Oregon Board of Pharmacy
REVISED BOARD MEETING AGENDA
Meeting Location: Teleconference
December 8-9, 2021

Public Attendance by Phone (503) 446-4951 Phone Conference ID: 452 764 187#
Due to COVID-19, the Portland State Office Building remains closed to the public.

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

Wednesday, December 8, 2021 @ 8:30AM
Thursday, December 9, 2021 @ 8:30AM

- All Board meetings except Executive or Closed Sessions are open to the public. Pursuant to ORS 192.660, Executive Sessions are closed, 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 Karen MacLean by **12:00PM on 12/9/2021**.

The meeting is accessible to persons with disabilities. A request for hearing impaired assistance and accommodations for persons with disabilities may be made via email to Karen MacLean or by calling 971-673-0001 with at least 48 hours' notice.

WEDNESDAY, December 8, 2021

I. OPEN SESSION, Wassim Ayoub RPh, Presiding
- a. Roll Call
- b. Agenda Review and Approval *Action Necessary*

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

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*

THURSDAY, December 9, 2021

I. OPEN SESSION, Wassim Ayoub RPh, Presiding
- a. Roll Call

II. MOTIONS RELATED TO DISCIPLINARY ACTIONS *Action Necessary*

III. GENERAL ADMINISTRATION
- a. Rules
  - i. Review Rulemaking Hearing Report & Comments – *Melvin* **#A** *Action Necessary*

ii. Consider Adoption of Rules – *Melvin/Davis*

1. Div 007- Compliance with OHA COVID rules **#B** *Action Necessary*
2. Div 007/Div 041/Div 045/Div 065 - USP, Storage, Labeling, Repackaging **#B1** *Action Necessary*
3. Div 010 – Board Administration & Policies **#B2** *Action Necessary*
4. Div 019/139 - Remote Dispensing Site Pharmacy/Telepharmacy **#B3** *Action Necessary*
5. ORS 475.973 - Pseudoephedrine/Ephedrine Classification **#B4** *Action Necessary*
6. Div 041/080 - Pseudoephedrine/Ephedrine **#B5** *Action Necessary*
7. Div 019/021- Pain Management CE **#B6** *Action Necessary*
8. Div 020 – Pharmacist Prescriptive Authority- COVID mAb, PEP & PrEP **#B7, B7a, B7b,B7c** *Action Necessary*
9. Div 043 – SPDO/DPDO/CHC - **#B8** *Action Necessary*
10. Div 060/110 – PDMP Fee Increase **#B9** *Action Necessary*
11. Div 006/041 – Telework/Remote Processing/TCVP **#B10, B10a, B10b, B10c** *Action Necessary*

iii. Rules in Development – *Davis*

- Div 143- Lockers, 2nd review
- Div 041/080/139- Drug Loss, 2nd review
- Div 025- Technicians, Procedural Rule Review
- Div 041- Workplace Conditions, Procedural Rule Review
- Div 041- Remote Processing, Procedural Rule Review
- Div 041- Interpreters, 2021 HB 2359

iv. Consider Adoption of Temporary Rules - *Davis*

1. Div 006 – Supervision by a Pharmacist **#C** *Action Necessary*
2. Div 041 – Temporary/Permanent Pharmacy Closures **#C1** *Action Necessary*
3. Div 021/025/110 – Pharmacy Technician Renewal **#C2** *Action Necessary*

v. Rulemaking Policy Discussion Items – *Davis*

1. Div 021 – CE **#C3**
2. Div 006/041/139 – Drug Storage **#C4**

vi. Rules Advisory Committee Update – *Davis*

b. Discussion Items

i. Public Health and Pharmacy Formulary Advisory Committee – *Davis*
ii. Annual 5 Year Legislative Rule Report – *Melvin* **#E**
iii. COVID-19 Update – *Schnabel*
iv. Strategic Plan Update – *Schnabel*
v. Financial/Budget Update – *MacLean* **#D**

IV. ISSUES AND ACTIVITIES* (*Items in this section may occur anytime during the meeting as time allows*)

c. Reports

i. Board Members

ii. Executive Director
iii. Compliance Director
iv. Administrative Director
v. Licensing Manager
vi. Pharmacist Consultant
vii. Operations Policy Analyst

2022 Board Meeting Dates

- February 9-10, 2022 Portland
- April 13-15, 2022* Portland
- June 8-9, 2022 Portland
- August 10-11, 2022 Portland
- October 12-14, 2022* Portland
- November 9-10, 2022 TBA (Strategic Planning)
- December 14-15, 2022 Portland

2023 Board Meeting Dates

- February 8-9, 2023 Portland
- April 12-14 2023* Portland
- June 7-8, 2023 Portland
- August 9-10, 2023 Portland
- October 11-13, 2023* Portland
- November 8-9, 2023 TBA (Strategic Planning)
- December 13-14, 2023 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.)

- March 29, 2022 – *Tentative*
- May 24, 2022
- November 22, 2022

Conferences/Meetings – *Schnabel*

UPCOMING MEETINGS

1. Lane County Mid-Winter Seminar – February 19-20, 2022
2. OSHP 2022 Annual Seminar – April 22-24, 2022 Sunriver Resort

V. APPROVE CONSENT AGENDA* *Action Necessary*

**Items listed under the consent agenda are considered to be 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 - **# CONSENT-1**
b. Board Meeting Minutes – October 2021 **#CONSENT-2**

VI. PUBLIC COMMENT

Adjourn *Action Necessary*

Oregon
Kate Brown, 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: November 24, 2021
To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: November 23, 2021

Hearing Location: Virtual via Teams

Title of Proposed Rules:

- Division 007 – Compliance with OHA COVID rules
- Division 007/041/045/065 – USP/Storage/Labeling/Repackaging
- Division 010 – Board Administration & Policies
- Divisions 019/139 – Remote Dispensing Site Pharmacy (RDSP)
- Division 041/080 – Pseudoephedrine/Ephedrine
- Division 019/021 – Pain Management CE
- Division 020 – Pharmacist Prescriptive Authority – COVID mAb, PEP & PrEP
- Division 043 – SPDO/DPDO/CHC
- Division 060/110 – PDMP Fee increase
- Division 006/041- Telework, Remote Processing & TCVP

The rulemaking hearing on the proposed rules was convened at 9:33AM. There were six oral comments provided during the hearing and 20 written comments were submitted to pharmacy.rulemaking@oregon.gov. The hearing adjourned at 10:33AM. The hearing was recorded, and copies of the proposed rules were available for attendees via the board website.

The following board and staff members participated virtually:

Board Member Ayoub
Board Member Murray
Board Member DeBarmore
Board Member Doyle
Board Member Joyce
Board Member Vipperman
Staff Member Davis
Staff Member MacLean
Staff Member Melvin
Staff Member Schnabel

Board member Doyle left the meeting at 10:29AM

Summary of Oral Testimony

RULES PROPOSED: Compliance with OHA COVID Rules
ADOPT: OAR 855-007-0088

- No comments.

RULES PROPOSED: USP, Storage, Labeling & Repackaging
AMEND: 855-007-0120, 855-041-1001, 855-041-1035, 855-041-1040, 855-041-1080, 855-041-1130, 855-041-1135, 855-041-1145, 855-041-6270, 855-045-0200, 855-045-0220, 855-045-0240, 855-065-0005.

- Kate Newhall- 3rd year OHSU Nursing Student: Signage for dual language labels. Thank you board for recognizing this as an issue for LEP patients. Encourages board to create a poster for pharmacists to hang and have the notice in each of the required 14 languages, easy to see from counter, easy to see size font. Consistent signage important.

RULES PROPOSED: Board Administration & Policies
AMEND: 855-010-0005, 855-010-0015, 855-010-0016, 855-010-0021, 855-010-0035, 855-010-0100, 855-010-0110, 855-010-0120, 855-010-0130.

REPEAL: 855-010-0001

- No comments.

RULES PROPOSED: Remote Dispensing Site Pharmacy
AMEND: 855-019-0300

ADOPT: 855-139-0001, 855-139-0005, 855-139-0010, 855-139-0015, 855-139-0020, 855-139-0025, 855-139-0030, 855-139-0050, 855-139-0100, 855-139-0120, 855-139-0125, 855-139-0130, 855-139-0150, 855-139-0155, 855-139-0200, 855-139-0205, 855-139-0210, 855-139-0215, 855-139-0220, 855-139-0225, 855-139-0230, 855-139-0300, 855-139-0305, 855-139-0310, 855-139-0315, 855-139-0320, 855-139-0325, 855-139-0350, 855-139-0355, 855-139-0400, 855-139-0405, 855-139-0410, 855-139-0450, 855-139-0455, 855-139-0460, 855-139-0500, 855-139-0550, 855-139-0555, 855-139-0600, 855-139-0602, 855-139-0650, 855-139-0710, 855-139-0715, 855-139-0720, 855-139-0725, 855-139-0730

- Mike Millard – OSHP: Definition of telepharmacy may be too broad and inadvertently include clinical pharmacy practice. Add clarity to make sure regulations do not hamper current clinical pharmacy practice in medical offices.

RULES PROPOSED: Pseudoephedrine & Ephedrine
AMEND: 855-041-1030, 855-080-0023, 855-080-0026, 855-080-0028, 855-080-0031, 855-080-0085

ADOPT: 855-080-0029

REPEAL: 855-080-0080

- No comments.

RULES PROPOSED: Pain Management CE
AMEND: 855-019-0120, 855-021-0001, 855-021-0005

- No comments.

RULES PROPOSED: Pharmacist Prescriptive Authority – COVID-19 mAb, PEP & PrEP
AMEND: 855-020-0110, 855-020-0300

- No comments.

RULES PROPOSED: SPDO/DPDO/CHC
AMEND: 855-043-0002, 855-043-0003, 855-043-0505, 855-043-0510, 855-043-0530, 855-043-0540, 855-043-0545, 855-043-0555, 855-043-0560, 855-043-0705, 855-043-0740

ADOPT: 855-043-0004

REPEAL: 855-043-0005, 855-043-0210, 855-043-0405, 855-043-0410, 855-043-0415, 855-043-0420, 855-043-0425, 855-043-0430, 855-043-0435, 855-043-0436, 855-043-0440, 855-043-0445, 855-043-0450, 855-043-0455

- No comments.

RULES PROPOSED: PDMP Fee Increase
AMEND: 855-060-0001, 855-110-0003, 855-110-0005, 855-110-0007, 855-110-0010

- No comments.

RULES PROPOSED: Telework, Remote Processing & TCVP
AMEND: 855-006-0005, 855-041-1060,

REPEAL: 855-041-3000, 855-041-3100, 855-041-3105, 855-041-3110, 855-041-3115, 855-041-3120, 855-041-3125, 855-041-3130, 855-041-5100, 855-041-5120, 855-041-5130, 855-041-5140, 855-041-5150, 855-041-5160, 855-041-5170

ADOPT: 855-041-3200, 855-041-3205, 855-041-3210, 855-041-3215, 855-041-3220, 855-041-3225, 855-041-3230, 855-041-3235, 855-041-3240, 855-041-3245, 855-041-3250

- Mike Millard – OSHP
  - Telework- Look forward to revisions based on comments submitted to the board.
    - 855-041-3205- He is very concerned that the practice of pharmacy outside of a drug outlet is now subject telework rules. Suggested language change provided in the submitted written comments (via audiovisual means).
    - 25% rule- Not practical. Goes beyond need for patient safety. Suggests 5%.
  - TCVP- Not a tremendous uptake by hospitals. Unclear on what should happen- Should they stop their program? Is TCVP now unregulated? The current rule states that any savings in time must be used for patient care. Eliminating this rule essentially takes away time from patient care. Concerned with rapid and unannounced elimination of rules.

- Michael Powell – St. Charles Healthcare: Signed up to speak, did not join the meeting

- Mike Selvaggio – Ridgelark/UFCW 555
    - TCVP- Urge to retain TCVP. Techs go through extensive training. Program performing well and does not present any problems. This could cause a cost increase for pharmacies which could be passed onto consumers. Feel that RPH should have broad oversight.

- Majid Tanas – Providence
    - TCVP- Delegate care under the practice of pharmacy. Program impacts workflow and job satisfaction. Many people are interested in this legislation. Showing support to keep it how it is or revise it. OHSP is willing to craft language. Colleagues across the country are astounded that TCVP repeal is being contemplated. Barcode medication administration adds an additional layer of safety.

- Amy Watson – Asante
    - TCVP- Oppose repeal of TCVP. Asante has been using it over a decade safely. Techs are proud to achieve ability to do TCVP. RPH appreciate additional clinical activities that TCVP allows. Healthcare crisis currently and Asante needs techs to feel they are making a difference. TCVP combats burnout by doing work that is meaningful.

All written comments received by the public comment deadline date of 11/23/2021 at 4:30PM **have been provided in their entirety** to the Board. Comments were received in response to the 10/25/2021 Notice of Proposed Rulemaking (sent via email, and USPS mail to all Rulemaking interested parties as well as posted on the Board's website).

From:	Rob Geddes
To:	PHARMACY RULEMAKING * BOP
Cc:	SCHNABEL Joseph * BOP
Subject:	Albertsons Hearing Comments
Date:	Monday, November 22, 2021 11:55:15 AM
Attachments:	Telepharmacy proposed rule comments Final 11-22-21.pdf Telework proposed rule comments Final 11-22-21.pdf

Rachel,

I hope you are doing well. Please accept these comments on two of the proposed regulations that are up for hearing tomorrow. Let me know if you have any questions.

Rob Geddes, PharmD
Director, Pharmacy Legislative and Regulatory Affairs
Albertsons Companies, Inc.
(M) 208.513.3470
(O) 208.395.3987
(F) 623.336.6641
Rob.Geddes@albertsons.com

November 22, 2021

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

Re: Proposed Telepharmacy Regulations

Dear Dr. Schnabel:

As you know, the Albertsons Companies family of pharmacies is one of the largest pharmacy providers in the state of Oregon. We currently operate 105 locations in the state, under the Albertson's and Safeway banners.

The pharmacy industry has been leveraged tremendously throughout this pandemic with the goal of meeting the rapidly evolving needs of the public during these challenging times. The Albertsons Companies pharmacies have been heavily engaged in the response to this pandemic, which has taught us invaluable lessons regarding readily available access to pharmacy services within the communities that we serve. One major issue within our industry that has become more evident throughout this pandemic is limited access to medication and pharmaceutical care in remote geographical settings, commonly referred to as "pharmacy deserts." The practice of telepharmacy is a very valuable tool for pharmacists and patients alike in these circumstances. It allows for greater access to medication, aides in and improves patient adherence to medication, and establishes integral relationships between pharmacists and underserved, rural communities.

We would like to thank the State of Oregon in recognizing and adopting telepharmacy as an accepted practice so that pharmacists may provide some of our most vulnerable communities with improved access to medications and pharmaceutical care. Senate Bill 629 ("SB 629"), introduced and sponsored by Senator Bill Hansell, is a great step forward to statutorily allow the practice of telepharmacy within the state. While we are very encouraged by this progress, we are also concerned with the current proposed telepharmacy regulations promulgated by the Board of Pharmacy (the "Board") and deem them to be overly prescriptive.

If these rules are adopted as written, it will severely limit the ability of pharmacists to provide telepharmacy services to areas where there is a pharmacy desert. There are numerous requirements that create immense administrative burden, in addition to other requirements that are costly to achieve. We fear that by combining administrative burden with costly requirements it will make it nearly impossible for pharmacies to provide this essential service to those who reside within pharmacy deserts. Additionally, a comparison of the current proposed telepharmacy regulations to the recently proposed telemedicine rules from the Oregon Health Authority (OHA) proves just how prescriptive the Board has become with their regulations. The rule packet from the OHA for an arguably more complex practice is five (5) pages in total compared

to the rule packet from the Board which is fifty-one (51) pages. We have enclosed the OHA rule packet for reference and, in addition, present our analyses and responses to the current proposed regulations below[1]:

855-139-0050

Item 3 requires the remote dispensing site to employ a certified pharmacy technician with at least one (1) year of experience in the preceding three (3) years. The remote dispensing site will be located in an area where there is no pharmacy. The likelihood of securing and retaining a certified pharmacy technician within a reasonable proximity of the remote dispensing site will be very low. This requirement will create a potential for operational access issues as technician turnover occurs over time. Considering there is a shortage of technicians in Oregon, we request that the board reevaluate this requirement to allow for a trained technician to work in the site and become certified within one (1) year of employment commencement.

Items 4 through 6 establish a technician-to-pharmacist ratio. Item 4 requires the Pharmacist in Charge ("PIC") to determine the number of licensed individuals they are capable of supervising and then in Item 5, the limit is set to four (4) licensed individuals between the affiliate pharmacy and the remote pharmacy. A ratio is an arbitrary number that fails to consider that the circumstances within each pharmacy are different and that associates ultimately have varying degrees of experience. We suggest striking Item 5 and deferring to the professional judgement of the PIC so that they may carefully and methodically determine appropriate staffing levels of both the affiliate pharmacy and the remote dispensing site.

~~*(5) When supervising a Certified Oregon Pharmacy Technician working at a Remote Dispensing Site Pharmacy, the Oregon licensed Pharmacist may supervise no more than four licensed pharmacy technicians among all locations, including the Affiliated Pharmacy.*~~

855-139-0100

Item 6(c) requires a two-way audiovisual link as part of the surveillance between the affiliate pharmacy and the remote dispensing pharmacy. As currently written, this requirement is somewhat unclear, and we request additional clarification on how the Board defines the use of a two-way audiovisual link.

855-139-0200

Item 2 requires the remote pharmacy to be located less than one-hundred-twenty (120) miles from the affiliate pharmacy, by means of the shortest surface street route. This maximum distance requirement limits the areas of the state that can support a pharmacy desert. If none of the pharmacies within 120 miles have a desire or capability to meet the cumbersome requirements outlined in these regulations, then that pharmacy desert will persist and have no options for pharmacy services in that area. We suggest striking this requirement altogether to promote increased pharmacy access in the rural areas of the state.

[1] Strike-through indicates deleted text; double-underline indicates where text has been added.

Outlet: General Requirements.

(1) An Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.

~~(2) An Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the Remote Dispensing Site Pharmacy.~~

855-139-0210

Item 2 states that a pharmacist "continuously supervises" technicians remotely by "using audio and visual technology." We believe the intent is for there to be continuous visual monitoring capability that allows the pharmacist to supervise the technicians as needed; however, the language implies that a pharmacist would be expected to constantly observe the visual monitoring device. We suggest the following change to provide additional clarification on the requirement:

(2) Ensure an Oregon licensed Pharmacist ~~continuously~~ supervises, directs and controls each Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy using audio and visual technology which must be recorded, reviewed and stored;

Item 3(a)-(c) requires a pharmacist to review twenty-five percent (25%) of the interactions with patients within 48 hours of service. Logistically, this will be the most burdensome requirement to comply with. There are so many different types of interactions that a patient can have with a pharmacy. To measure and document the number of interactions a technician has with patients will be virtually impossible to perform with any reliable measure of accuracy. Theoretically, this requires a technician to have a logbook where they record the number of patient interactions throughout the day. Valuable time will be lost on a cumbersome administrative task which distracts from the more important duties of a pharmacy technician. This inadvertently requires the pharmacist to be involved in every transaction occurring in the pharmacy, from reviewing the accuracy of data entry and final product verification, to offering patient counseling via the audiovisual connection. Remote technicians are expected to know and understand the limitations just as if they were working in a traditional community pharmacy setting and should not require continuous supervision. Complex regulation of this sort can introduce a wider potential for negative impact on patient care and workflow. The increased administrative burden that this requirement introduces will detract from the time the pharmacist should be interacting with patients in the affiliate and remote sites. As shown below, we suggest removing the minimum percentage of interactions that a pharmacist must review, in addition to eliminating the requirement to document the number of interactions a licensee has with patients:

(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a Remote Dispensing Site Pharmacy must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public

health and safety ~~with a minimum of 25% of patient interactions reviewed~~; and

(b) ~~Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;~~

~~(c) Document the following within 24 hours of the review in (3)(b):~~

~~(A) Number of each licensee's patient interactions;~~

~~(B) Number of each licensee's patient interactions pharmacist is reviewing;~~

~~(C) Date and time of licensee patient interaction pharmacist is reviewing;~~

~~(D) Date and time of pharmacist review of licensee's patient interaction; and~~

~~(E) Pharmacist notes of each interaction reviewed; and~~

~~(d)~~ Report any violation of OAR 855 to the Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.

~~(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.~~

855-139-0550

Item 4 requires all data, telephone audio, audio and video still image capture and store and forward images to be retained for 3 years. The fiscal section of these proposed regulations estimates a need for seventy-five (75) terabytes ("TB") of data storage to comply with this requirement. In our research, we found that the cost of enterprise storage is $34.67/TB per month, which would yield approximately $31,000 per year in annual costs for data storage. The fiscal impact statement assumes that a pharmacy will be able to offset these costs by selling prescriptions and OTC items. The reason that pharmacy deserts exist is due to the increasingly complex reimbursement landscape that often results in negative reimbursement of prescriptions. These catastrophic headwinds have challenged pharmacies in the past several years, resulting in many having to close their doors due to operational costs imposed by regulation. Every added cost incurred due to overly prescriptive and burdensome regulation introduces a higher likelihood of a negative reimbursement on a prescription, which is already at fifty percent (50%). The break even point for a pharmacy will be higher because of this requirement alone, discouraging pharmacy business owners from extending their services through the telepharmacy route to resolve pharmacy deserts across the state of Oregon.

We suggest requiring the "still image captured" and "store/forward images" are retained for a total of three (3) years, as this timeline will continue to support public safety and prove what product was ultimately dispensed to a patient. Storing recorded telephone communications and recorded video surveillance for more than three (3) years drastically increases data storage requirements and may ultimately be unnecessary. In general, it is common to store surveillance system footage for up to ninety (90) days due to the exorbitant costs to store for any additional amount of time. Please see our suggested edits below:

Records: General Requirements.

(1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The Remote Dispensing Site Pharmacy must maintain all required records unless these records are maintained in the Affiliated Pharmacy.

(3) Records retained by the Drug Outlet must include, but are not limited to:

(a) Patient profiles and records;

(b) Date, time and identification of each individual and activity or function performed;

(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(d) Controlled substance inventory and reconciliation;

(e) Oregon licensed Pharmacist physical inspection of Remote Dispensing Site Pharmacy;

(f) Audio and visual connection testing and individual training on use of the audio and visual connection;

(g) ~~Data, telephone audio, audio and video, s~~Still image capture~~,~~ and store and forward images~~, security and surveillance data~~. This must be retained according to (1);~~ and~~

(h) Data, telephone audio, security surveillance data. This must be stored for 90 days; and

~~(h)~~(i) Any errors or irregularities identified by the quality improvement program.

(4) All data, telephone audio, audio and video, still image capture and store and forward images collected by the telepharmacy, security and surveillance systems must be retained according to (1).

855-139-0600

Item 4 prohibits selling over-the-counter ("OTC") items if the affiliate pharmacy is closed. This seems to be an unnecessary restriction on the business. When a standard community pharmacy is closed, there is no restriction on the sale of OTC items. Additionally, businesses such as fuel station convenience stores can sell OTC items without a pharmacy onsite. For these reasons, we suggest removing the restriction of selling OTC items while the affiliate pharmacy is closed.

Prohibited Practices: General.

A Retail Drug Outlet Remote Dispensing Site Pharmacy may not:

> *(1) Allow a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;*
>
> *(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; and*
>
> *(3) Deliver a prescription;.*
>
> *~~(4) Provide non-prescription or prescription drugs when either the Remote Dispensing Site Pharmacy or Affiliated Pharmacy is closed;~~*

The intent of SB 629 is to solve the issue of pharmacy access in Oregon. It is our belief that the proposed regulations are unduly burdensome and will render SB 629 useless, only exacerbating the lack of access to pharmaceutical care that so many Oregonians are facing during these times. We respectfully request that the Board further consider these regulations at the December 2021 Board meeting to ensure a practical and effective solution is provided.

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.

I hope this communication finds you well and I look forward to one day meeting in person.

Sincerely,

Rob Geddes, PharmD
Director, Pharmacy Legislative and Regulatory Affairs

Enclosure
RG:kdd

OFFICE OF THE SECRETARY OF STATE
SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

FILED
10/28/2021 4:00 PM
ARCHIVES DIVISION
SECRETARY OF STATE

CHAPTER 410
OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

FILING CAPTION: Amends Overarching Telemedicine Rule Authorizing Coverage Of Remote Health Care Services Delivered Using Telecommunication Technologies

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/21/2021 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

CONTACT: Nita Kumar
503-847-1357
hsd.rules@dhsoha.state.or.us

500 Summer St. NE, Salem
Salem,OR 97301

Filed By:
Nita Kumar
Rules Coordinator

NEED FOR THE RULE(S)

The continued federally designated public health emergency has influenced how health care providers and patients interact. Amendments were needed for this rule to reflect current and developing practice standards utilizing telecommunication technologies as a modality of delivering health care services to individuals. Rule amendments necessary to align with language from 2021 legislation (HB 2508) which passed and was enrolled by the 81st Oregon Legislative Assembly and signed into law by Governor Kate Brown effective June 1, 2021. Rule amendments authorize the Division to operationalize intended coverage of telemedicine services as described in the Authority's Health Evidence Review Commission's (HERC) Prioritized List of Health Services and Guideline Notes.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Federal designation / renewal of public health emergency:
https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVDI-15Oct21.aspx
Enrolled legislation: https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB2508
HERC Prioritized List Guideline Note A5: https://www.oregon.gov/oha/HPA/DSI-HERC/SearchablePLdocuments//Prioritized-List-GN-A005.docx

FISCAL AND ECONOMIC IMPACT:

The Department/Authority does not anticipate there will be a fiscal impact from these rule changes.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost

of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) This amendment has no additional cost or administrative burdens for the state agency, local government or the public.
(2)
(a) The number of small businesses potentially impacted to be < 200. This could include independent medical / physician based practices, other licensed independent practices such as Advance Practice Nurses (Nurse Practitioners), independent therapy practices (physical, occupational, speech therapy), independent nutrition therapy (licensed dietitians).
(b) No additional documentation or administrative burden as standard documentation applies to support the clinical services provided and billed.
(c) No additional supplies or administrative activities are required or mandated.

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

Small businesses were notified were notified of the RAC participation invitation through outreach which included Traditional Health Worker Commission, Health Equity Committee, Health Care Interpreters, Oral Health providers, Community Partner Outreach Program, Speech/Physical/Occupational therapists' state associations, Oregon Health Leadership Council, directors of all the various state licensing boards for health care professions, Oregon Primary Care Association. There were nearly 50 RAC members in attendance at the meeting with varied representation.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

AMEND: 410-120-1990

RULE SUMMARY: This overarching telemedicine rule authorizes the Division to cover medically necessary and appropriate physical, behavioral and oral health services within Oregon Health Plan (OHP) covered benefit plans. The rule applies to OHP beneficiaries on fee for service coverage. The amendment aligns rule with state legislation passed by Oregon's 81st Legislative Assembly during the 2021 regular session as HB 2508 and the Act was signed into law effective June 1, 2021 in Chapter 117. This rule authorizes the Division to operationalize the intended coverage of Telehealth, Teleconsultations and Online / Telephonic Services as described in the Health Evidence Review Commission's (HERC) prioritized list and guideline notes which can be found at: https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritized-List.aspx

CHANGES TO RULE:

410-120-1990
Tele~~health~~medicine and Telehealth Delivered Health Care Services
(1) ~~For the purpose of this general rule, the Authority defines telehealth as the use of electronic informat~~The following definitions apply to the Divisi~~on and telecommunications technologies to support and promote long-distance clinical healthcare, patient and professional health-related education, public health and health administration. ¶~~
~~(a) Information related to telehealth services may be transmitted via landlines and wireless communications, including the Internet and telephone networks;¶~~
~~(b) Services can be synchronous (using audio and video, video only or audio-only) or asynchronous (using audio and~~'s administrative rules applicable to the medical assistance program.¶
(2) "Asynchronous" means not simultaneous or concurrent in time. For the purpose of this general rule, asynchronous telecommunication technologies for telemedicine or telehealth services may include audio and video, audio without video, ~~audio, or text-based media)~~client or member portal and may include transmission of data from remote monitoring devices.~~ Communications may be between providers, or between one or more providers and one or more patients, family members /caregivers /guardians. ¶~~
~~(2) Telehealth encompasses different types of programs, services and delivery mechanisms for medically appropriate services for covered physical, behavioral and oral health conditions within the p¶~~

(3) "Audio only" means the use of audio technology, permitting real-time communication between a health care provider and a member for the purpose of diagnosis, consultation or treatiment's defined benefit package. This overarching fee for service rule applies to all program-specific rules or as set forth in the individual program provider rules. Providers are prohibited from excluding or otherwise limiting OHP members to using exclus. "Audio only" does not include:¶
(a) The use of facsimile, electronic mail or text messages;¶
(b) The delivelry teleof health services, except where Autho that are customaritly has implemented section (7) of this rule. ¶
(3) Patient choice and accommodation for telehealth shall encompass the following standards and services:¶
(a) Providers shall provide meaningful access to telehealth services by assessing patients' capacities to use specific approved methods of telehealth delivery that comply with accessibility standards including alternate formats, and provides the optimal quality of care for the patient given their capacity;delivered by audio telephone technology and customarily not billed as separate services by a health care provider, such as the sharing of laboratory results.¶
(4) "Meaningful access" means client or member-centered access reflecting the following statute and standards:¶
(ba) Pursuant to Title VI of the Civil Rights Act of 1964 and, Section 1557 of the Affordable Care Act and the corresponding Code of Federal Regulation (CFR) at 45 CFR Part 92 (Section 1557) and The Americans with Disabilities Act and Amendments Act of 2008 (ADA), providers' telemedicine or telehealth services shall accommodate the needs of individuals who have difficulty communicating due to a medical condition, who need accommodation due to a disability, advanced age or who have lLimited English pProficiency (LEP) and including providing access to auxiliary aids and services as definscribed in Code of Federal Regulation (CFR) at 45 CFR Part 92 (Section1557); ¶
(c) Providers shall provide meaningful access to health care services for LEP and Deaf and hard of hearing patients and their families by working with qualified and certified health care interpreters, to provide language access services as described in OAR 333-002-0040;¶
(d) Providers'45 CFR Part 92;¶
(b) National Culturally and Linguistically Appropriate Services (CLAS) Standards at https://thinkculturalhealth.hhs.gov/clas/standards; and ¶
(c) As applicable to the client or member, Tribal based practice standards: https://www.oregon.gov/OHA/HSD/AMH/Pages/EBP.aspx;¶
(d) "Synchronous" means an interaction between a provider and a client or member that occurs at the same time using an interactive technology. This may include audio only, video only, or audio and video and may include transmission of data from remote monitoring devices.¶
(5) "Telecommunication technologies" means the use of devices and services for telemedicine or telehealth services shall be culturally and linguistically appropriate as described in the relevant standards:delivered services. These technologies include videoconferencing, store-and-forward imaging, streaming media including services with information transmitted via landlines, and wireless communications, including the Internet and telephone networks.¶
(A6) National Culturally and Linguistically Appropriate Services (CLAS) Standards: https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53."Telehealth" includes telemedicine and also includes the use of electronic information and telecommunications technologies to support long-distance clinical healthcare, client or member and professional health-related education, public health, and health administration. ¶
(B7) Tribal based practice standards: https://www.oregon.gov/OHA/HSD/AMH/Pages/EBP.aspx. ¶
(C) Services shall be provided using a trauma informed approach."Telemedicine" means the mode of delivering remote clinical health services using information and telecommunication technologies to provide consultation and education or to facilitate diagnosis, treatment, care management or self-management of a client or member's healthcare.¶
(8) "Trauma linformed Aapproach" means approach undertaken by providers and healthcare or human services programs, organizations, or systems in providing mental health and substance use disorders treatment wherein there is a recognition and understanding of the signs and symptoms of trauma in, and the intensity of such trauma on, individuals, families, and others involved within a program, organization, or system. It, and then considerstakes into account those signs, symptoms, and their intensity and fully integrates that knowledge when implementing and providing potential paths for recovery from mental health or substance use disorders. The Trauma Informed Approach also means that providers and healthcare or human services programs, organizations, or systems can actively resist re-traumatization of the individuals being served within their respective entities. ¶
(49) Privacy and security standards for telehealth services shall be met by satisfying the following:¶
(a) Prior to the delivery of services via a telehealth modality, a patient oral, recorded, or written"Trauma informed services" means those services provided using a Trauma Informed Approach.¶

(10) These rules apply to telemedicine or telehealth communications between providers, or between one or more providers and one or more clients or members, family members, caregivers and guardians.¶
(11) Providers shall ensure OHP clients or members are offered a choice of how services are received, including services offered via a telemedicine or telehealth modalities and in-person services, except where the Authority issues explicit guidance during a declared state of emergency or if a facility has implemented its facility disaster plan.¶
(a) If services are not able to be completed by a provider within the scope of their licensure, the provider shall refer the client or member to the appropriate service and service provider; and¶
(b) The provider shall maintain documentation of the referral and reason; and¶
(c) Document the client or member's choice of service. ¶
(12) Client or member choice and accommodation for telemedicine or telehealth shall encompass the following standards and services:¶
(a) Providers who offer telemedicine or telehealth delivered services shall offer meaningful access to services by assessing client or members' capacities to use specific approved methods of telemedicine or telehealth delivery that comply with accessibility standards including alternate formats, and provides the optimal quality of care for the client or member given considerations of client or member access to necessary devices, access to a private and safe location, adequate internet, digital literacy, cultural appropriateness of telemedicine or telehealth services, and other considerations of client or member readiness to use telemedicine or telehealth:¶
(b) Providers shall offer meaningful access to health care services for LEP and Deaf and hard of hearing clients or members and their families by working with qualified or certified health care interpreters, to provide language access services as described in OAR 333-002-0040. Such services shall not be significantly restricted, delayed, or inferior as compared to programs or activities provided to English proficient individuals:¶
(c) Providers shall collaborate with clients or members to identify and offer modalities for delivering health care services which best meets the needs of the member and considers the client or member's choice and readiness for the modality of service selected:¶
(d) Providers shall offer telemedicine or telehealth services which are culturally and linguistically appropriate as described in the relevant standards:¶
(A) National Culturally and Linguistically Appropriate Services (CLAS) Standards: https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53;¶
(B) Tribal based practice standards: https://www.oregon.gov/OHA/HSD/AMH/Pages/EBP.aspx.¶
(13) Privacy and security standards for telemedicine or telehealth services shall be met by satisfying the following:¶
(a) Prior to the delivery of services via a telemedicine or telehealth modality, a client or member's written, oral, or recorded consent to receive services using a telemedicine or telehealth delivery method in the language that the ~~pat~~client or member understands must be obtained and documented by ~~Providers annually~~the health system, clinic or provider in the client or member's health record. Consent must include an assessment of client or member readiness to access and participate in telemedicine or telehealth delivered services, including conveying all other options for receiving the health care service to the client or member. Consent must be updated at least annually thereafter. For LEP and Deaf and hard of hearing ~~pat~~clients or members and their families, providers must use qualified ~~and~~or certified health care interpreters when obtaining ~~pat~~client or member consent.;¶
(b) Consistent with ORS 109.640, provision of birth control information and services via a telemedicine or telehealth modality shall be provided to any person regardless of age without consent of parent or legal guardian.;¶
(c) Consistent with ORS 109.640, provision of any other medical or dental diagnosis and treatment via a telemedicine or telehealth modality shall be provided to any person 15 years of age or older without consent of parent or legal guardian.;¶
(d) Services provided using a telemedicine or telehealth platform shall comply with Health Insurance Portability and Accountability Act (HIPAA), https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996, and with the Authority's Privacy and Confidentiality Rules (Chapter 943 Division 14) except as noted in section (~~7~~9) below.;¶
(e) The ~~pat~~client or member may be located in the community, or in a health care setting.;¶
(f) OHP enrolled providers may be located in any location where ~~pat~~client or member privacy and confidentiality can be ensured.;¶
(g) Persons providing interpretive services and supports shall be in a location where ~~pat~~client or member privacy and confidentiality can be ensured.¶
(~~5~~14) Telemedicine or telehealth providers shall meet the following requirements:¶
(a) Shall be enrolled with the Authority as an Oregon Health Plan (OHP) provider, per 410-120-1260.;¶
(b) Shall provide services via telemedicine or telehealth that are within their respective certification or licensing board's scope of practice and comply with telemedicine or telehealth requirements including, but not limited to:¶

(A) Documenting ~~pat~~client or member and provider agreement of consent to receive services~~;~~.¶
(B) Allowed physical location of provider and ~~pat~~client~~;~~ or member.¶
(C) Establishing or maintaining an appropriate provider-~~pat~~client or member relationship.¶
(c) Providers billing for covered telemedicine or telehealth services are responsible for:¶
(A) Complying with HIPAA and the Authority's Privacy and Confidentiality Rules and security protections for the ~~patient~~member in connection with the telemedicine or telehealth communication and related records requirements (OAR chapter 943 division 14 and 120, OAR 410-120-1360 and 1380, 42 CFR Part 2, if applicable, and ORS 646A.600 to 646A.628 (Oregon Consumer Identity Theft Protection Act) except as noted in section (~~7~~16) below~~;~~.¶
(B) Obtaining and maintaining technology used in telemedicine or telehealth communication that is compliant with privacy and security standards in HIPAA and the Authority's Privacy and Confidentiality Rules described in subsection (A) except as noted in section (~~7~~16) below~~;~~.¶
(C) Developing and maintaining policies and procedures to prevent a breach in privacy or exposure of ~~pat~~ client or member health information or records (whether oral or recorded in any form or medium) to unauthorized persons and timely breach reporting~~;~~. ¶
(D) Maintaining clinical and financial documentation related to telemedicine or telehealth services as required in OAR 410-120-1360 and any program specific rules in OAR Ch 309 and Ch 410~~;~~. ¶
(E) Complying with all federal and state statutes as required in OAR 410-120-1380.¶
(~~6~~)15) The Authority will only pay for telemedicine or telehealth services meeting all of the following requirements:¶
(a) Services provided shall be medically and clinically appropriate for covered conditions within the Health Evidence Review Commission's (HERC) prioritized list and in compliance with relevant guideline notes;¶
(b) The Authority shall provide reimbursement for telemedicine or telehealth services at the same reimbursement rate as if it were provided in person. As a condition of reimbursement, providers shall agree to reimburse Certified and Qualified Health Care Interpreters (HCIs) for interpretation services provided via telemedicine or telehealth at the same rate as if interpretation services were provided in-person, per OARs 410-141-3515(12) and 410-141-3860(12)~~;~~.¶
(c) When allowed by individual certification or licensing boards' scope of practice standards, telemedicine or telehealth delivered services for covered conditions are covered:¶
(A) When an established relationship exists between a provider and ~~pat~~client ~~as~~or member defined ~~by~~as a ~~pat~~client or member who has received in-person professional services from the physician or other qualified health care professional within the same practice within the past three years; and~~.~~¶
(B) For establishing a ~~pat~~client or member-provider relationship.¶
(d) All physical~~,~~ and behavioral ~~and~~telemedicine or~~al~~ telehealth, and oral teledentristy services except School Based Health Services (SBHS) shall include Place of Service code 02~~;~~.¶
(e) All claim types except Dental services, shall use modifiers GT or 95 when the telemedicine or telehealth delivered service utilizes a synchronous audio and video modality. When provision of the same service via synchronous audio and video is not available or feasible (e.g.~~,~~ the ~~pat~~client or member declines to enable video, or necessary consents cannot reasonably be obtained with appropriate documentation in ~~pat~~client or member's medical record) the claim should not include any modifiers but should continue billing Place of Service as 02.¶
(~~7~~16) In the event of a declared emergency or changes in federal requirements, the Authority may adopt flexibilities to remove administrative barriers and support telemedicine or telehealth delivered services:¶
(a) The Authority will follow guidance from the US Department of Health and Human Services (HHS) Office for Civil Rights (OCR) which may allow enforcement discretion related to privacy or security requirements~~;~~.¶
(b) The Authority may expand network capacity through remote care and telemedicine or telehealth services provided across state lines~~;~~.¶
(c) The Authority may expand ~~access to telehealth services for new patient~~the definition of an established client or member-provider relationship beyond the standard of an in-person encounter every three (3) years.
Statutory/Other Authority: ORS 413.042
Statutes/Other Implemented: ORS 414.025, 414.065

November 22, 2021

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

Re: Telework "Remote Processing" Proposed Regulations

Dear Dr. Schnabel,

As you know, the Albertsons Companies family of pharmacies is one of the largest pharmacy providers in the state of Oregon. We currently operate 105 locations in the state, under the Albertson's and Safeway banners.

The pharmacy industry has been leveraged tremendously throughout this pandemic with the goal of meeting the rapidly evolving needs of the public during these challenging times. The Albertsons Companies pharmacies have been heavily engaged in the response to this pandemic, which has taught us invaluable lessons regarding readily available access to pharmacy services within the communities that we serve.

Many variables have changed during this pandemic, including the dynamics of workflow within a pharmacy. In the beginning, there was a rush from the public to stock up on their medications due to the unknowns from impending lockdowns and rising infection rates. Then, during the first flu season of this pandemic, our pharmacies administered record high volumes of flu vaccines. Finally, the COVID-19 vaccine arrived in pharmacies in the first part of 2021, bringing with it high volumes of patients who were administered the vaccine. The number of patients seeking a COVID-19 vaccine has continued to ebb and flow as new age groups are approved for use, in addition to the introduction of COVID-19 booster vaccines. Most recently, the approval of the vaccine for pediatric use has created another swell of patients accessing the services of a pharmacy. All these events have coincided with consistent staffing challenges, including staff testing positive for COVID-19, staff exposure to positive cases resulting in quarantine, an increased demand for pharmacists and technicians, and standard turnover.

With each new hurdle introduced during this pandemic, our pharmacy staff have done their very best to service the needs of their patients. This was all made possible by swift action from the Oregon Board of Pharmacy ("Board"), who issued certain waivers that allowed us to keep our pharmacies open and operational. On March 23, 2020, the Board issued a waiver to allow for remote supervision of pharmacy technicians and interns by a pharmacist which has allowed us to support our pharmacy teams during some of their most challenging times. This waiver has now been in place for approximately eighteen (18) months. While we appreciate the board taking steps to make this waiver permanent, we believe the additional requirements added to the remote processing checklist are unnecessary and unduly burdensome for pharmacy teams that are already doing so much to provide pharmacy services and patient care. We believe the current waiver and accompanying checklist requirements can be implemented without additional burden to pharmacy teams.

Additionally, composing these rules concurrently with Telepharmacy rules has led to confusion on what should occur in a remote dispensing site versus a remote processing situation. Below are the suggested changes to each of the corresponding excerpts of the regulation[1].

855-041-3220

Item 2 requires all telephone audio to be recorded, reviewed, and stored. In remote telework processing, the telephone audio is most likely to be conversations between the pharmacist and the technician. It is cost prohibitive to have to purchase recording technology to record and store every phone interaction the technician has when performing data entry outside of a licensed facility. Additionally, if a pharmacist is working remotely, it would be outside of the standard of practice to record the interactions they have with a patient. This requirement is costly and burdensome. We suggest it be stricken from the proposed regulations.

Item 4 requires a pharmacist to use their professional judgement in determining the frequency of which they supervise their technician via an audio/visual system; though, no less than once per work shift to ensure patient safety. It also requires that the pharmacist formally document each interaction. Typically, in a remote processing situation, a technician will consult their pharmacist when there is a question or to seek advice on how to proceed with a prescription. Technician performance, from a data entry perspective, is reviewed by a pharmacist in the same manner as if they were working side-by-side in the pharmacy. The additional stipulation to the supervision requirement contradicts how the pharmacist may operate under their professional judgement. Further, the requirement to document each interaction adds another administrative burden to an already demanding workload for the pharmacist and will yield no improvement to patient safety. We believe that a more efficient way to address this issue is to require that a technician (or intern) has immediate access to a pharmacist as needed.

Item 7 is a carryover requirement from the Telepharmacy regulations, which we believe does not belong within the telework "remote processing" regulations. A technician working remotely performs data entry and does not interact directly with patients. All work performed during data entry is reviewed by the pharmacist. An additional review of interactions would be duplicative and again, burdensome to the pharmacist. We recommend these requirements be stricken from this section.

Please see the recommended changes to this section below:

Telework: Supervision Requirements.

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the supervising Oregon licensed Pharmacist from the Drug Outlet must:

(1) Utilize technology that enables real-time audio and visual connection and have appropriate technology or interface to allow access to information required to complete assigned duties;

~~*(2) Ensure all telephone audio is recorded, reviewed and stored;*~~

(~~3~~2) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon Pharmacy Technician and that the ~~continuous~~ audio/visual connection is fully operational;

(~~4~~3) Ensure that an Oregon licensed Pharmacist using professional judgment, determines the frequency of "checkins" for each licensee being supervised via the real-

[1] Strike-through indicates deleted text; double-underline indicates where text has been added.

time audio and visual connection ~~with a minimum of at least once per work shift~~ to ensure patient safety, compliance with federal and state laws~~, and documents the interaction~~;

(~~5~~4) Be readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and

(~~6~~5) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction and control at all times.

(~~7~~6) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy Technician at a Telework Site must~~:~~

~~(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;~~

~~(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;~~

~~(c) Document the following within 24 hours of the review in (b):~~

~~(A) Number of each licensee's patient interactions;~~

~~(B) Number of each licensee's patient interactions pharmacist is reviewing;~~

~~(C) Date and time of licensee patient interaction pharmacist is reviewing;~~

~~(D) Date and time of pharmacist review of licensee's patient interaction; and~~

~~(E) Pharmacist notes of each interaction reviewed; and~~

~~(d) R~~report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of discovery and to the board within 10 days.

855-041-3230

This section is derived from the Telepharmacy regulations and infers that a technician working outside of a licensed pharmacy would be preparing medication for dispensing to a patient. While it is written in the context of Telepharmacy, it does not belong under this section. We suggest removing this section entirely from the proposed rules, so as not to confuse the two areas of pharmacy practice. We believe this could potentially lead to gross non-compliance with where drugs may be stored and/or handled.

855-041-3235

Item 3 requires an intern or certified technician to have at least one (1) year of retail drug outlet experience before being permitted to work in a Telework environment. This is another unnecessary requirement borrowed from the Telepharmacy regulations as all Telework is supervised and directed by a pharmacist, to whom the interns and technicians have immediate access. An appropriately trained and certified individual should be able to work remotely without being required to have one (1) year of retail drug outlet experience.

Item 5 institutes the same ratio as used in the Telepharmacy regulations, which when applied to a Telework environment, is wholly unnecessary. In a Telework environment, a pharmacist checks the work of a technician and does not have to monitor handling of the physical inventory. All pharmacies differ, and the number of licensed individuals it is safe to supervise should continue to be left up to the consideration and professional judgment of the pharmacist.

We suggest the following revisions to this section:

Telework: Personnel.

(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all operations at Drug Outlet Pharmacy including responsibility for the continuous audio and visual connection and enforcing policies and procedures.

(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel at Telework Sites.

~~*(3) An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have at least one year experience performing similar services for an Oregon registered Drug Outlet Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy Technician begins teleworking.*~~

(~~4~~3) The Oregon licensed Pharmacist from the Drug Outlet Pharmacy who is supervising a licensee at a Telework Site must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided.

~~*(5) When supervising an Intern or Certified Oregon Pharmacy Technician working at a Telework Site, the Oregon licensed Pharmacist may supervise no more than four licensees among all locations, including the Drug Outlet Pharmacy.*~~

(~~6~~4) The Drug Outlet Pharmacy is required to comply with the pharmacist's determination in (4) and retain records.

(~~7~~5) Prior to working at a Telework Site, the Intern or Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on the use of all equipment necessary for secure operation of the Telework Site.

855-41-3250

Item 3(g) requires the retention of all Telework data, telephone audio, audio/visual, still image capture and security/surveillance data to be recorded and stored for up to three (3) years. In a remote processing situation, there is no manipulation of physical inventory, no surveillance system, nor conversations between employees. This is another requirement that was carried over from the proposed Telepharmacy regulations and we do not feel that it directly relates to the actual function of remote processing from a Telework site, which should only be required to store and access records electronically to aid in the practice of pharmacy.

Item 3(d) implies that filling prescriptions will take place in a Telework site, which we believe to be an error in drafting the regulations. We suggest this be removed so as not to infer that filling is permissible from a Telework site.

Please see the recommended changes to this section below:

Telework: Records.

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the recordkeeping requirements OAR 855-041-3205 through OAR 855-041-3250 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules must be retained for three years and made available to the board for inspection upon request. Records created at Telework Sites must be stored at the Drug Outlet for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) Records must be stored at the Telework site in a manner that prevents unauthorized access.

(3) Records must include, but are not limited to:

(a) Patient profiles and records;

(b) Patient contact and services provided;

(c) Date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site;

~~*(d) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;*~~

(~~e~~d) List of employees working from Telework Sites that includes:

(A) Name;

(B) License number;

(C) Verification of each license;

(D) Address of Telework Site; and

(E) Name of the Oregon licensed Pharmacist who verified each licensure, approved licensee to telework and approved each Telework Site;

(f) Audio and visual connection testing and training;

~~*(g) Data, telephone audio, audio and video, still image capture, store and forward images, security and surveillance data. This must be retained according to (1);*~~ *and*

(~~h~~g) Any errors or irregularities identified by the quality improvement program.

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
Director, Pharmacy Legislative and Regulatory Affairs

From: Krista McCormick
To: PHARMACY RULEMAKING * BOP
Subject: HB 2648 Comment on Rules
Date: Monday, November 22, 2021 7:50:17 AM
Attachments: image001.png

Good Morning,

Appriss Insights, the technology provider of NPLEx, is in agreement with the rules written by the board in accordance with HB 2648. It is what we expected and in line with the NPLEx bill.

We look forward to the partnership and providing NPLEx in Oregon! Thank you for all your hard work on this!

Regards,

Krista McCormick
Manager, Compliance
t 502.815.5678 · **m** 502.693.8055
krista.mccormick@equifax.com

APPRISS® INSIGHTS
An Equifax Company

Website / LinkedIn / Twitter / Blog

From:	Watson, Amy
To:	PHARMACY RULEMAKING * BOP
Cc:	Garcia, Michael; Lanning, Michael; Moscoe, Gwendolyn
Subject:	Comments: Repeal OAR 855-041-5100 through OAR 855-041-5170
Date:	Wednesday, November 10, 2021 10:09:39 AM
Attachments:	2021 11 Asante Comments TCVP Repeal.pdf

To: The Oregon Board of Pharmacy

Please see the attached comments from Asante and the three Asante hospitals regarding the proposed repeal of the TCVP program currently allowed under OAR 855-041-5100 through OAR 855-041-5170. We would appreciate your consideration to maintain and improve these rules to better meet the needs of the state. If this program is repealed, our health system will be impacted both in quality of care and financially.

Please feel free to reach out to any of us to learn more about how this program safely and effectively helps us serve more patients across our health system.

Sincerely,

Amy R. Watson PharmD, MBA, FACHE
Director Pharmacy Services & Chief Pharmacy Officer | Asante
Email: Amy.Watson@asante.org | Phone: 541-789-5031
Excellence | Respect | Honesty | Service | Teamwork

ASANTE®

November 8, 2021

To: Oregon Board of Pharmacy

Re: Tech-Check-Tech Board Rule Repeal Proposal

Asante is the longest standing user of TCVP in Oregon, dating back to September 2012 when Asante Rogue Regional Medical Center worked closely with the Board to establish OAR 855-041-5100. Since that time, two Asante hospitals plus many others across Oregon have provided validated, safe medication delivery to nurses or other licensed administering staff who then professionally administer those medications to patients. Through robust auditing required by the OAR, participating facilities can prove in detail their safe use of TCVP.

We are perplexed by the sudden interest by the Board to rescind OAR 855-041-5100. To our knowledge, TCVP has proven to be a safe and efficient mechanism for providing accurate medication delivery to administering staff. It would be helpful to understand the reasoning for the sudden change in Board direction. We'd encourage the Board to engage in a spirit of collaboration with TCVP-using sites to determine if elimination of the program is the best resolution to the unstated concern. It may be that there are other equally or even more safe solutions that would be less onerous to participating sites.

At Asante, we have directed the time saved by pharmacists through our TCVP program directly into operating a more robust medication history improvement and validation program than would otherwise be possible. All medication history improvement and validation work at Asante is performed by licensed pharmacists, something that would much more financially challenging were it not for TCVP efficiencies. Asante believes our patients are best served using TCVP to ensure validated safe and accurate medication delivery to administering staff while using licensed pharmacists to perform medication history improvement and validation.

Thank you for reviewing our concerns. We invite the Board to engage organizations using TCVP to jointly examine the source of the Board's concern and collaboratively develop a solution which retains the proven safety and accuracy of TCVP. This is a program worth improving, not eliminating.

Sincerely,

Amy Watson
Dir Pharmacy Services & Chief Pharmacy Officer
Asante Health System

Gwendolyn Moscoe
Pharmacy Manager
Asante Three Rivers Medical Center

Michael Lanning
Pharmacy Manager
Asante Rogue Regional Medical Center

Michael Garcia
Pharmacy Manager
Asante Ashland Community Hospital

From:	DiMarco, Benjamin S
To:	PHARMACY RULEMAKING * BOP
Subject:	Nov 23 Rules Hearing Comments
Date:	Tuesday, November 23, 2021 4:27:56 PM
Attachments:	image001.png CVS Health Comments OR +BSD.pdf

Please see attached communication.

Benjamin DiMarco | Senior Legal Counsel
c (973) 886 6763
200 Campus Drive, Third Floor, Florham Park, NJ 07932

200 Highland Corporate Drive | Woonsocket, RI 02895

November 23nd, 2021

Joe Schnabel, RPh
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232
pharmacy.rulemaking@bop.oregon.gov

Re: Comments to Rules Hearing of November 23, 2021

Dear Executive Director Schnabel:

I am writing to you in my capacity as Senior Counsel 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 diverse access points to care to patients in the state of Oregon through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the Oregon State Board of Pharmacy proposed rule amendments. We would also like to thank the Board for their vigilance in continuously improve the laws and regulations that guide pharmacists, pharmacy interns and pharmacy technicians serving Oregon patients.

Proposed Rule Amendments in Division 019, 139 on remote dispensing/telepharmacy
Community pharmacy closures are associated with persistent, clinically significant declines in adherence to cardiovascular medications among older adults in the United States.[1] In parallel, research indicates telepharmacy interventions in the community setting, have an overall positive impact on outcomes related to clinical disease management, patient self-management, and adherence in the management of chronic diseases.[2] Telepharmacy opportunities have proven to be a safe pharmacy alternative and standard of practice in over 25 states, often creating patient access to the most vulnerable patients and given pharmacists an opportunity to engage in clinical patient services that prevent gaps in medication adherence. The prevention of telepharmacy practice directly fragments pharmacists' ability to curtail the estimated $500 billion in annual healthcare costs resulting from non-optimized drug therapy, with non-adherence being a critical factor.[3-4] Efforts to reduce non-adherence to prescription medications in Oregon should consider the role of pharmacy closures, especially among patients at highest risk.[1] Telepharmacy is nationally accepted by the National Association of Boards of Pharmacy (NABP), American Hospital Pharmacists Association (ASHP), and American Pharmacist Association (APhA) as a means to create new or maintain current patient access to pharmacy services.[5-7]

CVS Health appreciates the efforts the Board has undertaken to build out a telepharmacy platform in the state, however, we feel the proposed rules would create an environment that severely limits access and overall benefits that telepharmacy can provide. In the United States, telepharmacy has over two decades of defined patient safety and overall success. Telepharmacy has decreased the gaps in care patients experience due to pharmacy closures and allowed patients the opportunity and access to pharmacy care that are otherwise unavailable. patients have benefitted from the allowance of a telepharmacy practice in their state in both urban and rural settings.

In reviewing the statuory language from Senate Bill 629, we believe the proposed regulations overreach the statutory intent and require onerous language that will prevent patients from receiving expanded access to care. After reviewing the State of Oregon Legislative Counsel, we are aware that an administrative rule review process subject to ORS 183.710 to 183.730 allows for a review of state agency rules for legal sufficiency. We believe that the proposed rules do not appear to be within the intent and scope of the enabling legislation and are an overreach. Because of

this, we suggest the board work with industry partners, and subject matter experts to revaluate and reconsider the entire rule set to better ensure remote dispensing and telepharmacy practices are enabled in an effective and efficient way. As written, the proposed language severely limits operability and includes multiple areas in question that have been demonstrated in other states and jurisdiction without such requirements by regulation.

Examples of rules with unreasonable restrictions are provided for illustration:

855-139-0200 (2) requires the Affiliated Pharmacy and Remote Dispensing Site Pharmacy being less than 120 miles apart. Placing this arbitrary geographic limitation creates a restriction to implementing telepharmacy to remote locations – which we believe is precisely contrary to the goal of providing pharmacy access to patients in remote locations.

855-139-0200 (3)(i) requires in person inspection by an Oregon licensed pharmacist every 28 days. This rule creates several unnecessary burdens. First, this 28 day recurring period is arbitrary and may prove to be unnecessary when every 45 or 60 days may suffice in the professional judgment of the Pharmacist-in-charge. Additionally, with available audio and visual technololgy, physical travel to the Remote Dispensing Site can be alleviated with virtual inspection which enables more effective use of the inspecting Oregon licensed pharmacist's time.

855-139-0600 (1) prohibits a Remote Dispensing Site Pharmacy from allowing a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist. Giving this language its broadest interpretation, a Oregon Certified Pharmacy Technician would be prohibited from administrative functions such as asking about insurance information or any other non-clinical conversations that typically are conducted with patients.

855-139-0600 (4) prohibits a Remote Dispensing Site Pharmacy from providing non-prescription or prescription drugs when either the Remote Dispensing Site Pharmacy or Affiliated Pharmacy is closed. While we appreciate the importance of providing pharmacist access when the pharmacy is open, in settings where the pharmacy department is closed and the front store remains open, sale of over the counter medications such as acetaminophen and aspirin should not be restricted.

Proposed Rule Amendments in Division 006, 041 on telework, remote processing

The pandemic has necessitated the opportunity for remote work characterized as telework in the proposed rules. The specific rules around technology and oversight are overly burdensome and we believe that the proposed rules do not appear to be within the intent and scope of the enabling legislation and are an overreach. Because of this, we suggest the board work with industry partners here alsos, and subject matter experts to revaluate and reconsider the entire rule set to better ensure remote dispensing and telepharmacy practices are enabled in an effective and efficient way. As written, the proposed language severely limits operability and includes multiple areas in question that have been demonstrated in other states and jurisdiction without such requirements by regulation.

CVS Health appreciates the opportunity to submit comments for the proposed amendment of these rules. If you have any questions, please contact me directly at Benjamin_dimarco@cvshealth.com.

Sincerely,
Ben DiMarco

CVS Health

Citations:

References:

1. Qato, Dima M., et al. "Association between pharmacy closures and adherence to cardiovascular medications among older US adults." JAMA network open 2.4 (2019): e192606-e192606
2. Niznik, Joshua D., Harvey He, and Sandra L. Kane-Gill. "Impact of clinical pharmacist services delivered via telemedicine in the outpatient or ambulatory care setting: A systematic review." Research in Social and Administrative Pharmacy 14.8 (2018): 707-717.
3. Watanabe, Jonathan H., Terry McInnis, and Jan D. Hirsch. "Cost of prescription drug–related morbidity and mortality." Annals of Pharmacotherapy 52.9 (2018): 829-837.
4. Viswanathan, Meera, et al. "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review." Annals of internal medicine 157.11 (2012): 785-795.
5. National Association of Boards of Pharmacy. Model State Pharmacy Act and Model Rules. 2020. Available from: https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/ (Accessed May 27, 2020)
6. American Society of Health-System Pharmacists. The Consensus of the Pharmacy Practice Model Summit. Am J Health-Syst Pharm. 2011; 68:1148-52.
7. American Pharmacist Association. APhA House of Delegates Policy and Procedure Manual. 2019. Available from: https://media.pharmacist.com/HOD/18512+-+HOD+Policy+and+Procedures+Manual+2020_online.pdf (Accessed May 27, 2020).

From:	Downey, Kristen J
To:	SCHNABEL Joseph * BOP; PHARMACY RULEMAKING * BOP
Subject:	RE: Chapter 855 Proposed Rules: Hospital comment letter
Date:	Tuesday, November 23, 2021 4:35:53 PM

*Resending, the rulemaking email address was wrong on the notice and I got a bounce back.

Kristen Downey
Director, Government Relations - Oregon

Providence Health & Services
4400 NE Halsey Street, Bldg 2, Ste 592
Portland, OR 97213
c: 503.887.0654

From: Downey, Kristen J
Sent: Tuesday, November 23, 2021 4:26 PM
To: joseph.schnabel@bop.oregon.gov; pharmacy.rulemaking@bop.oregon
Cc: Elizabeth M Edwards <Elizabeth.M.Edwards@kp.org>; Cole-Plasker, Gina E :LSO VP Government Affairs <GECOLE@LHS.ORG>; Julie Hanna <hannaju@ohsu.edu>; Michael T. Gay <Michael.Gay@salemhealth.org>; Bill Bouska <wbouska@samhealth.org>
Subject: Chapter 855 Proposed Rules: Hospital comment letter

Dear Executive Director Schnabel and Ms. Melvin,

The undersigned Oregon hospitals have serious concerns about the Oregon Board of Pharmacy's proposed chapter 855 rules. Please see our attached comments requesting an immediate delay in adoption of these rules.

Respectfully,

Kristen Downey
Director, Government Relations - Oregon

Providence Health & Services
4400 NE Halsey Street, Bldg 2, Ste 592
Portland, OR 97213
c: 503.887.0654

November 23, 2021

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

Re: Chapter 855 - Proactive procedural rule review proposes telework rules, repeals outdated regulations for remote processing and TCVP

Dear Ms. Melvin:

Oregon hospitals have serious concerns about the Oregon Board of Pharmacy's proposed chapter 855 telework rules and the repeal of regulations for remote processing and Technician Checking Validation Program. In order to allow sufficient time for our organizations to have a meaningful conversation with the Governor's Office and leadership at the OBOP, we respectfully request an immediate delay in adoption of these rules.

The described need for these changes suggests they are a result of the board's 2020-2024 Strategic Plan and that the TCVP regulations are outdated. Our organizations would argue the program is ensures excellent patient care and one we need to expand across the state. The pandemic has shone a spotlight on workforce needs across provider types. It is critical that we can maintain and improve upon collaborative models of care that allow providers to work at the top of their license providing high quality care to patients while extending the reach of our providers. To this end, pharmacy technicians and the TCVP play an important role in ensuring that acute care patients receive the medications they need in a safe and timely manner. The requirements of this program is are already very rigorous and we are unaware of any demonstrated adverse patient event from the program in Oregon.

As the workforce across the care continuum continues to evolve, it is critical that Oregon's licensing boards identify opportunities for individuals to develop task-based competencies through programs like the TCVP. Regulations that encourage this type of career pathway allow for the safe expansion of pharmacy technician roles, encouraging both technicians and pharmacist to practice at the top of their training and license or certification. Removing the ability for Oregon hospitals to implement the TCVP takes the state in the opposite direction.

With consideration for the demonstrated safety and quality protocols built in to the TCVP, and the immediate need to address workforce shortages post-pandemic, please consider our request for an immediate delay of the proposed rules. We look forward to opportunities for additional discussion regarding the TCVP to determine

path forward that ensures simultaneously that Oregonians receive the highest quality care and Oregon's workforce is appropriately utilized to its fullest potential.

Thank you,
Elizabeth Edwards, Director, Government Relations, Kaiser Permanente Northwest Region
Gina Cole, Vice President, Government Affairs, Legacy Health
Julie Hanna, Director, State Relations, Oregon Health & Sciences University
Kristen Downey, Director, Government Affairs, Providence
Michael Gay, Director, Government relations
Salem Health Bill Bouska, MPA, Director, Government Relations, Samaritan Health Services

From: Jacobo Flores
To: PHARMACY RULEMAKING * BOP
Subject: Dual-Language Prescription Label Sign
Date: Tuesday, November 23, 2021 4:20:40 PM
Attachments: Flores J Prescription Label Sign.docx

To: Rachel Melvin, OBOP Rules Coordinator

From: Jacobo Flores, OHSU Nursing Student Class of Winter 2022

Re: Division 007/041/045/065 Empower community with dual-language prescription label sign

---

I wanted to thank you for taking the time to review the dual-language prescription labeling as related to USP, storage, labeling, and repackaging. I believe that a universal statewide sign in pharmacies informing patients of their right to free interpretation, as well as translated medication instructions in the 14 suggested languages, is necessary. Having a sign will not only help pharmacies communicate with their patients, but it will also benefit the community to be aware of SB698. As a nursing student I have witnessed the complexity of navigating the health care system and the discouragement it brings to patients when they cannot understand their medications instructions in English. This is a concern because patients should feel empowered to improve their health. Some patients are lucky enough to have a family member to interpret what is on the medication bottle, but what about those who do not? The lack of translated medication labels has the potential to cause medication errors and delay treatment which is a serious harm to members of the community.

It is important for pharmacies to have a visible sign reminding the public of their right to language services, including an interpreter and a translated label. This helps to ensure the community receives quality care.

Sincerely,

Jacobo Flores

To: Rachel Melvin, OBOP Rules Coordinator

From: Jacobo Flores, OHSU Nursing Student Class of Winter 2022

Re: Division 007/041/045/065 Empower community with dual-language prescription label sign

---

I wanted to thank you for taking the time to review the dual-language prescription labeling as related to USP, storage, labeling, and repackaging. I believe that a universal statewide sign in pharmacies informing patients of their right to free interpretation, as well as translated medication instructions in the 14 suggested languages, is necessary. Having a sign will not only help pharmacies communicate with their patients, but it will also benefit the community to be aware of SB698. As a nursing student I have witnessed the complexity of navigating the health care system and the discouragement it brings to patients when they cannot understand their medications instructions in English. This is a concern because patients should feel empowered to improve their health. Some patients are lucky enough to have a family member to interpret what is on the medication bottle, but what about those who do not? The lack of translated medication labels has the potential to cause medication errors and delay treatment which is a serious harm to members of the community.

It is important for pharmacies to have a visible sign reminding the public of their right to language services, including an interpreter and a translated label. This helps to ensure the community receives quality care.

Sincerely,

Jacobo Flores

From:	Kate Newhall
To:	PHARMACY RULEMAKING * BOP
Subject:	Division 007/041/045/065 rule comments
Date:	Tuesday, November 23, 2021 4:14:06 PM
Attachments:	OBOP OAR Division 007041045065 Comments11.23.21.pdf

---

Please see attached comments. Thanks!

Kate
503-302-4895

November 23, 2021

To: Rachel Melvin, OBOP Rules Coordinator

Re: Division 007/041/045/065 - related to USP, Storage, Labeling, Repackaging

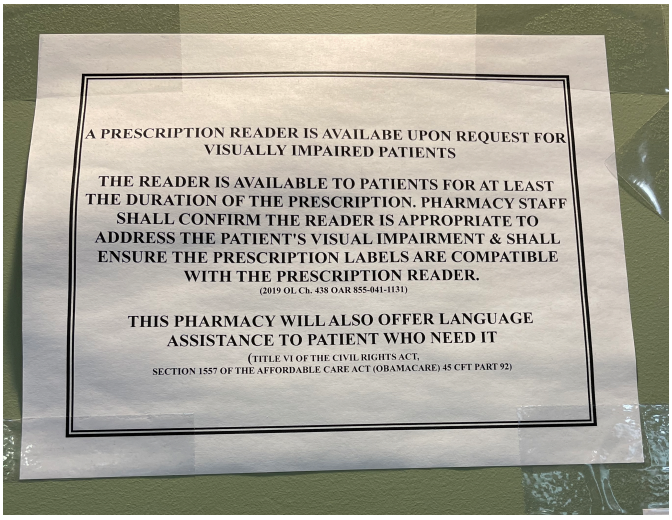
---

We appreciate the opportunity to provide comments today on OBOP proposed Division 007/041/065 rules related to USP, Storage, Labeling, Repackaging. Our comments are in support of the specific component of these rules that would require pharmacies to post signage notifying customers of the right to obtain dual-language prescription labels. We believe this is an important addition to current rules that simply require signage on the right to free, competent oral interpretation and translation services for all.

First, we want to thank the Board for acting on this important issue. We think the proposed rule is in closer alignment with the Legislature's intent in passing SB 698 (2019), particularly in guaranteeing patients experiencing limited English proficiency have the right to access dual-language prescription drug labels. Including notification of this right on required signage in pharmacies helps alert this population of their right to obtain prescription directions in a language they can understand – and notice should be provided in a language they can also understand.

While we support this proposed rule and appreciate the Board's work on this issue, we also want to encourage you to go even further. We are again asking that OBOP create the poster required by the signage rule and include on the poster notice of rights in all of the 14 languages covered by SB 698 and OBOP rules. If we truly want to provide meaningful language access and avoid medication errors, patients must know of their rights – and we can't expect them to be able to read an English-only sign, or a sign in very small font or in a place not easily visible to customers. Ideally, poster rules would require that the poster be in a placed in a location easily viewed by patrons at the counter, in a readable font size and include notification in each of the 14 covered languages. Most posters required by law include these kind of sideboards (i.e., generic drug substitutions, labor law postings, OSHA, etc).

To illustrate the point of how important these aspects are to meaningful language access, we are sharing examples of signs found in two pharmacies in Sisters, OR and Silverton, OR (respectively). These examples may meet the technical requirements of the law, but do not sufficiently provide notice to a client with limited English proficiency or vision impairment notice of their rights:



(Continued)

Having an OBOP created poster would make it easier for pharmacies to comply with the signage requirement, provide for more consistent signage being displayed in pharmacies across Oregon and ensure required signage is easily understood by the population it is intended to serve.

We appreciate the Board's continued work on implementing SB 698 and the dual-language prescription label law. The proposed rule is an important first step in achieving the intent of the law, and we continue to believe that more can be done to ensure meaningful language access for all Oregonians, regardless of their English proficiency.

With kind regards,

Kate Ballard, BSN, RN
Kristen Beiers-Jones, RN, MN
Stephanie Chance
Taylor Coleman
Jacobo Flores
Molly Greco
Alisha McBride
Kate Newhall
Brian Park, MD, MPH
Katie Reohr
Sarah Schaffer, BSN, RN
Anna R. Wheeler

From:	Katie Jaeger
To:	PHARMACY RULEMAKING * BOP
Subject:	Kaiser Foundation Health Plan of the Northwest-rulemaking comment submission
Date:	Tuesday, November 23, 2021 11:19:53 AM
Attachments:	Kaiser Permanente_Division 006_041_041 - related to Telework Remote Processing TCVP_Rulemaking Comments 11.23.21.pdf Kaiser Permanente_Division 007_041_045_065 - related to USP Storage Labeling Repackaging_Rulemaking Comments 11.23.21.pdf

---

Dear Officer Melvin,

Please see attached comments related to the rulemaking from Kaiser Foundation Health Plan of the Northwest.

Regards,

Katie Jaeger

Katie Jaeger, Pharmacy Regulatory
Kaiser Permanente Northwest Region
Cell: 503-758-6887

KAISER PERMANENTE®

November 23, 2021

Kaiser Foundation Health Plan of the Northwest
Pharmacy Administration
5725 NE 138th Ave.
Portland, OR 97230

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

Dear Officer Melvin,

Re: Proposed Rules - Division 006/041

Thank you for the opportunity to provide comments on the proposed rulemaking.

Telework

As the practice of pharmacy has advanced, pharmacists, and the pharmacy technicians/interns that assist them, have become an integral part of the care team, working alongside physicians and other health care professionals as the drug experts. This includes providing specialized drug information, working under clinical pharmacy agreements, and optimizing medication regimens for improved quality of care and safety. This type of practice has occurred outside of and unassociated with registered drug outlets in the state of Oregon for many years.

The definitions of Telework and Telework site as proposed, can be interpreted to limit the practice of pharmacy to cases only in which a pharmacist, and the pharmacy technicians/interns that assist them, are employees of an Oregon registered drug outlet.

855-041-3205 Telework: Definitions

"(1) "Telework" means the practice or assistance in the practice of pharmacy physically outside of a registered drug outlet in a telework site.

(2) "Telework Site" means a location that is not a registered drug outlet where an Oregon licensed Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist in the practice of pharmacy as employees of an Oregon registered drug outlet."

We are concerned that these definitions could threaten the longstanding practice of pharmacists, and the pharmacy technicians/interns that assist them, providing clinical pharmacy services in settings that are not registered drug outlets such as anti-coagulation clinics and other ambulatory care clinics.

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Additionally, while the Board's effort to promulgate telework rules is greatly appreciated, the telework language as proposed is very restrictive, personally invasive and cost prohibitive.

As was discussed during the Board's November Strategic Planning meeting, pharmacy technician availability in the state is critically low. This pharmacy technician shortage has the potential to negatively impact the ability of pharmacies and pharmacists to operate in a safe manner. Additionally, staffing shortages have led to unexpected pharmacy closures throughout the state.

Allowing pharmacy technicians/interns the ability to work in alternate locations can benefit the public and pharmacists in many ways. Not only can it provide a work environment that is quiet and uninterrupted, but it can also provide more options for social distancing and more options for those that may not be able to tolerate a position in a traditional pharmacy setting due to physical or personal barriers. This creates a safer, more productive work environment, both inside and outside the licensed pharmacy space which we hope will create work opportunities that are desirable for more pharmacy technicians.

The use of technology has also advanced along with the practice of pharmacy. Technology has allowed for safer and more efficient practices and workflows to ensure the right patient is getting the right medication(s). Contemporary pharmacy computer systems and automation also provide the ability to track who completed every step of the prescription filling process, no matter where they are located.

Many pharmacy computer systems today also restrict task work that can occur to properly licensed staff. For instance, a technician cannot access the queue where a pharmacist only task like drug utilization review (DUR) or product verification occurs. The queues a technician works from flows to the pharmacist queues for review – data entry (tech) >> DUR (RPh) >> fill (tech) >> product verification (RPh).

We encourage the Board to strongly consider rewriting the proposed telework rule with less restrictive language. In particular, we believe that the rule should allow for pharmacists and/or outlets to determine the appropriate level of oversight (including number of technicians a pharmacist is comfortable supervising) and quality assurance required based on where staff are working and what type of work will be occurring. The fact is, many pharmacists and pharmacy technicians have maintained the necessary focus on patient centered care from non-pharmacy locations over the last 19 months with far fewer restrictions on their practice compared with the proposed rule. We believe that continuing with a more flexible model, as has been in place during the public health emergency, would be a win for pharmacy and a win for patient care.

Repealing 855-041-3100-3130 Remote Processing Language

Remote processing or "load balancing" is technology used by many outlets to allow one location to assist another location with work. This is especially useful when a pharmacy is experiencing unexpected volume fluctuations or staffing challenges. For example, Kaiser uses this functionality in our outpatient, hospital, oncology and home infusion pharmacies. This allows us to shift resources where help may be needed, but not physically available to go.

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Kaiser also utilizes a centralized call center that takes all calls that would normally come into the outpatient pharmacies. This has significantly reduced the noise and interruption that occur in the retail pharmacy setting. One part of the call center workflow is initiating prescription orders for members.

By repealing this language, we are concerned these critical business functions will no longer be allowed.

Thank you for taking the time to consider our comments.

Respectfully,

Alfred Lyman, Jr., PharmD, BCPS
Executive Director, Regional Pharmacy Services
Phone: (503) 261-7566
Email: alfred.e.lyman@kp.org

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November 23, 2021

Kaiser Foundation Health Plan of the Northwest
Pharmacy Administration
5725 NE 138th Ave.
Portland, OR 97230

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

Dear Officer Melvin,

Re: Proposed Rules - Division 007/041/045/065 - related to USP, Storage, Labeling, Repackaging

Thank you for the opportunity to provide comment on the proposed rulemaking.

855-041-1135(a) Proposed language

Utilize a unit-dose container-closure system that meets the testing requirements under USP <671> Containers-Performance Testing (12/01/2020) for either Class A or Class B containers and meets or exceeds the original container's specification for light resistance;

We believe that the phrase 'the original container's specification' is unclear and would present a significant barrier to repackaging by pharmacies. We recommend that the Board modify that sentence to provide a clear light protection standard for the containers used in pharmacy repackaging.

In reviewing the relevant USP chapters and FDA guidance language related to repackaging into single-unit dose containers, we could not find reference to light resistance specifications of a drug product's original container. The information that is readily available on manufactures' bottles and package inserts includes language like 'protect from light' and 'dispense in a tight, light-resistant container as defined by USP'.

USP <659> Packaging and Storage Requirements defines light resistant container as: "A Container–closure system that protects the contents from the effects of light by virtue of the specific properties of the material of which it is composed, including any coating applied to it. A clear and colorless or a translucent container may be made light-resistant by means of an opaque covering or by use of secondary packaging, in which case the label of the container bears a statement that the opaque covering or secondary packaging is needed until the articles are to be used or administered. Where it is directed to 'protect from light' in an individual monograph, preservation in a light resistant container is intended."

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In order to provide a standard that pharmacies are able to understand and comply with, we ask the Board to consider the following change to the proposed regulation: … and meets or exceeds the manufacturer's recommendation for protection from light;

855-041-6270(4) Proposed language

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

There are circumstances in which a patient starts a unit of use product, such as an inhaler, during an inpatient stay and will continue that medication when they are discharged. In an effort to reduce health care waste, there is a desire to send a product of this nature home with a patient. This medication has already been ordered and dispensed by an inpatient pharmacy and can be re-labeled with elements necessary to meet patient safety standards prior to discharge.

Dispensing per ORS 689.005(9) *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*.

In the circumstance described above, the order was issued to the inpatient pharmacy and could not be used again for the same drug product, in potentially a different pharmacy. We ask the Board to consider excluding circumstances such as this from the proposed language. One potential approach would be to modify the proposed regulation as follows: A drug that is provided for outpatient use must be dispensed by a retail drug outlet. A unit of use drug previously dispensed by an institutional pharmacy for continued outpatient use will be labeled in accordance with 855-041-1130.

Thank you for taking the time to consider our comments.

Respectfully,

Alfred Lyman, Jr., PharmD, BCPS
Executive Director, Regional Pharmacy Services
Phone: (503) 261-7566
Email: alfred.e.lyman@kp.org

From: mike@ridgelark.com
To: PHARMACY RULEMAKING * BOP
Subject: KEEP THE TCVP! Oppose the rule change!
Date: Monday, November 22, 2021 7:47:22 AM

Dear Board of Pharmacy,

Please retain the Technician Checking Validation Program, and vote NO on the rule change to eliminate it. Technicians who participate in TCVP go through extensive training, resulting in a safe and more efficient method of disbursing medication.

As healthcare costs continue to rise, please don't actively contribute to those cost increases by helps keep those costs under control. In your own materials, the Board of Pharmacy notes that registrant pharmacies will see costs go up tens of thousands of dollars -- costs that will likely have to be passed on to consumers.

It's important to have Board-Licensed Pharmacists provide broad oversight, but this program helps keep costs reasonable and keeps our local pharmacy efficient.

Consumers, labor unions, and health care providers agree: Keep the Technician Checking Validation Program!

From: Mike

From: Susannjordan2000@yahoo.com
To: PHARMACY RULEMAKING * BOP
Subject: KEEP THE TCVP! Oppose the rule change!
Date: Saturday, November 20, 2021 12:15:53 PM

Dear Board of Pharmacy,

Please retain the Technician Checking Validation Program, and vote NO on the rule change to eliminate it. Technicians who participate in TCVP go through extensive training, resulting in a safe and more efficient method of disbursing medication.

As healthcare costs continue to rise, please don't actively contribute to those cost increases by helps keep those costs under control. In your own materials, the Board of Pharmacy notes that registrant pharmacies will see costs go up tens of thousands of dollars -- costs that will likely have to be passed on to consumers.

It's important to have Board-Licensed Pharmacists provide broad oversight, but this program helps keep costs reasonable and keeps our local pharmacy efficient.

Consumers, labor unions, and health care providers agree: Keep the Technician Checking Validation Program!

From: Susan Korenkov

From: Sandra Guckian
To: PHARMACY RULEMAKING * BOP
Subject: NACDS" Comments on Division 006/041 - related to Telework, Remote Processing & TCVP
Date: Tuesday, November 23, 2021 1:13:39 PM

On behalf of our members operating chain pharmacies in the state of Oregon, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment to the Oregon Board of Pharmacy on the proposed rulemaking to significantly revise current practices for remote processing and centralized prescription drug filling by a pharmacy. NACDS has concerns with the new, proposed model that may create impediments to current efficiencies related to prescription processing and may have adverse impacts on patients at a time where there is increasing demands on pharmacists and pharmacies as a result of the current COVID-19 pandemic and beyond as patients have come to rely upon local pharmacists and pharmacies as a trusted, primary healthcare destination.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

NACDS strongly urges the Board of Pharmacy to retain the following related to remote processing and centralized prescription drug filling: 855-041-1060, 855-041-3000, 855-041-3100, 855-041-3105, 855-041-3110, 855-041-3115, 855-041-3120, 855-041-3125, and 855-041-3130. Furthermore, we request retaining and revising the definition of “supervision by a pharmacist” to remove the reference to a time frame, thereby making the definition permanent.

> Retain the following:
> ~~(30) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.~~ ¶
>
> With this revision:
> (30) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be

responsible for the pharmacy technician or certified Oregon pharmacy technician's action. ~~**During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "s**~~Supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.

If the Board of Pharmacy is unable to retain current practices for remote processing and centralized prescription drug filling, then NACDS urges the Board to create a new diverse stakeholder group to explore an alternate model reflective and representative of the viewpoints of pharmacists, technicians, interns, patients, and pharmacies.

NACDS fully supports pharmacies' abilities to perform remote processing and centralized prescription drug filling expanding patient access to quality patient care and medications for Oregon residents. Amid the COVID-19 pandemic and beyond, NACDS strongly urges the Board to permit these practices to continue without interruption or unnecessary requirements and barriers that may prevent or delay patients from receiving the medications they need.

If you have any questions, please contact me.

Thanks, Sandra

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From:	Trinh, Long D
To:	SCHNABEL Joseph * BOP; PHARMACY RULEMAKING * BOP
Cc:	aburns@aphanet.org; "Joshua Free"; Hissam, Jennifer M; Junior Lyman; lincpalex@gmail.com; Yen Pham; Anne Policastri; Michael Powell; Daniel Rackham; cory.rahn@salemhealth.org; Tanas, Majid :LSO VP Chief Pharmacy Officer; "Amy.Watson@asante.org"
Subject:	Opposition of the BOP Proposed Repeal of TCVP
Date:	Monday, November 22, 2021 12:20:37 PM
Attachments:	image001.png Opposition Response to TCVP Repeal_11.19.21.pdf

Hello Joe,

I hope you are well.

On behalf of Oregon health-system pharmacies and associations, kindly accept the attached opposition to the proposed repeal of Technician Checking Validation Program.

TCVP is safe, and aligns with our collective goals to provide quality patient care as well as advancement of pharmacy practice. A priority of pharmacies is to address the staffing crisis, and a consequence from the repeal is impacting strategic workforce planning efforts, and in the process, patient safety/quality.

Thank for the opportunity to comment, and ensuring the safety of the community and high standards in the practice of pharmacy. We look forward to engaging with you in this matter to assess current regulations and opportunities for process improvement.

Best wishes to a safe and happy Thanksgiving.

Regards,
Long

Long D. Trinh, PharmD, MS, MBA, BCPS
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November 19, 2021

Oregon Board of Pharmacy
800 NE Oregon St, Portland, OR 97232

RE: BOP Repeal of TCVP Public Comment

To Oregon Board of Pharmacy:

The American Society of Health-System Pharmacists (ASHP), American Pharmacists Association (APhA), Oregon Society of Health-System Pharmacists (OSHP), Oregon State Pharmacy Association (OSPA), The Oregon Pharmacy Coalition, Asante, Kaiser Permanente Northwest Region, Legacy Health, Oregon Health & Science University, Providence St. Joseph Health, Salem Health, Samaritan Health Services, and St. Charles Healthcare oppose the repeal of the Technician Checking Validating Program (TCVP) (OAR 855-041-5100 through OAR 855-041-5170), ultimately making Oregon less progressive in the practice of Pharmacy.

- The model of tech-check-tech or TCVP has become a national standard across multiple states, with at least twelve states allowing an analogous TCVP (WA, CA, IA, KS, KY, MN, NV, OR, SC, TN, TX, WI).
- There have been numerous peer reviewed publications demonstrating that TCVP is safe, and well researched on the improved and/or equal outcomes from technician checking technician practice models as well as health system professions continued evaluation of the practice.[1-5]
- In a 2020 ASHP National Survey, 30.6% of respondents indicate they had technicians checking other technicians.
- With appropriate training and quality assurance monitoring, pharmacy technicians can perform as accurately as pharmacists on the checking of another technician's order-filling in an institutional-settings.
- The medication use process for Inpatient also includes barcode scanning of medications prior to loading into automated dispensing cabinet and at the point of administration.

The pandemic has demonstrated there is a growing need for Pharmacists to practice as clinicians to serve Oregonians. By repealing the OARs, Health-System Pharmacists will be required to spend more time performing distributive duties which will remove them from the floors, where they provide clinical care resulting in an impact to patient safety. For the duration of the OAR, checking of prescriptions has evolved into a technician's duty and a movement in Health-System Pharmacy across the country. Placing this responsibility back to a pharmacist would be done without any demonstrative benefit to the medication use system, adds cost, and would not achieve the desired effect to impact safety.

TCVP provides the opportunity to design the Pharmacy Technician work to enhance job satisfaction, compensation with expanded duties, and minimize technician turnover. The program favorably enhances collaboration among the technician and pharmacist workforce, ensuring our medication-use processes are sustainable, operationally efficient, clinically effective, and safe.

At a national level, ASHP and APhA support state Board of Pharmacy approval of technician-checking-technician programs with appropriate quality control measures to permit redirection of pharmacist resources to patient care activities. ASHP's statement on role of pharmacy technicians describes the roles for advanced technicians, including tech-check-tech, developed by evaluating the evidence and safety and ASHP's member consensus (https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/roles-of-pharmacy-technicians.pdf. APhA policy encourages and supports regulations that allow the expansion of pharmacy technician roles that allow both technicians and pharmacists to practice at the top of their training and license or certification.

Thank you for the opportunity to comment on these proposed rulemakings for your consideration. OSHP will continue to collaborate with the Board to advocate for legislation to further advance the practice of Pharmacists and Pharmacy Technicians. We look forward to engaging with you in this matter to assess current regulations and opportunities for process improvement.

American Society of Health-System Pharmacists

American Pharmacists Association
Scott J. Knoer, PharmD, MS, FASHP
Executive Vice President and CEO

Oregon Society of Health-System Pharmacists
Alfred Lyman, Jr., PharmD, BCPS
President

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Alfred Lyman
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Oregon State Pharmacy Association
Lincoln Alexander, PharmD
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The Oregon Pharmacy Coalition
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Chairman

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Asante
Amy Watson, RPH
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Oregon Health & Sciences University
Yen T. Pham, RPh, MBA
Chief Pharmacy Officer

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Salem Health
Cory Rahn, PharmD, BCPS
System Director of Pharmacy

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Samaritan Health Services
Daniel M. Rackham, PharmD, BCPS
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St. Charles Health System
Michael Powell, RPh
Chief Pharmacy Officer

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Michael Powell
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References:

1. Assessment of technician barcode scanning verification compared to pharmacist verification ; Annie U Shelton, Pharm.D., M.H.A, Matt Wolf, Pharm.D., M.S, Noah Franz, Pharm.D., M.H.A, Philip W Brummond, Pharm.D., M.S., FASHP; *American Journal of Health-System Pharmacy*, Volume 76, Issue 3, 1 February 2019, Pages 148–152, https://doi.org/10.1093/ajhp/zxy018
2. "Tech-check-tech": A review of the evidence on its safety and benefits ; Alex J. Adams, Pharm.D., Steven J. Martin, Pharm.D., FCCP, FCCM, BCPS, Samuel F. Stolpe, Pharm.D.; *American Journal of Health-System Pharmacy*, Volume 68, Issue 19, 1 October 2011, Pages 1824–1833, https://doi.org/10.2146/ajhp110022
3. Evaluating the accuracy of **technicians** and pharmacists in checking unit dose medication cassettes ; Peter J. Ambrose, Pharm.D., FASHP, Frank G. Saya, Pharm.D., FASHP, Larry T. Lovett, Pharm.D., Sandy Tan, Pharm.D., Dale W. Adams, Pharm.D.; *American Journal of Health-System Pharmacy*, Volume 59, Issue 12, 15 June 2002, Pages 1183–1188, https://doi.org/10.1093/ajhp/59.12.1183
4. Accuracy of technicians versus pharmacists in checking syringes prepared for a dialysis program ; Scott R. Andersen, John V. St. Peter, Pharm.D., BCPS, Mark G. Macres, M.S., Wendy L. St. Peter, Pharm.D., FCCP, BCPS; *American Journal of Health-System Pharmacy*, Volume 54, Issue 14, 15 July 1997, Pages 1611–1613, https://doi.org/10.1093/ajhp/54.14.1611
5. Minnesota Society evaluates use of pharmacy technicians to check unit dose cassettes ; *American Journal of Hospital Pharmacy*, Volume 47, Issue 2, 1 February 1990, Pages 259–265, https://doi.org/10.1093/ajhp/47.2.259; Published: 01 February 1990

From:	Millard, Michael
To:	PHARMACY RULEMAKING * BOP
Subject:	Revised testimony
Date:	Tuesday, November 23, 2021 9:43:12 AM
Attachments:	OSHP Comments to OBOP Nov rulemaking public hearing v2.docx

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Please find attached a copy without the tracked changes.

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"A lie is not the truth because you believe it"

Michael Millard B.Pharm MS FOSHP
Professor Emeritus
Pacific University School of Pharmacy
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Oregon Society of Health-System Pharmacists: Recommendation to Advance Pharmacy Practice

The Oregon Society of Health-System Pharmacists (OSHP) is a professional organization affiliated with the American Society of Health-System Pharmacy (ASHP). OSHP, representing licensed practitioners in the State of Oregon, is dedicated to the advancement of pharmacy practice in Oregon through education, collaboration, and advocacy. We appreciate the focus by the Oregon Board of Pharmacy (OBOP) on patient safety and responsiveness to the advancing practice roles and challenges of pharmacists and pharmacy technicians. We would like to provide our input into the current rule making process and the future of the OBOP regulation of the profession.

The COVID-19 pandemic has highlighted the practice of pharmacy in its importance providing essential services and opportunities to serve patients as the pandemic continues to strain our nation's healthcare system. It has also highlighted the importance of being flexible and nimble to adjust to patient care needs while upholding the highest standards of quality and safety.

Telework and Remote Processing

For the declared emergency timeframe, the OBOP allows a pharmacy to consider remote processing functions, to include the option of pharmacy interns and pharmacy technicians to perform limited functions from a secure off-site, non-pharmacy location for the functions of prescription order entry, other data entry, and insurance processing of prescriptions and medication orders. Currently, 25 states permit telepharmacy and OSHP strongly advocates for this practice to be continued on a permanent basis to serve our patients in Oregon, regardless of geographic location or distance from a licensed pharmacy.

The definition of telepharmacy may be too broad if it includes all patient interactions conducted outside of a registered drug outlet. Many ambulatory clinical pharmacists provide consultation and clinical pharmacy service to patients from medical clinics or other non-registered locations.

OSHP strongly advocates for the retention of regulations put in place to support telework and remote processing, including remote supervision of pharmacy interns and technicians, beyond the COVID-19 public health emergency. OSHP applauds the OBOP for recognizing this as a priority as evidenced by the proposal presented at the October 2021 OBOP Meeting to create rules that allow a pharmacist, pharmacy intern, or pharmacy technician to work remotely. OSHP strongly

encourages the OBOP to consider provisions pertaining to non-traditional practices, such as clinical pharmacy telemedicine, as well as allowing telework for pharmacists and their supporting interns and technicians not associated with Registered Drug Outlets. OSHP would also ask that the OBOP carefully consider the practicality of any requirements for call recording, surveillance, and quality assurance to balance the need for regular reviews for compliance with feasibility to implement, including impact to the cost of providing care. During the course of the pandemic, pharmacists and pharmacy technicians have demonstrated that telework can be performed in a manner that does not compromise patient safety or quality of care.

Telepharmacy can offer convenient access to medications and a pharmacist and compliments local clinic or point of care to improve fill rates and adherence. The COVID-19 pandemic has highlighted barriers to workforce and workflow issues in addition to various shortages. Continuing pharmacy remote processing functions and telepharmacy will allow patients to receive the most accessible and affordable medications.

Medication Reconciliation

OSHP asks the OBOP to clarify the use of CPhT licensees to perform intake drug reconciliation interviews and submit the results to the electronic medical record of the patient for review by physicians and pharmacists providing care for these patients. Accurate medication histories are a critical component of high quality and safe hospital care. Having patients assisted by CPhT licensees in completing a comprehensive history of drug prescription and current utilization is a valuable process in beginning to evaluate medication use by the pharmacist or physician.

Primary Intended Outcomes of Medication Reconciliation by CPhT licensees:

- Improve medication safety by assisting pharmacists to collect up-to-date, prior-to-admission medication lists for patient admitted to the hospital.
- Update and clarify allergy information in patients' records in an electronic medical record.
- Optimize the medication reconciliation process and decrease the number of med errors and adverse drug events due to incomplete or inaccurate medication information.

ASHP published a study focused on medication reconciliation that incorporated Medication Reconciliation Technicians.[1] MultiCare is a private, non-profit, acute, integrated, tertiary medical center located in Tacoma, Washington, and surrounding areas. Technicians who could devote their time to medication reconciliation helped nurses and pharmacists improve home medication review lists from 65% to 100% over a 6-month time period ($p<0.001$). Medication reconciliation by admitting physicians conducted within 24 hours of admission, a Joint Commission standard, also

improved from 30.5% to 88% ($p<0.0001$). In this time frame, the rate of adverse medication events decreased by more than 25% while medication harm events dropped by almost 50%.

Workload and Pharmacist Staffing

The current environment in both retail and institutional pharmacy is in a critical state. The many enhanced duties and responsibilities, such as prescribing, have met the reality of reduced reimbursement and pharmacist staffing. The OBOP must address the current crisis of insufficient and unsafe professional and technical manpower in our corporate practices. The independent practitioner who determines the work practices in a licensed pharmacy is a thing of the past. OBOP must recognize their responsibility to regulate outlets to the same degree that they have previously regulated practitioners. OSHP stands ready to collaborate with the OBOP on proposals to meet this patient safety challenge.

CURRENT BOARD OF PHARMACY RULES:

OSHP would like to comment on the proposed rule changes under current review.

855-007-0088 Compliance with COVID rules
OSHP supports this rule.

855-007-0120 Damage to a Pharmacy and Drug Integrity
OSHP supports this rule

855-010-0005 Meetings
OSHP supports this rule

855-139-0200 Outlet: General Requirements

(1) An Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.

2) An Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the Remote Dispensing Site Pharmacy.

(3) A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

> (i) Develop, implement and enforce a process for an in person physical inspection of the Remote Dispensing Site Pharmacy by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed Pharmacist-in-

charge of the Affiliated Pharmacy. The inspection must utilize the Remote Dispensing Site Pharmacy self-inspection form, be documented and records retained.

OSHP does not support a regulatory limit on the number or location of remote dispensing sites. It seems if a rural location would be served by remote pharmacist supervision by an Affiliated Pharmacy, the location could easily be quite remote (over 120 miles away). We also believe that while a physical inspection might be needed for appropriate safety and control, monthly inspection is not needed. OSHP suggests that an ability to conduct a virtual or in-person inspection as needed would be sufficient. The actual frequency of inspection should be determined by the Affiliated Pharmacy assessment of need. The inspection could also be done via camera/remote technology.

855-139-0210 Outlet: Supervision

(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a Remote Dispensing Site Pharmacy must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;

OSHP does not support a 25% minimum patient encounter review. The Affiliated Pharmacy should use professional judgement (as outlined in the rule). Reviewing 25% may be the correct amount in the beginning, but would be burdensome after all procedures are well implemented and staff is trained. A 5% sample of the encounters would be a valid quality assurance check on policy compliance.

A reporting requirement for those interactions that are found to be out of compliance should be considered. 855-139-0550 (3h) only requires “errors”. Reporting errors and omissions to the Pharmacy Quality Assurance Plan for board inspection would be critical to assure patient safety in the remote dispensing site.

(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;

(c) Document the following within 24 hours of the review in (3)(b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions pharmacist is reviewing;

(C) Date and time of licensee patient interaction pharmacist is reviewing;

(D) Date and time of pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

Are these items only for the reviewed interactions, or for all interactions? OSHP does not support the review of numerical reporting of workload as a quality or patient safety measure. The number of interactions is not a quality indicator.

(d) Report any violation of OAR 855 to the Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.

OSHP strongly supports this regulation.

(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.

OSHP strongly supports this regulation

(5) Ensure all telephone audio is recorded, reviewed and stored.

This seems to be in conflict with 3(a) which only required 25% review. It seems that the patient would have to consent to having their likeness stored and identified by the pharmacy.

855-139-0215 Outlet: Pharmacist Utilization

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Utilize an Oregon licensed Pharmacist from the Affiliated Pharmacy to perform the professional tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is dispensed; and

(2) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 and when requested and document the interaction.

If the patient must be linked to the pharmacist at the Affiliated Pharmacy for a refill refusal, then in fact they could not refuse the counseling since they would be waiting for the pharmacist in a similar fashion to a patient receiving counseling. Would this be mandatory counseling? Also, if they left without the pharmacist refusal of counseling, would this be a violation of this regulation?

855-139-0220 Outlet: Non-Prescription Drugs

(2) Ensure that an Oregon-licensed Pharmacist is immediately available to provide counseling or recommendations involving non-prescription drugs

855-139-0550 Records: General Requirements

(1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

Video storage is costly and storing 3 years of video with daily use would cost 10's of thousands of dollars. This would provide a significant fiscal impact to outlets for compliance. Cloud storage can be more cost effective, efficient, and more secure than onsite storage. In fact, HIPAA security protocols may prohibit onsite storage of digital data.

(2) The Remote Dispensing Site Pharmacy must maintain all required records unless these records are maintained in the Affiliated Pharmacy.

(3) Records retained by the Drug Outlet must include, but are not limited to:

(b) Date, time and identification of each individual and activity or function performed;

(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(d) Controlled substance inventory and reconciliation;

(e) Oregon licensed Pharmacist physical inspection of Remote Dispensing Site Pharmacy;

What would be the components of the physical inspection? Would there be a checklist of required elements of the physical inspection?

(f) Audio and visual connection testing and individual training on use of the audio and visual connection;

(g) Data, telephone audio, audio and video, still image capture, store and forward images, security and surveillance data. This must be retained according to (1); and

Would the pharmacy need consent from the patient to be photographed?

(h) Any errors or irregularities identified by the quality improvement program.

Would this documentation be required recordkeeping?

(4) All data, telephone audio, audio and video, still image capture and store and forward images collected by the telepharmacy, security and surveillance systems must be retained according to (1).

855-139-0600 Prohibited Practices: General A Retail Drug Outlet Remote Dispensing Site Pharmacy may not:

(1) Allow a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;

(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) Deliver a prescription;

OSHP does not support this regulation. There may be circumstances where the patient is non-ambulatory and the filled prescription may be needed to be delivered after the appropriate audio visual consultation. The Remote Dispensing Site is not the only location that audio visual consultation can be delivered.

(4) Provide non-prescription or prescription drugs when either the Remote Dispensing Site Pharmacy or Affiliated Pharmacy is closed;

(5) Compound sterile preparations; or

(6) Repackage drugs.

Division 041/080 - related to Pseudoephedrine/Ephedrine
OSHP supports this rule

855-080-0026 Schedule V
OSHP supports this rule*
Should the OBOP specify the application where the required information is entered?

Division 020 - related to Pharmacist Prescriptive Authority - COVID mAb, PEP & PrEP
OSHP supports this rule

Division 043 - related to SPDO/DPDO/CHC
OSHP supports this rule

Division 060/110 - related to PDMP Fee Increase
OSHP Supports this rule

Division 006/041- related to Telework, Remote Processing & TCVP

855-041-3205 Telework: Definition

(1) "Telework" means the practice or assistance in the practice of pharmacy physically outside of a registered drug outlet using audio and visual means in a telework site
(2) "Telework Site" means a location that is not a registered drug outlet where an Oregon licensed Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist in the practice of pharmacy as employees of an Oregon registered drug outlet.

Due to advanced pharmacy practice often takes place in settings outside of a "registered drug outlet", OSHP is concerned about broader implications, particularly as ambulatory care pharmacists, such as pharmacists working in physician offices or health system practices, tend to take place outside of a registered drug outlet. OSHP supports clarifying the definition of telework as suggested above.

855-041-3220 Telework: Supervision Requirements

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the supervising Oregon licensed Pharmacist from the Drug Outlet must:
(1) Utilize technology that enables real-time audio and visual connection and have appropriate technology or interface to allow access to information required to complete assigned duties;
(2) Ensure all telephone audio is recorded, reviewed and stored;
(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon Pharmacy Technician and that the continuous audio/visual connection is fully operational;
(4) Ensure that an Oregon licensed Pharmacist using professional judgment, determines the frequency of "checkins" for each licensee being supervised via the real-time audio and visual connection with a minimum of at least once per work shift to ensure patient safety, compliance with federal and state laws, and documents the interaction;
(5) Be readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and
(6) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction and control at all times.
(7) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy Technician at a Telework Site must:
(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;
(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;
(c) Document the following within 24 hours of the review in
    (A) Number of each licensee's patient interactions;
    (B) Number of each licensee's patient interactions pharmacist is reviewing;
    (C) Date and time of licensee patient interaction pharmacist is reviewing;
    (D) Date and time of pharmacist review of licensee's patient interaction; and
    (E) Pharmacist notes of each interaction reviewed; and

Are these items only for the reviewed interactions, or for all interactions? OSHP does not support the review of numerical reporting of workload as a quality or patient safety measure. The number of interactions is not a quality indicator.

(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of discovery and to the board within 10 days. (8) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination

OSHP does not support a 25% minimum patient encounter review. The Affiliated Pharmacy should use professional judgement (as outlined in the rule). Reviewing 25% may be the correct amount in the beginning, but would be burdensome after all procedures are well implemented and staff is

trained. A 5% sample of the encounters would be a valid quality assurance check on policy compliance.

855-041-5100 Elimination of TCVP

OSHP is concerned about the several institutional outlets that have implemented a TCVP program for kits and ADM refill processes. Does the elimination of these rules imply that these programs must be stopped? While these programs are not widely used, these institutions have used the pharmacist manpower savings to provide for pharmacist professional services in other programs within the institution. It would be harmful for these programs to be eliminated by the OBOP action. OSHP will continue to support and advocate for legislation to further expand and advance technician roles.

References:

1. "Medication Reconciliation Technician." ASHP, https://www.ashp.org/pharmacy-technician/about-pharmacy-technicians/advanced-pharmacy-technician-roles/medication-reconciliation-technician.

From:	Brian Mayo
To:	PHARMACY RULEMAKING * BOP
Subject:	Oregon Board of Pharmacy Rulemaking Hearing Written Comment 11_23_21
Date:	Tuesday, November 23, 2021 1:31:23 PM
Attachments:	Telepharmacy response to OBOP proposed rules FINAL 11.23.21_jrs edits.pdf

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Oregon Board of Pharmacy,

Please find attached the written testimony from the OSPA, OSHP and the Oregon Pharmacy Coalition for today's rulemaking hearing which has a deadline for submission of 4:30pm.

Brian Mayo
Executive Director
Oregon State Pharmacy Association
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Leading Pharmacy, Advancing Healthcare!

11/23/2021

Oregon Board of Pharmacy
800 NE Oregon St, Portland, OR 97232

RE: Telepharmacy proposed rules

To Oregon Board of Pharmacy:

The Oregon State Pharmacy Association (OSPA), Oregon Society of Health-System Pharmacists (OSHP), and the Oregon Pharmacy Coalition request the following changes to the proposed telepharmacy rules which can be found under the Division 019/139 - related to Remote Dispensing Site Pharmacy and Division 006/041 - related to Telework, Remote Processing & TCVP

1) **Length of data recording keeping to less than 3 years.**

Video storage is expensive and storing three years of video with daily use will cost pharmacies thousands of dollars every year. Additionally, of the twenty-seven states which permit telepharmacy, twenty-five limit record retention of surveillance to less than 90 days or do not mention a requirement. Currently, California is the outlier and requires 120 days, and Kansas is still promulgating rules.

For your reference, we have attached a summary table provided by Telepharm of the storage requirements for the other states that permit telepharmacy. Unlike the draft language in Oregon, none of the states permit the recording of patient communications.

In addition, the requirement for onsite storage is outdated. Cloud storage can be cheaper, more efficient, and more secure than onsite storage. In fact, HIPAA security protocols for some businesses prohibit onsite storage of digital data. We ask that you remove the requirement for on-site data storage.

> *855-139-0550 Records: General Requirements (1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years, and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two. (4) All data, telephone audio, audio and video, still image capture and store and forward images collected by the telepharmacy, security and surveillance systems must be retained according to (1).*

2) **Reduce the required amount of patient review within 48 hours.**

Review of 25% of patient interactions is excessive. This may be useful during initial training, but rule needs to be reduced to 5%.

(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a Remote Dispensing Site Pharmacy must: (a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed; (b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request; (c) Document the following within 24 hours of the review in (3)(b): (A) Number of each licensee's patient interactions; (B) Number of each licensee's patient interactions pharmacist is reviewing; (C) Date and time of licensee patient interaction pharmacist is reviewing; (D) Date and time of pharmacist review of licensee's patient interaction; and (E) Pharmacist notes of each interaction reviewed; and (d) Report any violation of OAR 855 to the Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.

3) Telepharmacy/telework should not be tied to a registered drug outlet.

Clinical pharmacy practice often takes place in settings outside of a registered drug outlet. There are Oregon pharmacists and technicians that work in Clinical Pharmacy doing telephone work that could do it from anywhere and today, they are not associated with a registered drug outlet. We are concerned these definitions could impact high-quality, safe care provided by pharmacists and technicians across multiple different Clinical Pharmacy practices (e.g., anticoagulation, diabetes management, etc.) that are not registered drug outlets.

855-041-3205 Telework: Definitions (1) "Telework" means the practice or assistance in the practice of pharmacy physically outside of a registered drug outlet in a telework site. (2) "Telework Site" means a location that is not a registered drug outlet where an Oregon licensed Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist in the practice of pharmacy as employees of an Oregon registered drug outlet. Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205 Statutes/Other Implemented: ORS 689.155

4) Personnel performing remote work should only be required to be licensed in the state they are working if they are supervised by a PIC licensed in Oregon and working for a pharmacy licensed in Oregon. (Current rule)

To improve patient access to care, it is critical Oregon pharmacies be able to innovate so tasks may be performed by any licensed person anywhere, at any time. Pharmacists working with specific instruction and workflows, supervised by an Oregon licensed PIC, may still perform tasks and pharmacist functions safely. We encourage the Board to consider some out of state pharmacies have over 300 licensed employees who rotate 24/7 to perform very specific tasks. These tasks then enable Oregon patients to have quicker access to medications and 24-hour real-time information to provide high quality, safe care. Requiring all personnel who may touch a patient or prescription to be licensed in Oregon may disrupt this model or make it cost prohibitive and may further adversely impact care to Oregonians.

855-041-3215
Telework: General Requirements (1) Each Oregon registered Drug Outlet Pharmacy and Pharmacist-in-charge of a Drug Outlet Pharmacy must ensure that Interns and Certified Oregon Pharmacy Technicians working from a Telework Site work under the supervision, direction and control of an Oregon licensed Pharmacist. (2) A Pharmacist that engages in the practice of pharmacy and an Intern or Certified Oregon

Pharmacy Technician that assists in the practice of pharmacy from a Telework Site for any person or facility located in Oregon must: (a) Be licensed by the board; and…

Overall, our groups feel that the proposed new rules should be less prescriptive. It should be left to the individual organizations to ensure proper supervision of technicians that do not have an impact on quality and safety. The new requirements as laid out do not provide any tangible impact on the prescriptions being dispensed.

Thank you for the opportunity to comment on these proposed rulemakings for your consideration. OSPA, OSHP and the Oregon Pharmacy Coalition will continue to collaborate with the Board to advocate for legislation to further advance the practice of Pharmacists and Pharmacy Technicians. We look forward to engaging with you in this matter to assess current regulations and opportunities for process improvement.

Oregon Society of Health-System Pharmacists
Alfred Lyman, Jr., PharmD, BCPS
President

Oregon State Pharmacy Association
Lincoln Alexander, PharmD
President

The Oregon Pharmacy Coalition
Joshua Free, PharmD, MBA
Chairman

From:	Adams, Jessica (Regulatory Affairs)
To:	PHARMACY RULEMAKING * BOP
Subject:	Re: Proposed Rules related to Remote Dispensing Site Pharmacy
Date:	Tuesday, November 23, 2021 11:21:30 AM
Attachments:	image001.png image002.png Oregon tp rules 112321.pdf

Good afternoon Rachel,

Attached are comments for the proposed Oregon Administrative rules for Division 139 - related to Remote Dispensing Site Pharmacy. Please let me know if you have any questions.

Regards,

Jessica Adams, PharmD
Director of Regulatory Affairs, TelePharm
123 N Linn St Suite 2F, Iowa City, IA
512.426.6868 mobile

TelePharm is joining forces with OutcomesMTM™ and mscripts™ to form Outcomes™. Learn more here.

November 21, 2021

Rachel Melvin, Operations Policy Analyst
Oregon Board of Pharmacy
800 NE Oregon St, Suite 150
Portland, OR 97232-2142
Cc via email: pharmacy.rulemaking@bop.oregon.gov

Re: Proposed rules related to Remote Dispensing Site Pharmacy

Dear Ms. Melvin:

TelePharm and Cardinal Health thank the Oregon Board of Pharmacy (OBoP) for the opportunity to comment regarding the proposed rules for Remote Dispensing Site Pharmacies. The OBoP has done a remarkable job reviewing new pharmacy technologies to further the implementation of SB 629, and we applaud the OBoP's effort, and request for input regarding the proposed rules.

We appreciated the opportunity to provide assistance in the OBoP's research on telepharmacy by giving a tour of an existing remote dispensing site location and explaining how telepharmacy works, and submitting detailed fiscal impact information based on our extensive experience nationwide. We were hopeful that the assistance and information we shared provided clarity regarding the practice, however, it was disheartening to see many items identified as financial or technological hurdles remain in the proposed rules as they will severely limit the practice of telepharmacy in the state of Oregon.

One of the charges addressed in the notice for public comment was a request to identify whether other options should be considered to allow the OBoP to achieve the rule's substantive goals while also reducing the negative economic impact of the rules on business. In order to achieve this goal and provide a greater benefit, as also identified in our estimated fiscal impact, we recommend the following revisions to the proposed rules.

855-139-0005 Definitions, and 855-139-0210 Outlet: Supervision

- These sections define the components of a telepharmacy system, outline the requirement for the recording of the delivery of pharmacy services through a telepharmacy system, and establish the requirement to review and document a percentage of the total daily interactions between licensees and patients or their agents.
- Currently there are 27 other states that permit telepharmacy. In all of these states, supervision and monitoring of patient interactions is achieved through electronic means via a surveillance or security system, not through the "telepharmacy system".
    - These surveillance systems can include various audio and visual technologies with full HD camera coverage that allows activity within the pharmacy to be captured for real time monitoring and then saved for future verification purposes without compromising patient safety.
    - The telepharmacy system is a *separate system* from the surveillance system and is limited to monitoring the preparation and dispensing of drugs, providing drug utilization review and the audio/video communication associated with counseling services.

- Telepharmacy systems available today are not surveillance systems; they do not have the capability to provide supervision, tracking of patient encounters, and recording (including both audio and visual), as addressed in sections 855-139-0005(10), 855-139-0210.
    - Additionally, because these are features not offered by telepharmacy systems, a pharmacist would have to extensively review phone transcripts (if provided) or video surveillance of all patient encounters for the day, including minor interactions, to determine which of those is equivalent to 25% of the daily activity.
    - This retroactive review and calculation of patient encounters will be time-consuming, increase the workload of the pharmacist who is providing supervision, and will ultimately divert them from focusing on the provision of safe pharmacy care at the affiliated pharmacy and any other remote dispensing site pharmacies they are actively supervising.
    - With the promulgation of these rules, Oregon will be the only state of the total 28 that permit telepharmacy with these requirements of daily retroactive review and recording of patient interactions.
- While these surveillance requirements may provide a perceived additional safeguard relating to the supervision, direction and control of the technicians located at a remote dispensing site pharmacy, they are features that developers of telepharmacy systems must build out, and alternative safeguards are already addressed through other provisions in the proposed rules.
    - Certified pharmacy technicians who will staff and operate a remote dispensing site pharmacy are already required to have additional training above and beyond those at a traditional pharmacy setting to ensure they operate within the limitations of their scope and do not negatively impact patient safety.
    - A pharmacist is reviewing activity in the remote dispensing site pharmacy in real time and is already required to be on-site once every 28 days where they can review surveillance footage if needed, and address any problems with staff and patients that haven't already been dealt with immediately after the incident occurs.
    - All prescriptions dispensed from a remote dispensing site pharmacy are completed just as they would be at a traditional pharmacy with verification and counseling performed only by a pharmacist as outlined in proposed rule 855-139-0215 Outlet: Pharmacist Utilization.
    - Staff training and review of an up-to-date policy and procedure are used to help reinforce the responsibilities of licensees who will be working at these locations.
- We recommend revising the proposed rules in these sections as they are not operationally achievable, and, in turn, will limit the number of remote dispensing site pharmacies which will be able to open, ultimately limiting improved access to a pharmacist in underserved areas. Our proposed revisions are as follows:

    855-139-0005 Definitions
    (10) "Telepharmacy system" means a system of telecommunications technologies that enables monitoring, documenting and ~~recording of the~~ delivery of pharmacy services at a remote location by an electronic method which must include the use of audio and video, still image capture, and store and forward.

    855-139-0210 Outlet: Supervision
    A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) *Ensure prescription drugs are only dispensed at the Remote Dispensing Site Pharmacy if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician utilizing the surveillance ~~telepharmacy~~ system, and the telepharmacy system is fully operational;*

(2) *Ensure an Oregon licensed Pharmacist continuously supervises, directs and controls each Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy using audio and visual technology which must be recorded, reviewed and stored;*

~~(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a Remote Dispensing Site Pharmacy must:~~

~~(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;~~

~~(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;~~

~~(c) Document the following within 24 hours of the review in (3)(b):~~

~~(A) Number of each licensee's patient interactions;~~

~~(B) Number of each licensee's patient interactions pharmacist is reviewing;~~

~~(C) Date and time of licensee patient interaction pharmacist is reviewing;~~

~~(D) Date and time of pharmacist review of licensee's patient interaction; and~~

~~(E) Pharmacist notes of each interaction reviewed; and~~

~~(d) Report any violation of OAR 855 to the Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.~~

~~(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.~~

~~(5) Ensure all telephone audio is recorded, reviewed and stored.~~

~~(6)~~ (3) *Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy.*

855-139-0550 Records: General Requirements

- This section outlines the requirements for the recording of telephone audio, and also the requirement for the retention and storage of all data including telephone audio, and video and surveillance footage to be stored for a minimum of three years.
- None of the states that permit telepharmacy or remote dispensing require the recording or retention of telephone audio as HIPAA and other regulations severely limit this practice and require patient and provider consent.
- At minimum, a 75 terabyte hard drive would be needed to comply with the three year, real-time, continuously accessible requirement as outlined per the record retention requirements in the proposed rule.
    - This large amount of data storage will be cost prohibitive to purchase and even more to maintain.
    - Of the 27 states that permit telepharmacy or remote dispensing, Oregon will be the only state with such a surveillance requirement. Twenty-five states limit this requirement to 90 days or less, or do not mention such a requirement.
    - This extensive storage requirement appears arbitrary and capricious and does not appear to be related to patient safety. A pharmacist is already required to perform

once monthly inspections where they can review footage and investigate any issues that haven't already been addressed when the situations originally occurred.
    - In the event footage is needed to be recalled and reviewed, three years is outside a reasonable time period to intervene as patient safety would have already been impacted and likely jeopardized.
- In order to reduce the negative economic impact of this rule on business and to avoid the unnecessary invasion of patient privacy with the recording and retention of audio, we recommend the following edit:

855-139-0550 Records: General Requirements
(1)-(2)
(3) Records retained by the Drug Outlet must include, but are not limited to:
(g) Data, ~~telephone audio~~, ~~audio and video~~, still image capture, and store and forward images, ~~security and surveillance data~~. This must be retained according to (1); and
(h) Any errors or irregularities identified by the quality improvement program.
(4) All ~~data, telephone audio~~, audio and video~~, still image capture and store and forward images~~ collected by the~~ telepharmacy,~~ security and surveillance systems must be retained for a minimum of 90 days ~~according to (1)~~.

855-139-0220 Outlet: Non-Prescription Drugs, and 855-139-0600 Prohibited Practices: General

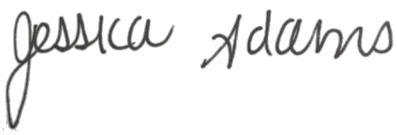
- These sections define the requirements that a remote dispensing site pharmacy must follow if non-prescription (OTC) drugs are offered for sale, and require that a supervising pharmacist be immediately available to provide counseling or recommendations for these drugs.
- In order for a pharmacist to be immediately available for the sale of OTC drugs, the affiliated pharmacy where they are located will have to be simultaneously open.
- Traditional retail drug outlets are not prohibited from selling OTC drugs when the prescription department is closed and a pharmacist is not available. This is commonly seen with retail drug outlets that have a pharmacy department with limited hours and a front-end area stocked with OTC drugs that is open with more extended hours.
- Similarly, gas stations, airports, malls and other convenience stores do not require a pharmacist on site or immediately available for recommendations or counseling in order to sell these products.
- Of the 27 other states that permit telepharmacy, none have this requirement regarding the sale of OTC drugs.
- We recommend revising this section to align with the sale of these goods in other settings and to avoid limiting patient access to non-prescription medications:

855-139-0220 Outlet: Non-Prescription Drugs
If non-prescription drugs are offered for sale at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:
(1) Ensure that the Certified Oregon Pharmacy Technician does not provide advice, information that requires judgment, or recommendations involving non-prescription drugs; and
(2) *Ensure that an Oregon-licensed Pharmacist ~~is immediately available to~~ provide*s *counseling or recommendations involving non-prescription drugs*.

855-139-0600 Prohibited Practices: General
A Retail Drug Outlet Remote Dispensing Site Pharmacy may not
(4) Provide ~~non-prescription or~~ prescription drugs when either the Remote Dispensing Site Pharmacy or Affiliated Pharmacy is closed;
(5) Compound sterile preparations; or
(6) Repackage drugs.

Thank you for your time and consideration on this matter. I can be reached at jessica.adams01@cardinalhealth.com or on my cell at (512)426-6868 for any questions.

Sincerely,



Jessica Adams, PharmD
Director, Regulatory Affairs

From:	Walmsley, Lorri
To:	PHARMACY RULEMAKING * BOP; SCHNABEL Joseph * BOP
Subject:	Walgreens Comments
Date:	Tuesday, November 23, 2021 10:55:58 AM
Attachments:	OR Comments_Telework.pdf OR Comment Letter_Telepharmacy.pdf

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Hello,

Please accept the attached comments on behalf of Walgreen Co.

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs

Walgreen Co.
Telephone 602-214-6618

Member of Walgreens Boots Alliance ¦ MyWalgreens.com

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November 15, 2021

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: Proposed Rules to Implement 2021 SB 629

Dear Dr. Schnabel,

On behalf of all pharmacies owned and operated by Walgreen Co., we thank the Board for the opportunity to comment on the proposed rules regarding the implementation of 2021 SB 629. We request that the Board consider the following modifications to keep with the legislative intent to keep make this service broadly available to expand access to pharmacy services to Oregonians:

855-13-0005 - Definitions

The Board's current definition of a Telepharmacy system is not consistent with what capabilities current telepharmacy systems currently provide. The monitoring is done by a surveillance system rather than the telepharmacy system.

(10) "Telepharmacy system" means a system of telecommunications technologies that ~~enables monitoring, documenting and recording of the delivery of pharmacy services at a remote location by an electronic method which must include the~~ use of audio and video, still image capture~~, and~~ to store and forward prescriptions for processing and to provide counseling.

855-139-0050 – Personnel

Oregon currently allows the PIC to determine the ratio that they are capable of supervising. As proposed, 855-139-0050 limits the Pharmacist to a total of 4 technicians at all locations. This limitation may not best serve the public when the Pharmacist is overseeing two remote locations and the host site as allowed in the current draft of the rule. We suggest that the Board retain language related to supervision, consistent with other practice locations in Oregon. In addition, documentation of the capabilities of supervision is extremely difficult and unusual. We believe the existing language in (4) is sufficient.

(4) The Oregon licensed Pharmacist from the Affiliated Pharmacy who is supervising a Remote Dispensing Site Pharmacy must determine ~~and document~~ how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided.

~~(5) When supervising a Certified Oregon Pharmacy Technician working at a Remote Dispensing Site Pharmacy, the Oregon licensed Pharmacist may supervise no more than four licensed pharmacy technicians among all locations, including the Affiliated Pharmacy.~~

855-139-0100 – Security

The security requirements proposed under 855-139-0100(9) add additional costs that are not necessary to maintain patient safety. If the pharmacy is required to maintain a surveillance system that continuously records all areas of the pharmacy, it is unnecessary to add additional documentation requirements and specific entry devices. Diversion can

be sufficiently monitored by the perpetual inventory, surveillance, and monthly supervision visits as required. Additionally, the requirement for the surveillance system to record audio, in addition to the video, is highly onerous and could pose patient HIPAA concerns. No other states require the recording of audio for any components of the telepharmacy system or surveillance.

Adding additional costs may be prohibitive for companies to utilize such technology to improve patient access to pharmaceutical care. We request that the Board strike these requirements, consistent with the approach from other states.

(1) Minimum security methods must include a properly functioning:
~~(a) Alarm system with an audible alarm at the Remote Dispensing Site Pharmacy and real-time notification to a designated licensee of the Affiliated Pharmacy;~~
~~(b) Electronic keypad or other electronic entry system that records the:~~
~~(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the Remote Dispensing Site Pharmacy; and~~
~~(B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the Remote DispensingSite Pharmacy; and~~
(c) ~~Date and time of each activity~~. Surveillance system that utilizes continuously ~~accessible and~~ records ~~two-way visual link between the Affiliated Pharmacy and~~ the Remote Dispensing Site Pharmacy. The system must provide a clear view of:
(A) Dispensing site entrances;
(B) Preparation areas;
(C) Drug storage areas
(D) Pick up areas
(E) Office areas; and
(F) Publicly accessible areas.

855-139-0125 Drug: Storage

We recommend a slight modification to permit the utilization of technology that monitors temperatures continuously and can produce excursions as required by (2)(a)(D).

(2)(b)(C) (C) Maintenance of records of temperature logs for a minimum of three years, unless utilizing a system that offers continuous temperature monitoring;

855-139-0205 - Outlet: Technology

Since manufacturers are still not required to comply with DSCSA until 2023; information on manufacturers expiration and the lot is not readily available by barcode scanning and requiring this information to be part of the dispensing record will create an additional recordkeeping burden for pharmacies to comply with that are not required for other pharmacy types in the state. We respectfully request that this be stricken until this technology becomes readily available in compliance with DSCSA.

855-139-0205
Outlet: Technology

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must;
(1) Utilize a shared telepharmacy system and have appropriate technology or interface to allow access toinformation required to process and fill a prescription drug order;

(2) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Affiliated Pharmacy can visually identify each:

~~(a)~~ Source container including manufacturer, name, strength~~, lot, and expiration~~

(b) Source ingredient including the imprint and physical characteristics if compounding;

(c) Dispensed product including the imprint and physical characteristics;

(d) Completed prescription container including the label; and

(e) Ancillary document provided to patient at the time of dispensing.

(3) Utilize barcode, radio-frequency identification or quick response code technology to record information in (2) if available;

(4) Test the telepharmacy system and document that it operates properly before providing pharmacy services; and

(5) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system.

855-139-0210 - Outlet: Supervision

The requirement for the surveillance system to record audio and video is extremely onerous and could pose patient HIPAA concerns. No other states require the recording of audio for any components of the telepharmacy system or surveillance. Additionally, no other state requires the recording of telephone calls. The arbitrary requirement to have the pharmacist review 25% of interactions is very burdensome and impossible to comply with since it could not be easily measured.

Adding additional costs may be prohibitive for companies to utilize such technology to improve patient access to pharmaceutical care. We request that the Board strike these requirements, consistent with the approach from other states.

855-139-0210 Outlet: Supervision

A Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:

(1) Ensure prescription drugs are only dispensed at the Remote Dispensing Site Pharmacy if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician utilizing the telepharmacy system, and the telepharmacy system is fully operational;

(2) Ensure an Oregon licensed Pharmacist continuously supervises, directs and controls each Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy using visual technology which must be recorded, ~~reviewed~~ and stored;

(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a Remote Dispensing Site Pharmacy must:

~~(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;~~

~~(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;~~

~~(c) Document the following within 24 hours of the review in (3)(b):~~

~~(A) Number of each licensee's patient interactions;~~

~~(B) Number of each licensee's patient interactions pharmacist is reviewing;~~

~~(C) Date and time of licensee patient interaction pharmacist is reviewing;~~

~~(D) Date and time of pharmacist review of licensee's patient interaction; and~~

~~(E) Pharmacist notes of each interaction reviewed; and~~

~~(d) Report any violation of OAR 855 to the Affiliated Pharmacy within 24 hours of discovery and to the Board within 10 days.~~

(4) The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.

(5) Ensure all telephone audio is recorded, reviewed and stored

(6) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy.

855-139-0225 - Outlet: Controlled Substances

The proposed requirement to store and secure all controlled substances in a locked cabinet is too restrictive and would require physical changes for pharmacies to comply. We respectfully request the below medication in compliance with current Oregon and DEA requirements for other pharmacies.

855-139-0225
Outlet: Controlled Substances
If controlled substances are at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:
(1) Comply with controlled substance regulations;
(2) Store ~~all~~ schedule II controlled substances in a secure locked cabinet;
(3) Maintain an accurate controlled substance perpetual inventory; and
(4) Ensure an Oregon licensed Pharmacist conducts a controlled substance inventory at least once every 28 days and reconciles all discrepancies at the time of in person physical inspection.

855-139-0230- Outlet: Non-Sterile Compounding

As mentioned in the earlier sections, the real-time visual requirement is not a feasible solution. Available telepharmacy systems use still-capture imaging to forward information to the home pharmacy.

855-139-0230
Outlet: Non-Sterile Compounding
If non-sterile preparations are compounded at the Remote Dispensing Site Pharmacy, the Remote Dispensing Site Pharmacy and its Affiliated Pharmacy must:
(1) Adhere to the requirements of
OAR 855- 045;(2) Ensure an
Oregon license Pharmacist:
(a) Supervises via a ~~real-time visual~~ connection all steps of the compounding;
and
(b) (b) Documents and visually verifies each item required in OAR 855-139-0041.

855-139-0550 - Records: General Requirements

As mentioned in prior sections, the pharmacy's requirement for telephone and audio recording are too onerous and could result in pharmacies not choosing to leverage telepharmacy services to expand patient access. We respectfully request the amendments as indicated below.

855-139-0550
Records: General Requirements
(1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other

(2) recordkeepingrules of the Board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable withinthree business days. Records and documentation may be written, electronic or a combination of the two.
(3) The Remote Dispensing Site Pharmacy must maintain all required records unless these records are maintainedin the Affiliated Pharmacy.
(4) Records retained by the Drug Outlet must include, but are not limited to:
(a) Patient profiles and records;
(b) Date, time and identification of each individual and activity or function performed;
(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;
(d) Controlled substance inventory and reconciliation;
(e) Oregon licensed Pharmacist physical inspection of Remote Dispensing Site Pharmacy;
(f) ~~Audio and visual connection~~ Surveillance and telepharmacy system testing and individual training on use of both systems the ~~audio and visual connection~~;
(g) Data, ~~telephone audio, audio and video~~, still image capture, store and forward images, security and surveillance data. This must be retained according to (1); and
(h) Any errors or irregularities identified by the quality improvement program.
(5) All data, telephone audio, audio and ~~video, still image capture and store and forward images collected by the~~telepharmacy, security and surveillance systems must be retained according to (1).

855-139-0600 - Prohibited Practices: General

Many pharmacies sell OTC products when the pharmacy is not open, and even some non-pharmacy outlets, limiting the sale of OTC items when the affiliated pharmacy is not open is not suitable for patient access and should be removed.

855-139-0600
Prohibited Practices: General
A Retail Drug Outlet Remote Dispensing Site Pharmacy may not:
(1) Allow a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent which scree nand/or limit interaction with the Oregon licensed Pharmacist;
(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacyservices unless the person is registered with the Board pursuant to ORS 689.305.
(3) Deliver a prescription;
(4) Provide ~~non-prescription~~ or prescription drugs when either the Remote Dispensing Site Pharmacy or Affiliated Pharmacy is closed;
(5) Compound sterile preparations; or
(6) Repackage drugs.

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

Lorri Walmsley, RPh, FAzPA

Lorri Walmsley, RPh., FAzPA
Director, Pharmacy Affairs
Walgreen Co.
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November 15, 2021

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: Proposed Rules to Implement Telework

Dear Dr. Schnabel,

Please accept these comments on behalf of all pharmacies owned and operated by Walgreen Co., including AllianceRx Walgreens Prime, that are located in or service Oregon-located patients. We appreciate the Board's flexibility during the pandemic to allow our employees to work at home until permanent rules could be adopted. While we appreciate that this new model is being permanently considered, we have many concerns regarding your current draft language.

Our broadest concerns involve eliminating the remote processing and central fill language for both resident and non-resident pharmacies. While some of the prescription fulfillment and other functions of a technician and a pharmacist may be performed from a non-pharmacy telework site, some functions may only be performed in a facility, central fill for example, and other functions that should be allowed from both a pharmacy and a telework site; examples include prescription data entry, phone calls, MTM services, and others. We respectfully ask that the board retain the existing language regarding central fill and remote processing in 855-041-1060, 855-041-3000, 855-041-3100, 855-041-3105, 855-041-3115, 855-041-3120, 855-041-3125, 855-041-3130. While the Board's goal was to simplify the rules, it unintentionally removes support from pharmacies already occurring today in Oregon and does not contribute to patient safety. In the event that the Board does not retain the existing language related to central fill and remote processing, we would broadly request that the Board remove all references to Oregon licensed-certified technicians and Oregon-Licensed Pharmacists throughout all the proposed rules so that remote processing from out-of-state individuals tied to a non-resident Oregon licensed outlet may continue.

855-041-3215 - Telework: General Requirements

The work performed by pharmacy technicians remotely is data entry, third party resolution, and non-licensed clerical functions, all of which are supervised on a 1:1 basis, where each step of the prescription is checked by a pharmacist, just like within a retail drug outlet. The requirement to specifically list each Pharmacist that supervises a technician does not contribute to patient safety because the Pharmacist who is ultimately responsible for the prescription is captured as part of the standard record keeping process with the prescription. The work-at-home employees' hours may change based on the business needs and may vary based on unanticipated business needs. We respectfully request the amendments as outlined below.

855-041-3215
Telework: General Requirements
(1) Each Oregon registered Drug Outlet Pharmacy, and Pharmacist-in-charge of a Drug Outlet Pharmacy must ensure that Interns and Certified Oregon Pharmacy Technicians working from a Telework Site work under the supervision, direction and control of an Oregon licensed Pharmacist.
(2) A Pharmacist that engages in the practice of pharmacy and an Intern or Certified Oregon Pharmacy Technicianthat assists in the practice of pharmacy from a Telework Site for any person or facility located in Oregon must:
(a) Be licensed by the Board; and
(b) Comply with all applicable federal and state laws and rules.
(3) Drugs and devices may not be at a Telework Site.
(4) The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of a Drug Outlet Pharmacy must:

(a) Have a written agreement that includes all conditions, duties and policies governing the licensee engaged in telework activities;
(b) Maintain a continuously updated list of all licensees engaged in telework and the Telework Sites to include:
(A) Address, and phone number ~~and hours~~ for each Telework Site where telework is performed; and
(B) Functions being performed by licensees engaged in telework;
~~(C) The Oregon licensed Pharmacist providing supervision, direction and control for each non-pharmacist licensee;~~
(c) Develop, implement and enforce a continuous quality improvement program for services provided from a Telework Site 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;¶
(d) Develop, implement and enforce a procedure for identifying the Oregon licensed Pharmacist, Intern and Certified Oregon Pharmacy Technician responsible for each telework function;
~~(e) Develop, implement and enforce a process for a virtual inspection of the Telework Site by an Oregon licensed Pharmacist at least once every 6 months or more frequently as deemed necessary by the Oregon licensed Pharmacist. The inspection must be documented and records retained; and~~
(f) Utilize an Oregon licensed Pharmacist and real-time audio communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 or when requested and document the interaction.

855-041-3220 - Telework: Supervision Requirements

As stated in the prior section, pharmacy technicians' work provided in a telework environment is generally limited to functions like data entry, third-party processing, and non-technician clerical functions; each prescription is verified as if the prescription was processed entirely at a pharmacy retail outlet. The arbitrary and capricious requirements for audio and visual technology, check-ins, and verification of patient interactions are not consistent with telework rules from any other state, rendering them too restrictive for businesses to implement and potentially harming patient safety by limiting additional resources that may be otherwise effectively provided by pharmacies in Oregon to support patients. Pharmacies within the state are currently being provided much needed telework support by Oregon-permitted non-resident pharmacies where the pharmacists and technicians are duly licensed in the state where they reside. The additional licensure requirements within these rules would no longer allow for these facilities to continue supporting pharmacies located in Oregon. This would have a potential downstream impact to patients in Oregon. We would urge that all references to mandatory Oregon licensure requirements for pharmacists and technicians be stricken.

855-041-3220
Telework: Supervision Requirements
The Oregon registered Drug Outlet Pharmacy and the Oregon-licensed Pharmacist-in-charge of the Drug Outlet t must:
(1) Utilize technology that enables a real-time ~~audio and visual~~ connection and have appropriate
(2) technology or interface to allow access to information required to complete assigned duties;
(3) Ensure all telephone audio is recorded, ~~reviewed~~ and stored;
(4) Ensure a Pharmacist is supervising, directing and controlling each Intern and Pharmacy Technician and that the continuous ~~audio/visual~~ connection is fully operational;
~~(5) Ensure that an Oregon licensed Pharmacist using professional judgment, determines the frequency of "check-ins" for each licensee being supervised via the real-time audio and visual connection with a minimum of at least once per work shift to ensure patient safety, compliance with federal and state laws, and documents the interaction;~~
(6) Be readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and
(7) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon licensed ~~Pharmacist~~ PIC who is providing supervision, direction and control ~~at all times~~.
(8) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy Technician at a

Telework Site must:

~~(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;~~

~~(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;~~

~~(c) (c) Document the following within 24 hours of the review in (b):~~

~~(A) Number of each licensee's patient interactions;~~

~~(B) Number of each licensee's patient interactions pharmacist is reviewing;~~

~~(C) Date and time of licensee patient interaction pharmacist is reviewing;~~

~~(D) Date and time of pharmacist review of licensee's patient interaction; and~~

~~(E) Pharmacist notes of each interaction reviewed; and~~

~~(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of discovery and to the Board within 10 days.~~

The Oregon registered Drug Outlet Pharmacy must comply with the Pharmacist's determination in (7)(a), employ ~~adequate staff to allow for completion of the review within 24 hours, and retain records~~

855-041-3230 - Telework: Technology

The language in this section is very confusing and appears to be taken directly from the proposed telepharmacy rule. These types of system requirements do not make sense for most types of telework environments. For example, why would a pharmacy need still capture image for a technician performing data entry of an electronic prescription? We request modifications to clarify the scope of the rule is intended for virtual product review or strike this section entirely since security and patient privacy are covered under 855-041-3240.

855-041-3230

Telework: Technology

If the scope of work includes virtual product review, the Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the Pharmacist from the Drug Outlet must:

(1) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each:

(a) Source container including manufacturer, name, strength, ~~lot, and expiration;~~

(b) Dispensed product including the imprint and physical characteristics;

(c) Completed prescription container including the label; and

(d) Ancillary document provided to patient at the time of dispensing.

(2) Test the ~~continuous audio and visual~~ connection and document that it operates properly before engaging in telework.

(3) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising, directing and controlling the Intern and Certified Oregon Pharmacy Technician at the Telework Site.

(4) Ensure access to:

(a) Appropriate and current pharmaceutical references based on the services offered; and

(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.

(5) Train the Oregon licensed Pharmacists, Interns and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system ~~continuous audio and visual connection~~.

855-041-3235 - Telework: Personnel

The requirement for audio and visual recording and monitoring for the scope of telework is arbitrary and unnecessary since each step of the prescription is still verified by a pharmacist and no drugs would be stored or dispensed at a telework site. The addition of a ratio for individuals working in a telework environment is arbitrary since Oregon does not have a ratio for any other type of pharmacy today. Record keeping of this nature is highly unorthodox and not standard. We would recommend striking. The requirements in (4) provide the direction and requirements.

855-041-3235
Telework: Personnel
(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all operations at Drug Outlet Pharmacy including responsibility for the continuous ~~audio and visual~~ connection and enforcing policies and procedures.
(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel at Telework Sites.
(3) An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have at least one year experience performing similar services for an Oregon registered Drug Outlet Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy Technician begins teleworking.
(4) The Oregon licensed Pharmacist from the Drug Outlet Pharmacy who is supervising a licensee at a TeleworkSite must determine and document how many licensed individuals the Pharmacist is capable of supervising, directing and controlling based on the services being provided.
(5) ~~When supervising an Intern or Certified Oregon Pharmacy Technician working at a Telework Site, the Oregon licensed Pharmacist may supervise no more than four licensees among all locations, including the Drug Outlet Pharmacy.~~
(6) ~~The Drug Outlet Pharmacy is required to comply with the Pharmacist's determination in (4) and retain records~~.
(7) Prior to working at a Telework Site, the Intern or Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on the use of all equipment necessary for secure operation of the Telework Site.

855-041-3240 - Telework: Environment and Security

Real-time audio and visual technology is not always needed based on the type of work performed at a telework site and does not contribute to patient safety since each step of the prescription are still validated by a pharmacist before dispensing.

855-041-3240
Telework: Environment and Security
(1) Telework Sites must be located in a designated area where:
(a) All equipment is stored;
(b) All work is performed; and
(c) Confidentiality is maintained such that patient information cannot be viewed or overheard by anyone other than the Pharmacist, Intern or Certified Oregon Pharmacy Technician.
(2) The Pharmacist-in-charge of the Drug Outlet Pharmacy and each Oregon licensed Pharmacist supervising a Telework Site is responsible for ensuring the Telework Site has a designated work area that is secure and has been approved and documented by an Oregon licensed Pharmacist prior to utilization.
(3) All computer equipment used at the Telework Site must:
(a) Establish and maintain a secure connection to the pharmacy and patient information;
(b) Utilize equipment that prevents unauthorized access to the pharmacy and patient information; and
(c) Be configured so that the pharmacy and patient information is not accessible when:
(A) There is no Oregon licensed Pharmacist actively supervising the Intern or Certified Oregon Pharmacy Technician who is assisting in the practice of pharmacy from a Telework Site; or

(B) There is no Pharmacist, Intern or Certified Oregon Pharmacy Technician present at the Telework Site; or
(C) Any component of the real-time ~~audio and visual~~ connection is not functioning; and
(d) Comply with all security and confidentiality requirements.
(4) A record must be maintained with the date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site.
(5) Interns and Certified Oregon Pharmacy Technicians may only work from a Telework Site when authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the Telework Site.

855-041-3245 - Telework: Policies and Procedures and 855-041-3250- Telework: Records

As mentioned in prior sections, the requirement of audio and visual connections does not make sense for all types of telepharmacy work and is too restrictive. We respectfully request the amendments as outlined below to 855-041-3245 and 855-041-3250.

855-041-3245
Telework: Policies and Procedures
(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the Drug Outlet Pharmacy and the Oregon licensed Pharmacist-in-charge is accountable for establishing, maintaining, and enforcing written policies and procedures for the licensees working from a Telework Site. 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 services, responsibilities and accountabilities of the licensee engaging in telework including;
(a) Security;
(b) Operation, testing and maintenance of the ~~audio and visual~~
(c) connection;
(d) Detailed description of work performed;
(d) Oregon licensed Pharmacist supervision, direction and control of Interns and Certified Oregon Pharmacy Technicians;
(e) Recordkeeping;
(f) Patient confidentiality;
(g) Continuous quality improvement;
(h) Plan for discontinuing and recovering services if ~~audio and visual~~ connection disruption occurs;
(i) Confirmation of dedicated, secure Telework Sites;
(j) Documenting the identity, function, location, date and time of the licensees engaging in telework;
(k) Written agreement with licensees engaging in telework outlining specific functions performed, conditions and policies governing the operation of the Telework Site; and
(l) Equipment.

855-041-3250
Telework: Records
(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the recordkeeping requirements OAR 855-041-3205 through OAR 855-041-3250 are in addition to the requirements of other recordkeeping rules of the Board. Unless otherwise specified, all records and documentation required by these rules must be retained for three years and made available to the Board for inspection upon request. Records created at Telework Sites must be stored at the Drug Outlet for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.
(2) Records must be stored at the Telework site in a manner that prevents unauthorized access.
(3) Records must include, but are not limited to:
(a) Patient profiles and records;
(b) Patient contact and services provided;
(c) Date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site;
(d) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(e) List of employees working from Telework Sites that includes:
(A) Name;
(B) License number;
(C) Verification of each license;
(D) Address of Telework Site;
and
(E) Name of the Oregon licensed Pharmacist who verified each licensure, approved licensee to telework, and approved each Telework Site;
(f) ~~Audio and visual connection~~ testing and training;
(g) As applicable by function type Data, telephone audio, ~~audio and video~~, still image capture, store and forward images, security ~~and surveillance data~~. This must be retained according to (1); and
Any errors or irregularities identified by the quality improvement program.

With the Board's recent discussion regarding burnout and staffing challenges in pharmacies, it is imperative the Board must both retain the remote processing language and implement the telework rules so that organizations can operationalize them. Both offer unique ways that pharmacies may safely support the work performed in traditional retail pharmacy outlets. Telework provides many advantages for the Board to consider from a pharmacy team member engagement and burnout perspective. First, allowing pharmacy team members to perform work for pharmacies in a telework environment provides an alternative work environment that can be used for team members at higher risk for COVID-19 infection. Secondly, it will allow pharmacies to add additional staff while safely maintaining the social distancing requirements in pharmacies. And finally, telework may offer a different staffing alternative for team members suffering from burnout, that need a change from their current work environment.

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

Lorri Walmsley, RPh, FAzPA

From:	Yanira Perez
To:	PHARMACY RULEMAKING * BOP
Subject:	comments on dual prescription labeling
Date:	Tuesday, November 23, 2021 8:33:35 AM
Attachments:	Perez Y Comment prescription label signage v3.docx

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Good morning,
Please find my attached comment letter regarding this very important ruling. I can be reached by email or phone if further clarification is needed.
Thank you
Yanira Pérez

617-949-6463

To: Rachel Melvin, OBOP Rules Coordinator

From: Yanira Pérez, OHSU Nursing Student Class of 2022

Re: Division 007/041/045/065 proposed rules and required signage for dual-language prescription labels

I would like to thank you for taking the time to read my letter regarding the dual prescription labeling as related to USP, storage, labeling and repackaging. I am writing to support the implementation of a standard, visible sign produced by OBOP that will be posted at every pharmacy across the state of Oregon; the sign also needs to include all 14 available language formats covered by the law. The reasons for ensuring standardized signage are plentiful. Firstly, it serves as a standard that provides the pharmacies with clear instructions in all 14 languages. Secondly, having a sign be written in only English to announce the availability for dual language labeling negates the efforts intended with the law; Efforts such as increasing medication health literacy need to be in the individual's native tongue. Third, as a daughter of a Limited English Proficiency speaker, I cannot stress enough the seriousness of neglecting to take your medication because you are waiting to speak to your daughter so she can translate what they say. Patients like my mother nods when the American doctor tells her she has diabetes and must take this medication. She nods as she schedules her next appointment and lab work. Finally, she nods when the pharmacists ask her, in English, if she understands how to take this medication. She nods because she doesn't know how else to express in her limited English that she doesn't even understand what diabetes is, let alone how to manage it. Fortunately, my mother has adult English-speaking children but what of others not as fortunate?

As a previous Health Navigator, I know that healthcare can get very complex very quickly for some more than others and I think that having a sign, displaying all 14 languages, and formats (i.e., braille, large print) can make a huge difference in medication compliance and treatments. The standard of a poster will aid pharmacies that may not have the staff available to create their own signage and having a poster produced by OBOP will ensure the translations are accurate.

In conclusion, having a standard sign be produced and distributed by OBOP will not only ensure the new law will be implemented across all pharmacies but it would ensure visibility of the OBOP commitment to providing patient centered care.

Best,

Yanira Pérez

617-949-6463

DIVISION 007
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

Division 7
PUBLIC HEALTH EMERGENCY

855-007-0120
Damage to a Pharmacy and Drug Integrity

(1) If a pharmacy prescription department sustains damage, whether by flood or otherwise, the entire drug inventory, including any prescriptions that are awaiting pickup, is unfit for dispensing, **must** be classified as adulterated and must be destroyed unless, **the drugs are** deemed safe for dispensing **pursuant to OAR 855-041-1036.** Any incident of this nature must be reported to the **b**oard within three working days.

(2) If a pharmacy loses power that affects temperature or humidity controls such that **the** proper storage of drugs **pursuant to OAR 855-041-1036 has** been violated, such drugs **must** be classified as adulterated and may not be dispensed.

(3) Controlled substances damaged, lost or stolen **must** be documented and reported to the DEA and the **b**oard on DEA Form 41**, ~~or~~** DEA Form 106**, or DEA Form 107** as appropriate.

(4) A pharmacy that is required to temporarily close or relocate due to an emergency must report this event to the **b**oard within three working days.

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

Division 41
OPERATION OF PHARMACIES

855-041-1001
Definitions

(1) “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.

(2) “Biosimilar product” means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) **(12/01/2021)**.

(3) “Drug room” is a drug storage area registered with the **b**oard which is secure and lockable.

(4) “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) **(12/01/2021)**.

(5) “Reference biological product” means the biological product licensed pursuant to 42 USC 262(a) **(12/01/2021)** 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.

(6) “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.

Statutory/Other Authority: ORS 689.205 & 689.522
Statutes/Other Implemented: ORS 689.155 **ORS** 689.522

855-041-1035
Minimum Equipment Requirements

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

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

(**b**) **Appropriate and c**urrent 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; and

(D) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-041-2340.

(**h**) **Additional e**quipment 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 689.508**,** ORS 689.155**, ORS 689.515, ORS 689.564 & ORS 689.686**

855-041-1040
Drug Outlet Procedures

Each drug outlet is accountable for establishing, maintaining, and enforcing their written procedures for:

(1) Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;

(2) Performing mandatory prospective drug utilization reviews; on all prescriptions both new and refilled;

(3) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;

(4) Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;

(5) Ensuring the delivery of each completed prescription to the correct party;

(6) Providing appropriate confidential professional advice concerning medications to patients or their agents;

(7) Prescribing services and maintenance of records for prescribing pharmacist;

(8) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties;

(9) Establishing and maintaining a Continuous Quality Assurance Program;

(10) Providing oral interpretation and translation services for any patient who is of limited English proficiency, and prescription readers for a visually impaired patient as required by OAR 855-041-1131 and OAR 855-041-1132**; and**

(11) Ensuring drugs are stored as required by OAR 855-041-1036.

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

855-041-1080
Pharmacy Registration (Both Retail and Institutional Drug Outlets)

(1) Pharmacies **must** be registered as either retail drug outlets or institutional drug outlets or both.

(2) An application for registration of a new pharmacy **must** be accompanied by a floor plan drawn to scale and **must** be approved by the **b**oard prior to opening.

(3) The application **must** specify the location of the pharmacy and **must** indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application **must** indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owner, the names of the partners or persons holding the five largest interests **must** be indicated on the application;

(b) If the owner is a corporation, the name filed **must** be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests **must** be indicated on the application.

(4) Upon request by the **b**oard, the applicant **must** furnish such information as required by the **b**oard regarding the partners, stockholders, or other persons not named in the application.

(5) The application **must** also identify any person who has incidents of ownership in the pharmacy who also has financial interest in any long-term care facility as defined in ORS 442.015.

(6) A certificate of registration will be issued upon **b**oard approval of the application.

(7) All registration renewal applications **must** be accompanied by the annual fee and **must** contain the same information required in sections (3) and (4) of this rule.

(8) The initial and annual registration fee for pharmacies is set out in **OAR 855-110**.

(9) Pharmacy registration expires March 31, annually. If the annual registration fee referred to in **OAR 855-110** is not paid by March 31 of the current year, a **late** fee as set out in **OAR 855-110 must** be included with the application for registration renewal.

(10) The registration is not transferable and the registration fee cannot be prorated.

(11) A change of ownership requires the approval of the **b**oard and new certificate of registration. Application **must** be on a form supplied by the **b**oard.

(12) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(13) Applicants for change in ownership **must** provide the **b**oard with the information required in sections (3), (4), and (5) of this rule.

(14) A change of ownership **must** be reported to the **b**oard 15 days **prior to** occurrence.

(15) No pharmacy **may** be operated until a certificate of registration has been issued to the pharmacy by the **b**oard.

Statutory/Other Authority: ORS 475.035 & **ORS** 689.205
Statutes/Other Implemented: ORS 689.155

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling

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 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.

(11) 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

855-041-1135
Labeling and Container Requirements for Repackage**d** Drugs

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

(2) A single oral solid drug product repackaged by a pharmacy **into unit-dose packaging** must:

(a) Utilize a unit-dose container–closure system that meets the testing requirements under USP <671> Containers—Performance Testing (12/01/2020) for either Class A or Class B containers and meets or exceeds the original container's specification for light resistance;

(b) Be labeled to identify at a minimum:

(A) Brand name~~,~~ or generic name;

(B) Strength;

(C) Manufacturer and lot number **or an internal pharmacy code that references manufacturer and lot number**; **and**

(D) Expiration date. The expiration date used for the repackaged product must not exceed:

(i) 6 months from the date of repackaging; or

(ii) The manufacturer's expiration date; or

(iii) 25% of the time between the date of repackaging and the expiration date shown on the manufacturer's bulk article container of the drug being repackaged, whichever is earlier.

(3) A single oral solid drug product repackaged by a pharmacy into multiple-unit packaging must:

(a) Utilize an equivalent container–closure system that is at least as protective as, or more protective than, the original system, complies with criteria established for equivalency and meets or exceeds the original container's specification for light resistance;

(b) Be labeled to identify at a minimum:

(A) Brand name or generic name;

(B) Strength;

(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot number; and

(D) Expiration date. The expiration date used for the repackaged product must not exceed the manufacturer's expiration date or one year from the date the drug was placed in the new container, whichever date is earlier.

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

855-041-1145
New Containers

Each pharmacy must dispense a drug in a new container **that** compl**ies** with the current provisions of the **Poison Prevention** Packaging Act in **16 CFR 1700 (04/01/2021), 16 CFR 1701 (04/01/2021), and 16 CFR 1702 (04/01/2021).**

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

Statutory/Other Authority: ORS 689**.205**
Statutes/Other Implemented: **ORS 689.155**

855-041-6270
Institutional Drug Outlet Pharmacy Prescription Labeling

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

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

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

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

(c) The strength of the drug.

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

(a) Name and location of patient;

(b) Name and strength of drug;

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

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

(e) Auxiliary labels as needed, and

(f) Expiration date.

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

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

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

(a) **N**ame, quantity and concentration of the drug added and the primary solution;

(b) **D**ate and time of addition;

(c) **E**xpiration date;

(d) **S**cheduled time for administration;

(e) **I**nfusion rate, when applicable;

(f) **N**ame or initials of person performing admixture;

(g) **I**dentification of the pharmacy where the admixture was performed; and

(h) **N**ame or initials of the verifying pharmacist.

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & **ORS** 689.505

Division 45
DRUG COMPOUNDING

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 **b**oard as a drug outlet and comply with **b**oard 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 **(08/01/2016) , 1231 (08/01/2018), and 1821 (05/01/2017).**

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 **b**oard 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

855-045-0240
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

Division 65
WHOLESALE DRUG OUTLETS

855-065-0005
Definitions

(1) “Affiliate” means a business entity that has a relationship, or is an authorized trading partner, with a second business entity if, directly or indirectly:

(a) One business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both of the business entities.

(2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with either or both of the following:

(a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; or

(b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer no less than monthly.

(3) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession of the brokered substance.

(4) "Chain Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse and performs intra company sales or transfers of drugs to a group of chain pharmacies that have the same common ownership and control.

(5) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and exclusive group of patients and is not open for dispensing to the general patient population and cannot be registered as a wholesale distributor.

(6) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(7) "Designated Representative" means an individual designated by each wholesale distributor registered by the **b**oard who will serve as the primary contact person for the wholesale distributor with the **b**oard and who is responsible for managing the company's operations at that registered location.

(8) "Drug Sample" means a unit of a drug that is intended to promote the sale of the drug, but which is not itself for sale.

(9) “Illegitimate Product” means a product for which credible evidence shows that the product is:

(a) Counterfeit, diverted, or stolen;

(b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) The subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death.

(10) "Intra Company Transfer" means the transfer of any drug between a division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity.

(11) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(12) "Pedigree" for the purpose of this Division consists of:

(a) “Transaction History,” which means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(b) “Transaction Information,” which must include, but is not limited to:

(A) The proprietary or established name or names of the product;

(B) The strength and dosage form of the product;

(C) The National Drug Code number of the product;

(D) The container size;

(E) The number of containers;

(F) The lot number of the product;

(G) The date of the transaction;

(H) The date of the shipment, if more than 24 hours after the date of the transaction;

(I) The business name and address of the person from whom ownership is being transferred; and

(J) The business name and address of the person to whom ownership is being transferred.

(c) “Transaction Statement,” which is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with Food and Drug Administration (FDA) regulations set forth by the Drug Quality and Security Act and includes but is not limited to:

(A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain Security Act;

(B) Acknowledgement that product is received from an authorized or registered entity, as required under the Drug Supply Chain Security Act;

(C) Confirmation of receipt of transaction information and of transaction statement from the prior owner of the product, as required under the Drug Supply Chain Security Act;

(D) Verification that a suspect or illegitimate product was not knowingly shipped;

(E) Confirmation that systems and processes are in place to comply with verification requirements under the Drug Supply Chain Security Act;

(F) Confirmation that false transaction information was not knowingly provided; and

(G) Confirmation that transaction history was not knowingly altered.

(13) "Prescription Drug" means any drug required by law to be dispensed only by a prescription.

(14) “Quarantine” means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

(**15**) “Suspect Product” means a product for which there is reason to believe that such product is:

(a) Potentially counterfeit, diverted, or stolen;

(b) Potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) Potentially the subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would result in serious adverse health consequences or death.

(**16**) “Trading Partner” means:

(a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(**17**) “Validate” means to verify that each transaction listed on the pedigree and other accompanying documentation has occurred and is accurately recorded.

(**18**) "Wholesale Distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

(a) Delivery by a retail pharmacy of a prescription drug to a patient or patient's agent pursuant to the lawful order of a licensed practitioner.

(b) The sale of minimal quantities of a prescription drug by retail or institutional pharmacies to licensed practitioners for office use.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug which may include:

(A) Emergency medical reasons;

(B) Drug or devices used during a federal or state declared emergency; or

(C) The transfer of a drug by a pharmacy to another pharmacy to alleviate a temporary shortage.

(d) Intra company transfer of drugs as defined in these rules.

(e) The lawful distribution of a drug sample by a manufacturer's or a distributor's representative.

(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a non-profit affiliate of the organization to the extent permitted by law.

(g) The purchase or acquisition of a drug by a hospital or other health care entity that is a member of a group purchasing organization, for the hospital's or health care entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the organization or under common control.

(h) The transfer of a prescription drug between pharmacies pursuant to a shared pharmacy service agreement as defined in OAR 855-006-0005.

(i) The distribution by a manufacturer, as part of a prescription assistance program, of a drug intended for a specific patient, to a person authorized to prescribe, administer or dispense prescription drugs.

(j) The sale, purchase, or trade of blood and blood components intended for transfusion.

(k) Drug returns, when conducted in accordance with state and federal laws and regulations. A drug return includes the sale or transfer from a dispenser, retail pharmacy, or chain pharmacy warehouse of expired, damaged, returned or recalled drugs to the original manufacturer, wholesale distributor, or to a reverse wholesaler, and the returns of saleable drugs to the original manufacturer or wholesaler.

(l) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy.

(m) The distribution of drugs by a manufacturer registered under **OAR 855-065** division of this chapter of rules of its own products to a person other than a patient.

(**19**) "Wholesale Distributor" means any entity engaged in the wholesale distribution of drugs. The term "Wholesale Distributor" includes but is not limited to, own-label distributors; private-label distributors; warehouses, including manufacturers' and distributors' warehouses; drug wholesalers or distributors; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

(**20**) "Wholesaler" means any wholesale distributor:

(a) "Class I Wholesaler" for the purpose of these rules means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which prescription drugs, including controlled drugs, devices containing prescription drugs, medicinal chemicals, or poisons are sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally licensed drug outlets or persons and is required to comply with all pedigree requirements;

(b) "Class II Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any non-prescription drugs are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer.

(c) “Class III Wholesaler” means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any of the products in paragraphs (A)-(F) below are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer and is exempted from Federal recordkeeping requirements:

(A) Drugs distributed exclusively for veterinary use. If any prescription drugs not intended for veterinary use are offered for sale, the wholesaler must register as a Class I wholesaler;

(B) Prescription devices that do not contain a prescription drug;

(C) Drugs or devices possessed by a state or local government agency, or non-profit relief organization approved by the **b**oard;

(D) Oxygen USP and medical gases;

(E) Intravenous drugs; by which formulation, are intended for the replenishment of fluids, electrolytes or calories;

(F) Medical convenience kits which includes any non controlled drug product or biological product, assembled in kit form.

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

Division 10
BOARD ADMINISTRATION AND POLICIES

~~855-010-0001~~
~~Definitions~~

~~(1) "Accredited": In these rules, accredited shall mean a school or college that is currently accredited by the Accreditation Council for Pharmacy Education (ACPE) or that is in a pre-candidate or candidate status with ACPE.~~

~~(2) "Board" means Oregon State Board of Pharmacy.~~

~~Statutory/Other Authority: ORS 475.005 & 689.205~~
~~Statutes/Other Implemented: ORS 689.115~~

855-010-0005
Meetings

(1) The **b**oard meetings **must** be held not less than once every three months as designated by the **b**oard.

(2) The President of the **b**oard **must** have power to call special meetings, subject to ORS 689.185, when it may be deemed necessary or upon request of a majority of members.

(3) The **b**oard **must** hold an annual meeting each year for the election of officers, the reorganization of the **b**oard and the transaction of other business, which may include but is not limited to:

(a) Approval of **providers of continuing pharmacy education accredited by the** Accreditation Council for Pharmacy Education **(**ACPE**)**;

(**b**) Approval of schools and colleges of pharmacy **accredited, accredited with probation, pre-candidate or candidate status by ACPE**;

(**c**) Review and adopt **standards** by reference.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135, **ORS** 689.151, **ORS** 689.185 & **ORS** 689.255

855-010-0015
Individual Commitments

(1) Board members **must** be governed by **b**oard action and **must** make no individual commitments or promises on matters of **b**oard policies.

(2) No declaration **must** be made or vote taken on any question, except at **b**oard meetings.

Statutory/Other Authority: ORS 689; **ORS 183**
Statutes/Other Implemented: ORS 183

855-010-0016
Board Administration and Policies: Pharmacy Board Member **and Public Health and Pharmacy Formulary** Advisory Committee Member Compensation

(1) A board member **and Public Health and Pharmacy Formulary Advisory Committee member** of the Oregon Board of Pharmacy who is entitled to compensation under ORS 292.495 is eligible to receive **an amount equal to the per diem amount paid to members of the Legislative Assembly under ORS 171.072** when engaged in the performance of official duties for each day **or portion thereof.**

(2) For the purpose of compensation, a board member or member of **the Public Health and Pharmacy Formulary A**dvisory **C**ommittee is considered engaged in the performance of official duties when:

(a) The activity furthers the **b**oard's mission, such as attending a board meeting;

(b) Engaged in an activity at the request of the board chair or authorized by a vote of the board in advance of the activity; or

(c) Attending an **authorized** meeting.

(3) Except as otherwise provided by law, all members, including those employed in full-time public service, may receive actual and necessary travel or other expenses actually incurred in the performance of their official duties within the limits provided by law or by the Oregon Department of Administrative services under ORS 292.210**, ORS 292.220, ORS 292.230, and ORS** 292.250.

(4) **A** board **member** or **Public Health and Pharmacy Formulary Advisory C**ommittee member **is not** required to accept compensation or reimbursement of travel expenses while performing their official duties as a board or **appointed** committee member.

Statutory/Other Authority: ORS 689.115 & ORS 689.205
Statutes/Other Implemented: ORS 29**2**.495, ORS 689.175, ORS 689.645**, ORS 689.649 & ORS 171.072**

855-010-0021
Adoption by Reference

(1) The board adopts standards and other publications by reference, as necessary, through administrative rule. When a matter is included in a referenced publication that is in conflict with Oregon Revised Statutes or Oregon Administrative Rules, the statute or rule applies and the standard provision does not. All remaining parts or application of the standard remain in effect.

(2) All outside standards, statutes, rules and publications referred to in any rules adopted by the **b**oard are by those references made a part of those rules as though fully set forth. Copies are available **for inspection** in the office of the Board of Pharmacy.

Statutory/Other Authority: ORS 689**.205**
Statutes/Other Implemented: ORS 689**.205**

855-010-0035
Board Compliance Program

The **b**oard's Compliance Director and **Compliance Officers must** be pharmacists licensed in the State of Oregon.

Statutory/Other Authority: ORS 689**.205**
Statutes/Other Implemented: **ORS 689.195**

855-010-0100
State and Nationwide Criminal Background Checks for Licensure

(1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure; directors, officers and designated representatives of drug outlets applying for registration; and individuals subject to investigation by the **b**oard, in order to determine if they have a history of criminal behavior such that they are not fit to be granted or retain a license or registration issued by the **b**oard.

(2) "Subject individual" means a person from whom the **b**oard may require legible fingerprints for the purpose of a state or nationwide criminal records check and fitness determination. In this rule, subject individual means: applicants for licensure or renewal of a license; directors, officers and designated representatives of drug outlets applying for registration or renewal of a registration; and individuals subject to an investigation by the **b**oard.

(3) Criminal records checks and fitness determinations are conducted according to ORS 181A.170**, ORS 181A.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205 ORS 181A.210, ORS** 181A.215, ORS 670.280, OR**S** 676.303, OAR 125-007-0200**, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, OAR** 125-007-0310**, and OAR 125-007-0330**.

(a) The **b**oard will request that the Oregon Department of State Police conduct a state and nationwide criminal records check, using fingerprint identification of subject individuals. The **b**oard may conduct state criminal records checks on subject individuals and any licensee through the Law Enforcement Data System maintained by the **Oregon** Department of State Police in accordance with rules adopted, and procedures established, by the **Oregon** Department of State Police. Criminal history information obtained from the Law Enforcement Data System must be handled in accordance with ORS Chapter 181A, OAR 257-010 **and OAR** 257-015 and applicable Oregon **Department of** State Police procedures.

(b) The applicant or licensee must disclose all arrests, charges, and convictions regardless of the outcome or date of occurrence. Disclosure includes any military or criminal records.

(c) The **b**oard may require additional information from the applicant or licensee, such as, but not limited to, proof of identity, previous names, residential history or additional criminal, judicial or other background information.

(4) In making licensing fitness determinations **subject to the requirements of ORS 670.280**, the **b**oard will consider the following:

(a) The nature of any criminal record that reflects:

(A) Drug or alcohol offense;

(B) Felony;

(C) Misdemeanor;

(D) U.S. military or international crime;

(E) Offense involving fraud, theft, identity theft or other instance of dishonesty;

(F) Offense involving violation of federal importation or customs laws or rules;

(G) Offense requiring registration as a sex offender;

(H) Condition of parole, probation, or diversion program, or

(I) Unresolved arrest, charge, pending indictment or outstanding warrant.

(b) Intervening circumstances relevant to the responsibilities and circumstances of the license or registration. Intervening circumstances include but are not limited to:

(A) The passage of time since the commission of the crime;

(B) The age of the subject individual at the time of the crime;

(C) The likelihood of a repetition of offenses or of the commission of another crime;

(D) The subsequent commission of another relevant crime;

(E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and

(F) A recommendation of an employer**.**

(c) The facts that support the conviction or indictment, or that indicate the making of a false statement;

(d) The relevancy, if any, of the crime or the false statement to the specific requirements of the subject individual's license or registration; and

(e) Any false statement or omission made to the **b**oard regarding the individual's criminal history.

(f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint identification;

(g) Any other pertinent information obtained as part of an investigation.

(h) The **b**oard **must** evaluate a crime or offense on the basis of the law of the jurisdiction in which the crime or offense occurred.

(i) The following are examples of crimes likely to result in denial unless there are significant mitigating circumstances:

(A) Aggravated murder;

(B) Murder;

(C) Rape I;

(D) Sodomy I;

(E) Unlawful sexual penetration I;

(F) Sexual abuse I

(j) Under no circumstances **must** an applicant be denied under these rules because of a juvenile record that has been expunged or set aside pursuant to ORS 419A.260 **and ORS** 419A.262.

(k) Under no circumstances **must** an applicant be denied under these rules due to the existence or contents of an adult record that has been set aside pursuant to ORS 137.225.

(5) Criminal offender information is confidential. Dissemination of information received under this rule may only be made to people with a demonstrated and legitimate need to know the information. When the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS 676.175. Any fingerprint cards used to conduct a check **must** be destroyed by either the Federal Bureau of Investigation or the **Oregon** Department of State Police as specified in ORS 181A.195.

(6) The **b**oard will permit the subject individual for whom a fingerprint-based criminal records check was conducted to inspect the individual's own state and national criminal offender records and, if requested by the subject individual, provide the individual with a copy of the individual's own state and national criminal offender records.

(7) If an applicant, licensee or registrant is denied a license, they are entitled to a contested case hearing pursuant to ORS 183.413, ORS 183.415, ORS 183.417**, ORS 183.425, ORS 183.430, ORS 183.435, ORS 183.440, ORS 183.445, ORS 183.450, ORS 183.452, ORS 183.453, ORS 183.457, ORS 183.458, ORS 183.459, ORS 183.460, ORS 183.462, ORS 183.464, and ORS 183.**470 and in accordance with OAR 855-001-0005**, OAR 855-001-0012, OAR 855-001-0016, and OAR 855-001-**0017.

(8) A challenge to the accuracy or completeness of information provided by the **Oregon** Department of State Police, Federal Bureau of Investigation and agencies reporting information must be made through the **Oregon** Department of State Police, Federal Bureau of Investigation or reporting agency and not through the contested case process.

(9) Request for re-evaluation following correction. If the subject individual successfully contests the accuracy or completeness of information provided by the Oregon **Department of** State Police, the Federal Bureau of Investigation or other agency reporting information to the **b**oard, the **b**oard will conduct a new criminal history check and re-evaluate the criminal history upon submission of a new criminal history request form.

(10) The applicant or licensee must pay a criminal records check fee for the actual cost of acquiring and furnishing the criminal offender information.

Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195
Statutes/Other Implemented: ORS 676.303, ORS 181A.195, ORS 181A.170, ORS 181A.215 & ORS 676.175

855-010-0110
State and Nationwide Criminal Background Checks for Employees, Volunteers and Employment Applicants

(1) The **b**oard requires a criminal records check and fitness determination for **b**oard employees, volunteers or applicants for employment with the **b**oard.

(2) Criminal records checks and fitness determinations are conducted pursuant to ORS 181A.170**, ORS 181A.175, ORS 181A.180, ORS 181A.185, ORS 181A.190, ORS 181A.195, ORS 181A.200, ORS 181A.205 ORS 181A.210, ORS** 125-181A.215 and OAR 125-007-0200**, OAR 125-007-0210, OAR 125-007-0220, OAR 125-007-0250, OAR 125-007-0260, OAR 125-007-0270, OAR 125-007-0300, and OAR** 125-007-0310.

(a) To complete the criminal records check and fitness determination, the **b**oard may require additional information from the employee, volunteer or applicant, such as, but not limited to, proof of identity or additional criminal, judicial or other background information.

(b) If the employee, volunteer or applicant has potentially disqualifying criminal offender information, the **b**oard will consider factors listed in ORS 181A.195 before making a fitness determination.

(c) An approved fitness determination does not guarantee employment.

(d) An incomplete fitness determination does not entitle the employee, volunteer or applicant the right to appeal under OAR 125-007-0300.

(3) Pursuant to ORS 181A.195, and OAR 125-007-0310, information obtained in the criminal records check is confidential and will not be disseminated by the **b**oard except to persons with a demonstrated and legitimate need to know the information.

Statutory/Other Authority: ORS 676.303, ORS 689.205 & ORS 181A.195

Statutes/Other Implemented: ORS 181A.195, ORS 181A.170, ORS 181A.215 & ORS 676.303

855-010-0120
Criminal Background Checks – **Costs**

The applicant or licensee must pay **the board** the cost of acquiring and furnishing the criminal offender information. The **amount** will not exceed the cost to the **b**oard to obtain such information **on behalf of the applicant or licensee**, including fees charged to the **b**oard by the **Oregon Department of State Police** and the **Federal Bureau of Investigation**.

Statutory/Other Authority: ORS 676.303 & ORS 689.205
Statutes/Other Implemented: ORS 676.303, ORS 181A**.195** & ORS 689.207

855-010-0130
Military Spouse or Domestic Partner

(1) "Military spouse or domestic partner" means a spouse or domestic partner of an active member of the Armed Forces of the United States who is the subject of a military transfer to Oregon.

(2) To qualify for licensure under this rule, the military spouse or domestic partner must meet the following requirements:

(a) Meet the qualifications for licensure as stated in OAR Division 855-019 or OAR 855-025.

(b) Be married to, or in a domestic partnership with, a member of the Armed Forces of the United States who is assigned to a duty station located in Oregon by official active duty military order;

(c) Applicant must complete an application for licensure, provide the **b**oard with a valid email address, and complete and pass a national fingerprint-based criminal background check;

(d) Provide evidence of current licensure as a pharmacist or pharmacy technician issued by another state;

(e) Provide to the **b**oard, in a manner determined by the **b**oard, sufficient proof that the person is in good standing with the issuing out-of-state professional licensing board; and

(f) Demonstrate competency as a pharmacist or pharmacy technician by having at least one year of active practice during the three years immediately preceding the application.

(3) A temporary authorization under this section is valid until the earliest of the following:

(a) Two years after the date of issuance;

(b) The date the spouse or domestic partner of the person to whom the authorization was issued completes the spouse's term of service in this state; or

(c) The date the person's authorization issued by the other state expires.

(4) A temporary authorization issued under this section is not renewable.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.265, **ORS 670.400 & ORS 670.403**

Division 19
PHARMACISTS

855-019-0300
Duties of a Pharmacist-in-Charge

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis.

(2) In order to be a PIC, a pharmacist must have:

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

(b) Completed a board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the board, this course may be employer provided and may qualify for continuing education credit.

(3) A pharmacist may 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.

(4) The PIC must perform the following the duties and responsibilities:

(a) When a change of PIC occurs, both 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 may 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 30 days of receiving notice.

(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 inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained 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 Report;

(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 139
Remote Dispensing Site Pharmacy

855-139-0001
Purpose and Scope

The purpose of OAR 855-139 is to provide minimum requirements for the locations where telepharmacy services are conducted.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155

855-139-0005
Definitions

The following words and terms, when used in OAR 855-139, have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section has the definition set out in OAR 855-006.

(1) "RDSP Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon where an Oregon licensed Pharmacist provides pharmacy services through a telepharmacy system.

(2) "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.

(3) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (12/01/2021).

(4) "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) (12/01/2021).

(5) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (12/01/2021) 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.

(7) "Remote Dispensing Site Pharmacy" or "RDSP" means an Oregon location registered as a Retail Drug Outlet Remote Dispensing Site Pharmacy staffed by a Certified Oregon Pharmacy Technician under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.

(8) "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.

(9) "Telepharmacy" means the delivery of pharmacy services by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician.

(10) "Telepharmacy system" means a system of telecommunications technologies that enables monitoring, documenting and recording of the delivery of pharmacy services at a remote location by an electronic method which must include the use of audio and video, still image capture, and store and forward.

(11) "Still image capture" means a specific image captured electronically from a video or other image capture device.

(12) "Store and forward" means a video or still image record which is saved electronically for future review.

Statutory/Other Authority: ORS 689.205, ORS 689.522, 2021 SB 629

Statutes/Other Implemented: ORS 689.155, ORS 689.522, ORS 689.564, 2021 SB 629

855-139-0010
Registration: General

(1) A location in Oregon where the practice of pharmacy occurs by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician must be registered by the board in Oregon as a Retail Drug Outlet RDSP.

(2) If controlled substances are stored in the RDSP, the RDSP must have an active Controlled Substance Registration Certificate with the board and Drug Enforcement Administration (DEA).

(3) A Retail Drug Outlet RDSP application must specify the RDSP Affiliated Pharmacy and cannot operate without a RDSP Affiliated Pharmacy that is registered by the board as a Retail Drug Outlet Pharmacy.

(4) All registration renewal applications must be accompanied by the annual fee and must contain the same information required in OAR 855-139-0011(3) and (4).

(5) The initial and annual registration fee for pharmacies is set out in OAR 855-110.

(6) Retail Drug Outlet RDSP registration expires March 31, annually. If the annual registration fee referred to in OAR 855-110 is not paid by March 31 of the current year, a late fee as set out in OAR 855-110 must be included with the application for registration renewal.

(7) The registration is not transferable and the registration fee cannot be prorated.

(8) No RDSP may be operated until a certificate of registration has been issued to the pharmacy by the board.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, 2021 SB 629

855-139-0015
Registration: Application

(1) An application for registration of a new RDSP must be accompanied by a floor plan drawn to scale and must be approved by the board prior to opening.

(2) The application must specify the location of the RDSP and must indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application must indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owners, the names of the partners or persons holding the five largest interests must be indicated on the application;

(b) If the owner is a corporation, the name filed must be the same as filed with the Secretary of State. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests must be indicated on the application.

(3) Upon request by the board, the applicant must furnish such information as required by the board regarding the partners, stockholders, or other persons not named in the application.

(4) A certificate of registration will be issued upon board approval of the application.

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-139-0020
Registration: Change of Owner, Location, or RDSP Affiliated Pharmacy

(1) A change of location of the RDSP Affiliated Pharmacy or location of the Retail Drug Outlet RDSP requires:

(a) Submission of a new Retail Drug Outlet RDSP application 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the board; and

(d) New certificate of registration.

(2) A change in the RDSP Affiliated Pharmacy or ownership of the Retail Drug Outlet RDSP requires:

(a) Submission of a new Retail Drug Outlet RDSP application 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the board; and

(d) New certificate of registration.

(3) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(4) A certificate of registration will be issued upon board approval of the application.

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-139-0025

Registration: Change of Business Name or Closure

(1) A RDSP Affiliated Pharmacy must notify the board 15 days prior to any change of business name of a Retail Drug Outlet RDSP. The change must be reported by filing a new application for which no fee is required.

(2) A RDSP Affiliated Pharmacy must notify the board 15 days prior to discontinuing operation of a Retail Drug Outlet RDSP. Notification must include the:

(a) Final disposition of drugs stored in the Retail Drug Outlet RDSP including:

(A) Name and location where the drugs are transferred;

(B) Name and location where destruction occurred; and

(C) Name and location of the site that will store all records;

(c) Transfer all Schedule II medications on DEA 222 forms, and Schedule III, IV and V by invoice;

(d) Provide the board with:

(A) Oregon Board of Pharmacy state license(s); and

(B) Signed statement giving the effective date of closure; and

(e) Comply with the requirements of 21 CFR 1301.52 (04/01/2021).

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-139-0030

Non-Resident Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes a RDSP Affiliated Pharmacy located outside of Oregon and providing pharmacy services through a telepharmacy system to a Retail Drug Outlet RDSP located in Oregon.

(2) Each non-resident RDSP Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every non-resident RDSP Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) Each out-of-state non-resident RDSP Affiliated Pharmacy must designate an Oregon licensed Pharmacist-in-Charge (PIC), who is responsible for all pharmacy services and to provide supervision and control of the RDSP. To qualify for this designation, the person must:

(a) Hold a license to practice pharmacy in the resident state;

(b) Be normally working for the RDSP Affiliated Pharmacy a minimum of 20 hours per week;

(c) Complete the annual RDSP PIC self-inspection report prior to February 1 each year; and

(d) Provide the PIC self-inspection report as requested by the board.

(5) Every non-resident RDSP Affiliated Pharmacy will have a Pharmacist-in-Charge (PIC) who is licensed in Oregon prior to initial registration of the RDSP.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

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

855-139-0050
Personnel

(1) The Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy is responsible for all operations at the RDSP including responsibility for the telepharmacy system and enforcing policies and procedures.

(2) A RDSP may not utilize Interns, Pharmacy Technicians, or unlicensed personnel.

(3) A Certified Oregon Pharmacy Technician working at a RDSP is required to have at least one year experience working at an Oregon registered Retail Drug Outlet Pharmacy during the three years preceding the date the Certified Oregon Pharmacy Technician begins working at the RDSP.

(4) The Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy who is supervising a RDSP must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided.

(5) When supervising a Certified Oregon Pharmacy Technician working at a RDSP, the Oregon licensed Pharmacist may supervise no more than four licensed pharmacy technicians among all locations, including the RDSP Affiliated Pharmacy.

(6) The RDSP Affiliated Pharmacy is required to comply with the pharmacist's determination in (4) and retain records.

(7) The RDSP and RDSP Affiliated Pharmacy must ensure adequate staffing at both the RDSP and RDSP Affiliated Pharmacy.

(8) Prior to working at a RDSP, the Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the RDSP must have completed a training program on the proper use of the telepharmacy system.

(9) A RDSP Affiliated Pharmacy that terminates or allows a board licensee to resign in lieu of termination must report the termination or resignation to the board within 10 working days.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305

855-139-0100
Security

(1) The area in a registered RDSP where legend and/or controlled substances are stored, possessed, prepared, compounded or repackaged must be restricted in access by utilizing physical barriers to include floor to ceiling walls and a locked separate entrance to ensure the security of those drugs.

(2) The RDSP Affiliated Pharmacy, the RDSP, Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the RDSP is responsible for the security of the prescription area including provisions for adequate safeguards against loss, theft or diversion of prescription drugs, and records for such drugs.

(3) The RDSP must be locked and the security system armed to prevent entry when:

(a) There is no Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy actively supervising the RDSP; or

(b) There is no Certified Oregon Pharmacy Technician present in the RDSP; or

(c) Any component of the telepharmacy system is not functioning.

(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.

(5) No one may be in the prescription area of a RDSP unless authorized in real-time by an Oregon licensed Pharmacist who is supervising the RDSP and from the RDSP Affiliated Pharmacy.

(6) Minimum security methods must include a properly functioning:

(a) Alarm system with an audible alarm at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy;

(b) Electronic keypad or other electronic entry system that records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the RDSP;

(B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the RDSP; and

(C) Date and time of each activity.

(c) Surveillance system that utilizes continuously accessible and recorded two-way audiovisual link between the RDSP Affiliated Pharmacy and the RDSP. The system must provide a clear view of:

(A) Dispensing site entrances;

(B) Preparation areas;

(C) Drug storage areas;

(D) Pick up areas;

(E) Office areas; and

(F) Publicly accessible areas.

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-139-0120
Drug: Procurement

RDSP 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

855-139-0125
Drug: Storage

(1) A RDSP must maintain proper storage of all drugs. This includes, but is not limited to the following:

(a) All drugs must be stored according to manufacturer's published or USP guidelines.

(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.

(d) A RDSP must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.

(2) A RDSP must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).

(a) All drug refrigeration systems must:

(A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.

(B) Utilize a centrally placed, accurate, and calibrated thermometer;

(C) Be dedicated to pharmaceuticals only;

(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.

(b) A RDSP must adhere to a monitoring plan, which includes, but is not limited to:

(A) Documentation of training of all personnel;

(B) Maintenance of manufacturer recommended calibration of thermometers;

(C) Maintenance of records of temperature logs for a minimum of three years;

(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;

(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination by an Oregon licensed Pharmacist that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan;

(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment; and

(H) Documentation and review of temperature recordings at least once every 28 days by the Oregon licensed Pharmacist at the time of in person physical inspection.

(3) Vaccine Drug Storage:

(a) A RDSP that stores vaccines must comply with section two of this rule and the following:

(A) Vaccines must be stored in the temperature stable sections of the refrigerator;

(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C variance must be utilized;

(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;

(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and

(E) Must adhere to a written quality assurance process to avoid temperature excursions.

(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.

Statutory/Other Authority: ORS 689.205, ORS 689.325
Statutes/Other Implemented: ORS 689.155

855-139-0130
Drug: Loss

A RDSP and its RDSP Affiliated Pharmacy must:

(1) Ensure that disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices are reported to the board immediately.

(2) Ensure that confirmed significant drug loss or any loss related to suspected drug theft of a controlled substance is reported to the board within one business day.

(3) Ensure that a Report of Theft or Loss of Controlled Substances (DEA Form 106) or Report of Theft or Loss of Listed Chemicals (DEA Form 107) is sent to the Drug Enforcement Administration, a copy is sent to the board at the same time.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0150
Outlet: Sanitation

A RDSP and its RDSP Affiliated Pharmacy must:

(1) Ensure the RDSP is kept clean.

(2) Ensure the Certified Oregon Pharmacy Technician working in the RDSP practices appropriate infection control.

Statutory/Other Authority: ORS 689.305
Statutes/Other Implemented: ORS 689.305

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 855-139-0062 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 naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-139-0215; and

(D) Stating "This location is a RDSP, 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

(h) 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

855-139-0200
Outlet: General Requirements

(1) A RDSP Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.

(2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.

(3) A RDSP and its RDSP Affiliated Pharmacy must:

(a) Have the same owner; or

(b) Have a written contract that specifies:

(A) The services to be provided by each licensee and registrant;

(B) The responsibilities of each licensee and registrant; and

(C) The accountabilities of each licensee and registrant;

(c) Ensure each prescription is dispensed in compliance with OAR 855-019, OAR 855-025 and OAR 855-139;

(d) Comply with all applicable federal and state laws and rules;

(e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians authorized to access the RDSP and operate the telepharmacy system;

(f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system and RDSP;

(g) Develop, implement and enforce a continuous quality improvement program for dispensing services from a RDSP 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;

(h) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy; and

(i) Develop, implement and enforce a process for an in person physical inspection of the RDSP by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy. The inspection must utilize the RDSP self-inspection form, be documented and records retained.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155, 2021 SB 629

855-139-0205
Outlet: Technology

A RDSP and its RDSP Affiliated Pharmacy must:

(1) Utilize a shared telepharmacy system and have appropriate technology or interface to allow access to information required to process and fill a prescription drug order;

(2) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy can visually identify each:

(a) Source container including manufacturer, name, strength, lot, and expiration;

(b) Source ingredient including the imprint and physical characteristics if compounding;

(c) Dispensed product including the imprint and physical characteristics;

(d) Completed prescription container including the label; and

(e) Ancillary document provided to patient at the time of dispensing.

(3) Utilize barcode, radio-frequency identification or quick response code technology to record information in (2) if available;

(4) Test the telepharmacy system and document that it operates properly before providing pharmacy services; and

(5) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system.

Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155, 2021 SB 629

855-139-0210
Outlet: Supervision

A RDSP and its RDSP Affiliated Pharmacy must:

(1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician utilizing the telepharmacy system, and the telepharmacy system is fully operational;

(2) Ensure an Oregon licensed Pharmacist continuously supervises, directs and controls each Certified Oregon Pharmacy Technician at the RDSP using audio and visual technology which must be recorded, reviewed and stored;

(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a RDSP must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;

(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;

(c) Document the following within 24 hours of the review in (3)(b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions pharmacist is reviewing;

(C) Date and time of licensee patient interaction pharmacist is reviewing;

(D) Date and time of pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

(d) Report any violation of OAR 855 to the RDSP Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.

(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.

(5) Ensure all telephone audio is recorded, reviewed and stored.

(6) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy Technician at the RDSP.

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.305

855-139-0215
Outlet: Pharmacist Utilization

A RDSP and its RDSP Affiliated Pharmacy must:

(1) Utilize an Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy to perform the professional tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is dispensed; and

(2) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 and when requested and document the interaction.

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

855-139-0220
Outlet: Non-Prescription Drugs

If non-prescription drugs are offered for sale at the RDSP, the RDSP and its RDSP Affiliated Pharmacy must:

(1) Ensure that the Certified Oregon Pharmacy Technician does not provide advice, information that requires judgment, or recommendations involving non-prescription drugs; and

(2) Ensure that an Oregon-licensed Pharmacist is immediately available to provide counseling or recommendations involving non-prescription drugs.

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

855-139-0225
Outlet: Controlled Substances

If controlled substances are at the RDSP, the RDSP and its RDSP Affiliated Pharmacy must:

(1) Comply with controlled substance regulations;

(2) Store all controlled substances in a secure locked cabinet;

(3) Maintain an accurate controlled substance perpetual inventory; and

(4) Ensure an Oregon licensed Pharmacist conducts a controlled substance inventory at least once every 28 days and reconciles all discrepancies at the time of in person physical inspection.

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

855-139-0230
Outlet: Non-Sterile Compounding

If non-sterile preparations are compounded at the RDSP, the RDSP and its RDSP Affiliated Pharmacy must:

(1) Adhere to the requirements of OAR 855-045;

(2) Ensure an Oregon licensed Pharmacist:

(a) Supervises via a real-time audio-visual connection all steps of the compounding; and

(b) Documents and visually verifies each item required in OAR 855-139-0041.

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

855-139-0300
Prescription: General Requirements

(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization. When a prescription is transmitted orally, it must be transmitted to the Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy and both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.

(2) Each RDSP must document the following information for each prescription:

(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal.

(b) If for an animal, the name of the patient, name the owner and the species of the animal.

(c) The full name, address, and contact phone number of the practitioner. If for a controlled substance, the Drug Enforcement Administration registration number of the practitioner and other number as authorized under rules adopted by reference under rule OAR 855-080-0085;

(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

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

(f) The date of filling, and the total number of refills authorized by the prescribing practitioner.

(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name 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 must clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

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

(4) A RDSP or Oregon licensed 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 RDSP or Oregon licensed 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

(5) The RDSP must dispense prescriptions accurately and to the correct party.

Statutory/Other Authority: ORS 689.205 & ORS 689.522
Statutes/Other Implemented: ORS 689.505, 689.515 & ORS 689.522

855-139-0305
Prescription: Tamper-resistant

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

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

855-139-0310
Prescription: Verification of Authenticity

Alteration of a written prescription, other than by an Oregon licensed Pharmacist's or practitioner's authorization, in any manner constitutes an invalid order unless verified with the prescriber.

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

855-139-0315
Prescription: Refills

(1) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III, IV and V are limited to five refills or six months from date of issue, whichever comes first.

(2) If the practitioner is not available and in the professional judgment of the Oregon licensed Pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the Oregon licensed Pharmacist may authorize the Certified Oregon Pharmacy Technician to prepare for pharmacist verification a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner must be promptly notified of the emergency refill.

(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include;

(a) The identity of the Certified Oregon Pharmacy Technician and responsible Oregon licensed Pharmacist;

(b) Name of the patient;

(c) Name of the medication;

(d) Date of refill; and

(e) Quantity dispensed.

(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled substance or psychotherapeutic drug and the prescriber is notified of the change.

(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient's agent. A request specific to each prescription medication is required, unless the requested fill or refill is part of an auto-refill program and is a continuation of therapy.

(6) A prescription must be refilled in context with the approximate dosage schedule unless specifically authorized by the prescriber.

(7) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may use a program that automatically refills non-controlled prescription medications, that have existing refills available and are consistent with the patient's current medication therapy only when the following conditions are met:

(a) A patient or patient's agent must enroll each prescription medication in an auto-refill program before a pharmacy can include the prescription medication as part of the auto-refill program;

(b) The prescription is not a controlled substance;

(c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or patient's agent;

(d) Pick-up notification to a patient or patient's agent may be generated upon completion of a prescription refill; and

(e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription medication is removed from the auto-refill program for that patient.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-139-0320
Prescription: Expiration

This section of rule addresses the expiration date of the prescription and not the expiration date of the drug.

(1) After one year from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber.

(2) When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled substance means that the medication can be refilled in proper context for a period of one year.

(a) When this abbreviation is used alone as a means to authorize refills for a controlled substance, the medication can be refilled in proper context for a period of six months or five refills, whichever comes first.

(b) When this abbreviation is used in conjunction with a definite time period, or a specific number of refills, the non-controlled medication can be refilled in proper context for a period not to exceed one year.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-139-0325
Prescription: Transfers

(1) Prescriptions may be transferred between pharmacies for the purpose of 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.

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

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

855-139-0350
Dispensing: Containers

Each pharmacy must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (04/01/2021), 16 CFR 1701 (04/01/2021), and 16 CFR 1702 (04/01/2021).

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

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

855-139-0355
Dispensing: Customized Patient Medication Packages

In lieu of dispensing two or more prescribed drug products in separate containers, an Oregon licensed Pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (patient med pak). A patient med pak is a package prepared by a Certified Oregon Pharmacy Technician and verified by a pharmacist for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms. The patient med pak is so designed for each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken:

(1) Label:

(a) The patient med pak must bear a label stating:

(A) The name of the patient;

(B) A serial number for each patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;

(C) The name, strength, physical description or identification, and total quantity of each drug product contained therein;

(D) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product therein;

(E) Any storage instructions or cautionary statements required by the official compendia;

(F) The name of the prescriber of each drug product;

(G) The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date must be no later than 60 days from the date of preparation);

(H) The name, address, and telephone number of the dispenser and the dispenser's registration number where necessary; and

(I) Any other information, statements, or warnings required for any of the drug products contained therein.

(b) If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container must bear a label identifying each of the drug products contained therein.

(2) Labeling: The patient med pak must be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the RDSP for the total patient med pak.

(3) Packaging:

(a) In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak must comply with the moisture permeation requirements for a Class B single-unit or unit-dose container. Each container must be either not reclosable or so designed as to show evidence of having been opened;

(b) There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards must be placed in an outer package that does comply, or the necessary consent of the purchaser or physician, to dispense in a container not intended to be child-resistant, must be obtained.

(4) Guidelines: It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the medications. In this regard, pharmacists are encouraged to report to USP headquarters any observed or report incompatibilities.

(5) Recordkeeping: In addition to any individual prescription filing requirements, a record of each patient med pak must be made and filed. Each record must contain, as a minimum:

(a) The name and address of the patient;

(b) The serial number of the prescription order for each drug product contained therein;

(c) The name of the manufacturer or labeler and lot number for each drug product contained therein;

(d) Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

(e) The date of preparation of the patient med pak and the beyond-use date that was assigned;

(f) Any special labeling instructions; and

(g) The name or initials of the Certified Oregon Pharmacy Technician who prepared the med pak and the Oregon licensed Pharmacist who verified the patient med pak.

(6) Ensure an Oregon licensed Pharmacist visually verifies and documents each item required in OAR 855-139-0041 for each individual dosage unit in the med pak.

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

855-139-0400
Labeling: General Requirements

(1) Prescriptions must be labeled with the following information:

(a) Name, address and telephone number of the RDSP;

(b) Date;

(c) Identifying number;

(d) Name of patient;

(e) 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;

(f) Directions for use by the patient;

(g) Name of practitioner;

(h) Required precautionary information regarding controlled substances;

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

(j) 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 unless, in the Oregon licensed Pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an expiration date must not be dispensed beyond the said expiration date of the drug;

(k) 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; and

(l) Address and telephone number of the RDSP Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & 689.515

855-139-0405
Labeling: Prescription Reader Accessibility

(1) A pharmacy must notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request; a prescription reader is a device designed to audibly convey labeling information.

(2) If a person informs the pharmacy that the person identifies as a person who is blind, the pharmacy must provide to the person a prescription reader that is available to the person for at least the duration of the prescription, must confirm it is appropriate to address the person's visual impairment, and must ensure that prescription labels are compatible with the prescription reader. This requirement does not apply to an institutional drug outlet, dispensing a drug intended for administration by a healthcare provider.

(3) The pharmacy must ensure an Oregon licensed Pharmacist verifies and documents that the correct electronic label was placed on each prescription container and that the audio information produced by the prescription reader is accurate prior to dispensing the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.561

855-139-0410
Labeling: Limited English Proficiency and Accessibility

(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide labels and informational inserts in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

855-139-0450
Drugs and Devices: Disposal

Drugs and devices that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0455
Drug and Devices: Return

(1) A Certified Oregon Pharmacy Technician may accept the return of a drug or device as defined by ORS 689.005 once the drug or device have been dispensed from the pharmacy if they were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, or are subject of a drug or device recall only if:

(a) An Oregon licensed Pharmacist has approved the return;

(b) The drugs or devices are accepted for destruction or disposal; and

(c) An Oregon licensed Pharmacist verifies the destruction or disposal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

855-139-0460
Drugs and Devices: Take-back Program

(1) A RDSP that operates a drug take-back collection program or that participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered with the DEA as an authorized collector to collect controlled and non-controlled drugs for destruction.

(2) A RDSP that operates as a Drug Enforcement Agency (DEA) authorized collector must notify the board within 30 days of initiating or terminating the program and must establish and enforce policies and procedures, including but not limited to:

(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is accessible to the public, within view of the pharmacy counter and must not be located behind the pharmacy counter; and

(b) Provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation and key accountability; and

(c) Personnel training and accountability.

(3) A RDSP must inform consumers to directly deposit drugs into the collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected.

(4) A RDSP must not dispose of drugs from pharmacy stock in a collection receptacle.

(5) The liner must be inserted and removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed or penetrated at any time by the pharmacy or pharmacy personnel.

(6) Liners that have been removed from a collection receptacle and immediately sealed must be directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution agent (such as registered UPS, FedEx or USPS) or a reverse wholesaler registered with the DEA and the board.

(7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to the board in writing within one day of discovery.

(8) A RDSP must maintain all drug disposal records for a minimum of 3 years.

(9) Authorized collectors are required to comply with the following federal and state laws:

(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236, ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;

(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370, and OAR 340-098-0390;

(c) 21 CFR 1317.30 (04/01/2020), 21 CFR 1317.35 (04/01/2020), 21 CFR 1317.40 (04/01/2020), 21 CFR 1317.55 (04/01/2020), 21 CFR 1317.60 (04/01/2020), 21 CFR 1317.65 (04/01/2020), 21 CFR 1317.70 (04/01/2020), 21 CFR 1317.75 (04/01/2020), 21 CFR 1317.80 (04/01/2020), and 21 CFR 1317.85 (04/01/2020); and

(d) 21 USC 822 (04/01/2021), 21 USC 822a (04/01/2021).

Statutory/Other Authority: ORS 689.205 & ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215 & ORS 495A.218

855-139-0500
Policies and Procedures

(1) The Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy and the RDSP Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the RDSP. The written policies and procedures must be maintained at the RDSP Affiliated Pharmacy and the RDSP and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the responsibilities of the RDSP Affiliated Pharmacy and each RDSP including;

(a) Security;

(b) Operation, testing and maintenance of the telepharmacy system;

(c) Sanitation;

(d) Storage of drugs;

(e) Dispensing;

(f) Oregon licensed Pharmacist supervision, direction and control of pharmacy technicians;

(g) Documenting the identity, function, location, date and time of the licensees engaging in telepharmacy;

(h) Drug and/or device procurement;

(i) Receiving of drugs and/or devices;

(j) Delivery of drugs and/or devices;

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

(l) Recordkeeping;

(m) Patient confidentiality;

(n) On-site inspection by an Oregon licensed Pharmacist;

(o) Continuous quality improvement;

(p) Plan for discontinuing and recovering services if telepharmacy system disruption occurs;

(q) Training: initial and ongoing; and

(r) Interpretation, translation and prescription reader services.

(3) If non-prescription drugs are offered for sale at the RDSP, the policies and procedures must outline the process for the Oregon licensed Pharmacist counseling and advice.

(4) If non-sterile preparations are compounded at the RDSP, the policies and procedures must meet the requirements of OAR 855-045.

(5) If controlled substances are stored at the RDSP, the policies and procedures must include the following processes:

(a) Reviewing of controlled substance prescriptions for unauthorized alterations and inspected for legitimacy by the Oregon licensed Pharmacist during inspection visits;

(b) Maintaining an accurate controlled substance perpetual inventory for all controlled substances that are stocked at the RDSP; and

(c) Conducting and reconciling the controlled substance inventory.

(6) A RDSP Affiliated Pharmacy that provides remote pharmacy services through a telepharmacy system at a RDSP must review its written policies and procedures every 12 months, revise them if necessary, and document the review.

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

855-139-0550

Records: General Requirements

(1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The RDSP must maintain all required records unless these records are maintained in the RDSP Affiliated Pharmacy.

(3) Records retained by the Drug Outlet must include, but are not limited to:

(a) Patient profiles and records;

(b) Date, time and identification of each individual and activity or function performed;

(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(d) Controlled substance inventory and reconciliation;

(e) Oregon licensed Pharmacist physical inspection of RDSP;

(f) Audio and visual connection testing and individual training on use of the audio and visual connection;

(g) Data, telephone audio, audio and video, still image capture, store and forward images, security and surveillance data. This must be retained according to (1); and

(h) Any errors or irregularities identified by the quality improvement program.

(4) All data, telephone audio, audio and video, still image capture and store and forward images collected by the telepharmacy, security and surveillance systems must be retained according to (1).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508

855-139-0555

Records: Patient

A patient record system must be maintained by pharmacies for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing

Oregon licensed Pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing. The pharmacist must make a reasonable effort to obtain, record, and maintain the following information:

(1) Full name of the patient for whom the drug is intended;

(2) Address and telephone number of the patient;

(3) Patient's age or date of birth;

(4) Patient's gender;

(5) Chronic medical conditions;

(6) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(7) Known allergies, drug reactions, and drug idiosyncrasies; and

(8) If deemed relevant in the Oregon licensed Pharmacist's professional judgment:

(a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

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

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet RDSP may not:

(1) Allow a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;

(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) Deliver a prescription;

(4) Provide non-prescription or prescription drugs when either the RDSP or RDSP Affiliated Pharmacy is closed;

(5) Compound sterile preparations; or

(6) Repackage drugs.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0602
Prohibited Practices: Disclosure of Patient Information

A Retail Drug Outlet RDSP may not:

(1) Allow a licensee or registrant of the board who obtains any patient information to disclose that information to a third party without the consent of the patient except as provided in (2) of this rule.

(2) A licensee may disclose patient information:

(a) To the board;

(b) To a practitioner, Oregon licensed Pharmacist, Intern, Pharmacy Technician, or Certified Oregon Pharmacy Technician, if disclosure is authorized by an Oregon-licensed Pharmacist who reasonably believes that disclosure is necessary to protect the patient's health or well-being; or

(c) To a third-party when disclosure is authorized or required by law; or

(d) As permitted pursuant to federal and state patient confidentiality laws; or

(e) To the patient or to persons as authorized by the patient.

(3) Allow a licensee or registrant of the board to access or obtain any patient information unless it is accessed or obtained for the purpose of patient care.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0650
Grounds for Discipline

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(1) Unprofessional conduct as defined in OAR 855-006-0020;

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:

(a) Is false, fraudulent, deceptive, or misleading; or

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.

(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with an Oregon licensed Pharmacist's ability to practice with reasonable competency and safety.

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

(c) Adequate time for an Oregon licensed Pharmacist to complete professional duties and responsibilities including, but not limited to:

(A) Drug Utilization Review;

(B) Verification of the accuracy of a prescription;

(C) Counseling; and

(D) All other duties and responsibilities of an Oregon licensed Pharmacist as specified in OAR 855-019.

(4) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.

(5) Incenting or inducing the transfer of a prescription absent professional rationale.

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

855-139-0710
Service: Epinephrine- Definitions

The following words and terms, when used in OAR 855-139-0210 through OAR 855-139-0211 have the following meanings, unless the context clearly indicates otherwise.

(1) "Allergic reaction" means a medical condition caused by exposure to an allergen, with physical symptoms that may be life threatening, ranging from localized itching to severe anaphylactic shock and death.

(2) "Authorization to Obtain Epinephrine" means a certificate that contains the name, signature, and license number of the supervising professional authorizing the dispensing of epinephrine to the individual whose name appears on the certificate. Additionally, the certificate contains a record of the number of epinephrine orders filled to date.

(3) "Statement of Completion" means a certificate that states the specific type of emergency the trainee was trained to respond to, the trainee's name and address, the name of the authorized trainer and the date that the training was completed.

(4) "Trainee" means an individual who has attended and successfully completed the formal training pursuant to the protocols and criteria established by the Oregon Health Authority, Public Health Division.

Statutory/Other Authority: ORS 689.205 & ORS 689.681
Statutes/Other Implemented: ORS 689.155 & ORS 689.681

855-139-0715
Service: Epinephrine- General Requirements

(1) A Certified Oregon Pharmacy Technician may prepare for Oregon licensed Pharmacist verification an order for epinephrine to be used by trainees to treat an anaphylactic reaction. Trainees must be 18 years of age or older and must have responsibility for or contact with at least one (1) other person as a result of the trainee's occupation or volunteer status, such as, but not limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide or chaperone.

(2) Individuals must successfully complete a training program approved by the Oregon Health Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:

(a) Statement of Completion; and

(b) Authorization to Obtain Epinephrine.

(3) Acquisition of epinephrine from a pharmacy to be used for the treatment of allergic emergencies may occur in the following manners:

(a) An Oregon licensed Pharmacist may dispense epinephrine to a trainee upon presentation of the Statement of Completion and Authorization to Obtain Epinephrine certificate to a pharmacy when:

(A) An Oregon licensed Pharmacist may generate a prescription for and dispense an emergency supply of epinephrine for not more than one adult and one child dose package, as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Epinephrine certificate.

(B) The Oregon licensed Pharmacist who generates the hardcopy prescription for epinephrine in this manner must reduce the prescription to writing and file the prescription in a manner appropriate for a non-controlled substance.

(C) Once the Oregon licensed Pharmacist generates the epinephrine prescription, the Certified Oregon Pharmacy Technician must write in the appropriate space provided on the Authorization to Obtain Epinephrine certificate the date and the number of doses dispensed, the Oregon licensed Pharmacist must verify the accuracy of data written on the certificate and the Certified Oregon Pharmacy Technician must return the completed certificate to the trainee.

(D) The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used to obtain epinephrine up to four (4) times within three (3) years from the date of the initial training.

(E) Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire three (3) years from the date of the trainee's last Oregon Health Authority approved allergy response training.

(F) Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.

(b) A Certified Oregon Pharmacy Technician may prepare for Oregon licensed Pharmacist verification epinephrine to be dispensed to an entity when:

(A) The epinephrine is acquired by a valid prescription presented to the pharmacy;

(B) The prescription identifies the entity as the patient for the purpose of prescribing and labeling the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 433.825

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

855-139-0725
Service: Expedited Partner Therapy (EPT)- Purpose

(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.

(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.

(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

855-139-0730
Service: Expedited Partner Therapy (EPT) - Procedures

(1) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(2) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule govern.

(3) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon Health Authority (OHA) to be appropriately used for EPT.

Prescription

(4) An EPT treatment protocol must conform to the following:

(a) It must include a prescription for each named or unnamed partner of the patient;

(b) It must contain a handwritten or electronic signature of the prescribing practitioner;

(c) The practitioner must identify the prescription in the following manner:

(A) Write "for EPT," or a similar notation, on the face of the prescription;

(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;

(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe – Partner 1" or by labeling the prescription as "EPT Partner"

(d) An EPT Prescription expires 30 days after the date written;

(e) An EPT Prescription may not be refilled;

(f) If any component of the prescription is missing, the Oregon licensed Pharmacist must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.

(5) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may give all prescriptions to one pharmacy and then give the dispensed drugs to each unnamed partner.

Labeling

(6) The Certified Oregon Pharmacy Technician must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the pharmacy may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.

(7) The Oregon licensed Pharmacist must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling

(8) The Oregon licensed Pharmacist is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the Oregon licensed Pharmacist must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The Oregon licensed Pharmacist should advise the patient to encourage each partner to call the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records

(9) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the board upon request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

SBAR: ORS 475.973

Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records

S

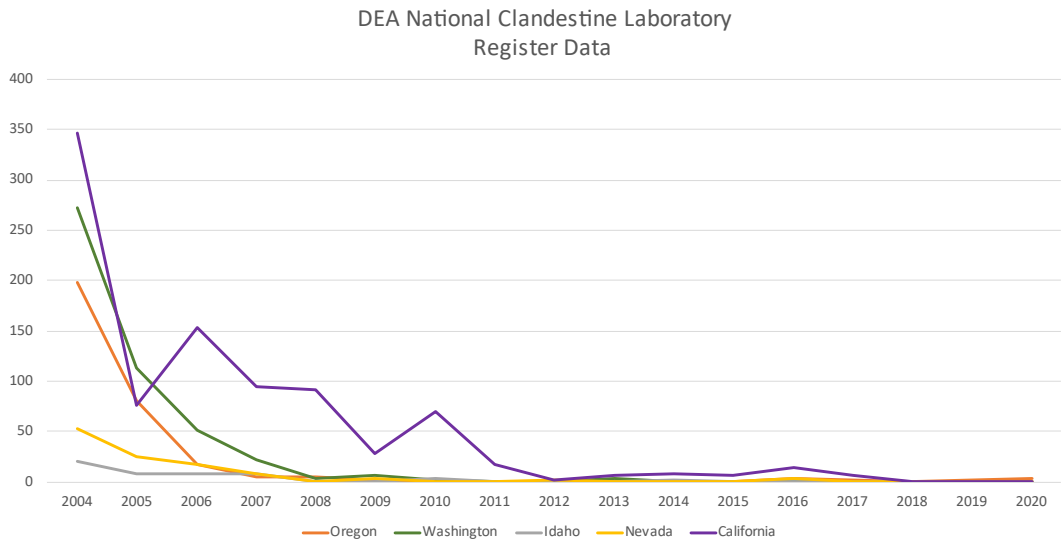
Situation:

- 2021 HB 2648 allows for transfer of drug containing pseudoephedrine or ephedrine without prescription to person who is at least 18 years of age and presents person's valid government-issued photo identification.
- 2021 HB 2648 did not repeal ORS 475.973(1)(a) The State Board of Pharmacy may not adopt rules that exempt a product containing ephedrine or pseudoephedrine from classification as a controlled substance.
- ORS 475.973 requires that if the Board of Pharmacy modifies ephedrine, pseudoephedrine or phenylpropanolamine from a schedule III to another schedule (ie. V) the board must find that restrictions on products containing ephedrine, pseudoephedrine or phenylpropanolamine does not significantly reduce the number of methamphetamine laboratories within the state.

B

Background:

- In 2006, Oregon became the first state in the country to schedule pseudoephedrine, ephedrine and phenylpropanolamine as a schedule III controlled substance.



https://www.dea.gov/clan -lab
Accessed 7/26/202 1

- In 2012, the National Precursor Log Exchange (NPLEx) was developed. The system monitors proposed purchases of pseudoephedrine and ephedrine products in real time by electronically receiving ID and product information from pharmacies and blocks the illegal sale of pseudoephedrine and ephedrine at the point-of-sale and across state lines. Use of the NPLEx system is mandated by 36 states nationwide. Two states (California and New York) allow its use voluntarily and greater than 80% of pharmacies in those states are utilizing the technology.

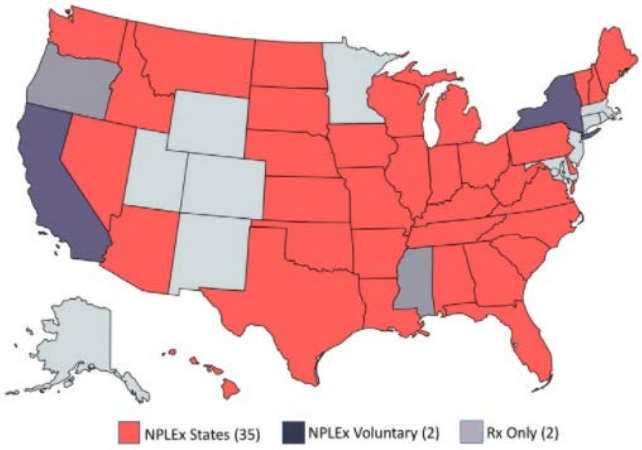


Figure 1- https://apprissinsights.com/solutions/nplex/

Related Resources

- Drug Enforcement Administration National Drug Threat Assessment, March 2021.
  - 2020 National Drug Threat Assessment (NDTA)
- Office of National Drug Control Policy (ONDCP) Oregon-Idaho High Intensity Drug Trafficking Area (HIDTA), April 22, 2021.
  - 2020 Annual Report
- National Association of State Controlled Substance Authorities, April 16, 2016.
  - 2016 White Paper- Impact of State Laws Regulating Pseudoephedrine on Methamphetamine Production and Abuse: A White Paper of the National Association of State Controlled Substance Authorities
- Drug Enforcement Agency, Accessed July 26, 2021
  - DEA National Clandestine Laboratory Register Data

Related Statutes and Rules:

- **ORS 475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records.** (1)(a) The State Board of Pharmacy may not adopt rules that exempt a product containing ephedrine or pseudoephedrine from classification as a controlled substance. Except as otherwise provided in this paragraph, the State Board of Pharmacy shall adopt rules to classify ephedrine, pseudoephedrine and phenylpropanolamine as Schedule III controlled substances. The Schedule III classification may be modified by the State Board of Pharmacy if the State Board of Pharmacy finds that restrictions on products containing ephedrine, pseudoephedrine or phenylpropanolamine under a Schedule III designation do not significantly reduce the number of methamphetamine laboratories within the state.

A

Assessment:

- ORS 475.973 requires the Board to find that modifying the schedule of products containing ephedrine, pseudoephedrine or phenylpropanolamine from C-III to C-V does not significantly reduce the number of methamphetamine laboratories within the state.
- Board to discuss if this finding is in best interest of the public health and safety.

	• Board will need to affirm the finding(s) by formal motion and vote as part of the rulemaking process if and when the Board enacts a rule modifying ephedrine, pseudoephedrine or phenylpropanolamine from a schedule III to another schedule (ie. V).
R	**Recommendation:** • Board discussion

Board Review Date: 8/12/2021

Division 41
OPERATION OF PHARMACIES (AMBULATORY AND RESIDENTIAL DRUG OUTLETS)

855-041-1030
Reporting Drug Loss

(1) Disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices **must** immediately be reported to the **b**oard.

(2) The outlet **must ensure that confirmed** significant drug loss or **any loss** related to **suspected** drug theft **of a controlled substance is reported to the board** within one business day.

(3) At the time a Report of Theft or Loss of Controlled Substances (DEA Form 106) **or Report of Theft or Loss of Listed Chemicals (DEA Form 107)** is sent to the Drug Enforcement Administration, a copy **is** sent to the **b**oard.

Statutory/Other Authority: ORS 475.035, **ORS** 689.155, **ORS** 689.205, **ORS** 689.305, **ORS** 689.315
Statutes/Other Implemented: ORS 689.155

Division 80
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0023
Schedule III

Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.13 (04/01/2020).

Statutory/Other Authority: ORS 689.205, ORS 475.973
Statutes/Other Implemented: ORS 475.035

855-080-0026
Schedule V

Schedule V consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.15 (04/01/2020)~~;~~ **and**

(1) Products containing pseudoephedrine or the salts of pseudoephedrine as an active ingredient.

(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.

(3) Products containing phenylpropanolamine or the salts of phenylpropanolamine as an active ingredient.

(4) In order to provide non-prescription pseudoephedrine or ephedrine to a purchaser, a pharmacy must:

(a) Store all pseudoephedrine and ephedrine behind the pharmacy counter in an area that is inaccessible to the public;

(b) Utilize an electronic system meeting the requirements under section 2 of HB 2648 (2021);

(c) Train individuals who are responsible for providing pseudoephedrine or ephedrine to purchasers on the requirements of the Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177), the Combat Methamphetamine Enhancement Act of 2010, P.L. 111-268, and use of the electronic system as described in 2021 HB 2648;

(d) Ensure that only a Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician provides pseudoephedrine or ephedrine to the purchaser after:

(A) Verifying that the purchaser is 18 years of age or older;

(B) Verifying the identity of the purchaser with valid government-issued photo identification; and

(C) Confirming the purchase is allowed via the electronic system; and

(e) Maintain an electronic log for at least three years from the date of the transaction that documents the following elements:

(A) Date and time of the purchase;

(B) Name, address and date of birth of the purchaser;

(C) Form of government-issued photo identification and the identification number used to verify the identity of the purchaser;

(D) Name of the government agency that issued the photo identification in (C);

(E) Name of product purchased;

(F) Quantity in grams of product purchased;

(G) Name or initials of Pharmacist, Certified Oregon Pharmacy Technician or Pharmacy Technician who provides the drug; and

(H) Signature of the purchaser. The signature of the purchaser may be recorded on a written log that also contains the transaction ID generated by the electronic system.

(5) All sales of pseudoephedrine or ephedrine are subject to the following quantity limits and restrictions:

(a) No more than 3.6 grams in a 24-hour period, no more than 9 grams in a 30-day period without regard to the number of transactions; and

(b) For non-liquids, product packaging is limited to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches.

(6) Sections (4) and (5) do not apply to a pseudoephedrine or ephedrine when the drug is dispensed pursuant to a prescription.

(7) Pharmacies, Pharmacists, Certified Oregon Pharmacy Technicians and Pharmacy Technicians involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/2020), 21 CFR 1314.02 (04/01/2020), 21 CFR 1314.03 (04/01/2020), 21 CFR 1314.05 (04/01/2020), 21 CFR 1314.10 (04/01/2020), 21 CFR 1314.15 (04/01/2020), 21 CFR 1314.20 (04/01/2020), 21 CFR 1314.25, (04/01/2020); 21 CFR 1314.30 (04/01/2020), 21 CFR 1314.35 (04/01/2020), 21 CFR 1314.40 (04/01/2020), 21 CFR 1314.42 (04/01/2020), 21 CFR 1314.45 (04/01/2020); and 21 CFR 1314.50 (04/01/2020).

Statutory/Other Authority: ORS 689.205, **2021 HB 2648**
Statutes/Other Implemented: ORS 475.035, **2021 HB 2648**

855-080-0028
Excluded **or Exempted** Substances

(1) The board adopts the excluded substances list found in 21 CFR 1308.22 (04/01/2020).

(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/2020).

(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (06/26/2021) pursuant to 21 CFR 1308.32 (04/01/2020).

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

855-080-0029
Acceptable Subpoenas for Law Enforcement Agencies to Obtain Pseudoephedrine or Ephedrine Log Information

(1) "Law Enforcement Agency" includes the following:

(a) County sheriffs, municipal police departments, police departments established by a university under ORS 352.121 or 353.125 and state police;

(b) Other police officers of this state or another state, including humane special agents as defined in ORS 181A.345;

(c) The Oregon Department of Justice when conducting a criminal investigation;

(d) A tribal government as defined in ORS 181A.680 that employs authorized tribal police officers as defined in ORS 181A.680; and

(e) Law enforcement agencies of the federal government.

(2) Acceptable subpoenas for a law enforcement agency to obtain information in a pseudoephedrine or ephedrine log are subpoenas lawfully issued by:

(a) A grand jury under ORS 136.563;

(b) A district attorney under ORS 136.565;

(c) The Oregon Attorney General under ORS 183.073;

(d) A law enforcement agency of a tribal government under tribal subpoena authority; and

(e) A federal law enforcement agency under federal subpoena power.

(3) Subpoenas that meet the criteria in (2) are accepted by the Board under section 2, subsection 5 of HB 2648 (2021). The Board does not act as a decisionmaker as to a subpoena issued for pseudoephedrine or ephedrine logs under this rule. The Board is not a party to a subpoena for information contained in a pseudoephedrine or ephedrine log under this rule.

Statutory/Other Authority: ORS 689.205, **2021 HB 2648**
Statutes/Other Implemented: ORS 475.035, **2021 HB 2648**

855-080-0031
Registration Requirements

(1) Every person who manufactures, delivers or dispenses any controlled substance within this state or who proposes to engage in the manufacture, delivery or dispensing of any controlled substance within this state must obtain a controlled substance registration annually issued by the State Board of Pharmacy.

(2) The board adopts the exceptions to registration for distribution by dispenser to another practitioner pursuant to 21 CFR 1307.11 (04/01/2020).

(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/2020).

Statutory/Other Authority: ORS 689.155 & ORS 689.205
Statutes/Other Implemented: ORS 475.125

~~855-080-0080~~
~~Special Exceptions~~

~~The board adopts the exceptions to registration found in 21 CFR 1307.11 (04/01/2020) and 21 CFR 1307.13 (04/01/2020).~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 475.035~~

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 (04/01/2020), 21 CFR 1306.02 (04/01/2020), 21 CFR 1306.03 (04/01/2020), 21 CFR 1306.04 (04/01/2020), 21 CFR 1306.05 (04/01/2020), 21 CFR 1306.06 (04/01/2020), 21 CFR 1306.07 (04/01/2020), 21 CFR 1306.08 (04/01/2020), 21 CFR 1306.09 (04/01/2020); 21 CFR 1306.11 (04/01/2020), 21 CFR 1306.12 (04/01/2020), 21 CFR 1306.13 (04/01/2020), 21 CFR 1306.14 (04/01/2020), 21 CFR 1306.15 (04/01/2020); 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25 (04/01/2020), 21 CFR 1306.27 (04/01/2020); and 21 CFR 1304.03(d) (04/01/2020).

(2) Controlled substances listed in 21 CFR 1308.15 (04/01/2021) as schedule V are prescription drugs.

(3) Pseudoephedrine and ephedrine may be:

(a) Provided to a patient without a prescription under section 2 of HB 2648 (2021).

(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR 1306.24 (04/01/2020), 21 CFR 1306.25 (04/01/2020), and 21 CFR 1306.27 (04/01/2020).

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

Division 19
PHARMACISTS

855-019-0120
Licensure

(1) Before licensure as a pharmacist, an applicant must meet the following requirements:

(a) Provide evidence from a school or college of pharmacy approved by the **b**oard that they have successfully completed all the requirements for graduation and, starting with the graduating class of 2011, including not less than 1440 hours of School-based Rotational Internships as that term is defined in OAR 855-031-0005, and that a degree will be conferred;

(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. This score **is** valid for only one year unless the **b**oard grants an extension. A candidate who does not attain this score may retake the exam after a minimum of 45 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times**;**

(c) Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) exam with a score of not less than 75. The applicant may not take the MPJE until they have graduated from a school or college of pharmacy approved by the **b**oard. A candidate who does not attain this score may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 times. The MPJE score **is** valid for 6 months unless extended by the **b**oard;

(d) Complete an application for licensure, provide the **b**oard with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check**; and**

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

(2) A license, once obtained, will expire on June 30 in odd numbered years and must be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & **2021 HB 2078**

Division 21
CONTINUING PHARMACY EDUCATION

855-021-0001
Definitions

(1) “Continuing Pharmacy Education” or “CPE” means classes of post graduate studies, informal study group participation, institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, planned and professional meetings, self-study courses, cassette or audio visual tape/slides or materials, and other self-instruction units applicable to the practice of pharmacy.

(2) “Contact hour” means fifty minutes of continuing pharmacy education.

(3) “Patient safety” means systems, procedures and processes that ensure that the correct patient receives the correct drug in the correct dose and is counseled appropriately.

(4) “Medication error prevention” means systems, procedures and processes to prevent and avoid adverse events and to ensure that the correct patient receives the correct drug in the correct dose.

(5) "Pain management education program" means a specific one hour web-based program developed by the Pain Management Commission of the Oregon Health Authority.

(6) “Cultural competence” means the lifelong process of examining the values and beliefs and developing and applying an inclusive approach to health care practice in a manner that recognizes the content and complexities of provider-patient communication and interaction and preserves the dignity of individuals, families, and communities.

(a) Cultural competence applies to all patients.

(b) Culturally competent providers do not make assumptions on the basis of an individual’s actual or perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital status, socio-economic status, veteran’s status, sexual orientation, gender identity, gender expression, gender transition status, level of formal education, physical or mental disability, medical condition or any consideration recognized under federal, state and local law.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 413.590

855-021-0005
Continuing Pharmacy Education Required for Pharmacist License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a pharmacist must have satisfactorily completed **at least** 30 hours of continuing pharmacy education. These hours must include **at least**:

(a) Two hours of continuing pharmacy education in pharmacy law;

(b) Two hours of continuing pharmacy education in patient safety or medication error prevention;

(c) Two hours of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(d) One hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority; and

(**e**) Twenty **three** additional hours of continuing pharmacy education.

(**2**) Section (1) does not apply to pharmacists applying for the first renewal of their license if they have not been licensed by the board for at least one year prior to July 1 of the renewal period.

(**3**) A pharmacist must retain documentation of completed continuing pharmacy education for six years and must provide this documentation if requested by the board.

(**4**) Continuing pharmacy education credit accumulated in excess of the required 30 contact hours for biennial license renewal cannot be carried forward.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 689.285, ORS 413.450, ORS 413.590 & **2021 HB 2078**

Division 20
PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0110
Prescribing Practices

(1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist **may** only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.

(2) A pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services pursuant to statewide drug therapy management protocols. The policies and procedures **must** describe current and referenced clinical guidelines, and include but not be limited to:

(a) Patient inclusion and exclusion criteria;

(b) Explicit medical referral criteria;

(c) Care plan preparation, implementation, and follow-up;

(d) Patient education; and

(e) Provider notification; and

(f) Maintaining confidentiality.

(3) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.

(4) For each drug or device the pharmacist prescribes, the pharmacist must:

(a) Assess patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient's health history and clinical status. The pharmacist's **physical** assessment **must** be performed in a face-to-face, in-person interaction and not through electronic means; and

(b) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the statewide drug therapy management protocol and policies and procedures; and

(c) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and

(d) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a Compendia drug or device.

(5) The pharmacist **must** maintain all records associated with prescribing and other related activities performed for a minimum of 10 years, and a copy must be made available to the patient and provider upon request. Pharmacy records must be retained and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use real-time audio-visual communication to conduct the consultation.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645 & ORS 689.649

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 (v. 06/2021)

(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); and

(D) Intranasal corticosteroids (v. 06/2021)

(b) Vulvovaginal candidiasis (VVC) Protocol (v. 06/2021)

(c) COVID-19 Monoclonal Antibody (mAb) Protocol (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) and Non-NRT Protocol (v. 06/2021);

(d) Travel Medications Protocol (v. 06/2021)

(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. **12**/2021); and

(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. **12**/2021)

[Publications referenced are available for inspection in the office of the Board of Pharmacy per OAR 855-010-0021.]

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645 & ORS 689.649

CONDITIONS

COVID Monoclonal Antibodies (REGEN-COV™) TREATMENT and POST-EXPOSURE PROPHYLAXIS

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 monoclonal antibodies casirivimab and imdevimab (REGEN-COV™).

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized COVID mAb Patient Intake Form (pg. 4-5)
  - Utilize the standardized COVID mAb Assessment and Treatment Care Pathway (pg. 6-21)
  - Utilize the standardized COVID mAb Patient Informational: Fact Sheet for Patients, Parents and Caregivers: EUA of REGEN-COV™ (pg. 23-27)
  - Utilize the standardized COVID mAb Provider Notification (pg. 28)

  PHARMACIST TRAINING/EDUCATION:
  - Completion of APhA Pharmacy-Based Immunization Delivery certificate (or equivalent)
  - Ensure Pharmacist is competent in pertinent physical assessment technique (ie. respiratory rate, pulse oximetry, blood pressure) and familiar with approved subcutaneous injection sites for REGEN-COV™.
  - Review REGEN-COV™ resources for healthcare providers, available at: https://www.regencov.com/hcp/resources
  - A minimum of 1 hour of training or continuing education (CE) on COVID monoclonal antibody treatment
    - CDC 8/12/2021 Webinar: CDC Therapeutic Options to Prevent Severe COVID-19 in Immunocompromised People
    - OHA 8/26/2021 Webinar: COVID-19 Monoclonal Antibody Webinar
    - CE: COVID-19 Monoclonal Antibody Assessment & Administration
    - CE: Pharmacists on the Frontline of COVID-19: From Testing to Treatment and Prevention

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

REALD Data Collection Form

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____

Legal Name_____ Preferred Name _____

1. Which of the following describes your **Racial or Ethnic identity**? Please check **ALL** that apply.

Hispanic and Latino/a/x
□ Central American
□ Mexican
□ South American
□ Other Hispanic or Latino/a/x

Native Hawaiian and Pacific Islander
□ CHamoru (Chamorro)
□ Marshallese
□ Communities of the Micronesian Region
□ Native Hawaiian
□ Samoan
□ Other Pacific Islander

White
□ Eastern European
□ Slavic
□ Western European
□ Other White

American Indian and Alaska Native
□ American Indian
□ Alaska Native
□ Canadian Inuit, Metis, or First Nation
□ Indigenous Mexican, Central American, or South American

Black and African American
□ African American
□ Afro-Caribbean
□ Ethiopian
□ Somali
□ Other African (Black)
□ Other Black

Middle Eastern/North African
□ Middle Eastern
□ North African

Asian
□ Asian Indian
□ Cambodian
□ Chinese
□ Communities of Myanmar
□ Filipino/a
□ Hmong
□ Japanese
□ Korean
□ Laotian
□ South Asian
□ Vietnamese
□ Other Asian

Other Categories
□ Other (please list)
_____
□ Don't know
□ Don't want to answer

2. If you checked **more than one** category above, is there **<u>one</u>** you think of as your **primary** racial or ethnic identity?
   □ Yes. Please circle your primary racial or ethnic identity above.
   □ I do not have just one primary racial or ethnic identity.
   □ No. I identify as Biracial or Multiracial.
   □ N/A. I only checked one category above.
   □ Don't know
   □ Don't want to answer

Language (*Interpreters are available at no charge*)

3. What language or languages do you **use at home**? _____
   → Skip to question 9 if you indicated English only

4. In what language do you want us to communicate in **person, on the phone, or virtually** with you?

5. In what language do you want us to **write** to you? _____

6. Do you need or want an **interpreter** for us to communicate with you?
   □ Yes □ No □ Don't know □ Don't want to answer

7. If you need or want an interpreter, what type of interpreter is preferred?
□ Spanish language interpreter □ Deaf Interpreter for DeafBlind, additional barriers, or both
□ American Sign Language interpreter □ Contact sign language (PSE) interpreter
□ Other (**please list**): _____

→ Skip to question 9 if you do not use a language other than English or sign language

8. How well do you speak English?
□ Very Well □ Well □ Not Well □ Not at all □ Don't know □ Don't want to answer

	Disability Your answers will help us find health and service differences among people with and without functional difficulties. Your answers are confidential.	Yes	***If yes**, at what age did this condition begin?	No	Don't know	Don't want to answer	Don't know what this question is asking
9.	Are you deaf or do you have serious difficulty hearing?						
10.	Are you blind or do you have serious difficulty seeing, even when wearing glasses?						
11.	Do you have serious difficulty walking or climbing stairs?						
12.	Because of a physical, mental or emotional condition, do you have serious difficulty concentrating, remembering or making decisions?						
13.	Do you have difficulty dressing or bathing?						
14.	Do you have serious difficulty learning how to do things most people your age can learn?						
15.	Using your usual (customary) language, do you have serious difficulty communicating (for example understanding or being understood by others)?						
16.	Because of a physical, mental or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping?						
17.	Do you have serious difficulty with the following: mood, intense feelings, controlling your behavior, or experiencing delusions or hallucinations?						

All health care providers must begin collecting and reporting REALD data in accordance with current REALD standards and Oregon Disease Reporting rules starting October 1, 2021.

COVID Monoclonal Antibodies (REGEN-COV™) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____
Which of the following describes your racial or ethnic identity? Please check **ALL** that apply.
□ Black/African American □ Hispanic and Latino/a/x □ American Indian/Alaska Native □ Asian □ Other
□ Native Hawaiian/Pacific Islander □ Middle Eastern/North African □ White □ Not specified
Are you houseless? Yes / No
Do you live in a shelter, encampment or transitional housing? Yes / No
Do you have a disability? Yes / No

Background Information:

1.	Are you under 12 years old?	□ Yes □ No
2.	Do you weigh under 88 lbs (40 kg)?	□ Yes □ No
3.	Have you had a positive COVID (SARS-CoV-2) antigen test within the past 14 days? If yes, please indicate the date of the positive test ___/___/_____.	□ Yes □ No
4.	In the past 10 days, have you experienced new or worsening of any of the following symptoms within the past 10 days? If yes, select any/all that apply: □ Fever □ Chills □ Cough □ Shortness of breath □ Difficulty breathing □ Fatigue □ Headache □ Muscle or body aches □ New loss of taste or smell □ Sore throat □ Congestion □ Runny nose □ Nausea □ Vomiting □ Diarrhea	□ Yes □ No
5.	Have you been in close contact of someone with COVID-19 disease within the last 96 hours (4 days), or living in a setting where risk of exposure is high? Note: Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (e.g., hugging or kissing), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (e.g., sneezing or coughing)	□ Yes □ No
6.	Are you fully vaccinated for COVID-19? If yes, indicate when Brand/Dose 1: _____ Brand/Dose 2: _____ Brand/Dose 3: _____	□ Yes □ No
7.	Do you have or have you had any of the following?	
	A. Age ≥65 years of age……	□ Yes □ No
	B. Cancer……	□ Yes □ No
	C. Chronic kidney disease……	□ Yes □ No
	D. Chronic lung diseases (e.g., chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)……	□ Yes □ No
	E. Dementia or other neurological conditions……	□ Yes □ No
	F. Diabetes (Type 1 or Type 2) ……	□ Yes □ No
	G. Heart conditions (such as heart failure, coronary artery disease, cardiomyopathies or hypertension) ……	□ Yes □ No
	H. HIV Infection……	□ Yes □ No
	I. Immunocompromised state (weakened immune system) ……	□ Yes □ No
	J. Liver Disease……	□ Yes □ No
	K. Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or oxygen supplementation (not related to COVID 19)……	□ Yes □ No
	L. Neurodevelopmental disorders (e.g., cerebral palsy, intellectual or developmental disabilities including down syndrome) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies)……	□ Yes □ No

COVID Monoclonal Antibodies (REGEN-COV™) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

	M. Overweight or obese……	□ Yes □ No
	N. Pregnancy……	□ Yes □ No
	O. Sickle cell disease or thalassemia……	□ Yes □ No
	P. Smoking, current or former……	□ Yes □ No
	Q. Solid organ or blood stem cell transplant……	□ Yes □ No
	R. Stroke or cerebrovascular disease, which affects blood flow to the brain……	□ Yes □ No
	S. Substance use disorders……	□ Yes □ No
8.	Do you have any other medical problems? If yes, list them here: _____ _____	□ Yes □ No
9.	Are you allergic to casirivimab, imdevimab, histidine, histidine monohydrochloride monohydrate , polysorbate 80, or sucrose? If yes, please circle allergy.	□ Yes □ No
10.	Do you have any other allergies? If yes, list them here: _____ _____	□ Yes □ No
11.	Do you take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No

Signature_____ Date ____/_____/_____

To Be Completed by a Pharmacist:

1. Weight _____ lbs. Height __ ft. ___ in. BMI _____
2. Oxygen Reading _____% SpO2, Respiratory Rate ____/min
3. Blood Pressure Reading _____/_____ mmHg, Pulse ____/min
4. Vaccination status in #6 should be confirmed via ALERT or CDC immunization card or self-reported (circle one)

If patient received therapy:

1. EUA Fact Sheet for Patients, Parents and Caregivers Provided: Version Date____/_____
2. Dose (check box and circle indication):
   - □ Casirivimab 600 mg and imdevimab 600 mg for treatment or post-exposure prophylaxis **-or-**
   - □ Casirivimab 300 mg and imdevimab 300 mg for ongoing exposure **-or-**
   - □ *Partial dose administered: Casirivimab _____mg and imdevimab _____mg due to: _____
3. Product/Lot: _____ Expiration: ___/___/_____ Product/Lot: _____ Expiration: ___/___/_____
4. Injection Sites:
   - □ R thigh □ R back of the upper arm □ Upper R quadrant of abdomen □ Lower R quadrant of abdomen
   - □ L thigh □ L back of the upper arm □ Upper L quadrant of abdomen □ Lower L quadrant of abdomen
5. Time Administration Began: ____:_____ AM/PM Time Administration Ended: ____:_____ AM/PM
6. Time Monitoring* Began: ____:_____ AM/PM Time Monitoring Ended: ____:_____ AM/PM
   *NOTE: 60 minutes of monitoring is still required even in patient received an incomplete dose.
7. Primary Care Provider (if known) contacted/notified of therapy Date _____/_____/_____
8. FDA MedWatch Report submitted (if adverse event occurred) Date _____/_____/_____

RPH Signature_____ Date ____/_____/_____

9. Follow-up with patient completed on Date ____/_____/_____

RPH Signature_____ Date ____/_____/_____

Standardized Assessment and Treatment Care Pathway
COVID Monoclonal Antibodies (REGEN-COV™)

1) COVID Monoclonal Antibody Screen (Form Qs: #1-2 and pharmacist physical assessment)

a. Age < 12 years old → **Refer to healthcare provider**
b. Weight < 88 lbs (40 kg) → **Refer to healthcare provider**
c. Clinical Factors:
    i. Oxygenation:
        i. SpO2 < 94% or if patient self-reports SpO2 is regularly 91-93% and SpO2 is lower than normal for the patient→ **Refer immediately to local Emergency Department or call 911**
        ii. If chronic oxygen supplementation required and, based on self-report, oxygen need has increased after positive COVID-19 test or exposure → **Refer to local Emergency Department or call 911**
        iii. If on oxygen supplementation due to current or previous COVID infection → **Refer for medical evaluation by a healthcare provider**
    ii. Respiratory rate >30/min → **Refer immediately to local Emergency Department or call 911**
    iii. Blood Pressure:
        i. Systolic Blood Pressure >180 mmHg or Diastolic Blood Pressure >120 mmHg → **Refer immediately to local Emergency Department or call 911**
        ii. Systolic Blood Pressure <90 mmHg or Diastolic Blood Pressure <60 mmHg → **Refer immediately to local Emergency Department or call 911**
        iii. Pulse <60 or >100 → **Refer for medical evaluation by a healthcare provider or call 911.**
    iv. Emergency warning signs:
        i. For COVID-19: Trouble breathing; persistent pain or pressure in the chest; new confusion; inability to wake or stay awake; pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone. → **Refer immediately to local Emergency Department or call 911**
        ii. For Hypoxia (<94% or <91% for those patients reporting lower baseline oxygen readings) Headache; shortness of breath; fast heartbeat; coughing; wheezing; confusion; bluish color in skin, fingernails, and lips → **Refer immediately to local Emergency Department or call 911**

The Pharmacist must document the physical assessment of the patient on the Patient Self-Screening Intake Form. The pharmacy must utilize medical grade devices for physical assessment of the patient.

If referral criteria not met, proceed to Step 2a.

2a) Treatment Screen (Form Qs: #3-4)

a. Positive SARS-CoV-2 molecular or antigen test within past 14 days associated with current symptoms?

    NOTE: Test results that are indeterminate or inconclusive results can suggest the presence of SARS-CoV2 in quantities insufficient for the molecular or antigen test to be positive. It is recommended to collect a new specimen and retest. If the results are still indeterminate or inconclusive, the patient should be referred to their healthcare provider for further evaluation.

AND

b. Onset of mild to moderate COVID-19 symptoms within past 10 days?

NOTE: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; and/or diarrhea)

If YES to BOTH questions above, proceed to Step 3.
If NO to EITHER question above, proceed to Step 2b.

2b) Post-Exposure Prophylaxis Screen (Form Qs: #5-6, 7I)

a. Has the patient been in close contact of someone with COVID-19 disease within the last 96 hours, or living in a setting where risk of exposure is high?

NOTE: Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (e.g., hugging or kissing), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (e.g., sneezing or coughing)

AND

b. Is the patient:
   i. Unvaccinated OR
   ii. Partially vaccinated OR
   iii. Vaccinated but not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications)?

NOTE: The CDC defines moderate to severe immunocompromised as the following:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

The pharmacist must check the ALERT Immunization Information System (IIS) to determine whether the patient is fully vaccinated. If ALERT IIS is unavailable, use available documentation and patient statement. The patient should not be vaccinated until 90 days after last receipt of COVID-19 Monoclonal Antibodies (REGEN-COV™).

NOTE: Individuals are considered to be fully vaccinated 2 weeks after their final dose of a multi-dose series, or 2 weeks after a single-dose vaccine. For additional information visit- https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

If YES to BOTH questions above, proceed to Step 3.

If NO to EITHER question above, COVID monoclonal antibody (mAb) therapy is not indicated at this time and pharmacists are not authorized to prescribe or administer COVID mAb treatment in accordance with this RPH protocol. → ***Refer*** *the patient for further evaluation and management by the patient's primary care provider. If patient has not had a SARS-CoV-2 molecular or antigen test, obtain test and repeat question #2a once results are available.*

3) Risk of Progression Screen (Form Qs: #7, demographics and REALD)

a. Does the patient have at least one of the conditions or factors met in #7 of the Self-Screening Patient Intake Form which places an individual at high risk of progression to severe COVID-19?

b. Does the patient identify as Black, African American, Latina/o/x, American Indian/Alaska Native, Asian, Asian American, or Pacific Islander on the Self-Screening Patient Intake Form which places an individual at high risk of progression to severe COVID-19?

NOTE: Other factors, such as race, ethnicity, disability or houselessness place individual patients at high risk for progression to severe COVID-19. Data indicates that:

- Patients of color or from tribal communities are most harmed by health inequities and the risk of hospitalization and death for these groups is greater than that of white patients. These patients may face higher risk than white patients, due to longstanding societal injustices including racism, discrimination, colonization, etc., which have and continue to negatively impact health outcomes. For this reason, people who identify as Black/African American, Latino/a/x, American Indian/Alaska Native, Asian or Pacific Islander are eligible for REGEN-COV™ under this protocol.
- Patients with the following disabilities might be at increased risk of becoming infected or having unrecognized illness or progression to severe disease.
  - People who have limited mobility or who cannot avoid coming into close contact with others who may be infected, such as direct support providers and family members
  - People who have trouble understanding information or practicing preventive measures, such as hand washing and social distancing
  - People who may not be able to communicate symptoms of illness

  https://www.cdc.gov/ncbddd/humandevelopment/covid-19/people-with-disabilities.html
- There is increased transmission of virus in congregate settings and outdoor settings that do not provide protection from the environment, adequate access to hygiene and sanitation facilities, or connection to services and healthcare. These settings include houselessness, sleeping outdoors or in an encampment setting.

Pharmacist must obtain patient weight, height, and calculate BMI to verify condition of overweight/obese in #7M on the Patient Intake Form.
https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

If YES to either question above, proceed to Step 4.
If NO, COVID monoclonal antibody (mAb) treatment is not indicated at this time and pharmacists are not authorized to prescribe or administer COVID mAb treatment in accordance with this RPH protocol. → ***Refer*** *the patient for further evaluation and management by the patient's primary care provider.*

4) Allergy Screen (Form Qs: 9)

a. Does the patient have a known hypersensitivity to any ingredient of REGEN-COV™?

If YES → ***Refer***
If NO, proceed to Step 5.

5) Document the Patient Education per Section X (pg. 11)

Document that you communicated to your patient or parent/caregiver, as age appropriate, information consistent with the "Fact Sheet for Patients, Parents, and Caregivers- Emergency Use Authorization (EUA) of REGEN-COV™" and provided a copy of the Fact Sheet to the patient or parent/caregiver prior to the patient receiving REGEN-COV™ (casirivimab and imdevimab), including:

a. FDA has authorized the emergency use of REGEN-COV™ (casirivimab and imdevimab) for the two indications described in this protocol (**see Indications**).
b. The patient or parent/caregiver has the option to accept or refuse REGEN-COV™.
c. The significant known and potential risks and benefits of REGEN-COV™, and the extent to which such risks and benefits are unknown.
d. Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials*.
   NOTE: **Intravenous monoclonal antibody therapy is preferred for *treatment* of COVID-19 unless it would result in a delay of therapy**. Refer to Fact sheet for Healthcare Providers- Emergency Use Authorization (EUA) of REGEN-COV™ for other alternatives. For information on clinical trials that are testing the use of REGEN-COV™ related to COVID-19, please see www.clinicaltrials.gov.
e. Patients treated with REGEN-COV™
   i. should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.
   ii. may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.

6) Administer therapy per Section VI, VII and VIII (pg. 8-10)

If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, Pharmacists must immediately discontinue administration and follow the Oregon Immunization Program's Guidelines for Managing Severe Adverse Events Following Immunization.

NOTE: Patients administered partial/incomplete therapy may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.

7) Monitor patient per Section IX (pg. 10-11) and report any witnessed or known serious advents potentially related to treatment per Section XI (pg. 11)

Ask patient to remain seated in the clinic for 60 minutes after administering therapy to decrease the risk of injury should they faint, and for the Pharmacist must monitor for visible signs of drug reactions and for anaphylaxis.

NOTE: Patients administered partial/incomplete therapy must be observed for 60 minutes.

If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, Pharmacists must follow the Oregon Immunization Program's Guidelines for Managing Severe Adverse Events Following Immunization and report to FDA Medwatch.

8) Notify primary care provider (if known) within 5 days of receipt of therapy, fax form required

9) Document follow-up with patient within 7 days, phone consultation permitted

Oregon licensed pharmacist must adhere to the EUA when prescribing/administering REGEN-COV™

Standardized Assessment and Treatment Care Pathway
COVID Monoclonal Antibodies (REGEN-COV™)

REGEN-COV™ (casirivimab and imdevimab)

I. INDICATIONS:

1. **Treatment:** The U.S. Food and Drug Administration (FDA) has issued an EUA to permit the emergency use of the unapproved product REGEN-COV™ for the treatment of mild to moderate COVID-19 within 10 days of symptom* onset in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

   *Mild or moderate COVID-19 symptoms may include: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; and/or diarrhea.

   Limitations of Authorized Use as Treatment:

   - REGEN-COV™ is not authorized for use in patients:
     - who are hospitalized due to COVID-19, OR
     - who require oxygen therapy due to COVID-19, OR
     - who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related co-morbidity.

2. **Post-exposure Prophylaxis:** The FDA also issued an EUA to permit the emergency use of the unapproved product REGEN-COV™ in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:
   a. not fully vaccinated* or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications**) AND
      i. Who have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC)*** OR
      ii. Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (e.g., nursing homes, prisons)

   * Individuals are considered to be fully vaccinated 2 weeks after their final dose of a multi-dose series, or 2 weeks after a single-dose vaccine.

   **See this website for more details: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

   ***Close contact with an infected individual is defined as: being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (e.g., hugging or kissing), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (e.g., sneezing or coughing). See this website for additional details: https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html

Limitations of Authorized Use as Post-exposure Prophylaxis:

- Post-exposure prophylaxis with REGEN-COV™ is not a substitute for vaccination against COVID-19. Patients may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.
- REGEN-COV™ is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

II. PATIENT ELIGIBILITY:

An eligible patient must meet the criteria within one of the two authorized indications. For both indications, a patient must be at high risk for progression to severe COVID-19, including hospitalization or death. Patients at high risk include, but are not limited to, individuals with at least one of the following risk factors:

- Older age (age ≥65 years of age)
- Obesity or being overweight (BMI >25 kg/m^2, or if age 12-17 years, have BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm)
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung disease (e.g., chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies)
- Have a medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19)

Authorization of REGEN-COV™ under the EUA is not limited to the medical conditions or factors listed above. Other factors, such as race or ethnicity may also place individual patients at high risk for progression to severe COVID-19. For example, data show that patients of color or from tribal communities are most harmed by health inequities and the risk of hospitalization and death for these groups is greater than that of white patients. These patients may face higher risk than white patients, due to longstanding societal injustices including racism, discrimination, colonization, etc., which have and continue to negatively impact health outcomes. For this reason, people who identify as Black, African American, Latina/o/x, American Indian/Alaska Native, Asian, Asian American or Pacific Islander are eligible for REGEN-COV™ under this protocol.

If a patient requesting monoclonal antibody treatment does not fall into one of the categories specified above, pharmacists should refer the patient to a medical provider for risk-benefit consideration.

For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.

III. CONTRAINDICATIONS:

REGEN-COV™ is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to REGEN-COV™.

IV. AVAILABLE DOSAGE FORMS:

REGEN-COV™ is available as:

1. A single-dose vial co-formulated in a 1:1 ratio of casirivimab and imdevimab

Antibody	Concentration
REGEN-COV™ (casirivimab and imdevimab)	600 mg/600 mg per 10 mL (60 mg/60 mg per mL)

OR

2. Individual antibody solutions in separate single-dose vials, which may be supplied in separate cartons or in a dose pack.

Antibody	Concentration
Casirivimab REGN10933	1,332 mg/11.1 mL (120 mg/mL)
	300 mg/2.5 mL (120 mg/mL)
Imdevimab REGN10987	1,332 mg/11.1 mL (120 mg/mL)
	300 mg/2.5 mL (120 mg/mL)

The REGEN-COV™ dose packs contain individual vials of casirivimab and imdevimab. Configurations of 2, 5 and 8 cartons may vary in vial size, strength, and appearance. Dose packs are sufficient to prepare up to two treatment doses:

Dose Pack Size	Dose Pack Components	Concentration
2 Cartons	1 casirivimab REGN10933	1,332 mg/11.1 mL (120 mg/mL)
	1 imdevimab REGN10987	1,332 mg/11.1 mL (120 mg/mL)
8 Cartons	4 casirivimab REGN10933	300 mg/2.5 mL (120 mg/mL)
	4 imdevimab REGN10987	300 mg/2.5 mL (120 mg/mL)
5 Cartons	1 casirivimab REGN10933	1,332 mg/11.1 mL (120 mg/mL)
	4 imdevimab REGN10987	300 mg/2.5 mL (120 mg/mL)
5 Cartons	4 casirivimab REGN10933	300 mg/2.5 mL (120 mg/mL)
	1 imdevimab REGN10987	1,332 mg/11.1 mL (120 mg/mL)

The 11.1 mL vials may be used to prepare multiple doses simultaneously as appropriate. Immediately discard any product remaining in the vial.

The vial stoppers for all dosage forms are not made with natural rubber latex.

V. STORAGE AND HANDLING:

Refrigerate unopened vials at 2 °C to 8 °C (36 °F to 46 °F) in the individual original carton to protect from light.

Remove the casirivimab and imdevimab vial(s) from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation. Do not expose to direct heat. Do not shake the vials.

DO NOT FREEZE. DO NOT EXPOSE TO DIRECT LIGHT. DO NOT SHAKE. DO NOT EXPOSE TO DIRECT HEAT.

Casirivimab is preservative-free. Discard any unused portion.

Imdevimab is preservative-free. Discard any unused portion.

VI. DOSAGE:

Treatment Dosage:

Casirivimab 600 mg and imdevimab 600 mg administered together by subcutaneous injection as soon as possible after positive SARS-CoV-2 viral testing and within 10 days of mild or moderate symptom* onset.

*Mild or moderate COVID-19 symptoms may include: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; and/or diarrhea.

Post-exposure Prophylaxis Dosage:

Casirivimab 600 mg and imdevimab 600 mg administered together by subcutaneous injection as soon as possible after exposure to SARS-CoV-2. The clinical trial leading to authorization studied patients that were dosed within 96 hours of exposure.

Repeat Dosing Dosage:

The pharmacist may prescribe repeat dosing for individuals with ongoing exposure* to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination. Following the initial subcutaneous dose of casirivimab 600 mg and imdevimab 600 mg, dosing of casirivimab 300 mg and imdevimab 300 mg by subcutaneous injection is repeated once every 4 weeks for the duration of the ongoing exposure.

*Ongoing exposure is any resident in a congregate care setting with active exposure or repeated exposure to household contact with COVID.

Dosage Adjustments:

No dosage adjustment is recommended in pregnant or lactating women and in patients with renal impairment.

VII. PREPARATION OF SUBCUTANEOUS INJECTION:

Remove the casirivimab and imdevimab vial(s) from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before preparation**. Do not expose to direct heat. Do not shake the vials**.

Inspect casirivimab and imdevimab vial(s) visually for particulate matter and discoloration prior to administration. Should either be observed, the vial must be discarded and replaced with a new vial. The solution for each vial should be clear to slightly opalescent, colorless to pale yellow.

1. Casirivimab and imdevimab should be prepared using the appropriate number of syringes (see Table 1). Obtain 3 mL or 5 mL polypropylene Luer Lock syringes with luer connection and 21-gauge 1½ inch transfer needles.
2. Withdraw the appropriate amount of solution into each syringe (see Table 1). Prepare all syringes at the same time.
3. Replace the 21-gauge transfer needle with a 25-gauge or 27-gauge needle for subcutaneous injection.
4. This product is preservative-free and therefore, the prepared syringes should be administered immediately. If immediate administration is not possible, store the prepared casirivimab and imdevimab syringes in the refrigerator between 2 °C to 8 °C (36 °F to 46 °F) for no more than 4 hours or at room temperature up to 25°C (77 °F) for no more than 4 total hours. If refrigerated, allow the syringes to equilibrate to room temperature for approximately 20 minutes prior to administration.

Preparation of 600 mg of Casirivimab and 600 mg of Imdevimab for Subcutaneous Injections.

Prepare 600 mg of Casirivimab and 600 mg of Imdevimab	Preparation of **4 Syringes**
Using Casirivimab and Imdevimab *Co-formulated Vial*	Withdraw 2.5 mL solution per syringe into FOUR separate syringes.
Using Casirivimab *individual vial* and Imdevimab *individual vial*	• Casirivimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes. • Imdevimab: Withdraw 2.5 mL solution per syringe into TWO separate syringes. For total of 4 syringes.

Preparation of 300 mg of Casirivimab and 300 mg of Imdevimab for Subcutaneous Injections for Repeat Dosing*.

Prepare 300 mg of Casirivimab and 300 mg of Imdevimab	Preparation of **2 Syringes**
Using Casirivimab and Imdevimab *Co-formulated Vial*	Withdraw 2.5 mL solution per syringe into TWO separate syringes.
Using Casirivimab *individual vial* and Imdevimab *individual vial*	• Casirivimab: Withdraw 2.5 mL solution per syringe into ONE syringe. • Imdevimab: Withdraw 2.5 mL solution per syringe into ONE syringe. For total of 2 syringes.

* Subsequent repeat dosing every 4 weeks for the duration of ongoing exposure after the initial 600 mg casirivimab and 600 mg imdevimab doses.

VIII. ADMINISTRATION OF SUBCUTANEOUS INJECTION:

Administer the subcutaneous injections consecutively, each at a different injection site, into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel. The waistline should be avoided.

When administering the subcutaneous injections, it is recommended that providers use different quadrants of the abdomen or upper thighs or back of the upper arms to space apart each 2.5 mL subcutaneous injection of casirivimab and imdevimab. DO NOT inject into skin that is tender, damaged, bruised, or scarred.

IX. POST-TREATMENT MONITORING:

Ask patient to remain seated in the clinic for 60 minutes after administering therapy to decrease the risk of injury should they faint and for the Pharmacist to monitor for visible signs of drug reactions and for anaphylaxis.

Pharmacists must submit a report on all medication errors and any witnessed or known SERIOUS ADVERSE EVENTS potentially related to REGEN-COV™. See Section **Adverse Reactions and Medication Errors Reporting Requirements and Instructions**.

Hypersensitivity Reactions Including Anaphylaxis:

REGEN-COV™ may only be administered in settings in which pharmacists have immediate access to medications to treat severe hypersensitivity reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, Pharmacists must immediately discontinue administration and follow the Oregon Immunization Program's Guidelines for Managing Severe Adverse Events Following Immunization.

Clinical Worsening After Administration:

Clinical worsening of COVID-19 after administration of REGEN-COV™ has been reported and may include signs or symptoms of fever, hypoxia or increased respiratory difficulty, arrhythmia (e.g., atrial fibrillation, tachycardia, bradycardia), fatigue, and altered mental status. Some of these events required hospitalization. It is not known if these events were related to REGEN-COV™ use or were due to progression of COVID-19.

Adverse Effects:

See Clinical Summary in Appendix 1 for a summary of adverse effects noted in clinical trials. Additional adverse events associated with REGEN-COV™, some of which may be serious, may become apparent with more widespread use.

X. PATIENT EDUCATION:

As the health care provider, you must communicate to your patient or parent/caregiver, as age appropriate, information consistent with the "Fact Sheet for Patients, Parents and Caregivers" (and provide a copy of the Fact Sheet) prior to the patient receiving REGEN-COV™ (see References), including:

- FDA has authorized the emergency use of REGEN-COV™ for the two indications described in this protocol (**see Indications**).
- The patient or parent/caregiver has the option to accept or refuse REGEN-COV™.
- The significant known and potential risks and benefits of REGEN-COV™, and the extent to which such risks and benefits are unknown.
- Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials*.

  * *NOTE:* **Intravenous monoclonal antibody therapy is preferred for *treatment* of COVID-19 unless it would result in a delay of therapy**. Refer to Fact sheet for Healthcare Providers- Emergency Use Authorization (EUA) of REGEN-COV™ for other alternatives. For information on clinical trials that are testing the use of REGEN-COV™ related to COVID-19, please see www.clinicaltrials.gov.

- Patients treated with REGEN-COV™:
  - **should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines**.
  - may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.

XI. REQUIRED DOCUMENTATION:

Pharmacists must review the Patient Self-Assessment Intake form, utilize this Patient Assessment and Treatment Care pathway and document required elements of the pathway in the patient's medical record and record that the patient/caregiver has been:

1. Given the "Fact Sheet for Patients, Parents, and Caregivers- Emergency Use Authorization (EUA) of Regen-COV™" (see References),
2. Informed of alternatives to receiving REGEN-COV™, and
3. Informed that REGEN-COV™ is an unapproved drug that is authorized for use under this Emergency Use Authorization.

XII. ADVERSE REACTIONS AND MEDICATION ERRORS REPORTING REQUIREMENTS:

The prescribing pharmacist a is responsible for mandatory reporting of all medication errors and any witnessed or known serious adverse events* potentially related to treatment within 7 calendar days from the onset of the event to both the patient's primary care provider (if known) and FDA MedWatch. The reports should include unique identifiers and the words "REGEN-COV™ use for COVID-19 under Emergency Use Authorization (EUA)" in the description section of the report.

- Submit adverse event reports to FDA MedWatch using one of the following methods:
  - Complete and submit the report online: www.fda.gov/medwatch/report.htm, or
  - Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by:
    - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
    - Fax (1-800-FDA-0178), or
  - Call 1-800-FDA-1088 to request a reporting form
  - Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" a statement "REGEN-COV™ use for COVID-19 under Emergency Use Authorization (EUA)."

*Serious Adverse Events are defined as:

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

The prescribing pharmacist is responsible for mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of REGEN-COV™.

IMPORTANT: When reporting adverse events or medication errors to MedWatch, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient initials, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of REGEN-COV™
- Pertinent laboratory and virology information

- Outcome of the event and any additional follow-up information if it is available at the time of the MedWatch report. Subsequent reporting of follow-up information should be completed if additional details become available.

In addition, please provide a copy of all FDA MedWatch forms to:

- Regeneron Pharmaceuticals, Inc
  - Fax: 1-888-876-2736
  - E-mail: medical.information@regeneron.com
  - Or call Regeneron Pharmaceuticals at 1-844-734-6643 to report adverse events.

XIII. OTHER REPORTING REQUIREMENTS:

Healthcare facilities and providers must report therapeutics information and utilization data through HHS Protect, Teletracking or National Healthcare Safety Network (NHSN) as directed by the U.S. Department of Health and Human Services.

XIV. REFERENCES:

REGEN-COV™ (casirivimab and imdevimab) [Emergency Use Authorization Fact Sheet for Health Care Providers]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. July 2021. Available at https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

REGEN-COV™ (casirivimab and imdevimab) [Emergency Use Authorization Fact Sheet for Patients, Parents and Caregivers]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. July 2021. Available at https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-patient.pdf. Spanish edition available https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-patient-spanish.pdf.

Standardized Assessment and Treatment Care Pathway
COVID Monoclonal Antibodies (REGEN-COV™)

APPENDIX 1. Clinical Summary

Reference: REGEN-COV™ (casirivimab and imdevimab) [Emergency Use Authorization Fact Sheet for Health Care Providers]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. July 2021. Available at https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

Overall, approximately 16,000 subjects have been exposed to REGEN-COV™ (casirivimab and imdevimab) in clinical trials in hospitalized and non-hospitalized subjects. Approximately 13,500 subjects received intravenous infusions and 2,500 subjects received subcutaneous injections.

The safety of REGEN-COV™ (casirivimab and imdevimab) is based on analyses from:

- COV-2067, a Phase 1/2/3 trial of ambulatory (non-hospitalized) subjects with COVID-19;
- COV-2069, a Phase 3 post-exposure prophylaxis trial for prevention of COVID-19; and
- COV-2093, a Phase 1 trial evaluating the safety and pharmacokinetics of REGEN-COV™ repeat subcutaneous dosing every 4 weeks for 24 weeks.

COV-2067 :

This is a randomized, double-blind, placebo-controlled clinical trial (NCT04425629) in subjects with mild to moderate COVID-19. In the phase 3 portion of the trial, subjects were treated with a single intravenous infusion of 600 mg of casirivimab and 600 mg of imdevimab (n=827), or 1,200 mg of casirivimab and 1,200 mg of imdevimab (n=1,849) (unauthorized dose under EUA), or 4,000 mg of casirivimab and 4,000 mg of imdevimab (n=1,012) (unauthorized dose under EUA), or placebo (n=1,843).

At baseline, in all randomized subjects with at least one risk factor, the median age was 50 years (with 13% of subjects ages 65 years or older), 52% of the subjects were female, 84% were White, 36% were Hispanic or Latino, and only 5% were Black or African American. In subjects with available baseline symptom data, 15% had mild symptoms, 42% had moderate, 42% had severe symptoms, and 2% reported no symptoms at baseline; the median duration of symptoms was 3 days.

The primary endpoint was the proportion of subjects with ≥1 COVID-19-related hospitalization or all-cause death through Day 29. The results for subjects treated with 600 mg of casirivumab and 600 mg of imdevimab compared to placebo are outlined in **Table 1**.

Table 1. Total Events (COVID-19-related hospitalization or all-cause death) through Day 29.

	Casirivumab 600 mg and Imdevimab 600 mg (IV) (n=736)	Placebo (n=748)
COVID-19-related hospitalization or all-cause death	7 (1.0%)	24 (3.2%)
Relative Risk Reduction	70% (p=0.0024)	
Absolute Difference	2.2%, NNT = 46	

Abbreviations: IV = intravenous; NNT = number needed-to-treat to prevent one event COVID-19-related hospitalization or all-cause death.

In pooled phase 1/2/3 analysis, infusion-related reactions (adverse event assessed as causally related by the investigator) of grade 2 or higher severity have been observed in 10/4,206 (0.2%) of those who received REGEN-COV™ at the authorized dose or a higher dose. The infusion was permanently discontinued in 4 subjects who developed infusion-related reactions (urticaria, pruritus, flushing,

pyrexia, shortness of breath, chest tightness, nausea, vomiting, rash) but each received doses higher than what is authorized under EUA.

Anaphylactic reactions have been reported in subjects receiving REGEN-COV™. The events began within 1 hour of completion of the infusion, and in at least one case required treatment including epinephrine. The events resolved.

COV-2069:

This is a Phase 3, randomized, double-blind, placebo-controlled clinical trial (NCT04452318) that assessed the efficacy and safety of REGEN-COV™ (casirivimab and imdevimab) for post-exposure prophylaxis of COVID-19 in household contacts of individuals infected with SARS-CoV-2. The trial enrolled subjects who were asymptomatic and who lived in the same household with a SARS-CoV-2 infected patient. Subjects who were SARS-CoV-2 negative (PCR negative and seronegative) at baseline were enrolled and received a single dose of 600 mg of casirivimab and 600 mg of imdevimab subcutaneously (n=751) or placebo (n=752). Subjects who were SARS-CoV-2 positive at baseline were enrolled in Cohort B and received a single dose of 600 mg of casirivimab and 600 mg of imdevimab subcutaneously or placebo.

Cohort A:

At baseline, the median age was 44 years (with 9% of subjects ages 65 years or older), 54% of the subjects were female, 86% were White, 41% were Hispanic or Latino, and 9% were Black or African American. The primary efficacy endpoint was the proportion of subjects who developed PCR-confirmed COVID-19 through Day 29. The results for subjects treated with 600 mg of casirivumab and 600 mg of imdevimab compared to placebo are outlined in **Table 2**. In a post-hoc analysis in a subgroup of subjects who met the criteria for high risk for progression to severe COVID-19, there was a 76% relative risk reduction in COVID-19 with REGEN-COV™ treatment versus placebo [10/570 (2%) vs. 42/567 (7%); adjusted odds ratio 0.22; p<0.0001].

Table 2. Total PCR-confirmed Positive COVID-19 Test through Day 29.

	Casirivumab 600 mg and Imdevimab 600 mg SC (n=753)	Placebo (n=752)
PCR-confirmed Positive COVID-19 Test	11 (1.5%)	59 (7.8%)
Relative Risk Reduction	81% (Adjust OR = 0.17; p<0.0001)	
Absolute Difference	6.3%, NNT = 16	

Abbreviations: NNT = number needed-to-treat to prevent one positive COVID-19 infection; SC = subcutaneous.

Adverse events were reported in 265 subjects (20%) in the REGEN-COV™ group and 379 subjects (29%) in the placebo group. Injection site reactions (all grade 1 and 2) occurred in 55 subjects (4%) in the REGEN-COV™ group and 19 subjects (2%) in the placebo group. The most common signs and symptoms of injection site reactions which occurred in at least 1% of subjects in the REGEN-COV™ group were erythema and pruritus. Hypersensitivity reactions occurred in 2 subjects (0.2%) in the REGEN-COV™ group and all hypersensitivity reactions were grade 1 in severity. There were no cases of anaphylaxis.

Cohort B:

In a post-hoc analysis of the overall combined Cohort A and Cohort B (regardless of serology status at baseline), there was a 62% risk reduction in COVID-19 with REGEN-COV™ treatment versus placebo [46/1201 (4%) vs. 119/1177 (10%); adjusted odds ratio 0.35; p<0.0001].

Adverse events were reported in 52 subjects (34%) in the REGEN-COV™ group and 75 subjects (48%) in the placebo group. Injection site reactions, all of which were grade 1 or 2, occurred in 6 subjects (4%) in the REGEN-COV™ group and 1 subject (1%) in the placebo group. The most common signs and symptoms of injection site reactions which occurred in at least 1% of subjects in the REGEN-COV™ group were ecchymosis and erythema. There were no cases of hypersensitivity reaction or anaphylaxis.

COV-2093:

This is a randomized double-blind, placebo-controlled Phase 1 trial evaluating the safety, pharmacokinetic and immunogenicity of repeated doses of 600 mg of casirivimab and 600 mg of imdevimab administered subcutaneously in healthy adult subjects. Subjects were randomized 3:1 to REGEN-COV™ (n=729) or placebo (n=240) administered every 4 weeks for 24 weeks. Adverse events were reported in 380 subjects (52%) in the REGEN-COV™ group and 111 subjects (46%) in the placebo group. Injection site reactions occurred in 12% and 4% of subjects following single dose administration in the REGEN-COV™ and placebo groups, respectively.

With repeat dosing, injection site reactions occurred in 252 subjects (35%) in the REGEN-COV™ group and 38 subjects (16%) in the placebo group; all injection site reactions were grade 1 or 2 in severity. Hypersensitivity reactions occurred in 8 subjects (1%) in the REGEN-COV™ group; and all hypersensitivity reactions were grade 1 or 2 in severity. There were no cases of anaphylaxis.

COVID Monoclonal Antibodies (REGEN-COV™) Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Rx

☐ Drug: Casirivimab 600 mg and imdevimab 600 mg (REGEN-COV™) administered subcutaneously by Pharmacist for ☐ initial treatment or ☐ post-exposure prophylaxis of SARS-CoV-2.

- Sig: Inject according to protocol
- Quantity: #10mL
- Refills: none

☐ Drug: Casirivimab 300 mg and imdevimab 300 mg (REGEN-COV™) administered subcutaneously by Pharmacist for ongoing exposure to SARS-CoV-2 lasting longer than 4 weeks

- Sig: Inject according to protocol
- Quantity: #5mL
- Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV™
(casirivimab and imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given a medicine called **REGEN-COV (casirivimab and imdevimab)** for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV.

Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.

Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

WHAT IS COVID-19?

COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

WHAT ARE THE SYMPTOMS OF COVID-19?

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

WHAT IS REGEN-COV (casirivimab and imdevimab)?

REGEN-COV is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for severe COVID-19, including hospitalization or death for:

- treatment of mild to moderate symptoms of COVID-19
- post-exposure prevention of COVID-19 in persons who are:
    - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**,
    - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising

conditions, including someone who is taking immunosuppressive medications), **and**

- have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html, **or**
- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, as nursing homes, prisons,).

REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19 or to prevent COVID-19 in people who are at high risk of being exposed to someone who is infected with SARS-CoV-2. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of REGEN-COV for the treatment of COVID-19 and the post-exposure prevention of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

WHO SHOULD NOT TAKE REGEN-COV?

Do not take REGEN-COV if you have had a severe allergic reaction to REGEN-COV.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have had a severe allergic reaction including anaphylaxis to REGEN-COV previously
- Have received a COVID-19 vaccine.
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE REGEN-COV (casirivimab and imdevimab)?

- REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together at the same time through a vein (intravenous or IV) or injected in the

tissue just under the skin (subcutaneous injections). **Your healthcare provider will determine the most appropriate way for you to be given REGEN-COV.**

- Treatment: If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.
    - If your healthcare provider determines that you are unable to receive REGEN-COV as an intravenous infusion which would lead to a delay in treatment, then as an alternative, REGEN-COV can be given in the form of subcutaneous injections. If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time.
- Post-exposure prevention: If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time. If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer.
    - After the initial dose, if your healthcare provider determines that you need to receive additional doses of REGEN-COV for ongoing protection, the additional intravenous or subcutaneous doses would be administered monthly.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab and imdevimab)?

Possible side effects of REGEN-COV are:

- Allergic reactions. Allergic reactions can happen during and after infusion or injection of REGEN-COV. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These reactions may be severe or life threatening.
- Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. The side effects of getting any medicine by subcutaneous injection may include pain, bruising of the skin, soreness, swelling, and possible infection at the injection site.

These are not all the possible side effects of REGEN-COV. Not a lot of people have been given REGEN-COV. Serious and unexpected side effects may happen. REGEN-COV is still being studied so it is possible that all of the risks are not known at this time.

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV may reduce your body’s immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

WHAT OTHER TREATMENT CHOICES ARE THERE?
Like REGEN-COV (casirivimab and imdevimab), FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA that are used to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?
Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of REGEN-COV does not replace vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
There is limited experience using REGEN-COV (casirivimab and imdevimab) in pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving REGEN-COV may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH REGEN-COV (casirivimab and imdevimab)?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

HOW CAN I LEARN MORE?
- Ask your health care provider.
- Visit www.REGENCOV.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made REGEN-COV (casirivimab and imdevimab) available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

REGEN-COV has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for REGEN-COV is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

REGENERON

Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591-6707

Revised: 07/2021

Provider Notification
COVID Monoclonal Antibodies (REGEN-COV™) Administration

Pharmacy Name:_____

Pharmacy Address:_____

Pharmacy Phone: _____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) was:

☐ **Prescribed and administered COVID Monoclonal Antibodies** (REGEN-COV™) at our Pharmacy noted above. The prescription issued and administered consisted of:

- ☐ Treatment of COVID-19: Casirivimab 600 mg and imdevimab 600 mg (REGEN-COV™) administered subcutaneously by the Pharmacist for initial treatment of SARS-CoV-2. Prior to prescribing and administration of COVID Monoclonal Antibodies (REGEN-COV™) for treatment of COVID-19, your patient was tested for and/or indicated the following:

Test Name	Date of Test	Result
SARS-CoV-2 (molecular or antigen)	1) _____/_____/_____	□ reactive □ *indeterminate/inconclusive* □ negative
	2*) _____/_____/_____	□ reactive □ *indeterminate/inconclusive* □ negative

*2nd test only required if 1st test is *indeterminate/inconclusive*

- ☐ Post-Exposure Prophylaxis of COVID-19: Casirivimab 600 mg and imdevimab 600 mg (REGEN-COV™) administered subcutaneously by the Pharmacist as soon as possible after exposure to SARS-CoV-2.
- ☐ Ongoing Exposure: Casirivimab 300 mg and imdevimab 300 mg (REGEN-COV™) administered subcutaneously by the Pharmacist for ongoing exposure to SARS-CoV-2 lasting longer than 4 weeks.

Your patient was:

- Provided with the FDA EUA REGEN-COV™ Fact Sheet for Patients, Parents, & Caregivers https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-patient.pdf
- Informed that an office visit with you or another provider on your team is recommended after monoclonal antibody administration.
- For treatment or post-exposure prevention of COVID-19, the patient was also advised that they should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.
- For post-exposure prophylaxis, the patient was also informed that REGEN-COV™ does not replace vaccination against COVID-19 and, if applicable, they may not be vaccinated for COVID-19 until 90 days after treatment with REGEN-COV™.

☐ **Tested for SARS-CoV-2 (molecular or antigen) twice, both results were *indeterminate or inconclusive* and therefore the patient is being referred to you for follow-up**. COVID monoclonal antibodies were not prescribed or administered to your patient.

If you have further questions: Please contact the prescribing pharmacy or call Regeneron Medical Information Department at 1-844-REGN-MID (1-844-734-6643). Clinicians can review the NIH COVID-19 Treatment Guidelines as well as the FDA EUA for the therapy.

- NIH COVID-19 Treatment Guidelines: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/hospitalized-adults--therapeutic-management/
- FDA EUA for REGEN-COV™: https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf

PREVENTIVE CARE

HIV POST-EXPOSURE PROPHYLAXIS (PEP)

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 post-exposure prophylaxis (PEP) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PEP Patient Intake Form (pg. 2)
  - Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-5)
  - Utilize the standardized PEP Patient Informational Handout (pg. 7)
  - Utilize the standardized PEP Provider Fax (pg. 8)

  PHARMACIST TRAINING/EDUCATION:
  - Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information:

1.	Do you think you were exposed to Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
2.	What was the date of the exposure?	___/___/___
3.	What was the approximate time of the exposure?	___:___ *AM/PM*
4.	Was your exposure due to unwanted physical contact or a sexual assault?	□ Yes □ No □ Not sure
5.	Was the exposure through contact with any of the following body fluids? Select any/all that apply: □ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____	□ Yes □ No □ Not sure
6.	Did you have vaginal or anal sexual intercourse without a condom?	□ Yes □ No □ Not sure
7.	Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner?	□ Yes □ No □ Not sure
8.	Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner?	□ Yes □ No □ Not sure
9.	Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin?	□ Yes □ No □ Not sure
10.	Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals? □persons with known HIV infection □men who have sex with men with unknown HIV status □persons who inject drugs □sex workers	□ Yes □ No □ Not sure
11.	Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____	Yes □ No □ Not sure

Medical History:

12.	Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)?	□ Yes □ No □ Not sure
13.	Are you seeing a provider for management of Hepatitis B?	□ Yes □ No □ Not sure
14.	Have you ever received immunization for Hepatitis B? If yes, indicate when:_____ If no, would you like a vaccine today? *Yes/No*	□ Yes □ No □ Not sure
15.	Are you seeing a kidney specialist?	□ Yes □ No □ Not sure
16.	Are you currently pregnant?	□ Yes □ No □ Not sure
17.	Are you currently breast-feeding?	□ Yes □ No □ Not sure
18.	Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum	□ Yes □ No □ Not sure
19.	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____ _____	□ Yes □ No □ Not sure

Signature_____ Date_____

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

Name: _____Date of Birth:____/____/_____ Today's Date:____/____/_____

<table>
<tr><td colspan="2">1. Is the patient less than 13 years old?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic</td><td>☐ No: Go to #2</td></tr>
<tr><td colspan="2">2. Was the patient a survivor of sexual assault?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.**</td><td>☐ No: Go to #3</td></tr>
<tr><td colspan="2">3. Is the patient known to be HIV-positive?</td><td rowspan="2">Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure.</td></tr>
<tr><td>☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic.</td><td>☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional).</td></tr>
<tr><td colspan="2">4. What time did the exposure occur?</td><td rowspan="2">Notes:</td></tr>
<tr><td>☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department.</td><td>☐ ≤72 hours ago: go to #5</td></tr>
<tr><td colspan="2">5. Was the exposure from a source person known to be HIV-positive?</td><td rowspan="2"></td></tr>
<tr><td>☐ Yes: Go to #6</td><td>☐ No: Go to #7</td></tr>
<tr><td colspan="2">6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids:</td><td rowspan="2">Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood.</td></tr>
<tr><td>Please check any/all that apply:
☐Blood
☐Semen
☐Vaginal secretions
☐Rectal secretions
☐Breast milk
☐Any body fluid that is visibly contaminated with blood

If any boxes are checked, go to #9.</td><td>Please check any/all that apply (Note: only applicable if not visibly contaminated with blood):
☐Urine
☐Nasal Secretions
☐Saliva
☐Sweat
☐Tears
☐None of the above

Go to #7</td></tr>
<tr><td colspan="2">7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: This type of exposure puts the patient at a high risk for HIV acquisition</td></tr>
<tr><td>☐ Yes: Go to #9</td><td>☐ No: Go to #8</td></tr>
</table>

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)
Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

<table>
<tr><td colspan="2">8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status?</td><td rowspan="2">Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance.</td></tr>
<tr><td>☐ Yes: Please check all that apply and go to #9:
☐Was the source person known to be HIV-positive?
☐Were there cuts/openings/sores/ulcers on the oral mucosa?
☐Was blood present?
☐Has this happened more than once without PEP treatment?
☐None of the above</td><td>☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9.</td></tr>
<tr><td colspan="2">9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up?</td><td rowspan="2">Notes: Connection to care is critical for future recommended follow-up.</td></tr>
<tr><td>☐ Yes: Go to #10</td><td>☐ No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td></tr>
<tr><td colspan="2">10. Does the patient have history of known Hepatitis B infection (latent or active)?</td><td rowspan="4">Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare.</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No. Go to #11</td></tr>
<tr><td colspan="2">11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No
Verify vaccine records or Alert-IIS. Dates:_____</td></tr>
<tr><td>☐ Yes: Go to #13</td><td>☐ No: Go to #12</td></tr>
<tr><td colspan="2">12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.
☐Vaccine administered
Lot:_____ Exp:_____ Signature:_____</td><td></td></tr>
<tr><td colspan="2">13. Does the patient have known chronic kidney disease or reduced renal function?</td><td rowspan="2">Notes: Truvada® requires renal dose adjustment when the CrCl <50 mL/min</td></tr>
<tr><td>☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept.</td><td>☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient.</td></tr>
</table>

Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV) Assessment and Treatment Care Pathway

(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumurate 300 mg) one tablet by mouth daily for 30 days

PLUS

Isentress® (raltegravir 400 mg) one tablet by mouth twice daily for 30 days

Notes:

- There may be other FDA-approved regimens available for treatment of PEP. Truvada® plus Isentress® is the only regimen permitted for pharmacist prescribing at this time.
- Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such.
- Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com
- If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance.

COUNSELING POINTS:

- Truvada®:
  - Take the tablet every day as prescribed with or without food. Taking it with food may decrease stomach upset.
  - Common side effects include nausea/vomiting, diarrhea for the first 1-2 weeks.
- Isentress®:
  - Take the tablet twice daily as prescribed with or without food. Taking it with food might decrease any stomach upset.
  - If you take vitamins or supplements with calcium or magnesium, take the supplements 2 hours before or 6 hours after the Isentress®.
- Do not take one of these medications without the other. Both medications must be taken together to be effective and to prevent possible resistance. You must follow up with appropriate provider for lab work.
- Discuss side-effects of "start-up syndrome" such as nausea, diarrhea, and/or headache which generally resolve within a few days to weeks of starting the medications.
- Discuss signs and symptoms of seroconversion such as flu-like symptoms (e.g. fatigue, fever, sore throat, body aches, rash, swollen lymph nodes).

*Oregon licensed pharmacists are mandatory reporters of child abuse, per ORS Chapter 419B. Reports shall be made to Oregon Department of Human Services @ **1-855-503-SAFE (7233)**.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____Date____/____/_____

PEP Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Note: RPh must refer patient if exposure occurred >72 hours prior to initiation of medication

Rx

- Drug: emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (Truvada)
  Sig: Take one tablet by mouth once daily in combination with Isentress for 30 days
  Quantity: #30
  Refills: none

AND

- Drug: raltegravir 400mg (Isentress)
  Sig: Take one tablet by mouth twice daily in combination with Truvada for 30 days.
  Quantity: #60
  Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:
Lot:_____Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____
_____
_____
_____

Pharmacy Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

This page contains important information for you; please read it carefully.

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are the medications and directions you have been prescribed, some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

Medications: You must start these within 72 hours of your exposure

- Truvada (emtricitabine/tenofovir disoproxil) 200 mg/300 mg – take 1 tablet by mouth daily for 30 days, **AND**
- Isentress (raltegravir) 400 mg – take 1 tablet by mouth twice daily for 30 days

Key Points

- Take every dose. If you miss a dose, take it as soon as you remember.
  - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking either medication without first asking your doctor or pharmacist.
- Truvada and Isentress don't have side effects most of the time. The most common side effects (if they do happen) are stomach upset. Taking Truvada and Isentress with food can help with stomach upset. Over-the-counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you. ~~The pharmacy cannot do these lab tests.~~
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
   - ☐ HIV antigen/antibody 4th generation
   - ☐ Hepatitis B surface antigen and surface antibody
   - ☐ Hepatitis C antibody
   - ☐ Treponema pallidum antibody
   - ☐ Comprehensive metabolic panel
4. If you think that you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

Provider Notification
Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) has been prescribed HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

This regimen consists of:

- Truvada (emtricitabine/tenofovir disoproxil) 200/300mg tablets - one tab by mouth daily for 30 days AND
- Isentress (raltegravir) 400mg tablets - one tab by mouth twice daily for 30 days.

This regimen was initiated on _____(Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

Provider pearls for HIV PEP:

- Truvada needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- Truvada and Isentress are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs at **6 weeks** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis B surface antigen and surface antibody
- ☐ Hepatitis C antibody
- ☐ Comprehensive metabolic panel
- ☐ Treponema pallidum antibody as appropriate
- ☐ Pregnancy test as appropriate
- ☐ STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis C antibody

If you have further questions, please contact the prescribing pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.

PREVENTIVE CARE

HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)

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 pre-exposure prophylaxis (PrEP) drug regimen.

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PrEP Patient Intake Form (pg. 2-3)
  - Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-9)
  - Utilize the standardized PrEP Provider Fax (pg.11)

  PHARMACIST TRAINING/EDUCATION:
  - Completion of a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Preferred Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? Yes / No Insurance Provider Name _____
Any allergies to medications? Yes / No If yes, please list _____

Background Information: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

Do you answer yes to any of the following? □ yes □ no

1. Do you sexually partner with men, women, transgender, or non-binary people?
2. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom. _____% of the time __/__/__ last sex without a condom
3. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
4. Do you have vaginal sex? • Receptive- you have a vagina and you use it for vaginal sex • Insertive- you have a penis and you use it for vaginal sex
5. Do you have anal sex? • Receptive- someone uses their penis to perform anal sex on you • Insertive- you use your penis to perform anal sex on someone else
6. Do you inject drugs?
7. Are you in a relationship with an HIV-positive partner?
8. Do you exchange sex for money or goods? (includes paying for sex)
9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex?

Medical History: These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)?	□ yes □ no
2. Do you see a (healthcare provider) for management of Hepatitis B?	□ yes □ no
3. Have you ever received an immunization for Hepatitis B? If yes, when: • If no, would you like a Hepatitis B immunization today? □ yes □ no	□ yes □ no Date of vaccine __/__/__
4. Do you see a healthcare provider for problems with your kidneys?	□ yes □ no
5. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? • Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)	□ yes □ no
6. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no
7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	□ yes □ no

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Testing and Treatment:

1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription. • I may be able to have tests performed at the pharmacy. • I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks. o I brought my labs in today □ Yes □ No • I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month.	□ Yes □ No
2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV. • I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate.	□ Yes □ No
3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV.	□ Yes □ No

Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.

Please list any questions you have for the pharmacy staff:

Patient Signature: _____ **Date:** _____

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

Risk Factor:	Notes and considerations
1. Sexual partners	• MSM activity is highest risk for HIV. • Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present.
2. Estimated condom use _____% of the time __/__/__ last sex without a condom	• Condomless sex greatly increases risk of HIV and STIs. • For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP). • Condomless sex within last 14 days, repeat HIV test in one month.
3. Oral sex	• Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals. • STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex.
4. Vaginal sex	• Receptive vaginal sex can be high risk for HIV. • Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present.
5. Anal sex	• Receptive anal sex has the most risk of HIV of any sex act. • Insertive anal sex has high risk for HIV. • STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex.
6. Injection drug use	• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
7. HIV-positive partner	• People living with HIV who have undetectable viral loads will not transmit HIV. • For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP.
8. Exchanging sex for money or goods	• People who buy or sell sex are at high risk for HIV.
9. Popper and/or methamphetamine use	• Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV. • Recommend adequate lubrication in persons who use poppers for sex.

1. Is one or More Risk Factor Present: □ **yes** □ ***no***

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Testing:

The pharmacist must verify appropriate labs are complete. *Italics* below indicate need for referral.

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen) test:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing. NOTE: HIV test must be performed within the 14 days prior to prescribing and dispensing. Order lab at initial intake and every 90 days thereafter.			
• Syphilis/Treponemal antibody:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing. Order lab at initial intake and every 90-180 days depending on risk.			
• Hepatitis B surface antigen:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician. Confirmation of being fully vaccinated for hepatitis B via ALERT or medical record may meet criteria for negative Hepatitis B surface antigen. If records of vaccination are not available, order lab at initial intake only.			
• *Hepatitis C antibody:*	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
Positive antibody indicates exposure to Hepatitis C virus. The pharmacist will refer this person for confirmatory testing and treatment. It is permissible to proceed with PrEP prescribing in this scenario. Order lab at initial intake and annually thereafter.			
• Gonorrhea/Chlamydia:	____/____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ non-reactive	Pharyngeal test result: □ *reactive* □ *indeterminate* □ non-reactive	Rectal test result: □ *reactive* □ *indeterminate* □ non-reactive	
All reactive or indeterminate chlamydia and/or gonorrhea results will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment. Order lab at initial intake and every 90-180 days depending on risk.			
• Renal function (CrCl): SCr _____mg/dL	____/____/_____	_____ mL/min □ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min*	□ *Yes*
CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy.* Order lab at initial intake and annually thereafter.			
• Signs/symptoms of STI not otherwise specified:	____/____/_____	□ *Present*	□ *Yes*
• Condomless sex in past two weeks	____/____/_____	□ *Yes*	□ *Yes*

2. Is HIV ab/ag 4th gen test complete? □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes and non-reactive: Proceed to question #3
- *If yes and reactive or indeterminate: RPH many NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

3a. If initial visit: Are required initial labs complete? □ **yes** □ ***no***

- If yes, RPH may prescribe PrEP. Proceed to next section: Medical History.
  - □ Labs required today are: HIV, Syphilis/Treponemal antibody, Gonorrhea/Chlamydia, Hepatitis B (if no documentation of full vaccination), Hepatitis C and renal function.
- If no, RPH may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

→ *See next page for follow-up visit lab requirements and sample language for reactive (indeterminate) HIV and STI tests.*

3b. If follow-up visit: Are required follow-up labs complete? □ **yes** □ ***no***

- □ Every 90 days- HIV
- □ Every 90-180 days- Syphilis/Treponemal antibody and Gonorrhea/Chlamydia,
- □ Annually - Hepatitis C and renal function.

- If yes, RPH may prescribe PrEP. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

Sample language for reactive or indeterminate tests:

Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.

Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

County Health Department Directory:
https://www.oregon.gov/oha/ph/providerpartnerresources/localhealthdepartmentresources/pages/lhd.aspx

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Medical History: The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

Medical history factor	Notes and considerations
	REFERRAL CONDITIONS
1. Positive HIV test *Needs Referral:* □ *yes* □ no	• A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation. • Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management.
2. Presence of Hepatitis B infection *Needs Referral:* □ *yes* □ no	• Truvada and Descovy are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare. • People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist.
3. Presence of Hepatitis C exposure *Needs Referral:* □ *yes* □ no	• People with HepC exposure must be referred to primary care or other appropriate community health outreach organization (e.g. HIV Alliance, Cascade AIDS Project, Eastern Oregon Center for Independent Living). Pharmacist may proceed with prescribing PrEP.
4. Impaired kidney function (<30mL/min) *Needs Referral:* □ *yes* □ no	• Truvada is approved for patients with a CrCl >60mL/min. • Consider Descovy in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min. • Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease.
5. Other medications *Needs Referral:* □ *yes* □ no	• Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density. • For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Descovy over Truvada.
	CONSIDERATIONS
6. NSAID use Precaution- Counseled on limiting use: □ yes □ no	• Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage. • Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use.
7. Hepatitis B vaccinated If not, would the patient like to be vaccinated? □ yes □ no	• Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP. • Counsel on risk factors for Hepatitis B and recommend vaccination. • If patient would like to be vaccinated, proceed according to OAR 855-019-0280.
8. Pregnant or breastfeeding	• Pregnancy and breastfeeding are not contraindications for PrEP. • Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence. • Truvada is preferred due to better data in these populations.

4. Are One or More Referral Condition(s) Present? □ *yes* □ no

- *If yes, HIV PrEP is recommended but pharmacists are not authorized to prescribe in accordance with this RPH protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.*
- If no, HIV PrEP is recommended and pharmacists are authorized to prescribe and dispense PrEP in accordance with this RPH protocol. Proceed to next sections: Regimen Selection and Prescription.

Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

(CONFIDENTIAL- Protected Health Information)

Regimen Selection:

Considerations*	Preferred regimen
Cis-gender male or male to female transgender woman. • Both Truvada and Descovy are FDA approved in these populations. May prescribe based on patient preference.	May choose Truvada or Descovy
Cis-gender female or female to male transgender man. • Only Truvada is FDA approved in these populations. • If patient has low bone mineral density or renal function that would preclude Truvada use, but has risk factors for HIV, refer the patient to a specialist for PrEP management.	Truvada
NSAID use • If patient is male or a male to female transgender woman, consider Descovy	Descovy
Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist. • If patient is male or male to female transgender woman, consider Descovy	Descovy
Patient has decreased bone mineral density or on medications that affect bone mineral density. • If patient is male or male to female transgender woman, consider Descovy.	Descovy
Patient is pregnant or breastfeeding • Descovy has not been studied in these populations. Truvada is approved in these populations.	Truvada

*generic versions are acceptable in all cases if available.

PrEP Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Note: RPh may not prescribe and must refer patient if HIV test reactive or indeterminate

Rx

☐ **Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

-or-

☐ **Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets**

- Take one tablet by mouth daily for 90 days, #90, 0 refills

Written Date: _____

Expiration Date: (This prescription expires 90 days from the written date) _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

☐ Hepatitis B Vaccination administered:

Lot:_____ Expiration Date:_____ Dose: _____ of 2 or 3 (circle one)

Notes:_____

_____

_____

_____

Manufacturer Copay Card Information:

RXBIN:	RXPCN:	GROUP:
ISSUER:	ID:	

Provider Notification
Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name) (____) _____ -_____ (FAX)

Your patient _____ (name) _____/_____/_____ (DOB) has been prescribed HIV Pre-Exposure Prophylaxis (PrEP) by _____, RPH. This regimen was filled on _____/_____/_____ (Date) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

This regimen consists of the following (check one):

☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
- Take one tablet by mouth daily for 90 days

☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
- Take one tablet by mouth daily for 90 days

Your patient has been tested for and/or indicated the following:

Test Name	Date of Test	Result	Needs referral
• HIV ag/ab (4th gen):	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• Syphilis/Treponemal antibody:	____/____/_____	□ *reactive* □ *indeterminate* □ non-reactive	□ *Yes*
• Hepatitis B surface antigen:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
• Hepatitis C antibody:	____/____/_____	□ *reactive* □ non-reactive	□ *Yes*
• Gonorrhea/Chlamydia:	____/____/_____		□ *Yes*
Urinalysis result: □ *reactive* □ *indeterminate* □ non-reactive	Pharyngeal test result: □ *reactive* □ *indeterminate* □ non-reactive	Rectal test result: □ *reactive* □ *indeterminate* □ non-reactive	
• Renal function (CrCl):	____/____/_____	_____ mL/min	□ *Yes*
□ CrCl >60mL/min	□ CrCl 30mL/min - 60mL/min	□ *CrCl <30mL/min*	
• Signs/symptoms of STI not otherwise specified:	____/____/_____	□ *present*	□ *Yes*
• Condomless sex in past two weeks	____/____/_____	□ *yes*	□ *Yes*

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

Provider pearls for HIV PrEP:

- Truvada is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada and Descovy are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

Pharmacy monitoring of HIV PrEP:

- The pharmacy prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

Division 43
PRACTITIONER DISPENSING

855-043-0002
Definitions

In this division of rules:

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient by:

(a) A practitioner or the practitioner's authorized agent; or

(b) The patient at the direction of the practitioner.

(2) "Counseling" means an oral or other appropriate communication process between a practitioner and a patient or a patient's agent in which the practitioner obtains information from the patient or patient's agent, and, where appropriate, the patient's medical records, assesses that information and provides the patient or patient's agent with professional advice regarding the safe and effective use of the drug or device for the purpose of assuring therapeutic appropriateness.

(**3**) "Dispense" or "Dispensing" 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.

(4) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.

(**5**) "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or preventative measures such as immunization or birth control approved by the **b**oard or by the **Oregon Health Authority (OHA)**.

(**6**) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of Naturopathic Medicine and employed by or under contract with a county or district health department or **OHA**.

~~(**7**) "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center, treatment center, or other establishment from which a physician assistant dispenses drugs, but that is not otherwise registered with the Board in the category of Retail Drug Outlet.~~

NOTE: (7) will be repealed on 3/31/2022.

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

855-043-0003
Expedited Partner Therapy

(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.

(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.

(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

855-043-0004
Expedited Partner Therapy (EPT) - Procedures

(1) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule governs.

(2) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon Health Authority to be appropriately used for EPT.

Prescription
(3) An EPT treatment protocol must conform to the following:

(a) It must include a prescription for each named or unnamed partner of the patient;

(b) It must contain a hand written or electronic signature of the prescribing practitioner;

(c) The practitioner must identify the prescription in the following manner:

(A) Write "for EPT," or a similar notation, on the face of the prescription;

(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;

(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe – Partner 1" or by labeling the prescription as "EPT Partner"

(d) An EPT Prescription expires 30 days after the date written;

(e) An EPT Prescription may not be refilled;

(f) If any component of the prescription is missing, the DPDO must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.

(4) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may elect for a DPDO to dispense all prescriptions and then give the dispensed drugs to each unnamed partner.

Labeling
(5) The DPDO must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the DPDO may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.

(6) The DPDO must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

Counseling
(7) The DPDO is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the DPDO must:

(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The DPDO should advise the patient to encourage each partner to call the DPDO before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;

(b) Document counseling.

Records
(8) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the board upon request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

~~855-043-0005~~
~~Practitioner Labeling~~

~~All drugs dispensed by a practitioner must be labeled with the following information:~~

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

~~(2) Date;~~

~~(3) Name of the patient or the owner of the animal for which the drug is dispensed. If the prescription is for an animal, the species of the animal for which the drug is dispensed;~~

~~(4) Name of drug, strength, the quantity dispensed. When a generic name is used, the label must also contain the name of the manufacturer or distributor;~~

~~(5) Directions for use;~~

~~(6) Required precautionary information regarding controlled substances;~~

~~(7) Such other cautionary information as required for patient safety; and~~

~~(8) An expiration date after which the patient should not use the drug or medicine. The expiration date on a drug dispensed must be the same as that on the original container unless, in the practitioner's professional judgment, a shorter expiration date is warranted. A drug must not be dispensed after the expiration date of the drug.~~

~~(9) Not withstanding the labeling requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient or the patient's partner may be omitted from the label.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155 & ORS 689.505~~

~~855-043-0210~~
~~Oregon Nurse Practitioner Dispensing~~

~~The Oregon State Board of Nursing may grant to a certified nurse practitioner or Clinical Nurse Specialist the privilege of writing prescriptions described in the formulary under ORS 678.385. A certified nurse practitioner or Clinical Nurse Specialist may submit an application to the Oregon State Board of Nursing to dispense prescription drugs. An application for the authority to dispense prescription drugs as authorized by ORS 678.385 shall include evidence of completion of a prescription drug dispensing training program jointly developed and adopted by rule by the Oregon State Board of Nursing (851-050-0162) and the State Board of Pharmacy. The training program shall be as follows:~~

~~(1) Documented review of content regarding safe dispensing listed below:~~

~~(a) Board of Nursing handbook "Prescriptive Authority in Oregon for Nurse Practitioners and Clinical Nurse Specialists";~~

~~(b) The Drug Enforcement Administration Pharmacist's Manual (2004);~~

~~(c) OAR 851, division 56;~~

~~(d) ORS Chapter 689 and OAR chapter 855;~~

~~(e) US Consumer Product Safety Commission publication "Poison Prevention Packaging: A Text for Pharmacist's and Physicians;"~~

~~(f) The Institute for Safe Medication Practices (ISMP) "List of Error-Prone Abbreviations, Symbols, and Dose Designations" (Nov. 2006); and~~

~~(g) Information on available electronic or hard copy prescription drug references which provide information to professionals authorized to dispense prescription medications~~

~~(2) Successful self examination as provided by the Board of Nursing on these materials.~~

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

~~Statutory/Other Authority: ORS 678.390 & ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.205~~

NOTE: 855-043-0405 through 855-043-0455 will be repealed on 3/31/2022.

~~855-043-0405~~
~~Supervising Physician Dispensing Outlet - Purpose and Scope~~

~~A supervising physician or supervising physician organization that supervises a physician assistant with dispensing authority must register the dispensing site with the Board as a Supervising Physician Dispensing Outlet (SPDO) and must comply with the rules in OAR chapter 855, division 43.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0410~~
~~Supervising Physician Dispensing Outlet - Registration~~

~~(1) A Supervising Physician Dispensing Outlet must register with the Board as a SPDO in the category of Retail Drug Outlet on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.~~

~~(2) The initial application must state the location of the SPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant's affiliation with the owner.~~

~~(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.~~

~~(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.~~

~~(3) Upon request by the Board, the applicant must furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.~~

~~(4) An initial application must be accompanied by the fee established in division 110 of this chapter.~~

~~(5) A certificate of registration will be issued upon Board approval of the application.~~

~~(6) All registration renewal applications must be accompanied by the annual renewal fee established in Division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.~~

~~(7) The SPDO registration expires March 31, annually. If the annual renewal fee referred to in section (5) of this rule is not paid by February 28 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this chapter with the renewal application.~~

~~(8) The registration is not transferable and the registration fee cannot be prorated.~~

~~(9) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, consultant pharmacist or supervising physician.~~

~~(10) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in division 110 of this chapter within 15 days of the change.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0415~~
~~Supervising Physician Dispensing Outlet - Consulting Pharmacist~~

~~(1) A SPDO must retain a pharmacist licensed in Oregon for consultation purposes.~~

~~(2) The consulting pharmacist must conduct and document an annual inspection of the outlet on a form provided by the Board. The completed inspection report form must be filed in the outlet, retained on file for three years and be available to the Board for inspection.~~
~~(3) The duties of the consulting pharmacist shall be clearly defined in writing within the organization. The consulting pharmacist must:~~

~~(a) Develop policies and procedures for the outlet in collaboration with the supervising physician; and~~

~~(b) Work in consultation with the supervising physician in the development of the formulary of drugs and classes of drugs for the outlet.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0420~~
~~Supervising Physician Dispensing Outlet - Policies and Procedures~~

~~The registered SPDO must:~~

~~(1) Maintain written policies and procedures for drug management, including storage, security, integrity, access, dispensing, disposal, record keeping and accountability;~~

~~(2) Maintain all drug records required by federal and state law;~~

~~(3) Establish procedures for procurement of drugs; and~~

~~(4) Establish procedures to train physician assistants who dispense drugs and to ensure the continued competence of physician assistants who dispense drugs.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0425~~
~~Supervising Physician Dispensing Outlet - Security~~

~~(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.~~

~~(2) No drug dispensing machine may be placed in a waiting room or an area that is accessible by the public.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0430~~
~~Supervising Physician Dispensing Outlet - Storage of Drugs~~

~~All drugs, including drug samples, must be stored under conditions that ensure proper sanitation, temperature, light, ventilation, moisture control, and any other condition recommended by the manufacturer.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0435~~
~~Supervising Physician Dispensing Outlet - Labeling~~

~~(1) A prescription must be labeled with the following information:~~

~~(a) Unique identifier;~~
~~(b) Name of patient;~~

~~(c) Name of prescriber;~~

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

~~(e) Date of dispensing;~~

~~(f) 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;~~

~~(g) Quantity dispensed;~~

~~(h) Directions for use;~~

~~(i) Initials of the physician assistant or practitioner dispensing;~~

~~(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; and~~

~~(l) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall 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 855-041-4000 through 4005, the name of the patient may be omitted.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0436~~
~~Supervising Physician Dispensing Outlet - Limited English Proficiency and Accessibility~~

~~(1) Upon request of a patient or a patient's agent, each drug dispensed by a drug outlet for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.~~

~~(2) When dispensing a drug under (1), a drug outlet must provide labels and informational inserts in both English and one of the following languages:~~

~~(a) Spanish;~~

~~(b) Russian;~~

~~(c) Somali;~~

~~(d) Arabic;~~

~~(e) Chinese (simplified);~~

~~(f) Vietnamese;~~

~~(g) Farsi;~~

~~(h) Korean;~~

~~(i) Romanian;~~

~~(j) Swahili;~~

~~(k) Burmese;~~

~~(l) Nepali;~~

~~(m) Amharic; and~~

~~(n) Pashtu.~~

~~(3) The board must reassess and update (2) as necessary and at least every ten years.~~

~~Statutory/Other Authority: ORS 689.564~~
~~Statutes/Other Implemented: ORS 689.205~~

~~855-043-0440~~
~~Supervising Physician Dispensing Outlet - Dispensing and Drug Delivery~~

~~(1) Drugs dispensed from a SPO by a physician assistant with dispensing authority or a practitioner must be personally dispensed by the practitioner or physician assistant.~~

~~(2) Prior to dispensing a medication a drug utilization review must be performed by the physician assistant or practitioner which includes but is not limited to drug interactions, drug allergies and duplicate drug therapy.~~

~~(3) The physician assistant or practitioner must orally counsel the patient concerning all new drugs, unless circumstances would render oral counseling ineffective.~~

~~(4) When dispensed, a drug must be accompanied by written information that contains at least the following information:~~

~~(a) Drug name, class and indications;~~

~~(b) Proper use and storage;~~
~~(c) Common side effects;~~

~~(d) Precautions and contraindications; and~~

~~(e) Significant drug interactions.~~

~~(5) 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.~~

~~(6) Any other requirement of State or federal law.~~

~~(7) A SPDO must dispense a drug in a new container that complies with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.~~

~~(8) Drugs must be prepackaged by a pharmacy or manufacturer registered with the Board.~~

~~(9) A SPDO 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.~~

~~(10) 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.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0445~~
~~Supervising Physician Dispensing Outlet - Drug Dispensing Training Program~~

~~A physician assistant must complete a drug dispensing training program jointly developed by the Oregon Medical Board and the Board of Pharmacy before dispensing drugs to patients.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0450~~
~~Supervising Physician Dispensing Outlet - Disposal of Drugs~~

~~Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

~~855-043-0455~~
~~Supervising Physician Dispensing Outlet - Record Keeping~~

~~(1) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:~~

~~(a) Name of patient;~~

~~(b) Unique identifier;~~

~~(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;~~

~~(d) Directions for use;~~

~~(e) Date of dispensing; and~~

~~(f) Initials of person dispensing the prescription.~~

~~(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.~~

~~(3) Records documenting training required by OAR 855-043-0445 must be kept for three years.~~

~~(4) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 677.511~~

855-043-0505
Dispensing Practitioner Drug Outlets - Purpose

Unless subject to an exemption in OAR 855-043-0510(2), a practitioner that engages in dispensing human prescription drug therapies must register their dispensing site with the **b**oard as a Dispensing Practitioner Drug Outlet (DPDO).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.305

855-043-0510
Dispensing Practitioner Drug Outlets - Registration

(1) **Unless subject to an exemption in OAR 855-043-0510(2), a practitioner that engages in dispensing human prescription drug therapies** must register the dispensing site with the **b**oard as a DPDO on a form **prescribed** by the **b**oard, and must renew its registration annually on a renewal form **prescribed** by the **b**oard.

(2) A practitioner's facility is exempt from this registration requirement if the practitioner and facility only engages in:

(A) Dispensing FDA approved drug samples; or

(B) Dispensing Medication Assistance Program (MAP) drugs; or

(C) Dispensing homeopathic products; or

(D) Dispensing natural thyroid supplemental products; or

(E) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72 hour supply; or

(F) An amount greater than a 72 hour supply if the drug is:

(i) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-inhaler or bottle of fluoride rinse; or

(ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient's best interest, such as a course of antibiotic therapy.

(3) The initial **and renewal** application**s** must state the location of the DPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant's affiliation with the owner.

(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.

(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.

(4) Upon request by the **b**oard the applicant must furnish such information as required by the **b**oard regarding the partners, stockholders, or other persons not named in the application.

(5) An initial **and renewal** application**s** must be accompanied by the fee established **OAR 855-110**.

(6) A certificate of registration will be issued upon **b**oard approval of the application.

(**7**) The DPDO registration expires March 31, annually. If the annual renewal fee is not paid by **March 31** of the current year, the applicant for renewal must submit the **late renewal** fee established in **OAR 855-110** with the renewal application.

(**8**) The registration is not transferable and the registration fee cannot be prorated.

(**9**) The registrant must notify the **b**oard 15 days **prior to** any substantial change to the information provided on the registration application. Substantial change include**s** but **is** not limited to: change of ownership; change of business name; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, **or** officers.

(**10**) A new registration form is required for a change of ownership or location and must be submitted to the **b**oard with the fees as specified in **OAR 855-110** 15 days **prior to** the change.

(**11**) The **b**oard may grant a time-limited waiver exempting DPDO registration when a practitioner licensing board submits a request to the **b**oard with a plan to annually inspect the dispensing facility to the standards of the **b**oard.

(12) All Supervising Physician Dispensing Outlet registrations expire on March 31, 2022. Outlets that utilize dispensing Physician Assistants must apply for and be granted registration as a Dispensing Practitioner Drug Outlet upon the expiration of the Supervising Physician Dispensing Outlet Registration unless subject to an exemption in OAR 855-043-0510(2).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **ORS** 689.305, **ORS 475.125**

855-043-0530
Dispensing Practitioner Drug Outlets - Drug **Procurement**

The registered DPDO **may only receive** drugs from a**n Oregon Registered Drug Outlet (e.g. Wholesaler, Manufacturer or Pharmacy)**.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **ORS** 689.305

855-043-0540
Dispensing Practitioner Drug Outlet - Labeling

(1) 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

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 **b**oard.

(**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 (04/01/2021), 16 CFR 1701 (04/01/2021) and 16 CFR 1702 (04/01/2021)**.

(**5**) D**ispensed d**rugs must be packaged by the **DPDO**, a pharmacy, or a manufacturer registered with the **b**oard.

(**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) 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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **ORS** 689.305

855-043-0555
Dispensing Practitioner Drug Outlets - Record**s**

(1) A unique dispensing record **must** be maintained, be readily retrievable, and kept for a minimum of three years. The record must show, at a minimum, the following:

(a) Name of patient;

(b) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;

(c) Directions for use;

(d) Date of dispensing; and

(e) Initials of person dispensing the prescription.

(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

(3) All records and documents required by ORS 475, ORS 689, and OAR 855:

(a) Must be stored on-site for 12 months and must be provided to the board immediately upon request at the time of inspection;

(b) May be stored in a secured off-site location after 12 months of on-site storage and must be provided to the board upon request within three business days; and

(c) May be in written or electronic format.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **ORS** 689.305

855-043-0560
Dispensing Practitioner Drug Outlets - Inspections

(1) The DPDO must complete the **b**oard Self Inspection Form by February 1, annually.

(2) Each DPDO will be inspected **per OAR 855-001-0040** on a routine basis and **must** be scheduled in advance with the **DPDO**, to occur during normal business hours.

(3) The inspection **must** focus on the acquisition, storage, labeling and recordkeeping of drugs intended for dispensing and any violation will apply to the DPDO registration and not to the practitioner.

(4) The Board of Pharmacy **must** notify the practitioner's licensing **b**oard of any disciplinary action taken against a DPDO.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **ORS** 689.305

855-043-0705
Community Health Clinic (CHC) - Registration

(1) A Community Health Clinic Drug Outlet must register with the **b**oard on a form prescribed by the **b**oard, and must renew its registration annually on a renewal form prescribed by the **b**oard.

(2) An initial application and renewal application must be accompanied by the fee established in **OAR 855-110**.

(3) A certificate of registration will be issued upon **b**oard approval of the application.

(4) The CHC Drug Outlet registration expires March 31, annually. If the annual renewal fee is not paid by **March 31** of the current year, the applicant for renewal must submit the **late renewal** fee established in **OAR 855-110** with the renewal application.

(5) The registration is not transferable and the registration fee cannot be prorated.

(6) The registrant must notify the **b**oard, within 15 days, of any substantial change to the information provided on the registration application. A substantial change shall include but not be limited to: a change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or Medical Director.

(7) A new registration form is required for a change of ownership or location and must be submitted to the **b**oard with the fees as specified in **OAR 855-110** within 15 days of the change.

(8) A CHC Drug Outlet may be inspected by the **b**oard.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

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 (04/01/2021), 16 CFR 1701 (04/01/2021) and 16 CFR 1702 (04/01/2021)**.

(7) D**ispensed d**rugs must be packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the **b**oard.

(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) 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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

Division 60
PHARMACEUTICAL MANUFACTURERS

855-060-0001
Application

No place of manufacturing, wholesaling or repackaging of drugs or medicines, as defined in ORS 689.005(20), (35), and (36) ~~shall~~ **may** be conducted or operated until it has been registered by the State Board of Pharmacy~~., except that compounding or repackaging, as a part of a Shared Pharmacy Services agreement as defined in OAR 855-006- 0005(20), does not constitute manufacturing. Manufacturing registration expires September 30th annually~~:

(1) All applications for registration of a new or relocated manufacturer shall be accompanied by the required fees as set forth in **OAR** 855-110~~-0007(3)~~.

(2) Application ~~shall~~ **must** specify the location of the manufacturer premises. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant's affiliation with the owner;

(a) If the owner is a partnership or other multiple owner, the names of the partners or person holding the five largest interests shall be indicated on the application.

(b) If the owner is a corporation, the name filed ~~shall~~ **must** be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.

(c) Upon request by the **b**oard, the applicant ~~shall~~ **must** furnish such information as required by the **b**oard regarding the partners, stockholders, or other persons not named in the application.

(3) All registration renewal applications ~~shall~~ **must** be accompanied by the annual fee and contain the same information required in subsection (2)(a), (b), and (c) of this rule.

(4) A change of ownership or location requires a new application, fee, and registration within 15 days.

(5) The registration certificate is issued to a person or firm and is non-transferable. Additions or deletions of a partner/partners ~~shall~~ **must** be considered as a change of ownership.

(6) **Manufacturer registration expires September 30th annually.** The registration cannot be prorated.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, **ORS** 689.305, **ORS** 689.315 & **ORS** 689.325

Division 110
FEES

855-110-0003
General

(1) All fees paid under these rules are non-refundable.

(2) Fees cannot be prorated.

(3) Fees for initial licensure as a Pharmacist or Certified Oregon Pharmacy Technician may be reduced to one-half of a biennial rate, if the application is received ~~or the mailing date of the application is postmarked~~ within 180 days of expiration.

(4) A ~~delinquent~~ **late** fee must be paid

~~(a) When an~~ when a renewal application is ~~postmark~~ received after the date specified in these rules; ~~or~~

~~(b) When the Board requests additional information from an applicant and this information is not provided within 30 days.~~

~~(5) A delinquent fee may be assessed when an application is submitted incomplete and the Board requests the missing information.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135

855-110-0005
Licensing Fees

(1) Pharmacist license examination (NAPLEX) ~~and re-examination~~ fee - $50.

(2) Pharmacist jurisprudence (MPJE) re-examination fee - $25.

(3) Pharmacist licensing by reciprocity fee - $~~25~~**100**.

(4) Pharmacist licensing by score transfer fee - $~~2~~50.

(5) Intern license fee. Expires November 30 every two years - $100.

(6) Pharmacist:

(a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is - $250. Late renewal fee (received after June 30) - $50.

(b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially - $5~~7~~0. (This is a mandatory fee, required by ORS 431~~.972~~**A.880** that must be paid with the pharmacist license renewal fee).

(c) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.)

(7) Certification of approved provider of continuing education course fee, none at this time.

(8) Pharmacy Technician license fee - $100.

(9) Certified Oregon Pharmacy Technician:

(a) Biennial license fee. Expires June 30 each even numbered year - $100. Late renewal fee (received after June 30) - $20.

(b) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy Technician license renewal fee.)

Statutory/Other Authority: ORS 689.205, ORS 291.055 & ORS 183.705
Statutes/Other Implemented: ORS 689.135, ORS 676.410 & ORS 431A.880

855-110-0007
Fees for Registration, Renewal, and Reinspection of Drug Outlets

(1) Community Health Clinic. Expires March 31 annually - $100. Late renewal fee (received after March 31) - $25.

(2) Drug Distribution Agent. Expires September 30 annually - $400. Late renewal fee (received after September 30) - $100.

(3) Drug Room (including **C**orrectional **F**acility). Expires March 31 annually - $100. Late renewal fee (received after March 31) - $75.

(4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually - $525. Late renewal fee (received after September 30) - $100.

(5) Medical Device, Equipment & Gas Class C. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.

(6) Nonprescription Class A. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.

(7) Nonprescription Class B. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.

(8) Nonprescription Class D. Expires January 31 annually - $100. Late renewal fee (received after January 31) - $25.

(9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - $50. Expires December 31 annually.

(10) Re-inspection fee - $100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.

(11) Retail, Institutional, or Consulting/"Drugless". Expires March 31 annually - $225. Late renewal fee (received after March 31) - $75.

(12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually - $525. Late renewal fee (received after September 30) - $100.

(13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually - $120. Due by March 31 annually.

(14) Charitable Pharmacy. Expires March 31 annually - $75. Late renewal fee (received after March 31) - $25.

(15) Home Dialysis. Expires March 31 annually - $225. Late renewal fee (received after March 31) - $75.

~~(16) Supervising Physician Dispensing Outlet. Expires March 31 annually - $175. Late renewal fee (received after March 31) - $75.~~

NOTE: (16) will be repealed on 3/31/2022.

(**16**) Dispensing Practitioner Drug Outlet. Expires March 31 annually - $100. Late renewal fee (received after March 31) — $25.

Statutory/Other Authority: ORS 689.205 & ORS 291.055
Statutes/Other Implemented: ORS 689.135, ORS 689.774 & ORS 689.305

855-110-0010
Fees for Registration for Controlled Substances ~~under ORS 475.095~~

(1) Animal Euthanasia controlled substance registration fee — $75 annually.

(2) Drug Distribution Agent controlled substance registration fee — $100 annually.

(3) Drug Room (including **C**orrectional **F**acility) controlled substance registration fee — $100 annually.

(4) Manufacturer controlled substance registration fee — $100 annually.

(5) Retail or Institutional Drug Outlet controlled substance registration fee — $100 annually.

(6) Schedule II Precursor registration fee — $75 annually.

(7) Wholesaler controlled substance registration fee — $100 annually.

(8) Remote Distribution Facility controlled substance registration fee — $100 annually.

Statutory/Other Authority: ORS 689.205**,** ~~&~~ ORS 291.055, **ORS 475.095**
Statutes/Other Implemented: ORS 689.135

Board: Please note that this rule was filed with the Secretary of State with an error that was not consistent with the Board vote in October. Below you will see a blue highlight on two subsections that were inadvertently and wrongly filed with the Secretary of State's office and a comment with an explanation of what occurred and what staff is proposing as a solution.

855-006-0005
Definitions

As used in OAR Chapter 855

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).

(2) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(~~2~~3) "Certified Oregon 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 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 pharmacy technicians.

(~~3~~4) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.

(~~4~~5) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to 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 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.

(~~5~~6) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(a) 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 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.

(~~6~~7) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(~~7~~8) "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.

(~~8~~9) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(~~9~~10) "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.

(~~10~~11) "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.

(~~11~~12) "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.

(~~12~~13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).

(14) "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~~ must not be construed to prohibit monitoring by practitioners or their agents.

(~~13~~15) "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.

(~~14~~16) "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.

(~~15~~17) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not
restricted to use by practitioners only.

(~~16~~18) "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.

(~~17~~19) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary<NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States <HPUS> (v.2021), or any supplement to any of these.

(20) "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.

(~~18~~21) 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.

(~~19~~22) "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.

(~~20~~23) "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.

(~~21~~24) "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.

(~~22~~25) "Practice of pharmacy" is as defined in ORS 689.005.

Board: You did not vote at the October meeting to propose to repeal this definition of "prescription drug." Staff inadvertently filed this proposed repeal of the definition of "prescription drug" with the Oregon Secretary of State with the rulemaking notice. Staff has drafted a motion for your consideration in which you vote NOT to permanently repeal this subsection

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~~(23) "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.~~

(~~24~~26) "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.

(~~25~~27) "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.

(~~26~~28) "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.

(~~27~~29) "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.

(~~28~~30) "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.

(~~29~~31) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as 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 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 or pharmacy technicians;

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

(C) A trade association recognized by the board as representing pharmacies.

Board: You did not vote at the October meeting to propose to repeal this definition of "supervision by a pharmacist." Staff inadvertently filed this proposed repeal with the Secretary of State's office. Staff has: (a) drafted a motion for your consideration in which you do NOT repeal this subsection and (b) Staff has proposed that you file, as a temporary rule, the language that you did vote at the October board meeting to amend this subsection and will present that language at this meeting for consideration.

~~(30) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the~~

~~following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.~~

(~~31~~32) "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.

(~~32~~33) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.

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

POLICY DISCUSSION: Technical filing error

Board: In order to address the inadvertent filing error, and presuming the Board wishes to adopt all of the other proposed changes filed with the Oregon Secretary of State, the Board will need to affirmatively vote no on the proposed repeals of "prescription drug" and "supervision of a pharmacist" and vote yes on all of the other proposed changes to the rule below. The language below is what would be adopted if the Board so chooses to vote in this manner.

Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).

(~~1~~**2**) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(~~2~~**3**) "Certified Oregon 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 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 pharmacy technicians.

(~~3~~**4**) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.

(~~4~~**5**) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to 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 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.

(~~5~~**6**) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(a) 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 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.

(~~6~~7) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(~~7~~**8**) "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.

(~~8~~**9**) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(~~9~~**10**) "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.

(~~10~~**11**) "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.

(~~11~~**12**) "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.

(13) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).

(~~12~~**14**) "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.

(~~13~~**15**) "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.

(~~14~~**16**) "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.

(~~15~~**17**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(~~16~~**18**) "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.

(19) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States <HPUS> (v.2021), or any supplement to any of these.

(~~17~~**20**) "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.

(~~18~~**21**) 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.

(~~19~~**22**) "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.

(~~20~~**23**) "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.

(~~21~~**24**) “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.

(~~22~~**25**) “Practice of pharmacy” is as defined in ORS 689.005.

(~~23~~**26**) "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.

POLICY DISCUSSION: Technical filing error

(~~24~~**27**) "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.

(~~25~~**28**) “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.

(~~26~~**29**) "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.

(~~27~~**30**) “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.

(~~28~~**31**) "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.

(~~29~~**32**) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as 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 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 or pharmacy technicians;

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

(C) A trade association recognized by the board as representing pharmacies.

(~~30~~**33**) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action.

During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.

POLICY DISCUSSION: Technical filing error. Proposed temporary rule in December 2021 Board Meeting agenda to align with Board motion from October 2021 Board Meeting.

(~~31~~**34**) "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.

(~~32~~**35**) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.

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

855-041-1060
Non-Resident Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy **is any establishment located out of Oregon that engages in the dispensing, delivery or distribution of drugs 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 pharmacy that provides drugs, devices or services to a resident in this state **must** be registered with the Oregon Board of Pharmacy.

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

(4) Every out-of-state non-resident pharmacy **must** designate an Oregon licensed Pharmacist-in-Charge (PIC), who **must** be responsible for all pharmacy services provided to residents in Oregon, and to provide supervision and control in the pharmacy. To qualify for this designation, the person must:

(a) Hold a license to practice pharmacy in the resident state;

(b) Be normally present in the pharmacy for a minimum of 20 hours per week;

(c) Complete the annual non-resident PIC self-inspection report prior to February 1 each year; and

(d) Provide the PIC self-inspection report as requested by the **b**oard.

(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) A new Pharmacist-in-Charge must be appointed, and communication made to the **b**oard within 90 days, or the non-resident pharmacy will cease drug distribution and provision of pharmacy services in Oregon.

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

855-041-3200
Telework: Purpose and Scope

The purpose of OAR 855-041-3200 through OAR 855-041-3250 is to provide minimum requirements for pharmacy services conducted via telework.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3205
Telework: Definitions

(1) "Telework" means the practice or assistance in the practice of pharmacy physically outside of a registered drug outlet in a telework site.

(2) "Telework Site" means a location that is not a registered drug outlet where an Oregon licensed Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist in the practice of pharmacy as employees of an Oregon registered drug outlet.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3210
Telework: Registration

The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of the Drug Outlet Pharmacy are responsible for all licensees engaging in the practice of pharmacy or assisting in the practice of pharmacy from Telework Sites.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3215
Telework: General Requirements

(1) Each Oregon registered Drug Outlet Pharmacy and Pharmacist-in-charge of a Drug Outlet Pharmacy must ensure that Interns and Certified Oregon Pharmacy Technicians working from a Telework Site work under the supervision, direction and control of an Oregon licensed Pharmacist.

(2) A Pharmacist that engages in the practice of pharmacy and an Intern or Certified Oregon Pharmacy Technician that assists in the practice of pharmacy from a Telework Site for any person or facility located in Oregon must:

(a) Be licensed by the board; and

(b) Comply with all applicable federal and state laws and rules.

(3) Drugs and devices may not be at a Telework Site.

(4) The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of a Drug Outlet Pharmacy must:

(a) Have a written agreement that includes all conditions, duties and policies governing the licensee engaged in telework activities;

(b) Maintain a continuously updated list of all licensees engaged in telework and the Telework Sites to include:

(A) Address, phone number and hours that telework is performed for each Telework Site;

(B) Functions being performed by licensees engaged in telework; and

(C) The Oregon licensed Pharmacist providing supervision, direction and control for each non-pharmacist licensee;

(c) Develop, implement and enforce a continuous quality improvement program for services provided from a Telework Site 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;

(d) Develop, implement and enforce a procedure for identifying the Oregon licensed Pharmacist, Intern and Certified Oregon Pharmacy Technician responsible for each telework function;

(e) Develop, implement and enforce a process for a virtual inspection of the Telework Site by an Oregon licensed Pharmacist at least once every 6 months or more frequently as deemed necessary by the Oregon licensed Pharmacist. The inspection must be documented and records retained; and

(f) Utilize an Oregon licensed Pharmacist and real-time audio communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 or when requested and document the interaction.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3220

Telework: Supervision Requirements

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the supervising Oregon licensed Pharmacist from the Drug Outlet must:

(1) Utilize technology that enables real-time audio and visual connection and have appropriate technology or interface to allow access to information required to complete assigned duties;

(2) Ensure all telephone audio is recorded, reviewed and stored;

(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon Pharmacy Technician and that the continuous audio/visual connection is fully operational;

(4) Ensure that an Oregon licensed Pharmacist using professional judgment, determines the frequency of "check-ins" for each licensee being supervised via the real-time audio and visual connection with a minimum of at least once per work shift to ensure patient safety, compliance with federal and state laws, and documents the interaction;

(5) Be readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and

(6) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction and control at all times.

(7) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy Technician at a Telework Site must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 25% of patient interactions reviewed;

(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;

(c) Document the following within 24 hours of the review in (b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions pharmacist is reviewing;

(C) Date and time of licensee patient interaction pharmacist is reviewing;

(D) Date and time of pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of discovery and to the board within 10 days.

(8) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (7)(a), employ adequate staff to allow for completion of the review within 24 hours, and retain records.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3225
Telework: Confidentiality

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet Pharmacy, and the Pharmacist, Intern and Certified Oregon Pharmacy Technician from the Drug Outlet Pharmacy must:

(1) Ensure patient and prescription information is managed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, and OAR 855-041.

(2) Ensure the security and confidentiality of patient information and pharmacy records.

(3) Document and report any confirmed breach in the security of the system or confidentiality. Report of the breach must be reported in writing to the board within ten days of discovery of the event.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3230
Telework: Technology

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the Pharmacist from the Drug Outlet must:

(1) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each:

(a) Source container including manufacturer, name, strength, lot, and expiration;

(b) Dispensed product including the imprint and physical characteristics;

(c) Completed prescription container including the label; and

(d) Ancillary document provided to patient at the time of dispensing.

(2) Test the continuous audio and visual connection and document that it operates properly before engaging in telework.

(3) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising, directing and controlling the Intern and Certified Oregon Pharmacy Technician at the Telework Site.

(4) Ensure access to:

(a) Appropriate and current pharmaceutical references based on the services offered; and

(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.

(5) Train the Oregon licensed Pharmacists, Interns and Certified Oregon Pharmacy Technicians in the operation of continuous audio and visual connection.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3235
Telework: Personnel

(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all operations at Drug Outlet Pharmacy including responsibility for the continuous audio and visual connection and enforcing policies and procedures.

(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel at Telework Sites.

(3) An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have at least one year experience performing similar services for an Oregon registered Drug Outlet Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy Technician begins teleworking.

(4) The Oregon licensed Pharmacist from the Drug Outlet Pharmacy who is supervising a licensee at a Telework Site must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided.

(5) When supervising an Intern or Certified Oregon Pharmacy Technician working at a Telework Site, the Oregon licensed Pharmacist may supervise no more than four licensees among all locations, including the Drug Outlet Pharmacy.

(6) The Drug Outlet Pharmacy is required to comply with the pharmacist's determination in (4) and retain records.

(7) Prior to working at a Telework Site, the Intern or Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on the use of all equipment necessary for secure operation of the Telework Site.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3240
Telework: Environment and Security

(1) Telework Sites must be:

(a) Located in a designated area where:

(A) All equipment is stored;

(B) All work is performed; and

(C) Confidentiality is maintained such that patient information cannot be viewed or overheard by anyone other than the Pharmacist, Intern or Certified Oregon Pharmacy Technician.

(2) The Pharmacist-in-charge of the Drug Outlet Pharmacy and each Oregon licensed Pharmacist supervising a Telework Site is responsible for ensuring the Telework Site has a designated work area that is secure and has been approved and documented by an Oregon licensed Pharmacist prior to utilization.

(3) All computer equipment used at the Telework Site must:

(a) Establish and maintain a secure connection to the pharmacy and patient information;

(b) Utilize equipment that prevents unauthorized access to the pharmacy and patient information; and

(c) Be configured so that the pharmacy and patient information is not accessible when:

(A) There is no Oregon licensed Pharmacist actively supervising the Intern or Certified Oregon Pharmacy Technician who is assisting in the practice of pharmacy from a Telework Site; or

(B) There is no Pharmacist, Intern or Certified Oregon Pharmacy Technician present at the Telework Site; or

(C) Any component of the real-time audio and visual connection is not functioning; and

(d) Comply with all security and confidentiality requirements.

(4) A record must be maintained with the date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site.

(5) Interns and Certified Oregon Pharmacy Technicians may only work from a Telework Site when authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the Telework Site.

(6) All records must be stored in a secure manner that prevents access by unauthorized persons.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3245
Telework: Policies and Procedures

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the Drug Outlet Pharmacy and the Oregon licensed Pharmacist-in-charge is accountable for establishing, maintaining, and enforcing written policies and procedures for the licensees working from a Telework Site. 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 services, responsibilities and accountabilities of the licensee engaging in telework including;

(a) Security;

(b) Operation, testing and maintenance of the audio and visual connection;

(c) Detailed description of work performed;

(d) Oregon licensed Pharmacist supervision, direction and control of Interns and Certified Oregon Pharmacy Technicians;

(e) Recordkeeping;

(f) Patient confidentiality;

(g) Continuous quality improvement;

(h) Plan for discontinuing and recovering services if audio and visual connection disruption occurs;

(i) Confirmation of dedicated, secure Telework Sites;

(j) Documenting the identity, function, location, date and time of the licensees engaging in telework;

(k) Written agreement with licensees engaging in telework outlining specific functions performed, conditions and policies governing the operation of the Telework Site; and

(l) Equipment.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3250
Telework: Records

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the recordkeeping requirements OAR 855-041-3205 through OAR 855-041-3250 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules must be retained for three years and made available to the board for inspection upon request. Records created at Telework Sites must be stored at the Drug Outlet for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) Records must be stored at the Telework site in a manner that prevents unauthorized access.

(3) Records must include, but are not limited to:

(a) Patient profiles and records;

(b) Patient contact and services provided;

(c) Date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site;

(d) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(e) List of employees working from Telework Sites that includes:

(A) Name;

(B) License number;

(C) Verification of each license;

(D) Address of Telework Site; and

(E) Name of the Oregon licensed Pharmacist who verified each licensure, approved licensee to telework and approved each Telework Site;

(f) Audio and visual connection testing and training;

(g) Data, telephone audio, audio and video, still image capture, store and forward images, security and surveillance data. This must be retained according to (1); and

(h) Any errors or irregularities identified by the quality improvement program.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

~~855-041-3000~~
~~Central Fill and Remote Processing Outlet Designations and Consulting/Drugless Pharmacy Outlets - Purpose and Scope~~

~~(1) The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of operation for centralized prescription drug filling by a pharmacy.~~

~~(2) The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription processing by a pharmacy.~~

~~(3) Prior to initiating one of the above drug outlet models, a description of how the model will be utilized must be submitted to the Board.~~

~~(4) The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a consulting or drugless pharmacy. Prior to initiating this model, a description of how the model will be utilized to improve patient safety must be submitted to the Board.~~

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

~~855-041-3100~~
~~Remote Processing - Purpose and Scope~~

~~The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription drug processing by a pharmacy. Any facility that processes drug orders on behalf of an Oregon pharmacy shall be licensed in Oregon as a retail or institutional drug outlet. An applicant must submit its policies and procedures to the Board of Pharmacy. An applicant must submit to the Board for approval policies and procedures and a description of how using remote processing will improve patient safety.~~

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

~~855-041-3105~~
~~Remote Processing - Definitions~~

~~The following words and terms, when used in OAR 855-041-3100 through 855-041-3130, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in OAR chapter 855, division 006.~~

~~(1) "Remote Processing Pharmacy" means an Oregon licensed pharmacy operated under the direction of a pharmacist-in-charge that processes information related to the practice of pharmacy and engages in remote prescription processing, including central processing.~~

~~(2) "Remote Processing Functions" may include, but are not limited to, data entry, prospective drug utilization reviews, refill authorizations and interventions. This does not include the filling process.~~

(3) "Primary Pharmacy" means an instate Oregon licensed pharmacy that receives a patient's or a prescribing practitioner's request to fill a prescription or drug order and delivers the drug or device directly to the patient or patient's agent, and maintains ownership of the prescription or drug order.

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

855-041-3110
Remote Processing - General Requirements

An Oregon licensed pharmacy may outsource prescription drug processing to a remote processing pharmacy provided both pharmacies:

(1) Have the same owner; or

(2) Have a written shared pharmacy services contract or agreement that specifies:

(a) The services to be provided by each pharmacy;

(b) The responsibilities of each pharmacy; and

(c) The accountabilities of each pharmacy.

(3) Maintain a separate Oregon pharmacy license for each location involved in providing services;

(4) Share a common electronic file or have appropriate technology or interface to allow access to information required to process and fill a prescription drug order;

(5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3115;

(6) Ensure that each prescription has been properly processed, filled and counseling has been provided to the patient;

(7) Designate a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the pharmacy's resident state if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;

(8) Allow prospective drug utilization reviews, refill authorizations, interventions, and patient counseling for an Oregon patient must be performed only by a licensed pharmacist in Oregon or in the state in which the pharmacy is located;

(9) Ensure that each technician processing an order for an Oregon patient is a Certified Oregon Pharmacy Technician and is supervised by a licensed pharmacist or is a licensed technician in the state in which the pharmacy is located and is supervised by a licensed pharmacist in the state in which the pharmacy is located;

(10) Comply with all applicable federal and state laws and rules;

~~(11) Conduct an annual review of the written policies and procedures and document such review.~~

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

~~855-041-3115~~
~~Remote Processing - Policies and Procedures~~

~~(1) In addition to the requirements of OAR 855-041-1040, the primary and the remote processing pharmacy is each accountable for establishing, maintaining, and enforcing its own written policies and procedures manual. The policies and procedures manual must include, but need not be limited to the following:~~

~~(a) The responsibilities of each pharmacy;~~

~~(b) The policies and procedures that protect confidentiality and ensure the integrity of patient information;~~

~~(c) Compliance with all applicable federal and state laws and rules;~~

~~(d) Records sufficient to identify by name, initials, or unique identification code, the identity and the specific activities of each pharmacist or technician who performed any processing function, and the location where each activity was performed;~~

~~(e) A continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to pursue opportunities to improve patient care, and to resolve identified problems; and~~

~~(f) Documentation of any errors or irregularities identified by the quality improvement program.~~

~~(2) The written policies and procedures manual shall be maintained at all pharmacies involved in remote processing and must be available to the Board upon request.~~

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

~~855-041-3120~~
~~Remote Processing - Records~~

~~(1) The recordkeeping requirements OAR 855-041-3100 through 855-041-3130 are in addition to the requirements of other recordkeeping rules of the Board.~~

~~(2) The remote processing pharmacy must maintain all required records unless these records are maintained in the primary pharmacy.~~

~~(3) Both recordkeeping systems must:~~

~~(a) List the name, address, telephone number, and all license and registration numbers of each pharmacy involved in remote prescription processing;~~

~~(A) Document verification of each license and registration;~~

~~(B) Document the name of the individual responsible for verification of licensure and registration status.~~

~~(b) Identify by name, initials, or unique identification code the identity and the specific activities of each pharmacist or technician who performed any part of the prescription process;~~

~~(c) Include quality improvement program documentation;~~

~~(d) Be able to produce an audit trail showing each prescription process.~~

~~(4) Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two;~~

~~(5) The primary pharmacy shall maintain records that:~~

~~(a) Indicate the date the request for processing was transmitted to the remote processing pharmacy; and~~

~~(b) Indicate the date the prescription information was received by the primary pharmacy.~~

~~(6) The remote processing pharmacy shall maintain records that:~~

~~(a) Track the prescription drug order during each step in the order entry process;~~

~~(b) Identify the name, initials, or unique identification code and the specific activity of each pharmacist or pharmacy technician who performed any activity related to processing the prescription including receipt, transmission or delivery of information.~~

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

~~855-041-3125~~
~~Remote Processing - Prescription or Drug Order Processing~~

~~A prescription or drug order for a controlled substance may be processed by a remote processing pharmacy when permitted by law and consistent with federal rules.~~

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

~~855-041-3130~~

~~Remote Processing - Prohibited Practices~~

~~A remote processing pharmacy may not process a prescription on behalf of a primary pharmacy that is not registered with the Board, if required by the laws and rules of Oregon to be registered.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

~~855-041-5100~~
~~Definitions - Technician Checking Validation Program (TCVP)~~

~~(1) "Error" in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item counts as one error.~~

~~(2) "Error" in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date. All errors in any single dose count as one error.~~

~~(3) "Line Item" is a checking unit for ADC restocking (example: one specific drug and dose, regardless of quantity).~~

~~(4) "Technician Checker" is an Oregon certified technician who has completed the TCVP validation process and is currently authorized to check another technician's work.~~

~~(5) "Technician Checking Validation Program (TCVP)" is a program that uses a technician checker to check functions completed by another technician.~~

~~(6) "Unit Dose" is the physical quantity of a drug product designed to be administered to a patient specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged, oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed IV products.~~

~~NOTE: Technician Checking Validation Program (TCVP) The TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and SEP appropriateness of the medications ordered and on educating staff and patients. The development of individualized training programs is the responsibility of each pharmacy in order to tailor the program to the patient population and medication distribution system of the institution. Assessment questions must be tailored to the site and be changed periodically as appropriate. It is the responsibility of the pharmacist-in-charge to ensure that all training is completed and documented prior to a technician SEP performing as a technician checker.~~

~~855-041-5120~~
~~Technician Checking Validation Program (TCVP) - Hospital and Pharmacist in Charge Requirements~~

~~(1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital pharmacy must meet the following requirements:~~

~~(a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be available in the pharmacy for board inspectors.~~

~~(b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can be implemented;~~

(c) The hospital pharmacy must have a drug distribution system that is structured to allow for one additional check of the distributed medications by a licensed nurse or other licensed health care professional with authority to administer medications after the delivery of checked medications; and

(d) The Pharmacist-in-Charge is responsible for the TCVP and will document any error, or irregularity in the quality assurance documentation records.

(2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of Pharmacy. To apply for approval, the hospital must submit the following to the Board:

(a) Copies of written training material that will be used to train technicians as technician checkers;
(b) Copies of quality assurance documentation records and forms that will be used to evaluate the technician checkers and the proposed TCVP;

(c) Copies of the policy and procedures for the proposed TCVP; and

(d) A description of how the proposed TVCP will improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.
(e) Other items as requested by the Board.

855-041-5130
Technician Checking Validation Program (TCVP) - Technician Eligibility and Training

(1) Only Oregon certified technicians who undergo specific training may work as technician checkers. The training must include the following:

(a) A minimum of one year of drug distribution experience;

(b) Didactic lecture or equivalent training with a self-learning packet;

(c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a pharmacist; and

(d) Initial Validation Process as described in OAR 855-041-5140(1).

(2) The practical training sessions must include:

(a) The trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning;

(b) The trainee performing the initial check with a pharmacist verifying all doses;

(c) The trainee completing the validation process with a pharmacist verifying all doses;

(d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors. Artificial errors introduced into the live environment, which are not corrected by the technician, must be removed.

~~(e) The pharmacist must document and notify a technician checker of any errors found during training.~~

~~(3) If at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.~~

~~855-041-5140~~
~~Technician Checking Validation Program (TCVP) - Initial Validation Process and Quality Assurance Process~~

~~(1) Initial Validation Process: The initial process to validate a trainee's ability to accurately check another technician's work must include:~~

~~(a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who makes more than three errors in 1500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.~~

~~(A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.~~

~~(B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.~~

~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.~~

~~(b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.~~

~~(A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.~~

~~(B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.~~

~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.~~

~~(2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of technician checkers must include:~~

(a) Quality checks conducted in the same manner as the applicable initial validation process described in section one of this rule, except that the quality check sample must consist of at least 300 doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.

(b) The quality checks must occur on random and unannounced dates and times.

(c) A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.

(d) The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.

(3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.

(4) A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.

(5) A description of the quality assurance process must be included in the hospital's and the pharmacy's quality assurance program and error reporting system.

855-041-5150
Technician Checking Validation Program (TCVP) - Checking Procedure

(1) A technician checker must use the following procedure when checking another technician's work:

(a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits.

(b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.

(c) If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction. A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker

(d) If a technician checker is not available, then all doses must be checked by a pharmacist.

(2) This checking process continues until all doses have been checked and determined to be correct.

~~855-041-5160~~

~~Technician Checking Validation Program (TCVP) – Eligible Specialized Functions~~

~~(1) The following specialized functions are eligible for participation in the TCVP:~~

~~(a) Cart fill;~~

~~(b) ADC batch replacement; and~~

~~(c) Non-Emergent kits and trays.~~

~~(2) Upon written request, the Board may permit additional specialized functions if to do so will further public health or safety. A waiver granted under this section shall be effective only when issued in writing and approved by the Board.~~

~~855-041-5170~~

~~Technician Checking Validation Program (TCVP) – Records~~

~~(1) Unless specified otherwise, all records and documentation required by these rules must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.~~

~~(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:~~

~~(a) Technician checker training documents;~~

~~(b) List of high risk medications;~~

~~(c) Documentation of any errors, irregularities and results of each initial validation check.~~

~~(d) Documentation of quality assurance and forms used to evaluate the technician checker including:~~

~~(A) Total number of doses or line item checks;~~

~~(B) Description of errors;~~

~~(C) Total number of errors; and~~

~~(D) Percent error rate.~~

~~(e) Documentation of the initial validation check.~~

Division 006– Definitions (Supervision by a Pharmacist)

Filing Caption (15 word limit)**:** Amends definition "supervision by a pharmacist."

Need for Rules:

At the October board meeting, the Board voted to propose rules that allow for telework with supervision by a Pharmacist when Interns and Certified Oregon Pharmacy Technicians are not stationed within the same work area as the Pharmacist. There was an inadvertent filing error with the Secretary of State's office regarding the Board's vote on proposed changes to the definition of the "supervision by a pharmacist." This temporary filing is proposed to solve the inadvertent filing error and amend the definition for "supervision by a pharmacist" to eliminate conflict with the newly adopted rules and be consistent with the Board's proposed amendments at the October meeting.

Justification of Temporary Filing:

Licensees are currently permitted to work remotely at a secured off-site, non-pharmacy location, during the COVID-19 public health emergency for the functions of prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders. Enforcing these rules is necessary to assure compliance and reduce transmission of COVID-19. The Board of Pharmacy may utilize this rule to enforce licensee and registrant compliance.

When the public health emergency ends, newly adopted telework rules in OAR 855-041-3200 through 855-041-3250 must be utilized by pharmacies to permit licensees the option to work remotely. The COVID-19 pandemic has highlighted ongoing workforce shortages and conditions. Failure to implement this temporary rule may result in Oregonians being unable to access their medications in a timely manner and continued workforce issues. Inability to access prescription medications in a timely manner is a danger to the public health and safety.

Fiscal Impact:

None anticipated.

Documents relied upon include:

None.

Rules Summary:

Procedural rule review and revisions to ensure clarity, transparency and promote patient safety. Rules permit Pharmacists, Interns and Certified Oregon Pharmacy Technicians who are not stationed within the same work area as the Pharmacist to work remotely at a secured off-site, non-pharmacy location.

Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

(1) “Adulterated” has the same meaning as set forth in 21 USC 351 (v. 12/01/2021).

(2) “Board” means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(3) "Certified Oregon 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 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 pharmacy technicians.

(4) “Clinical Pharmacy Agreement” means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.

(5) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to 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 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.

(6) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(a) 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 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.

(7) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(8) "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.

(9) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(10) "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.

(11) "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.

(12) "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.

(13) “Misbranded” has the same definition as set forth in 21 USC 352 (v. 12/01/2021).

(14) "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.

(15) "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.

(16) "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.

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

(18) "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.

(19) “Official compendium” means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States <HPUS> (v.2021), or any supplement to any of these.

(20) "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.

(21) 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.

(22) "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.

(23) "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.

(24) “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.

(25) “Practice of pharmacy” is as defined in ORS 689.005.

(26) "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

(27) "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.

(28) “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.

(29) "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.

(30) “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.

(31) "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.

(32) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as 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 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 or pharmacy technicians;

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or

(C) A trade association recognized by the board as representing pharmacies.

(33) "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 pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.

(34) "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.

(35) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.

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

Division 041: Operation of Pharmacies (Pharmacy Closures)

Filing Caption (max 15 words):

Requires pharmacies to post accurate hours of operation and to update them when there is a closure.

Need for Rules:

During the COVID-19 pandemic, pharmacies are experiencing an increase in temporary closures due to extenuating circumstances (e.g. illness, staffing shortages). In addition, there has been an increase in permanent closures. Accurate pharmacy hours of operation must be available to patients and providers to ensure timely access to prescription medication. Registrants need clear direction on orderly disposition of pharmacy records and drugs when a pharmacy permanently closes.

Justification of Temporary Filing:

Pharmacies must have accurate hours of operation posted at all times. If a pharmacy must temporarily close, Oregonians will be unable to access their medications in process or filled by that pharmacy. If a pharmacy permanently closes, Oregonians need to be communicated with and made aware of alternative options for receiving their prescriptions. Failure to adopt this temporary rule will continue to result in patients and healthcare providers being unable to determine if the pharmacy is operating and patients being unable to access medications. Inability to access prescription medications and records in a timely manner is a danger to public health and safety.

Fiscal Impact:

None anticipated

Documents Relied Upon:

None

Resources:

Other State Regulations:

ME 392-13-2 Hours of Operation; Posting of Hours

ME 392-13-9 Permanent Closing of a Pharmacy

TX 291.5 Closing a Pharmacy

WA 246-945-480 Facility Reporting Requirements

Surescripts: Emergency Response Action Plans

NCPDP: Emergency Preparedness Guidance (v. 1.9)

Rules Summary:

This rule requires pharmacies to post accurate hours and to update operating hour information in the event of a closure. Accurate pharmacy operating hours must be available to patients and prescribers so they can seek alternate sources of prescription medication when a pharmacy is closed.

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POLICY DISCUSSION: Temporary vs. permanent rule

855-041-1015

Operation of Pharmacy (Both Retail and Institutional Drug Outlets)

*No proposed changes. Included for quick reference.

(1) Supervision. A pharmacy may only be operated when a pharmacist licensed to practice in this state is present. This means that the pharmacist must be physically present in the pharmacy or institutional facility.

(2) Sanitation:

(a) Pharmacies shall be kept clean.

(b) Persons working in a pharmacy shall practice appropriate infection control.

(3) A Pharmacy must conspicuously display accurate hours of operation at each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).

855-041-1092

Pharmacy Closures

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a pharmacy is temporarily closed to the public the pharmacy must:

(a) Post updated hours as required in OAR 855-041-1015(3) as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must Include:

(A) Period of time the pharmacy will be closed;

(B) Name, street address and telephone number of a nearby pharmacy that is available to serve the public during the period of closure on the notice; and

(C) Options for prescription pick-up (e.g. another pharmacy, new prescription) and for reversing processed prescriptions.

POLICY DISCUSSION: # of hours, vary by type of posting, posting elements

(b) If the closure is expected to last or lasts more than 24 hours, configure systems to provide notification to providers and patients of the temporary closure and prevent receipt of new prescriptions or refill requests;

POLICY DISCUSSION: Vary by length of closing

(c) Notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for temporary closure; and

POLICY DISCUSSION: Requirement

(d) Federal and state holidays are exempt from the requirements of (4)(b) and (4)(c).

(2) Permanent Closing. If a pharmacy is permanently closing to the public, the pharmacy must:

(a) Prior to closing, the pharmacy must comply with the following:

(A) Provide notification to patients with active prescriptions on file a minimum of 30 days prior to closing. The notification must include:

POLICY DISCUSSION: # of days

(i) The last day the pharmacy will be open;

(ii) Name, address and telephone number of the pharmacy to which prescription records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(B) The notification must be made via:

(i) Distribution by direct mail;

(ii) Public notice in a newspaper of general circulation in the area served by the pharmacy; and

(iii) Posting a closing notice at each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).

(iv) In addition to (i), (ii) and (iii), the pharmacy may also provide notification via email or text.

POLICY DISCUSSION: Methods

(C) Provide any new patients filling prescriptions during the 30-day period prior to the pharmacy closing with written notification that includes:

(i) The last day the pharmacy will be open;

(ii) Name, address and telephone number of the pharmacy to which prescription records will be transferred or the Oregon licensed pharmacist who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (XX/XX/XXXX).

(b) On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:

POLICY DISCUSSION: # hours

(A) Complete and document an inventory of all drugs and devices.

(B) If the pharmacy dispenses prescriptions:

(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed pharmacist who will serve as the custodian of records;

(ii) Update the pharmacy operating status with each electronic prescribing vendor; and

(iii) Remove all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications).

(c) After closing. Within 10 days after the closing of the pharmacy, the pharmacist-in-charge must:

POLICY DISCUSSION: # of days

(A) Remove all prescription drugs from the pharmacy by one or a combination of the following methods:

(i) Return prescription drugs to manufacturer or supplier (for credit/disposal);

(ii) Transfer (sell or give away) prescription drugs to a licensed healthcare provider or outlet who is legally authorized to possess drugs (e.g. physician, drug outlet); or

(iii) Destroy and document the destruction of prescription drugs in the presence of two board licensed staff.

(B) Provide the board a written notice of the closing on a board prescribed form which includes the following information:

(i) Date of closing to the public and discontinuance of the business;

(ii) Date and time the inventory of all prescription drugs and devices was conducted;

(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the pharmacy were transferred or disposed;

(iv) If drugs were destroyed, name and license numbers of individuals that witnessed the destruction;

(v) If the pharmacy is registered to possess controlled substances, confirmation that the pharmacy complied with all applicable federal requirements in 21 CFR 1301.52 (XX/XX/XXXX) for discontinuing operation as a pharmacy that dispenses controlled substances.

(vi) If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or Oregon licensed pharmacist who will serve as the custodian of records to which the prescriptions, including refill information, and patient medication records were transferred;

(vii) Confirmation all pharmacy labels and blank prescriptions were destroyed;

(viii) Confirmation all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and

(ix) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.

POLICY DISCUSSION: Elements

(C) Once the pharmacy has notified the board that the pharmacy is permanently closed, the license may not be renewed. The pharmacy may apply for a new license as specified in OAR 855-041-1080.

(3) Emergency closing. If pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

(4) Non-resident pharmacies are exempt from (1)-(3) and must follow laws and rules in the pharmacy's state of residence pertaining to temporary, permanent and emergency closures. The non-resident pharmacy must provide the board a written notice of the closing within 10 days on a form prescribed by the board which includes the following information:

(a) Date of closing to the public and discontinuance of the business;

(b) If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or Oregon licensed pharmacist who will serve as the custodian of records for Oregon patients to which the prescriptions, including refill information, and patient medication records were transferred; and

(c) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.

(5) The board may conduct an inspection to verify all requirements in subsection (1), (2), (3) and (4) of this section have been completed.

855-041-1090

Registration: Change of Business Name~~, or Closure~~ (Both Retail and Institutional Drug Outlets)

~~(1)~~ Any change of business name of a pharmacy must be reported to the Board within 15 days by filing a new application for which no fee is required.

~~(2) Any closure of a pharmacy shall be reported to the Board within 15 days and include notification of the disposition of controlled substances, dangerous, legend, and restricted drugs.~~

Division 021/025/110: Pharmacy Technicians and Certified Oregon Pharmacy Technician Licensure (PT Renewal)

Filing Caption (max 15 words):

Updates Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules

Need for Rules (describe what we are changing in rule):

Clarifies licensure qualifications, elements of a complete application and renewal/reinstatement requirements for Pharmacy Technicians (PT) and Certified Oregon Pharmacy Technicians (COPT); Revises PT license fees; Allows PT to renew or reinstate their license; Adds CE requirements for PT.

Justification of Temporary Filing (serious prejudice):

During the COVID-19 pandemic, pharmacies are experiencing a shortage of licensed personnel to assist in the practice of pharmacy. In addition, the current PT and COPT rules present unintended barriers to licensure by requiring those who have never held a national certification to obtain it in order to remain licensed. A shortage of licensed personnel reduces timely access to prescription medication. Inability to access prescription medications and records in a timely manner is a danger to public health and safety.

Having this rule in place by 1/1/2022 will allow current PT licensees to plan ahead and determine if they want to apply for a COPT license.

Fiscal Impact:

In Oregon, it is estimated that 1,528 PTs will be impacted by the new continuing pharmacy education (CPE) requirements. CPE is currently available at no cost through various vendors.

The exact number of PTs who will opt to renew is unknown. Using 1/2 of current active PT licensees (~760) as an estimate:

- PTs who opt to renew their PT license will not be required to have taken and passed a national certification in order to apply for a COPT license. The Pharmacy Technician Certification Board (PTCB) exam is $129 and the National Healthcareer Association (NHA) is $117.

- PTs who opt to renew their PT license will be subject to the biennial $4 Workforce Data Collection Fee.

- PTs who opt to renew their license will not be subject to an additional National Fingerprint-based Background Check $46.25 in order to apply for a COPT license.

Opting to renew their PT license may result in a $4 Workforce Data Collection Fee, a reduction of -$117 to -$129 for exam fees, and a reduction of $46.25 in National Fingerprint-based Background Check fees for a net impact of -$159.25 to -$171.25 to the licensee.

Collecting the Workforce Data Collection Fee may result in an additional +$3,040 increase in agency revenue. Collecting the National Fingerprint-based Background Check may result in an agency revenue reduction of -$35,228 for a net impact of -$32,188. Both fees are “pass through” fees that are sent to the Oregon Health Authority and Oregon State Police respectively for actual costs.

Documents Relied Upon:

None

Rules Summary (Indicates the change to the rule and why):

The proposed rule amendments are to assist in alleviating the shortage of licensed personnel remove barriers to licensure of PTs and COPTs by clarifying licensure qualifications, the elements of a complete application and the requirements for renewal/reinstatement. The rules also allow a PT to renew or reinstate their license. As a result, the PT licensee must pay the workforce data collection fee and complete biennial CPE requirements.

POLICY DISCUSSION: Temporary vs. permanent rule

855-025-0005

Licensure: Qualifications- ~~for Licensure~~ as a Pharmacy Technician or Certified Oregon Pharmacy Technician

(1) To qualify for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician, an applicant must demonstrate that the applicant is at least 18 years of age and has ~~obtained~~ **completed** ~~a~~ high school **(or equivalent)** ~~diploma or GED~~.

(2) ~~Section one does not apply to persons under the age of 18 licensed by the Board as a Pharmacy Technician prior to January 1, 2015.~~ **To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must also demonstrate that the applicant has taken and passed a national pharmacy technician certification examination offered by:**

(a) Pharmacy Technician Certification Board (PTCB); or

(b) National Healthcareer Association (NHA).

~~(3) An applicant for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician must complete an application for licensure, provide the Board with a valid e-mail address and furnish documentation required to conduct a criminal background check.~~

(4**3**) No person whose license has been denied, revoked, suspended or restricted by any healthcare professional regulatory Board may be licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician unless the Board determines that licensure will pose no danger to patients or to the public interest.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & **ORS** 689.486

855-025-0010

Licensure: Application- ~~as a~~ Pharmacy Technician

(1)~~The license of a Pharmacy Technician expires the second June 30 from the date of issue and is not to exceed two years, except that due to the COVID-19 declared public health emergency, Pharmacy Technician (PT) licenses set to expire June 30, 2020, will instead expire on 12/31/2020~~ **An application for licensure as a Pharmacy Technician may be accessed on the board website**.

(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline;

(3) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.

(~~2~~**4**) ~~The Pharmacy Technician license is not renewable.~~ **The board may issue a license to a qualified Pharmacy Technician after the receipt of:**

(a) A completed application;

(b) Payment of the fee prescribed in OAR 855-110;

(c) A current, passport regulation size photograph (full front, head to shoulders);

(d) Personal identification or proof of identity; and

(e) A completed national fingerprint-based background check.

(~~3~~**5**) ~~A time limited extension of a Pharmacy Technician license may be granted once by petition to the Board. The written completed petition must be received by the Board prior to the expiration of the PT license~~ **The license of a Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.**

~~(4) An individual may reapply for a Pharmacy Technician license if the previous PT license is lapsed for a period greater than five years.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-025-0011
Licensure: Renewal or Reinstatement- Pharmacy Technician

(1) An applicant for renewal of a Pharmacy Technician license must:

(a) Pay the biennial license fee required in OAR 855-110.

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-021;

(c) Be subject to an annual criminal background check.

(2) A Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A Pharmacy Technician or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-025-0010; and

(b) Provide certification of completion of 10 continuing education hours. These hours may not be counted toward renewal; and must include:

(A) One hour of continuing pharmacy education in pharmacy law;

(B) One hour of continuing pharmacy education in patient safety or error prevention; and

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

POLICY DISCUSSION: Retain CE requirement, CCCE

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, ORS 689.486, ORS 413.450

855-025-0012
Licensure: Application- ~~as a~~ Certified Oregon Pharmacy Technician

(1) ~~To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must demonstrate that he or she has taken and passed a national pharmacy technician certification examination offered by:~~ **An application for licensure as a Pharmacy Technician may be accessed on the board website**.

(~~a~~**2**) ~~The Pharmacy Technician Certification Board (PTCB); or~~ **Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline.**

(~~b~~**3**) ~~The National Healthcareer Association (NHA).~~ **Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.**

(~~2~~**4**) ~~The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and must be renewed biennially.~~ **The board may issue a license to a qualified Certified Oregon Pharmacy Technician after the receipt of:**

(a) A completed application;

(b) Payment of the fee prescribed in OAR 855-110;

(c) A current, passport regulation size photograph (full front, head to shoulders);

(d) Personal identification or proof of identity;

(e) A completed national fingerprint-based background check; and

(f) Proof that the applicant has taken and passed a national pharmacy technician certification offered by the PTCB or the NHA.

(5) The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & **ORS** 689.486

855-025-0015
~~**Renewal of**~~ **Licensure: Renewal or Reinstatement- ~~as a~~ Certified Oregon Pharmacy Technician**

(1) A person who has taken and passed a national pharmacy technician certification examination listed in OAR 855-025-0012(1)(a)–(b) may use the following title, and is referred to in these rules as, and is licensed as a "Certified Oregon Pharmacy Technician."

(2) An applicant for renewal of a Certified Oregon Pharmacy Technician license must:

(a) Pay the biennial license fee required in OAR 855-110~~.~~**;**

(b) Complet**e**~~ion of~~ **the** continuing pharmacy education requirements as directed in OAR 855-021; **and**

(c) Be subject to an annual criminal background check.

(3) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.

(4) A Certified Oregon Pharmacy Technician who fails to renew ~~his or her~~ **their** license by the expiration date and whose license has been lapsed for ~~less than~~ one year **or less** may renew ~~his or her~~ **their** license **and must pay a late fee required in OAR 855-110.** ~~as follows:~~

~~(a) Complete the renewal process;~~

~~(b) Pay the biennial license fee as prescribed in OAR 855-110;~~

~~(c) Pay a late fee; and~~

~~(d) Complete the required continuing pharmacy education pursuant to OAR 855-021.~~

~~855-025-0060~~
~~Reinstatement of a **Pharmacy Technician** or Certified Oregon Pharmacy Technician License~~

(~~1~~**5**) A Certified Oregon Pharmacy Technician who fails to renew their license by the ~~deadline~~ **expiration date** and whose license has been lapsed for greater than one year may **apply to** reinstate their license as follows:

(a) ~~Complete a new application for licensure and provide the board with a valid e-mail address;~~ **Must apply per OAR 855-025-0010; and**

~~(b) Pay the biennial license fee as prescribed in OAR 855-110;~~

~~(c) Submit to a national fingerprint background check; and~~

(d) Provide certification of completion of 10 continuing education hours. These hours may not be counted toward renewal~~;~~ and must include:

(A) One hour of continuing pharmacy education in pharmacy law;

(B) One hour of continuing pharmacy education in patient safety or error prevention; and

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

~~(2) A Certified Oregon Pharmacy Technician whose license has been lapsed~~ greater than five years ~~must:~~

~~(a) Re-take and pass a national pharmacy technician certification examination offered by:~~

~~(A) The Pharmacy Technician Certification Board (PTCB); or~~

~~(B) National Healthcareer Association (NHA).~~

~~(b) Satisfy reinstatement requirements pursuant to OAR 855-025-0060(1).~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, ORS 689.486, **ORS 413.450**

855-110-0003
General
*Currently proposed language in draft rules being motioned for adoption at December Board meeting

(1) All fees paid under these rules are non-refundable.

(2) Fees cannot be prorated.

(3) Fees for initial licensure as a Pharmacist**, Pharmacy Technician** or Certified Oregon Pharmacy Technician ~~may~~ **will** be reduced to one-half of a biennial rate, if the application is received within 180 days of expiration.

(4) A late fee must be paid:

(a) When a renewal application is received after the date specified in these rules; or

(b) When the Board requests additional information from an applicant and this information is not provided within 30 days.

(5) A delinquent fee may be assessed when an application is submitted incomplete and the Board requests the missing information.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135

855-110-0005
Licensing Fees
*Currently proposed language in draft rules being motioned for adoption at December Board meeting

(1) Pharmacist license examination (NAPLEX) fee - $50.

(2) Pharmacist jurisprudence (MPJE) re-examination fee - $25.

(3) Pharmacist licensing by reciprocity fee - $100.

(4) Pharmacist licensing by score transfer fee - $50.

(5) Intern license fee. Expires November 30 every two years - $100.

(6) Pharmacist:

(a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is - $250. Late renewal fee (received after June 30) - $50.

(b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially - $70. (This is a mandatory fee, required by ORS 431A.880 that must be paid with the pharmacist license renewal fee).

(c) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.)

(7) Certification of approved provider of continuing education course fee, none at this time.

(8) Pharmacy Technician license fee~~- $100.~~**:**

(a) Expires June 30 each even numbered year. The biennial license fee is - $100. Late renewal fee (received after June 30) - $20.

(b) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacy Technician license renewal fee.)

(9) Certified Oregon Pharmacy Technician:

(a) Biennial license fee. Expires June 30 each even numbered year - $100. Late renewal fee (received after June 30) - $20.

(b) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy Technician license renewal fee.)

Statutory/Other Authority: ORS 689.205, ORS 291.055, ORS 183.705
Statutes/Other Implemented: ORS 689.135, ORS 676.410, ORS 431A.880

855-021-0009

Continuing Pharmacy Education Required for Pharmacy Technician or Certified Oregon Pharmacy Technician License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a **Pharmacy Technician or** Certified Oregon Pharmacy Technician must have satisfactorily completed 20 contact hours of continuing pharmacy education. These hours must include:

(a) Two hours of continuing pharmacy education in pharmacy law;

(b) Two hours of continuing pharmacy education in patient safety or medication error prevention;

(c) Two hours of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(d) Fourteen additional hours of continuing pharmacy education or documented onsite training approved by the board.

(2) Section (1) does not apply to a **Pharmacy Technician or** Certified Oregon Pharmacy Technician applying for the first renewal of their license if they have not been licensed by the board for at least one year prior to July 1 of the renewal period.

(3) A **Pharmacy Technician or** Certified Oregon Pharmacy Technician must retain documentation of completed continuing pharmacy education for six years and must provide this documentation if requested by the board.

(4) Continuing pharmacy education credit accumulated in excess of the required 20 contact hours for biennial license renewal cannot be carried forward.

(5) If a license renewal is submitted after June 30th of the license renewal cycle, continuing pharmacy education must be completed prior to submission of the license renewal.

(6) Section (1) does not apply to a Pharmacy Technician applying for the first renewal of their license prior to 7/1/2021.

POLICY DISCUSSION: Same CE requirement

336 Statutory/Other Authority: ORS 689.205
337 Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 676.850

Division 135–Continuing Pharmacy Education (Procedural Rule Review)

Filing Caption (max 15 words):

- Proactive procedural rule review.

Need for Rules:

- Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Fiscal Impact:

- None anticipated.

Documents Relied Upon:

Rules Advisory Committee- Continuing Pharmacy Education: May 2021 minutes & October 2021 minutes.

Resources:

Other State Regulations:

CA: CCR 1732

OH: OAC 4729:1-5

TX: TAC 295.8 Continuing Education Requirements

WA: WAC 246-861 Pharmacists—Professional Pharmaceutical Education

Rules Summary:

- Procedural rules revisions to ensure clarity, transparency and promote patient safety.

Division ~~21~~**135**
CONTINUING PHARMACY EDUCATION

855-~~021~~135-0001
Continuing Pharmacy Education: Definitions

(1) "Accredited program" means continuing pharmacy education (CPE) which has been reviewed and approved by a provider of continuing pharmacy education accredited by the Accreditation Council on Pharmaceutical Education (ACPE).

(2) "AMA Category 1 Program" means a program reviewed and approved for American Medical Association (AMA) as Category 1 Continuing Medical Education (CME) by a provider of continuing medical education accredited by the Accreditation Council for Continuing Medical Education (ACCME).

(3) "Approved provider" means any person, institution, organization, association, corporation, or agency approved either by the board or ACPE to conduct continuing pharmacy education programs.

(4) "Board-approved program" means continuing pharmacy education which has been reviewed and approved by the board or a board-approved provider.

(5) "Certificate of completion" means a certificate or other official document issued to a participant certifying the successful completion of an approved continuing pharmacy education program.

(~~1~~**6**) "Continuing Pharmacy Education" or "CPE" **means an accredited or approved structured educational activity designed to support the continuing development of pharmacists, interns, or pharmacy technicians to maintain and enhance their competence applicable to the practice of pharmacy or the assistance of the practice of pharmacy**. ~~classes of post graduate studies, informal study group participation, institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, planned and professional meetings, self-study courses, cassette or audio visual tape/slides or materials, and other self-instruction units applicable to the practice of pharmacy~~.

(~~2~~**7**) "Contact hour" means ~~fifty~~ **sixty** minutes of continuing pharmacy education.

(8) "CPE Monitor" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy (NABP) for monitoring continuing pharmacy education that pharmacists, interns, and pharmacy technicians receive from participating providers;

(~~6~~**9**) "Cultural competence" means the lifelong process of examining the values and beliefs and developing and applying an inclusive approach to health care practice in a manner that recognizes the content and complexities of provider-patient communication and interaction and preserves the dignity of individuals, families, and communities.

(a) Cultural competence applies to all patients.

(b) Culturally competent providers do not make assumptions on the basis of an individual's actual or perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital status, socio-economic status, veteran's status, sexual orientation, gender identity, gender expression, gender transition status, level of formal education, physical or mental disability, medical condition or any consideration recognized under federal, state and local law.

(4**10**) "Medication error prevention" means **the prevention of an event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer** ~~systems, procedures and processes to prevent and avoid adverse events and to ensure that the correct patient receives the correct drug in the correct dose~~.

(~~3~~**11**) "Patient safety" means **the prevention of healthcare related errors or the elimination or mitigation of patient injury caused by healthcare related errors** ~~systems, procedures and processes that ensure that the correct patient receives the correct drug in the correct dose and is counseled appropriately~~.

(~~5~~**12**) "Pain management education program" means a specific one-hour web-based program developed by the Pain Management Commission of the Oregon Health Authority.

(13) "Pharmacy law" means the body of laws and doctrines relating to pharmacy practice.

(14) "Structured" means the inclusion of defined learning objectives, qualified instructors, and a learning assessment in a continuing pharmacy education program.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 413.590

855-~~021~~135-0010
Continuing Pharmacy Education Programs: General Requirements

(1) CPE programs must consist of subject matter pertinent to pharmacy including:

(a) Socio-economic aspects of healthcare;

(b) Legal aspects of healthcare;

(c) Properties and actions of drugs and dosage forms;

(d) Etiology, characteristics, therapeutics, and prevention of disease states; or

(e) General topics related to pharmacy.

(2) Full CPE credit (hour for hour) is granted when:

(a) Content is delivered by an instructor;

(b) Content is delivered by a panel of instructors;

(c) The program is a structured discussion, workshop or demonstration;

(d) The program is a structured question and answer session;

(d) The program is an accredited or approved program;

(e) The program is accredited as an AMA Category 1 program. Licensees may earn a maximum of 10 hours of continuing pharmacy education for AMA Category 1 programs per renewal cycle; and

(f) The program provider has granted credit to the participant as authorized by the program accreditor or approval authority.

(3) CPE credit is not granted for:

(a) Welcoming remarks;

(b) Time spent for meals or social functions;

(c) Business sessions;

(d) Unstructured discussion, workshops, and demonstrations;

(e) Unstructured question and answer sessions;

(f) Degree programs;

(g) Non-ACPE approved certificate programs;

(h) Licensing or certification examinations (e.g. MPJE, BPS, CPhT-Adv);

(i) Skills training programs (e.g. CPR, ACLS);

(j) Software training programs (e.g. NPLEx, PDMP, ALERT-IIS, REMS);

(k) Learning assessments;

(l) Program evaluations; and

(m) Attending continuing pharmacy education programs for which credit was not granted by the provider.

(4) For each board-approved program, the licensee must retain a certificate of completion for each completed program that must include:

(a) Licensee name;

(b) Title and activity number of the program;

(c) Category;

(d) Name of the program provider;

(e) Date of completion of the program;

(f) Number of contact hours earned by category; and

(g) Statement of credit granted.

(5) For each ACPE-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor.

(6) For each board-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or uploaded to the licensee's Oregon Board of Pharmacy e-Gov profile.

855-~~021~~135-0020

Continuing Pharmacy Education Programs: Approved Providers

(1) A provider may apply to the board on forms provided by the board for qualification as an approved provider. If a provider is approved, the board will issue a certificate or other notification of qualification. The approval is effective for a period of two years. Providers who apply to the board for approved provider status must document the following:

(a) Identify the individual responsible for the providers' CPE program;

(b) Provide copies of CPE program material and information used by the provider in the previous two years with each renewal; and

(c) Develop a procedure for establishing:

(A) Educational goals and learning objectives for each program;

(B) Learning assessment component for each program; and

(C) Program evaluation component for each program.

(d) A CPE provider must supply each participant with a written program description which lists the topic(s) covered, an assigned activity number, names of instructors, time devoted to the program topic(s), and the learning objectives of the program. The program description must also bear a statement of the number of hours by category of CPE credit assigned by the provider.

(e) The provider must make available to each participant a certificate of completion that must include:

(A) Licensee name;

(B) Title and activity number of the program;

(C) Category;

(D) Name of the program provider;

(E) Date of completion of the program;

(F) Number of contact hours earned by category; and

(G) Statement of credit granted.

(H) The provider must retain, for a period of six years, a list of persons to whom a certificate of completion as specified in (e) was supplied.

(2) The board must establish the standards and specifications necessary for a provider to obtain approval.

(3) The board may revoke or suspend an approval of a provider if the provider fails to maintain the necessary standards and specifications required.

POLICY DISCUSSION: Provider-approval

855-~~021~~135-0030
Continuing Pharmacy Education Programs: Applications for Approval

(1) An application for approval of a CPE program which is not an accredited program or provided by an approved provider must be made on a form provided for this purpose by the board. A complete application includes:

(a) Program provider or sponsor name;

(b) Program name;

(c) Program category

(d) Licensee type;

(e) Total number of contact hours offered by category;

(f) Description of program goals and learning objectives;

(g) Program format (e.g. interactive discussion, panel, speaker);

(h) Name and qualifications of each instructor;

(i) Dates and location of program;

(j) Learning assessment; and

(k) Program evaluation

(2) The provider must submit an application form a minimum of forty-five days prior to the date the program will be held. Applications submitted less than forty-five days prior to the date the program will be held will not be approved.

(3) Incomplete applications will not be approved.

(4) An application for post-approval of a CPE program will not be approved.

POLICY DISCUSSION: Post-approval, accepting other state board approvals

855-~~021~~135-0040

Continuing Pharmacy Education Programs: Instructors' Credit Toward CPE Hours

(1) Any pharmacist whose primary responsibility is not the education of health professionals, who instructs a group of health professionals on pharmacy-related topics in organized CPE may be granted two hours of CPE credit for each hour spent in presenting the initial course or program which has been approved for CPE credit.

(2) Any pharmacist whose primary responsibility is the education of health professionals may be granted CPE credit as in (1) when instructing a group of health professionals on pharmacy-related topics outside of their formal course responsibilities in a learning institution.

(3) An instructor may not be granted multiple credit for multiple presentations of the same program of CPE.

(4) An instructor may earn a maximum of 10 hours of CPE for instruction per renewal cycle.

855-~~021~~135-00~~0~~50

Continuing Pharmacy Education: Requirements~~d~~ for Pharmacist License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a pharmacist must have satisfactorily completed at least 30 hours of ~~continuing pharmacy education~~ **CPE**. These hours must include at least:

(a) Two hours of ~~continuing pharmacy education~~ **CPE** in pharmacy law;

(b) Two hours of ~~continuing pharmacy education~~ **CPE** in patient safety or medication error prevention;

(c) Two hours of ~~continuing pharmacy education~~ **CPE** in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(d) One hour of ~~continuing pharmacy education~~ **CPE** in pain management, provided by the Pain Management Commission of the Oregon Health Authority; and

(e) Twenty-three additional hours of ~~continuing pharmacy education~~ **CPE in general pharmacy topics**.

(2) Section (1) does not apply to pharmacists applying for the first renewal of their license if they have not been licensed by the board for at least one year prior to July 1 of the renewal period.

(3) A pharmacist must register with the CPE Monitor for tracking completed ACPE credit hours.

(~~3~~4) A pharmacist must retain documentation of completed ~~continuing pharmacy education~~ **CPE** for six years and must provide this documentation if requested by the board.

(4~~5~~) ~~continuing pharmacy education~~ **CPE** credit accumulated in excess of the required 30 contact hours for biennial license renewal cannot be carried forward.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 689.285, ORS 413.450, ORS 413.590 & 2021 HB 2078

855-~~021~~135-00~~07~~60
Continuing Pharmacy Education: Requirementsd for Intern License Renewal

(1) During each license renewal cycle, an intern must have satisfactorily completed 2 contact hours of approved ~~continuing pharmacy education~~ **CPE** in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(2) An intern must retain documentation of completed ~~continuing pharmacy education~~ **CPE** for six years and must provide this documentation if requested by the board.

(3) An intern must register with the CPE Monitor for tracking completed ACPE credit hours.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285, ORS 676.850, ORS 413.450 & ORS 689.151

855-~~021~~135-00~~09~~70
Continuing Pharmacy Education: Requirementsd for Certified Oregon Pharmacy Technician License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a Certified Oregon Pharmacy Technician must have satisfactorily completed 20 contact hours of ~~continuing pharmacy education~~ **CPE prior to submitting a renewal application**. These hours must include:

(a) Two hours of ~~continuing pharmacy education~~ **CPE** in pharmacy law;

(b) Two hours of ~~continuing pharmacy education~~ **CPE** in patient safety or medication error prevention;

(c) Two hours of ~~continuing pharmacy education~~ **CPE** in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(d) Fourteen additional hours of ~~continuing pharmacy education~~ **CPE in general pharmacy topics**. ~~or documented onsite training approved by the board~~.

(2) A Certified Oregon Pharmacy Technician must register with the CPE Monitor for tracking completed ACPE credit hours.

(~~2~~**3**) Section (1) does not apply to a Certified Oregon Pharmacy Technician applying for the first renewal of their license if they have not been licensed by the board for at least one year prior to July 1 of the renewal period.

(~~3~~**4**) A Certified Oregon Pharmacy Technician must retain documentation of completed ~~continuing pharmacy education~~ **CPE** for six years and must provide this documentation if requested by the board.

(4**5**) ~~continuing pharmacy education~~ **CPE** credit accumulated in excess of the required 20 contact hours for biennial license renewal cannot be carried forward.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 676.850

~~**855-021-0010**~~
~~**Continuing Pharmacy Education Programs**~~

~~(1) A continuing pharmacy education program must consist of therapeutics, or pharmacy and drug law or other aspects of health care applicable to the practice of pharmacy.~~

~~(2) Programs must provide for examinations or other methods of evaluation to assure satisfactory completion by participants.~~

~~(3) The person or persons who are to instruct or who are responsible for the delivery or content of the program must be qualified in the subject matter by education and experience.~~

~~(4) Continuing pharmacy education programs must be approved by the Board of Pharmacy. Application for approval must be made on and in accordance with forms established by the board. The forms must require information relating to:~~

~~(a) Name of provider or sponsor;~~

~~(b) Type of program offered;~~

~~(c) Description of subject matter;~~

~~(d) Number of contact hours offered;~~

~~(e) Total number of contact hours in therapeutics or pharmacy and drug law or other aspects of health care applicable to the practice of pharmacy;~~

~~(f) Method of determining satisfactory completion of program;~~

~~(g) Dates and location of program;~~

~~(h) Name and qualification of instructors or other persons responsible for the delivery or content of the program.~~

~~(5) CE programs are not required to carry approval of American Council on Pharmaceutical Education (ACPE). Programs presented by providers approved by the American Council on Pharmacy Education (ACPE) are accepted.~~

~~(6) Providers must provide attendees with proof of attendance that shows the date and number of contact hours provided. Providers must maintain attendance lists for six years.~~

~~(7) A maximum of 10 contact hours may be earned in any licensing cycle by preparing and presenting CE programs. Pharmacists and Certified Oregon Pharmacy Technicians presenting CE programs may earn one contact hour for preparation time of one hour or more, plus credit for the actual contact hour time of the presentation. A pharmacist or Certified Oregon Pharmacy Technician must show content of the course, and a description of the intended audience (e.g., pharmacists, technicians, physicians, nurses). Public service programs, such as presentations to school children or service clubs, are not eligible for continuing education credit.~~

~~(8) Pharmacists or Certified Oregon Pharmacy Technicians taking post graduate studies applicable to graduate or professional degrees may submit the course syllabus and evidence of satisfactory completion of the course for continuing education credit approval by the board.~~

~~(9) The board may approve up to 26 contact hours of CE credit for pharmacists who have successfully completed nationally certified Disease State Management courses.~~

~~(10) Board members or staff may attend CE programs for the purpose of evaluating content, format and appropriateness of material for Continuing Pharmacy Education credit. Subsequent programs by CE providers whose current programs are deemed deficient by on-site evaluation may be required to obtain prior approval by the board. The board will provide feedback to CE providers regarding evaluated CE presentations.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.285~~

855-~~021~~135-0080
Continuing Pharmacy Education: Requirements for Licensees Licensed in Other Health Professions

A Pharmacist, Intern, or Certified Oregon Pharmacy Technician who is licensed to practice another health profession must meet the same CPE requirements in the same manner as all other board licensees and must otherwise comply with this chapter.

855-~~021~~135-004~~5~~85
Continuing Pharmacy Education: Notification of Biennial License Renewal

The board will send a biennial renewal notice to be issued to all licensed pharmacists, interns, and Certified Oregon Pharmacy Technicians at least 60 days prior to the license expiration date that states the biennial license fee, ~~continuing pharmacy education~~ **CPE** requirements and other information necessary for renewal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.275 & ORS 689.486

855-~~21~~135-005~~0~~90
Continuing Pharmacy Education: Audits

(1) The biennial renewal application must be submitted to the board with the appropriate fee and the licensee must attest that they have satisfactorily completed the ~~continuing pharmacy education~~ **CPE** requirements **prior to submitting the application**.

(2) The Board may randomly select and audit applications for renewal to verify completion of ~~continuing pharmacy education~~ **CPE** by pharmacists, interns and Certified Oregon Pharmacy Technicians ~~or documented on-site training by Certified Oregon Pharmacy Technicians~~ reported on the application for renewal.

(a) Pharmacists whose applications for renewal are selected for audit must provide documentation of completion of the ~~continuing pharmacy education~~ **CPE** programs reported. A pharmacist who fails to provide the requested documentation to the board or who fails to complete the biennial ~~continuing pharmacy education~~ **CPE** requirement may be disciplined for unprofessional conduct.

(b) Interns whose applications for renewal are selected for audit must provide documentation of completion of the cultural competency ~~continuing pharmacy education~~ **CPE**. An intern who fails to provide the requested documentation to the board or who fails to complete the biennial ~~continuing education~~ **CPE** requirement may be disciplined for unprofessional conduct.

(c) Certified Oregon Pharmacy Technicians whose applications for renewal are selected for audit must provide documentation of completion of the ~~continuing pharmacy education~~ **CPE** ~~or documented onsite training reported~~. A Certified Oregon Pharmacy Technician who fails to provide the requested documentation to the board or who fails to complete the biennial ~~continuing education~~ **CPE** requirement may be disciplined for unprofessional conduct.

(3) The board may utilize the National Association of Boards of Pharmacy CPE Monitor service when auditing licensees.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.275

Division 006/041/139– Definitions/Drug Storage

Need for Rules: The proposed revisions are to clarify the date of incorporated standards of reference, as discussed in with the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019).

Each year the board will adopt the updated USP-NF standards and USCs. The board is tasked with verifying that every USP-NF standard and USC is current and referenced appropriately.

Fiscal Impact:
As of 12/2/2021 there are currently 1,898 registered outlets. Staff emailed stakeholders and licensees a request for fiscal impact information related to estimated costs associated with procurement and all associated processes related to temperature monitoring. We received one response, who stated that in 2019, they received a quote of $10,000 for seven pharmacies ($1,429 for one outlet) which included one year of service. This vendor also charges for ongoing annual fees, however that information was not provided. Using that information, it is estimated that for an outlet to comply with the proposed rules, it could potentially cost $2,858 ($1,429 x 2 thermometers) for procurement and 1 year of service plus additional annual service fees.

Documents Relied Upon:
United States Pharmacopeia -National Formulary <NF> (USP 43-NF38 v. 2021) https://www.uspnf.com/

National Institute of Standards and Technology (NIST)
- Optimizing Data Logger Setup and Use for Refrigerated Vaccine Temperature Monitoring (2015)
- Thermal Analysis of Refrigeration Systems Used for Vaccine Storage: Report on Pharmaceutical Grade Refrigerator and Household Refrigerator/Freezer (2010)
- Accurate Cold Chain Temperature Monitoring Using Digital Data Logger Thermometers (2012)

Oregon VFC Vaccine Management Guide
CDC Vaccine Storage and Handling Toolkit

Rules Summary:
Procedural rules revisions to ensure clarity, transparency and promote patient safety.

1

Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

( ) "Temperature excursion" means an event in which a drug is exposed to a temperature outside of the manufacturer's required storage conditions. If the drug's manufacturer does not include required storage conditions, "temperature excursion" means an event in which a drug is exposed to a temperature outside of that required in an official compendium to ensure that the drug identity, strength, quality, and purity are not adversely affected.

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

855-041-1036
Proper Storage of Drugs

(1) A pharmacy must store each drug according to the manufacturer's storage requirements for temperature, light, humidity, sanitation, ventilation, and space.

(2) If the drug's manufacturer does not include a storage requirement, the drug must be stored as required in an official compendium, to ensure that the drug identity, strength, quality, and purity are not adversely affected.

(3) Each pharmacy must:

(a) Unless the manufacturer specifies differently, maintain drug required to be stored at controlled room temperature between 20 to 25 °C (68 to 77 °F); refrigerated products between 2 to 8 °C (35.6 to 46.4 °F); frozen products between -25 to -10 °C (-13 to 14 °F);

(b) Utilize continuous temperature monitoring device(s) that:

(i) Has a buffered probe (glycol, glass beads, or similar) that is:

(A) Centrally located;

(B) Contained in a tray with a solid base and solid sides without perforations to maintain the probe in a stable position to minimize temperature fluctuations;

(C) Records the temperature of each drug storage area at least every 15 minutes; and

(D) Accurate and calibrated on a schedule determined by the manufacturer within a plus or minus 0.5°C (1 °F) variance. A copy of the calibration certificate must be retained that includes:

(i) Model/device name or number;

(ii) Serial number;

(iii) Calibration date (report or issue date); and

(iv) Confirmation that the instrument passed testing (or instrument is in tolerance).

(c) Review all temperature data for the last 24 hours twice daily for proper drug storage and for temperature excursions. Date, time and identity of the reviewer must be documented;

(d) Utilize a system that notifies a pharmacist of each temperature excursion in real-time;

(e) Ensure drug storage refrigerators and freezers are dedicated to drugs and vaccines only and utilize refrigerator or freezer compartments with its own exterior door and independent thermostat control;

(f) Position drugs in refrigerators and freezers leaving space between the drugs, walls, ceiling, floor, and door to promote air circulation. If using a household grade unit, drugs may not be stored in any part of the unit that does not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in drawers, or on refrigerator door shelves;

(g) Maintain proper drug storage conditions during transfers between facilities and delivery to patients;

(h) Ensure that drugs stored outside of the manufacturer's drug storage requirements are physically separated from other drugs until the manufacturer determines that the drug is safe and effective for continued use, is safe and effective for continued use with limitations (i.e. shortened expiration date), needs to be returned to the supplier, or destroyed;

(i) Ensure that the following is completed at a minimum of every 3 months:

(A) Test and document that all components of the temperature monitoring system(s) for each storage area are recording temperature accurately and issuing appropriate alerts;

(B) Review and assess temperature records for long-term trends or recurring problems. Date, time and identity of the reviewer must be documented;

(j) Establish, maintain, and enforce a written quality assurance plan to prevent, identify, and appropriately respond to temperature excursions;

(k) Establish, maintain, and enforce a written action plan to ensure proper drug storage in the event of an emergency (i.e. power outage or natural disaster) that includes identification of backup storage and a procedure for transfer of product between units or facilities;

(l) Document the training of all pharmacy personnel on use of temperature monitoring system(s), quality assurance plan and written action plan to ensure proper drug storage in the event of an emergency;

(m) Recalibrate temperature monitoring device(s) at least once every 24 months or per manufacturer specifications, whichever is more frequent;

(n) Document the following for each temperature excursion:

(A) Date of temperature excursion;

(B) Start and end time;

(C) Minimum and maximum temperatures reached;

(D) List of each drug involved in the temperature excursion including the drug name, quantity, National Drug Code, lot number, expiration date, manufacturer, and the date(s) of previous temperature excursions experienced by the drug(s);

(E) Each drug involved in the temperature excursion must be clearly labeled with the date of temperature excursion and any shortened expiration date if determined by the manufacturer; and

(F) Name of person(s) involved in responding to the temperature excursion event discovery and response;

(o) Before a drug that has experienced a temperature excursion is dispensed, the following items must be documented:

(A) Drug manufacturer information utilized indicating each drug is safe for use;

(B) Name of the representative providing the information;

(C) Manufacturer contact information;

(D) Copy of information and case number if provided by manufacturer;

(E) Date and time information was obtained from manufacturer;

(F) Reference number associated with manufacturer contact;

(G) Name of the Oregon licensed pharmacist that reviewed the manufacturer data and confirmed the drug safe for continued use; and

(H) In the absence of (B) and (C), documentation of a drug manufacturer online reference that applies to the specific temperature excursion, documentation of this reference must be maintained; and

(p) Have at least one accurate and calibrated back-up buffered temperature probe.

(q) In case the device in use breaks or malfunctions, place a back-up buffered temperature probe in the storage unit to determine the temperature.

(r) Maintain all records required by OAR 855-041-1036 for a minimum of three years.

~~(1) A pharmacy must maintain proper storage of all drugs. This includes, but is not limited to the following:~~

~~(a) All drugs must be stored according to manufacturer's published or USP guidelines.~~

~~(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.~~

~~(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.~~

~~(d) A pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.~~

~~(2) A pharmacy must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).~~

~~(a) All drug refrigeration systems must:~~

~~(A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.~~

~~(B) Utilize a centrally placed, accurate, and calibrated thermometer;~~

~~(C) Be dedicated to pharmaceuticals only; and~~

~~(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.~~

~~(b) A pharmacy must adhere to a monitoring plan, which includes, but is not limited to:~~

~~(A) Documentation of training of all personnel;~~

~~(B) Maintenance of manufacturer recommended calibration of thermometers;~~

~~(C) Maintenance of records of temperature logs for a minimum of three years;~~

~~(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;~~

~~(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination that it is safe for continued use. This documentation must include details of the information source;~~

~~(F) A written emergency action plan; and~~

~~(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment.~~

~~(3) Vaccine Drug Storage:~~

~~(a) A pharmacy that stores vaccines must comply with section two of this rule and the following:~~

~~(A) Vaccines must be stored in the temperature stable sections of the refrigerator;~~

~~(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C variance must be utilized;~~

~~(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;~~

~~(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and~~

~~(E) Must adhere to a written quality assurance process to avoid temperature excursions.~~

~~(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.~~

Statutory/Other Authority: ORS 689.205 & **ORS** 689.325
Statutes/Other Implemented: ORS 689.155
Statutes/Other Implemented: ORS 689.155

855-139-0125
Drug: Storage

(1) A pharmacy must store each drug according to the manufacturer's storage requirements for temperature, light, humidity, sanitation, ventilation, and space.

(2) If the drug's manufacturer does not include a storage requirement, the drug must be stored as required in an official compendium, to ensure that the drug identity, strength, quality, and purity are not adversely affected.

(3) Each pharmacy must:

(a) Unless the manufacturer specifies differently, maintain drug required to be stored at controlled room temperature between 20 to 25 °C (68 to 77 °F); refrigerated products between 2 to 8 °C (35.6 to 46.4 °F); frozen products between -25 to -10 °C (-13 to 14 °F);

(b) Utilize continuous temperature monitoring device(s) that:

(i) Has a buffered probe (glycol, glass beads, or similar) that is:

(A) Centrally located;

(B) Contained in a tray with a solid base and solid sides without perforations to maintain the probe in a stable position to minimize temperature fluctuations;

(C) Records the temperature of each drug storage area at least every 15 minutes; and

(D) Accurate and calibrated on a schedule determined by the manufacturer within a plus or minus 0.5°C (1 °F) variance. A copy of the calibration certificate must be retained that includes:

(i) Model/device name or number;

(ii) Serial number;

(iii) Calibration date (report or issue date); and

(iv) Confirmation that the instrument passed testing (or instrument is in tolerance).

(c) Review all temperature data for the last 24 hours twice daily for proper drug storage and for temperature excursions. Date, time and identity of the reviewer must be documented;

(d) Utilize a system that notifies a pharmacist of each temperature excursion in real-time;

(e) Ensure drug storage refrigerators and freezers are dedicated to drugs and vaccines only and utilize refrigerator or freezer compartments with its own exterior door and independent thermostat control;

(f) Position drugs in refrigerators and freezers leaving space between the drugs, walls, ceiling, floor, and door to promote air circulation. If using a household grade unit, drugs may not be stored in any part of the unit that does not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in drawers, or on refrigerator door shelves;

(g) Maintain proper drug storage conditions during transfers between facilities and delivery to patients;

(h) Ensure that drugs stored outside of the manufacturer's drug storage requirements are physically separated from other drugs until the manufacturer determines that the drug is safe and effective for continued use, is safe and effective for continued use with limitations (ie. shortened expiration date), needs to be returned to the supplier, or destroyed;

(i) Ensure that the following is completed at a minimum of every 3 months:

(A) Test and document that all components of the temperature monitoring system(s) for each storage area are recording temperature accurately and issuing appropriate alerts;

(B) Review and assess temperature records for long-term trends or recurring problems. Date, time and identity of the reviewer must be documented;

(j) Establish, maintain, and enforce a written quality assurance plan to prevent, identify, and appropriately respond to temperature excursions;

(k) Establish, maintain, and enforce a written action plan to ensure proper drug storage in the event of an emergency (i.e. power outage or natural disaster) that includes identification of backup storage and a procedure for transfer of product between units or facilities;

(l) Document the training of all pharmacy personnel on use of temperature monitoring system(s), quality assurance plan and written emergency action plan to ensure proper drug storage in the event of an emergency;

(m) Recalibrate temperature monitoring device(s) at least once every 24 months or per manufacturer specifications, whichever is more frequent;

(n) Document the following for each temperature excursion:

(A) Date of temperature excursion;

(B) Start and end time;

(C) Minimum and maximum temperatures reached;

(D) List of each drug involved in the temperature excursion including the drug name, quantity, National Drug Code, lot number, expiration date, manufacturer, and the date(s) of previous temperature excursions experienced by the drug(s);

(E) Each drug involved in the temperature excursion must be clearly labeled with the date of temperature excursion and any shortened expiration date if determined by the manufacturer; and

(F) Name of person(s) involved in responding to the temperature excursion event discovery and response;

(o) Before a drug that has experienced a temperature excursion is dispensed, the following items must be documented:

(A) Drug manufacturer information utilized indicating each drug is safe for use;

(B) Name of the representative providing the information;

(D) Copy of information and case number if provided by manufacturer;

(E) Date and time information was obtained from manufacturer;

(F) Reference number associated with manufacturer contact;

(G) Name of the Oregon licensed pharmacist that reviewed the manufacturer data and confirmed the drug safe for continued use; and

(H) In the absence of (B) and (C), documentation of a drug manufacturer online reference that applies to the specific temperature excursion, documentation of this reference must be maintained; and

(p) Have at least one accurate and calibrated back-up buffered temperature probe.

(q) In case the device in use breaks or malfunctions, place a back-up buffered temperature probe in the storage unit to determine the temperature

(r) Maintain all records required by OAR 855-139-0032 for a minimum of three years.

Statutory/Other Authority: ORS 689.205, ORS 689.325
Statutes/Other Implemented: ORS 689.155

Oregon Board of Pharmacy

Budget Report: October 2021 (Month 4)

Revenue:

Through October, revenue is $1,810,463 (19.5%) **over** budget

Expenditures:

Through October, **total expenditures** are $1,550,219 (16%) **under** budget

Personal services are $1,036,943 (4.0%) **under** budget

Services and Supplies are $513,276 (-3.6%) **over** budget

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

Revenues less Expenditures: $247,797

Cash Balance:

Cash balance through October is $4,714,145 which represents (12.62 months of operating expense)

Note: This the above is a snap-shot of the biennium to date through October 2021. It does not include projections for the remainder of the biennium.

End of biennium estimated cash balance is $6,146,445, which represents (15.87 months of operating expense*)

Cash balance target is $2,323,077, (6.0 months of operating expense)

*Note: The end of biennium estimated 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 OCTOBER 2021				
		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	10,399,733.00	(1,683,233.00)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	271,314.00	(78,319.00)
505	FINES AND FORFEITS	410,000.00	380,544.23	29,455.77
605	INTEREST AND INVESTMENTS	131,250.00	58,617.92	72,632.08
975	OTHER REVENUE	84,335.00	57,517.00	26,818.00
	TOTAL REVENUE	**9,535,080.00**	**11,167,726.15**	**(1,632,646.15)**
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	443,120.00	-
	TOTAL TRANSFER OUT	**443,120.00**	**443,120.00**	**0.00**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,092,836.00	4,130,411.54	(37,575.54)
3160	TEMPORARY APPOINTMENTS	27,306.00	-	27,306.00
3170	OVERTIME PAYMENTS	-	562.89	(562.89)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	198,616.00	249,679.37	(51,063.37)
3210	ERB ASSESSMENT	1,276.00	1,262.40	13.60
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	728,465.00	775,440.09	(46,975.09)
3221	PENSION BOND CONTRIBUTION	246,725.00	240,341.44	6,383.56
3230	SOCIAL SECURITY TAX	319,688.00	326,496.62	(6,808.62)
3240	UNEMPLOYMENT ASSESSMENT	-	-	-
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	1,004.59	7.41
3260	MASS TRANSIT	25,912.00	26,068.43	(156.43)
3270	FLEXIBLE BENEFITS	841,104.00	776,125.15	64,978.85
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,482,940.00**	**6,527,392.51**	**(44,452.51)**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	16,911.23	98,982.77
4125	OUT-OF-STATE TRAVEL	17,024.00	1,032.87	15,991.13
4150	EMPLOYEE TRAINING	22,320.00	14,705.45	7,614.55
4175	OFFICE EXPENSES	134,566.00	78,514.58	56,051.42
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	60,819.02	(9,889.02)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	202,527.60	13.40
4250	DATA PROCESSING	318,678.00	363,554.87	(44,876.87)
4275	PUBLICITY & PUBLICATIONS	43,329.00	15,417.97	27,911.03
4300	PROFESSIONAL SERVICES	339,713.00	227,849.28	111,863.72
4315	IT PROFESSIONAL SERVICES	134,467.00	48,000.00	86,467.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	861,829.68	(239,994.68)
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	4,105.00	1,313.00
4425	FACILITIES RENT & TAXES	229,042.00	281,353.92	(52,311.92)
4475	FACILITIES MAINTENANCE	55.00	-	55.00
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	1,000.00	202.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	198,679.07	51,799.93
4650	OTHER SERVICES AND SUPPLIES	411,285.00	400,563.50	10,721.50
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	10,000.00	4,108.00
4715	IT EXPENDABLE PROPERTY	45,228.00	26,195.35	19,032.65
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,813,059.39**	**145,735.61**
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	**9,463,698.00**	**9,340,451.90**	**123,246.10**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,308,114**	**6,098,300**	
	End of biennium projected cash balance in months		15.67	
	Cash balance target of 6.0 months (working capital)		2,335,113	

DECEMBER 2021/ E

ANNUAL 5 YEAR LEGISLATIVE RULE REPORT FOR RULES ADOPTED IN 2016

12/2021

OUR MISSION

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.

ORS 183.405 AGENCY REVIEW OF RULES; REPORT BY SOS

REQUIRED FOR NEW RULES ONLY NO LATER THAN 5 YEARS AFTER ADOPTION

DOESN'T APPLY TO:

- **RULES IN EXISTENCE AS OF 1/1/2006**
- **AMENDMENTS OR REPEAL OF RULE**
- **RULES ADOPTING A FEDERAL LAW OR RULE BY REFERENCE**
- **RULES ADOPTED TO IMPLEMENT LEGISLATIVELY APPROVED FEE CHANGES**
- **RULES ADOPTED TO CORRECT ERRORS OR OMISSIONS (SMCS)**
  - **The APA (Administrative Procedures Act) does not require an agency to engage in any particular process when new rules are reviewed but must produce a "report" and a copy of the report must be provided to SOS.**

Agencies are not required to take any particular action in response to the findings in the report but may use the information from the report to amend or repeal rules in appropriate cases.

REQUIRED IN THE REPORT

- **Whether the rule has had the intended effect;**
- **Whether the anticipated fiscal impact of the rule was underestimated or overestimated;**
- **Whether subsequent changes in the law require that the rule be repealed or amended;**
- **Whether there is continued need for the rule; and**
- **What impacts the rule has on small businesses.**
- **Was there a RAC?**

2016 RULES TO BE REVIEWED

UNPROFESSIONAL CONDUCT	COMMUNITY HEALTH CLINIC (CHC)	NALOXONE
OAR 855-006-0020	**OAR 855-043-0700,0705,0710,0715, 0720,0725,0730,0735, 0740,0745,0750**	**OAR 855-019-0460 & OAR 855-041-2340**
Adopted 6/2016	Adopted 6/2016	Adopted 6/2016

UNPROFESSIONAL CONDUCT

- Had the intended effect?
- Anticipated fiscal impact under or over estimated?
- Changes in the law require the rule to be repealed or amended?
- Continued need for the rule?
- What impacts the rule has on small business?
- Was there a RAC?

This rule is not technically a new rule, it was relocated from OAR 855-006-0005 Definitions and adopted as OAR 855-006-0020 in 2016, without any additional amendments.

Because it is listed on the Secretary of State's website as a newly adopted rule in 2016, we will add the statement above to the report for transparency.

- Board staff agreed that there is a continued need for the rule.
- One suggestion received from board staff – "maybe amend rule and add that threatening/abusive behavior toward Board members or Board staff when performing their duties"

COMMUNITY HEALTH CLINIC (CHC)

- Had the intended effect?
- Anticipated fiscal impact under or over estimated?
- Changes in the law require the rule to be repealed or amended?
- Continued need for the rule?
- What impacts the rule has on small business?
- Was there a RAC?

- Yes, had the intended effect. Proposed rules in Division 043 combine two very similar rules and eliminate the need for an outlet to register as both a Family Planning Clinic and County Health Clinic. These draft rules combine the drug formularies that are in the Family Planning and County Health Clinic rules.
- Changes needed: Suggest statutory review of statutory authority for rules and BOP authorizing RN to work beyond scope of BON licensure. Review and reconcile with DPDO.
- Yes, there is a continued need for these rules.

NALOXONE

Had the intended effect?

Anticipated fiscal impact under or over estimated?

Changes in the law require the rule to be repealed or amended?

Continued need for the rule?

What impacts the rule has on small business?

Was there a RAC?

- Yes, it had the intended effect. I think it has increased the availability of naloxone in a community pharmacy.
- Yes, it had the intended effect. I have prescribed naloxone in my practice of pharmacy. Provides additional opportunity to counsel on patient safety w/ opioid use
- There were subsequent changes to this law amending training requirements, possession, distribution, prescribing, recordkeeping, and counseling: BP 11-2019, amend filed 12/20/2019, effective 12/20/2019, BP 2-2018, amend filed 06/15/2018, effective 06/19/2018, BP 11-2017, temporary amend filed 12/29/2017, effective 12/29/2017 through 06/26/2018, BP 5-2017, amend filed 12/22/2017, effective 12/26/2017
- Changes in the rule: Consider 855-019-0460(7) and clarifying re-distribution/distribution, corresponding requirements for this to occur
- Changes in the rule: I think (1)(a) should reduce MME as certain patients (ex/pediatric) may not reach 50 MME but still be at risk. Statute requires MME or I'd remove it. Also maybe add minimum expiration date for dispensed product (6 or 12 months?)
- Yes there is continued need for the rule, but I would like to see all RPH prescribing requirements be brought into a single place in our rules as they are scattered across div 019, 041 and 020.
- Yes there is continued need for the rule, ORS 689.681, ORS 689.682, ORS 689.684, ORS 689.686
- Yes there is continued need for the rule, this access can save lives!

NEXT STEPS & QUESTIONS

- AGENCY WILL SUBMIT REPORT BY 12/31/2020 TO SECRETARY OF STATE
- SOS SENDS REPORT TO LEGISLATIVE ASSEMBLY BY 2/1/2021