Oregon Board of Pharmacy
* 2nd REVISED BOARD MEETING AGENDA
October 11-13, 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: 734 116 245#**
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, October 11, 2023 @ 8:30AM
Thursday, October 12, 2023 @ 8:30AM
Friday, October 13, 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 10/13/2023**

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, OCTOBER 11, 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*

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. Legal Advice
b. Deliberation on Disciplinary Cases and Investigations
c. 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
*** 2nd REVISED BOARD MEETING AGENDA**
October 11-13, 2023

THURSDAY, OCTOBER 12, 2023

I. OPEN SESSION, Ian Doyle RPh, Presiding
****Please note that the board will meet in Executive Session immediately after roll call and will resume Open Session at 10:00AM.**

a. Roll Call

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. Legal Advice
b. Deliberation on Disciplinary Cases and Investigations
c. 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

d. New Board Member Introduction – *Schnabel/Doyle*
e. Rules
   i. Review Rulemaking Hearing Report & Comments – *Melvin* **#A** *Action Necessary*
   ii. Consider Adoption of Temporary Rules – None
   iii. Consider Adoption of Rules **–** *Melvin*
      1. **Div 007** – Compliance with OHA COVID-19 rules **#B** *Action Necessary*
      3. **Div 019/041/043/044/139** – Short-acting Opioid Antagonist **#B1** *Action Necessary*
      4. **Div 045** – USP <795> and USP <797> **#B2** *Action Necessary*
      5. **Div 115** – Short-acting Opioid Antagonist **#B3** *Action Necessary*
      6. **Div 115/125** – RPH Applicability, Definitions, Counseling; COPT/PT Prohibited Practices **#B4** *Action Necessary*
   iv. Rules in Development - *Davis*
   v. Rulemaking Policy Discussion Items – *Davis*
      1. **Div 041/043/183** – Drug Compounding **#C** *Action Necessary*
      2. **Div 019/025/041/139 –** Vaccinations (2023 HB 2486 & 2023 HB 2278) **#C1** *Action Necessary*
      3. **Div 115/125** – Vaccinations (2023 HB 2486 & 2023 HB 2278) **#C2** *Action Necessary*
      4. **Div 115** – CPA/CDTM **#C3** *Action Necessary*
      5. **Div 041** – RP/IP Alignment **#C4** *Action Necessary*
      6. **Div 080** – Pharmacist Changes to a Schedule II Prescription **#C5** *Action Necessary*
      7. **Div 115** – Pharmacists – PIC Qualifications & Limitations **#C6** *Action Necessary*
      8. **Div 115** – Pharmacists – Supervision **#C7** *Action Necessary*
      9. **Div 125** – Pharmacy Technicians – Prohibited Practices **#C8** *Action Necessary*
      10. **Div 115** – Pharmacists – Applicability **#C9** *Action Necessary*
      11. **Div 020** – Pharmacists – Prescriptive Authority: Protocol Compendium - Vaccinations **#C10** *Action Necessary*

a. Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway **#C10a**
b. Standard Protocol for All Vaccines: Managing Adverse Reactions **#C10b**
c. Cholera **#C10c**
d. Coronavirus 19 **#C10d**
e. Haemophilus influenzae type b **#C10e**
f. Hepatitis A **#C10f**
g. Hepatitis B **#C10g**
h. Human Papillomavirus **#C10h**
i. Influenza (IIV RIV 2023-24) **#C10i**
j. Influenza (LAIV 2023-24) **#C10j**
k. Japanese Encephalitis **#C10k**
l. Measles, Mumps & Rubella **#C10l**
m. Meningococcal **#C10m**
n. Pneumococcal **#C10n**
o. Polio **#C10o**
p. Rabies **#C10p**
q. Respiratory Syncytial Virus (RSV) **#C10q**
r. Tetanus, Diphtheria (Td/Tdap) **#C10r**
s. Typhoid **#C10s**
t. Varicella **#C10t**
u. Yellow Fever **#C10u**
v. Zoster **#C10v**

12. **Div 115** – Pharmacists – Services: Prescribing – Protocol Compendium-Vaccinations Temporary Rule, eff. 3/1/2024 **#C11**- (*see **#C10c-C10v** above for remaining protocols)
    a. Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway **#C11a**
    b. Standard Protocol for All Vaccines: Managing Adverse Reactions **#C11b**
    c. Coronavirus 19 **#C11d**

13. **Div 006** – Definitions **#C12** *Action Necessary*

Adjourn *Action Necessary*

Oregon Board of Pharmacy
*** 2nd REVISED BOARD MEETING AGENDA**
October 11-13, 2023

FRIDAY, OCTOBER 13, 2023

I. OPEN SESSION, Ian Doyle RPh, Presiding

a. Roll Call

II. MOTIONS RELATED TO DISCIPLINARY ACTIONS – *Efremoff* *Action Necessary*

**At this time the board will vote on cases, including proposed disciplinary actions against licensees/registrants.*

III. GENERAL ADMINISTRATION

b. Rules Policy Discussion Continued

c. Discussion Items

i. Waiver Requests

1. SBAR - FPGEC Certification – *Hennigan* **#D2** *Action Necessary*
2. SBAR - Intern Renewal – *Hennigan* **#D3** *Action Necessary*

ii. Buprenorphine Access Position Statement - *Schnabel* **#E** Action Necessary

iii. Petition Request (OAR 137-001-0070) – *Schnabel* **#F**

iv. Board Action Report – *Efremoff* **#G**

v. Strategic Plan Update **–** *Schnabel*

vi. Financial/Budget Report – *MacLean* **#H**

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

2023 Board Meeting Dates

- November 8-9, 2023 Newport, OR (Strategic Planning)
- December 13-15, 2023 Portland

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

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.)

- November 21, 2023

Conferences/Meetings

- NABP Districts 6, 7, 8 Meeting – October 22-25, 2023 Jackson Hole, WY

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 7.25.2023-9.25.2023 **# CONSENT-1**
b. Board Meeting Minutes – August 2023 **# CONSENT-2**
c. Special Board Meeting Summary – September 2023 **# CONSENT-3**

VI. PUBLIC COMMENT

Adjourn *Action Necessary*

Oregon
Tina Kotek, Governor

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
www.oregon.gov/pharmacy

Date: September 28, 2023
To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: September 27, 2023

Hearing Location: Virtual Hearing via Teams

Proposed Rules:

- Division 007 related to Compliance w/OHA COVID-19 rules *Repeal
- Divisions 019/041/043/044/139 related to Short-acting Opioid Antagonist (2023 HB 2395 & 2023 SB 450)
- Division 045 related to USP <795> and USP <797> Standards Adopted by Reference
- Division 115 related to related to Short-acting Opioid Antagonist (2023 HB 2395 & 2023 SB 450)
- Division 115/125 related to RPH Applicability, Definitions, Counseling; COPT/PT Prohibited Practices

On August 17, 2023, the September 27, 2023 Rulemaking Hearing public notice was sent out via GovDelivery to 3,907 rulemaking/adopted rules subscribers and 19,635 licensees/registrants (23, 542 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 9:32AM and adjourned at 9:40AM. #12 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. #8 written comments were received during the open comment period from 8/16/2023 through 4:30PM on 9/27/2023. The hearing was recorded, and the notice of proposed rulemaking filings were available on our website.

The following board and staff members participated:

Board member Beaman
Board member Vipperman
Staff Member Davis
Staff Member Melvin

Oregon
Tina Kotek, Governor

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
www.oregon.gov/pharmacy

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Compliance with OHA COVID-19 Rules

REPEAL: OAR 855-007-0088

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Short-acting Opioid Antagonist

AMEND: OAR 855-019-0460, OAR 855-041-1035, OAR 855-041-1130, OAR 855-043-0540, OAR 855-043-0630, OAR 855-043-0735, OAR 855-044-0060, and OAR 855-139-0155

REPEAL: OAR 855-041-2340 and OAR 855-139-0720

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: USP <795> and USP <797> Standards Adopted by Reference

ADOPT: OAR 855-045-0205

- No oral testimony was provided.

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: Short-acting Opioid Antagonist

ADOPT: OAR 855-115-0350

- No oral testimony was provided.

Oregon
Tina Kotek, Governor

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR, 97232
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www.oregon.gov/pharmacy

SUMMARY OF ORAL TESTIMONY:

RULES PROPOSED: RPH Applicability, Definitions, Counseling; COPT/PT Prohibited Practices

ADOPT: OAR 855-115-0001, OAR 855-115-0005, OAR 855-115-0145, and OAR 855-125-0150.

- Victoria Kroeger/Walgreens concerning OAR 855-125-0150 COPT/PT Prohibited Practices:
  - Believes rule may cause confusion. Lists of tasks in rule does not match what is in statutory definition of the "Practice of pharmacy" in ORS 689.005(31) thus causing potential confusion. Provided examples in the proposed rule of conducting Medication Therapy Management in (h), monitoring laboratory tests in (l) and delegating tasks to other healthcare professionals in (n).

All written comments received by the public comment deadline date of 9/27/2023 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 8/17/2023 Notice of Proposed Rulemaking.

September 20, 2023

Joseph Schnabel, PharmD
Executive Director
Oregon State Board of Pharmacy
800 N.E. Oregon Street, Suite 150
Portland, OR 97232

Re: Proposed Rules 855-115-0001, 855-115-0145, 855-125-0150

Dear Dr. Schnabel:

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.

ACI appreciates the robust discussion the Board Members had on the previous rule making packages for 855-115, 855-120, and 855-125 regarding pharmacists, technicians, and interns. We applaud the Board Members for listening to the stakeholder feedback collected during the rule making hearing held on July 26, 2023, and making substantive changes to the proposed language that had been offered. It is our opinion that the changes made at the most recent August board meeting and proposed in this current rule package address many of the concerns we raised.

855-115-0001 – Applicability

We recognize the change made from the previously proposed regulations to continue the previously recognized exemptions for pharmacists working in an out-of-state licensed Drug Outlet Pharmacy. These exemptions preserve access to vital pharmacy services that are provided to the residents of Oregon and services provided by out-of-state pharmacies licensed in Oregon to pharmacies licensed and located in the state of Oregon. In either case, in our opinion this was the correct course of action in the best interests of public safety in the state of Oregon.

Out-of-state pharmacies licensed in Oregon support the state in many ways and had the direction not changed, we believed that some of these vital services would have ceased to exist in the state. Pharmacies in Oregon are working hard right now to meet the needs of the patients they serve and any support we can provide them from either within the state or from outside the state is welcome relief.

855-115-0005 – Definitions

ACI appreciates the revision the Board Members made to the proposed language for the definition of counseling. We believe the current proposed language is much clearer and allows for various pathways for providing important information to patients in the state. Our pharmacists counsel patients routinely and there are ample opportunities for patients to access a pharmacist when they have questions on the safe use of their medications. Again, it is our opinion that this revision to the definition is in the best interests of public safety and promotes safe use of medication without unintended delays in care.

855-115-0145 – Counseling

ACI agrees with the direction the Board Members have taken with the revisions to the counseling section of Division 115. We are encouraged by the alignment of the regulations with what patients' expectations are by allowing for an offer of counseling to be made on new prescriptions or changes in therapy. This allows a patient to be more fully involved in the care they are offered and take advantage of counseling by the pharmacist. Our pharmacists are available upon request any time a patient needs a consultation, either in person or by phone. We believe this will continue and the pharmacist will remain accessible to patients without any barriers.

We also thank the board for the additional clarification and flexibility offered in item (5) relative to what is required when counseling information is only provided in a written format. This is a common practice for mailed and delivered prescriptions and will not be onerous to implement.

855-125-0150 – Prohibited Practices

Pharmacy technicians are vital to the success of a pharmacy and their contributions are essential to protecting the public. Pharmacists are an invaluable resource, and their training, education, and experience needs to be leveraged as much as possible where appropriate. Leveraging pharmacists can be facilitated by allowing pharmacy technicians to increase the ways they can support their pharmacist. We appreciate the Board Members exhibiting a high level of trust in pharmacy technicians and their ability to support the pharmacist. We support the revision to the prohibited practices section of Division 125 to allow pharmacy technicians to administer vaccines, extend the offer for counseling on behalf of the pharmacist, facilitate transfers, and call a prescriber's office for clarifications that do not require a pharmacist's professional judgement. These are all tasks that pharmacy technicians successfully perform in other states.

Pharmacy technicians have been administering vaccines in Oregon for approximately three years as a result of COVID flexibilities granted under the PREP Act, and we look forward to the continuation of that practice. Additionally, the ability of a pharmacy technician to extend an offer to counsel on behalf of a pharmacist and document the acceptance or refusal of such offer will

improve public safety. Under the current rules, a pharmacist must come to the counter for any prescription that would require counseling. This results in significant interruptions to the pharmacist's workflow and every time an interruption occurs there is risk of omitting an important step of the professional review. Reducing the number of interruptions for a pharmacist will improve patient care and safety.

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
Subject:	Rulemaking Comments 9/27 hearing
Date:	Thursday, September 21, 2023 1:08:40 PM
Attachments:	September 2023 Rulemaking Comments Final 9-20-23.pdf

Rachel,

Attached are our comments for the rulemaking hearing on 9/27.

Thank you.

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

CVSHealth

Lauren Paul, PharmD, MS | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

September 26, 2023

Joseph Schnabel, PharmD, RPh
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Amendments to Division 115 Pharmacists and Division 125 Pharmacy Technicians

Dear Executive Director Schnabel and Members of the Oregon State Board of Pharmacy:

I am writing to you in my capacity 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 855-115-0001 Applicability and 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.

855-125-0150 Prohibited Practices

We also appreciate the Board's discussion and proposed amendments which permit a pharmacy technician to receive new prescriptions, conduct transfers over the telephone, and clarify that a pharmacy technician can perform clarifications with health care professionals that do not require clinical or professional judgement.
CVS Health supports the allowances, which modernizes pharmacy technician practice in Oregon.

CVS Health appreciates the opportunity to submit comments to the Board for review. Please contact me directly at 540-604-3661 if you have any questions.

Sincerely,

Lauren Paul, PharmD

Lauren Paul, PharmD., MS
Executive Director, Pharmacy Regulatory Affairs
CVS Health

From:	Paul, Lauren N.
To:	PHARMACY RULEMAKING * BOP
Subject:	CVS Health Comments Divs 115/125 related to RPH Applicability, Definitions, Counseling; COPT/PT Prohibited Practices
Date:	Tuesday, September 26, 2023 2:44:41 PM
Attachments:	CVS Health Comments on Proposed Amendments to Division 115 Pharmacists and Division 125 Pharmacy Technicians .pdf

Good Evening,

Attached please find CVS Health comments on Divisions 115/125 related to RPh applicability, definitions, counseling; COPT/PT Prohibited Practices.

Lauren Paul, PharmD, MS | Executive Director, Pharmacy Regulatory Affairs
p 540-604-3661 | **f** 401-733-0479
1 CVS Drive, Mail Code 2325, Woonsocket, RI 02895

Planned Business Travel: September 25th-27th, October 11th-13th, October 19th-25th, November 7th, November 13th-15th, November 28th-29th

PTO: November 10th, 22nd and 24th

From:	Mike Gilbert
To:	PHARMACY RULEMAKING * BOP
Subject:	Comment on Proposed Rule
Date:	Friday, August 18, 2023 8:49:06 AM

Dear Madam or Sir,

I think this proposed rule is confusing, wordy, and not clear. In particular, part (3.) It is not clear as to whom this rule applies and the problems that it addresses.

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 licensed 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).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.255

Can you please provide me with some clarification as to the problem that gave rise to this proposed rule?

-Mike

Mike Gilbert
PO Box 494
Rogue River, OR 97537
503-413-0342

September 25, 2023

Subject: Comments on proposed rules divisions 115 and 125

Dear Board of Pharmacy,

Thank you for your consideration when reviewing my comments on the following sections of the proposed Divisions 115 and 125.

Sincerely,
Natalie Gustafson, PharmD

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

855-115-0145 Counseling

First, we would like to thank the Board for consideration of previous comments about counseling. We greatly appreciate the changes to this rule that have been made.

Quick clarification: it appears the goal of the new rule is to broaden who may offer for a pharmacist to counsel and then receive the refusal. However, there are two sections which appear to possibly be in conflict if so.

Section (6) states:
(6) 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.

However, in section (3) it states:

(3) The pharmacist must offer to counsel the patient or patient's agent on the use of a drug or device

Are other licensees (e.g. pharmacy technician), allowed to offer for a pharmacist to counsel and then accept the refusal?

855-125-0150 Prohibited Practices

Recommendation: Do not make a prohibited practice that prevents technicians from being supervisors. Many supervisory responsibilities that a technician can perform have nothing to do with clinical or professional judgment (e.g. setting a schedule, handling callouts, training tasks).

Current proposed rule: [technicians must not] “(m) Supervise, direct, or control another licensee in the licensee practicing or assisting in the practice of pharmacy”

It is important that technicians be allowed to help in the operations and logistics of pharmacy operations. Our concern is that this wording could be interpreted to restrict a technician from having a managerial job title or responsibilities. In the last Board meeting discussion it did not seem that was the intent of this restriction, however, as currently worded a regulator or inspector could interpret otherwise.

Many places have “lead” technicians who oversee workflow and operational duties (e.g. scheduling employees, handling call outs, shifting workflow responsibilities, resolving minor HR issues, training tasks, ensuring high quality customer service, insurance billing, ordering, ensuring timeliness of processing prescriptions, cleaning). All these tasks are critical and could be considered to be assisting in the practice of pharmacy, but do not require any professional or clinical judgment.

There is currently a pharmacy staff shortage, which makes being able to delegate responsibilities and certain oversight to technicians even more important.

From:	Pharmacist Lloyd Central Pharmacy
To:	PHARMACY RULEMAKING * BOP
Subject:	Comments for Division 115 and 125 Rulemaking Hearing 9.27.2023
Date:	Monday, September 25, 2023 12:59:41 PM
Attachments:	LCRX Comments OBOP Divs 115 and 125 Rulemaking 2023.09.27.pdf

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Hello Oregon Board of Pharmacy,

Please see attached comments for Divisions 115 and 125 for the rulemaking hearing.

Thank you for your consideration,
Natalie Gustafson, PharmD

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

OREGON STATE PHARMACY ASSOCIATION
19363 Willamette Drive #260 • West Linn, Oregon 97068
(503) 582-9055 • www.oregonpharmacy.org • info@oregonpharmacy.org

September 27, 2023

To: Oregon Board of Pharmacy

RE: Rulemaking comment for proposed rule 855-045-0205 pertaining to USP 795 and 797 standards.

The Oregon State Pharmacy Association is requesting comment from Board of Pharmacy staff or board members regarding intent and effect of this rule.

It is our understanding that this rule will make permanent the ability of pharmacies to be compliant with Oregon compounding rules by being compliant with 2022 USP 795 and 797 national standards. Is this a correct interpretation?

If so, we are in support of this rule and others which allow pharmacies to be compliant by following industry standards rather than separate detailed rules for Oregon. It is administratively difficult and costly to follow two sets of rules/standards particularly when available resources and software are based on national standards and not different state-specific rules.

In addition, OSPA would like to commend the Board of Pharmacy members for the recent adoption of the pharmacy technician rule changes. We appreciate the Board engaging with stakeholders on these regulations and for the feedback provided throughout the process.

Thank you for the opportunity to comment on these rules.

Sincerely,
Brian Mayo
Executive Director

From:	Brian Mayo
To:	PHARMACY RULEMAKING * BOP
Subject:	OSPA Public Comments
Date:	Wednesday, September 27, 2023 10:05:34 AM
Attachments:	2023 September rulemaking letter.pdf

Please see the attached letter on behalf of OSPA and our members.

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

September 25, 2023

To: Oregon Board of Pharmacy

Re: Rulemaking comment for proposed rule 855-115-0001 (3)

(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 licensed Drug Outlet Page 2 of 6 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).

Prescryptive Health is in support of this rule which includes "counseling" in the list of exceptions of tasks an out of state pharmacist may perform without licensure in Oregon. The technology of pharmacy is changing as are the new ways patients can access medications and pharmacists. Imagine a local community pharmacy in Oregon with prescription pick up and counseling available 24 hours a day. It would not be feasible to employ an Oregon pharmacist for after hours consultation, but it could be affordable and practical to contract with a national pharmacy for after-hours support.

Also, imagine sophisticated patient centered software that detects a patient at risk for an adverse medication event and gives them the option to "talk to a pharmacist now". This would require a national support center where the pharmacist on call may not be an Oregon licensed pharmacist. The possibilities are endless but are dependent on the flexibility of state rules to allow safe and cost-effective innovation. Thank you for your consideration.

Sincerely,

Kevin Russell RPh, MBA, BCACP
Director of Pharmacy | Clinical Operations
Prescryptive Health
2127 S HWY 97 STE 150
Redmond, OR 97756
Office: (206) 413-9475
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From:	Kevin Russell
To:	PHARMACY RULEMAKING * BOP
Subject:	Rulemaking comments for proposed rule 855-115-0001
Date:	Monday, September 25, 2023 4:38:59 PM
Attachments:	image001.png Prescryptive Oregon BOP rulemaking comments 9-25-2023.docx

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Kevin Russell RPh, MBA, BCACP
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Joseph Schnabel, PharmD, RPh
Executive Director, Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

September 22, 2023

Re: Proposed Amendments to Division 115 Pharmacists

Dear Executive Director Schnabel,

On behalf of Ro, we are writing to express our strong support to the Proposed Rulemaking regarding Division 115: Pharmacists issued on August 17, 2023.

Ro is a patient-driven digital health company that puts patients in control of their health. With our affiliated provider network, diagnostics and a network of mail order pharmacies, Ro provides high-quality, affordable healthcare to Oregon patients. Ro currently owns six pharmacies, many of which serve Oregon-based patients through mail-order fulfillment. Ro's custom-built EMR and pharmacy management software enable pharmacists and pharmacy technicians to interact directly with healthcare providers, including doctors, nurses, and customer service teams to provide coordinated care.

Ro appreciates the Board's collaborative approach and its thoughtful consideration of stakeholder feedback throughout the rulemaking process. We believe many provisions in the current draft of the proposed rules improve and provide added clarity upon previous iterations. Specifically, we support how the proposed rules explicitly acknowledge the option for written counseling (855-115-0005) and remove previous mandates that would have required pharmacists to affirmatively counsel patients under a number of circumstances. These new changes both reinforce and better align with the Board's expectation that pharmacists "determine the manner and amount of counseling that is reasonable and necessary under the circumstance." Further, in retaining pharmacists' ability to offer written counseling where appropriate, the proposed rules will enable pharmacists to continue to engage patients in the mail-order context and will not require substantial or costly upheaval to existing pharmacy operations. In addition, this gives pharmacists the ability to practice at the top of their license and pursue other methods of counseling if determined to be appropriate.

We believe the proposed rules ensure safe and effective pharmacy services for Oregon patients. We encourage the Board to adopt the proposed rules as drafted and appreciate the opportunity to provide comments throughout this process.

Thank you,

Ruey Ju, PharmD, JD
Director, Assistant General Counsel, Roman Health

From:	Ruey Ju
To:	PHARMACY RULEMAKING * BOP
Subject:	Ro Comment on NOPM Division 115
Date:	Friday, September 22, 2023 12:48:32 PM
Attachments:	Ro Comments on NOPM Division 115_092223.pdf

Hello Ms. Melvin-

Please see the attached comment from Ro on the NOPM for Division 115.

Thank you,
Ruey
--

Ruey Ju | He/him
Director, Assistant General Counsel | Ro

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

September 23rd, 2023
Oregon State Board of Pharmacy
Attention: Joe Schnabel, Executive Director
800 NE Oregon St., Suite 150
Portland, OR 97232
Via Email: joseph.schnabel@oregon.gov

RE: Divisions 115 and 125 – Pharmacists and Pharmacy Technicians

Dear Dr. Schnabel 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 commends the board for its discussion in its previous meetings regarding OAR 855-115-0001(3) 'Applicability'. Continuing to allow non-resident outlets with non-Oregon licensed pharmacists the ability to provide a patient's consultation and other remote prescription services demonstrates the boards commitment to its mission of promoting health and protecting the people of Oregon. Walgreens thanks the board for updating the language to ensure clarity for pharmacists working in a non-resident pharmacy and for reducing the burden of the workload for in-state pharmacies.

Walgreens also commends the board for its thoughtful consideration of the impact of counseling in all pharmacy settings. Walgreens specifically appreciates the board's willingness to allow appropriately licensed individuals to accept the declination of counseling in OAR 855-115-0145(6). This allows patients to make the choice of when and where they are counseled, unless specifically required by the pharmacist. This update demonstrates Oregon's progressive and patient first approach to healthcare.

While many of these rule changes are favorable for patients in Oregon, Walgreens seriously urges the board to have robust discussions regarding the prohibited practices of technicians. Walgreens supports and promotes professional judgment and autonomy for pharmacists on duty and asks the board to simplify the rule 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. OAR 855-125-0150(1) seemingly restricts a pharmacist's ability and autonomy to allow technicians to assist in the practice of pharmacy or delegate tasks to another licensee when appropriate. We ask 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.

<u>855-125-0150 Prohibited Practices</u>
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:

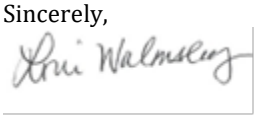
   a. Evaluate and interpret a prescription;
   b. Conduct a Drug Utilization Review or Drug Regimen Review;
   c. Consult with any prescriber, other healthcare professional or authorized agent regarding a patient and any medical information pertaining to the patient's prescription that requires judgment;

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. Supervise, direct, or control another licensee in the ~~licensee practicing or~~ assisting in the practice of pharmacy without authorization from the pharmacist-in charge or pharmacist on duty.
n. ~~Delegate tasks to healthcare providers and~~
o. 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

From:	Walmsley, Lorri
To:	PHARMACY RULEMAKING * BOP
Cc:	SCHNABEL Joseph * BOP; Kroeger, Victoria
Subject:	Walgreens Comments
Date:	Wednesday, September 27, 2023 8:25:38 AM
Attachments:	image001.png OR Comments 9.23.pdf

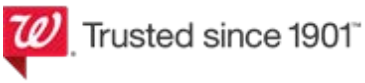
Hello,

Please see attached on behalf of Walgreens.

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs
Walgreen Co.
She/Her why this matters



Division 007: Compliance with the Oregon Health Authority's COVID-19 Requirements

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Repeals COVID-19 related rule no longer in effect

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Repeals rule that required licensees and registrants to comply with the Oregon Health Authority's (OHA) requirements that were issued to control COVID-19.

Documents Relied Upon per ORS 183.335(2)(b)(D): OAR 333-019-1011, OAR 333-019-1025, OHA Public Health Order Rescinding Health Care Masking

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rule repeal provides clarity for licensees and registrants. It is anticipated that repeal of this rule will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommend repealing the rule for clarity for licensees and registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): The OHA rescinded provisions in OAR 333-019-1011 which required workers in health care settings to wear masks on 4/3/2023 and repealed OAR 333-019-1010 requiring workers in health care settings to be COVID-19 vaccinated on 5/11/2023. With the OHA's rescission of these rules, the board rule is no longer needed. The proposed rulemaking would repeal the board's rule in its entirety.

Division 7
PUBLIC HEALTH EMERGENCY

~~855-007-0088~~
~~Compliance with the Oregon Health Authority's COVID-19 Requirements~~

~~(1) The Oregon Health Authority (OHA) has adopted certain rules to control the communicable disease COVID-19. Unprofessional conduct includes failing to comply with any applicable provision of an OHA COVID-19 related rule or any provision of this rule.~~

~~(2) Failing to comply as described in subsection (1) includes, but is not limited to:~~

~~(a) Failing to comply with OHA's rules requiring masks, face coverings or face shields, including OAR 333-019-1011 and OAR 333-019-1025.~~

~~(b) Failing to comply with OHA's rules requiring vaccinations, including OAR 333-019-1010.~~

~~(3) No disciplinary action or penalty action will be taken under this rule if the rule alleged to have been violated is not in effect at the time of the alleged violation.~~

~~(4) Imposition of discipline for violating this rule is as authorized by ORS 689.405 and ORS 689.445. Any such discipline will be imposed in accordance with ORS Ch. 183.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151~~

Divisions 019/041/043/044/139: Short-acting Opioid Antagonist (naloxone/nalmefene); DPDO, CF, CHC, Charitable Pharmacy Labeling; Minimum Equipment Requirements

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Short-acting Opioid Antagonist; Labeling exemption

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments are legislative mandates of 2023 SB 450 and 2023 HB 2395. Amends existing rules related to naloxone by utilizing the newly defined term "short-acting opioid antagonist" instead of "naloxone" per directives of 2023 HB 2395. Amends existing rules for Pharmacies, Dispensing Practitioner Drug Outlet (DPDO), Correctional Facility (CF), Community Health Clinic (CHC) and Charitable Pharmacies by incorporating labeling exemption requirements that apply when a prescriber personally dispenses a short-acting opioid antagonist in the form of a nasal spray per directives of 2023 SB 450. Repeals OAR 855-041-2340 Naloxone and OAR 855-139-0720 Naloxone General Requirements as these requirements can be found in other existing rules.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 SB 450, 2023 HB 2395, Narcan (naloxone) package insert, Opvee (nalfemene) package insert

Spencer MR, Miniño AM, Warner M. Drug overdose deaths in the United States, 2001–2021. NCHS Data Brief, no 457. Hyattsville, MD: National Center for Health Statistics. 2022. DOI: https://stacks.cdc.gov/view/cdc/122556

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed amendments and repeals would possibly have a positive impact on racial equity in Oregon. According to the CDC, Black, Indigenous, and people of color and American Indian/Alaska Native (BIPOC-AI/AN) people are disproportionately likely to die from opioid overdoses. By making short-acting opioid antagonists more accessible, reducing stigma, and improving access to care, the rules could help to reduce the number of opioid overdose deaths in the state, particularly among BIPOC-AI/AN people.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Proposed amendments are legislative mandates of 2023 SB 450 and 2023 HB 2395.

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

OAR 855-019-0460 - Proposed amendments in OAR 855-019-0460 include striking the term "naloxone" and alternatively utilizing "short-acting opioid antagonist" as defined in 2023 HB 2395; adds labeling exemptions when a Pharmacist personally dispenses a FDA approved short-acting opioid antagonist in

the form of a nasal spray as mandated in 2023 SB 450 and removes requirement for Pharmacist to determine individual seeking naloxone understands educational materials related to opioid overdose prevention and repeals duplicative rule concerning counseling that is contained in OAR 855-019-0230.

OAR 855-041-1035 - Proposed amendments include striking the term "naloxone" and replacing it with "short-acting opioid antagonist" due to directives from 2023 HB 2395.

OAR 855-041-1130 - Proposes amending OAR 855-041-1130 by incorporating statutory reference “2023 SB 450” labeling exemptions when dispensing an FDA approved short-acting opioid antagonist in the form of a nasal spray on behalf of a prescribing pharmacist.

OAR 855-041-2340 – Repeals the rule

OAR 855-043-0540 - Amends OAR 855-043-0540 by incorporating statutory reference to the labeling exemptions contained in 2023 SB 450 that apply to a Dispensing Practitioner Drug Outlet (DPDO) when a prescriber personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray.

OAR 855-043-0630 - Amends OAR 855-043-0630 by incorporating statutory reference to the labeling exemptions contained in 2023 SB 450 that apply to a Correctional Facility (CF) when a prescriber personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray.

OAR 855-043-0735 - Amends OAR 855-043-0735 by incorporating statutory reference to the labeling exemptions contained in 2023 SB 450 that apply to a Community Health Clinic (CHC) when a prescriber personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray.

OAR 855-044-0060 - Amends OAR 855-044-0060 by incorporating statutory reference to the labeling exemptions contained in 2023 SB 450 that apply to Charitable Pharmacies when a prescriber personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray.

OAR 855-139-0155 - Proposed amendments include striking the term "naloxone" and replacing it with "short-acting opioid antagonist" due to directives of 2023 HB 2395.

OAR 855-139-0720 – Repeals rule

Division 19
PHARMACISTS

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 41
OPERATION OF PHARMACIES

855-041-1035
Minimum Equipment Requirements

(1) Each retail drug outlet and institutional drug outlet must have the following:

(a) Appropriate and current pharmaceutical references (e.g., pharmacology, injectables, and veterinary drugs) based on services offered by the outlet;

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g., USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;

(c) Access to appropriate electronic reporting databases (e.g., PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(d) Appropriate equipment to maintain the proper storage of drugs;

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g., USP) based on services offered by the outlet;

(f) A sink with running hot and cold water;

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating “This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve.” The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up pharmacy per OAR 855-041-2100;

(D) Providing written notice in a conspicuous manner that short-acting opioid antagonists (e.g., naloxone, nalmefene) and the necessary medical supplies to administer short-acting opioid antagonists are available at the pharmacy if short-acting opioid antagonist services are provided by the pharmacy; and

(E) Providing notification of accurate hours of operation at each pharmacy entrance; and

(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).

(i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508, ORS 689.515, ORS 689.564, ORS 689.686, 2023 HB 2395

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling

Except as described in SB 450 (2023), prescriptions must be labeled with the following information:

(1) Name, address and telephone number of the pharmacy;

(2) Date of fill;

(3) Identifying number;

(4) Name of patient;

(5) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(6) Directions for use by the patient;

(7) Name of practitioner;

(8) Required precautionary information regarding controlled substances;

(9) Such other and further accessory cautionary information as required for patient safety;

(10) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must not exceed:

(a) That on the manufacturer's container if dispensed in the manufacturer's container; or

(b) The earliest date of either:

(A) The manufacturer's expiration date; or

(B) One year from the date the drug was repackaged and dispensed.

(11) Any drug expiring before the expected length of time for the course of therapy must not be dispensed.

(12) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505,ORS 689.515, 2023 SB 450

~~855-041-2340~~
~~Naloxone~~

~~Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:~~

~~(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction;~~

~~(2) Documentation and recordkeeping: and~~

~~(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682 & 2019 OL Ch. 470~~

Division 43
PRACTITIONER DISPENSING

855-043-0540
Dispensing Practitioner Drug Outlet - Labeling

(1) Except as described in SB 450 (2023), a prescription must be labeled with the following information:

(a) Name of patient;

(b) Name of prescriber;

(c) Name, address, and phone number of the clinic;

(d) Date of dispensing;

(e) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(f) Quantity dispensed;

(g) Directions for use;

(h) Cautionary statements, if any, as required by law; and

(i) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier. Any drug expiring before the expected length of time for course of therapy must not be dispensed.

(j) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules.

(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-043-0004, the name of the patient may be omitted.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305, 2023 SB 450

855-043-0630
Correctional Facility - Drug Delivery and Control

(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.

(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 patient/inmates who self administer or who are given prescription drugs when they are released from the CF.

(6) Administration: Drugs must be administered to inmate/ patients 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 registered nurses from manufacturer's or Pharmacist's bulk drug containers must not be administered by unlicensed persons, 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, 2023 SB 450

855-043-0735
Community Health Clinic (CHC) - Labeling

(1) Except as described in SB 450 (2023), a prescription must be labeled with the following information:

(a) Unique identifier (i.e. prescription number);

(b) Name of patient;

(c) Name of prescriber;

(d) Name, address, and phone number of the clinic;

(e) Date of dispensing;

(f) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(g) Quantity dispensed;

(h) Directions for use;

(i) Initials of the practitioner who has been given dispensing privileges by their licensing Board or the Registered Nurse;

(j) Cautionary statements, if any, as required by law; and

(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.

(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from the label, the patient's name may be omitted from the records and a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, 2023 SB 450

Division 44
CHARITABLE PHARMACIES

855-044-0060
Labeling

(1) Except as defined in SB 450 (2023), the label on a drug dispensed or distributed from a charitable pharmacy must meet all federal rules and laws and must contain:

(a) The name, address and telephone number of the pharmacy;

(b) The name of the prescribing practitioner;

(c) The initials of the dispensing practitioner;

(d) Date dispensed;

(e) The name of the patient;

(f) Name and manufacturer of drug, drug strength, the quantity dispensed;

(g) Directions for use;

(h) The expiration date;

(i) A unique identifier; and

(j) Any further cautionary information required for patient safety.

(2) All original patient identification must be removed.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.774, 2023 SB 450

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon Retail Drug Outlet RDSP must have the following:

(a) Appropriate and current pharmaceutical references (e.g., pharmacology, injectables, and veterinary drugs) services offered by the outlet;

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g., USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;

(c) Access to appropriate electronic reporting databases (e.g., PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;

(d) Appropriate equipment to maintain the proper storage of drugs;

(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g., USP) based on services offered by the outlet;

(f) A sink with running hot and cold water;

(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered:

(A) Stating “This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve.” The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-139-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing written notice in a conspicuous manner that short-acting opioid antagonists (e.g., naloxone, nalmefene) and the necessary medical supplies to administer short-acting opioid antagonists are available at the pharmacy if short-acting opioid antagonist services are provided by the pharmacy;

(D) Stating "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed Pharmacist from (insert name of RDSP Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and

(E) Providing notification of accurate hours of operation at each pharmacy entrance; and

(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).

(i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

Statutory/Other Authority: ORS 689.205, ORS 689.686, ORS 689.515 & 2021 SB 629,
Statutes/Other Implemented: ORS 689.155, 2023 HB 2395

~~855-139-0720~~
~~Service: Naloxone- General Requirements~~

~~Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:~~

~~(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction;~~

~~(2) Documentation and recordkeeping: and~~

~~(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.305, ORS 689.681 & ORS 689.682~~

Division 045: Drug Compounding (USP <795> and USP <797>)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Incorporates additional USP <795> and USP <797> standards adopted by reference

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Permits Drug Outlet pharmacies to implement USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (v. 11/01/2022) and <797> Pharmaceutical Compounding—Sterile Preparations (v. 11/01/2022) as an alternative to USP <795> (05/01/2020 v. 2014) and USP <797> (05/01/2020 v. 2008). This is currently a temporary rule that needs to be permanently adopted prior to the temporary rule 10/31/2023 expiration date in order to facilitate timely compliance with USP standards.

Documents Relied Upon per ORS 183.335(2)(b)(D):

- USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (v. 11/01/2022) – Publication Announcement

- USP <797> Pharmaceutical Compounding—Sterile Preparations (v. 11/01/2022)- Publication Announcement

OAR 855-045-0205 Temporary Rule

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed rule amendments provide clarity for licensees, registrants. It is anticipated that these amendments will not impact any group of people differently than others.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed amendments.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. This is currently a temporary rule that needs to be permanently adopted prior to the temporary rule 10/31/2023 expiration date in order to facilitate timely compliance with USP standards.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Permanently adopts the current temporary rule that allows Drug Outlet pharmacies to implement USP <795> Pharmaceutical Compounding Non-Sterile Preparations (v. 11/01/2022) and <797> Pharmaceutical Compounding – Sterile Preparations (v. 11/01/2022).

The United States Pharmacopeia (USP) published its revised standards for USP General Chapters <795> and <797> on November 1, 2022. These new USP standards will be effective on November 1, 2023. The board anticipates future rulemaking to adopt USP <795> (v. 11/01/2022) and <797> (v. 11/01/2022)by reference and repeal USP Chapters <795> (05/01/2020 v. 2014) and USP <797> (05/01/2020 v. 2008).

Due to the numerous and complex process changes required for compliance, registrants may implement the revised USP <795> (v. 11/01/2022) and <797> (v. 11/01/2022).

DIVISION 45
DRUG COMPOUNDING

855-045-0205
Compliance with New Standards

As an alternative to the requirements in OAR 855-045-0200(3)(a) and (3)(b) registrants may comply with any or all standards contained in:

(1) USP <795> Pharmaceutical Compounding—Non-Sterile Preparations (11/1/2022).

(2) USP <797> Pharmaceutical Compounding—Sterile Preparations (11/1/2022).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

Division 115: Short-acting Opioid Antagonist (naloxone/nalmefene)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Short-acting Opioid Antagonist; Labeling exemption

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed rule incorporates the newly defined term "short-acting opioid antagonist" from 2023 HB 2395 and adds labeling exemption requirements that apply when a prescriber personally dispenses a short-acting opioid antagonist in the form of a nasal spray per directives of from 2023 SB 450.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2023 SB 450, 2023 HB 2395, Narcan (naloxone) package insert, Opvee (nalfemene) package insert;

Spencer MR, Miniño AM, Warner M. Drug overdose deaths in the United States, 2001–2021. NCHS Data Brief, no 457. Hyattsville, MD: National Center for Health Statistics. 2022. DOI: https://stacks.cdc.gov/view/cdc/122556

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 may have a positive impact on racial equity in Oregon. According to the CDC, Black, Indigenous, and people of color and American Indian/Alaska Native (BIPOC-AI/AN) people are disproportionately likely to die from opioid overdoses. By making short-acting opioid antagonists more accessible, reducing stigma, and improving access to care, the rules could help to reduce the number of opioid overdose deaths in the state, particularly among BIPOC-AI/AN people.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Proposed rules are legislative mandates of 2023 SB 450 and 2023 HB 2395.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments relocate and revise OAR 855-019-0460 to OAR 855-115-0350. Revisions include striking the term "naloxone" and alternatively utilizing "short-acting opioid antagonist" as defined in 2023 HB 2395, adds labeling exemptions when a Pharmacist personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray as mandated in 2023 SB 450 and removes requirement for Pharmacist to determine individual seeking naloxone understands educational materials related to opioid overdose prevention and repeals duplicative rule concerning counseling that is contained in OAR 855-019-0230.

1
2 Division 115
3 PHARMACISTS

855-115-0350

Services: Prescribing Practices - Short-acting Opioid Antagonists

(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.

(3) The Pharmacist must document the encounter, the prescription and maintain records according to OAR 855-104-0055.

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 115/125: Pharmacists and Pharmacy Technicians; Proactive procedural rule review

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; Pharmacists and Pharmacy Technicians

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Relocates and reorganizes existing Pharmacist rules from Division 019 related to applicability, definitions and counseling. Removes some prohibited practices for Certified Oregon Pharmacy Technicians and Pharmacy Technicians. Board staff are reorganizing proposed rules 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): OBOP 2022-2026 Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring licensees and registrants can easily locate licensure and compliance requirements will positively impact all Oregonians in all communities.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the agency, other state or local government, small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of proposed revisions to the rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff suggests reorganizing proposed rules for transparency and clarity for licensees pursuant to the board's 2022-2026 Strategic Plan.

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

OAR 855-115-0001- Proposed rule relocates and revises existing rule 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.

OAR 855-115-0005 - Proposed rule relocates and revises the existing definition of "Counseling" from OAR 855-019-0110 and adds revised definition of "Drug utilization review or "DUR" from OAR 855-006-0005 to OAR 855-115-0005.

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 offer counseling, removes reference to Intern provided counseling that is now included in OAR 855-120-0135, introduces provisions for written counseling and supplemental information when required by federal

law, permits any board licensee to accept declination of counseling and adds requirements for documentation of the licensees identity for counseling, attempts to counsel or declination of counseling.

OAR 855-125-0150 - Proposed rule relocates and revises portions of existing rule in OAR 855-019-0200(3) to OAR 855-125-0150 related to prohibited practices for Certified Oregon Pharmacy Technicians and Pharmacy Technicians. Each Certified Oregon Pharmacy Technician and Pharmacy Technician must adhere to specific limitations and responsibilities, which include refraining from engaging in the practice of pharmacy, not performing tasks requiring judgment without pharmacist verification, not engaging in discriminatory behavior, and not refusing Pharmacist interactions requested by patients, patient agents, or practitioners.

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 licensed 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).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.255

855-115-0005
Definitions

(1) "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.

(2) "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

855-115-0145

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) The pharmacist must counsel the patient or patient's agent on the use of a drug or device upon request.

(3) The pharmacist must offer to counsel 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.

(4) 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.

(5) 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.

(6) 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.

(7) Counseling must be provided under conditions that maintain patient privacy and confidentiality.

(8) Counseling, offers to counsel or declinations of counseling regarding prescriptions must be documented with the licensee's identity.

(9) 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 & 689.155

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) Supervise, direct, or control another licensee in the licensee practicing or assisting in the practice of pharmacy;

(n) Delegate tasks to healthcare providers; and

(o) 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

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.

In order 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 in order 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 a 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 October 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.
  - **Mark**~~up~~ 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 amendment is also listed in rule package #C12

As used in OAR Chapter 855:

(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
Outlet: General Requirements
NOTE: This rule is also listed in mailing #D4 for all amendments except proposed amendments in (1)(c).

A ~~d~~**D**rug ~~o~~**O**utlet ~~p~~**P**harmacy must:

(1) Ensure each:

(a) Prescription is dispensed in compliance with OAR 855-~~019~~**115**, **OAR 855-120,** OAR 855-~~025~~**125**, ~~OAR 855-031 and~~ OAR 855-041 **and 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 855-183; 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.

(46) ~~Ensure~~ **Establish, maintain and** enforce the drug outlet written procedures **required in OAR 855-041-1040** ~~for use of Certified Oregon Pharmacy Technicians or Pharmacy Technicians as required by OAR 855-025-0035;~~

(~~5~~7) Comply with the Pharmacist's determination in OAR ~~855-019-0200(4)(c)~~ **855-115-0120(1)(k);**

(~~6~~8) Develop, implement and enforce a continuous quality improvement program for dispensing services from a ~~d~~**D**rug ~~o~~**O**utlet ~~p~~**P**harmacy 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 & 2022 HB 4034
Statutes/Other Implemented: ORS 689.151, 2022 HB 4034, ORS 689.508 & 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**) Each 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: This rule is also listed in mailing #B1 for all amendments except proposed amendments in (2)

(1) Policies and Procedures: The ~~p~~**P**harmacist and the practitioner representing the facility ~~shall be~~ **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 ~~shall~~ **must** be reviewed and updated annually by the ~~p~~**P**harmacist and the practitioner, maintained in the facility; and be made available to the ~~B~~**b**oard for inspection. The facility ~~shall~~ **must** submit to the ~~B~~**b**oard for approval, the name of any employee ~~p~~**P**harmacist or a written agreement between the ~~p~~**P**harmacist and the facility regarding drug policies and procedures. The facility ~~shall~~ **must** notify the ~~B~~**b**oard of any change of ~~p~~**P**harmacist within 15 days of the change.

(2) Dispensing: Prescription drugs ~~shall~~ **must** be dispensed by a ~~p~~**P**harmacist 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 ~~shall~~ **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 ~~p~~**P**harmacist to verify the prescriber's original order;

(v) Provide a means for the ~~p~~**P**harmacist 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 ~~correctional facility~~ **CF** utilizing a unit dose dispensing system ~~shall~~ **must** establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies ~~shall~~ **must** be available in the pharmacy for inspection by the ~~B~~**b**oard:

(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 ~~O~~AR 855-041-~~0177~~(4).

(c) The ~~p~~**P**harmacist ~~shall~~ **must** certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.

(d) All medication ~~shall~~ **must** be stored in a locked area or locked cart.

(4) Labeling: Prescription drugs dispensed in individual containers or medication cards ~~shall~~ **must** be labeled with the following information:
NOTE: This rule is currently in rulemaking

(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 ~~p~~**P**harmacist of the patient's record, the ~~p~~**P**harmacist ~~shall~~ **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 ~~p~~**P**harmacist 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 ~~shall~~ **must** include information that a reasonable and prudent ~~p~~**P**harmacist 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 ~~shall~~ **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 ~~shall~~ **must** be in writing and by free access to the ~~p~~**P**harmacist by phone.

(d) Subsections (a) and (b) of this section ~~shall~~ **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 ~~p~~**P**harmacist is not required to provide oral counseling when a patient refuses the ~~p~~**P**harmacist 's attempt to counsel, or when the ~~p~~**P**harmacist, 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 patient/inmates who self administer or who are given prescription drugs when they are released from the ~~correctional facility~~ **CF**.

(6) Administration: Drugs ~~shall~~ **must** be administered to inmate/ patients by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined ~~in~~ by the **Oregon State Board of Nursing in** ~~Board administrative rule 851-047-0020~~ **OAR 851-045-0060**. Drugs selected by registered nurses from manufacturer's or ~~p~~**P**harmacist's bulk drug containers ~~shall~~ **must** not be administered by unlicensed persons, 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**) Each 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:

(~~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

855-183-0600
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~~

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: 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? 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 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).

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 adding (b) which prohibits a COPT/PT at a RDSP to "Administer a vaccine."

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the October 2023 board meeting.

- Highlights
  - Highlights- Yellow highlight indicates change since package included in August 2023 packet for board review
  - **Mark**~~up~~ in this package is in comparison to current rules in Div 019, 041, and 139.

Division 019
PHARMACISTS

855-019-0270
Vaccination: Qualifications

~~(1) In this rule and in OAR 855-019-0280, an intern who is appropriately trained and qualified in accordance with Section (3) of this rule may perform the same duties as a pharmacist, provided that the intern is supervised by an appropriately trained and qualified pharmacist.~~

~~(2) A pharmacist may administer vaccines to persons who are at least 7 years of age as provided by these rules. For the purposes of this rule, a person is at least 7 years of age on the day of the person's seventh birthday.~~

(~~3~~**1**) A ~~p~~**P**harmacist may administer vaccines ~~under section (1) or section (2) of this rule only~~ if the Pharmacist:

(a) ~~The pharmacist h~~**H**as completed a course of training approved by the Board and maintained competency~~;~~

~~(b) The pharmacist training~~ **that** includes, injection site, and Cardiopulmonary Resuscitation (CPR) specific to the age and population **of patients being vaccinated by the** ~~p~~**P**harmacist ~~treats~~;

(~~c~~**b**) ~~The pharmacist h~~**H**olds 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~~, and documentation of the certification is placed on file in the pharmacy~~;

~~(d) The vaccines are Prescribes, administered in accordance with an administration protocol written and approved by the Oregon Health Authority (OHA); and~~

(~~e~~**c**) ~~The pharmacist h~~**H**as **access to the** ~~a~~ current ~~copy~~ **edition** of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases."

~~(4) A pharmacist otherwise in compliance with section three of this rule may, during a declared emergency, administer a vaccine to a person who is at least three (3) 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.~~

~~(5) A pharmacist may not delegate the administration of vaccines to another person.~~

Statutory/Other Authority: ORS 689.205 **ORS 689.645**, **ORS** 433.441, **ORS** 433.443 & ~~2015 OL Ch 295,~~**2023 HB 2278, 2023 HB 2486**
Statutes/Other Implemented: ORS 689.151, 689.155, 689.645 & ~~2015 OL Ch 295,~~ **2023 HB 2278, 2023 HB 2486**

855-019-0280
~~Immunization~~ **Vaccination:** Protocols, Policies and Procedures

(1) Prior to **prescribing,** administering **or dispensing** a vaccine, ~~to a person who is at least 7 years of age~~ a ~~p~~**P**harmacist ~~must follow protocols~~**:**

(a) Until January 31, 2024, must follow protocols written and approved by the Oregon Health Authority (OHA) for ~~administration of~~ 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

(~~2~~**c**) ~~A pharmacist during a declared emergency may administer a vaccine~~ ~~t~~To a person who is at least three ~~(3)~~ years of age when;

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

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

~~(3) The pharmacy must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.~~

(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);

(4**d**) ~~The pharmacist must give~~ **Ensure** the appropriate Vaccine Information Statement (VIS) **is provided** to the patient or legal representative ~~with~~ **prior to** each dose of vaccine ~~covered by these forms. The pharmacist must ensure that the patient or legal representative is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the 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;

(~~5~~**h**) ~~The pharmacist must report~~ **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 vaccinations under their supervision are appropriately trained and qualified.

~~(6) The pharmacist may prescribe, administer or dispense immunizations, including oral vaccines, as established by written protocols approved by OHA.~~

(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.

Statutory/Other Authority: ORS 689.205, **ORS 689.645,** 433.441, 433.443 & ~~2015 OL Ch 295~~ **2023 HB 2278, 2023 HB 2486**
Statutes/Other Implemented: ORS 689.151, 689.155, 689.645 & ~~2015 OL Ch 295~~, **2023 HB 2278, 2023 HB 2486**

855-019-0290

Vaccination: Record Keeping and Reporting

~~(1)~~ A ~~p~~**P**harmacist who administers **or supervises each administration of** a vaccine to a patient must**:**

(1) ~~f~~**F**ully document the administration in the patient's permanent record.

(2) ~~A pharmacist who administers any vaccine must r~~**R**eport the following elements to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A ~~p~~**P**harmacist is not required to notify the primary health care provider.

(~~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) ~~A pharmacist who administers any vaccine will k~~**K**eep documentation of current CPR training. This documentation will be kept on site and available for inspection.

(4) ~~A pharmacist who administers any vaccine will f~~**F**ollow 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 ~~p~~**P**harmacist is recognized as a prescriber.

(6**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, 689.155 & 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, 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 2278, 2023 HB 2486
Statutes/Other Implemented: ORS 689.151, 2023 HB 2278, 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;

(~~l~~**m**) Delivery of drugs and/or devices;

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

(~~n~~**o**) Recordkeeping;

(~~o~~**p**) Patient confidentiality;

(~~p~~**q**) Continuous quality improvement;

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

(~~r~~**s**) Training: initial and ongoing; and

(~~s~~**t**) Interpretation, translation and prescription reader services.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034, **2023 HB 2278, 2023 HB 2486**
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508 & 2022 HB 4034, **2023 HB 2278, 2023 HB 2486**

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) ~~ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist~~**. 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 689.315 & **ORS 689.700** ~~2022 HB 4034~~
Statutes/Other Implemented: ORS 689.155, **ORS 689.700** & ~~2022 HB 4034~~, **2023 HB 2486**

Divisions 115/125: 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 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: 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? 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: Adds vaccine administration requirements for Pharmacists who provide or supervise the administration of a vaccine, including training, verification and documentation requirements; Permits an Intern to perform the same duties as a Pharmacist except as prohibited in OAR 855-120-0150; Permits a COPT or 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. Removes proposed rule language that is no longer necessary due to the new legislation.

OAR 855-125-0305: Adds vaccine administration requirements for COPTs or PTs, 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.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the October 2023 board meeting.

- Highlights/Markup
  - Highlights
    - Rule language highlighted in green denote rules moved within the package
    - Rule language highlighted in yellow denote staff proposed amendments to rules moved within the package.
  - **Mark~~up~~** in this package is in comparison to the Div 115 and 125 rules filed for rulemaking in June 2023.

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~~;~~.

~~(A) For vaccines, the training:~~

~~(i) May include programs 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; and~~

~~(ii) Must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.~~

~~(B)~~ For orally administered drugs, training is not required~~; and~~.

~~(C) Records of training must be retained according to OAR 855-104-0055.~~

(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, 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;

~~(a) Follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022);~~

~~(b) Have access to a current copy of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);~~

~~(c) Give the appropriate Vaccine Information Statement (VIS) to the patient or patient's agent with each dose of vaccine covered by these forms. The Pharmacist must ensure that the patient or patient's agent is available and has read, or has had read to them, the information provided and has had their questions answered prior to administering the vaccine;~~

~~(d) Report all vaccinations administered to the ALERT IIS in accordance with OAR 333-049-0050, and for COVID-19 immunizations, in accordance with OAR 333-047-1000; and~~

(~~e~~**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 vaccinations under their supervision are appropriately trained and qualified;

(m) Follow the guidance in the Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit (v. 4/12/2022); and

(n) Have access to a current edition of the CDC reference, "Epidemiology and Prevention of Vaccine-Preventable Diseases" (v. 8/2021);

~~(4) 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 clinical pharmacy agreement or collaborative drug therapy management agreement per OAR 855-115-0315; or~~

~~(c) In accordance with a written administration protocol issued by the Oregon Health Authority and approved by the board.~~

(5) The Pharmacist may administer a drug or device in conjunction with training the patient or the patient's agent how to administer or self-administer the drug or device.

(6) ~~Except as required in (2), r~~**R**ecords 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 855-120-0305.

(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.

Statutory/Other Authority: ORS 689.205, **2023 HB 2486, 2023 HB 2278**
Statutes/Other Implemented: ORS 689.655, 2**023 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, 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, 2023 HB 2278
Statutes/Other Implemented: ORS 689.151, 2023 HB 2486, 2023 HB 2278

Division 115: Clinical Pharmacy Agreement (CPA) & Collaborative Drug Therapy Management (CDTM)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Clinical Pharmacy Agreement (CPA) & Collaborative Drug Therapy Management (CDTM)

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): 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): None available.

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 rule is not expected to affect racial equity in this state.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed new rule and existing 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 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: 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? 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 855-115-0315: Adds requirements for Pharmacists who provide Clinical Pharmacy Agreement 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 and proposes repealing OAR 855-019-0260 upon the effective date of OAR 855-115-0315.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the October board meeting.

- Highlights/Markup
  - Highlights- Yellow highlight indicates change to rule package since noticed for the August 2023 board meeting.
  - **Mark**~~up~~ in this package is in comparison to current rules in Div 006 and Div 019.

Division 006
DEFINITIONS

855-006-0005
Definitions
Note: Please note that these proposed amendments are just a snapshot of the rule. See mailing #C12 for the entire rule.

(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 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: This proposed amendment is also listed in rule package #C12

(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: This proposed amendment is also listed in rule package #C12.

Statutory/Other Authority: ORS 689.205 & 2022 HB 4034
Statutes/Other Implemented: **ORS 689.005**, ORS 689.151, ORS 689.155 & 2022 HB 4034

Division 115
PHARMACISTS

~~855-019-0260~~ **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 providers 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 concerning:

(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.

~~(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~~**4**) A ~~p~~**P**harmacist ~~shall~~ **may** engage in ~~c~~**C**ollaborative ~~d~~**D**rug ~~t~~**T**herapy ~~m~~**M**anagement **under a written protocol** with a ~~practitioner~~ **health care provider who is acting within their scope.** ~~only under a written arrangement that includes:~~

(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;

(~~a~~**b**) The identification, either by name or by description, of each ~~of the~~ participating ~~p~~**P**harmacist~~s~~;

(~~b~~**c**) The identification, by name or description, of each of the participating **health care provider** ~~practitioners~~ or group of **health care providers** ~~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**d**) A detailed description of the: ~~types of diseases, drugs, or drug categories involved, and the activities allowed in each case;~~

(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;

~~(B) A detailed description of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting allowed activities;~~

(C**e**) ~~A detailed description of the activities the pharmacist is to follow including~~ ~~d~~**D**ocumentation ~~of~~ **the Pharmacist is to complete concerning** ~~decisions made~~ **actions taken** and a plan or appropriate mechanism for communication, feedback, and reporting to the ~~practitioner~~ **health care provider** concerning specific ~~decisions made~~ **actions taken**. ~~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~~**f**) Circumstances which will cause the ~~p~~**P**harmacist to initiate communication with the ~~practitioner~~ **health care provider;** ~~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~~g) Training requirement for ~~p~~**P**harmacist 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~~**6**) ~~A requirement for the collaborative drug therapy arrangement to~~ **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.

(~~3~~**8**) ~~The collaborative drug therapy arrangement and associated r~~**R**ecords **and documents** must ~~be kept on file in the pharmacy and made available to any appropriate health licensing board upon request~~ **retained according to OAR 855-104-0055.**

~~(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**,** ~~,~~ ~~&~~ **ORS** 689.155

Division 041: 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. Repeals requirements for tamper-resistant prescriptions.

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: 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? 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 a proposed rule and were able to provide information necessary to amend the rules.

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 adding PIC requirements for out of state pharmacies who dispense, deliver or distribute drugs into Oregon.

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.

OAR 855-041-1110- Repeals outdated rule that is no longer necessary.

OAR 855-041-1115 – Amends rule by 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.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the October 2023 board meeting.

- Highlights/Markup
  - Highlights- None, 1st review
  - **Mark~~up~~** in this package is in comparison to the applicable Division 041 rules.

Division 41
OPERATION OF PHARMACIES

855-041-1010
Outlet (RP & IP): Personnel

Each Drug Outlet Pharmacy must:

(1) **At all times** ~~H~~**h**ave one Pharmacist-in-~~c~~**C**harge **(PIC)** ~~employed on a regular basis at that location~~ 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** ~~shall be responsible for the daily operation of the pharmacy~~. ~~The Pharmacist-in-charge shall be indicated on the application for a new or relocated pharmacy and for pharmacy renewal registration.~~

(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.

(~~2~~**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, the date, and the reason for the termination.**

~~(3) Ensure that it is in compliance with all state and federal laws and rules governing the practice of pharmacy.~~

(4**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-~~019~~**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

NOTE: This rule is also listed in mailing #C for proposed amendments in (1)(c).

A ~~d~~**D**rug ~~o~~**O**utlet ~~p~~**P**harmacy must:

(1) Ensure each:

(a) Prescription is dispensed in compliance with OAR 855-~~019~~**115**, **OAR 855-120,** OAR 855-~~025~~**125**, ~~OAR 855-031 and~~ OAR 855-041 **and 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.

(~~4~~**6**) ~~Ensure~~ **Establish, maintain and** enforce the drug outlet written procedures **required in OAR 855-041-1040** ~~for use of Certified Oregon Pharmacy Technicians or Pharmacy Technicians as required by OAR 855-025-0035;~~

(~~5~~**7**) Comply with the Pharmacist's determination in OAR ~~855-019-0200(4)(e)~~ **855-115-0120(1)(k);**

(~~6~~**8**) Develop, implement and enforce a continuous quality improvement program for dispensing services from a ~~d~~**D**rug ~~o~~**O**utlet ~~p~~**P**harmacy 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 & 2022 HB 4034

Statutes/Other Implemented: ORS 689.151, 2022 HB 4034, ORS 689.508 & 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

~~Non-Resident~~ **Out-of-State** Pharmacies

(1) ~~For the purpose of these rules, a~~ **An "**~~non-resident~~ **out-of-state** pharmacy**"** is any establishment located out**side** of Oregon that engages in the dispensing, delivery or distribution of drugs **in**to Oregon. ~~A non-resident pharmacy also includes entities that provide pharmacy services to Oregon, such as drugless/consulting outlets, even if the entity is not dispensing, delivering or distributing drugs into Oregon.~~

(2) Every ~~non-resident~~ **out-of-state** pharmacy that provides drugs, devices or services to a ~~resident~~ **person** in ~~this state~~ **Oregon** must be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every ~~non-resident~~ **out-of-state** pharmacy must be registered ~~and in good standing~~ with the Board of Pharmacy in the ~~pharmacy's~~ state **where the pharmacy is physically located** ~~of residence~~.

(4) Every out-of-state ~~non-resident~~ pharmacy must ~~designate an~~ **have, at all times when dispensing, delivering or distributing drugs into Oregon, an** Oregon licensed ~~Pharmacist-in-Charge (~~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** ~~must be~~ **and is** responsible for **ensuring compliance with all applicable Oregon laws and rules when dispensing, delivering or distributing drugs into Oregon** ~~all pharmacy services provided to residents in Oregon, and to provide supervision and control in the pharmacy~~. To qualify for this designation, the ~~person~~ **individual** must:

(a) Hold a license to practice pharmacy in the ~~resident~~ state **where the pharmacy is physically located**;

(b) **Comply with the PIC qualifications and limitations in OAR 855-115-0205** ~~Be normally present in the pharmacy for a minimum of 20 hours per week~~; **and**

(c) **Comply with the PIC requirements in OAR 855-115-0210(1)(a-h) and (2).** ~~Annually complete a self-inspection form using the board's Non-Resident Retail Drug Outlet Self-Inspection Form prior to July 1; and~~

~~(d) Provide the PIC Self-Inspection Form as requested by the board.~~

~~(5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within four months of initial licensure of the pharmacy.~~

~~(6) When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the board within ten business days and identify a contact person. The pharmacy will have an Oregon licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the pharmacy's state of residence and is responsible for the following:~~

~~(a) Supervision of pharmacy staff and ensuring compliance with laws and rules; and~~

~~(b) Responding to board correspondence and inquiries.~~

(~~7~~**5**) A**n** ~~new Pharmacist-in-Charge must be appointed, and communication made to the board within 90 days, or the non-resident~~ **out-of-state** pharmacy ~~will~~ **must** cease drug **dispensing, delivery,** distribution and provision of pharmacy services in**to** 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.

POLICY DISCUSSION: Resident vs. non-resident practice of pharmacy

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.225

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

Each Drug Outlet Pharmacy must ensure that:

(1) Prescriptions, prescription refills, and drug orders **are** ~~must be correctly~~ 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) ~~i~~**I**n accordance with the prescribing practitioner's authorization**.** ~~When a prescription is transmitted orally, both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.~~

(2) ~~Each pharmacy must document t~~**T**he following information **is required for each new or refilled prescription drug or device**:

(a) The name ~~of the patient~~ **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,** ~~or~~ **name of** the owner ~~of the animal~~ and the species of the animal ~~for which, the drug is dispensed~~;

(b) The full name**, address, and contact phone number** and, in the case of controlled substances, the address and the Drug Enforcement Administration registration number of the practitioner ~~or other number as authorized under rules adopted by reference under rule OAR 855-080-0085~~;

(c) The name, strength, dosage form~~s~~ of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

(d) The directions for use~~, if given by the practitioner~~; ~~and~~

(e) The date of **issuance and, if different from the date of issuance, the date of** filling~~, and~~

(f) ~~t~~**T**he 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.

(iv) In (i) and (ii), manually-signed specifically excludes a signature stamp or any form of digital signature unless permitted under federal regulations; and

(h) Any other information required for controlled substances pursuant to federal regulations.

~~855-019-0210~~
~~Duties of the Pharmacist Receiving a Prescription~~

(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) ~~For Oral Prescription: Upon receipt of a~~**A**n oral prescription, ~~the Pharmacist must~~ **must:**

(a) Be promptly reduce**d** ~~the oral prescription~~ to writing or ~~create a permanent~~ entered into an electronic record **system and must include:** ~~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 080 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~~**A**) The ~~written signature~~ **name,** ~~or~~ initials or electronic identifier of the **licensee** receiving ~~Pharmacist or Intern~~ **the prescription;** ~~and~~

(B) ~~t~~**T**he ~~identity~~ **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.

POLICY DISCUSSION: Confirmation of accuracy

~~(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 080 of this chapter of rules.~~

(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.

(~~3~~**7**) In accordance with ORS 689.515(3) **and ORS 689.522**, the **pharmacy dispenses the prescription pursuant to the** ~~a~~ **prescribing** practitioner**'s request** ~~may specify in writing, by a telephonic communication or by electronic transmission~~ that there may be no substitution for the specified brand name **or manufacturer of a** drug ~~in a prescription~~.

(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 ~~shall~~ **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 ~~shall~~ **must** not be default values on the prescription.

(~~i~~**7**) The written or electronic record of ~~the oral~~ **each** prescription must be retained on file as required by ~~Division 41 of this chapter of rules~~ **OAR 855-041-1160**, and in the case of controlled substances, under rules adopted by reference in ~~Division~~ **OAR 855-**080 ~~of this chapter of rules~~.

~~(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:~~
~~(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;~~

~~(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;~~

~~(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;~~

~~(d) The pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three (3) business days of dispensing the biosimilar product; and~~

~~(e) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three~~

~~(3) years.~~

~~(5) Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.~~

Statutory/Other Authority: ORS 689.205 & ~~2013 OL Ch. 342~~, **ORS 689.522**
Statutes/Other Implemented: ORS 689.505, 689.515 & ~~2013 OL Ch. 342~~, **ORS 689.522**

~~855-041-1110~~
~~Tamper-resistant Prescription~~

~~When the use of a tamper-resistant prescription is required by any federal or state law or rule, the term "tamper-resistant" shall have the meaning as defined in OAR 855-006-0015.~~

~~Statutory/Other Authority: 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

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, but 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; ~~Alteration of a written prescription, other than by a pharmacist's or practitioner's authorization, in any manner constitutes an invalid order unless verified with the prescriber.~~

(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 49.35 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
~~Transfer of~~ Prescription**: Transfers** ~~Information Between Pharmacies~~

(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 by federal regulation**.

~~(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.~~

~~855-019-0210~~
~~Duties of the Pharmacist Receiving a Prescription~~

(5**4**) ~~Computer Transfer of Prescription Information between Pharmacies:~~ A pharmac**y**~~ist~~ 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.** ~~Compliance with all relevant state and federal laws and rules regarding the transfer of controlled substance prescriptions.~~

(4**5**) 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: 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 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.

NOTES:

- History of rule package review
  - The board will complete a 1st review of these rules at the October board meeting.

- Highlights/Markup
  - Highlights- None, 1st review
  - **Mark~~up~~** in this package is in comparison to current rules in Div 080.

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;

(F) Prescriber's address; and

(G) 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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.185 & ORS 475.188

Division 115: Pharmacists (Pharmacist-in-Charge (PIC) Qualifications and Limitations)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Modifies Pharmacist-in-Charge qualifications and limitations

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): 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.

Documents Relied Upon per ORS 183.335(2)(b)(D): OAR 855-115-0200, effective 3/1/2024 (pg. 21)

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 Oregon Board of Pharmacy PIC training course is currently held virtually via Teams approximately once per month. Licensees can sign up for the course online and must complete all 3 parts of the course to earn a PIC training course certificate. The certificate provides the participant with three hours of Oregon CPE credit in law (1hr), patient safety (1hr) and other (1hr). The CPE credit is not ACPE accredited. There is no charge for the PIC training course.

- Part 1: Attend/watch the live course presentation (virtual / live) - Approximately 2.5 hours
- Part 2: Participate in a live Q/A session (virtual / live) - Approximately 15 minutes
- Part 3: Complete and pass a quiz on the presentation (virtual / anytime) - Approximately 15 minutes

On 5/24/2023, board staff sent out a fiscal impact request email notification via GovDelivery to 11,869 licensee subscribers and 3,743 rulemaking notice/adopted rule subscribers requesting estimated fiscal impacts associated with compliance, implementation, and operational costs associated with the proposed rules for OAR 855-115 as written in May 2023. Licensees, registrants and stakeholders had an additional opportunity to provide public comment including fiscal impact estimates when the proposed rules were noticed for rulemaking hearing on 6/16/2023. The fiscal impacts received pursuant to this request were included in the original rulemaking for OAR 855-115-0200.

If the board decides to send the proposed rules to rulemaking hearing, licensees, registrants and stakeholders will have additional opportunities to provide new fiscal and economic impact statements on the modified proposed rule as written in October 2023.

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 these registrants identify as a small businesses.
(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.
(c) The rulemaking requires 3 hours of Pharmacist labor (~$100/hour including OPE) every 5 years (total $500 every 5 years) and access to a computer with audio/visual capabilities to complete the course.

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? 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 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 855-115-0200: Propose repealing the rule because it does not include requirements for a PIC between the effective date of the rule, 3/1/2024, and 7/1/2025 and it does not include limitations for a PIC. The board is unable to amend this rule since it is currently not effective.

OAR 855-115-0205: Proposed new rule adds PIC qualifications and limitations currently in place 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 outlet.

- History of rule package review
    - June 2022- The board completed a 1st review the licensing rules (OAR 855-115-0001 to 855-115-0070).
    - August 2022- The board completed a 2nd review of the 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 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 (OAR 855-115-0070 to 855-115-0086).
        - Board sent proposed rules to November 2022 rulemaking seeking ~~for~~ 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 licensing (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 a Workgroup for OAR 855-115-0120. Workgroup was held May 2023.
  - April 2023- The board completed a 3rd review of associated definitions (OAR 855-006-0005), a 5th review of 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 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 also revised OAR 855-115-0001, OAR 855-115-0005, OAR 855-115-0145.
    - Board sent OAR 855-115-0001, OAR 855-115-0005, OAR 855-115-0145 to September 2023 rulemaking
  - October 2023- The board will complete a 6th review of rules related to Pharmacist-in-Charge (PIC) currently located in OAR 855-115-0200.
- Highlights/Markup
  - Highlights- None, 1st review.
  - **Mark**~~up~~ in this package is in comparison to current rules in Div 019. ***Italics/Bold-*** Indicates language that is currently in rule OAR 855-115-0200 effective 3/1/2024

DIVISION 115
PHARMACISTS

~~855-115-0200~~
~~Pharmacist-in-Charge: Qualifications and Limitations~~

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

~~(1) 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.~~

~~(2) Complete a board-provided PIC training course at least every five years.~~

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

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

~~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~~**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 ~~approved~~ **provided** PIC training course either before the appointment or within ~~30~~ **90** days after the appointment~~. With the approval of the board, this course may be employer provided and may qualify for continuing education credit.~~**; and**

(c) Be employed by the outlet.

(~~3~~**2**) 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.~~ **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~~ do not count toward this limit~~.

(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:

(i) 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.

(ii) 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:

(i) Pharmacy Prescription Kiosk in OAR 855-141; and

(ii) Pharmacy Prescription Locker in OAR 855-143.

~~(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

Division 115: Pharmacists (Supervision)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Ratios for Supervision of Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): 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.

Documents Relied Upon per ORS 183.335(2)(b)(D): OAR 855-120-1122 Responsibilities: Supervision – Preceptor, effective 3/1/2024.

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): 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. The fiscal and economic impact of the proposed rule is to be determined. When the board sends the proposed rule to 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 will have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule applies to licensees/registrants of the Oregon Board of Pharmacy. Approximately 30% of these registrants identify as small businesses.

(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. Why? The board did not direct staff to convene a Rules Advisory Committee or Workgroup to advise on the proposed rules. 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 855-115-0122: New rule that applies to all Pharmacists and aligns with OAR 855-120-1122 Responsibilities: Supervision- Preceptor to permit a Pharmacist to supervise up to four Interns for direct patient care activities and supervise a suitable number for non-direct care activities. Adds rule that there is no ratio for supervision, direction and control of a COPT/PT.

- History of rule package review
  - The board will complete a 1st review of this rule at the October 2023 board meeting.

- Highlights/Markup
  - Highlights- None, 1st review
  - **Mark~~up~~** – None, new rule

DIVISION 115
PHARMACISTS

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

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. When the board sends the proposed rule 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 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. Approximately30 % 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: When 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? 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.

- History of rule package review
  - June 2022- The board completed a 1st review
  - August 2022- The board completed a 2nd review
  - October 2022- Board sent rules to November 2022 rulemaking seeking public comment only
  - February 2023- The board completed a 3rd review
  - April 2023- The board completed a 4th review
  - June 2023- The board completed a 5th review
    - Board sent rules to July 2023 rulemaking
  - August 2023- Board adopted proposed rules OAR 855-125-0001, OAR 855-125-0005, OAR 855-125-0010, OAR 855-125-0030, OAR 855-125-0035, OAR 855-125-0040, OAR 855-125-0050, OAR 855-125-0105, OAR 855-125-0110, OAR 855-125-0115 and OAR 855-125-0135.
  - Board sent 855-125-0150 to September 2023 rulemaking
  - October 2023- The board will complete a 6th review of OAR 855-125-015

- Highlights/Markup
  - Highlights- Rule language highlighted in yellow denotes staff proposed modifications to the rule since the rule was sent to the September 2023 rulemaking hearing.
  - **Mark~~up~~** in this package is in comparison to the Div 115 rules filed for rulemaking in August 2023.

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 a new or provide transferred prescription for a controlled substance orally;

(n) Supervise, direct, or control another licensee in the licensee practicing 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 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 855-019-0001 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 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 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 **s**ends 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 will complete a 7th review of OAR 855-115-0001.

- Highlights/Markup
  - Highlights- Rule language highlighted in yellow denotes staff proposed modifications to the rule since the rule was sent to the September rulemaking hearing.
  - **Mark~~up~~** in this package is in comparison to the Div 115 rules filed for rulemaking in August 2023.

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

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 (v. 10/2023)
Hepatitis B (v. 10/2023)
Human Papillomavirus (v. 10/2023)
Influenza (IIV RIV 2023-24) (v.10/2023)
Influenza (LAIV 2023-24) (v.10/2023)
Japanese Encephalitis (v. 10/2023)
Measles, Mumps & Rubella (v. 10/2023)
Meningococcal (v. 10/2023)
Pneumococcal (v. 10/2023)
Polio (v. 10/2023)
Rabies (v. 10/2023)
Respiratory Syncytial Virus (RSV) (v. 10/2023)
Tetanus, Diphtheria (Td/Tdap) (v. 10/2023)
Typhoid (v. 10/2023)
Varicella (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. If the board sends the proposed rule 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 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: 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? Subject Matter Experts (SME) are responsible for drafting proposed protocols and then the Public Health and Pharmacy Formulary Advisory Committee is responsible for recommending changes to the drafts or recommending the proposed protocols are sent to the board for consideration.

Rules 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.

- History of rule package review
  - The board will complete a 1st review of these rules at the October 2023 board meeting.

- Highlights/Markup
  - Highlights- None, 1st review
  - **Mark**~~up~~ – None, new rule

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, ~~NRT (~~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: 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

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)
- 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. N/A

2. Immunization Protocol

A. Administer a dose of updated 2023–2024 Pfizer or Moderna Coronavirus 19 (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.[1-4] Novavax monovalent vaccine may be used as a first booster in an adult patient only if an FDA-authorized mRNA bivalent booster is not accessible or clinically appropriate, or the patient elects to receive the Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine.[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 years of age who has received at least 1 dose of updated 2023–2024 COVID-19 vaccine is currently up-to-date.[6]

B. Any immunocompetent unvaccinated person ≥7 years of age may be brought up-to-date with a single dose of updated 2023–2024 COVID-19 vaccine.[6]

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

Preferred Vaccines

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

*Not withstanding 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.

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

Children 3-4 years previously vaccinated with Moderna COVID-19 vaccine, any formulation[2] ***For Informational Purposes Only- 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) ***For Informational Purposes Only- 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 ***For Informational Purposes Only- 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.

Alternate vaccine not preferred.

NOVAVAX[5]

Novavax, adjuvanted vaccine Dose and Route –0.5-mL, 5 mcg, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥12 years	
2		21 days
Booster*	≥18 years	6 months

*For use only in individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, or in individuals 18 years of age and older who elect to receive a Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine. This dose is not authorized to follow any prior booster dose.[7]

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Cap/Label Color**
Preferred Vaccines				
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
Non_Preferred Vaccines				
NVX-CoV2373[3] (NOVAVAX®)[5]	Protein subunit	2.5 mL, 5-dose vial	≥ 12 years ≥ 18 years (booster)	Royal Blue Cap

5. Recommendations for Use[1-7]

A. An updated, 2023–24 mRNA COVID-19 vaccine dose should be offered to all persons aged ≥ 7 years. For adults and children ≥12 years of age, a 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. Though not preferred, Novavax vaccine is currently approved as a two-dose primary series and as a first booster dose in certain circumstances, regardless of immunocompetency status. Persons who complete the Novavax series may receive a 2023-24 mRNA dose at least 2 months after their final dose of Novavax. Alternatively, Novavax may be administered as a first booster dose 6 months after completion of a primary series for individuals 18 and older for whom an FDA-authorized mRNA 2023–2024 vaccine is not accessible or clinically appropriate, or who elect to receive the Novavax COVID-19 vaccine because they would otherwise not receive an mRNA COVID-19 vaccine. A Novavax booster dose is not authorized to follow any prior booster dose.[5]

E. 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]

F. 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]

G. Persons with immune compromise may self-attest to the need for additional doses. No other documentation is necessary.

H. 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®)[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 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 be any 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%

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

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 6 hours. Discard the vial 6 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.
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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, May 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

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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

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3. TWINRIX® [Package insert]. April 2023. Available at: https://www.fda.gov/media/119351/download. Accessed 11 July 2023.
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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

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2. Heplisav-B®. [Package insert]. May 2023. Available at: www.fda.gov/media/108745/download. 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]

Protocol for Human Papillomavirus Vaccine (Gardasil® 9)

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

1. Merck and Company, HPV 9 (Gardasil ®9) 2014 package insert. Available at: https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Package-Insert--Gardasil.pdf. Accessed 5 June 2023.
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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

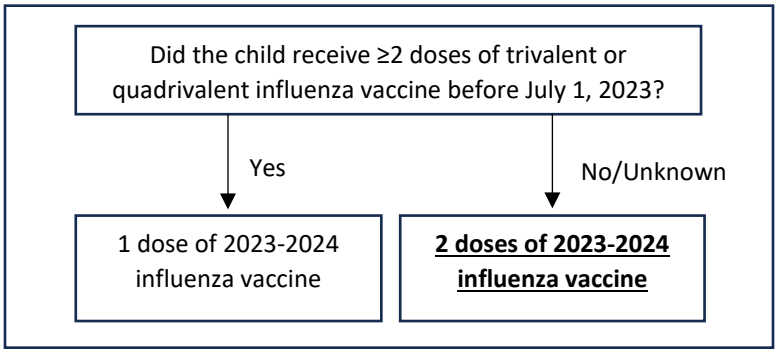
4. Licensed Vaccines

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

1. Afluria® 2023–2024. [Package insert]. Available at: www.fda.gov/media/117022/download. Accessed 14 Jul 2023
2. Fluarix® Quadrivalent 2023–2024. [Package insert]. Available at: www.fda.gov/media/79278/download. Accessed 14 Jul 2023.
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.
5. Fluzone® Quadrivalent 2023–2024. [Package insert]. Available at: https://www.fda.gov/media/170019/download. Accessed 14 Jul 2023.
6. Flublok® RIV4 2023–2024. [Package insert]. Available at: www.fda.gov/media/123144/download. Accessed 14 Jul 2023.
7. Flucelvax® IIV4 2023–2024. [Package insert]. Available at: www.fda.gov/media/115862/download. Accessed 14 Jul 2023.
8. Fluad® Quadrivalent 2023-2024. [Package insert]. Available at: www.fda.gov/media/135432/download. Accessed 14 Jul 2023.
9. World Health Organization. Recommended composition of influenza virus vaccines for use in the 2023–2024 northern hemisphere influenza season. Available at: www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2023-2024-northern-hemisphere-influenza-season. Accessed 14 Jul 2023.
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13. Rubin LG, Levin MJ, Ljungman P, et al. 2013 IDSA Clinical practice guideline for vaccination of the immunocompromised host. Clin Infect Dis 2014; 58:e44– 100. Available at: https://academic.oup.com/cid/article/58/3/e44/336537. Accessed 23 Jul 2023.

CDC. Vaccine Excipient Summary. November 2021. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf. Accessed 23 July 2023.

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

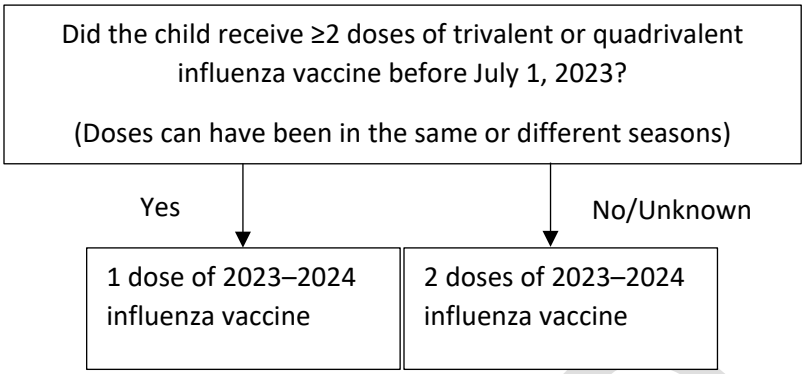
Product Name	Presentation	FDA Approved Age Range	Thimerosal
FluMist® Quadrivalent[1]	0.2 mL pre-filled intranasal sprayer	2-49 years	None

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.

Protocol for Live Attenuated Influenza Vaccine
(FluMist® Quadrivalent)



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

1. FluMist® Quadrivalent 2023–2024. [Package insert]. Available at https://www.fda.gov/media/160349/download. Accessed 21 July 2023.
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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 <u>recommended</u> 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 <u>considered</u> 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.

11. References

1. IXIARO® (2018) package insert, available at: www.fda.gov/media/75777/download. Accessed 12 April 2023.
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.
3. CDC. Japanese Encephalitis Vaccine: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2019; 68(RR-2): 1–33. Available at: www.cdc.gov/mmwr/volumes/68/rr/pdfs/rr6802a1-H.pdf. Accessed 12 April 2023.

4. Kroger AT, Bahta L, Long S, Sanchez 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/index.html. Accessed 12 April 2023.

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]

Protocol for Measles, Mumps and Rubella Containing Vaccines (M-M-R®II, PRIORIX™ and ProQuad®)

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

1. M-M-R®II package insert (March 2023). Available at https:/www.fda.gov/media/75191/download. Accessed 12 June 2023.
2. ProQuad® package insert (February 2023). Available at https://www.fda.gov/media/147563/download. Accessed 12 June 2023.
3. PRIORIX™ package insert (June 2022). Available at https://www.fda.gov/media/158941/download. Accessed 12 June 2023.
4. McLean H, Fiebelkorn A, Temte J, Wallace G. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013 summary: recommendations of the ACIP. MMWR 2013; 62(RR04):1–34. Available at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6204a1.htm. Accessed 12 June 2023.
5. Krow-Lucal E, Marin M, Shepersky L, Bahta L, Loehr J, Dooling K. Measles, mumps, rubella vaccine (PRIORIX™): Recommendations of the Advisory Committee on Immunization Practices—United States, 2022. MMWR 2022;71:1465–70. Available at http://dx.doi.org/10.15585/mmwr.mm7146a1. Accessed 12 June 2023.
6. CDC. 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.
7. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP), updated February 10, 2023. Available at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html. Accessed 12 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 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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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	

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12. Appendix

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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.	

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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.
2. RabAvert®. Package insert. Philadelphia, PA: GlaxoSmithKline; Updated 2018. https://www.fda.gov/media/83874/download. Accessed 13 April 2023.
3. Use of a Modified Preexposure Prophylaxis Vaccination Schedule to Prevent Human Rabies: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. MMWR 2022;71(18) 619-627. Available at: https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7118a2-H.pdf. Accessed 13 April 2023.
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5. Human Rabies Prevention—United States, 2008. MMWR 2008; 57(03). Available at: https://www.cdc.gov/mmwr/PDF/rr/rr5703.pdf. Accessed 13 April 2023.

12. Appendix

A. N/A

Protocol for Respiratory Syncytial Virus Vaccine (ABRYSVO™, AREXVY™)

1. What's New

A. N/A

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	

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]

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 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.

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]

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.

8. Other Considerations[1,2]

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.

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%
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.

11. References

1. Abrysvo™. [Package insert]. May 2023. https://www.fda.gov/media/168889/download. Accessed 13 August 2023.
2. Arexvy™. [Package insert]. May 2023. https://www.fda.gov/media/167805/download. Accessed 13 August 2023.
3. Melgar M, Britton A, Roper LE, et. al. Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR 2023; 72: 793-801. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm. Accessed 13 August 2023.

12. Appendix

A. Centers for Disease Control and Prevention. Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2023. Available from: https://www.cdc.gov/vaccines/vpd/rsv/downloads/provider-job-aid-for-older-adults-508.pdf

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.

11. References

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4. Boostrix®. [Package insert]. June 2023. https://www.fda.gov/media/124002/download. Accessed 23 July 2023.
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8. 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). 20 June 2023. Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed 23 July 2023.

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)		

11. References

1. Typhoid Vi Polysaccharide Vaccine (Typhim Vi®) package insert 2020. Available at: www.fda.gov/media/75993/download. Accessed 13 April 2023.
2. Typhoid Vaccine Live Oral Ty21a (Vivotif®) package insert 2013. Available at: www.fda.gov/media/75988/download. Accessed 13 April 2023.
3. CDC. Updated recommendations for the use of Typhoid Vaccine – Advisory Committee on Immunization Practices, United States, 2015. MMWR 2015; 64:305–8. Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a4.htm. Accessed 13 April 2023.
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7. Collins J, Ryan E, Wong K, et al. Cholera Vaccine: Recommendations of the Advisory Committee on Immunization Practices, 2022. Available at: https://www.cdc.gov/mmwr/volumes/71/rr/rr7102a1.htm. Accessed 13 April 2023.

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

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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.

Protocol for Yellow Fever Vaccine
(YF-VAX®)

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

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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 115: Pharmacists (Protocol Compendium-Vaccines)

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

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

Board staff met with Oregon Immunization Program (OIP) staff in September 2021 to discuss moving the pharmacy immunization protocols from the Oregon Health Authority (OHA) to the Public Health and Pharmacy Formulary Committee (PHPFAC) pursuant to ORS 689.645(1)(b). The OIP protocols are a standard that the OBOP needs to adopt by reference in our rules. Under this construct, OIP serves as one of the Subject Matter Experts (SME) and continues to assist in authoring/revising the immunization protocols. Other Pharmacist SMEs are also involved in authoring/revising the protocols. Protocols are then reviewed by the OBOP's Public Health and Pharmacy Formulary Committee (PHPFAC) pursuant to ORS 689.645(1)(b), and referred to the Board to adopt by reference. This process is consistent with all of the other statewide protocols referred to the board by the PHPFAC.

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): OAR 855-115-0345 was adopted by the board in August 2023, to be effective 3/1/2024. Due to Oregon Administrative Rules Database (OARD)filing limitations, the board is unable to amend OAR 855-115-0345 until on/after 3/1/2024. A temporary rule filed and effective 3/1/2024 will permit the protocols to be effective on the same date as the rule becomes effective ensuring there is not a gap in the Pharmacists ability to provide vaccines to the public. Failure to implement immunization protocols in OAR 855-115-0345 may result in compromised patient access and care, posing a significant risk to public health by leaving individuals vulnerable to preventable diseases and potentially overwhelming other healthcare providers. The board will consider permanent adoption during the April 2024 board meeting.

Documents Relied Upon per ORS 183.335(2)(b)(D):
Standard Protocol for All Vaccines: Cover Page & Assessment and Treatment Care Pathway
Standard Protocol for All Vaccines: Managing Adverse Reactions
Cholera
Coronavirus 19
Haemophilus influenzae type b
Hepatitis A
Hepatitis B
Human Papillomavirus
Influenza (IIV RIV 2023-24)
Influenza (LAIV 2023-24)
Japanese Encephalitis
Measles, Mumps & Rubella
Meningococcal
Pneumococcal
Polio
Rabies
Respiratory Syncytial Virus (RSV)

Tetanus, Diphtheria (Td/Tdap)
Typhoid
Varicella
Yellow Fever
Zoster

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):
OAR 855-115-0345: Proposed amendments add vaccine protocols to the compendium.

- History of rule package review
  - The board will complete a 1st review of these rules at the October board meeting.

- Highlights/Markup
  - Highlights- None, 1st review
  - **Mark~~up~~** – None, new rule

Division 115
PHARMACISTS

855-115-0345
Services: Prescribing – 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, ~~NRT (~~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) 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) Measles Mumps & Rubella containing vaccines (v. 2/2024);

(M) Meningococcal 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: 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

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 855-115-0330 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 Events when applicable

PHARMACIST TRAINING/EDUCATION:

- The Pharmacist has completed a course of training as outlined in OAR 855-115-0305.
- The Pharmacist maintains active CPR certification as outlined in OAR 855-115-0305.

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)
- 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 855-115-0330 a pharmacist licensed and located in Oregon may prescribe and administer medications used in the acute management of severe adverse events 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 855-115-0305
- The Pharmacist maintains active CPR certification as outlined in OAR 855-115-0305

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)

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 855-104-0055
- 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

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

1. What's New

A. N/A

2. Immunization Protocol

A. Administer a dose of updated 2023–2024 Pfizer or Moderna Coronavirus 19 (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.[1-4] Novavax monovalent vaccine may be used as a first booster in an adult patient only if an FDA-authorized mRNA bivalent booster is not accessible or clinically appropriate, or the patient elects to receive the Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine.[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 years of age who has received at least 1 dose of updated 2023–2024 COVID-19 vaccine is currently up-to-date.[6]

B. Any immunocompetent unvaccinated person ≥7 years of age may be brought up-to-date with a single dose of updated 2023–2024 COVID-19 vaccine.[6]

C. The PREP Act currently allows pharmacists to administer COVID-19 vaccines to persons aged 3-18 years old until 12/31/24.[2] Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.

Preferred Vaccines

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 855-115-0305.***		
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

*Not withstanding 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 855-115-0305.***		
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 855-115-0305.***		
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 855-115-0305.**		
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.

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

Children 3-4 years previously vaccinated with Moderna COVID-19 vaccine, any formulation[2] ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.***		
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) ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.***		
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 ***For Informational Purposes Only- Pharmacists are only permitted to vaccinate patients ≥ 7 years per OAR 855-115-0305.***		
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.

Alternate vaccine not preferred.

NOVAVAX[5]

Novavax, adjuvanted vaccine Dose and Route –0.5-mL, 5 mcg, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥12 years	
2		21 days
Booster*	≥18 years	6 months

*For use only in individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, or in individuals 18 years of age and older who elect to receive a Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine. This dose is not authorized to follow any prior booster dose.[7]

4. Licensed Vaccines

Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Cap/Label Color**
Preferred Vaccines				
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
Non_Preferred Vaccines				
NVX-CoV2373[3] (NOVAVAX®)[5]	Protein subunit	2.5 mL, 5-dose vial	≥ 12 years ≥ 18 years (booster)	Royal Blue Cap

5. Recommendations for Use[1-7]

A. An updated, 2023–24 mRNA COVID-19 vaccine dose should be offered to all persons aged ≥ 7 years. For adults and children ≥12 years of age, a 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. Though not preferred, Novavax vaccine is currently approved as a two-dose primary series and as a first booster dose in certain circumstances, regardless of immunocompetency status. Persons who complete the Novavax series may receive a 2023-24 mRNA dose at least 2 months after their final dose of Novavax. Alternatively, Novavax may be administered as a first booster dose 6 months after completion of a primary series for individuals 18 and older for whom an FDA-authorized mRNA 2023–2024 vaccine is not accessible or clinically appropriate, or who elect to receive the Novavax COVID-19 vaccine because they would otherwise not receive an mRNA COVID-19 vaccine. A Novavax booster dose is not authorized to follow any prior booster dose.[5]

E. 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]

F. 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]

G. Persons with immune compromise may self-attest to the need for additional doses. No other documentation is necessary.

H. 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®)[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 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 be any 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%

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

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 6 hours. Discard the vial 6 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.
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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, May 2023: https://www.cdc.gov/vaccines/covid-19/downloads/covid-19-immunization-schedule-ages-6months-older.pdf

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. Proposes repeal OAR 855-006-0015 including definitions for Electronically Transmitted Prescription (ETP) and Tamper Resistant Prescription from OAR 855-006-0015.

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 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.

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. ETP and Tamper Resistant Prescription rules are existing rules being relocated from and older rule but should be incorporated with other existing Definitions in OAR 855-006-0005.

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 proposed in OAR 855-115-0005 effective 3/1/2024 which currently went to rulemaking hearing on 9/27/2023 *see mailing #B4. 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 3/1/2024, and renumbers existing rules.

OAR 855-006-0015: To ensure clarity for licensees and registrants, repeals definitions for Electronically Transmitted Prescription and Tamper resistant Prescription from OAR 855-006-0015.

- History of rule package review
  - The board will complete a 1st review of these rules at the October 2023 board meeting.

- Highlights/Markup
  - Highlights- Yellow highlight indicates definitions with proposed changes, 1st 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.~~

(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 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: This proposed amendment is also listed in rule package #C3

(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: This proposed amendment is also listed in rule package #C3

(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.~~

Note: This proposed amendment is also listed in rule package #C

(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.

(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.
Note: Definition proposed in mailing #B4 in OAR 855-115-0005 to be effective 3/1/2024. Remove from this mailing if not adopted in #B4.

(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.

(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.
Note: Definition proposed in mailing #B4 in OAR 855-115-0005 to be effective 3/1/2024. Remove from this mailing if not adopted in #B4.

(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.

(21**3**) “Health care interpreter” has the meaning given that term in ORS 413.550.

(22**4**) “Health care interpreter registry” means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.

(23**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.

(24~~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).

(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.
Note: Definition adopted in OAR 855-120-0005 effective 3/1/2024.

(25~~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.

(26~~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.

(30~~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.

(31~~4~~) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(32~~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.

~~(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.~~

~~(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.

(4~~4~~**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.

~~(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.

(5~~5~~**4**) "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.

(5~~6~~**5**) "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~~

SBAR: 8/15/2023 FPGEC Waiver

S	**Situation: The Board received a request for a waiver of the FPGEC Certification requirements based on ORS 689.255.** **Individual is a pharmacist licensed by the Syndicate of Pharmacist in Egypt who obtained a Bachelor of Science degree in pharmacy from Modern Science & Arts University in Egypt on 7/30/2019. Individual holds dual BSc degrees – Pharmacy from Egypt and Pharmaceutical Sciences from the UK.** **Individual is requesting a waiver of the TOEFL & FPGEC qualifications for licensure.**
B	Individual graduated from the Modern Science and Arts University in Egypt with a BS in Pharmacy – 7/30/2019 • Graduated with a dual degree from the University of Greenwich in Pharmaceutical Sciences on 7/30/2019 • Provided Certificate from the Syndicate of Pharmacist, Cairo Egypt verifying a license to practice pharmacy since 8/17/2020 • Provided copy of US VISA authorizing employment, dated 7/29/2023 • Provided course by course analysis from World Education Services • Has not taken the TOEFL (Test of English as a Foreign Language) • Is not licensed in any US State or Territory
A	**Assessment:** • NABP requires FPGEC Certification to ensure foreign applicants are thoroughly reviewed. NABP strongly recommends that Member Boards follow their guidelines and require FPGEC Certification. • ORS 689.255 allows the Board to consider the qualifications of any person who has received a professional degree from a school or college of pharmacy located outside the US which has not been approved by the Board. • Effective 3/1/2024, the rules do not allow for a waiver of the FPGEC Certification unless they have attended one of the two pharmacy degree programs listed below: a) A Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program located in Canada or its jurisdiction with a curriculum taught in English and who graduated between 1993 and June 30, 2004. b) The ACPE-accredited program at the Lebanese American University in Byblos, Lebanon with a Doctor of Pharmacy degree and graduated after 2002. • If the Board were to issue a waiver of FPGEC Certification, the individual would likely not be able to obtain the required 1440 pharmacy practice hours, take and pass the NAPLEX and Oregon MPJE, and obtain licensure by 2/29/2024 to be licensed under current rules which would allow a waiver of FPGEC certification.
R	**Recommendation:** *Board Discussion*

Related <u>OAR(s):</u>

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.

Related Rules effective 3/1/2024 –

855-115-0010 Licensure: Qualifications – General

(1) Before licensure as a Pharmacist, an applicant must meet the qualifications required that are applicable to their method of licensure:
   (a) Examination or Score Transfer in OAR 855-115-0020; or
   (b) Reciprocity in OAR 855-115-0025.

(2) If residing in the United States, proof of citizenship, legal permanent residency or qualifying visa, as required by 8 USC 1621.

(3) Foreign pharmacy graduates must also meet the requirements of OAR 855-115-0015 prior to applying for a Pharmacist license.

855-115-0015 Licensure: Qualifications - Foreign Pharmacy Graduate Education

(1) An applicant for pharmacist licensure who graduated from a foreign school, college, or program of pharmacy must meet the following educational requirements:
(a) Obtain certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC); and
(b) Submit evidence of 1440 hours in pharmacy practice as an intern or pharmacist in the United States or its jurisdiction.

(2) (1)(a) is not required for graduates of:
   (a) A Canadian Council for Accreditation of Pharmacy Programs (CCAPP) accredited pharmacy program located in Canada or its jurisdiction with a curriculum taught in English and who graduated between 1993 and June 30, 2004.
   (b) The ACPE-accredited program at the Lebanese American University in Byblos, Lebanon with a Doctor of Pharmacy degree and graduated after 2002.

(3) If (1)(a) is required, an applicant must not count internship hours or practice as a pharmacist towards the requirement in (1)(b) that was completed before achieving the FPGEC certification.

(4) Once the educational qualifications in this rule are met, an applicant must also comply with the requirements for licensure in OAR 855-115-0020 for examination or score transfer or OAR 855-115-0025 for reciprocity.

855-115-0020 Licensure: Qualifications - Examination or Score Transfer

1) To receive licensure as a Pharmacist by examination or score transfer, an applicant must meet the following requirements:

(a) Provide evidence in the form of an official transcript from an Accreditation Council for Pharmacy Education (ACPE) accredited college or school of pharmacy or compliance with OAR 855-115-0015 that:

(A) A degree has been conferred; and

(B) The applicant has completed a minimum of 1440 hours in an Internship Program as that term is defined in OAR 855-031-0005.

(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam. A passing result is valid for 12 months. A candidate who does not pass 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 failed attempts;

(c) Pass the Oregon Multistate Pharmacy Jurisprudence Examination (MPJE) exam. A passing result is valid for 12 months. A candidate who does not pass 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 failed attempts; and

(d) Complete one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority.

(*2) An applicant who has obtained their professional degree outside the United States is not eligible for licensure via examination or score transfer until they have met the requirements of OAR 855-115-0015*.

(3) An applicant applying via score transfer must request the National Association of Boards of Pharmacy to transfer their NAPLEX score to Oregon.

ORS 689.255 Qualifications for licensure by examination allows the Board to consider:

(4) Any person who has received a professional degree from a school or college of pharmacy located outside the United States which has not been approved by the board, but who is otherwise qualified to apply for a license to practice pharmacy in the State of Oregon may be deemed to have satisfied the degree requirements of subsection (1)(d) of this section by verification to the board of the academic record and graduation of the person and by meeting such other requirements as the board may establish. The board may require such person to successfully pass an examination or examinations given or approved by the board to establish proficiency in English and equivalency of education of such person with qualified graduates of a degree program referred to in subsection (1)(d) of this section as a prerequisite of taking the licensure examination provided for in subsection (1)(f) of this section.

SBAR: Waiver – Intern renewal requirements

S	**Situation:** • The Board received a request for a waiver of OAR 855-031-0010(3)(c) to allow additional renewal of Intern license expiring 11/30/2023. Waiver of OAR 855-031-0010(3)(5)(b) permitted under OAR 855-031-0010(5).
B	**Background:** • Graduated from the Pacific University School of Pharmacy on 5/21/2022 • Experienced family hardship shortly after graduation • Has made 3 NAPLEX attempts, 2/3/2023, 4/6/2023, 7/14/2023 • Eligible for 4th NAPLEX attempt on 2/4/2024 • Requesting exception to allow renewal of intern license • Currently employed in a rural pharmacy
A	**Assessment:** • Current rule in OAR 855-031-0010(5) allows for a waiver of any of the requirements of OAR 855-031-0010(3)On 3/1/2024, per OAR 855-120-0035(2) o Intern will be eligible to renew Intern license because the license will not have been expired for a period of more than one year • An active intern license is not a requirement to take the NAPLEX or MPJE • Individual is eligible for reinstatement of pharmacy technician license • It may be in the interest of public health and safety to have additional workers in the pharmacy who can practice vs. assist in the practice of pharmacy
R	**Recommendation:** • Approve waiver of OAR 855-031-0030(3)(c) to allow individual to renew intern license through 11/30/25. This will allow individual to continue working in a pharmacy as an Intern until next allowable NAPLEX attempt and pharmacist licensure once other requirements are met.

Related OAR(s):

OAR 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.

Effective 3/1/2024 -

OAR 855-120-0030 Licensure: Application – Intern
(1) An application for licensure as an Intern may be accessed on the board website.
(2) The board may issue a license to a qualified applicant after the receipt of:
(a) Documentation required in OAR 855-120-0030 and for FPGEC certified documentation required in OAR 855-120-0015; and
(b) A completed application including:
(A) Payment of the fee prescribed in OAR 855-110;
(B) A current, passport regulation size photograph (full front, head to shoulders);
(C) Personal identification or proof of identity;
(D) A completed national fingerprint-based background check; and
(E) A completed moral turpitude statement or a written description and documentation regarding all conduct that is required to be disclosed.
(3) Penalties may be imposed for:
(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;
(b) Failure to disclose any requested information on the application;
(c) Failure to respond to requests for information resulting from the application;
(d) Any other grounds found in ORS 689.405.
(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.
(5) The license of an Intern expires November 30 and may be renewed as follows:
(a) Biennially prior to graduation from a COP or SOP.
(b) Once after graduation from a COP or SOP.
(c) Once if FPGEC certified or a graduate of a CCAPP program between 1993 and June 30, 2004.
OAR 855-120-0035 Licensure: Renewal or Reinstatement – Intern
(1) When applying for renewal of an Intern license, an applicant 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 a criminal background check; and
(d) Provide a written description and documentation regarding all conduct that is required to be disclosed.
(2) An Intern 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.
(3) An Intern 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 855-120-0010; and
(4) A person whose Intern 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 may apply to reinstate per OAR 855-120-0010.

Statement on Access to Buprenorphine for Patients Requiring Medication-Assisted Treatment for Opioid Use Disorder

Adopted October 2023

The Oregon Board of Pharmacy is committed to protecting the health, safety and welfare of all Oregonians. Addressing the opioid epidemic is a critical public health priority, and ensuring access to evidence-based treatments, such as medication-assisted treatment (MAT), is essential to combating this crisis. Buprenorphine, a proven and effective medication, plays a significant role in supporting individuals with opioid use disorder (OUD) on their path to recovery. Recognizing the importance of accessible and convenient care, the Board of Pharmacy encourages all wholesale distributors and pharmacies to maintain adequate supplies of buprenorphine to facilitate access for patients seeking treatment of OUD.

Opioid use disorder is a complex and challenging health issue affecting countless individuals across the US and the State of Oregon. Medication-assisted treatment has demonstrated efficacy in reducing the harms associated with opioid misuse, including overdose and infectious disease transmission, while promoting sustained recovery and improved quality of life. Buprenorphine, a partial opioid agonist, has been shown to be safe and effective in managing withdrawal symptoms and cravings, allowing individuals to regain stability and function within their communities.

Community pharmacies play a vital role in healthcare delivery and are well-positioned to partner in the effective management of OUD by making buprenorphine available to patients seeking treatment. Pharmacies, particularly those in rural and underserved communities, are often the first point of contact for individuals seeking healthcare services, making them a critical and accessible resource for patients requiring MAT. Pharmacists are important members of the healthcare team providing services that help support patients' physical, psychological, and social needs throughout their recovery.

The Board of Pharmacy supports minimizing barriers to accessing buprenorphine and other essential medications for those seeking treatment for OUD. Wholesale distributors and pharmacies are encouraged to make buprenorphine products available to the extent possible to support patients being treated for OUD.

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]

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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

Oregon Board of Pharmacy

Disciplinary Action Report

4/1/2023 - 4/30/2023

The Board has issued disciplinary action against the following licensees/respondents. These are public records and available for review pursuant to public disclosure laws. For those with a license number, please use the online licensure verification to search by a person/facility name or license number; if an Order has been executed, it will be available to view under the Board Orders section. For those without a license number, you may submit a public records request.

Orders Executed:

Name	License Number	Case Number
CH	RPH-0000000	2021-0067
RP	Unlicensed	2021-0237
LL	RPH-0000000	2021-0352
PSP	RP-0000000	2021-0667
FMP	RP-0000000	2022-0142
FMP	RP-0000000	2022-0143
FMP	RP-0000000	2022-0144
FMP	RP-0000000	2022-0145
GMP	RP-0000000 IP-0000000	2022-0448
MC	RPH-0000000	2022-0756
TM	CPT-0000000	2022-0774
CP	RP-0000000	2022-0803
CS	T-0000000	2022-0968
PW	RPH-00000000	2022-0990
TH	T-0000000	2022-1039
VL	RPH-00000000	2022-1041
TC	CPT-00000000	2022-1042
CB	T-0000000	2022-1044

If additional information is needed, please submit a public records request via The Board of Pharmacy's request form. State law prohibits the disclosure of complaint information.

Oregon Board of Pharmacy

Budget Report: June 2023 (Month 24)

Revenue:

Through June, revenue is $9,970,828 (14.4%) **over** budget

Expenditures:

Through June, **total expenditures** are $8,930,846 (3.8%) **under** budget

Personal services are $6,475,581 (-0.7%) **over** budget

Services and Supplies are $2,455,265 (15.8%) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: ($1,039,982)

Cash Balance:

Cash balance through June is $4,030,797 which represents (9.98 months of operating expense)

Note: This the above is a snap-shot of the biennium to date through June 2023. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $5,523,653, which represents (14.83) months of operating expense*)

Cash balance target is $2,234,940, (6.0 months of operating expense)

*Note: The end of biennium projected cash balance is calculated based on the biennium to date plus the remaining months projections for 2021-23.

Oregon Board of Pharmacy				
Total All Funds - LAB 2021-2023				
Actuals through June 2023				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**3,679,852**	**4,714,145**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	8,716,500.00	9,172,758.24	(456,258.24)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	293,667.50	(100,672.50)
505	FINES AND FORFEITS	410,000.00	323,180.66	86,819.34
605	INTEREST AND INVESTMENTS	131,250.00	155,869.58	(24,619.58)
975	OTHER REVENUE	84,335.00	64,805.63	19,529.37
	TOTAL REVENUE	**9,535,080.00**	**10,010,281.61**	**(475,201.61)**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	443,120.00	261,014.00	182,106.00
	TOTAL TRANSFER OUT	**443,120.00**	**261,014.00**	**182,106.00**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,283,003.00	4,176,445.78	106,557.22
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	13,727.18	(13,727.18)
3180	SHIFT DIFFERENTIAL	-	18.50	(18.50)
3190	ALL OTHER DIFFERENTIAL	198,616.00	173,642.12	24,973.88
3210	ERB ASSESSMENT	1,276.00	1,236.00	40.00
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	754,330.87	6,406.13
3221	PENSION BOND CONTRIBUTION	236,241.00	232,657.88	3,583.12
3230	SOCIAL SECURITY TAX	334,236.00	310,940.62	23,295.38
3240	UNEMPLOYMENT ASSESSMENT	-	219.10	(219.10)
3241	PAID LEAVE OREGON-EMPLOYER	-	5,058.14	(5,058.14)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	857.27	154.73
3260	MASS TRANSIT	27,053.00	25,807.31	1,245.69
3270	FLEXIBLE BENEFITS	841,104.00	778,440.19	62,663.81
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,475,580.52**	**235,003.48**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	69,786.34	46,107.66
4125	OUT-OF-STATE TRAVEL	17,024.00	1,825.77	15,198.23
4150	EMPLOYEE TRAINING	22,320.00	24,839.27	(2,519.27)
4175	OFFICE EXPENSES	134,566.00	55,550.65	79,015.35
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	54,773.38	(3,843.38)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	203,140.10	(599.10)
4250	DATA PROCESSING	318,678.00	356,542.08	(37,864.08)
4275	PUBLICITY & PUBLICATIONS	43,329.00	22,794.66	20,534.34
4300	PROFESSIONAL SERVICES	339,713.00	241,434.18	98,278.82
4315	IT PROFESSIONAL SERVICES	134,467.00	1,690.00	132,777.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	507,726.36	114,108.64
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,806.63	1,611.37
4425	FACILITIES RENT & TAXES	229,042.00	276,842.31	(47,800.31)
4475	FACILITIES MAINTENANCE	55.00	1,851.13	(1,796.13)
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	500.00	702.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	221,822.25	28,656.75
4650	OTHER SERVICES AND SUPPLIES	411,285.00	409,993.89	1,291.11
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	5,423.49	8,684.51
4715	IT EXPENDABLE PROPERTY	45,228.00	3,836.87	41,391.13
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,464,179.36**	**494,615.64**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,691,342.00**	**8,939,759.88**	**751,582.12**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**5,523,653**	
	End of biennium projected cash balance in months		14.83	
	Cash balance target of 6.0 months (working capital)		2,234,940	

Oregon Board of Pharmacy

Budget Report: July 2023 (Month 13)

Revenue:

Through July, revenue is $946,3974 (8.6%) **over** budget

Expenditures:

Through July, **total expenditures** are $9,064,305 (2.4%) **under** budget

Personal services are $6,494,147 (-1.0%) **over** budget

Services and Supplies are $2,570,158 (10.7%) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: ($399,669)

Cash Balance:

Cash balance through July is $2,997,451 which represents (7.42) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through July 2023.

End of biennium projected cash balance is $5,113,815, which represents (13.54) months of operating expense*)

Cash balance target is $2,266,076, (6.0 months of operating expense)

*Note: The end of biennium projected cash balance is calculated based on the biennium to date. The 2021-23 biennium close out is 12/31/2023.

Oregon Board of Pharmacy				
Total All Funds - LAB 2021-2023				
Actuals through Month 13 2023				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**3,679,852**	**4,714,145**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	8,716,500.00	9,173,958.24	(457,458.24)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	293,760.00	(100,765.00)
505	FINES AND FORFEITS	410,000.00	331,692.78	78,307.22
605	INTEREST AND INVESTMENTS	131,250.00	155,869.58	(24,619.58)
975	OTHER REVENUE	84,335.00	64,820.63	19,514.37
	TOTAL REVENUE	**9,535,080.00**	**10,020,101.23**	**(485,021.23)**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	443,120.00	556,127.00	(113,007.00)
	TOTAL TRANSFER OUT	**443,120.00**	**556,127.00**	**(113,007.00)**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,283,003.00	4,189,914.57	93,088.43
3160	TEMPORARY APPOINTMENTS	27,306.00	2,199.56	25,106.44
3170	OVERTIME PAYMENTS	-	13,727.18	(13,727.18)
3180	SHIFT DIFFERENTIAL	-	18.50	(18.50)
3190	ALL OTHER DIFFERENTIAL	198,616.00	173,642.12	24,973.88
3210	ERB ASSESSMENT	1,276.00	1,236.00	40.00
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	756,650.89	4,086.11
3221	PENSION BOND CONTRIBUTION	236,241.00	233,412.36	2,828.64
3230	SOCIAL SECURITY TAX	334,236.00	310,940.62	23,295.38
3240	UNEMPLOYMENT ASSESSMENT	-	219.10	(219.10)
3241	PAID LEAVE OREGON-EMPLOYER	-	5,058.14	(5,058.14)
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	857.27	154.73
3260	MASS TRANSIT	27,053.00	25,807.31	1,245.69
3270	FLEXIBLE BENEFITS	841,104.00	780,463.15	60,640.85
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,494,146.77**	**216,437.23**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	66,581.89	49,312.11
4125	OUT-OF-STATE TRAVEL	17,024.00	1,825.77	15,198.23
4150	EMPLOYEE TRAINING	22,320.00	24,896.67	(2,576.67)
4175	OFFICE EXPENSES	134,566.00	49,146.42	85,419.58
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	57,865.05	(6,935.05)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	203,140.10	(599.10)
4250	DATA PROCESSING	318,678.00	359,286.79	(40,608.79)
4275	PUBLICITY & PUBLICATIONS	43,329.00	22,794.66	20,534.34
4300	PROFESSIONAL SERVICES	339,713.00	246,179.78	93,533.22
4315	IT PROFESSIONAL SERVICES	134,467.00	1,690.00	132,777.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	553,382.96	68,452.04
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,806.63	1,611.37
4425	FACILITIES RENT & TAXES	229,042.00	288,565.39	(59,523.39)
4475	FACILITIES MAINTENANCE	55.00	1,851.13	(1,796.13)
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	-	1,202.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	241,346.00	9,133.00
4650	OTHER SERVICES AND SUPPLIES	411,285.00	442,852.45	(31,567.45)
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	1,109.56	12,998.44
4715	IT EXPENDABLE PROPERTY	45,228.00	3,836.87	41,391.13
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,570,158.12**	**388,636.88**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,691,342.00**	**9,064,304.89**	**627,037.11**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**5,113,815**	
	End of biennium projected cash balance in months		13.54	
	Cash balance target of 6.0 months (working capital)		2,266,076	

Oregon Board of Pharmacy

Budget Report: July 2023 (Month 1)

Revenue:

Through July, revenue is $795,708 (103.6%) **over** budget

Expenditures:

Through July, **total expenditures** are $283,346, (36.1%) **under** budget

Personal services are $280,489 (8.3%) **under** budget

Services and Supplies are $2,857 (4715.8%) **under** budget

Revenues less Expenditures: ($512,362)

Cash Balance:

Cash balance through July is $3,555,652 which represents (8.02) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through July 2023. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $3,965,928, which represents (9.93) months of operating expense*)

Cash balance target is $2,395,337, (6.0 months of operating expense)

*Note: The end of biennium projected cash balance is calculated based on the biennium to date plus the remaining months projections for 2023-25.

Also note the full financial plan for 2023-25 is in the process of being developed and projections are anticipated to changed on the next report.

Oregon Board of Pharmacy				
Total All Funds - LAB 2023-2025				
Actuals through July 2023				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**0**	**4,819,712**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	9,290,005.00	752,230.25	8,537,774.75
210	OTHER NONBUSINESS LICENSES AND FEES	306,570.00	11,076.50	295,493.50
505	FINES AND FORFEITS	287,760.00	8,630.00	279,130.00
605	INTEREST AND INVESTMENTS	50,000.00	20,894.48	29,105.52
975	OTHER REVENUE	63,975.00	2,877.25	61,097.75
	TOTAL REVENUE	**9,998,310.00**	**795,708.48**	**9,202,601.52**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	617,120.00	-	617,120.00
	TOTAL TRANSFER OUT	**617,120.00**	**0.00**	**617,120.00**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,689,308.00	4,720,965.12	(31,657.12)
3160	TEMPORARY APPOINTMENTS	28,453.00	-	28,453.00
3170	OVERTIME PAYMENTS	-	398.64	(398.64)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	206,958.00	259,384.74	(52,426.74)
3210	ERB ASSESSMENT	1,219.00	1,174.18	44.82
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	870,442.00	942,328.25	(71,886.25)
3221	PENSION BOND CONTRIBUTION	244,713.00	278,748.30	(34,035.30)
3230	SOCIAL SECURITY TAX	359,628.00	381,777.00	(22,149.00)
3240	UNEMPLOYMENT ASSESSMENT	-	-	-
3250	WORKERS' COMPENSATION ASSESSMENT	1,058.00	1,004.43	53.57
3260	MASS TRANSIT	30,091.00	29,965.24	125.76
3270	FLEXIBLE BENEFITS	910,800.00	912,730.21	(1,930.21)
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**7,342,670.00**	**7,528,476.11**	**(185,806.11)**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	121,084.00	107,100.00	13,984.00
4125	OUT-OF-STATE TRAVEL	17,739.00	-	17,739.00
4150	EMPLOYEE TRAINING	24,871.00	28,800.00	(3,929.00)
4175	OFFICE EXPENSES	142,250.00	71,400.00	70,850.00
4200	TELECOMM/TECH SVC AND SUPPLIES	56,862.00	55,300.00	1,562.00
4225	STATE GOVERNMENT SERVICE CHARGES	265,996.00	16.70	265,979.30
4250	DATA PROCESSING	332,540.00	317,904.46	14,635.54
4275	PUBLICITY & PUBLICATIONS	45,388.00	26,500.00	18,888.00
4300	PROFESSIONAL SERVICES	369,608.00	565.80	369,042.20
4315	IT PROFESSIONAL SERVICES	169,185.00	-	169,185.00
4325	ATTORNEY GENERAL LEGAL FEES	687,079.00	518,000.00	169,079.00
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	949.00	-	949.00
4400	DUES AND SUBSCRIPTIONS	5,885.00	1,416.00	4,469.00
4425	FACILITIES RENT & TAXES	328,585.00	320,869.92	7,715.08
4475	FACILITIES MAINTENANCE	57.00	-	57.00
4525	MEDICAL SUPPLIES AND SERVICES	1,252.00	-	1,252.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	260,999.00	145,000.00	115,999.00
4650	OTHER SERVICES AND SUPPLIES	408,987.00	460,000.00	(51,013.00)
4700	EXPENDABLE PROPERTY $250-$5000	16,136.00	-	16,136.00
4715	IT EXPENDABLE PROPERTY	47,128.00	-	47,128.00
	TOTAL SERVICES & SUPPLIES	**3,302,580.00**	**2,052,872.88**	**1,249,707.12**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	-	-	-
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**0.00**	**0.00**	**0.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	-	-	-
	Total Special Payments	**0.00**	**0.00**	**0.00**
	TOTAL EXPENDITURES	**10,645,250.00**	**9,581,348.99**	**1,063,901.01**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**(1,264,060)**	**(3,965,928)**	
	End of biennium projected cash balance in months		(9.93)	
	Cash balance target of 6.0 months (working capital)		2,395,337	