or application of the standard remain in effect.~~

~~(2) All outside standards, statutes, rules and publications referred to in any rules adopted by the board are by those references made a part of those rules as though fully set forth. Copies are available for inspection in the office of the Board of Pharmacy.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.205~~

~~855-010-0035~~
~~Board Compliance Program~~

~~The board's Compliance Director and Compliance Officers must be pharmacists licensed in the State of Oregon.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.195~~

~~855-010-0100~~
~~State and Nationwide Criminal Background Checks for Licensure~~

~~(1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure; directors, officers and designated representatives of drug outlets applying for registration; and individuals subject to investigation by the board, in order to determine if they have a history of criminal behavior such that they are not fit to be granted or retain a license or registration issued by the board.~~

~~(2) "Subject individual" means a person from whom the board may require legible fingerprints for the purpose of a state or nationwide criminal records check and fitness determination. In this rule, subject individual means: applicants for licensure or renewal of a license; directors, officers and designated representatives of drug outlets applying for registration or renewal of a registration; and individuals subject to an investigation by the board.~~

~~(3) Criminal records checks and fitness determinations are conducted according to ORS 181A.170, ORS 181A.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205 ORS 181A.210, ORS 181A.215, ORS 670.280, ORS 676.303, OAR 125-007-0200, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, OAR 125-007-0310, and OAR 125-007-0330.~~

~~(a) The board will request that the Oregon Department of State Police conduct a state and nationwide criminal records check, using fingerprint identification of subject individuals. The board may conduct state criminal records checks on subject individuals and any licensee through the Law Enforcement Data System maintained by the Oregon Department of State Police in accordance with rules adopted, and procedures established, by the Oregon Department of State Police. Criminal history information~~

~~obtained from the Law Enforcement Data System must be handled in accordance with ORS Chapter 181A, OAR 257-010 and OAR 257-015 and applicable Oregon Department of State Police procedures.~~
~~(b) The applicant or licensee must disclose all arrests, charges, and convictions regardless of the outcome or date of occurrence. Disclosure includes any military or criminal records.~~

~~(c) The board may require additional information from the applicant or licensee, such as, but not limited to, proof of identity, previous names, residential history or additional criminal, judicial or other background information.~~

~~(4) In making licensing fitness determinations subject to the requirements of ORS 670.280, the board will consider the following:~~

~~(a) The nature of any criminal record that reflects:~~

~~(A) Drug or alcohol offense;~~

~~(B) Felony;~~

~~(C) Misdemeanor;~~

~~(D) U.S. military or international crime;~~

~~(E) Offense involving fraud, theft, identity theft or other instance of dishonesty;~~

~~(F) Offense involving violation of federal importation or customs laws or rules;~~

~~(G) Offense requiring registration as a sex offender;~~

~~(H) Condition of parole, probation, or diversion program, or~~

~~(I) Unresolved arrest, charge, pending indictment or outstanding warrant.~~

~~(b) Intervening circumstances relevant to the responsibilities and circumstances of the license or registration. Intervening circumstances include but are not limited to:~~

~~(A) The passage of time since the commission of the crime;~~

~~(B) The age of the subject individual at the time of the crime;~~

~~(C) The likelihood of a repetition of offenses or of the commission of another crime;~~

~~(D) The subsequent commission of another relevant crime;~~

~~(E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and~~

~~(F) A recommendation of an employer.~~

~~(c) The facts that support the conviction or indictment, or that indicate the making of a false statement;~~

~~(d) The relevancy, if any, of the crime or the false statement to the specific requirements of the subject individual's license or registration; and~~

~~(e) Any false statement or omission made to the board regarding the individual's criminal history.~~

~~(f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint identification;~~

~~(g) Any other pertinent information obtained as part of an investigation.~~

~~(h) The board must evaluate a crime or offense on the basis of the law of the jurisdiction in which the crime or offense occurred.~~

~~(i) The following are examples of crimes likely to result in denial unless there are significant mitigating circumstances:~~

~~(A) Aggravated murder;~~

~~(B) Murder;~~

~~(C) Rape I;~~

~~(D) Sodomy I;~~

~~(E) Unlawful sexual penetration I;~~

~~(F) Sexual abuse I~~

~~(j) Under no circumstances must an applicant be denied under these rules because of a juvenile record that has been expunged or set aside pursuant to ORS 419A.260 and ORS 419A.262.~~

~~(k) Under no circumstances must an applicant be denied under these rules due to the existence or contents of an adult record that has been set aside pursuant to ORS 137.225.~~

~~(5) Criminal offender information is confidential. Dissemination of information received under this rule may only be made to people with a demonstrated and legitimate need to know the information. When the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS 676.175. Any fingerprint cards used to conduct a check must be destroyed by either the Federal Bureau of Investigation or the Oregon Department of State Police as specified in ORS 181A.195.~~

~~(6) The board will permit the subject individual for whom a fingerprint-based criminal records check was conducted to inspect the individual's own state and national criminal offender records and, if requested by the subject individual, provide the individual with a copy of the individual's own state and national criminal offender records.~~

~~(7) If an applicant, licensee or registrant is denied a license, they are entitled to a contested case hearing pursuant to ORS 183.413, ORS 183.415, ORS 183.417, ORS 183.425, ORS 183.430, ORS 183.435, ORS~~

~~183.440, ORS 183.445, ORS 183.450, ORS 183.452, ORS 183.453, ORS 183.457, ORS 183.458, ORS 183.459, ORS 183.460, ORS 183.462, ORS 183.464, and ORS 183.470 and in accordance with OAR 855-001-0005, OAR 855-001-0012, OAR 855-001-0016, and OAR 855-001-0017.~~

~~(8) A challenge to the accuracy or completeness of information provided by the Oregon Department of State Police, Federal Bureau of Investigation and agencies reporting information must be made through the Oregon Department of State Police, Federal Bureau of Investigation or reporting agency and not through the contested case process.~~

~~(9) Request for re-evaluation following correction. If the subject individual successfully contests the accuracy or completeness of information provided by the Oregon Department of State Police, the Federal Bureau of Investigation or other agency reporting information to the board, the board will conduct a new criminal history check and re-evaluate the criminal history upon submission of a new criminal history request form.~~

~~(10) The applicant or licensee must pay a criminal records check fee for the actual cost of acquiring and furnishing the criminal offender information.~~

~~Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195~~
~~Statutes/Other Implemented: ORS 676.303, ORS 181A.195, ORS 181A.170, ORS 181A.215 & ORS 676.175~~

~~855-010-0110~~
~~State and Nationwide Criminal Background Checks for Employees, Volunteers and Employment Applicants~~

~~(1) The board requires a criminal records check and fitness determination for board employees, volunteers or applicants for employment with the board.~~

~~(2) Criminal records checks and fitness determinations are conducted pursuant to ORS 181A.170, ORS 181A.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205 ORS 181A.210, ORS 125-181A.215 and OAR 125-007-0200, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, and OAR 125-007-0310.~~

~~(a) To complete the criminal records check and fitness determination, the board may require additional information from the employee, volunteer or applicant, such as, but not limited to, proof of identity or additional criminal, judicial or other background information.~~

~~(b) If the employee, volunteer or applicant has potentially disqualifying criminal offender information, the board will consider factors listed in ORS 181A.195 before making a fitness determination.~~

~~(c) An approved fitness determination does not guarantee employment.~~

~~(d) An incomplete fitness determination does not entitle the employee, volunteer or applicant the right to appeal under OAR 125-007-0300.~~

~~(3) Pursuant to ORS 181A.195, and OAR 125-007-0310, information obtained in the criminal records check is confidential and will not be disseminated by the board except to persons with a demonstrated and legitimate need to know the information.~~
~~Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195~~
~~Statutes/Other Implemented: ORS 181A.195, ORS 181A.170, ORS 181A.215 & ORS 676.303~~

~~855-010-0120~~
~~Criminal Background Checks - Costs~~

~~The applicant or licensee must pay the board the cost of acquiring and furnishing the criminal offender information. The amount will not exceed the cost to the board to obtain such information on behalf of the applicant or licensee, including fees charged to the board by the Oregon Department of State Police and the Federal Bureau of Investigation.~~

~~Statutory/Other Authority: ORS 676.303 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 676.303, ORS 181A.195 & ORS 689.207~~

~~855-010-0130~~
~~Military Spouse or Domestic Partner~~

~~(1) "Military spouse or domestic partner" means a spouse or domestic partner of an active member of the Armed Forces of the United States who is the subject of a military transfer to Oregon.~~

~~(2) To qualify for licensure under this rule, the military spouse or domestic partner must meet the following requirements:~~

~~(a) Meet the qualifications for licensure as stated in OAR Division 855-019 or OAR 855-025.~~

~~(b) Be married to, or in a domestic partnership with, a member of the Armed Forces of the United States who is assigned to a duty station located in Oregon by official active duty military order;~~

~~(c) Applicant must complete an application for licensure, provide the board with a valid email address, and complete and pass a national fingerprint-based criminal background check;~~

~~(d) Provide evidence of current licensure as a pharmacist or pharmacy technician issued by another state;~~

~~(e) Provide to the board, in a manner determined by the board, sufficient proof that the person is in good standing with the issuing out-of-state professional licensing board; and~~

~~(f) Demonstrate competency as a pharmacist or pharmacy technician by having at least one year of active practice during the three years immediately preceding the application.~~

~~(3) A temporary authorization under this section is valid until the earliest of the following:~~

~~(a) Two years after the date of issuance;~~

~~(b) The date the spouse or domestic partner of the person to whom the authorization was issued completes the spouse's term of service in this state; or~~

~~(c) The date the person's authorization issued by the other state expires.~~

~~(4) A temporary authorization issued under this section is not renewable.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.151, ORS 689.265, ORS 670.400 & ORS 670.403~~

Division 019: Pharmacists (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 019; Pharmacists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 019 Pharmacist rules in its entirety, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 115 Pharmacists Permanent Administrative Order

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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 repeal 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 the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 115 Pharmacists rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 019 Pharmacists rules in its entirety. The board adopted Division 115 Pharmacists rules in August 2023, which replaces Division 019. Division 019 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 115 rules to become effective at 12:00AM on 3/1/2024.

~~Division 19~~
~~PHARMACISTS~~

~~855-019-0100~~
~~Application~~

~~(1) This Division applies to any pharmacist who is licensed to practice pharmacy in Oregon including any pharmacist located in another state who is consulting, or providing any other pharmacist service, for a patient, pharmacy or healthcare facility in Oregon.~~

~~(2) Where so indicated, these rules also apply to an intern who is licensed in Oregon.~~

~~(3) Any pharmacist who engages in the practice of pharmacy in Oregon must be licensed by the Board in accordance with the following rules.~~

~~(4) A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon, is not required to be licensed by the Board unless they are the pharmacist-in-charge (PIC).~~

~~(5) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, 689.155 & 689.255~~

~~855-019-0110~~
~~Definitions~~

~~In this Division of Rules: "Counseling" means an oral or other appropriate communication process between a pharmacist and a patient or a patient's agent in which the pharmacist obtains information from the patient or patient's agent, and, where appropriate, the patient's pharmacy records, assesses that information and provides the patient or patient's agent with professional advice regarding the safe and effective use of the drug or device for the purpose of assuring therapeutic appropriateness.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005, ORS 689.151 & ORS 689.155~~

~~855-019-0120~~
~~Licensure~~

~~(1) Before licensure as a pharmacist, an applicant must meet the following requirements:~~

~~(a) Provide evidence from a school or college of pharmacy approved by the board that they have successfully completed all the requirements for graduation and, starting with the graduating class of 2011, including not less than 1440 hours of School-based Rotational Internships as that term is defined in OAR 855-031-0005, and that a degree will be conferred;~~

~~(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. This score is valid for only one year unless the board grants an extension. A candidate who does~~

~~not attain this score may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times;~~

~~(c) Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) exam with a score of not less than 75. The applicant may not take the MPJE until they have graduated from a school or college of pharmacy approved by the board. A candidate who does not attain this score may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times. The MPJE score is valid for 6 months unless extended by the board;~~

~~(d) Complete an application for licensure, provide the board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check; and~~

~~(e) Complete one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority.~~

~~(2) A license, once obtained, will expire on June 30 in odd numbered years and must be renewed biennially.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 2021 HB 2078~~

~~855-019-0122~~
~~Renewal of Licensure as a Pharmacist~~

~~(1) An application for renewal of a pharmacist license must include documentation of:~~

~~(a) Completion of continuing pharmacy education requirements as outlined in OAR 855-135; and~~

~~(b) Payment of the biennial license fee required in OAR 855-110.~~

~~(2) A pharmacist will be subject to an annual criminal background check.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-019-0123~~
~~Liability Limitations for Volunteers~~

~~(1) A pharmacist may register with the Board for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services without compensation under the terms of the law.~~

~~(2) A no cost registration may be issued by the Board upon receipt of a completed application. Registration requires submission of a signed form provided by the Board in accordance with ORS 676.345(2).~~

~~(3) Registration will expire at the licensee's next license renewal date and may be renewed biennially. It is the licensee's responsibility to ensure his or her active registration in this program.~~

~~(4) Nothing in this section relieves licensee from the responsibility to comply with Board regulations and still may be subject to disciplinary actions.~~

~~(5) Pharmacists providing care under the provisions of ORS 676.340 and 676.345 remain subject to the Board complaint investigation process articulated in ORS 676.175.~~

~~Statutory/Other Authority: ORS 676.340 & 689.205~~
~~Statutes/Other Implemented: ORS 676.340 & 676.345~~

~~855-019-0124~~
~~Notification: Out-of-State Volunteer Pharmacist~~

~~(1) A pharmacist who is not licensed in Oregon may, without compensation and in connection with a coordinating organization or other entity, practice pharmacy for 30 days each calendar year. The pharmacist is not required to apply for licensure or other authorization from the board to practice pharmacy under this section.~~

~~(2) To practice pharmacy under this section, the pharmacist who is not licensed in Oregon must submit on a form prescribed by the board, at least 10 days prior to commencing practice in this state, to the board:~~

~~(a) Proof that the pharmacist is in good standing and is not the subject of an active disciplinary action in any jurisdiction in which the pharmacist is authorized to practice;~~

~~(b) An acknowledgement that the pharmacist must provide services only within the scope of practice of pharmacy and will provide services pursuant to the scope of practice of this state or the health care practitioner's licensing agency, whichever is more restrictive;~~

~~(c) An attestation that the pharmacist will not receive compensation for practice in this state;~~

~~(d) The name and contact information of the coordinating organization or other entity through which the pharmacist will practice; and~~

~~(e) The dates on which the pharmacist will practice in this state.~~

~~(3) Except as otherwise provided, the pharmacist practicing under this section is subject to the laws and rules governing the pharmacy profession that the pharmacist is authorized to practice and to disciplinary action by the appropriate health professional regulatory board.~~

~~Statutory/Other Authority: ORS 689.205, ORS 689.315 & 2022 HB 4096~~
~~Statutes/Other Implemented: ORS 689.151 & 2022 HB 4096~~

~~855-019-0125~~
~~Coaching from Board and Staff~~

~~No member or employee of the Board shall discuss the contents of an examination, its preparation or use with any candidate or other person. No member or employee of the Board shall coach a candidate or any other person on materials that may be used in the examination nor shall they accept any fees for any act of assistance that would bear on the examination.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-019-0130~~
~~Licensure by Reciprocity~~

~~(1) An applicant for licensure as a pharmacist by reciprocity must meet the requirements of ORS 689.265 and the following requirements:~~

~~(a) Be a graduate of a school or college of pharmacy approved by the Board;~~

~~(b) Have passed the NAPLEX or equivalent examination with a score of not less than 75;~~

~~(c) Have passed the MPJE with a score of not less than 75;~~

~~(d) Be licensed and in good standing in the state from which the applicant bases the reciprocity application;~~

~~(e) Have either:~~

~~(A) Been engaged in the practice of pharmacy for period of at least one year including a minimum of 1440 hours of work experience as a licensed pharmacist. Evidence supporting this work experience shall be provided at time of application; or~~

~~(B) Met the internship requirements of this state within the one-year period immediately before the date of this application. Evidence from the school or college of pharmacy supporting this internship shall be provided at time of application.~~

~~(2) Licensure as a pharmacist in another state precludes licensure to practice as an intern in the State of Oregon, except an applicant that has been accepted into an Oregon pharmacy residency program or for licensure by examination or by reciprocity who must acquire internship hours to become eligible for licensure, and then only until the required hours have been acquired.~~

~~(3) An applicant who has obtained their professional degree outside the United States is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-019-0150.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.265~~

~~855-019-0140~~

~~NAPLEX Score Transfer~~

~~(1) An applicant for score transfer must be a graduate of a school or college of pharmacy approved by the Board and must have passed the NAPLEX or equivalent examination with a score of at least 75.~~

~~(2) Prior to taking the NAPLEX examination for their initial state of licensure, an applicant must have requested the National Association of Boards of Pharmacy to score transfer their NAPLEX score to Oregon.~~

~~(3) An applicant must provide the following documentation:~~

~~(a) Oregon Score Transfer Application;~~

~~(b) A passport regulation photograph;~~

~~(c) A copy of a birth certificate, US passport or naturalization documents, or a foreign passport endorsed with a US visa permitting full time employment;~~

~~(d) Evidence of successful completion of all graduation requirements from a school or college of pharmacy approved by the Board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.265~~

~~855-019-0150~~

~~Foreign Pharmacy Graduates~~

~~(1) Foreign Pharmacy Graduates applying for licensure in Oregon must meet the following requirements:~~

~~(a) Provide a copy of a valid visa permitting full time employment;~~

~~(b) Provide a copy of the original certificate issued by the NABP Foreign Pharmacy Graduate Examination Committee (FPGEC); and~~

~~(c) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 91 days. This score shall only be valid for one year unless the Board grants an extension;~~

~~(d) After having completed the required number of intern hours, pass the MPJE with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 30 days. The MPJE score shall only be valid for 6 months unless extended by the Board.~~

~~(2) An applicant must complete 1440 hours in pharmacy practice as an intern that must be certified to the Board by the preceptors.~~

~~(3) An applicant may not count internship hours or practice as a pharmacist completed outside the United States toward Oregon's internship requirement.~~

~~(4) An applicant may not count internship hours or practice as a pharmacist that is completed before passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE), and either the TOEFL with TSE, or TOEFL (IBT) exams toward Oregon's internship requirement.~~

~~(5) The Board may waive any requirement of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & ORS 689.255~~

~~855-019-0160~~
~~Nuclear Pharmacists~~

~~In order to qualify under these rules as a nuclear pharmacist, a pharmacist shall:~~

~~(1) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Protection Services of the Department of Human Services; and~~

~~(2) Be a pharmacist licensed to practice in Oregon; and~~

~~(3) Submit to the Board of Pharmacy either:~~

~~(a) Evidence of current certification in nuclear pharmacy by the Board of Pharmaceutical Specialties; or~~

~~(b) Evidence that they meet both the following:~~

~~(A) Certification of a minimum of six month on-the-job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radiopharmaceutical services; and~~

~~(B) Certification of completion of a nuclear pharmacy training program in a college of pharmacy or a nuclear pharmacy training program approved by the Board.~~

~~(4) Receive a letter of notification from the Board that the evidence submitted by the pharmacist meets the above requirements and has been accepted by the Board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-019-0170~~
~~Reinstatement of License~~

~~(1) A pharmacist who fails to renew their license by the deadline may reinstate their license as follows:~~

~~(a) By payment of the license fees and delinquency fees for all years during which the license was lapsed and for the current year; and~~

~~(b) By providing certification of completion of the continuing pharmacy education requirement in OAR 855-135 for all years in which the license was lapsed; and~~

~~(c) If their license has been lapsed for more than one year, pass the MPJE with a score of not less than 75; and~~

~~(d) Complete an application for licensure, provide the board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check.~~

~~(2) A pharmacist in good standing who retired from the practice of pharmacy after having been licensed for not less than 20 years need only pay the annual license fees for the year in which they seek a license, however they must provide certification of completion of continuing pharmacy education requirement in OAR 855-135 for all years since their retirement and pass the MPJE with a score of not less than 75.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & ORS 689.275~~

~~855-019-0171~~
~~Reinstatement of a Revoked or Surrendered License~~

~~A person whose pharmacist license has been revoked or surrendered shall have the right, at reasonable intervals, to petition to the Board in writing for reinstatement of such license. The written petition to the Board shall be made in conjunction with the application process identified in OAR 855-019-0120.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.275~~

~~855-019-0200~~
~~Pharmacist: General Responsibilities~~

~~ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A Pharmacist licensed to practice pharmacy by the board has the duty to use that degree of care, skill, diligence and reasonable professional judgment that is exercised by an ordinarily careful Pharmacist in the same or similar circumstances.~~

~~(1) A Pharmacist is responsible for their own actions; however, this does not absolve the pharmacy from responsibility for the Pharmacist's actions.~~

~~(2) A Pharmacist and pharmacy are responsible for the actions of Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians.~~

~~(3) Only a Pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require reasonable professional judgment of a Pharmacist include but are not limited to:~~

~~(a) Drug Utilization Review;~~

~~(b) Counseling;~~

~~(c) Drug Regimen Review;~~

~~(d) Medication Therapy Management;~~

~~(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;~~

~~(f) Practice pursuant to State Drug Therapy Management Protocols;~~

~~(g) Prescribing a drug or device, as authorized by statute;~~

~~(h) Ordering, interpreting and monitoring of a laboratory test;~~

~~(i) Oral receipt or transfer of a prescription; and~~

~~(j) Verification of the work performed by those under their supervision.~~

~~(4) A Pharmacist must:~~

~~(a) Comply with all state and federal laws and rules governing the practice of pharmacy;~~

~~(b) Control each aspect of the practice of pharmacy;~~

~~(c) Ensure each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;~~

~~(d) Ensure non-Pharmacist personnel only perform duties they are licensed and trained to perform.~~

~~(e) Know the identity of each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction and control at all times;~~

~~(f) Ensure that the supervision of non-Pharmacist personnel does not exceed their capacity to supervise based on the workload and services being provided.~~

~~(g) Conduct themselves in a professional manner at all times and not engage in any form of discrimination, harassment, intimidation, or assault in the workplace.~~

~~(h) Ensure and enforce the drug outlet written procedures for use of Certified Oregon Pharmacy Technicians and Pharmacy Technicians as required by OAR 855-025-0035;~~

~~(i) Ensure the security of the pharmacy area including:~~

~~(A) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;~~

~~(B) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;~~

~~(C) Ensuring that only a Pharmacist has access to the pharmacy when the pharmacy is closed.~~

~~(5) A Pharmacist may delegate final verification of drug and dosage form, device, or product to a Certified Oregon Pharmacy Technician or Pharmacy Technician per ORS 689.005 when the following conditions are met:~~

~~(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;~~

~~(b) The Certified Oregon Pharmacy Technician or Pharmacy Technician does not use discretion in conducting final verification;~~

~~(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and~~

~~(d) Ensure the Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.~~

~~(6) A Pharmacist may permit an Intern under their direction and supervision to perform any task listed in OAR 855-019-0200(3), except that an Intern must not:~~

~~(a) Perform the duties of a Pharmacist until after the Intern has successfully completed their first academic year, and only after successful completion of coursework corresponding to those duties;~~

~~(b) Prescribe a drug or device; or~~

~~(c) Perform final verification or verification as defined in OAR 855-006-0005.~~

~~(7) Each Pharmacist on duty and the PIC is responsible for the conduct, operation, management and control of the pharmacy;~~

~~Statutory/Other Authority: ORS 689.205 & 2022 HB 4034~~
~~Statutes/Other Implemented: ORS 689.025, ORS 689.151, ORS 689.155, ORS 689.645, ORS 689.682, ORS 689.689 & 2022 HB 4034~~

~~855-019-0205~~
~~Duty to Report~~

~~(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.~~

(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.

(3) A pharmacist must report to the board within 10 days if they:

(a) Are convicted of a misdemeanor or a felony; or

(b) If they are arrested for a felony.

(4) A pharmacist who has reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting pharmacist must report the conduct without undue delay, but in no event later than 10 working days after the pharmacist learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.

(5) A pharmacist who reports to a board in good faith as required by section (4) of this rule is immune from civil liability for making the report.

(6) A pharmacist who has reasonable grounds to believe that any violation of these rules has occurred, must notify the board within 10 days. However, in the event of a significant drug loss or violation related to drug theft, the pharmacist must notify the board within one (1) business day.

(7) A pharmacist must notify the board in writing, within 15 days of any change in e-mail address, employment location or residence address.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.455

855-019-0210
Duties of the Pharmacist Receiving a Prescription

(1) A Pharmacist must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed or prepared for administration in accordance with the prescribing practitioner's authorization.

(2) A Pharmacist receiving a prescription is responsible for:

(a) Using professional judgment in dispensing only pursuant to a valid prescription. A Pharmacist must not dispense a prescription if the Pharmacist, in their professional judgment, believes that the prescription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner includes a clinical associate of the practitioner or any other practitioner acting in the practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and issued pursuant to a valid patient-practitioner relationship; and

~~(b) Ensuring that the prescription contains all the information specified in Division 41 of this chapter of rules including the legible name and contact phone number of the prescribing practitioner for verification purposes.~~

~~(3) A Pharmacist may refuse to dispense a prescription to any person who lacks proper identification.~~

~~(4) Oral Prescription: Upon receipt of an oral prescription, the Pharmacist must promptly reduce the oral prescription to writing or create a permanent electronic record by recording:~~

~~(a) The date when the oral prescription was received;~~

~~(b) The name of the patient for whom, or the owner of the animal for which, the drug is to be dispensed;~~

~~(c) The full name and, in the case of controlled substances, the address and the DEA registration number, of the practitioner, or other number as authorized under rules adopted by reference under Division 80 of this chapter of rules;~~

~~(d) If the oral prescription is for an animal, the species of the animal for which the drug is prescribed;~~

~~(e) The name, strength, dosage form of the substance, quantity prescribed;~~

~~(f) The direction for use;~~

~~(g) The total number of refills authorized by the prescribing practitioner;~~

~~(h) The written signature or initials or electronic identifier of the receiving Pharmacist or Intern and the identity of the person transmitting the prescription;~~

~~(i) The written or electronic record of the oral prescription must be retained on file as required by Division 41 of this chapter of rules, and in the case of controlled substances, under rules adopted by reference in Division 80 of this chapter of rules.~~

~~(5) Facsimile Prescription: Upon receipt of a facsimile prescription, the Pharmacist must be confident that the prescription was sent by an authorized practitioner or practitioner's agent, and they must verify that:~~

~~(a) The facsimile contains all the information specified in Division 41 and Division 80 of this chapter of rules; and~~

~~(b) The facsimile prescription is not for a Schedule II controlled substance unless so permitted under federal regulations or Division 80 of this chapter of rules; and~~

~~(c) If the facsimile prescription is for a controlled substance, the prescription contains an original, manually signed signature of the prescriber. In this rule, manually signed specifically excludes a signature stamp or any form of digital signature unless permitted under federal regulations.~~

~~(6) Electronic Prescription: Before filling a prescription that has been received electronically, the Pharmacist must ensure that:~~

~~(a) The prescription was originated by an authorized practitioner or practitioner's agent;~~

~~(b) The prescription contains all the information specified in Division 41 of this chapter of rules.~~

~~(c) The prescription is not for a controlled substance unless permitted by federal regulations.~~

~~(7) The Pharmacist must ensure that a written prescription that is hand-carried or mailed into the pharmacy contains an original manually signed signature of the prescribing practitioner or practitioner's agent.~~

~~(8) Computer Transfer of Prescription Information between Pharmacies: A Pharmacist that transmits or receives prescription information to or from another pharmacy electronically must ensure as appropriate:~~

~~(a) The accurate transfer of prescription information between pharmacies;~~

~~(b) The creation of an original prescription or image of an original prescription containing all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability and that the Pharmacist will use in verifying the prescription;~~

~~(c) The prescription is invalidated at the sending pharmacy; and~~

~~(d) Compliance with all relevant state and federal laws and rules regarding the transfer of controlled substance prescriptions.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508 & 2022 HB 4034~~

~~855-019-0220~~
~~Drug Utilization Review (DUR)~~

~~(1) A pharmacist shall maintain a record for each patient that contains easily retrievable information necessary for the pharmacist to perform a DUR and to identify previously dispensed drugs at the time a prescription or drug order is presented for dispensing or preparing for administration. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:~~

~~(a) Full name of the patient for whom the drug is prescribed;~~

~~(b) Address and telephone number of the patient;~~

~~(c) Patient's gender, age or date of birth;~~

~~(d) Chronic medical conditions and disease states of the patient;~~

~~(e) A list of all drugs or devices the patient is currently obtaining at that pharmacy showing the name of the drug or device, strength of the drug, the quantity and date received, and the name of the prescribing practitioner;~~

~~(f) Known allergies, adverse drug reactions, and drug idiosyncrasies;~~

~~(g) Pharmacist comments relevant to the individual's drug therapy, including any other information specific to that patient or drug; and~~

~~(h) Additional information, which may relate to DUR, or for the monitoring of the patient as appropriate.~~

~~(2) Patient records shall be maintained for at least three years.~~

~~(3) The pharmacist or intern shall perform a DUR prior to dispensing or preparing for administration any prescription or refill.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.155~~

~~855-019-0230~~
~~Counseling~~

~~(1) The Pharmacist or Intern must orally counsel the patient or patient's agent on the use of a drug or device as appropriate:~~

~~(a) The Pharmacist or Intern must counsel the patient on a new prescription and any changes in therapy, including but not limited to a change in directions or strength, or a prescription which is new to the pharmacy;~~

~~(b) Only the Pharmacist or Intern may accept a patient's or patient's agent's request not to be counseled. If, in their reasonable professional judgment, the Pharmacist or Intern believes that the patient's safety may be affected, the Pharmacist or Intern may choose not to release the prescription until counseling has been completed;~~

~~(c) The Pharmacist or Intern that provides counseling or accepts the request not to be counseled must document the interaction;~~

~~(d) A Pharmacist must not allow non-Pharmacist personnel to release a prescription that requires counseling, or accept the request not to be counseled;~~

~~(e) For a prescription delivered to a patient, except at a pharmacy or a pharmacy prescription locker, the Pharmacist must offer in writing, to provide direct counseling and information about the drug, including information on how to contact the Pharmacist;~~
~~(f) For each patient, the Pharmacist or Intern must determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.~~

~~(g) When communicating (e.g. counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered~~

by the Oregon Health Authority under ORS 413.558 unless the Pharmacist is proficient in the patient's preferred language.

(2) Counseling on a refill prescription must be such as a reasonable and prudent Pharmacist would provide including but not limited to changes in strength or directions.

(3) A Pharmacist may provide counseling in a form other than oral counseling when, in their reasonable professional judgment, a form of counseling other than oral counseling would be more effective.

(4) A Pharmacist or Intern must initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

(5) For a discharge prescription from a hospital, the Pharmacist must ensure that the patient receives appropriate counseling.

Statutory/Other Authority: ORS 689.205 & 2021 HB 2359
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & 2021 HB 2359

855-019-0240
Consulting Pharmacist Practice

(1) Subject to the provisions of OAR 855-019-0100(4), a consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist.

(2) A consulting pharmacist for an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure as well as by any relevant federal and state laws and rules.

(3) A consulting pharmacist must maintain appropriate records of their consulting activities for three years, and make them available to the Board for inspection.

(4) A consulting pharmacist is responsible for the safe custody and security of all their records and must comply with all relevant federal and state laws and regulations concerning the security and privacy of patient information.

(5) A consulting pharmacist may store health protected records outside an Oregon licensed facility if registered as an Oregon Consulting or Drugless Pharmacy outlet as defined by OAR Chapter 855, division 41.

(6) A consulting pharmacist for a facility that is required by the Board to have a consultant pharmacist but which does not have additional consulting requirements under the terms of its licensure with any other state agency, shall provide services that include but are not limited to the following:

(a) Provide the facility with policies and procedure relating to security, storage and distribution of drugs within the facility;

~~(b) Provide guidance on the proper documentation of drug administration or dispensing;~~

~~(c) Provide educational materials or programs as requested.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.155~~

~~855-019-0250~~
~~Medication Therapy Management~~

~~(1) Medication Therapy Management (MTM) is a distinct service or group of services that is intended to optimize the therapeutic outcomes of a patient. Medication Therapy Management can be an independent service provide by a pharmacist or can be in conjunction with the provision of a medication product with the objectives of:~~

~~(a) Enhancing appropriate medication use;~~

~~(b) Improving medication adherence;~~

~~(c) Increasing detection of adverse drug events;~~

~~(d) Improving collaboration between practitioner and pharmacist; and~~

~~(e) Improving outcomes.~~

~~(2) A pharmacist that provides MTM services shall ensure that they are provided according to the individual needs of the patient and may include but are not limited to the following:~~

~~(a) Performing or otherwise obtaining the patient's health status assessment;~~

~~(b) Developing a medication treatment plan for monitoring and evaluating the patient's response to therapy;~~

~~(c) Monitoring the safety and effectiveness of the medication therapy;~~

~~(d) Selecting, initiating, modifying or administering medication therapy in consultation with the practitioner where appropriate;~~

~~(e) Performing a medication review to identify, prevent or resolve medication related problems;~~
~~(f) Monitoring the patient for adverse drug events;~~

~~(g) Providing education and training to the patient or the patient's agent on the use or administration of the medication;~~

~~(h) Documenting the delivery of care, communications with other involved healthcare providers and other appropriate documentation and records as required. Such records shall:~~

(A) Provide accountability and an audit trail; and

(B) Be preserved for at least three years and be made available to the Board upon request except that when records are maintained by an outside contractor, the contract must specify that the records be retained by the contractor and made available to the Board for at least three years.

(i) Providing necessary services to enhance the patient's adherence with the therapeutic regimen;

(j) Integrating the medication therapy management services within the overall health management plan for the patient; and

(k) Providing for the safe custody and security of all records and compliance with all relevant federal and state laws and regulations concerning the security and privacy of patient information.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & 689.155

855-019-0260
Collaborative Drug Therapy Management

(1) As used in this rule "Collaborative Drug Therapy Management" (CDTM) means the participation by a practitioner and a pharmacist in the management of drug therapy pursuant to a written agreement that includes information on the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

(a) Is agreed to by one practitioner and one pharmacist; or

(b) Is agreed to by one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee, and one or more pharmacists.

(2) A pharmacist shall engage in collaborative drug therapy management with a practitioner only under a written arrangement that includes:

(a) The identification, either by name or by description, of each of the participating pharmacists;

(b) The identification, by name or description, of each of the participating practitioners or group of practitioners;

(c) The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement;

(d) The types of decisions that the pharmacist is allowed to make, which may include:

(A) A detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case;

~~(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;~~

~~(C) A detailed description of the activities the pharmacist is to follow including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system;~~

~~(D) Circumstances which will cause the pharmacist to initiate communication with the practitioner, including but not limited to the need for a new prescription order and a report of a patient's therapeutic response or any adverse effect.~~

~~(e) Training requirement for pharmacist participation and ongoing assessment of competency, if necessary;~~

~~(f) Quality assurance and periodic review by a panel of the participating pharmacists and practitioners;~~

~~(g) Authorization by the practitioner for the pharmacist to participate in collaborative drug therapy; and~~

~~(h) A requirement for the collaborative drug therapy arrangement to be reviewed and updated, or discontinued at least every two years;~~

~~(3) The collaborative drug therapy arrangement and associated records must be kept on file in the pharmacy and made available to any appropriate health licensing board upon request.~~

~~(4) Nothing in this rule shall be construed to allow therapeutic substitution outside of the CDTM agreement.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.155~~

~~855-019-0265~~
~~Administration of Drugs~~

~~(1) In accordance with ORS 689.655, a pharmacist may administer a drug or device as specified in this rule.~~

~~(2) A pharmacist who administers a drug or device must:~~

~~(a) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device; and~~

~~(b) Ensure a record is kept for three years of such activities. This record shall include but is not limited to:~~

~~(A) Patient identifier;~~

~~(B) Drug or device and strength;~~

~~(C) Route and site of administration;~~

~~(D) Date and time of administration;~~

~~(E) Pharmacist identifier.~~

~~(3) The pharmacist must be acting:~~

~~(a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice or;~~

~~(b) In accordance with a written protocol or collaborative drug therapy agreement with a licensed practitioner.~~

~~(4) The pharmacist must be able to document that they have received training on the drug or device to be administered and the route of administration. Such training may include a program approved by the ACPE, curriculum based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the Board.~~

~~(5) The pharmacist may administer a drug or device in conjunction with training the patient or the patient's caregiver how to administer or self-administer the drug or device.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.655~~

~~855-019-0270~~ ***View current SOS version**
~~Vaccination Qualifications~~
NOTE: The version shown below is currently being considered for permanent adoption: mailing **#D**

~~A Pharmacist may administer vaccines if the Pharmacist:~~

~~(1) Has completed a course of training approved by the board and maintained competency that includes, injection site, and Cardiopulmonary Resuscitation (CPR) specific to the age and population of patients being vaccinated by the Pharmacist;~~

~~(2) Holds active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program intended for a healthcare provider that contains a hands-on training component and is valid for not more than three years;~~

~~(3) Has access to the current edition of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."~~

~~Statutory/Other Authority: ORS 689.205, ORS 689.645~~
~~Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645~~

~~855-019-0280~~ ***View current SOS version**

~~Immunization Protocols, Policies and Procedures~~

NOTE: The version shown below is currently being considered for permanent adoption: mailing **#D**

~~(1) Prior to prescribing, administering or dispensing a vaccine, a Pharmacist:~~

~~(a) Until January 31, 2024, must follow protocols written and approved by the Oregon Health Authority (OHA) for vaccines and the treatment of severe adverse events following administration of a vaccine.~~

~~(b) Effective February 1, 2024, must follow a statewide drug therapy management protocol per OAR 855-020-0300 or a collaborative drug therapy management agreement per OAR 855-019-0260.~~

~~(2) A Pharmacist may administer vaccines:~~

~~(a) To a person who is seven years of age or older;~~

~~(b) To a person who is six months of age or older if the vaccine administered is an influenza vaccine; and~~

~~(c) To a person who is at least three years of age when:~~

~~(A) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or~~

~~(B) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.~~

~~(3) A Pharmacist who administers or supervises administration of any vaccine must:~~

~~(a) Make vaccine recommendations;~~

~~(b) Select each vaccine to be administered;~~

~~(c) Ensure compliance with (1);~~

~~(d) Ensure the appropriate Vaccine Information Statement (VIS) is provided to the patient or legal representative prior to each dose of vaccine;~~

~~(e) Perform verification prior to administration that includes but is not limited to:~~

~~(A) Prescription order accuracy verification; and~~

~~(B) Vaccine product accuracy review;~~

~~(f) Advise or counsel on therapeutic values, content, hazards and use of each vaccine;~~

~~(g) Manage adverse events;~~

-

~~(h)Report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient;~~

~~(i) Verify accuracy and completeness of documentation for vaccine administration; and~~

~~(j) Ensure all persons administering vaccines under their supervision are appropriately trained and qualified.~~

~~(4) An appropriately trained and qualified Pharmacist may permit an appropriately trained and qualified:~~

~~(a) Intern to perform the same duties as a Pharmacist except as prohibited in OAR 855-019-0200(6).~~

~~(b) Certified Oregon Pharmacy Technician or Pharmacy Technician to conduct the physical act of administering a vaccine in accordance with OAR 855-025-0024.~~

~~(5) The appropriately trained and qualified Pharmacist who is supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician in administering a vaccine must be immediately available to the vaccinator to respond to adverse reactions and any other issues that may arise.~~

~~Statutory/Other Authority: ORS 689.205, ORS 689.645, ORS 433.441, ORS 433.443, 2023 HB 2278, 2023 HB 2486~~
~~Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645, 2023 HB 2278, 2023 HB 2486~~

~~855-019-0290~~ ***View current SOS version**
~~Vaccination: Record Keeping and Reporting~~
NOTE: The version shown below is currently being considered for permanent adoption: mailing **#D**

~~A Pharmacist who administers or supervises each administration of a vaccine to a patient must:~~

~~(1) Fully document the administration in the patient's permanent record.~~

~~(2) Report the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration.~~

~~(a) The name, address, gender and date of birth of the patient;~~

~~(b) The date of administration of the vaccine;~~

~~(c) The NDC number of the vaccine, or other acceptable standardized vaccine code set;~~

~~(d) The address of the pharmacy where vaccine was administered unless automatically embedded in the electronic report provided to the OHA ALERT Immunization System;~~

~~(e) The phone number of the patient when available;~~

~~(f) The dose amount, manufacturer, site of administration, lot number and expiration date of the vaccine when available;~~

~~(3) Keep documentation of current CPR training. This documentation will be kept on site and available for inspection.~~

~~(4) Follow storage and handling guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC).~~

~~(5) For the purpose of participation in the Oregon Vaccines for Children program,~~

~~(a) The vaccine eligibility code for each dose must be reported to the ALERT Immunization Information System in the manner prescribed by OHA, and~~

~~(b) The Pharmacist is recognized as a prescriber.~~

~~(c) If providing state or federal vaccines during a pandemic as determined by the CDC, the event and priority code as specified by OHA must be provided upon request in the manner prescribed by OHA.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.645, 2023 HB 2278, 2023 HB 2486~~

~~855-019-0300~~
~~Duties of a Pharmacist-in-Charge~~

~~(1) In accordance with OAR 855-041 and OAR 855-139, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) who is normally present in the pharmacy on a regular basis.~~

~~(2) In order to be a PIC, a Pharmacist must have:~~

~~(a) Completed at least one year of pharmacy practice; or~~

~~(b) Completed a board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the board, this course may be employer provided and may qualify for continuing education credit.~~

~~(3) A Pharmacist must not be designated PIC of more than three pharmacies without prior written approval by the board. If such approval is given, the Pharmacist must comply with the requirements in sub-section (4)(e) of this rule. Pharmacy Prescription Kiosks in OAR 855-141 and Pharmacy Prescription Lockers in OAR 855-143 do not count toward this limit.~~

~~(4) The PIC must perform the following the duties and responsibilities:~~

~~(a) When a change of PIC occurs, both the outgoing and incoming PICs must report the change to the board within 15 days of the occurrence, on a form provided by the board;~~

~~(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;~~

~~(c) The PIC must not authorize non-Pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;~~

~~(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a Pharmacist;~~

~~(e) A Pharmacist designated as PIC for more than one pharmacy must personally conduct and document a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit Form provided by the board;~~

~~(f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within the time allowed by the board.~~

~~(g) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.~~

~~(5) The PIC is responsible for ensuring that the following activities are correctly completed:~~

~~(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;~~

~~(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the board;~~

~~(c) Conducting an annual self-inspection of the pharmacy using the annual Self-Inspection Form provided by the board, by July 1 each year. The completed self-inspection forms must be signed and dated by the PIC and retained for three years from the date of completion;~~

~~(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;~~

~~(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.~~

~~(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Form;~~

~~(g) Implementing a quality assurance plan for the pharmacy.~~

~~(h) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.~~

~~(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all~~

~~controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & ORS 689.155~~

~~855-019-0310~~
~~Grounds for Discipline~~

~~The State Board of Pharmacy may suspend, revoke, or restrict the license of a pharmacist or intern or may impose a civil penalty upon the pharmacist or intern upon the following grounds:~~

~~(1) Unprofessional conduct as defined in OAR 855-006-0020;~~

~~(2) Repeated or gross negligence;~~

~~(3) Impairment, which means an inability to practice with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;~~

~~(4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;~~

~~(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a license to practice pharmacy or a drug outlet registration;~~

~~(8) Permitting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;~~

~~(9) Aiding and abetting an individual to engage in the practice of pharmacy without a license or falsely using the title of pharmacist;~~

~~(10) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto; or~~

~~(11) Failure to perform appropriately the duties of a pharmacist while engaging in the practice of pharmacy as defined in ORS 689.005.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151, 689.155 & 689.405~~

~~855-019-0460~~

~~Short-acting Opioid Antagonist~~

~~(1) A Pharmacist may prescribe any FDA-approved short-acting opioid antagonist (e.g., naloxone, nalmefene) and the necessary medical supplies to administer a short-acting opioid antagonist for opiate overdose:~~

~~(a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME);~~

~~(b) To an individual seeking a short-acting opioid antagonist;~~

~~(c) To an entity seeking a short-acting opioid antagonist.~~

~~(2) A Pharmacist is not required to label the prescription according to OAR 855-041-1130 if dispensing a FDA-approved short-acting opioid antagonist in the form of a nasal spray.~~

~~(3) The Pharmacist must document the encounter, the prescription and maintain records for three years.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682, ORS 689.684, 2023 HB 2395 & 2023 SB 450~~

Division 020: Pharmacist Prescriptive Authority (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 20; Pharmacist Prescriptive Authority

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 020 Pharmacist Prescriptive Authority rules in its entirety, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 115 Pharmacists Permanent Administrative Order

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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 repeal 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 the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 115 Pharmacists rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 020 Pharmacist Prescriptive Authority rules in its entirety. The board adopted Division 115 Pharmacists rules in August 2023, which replaces Division 020. Division 020 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 115 rules to become effective at 12:00AM on 3/1/2024.

~~Division 20~~
~~PHARMACIST PRESCRIPTIVE AUTHORITY~~

~~855-020-0110~~
~~Prescribing Practices~~

~~(1) A Pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A Pharmacist must only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.~~

~~(2) A Pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services pursuant to statewide drug therapy management protocols. The policies and procedures must describe current and referenced clinical guidelines, and include but not be limited to:~~

~~(a) Patient inclusion and exclusion criteria;~~

~~(b) Explicit medical referral criteria;~~

~~(c) Care plan preparation, implementation, and follow-up;~~

~~(d) Patient education; and~~

~~(e) Provider notification; and~~

~~(f) Maintaining confidentiality.~~

~~(3) 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.~~

~~(4) For each drug or device the Pharmacist prescribes via the Formulary or Protocol Compendia, the Pharmacist must:~~

~~(a) Ensure training and education requirements have been met prior to engaging in prescribing activities. An attestation of or certificate of completion of all required training and education must be retained for 6 years or uploaded into the Pharmacist's electronic licensing record with the board;~~

~~(b) Assess patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient's health history and clinical status. The Pharmacist's physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means;~~

~~(c) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the statewide drug therapy management protocol and policies and procedures;~~

~~(d) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and~~

~~(e) 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.~~

~~(5) The Pharmacist must maintain all records associated with prescribing and other related activities performed for a minimum of 7 years, and a copy must be made available to the patient and provider upon request. Pharmacy records must be retained and made available to the board for inspection upon request. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days. Records and documentation must be written, electronic or a combination of the two.~~

~~(6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use an audiovisual communication system to conduct the consultation.~~

~~Statutory/Other Authority: ORS 689.205 & ORS 689.689~~
~~Statutes/Other Implemented: ORS 689.645, ORS 689.649 & ORS 689.689~~

~~855-020-0120~~
~~Prescribing Prohibited Practices~~

~~A Pharmacist must not prescribe a drug or device:~~

~~(1) To self or a spouse, domestic partner, parent, guardian, sibling, child, aunt, uncle, grandchild and grandparent, including foster, in-law, and step relationships or other individual for whom a Pharmacist's personal or emotional involvement may render the Pharmacist unable to exercise detached professional judgment in prescribing pursuant to the Formulary and Protocol Compendia.~~

~~(2) An Intern must not prescribe a drug or device.~~

~~(3) 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 & ORS 689.689~~

~~855-020-0200~~
~~Formulary Compendium~~

~~A pharmacist may prescribe, according to rules in this Division, an 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~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.645 & ORS 689.649~~

~~855-020-0300~~ ***View current SOS version**
~~Protocol Compendium~~
NOTE: The version show below is currently being considered for permanent adoption: mailing **#D1**

~~A Pharmacist may prescribe, via statewide drug therapy management protocol and according to rules outlined in this Division, an FDA-approved drug and device listed in the following compendium:~~

~~(1) Continuation of therapy including emergency refills of insulin (v. 06/2023)~~

~~(2) Conditions~~

~~(a) Cough and cold symptom management~~

~~(A) Pseudoephedrine (v. 06/2021);~~

~~(B) Benzonatate (v. 06/2021);~~

~~(C) Short-acting beta agonists (v. 06/2021);~~

~~(D) 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, Nicotine Replacement Therapy (NRT) and Non-NRT (v. 06/2022);~~

~~(d) Travel Medications (v. 06/2023);~~

~~(e) HIV Post-exposure Prophylaxis (PEP) (v. 06/2023);~~

~~(f) HIV Pre-exposure Prophylaxis (PrEP) (v. 06/2023); and~~

~~(g) Contraception (v. 06/2023); and~~

~~(h) Effective 2/1/2024, vaccinations:~~

~~(A) Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway (v. 2/2024);~~

~~(B) Standard Protocol for All Vaccines: Managing Adverse Reactions (v. 2/2024);~~

~~(C) Cholera (v. 2/2024);~~

~~(D) Coronavirus 2019 (v. 2/2024);~~

~~(E) Haemophilus Influenza type b (v. 2/2024)~~

~~(F) Hepatitis A containing vaccines (v. 2/2024);~~

~~(G) Hepatitis B containing vaccines (v. 2/2024);~~

~~(H) Human Papillomavirus (v. 2/2024);~~

~~(I) Influenza - Inactivated Influenza Vaccines and Recombinant Influenza Vaccines 2023-24 (v. 2/2024);~~

~~(J) Influenza - Live Attenuated Influenza Vaccine 2023-24 (v. 2/2024);~~

~~(K) Japanese Encephalitis (v. 2/2024);~~

~~(L) Meningococcal containing vaccines (v. 2/2024);~~

~~(M) Measles Mumps & Rubella containing vaccines (v. 2/2024);~~

~~(N) Pneumococcal (v. 2/2024);~~

~~(O) Polio (v. 2/2024);~~

~~(P) Rabies (v. 2/2024);~~

~~(Q) Respiratory Syncytial Virus (v. 2/2024);~~

~~(R) Tetanus Diphtheria containing vaccines (v. 2/2024);~~

~~(S) Typhoid (v. 2/2024);~~

~~(T) Varicella containing vaccines (v. 2/2024);~~

~~(U) Yellow fever (v. 2/2024);~~

~~(V) Zoster (v. 2/2024).~~

~~[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, ORS 689.696~~

Division 025: Certified Oregon Pharmacy Technicians and Pharmacy Technicians (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 025; Certified Oregon Pharmacy Technicians and Pharmacy Technicians

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 025 Certified Oregon Pharmacy Technicians and Pharmacy Technicians rules in its entirety, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 125 Pharmacy Technicians Permanent Administrative Order

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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 repeal 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 the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 125 Pharmacy Technicians rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 025 Certified Oregon Pharmacy Technician and Pharmacy Technicians rules in its entirety. The board adopted Division 125 Pharmacy Technicians rules in August 2023 which replaces Division 025. Division 025 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 125 rules to become effective at 12:00AM on 3/1/2024.

~~Division 25~~
~~CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS~~

~~855-025-0001~~
~~Purpose and Scope~~

~~The purpose of the Pharmacy Technician (PT) license is to provide an opportunity for an individual to obtain competency in the role as a Pharmacy Technician. This license will allow an individual time to take and pass a national pharmacy technician certification examination, which is required to be eligible for licensure as a Certified Oregon Pharmacy Technician (CPT). These rules facilitate the initial licensure of a nationally certified Pharmacy Technician seeking licensure in Oregon.~~

~~Statutory/Other Authority: 689.205~~
~~Statutes/Other Implemented: 689.225 & 689.486~~

~~855-025-0005~~
~~Licensure: Qualifications - Pharmacy Technician or Certified Oregon Pharmacy Technician~~

~~(1) To qualify for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician, an applicant must demonstrate that the applicant is at least 18 years of age and has completed high school (or equivalent).~~

~~(2) To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must also demonstrate that the applicant has taken and passed a national pharmacy technician certification examination offered by:~~

~~(a) Pharmacy Technician Certification Board (PTCB); or~~

~~(b) National Healthcareer Association (NHA).~~

~~(3) No person whose license has been denied, revoked, suspended or restricted by any healthcare professional regulatory board may be licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician unless the board determines that licensure will pose no danger to patients or to the public interest.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225 & ORS 689.486~~

~~855-025-0010~~
~~Licensure: Application- Pharmacy Technician~~

~~(1) An application for licensure as a Pharmacy Technician may be accessed on the board website.~~

~~(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline;~~

~~(3) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(4) The board may issue a license to a qualified applicant after the receipt of:~~

~~(a) A completed application;~~

~~(b) Payment of the fee prescribed in OAR 855-110;~~

~~(c) A current, passport regulation size photograph (full front, head to shoulders);~~

~~(d) Personal identification or proof of identity; and~~

~~(e) A completed national fingerprint-based background check.~~

~~(5) The license of a Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225 & ORS 689.486~~

~~855-025-0011~~
~~Licensure: Renewal or Reinstatement- Pharmacy Technician~~

~~(1) An applicant for renewal of a Pharmacy Technician license must:~~

~~(a) Pay the biennial license fee required in OAR 855-110.~~

~~(b) Complete the continuing pharmacy education requirements as directed in OAR 855-135;~~

~~(c) Be subject to an annual criminal background check.~~

~~(2) A Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license and must pay a late fee required in OAR 855-110.~~

~~(3) A Pharmacy Technician or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:~~

~~(a) Must apply per OAR 855-025-0010; and~~

~~(b) Provide certification of completion of 10 continuing education hours earned in the prior 12 months. These hours may not be counted toward a future renewal; and must include:~~

~~(A) One hour of continuing pharmacy education in pharmacy law;~~

~~(B) One hour of continuing pharmacy education in patient safety or error prevention; and~~

~~(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and~~

~~(D) Seven other hours of pharmacy technician-specific continuing education.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225, ORS 689.486 & ORS 413.450~~

~~855-025-0012~~
~~Licensure: Application- Certified Oregon Pharmacy Technician~~

~~(1) An application for licensure as a Certified Oregon Pharmacy Technician may be accessed on the board website.~~

~~(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline.~~

~~(3) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(4) The board may issue a license to a qualified applicant after the receipt of:~~

~~(a) A completed application;~~

~~(b) Payment of the fee prescribed in OAR 855-110;~~

~~(c) A current, passport regulation size photograph (full front, head to shoulders);~~

~~(d) Personal identification or proof of identity;~~

~~(e) A completed national fingerprint-based background check; and~~

~~(f) Proof that the applicant has taken and passed a national pharmacy technician certification offered by the PTCB or the NHA.~~

~~(5) The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225 & ORS 689.486~~

~~855-025-0015~~
~~Licensure: Renewal or Reinstatement- Certified Oregon Pharmacy Technician~~

~~(1) A person who has taken and passed a national pharmacy technician certification examination listed in OAR 855-025-0012(1)(a) (b) may use the following title, and is referred to in these rules as, and is licensed as a "Certified Oregon Pharmacy Technician."~~

~~(2) An applicant for renewal of a Certified Oregon Pharmacy Technician license must:~~

~~(a) Pay the biennial license fee required in OAR 855-110;~~

~~(b) Complete the continuing pharmacy education requirements as directed in OAR 855-135; and~~

~~(c) Be subject to an annual criminal background check.~~

~~(3) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.~~

~~(4) A Certified Oregon Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may renew their license and must pay a late fee required in OAR 855-110.~~

~~(5) A Certified Oregon Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:~~

~~(a) Must apply per OAR 855-025-0012; and~~

~~(b) Provide certification of completion of 10 continuing education hours earned in the prior 12 months. These hours may not be counted toward a future renewal; and must include:~~

~~(A) One hour of continuing pharmacy education in pharmacy law;~~

~~(B) One hour of continuing pharmacy education in patient safety or error prevention; and~~

~~(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and~~

~~(D) Seven other hours of pharmacy technician-specific continuing education.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225, ORS 689.486 & ORS 413.450~~

~~855-025-0020~~
~~Duty to Report~~

~~(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.~~

~~(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(3) A Pharmacy Technician or Certified Oregon Pharmacy Technician must report to the board within 10 days if they:~~

~~(a) Are convicted of a misdemeanor or a felony; or~~

~~(b) If they are arrested for a felony.~~

~~(4) A Pharmacy Technician or Certified Oregon Pharmacy Technician who has reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting Pharmacy Technician or Certified Oregon Pharmacy Technician must report the conduct without undue delay, but in no event later than 10 working days after the reporting Pharmacy Technician or Certified Oregon Pharmacy Technician learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.~~

~~(5) A Pharmacy Technician or Certified Oregon Pharmacy Technician who reports to a board in good faith as required by section (4) of this rule is immune from civil liability for making the report.~~

~~(6) A Pharmacy Technician or Certified Oregon Pharmacy Technician who has reasonable grounds to believe that prescription drugs or records have been lost or stolen, or any violation of these rules has occurred, must notify the board within 1 day.~~

~~(7) A Pharmacy Technician or Certified Oregon Pharmacy Technician must notify the board in writing, within 15 days, of any change in email address, employment location or residence address except that a Pharmacy Technician who is employed at more than one pharmacy need only report the name and address of the pharmacy at which the technician normally works the most hours.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155 & ORS 689.486~~

~~855-025-0023~~
~~Certified Oregon Pharmacy Technician and Pharmacy Technician: General Responsibilities~~

~~(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician is responsible for their own actions; however, this does not absolve the Pharmacist and the pharmacy from responsibility for the Certified Oregon Pharmacy Technician or Pharmacy Technician's actions.~~

~~(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician must:~~

~~(a) Comply with all state and federal laws and rules governing the practice of pharmacy;~~

~~(b) Only assist in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;~~

~~(c) Know the identity of the Pharmacist who is providing supervision, direction and control at all times;~~

~~(d) Only work within the scope of duties permitted by their license;~~

~~(e) Only perform duties they are trained to perform; and~~

~~(f) Only access the pharmacy area when a Pharmacist is on duty.~~

~~(3) A Certified Oregon Pharmacy Technician or Pharmacy Technician may not engage in the practice of pharmacy as defined in ORS 689.005.~~

~~(4) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification of the drug and dosage, device or product when:~~

~~(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;~~

~~(b) No discretion is needed;~~

~~(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and~~

~~(d) The Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.~~

~~Statutory/Other Authority: ORS 689.205 & 2022 HB 4034~~
~~Statutes/Other Implemented: ORS 689.155 & 2022 HB 4034~~

~~855-025-0024~~
~~Services: Vaccine Administration~~
~~NOTE:~~ The version below is currently being considered for permanent adoption: mailing **#D**

~~(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform the physical act of administering vaccines under the supervision of an appropriately trained and qualified Pharmacist:~~

~~(a) To a person who is seven years of age or older;~~

~~(b) To a person who is at least three years of age when;~~

~~(A) The Governor declares a state of public health emergency and authorizes the reduced age limitation; or~~

~~(B) The Public Health Director, during a declared disease outbreak, authorizes a reduction in the age limit.~~

~~(2) A Certified Oregon Pharmacy Technician or Pharmacy Technician must:~~

~~(a) Prior to administration of a vaccine, receive practical training that includes infection control, recognition of anatomical landmarks and competency in hands-on administration technique.~~

~~(b) Prior to administration of a vaccine, hold active CPR certification issued by the American Heart Association or the American Red Cross or any other equivalent program that is specific to the age and population receiving the vaccine, contains a hands-on training component, and is valid for not more than three years.~~

~~(3) Document the vaccine administration including but not limited to the vaccine administered, dose, expiration date, lot number, and injection site.~~

~~(4) Notify the supervising Pharmacist immediately in the event of a suspected adverse reaction to a vaccine.~~

~~(5) The training required in (2) may include programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college or school of pharmacy, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the board.~~

~~(6) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.~~

~~Statutory/Other Authority: ORS 689.205, 2023 HB 2486~~
~~Statutes/Other Implemented: ORS 689.151, 2023 HB 2486~~

~~855-025-0025~~
~~Use of Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~(1) A Pharmacist or pharmacy may use Pharmacy Technicians or Certified Oregon Pharmacy Technicians only as authorized by the rules of the Board.~~

~~(2) Pharmacy Technicians or Certified Oregon Pharmacy Technicians must be supervised by a Pharmacist.~~

~~(3) Pharmacists, Pharmacist Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians must be clearly identified as such to the public.~~

~~(4) Work performed by Pharmacy Technicians and Certified Oregon Pharmacy Technicians assisting the Pharmacist to prepare medications must be verified by a Pharmacist prior to release for patient use. Verification must be documented, available and consistent with the standard of practice.~~

~~(5) The pharmacist-in-charge must prepare and maintain in the pharmacy written procedures that describe the tasks performed by Pharmacy Technicians or Certified Oregon Pharmacy Technicians, and the methods of verification and documentation of work performed by Pharmacy Technicians or Certified Oregon Pharmacy Technicians. Written procedures must be available for inspection by the Board or its representatives. The pharmacist-in-charge must review written procedures annually and document that review on the annual pharmacist-in-charge inspection sheet.~~

~~(6) Training:~~

~~(a) The pharmacist-in-charge must outline, and each Pharmacy Technician or Certified Oregon Pharmacy Technician must complete initial training that includes on-the-job and related education that is commensurate with the tasks that the Pharmacy Technician or Certified Oregon Pharmacy Technician will perform, prior to the performance of those tasks.~~

~~(b) The pharmacist-in-charge must ensure the continuing competency of Pharmacy Technicians or Certified Oregon Pharmacy Technicians.~~

~~(c) The pharmacist-in-charge must document initial training of each Pharmacy Technician or Certified Oregon Pharmacy Technician and make that documentation available to the Board or its representatives upon request.~~

~~(7) Upon written request, the Board may waive any of the requirements of this rule upon a showing that a waiver will further public health or safety or the health or safety of a patient or other person. A waiver granted under this section is effective only when issued by the Board in writing.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

~~855-025-0030~~
~~Confidentiality~~

~~(1) No licensee of the Board who obtains any patient information shall disclose that information to a third-party without the consent of the patient except as provided in section two of this rule.~~

~~(2) A licensee may disclose patient information:~~

~~(a) To the Board;~~

~~(b) To a practitioner, Pharmacist, Pharmacy Technician, or Certified Oregon Pharmacy Technician, if disclosure is authorized by a Pharmacist who reasonably believes that disclosure is necessary to protect the patient's health or well-being; or~~

~~(c) To a third-party when disclosure is authorized or required by law; or~~

~~(d) As permitted pursuant to federal and state patient confidentiality laws.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

~~855-025-0035~~
~~Pharmacy and Pharmacist Responsibility for Supervising Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~(1) The supervising Pharmacist and the pharmacist-in-charge are responsible for the actions of Pharmacy Technicians or Certified Oregon Pharmacy Technicians. The use of Pharmacy Technicians or Certified Oregon Pharmacy Technicians to perform tasks not included in written procedures maintained by the pharmacy constitutes unprofessional conduct on the part of the supervising Pharmacist and the pharmacist-in-charge.~~

~~(2) The pharmacy must maintain on file and post the current license of each Pharmacy Technician or Certified Oregon Pharmacy Technician.~~

(3) Before allowing any person to work as a Pharmacy Technician or Certified Oregon Pharmacy Technician, the pharmacy and Pharmacist shall verify that the person is currently licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician.

(4) Prior to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician, a person must provide to the Pharmacist or pharmacist-in-charge a copy of the person's current Pharmacy Technician license or current Certified Oregon Pharmacy Technician license.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-025-0040
Certified Oregon Pharmacy Technician and Pharmacy Technician: Tasks and Guidelines

(1) Non-licensed pharmacy personnel may enter non-prescription information into a computer record system and may perform clerical duties such as filing prescriptions, delivery, housekeeping, and general record keeping, but the responsibility for the accuracy of the non-licensed pharmacy personnel's work lies with the Pharmacist.

(2) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician, acting in compliance with all applicable statutes and rules and under the supervision of a Pharmacist, may assist in the practice of pharmacy by the following:

(a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

(b) Reconstituting prescription medications. The supervising Pharmacist must verify the accuracy in all instances.

(c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.
(d) Entering information into the pharmacy computer. The Certified Oregon Pharmacy Technician or Pharmacy Technician shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising Pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.

(e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;

(f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The Pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.

~~(g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The Pharmacist must verify the accuracy of the finished task unless the requirements of OAR 855-025-0023(4) are met.~~

~~(h) Checking nursing units in a hospital or nursing home for nonjudgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a Pharmacist.~~

~~(i) Recording patient or medication information in computer systems for later verification by the Pharmacist.~~

~~(j) Bulk Compounding; Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(k) Preparation of parenteral products as follows:~~

~~(A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(l) Performing related activities approved in writing by the board.~~

~~(3) In order to protect the public, safety, health and welfare, Certified Oregon Pharmacy Technicians or Pharmacy Technicians shall not:~~

~~(a) Communicate or accept by oral communication a new or transferred prescription of any nature;~~

~~(b) Receive or transfer a prescription to another pharmacy without the prior verification of a Pharmacist.~~

~~(c) Provide a prescription or medication to a patient without a Pharmacist's verification of the accuracy of the dispensed prescription;~~

~~(d) Counsel a patient on medications or perform a drug utilization review;~~

~~(e) Perform any task that requires the professional judgment of a Pharmacist; or~~

~~(f) Engage in the practice of pharmacy as defined in ORS 689.~~

~~Statutory/Other Authority: ORS 689.205 & 2022 HB 4034~~
~~Statutes/Other Implemented: ORS 689.155 & 2022 HB 4034~~

~~855-025-0050~~
~~Grounds for Discipline of Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~The State Board of Pharmacy may refuse to issue or renew; or may suspend, revoke, or restrict the license of a Pharmacy Technician or Certified Oregon Pharmacy Technician; or may impose a civil penalty upon a Pharmacy Technician or Certified Oregon Pharmacy Technician upon the following grounds including but not limited to:~~

~~(1) Unprofessional conduct as defined in OAR 855-006-0020;~~

~~(2) Repeated or gross negligence in performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician;~~

~~(3) Impairment, which means an inability to assist in the practice of pharmacy with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;~~

~~(4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;~~

~~(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a Pharmacy Technician or Certified Oregon Pharmacy Technician license;~~

~~(8) Allowing an individual to engage in the duties of a Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician without a license or to use falsely the title of Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician;~~

~~(9) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto;~~

~~(10) Failure to appropriately perform the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician as outlined in OAR 855-025-0040 while assisting a Pharmacist in the practice of pharmacy as defined in ORS 689.005;~~

~~(11) Any act or practice relating to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician which is prohibited by state or federal law or regulation; or~~

~~(12) Any conduct or practice by a Pharmacy Technician, Certified Oregon Pharmacy Technician or pharmacy that the Board determines is contrary to the accepted standards of practice.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.405~~

Division 031: Interns (Repeal)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals Division 031; Interns

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 031 Intern rules in its entirety, effective at 11:59PM on 2/29/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 120 Interns and Preceptors Permanent Administrative Order

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule repeal is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule repeal has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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 repeal 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 the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule repeal.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 120 Interns and Preceptors rules in August 2023, effective 3/1/2024. The nature of the proposed rule repeal does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Repeals Division 031 Interns rules in its entirety. The board adopted Division 120 Interns and Preceptors rules in August 2023, which replaces Division 031. Division 031 needs to be repealed effective at 11:59PM on 2/29/2024 to allow Division 125 rules to become effective at 12:00AM on 3/1/2024.

~~Division 31~~
~~INTERNS~~

~~855-031-0005~~
~~Definitions~~

~~(1) An "intern" means any person who:~~

~~(a) Is enrolled in a course of study and is in good academic standing at a school or college of pharmacy that is approved by the Oregon Board of Pharmacy; or~~

~~(b) Is a graduate of a school or college of pharmacy that is approved by the board; or~~

~~(c) Is a foreign pharmacy graduate and holds a certificate from the Foreign Pharmacy Graduate Equivalency Committee (FPGEC); and~~

~~(d) Is licensed with the board as an intern.~~

~~(2) A "preceptor" means a pharmacist or a person licensed by the board to supervise the internship training of an intern.~~

~~(3) "Internship" means a professional experiential program or work experience.~~

~~(a) "Traditional Pharmacy-practice Internship (TPI)" means experience toward achieving competency in the practice of pharmacy for which no academic credit is granted to the intern.~~

~~(b) "School-based Rotational Internship (SRI)" means experience toward achieving competency in the practice of pharmacy in programs developed and administered by a school of pharmacy.~~

~~(c) "Other Internship" means experience toward achieving competency in the practice of pharmacy, other than in an internship as defined in (a) or (b), in a program approved by a school of pharmacy or the board.~~

~~(4) "School of pharmacy": In this division of rules, "school of pharmacy" means a school or college of pharmacy that is approved by the board.~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.255~~

~~855-031-0010~~
~~Intern License Application~~

~~(1) Applications for licensure as an intern may be obtained from the board website.~~

~~(a) Failure to completely, accurately and honestly answer all questions on the application form for licensure or renewal of licensure is grounds for discipline;~~

~~(b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

~~(2) The board may issue a license to a qualified intern after the receipt of:~~

~~(a) A completed application;~~

~~(b) Payment of the fee prescribed in OAR 855-110;~~

~~(c) A current, passport regulation size photograph (full front, head to shoulders);~~

~~(d) Furnish documentation required to conduct a national fingerprint-based background check; and~~

~~(e) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study, except for foreign pharmacy graduates who must:~~

~~(A) Provide a copy of a valid visa permitting full-time employment;~~

~~(B) Provide a copy of the original certificate issued by the Foreign Pharmacy Graduate Equivalency Examination Committee; and~~

~~(C) Provide evidence that they have passed the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT).~~

~~(3) The board may issue an intern license after processing the application, however unless the applicant is a foreign graduate or an applicant for licensure by reciprocity, it is not valid until the intern has started a course of study. The initial license is valid until the last day of November following the second anniversary of issue unless terminated automatically by any one of the following events. Renewed licenses are valid for two years unless terminated automatically by any one of the following events:~~

~~(a) Licensure to practice pharmacy is granted in any state; or~~

~~(b) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, fails to maintain enrollment or active registration in a pharmacy degree program for a period greater than one year; or~~

~~(c) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, has been graduated from a school of pharmacy for 12 months;~~

~~(d) The intern is dismissed, terminated or expelled by the school of pharmacy, or withdraws from the program.~~

~~(4) An intern must surrender their license to the board within 30 days of one of the above events.~~

~~(5) Notwithstanding the requirements of section (3) above, upon written request the board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section must only be effective when it is issued in writing.~~

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

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.207, ORS 689.255 & ORS 689.455~~

~~855-031-0016~~
~~Renewal of Licensure as an Intern~~

~~(1) An application for renewal of an intern license must include documentation of:~~

~~(a) Completion of continuing pharmacy education requirements as directed in OAR 855-135; and~~

~~(b) Payment of the license fee required in OAR 855-110.~~

~~(2) An intern will be subject to an annual criminal background check.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

~~855-031-0020~~
~~Intern Requirements and Responsibilities~~

~~(1) A licensed intern may practice in any one or a combination of the following approved internship experience areas:~~

~~(a) Traditional Pharmacy-practice Internship (TPI): an intern may not work in a TPI until after satisfactorily completing the first academic year in a school of pharmacy. An intern working in a TPI must be supervised by a licensed pharmacist or pharmacist preceptor;~~

~~(b) School-based Rotational Internship (SRI): an intern must be supervised by a licensed pharmacist or other person approved by a school of pharmacy to obtain credit for SRI hours;~~

~~(c) Other Internship.~~

~~(2) An intern may not work more than 48 hours per week in SRIs and must comply with all supervision and ratio requirements.~~

~~(3) An intern must verify that their preceptor is currently licensed with the board.~~

~~(4) An intern may not work in the practice of pharmacy unless supervised by a licensed pharmacist, except when an intern is working in a federal facility, however, to obtain credit for SRI experience in a federal facility located in Oregon, the intern must be licensed with the board.~~

~~(5) An intern who is working in a pharmacy or other place of business must conspicuously display their intern license in the pharmacy or place of business and must be clearly identified as an intern at all times.~~

~~(6) An intern may perform only the duties listed in Division 025 of this Chapter before completion of the first academic year in a school of pharmacy.~~

~~(7) An intern may, after successful completion of their first academic year, perform the duties of an intern listed in Division 019 of this Chapter, but only after successful completion of coursework corresponding to those duties at their school of pharmacy and only with the permission of their supervising pharmacist.~~

~~(8) An intern is responsible for his or her own actions and must comply with all board regulations.~~

~~(9) An intern must notify the board within 15 days of any change in their academic status that might affect their eligibility to work as an intern.~~

~~(10) An intern must notify the board in writing within 15 days of a change in permanent residence and TPI site.~~

~~(11) An intern must report to the board within 10 days if they are:~~

~~(a) Convicted of a misdemeanor or a felony; or~~

~~(b) Arrested for a felony.~~

~~(12) An intern who has reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The intern must report the conduct without undue delay, but in no event later than 10 working days after the intern learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.~~

~~(13) If needed by an intern for compliance with another board's requirement, an intern must maintain written or electronic records that support the number of TPI hours claimed by an intern and have those hours certified by a preceptor.~~

~~(14) An intern may make a voluntary report to the board on any preceptor's aptitude and professionalism in performing the duties of a preceptor. An intern must make such a report upon request by the board.~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.255 & ORS 689.455~~

~~855-031-0026~~
~~Ratio & Supervision~~

~~(1) A Pharmacist may not supervise more than one Intern at a time at a TPI site who performs the duties of an Intern as listed in OAR 855-019-0200(6). A Pharmacist may supervise more than one Intern if only one intern performs the duties of an Intern as listed in OAR 855-019-0200(6) and if other Interns supervised by the Pharmacist perform the duties listed in OAR 855-025-0040.~~

~~(2) A preceptor may not supervise more than two Interns simultaneously during a shift at an SRI site where patient specific recommendations for care or medications are provided without prior written authorization of the board.~~

~~(3) With the written approval of a school of pharmacy, and when in their reasonable professional judgment it is appropriate, a preceptor may supervise up to 10 Interns at public-health outreach programs such as informational health fairs that provide general information but not direct patient care.~~

~~(4) For immunization clinics, an immunizing Pharmacist may supervise up to two immunizing Interns.~~

~~(5) A licensed preceptor may delegate the preceptor responsibilities to another licensed Pharmacist or preceptor.~~

~~(6) The majority of an Intern's overall experience must be with a licensed Pharmacist preceptor.~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.255~~

~~855-031-0030~~
~~Out-of-State Internship Experience~~

~~(1) In order for an Oregon intern to obtain credit for SRI experiences outside the State of Oregon, an intern must:~~

~~(a) Be licensed as required by state laws and rules in the state in which they will practice;~~

~~(b) Meet or exceed the minimum SRI requirements of the board;~~

~~(2) In order for an out-of-state intern to practice in the State of Oregon, the intern must meet all requirements of these rules.~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.255~~

~~855-031-0045~~
~~School and Preceptor Registration and Responsibilities~~

~~(1) A preceptor license may be issued by the board upon receipt of a completed application.~~

~~(2) A pharmacist preceptor must have been an actively practicing pharmacist for at least one year immediately prior to supervising an intern.~~

~~(3) A preceptor license must be renewed biennially and will expire on June 30 in odd numbered years.~~

~~(4) The preceptor may report to the board voluntarily, the progress and aptitude of an intern under the preceptor's supervision, or must do so upon request of the board.~~

~~(5) The preceptor must be responsible for supervision of the majority of the intern's SRI hours and must provide the intern with internship experiences, which in the preceptor's judgment will increase the intern's competency in the practice of pharmacy.~~

~~(6) Before supervising an intern in an SRI program, a preceptor must complete any training program required by the school of pharmacy.~~

~~(7) A preceptor must advise each school of pharmacy when they are supervising students from more than one school at the same time. This applies to both in-state and out-of-state schools or colleges of pharmacy.~~

~~(8) A preceptor must verify that their intern is currently licensed with the board.~~

~~(9) A pharmacist acting as a preceptor in a federal facility is not required to be licensed as a pharmacist in Oregon, but is required to be licensed as a preceptor with the board.~~

~~(10) The school of pharmacy must maintain a record of each intern's SRIs. This record must be made available to the board upon request.~~

~~(11) A school of pharmacy located in Oregon must submit a report on their experiential education program to the board at the end of each academic year. This report must include the names of students who successfully completed the program and graduated from the school. The school must maintain a list of preceptors and SRI sites, in and out-of-state, approved by the school and must make this list available to the board upon request.~~

~~(12) All records related to a student must be available for three years after the student graduates.~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.255~~

~~855-031-0050~~
~~Eligibility for Exams — Foreign Pharmacy Graduates~~

~~In addition to the other requirements of this Division, a foreign pharmacy graduate must complete 1440 internship hours before applying to take the Multistate Pharmacy Jurisprudence Examination (MPJE) and before applying for licensure as a pharmacist as specified in OAR 855-019-0150. Evidence of completing this requirement must be provided to the board by the applicant and must be authenticated by each preceptor.~~

~~Statutory/Other Authority: ORS 689.151 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.255~~

~~855-031-0055~~
~~Eligibility for Exams and Pharmacist Licensure~~

~~(1) An intern is eligible to take the North American Pharmacist Licensure Examination (NAPLEX) and the MPJE, upon graduation and notification to the board by the school of pharmacy that their degree, with not less than 1440 hours of SRI, has been conferred.~~

~~(2) Upon meeting all requirements for pharmacist licensure, and before practicing pharmacy in the State of Oregon, a person must:~~

~~(a) Complete an application for licensure including providing any fingerprint card or other documentation required by the board to conduct a criminal background check;~~

~~(b) Pay the license fee as prescribed in OAR 855-110; and~~

~~(c) Obtain a license, which will expire on June 30 in odd-numbered years.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.135, ORS 689.207, ORS 689.225 & ORS 689.275~~

Divisions 041/110 - Operation of Pharmacies & Fees

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Consulting Drugless Pharmacy rule amendments and rule repeals

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes striking Division 041 rules related to Consulting/Drugless Pharmacies and amending OAR 855-041-3000, effective at 12:00AM on 3/1/2024. Proposes amending OAR 855-110-0007(7)(a)(A) by striking Consulting "Drugless" Drug Outlet Pharmacy, effective at 12:00AM on 3/1/2024. Rules related to Consulting "Drugless" Pharmacies are no longer necessary as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 115 Pharmacists Permanent Administrative Order, Div 104 Universal Rules Permanent Administrative Order

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule amendments and rule repeals are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The agency estimates a reduction in revenue in the amount of $9900 in licensing fees for the 2023-2025 biennium by repealing Consulting/Drugless pharmacy rules.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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 agency anticipates a reduction in revenue in the amount of $9900 for the 2023-2025 biennium by repealing Consulting/Drugless pharmacy rules. The proposed rule amendments and rule repeals have no additional economic impact on 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 the rules: Small businesses were not involved in determining whether the rules should be amended or repealed. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule amendments and repeals.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The nature of the proposed rule amendments and rule repeals does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-041-3000 – Proposes to strike "Consulting/Drugless Pharmacy Outlets Purpose and Scope" from the rule title as well as strikes (4) as the rules referenced are being proposed to be repealed.

OAR 855-041-3300, OAR 855-041-3305, OAR 855-041-3310, OAR 855-041-3315, OAR 855-041-3315, OAR 855-041-3320, OAR 855-041-3325, OAR 855-041-3330, OAR 855-041-3335 and OAR 855-041-3340 are proposed to be repealed in their entirety effective at 11:59PM on 2/29/2024 due to Consulting/Drugless Pharmacy Outlets new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

OAR 855-110-0007 – Proposes amending the rule by striking 7(A) "Consulting/Drugless Pharmacy as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

Division 41
OPERATION OF PHARMACIES

855-041-3000
Central Fill and Remote Processing Outlet Designations ~~and Consulting/Drugless Pharmacy Outlets - Purpose and Scope~~

(1) The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of operation for centralized prescription drug filling by a pharmacy.

(2) The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription processing by a pharmacy.

(3) Prior to initiating one of the above drug outlet models, a description of how the model will be utilized must be submitted to the Board.

~~(4) The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a consulting or drugless pharmacy. Prior to initiating this model, a description of how the model will be utilized to improve patient safety must be submitted to the Board.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~855-041-3300~~
~~Consulting/Drugless Pharmacy - Purpose and Scope~~

~~The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a single physical location. This location may be an office located in a home or other secure location. Registration is not required if records used or generated by a consulting pharmacist are stored in a location registered by the Board as a retail or institutional drug outlet or if the location is under the control of a practitioner who uses the services of the consulting pharmacist. The consulting pharmacist must be able to provide the Board with documentation of their pharmaceutical care activities. These rules are intended to ensure that a location where a pharmacist is engaged in Independent Pharmacy Practice may safely store records and protected health information. An applicant must submit to the~~

Board for approval policies and procedures and a description of how their consulting or drugless pharmacy will be utilized to improve patient safety.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3305
Consulting/Drugless Pharmacy - Definitions

The following words and terms, when used OAR 855-041-3300 through 855-041-3340 shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the OAR chapter 855, division 6.

(1) "Consulting or Drugless Pharmacy" means any single physical location where pharmaceutical care services are performed or protected health information may be stored without the storage, possession, or ownership of any drug.

(2) "Consulting Pharmacist" means any pharmacist as defined by OAR chapter 855, division 6 and is described by chapter 855, division 19.

(3) "Independent Pharmacy Practice" means the provision of pharmaceutical services not related to physically handling or dispensing pharmaceuticals drugs or devices. This practice is characterized by the practice of an Oregon licensed pharmacist acting as an independent contractor whether or not directly employed or affiliated with an entity that is licensed by the Board. This service also does not include the provision of pharmaceutical care that is conducted within the physical confines or location of a licensed pharmacy registered with the Board.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3310
Consulting/Drugless Pharmacy - Registration

(1) The Consulting Pharmacy shall be registered as a retail or institutional drug outlet and comply with all the requirements of licensure as defined in OAR 855-041-1080 through 855-041-1100.

(2) The location must be available for inspection by the Board.

(3) A consulting pharmacist for an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure, as well as any applicable federal and state laws and rules.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~855-041-3315~~

~~Consulting/Drugless Pharmacy - Personnel~~

~~(1) Each pharmacy must have a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the state in which the pharmacy is located if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;~~

~~(2) The pharmacy must comply with all applicable state and federal laws and rules governing the practice of pharmacy and maintain records in compliance with requirements of federal law and Board rules;~~

~~(3) A consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon; and~~

~~(4) Prospective drug utilization reviews, refill authorizations, interventions and patient counseling not associated with the dispensing of a drug for an Oregon patient must be performed by an Oregon licensed pharmacist.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

~~855-041-3320~~

~~Consulting/Drugless Pharmacy - Confidentiality~~

~~(1) Each consulting pharmacy must comply with all applicable federal and state laws and rules regarding confidentiality, integrity and privacy of patient information.~~

~~(2) Each consulting pharmacy must ensure that electronic data systems are secure and comply with applicable federal and state laws and rules.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

~~855-041-3325~~

~~Consulting/Drugless Pharmacy - General Provisions and Minimum Standards~~

~~(1) A consulting pharmacy shall:~~

~~(a) Maintain appropriate reference materials for drug information according to the scope of consulting services.~~

~~(b) Be located in a secure room with a door and suitable lock, and accessible only to persons authorized by the pharmacist-in-charge.~~

~~(c) Provide storage sufficient to secure confidential documents and any hardware necessary to access information.~~

~~(d) Be constructed in a manner of materials that make the space separate and distinct from the rest of the home or office building, and that protects the records from unauthorized access.~~

~~(2) A consulting pharmacy located in a residence must be approved by the Board.~~

~~(3) The consulting pharmacist must be able to provide the Board, upon request, with documentation of their pharmaceutical care activities.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

~~855-041-3330~~
~~Consulting/Drugless Pharmacy - Security Requirements~~

~~(1) All consulting services must occur in a secure environment that includes but is not limited to:~~

~~(a) A closed system or other electronic storage device that is password protected;~~

~~(b) A secure room or safe that is locked to store records when the pharmacist is not directly monitoring them;~~

~~(c) Sufficient encryption for securing confidential documents and any hardware used in accessing authorized patient health information by electronic connection; and~~

~~(d) A data processing system that complies with all federal and state laws and rules to ensure compliant security software.~~

~~(2) Records stored at a practitioner's office must be kept secure either with other records at the facility or independently in a locked room where only the pharmacist, and physician and their agents have access;~~

~~(3) All records must be stored at the approved consulting or drugless pharmacy; and~~

~~(4) Any breach in the security of the system or breach of confidentiality must be documented and reported to the Board within seven days.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

~~855-041-3335~~
~~Consulting/Drugless Pharmacy - Policies and Procedures~~

~~The consulting pharmacy must maintain a current policy and procedures manual that includes at a minimum:~~

~~(1) A policy on protecting confidentiality and integrity of patient information;~~

~~(2) An outline of responsibilities and scope of services;~~

~~(3) A policy on compliance with federal and state laws and rules;~~

~~(4) An operational Quality Assurance Program;~~

~~(5) A policy that describes use of computer systems.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

~~855-041-3340~~
~~Consulting/Drugless Pharmacy - Records~~

~~(1) The recordkeeping and storage requirements in OAR 855-041-3300 through 855-041-3340 are in addition to the requirements of other recordkeeping and storage rules of the Board. Records and documentation may be written, electronic or a combination of the two.~~

~~(2) Each recordkeeping system must include quality improvement program documentation;~~

~~(3) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety, and welfare. Records must include but need not be limited to:~~

~~(a) Patient profiles and records;~~

~~(b) A list of current employees and their license numbers;~~

~~(A) Verification of each license and registration;~~

~~(B) The name of the individual responsible for verification of licensure and registration status.~~

~~(c) Copies of all contracts for consulting services and collaborative therapy agreements;~~

~~(d) Copies of all consultation reports submitted to practitioners and facilities.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

Division 110
FEES

855-110-0007
Fees for Registration, Renewal, and Reinspection of Drug Outlets

(1) Drug Distribution Agent. Expires September 30 annually - $400. Late renewal fee (received after September 30) - $100.

(2) Drug Room (including Correctional Facility). Expires March 31 annually - $100. Late renewal fee (received after March 31) - $75.

(3) Manufacturer (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually - $525. Late renewal fee (received after September 30) - $100.

(4) Nonprescription Drug Outlet. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.

(a) This includes the following categories of registration:

(A) Nonprescription Class A.

(B) Nonprescription Class B.

(C) Medical Device, Equipment & Gas Class C.

(b) Other nonprescription Drug Outlet registration category fees are as follows:

(A) Nonprescription Class D. Expires January 31 annually - $100. Late renewal fee (received after January 31) - $25.

(B) Nonprescription Class E. Expires January 31 annually - $0. Late renewal fee (received after January 31) - $0.

(5) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - $50. Expires December 31 annually.

(6) Re-inspection fee - $100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.

(7) Retail or Institutional Drug Outlet Pharmacy. Expires March 31 annually - $225. Late renewal fee (received after March 31) - $75.

(a) This includes the following categories of registration:

~~(A) Consulting "Drugless" Drug Outlet Pharmacy~~

(~~B~~**A**) Home Dialysis Retail Drug Outlet Pharmacy

(~~C~~**B**) Institutional Drug Outlet Pharmacy

(~~D~~**C**) Remote Dispensing Site Retail Drug Outlet Pharmacy

(~~E~~**D**) Retail Drug Outlet Pharmacy

(b) Other Retail/Institutional Drug Outlet registration category fees are as follows:

(A) Charitable Retail Drug Outlet Pharmacy. Expires March 31 annually - $75. Late renewal fee (received after March 31) - $25.

(B) Community Health Clinic (CHC) Retail Drug Outlet Pharmacy. Expires March 31 annually - $100. Late renewal fee (received after March 31) - $25.

(C) Dispensing Practitioner Drug Outlet (DPDO) Retail Drug Outlet Pharmacy. Expires March 31 annually - $100. Late renewal fee (received after March 31) - $25.

(D) Prescription Kiosk Retail Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(E) Prescription Locker Retail Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(F) Remote Dispensing Machine Institutional Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(G) Remote Distribution Facility Institutional Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(8) Wholesaler (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually - $525. Late renewal fee (received after September 30) - $100.

Statutory/Other Authority: ORS 689.205, ORS 291.055
Statutes/Other Implemented: ORS 689.135, ORS 689.774, ORS 689.305

Division 115: Pharmacists (Applicability)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Applicability of Pharmacy Practice Regulations and Licensing Requirements for Pharmacists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed rule adds new language related to applicability. Relocates and revises OAR 855-019-0100 related to applicability. Removes waiver authority and reference to Interns.

Documents Relied Upon per ORS 183.335(2)(b)(D): None

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal anticipated. When the board sends the proposed rule to a rulemaking hearing, licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): (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).
(1) The proposed rule will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a)The proposed rule applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: If the board sends the proposed rule to rulemaking hearing, licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not convened. Why? The resources involved in convening a RAC were not necessary to amend this rule. Board members represent the interests of persons and communities likely to be affected by a proposed rule and were able to provide information necessary to amend the rule.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-115-0001: Proposed new rule relocates and revises existing rule language from OAR 855-019-0100 to OAR 855-115-0001 related to applicability. Removes provision for Interns that is now included in OAR 855-120-0135 and removes board waiver of rule. Clarifies which pharmacists working for out-of-state pharmacies must be licensed by the board.

- History of rule package review
    - June 2022- The board completed a 1st review the RPH licensing rules (OAR 855-115-0001 to 855-115-0070).
    - August 2022- The board completed a 2nd review of the RPH licensing rules (OAR 855-115-0001 to 855-115-0070) and a 1st review of the associated definitions (OAR 855-006-0005) and responsibilities rules (OAR 855-115-0200 to 855-115-0086(1)).
    - October 2022- The board completed a 3rd review of the RPH licensing rules (OAR 855-115-0001 to 855-115-0070) and a 2nd review of the associated definitions (OAR 855-006-0005) and responsibilities rules (855-115-0070 to 855-115-0086).
        - Board sent rules to November 2022 rulemaking seeking public comment only
    - December 2022- The board completed a 3rd review of responsibilities rules (OAR 855-115-0070 to 855-115-0086) and 1st review of services rules (OAR 855-115-0100 to 855-115-0150(1)(c)).
    - February 2023- The board completed a 4th review of RPH licensing rules (OAR 855-115-0001 to 855-115-0066) and responsibilities rules (OAR 855-115-0070A to 855-115-0150(1)(c)), 2nd review of services rules (OAR 855-115-0105 to OAR 855-115-0120(1)(c), and 1st review of services rules (OAR 855-115-0120(1)(d) to 855-115-0185)
        - Board requested staff convene a Workgroup for OAR 855-115-0120 and a Workgroup meeting was held May 2023.
    - April 2023- The board completed a 3rd review of associated definitions (OAR 855-006-0005), a 5th review of RPH licensing rules (OAR 855-115-0001 to 855-115-0070) and responsibilities rules (OAR 855-115-0105 to 855-115-0145).
    - June 2023- The board completed a 6th review of RPH licensing rules (OAR 855-115-0001 to 855-115-0070) and responsibilities rules (OAR 855-115-0105 to 855-115-0145), a 4th review of responsibilities rules (OAR 855-115-0150 to 855-115-0210), a 2nd/3rd review of services rules (OAR 855-115-0300 to 855-115-0350).
        - Board sent rules (OAR 855-115-0001 to 855-115-0350) to July 2023 rulemaking
    - August 2023- Board adopted proposed rules OAR 855-115-0010, OAR 855-115-0015, OAR 855-115-0020, OAR 855-115-0025, OAR 855-115-0030, OAR 855-115-0035, OAR 855-115-0040, OAR 855-115-0045, OAR 855-115-0050, OAR 855-115-0060, OAR 855-115-0065, OAR 855-115-0070, OAR 855-115-0105,OAR 855-115-0110, OAR 855-115-0115, OAR 855-115-0120, OAR 855-115-0125, OAR 855-115-0130, OAR 855-115-0140, OAR 855-115-0210, OAR 855-115-0300, OAR 855-115-0310, OAR 855-115-0320, OAR 855-115-0330, OAR 855-115-0335, OAR 855-115-0340, and OAR 855-115-0345.
        - The board did not permanently adopt proposed rules OAR 855-115-0001, OAR 855-115-0005, OAR 855-115-0145 but revised the rules during the board meeting.
        - Board sent OAR 855-115-0001, OAR 855-115-0005, OAR 855-115-0145 to September 2023 rulemaking
    - October 2023- The board completed a 7th review of OAR 855-115-0001.
        - Board sent rule OAR 855-115-0001 to November 2023 rulemaking

- December 2023- The board will complete an 8th review of OAR 855-115-0001.

- Highlights/Markup
  - Highlights- None
  - **Mark~~up~~** in (3) of this package is in comparison to the current rule in OAR 855-019-0100.

Division 115
PHARMACISTS

855-115-0001
Applicability

(1) This Division applies to any Pharmacist who engages in the practice of pharmacy.

(2) Only persons licensed with the board as a Pharmacist may practice pharmacy and must act in compliance with statutes and rules unless exempt under ORS 689.225.

CURRENT RULE IN OAR 855-019-0100
(3-a) A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon, is not required to be licensed by the Board unless they are the pharmacist-in-charge (PIC).

CURRENT RULE IN OAR 855-019-0100 with edits
(3-b) A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the ~~B~~**b**oard in accordance with the following rules, except that a pharmacist **located in another state who is** working ~~in~~ **for** an out-of-state **registered Drug Outlet** ~~p~~**P**harmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon, is not required to be licensed by the ~~B~~**b**oard unless they are the pharmacist-in-charge (PIC). **A pharmacist who is providing other pharmacy services into Oregon must be licensed in Oregon.**

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.255

RULE AS NOTICED FOR JULY 2023 RULEMAKING HEARING
A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the ~~B~~**b**oard in accordance with the following rules, except that a Pharmacist **located in another state who is** working ~~in~~ **for** an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with the~~ir~~ **out-of-state pharmacy** dispensing of a drug ~~to a patient~~ **into** Oregon, is not required to be licensed by the ~~B~~**b**oard ~~unless they are the pharmacist-in-charge (PIC)~~.

RULE AS NOTICED FOR SEPTEMBER 2023 RULEMAKING HEARING

A Pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the ~~B~~**b**oard in accordance with the following rules, except that a pharmacist **located in another state who is** working ~~in~~ **for** an out-of-state **licensed Drug Outlet** ~~p~~**P**harmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification ~~associated with their dispensing of a drug to a patient in Oregon,~~ is not required to be licensed by the board unless they are the ~~p~~**P**harmacist-in-charge (PIC).

RULE AS NOTICED FOR NOVEMBER 2023 RULEMAKING HEARING

A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a pharmacist **located in another state who is** working ~~in~~ **for** an out-of-state **registered Drug Outlet** ~~p~~**P**harmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification ~~associated with their dispensing of a drug to a patient in Oregon,~~ is not required to be licensed by the Board unless they are the ~~p~~**P**harmacist-in-charge (PIC). **This exception applies only when a pharmacist is dispensing, delivering or distributing drugs into Oregon from a registered drug outlet. A pharmacist who is providing other pharmacy services into Oregon must be licensed in Oregon.**

Division 120: Licensure: Renewal or Reinstatement (Preceptor)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Preceptor License Renewal or Reinstatement

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed new rule that adds Preceptor licensure renewal or reinstatement requirements to be effective at 12:00AM on 3/1/2024.

Documents Relied Upon per ORS 183.335(2)(b)(D): Division 120 Interns and Preceptors Permanent Administrative Order

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule has no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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 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 the rules: Small businesses were not involved in determining to repeal the rule. A notice of rulemaking hearing will be sent to interested parties, some of whom may identify as a small business and will have an opportunity to provide public comment on the proposed rule.

Was a RAC consulted? If not, why? per ORS 183.335(2)(b)(G): No. The board adopted new Division 120 Interns and Preceptors in August 2023, effective 3/1/2024. The nature of the proposed rule does not require input from an advisory committee.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-120-1035 – Proposed new rule adds Preceptor licensure renewal or reinstatement requirements. Newly adopted Division 120 Interns and Preceptors contains components related to applying for a Preceptor license, qualifications, lapsing a license, voluntary surrendering a license, responsibilities, confidentiality, duty to report, supervision, prohibited practices, and grounds for discipline, but does not currently contain licensure requirements for renewing or reinstating a Preceptor license. All licensees and registrants must be aware of the process and requirements for renewing or reinstating a Preceptor license. To be effective at 12:00AM on 3/1/2024.

Division 120
INTERNS AND PRECEPTORS

855-120-1035
Licensure: Renewal or Reinstatement - Preceptor

(1) A Preceptor who holds a Pharmacist license will be automatically renewed with each Pharmacist license renewal unless the Pharmacist requests to lapse their Preceptor license per OAR 855-120-1040.

(2) Each Healthcare Preceptor or Other Preceptor must complete a new Preceptor application for license renewal per OAR 855-120-1010.

(3) A Preceptor who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license.

(4) A Preceptor or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate per OAR 855-120-1010; and

(5) A person whose Preceptor license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition to the board in writing for reinstatement of such license pursuant to ORS 689.445 and may apply to reinstate per OAR 855-120-1010.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.275, ORS 689.445

Divisions: 041/043/045/183: Drug Compounding

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural review; Repeals Division 45 and creates new Division 183 for Drug Compounding

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals Division 45 and creates a new Division 183 for Drug Compounding. Adds additional general requirements for Drug Outlet Pharmacies, Dispensing Practitioner Drug Outlets (DPDO), Correctional Facilities (CF) and Community Health Clinics (CHC) related to dispensing compounded drugs in Divisions 041 and 043. These rules apply to the preparation and dispensing of compounded drugs from a Drug Outlet. These rules do not apply to the preparation and direct administration of compounded drugs by a healthcare provider.

Documents Relied Upon per ORS 183.335(2)(b)(D):

USP Chapters: USP Compounding Compendium; State Compliance with USP Chapters (v. 2021)

Designated Person Responsibilities: ASHP List

Sterile Compounding Technology:

- ISMP Guidelines for Sterile Compounding and the Safe Use of Sterile Compounding Technology (2016 and 2022)

- Pedersen CA, Schneider PJ, Ganio MC, Scheckelhoff DJ. ASHP National Survey of Pharmacy Practice in Hospital Settings: Dispensing and Administration-2020. Am J Health Syst Pharm. 2021 Jun 7;78(12):1074-1093. DOI: 10.1093/ajhp/zxab120. PMID: 33754638; PMCID: PMC8083667.

- Moniz TT, Chu S, Tom C, Lutz P, Arnold A, Gura KM, Patterson A. Sterile Product Compounding Using an I.V. Compounding Workflow Management System at a Pediatric Hospital. Am J Health Syst Pharm. 2014 Aug 1;71(15):1311-7. DOI: 10.2146/ajhp130649. PMID: 25027539.

- Speth SL, Fields DB, Schlemmer CB, Harrison C. Optimizing I.V. Work-Flow. Am J Health Syst Pharm. 2013; 70(23):2076,2078-80. DOI: 10.2146/ajhp120738

- Deng Y, Lin AC, Hingl J, Huang G, Altaye M, Maynard H, Mayhaus D, Penm J. Risk factors for I.V. Compounding Errors When Using an Automated Workflow Management System. Am J Health Syst Pharm. 2016 Jun 15;73(12):887-93. DOI: 10.2146/ajhp150278. PMID: 27261239.

- NV: NAC 639.67017 Use of automated compounding devices.

Sterile Compounding Accreditation: PCAB/ACHC, NABP, TJC

Standard Operating Procedures: ASHP List 795 797

Compounded Drug Recalls: CA Law 4126.9. Recall of Nonsterile Compounded Drugs; 4127.8. Pharmacies that Compound Sterile Drug Products; Recalls; Requirements

Requirements For Use by a Veterinarian: Compounding Animal Drugs from Bulk Drug Substances Guidance for Industry (August 2022), Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

Essential Copies: Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (January 2018), FDA drug shortages database, ASHP drug shortages database

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): The proposed new rules and existing rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): On 8/4/2023 board staff sent out an email notification via GovDelivery to 19,647 licensee and registrant subscribers and 3,882 rulemaking interested party subscribers requesting fiscal and economic impact of the proposed rules. A Workgroup was utilized in the development of the proposed rules. Workgroup members provided estimated fiscal and economic impact of the proposed rules on 05/16/2023 and 07/18/2023. All Workgroup and board meetings where proposed rules were discussed were noticed to the public and public comment was requested. The board noticed the proposed rules for rulemaking hearing on 6/16/2023; however, the board was seeking public comment only and did not intend to adopt the rules in August 2023. The public had an opportunity to provide estimated fiscal impact information during the public comment period from 6/16/2023 – 7/26/2023.

To comply, Drug Outlet pharmacies, DPDOs, CFs and CHCs who engage in compounding will need to pay for access to the USP Compounding Compendium which is estimated to cost $250 per year per user.

-The board received estimated fiscal impact statements from six different licensee/registrant/stakeholders who provided a wide range of estimated costs that could potentially cost their organizations/patients/customers anywhere from $1.00 to $10 Million to comply with the proposed rules.

- Related to sterile compounding technology- Compounding Workgroup members stated that in their experience, barcoding and imaging technology procurement, implementation, ongoing maintenance, and training is estimated to cost between $30,000 - $130,000 initially and $50,000 annually. This type of technology is typically customized, requires specialized training and requires extra staff to operate.

- Related to sterile compounding accreditation/certification through PCAB/ACHC, NABP and TJC- Compounding Workgroup members stated in their experience, the estimated cost is between $4,500 to $17,500 depending on the vendor for a three-year accreditation/certification.

Interested parties will have an additional opportunity to provide fiscal and economic impact statements during future rulemaking.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public): (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).

(1) The proposed new rules and existing rule amendments will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed new rules and existing amendments apply to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.

(b) The rulemaking imposes the same mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) In order to comply, Drug Outlet pharmacies, DPDOs, CFs and CHCs who identify as a small business and engage in compounding will need to pay for access to the USP Compounding Compendium which is estimated to cost $250 per year per user.

Describe how small businesses were involved in development of the rules ORS 183.335: Licensees and registrants identify as small businesses were sent an email notice of proposed rulemaking via GovDelivery and had an opportunity to provide public comment when the proposed rules were noticed for rulemaking hearing on 6/16/2023. On 08/04/2023 the board sent out an email communication via GovDelivery to licensees and registrants requesting fiscal impact information on the proposed rules and small businesses had an opportunity to provide estimated fiscal information.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not consulted. The board directed staff to convene a Drug Compounding Workgroup consisting of Subject Matter Experts who had expertise related to drug compounding to assist with the development of proposed rules/amendments. The Compounding Workgroup held meetings on 2/21/2023, 4/18/2023, 5/16/2023, 6/20/2023 and 7/18/2023 and provided expertise and information that board staff utilized to draft proposed rules related to drug compounding.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

Proposed new rules and existing rule amendments are a result of the board's 2022-2026 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety. USP 795 (v. 11/1/2022) and USP 797 (v. 11/1/2022) become enforceable on 11/1/2023. Board rules related to compounding must be updated to reflect the new standards.

OAR 855-041-1018 - Proposed amendments add compliance requirements related to dispensing compounded preparations and radiopharmaceutical prescriptions.

OAR 855-043-0545 - Proposed amendment adds compliance requirements for a DPDO who dispenses compounded preparations.

OAR 855-043-0630 - Proposed amendments include revising "shall" to "must" and adds that a correctional facility must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

OAR 855-043-0740 - Proposed amendment adds that a CHC must ensure that compounded preparations are dispensed in compliance with OAR 855-183

OAR 855-045-0200 – Repeals rule

OAR 855-045-0210 – Repeals rule

OAR 855-045-0220 – Repeals rule

OAR 855-045-0240 – Repeals rule

OAR 855-045-0270 – Repeals rule

OAR 855-183-0001 - Proposed rule revises and relocates existing rule OAR 855-045-0200 to OAR 855-183-0001 related to applicability.

OAR 855-183-0005 - Proposed rule revises and relocates rule OAR 855-006-0005(11) to OAR 855-183-0005 and adds new language related to compounding definitions.

OAR 855-183-0010 - Proposed new rule adds general designation requirements for each Drug Outlet that practices drug compounding.

OAR 855-183-0050 - Proposed rule revises and relocates existing rule OAR 855-045-0220 to OAR 855-183-0050 related to personnel requirements.

OAR 855-183-0200 - Proposed rule revises and relocates existing rule OAR 855-045-0200(3) to OAR 855-183-0200 and adds general requirements for drug compounding.

OAR 855-183-0205 - Proposed new rule adds compounding technology requirements related to Automated Compounding Devices (ACDs).

OAR 855-183-0370 - Proposed new rule adds delivery requirements for each Drug Outlet Pharmacy who ships or delivers compounded preparations.

OAR 855-183-0400 - Proposed rule revises and relocates existing rule OAR 855-045-0240 to OAR 855-183-0400 related to labeling requirements for compounded non-sterile preparations (CNSPs).

OAR 855-183-0410 - Proposed rule revises and relocates existing rule OAR 855-045-0240 to OAR 855-183-0410 related to labeling requirements for compounded sterile preparations.

OAR 855-183-0420 - Proposed new rule adds labeling requirements for Compounded Non-Sterile Preparations (CNSPs) and Compounded Sterile Preparations (CSPs) for future use.

OAR 855-183-0450 - Proposed new rule adds drug disposal requirements for hazardous and infectious waste.

OAR 855-183-0500 - Proposed rule revises and relocates existing rule OAR 855-045-0220 to OAR 855-183-0500 related to policies and procedures for registrants who practice drug compounding.

OAR 855-183-0520 - Proposed new rule adds requirements for compounded drug recalls.

OAR 855-183-0550 - Proposed rule revises and relocates existing rule OAR 855-045-0270 to OAR 855-183-0550 related to general records requirements.

OAR 855-183-0560 - Proposed rule revises and relocates existing rule OAR 855-045-0270(2) to OAR 855-183-0560 related to master formulation records (MFR) for compounded non-sterile preparations.

OAR 855-183-0565 - Proposed rule revises and relocates existing rule OAR 855-045-0270(2) to OAR 855-183-0565 related to master formulation records (MFR) for compounded sterile preparations.

OAR 855-183-0570 - Proposed rule revises and relocates existing rule OAR 855-045-0270(3) to OAR 855-183-0570 related to requirements for compounding records for compounded non-sterile preparations.

OAR 855-183-0575 - Proposed rule revises and relocates existing rule OAR 855-045-0270(3) to OAR 855-183-0575 related to requirements for compounding records for compounded sterile preparations.

OAR 855-183-0600 - Proposed new rule adds prohibited practices related to compounded drug preparation.

OAR 855-183-0700 - Proposed new rule adds requirements for compounding services related to preparation according to FDA approved labeling.

OAR 855-183-0710 - Proposed new rule adds requirements for compounding services related to copies of an approved drug.

OAR 855-183-0730 - Proposed new rule adds requirements for compounding services related to use by a veterinarian.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the December 2023 board meeting.
  - The rules were sent to rulemaking at the June 2023 board meeting for the July 2023 rulemaking hearing for public comment only.

- Highlights/Markup
  - Rule language highlighted in yellow denote staff proposed amendments made since the rule package was sent to rulemaking at the June 2023 board meeting for the July 2023 rulemaking hearing for public comment only.
  - **The markup** in this package is in comparison to the current rules for Div 006, 041, 043, and 045.

Division 6
DEFINITIONS

855-006-0005
Definitions

Note: This proposed rule amendment is for board review, to view OAR 855-006-0005 as proposed in its ent rety, view December 2023 Bd Mtg mailing **#E10**.

(11) "Compounding" means the **process of combining, admixing, diluting, pooling, reconstituting, or otherwise altering a drug product or bulk drug substance to create a new preparation.** ~~preparation, mixing, assembling, packaging, or labeling of a drug or device:~~

(a) **For non-sterile preparations, compounding does not include reconstituting according to the manufacturers labeling.** ~~As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the Pharmacist and the patient, in the course of professional practice; or~~

(b) **For sterile preparations, compounding includes repackaging.** ~~For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or~~

~~(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.~~

Division 41
OPERATION OF PHARMACIES

855-041-1018 ***View current SOS version**
Outlet: General Requirements

NOTE: *The version shown below is currently being considered for permanent adoption: mailing* **#D2.**

A Drug Outlet Pharmacy must:

(1) Ensure each:

(a) Prescription is dispensed in compliance with OAR 855-041, OAR 855-115, OAR 855-120, OAR 855-125, OAR 855-139, OAR 855-141 and OAR 855-143;

(b) Controlled substance is dispensed in compliance with OAR 855-080;

(c) Compounded preparation is dispensed in compliance with OAR 855-~~045~~**183**; and

(d) Radiopharmaceutical is dispensed in compliance with OAR 855-042.

(2) Comply with all applicable federal and state laws and rules;

(3) Ensure all licensees are trained to appropriately perform their duties prior to engaging or assisting in the practice of pharmacy.

(4) Ensure each licensed and non-licensed individual only perform duties they are licensed and trained to perform.

(5) Be responsible for the actions of each licensed and non-licensed individual.

(6) Establish, maintain and enforce the drug outlet written procedures required in OAR 855-041-1040.

(7) Comply with the Pharmacist's determination in OAR 855-115-0120(1)(k);

(8) Develop, implement and enforce a continuous quality improvement program for dispensing services from a Drug Outlet Pharmacy designed to objectively and systematically:

(a) Monitor, evaluate, document the quality and appropriateness of patient care;

(b) Improve patient care; and

(c) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

Division 43
PRACTITIONER DISPENSING

855-043-0545
Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery

(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by the practitioner's licensing board.

(2) Drugs dispensed from the DPDO must be dispensed in compliance with the requirements of the practitioner's licensing board.

(3) A DPDO must comply with all requirements of State or federal law.

(4) A DPDO must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

(5) Dispensed drugs must be packaged by the DPDO, a pharmacy, or a manufacturer registered with the board.

(6) A DPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(7) A DPDO may deliver or mail prescription to the patient if:
(a) Proper drug storage conditions are maintained; and

(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(8) The DPDO must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(9) The DPDO must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

(~~9~~**10**) **Unless an exemption applies,** ~~E~~**e**ach authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed ~~unless an exemption applies~~.

[~~Publications:~~ Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.305

855-043-0630
Correctional Facility **(CF)** - Drug Delivery and Control
NOTE: The Board adopted amendments to this rule related to short-acting opioid antagonists in October 2023.

(1) Policies and Procedures: The Pharmacist and the practitioner representing the facility are responsible for establishing written policies and procedures for medication management including, but not limited to, drug procurement, dispensing, administration, labeling, medication counseling, drug utilization review, medication records, parenterals, emergency and nonroutine dispensing procedures, stop orders, over-the-counter drugs, security, storage and disposal of drugs withing the facility. Policies and procedures must be reviewed and updated annually by the Pharmacist and the practitioner, maintained in the facility; and be made available to the board for inspection. The facility must submit to the board for approval~~,~~ the name of any employee Pharmacist or a written agreement between the Pharmacist and the facility regarding drug policies and procedures. The facility must notify the board of any change of Pharmacist within 15 days of the change.

(2) Dispensing: Prescription drugs must be dispensed by a Pharmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system. **The Correctional Facility (CF) must ensure that compounded preparations are dispensed in compliance with OAR 855-183.**

(3) Unit Dose Dispensing System. The "Unit Dose Dispensing System" is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stock from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled:

(a) A unit dose dispensing system must:

(A) By nature of the system;

(i) Provide for separation of medications by patient name and location; and

(ii) Provide for separating medications by day of administration.

(B) By means of an individual patient medication record:

(i) Record the drug and dosing regimen of those drugs dispensed by the pharmacy;

(ii) Record the actual doses dispensed and returned to the pharmacy;

(iii) Record the date of the original order and the date the order is discontinued;

(iv) Provide a means for the Pharmacist to verify the prescriber's original order;

(v) Provide a means for the Pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient; and

(vi) Provide a mechanism to easily identify those drugs dispensed by pharmacy that are controlled substances.

(b) Each CF utilizing a unit dose dispensing system must establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies must be available in the pharmacy for inspection by the board:

(A) Proper utilization of the unit dose system requires that, in as far as is practicable, all medications be in unit dose packaging when dispensed.

(B) Controlled substances may be included in the unit dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.

(C) Drugs not dispensed in unit dose packaging must be labeled in accordance with (4).

(c) The Pharmacist must certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.

(d) All medication must be stored in a locked area or locked cart.

(4) Labeling: Except as described in SB 450 (2023), prescription drugs dispensed in individual containers or medication cards must be labeled with the following information:

(a) Name and identifying number of the patient/inmate;

(b) Name, strength, and quantity of the drug dispensed. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(c) Name of the prescriber;

(d) Initials of the dispenser and the date of dispensing;

(e) Directions for use;

(f) Auxiliary labels and cautionary statements as required;

(g) Manufacturer's expiration date, or an earlier date if preferable; and

(h) Name of the pharmacy.

(5) Patient counseling:

(a) Upon receipt of a prescription drug order and following review by the Pharmacist of the patient's record, the Pharmacist must initiate and provide oral counseling to the patient or to the patient's agent or care giver in all ambulatory care settings and for discharge medications in institutions:

(A) Upon request; or

(B) On matters which a reasonable and prudent Pharmacist would deem significant; or

(C) Whenever the drug prescribed has not previously been dispensed to the patient; or

(D) Whenever the patient's medication record shows the drug has not been previously dispensed to the patient in the same dosage, form, strength or with the same written directions.

(b) When counseling is provided it must include information that a reasonable and prudent Pharmacist would deem necessary to provide for the safe and effective use of the drug. Such information may include the following:

(A) The name and description of the drug;

(B) The dosage form, dose, route of administration, and duration of drug therapy;

(C) The intended use of the drug and expected actions;

(D) Special directions and precautions for preparation, administration, and use by the patient;

(E) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(F) The possible dangers of taking the drug with alcohol, or taking the drug and then operating a motor vehicle or other hazardous machinery;

(G) Techniques for self-monitoring drug therapy;

(H) Proper storage;

(I) Prescription refill information;

(J) Action to be taken in the event of a missed dose; and

(K) Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

(c) Patient counseling must be in person whenever practicable. Whenever the prescription is delivered outside the confines of the pharmacy by mail or other third-party delivery, counseling must be in writing and by free access to the Pharmacist by phone.

(d) Subsections (a) and (b) of this section must not apply to those prescription drug orders for inpatients in hospitals or institutions where the drug is to be administered by a nurse or other individual authorized to administer drugs.

(e) Notwithstanding the requirements set forth in subsection (a), a Pharmacist is not required to provide oral counseling when a patient refuses the Pharmacist 's attempt to counsel, or when the Pharmacist, on a case-by-case basis and in the exercise of professional judgment, determines that another form of counseling would be more effective.

(f) Board rules for patient counseling must be observed for **each inmate /** patient~~/inmates~~ who self-administer**s** or who ~~are~~ **is** given prescription drugs when they are released from the CF.

(6) Administration: Drugs must be administered to **each** inmate/ patient~~s~~ by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined by the Oregon State Board of Nursing in OAR 851-045-0060. Drugs selected by **a** registered nurse~~s~~ from ~~manufacturer's container or Pharmacist's~~ **a** bulk drug container~~s~~ **as defined in OAR 855-043-0610** must not be administered by **an** unlicensed person~~s~~, except under certain emergency and nonroutine situations as described in the facility's policies and procedures.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-043-0740
Community Health Clinic (CHC) - Dispensing and Drug Delivery

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.

(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.

(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.

(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.

(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2022), 16 CFR 1701 (01/01/2022) and 16 CFR 1702 (01/01/2022).

(7) Dispensed drugs must be packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the board.

(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(9) A CHC must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

(10) A CHC may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The CHC offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(11) The CHC must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(12) The CHC must ensure that compounded preparations are dispensed in compliance with OAR 855-183.

(1**3**) **Unless an exemption applies,** ~~E~~**e**ach authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is ~~dispensed unless an exemption applies~~.

[Publications: Publications referenced are available for review at the agency.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

Division ~~45~~ **183**
DRUG COMPOUNDING

~~855-045-0200~~ **855-183-0001**
~~Application~~ **Applicability**

(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for ~~use or~~ **dispensing, delivery or** distribution in Oregon must register with the board as a drug outlet and comply with board regulations.

(2) These rules apply to sterile and non-sterile compounding of a drug **for humans and animals**.

(3) Entities that are registered with FDA as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act in 21 USC 353b (04/10/2023) must register with the board as a manufacturer in OAR 855-060.

~~(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:~~

~~(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (05/01/2020 v. 2014);~~

~~(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (05/01/2020 v. 2008);~~

~~(c) USP <800> Hazardous Drugs—Handling in Healthcare Settings (07/01/2020 v. 2020);~~

~~(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging (12/01/2020 v. 2020); and~~

~~(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2016), 1231 (12/01/2021), and 1821 (05/01/2017).~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0005
Definitions

Phrases or definitions used in OAR 855-183 are the same as included in the USP standard adopted by reference unless otherwise specified.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~855-045-0210~~ **855-183-0010**
~~Registration~~ **Designation**

Each Drug Outlet must maintain an accurate compounding status in the board's online registration system.

~~(1) A non-resident drug outlet that distributes a non-patient specific compounded drug into Oregon must be registered with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.~~

~~(2) A resident drug outlet that distributes a non-patient specific human compounded drug within or outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~855-045-0220~~ **855-183-0050**
Personnel ~~and Responsibilities~~

(1) All personnel who prepare and supervise the preparation of a compound must **obtain the education,** ~~complete appropriate~~ training**, and experience to demonstrate competency as required by the USP standards applicable to the preparation of compounded sterile and non-sterile products** and be capable and qualified to perform assigned duties **prior to independently engaging in compounding**.

(2) Training must be conducted by qualified individuals on a continuing basis and with sufficient frequency required by applicable USP standards to ensure that compounding personnel remain familiar with operations and policies and procedures.

(3) The training must be documented and records retained according to OAR 855-183-0550.

(4) Each Drug Outlet must ensure:

(a) For non-sterile compounding, personnel in the compounding area are authorized to be in the area by the person providing supervision when compounding activities are occurring.

(b) For sterile compounding, personnel in the compounding area are authorized by the person providing supervision to be in the area.

(c) The annual self-inspection is completed using the board's Compounding Self-Inspection Form by July 1 and retained for board inspection.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

~~(2) The Pharmacist-in-Charge (PIC) and the drug outlet must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR 855-045-0200(3) for all aspects of the compounding operation according to the type of compounding performed and must include written procedures for:~~

~~(a) Personnel qualifications, to include training, evaluation and requalification;~~

~~(b) Hand hygiene;~~

~~(c) Garbing;~~

~~(d) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;~~

~~(e) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;~~

~~(f) Components, to include selection, handling, and storage;~~

~~(g) Creating master formulation records, with documented pharmacist approval;~~

~~(h) Creating compounding records;~~

~~(i) Establishing beyond-use dates (BUDs);~~

~~(j) Continuous quality assurance program and quality controls, to include release testing, end-product evaluation, and quantitative/qualitative testing;~~

~~(k) Completed compounded preparations, to include handling, packaging, storage and transport;~~

~~(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0200
Requirements: General

~~855-045-0200~~
~~Application~~

(~~3~~**1**)All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:

(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations **(11/01/2022) and all chapters referenced therein, including but not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 659 (04/01/2021), 797 (11/01/2022), 800 (07/01/2020), 1112 (2013), 1163 (12/01/2020), and 1231 (12/01/2021)** ~~(05/01/2020 v. 2014)~~;

(b) USP <797> Pharmaceutical Compounding—Sterile Preparations **(11/01/2022) and all chapters referenced therein, including but not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018), 659 (04/01/2021), 788 (05/01/2013), 789 (08/01/2015), 800 (07/01/2020), 825 (12/01/2020), 1066 (08/01/2015), 1085 (12/01/2020), 1113 (2013), 1116 (2013), 1163 (12/01/2020), 1197 (05/01/2021), 1207 (08/01/2016), 1223 (05/01/2018), 1225 (08/01/2017), 1228.1 (08/01/2016), 1228.4 (11/01/2019), 1229 (08/01/2022), 1229.1 (2013), 1229.4 (05/01/2018), 1229.5 (08/01/2022), 1229.8 (05/01/2018), and 1229.9 (08/01/2016)** ~~(05/01/2020 v. 2008)~~;

(c) USP <800> Hazardous Drugs—Handling in Healthcare Settings **(07/01/2020) and all chapters referenced therein, including but not limited to Chapters 795 (11/01/2022), and 797 (11/01/2022)** ~~(07/01/2020 v. 2020)~~;

(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging **(12/01/2020) and all chapters referenced therein, including but not limited to Chapters 71 (2013), 85 (05/01/2018), 659 (04/01/2021), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1113 (2013), 1116 (2013), and 1163 (12/01/2020)** ~~(12/01/2020 v. 2020)~~; and

~~(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2016), 1231 (12/01/2021), and 1821 (05/01/2017).~~

(2) A drug must only be compounded and dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs except as provided in OAR 855-183-0730. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

NOTE: Remove 'except as provided in OAR 855-183-0730 if board does not send OAR 855-183-0730 to rulemaking.

(3) A drug may be compounded for a commercially available product according to OAR 855-183-0710.

NOTE: Remove (3) if board does not send OAR 855-183-0710 to rulemaking.

(4-1-1) Beginning July 1, 2025, verification of compounded non-sterile preparations (CNSPs) and compounded sterile preparations (CSPs) must utilize a system that incorporates barcoding to verify ingredients.

(4-1-2) Verification of compounded sterile preparations (CSPs) may use a system that incorporates imaging or gravimetrics to verify ingredient quantity and finished CSP volumes.

(4-2) Verification of compounded non-sterile preparations (CNSPs) and compounded sterile preparations (CSPs) may utilize a system that incorporates:

(a) Barcoding to verify ingredients; and

(b) Imaging or gravimetrics to verify ingredient quantity and finished volumes.

(4-3) Verification of compounded sterile preparations (CSPs) may utilize a system that incorporates:

(a) Barcoding to verify ingredients; and

(b) Imaging or gravimetrics to verify ingredient quantity and finished CSP volumes.

POLICY DISCUSSION: May vs. must with implementation dates

(5) It is recommended that verification of CNSPs and CSPs not rely solely on the verification of components after they have been added to the final container. This includes methods such as proxy verification and the syringe pull-back method.

POLICY DISCUSSION: Recommendation vs. must (prohibited practice) with implementation dates

(6) Beginning July 1, 2025, a Drug Outlet that prepares CSPs from non-sterile ingredients must maintain current:

(a) Compounding Pharmacy Accreditation through the Pharmacy Compounding Accreditation Board (PCAB) provided by the Accreditation Commission for Health Care (ACHC);

(b) Compounding Pharmacy Accreditation through the National Association of Boards of Pharmacy (NABP); or

(c) Medication Compounding Certification through The Joint Commission.

POLICY DISCUSSION: May vs. must with implementation dates

(7) For CNSPs, the compounding area must have a visible line of demarcation to designate the area used for compounding. Other activities may not occur in this area when compounding is occurring.

POLICY DISCUSSION: May vs. must with implementation dates

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0205
Technology: Automated Compounding Devices (ACDs)

(1) For the purposes of this rule, an "automated compounding device" is a device that compounds, measures, and/or packages a specified quantity of individual components in a predetermined sequence for a sterile preparation.

(2) A Drug Outlet Pharmacy, DPDO, CF or CHC may use an Automated Compounding Device (ACD) to:

(a) Assist with the compounding of a CSP; or

(b) Produce a final CSP.

(3) If a Drug Outlet Pharmacy, DPDO, CF or CHC uses an ACD as described in (1), the outlet must establish and maintain written policies and procedures, in addition to the policies and procedures established and maintained pursuant to OAR 855-183-0500, that address:

(a) The qualifications and training that a person must have to operate the ACD;

(b) The routine maintenance and cleaning required to be performed on the ACD which, at a minimum, satisfies the requirements for maintenance and cleaning established by the manufacturer of the ACD; and

(c) The testing required to be performed on the ACD to ensure that the ACD is measuring and dispensing the components of the compounded drug product and preparing the final compounded drug product within tolerances of not more than plus or minus 5 percent.

(4) If a Drug Outlet Pharmacy, DPDO, CF or CHC uses an ACD to assist with the compounding of a drug product for parenteral nutrition, the Drug Outlet Pharmacy, DPDO, CF or CHC must establish safe maximum limits for each additive that may be used in compounding such a drug product. The outlet must ensure that:

(a) The ACD will not allow compounding the drug product for parenteral nutrition if a maximum limit for an additive will be exceeded until a Pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order; or

(b) If an ACD cannot be programmed to not allow the compounding process as described in (a):

(A) The ACD is equipped with an audible alarm or some other mechanism that will alert the Pharmacist if a maximum limit for an additive has been exceeded; and

(B) The Drug Outlet Pharmacy, DPDO, CF or CHC has written policies and procedures to prevent the continuation of the compounding process once a maximum limit for an additive has been exceeded until a Pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

(5) If the Drug Outlet Pharmacy, DPDO, CF or CHC uses a computerized order entry system in conjunction with the ACD, the pharmacy must ensure that the computerized order entry system will cease processing the order if a maximum limit for an additive will be exceeded until a Pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

(6) A Drug Outlet Pharmacy, DPDO, CF or CHC must make and maintain records that evidence compliance by the outlet with the policies and procedures required by this section.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0370
Delivery

Each Drug Outlet Pharmacy, DPDO, CF and CHC, must ensure the environmental control, stability, and sterility of all preparations shipped. Therefore, any compounded preparation must be shipped or delivered to a patient or patient's agent in appropriate temperature-controlled delivery containers and stored appropriately according to USP <659> Packaging and Storage Requirements (04/01/2021). Information on appropriate storage must be provided to the patient or patient's agent.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~855-045-0240~~ **855-183-0400**
Labeling: ~~of~~ Compounded ~~Drugs~~ Non-Sterile Preparations (CNSPs)

In addition to the labeling requirements specified in **USP <795> (11/01/2022),** OAR 855-041, **OAR 855-043, and 855-139,** the label of a **CNSP** ~~compounded drug dispensed or distributed~~ must **prominently and legibly** contain the following, at a minimum:

~~(1) The generic or official name of each active ingredient;~~

(~~2~~**1**) The strength ~~or concentration~~ of each active ingredient~~, to include primary solution for a sterile parenteral preparation~~;

(~~3~~**2**) The ~~dosage form and~~ route of administration;

~~(4) Rate of infusion, for a sterile parenteral preparation;~~

~~(5) The total quantity of the drug product;~~

~~(6) A beyond-use date (BUD), compliant with standards required in OAR 855-045-0200(3); and~~

(3) Indication that the preparation is compounded.

(~~7~~**4**) Handling, storage or drug-specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.

(5) Compounding facility name and contact information if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~855-045-0240~~ **855-183-0410**

Labeling: ~~of~~ **Compounded** ~~Drugs~~ **Sterile Preparations (CSPs)**

In addition to the labeling requirements specified in **in USP <797> (11/01/2022),** OAR 855-041, **OAR 855-043 and 855-139,** the label of a **CSP** ~~compounded drug dispensed or distributed~~ must **prominently and legibly** contain the following, at a minimum:

~~(1) The generic or official name of each active ingredient;~~

(~~2~~**1**) The strength ~~or concentration~~ of each active ingredient, to include **the identity of the** ~~primary~~ **base** solution for a sterile parenteral preparation;

(~~3~~**2**) The ~~dosage form and~~ route of administration;

(4**3**) Rate of infusion **or titration parameters**, for a sterile parenteral preparation;

~~(5) The total quantity of the drug product;~~

~~(6) A beyond-use date (BUD), compliant with standards required in OAR 855-045-0200(3); and~~

(4) Indication that the preparation is compounded.

(~~7~~**5**) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.

(6) Compounding facility name and contact information if the CSP is to be sent outside of the facility or healthcare system in which it was compounded.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0420

Labeling: Batch Preparation

The label of a CNSP and CSP that is prepared in anticipation of a patient-specific prescription must contain the following:

(1) The name, strength or concentration, and quantity of each active ingredient used in the compounded drug preparation;

(2) The total quantity or volume of the compounded drug preparation;

(3) Internal lot number;

(4) The assigned beyond-use date (BUD);

(5) Indication that the preparation is compounded; and

(6) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary;

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0450
Disposal

The Drug Outlet Pharmacy, DPDO, CF and CHC must ensure the disposal of hazardous pharmaceutical waste is in accordance with applicable state and federal laws and USP <800> Hazardous Drugs – Handling in Healthcare Settings (07/01/2020).

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0500
Policies & Procedures

~~855-045-0220~~
~~Personnel and Responsibilities~~

~~(2) The Pharmacist-in-Charge (PIC) and the~~ **Each** ~~d~~**D**rug ~~o~~**O**utlet **Pharmacy, DPDO, CF and CHC** must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR **855-183-0200** ~~855-045-0200(3)~~ for all aspects of the compounding operation according to the type of compounding performed **(e.g., CNSP, CSP Type 1, 2 or 3)** and must include written procedures for:

(~~a~~**1**) Personnel qualifications, to include training~~, evaluation and requalification~~ **and ongoing competency assessment**;

(~~b~~**2**) Hand hygiene;

(~~c~~**3**) Garbing;

(~~d~~**4**) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;

(~~e~~**5**) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;

(~~f~~**6**) Components, to include selection, **receipt,** handling, ~~and~~ storage **and disposal**;

(~~g~~**7**) Creating master formulation records, with documented ~~pharmacist~~ approval **by a Pharmacist for a Drug Outlet Pharmacy or prescriber with prescribing and dispensing privileges for a DPDO, CF or CHC**;

(~~h~~**8**) Creating compounding records;

(~~i~~**9**) Establishing ~~beyond-use dates (~~BUDs~~)~~;

(10) Labeling;

(~~j~~**11**) Continuous quality assurance program and quality controls, to include**:**

(a) ~~r~~**R**elease testing, end-product evaluation, and quantitative/qualitative testing;

(b) Complaint handling process;

(c) Adverse event and error reporting process; and

(d) Recall procedure; and

(~~k~~**12**) Completed compounded preparations, to include handling, packaging, storage and transport.~~;~~

~~(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug.~~

NOTE: Consider adding 'The recall procedure must include notification to the board within 10 business days in the event of a patient-level recall of a compounded drug.' to (11)(d) if board does not send OAR 855-183-0520 to rulemaking.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0520
Recalls

(1) Each Drug Outlet Pharmacy, DPDO, CF and CHC that determines a recall is warranted must immediately issue a recall and immediately initiate communication with each recipient Drug Outlet, prescriber and patient receiving the recalled drug that was dispensed or intended for use in this state and document each attempt. Initial communication must be completed:

(a) Within 12 hours of the recall if use or exposure to the recalled compounded drug will cause serious adverse health consequences or death. If confirmation that the recipient received the communication cannot be established within this timeframe, the outlet must make two additional attempts to provide communication within 24 hours of the initial attempt.

(b) Within 36 hours of the recall if use or exposure to the recalled compounded drug might cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. If confirmation that the recipient received the communication cannot be established within this timeframe, the outlet must make two additional attempts to provide communication within 24 hours of the initial attempt.

(2) If the recalled drug is not likely to cause adverse health consequences, the recipient Drug Outlet, prescriber or patient receiving the recalled drug that was dispensed or intended for use in this state, must be notified within 72 hours of the recall and the outlet must document the notification.

(3) In the event that all attempts to inform the recipient are unsuccessful in (1), the outlet must send notification via certified mail.

(4) A Drug Outlet Pharmacy, DPDO, CF or CHC that has been advised that a patient has been harmed by using a compounded product potentially attributable to the outlet must report the event to MedWatch within 72 hours of the outlet being advised.

(5) The board must be notified of a recall in (1) on a form provided by the board within 10 business days of issuing the recall.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~855-045-0270~~ **855-183-0550**
Records: General Requirements

~~(1) All records must be maintained in written or electronic format, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if then retrievable within three business days. Required records include, but are not limited to:~~

In addition to record-keeping and reporting requirements of OAR 855, the following records must be maintained:

(1) All dispensing of CNSP and CSPs.

(2) Any other records required to conform to and demonstrate compliance with USP standards and federal law.

(3) Required records include, but are not limited to:

(a) Standard operating procedures, including documented annual review;

(b) Personnel training according to the type of compounding performed, ~~including~~ competency assessment~~,~~ and qualification records, ~~including~~ **and** corrective actions for any failures~~, including gloved fingertip and thumb sampling test and aseptic manipulation validation~~. The ~~pharmacy~~ **outlet** must maintain a training record for each person, including temporary personnel, who compound preparations~~. At a minimum, the record must contain:~~

~~(A) Name and signature of the person receiving the training;~~

~~(B) Documentation of initial and continuing competency evaluation, to include dates and results of required elements outlined in the outlet's policies and procedures; and~~

~~(C) Name and signature of the pharmacist who is designated as responsible for validation of the completion of all training.~~

(c) Engineering and environmental control records, including equipment, calibration, certification, environmental air and surface monitoring procedures and results, as well as documentation of any corrective actions taken; and

(d) Cleaning**, sanitizing** and disinfecting of all compounding areas and equipment.

(e) Receipt, handling, storage and disposal of components;

(~~2~~**f**) Master formulation records **for all**~~, including as appropriate~~:

(A) CNSPs;

(B) CSPs prepared for more than one patient;

(C) CSPs prepared from a non-sterile ingredient;

(g) Compounding records for all:

(A) CNSPs;

(B) CSPs; and

(C) Immediate-use CSPs prepared for more than one patient; and

(h) Release testing, end-product evaluation and quantitative/qualitative testing.

(4) Information related to complaints and adverse events including corrective actions taken.

(5) Results of investigations including corrective actions taken and recalls.

~~(a) The name, strength and dosage form of the preparation;~~

~~(b) Physical description of the final preparation;~~

~~(c) Ingredient identities and amounts;~~

~~(d) Complete instructions for preparing the product, including equipment, supplies, and a description of the compounding steps;~~

~~(e) Calculations needed to determine and verify quantities of components and doses of ingredients;~~

~~(f) Compatibility and stability information, including references;~~

~~(g) Beyond-use date (BUD) assignment and storage requirements, including reference source;~~

~~(h) Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration;~~

~~(i) Quality control procedures and expected results; and~~

~~(j) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.~~

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

~~(l) Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used;~~

~~(m) Total quantity compounded;~~

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

~~(o) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;~~

~~(p) Records of dispensing or transfer of all compounded preparations; and~~

~~(q) Any other information required by the pharmacy's policies and procedures.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0560
Records: Master Formulation Records (MFR) for CNSP

In addition to the MFR requirements specified in USP <795> (11/01/2022), the MFR for a CNSP must contain the following, at a minimum:

(1) Appropriate calculations to determine and verify quantities and concentrations of components and strength or activity of the Active Pharmaceutical Ingredients (APIs);

(2) Compatibility and stability information, including USP or other available references;

(3) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate;

(4) Other information needed to describe the compounding process and ensure repeatability; and

(5) Any other information required by the outlet's policies and procedures.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0565
Records: Master Formulation Records (MFR) for CSP

If a MFR is required for a CSP in USP <797> (11/01/2022), the MFR for a CSP must contain the requirements specified in the standard and the following, at a minimum:

(1) Appropriate calculations to determine and verify quantities and concentrations of components, and if performing non-sterile to sterile compounding the strength or activity of the APIs;

(2) Compatibility and stability information, including USP or other available references;

(3) Quality control procedures that include the expected results and limits of tolerability for quantitative results;
(4) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and

(5) Any other information required by the outlet's policies and procedures.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0570
Records: Compounding Records (CR) for CNSP

~~855-045-0270~~
~~Records~~

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

In addition to the CR requirements specified in USP <795> (11/01/2022), the CR for a CNSP must contain the following, at a minimum:

(~~l~~**1**) Pharmacist **or prescriber with prescribing and dispensing privileges performance and** documented verification **that each of the following are correct:** ~~of compounded product accuracy including the correct~~

(a) ~~f~~**F**ormula~~;~~**;**

(b) ~~c~~**C**alculations **to determine and verify quantities and/or concentrations of components and strength or activity of each API;~~;~~**

(c) ~~q~~**Q**uantities ~~and the correct measurements and drugs used~~;

(d) Compounding technique; and

(e) Accurate preparation of the CNSP.

(~~m~~**2**) **Final yield** ~~Total quantity compounded~~;

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

(~~o~~**3**) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;

(~~p~~**4**) Records of dispensing or transfer of all compounded preparations; and

(~~q~~**5**) Any other information required by the ~~pharmacy~~ **outlet**'s policies and procedures.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0575
Records: Compounding Records (CR) for CSP

~~855-045-0270~~
~~Records~~

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

In addition to the CR requirements specified in USP <797> (11/01/2022), the CR for a CSP must contain the following, at a minimum:

(~~I~~**1**) Pharmacist **or prescriber with prescribing and dispensing privileges performance and** documented verification **that each of the following are correct:** ~~of compounded product accuracy including the correct~~

(a) ~~f~~**F**ormula~~;~~

(b) ~~c~~**C**alculations **to determine and verify quantities and/or concentrations of components and strength or activity of each API**~~;~~

(c) ~~q~~**Q**uantities ~~and the correct measurements and drugs used~~;

(d) Compounding technique; and

(e) Accurate preparation of the CNSP.

(~~m~~**2**) **Final yield** ~~Total quantity compounded~~;

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

(~~o~~**3**) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;

(~~p~~**4**) Records of dispensing or transfer of all compounded preparations; and

(~~q~~**5**) Any other information required by the ~~pharmacy~~ **outlet**'s policies and procedures.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0600
Prohibited Practices

The following practices are prohibited in the compounding of a drug preparation:

(1) Carpet in compounding area; and

(2) Animals in the compounding area.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0700

Preparation According to FDA Labeling

Compounding does not include:

(1) Mixing, reconstituting, or other such acts that are performed in accordance with directions contained in FDA-approved labeling or supplemental materials provided by the product's manufacturer.

(2) Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's FDA-approved labeling when the:

(a) Product is prepared as a single dose for an individual patient; and

(b) Labeling includes information for the diluent, the resultant strength, the container closure system and BUD.

(3) Docking and activation of a proprietary bag and vial system in accordance with the FDA-approved labeling for immediate administration to an individual patient.

[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0710

Service: Copies of an Approved Drug

A Drug Outlet Pharmacy, DPDO, CF, CHC or outsourcing facility may only compound a drug preparation that is essentially a copy of a FDA-approved drug if:

(1) The compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. The relevant change and the significant clinical difference produced for the patient must be indicated on the prescription.

(2) The FDA-approved drug is identified as currently in shortage on the:

(a) FDA drug shortages database published on the FDA website, www.accessdata.fda.gov/scripts/drugshortages/default.cfm; or

(b) American Society of Health-System Pharmacists (ASHP) shortages database published on the ASHP website, www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages.

(3) The Drug Outlet is unable to obtain the approved drug from a Wholesale Distributor Drug Outlet. Documentation of good faith effort must be retained by the Drug Outlet.

POLICY DISCUSSION: FDA Guidance Essential Copies

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-183-0730
Service: For Use by a Veterinarian

(1) This rule only applies to drugs compounded by a Drug Outlet Pharmacy intended for non-food producing animal use by licensed veterinarians.

(2) A Drug Outlet Pharmacy may compound drugs intended for non-food producing animal use:

(a) Based on a patient-specific prescription from a licensed veterinarian.

(b) For in-office use (e.g., office stock) by a licensed veterinarian, specifically for a single treatment episode, not to exceed 120-hour supply.

(3) The compounded preparations must not be distributed by an entity other than the Drug Outlet Pharmacy that compounded such veterinary drug preparations.

POLICY DISCUSSION: FDA Guidance Compounding Animal Drugs Section III-B.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~855-045-0200~~
~~Application~~

~~(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for use or distribution in Oregon must register with the board as a drug outlet and comply with board regulations.~~

~~(2) These rules apply to sterile and non-sterile compounding of a drug.~~

~~(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:~~

~~(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (05/01/2020 v. 2014);~~

~~(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (05/01/2020 v. 2008);~~

~~(c) USP <800> Hazardous Drugs—Handling in Healthcare Settings (07/01/2020 v. 2020);~~

~~(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging (12/01/2020 v. 2020); and~~

~~(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018),151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2022), 1231 (12/01/2021), and 1821 (05/01/2017).~~

~~[Publications: Publications referenced are available for review at the agency or from the United States Pharmacopoeia.]~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

~~855-045-0210~~
~~Registration~~

~~(1) A non-resident drug outlet that distributes a non-patient specific compounded drug into Oregon must be registered with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.~~
~~(2) A resident drug outlet that distributes a non-patient specific human compounded drug within or outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

~~855-045-0220~~
~~Personnel and Responsibilities~~

~~(1) All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties.~~

~~(2) The Pharmacist-in-Charge (PIC) and the drug outlet must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR 855-045-0200(3) for all aspects of the compounding operation according to the type of compounding performed and must include written procedures for:~~

~~(a) Personnel qualifications, to include training, evaluation and requalification;~~

~~(b) Hand hygiene;~~

~~(c) Garbing;~~

~~(d) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;~~

~~(e) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;~~

~~(f) Components, to include selection, handling, and storage;~~

~~(g) Creating master formulation records, with documented pharmacist approval;~~

~~(h) Creating compounding records;~~

~~(i) Establishing beyond-use dates (BUDs);~~

~~(j) Continuous quality assurance program and quality controls, to include release testing, end-product evaluation, and quantitative/qualitative testing;~~

~~(k) Completed compounded preparations, to include handling, packaging, storage and transport;~~

~~(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug.~~

~~(3) The Pharmacist-in-Charge (PIC) must annually complete a self-inspection using the board's Compounding Self-Inspection Form by July 1 and retain for board inspection.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

~~855-045-0240~~
~~Labeling of Compounded Drugs~~

~~In addition to the labeling requirements specified in OAR 855-041, the label of a compounded drug dispensed or distributed must contain the following, at a minimum:~~

~~(1) The generic or official name of each active ingredient;~~

~~(2) The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation;~~

~~(3) The dosage form and route of administration;~~

~~(4) Rate of infusion, for a sterile parenteral preparation;~~

~~(5) The total quantity of the drug product;~~

~~(6) A beyond-use date (BUD), compliant with standards required in OAR 855-045-0200(3); and~~

~~(7) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

~~855-045-0270~~
~~Records~~

~~(1) All records must be maintained in written or electronic format, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if then retrievable within three business days. Required records include, but are not limited to:~~

~~(a) Standard operating procedures, including documented annual review;~~

~~(b) Personnel training according to the type of compounding performed, including competency assessment, and qualification records, including corrective actions for any failures, including gloved fingertip and thumb sampling test and aseptic manipulation validation. The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations. At a minimum, the record must contain:~~

~~(A) Name and signature of the person receiving the training;~~

~~(B) Documentation of initial and continuing competency evaluation, to include dates and results of required elements outlined in the outlet's policies and procedures; and~~

~~(C) Name and signature of the pharmacist who is designated as responsible for validation of the completion of all training.~~

~~(c) Engineering and environmental control records, including equipment, calibration, certification, environmental air and surface monitoring procedures and results, as well as documentation of any corrective actions taken; and~~

~~(d) Cleaning and disinfecting of all compounding areas and equipment.~~

~~(2) Master formulation records, including as appropriate:~~

~~(a) The name, strength and dosage form of the preparation;~~

~~(b) Physical description of the final preparation;~~

~~(c) Ingredient identities and amounts;~~

~~(d) Complete instructions for preparing the product, including equipment, supplies, and a description of the compounding steps;~~

~~(e) Calculations needed to determine and verify quantities of components and doses of ingredients;~~

~~(f) Compatibility and stability information, including references;~~

~~(g) Beyond-use date (BUD) assignment and storage requirements, including reference source;~~

~~(h) Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration;~~

~~(i) Quality control procedures and expected results; and~~

~~(j) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.~~

~~(3) Each compounded product must be documented and the unique compounding record must include, but is not limited to, the following:~~

~~(a) Drug name, strength, and dosage form of the preparation;~~

~~(b) Physical description of the final preparation, when dispensed to a patient for self-administration;~~

~~(c) Master formulation record reference for the preparation, when applicable;~~

~~(d) Quantity prepared;~~

~~(e) Date and time prepared;~~

~~(f) Pharmacy unique lot number;~~

~~(g) Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;~~

~~(h) Beyond-use date;~~

~~(i) Pharmacist documented verification of order accuracy;~~

~~(j) Identity of all personnel involved in each step of the process;~~

~~(k) Documentation of the proper weight and measurement of each ingredient;~~

~~(l) Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used;~~

~~(m) Total quantity compounded;~~

~~(n) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;~~

~~(o) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure;~~

~~(p) Records of dispensing or transfer of all compounded preparations; and~~

~~(q) Any other information required by the pharmacy's policies and procedures.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

Division 006: Definitions (COPT, CPA, CDTM, Compounding, Counseling, DUR, Intern, Pharmacy Technician, Additional Definitions- Electronically Transmitted Prescription, Tamper-resistant Prescription)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Definitions; Repeals Additional Definitions

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes to amend and revise existing definitions for Certified Oregon Pharmacy Technician (COPT), Clinical Pharmacy Agreement (CPA), Collaborative Drug Therapy Management (CDTM), Compounding, Counseling, Drug Utilization Review (DUR), Intern and Pharmacy Technician. Moves Tamper Resistant Prescription from OAR 855-006-0015. Proposes repeal of OAR 855-006-0015 including definition for Electronically Transmitted Prescription (ETP).

Documents Relied Upon per ORS 183.335(2)(b)(D):

For OAR 855-006-0015: OAR 855-041-0085 (2008) as referenced in the rule. CMS 8/17/2007 letter to State Medicaid Directors regarding "tamper-resistant prescriptions." Medicaid Tamper-Resistant Prescription Information for State Health Policymakers (v. 8/17/2007, v. 07/15/2008). FAQ Concerning the Tamper-resistant Prescription Law

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule amendments are not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed amendments have no anticipated fiscal and economic impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public):
(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).
(1) Proposed rule amendments have no additional economic impact on state agencies, units of local government, or the public.
(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.
(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.
(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

Describe how small businesses were involved in development of the rules: If the board sends the proposed rules to rulemaking hearing, licensees and 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 a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not convened. Why?

CPA/CDTM- The board directed staff to convene a CDTM – CPA Workgroup consisting of Subject Matter Experts with expertise related to CDTMs/CPAs to assist with the development of proposed rules/amendments. The CDTM/CPA workgroup held a meeting on 5/4/2023 and reviewed and provided input on all proposed rules/amendments related to CDTM and CPAs. The board reviewed and discussed the proposed rules at the October 2023 board meeting. Board members represent the interests of people and communities likely to be affected by a proposed rule. Overall, board members are licensees of the Oregon Board of Pharmacy or public members who represent Oregon.

Compounding- The board directed staff to convene a Compounding Workgroup consisting of Subject Matter Experts with expertise related to compounding to assist with the development of proposed rules/amendments. The Compounding workgroup held meetings on 2/21/2023, 4/18/2023, 5/16/2023, 6/20/2023 and 7/18/2023 and provided information on all proposed rules related to drug compounding.

Intern- The board directed staff to convene a Workgroup for Intern rules consisting of Subject Matter Experts with expertise related to compounding to assist with the development of proposed rules/amendments. The new Intern rules in Division 120 were permanently adopted by the board in August 2023 to be effective 3/1/2024.

Certified Oregon Pharmacy Technicians / Pharmacy Technicians- The board did not direct staff to convene a workgroup or RAC for the proposed definitions. The board permanently adopted new Division 125 for COPT/PT in August 2023, effective 3/1/2024 with a placeholder for Definitions in OAR 855-125-0005.

Counseling, DUR, ETP, Tamper Resistant Prescription – The board did not direct staff to convene a workgroup or RAC. New rules for Counseling and DUR were adopted by the board in August 2023 to be effective 3/1/2024. Tamper Resistant definition is being relocated to Definitions in OAR 855-006-0005. ETP is no longer needed.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):

OAR 855-006-0005: Proposed amendments are necessary to ensure clarity for licensees and registrants. Proposed amendments include removing requirements for a specialized education program and reference to clerical duties in "Certified Oregon Pharmacy Technician", adding statutory reference ORS 689.005 to OAR 855-006-0005(9) "Clinical Pharmacy Agreement", proposes revising the definition of "Collaborative Drug Therapy Management" by adding descriptive language related to the process in which a Pharmacist or pharmacy and a health care provider or group of health care providers agree to a pre-specified drug therapy management protocol is initiated for an individual patient on the prescription or prescription drug order of a participating provider. Proposes amending "Compounding" by defining specific components and itemizing non-sterile and sterile preparation requirements. Proposes adding definition for "Counseling" and "Drug Utilization Review or (DUR)" as Proposes to repeal definitions for "Oral Counseling", Participation in Drug Selection and Drug Utilization Review" and "Responsibility for advising, when necessary or when regulated, of

therapeutic values, content, hazards and use of drugs and devices", and "specialized education program", amends "Pharmacy Technician" by removing reference to specialized education program, adds definition of "Intern" that was previously adopted in OAR 855-120-0005 effective at 12:00AM on 3/1/2024, and Tamper Resistant Prescription from OAR 855-006-0015 and renumbers existing rules.

OAR 855-006-0015: To ensure clarity for licensees and registrants, moves Tamper-resistant Prescription to OAR 855-006-0005 and repeals definition for Electronically Transmitted Prescription from OAR 855-006-0015.

- History of rule package review
  - The board will complete a 2nd review of these rules at the December 2023 board meeting.

- Highlights/Markup
  - Highlights- Yellow highlight indicates definitions with proposed changes, 2nd review.
  - **Mark~~up~~** – None, new rule

Division 006
DEFINITIONS

855-006-0005
Definitions

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. 03/21/2023).

(2) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.

(3) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.

(4) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

(5) "Biosimilar" product means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (v. 12/28/2022).

(6) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(7) "Certified health care interpreter" has the meaning given that term in ORS 413.550.

(8) "Certified Oregon Pharmacy Technician" means a person **who has taken and passed a national pharmacy technician certification examination offered by the Pharmacy Technician Certification Board**

(PTCB); or National Healthcareer Association (NHA) and is licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board ~~and has completed the specialized education program pursuant to OAR 855-025-0005~~. ~~Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the Pharmacist are not considered Certified Oregon Pharmacy Technicians or Pharmacy Technicians.~~

*Note: The version shown below is currently being considered for permanent adoption: mailing **#D5.** If the board does not motion to adopt #D5, this language should not be amended.*

(9) "Clinical Pharmacy Agreement" means an agreement between a Pharmacist or pharmacy and a health care organization, or a ~~p~~**P**hysician as defined in ORS 677.010 or a ~~n~~**N**aturopathic ~~p~~**P**hysician as defined in ORS 685.010 that permits the Pharmacist to engage in the practice of clinical pharmacy **as defined in ORS 689.005** for the benefit of the patients of the health care organization, or ~~p~~**P**hysician or ~~n~~**N**aturopathic ~~p~~**P**hysician.

*Note: The version shown below is currently being considered for permanent adoption: mailing **#D5.** If the board does not motion to adopt #D5, this language should not be amended.*

(10) "Collaborative Drug Therapy Management" means **the process in which a Pharmacist or pharmacy and a health care provider or group of health care providers** ~~participation by a Pharmacist in the management of drug therapy pursuant to a written~~ **agree to a pre-specified drug therapy management** protocol that ~~includes information specific to the dosage, frequency, duration, and route of administration of the drug, authorized by a practitioner and~~ **is** initiated **for an individual patient on the** ~~upon a~~ prescription **or prescription drug** order of **a participating provider.** ~~for an individual patient and:~~

~~(a) Is agreed to by one Pharmacist and one practitioner; or~~

~~(b) Is agreed to by one or more Pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic, or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.~~

*Note: The version shown below is also located in mailing **#E.** If the board does not motion to send #E to rulemaking, this language should not be amended.*

(11) "Compounding" means the **process of combining, admixing, diluting, pooling, reconstituting, or otherwise altering a drug product or bulk drug substance to create a new preparation.** ~~preparation, mixing, assembling, packaging, or labeling of a drug or device:~~

(a) **For non-sterile preparations, compounding does not include reconstituting according to the manufacturers labeling.** ~~As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the Pharmacist and the patient, in the course of professional practice; or~~

(b) **For sterile preparations, compounding includes repackaging.** ~~For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or~~

~~(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.~~

(12) "Confidential Information" means any patient information obtained by a Pharmacist or pharmacy.

(13) "Consulting Pharmacist" means a Pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.

*Note: The version shown below is currently being considered for permanent adoption: mailing **#D5.** If the board does not adopt this definition in #D5, this proposed rule needs to be removed.*

(14) "Counseling" or "Counsel" means an oral, electronic or written communication between a pharmacist and a patient or a patient's agent in which the pharmacist provides the patient or patient's agent with advice regarding the safe and effective use of a drug or device.

(14**5**) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(15**6**) “Custodian of pharmacy records” means a board licensee or registrant who is responsible for the maintenance, care or keeping of pharmacy records based on the services provided by the pharmacy, regardless of whether the records are in that person's actual physical custody and control.

(16**7**) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(17**8**) "Drug Regimen Review” or “DRR" means the process conducted by a Pharmacist who is consulting for a long-term-care facility or other institution, either prior to dispensing or at a later time, with the goal of ensuring that optimal patient outcomes are achieved from the drug therapy.

*Note: The version shown below is currently being considered for permanent adoption: mailing **#D5.** If the board does not adopt this definition in #D5, this proposed rule needs to be removed.*

(19) "Drug utilization review" or "DUR" means evaluation of a prescription to identify and resolve potential problems through the review of information provided to the Pharmacist by the patient, patient's agent, prescriber and the patient's record.

(~~18~~**20**) “Entry system” enables control of access to a secured area.

(~~19~~**21**) “Final verification” means after prescription information is entered into a pharmacy’s electronic system and reviewed by a Pharmacist for accuracy, a physical verification that the drug and drug dosage, device or product selected from a pharmacy’s inventory pursuant to the electronic system entry is the prescribed drug and drug dosage, device, or product.

(20**2**) "Good standing" means a license or registration that is not suspended, revoked, or otherwise restricted from the practice of pharmacy or subject to a current disciplinary order.

(2~~1~~**3**) “Health care interpreter” has the meaning given that term in ORS 413.550.

(2~~2~~**4**) “Health care interpreter registry” means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.

(2~~3~~**5**) “Individual with limited English proficiency” means a person who, by reason of place of birth or culture, communicates in a language other than English and does not communicate in English with adequate ability to communicate effectively with a health care provider.

(2~~4~~**6**) “Interchangeable” means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 USC 262(k)(4) (v. 12/28/2022).

Note: Definition adopted in OAR 855-120-0005 effective 3/1/2024.

(27) "Intern" means a person who is enrolled in or has completed a course of study at a board approved college or school of pharmacy and who is licensed with the board as an Intern.

(2~~5~~**8**) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.

(2~~6~~**9**) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.

(~~27~~**30**) “Misbranded” has the same definition as set forth in 21 USC 352 (v. 12/28/2022).

(~~28~~**31**) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.

(~~29~~**32**) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.

(3~~0~~**3**) "Nationally Certified Exam" means an exam that is approved by the board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible, and valid.

(3~~1~~**4**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(3~~2~~**5**) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:

(a) The creation and retention of accurate and complete patient records;

(b) Assuming authority and responsibility for product selection of drugs and devices;

(c) Developing and maintaining a safe practice setting for the Pharmacist, for pharmacy staff and for the general public;

(d) Maintaining confidentiality of patient information.

(3~~3~~**6**) “Official compendium” means the official United States Pharmacopeia <USP>, official National Formulary <NF> (v. USP NF 2023, Issue 1), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2023), or any supplement to any of these.

Note: If the board does not adopt the new definition “counsel” or “counseling” in mailing #D5, this rule should not be struck.

~~(34) "Oral Counseling" means an oral communication process between a Pharmacist and a patient or a patient’s agent in which the Pharmacist obtains information from the patient (or agent) and the patient's pharmacy records, assesses that information, and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.~~

Note: If the board does not adopt the new definition “drug utilization review” or “DUR” in mailing #D5, this rule should not be struck.

~~(35) Participation in Drug Selection and Drug Utilization Review:~~

~~(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.~~

~~(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the Pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review include, but are not limited to:~~

~~(A) Over-utilization or under-utilization;~~

~~(B) Therapeutic duplication;~~

~~(C) Drug-disease contraindications;~~

~~(D) Drug-drug interactions;~~

~~(E) Incorrect drug dosage;~~

~~(F) Incorrect duration of treatment;~~

~~(G) Drug-allergy interactions; and~~

~~(H) Clinical drug abuse or misuse.~~

(3~~6~~**7**) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:

(a) Cure of a disease;

(b) Elimination or reduction of a patient's symptomatology;

(c) Arrest or slowing of a disease process; or

(d) Prevention of a disease or symptomatology.

(3~~7~~**8**) “Pharmacist” means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.

(3~~8~~**9**) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board ~~but has not completed the specialized education program pursuant to OAR 855-025-0012~~.

(~~39~~**40**) “Practice of clinical pharmacy” means:

(a) The health science discipline in which, in conjunction with the patient’s other practitioners, a Pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient’s health and wellness;

(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and

(c) The practice of pharmacy by a Pharmacist pursuant to a clinical pharmacy agreement.

(4~~0~~**1**) “Practice of pharmacy” is as defined in ORS 689.005.

(4~~1~~**2**) “Prescription drug” or “legend drug” is as defined in ORS 689.005 and:

(a) Required by federal law, prior to being dispensed or delivered, to be labeled with “Rx only”; or

(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.

(4~~2~~**3**) "Prescription released by the Pharmacist" means, a prescription which has been reviewed by the Pharmacist that does not require further Pharmacist intervention such as reconstitution or counseling.

(4~~3~~**4**) "Prohibited conduct" means conduct by a licensee that:

(a) Constitutes a criminal act against a patient or client; or

(b) Constitutes a criminal act that creates a risk of harm to a patient or client.

(44**5**) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:

(a) Assure retention of their purity and potency;

(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;

(c) Assure security and minimize the risk of their loss through accident or theft;

(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;

(e) Protect the health, safety and welfare of the Pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.

(4~~5~~**6**) "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.

(4~~6~~**7**) "Reasonable professional judgment" means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities, qualifications, and competencies, after careful review, analysis and consideration of the relevant subject matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion, or conclusion.

(4~~7~~**8**) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (v. 12/28/2022) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

(4~~8~~**9**) "Repackage" means the act of taking a drug from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug.

Note: If the board does not adopt the new definition "counsel" or "counseling" in mailing #D5, this rule should not be struck.

~~(49) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication,~~

~~the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.~~

~~(50) "Specialized Education Program" means;~~

~~(a) A program providing education for persons desiring licensure as Certified Oregon Pharmacy Technicians or Pharmacy Technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or~~

~~(b) A structured program approved by the board and designed to educate Certified Oregon Pharmacy Technicians or Pharmacy Technicians in one or more specific issues of patient health and safety that is offered by:~~

~~(A) An organization recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians;~~

~~(B) An employer recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians; or~~

~~(C) A trade association recognized by the board as representing pharmacies.~~

(5~~1~~**0**) “Still image capture” means a specific image captured electronically from a video or other image capture device.

(5~~2~~**1**) “Store and forward” means a video or still image record which is saved electronically for future review.

(5~~3~~**2**) "Supervision by a Pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician being supervised, coupled with the ability to control and be responsible for the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician's action.

(5~~4~~**3**) “Surveillance system” means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

(54) “Tamper-resistant Prescription” means a form for the purpose of issuing a handwritten or typed prescription, intended to be manually delivered to a pharmacy, which has been developed, and formatted to ensure security, integrity and authenticity using currently accepted technologies. Formatted features may include but are not limited to characteristics such as:

(a) The word “void” appears when photocopies are attempted;

(b) Background ink which reveals attempted alterations;

(c) Heat sensitive ink that changes colors;

(d) Penetrating ink to prevent chemical alterations;

(e) A watermark which cannot be photocopied;

(f) Coin reactive ink that reveals word when rubbed with a coin;

(g) Sequential numbering.

(55) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.

(56) "Verification" means the confirmation by the Pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an Intern, a Certified Oregon Pharmacy Technician, or a Pharmacy Technician.

[Publications: Publications referenced are available for review at the agency or from United States Pharmacopoeia.]

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: **ORS 689.005**, ORS 689.151, ~~ORS 689.155~~ & 2022 HB 4034

~~855-006-0015~~
~~Additional Definitions~~

~~(1) Electronically Transmitted Prescription:~~

~~(a) Where used in this chapter, Electronically Transmitted Prescription (ETP) means a prescription for a drug or medical device issued by a practitioner, who is licensed and authorized to prescribe pursuant to the laws of this state and is acting within the scope of his or her practice, which has been transmitted by an electronic means that may include but is not limited to:~~

~~(A) Transmission by facsimile or hand-held digital electronic device to a computer or facsimile;~~

~~(B) Transmission from a computer to another computer;~~

~~(C) Transmission by facsimile to computer; or~~

~~(D) Transmission from a computer to facsimile.~~

~~(b) ETP does not include an oral prescription that has been reduced to writing by a pharmacist pursuant to OAR 855-041-0085 and does not include prescriptions, or drug or device orders written for inpatient use in a hospital.~~

~~(c) For an ETP to be valid, it must contain the name and immediate contact information of the prescriber, and be electronically encrypted or in some manner protected by up-to-date technology from unauthorized access, alteration or use.~~

~~(2) Tamper-resistant Prescription:~~

~~(a) Where used in this chapter, Tamper-resistant Prescription means a form for the purpose of issuing a hand written or typed prescription, intended to be manually delivered to a pharmacy, which has been developed, produced and formatted to ensure security, integrity and authenticity using currently accepted technologies.~~

~~(b) Formatted features may include but are not limited to characteristics such as:~~

~~(A) The word "void" appears when photocopies are attempted;~~

~~(B) Background ink which reveals attempted alterations;~~

~~(C) Heat sensitive ink that changes colors;~~

~~(D) Penetrating ink to prevent chemical alterations;~~

~~(E) A watermark which cannot be photocopied;~~

~~(F) Coin reactive ink that reveals word when rubbed with a coin;~~

~~(G) Sequential numbering.~~

~~Statutory/Other Authority: 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

OCTOBER 2023 / F

SBAR: Petition to Amend OAR 855-115-0150(3)

S

Situation:

- The Oregon State Pharmacy Association has submitted a petition to amend **OAR 855-115-0150(3)**, which adds "Diagnose" to Prohibited Practices, as authorized under **OAR 137-001-0070 Petition to Promulgate, Amend, or Repeal Rule**
- The petition also raises the following concerns:
  - Lack of discussion on rule by board – specifically **OAR 855-115-0150(3)**
  - Prohibiting Pharmacist from diagnosing impacts access to immediate treatment – examples COVID-19 Antiviral Protocol and PrEP Protocols.

B

Background:

- Lack of discussion on rule by board – specifically **OAR 855-115-0150(3)**
  - Board discussed Pharmacists authority to diagnose during discussion on a proposed Shingles Protocol at the October 2022 Board Meeting #B4b (pg. 114-121)- Meeting Minutes (pg. 5-6)
  - Based on October 2022 Board Meeting, staff added prohibition of "diagnose" to **OAR 855-115-0150** (Incorrectly numbered **OAR 855-120-0090** in package) to the February 2023 Board Meeting #C (pg. 73). The same rule language was included in the:
    - April 2023 Board Meeting #A7 (pg. 191-192)
    - June 2023 Board Meeting #C2 (pg. 143)
    - July 2023 Rulemaking Notice- Division 115 related to Pharmacists (pg. 26)
    - August 2023 Board Meeting #C3 (pg. 218). Draft Minutes (pg. 13). Motioned separate from other rules in package: 7 in favor, 1 opposed
- Prohibiting Pharmacist from diagnosing impacts access to immediate treatment – examples COVID-19 Antiviral Protocol and PrEP Protocols.
  - COVID-19 Antiviral Protocol
    - September 26, 2022 EUA "with positive results of SARS-CoV2 viral testing"
      - October 2022 Board Meeting #A, Aa (pg. 4-27), Minutes (pg. 3)
      - November 2022 Rulemaking Notice- Divisions 010/019/020 - related to Pharmacist Prescriptive Authority / COVID-19 Antiviral (Paxlovid)
      - December 2022 Board Meeting #B4a (pg. 237-266)
    - February 1, 2023- Updated EUA "with a current diagnosis"
      - February 2023 Board Meeting Minutes (pg. 14)
      - April 2023 Board Meeting #A2 (pg. 48-49)
      - May 2023 Rulemaking Notice- Divisions 019/020 related to Pharmacist Prescriptive Authority COVID-19 Monoclonal Antibody & COVID-19 Antiviral Protocols *Repeal
      - June 2023 Board Meeting #B1 (pg. 46)
  - PrEP Protocol in **OAR 855-020-0300**
    - Preventative Care: HIV Pre-Exposure Prophylaxis (PrEP) – pg. 7

COMMUNICATION EXAMPLES:

Example A Reactive, positive, indeterminate, -or- detected result for: HIV Ag/Ab -or- HIV RNA	Your HIV test is [reactive, positive, -or- indeterminate]. This is not a diagnosis of HIV infection, but you do need further testing to confirm if this is a true result. Do you want to go to your Primary Care Provider, urgent care clinic, county health department, or an HIV specialist for further evaluation? It is important that you STOP taking PrEP now as it is an incomplete treatment for HIV and can lead to drug resistance in the future. Until you know your HIV test results/status, please use condoms during sex and/or use sterile injection equipment, not share with others. You may start PrEP again with a PrEP provider if it is determined that this was a false result and you do NOT have an HIV infection. I can help you make an appointment for further evaluation.

	Related Statutes and Rules (full text at end of document): • OAR 137-001-0070 Petition to Promulgate, Amend, or Repeal Rule • ORS 689.005 (31) "Practice of pharmacy" • ORS 689.645 Vaccines, patient care services, drugs and devices; formulary; rules • OAR 855-115-0150 Pharmacist: Prohibited Practices • ORS 677.010(4) "Diagnose" • ORS 677.085 What constitutes practice of medicine.
A	**Assessment:** • The board has discussed the fact that the practice of pharmacy does not include making a diagnosis on multiple occasions while drafting Division 115 for over one year. • The lack of ability to diagnose does not deter pharmacists from participating in formulary and protocol prescribing under **ORS 689.645**, **OAR 855-020** and the proposed **OAR 855-115**. • The purpose of the proposed rule in **OAR 855-115-0150(**3) is to provide clarity to licensees about that lack of statutory authority for a pharmacist to diagnose. • There has been a request to amend this rule pursuant to **OAR 137-001-0070**, and the Board of Pharmacy must invite public comment on this request, including whether options exist for achieving the rule's substantive goals in a way that reduces the negative economic impact on businesses (of which there is none). • The Board must, within 90 days of the request received on 9/25/2023, either deny the request in writing or initiate rulemaking.
R	**Recommendation:** • To comply with the provisions of **OAR 137-001-0070** staff will: 1. Solicit public comment on the petition and provide those comments to the board. 2. At the December board meeting, the board will review public comments and either deny the request in writing or initiate rulemaking.

Inquiry Date: 9/25/2023
Board Review Date: 10/13/2023

OAR 137-001-0070

Petition to Promulgate, Amend, or Repeal Rule

OAR 137-001-0070 was adopted by the Attorney General as required by ORS 183.390. Agencies must apply this rule without further adoption or amendment.

(1) An interested person may petition an agency to adopt, amend, or repeal a rule. The petition shall state the name and address of the petitioner and any other person known to the petitioner to be interested in the rule. The petition shall be legible, signed by or on behalf of the petitioner, and shall contain a detailed statement of:

(a) The rule petitioner requests the agency to adopt, amend, or repeal. When a new rule is proposed, the petition shall set forth the proposed language in full. When an amendment of an existing rule is proposed, the rule shall be set forth in the petition in full with matter proposed to be deleted and proposed additions shown by a method that clearly indicates proposed deletions and additions;

(b) Facts or arguments in sufficient detail to show the reasons for and effects of adoption, amendment, or repeal of the rule;

(c) All propositions of law to be asserted by petitioner.

(2) If the petitioner requests the amendment or repeal of an existing rule, the petition must also contain comments on:

(a) Options for achieving the existing rule's substantive goals while reducing the negative economic impact on businesses;

(b) The continued need for the existing rule;

(c) The complexity of the existing rule;

(d) The extent to which the existing rule overlaps, duplicates, or conflicts with other state or federal rules and with local government regulations; an

(e) The degree to which technology, economic conditions, or other factors have changed in the subject area affected by the existing rule, since the agency adopted the rule.

(3) If a petition requests the amendment or repeal of a rule, before denying a petition, the agency must invite public comment upon the rule, including whether options exist for achieving the rule's substantive goals in a way that reduces the negative economic impact on businesses.

(4) The agency

(a) May provide a copy of the petition, together with a copy of the applicable rules of practice, to all persons named in the petition;

(b) May schedule oral presentations;

(c) Shall, in writing, within 90 days after receipt of the petition, either deny the petition or initiate rulemaking proceedings.

ORS 689.005 Definitions

(31) "Practice of pharmacy" means:

(a) The interpretation and evaluation of prescription orders

(b) The compounding, dispensing and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices;

(c) The prescribing and administering of vaccines and immunizations and the providing of patient care services pursuant to ORS 689.645

(d) The administering of drugs and devices to the extent permitted under ORS 689.655;

(e) The participation in drug selection and drug utilization reviews

(f) The proper and safe storage of drugs and devices and the maintenance of proper records regarding the safe storage of drugs and devices;

(g) The responsibility for advising, where necessary or where regulated, of therapeutic values, content, hazards and use of drugs and devices;

(h) The monitoring of therapeutic response or adverse effect to drug therapy;

(i) The optimizing of drug therapy through the practice of clinical pharmacy;

(j) Patient care services, including medication therapy management and comprehensive medication review;

(k) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy;

(L) The prescribing and administering of injectable hormonal contraceptives and the prescribing and dispensing of self-administered hormonal contraceptives pursuant to ORS 689.689;

(m) The prescribing and dispensing of emergency refills of insulin and associated insulin-related devices and supplies pursuant to ORS 689.696; and

(n) The prescribing, dispensing and administering of preexposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies, pursuant to ORS 689.704 and rules adopted by the board under ORS 689.645 and 689.704.

ORS 689.645. Vaccines, patient care services, drugs and devices; formulary; rules.

(1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may:

(a) Administer vaccines:

(A) To persons who are seven years of age or older; or

(B) If authorized by the Governor under ORS 433.441 or the Public Health Director under ORS 433.443 or 433.444, to a person three years of age or older.

(b) Pursuant to a statewide drug therapy management protocol developed by the Public Health and Pharmacy Formulary Advisory Committee convened under ORS 689.649 and adopted by rule of the board, provide approved patient care services including smoking cessation therapy and travel health services.

(c) Using a form prescribed by the board, submit a concept for the development of a protocol, other than the protocols pharmacists may establish under subsection (5) of this section, to the committee for consideration by the committee and recommendation to the board for adoption by rule of the board.

(d) 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.

(2) The board may adopt rules allowing a pharmacist to prescribe vaccines, provide patient care services and submit protocol concepts under subsection (1) of this section. The rules related to the prescription of vaccines may be only as broad as necessary to enable pharmacists to enroll and participate in the Vaccines for Children Program administered by the Centers for Disease Control and Prevention.

(3) The board is authorized to issue, to licensed pharmacists who have completed training accredited by the Centers for Disease Control and Prevention, the Accreditation Council for Pharmacy Education or a similar health authority or professional body, certificates of special competency in the prescription and administration of vaccines.

(4) The board shall adopt rules relating to the reporting of the prescription and administration of vaccines to a patient's primary health care provider and to the Oregon Health Authority.

(5) The board shall adopt rules requiring pharmacists to establish protocols for the prescription and administration of vaccines and the provision of patient care services under subsection (1) of this section.

(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.

OAR 855-115-0150
Prohibited Practices

Pharmacists must not:

(1) Engage in the dispensing, distribution or delivery of drugs unless working for a registered Drug Outlet pharmacy.

(2) Possess personally or store drugs other than in a registered Drug Outlet pharmacy except for those drugs legally prescribed for the personal use of the Pharmacist or when the Pharmacist possesses or stores the drugs in the usual course of business and within the Pharmacist's scope of practice.

(3) Diagnose.

(4) Engage in any form of discrimination, harassment, intimidation, or assault.

(5) Permit any Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician to perform any task in which the supervising Pharmacist is not trained or qualified to perform.

(6) Permit any non-licensed pharmacy personnel to perform any function that constitutes the practice of pharmacy as defined in ORS 689 or the assistance of the practice of pharmacy. Non-licensed personnel may only perform functions permitted by the Pharmacist providing supervision.

ORS 677.010 Definitions for Chapter

(4) "Diagnose" means to examine another person in any manner to determine the source or nature of a disease or other physical or mental condition, or to hold oneself out or represent that a person is so examining another person. It is not necessary that the examination be made in the presence of such other person; it may be made on information supplied either directly or indirectly by such other person.

ORS 677.085 What constitutes practice of medicine.

A person is practicing medicine if the person does one or more of the following:

(1) Advertise, hold out to the public or represent in any manner that the person is authorized to practice medicine in this state.

(2) For compensation directly or indirectly received or to be received, offer or undertake to prescribe, give or administer any drug or medicine for the use of any other person.

(3) Offer or undertake to perform any surgical operation upon any person.

(4) Offer or undertake to diagnose, cure or treat in any manner, or by any means, methods, devices or instrumentalities, any disease, illness, pain, wound, fracture, infirmity, deformity, defect or abnormal physical or mental condition of any person.

(5) Except as provided in ORS 677.060, append the letters "M.D." or "D.O." to the name of the person, or use the words "Doctor," "Physician," "Surgeon," or any abbreviation or combination thereof, or any letters or words of similar import in connection with the name of the person, or any trade name in which the person is interested, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human diseases or conditions mentioned in this section. [Formerly 677.030; 1989 c.830 §3]

OREGON STATE PHARMACY ASSOCIATION
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(503) 582-9055 • www.oregonpharmacy.org • info@oregonpharmacy.org

September 25, 2023

Ian Doyle
President
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Dear Ian and Board of Pharmacy members,

We write today with grave concerns about a rule that was passed last month. Per OAR 137-001-0070 the Oregon State Pharmacy Association is formally requesting a **repeal** to rule 855-115-0150 for Prohibited Practices, that state "Pharmacists Must Not: Diagnose."

Prohibited Practices
Pharmacists must not:
(1) Engage in the dispensing, distribution or delivery of drugs unless working for a registered Drug
Outlet pharmacy.
(2) Possess personally or store drugs other than in a registered Drug Outlet pharmacy except for those
drugs legally prescribed for the personal use of the Pharmacist or when the Pharmacist possesses or
stores the drugs in the usual course of business and within the Pharmacist's scope of practice.
(3) Diagnose.
(4) Engage in any form of discrimination, harassment, intimidation, or assault.
(5) Permit any Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician to perform any
task in which the supervising Pharmacist is not trained or qualified to perform.
(6) Permit any non-licensed pharmacy personnel to perform any function that constitutes the practice of pharmacy as defined in ORS 689 or the assistance of the practice of pharmacy. Non-licensed personnel may only perform functions permitted by the Pharmacist providing supervision.
Statutory/Other Authority: ORS 689.205
828 Statutes/Other Implemented: ORS 689.155
Oregon Secretary of State Administrative Rules

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Rapid rule changes are leading to patient harm

The Board's rapid rule changes and vague definitions have led to general confusion and an inability to be certain about what is expected of licensees. We have expressed concerns in public comments, along with meetings held with the Executive Director and his staff. Board staff continues to send an outlandishly large volume of rules into rulemaking hearings. We recognize some are sent for comment only, but **the high volume of rules makes it virtually impossible for anyone to fully review, digest, and provide thoughtful feedback in the limited amount of time given, let alone assure compliance.**

The most recent Board agenda contained proposed rules that were difficult to decipher. Rather than a straight-forward red line comparison, a confusing new division was created; even text formatting became a hindrance when comparing the changes to the previous rule version. This matters. Members of the public deserve ease and clarity when unraveling revisions to the rules.

The August Board packet was 386 pages long, yet contained a change to accepted standards regarding a pharmacist's ability to diagnose. **"Pharmacists Must Not;" diagnose on page 218, line 816, will create harm to patients. If implemented, it will create a substantial barrier in rural areas of Oregon.**

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country "conducted >42 million COVID-19 tests". Authors estimate that pharmacists "averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs." 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists

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to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

During the Board of Pharmacy meetings, board members verbally request public comments, so they have support on the optimal way to address staff-led rule proposals. It is not realistic to expect the public to be able read through 300+ page documents and make verbal or written comments in the short amount of time currently allowed. If there are no public comments due to the aforementioned reason, we are deeply concerned that Board members are pressured to approve the rules without discussion and perhaps a limited understanding. The Board members must be empowered to guide the staff on rules, not the reverse order.

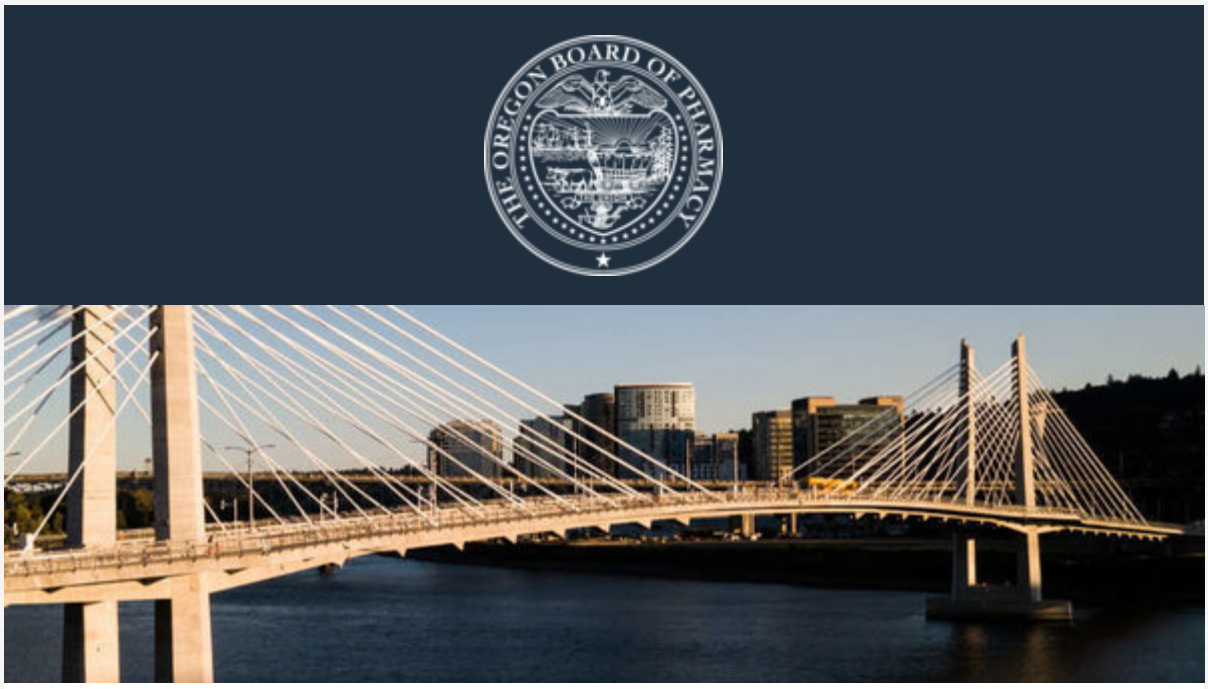
Transparency is lacking in rule adoption. Board members are not prompted to discuss rules publicly, thus the public cannot understand their intent. During the latest rule hearing, there were serious concerns around proposed rules with Counseling and with Compounding that took the focus away from identifying the problem in the obscure new section: “Diagnose”. **Previously the rules comported with ORS Chapter 689** *"pursuant to a diagnosis by a health care practitioner who has prescriptive authority and is qualified to make the diagnosis.”* Our view is that a change to this language was not required, and with no discussion from the Board about the need for this change, our licensees are left to question what changes are required to stay compliant.

Thank you for reading this letter and considering our request. Please reach out to us with questions or if you need any further information in order to assist us with our concerns.

Sincerely,
Brian Mayo
Executive Director

OBOP Notice for Invitation of Public Comment

Oregon Board of Pharmacy sent this bulletin at 10/23/2023 10:18 AM PDT



Oregon Board of Pharmacy
NOTICE FOR INVITATION
OF
PUBLIC COMMENT

NOTICE FOR INVITATION OF PUBLIC COMMENT

On August 11, 2023, the Oregon Board of Pharmacy voted to permanently adopt, effective March 1, 2024, OAR 855-115-0150(3) Pharmacist: Prohibited Practices. This rule says that pharmacists are not allowed to diagnose patients. The Board adopted this rule because there is no authority in ORS chapter 689 for pharmacists to diagnose and the Board wanted to make sure that pharmacists know this. On September 25, 2023, the Oregon Board of Pharmacy received a petition to repeal OAR 855-115-0150(3) pursuant to OAR 137-001-0070 Petition to Promulgate, Amend, or Repeal Rule.

Invitation for Public Comment

Pursuant to OAR 137-001-0070(3), the Board of Pharmacy is inviting written public comment on the adopted rule, including

(a) Options for achieving the existing rule's substantive goals while reducing the negative economic impact on businesses;

(b) The continued need for the existing rule;

(c) The complexity of the existing rule;

(d) The extent to which the existing rule overlaps, duplicates, or conflicts with other state or federal rules and with local government regulations;

(e) The degree to which technology, economic conditions, or other factors have changed in the subject area affected by the existing rule, since the agency adopted the rule; and

Written public comment may be submitted to the Board of Pharmacy by email at pharmacy.rulemaking@bop.oregon.gov. The public comment period will close on **November 15, 2023 at 4:30pm**. The board will review the public comments received at the December board meeting and will in writing, within 90 days after receipt of the petition, either deny the petition or initiate rulemaking proceedings pursuant to OAR 137-001-0070(4)(c).

Proposed Amendments

OAR 855-115-0150(3) Pharmacist: Prohibited Practices

Petitioner's proposed amendment:

"Pharmacists must not:"

"~~(3) Diagnose.~~"

If you have any questions, please reach out to the Rules Coordinator, at pharmacy.rulemaking@bop.oregon.gov

The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

oregon.gov/pharmacy

The Oregon Board of Pharmacy is an equal opportunity, affirmative action employer committed to a diverse work force.
We respect, reflect and respond to the diverse people we serve.

November 14, 2023

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
pharmacy.rulemaking@bop.oregon.gov

Dear Board of Pharmacy members,

Thank you for providing us with the opportunity to request a **repeal** to rule 855-115-0150 (3) for Prohibited Practices, which states "Pharmacists Must Not: Diagnose." We appreciate the process being undertaken to work through fixing this new rule. If left unchanged it will impact every pharmacist and add another barrier to serving patients effectively.

Our formal request addresses why we feel the rule should be repealed. On behalf of all pharmacists in the state of Oregon, not just OSPA members, we further submit the attached legal memorandum to the Board regarding the Board's consideration of our request.

As you will see in the memo, per our counsel's legal analysis, very strong support exists for the Board to grant our petition.

We look forward to your discussion of this request at the December meeting. Thank you again for working with us to recognize pharmacist's current role in serving the citizens of Oregon.

Sincerely,

Brian Mayo
Executive Director

Maureen McGee
maureen.mcgee@tonkon.com

503.802.5726 direct
503.221.1440 main

November 15, 2023

VIA EMAIL

Ian Doyle, Chair
Mr. Jamal T. Fox, Executive Director
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Re: OAR 855-115-0150 (3) Should be Deleted by Amendment

Dear Chair Doyle, Director Fox and Members of the Oregon Board of Pharmacy:

Thank you for the opportunity to comment on the Oregon State Pharmacy Association's (OSPA) petition (the Petition) under ORS 183.390 and OAR 137-001-0070, requesting an amendment to the recently-adopted Oregon Administrative Rule 855-115-0150 to delete subsection (3) of that rule, which declares that a pharmacist must not "diagnose."

For the reasons further explained below, OAR 855-155-0150 (3) is unnecessary and has the potential to raise considerable confusion among pharmacists that is likely have a chilling effect on pharmacists engaging in activities that are clearly authorized by statute. This outcome will disincentivize those who hold a pharmacist license from practicing to the full extent of their licensure and training, having a negative impact on the businesses where licensees work and reducing access to care for Oregonians.

OAR 183.390 and OAR 137-001-0070 therefore dictate that the best option for reducing these negative impacts while still achieving the rule's substantive goals is to grant the OSPA's petition and amend OAR 855-115-0150 to delete subsection (3).

I. BACKGROUND

In August of 2023, the Oregon Board of Pharmacy (the Board) adopted, among a host of other significant regulatory changes, a new rule provision set to become effective on March 1, 2024 that, for the first time, explicitly states in law that a pharmacist may not diagnose. OAR 855-115-0150 (3). OSPA submitted the Petition at issue asking the Board to delete that provision.

When reviewing a petition requesting the adoption, amendment or repeal of a rule under ORS 183.390 and OAR 137-001-0070, the Board shall request public comment on whether options exist for achieving the rule's substantive goals in a way that reduces the negative economic impact on businesses and "shall consider," among other factors, the statutory citation or legal

basis for the rule, the continuing need for the rule, and the nature of complaints received. ORS 183.390; OAR 137-001-0070. For the reasons explained below, an analysis of those criteria dictates that the Petition should be granted.

II. ANALYSIS

A. OAR 855-155-0150 (3) is unnecessary in the context of existing, well-established statutory law.

The scope of practice for pharmacists in Oregon is governed by provisions in ORS Chapter 689, which also grant the State Board of Pharmacy with authority to enforce those provisions and exercise general supervision over the practice of pharmacy in Oregon. Statute recognizes two levels of scope of practice within the profession, the "practice of clinical pharmacy" and the "practice of pharmacy," both as defined in ORS 689.005.

The ability to "diagnose" as contemplated in the context of other health professions—such as in the practice of medicine—is not included in the statutory scope of the practice of clinical pharmacy or the practice of pharmacy. *Cf.* ORS 677.085 (providing that person engages in practice of medicine if person offers or undertakes to diagnose, cure or treat in any manner, any disease); ORS 677.010 (4) (defining "diagnose" for purposes of statutes governing practice of medicine); ORS 677.060 (clarifying that the practice of pharmacy does not fall within scope of ORS Chapter 677). For that reason, the legislature has not deemed it necessary to provide for an explicit prohibition against diagnosis by pharmacists.

Given this background, the Board relied solely on its general authority in ORS 689.155 (7) and ORS 689.205 to adopt rules "necessary" to carry out, administer and enforce ORS Chapter 689, and has indicated that it adopted the rule "because there is no authority in ORS Chapter 689 for pharmacists to diagnose and the Board wanted to make sure that pharmacists know this." *Notice for Invitation of Public Comment*, Oregon Board of Pharmacy Bulletin. In other words, the Board appears to have adopted OAR 855-155-0150 (3) simply in an attempt to provide education to licensees about the existing state of the law.

There is no need in carrying out proper administration and enforcement of law to restate in rule what the law already is. This is particularly true where the Board has a variety of other means at its disposal to educate pharmacists about the boundaries of their scope of practice, such as continuing education or enforcement, and could just as easily communicate scope of practice decisions through those means. *See* ORS 689.285 (requiring continuing education by means determined by the Board); ORS 689.145 (providing the Board with broad enforcement authority).

Because the extent of a pharmacist's scope of practice is clear in statute and because the Board has other, well-established means at its disposal to educate pharmacists, adopting OAR 855-155-0150 (3) as a means to educate pharmacists about what is *not* included in their scope of practice was unnecessary, and there is no continuing necessity for the rule.

B. The nature of comments received shows that the rule has the potential to raise considerable confusion, having a negative effect on businesses that employ licensed pharmacists.

As evidenced by the OSPA's letter, the prohibition against diagnosis in OAR 855-155-0150 (3) has already sown confusion and raised significant questions as to whether pharmacists may continue to carry out activities that they are clearly authorized by law to do and that require some level of diagnostic skill.

No applicable statutes exist that explicitly define what "diagnosis" or engaging in diagnostic activities would mean in the context of the practice of pharmacy. Where a term is not statutorily defined, dictionary definitions can help in discerning the term's plain, natural and ordinary meaning. *See State v. Gaines,* 346 Or. 160, 175 (2009). Here, the dictionary defines the term "diagnose" in its common usage as "to identify (as a disease or condition) by symptoms or distinguishing characteristics." *Webster's Third New Int'l Dictionary* 622 (unabridged ed 2022).

While the ability to "diagnose" as contemplated in other health professions is not included within a pharmacist's statutory scope of practice, pharmacists *are* clearly authorized by statute to apply their skill and knowledge, in particular cases and subject to certain protocols, to identify diseases or conditions by their symptoms or distinguishing characteristics. *See, e.g. Sutton v. Cook,* 254 Or. 116, 121-22 (1969) (practitioner of a particular school of the healing arts is entitled to have his conduct tested by the standards of their own school). These abilities generally apply in the context of the prescribing authorities that have been added to the practice of pharmacy by the legislature over time in order to expand access to public health services. ORS 689.005 (31)(L) (prescribing and administering of injectable hormonal contraceptives and the prescribing and dispensing of self-administered hormonal contraceptives pursuant to ORS 689.689; ORS 689.005 (31)(m) (prescribing and dispensing of emergency refills of insulin and associated insulin-related devices and supplies pursuant to ORS 689.696); ORS 689.005 (31)(n) (prescribing, dispensing and administering of preexposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies, pursuant to ORS 689.704 and rules adopted by the board under ORS 689.645 and 689.704); ORS 689.005 and ORS 689.295 (authorizing clinical pharmacy agreements).

Pharmacists have also long provided clinical advice to include over-the-counter relief that may aid in decreasing unnecessary emergency room visits for common conditions. Providing such advice also requires application of diagnostic skill that has traditionally been considered well within the scope of a pharmacist's practice and that arguably fits within the dictionary definition of "diagnose."

In adopting OAR 855-115-0150 (3), the Board gave no guidance to pharmacists as to what it intended the scope of the term "diagnose" to mean within the context of the rule. Because of this lack of clarity, pharmacists are now expressing fear that because exercising their prescribing authority under statute could be interpreted by some to constitute "diagnosis" under the plain meaning of the term, they may be putting themselves at enforcement risk by engaging in those activities.

That confusion clearly does not appear to have been the intent of the Board in adopting OAR 855-115-0115 (3), but it is a result that must be seriously considered when evaluating whether a better opportunity exists to achieve the rule's substantive goals. Further, because the rule as written presents a significant risk of encouraging pharmacists to cease practicing to the full extent of their licensure and training, it also presents the risk of having a negative effect on both businesses that employ licensed pharmacists and patients who have come to rely on their pharmacists. Businesses may see less income as pharmacists step back from engaging in lawful prescribing activities, and patients may see lowered access to care, particularly in rural communities and other communities where health care delivery challenges exist.

C. Better opportunities exist for achieving the substantive goals for adopting OAR 855-155-0150 (3).

The Board has indicated that the substantive goal in adopting OAR 855-115-0115 (3) was to better educate pharmacists about their scope of practice. *See Notice for Invitation of Public Comment*, Oregon Board of Pharmacy Bulletin, October 23, 2023 (Accessed November 15, 2023). However, given the lack of statutory necessity for the rule and other issues raised above, it becomes clear that the Board could have just as easily achieved its substantive goals by increasing educational opportunities like continuing education courses.

Finally, it bears mention that the rulemaking process itself could have provided an opportunity for education and engagement in this instance, and could do so in the future. Under OAR 183.333, agencies are encouraged to seek public input to the maximum extent possible before giving notice of intent to adopt a rule, and are authorized to appoint rulemaking advisory committees (RAC) to obtain public views that will help in rule drafting. The Board did not utilize a RAC in this instance, despite the fact that OAR 855-0155-0150 (3) was adopted as part of a wide-ranging reorganization of the regulatory regime applicable to pharmacists. Had the Board convened a RAC, it could have engaged in dialog with stakeholders to communicate its intent for this particular rule, hear stakeholder concerns, and identify solutions for a path forward that would have increased a shared understanding regarding scope of practice without raising confusion among licensees.

III. CONCLUSION

For the reasons set forth above, OAR 855-155-0150 (3) is unnecessary and much more likely to sow confusion than provide clarity for licensees—having a harmful impact on businesses employing licensees. In applying the standards for review of a rulemaking petition under ORS 183.390 and OAR 137-001-0070, the Board should grant the Petition and initiate rulemaking to amend OAR 855-115-0150 by deleting subsection (3).

In endeavoring to provide direction regarding diagnosis and the scope of a pharmacist's practice in the future, the Board should provide that direction in a way that, clearly accounts for the historic and lawful practice of pharmacists applying in diagnostic skill, utilizes clear definitions, is combined with a robust continuing education offering for pharmacists, encourages pharmacists to practice to the full extent of their licensure and training, and is adopted pursuant

to an open, transparent rulemaking process that utilizes a rulemaking advisory committee appointed under the provisions of ORS 183.333.

Sincerely,

s/

Maureen McGee

From:	Brian Mayo
To:	PHARMACY RULEMAKING * BOP
Subject:	Public Comments for Rule Repeal
Date:	Wednesday, November 15, 2023 12:14:54 PM
Attachments:	MAM draft cover letter.docx OSPA Submission.pdf

Hi Rachel,

I hope you are doing well! Please see the attached files for OSPA public comments on our rule repeal request.

Brian Mayo
Executive Director
Oregon State Pharmacy Association
Office: (503) 582-9055
brian@oregonpharmacy.org | www.oregonpharmacy.org
Leading Pharmacy, Advancing Healthcare!

From: Alison Reta, PharmD, CDE
To: PHARMACY RULEMAKING * BOP
Subject: Comment on new rule 855-115- 0150
Date: Tuesday, November 14, 2023 12:31:43 PM
Attachments: image001.png
image002.png
image003.png

Dear Members of the Oregon State Board of Pharmacy,

I am writing to express concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions (new rule 855-115- 0150). I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

First and foremost, I must emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patient access to care. It will hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements routinely order, interpret, and monitor laboratory values such as blood glucose levels, cholesterol levels, and urine albumin-creatinine ratio results for patients referred for diabetes management. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

This rule change may disrupt vital test-to-treat programs. The COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers; this causes delays in treatment and increases the burden on an already strained healthcare system.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon’s Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management for conditions such as hyperlipidemia, kidney protection, and cardiovascular risk when pharmacists are referred patients for the management of diabetes. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make

recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service in abundance and without issue for decades.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board considers these arguments carefully and takes steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve in the State of Oregon.

Sincerely,

Alison Reta

Alison Reta, PharmD, CDCES

Clinical Pharmacist, Diabetes Specialist

Virginia Garcia Memorial Health Center

Address 2725 SW Cedar Hills Blvd #200, Beaverton, OR 97005

Phone 503-352-8150 (Tu/Wed/Thu) | **Email** areta@vgmhc.org

Website VirginiaGarcia.org

From: Amanda M
To: PHARMACY RULEMAKING * BOP
Subject: Response to Notice for Invitation of Public Comment
Date: Thursday, November 9, 2023 1:52:34 PM

Dear Oregon Board of Pharmacy members,

I have a Doctorate of Pharmacy, not a Juris Doctorate, so I am not an expert in the law. However, I implore every board member to use their common sense when reviewing the petition to repeal a rule and public comments. Does it really make sense that if something is not in statute, it is prohibited? If that is the case, you have a lot of rules to strike, including all of the counseling rules. Counseling is not mentioned in ORS 689. Don't take my non-lawyer opinion on it, search for it yourself. Is it really in the interest of public safety to prohibit counseling? If the answer is no, the same answer applies to diagnosing.

Pharmacists daily are asked to recommend drugs. Some of the time, they have a diagnosis. Other times, they have to walk patients through key questions in order to ensure they are providing appropriate care and not harming the public. This practice, which is often not compensated, is sometimes the ONLY access point the public has to a healthcare provider. The thought of having to turn people away from this service because of the actions of your board makes it easy to understand why pharmacists give up on trying to work within the rules you constantly change to make their life harder. It goes against the reason most people become pharmacists in the first place. It goes against the very mission statement you purport to uphold. You will cause harm to the public if you do not change this rules.

The Board's lawyer is available to you to give you legal advice, but as a licensee and Oregonian, I do not believe she is giving you advice that is in the best interest of citizens of this state. Some of the advice you appear to be relying on defies logic and common sense. The medical board and nursing board does not refuse to engage with licensees and tell them to ask a lawyer if they have questions about the rules written and enforced by their board.

Board members are the ones who make decisions. Please use the power invested in you by the state of Oregon to make good choices that help advance the health and safety of Oregonians, not the agenda forced upon you by someone who is not in charge. Please start treating pharmacists with the respect they deserve as healthcare professionals who are doing the best with what they have before our profession disappears in this state.

I hesitate to make comments as there is fear of retribution from Board staff towards pharmacists who have made public comments recently, and like most licensees I value my license and do not wish to be threatened for simply doing what I feel is right. I am a lifelong Oregonian, but the current environment of the profession in this state has made me seriously question whether I want to continue living and making professional contributions here. I am somewhat encouraged by the discussion of this Board at the recent strategic planning session. I look forward to a better working relationship between the Board and the profession of pharmacists, starting with revisiting this rule which was not ever commented on by Board members during a Board meeting so we could have this dialogue in a different manner. Please do not dismiss this petition out of hand.

Sincerely,
Amanda Meeker

From:	Watson, Amy
To:	PHARMACY RULEMAKING * BOP
Subject:	Request to Repeal - 855-115-0150 Prohibited Practices
Date:	Monday, November 13, 2023 11:19:55 AM
Attachments:	2023 11 Board of Pharmacy RPH diagnose.pdf

Dear Board of Pharmacy,
I am writing to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose." This rule, it will disrupt pharmacy services in Oregon and will be clinically devastating to patient access to safe care.
Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care testing was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country "conducted >42 million COVID-19 tests". Authors estimate that pharmacists "averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs." 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription. This unnecessarily increases health care costs and delays or prevents appropriate care.

Perhaps one of the greatest disruptions to care is the conflict between rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

With limited access to health care across our state including rural healthcare deserts, we cannot allow restrictions on appropriate care including by pharmacists utilizing appropriate diagnostic information to prescribe medications at the point-of-care.

Sincerely,

Amy R. Watson PharmD, MBA, FACHE
Director Pharmacy Services & Chief Pharmacy Officer | Asante
Email: Amy.Watson@asante.org | Phone: 541-789-5031
Excellence | Respect | Honesty | Service | Teamwork

From: Andrew Gibler
To: PHARMACY RULEMAKING * BOP
Subject: Public Comment on Proposed OAR 855-115-0150
Date: Wednesday, November 15, 2023 1:52:22 PM

Dear Board of Pharmacy,

Today I write to you as a licensed Oregon pharmacist, and my public comments may not be reflective of any view held by my colleagues at the Oregon Health Authority or on the Public Health and Pharmacy Formulary Advisory Committee.

Please do not adopt amendment OAR 855-115-0150(3) as written, which states, "pharmacists must not: diagnose."

Diagnosis is not defined in Chapter 689 for pharmacists, but it is defined in Chapter 677 for those practicing medicine. ORS 677.010(4) states that, "*diagnose means to examine another person* ***in any manner*** *to determine the source or nature of a disease or other physical or mental condition, or to hold oneself out or represent that a person is so examining another person. It is not necessary that the examination be made in the presence of such other person;* ***it may be made on information supplied*** *either directly or indirectly by such other person*." [note that bolded language is mine]

I am concerned that if this OAR is adopted as amended, it will dissuade many pharmacists from:

1) Providing over the counter (OTC) counseling; and
2) Prescribing from the Oregon Board of Pharmacy-approved formulary and protocol compendia.

Pharmacists are trained and proficient to use clinical judgement about whether a specific OTC treatment or referral is appropriate based on patient interview of past medical and social history, basic physical examination, and review of current signs and symptoms. Pharmacists may interpret OTC counseling as diagnostic and dissuade them from providing care if this OAR is adopted as amended.

Pharmacists prescribing from the Oregon Board of Pharmacy-approved formulary and protocol compendia must also use clinical judgement to determine if the patient is a candidate for such treatment under the protocol. The Board of Pharmacy should adopt rules that clearly state that practicing under these protocols, including interpretation of laboratory values, is not making a diagnosis. The current conditions that are treated under the formulary and protocol compendia do not require a diagnosis, but the amended language OAR 855-115-0150(3) is ambiguous enough that it may dissuade pharmacists from practicing under these protocols.

I have concerns that if pharmacists are discouraged to practice clinical pharmacy, it will result in delayed care and patient harm in our communities. Public comment like this would not be necessary if Board of Pharmacy staff could help interpret ambiguous OARs for licensed pharmacists as was commonly done in the past. I strongly urge the Board to only adopt OARs that are explicit enough that every pharmacist would interpret them the same way and be confident enough to use their knowledge, expertise, and experience to provide clinical services. We need clinical pharmacists more than ever.

Sincerely,

Andrew Gibler, PharmD *(RPH #11081)*

From: Andrew Hibbard
To: PHARMACY RULEMAKING * BOP
Subject: Response to Notice For Invitation to Public Comment
Date: Tuesday, November 14, 2023 11:45:42 AM

Dear Members of the Oregon State Board of Pharmacy,

I hope this letter finds you well. I am writing to express my deep concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

First and foremost, I must emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patient access to care. It will hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements routinely order, interpret, and monitor laboratory values such as blood glucose levels, cholesterol levels, and urine albumin-creatinine ratio results for referred for diabetes management. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

This rule change may disrupt vital test-to-treat programs. The COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers, causing delays in treatment and increasing the burden on an already strained healthcare system.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon’s Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management for conditions such as hyperlipidemia, kidney protection, and cardiovascular risk when pharmacists are referred patients for the management of diabetes. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service, in abundance, and

without issue for decades.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Sincerely,

Andrew Hibbard Pharm.D., BCACP, BCGP

November 13, 2023

Dear Board of Pharmacy,

I am writing to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose." This rule, it will disrupt pharmacy services in Oregon and will be clinically devastating to patient access to safe care.

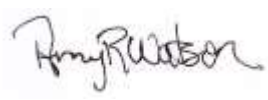
Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care testing was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country "conducted >42 million COVID-19 tests". Authors estimate that pharmacists "averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs." 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription. This unnecessarily increases health care costs and delays or prevents appropriate care.

Perhaps one of the greatest disruptions to care is the conflict between rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

With limited access to health care across our state including rural healthcare deserts, we cannot allow restrictions on appropriate care including by pharmacists utilizing appropriate diagnostic information to prescribe medications at the point-of-care.

Sincerely,



Amy R. Watson, PharmD, MBA, FACHE
Dir Pharmacy Services & Chief Pharmacy Officer, Asante

From:	Watson, Amy
To:	PHARMACY RULEMAKING * BOP
Subject:	Request to Repeal - 855-115-0150 Prohibited Practices
Date:	Monday, November 13, 2023 11:19:55 AM
Attachments:	2023 11 Board of Pharmacy RPH diagnose.pdf

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Sincerely,

Amy R. Watson PharmD, MBA, FACHE
Director Pharmacy Services & Chief Pharmacy Officer | Asante
Email: Amy.Watson@asante.org | Phone: 541-789-5031
Excellence | Respect | Honesty | Service | Teamwork

From:	Mosesman, Ashley
To:	PHARMACY RULEMAKING * BOP
Subject:	REPEAL - OAR 855-115-0150 Pharmacist: Prohibited Practices
Date:	Tuesday, November 7, 2023 5:23:43 PM

Dear Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be **clinically devastating to patient safety.**

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted >42 million COVID-19 tests”. Authors estimate that pharmacists “averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.” 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Take Care,

Ashley Mosesman
PharmD Candidate | Class of 2026
Pacific University, School of Pharmacy
Email: mose9897@pacificu.edu | Tel: (925) 351-8698

From: Dan Kennedy
To: PHARMACY RULEMAKING * BOP
Subject: Letter in support of Repeal
Date: Thursday, November 16, 2023 3:58:53 PM

OAR 137-001-0070 (3) Prohibited Practice-Diagnosis

To whom it may Concern;

I am writing to you today to express my support for the repeal of Rule 137-991-0070 (3) "Prohibited Practices" Pharmacists may **not** diagnose. While I understand the intent of including prohibited practices, addition of this rule essentially creates confusion and limits pharmacist's ability to further the scope of future pharmacy practice.
As this is not stated in statute, it gives the appearance that the Board of Pharmacy is making rules out of whole cloth without regard to different practice settings.The needs of Pharmacists in Ambulatory Care, Community Pharmacy etc. need to be considered. Retention could have a chilling effect on Pharmacist/Patient consultations where a patient is looking for professional advice. Community Pharmacists have long assessed their patients who present with a multitude of concerns.Patients rely upon Pharmacist advice up to and including the need for referral to another healthcare provider.

I believe this rule further complicates and confuses pharmacy professionals, is unnecessary and appears to micromanage the profession of pharmacy. I strongly urge you to repeal this rule.

Sincerely,

Dan Kennedy RPh, FAPhA
President of the Oregon State Pharmacy Association
(speaking on behalf of myself)

From: Petley, David
To: PHARMACY RULEMAKING * BOP
Subject: Please reconsider 855-115- 0150 “Pharmacists Must Not: Diagnose.”
Date: Wednesday, November 15, 2023 4:22:29 PM

David Thomas Petley, Pharm D, BCPS, BCCCP
61890 Ross Inlet Rd

Coos Bay, Oregon 97420

davidtpetley@gmail.com

541-870-6466

11/15/2023

Oregon State Board of Pharmacy 800 NE Oregon Street, Suite 150 Portland, OR 97232

Dear Members of the Oregon State Board of Pharmacy,

I hope this letter finds you well. I am writing to express my deep concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

First and foremost, I must emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patient access to care. It will hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements in ambulatory care and hospitals routinely order, interpret, and monitor laboratory values such as electrolyte levels, vancomycin levels, ANC, heparin anti Xa, aPTT, INR, blood glucose levels, cholesterol levels, and creatinine results for routine ambulatory and hospitalized care. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

This rule change may disrupt vital test-to-treat programs. The COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers, causing delays in treatment and increasing the burden on an already strained healthcare system.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon’s Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts

patient access to timely care, contradicting the committee's purpose.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management for conditions such as infectious diseases, diabetic ketoacidosis, hyperglycemia, anticoagulation, hyperlipidemia, kidney protection, and cardiovascular risk when pharmacists are consulted by hospital physicians. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service, in abundance, and without issue for decades.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Sincerely,

David T Petley, Pharm D, BCPS, BCCCP

Lead Inpatient Clinical Pharmacist

Bay Area Hospital

Coos Bay Oregon

November 15, 2023

Jamal T. Fox, MPA
Executive Director Oregon State Board of Pharmacy
800 N.E. Oregon Street, Suite 150
Portland, OR 97232

Re: Proposed Amendment OAR 855-115-0150(3) Pharmacist: Prohibited Practices

Dear Mr. Fox,

Pharmacists are positioned to play a critical role in shifting who has access to tools for HIV prevention by making pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) more visible and accessible to those who stand to benefit the most. PrEP is an important piece of the Oregon Health Authority (OHA) End HIV Oregon Campaign. The *Oregon Board of Pharmacy Preventative Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Drug Therapy Management for the Oregon Pharmacist* allows Oregon pharmacists to participate in a vital role in reducing the number of new HIV diagnoses in Oregon by increasing access and lowering systemic barriers to people receiving HIV PrEP and/or HIV PEP.

The Preventative Care: HIV Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway follows the CDC PrEP Guidelines 2021 for pharmacists to assess patients for PrEP therapy. The laboratory tests included in the *Oregon Board of Pharmacy Preventative Care HIV Pre-Exposure Prophylaxis (PrEP) Statewide Drug Therapy Management for the Oregon Pharmacist* are interpreted by the pharmacist to determine if PrEP is safe to start or continue and if PrEP is expected to be effective to prevent a new HIV acquisition.

HIV is not diagnosed by the result of one HIV test as false positives may occur with some tests and in certain circumstances. When the interpretation of the HIV test(s) and any symptoms that may be present is that there are safety or effectiveness concerns with starting or continuing HIV PrEP, then the protocol requires that the pharmacist must refer the patient for further HIV tests and/or evaluation by a provider. When the interpretation of gonorrhea, chlamydia, syphilis, and Hepatitis C tests is that there may be a new infection, then the pharmacist must refer to a provider for further evaluation and treatment if the provider determines the treatment is indicated. The other tests included in the protocol are to monitor for potential contraindications and/or adverse effects of the PrEP medication regimen. None of the tests are included for the purpose of diagnosis.

In addition, The Oregon Board of Pharmacy October_2023_Bd_Mtg_Agenda.pdf (oregon.gov) Mailing F states, T*he lack of ability to diagnose does not deter pharmacists from participating in formulary and protocol prescribing under ORS 689.645, OAR 855-020 and the proposed OAR 855- 11*

Respectfully submitted,

Devon Flynn, PharmD, MPH, BCPS, AAHIVP*
Sharon Rask, RPh

*Please note the above comments reflect my personal, professional perspective and do not in any way represent the opinion or perspective of my employer(s).

From: Devon Flynn
To: PHARMACY RULEMAKING * BOP
Cc: Rask, Sharon
Subject: Public Comments OAR 855-115-0150(3)
Date: Wednesday, November 15, 2023 2:35:49 PM
Attachments: OBOP PrEP Comments_Nov 2023.docx

To Oregon Board of Pharmacy,

Attached are comments regarding OAR 855-115-0150(3) that is on the agenda for the December 2023 Board meeting.

Thank you,
-Devon

11/15/2023

Dear Oregon Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.”
If you do not fix this rule, it will disrupt pharmacy services in Oregon. Additionally, patient safety will be seriously and devastatingly affected.
Pharmacists have been trained and are proficient in utilizing diagnostic information in their practice on a daily basis. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. Equipped with the knowledge of these values, pharmacists are able to make appropriate decisions and timely adjustments to medications to ensure patient health and safety.
They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary and preventing unnecessary drug use. The value of point-of-care tests was clearly established during the COVID-19 pandemic.
A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted >42 million COVID-19 tests”. Authors estimate that pharmacists “averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.” 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19."
Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.
Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to critical services they rely on, and current law will not be implemented.
Again, I earnestly appeal to you, as members of the Oregon Board of Pharmacy, to ask you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.”

Respectfully,

Irene C. Croswell, PharmD
RPH 0009231
Tualatin, OR

From: Irene Croswell
To: PHARMACY RULEMAKING * BOP
Subject: letter re: effects of prohibiting pharmacists from diagnosing
Date: Wednesday, November 15, 2023 2:20:09 PM
Attachments: Letter 11.15.23 Req repeal d.n diagnose.docx

Hello
Please see attached my letter addressing my concerns for the safety and health outcomes for patients that would be affected if pharmacists are prohibited to diagnose.
Thank you for your consideration,
Irene C Croswell PharmD

From: Melissa Netland
To: PHARMACY RULEMAKING * BOP
Subject: "not allowed to diagnose"
Date: Thursday, November 9, 2023 7:39:29 AM

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be clinically devastating to patient safety.

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted 42 million COVID-19 tests”. Authors estimate that pharmacists “averted 1 million deaths, 8 million hospitalizations, and $450 billion in health care costs.” The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19". Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Please do not take away our ability to provide immediate access to critical health care,

Sincerely,

James and Melissa Netland, Pharm BS, RPH's
Stayton Pharmacy and Sublimity Pharmacy owners

Your health.

Your clinic.

Your neighborhood.
NHCOregon.org

Jennifer McElravey, PharmD, BCACP, 340B ACE

7320 SW Hunziker Rd, Ste 102

Portland, OR 97223

mcelraveyj@nhcoregon.org 503-214-1075

11/15/2023

Oregon State Board of Pharmacy 800 NE Oregon Street, Suite 150 Portland, OR 97232

Dear Members of the Oregon State Board of Pharmacy,

I am writing to express my concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

There is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patients' access to care. It will hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and are proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements routinely order, interpret, and monitor laboratory values such as blood glucose levels, cholesterol levels, and urine albumin-creatinine ratio results for referred for diabetes management. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon's Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management for conditions such as hyperlipidemia, kidney protection, and cardiovascular risk when pharmacists are referred patients for the management of diabetes. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy

management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers, preventing effective implementation of team-based care models.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Sincerely,

Jennifer McElravey, Pharmacy Director and Oregon Licensed Pharmacist

From:	Jennifer McElravey
To:	PHARMACY RULEMAKING * BOP
Subject:	Public comment concerning the OSPA petition that challenged the recently approved pharmacy prohibited practice rules that state “pharmacist must not diagnose"
Date:	Wednesday, November 15, 2023 1:15:56 PM
Attachments:	image001.png 2023-11.14 NHC Pharmacy letter to Board of Pharmacy.pdf

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> You don't often get email from mcelraveyj@nhcoregon.org. Learn why this is important

Dear Oregon Board of Pharmacy,

I would like to submit my public comments in support of **repealing** the pharmacy prohibited practice rules that state that a pharmacist must not diagnose.

Thank you for your consideration,

Jennifer McElravey

Jennifer McElravey, PharmD, BCACP, 340B ACE *(she, her, hers)*
Director of Pharmacy
Cell: 503.926.4300 Direct: 503.214.1075 Fax 503.747.7013
7320 SW Hunziker Rd. Suite 102, Portland, OR 97223
mcelraveyj@nhcoregon.org | NHCOregon.org
Find us on Facebook, Instagram, and LinkedIn

From: DROLLINGER Kelly W * DOC
To: PHARMACY RULEMAKING * BOP
Subject: Prohibited practices
Date: Tuesday, November 14, 2023 12:46:53 PM

I remember being taught in pharmacy school that the BOP's specific role was to protect the public, not pharmacists. I recall being surprised by that statement (and wondering who supports and protects pharmacists) but can certainly appreciate your perspective as you serve in that role. I know that purpose is not taken lightly. I know the board's role in protecting the public was the intent of this rule, but I fear there are repercussions of the rule that could have a detrimental rather than positive impact.

In looking at the board's mission statement, "to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacturer and distribution of drugs." I share your mission statement to focus specifically on those words, "promote and protect public health."

My specific concern surrounds pharmacists' ability to use point-of-care (POC) testing, which may be considered a form of diagnosis in specific circumstances. I know as a pharmacist that we have not received the same training to diagnosis as physicians; however, the availability of certain labs or POC tests make certain disease states feasible to diagnose without expert training in physical exam.

For example, I have direct involvement in the development of a pending collaborative drug therapy management (CDTM) agreement for the OR Department of Corrections to have clinical pharmacists treat and monitor patients with hepatitis C. In the setting of this CDTM, if pharmacists are not allowed (and a provider is required) to make the diagnosis (a diagnosis made by simple labs), a significant number of patients will be lost to follow-up. I know this from experience and have witnessed this personally. Providers, especially in our setting, have a significant workload burden already placed on them because of staffing shortages. If these patients are lost to follow-up, fewer patients are treated and cured of HCV, which does not promote public health.

This law, without added clarity, has potential to interfere with the board's mission to promote public health. If my interpretation is correct, and we as pharmacists are not allowed to diagnose, even in the setting of a CDTM, our ability within ODOC to eradicate HCV will be weakened. More provider appointments will be required, which will result in treatment delays. In many cases, our setting is the most stable environment and the only opportunity for some of our patients to receive treatment prior to release.

Respectfully,

Kelly Drollinger, PharmD
Clinical Pharmacy Specialist

OR Dept of Corrections

Four Rivers Bldg.
88 SW 3rd Ave
Ontario, OR 97914
Office Phone: 503-986-6952
Mobile: 458-251-8543
Fax: 541-889-0027

From: LaceAnn Becker
To: PHARMACY RULEMAKING * BOP
Subject: Re: Rule 855-115- 0150
Date: Wednesday, November 8, 2023 3:28:34 PM

Dear Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be **clinically devastating to patient safety**.

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance,
a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted >42 million COVID-19 tests”. Authors estimate that pharmacists “averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.” 'The FDA recognized the capability of pharmacists during the pandemic and have
allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Thank you for your careful consideration in this matter and for keeping Oregonians safe.

Best,
LaceAnn Becker, RPh, PharmD

November 13th, 2023

Oregon State Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Re: Request to repeal new rule 855-115-0150 for Prohibited Practices that states, "Pharmacists must not: Diagnose."

Dear Board Members and Staff of the Oregon State Board of Pharmacy,

It has come to my attention that the prohibited practices for pharmacists in the State of Oregon have recently changed to include the statement that pharmacists must not diagnose.

This is surprising to me as many of the board members are/were practicing pharmacists. I can't tell you how many times over my 14-year career as a pharmacist I've diagnosed and suggested treatment for conditions such as ringworm, eczema, postnasal drip, etc. Likewise, there are also plenty of times I've encountered patient questions about conditions that were out of my scope of practice and subsequently I've suggested the patient see their primary care doctor or go to the emergency room. As pharmacists are the most accessible healthcare providers, we encounter many different types of patient questions and I personally enjoy this role in the healthcare ecosystem.

We can argue the semantics of what defines "diagnosing" for payment purposes, but when patients come to my pharmacy, show/tell me their symptoms, and ask my opinion about what I would suggest to treat their current medical ailment what would you say I am doing? If a patient shows me a rash on her arm and I use my expertise to determine it is ringworm and suggest she apply OTC clotrimazole 1% to the affected area twice a day for two to four weeks, wouldn't a reasonable person consider this "diagnosing"?

Additionally, we are just scratching the surface on the value of point-of-care testing in pharmacies and how this could potentially be a win-win situation in which patients get more convenient and less expensive healthcare, while also helping pharmacies stay viable and keep their doors open.

I understand that your primary concern working on the board of pharmacy is the safety of the public and not trying to increase patient access by keeping pharmacies from closing. However, your role shouldn't be to throw barriers in front of pharmacies to block viable business

opportunities while simultaneously decreasing patient access for conditions that any pharmacist can easily diagnose and suggest treatment.

Thank you for your time and consideration. Let's work together to help Oregonians live safe and healthy lives.

Sincerely,

Dr. Levi J. Martin, Pharm.D., RPh

Bend, OR

From:	Levi Martin
To:	PHARMACY RULEMAKING * BOP
Subject:	Public Comment
Date:	Monday, November 13, 2023 11:52:48 AM
Attachments:	Letter to OBOP.docx

Please find my attached comments for consideration.

Thank you,
Levi Martin

Sent from my iPhone

From:	Molly Bloom
To:	PHARMACY RULEMAKING * BOP
Subject:	Request to repeal 855-115-0150
Date:	Tuesday, November 14, 2023 2:27:04 PM

Dear Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose."

This change in language makes it seem as though a pharmacist is prohibited from even recommending over the counter medications to a patient. When assessing a patient during cough and cold or allergy season, pharmacists are essentially diagnosing a patient with rhinitis or seasonal allergies or common cold before recommending a product to use. Pharmacists have long been recognized as the most accessible health care professionals but if you take away our ability to recommend over the counter medications (for fear of it being seen as diagnosing), it will hugely impact the perception and utilization of our profession.

Furthermore, Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use. The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country "conducted 42 million COVID-19 tests". Authors estimate that pharmacists "averted 1 million deaths, 8 million hospitalizations, and $450 billion in health care costs." The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a diagnosis of COVID-19. **Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose.** As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor appointment to get a prescription.

Perhaps an even greater disruption to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Please consider rewording or revoking 855-115-0150 Prohibited Practices stating: Pharmacists Must Not: Diagnose"

Thank you,
Molly Bloom, PharmD

Multnomah County
Health Department
Community Health Center

November 14, 2023

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232

Dear Oregon Board of Pharmacy Members -

We are writing in response to your invitation for public comment related to the petition to repeal language in OAR 855-115-0150(3) Pharmacist: Prohibited Practices, a rule which was adopted by the Oregon Board of Pharmacy on August 11, 2023. We appreciate the opportunity to comment on the petitioner's September 25, 2023 request to the Board and agree with the petitioner that language which outlines that a pharmacist must not "diagnose" should be removed from OAR 855-115-0150(3) before the rule becomes effective on March 1, 2024.

The Board's stated rationale for adopting this language relates to the lack of authority in ORS Chapter 689 for pharmacists to diagnose, however, there is no language in statute that explicitly prohibits pharmacists from diagnosing. In fact, there are a variety of generally accepted expectations outlined for pharmacists which might be categorized as providing diagnostic services - and without specific legislative directive prompting the need for this prohibition to diagnose in rule, we are concerned this new language will conflict with existing practice and result in more confusion than clarity.

While "diagnose" is not defined in ORS Chapter 689 or in the adopted rule, it does appear in ORS Chapter 677 and is defined as, "to examine another person in any manner to determine the source or nature of a disease or other physical or mental condition, or to hold oneself out or represent that a person is so examining another person. It is not necessary that the examination be made in the presence of such other person; it may be made on information supplied either directly or indirectly by such other person."[1] While diagnosis is not the primary role of a pharmacist, there are certain functions within the current scope of practice for pharmacists that may fall within this definition.

The petitioner has enumerated several examples related to the pharmacists' role in interpreting diagnostic information and results from point of care testing, which outline ways in which this rule would conflict with existing care that is appropriate and crucial for pharmacists to deliver. The benefit of these services being available in the pharmacy setting is undeniable - in facilitating care that is necessary to improve health outcomes for individuals, minimizing contagion, and supporting cost and workforce efficiency within the larger health care system. Despite being critical services of great benefit to patients as well as other health care providers, the administration and interpretation of diagnostic tests by pharmacists will be subject to scrutiny under the new rule (jeopardizing equitable access).

Given the ambiguity in the definition of "diagnose", there are many situations in which a pharmacist may not be able to continue critical services. For example, pharmacists are explicitly authorized to provide immunizations to certain populations. Though uncommon, adverse reactions to vaccines are possible. As an example of the safety

[1] https://www.oregonlegislature.gov/bills_laws/ors/ors677.html

precautions put in place to ensure any adverse reaction can be appropriately managed in a pharmacy setting, administration of COVID-19 vaccination requires a 15-minute observation period. Pharmacists are trained to recognize the signs of an adverse reaction, and administer treatment or lifesaving intervention in the event of such a reaction. Doing so requires professional medical judgment that an adverse reaction is occurring, which might be considered "diagnosing" the patient. In this example, it is well within the scope of the pharmacist's practice to assess the situation ("diagnose" the adverse reaction and associated medical needs) and take steps necessary to act in the best interest of the patient. The FDA recognized the important role pharmacists have played in the pandemic and the need to grant federal authority to pharmacists to expand access to Paxlovid, which should be taken within 5 days of symptom onset. Our pharmacies were critical to dispensing Paxlovid and providing immediate access to high risk patients to prevent death and serious illness - as well as avert costs to the healthcare system associated with hospitalization. Without the ability to access these key services in the pharmacy setting, patients may encounter delays in life saving interventions or forgo them altogether due to the unwarranted barriers they face.

In addition to conflicting with current and appropriate practice, language prohibiting "diagnosis" may introduce hesitation from pharmacists in providing necessary and reasonable care. Rather than clarifying the pharmacist's role, this rule creates confusion. While the pharmacists' scope is well understood, it is unreasonable to anticipate every action that could be interpreted as falling under the umbrella of diagnosis - and the ambiguity as to what might be classified as "diagnosing" may prevent pharmacists from providing certain services due to liability concerns. Lack of access to services provided by pharmacists will be detrimental to health outcomes for patients, and disproportionately impact low-income individuals and residents of rural areas who rely on access to safety net services and community pharmacists to navigate their immediate health needs. Pharmacists are among the most accessible healthcare providers, with expertise in providing medical advice and interpreting medication responses and adverse reactions - resulting in improved outcomes. Removing their ability to perform the services for which they are trained will harm, not protect the public health, safety, and welfare outlined as central in the Board's mission statement - particularly in pharmacy deserts that most often disproportionately impact BIPOC communities.

Language referencing a prohibition of pharmacist to diagnose in OAR 855-115-0150(3) is narrowly constructed and unnecessarily restrictive, and has the potential to limit functions currently within the pharmacist's scope of practice - as "diagnose" may be interpreted broadly and encompass services which are appropriate for pharmacists to perform. If OAR 855-115-0150(3) becomes effective as currently written, language will not only conflict with provisions outlined within the pharmacist's responsibility, but will restrict patient access to critical services and unnecessarily raise liability concerns related to services which are within the pharmacists' scope.

We support the petition to repeal language in OAR 855-115-0150(3) that prohibits a pharmacist from diagnosing. The need for including this language in rule is unclear, and we look forward to further consideration of this matter when the Board convenes in December. Please do not hesitate to contact Laura Blanke at laura.blanke@multco.us or 503-545-9576 if you have questions or if we can be of any assistance.

Sincerely,

Michele Koder, PharmD, Pharmacy Director, Multnomah County Community Health Center
Bernadette Thomas, APRN, DNP, MPH, Chief Clinical Officer, Multnomah County Community Health Center
Amy Henninger, MD, Primary Care Medical Director, Multnomah County Community Health Center
Charlene Maxwell, FNP, DNP, Medical Director, Multnomah County Community Health Center

From: Laura Blanke
To: PHARMACY RULEMAKING * BOP
Subject: Public Comment on Oregon Board of Pharmacy Rule OAR 855-115-0150(3)
Date: Tuesday, November 14, 2023 8:47:29 AM
Attachments: Response to Oregon Board of Pharmacy Rule OAR 855-115-0150(3)_Multnomah County.pdf

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To The Members of the Oregon Board of Pharmacy -

Thank you for the opportunity to provide public comment related to the petition to repeal language in OAR 855-115-0150(3) Pharmacist: Prohibited Practices. Please find the response from the Multnomah County Health Center attached, and please do not hesitate to contact me if you have questions or need additional information.

Thanks again!

Laura Blanke, MPH (*she/her*)
Strategy, Policy & Research Analyst
Community Health Center
Multnomah County Health Department

 This email was encrypted for your privacy and security

From: Andrew Albanese
To: PHARMACY RULEMAKING * BOP
Subject: OSHP Testimony - Prohibitive Practices_New Rule 855_155_0150
Date: Wednesday, November 15, 2023 4:22:35 PM

November 15, 2023

Dear Members of the Oregon State Board of Pharmacy,

Thank you for your time considering OSHP's testimony.

OSHP would like to express our deep concerns regarding the recent rule change in 855-155-0150 that prohibits pharmacists from diagnosing medical conditions. We believe this rule change is detrimental to patient care, and want to emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

For more information please refer to Ryan Wargo’s letter that provides detail outlining the significant, negative impact this rule change will have on the practice of pharmacy in Oregon.

We urge the Board to reconsider this rule change and continue the status quo that allows pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Sincerely,

Andrew Albanese OSHP LRAC Chairman

From: Pamela Becker
To: PHARMACY RULEMAKING * BOP
Subject: Pharmacist diagnosing
Date: Monday, November 13, 2023 6:17:37 PM

Dear Board of Pharmacy members,
I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be **clinically devastating to patient safety.**

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted >42 million COVID-19 tests”. Authors estimate that pharmacists “averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.” 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Sent from my iPhone

From: PAT Hubbell
To: PHARMACY RULEMAKING * BOP
Subject: Diagnose repeal
Date: Wednesday, November 15, 2023 8:05:12 AM
Attachments: Outlook-bey450mn.png

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
pharmacy.rulemaking@bop.oregon.gov

Dear Board of Pharmacy members,

I am requesting a **repeal** to rule 855-115-0150(3) for Prohibited Practices, that state "Pharmacists Must Not: Diagnose." I appreciate the process to work through fixing this new rule. If left unchanged it will impact every pharmacist and add another barrier to serving patients effectively.

Pharmacists are the only front-line healthcare professionals that patients have direct access to without disturbingly long wait times for other healthcare providers. Pharmacists have been proven to demonstrate outstanding stewardship of all aspects of our professional abilities.

Let pharmacists continue to be an integral part of the healthcare team and serve Oregonians the best way possible.

We look forward to your discussion of this request at the December meeting. Thank you again for working with us to recognize pharmacist's current role in serving the citizens of Oregon.

Pat Hubbell, RPh, Owner
Oregon State Pharmacists Association President Elect
Portland Retail Druggist Association Spokesperson

Brooklyn Pharmacy
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Portland, OR 97202
P: 503-234-3488 - F: 503-235-0373
pat@brooklynpharmacyrx.com


BROOKLYN
PHARMACY

November 1, 2023

Members of the Oregon Board of Pharmacy
Cc: Mr. Jamal T. Fox - Executive Director
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Subject: Support for Repeal of OAR 137-001-0070(3) Pharmacist: Prohibited Practices

Dear Members of the Oregon Board of Pharmacy:

I'll be first to say, the term diagnose is a loaded term across healthcare. While simple on the surface, a diagnosis *can* have cascading impacts regarding billing, insurance, etc. That said, I write you to momentarily forget about your conceived notion of what defines a diagnosis – and let's talk about the practice of pharmacy.

For over 100 years, pharmacists have been the most accessible healthcare professionals across Oregon. Nearly every person in this state has walked up to a pharmacy and counter and asked, "I'm congested. Can the pharmacist help me find something?"

For over 100 years, that answer has been yes. Now, with OAR 137-001-0070(3), a reasonable pharmacists will conclude that helping that person appears to be a prohibited practice for pharmacists.

For over 100 years, pharmacists have been relied upon to ask the pertinent questions to determine if an over-the-counter (OTC) product would be indicated. In many cases, a pharmacist will recommend an OTC product. In other cases, the symptoms that they see, or the symptoms described by the patient, don't fit an OTC product causing them to refer them to their healthcare provider.

However – in order to make a conclusion about what product best suits their issue, we must come to a conclusion about what their problem is.

Merriam-Webster defines a diagnosis as "the art or act of identifying a disease from its signs and symptoms."[1] While we might split hairs on the definition of diagnose in healthcare, as described above, diagnosing has been an absolute core part of pharmacy for as long as there have been pharmacists.

With the implementation of OAR 137-001-0070(3), a pharmacist will violate administrative rule in Oregon by helping to figure out if someone has allergies or has a cold, by helping someone that has visible lice but hasn't been to their physician, or by helping hasn't had a bowel movement in three days for the first time in their life.

Pharmacists have been stewards of diagnosing over this entire period – understanding when they should say something definitive like "you have lice" (a diagnosis), something less definitive such as "I think you might have allergies, try cetirizine for a week, and contact your doctor if symptoms persist or get worse" (a diagnosis), and even definitive when the potential diagnosis is out of their scope by saying "you should probably seek medical attention right now" when a 70 year old male presents with shortness of breath & chest pain that radiates down their left arm (which.. they've likely made a preliminary diagnosis in their head while calmly telling that person that they probably aren't a candidate for an OTC therapy).

1- Merriam-Webster. (n.d.). Diagnose. In Merriam-Webster.com dictionary. Retrieved November 1, 2023, from https://www.merriam-webster.com/dictionary/diagnose

I get that there's nuance around the term diagnose. I also get that there isn't explicit direction that pharmacists can diagnose in Oregon statute. But, as described above, we have 100 years of precedent that states that diagnosing is within our scope and we need to acknowledge that, continue that, and celebrate the impacts on access that it's had on the state of Oregon.

Thank you,

Dr. Kevin Smith, PharmD, RPh

Portland, OR

From: Kevin Smith
To: PHARMACY RULEMAKING * BOP
Subject: Public Comment Submission: OAR 137-001-0070(3) Pharmacist: Prohibited Practices
Date: Thursday, November 2, 2023 12:58:50 PM
Attachments: image001.png
Request to Repeal OAR 137-001-0070.pdf

> You don't often get email from kevin.smith@prescryptive.com. Learn why this is important

Good afternoon Oregon Board of Pharmacy staff,

Please see attached letter for my public comment supporting the repeal of OAR 137-001-0070(3) Pharmacist: Prohibited Practices.
Please let me know if you have any issues with opening the letter, etc.

Thank you,
-Kevin Smith

--

Kevin Smith, PharmD | Principal Product Manager
Phone: (425) 655-2245
www.prescryptive.com

November 15, 2023

Dear Members of the Oregon State Board of Pharmacy,

I hope this letter finds you well. I am writing to express my deep concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is detrimental to patient care, and I would like to contest it on several grounds.

First and foremost, I must emphasize that there is no statutory authority explicitly allowing or prohibiting pharmacists from diagnosing in the state of Oregon. The current statutes do not clearly define this aspect of a pharmacist's scope of practice. Therefore, prohibiting pharmacists from diagnosing is not based on a statutory foundation.

This rule change will have significant negative consequences for patient access to care and may disrupt vital test-to-treat programs and hinder the ability of pharmacists to provide timely and effective care, particularly in rural areas where access to healthcare providers may be limited. As an example, the COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers, causing delays in treatment and increasing the burden on an already strained healthcare system.

Additionally, the prohibition of diagnosis via protocol is also at odds with the intent of Oregon's Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose. Pharmacists play a crucial role in utilizing diagnostic information to assess and address patient needs and proficient in utilizing diagnostic information in their practices. For instance, pharmacists practicing under collaborative drug therapy management agreements routinely order, interpret, and monitor laboratory values such as blood glucose levels, cholesterol levels, and urine albumin-creatinine ratio results when referred for diabetes management. This interpretation guides medication adjustments and ensures patient safety. By prohibiting pharmacists from diagnosing, we risk delaying necessary interventions and compromising patient outcomes.

Furthermore, this rule change stands as a significant barrier to physician rights to delegate to pharmacists using collaborative drug therapy management agreements. Collaborative practice agreements allow physicians to delegate specific healthcare tasks to pharmacists, leveraging their expertise to improve patient outcomes. This includes the authority to initiate prescription drug management of comorbid complications such as hyperlipidemia, kidney disease, and cardiovascular disease when pharmacists are referred patients for the management of diabetes. These collaborative agreements rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their, and the diagnostic providers, scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service, in abundance, and without issue for decades.

In conclusion, I strongly contest the recent rule change that prohibits pharmacists from diagnosing. The lack of statutory authority either permitting or prohibiting this practice should not lead to such a restrictive rule. Instead, I urge the Board to reconsider this rule change and continue allowing pharmacists to utilize their clinical expertise in providing patient care services and managing medical conditions within their scope of practice.

Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Professionally,

Ryan Wargo, PharmD, BCACP

From: Wargo, Ryan J :LSO Mgr Pharmacy
To: PHARMACY RULEMAKING * BOP
Subject: Regarding invitation for Public Comment on OAR 855-115-0150(3)
Date: Wednesday, November 15, 2023 2:44:01 PM
Attachments: Prohibitive Practices_New Rule 855_155_0150.pdf

Oregon State Board of Pharmacy,

Please the attached letter for comment on OAR 855-115-0150(3) Pharmacist: Prohibited Practices. Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Professionally,

Ryan Wargo, PharmD, BCACP
Manager - Ambulatory Pharmacy Services
Legacy Health
2225 NW Northrup St, Room 317
Portland, OR 97210
Phone: 503-415-5865

From: Santon Shagavah
To: PHARMACY RULEMAKING * BOP
Subject: Prohibiting Practice Diagnosing Letter.
Date: Wednesday, November 15, 2023 1:16:32 PM

> You don't often get email from santon.shagavah@multco.us. Learn why this is important

Santon Shagavah

6907 SE 47TH AVE, PORTLAND, OR 97206. santon.shagavah@multco.us. 11/15/2023

Oregon State Board of Pharmacy 800 NE Oregon Street, Suite 150 Portland, OR 97232

Dear Members of the Oregon State Board of Pharmacy,

I hope this letter finds you well. I am writing to express my deep concerns regarding the recent rule change that prohibits pharmacists from diagnosing medical conditions. I believe this rule change is both unnecessary and detrimental to patient care, and I would like to contest it on several grounds.

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This rule change may disrupt vital test-to-treat programs. The COVID-19 pandemic demonstrated the value of pharmacists in conducting tests and initiating treatment based on diagnostic results. The FDA recognized the capability of pharmacists to diagnose COVID-19, allowing them to dispense Paxlovid upon a "diagnosis of COVID-19." However, with the new rule in place, patients may be required to make additional appointments with healthcare providers, causing delays in treatment and increasing the burden on an already strained healthcare system.

The prohibition of diagnosis via protocol is also at odds with the intent Oregon’s Public Health and Pharmacy Formulary Advisory Committee, which aims to allow pharmacists to evaluate, assess, and prescribe treatment per statewide protocols. Prohibiting diagnosis through protocols restricts patient access to timely care, contradicting the committee's purpose.

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rely on pharmacists' ability to assess and diagnose patients per protocol parameters within their and the diagnostic providers scope of practice; ensuring that they meet guideline parameters for prescription drug therapy management. Prohibiting diagnosis through these agreements not only hampers patient care but also restricts the collaborative efforts of healthcare providers preventing effective implementation of team-based care models.

In addition, it is important to note that counseling, a significant aspect of a pharmacist's role, does not have a clear statutory basis either. Yet, pharmacists are required to counsel patients and have been recommending over-the-counter treatments for minor, self-limiting conditions for decades. For example, when a patient visits the pharmacy with complaints of heartburn and requests a recommendation for an appropriate over-the-counter treatment, pharmacists assess the severity of the patient's symptoms, duration, contributory risk factors, and warning signs. Based on this assessment, pharmacists make recommendations lifestyle modifications and/or over-the-counter treatments or refer patients to appropriate healthcare providers. This practice is akin to diagnosing minor self-limiting conditions, and pharmacists have been providing this service, in abundance, and without issue for decades.

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Thank you for your attention to this matter. I hope the Board will carefully consider these arguments and take steps to ensure that pharmacists can continue to provide the highest level of care to the patients we serve.

Sincerely,

Santon Shagavah, Clinical Pharmacist, Oregon Licensed Pharmacist

 This email was encrypted for your privacy and security

From: Melissa Netland
To: PHARMACY RULEMAKING * BOP
Subject: "not allowed to diagnose"
Date: Thursday, November 9, 2023 7:39:29 AM

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be clinically devastating to patient safety.

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted 42 million COVID-19 tests”. Authors estimate that pharmacists “averted 1 million deaths, 8 million hospitalizations, and $450 billion in health care costs.” The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19". Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

Perhaps one of the greatest disruptions to care is the conflict in rule and statute. In order for pharmacists to participate in the Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV, Syphilis/Treponemal, Chlamydia/Gonorrhea, Hepatitis B, and renal function. By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented.

Please do not take away our ability to provide immediate access to critical health care,

Sincerely,

James and Melissa Netland, Pharm BS, RPH's
Stayton Pharmacy and Sublimity Pharmacy owners

November 10, 2023

To Whom It May Concern

Dear Board of Pharmacy members,

I am writing to you today to request a repeal to the new rule 855-115- 0150 for Prohibited Practices that states, “Pharmacists Must Not: Diagnose.” If you don’t fix this rule, it will up-end pharmacy services in Oregon and will be **clinically devastating to patient safety.**

Pharmacists are proficient in utilizing diagnostic information in their practice. They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or international normalized ratios (INRs) for patients on anticoagulants. These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care tests as valuable decision support tools. For instance, a pharmacist can quickly rule out a bacterial or viral infection, helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use.

The value of point-of-care tests was clearly established during the COVID-19 pandemic. A recent study quantifying the contributions of pharmacists during the pandemic found that pharmacists across the country “conducted >42 million COVID-19 tests”. Authors estimate that pharmacists “averted >1 million deaths, >8 million hospitalizations, and $450 billion in health care costs.” 'The FDA recognized the capability of pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of COVID-19." Now, the Board has revoked the state protocol on the grounds that pharmacists cannot diagnose. As a result, patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription.

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Victor J Abreu

Victor Abreu, PharmD
Community-Based Pharmacy Resident
Oregon State University College of Pharmacy
Pronouns: he/him
abreuniv@oregonstate.edu 787.536.7788

From: Abreu Nicolas, Victor J
To: PHARMACY RULEMAKING * BOP
Subject: Comments to repeal the rule that states, “Pharmacists must not: diagnose.”
Date: Friday, November 10, 2023 8:40:52 AM
Attachments: lettert members to BOP.docx

Hello,

I'm attaching my thoughts regarding the rule-making in question

Best,
Victor

Victor Abreu, PharmD
Community-Based Pharmacy Resident
Oregon State University College of Pharmacy
Pronouns: he/him
abreuniv@oregonstate.edu 787.536.7788

From:	William Marais
To:	PHARMACY RULEMAKING * BOP
Subject:	Request to repeal the new rule 55-115-0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose"
Date:	Tuesday, November 14, 2023 6:10:29 PM

Dear Board of Pharmacy members, I am writing to you today to request a repeal to the new rule 55-115-0150 for Prohibited Practices that states, "Pharmacists Must Not: Diagnose". If you don't X this rule, it will up-end pharmacy services in Oregon and it will be clinically devastating to patient safety. All pharmacists are proficient in utilizing diagnostic information in their practice . They routinely interpret laboratory values, such as blood glucose levels for patients with diabetes or INR's for patients on anticoagulants These values guide professional decision making for timely medication adjustments and ensure patient safety. They have long used CLIA-waived point of care test as valuable decisions support tools, For instance the pharmacist can quickly rule out a bacterial or viral infection helping guide whether antibiotics or antivirals are necessary, preventing unnecessary drug use. The value of point of care tests was clearly established during the covid-19 pandemic. A recent study quantifying the contributions of Pharmacists during the pandemic found that pharmacists across the country conducted more than 42 million COVID- 19 tests. Authors estimate that pharmacist averted more than 1 million deaths, more than 8 million hospitalizations and $450 billion in healthcare costs . The FDA recognized the capability of Pharmacists during the pandemic and have allowed for them to dispense Paxlovid upon a "diagnosis of covid-19 ". Now the board has revoked the state protocol on the grounds that pharmacist cannot diagnose. As a result patients are not able to get immediate treatment at a pharmacy because they need to make a doctor's appointment to get a prescription. Perhaps one of the greatest disruptions to care is the conflict in rule i and statute in order for pharmacist to participate in Oregon Board of Pharmacy PrEP protocol, enacted in 2022, they are required to conduct and interpret lab tests for HIV / Syphilis / Treponemal / Chlamydia / Gonorrhea / Hepatitis B, and renal function, By prohibiting the ability of pharmacists to diagnose, patients will lose access to services they are reliant upon, and current law will not be implemented

Kind Regards

William Marais RPh

Albertsons Central Fill Pharmacy (RP-0003909) Alternative Verification Process Request

S	**Situation:** • Albertsons Companies Inc. (ACI), the parent company of Safeway Inc., is requesting approval to utilize an alternative Pharmacist Verification process in its Albertsons Central Fill Pharmacy Vancouver Facility located in Ridgefield, Washington. This site is currently licensed in Oregon as an out of state pharmacy (RP-0003909) with a Central Fill designation. This central fill facility supports commonly owned pharmacies in the state of Oregon. • The process that will be employed by the central fill facility is for a pharmacist to verify the contents of the automation canister each time it is filled and prior to the canister being loaded into the fulfillment automation. The verification performed by the pharmacist serves as the final verification check for any prescriptions that are subsequently filled from that canister. Another pharmacist does not check the prescription vial once it has been filled and labeled. There are routine quality assurance checks of a sampling of prescription vials filled during the life of the canister. These processes serve as a secondary safety and accuracy check.

B	**Background:**
	• 3 total similar approvals currently
	
	Most Recent Similar Request:
	8.17 Board Meeting Fred Meyer/PPS Request
	At the August 2017 Board Meeting, Fred Meyer/PPS requested permission to use an alternative pharmacist verification process using technology currently employed in other states. The board reviewed the request and was concerned about the implications of this technology, including:
	• Lack of clear rules: No specific regulations have been found in states using this process.
	• Responsibility for errors: It was unclear who bears responsibility if errors occur due to technology.
	• Patient interaction: Board members worried about how this process impacts pharmacist-patient interactions and understanding patient needs.
	• Circumventing existing rules: Some board members believe this proposal goes against the "final check" rule for prescriptions.
	• Job displacement: Concerns exist about potential job losses due to automation.
	• Next steps:
	  ○ Staff to gather more information:
	  ▪ Research regulations in other states.
	  ▪ Obtain data from Fred Meyer on errors made by humans vs. machines.
	  ▪ Explore potential job displacement and future implications of automation.
	• The board will revisit this request once additional information is available.
	• See *10/2017 Fred Meyer PPS Reference below

	10.17 Board Meeting Postal Prescription Services (PPS) Request After providing information requested by the board at the August 2017 Board Meeting, Fred Meyer/PPS provided an updated request at the October 2017 meeting. The board reviewed the request and • Approved the alternative verification for this location only. • Directed staff to facilitate the licensure designation for this specific case. • Requested future similar requests to be presented for board approval. The information provided and questions answered by Albertsons are the same requested from PPS/Fred Meyers in 2017. **Albertsons Stated:** • This form of pharmacist verification is used by central fill and mail order facilities who employ similar automation technologies. It is widely accepted as a safe and effective method to preserve patient safety and the accuracy of the medications they receive. • iA's NEXiA software and SmartPod pharmacy automation is used by many large-scale central fill and mail order facilities across the country. The alternative pharmacist verification technology is accepted by many states across the country including Idaho and Washington, which our facility will be supporting in addition to Oregon. Our estimate is that between 60-80% of all dispenses will leverage this technology. This is dependent on final formulary selection. No NIOSH hazardous drugs are run through the automation. Additionally, the central fill facility does not process any products that are associated with a REMS program and similarly does not fill any controlled substances.
A	**Assessment:** • **ACI is requesting approval to utilize alternative Pharmacist Verification processes supported by Innovation Associates (iA) automation and their NEXiA software. Can ACI activate these technological processes?** o This process is based on a pharmacist verifying the accuracy of the contents of a bulk canister used to replenish an automated counting machine. The pharmacist verification is intended to fulfill the final verification step without requiring the pharmacist to review each individual prescription vial apart from manually verified prescriptions as part of any ongoing QA processes. • **Are the default Quality Assurance measures satisfactory to the Oregon Board of Pharmacy?** o The default Quality Assurance measures include: canisters that electronically communicate with the dispenser to ensure appropriate verifications have been performed and the correct canister has been placed

	on the correct dispenser, specific NDC calibration associated with each canister, series of barcode scanning validation including hard halt processes when a mismatch occurs requiring pharmacist intervention to proceed, still picture images of each step of the replenishment process, video recording at each work station and applicable areas of the facility, and still picture images of final product. In addition to the safety checks and balances built into the replenishment and dispensing process driven by the automation technology, we are imposing additional safeguards including requiring the first 10 prescriptions and last 5 prescriptions filled to be routed for manual verification by a pharmacist. This will occur each time a new or replenished canister is inserted into a SmartPod automated counting machine, and any time a SmartPod or NEXiA system loses power or is restarted. Additionally, 2 of every 100 prescriptions filled outside of the first and last fills from the canister will be routed to a pharmacist for manual verification to ensure ongoing quality assurance occurs for the life of the canister. Lastly, to ensure counts remain consistent and accurate, the first 5 fills from all canisters will be routed for manual count verification. This involves personnel counting the contents of a prescription vial and entering the count into NEXiA to verify the result matches the expected amount. This is a blind count and the personnel do not have visibility into the amount expected in the vial. • **Which pharmacy staff will be impacted (pharmacists, technicians, and/or other staff)** o Pharmacists and Technicians. See attached SOP and brief description below: Pharmacists will interact with this alternative verification process related to their responsibilities to verify the contents of filled canisters prior to those canisters being loaded into a SmartPod automated device. This verification will serve as the basis for final verification for any prescriptions that are subsequently filled using the canister they verify. The pharmacist who verifies the canister is responsible for all prescriptions fulfilled from that canister. o Technicians are responsible for filling the canisters and preparing them for the pharmacist to review. They will also be responsible for loading the SmartPod with the approved canisters following the pharmacist's verification. • **Outline the types of technology that will be utilized, if applicable**. o NEXiA dispensing software, iA canisters, iA dispensers and SmartPod automation devices. • **Impact on other pharmacy practice settings.** o These processes would only be applicable to the central fill pharmacy and would not be leveraged in our local community pharmacies located in Oregon.

- **Specific way(s) this will further public health and safety**
    - This technology allows for a high volume and high throughput prescription fulfillment facility to be operationalized to support in-state local community pharmacies. By offloading prescription fulfillment for a percentage of prescriptions that are traditionally filled by hand in a pharmacy, the local pharmacy staff can focus on patient specific tasks that require their in-person attention. Specifically, this technology allows for a pharmacist to safely oversee the fulfillment process with minimal intervention to ensure the correct medication makes it into the correct vial and ultimately back to the local pharmacy for dispensing to the patient. We believe this technology leverages robust safety checks and balances to ensure the right medication makes it into the expected prescription vial and the ongoing quality assurance measures support those efforts to ensure everything behaves as expected.

Additional Information:

- **Video/photo storage and retrieval information collected?**
    - The video and still image photos taken as part of the pharmacist canister verification process will be stored for 90 days and retrievable upon demand. Following the 90 days, the still images will be archived and still retrievable. All task tracking data associated with the steps in the verification process will be stored on a server and retained consistent with state and company requirements.
- **Is there a specific policy related to the QA processes**?
    - There is not a specific QA policy related to this technology, but rather many processes built in to provide QA throughout the overall fulfillment process. These processes include the following:
        - Canisters have physical and electronic security features to prevent tampering.
            - Zip tie placed on the canister door following replenishment to lock the door shut and provide a visual confirmation of canister integrity.
            - Specific NDC associated with each canister.
            - Canister is calibrated for the characteristics of the medication contained within.
            - The canister will physically lock on the docking station if a mismatch NDC barcode scan occurs. Pharmacist intervention is required to unlock and proceed.
            - Canister can't be loaded into a SmartPod until it has been verified by a pharmacist.
                - If it is attempted, the SmartPod will lock and require a pharmacist intervention to unlock and be put back into use.

	• If a canister is opened at any time following the replenishment step and pharmacist verification, it will flag an exception and alert to notify staff it has been opened and there is a potential security violation that requires investigation. ▪ Still images taken during the canister replenishment process for pharmacist verification purposes and historical review if necessary. ▪ Still images taken during the individual prescription fulfillment for pharmacist verification purposes as part of the manual QA processes of a canister as well as for historical review if necessary. ▪ Barcode scanning during the replenishment process to add medication to a canister, load a canister on a shelf to wait for pharmacist verification, during pharmacist verification, loading a canister onto a replenishment cart, and when loading a canister into the SmartPod on its paired Dispenser. • Any mismatch scans that occur will lock the process with an alert in the software, which requires a pharmacist to review the exception and enter their credentials to proceed with the process. • All mismatch barcode scans are logged by NEXiA including the individual associated with the mismatch, time of the incorrect scan, expected NDC, scanned NDC, and timestamp. This allows for monitoring for trends that need to be addressed in the following manners including but not limited to policies and procedures, staff training, process design, and system design. ▪ Intelligent dispensers that track the lot number used for each patient specific prescription. ▪ Routine quality assurance audits are performed during the lifetime of a canister in addition to the required pharmacist verification. These are intended to proactively monitor for any issues that may have arisen during the replenishment process and were not caught by the required pharmacist verification. • Newly assigned NDC to Dispenser, newly inserted canister on a dispenser, and when the SmartPod or NEXiA system is restarted or loses power. o 10 first fills and 5 last fills routed for manual pharmacist final verification. o 2 of every 100 subsequent fills during the lifetime of a canister will be routed for pharmacist final verification. ▪ Dispenser counting audits to ensure accurate quantities are counted. • First 5 fills dispensed from a newly assigned and calibrated canister will be routed for manual verification.

	• The verification is blind and the personnel counting will enter the amount counted into NEXiA, which will validate if it matches the expected quantity in the vial. ▪ We are using a Patient Safety Organization which provides error management software to allow for the reporting and tracking of any errors discovered in the facility or by a receiving pharmacy for fills associated with the central fill facility. • This allows for root cause analysis and action plans to be developed which will guide the process of identifying contributing factors and resolutions to prevent a similar error from occurring in the future. • **What, if any, errors have occurred that have been identified by a pharmacist? And, have any errors occurred that were not identified by a pharmacist, and actually left the facility?** o This facility is currently using a pared down version of the iA system called "smart start." During this phase of the project, the alternative pharmacist verification is not leveraged. In January, we will begin the high-volume phase of our central fill operations, which will leverage significant automation technology. Oregon pharmacies will be supported after this high-volume transition occurs. Considering we have yet to leverage this new technology, there have been no errors related to this technology. • *See Canister Verification BOP Approval Outline below • *See High Volume Canister Verification v1.0 below • *See Albertsons Request for Additional Information below
R	**Recommendation:** Treat the same as similar requests and direct staff to facilitate correct licensure designation to allow this alternative pharmacist verification to occur at this location, under these circumstances. • Does the Board want to direct staff to present future similar requests and/or add to future Staff Delegated Authority assessment discussions? • Does the Board want to direct staff to include this type of technology or innovation as part of consideration for the assessment and revision for division 41?

Date:

Original: 7.20.2017
Updated: 9.15.2017 (new information begins on pg. 4, in red font)

Request/Inquiry Type:

Fred Meyer Central Fill and Mail Order Pharmacy (Postal Prescription Services - PPS) is requesting approval to utilize an alternative Pharmacist Verification process.

Essentially, this process differs from traditional pharmacist verification processes, in that the pharmacist validates the correct filling of medication canisters to be used on the fully-automated dispensing "line", however, a final check by a(nother) pharmacist once the bottle has been filled and labeled is not performed. Rather, a sampling of final products is routinely QA'd for process validation.

• *Question(s):*

Note-if inquiry contains multiple questions, the background, discussion, and related law & rules must be identified for each

1. Postal Prescription Services (PPS) is requesting approval to utilize an alternative Pharmacist Verification process supported by state of the art McKesson HVS pharmacy automation. Can PPS activate these technology processes?

   The process is based on Pharmacist Verification of counting technology replenishment. Fail safe safety checks and QA steps are built into the entire process to ensure world class pharmacy accuracy.

2. Are the default Quality Assurance measures satisfactory to the Oregon BOP?

   The default QA measures include; multiple levels of product and Rx vial barcode safety checks, video and still picture recording of each step in the replenishment the process, weight verification for product and count accuracy, still picture images of the final product, and direct pharmacist oversight. In addition, traditional pharmacist verification is completed for the first and last Rx dispensed through each verified and secured canister as well as any Rx that does not pass the weight verification step.

• *Background:*

(Include related Federal or national standards/guideline and other state's rules, if applicable)

- This established Pharmacist Verification process is well-accepted and utilized throughout the United States. The process and technology ensures all prescriptions will be accurately filled, dispensed, and the verifying pharmacist recorded.

- This process is prevalent in the industry and an already accepted form of verification in many states including Iowa, Illinois, Indiana, Florida, Michigan, Minnesota, Missouri, Nebraska, New Jersey, New Mexico, Nevada, New York, Ohio, and Texas. This process is currently utilized by a

variety of automated pharmacies including Wegmans, Meijer, Prime-Therapeutics, HyVee, Express Scripts, Prescription Solutions, Caremark, and several other central fill and/or mail order facilities currently in installation phase.

- The Kroger Columbus Central Fill facility has utilized this alternative Pharmacist Verification process since 2014 and sets the company standard for overall pharmacy accuracy results (surpasses six sigma accuracy level).

- ***Discussion:***

To include:

1. Which pharmacy staff will be impacted (pharmacists, technicians, and/or other staff)

Pharmacists and technicians; See Power Point presentation (slides, 13 and 14), and SOPs included as links below.

2. Outline the types of technology that will be utilized, if applicable

Kalish and Parata; See Power Point Presentation, and SOPs included as links below.

3. Impact on other pharmacy practice settings; and

There would be no impact on other pharmacy settings. The level of automation and safety checks built into a high volume pharmacy system would not be practical for lower volume settings.

4. Specific way(s) this will further public health and safety

Based on the results we have achieved at our Columbus Central Fill facility, we are confident that this process will further improve upon the already impressive level of accuracy being achieved at PPS. In addition, the efficiencies gained by this process will enable PPS to better serve our pharmacy customers by allowing pharmacists more time for consultation and delivery of clinical services.

BOP Staff questions:

- **Is this used for both central fill and mail order?**

  Yes, this process would be used for both central fill and mail order prescription fulfillment.

- **Is the video/photo and weight data collected at each step/approval kept and readily retrievable for 3 years?**

  Video, photo and weight data retention is configurable per BOP preference. At the Kroger Columbus Central Fill facility, video is saved on demand and still images are kept for 90 days. The responsible pharmacist for all steps in the process is kept on record for a minimum of 3 years.

- **QA: Is there a specific policy related to the QA processes? Board will need clearly articulated checks of this system, including error reporting, etc.**

  Quality Assurance steps are built into the entire fulfillment process and cannot be bypassed. These steps include; multiple levels of product and Rx vial barcode safety checks, video and still picture recording of each step in the replenishment the process, weight verification for product and count accuracy, still picture images of the final product, and direct pharmacist oversight. In addition, traditional pharmacist verification is completed for the first and last Rx dispensed through each verified and secured canister as well as any Rx that does not pass the weight verification step.

  All clinical pharmacy errors are reviewed by the Pharmacy Manager and reported to our Corporate Pharmacy safety group.

- **What, if any, errors have occurred that have been identified by a pharmacist? And, have any errors occurred that were not identified by a pharmacist, and actually left the facility?**

  No errors have occurred.

• *Related ORS/OARs:*

OAR 855-019-0200(2) Only a pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require the professional judgment of a pharmacist include but are not limited to:
(i) Final verification of the work performed by those under their supervision.

OAR 855-006-0005(32) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified pharmacy technician.

Staff Comments:

- Regarding QA/random auditing by traditional pharmacist verification processes:
  - It is stated that “traditional pharmacist verification is completed for the first and last Rx dispensed through each verified and secured canister as well as any Rx that does not pass the weight verification step”.
  - The Board should consider what it defines as a robust QA/validation process.
  - For example, the Board may want to consider traditional pharmacist verification at each first/last rx filled with canister changes AS WELL AS an additional random sampling of X% of all rxs filled.
  - To include thorough documentation of these audits made available in QA reporting.

- Regarding documentation and recordkeeping:
  - It is stated that “video is saved on demand and still images are kept for 90 days”.
  - The Board may want to consider requiring data to be kept longer, in accordance with other recordkeeping standards (i.e. 3 years)

- The "canister verifying" pharmacists must be fully aware of their responsibilities (i.e. that if an error occurs on the line, they and the outlet are the responsible licensees)

- Regarding "comfort level" with this alternative pharmacist verification process
  - The Board may want to consider authorizing a 1-year approval with the expectation that PPS returns in a year with a follow up report/summary.
    - This would be similar to TCVP approval procedures.
  - The Board may also want to consider requiring that only specific staff be allowed to perform these processes. They must be highly trained and therefore be dedicated to these processes. Caution when new people engage with alternative methods prior to being adequately trained.

INFORMATION PROVIDED POST-AUGUST 2017 MEETING

Q1: Background information / data from this process (and this technology) utilized in other states, specifically numbers of rxs being dispensed in this manner, errors, and cases. Please be sure to describe what constitutes an event being categorized as an error and provide comparison to human error rates. (For example, do you keep documentation of when a pharmacist discovers the wrong pill in a bottle? Aka "near miss").

A1: The alternative pharmacist verification process being proposed is currently being utilized by 11 high volume central fill and mail order pharmacies. Companies represented including Wegmans, Meijer, Prime-Therapeutics, HyVee, Express Scripts, Prescription Solutions, and Caremark. This process is prevalent in the industry and an already accepted form of verification in many states including Arkansas, Iowa, Illinois, Indiana, Florida, Michigan, Minnesota, Nebraska, New Jersy, New Mexico, Nevada, New York, Ohio, and Texas.

Annual volume for the 11 sites utilizing this process is estimated at 40.5 million central fill prescriptions and 10.2 million mail order prescriptions. Of this volume, 93% is fulfilled via alternate pharmacist verification. The additional 7% is processed via traditional verification due to being a manual fill product or included in the QA audit. Of the estimated 50.7 million prescriptions filled at these sites, 0.3% were flagged for weight discrepancies and routed for traditional pharmacist verification. This percentage includes both manual fills and alternate pharmacist verification fills. The vast majority of these exceptions are due to miscounts and are corrected.

The Kroger Columbus Central Fill facility fills over 200,000 prescription orders per week and has utilized this form of alternate pharmacist verification for almost 4 years now. Accuracy for this process is determined by the correct product in the container and correct label on the container. To date, accuracy is approximately 340 times higher than estimated retail pharmacy accuracy for the same workflow steps.

Q2: Describe fully the implication and/or their concerns of mail order AND central fill prescriptions being processed on the same "line"

A2: The alternative pharmacist verification process being proposed is currently being utilized by 11 high volume central fill and/or mail order pharmacies. Four of these sites (including Columbus Central Fill) are combination central fill/mail order sites.

PPS has complete confidence in the accuracy of this process for both central fill and mail order. The filling process and expectation for 100% accuracy is the same for both. If the BOP still has concerns about mail order processing, we could discuss additional QA options for this order type.

Q3: The proposal, review and approval details from the Ohio Board of Pharmacy to perform this function

> **A3:** The Ohio Board of pharmacy inspector scheduled an onsite visit to review the alternative pharmacist verification process. At the conclusion of this review, the inspector approved the process in writing on the inspection report.

Q4: Details of QA program currently at locations where this is already occurring – must include whether the various states require different % samples for random pharmacist review

> **A4:** At our Columbus Central Fill facility, the Ohio Board of Pharmacy was comfortable with the following QA audit process: Once the canister is approved by a pharmacist, the first and last prescription filled from that canister is routed for traditional verification by a second pharmacist. All fills must also pass a weight screening to ensure the correct product and count. In addition, a photo image of the contents of each fill is captured and saved.
>
> While we are not aware of any State required % of QA samples reviewed, there is some variety in what has been approved across the country. Two sites match the Columbus QA audit program with the addition of a random audit for every 1,000th Rx processed. Five sites match the Columbus QA program with the addition of a random audit for every 10,000th Rx processed. Three sites do not audit.

Q5: What will PPS be doing with the personnel (RPHs who are currently performing final verifications) to increase safety for patients, or did they just downsize(terminate)?

> A5: PPS has no plans to downsize pharmacist staffing. Pharmacists will be reallocated to the replenishment stations, mail order pre-verification, DUR review, and patient consultation activities.

Requester's Contact Info:

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Albertsons Companies Inc. – Waiver Request for Alternative Pharmacist Verification Process in Central Fill Environment.

Request Date: 11/28/23

Prepared by: Rob Geddes, PharmD, MBA

Request/Inquiry Type:

Albertsons Companies Inc. (ACI), the parent company of Safeway Inc., is requesting approval to utilize an alternative Pharmacist Verification process in its Albertsons Central Fill Pharmacy Vancouver Facility located in Ridgefield, Washington. This site is currently licensed in Oregon as an out of state pharmacy (RP-0003909) with a Central Fill designation. This central fill facility supports commonly owned pharmacies in the state of Oregon.

The process that will be employed by the central fill facility is for a pharmacist to verify the contents of the automation canister each time it is filled and prior to the canister being loaded into the fulfillment automation. The verification performed by the pharmacist serves as the final verification check for any prescriptions that are subsequently filled from that canister. Another pharmacist does not check the prescription vial once it has been filled and labeled. There are routine quality assurance checks of a sampling of prescription vials filled during the life of the canister. These processes serve as a secondary safety and accuracy check.

Questions:

Note-if inquiry contains multiple questions, the background, discussion, and related law & rules must be identified for each.

1. ACI is requesting approval to utilize alternative Pharmacist Verification processes supported by Innovation Associates (iA) automation and their NEXiA software. Can ACI activate these technological processes?
    a. This process is based on a pharmacist verifying the accuracy of the contents of a bulk canister used to replenish an automated counting machine. The pharmacist verification is intended to fulfill the final verification step without requiring the pharmacist to review each individual prescription vial apart from manually verified prescriptions as part of any ongoing QA processes.
2. Are the default Quality Assurance measures satisfactory to the Oregon Board of Pharmacy?
    a. The default Quality Assurance measures include: canisters that electronically communicate with the dispenser to ensure appropriate verifications have been performed and correct canister has been placed on the correct dispenser, specific NDC calibration associated with each canister, series of barcode scanning validation including hard halt processes when a mismatch occurs requiring pharmacist intervention to proceed, still picture images of each step of the replenishment process, video recording at each work station and applicable areas of the facility, and still picture images of final product. In addition to the safety checks and balances built into the replenishment and dispensing process driven by the automation technology, we are imposing additional safeguards including requiring the first 10 prescriptions and last 5 prescriptions filled

from a canister to be routed for manual verification by a pharmacist. This will occur each time a new or replenished canister is inserted into a SmartPod automated counting machine, and any tima a SmartPod or NEXiA system loses power or is restarted. Additionally, 2 of every 100 prescriptions filled outside of the first and last fills from the canister will be routed to a pharmacist for manual verification to ensure ongoing quality assurance occurs for the life of the canister. Lastly, to ensure counts remain consistent and accurate, the first 5 fills from all canisters will be routed for manual count verification. This involves personnel counting the contents of a prescription vial and entering the count into NEXiA to verify the result matches the expected amount. This is a blind count and the personnel do not have visibility into the amount expected in the vial.

Background:

(Include related Federal or national standards/guideline and other state's rules, if applicable.)

- This form of pharmacist verification is used by central fill and mail order facilities who employ similar automation technologies. It is widely accepted as a safe and effective method to preserve patient safety and the accuracy of the medications they receive.
- iA's NEXiA software and SmartPod pharmacy automation is used by many large scale central fill and mail order facilities across the country. The alternative pharmacist verification technology is accepted by many states across the country including Idaho and Washington, which our facility will be supporting in addition to Oregon. Our estimate is that between 60-80% of all dispenses will leverage this technology. This is dependent on final formulary selection. No NIOSH hazardous drugs are run through the automation. Additionally, the central fill facility does not process any products that are associated with a REMS program and similarly do not fill any controlled substances.

Discussion:

To include:

1. **Which pharmacy staff will be impacted (pharmacists, technicians, and/or other staff)**
    a. Pharmacists and Technicians. See attached SOP and brief description below:
        i. Pharmacists will interact with this alternative verification process related to their responsibilities to verify the contents of filled canisters prior to those canisters being loaded into a SmartPod automated device. This verification will serve as the basis for final verification for any prescriptions that are subsequently filled using the canister they verify. The pharmacist who verifies the canister is responsible for all prescriptions fulfilled from that canister.
        ii. Technicians are responsible for filling the canisters and preparing them for the pharmacist to review. They will also be responsible for loading the SmartPod with the approved canisters following the pharmacist's verification.
2. **Outline the types of technology that will be utilized, if applicable.**
    a. NEXiA dispensing software, iA canisters, iA dispensers and SmartPod automation devices.

3. **Impact on other pharmacy practice settings; and**
    a. These processes would only be applicable to the central fill pharmacy and would not be leveraged in our local community pharmacies located in Oregon.
4. **Specific way(s) this will further public health and safety**
    a. This technology allows for a high volume and high throughput prescription fulfillment facility to be operationalized to support in-state local community pharmacies. By offloading prescription fulfillment for a percentage of prescriptions that are traditionally filled by hand in a pharmacy, the local pharmacy staff can focus on patient specific tasks that require their in-person attention. Specifically, this technology allows for a pharmacist to safely oversee the fulfillment process with minimal intervention to ensure the correct medication makes it into the correct vial and ultimately back to the local pharmacy for dispensing to the patient. We believe this technology leverages robust safety checks and balances to ensure the right medication makes it into the expected prescription vial and the ongoing quality assurance measures support those efforts to ensure everything behaves as expected.

Additional Information:

1. **Video/photo storage and retrieval information:**
    a. The video and still image photos taken as part of the pharmacist canister verification process will be stored for 90 days and retrievable upon demand. Following the 90 days, the still images will be archived and still retrievable. All task tracking data associated with the steps in the verification process will be stored on a server and retained consistent with state and company requirements.
2. **Is there a specific policy related to the QA processes?**
    a. There is not a specific QA policy related to this technology, but rather many processes built in to provide QA throughout the overall fulfillment process. These processes include the following:
        i. Canisters have physical and electronic security features to prevent tampering.
            1. Zip tie placed on the canister door following replenishment to lock the door shut and provide a visual confirmation of canister integrity.
            2. Specific NDC associated with each canister.
            3. Canister is calibrated for the characteristics of the medication contained within.
            4. The canister will physically lock on the docking station if a mismatch NDC barcode scan occurs. Pharmacist intervention is required to unlock and proceed.
            5. Canister can't be loaded into a SmartPod until it has been verified by a pharmacist.
                a. If it is attempted, the SmartPod will lock and require a pharmacist intervention to unlock and be put back into use.
            6. If a canister is opened at any time following the replenishment step and pharmacist verification, it will flag an exception and alert to notify staff it has been opened and there is a potential security violation that requires investigation.

ii. Still images taken during the canister replenishment process for pharmacist verification purposes and historical review if necessary.
iii. Still images taken during the individual prescription fulfillment for pharmacist verification purposes as part of the manual QA processes of a canister as well as for historical review if necessary.
iv. Barcode scanning during the replenishment process to add medication to a canister, load a canister on a shelf to wait for pharmacist verification, during pharmacist verification, loading a canister onto a replenishment cart, and when loading a canister into the SmartPod on its paired Dispenser.
    1. Any mismatch scans that occur will lock the process with an alert in the software, which requires a pharmacist to review the exception and enter their credentials to proceed with the process.
    2. All mismatch barcode scans are logged by NEXiA including the individual associated with the mismatch, time of the incorrect scan, expected NDC, scanned NDC, and timestamp. This allows for monitoring for trends that need to be addressed in the following manners including but not limited to policies and procedures, staff training, process design, and system design.
v. Intelligent dispensers that track the lot number used for each patient specific prescription.
vi. Routine quality assurance audits are performed during the lifetime of a canister in addition to the required pharmacist verification. These are intended to proactively monitor for any issues that may have arisen during the replenishment process and were not caught by the required pharmacist verification.
    1. Newly assigned NDC to Dispenser, newly inserted canister on a dispenser, and when the SmartPod or NEXiA system is restarted or loses power.
        a. 10 first fills and 5 last fills routed for manual pharmacist final verification.
        b. 2 of every 100 subsequent fills during the lifetime of a canister will be routed for pharmacist final verification.
vii. Dispenser counting audits to ensure accurate quantities are counted.
    1. First 5 fills dispensed from a newly assigned and calibrated canister will be routed for manual verification.
    2. The verification is blind and the personnel counting will enter the amount counted into NEXiA, which will validate if it matches the expected quantity in the vial.
viii. We are using a Patient Safety Organization which provides error management software to allow for the reporting and tracking of any errors discovered in the facility or by a receiving pharmacy for fills associated with the central fill facility.
    1. This allows for root cause analysis and action plans to be developed which will guide the process of identifying contributing factors and resolutions to prevent a similar error from occurring in the future.

3. **What, if any, errors have occurred that have been identified by a pharmacist? And, have any errors occurred that were not identified by a pharmacist, and actually left the facility?**
    a. This facility is currently using a pared down version of the iA system called “smart start.” During this phase of the project, the alternative pharmacist verification is not leveraged. In January, we will begin the high-volume phase of our central fill operations, which will leverage significant automation technology. Oregon pharmacies will be supported after this high-volume transition occurs. Considering we have yet to leverage this new technology, there have been no errors related to this technology.

Appendix:

SmartPod:

Canister:

Figure 16: Open Canister Hopper Door and Pour Product

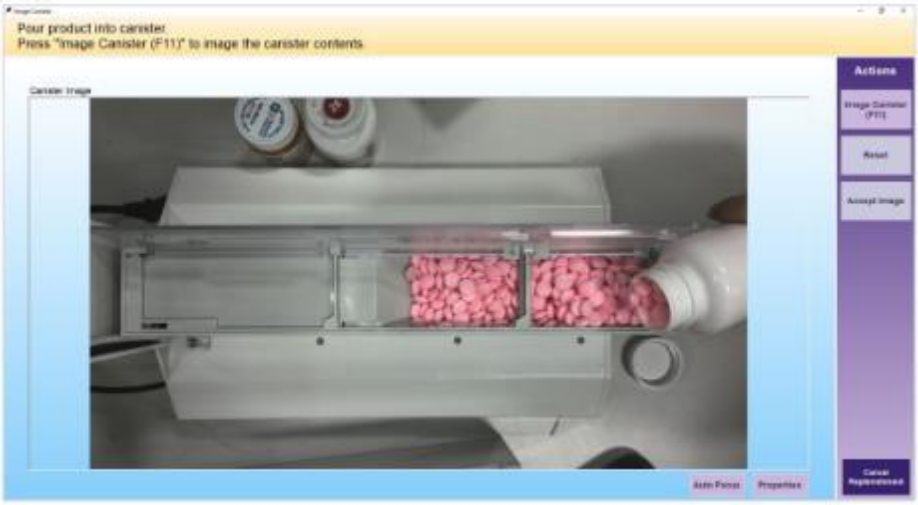


Figure 22: Image Canister Screen

Canister Fill Docking Station

Figure 3: Canister Docking Station

PURPOSE

This procedure outlines the Canister replenishment, Canister verification, and automated filling requirements for Albertsons Companies Central Fill pharmacists, technicians, and ancillary associates.

OVERVIEW

Select Albertsons Companies Central Fill ("CF") pharmacies will be utilizing fulfillment automation machines and technology to assist in the counting, labeling, and capping processes associated with filling prescription medications.

A critical part of the automation process is the utilization of medication-filled Canisters, which are affixed to the automated Dispensers within the SmartPod robotic machines. This SOP is intended to cover the various processes involved in replenishing drug stock within the Canisters, verifying the Canister contents to ensure all dispenses from the Canister are accurate, and other procedural safeguards that must be followed to ensure traceable and accurate use of the automated filling technology.

PROCESSES

A. Equipment Descriptions

1. **Canisters.** The Canister slides on top of a Dispenser, which allows for replenishing the SmartPod without interrupting the filling and counting processes. Pharmacists or technicians can add medication to the Canister through the Canister Replenishment process, described below. Canisters come in three sizes: a 4-liter, 2-liter, and 0.5-liter. Canisters are intelligent devices that have both physical and electronic security features. A Canister communicates electronically with the Dispenser it is mounted to, verifying NDCs, expiration dates, and security sensors before the product releases from the canister into the Dispenser.
2. **Dispensers**. The Dispensers (aka "SmartDispenser") always stay inside the SmartPod and is where the medication counting takes place. Dispensers can hold approx. 800 cc of medication in the hopper, which is where the Canisters attach and drop medication into the Dispenser. Dispensers are Canister compatible; they include a top rail that the canisters slide into and attach to when replenishing the Dispenser. Canisters remain attached to the Dispensers until they are completely empty at which time they are replaced with another Canister of the same size.
3. **SmartPod**. This automatically fills a prescription by labeling the empty bottle, filling the medication from a Dispenser, takes a picture of the contents of the filled bottle, and puts a cap on the bottle. Inside the SmartPod are cabinets with rows of Dispensers that have Canisters attached.

B. Canister and Dispenser Assignment to Specific NDCs

1. **Assigning an NDC to an available Dispenser.**
   - Scan the NDC on the manufacturer stock bottle against the barcode on the desired Dispenser within the SmartPod.
   - If the Dispenser is already assigned to another NDC, an "Assignment Warning" will display prompting users to take necessary steps to ensure elimination of any potential residual product prior to reassignment to a new NDC.
   - Every time an NDC is assigned to a Dispenser, the Dispenser must be calibrated to the specific NDC. This ensures the Dispenser appropriately counts the tablets/capsules based upon the size/characteristics of the medication.
2. **Assigning an NDC to an available Canister**.
   - At the Canister Docking Station, scan the Canister Serial Number barcode with the NDC QR code on the manufacturer stock bottle.

C. Canister Replenishment

The replenishment of Canisters occurs away from the production system in a designated area of the pharmacy

(e.g., at the Canister Replenishment Station) by pharmacists or technicians dedicated to that process. To replenish a Canister, follow these steps:

1. **Click on the Replenish Icon in the NEXiA Replenish Module and login using user credentials.**
   - Before performing any tasks, confirm with visual indicator that you are logged into the station.
2. **Select Canister for replenishment.**
   - In the "Replenish Canisters" window, a list of Canisters assigned to the workstation that need replenishment is displayed. Always select the **highest priority canister**.
3. **Retrieve Canister & slide into docking station.**
   - Use Canister display screen to select next Canister fill.
   - Firmly slide Canister into place on docking station in the Canister Replenishment Station.
   - NEXiA reads the Canister serial number, determines the assigned product based upon NDC, confirms the Canister is empty and checks for cross contamination issues.
4. **Retrieve & scan all stock bottle(s).**
   - Based on displayed Canister information, retrieve the corresponding drug product.
     - **NOTE**: Only **ONE** Drug/NDC may be at a Canister Replenishment Station at any time. It is critical that each Drug/NDC be returned to the appropriate shelf before starting another Canister Replenishment task with a clear workstation. Ensuring only one NDC is at a workstation reduces the risk of the wrong drug product being introduced into the Canister.
   - Before opening the bottle, scan the QR code available on stock bottle. The software verifies the scanned bottle matches the required product to ensure correct medication in the correct Canister.
   - If multiple bottles will be used to refill the Canister, **EVERY** stock bottle to be used in replenishing the Canister **MUST** be scanned. The minimum time required between scans will be configured, and if the scanning individual performs two scans too close to each other, then he/she will be alerted to rescan.
     - **NOTE**: If an incorrect stock bottle is scanned, then a warning beep will sound, and a Product Mismatch screen will be displayed indicating that the NDC does not match the Canister assignment. The individual MUST stop all activity, including pouring or opening other stock bottles, and the docking station will LOCK. This requires a pharmacist to enter their credentials to override the warning. The replenishment can be completed only after the correct product is scanned. A report that lists the individual logged-in at the time of the incorrect scan, expected NDC and scanned NDC with a timestamp and other information will be tracked through NEXiA.
   - If no QR is code available on a stock bottle, scan the linear barcode and manually enter lot code and expiration date individually for each stock bottle, press apply.
5. **Open and sort stock product in tray/bin.**
   - Remove desiccants, broken pills, and any residual powder which can damage Canisters/Dispensers.
   - DO NOT directly pour stock bottle contents into a canister.
6. **Confirm quantity and select "OK".**
   - Adjust quantity as needed and list appropriate reason.
   - Bypass quantity adjustment as needed and as overseen by a pharmacist.
7. **Open Canister door and fill Canister.**
   - Pour stock product into the Canister directly from the bin/tray.
   - Clear all pills from joints and Canister ledges.
   - For Canisters being replenished, the zip tie should still be intact and will need to be cut prior to being able to open the Canister door. If the zip tie is not intact at this step, follow the steps to quarantine the Canister, and alert the pharmacist for Canister auditing and tracking.
8. **Take image of product in Canister.**
   - Clear image area of any peripherals.
   - Take the image.
   - Confirm image is clear and focused for Canister Verification and patient safety.
9. **Close and seal Canister door.**
   - Tighten zip tie firmly – this should remain intact until the Canister is opened at the subsequent

replenishment.

10. **Move Canister to available Pickup Canister shelf location.**
    - Remove the Canister from the docking station and scan the Canister to a Pickup Canisters shelf slot location for pickup by the Dispenser replenishment team.
11. **Clean Tray/Bin/EyeCon to prepare for the next Canister.**
12. Ensure that there are no loose pills or debris in the tray. **Put away all unused stock.**
    - At no time should there be more than one NDC at the canister filling station.

D. <u>Canister Inherited Verification</u>

- Where permitted by state Boards of Pharmacy, Canister Inherited Verification allows all Rxs that are filled from a Dispenser to be given a Verified status and directed to the packing work center or SmartCollator.
- The operational efficiency resulting from Canister Inherited Verification is that a separate product verification (PV) by pharmacists is not required for prescriptions that are filled from a Verified Canister. Canister Inherited Verification constitutes PV for all scripts filled from that Canister. All prescriptions filled from a Verified Canister are the responsibility of the pharmacist that performed the Canister verification process.

<u>Process</u>: At the Digital Verification Station, a pharmacist performs a digital product verification of each Canister.

1. **Click Verify Icon.**
    - Icon is in the bottom left corner of the NEXiA home screen.
    - Pharmacist must log in and perform this action, first and last name is displayed on top left of screen.
2. **Click Verify Next Canister.**
    - Button will be in the top right corner, in the Actions tool bar. This will bring up the next Canister to verify, in the order they were filled.
3. **Verify Rx Information.**
    - Review the images and information on screen to verify the necessary information required to verify the Canister.
    - Every Canister must be verified visually by a pharmacist to ensure that the correct drug product is dispensed from the Canister.

➢ **IF Verification is a Pass**

4. **Click Pass**
    - Button will be in the top right corner, in the Actions toolbar.
    - When the Canister has been verified as accurate, click the Pass button, which releases to the Canister Pick Up queue.
    - All Canisters must be verified through this workflow to be loaded into the SmartPod.
5. **Return to Step 3**
    - NEXiA will automatically move to the next Canister until the verification queue is cleared.

➢ **IF Verification is a Fail**

4. **Click Problem**
    - Only send to problem queue if Canister cannot be verified.
    - Do not Pass if the required information is not visible or the drug is not correct.
5. **Select Problem Reason.**
    - Choose the appropriate reason for why this Canister cannot be passed.
    - Adds it to the offline queue, which tracks failed vials and Canisters, and designates Canister for inclusion on quarantine shelves so it can be corrected or re-replenished.
6. **Click Ok**
    - Button is in the top right corner of the Actions toolbar.

- Confirms there is a problem with this Canister and sends canister to the offline status, where it is quarantined as "Failed" to the Quarantine Shelf for processing by a pharmacist.

7. **Return to Step 3**
   - NEXiA will automatically move to next Canister until verification queue is cleared.
     - **NOTE:** Canisters, as well as single prescription bottles, may be routed from Pharmacist Verification to correct and verify.
     - **NOTE:** Failed Canisters must be zip tied and quarantined on the Quarantine Shelf for correction by a pharmacist within 2 days.

Verification of a Corrected Canister by Pharmacists

This step is required when a Canister previously failed verification but was subsequently corrected either by a pharmacist or a technician, depending on the nature of the failure.

1. **Select Verify Rx icon.**
   - Click the Verify Rx icon on NEXiA home screen.
2. **Scan Canister barcode**
   - Populates information for the scanned Canister.
   - Provides status and state of the scanned Canister, identifying the reason this Canister is an exception.
3. **Review Canister Information**
   - Review the images and information on screen to verify the necessary information required to pass the Rx.
   - Every canister must be **verified manually** (e.g., not via digital image) by a pharmacist, ensuring correct drug was dispensed and Canister complies with patient safety and regulatory requirements.
4. **Click Pass**
   - Button will be in the top right corner, in the Actions toolbar.
   - When the canister has been verified as accurate, click the Pass button.
   - Completes the verification process and releases to the pickup canister queue.
   - All canisters must be verified through this workflow to be loaded into the SmartPod.
5. **Select "Move Canister"**
   - Option will be in the Canister's dropdown at the top of the screen -- only option to assign the Canister a new location.
6. **Scan Canister barcode**
   - Barcode is on the front of the Canister
   - Use the hand scanner
   - The only barcode to scan to move forward in the process.
   - You will be walking the Canister to a new location on the pickup wall.
7. **Scan Canister Pick Up Location**
   - Any empty location on the canister pickup wall.
   - Set canister, then scan the location.
   - Empty locations are the only location available to assign canisters to.
   - Best practice to ensure correct canisters are in the correct location.

E. Canister Transport to and from Dispensers

1. **Canister pickup of Verified Canisters for attaching on Dispenser.**
   - A Canister Replenishment Cart with a Tablet Personal Computer running NEXiA software and a scanner are required for Canister transport to and from Dispensers. The "Pickup Canisters" window directs the transporting individual to the location of filled and Verified Canisters in the pickup shelf. Only Verified Canisters are displayed in the 'Pickup' list. If a filled, but not-yet-verified Canister is scanned at the Pickup module, then it will not be allowed to be 'Picked up.'
   - Scan the Replenishment Cart barcode. The Pickup Canisters window displays details for the replenished canisters and the priority. The highest priority canisters should be transported first.
   - Determine the position of the Canister, pick it from the outgoing window, scan the Canister barcode and slide the Canister onto the Replenishment Cart. At this point, the Canister is

registered to the Dispenser in one of the SmartPods on the production floor.

- Repeat these steps until the Replenishment Cart is loaded. Once loaded, the Replenishment Cart is taken to the floor to start replenishing the SmartPod's Dispensers.
  - **NOTE**: All Canisters, Replenishment Carts, and stock must be transported within the identified route (taped line on the floor) to the SmartPods and all prescription filling stations to ensure video tracking of the drug stock. At no time should Canisters, Replenishment Carts, or filled Dispensers leave the production floor.

2. Canister attachment onto Dispenser.

- Identify SmartPod where the Dispenser for the specific Canister is located.
- Select the "Attach Canister to SmartDispenser" drop down menu, which will display the "Attach Canisters" window. Again, the list displayed is by priority. The Canister on the Replenishment Cart is scanned and the "Attach Canister to SmartDispenser" window will provide information on location and the next step.
  - **NOTE**: Zip ties must remain intact during the Canister attachment process until the Canister is removed and transported back to the Replenishment Station. A warning with "this Canister has a security violation" will display if the zip tie is cut and the Canister door is opened. Opened Canisters are marked as opened in NEXiA.
- A green light on the Dispenser illuminates, identifying the Dispenser as replenished. Once the Canister is slid into the Dispenser, a message stating "Locking the Canister onto the SmartDispenser" is displayed indicating the Canister is attached.
  - **NOTE**: Canisters attached to a Dispenser do not release product into the Dispenser until the Dispenser is empty. If a Dispenser runs dry during a count and then a new Canister releases product, then the Rx will be associated to lot codes from both Canisters. The shortest expiration date will be associated with the Rx when multiple Canisters are used to fill the Rx.
  - **NOTE**: Unverified Canisters and Mismatched Canister-Dispensers will alert the user and the Canister door will not open in the Dispenser. The SmartPod Tablet will alert the user, and the Dispenser light will turn RED.

3. Empty/depleted Canister retrieval.

- Select the "Retrieve Canister from SmartDispenser" from the drop-down menu, which will display a request to scan the barcode on a Replenishment Cart.
- Scan the Replenishment Cart location and NEXiA will display the list of Canisters to retrieve in order of priority (e.g., low, medium, and high) on the "Retrieve Canisters" screen.
- Locate and scan a Canister to collect. NEXiA will unlock the Canister from the Dispenser. Remove the Canister and place it on the Replenishment Cart.
- Return to the Cart Load/Unload Station, remove the zip tie on the Canister, and place the Canister in an empty return location. The replenishment staff will retrieve the Canister from the empty Canister return area, scan it, and NEXiA will direct appropriate storage of the empty Canister in a location relative to the priority.
- At the end of the day, the Replenishment Cart is parked at the cart charging area to replenish its battery. Before moving the Replenishment Cart , take care to unplug it from the wall. Not doing so will result in damage to the cord/cart.

4. Transporting empty Canisters back to Canister Replenishment Stations

- The Fulfillment Specialist moves the canister to the Replenishment workstation window.
- The Fulfillment Specialist scans the canister.
- The Fulfillment Specialist scans the replenishment station location.
- The Fulfillment Specialist physically places the canister at the replenishment station location.

F. <u>Automated Filling by Smart Pods</u>

Bottles and caps are fed to the SmartPod using pneumatic delivery technology. The SmartPods contain autonomous, intelligent counting Dispensers. Rxs are assigned to any available Dispenser that contains the required NDC. The automated filling process in the SmartPods occur as asynchronous operations. Each Dispenser within a SmartPod counts the medication into its own secure buffer area. When the

Dispenser completes the counting operation, the prescription is queued for retrieval by the robotic arm. The system selects an appropriately sized vial and releases the vial from the queue into the print apply system. The empty vial is labeled, and its barcode is scanned to avoid the possibility of a mismatch. The label is scanned to ensure that the NDC on the label matches the Canister-Dispenser, and the vial is picked up by the robotic arm. The robotic arm moves to the appropriate Dispenser and retrieves the counted medication from the Dispenser secure buffer area. The Dispenser secures the buffer door. The robotic arm moves the vial directly to the capping unit and releases the vial. A picture of the vial contents is taken. The capping unit applies a cap and then discharges the vial onto the output conveyor.

G. <u>Routine Audits and Quality Assurance</u>

1. Product Verification
   - Newly Assigned NDC to Dispenser: 10 First Fills and 5 Last Fills from newly assigned Dispenser to be routed automatically to the PV Station for Virtual Verification, including the Pharmacist Corrected Canisters.
   - Newly inserted Canister on Dispenser: 10 First fills and 5 Last Fills from newly inserted Canisters to be routed automatically to the PV Station for Virtual Verification.
   - When SmartPod or NEXiA system is restarted or loses power: 10 First Fills and 5 Last Fills from impacted SmartPod/Dispenser to be routed automatically to PV Station for Virtual Verification.
   - 2 Fills out of every 100 Canister Fills are to be routed automatically to the Exceptions Pharmacist Station for Manual PV.
2. Counting Accuracy
   - Dispenser Count Audits must be performed for all newly assigned NDCs to a Dispenser and at least quarterly to verify counting accuracy of 5 first fills.
   - Process for Count Audit: at the Exceptions stations, a second manual count of a filled Rx at the Verification step, by auto-routing the script to a Manual Fill station for a blind count, which must match the Quantity to continue through the workflow.
     - Before Verification, the system displays the Count Audit screen with the Rx number, product image, patient name, drug name, and NDC. Rx quantity is not shown.
     - The Technician counts the number of pills in the filled Rx and enters the value on the screen.
     - The Technician counts the number of pill fragments in the filled Rx and enters the value on the screen.
     - If the entered quantity matches the ordered quantity, the audit is logged, and the Rx can continue through the workflow.
     - If the entered quantity does not match, the Technician is informed of the mismatch and asked if the entered value is correct.
     - If the Technician chooses No, the bottle is routed to the Pharmacist Exceptions Station, where it will then be routed as a Return to Stock bottle.
     - If the Technician chooses Yes, the count audit is logged, and the Rx can continue through the workflow.

H. <u>Return to Stock processing by Pharmacists.</u>

Only a pharmacist can return an Rx to stock when required.

- The pharmacist will begin the RTS process from the Fill Rxs Screen
- Select **Return to Stock** from the Fill Rxs Screen
- Scan the prescription barcode
- Confirm the product image, the lot code, expiration date and confirm the quantity returned
- Scan the stock location in the manual fill section, which should match the location noted on the screen
- Affix the Return to Stock label to the verified bottle (Dispenser RESETs will already have printed the label at RDS)
- Scan the barcode from the printed RTS Stock label
- Return the bottle to the appropriate shelf location at RDS
  - This step may be performed by the Inventory Specialist

- This RTS will be used for Canister replenishment.

When product is dispensed into a bottle as a Dispenser reset, but has not been labeled with patient information, a prescription has not been associated. The lot and expiration date are traceable and can be returned to the Canister during subsequent replenishment tasks.

- The RTS may be used for future manual filled prescriptions
- The RTS may be used for Canister replenishment

VERSION HISTORY

Version	Date	Updates	Reviewed By
1.0	11.28.23	n/a	HY, LIJ, LC, RG, ST

1. In B.1. is the 'user' a pharmacist?

The user in this workflow step is a technician.

- If the Dispenser is already assigned to another NDC, an "Assignment Warning" will display prompting users to take necessary steps to ensure elimination of any potential residual product prior to reassignment to a new NDC.

2. In B.6. I am unclear on what 'bypass' and 'overseen' means. Can you share how the pharmacist is supervising, directing, and controlling technicians here and the auditing process?

"bypass":
The Quantity field is auto-populated for the correct amount based on the number of stock bottles scanned.
The 2 bullet points are the 2 options a technician has at this point. They either adjust the quantity because a partial stock bottle was used or "bypass" this field if it is correct and as expected quantity is displayed.

"overseen":
The Canister Station pharmacists sits in a PV station which is adjacent to the Replenishment Area where a technician works to refill canisters. The pharmacist provide supervision similar to that of a standard retail pharmacy during a pill counting process by the technicians. The pharmacist is immediately available for any questions or concerns raised by a technician during workflow. They are also able to physically supervise and identify any concerns that need to be addressed based on their proximity to the technicians they are supervising.

6. **Confirm quantity and select "OK".**
   - Adjust quantity as needed and list appropriate reason.
   - Bypass quantity adjustment as needed and as overseen by a pharmacist.

Station for Manual PV.

2. Counting Accuracy
   - Dispenser Count Audits must be performed for all newly assigned NDCs to a Dispenser and at least quarterly to verify counting accuracy of 5 first fills.
   - Process for Count Audit: at the Exceptions stations, a second manual count of a filled Rx at the Verification step, by auto-routing the script to a Manual Fill station for a blind count, which must match the Quantity to continue through the workflow.
     - Before Verification, the system displays the Count Audit screen with the Rx number, product image, patient name, drug name, and NDC. Rx quantity is not shown.
     - The Technician counts the number of pills in the filled Rx and enters the value on the screen.
     - The Technician counts the number of pill fragments in the filled Rx and enters the value on the screen.
     - If the entered quantity matches the ordered quantity, the audit is logged, and the Rx can continue through the workflow.
     - If the entered quantity does not match, the Technician is informed of the mismatch and asked if the entered value is correct.
     - If the Technician chooses No, the bottle is routed to the Pharmacist Exceptions Station, where it will then be routed as a Return to Stock bottle.
     - If the Technician chooses Yes, the count audit is logged, and the Rx can continue through the workflow.

3. Can you clarify what 'necessary information' is? Does that include verifying canister is sealed, seal number (if there is a number on seal), each stock container, expiration date on each stock container, how much of 800cc container is viewable to RPH, etc? Does RPH verification correspond to a barcode/something on cannister to identify what has been verified and what has not been verified?

Necessary information includes:
Canister contents via top-down image, expected NDC with image of medication, number of stock bottles scanned, quantity added to the cannister, technician who replenished the canister. The zip tie is not a serialized tie and serves the purpose of physically locking the door. If the door of the canister is opened outside of the replenishment step, it will lock down the canister and a pharmacist exception review is initiated. The zip tie keeps the door shut so it doesn't open while being transported to and from the automation.

The canister verification is tracked electronically. The cannister can't be scanned and loaded onto a replenishment cart until a pharmacist has performed their verification of the canister. A canister remains electronically locked and is not authorized to be put into production until the pharmacist verification has been completed.

3. **Verify Rx Information.**
   - Review the images and information on screen to verify the necessary information required to verify the Canister.
   - Every Canister must be verified visually by a pharmacist to ensure that the correct drug product is dispensed from the Canister.

4. Are cannisters clear or opaque – If opaque how does RPH verify, if clear do they not use for light sensitive drugs?

They are Opaque except for a window on the top.

The Canisters are verified using a top-down image. The contents of the canisters are controlled by the scanning of each stock bottle before pouring. If an incorrect stock bottle is scanned during replenishment, the workstation will lock and require the Canister Station pharmacist to physically walk over and review and resolve the issue. The Canister Station pharmacist has direct view of the workstations where only one canister and its expected medication is handled at a time based on our

SOP. The filled Canister are place on shelving, where it is shielded by direct overhead lighting, until they are placed in the automation PODs, at which time, it is also shielded from direct light.

5. If more than one cannister is used, who is the responsible pharmacist if there is an error?

I am just waiting for a confirmation from the software vendor IA and will provide a response on this question as soon as possible.

- **NOTE:** Canisters attached to a Dispenser do not release product into the Dispenser until the Dispenser is empty. If a Dispenser runs dry during a count and then a new Canister releases product, then the Rx will be associated to lot codes from both Canisters. The shortest expiration date will be associated with the Rx when multiple Canisters are used to fill the Rx.

6. What is Virtual Verification as stated below?

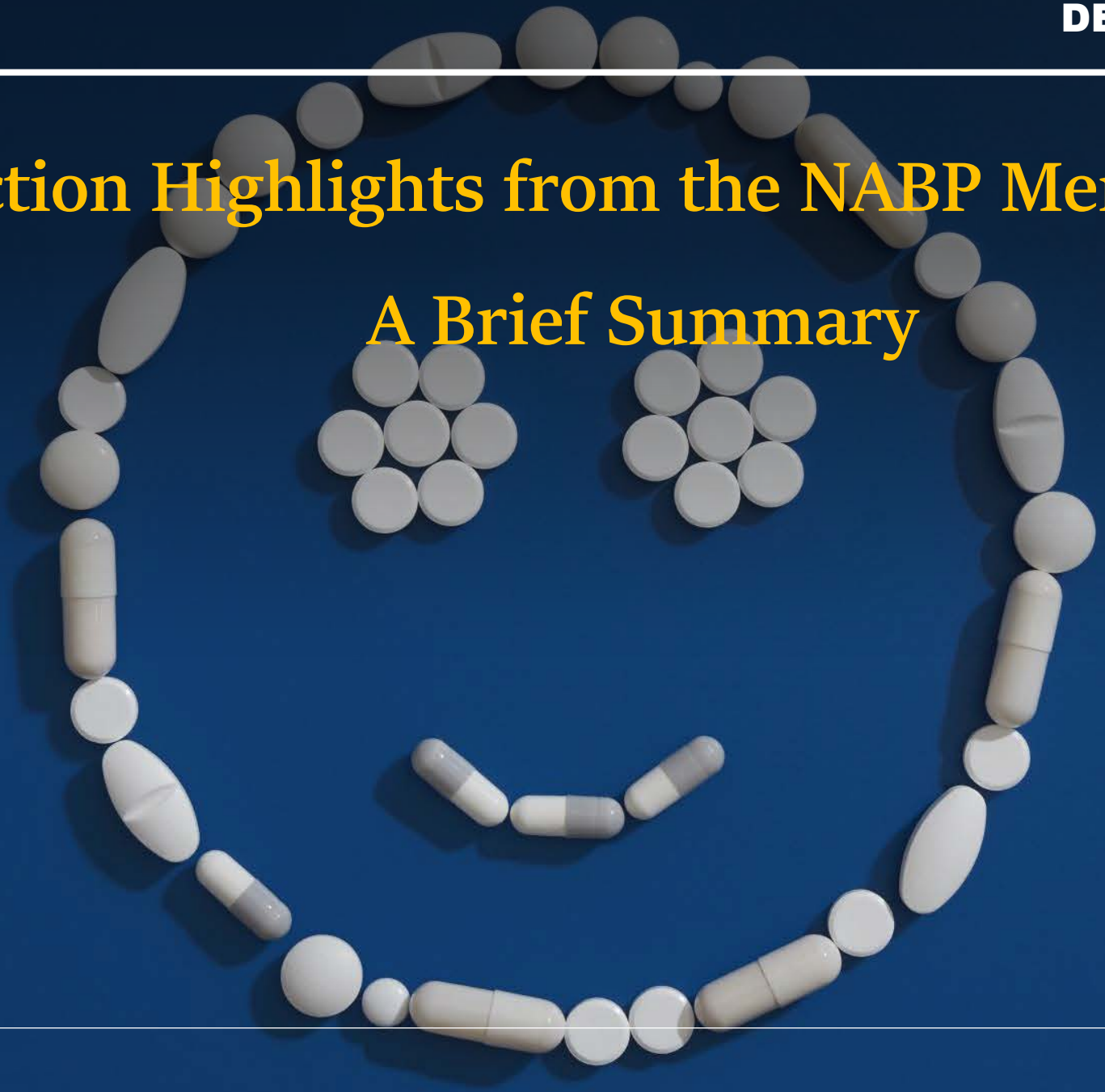
Virtual verification is using images that were taken by the automation to verify the label was applied appropriately and the correct medication was placed in the prescription vial. The pharmacist has the ability to find the actual vial and do a physical manual verification if necessary.

G. **Routine Audits and Quality Assurance**

1. Product Verification
   - Newly Assigned NDC to Dispenser: 10 First Fills and 5 Last Fills from newly assigned Dispenser to be routed automatically to the PV Station for Virtual Verification, including the Pharmacist Corrected Canisters.

Recollection Highlights from the NABP Member Forum:

A Brief Summary



Board Member Patel

NABP

Member Forum

Networking to Drive Pharmacist Well-Being, Patient Safety

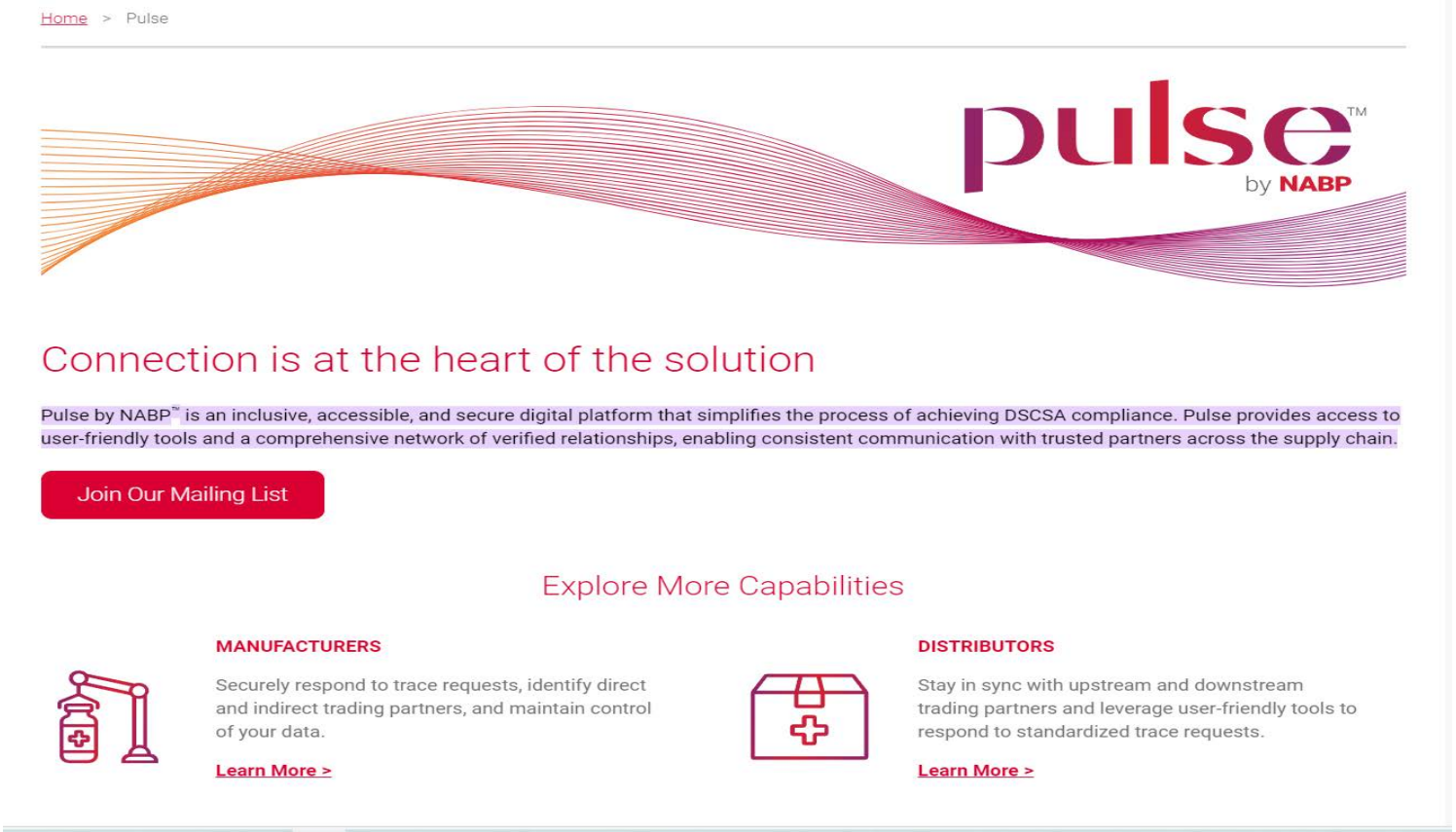
- NABP Verify and the Boards of Pharmacy
- All About Shared Services, Automated Pharmacy Systems, Remote Dispensing Sites, and Telepharmacy
- Drug Shortages, Compounding, & USP Revisions
    - USP <795> Updates
- AI Applications – How Can Pharmacy Regulators Ensure Patient Safety, Pharmacist Well-being?

NABP

Member Forum

Networking to Drive Pharmacist Well-Being, Patient Safety

- Driving Supply Chain Security Under DSCSA With Pulse by NABP



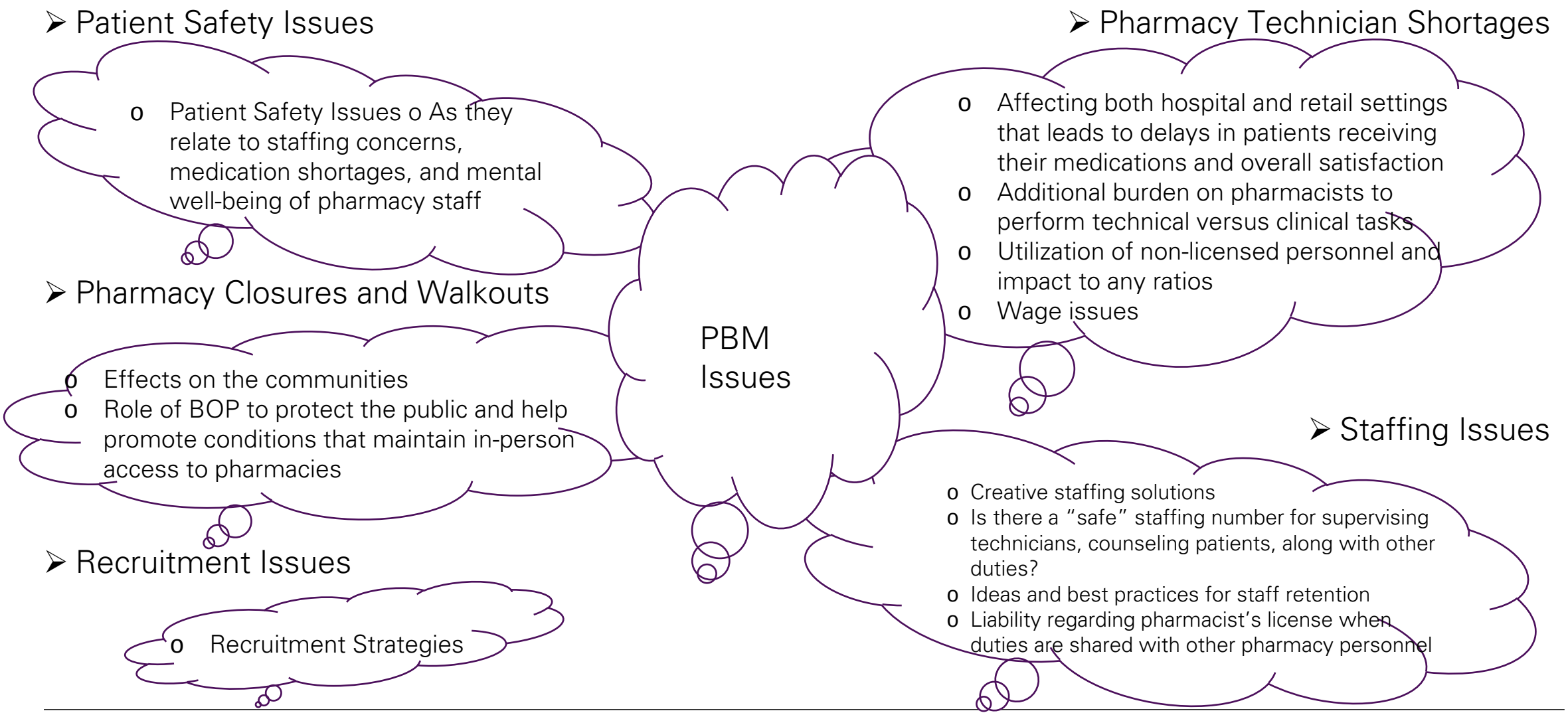
NABP

Member Forum

Networking to Drive Pharmacist Well-Being, Patient Safety

- Emerging Topics
  - MPJE Issues :
  - NAPLEX Testing Options
  - Marijuana (Medicinal and Recreational) and Psychedelic Mushroom Regulation

Pharmacy Working Conditions and Pharmacy Personnel Well-Being



- PBM Issues :

  - In the past, it was more of a business decision but has become a factor regarding access to care.
  - What can/are boards of pharmacy doing regarding PBM regulation? o Impact on retail, community, and specialty infusion pharmacies

- Reducing Regulatory Barriers and Administrative Burdens

  - Evaluating and reevaluating pharmacy regulations with the lens that existing regulations are necessary
  - Each regulation would need to be justified based on current needs, efficiency, and impact with the aim of creating a more streamlined and efficient regulatory framework

Tennessee State Board Of Pharmacy

Georgia State Board Of Pharmacy

Minnesota Updates Rules on Cannabinoids, Medication Repositories, and PBMs

Minnesota Governor Tim Walz recently signed legislation that has several provisions that will affect licensees and registrants of the Minnesota Board of Pharmacy. The changes address labeling of products that contain cannabinoids extracted from hemp, medication repositories, and PBM gag clauses.

New Arizona Legislation Impacts Several Areas of Pharmacy Practice

Several bills were recently signed into law by Arizona Governor Doug Ducey that address controlled substances, pharmacy benefit managers (PBMs), donated medicine, remote dispensing pharmacies, and more. Some specific highlights include House Bill 2787 – Occupational Regulation; Good Character; Definition, which defines moral turpitude and allows an individual to petition the Board to evaluate their documents prior to submitting an application. In addition, Senate Bill 1087 – Pharmacy Board; Regulation was signed, which allows for a remote hospital pharmacy, defines durable medical equipment (DME), allows for a DME distributor permit to be issued, clarifies third-party logistics provider, allows the Board to issue nondisciplinary civil penalty, and eliminates the requirement of a wall certificate for technician trainees.

For more details on all the legislative bills signed by Ducey, visit the Arizona State Legislature website at *https://apps.azleg.gov/BillStatus/BillOverview*. More information can also be found in the Arizona State Board of Pharmacy's July 2021 *Newsletter*.

Louisiana Regulatory Projects Address PBMs, CDS Licenses, Marijuana Products, and More

The Louisiana Board of Pharmacy has initiated several regulatory projects that are currently in various stages of the promulgation process, including:

- Project 2020-4 – Pharmacy Benefit Managers (PBMs), which requires a PBM engaged in certain activities construed to be within the scope of the practice of pharmacy to obtain and maintain a PBM permit from the Board;
- Project 2020-10 – CDS License for Hemp Facility, which establishes a hemp facility as an entity authorized to obtain a controlled dangerous substances (CDS) license;
- Project 2020-11 – Labeling and Delivery of Marijuana Products, which simplifies the labeling requirement imposed on producers of marijuana products, and authorizes marijuana pharmacies to deliver dispensed marijuana products to patients; and
- Project 2021-2 – Transfer of Marijuana Recommendations, which requires a marijuana pharmacy to transfer an

➢ Infusion Clinics :

- Do any boards have oversight responsibilities and if so , how ?
- Do other governmental agencies have oversight responsibilities ?
- Are any boards considering promulgating regulations and if so, where are you at in the process and can you share the specifics ?

NABP, FSMB, NCSBN Join Federal Agencies in Educating Regulators and Practitioners on Risks of IV Hydration Clinics

August 16, 2023
Categories: Industry News and Topics

IV hydration clinics allow consumers to select an IV infusion from a menu of various vitamins and supplements advertised for various uses and are purported to boost immunity, promote recovery, and remediate hangovers or fatigue. However, consumer caution is advised, as FDA has received reports of adverse events at medical offices, clinics, and other business models, such as IV hydration clinics, medical spas, and mobile IV infusion services.

FDA issued a compounding risk alert in October 2021 to caution health care providers about drug products being prepared under insanitary conditions at IV hydration clinics. The alert warns that businesses are compounding drugs that may not meet the conditions of the Federal Food, Drug, and Cosmetic Act or comply with state regulations.

As FSMB, NABP, and NCSBN have continued to see concerning activity in this area, the three organizations worked with FDA and FTC to develop this webinar as a means to inform regulators and practitioners on how to protect and educate patients. Following are the key points presented and discussed at the webinar:

- Regulators from the state boards of nursing, medicine, and pharmacy need to work together to ensure that businesses that offer IV hydration products are being inspected by the appropriate agency.
- Basic knowledge of FTC regulations as they relate to claims made by IV hydration product providers can be helpful for regulators and practitioners.
- Educating patients about these products, the claims being made, and the fact that such products need to be prescribed and administered by a licensed health care professional is important to the health and safety of patients.

The three organizations will continue to work with federal agencies and keep their members informed of what is happening in this space. Regulators and practitioners are encouraged to familiarize themselves with this issue so that they can do their part to protect patients. Slides and resources from the webinar can be viewed here.

- Removing Barriers to Practice at the Top of Training/Experience
  - While already able to practice at the top of their license, can boards be nimbler with rules to allow or encourage pharmacists to practice at the level of their training?
- Standard Of Care
  - Creating regulations that rely on "standards of care" versus rule-based prescriptive regulations
- OUD Stigma; Buprenorphine Stocking & Dispensing
- Substance Use Disorders
  - Use of collaborative practice to prescribe medications
  - The Idaho State Board of Pharmacy works in conjunction with the DEA to enable pharmacists to obtain a DEA license for prescribing Suboxone, Buprenorphine….