Oregon Board of Pharmacy
REVISED BOARD MEETING AGENDA
Meeting Location: Virtual
April 13-15, 2022

Public Attendance: Audio only (503) 446-4951 Phone Conference ID: 720 115 968#

Click here to join virtually: April 13-15 2022 Board Meeting via Teams
***You do not need to have a Microsoft account to join the Teams meeting, however if you use a smartphone or tablet, you may need to download the Teams app.**

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, April 13, 2022 @ 8:30AM
Thursday, April 14, 2022 @ 8:30AM
Friday, April 15, 2022 @ 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 4/15/2022**.

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, April 13, 2022

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 192.660(1)(2)(f)(L), ORS 192.690(1) ORS 676.165, ORS 676.175.
- a. Legal Advice
- b. Deliberation on Disciplinary Cases and Investigations
- c. Contested Case Deliberation *if applicable

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

Adjourn *Action Necessary*

THURSDAY, April 14, 2022

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

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

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

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

IV. GENERAL ADMINISTRATION

a. Rules
   i. Review Rulemaking Hearing Report & Comments – *Melvin* **#A** *Action Necessary*
   ii. Consider Adoption of Rules – *Melvin*
      1. **Div 006/041/139** - related to Definitions **#B** *Action Necessary*
      2. **Div 020** - COVID-19 Antigen Self-Test Protocol **#B1, B1a** *Action Necessary*
      3. **Div 020/041/065/139** - Alarm, Audiovisual Communication, Entry & Surveillance Systems **#B2** *Action Necessary*
      4. **Div 021/025/110** – PT/COPT Licensure **#B3** *Action Necessary*
      5. **Div 041** - Disclosure of Patient Information **#B4** *Action Necessary*
      6. **Div 041/139** - Accurate Pharmacy Hours/Temporary Pharmacy Closures **#B5** *Action Necessary*
      7. **Div 041/139** - Drug Storage **#B6** *Action Necessary*
      8. **Div 080** - Schedule I Exceptions **#B7** *Action Necessary*
      9. **Div 143** - Pharmacy Prescription Lockers **#B8** *Action Necessary*
   iii. Rules in Development – *Davis*
   iv. Consider Adoption of Temporary Rules - *Davis*
      1. **Div 006/019/025/041** – 2022 HB 4034 PT/COPT Final Verification **#C** *Action Necessary*
      2. **Div 080** – 2022 HB 4034 PSE/EPH Interns **#C1** *Action Necessary*
      3. **Div 041** – 2022 HB 4034 Telework **#C2** *Action Necessary*
      4. **Div 139** – 2022 HB 4034 RDSP **#C3** *Action Necessary*
   v. Rulemaking Policy Discussion Items – *Davis*
      1. **Div 006/019/025/041** – 2022 HB 4034 PT/COPT Final Verification **#D** *Action Necessary*
      2. **Div 080** – 2022 HB 4034 PSE/EPH Interns **#D1** *Action Necessary*
      3. **Div 041** – 2022 HB 4034 Telework **#D2** *Action Necessary*
      4. **Div 139** – 2022 HB 4034 RDSP **#D3** *Action Necessary*
      5. **Div 006 031** – PHE Rules Sunset **#D4** *Action Necessary*
      6. **Div 006/019/041/139** – Interpreters **#D5** *Action Necessary*
      7. **Div 020** – Tobacco Cessation & PrEP **#D6, D6a, D6b** *Action Necessary*
      8. **Div 041/139** – Permanent Pharmacy Closure **#D7** *Action Necessary*
      9. **Div 110** – Fees RDSP & PPLs **#D8** *Action Necessary*
      10. **Div 006/041/043/045/080/139** – Adopted Standards by Reference **#D9** *Action Necessary*
      11. **Div 143** – PPL Procedure Rule Review *Action Necessary*

FRIDAY, April 15, 2022

I. OPEN SESSION, Wassim Ayoub RPh, Presiding

a. Roll Call

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

III. GENERAL ADMINISTRATION CONTINUED – Rulemaking Policy Discussion Items

b. Discussion Items

i. Public Health and Pharmacy Formulary Advisory Committee – *Davis*

ii. RAC/Workgroup Updates – *Davis*

1. Safe Pharmacy Practice Conditions Workgroup
2. Safe Pharmacy Practice Conditions Survey Results

iii. Contraception CE Programs– *Davis*

iv. Legislative Update – *Schnabel* **#F**

v. COVID-19 Update – *Schnabel*

vi. Strategic Plan Update – *Schnabel* **#G** *Action Necessary*

vii. Financial/Budget Report – *MacLean*

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

2022 Board Meeting Dates – *Schnabel*

• June 8-10, 2022	Portland	
• August 10-12, 2022	Portland	
• October 12-14, 2022*	Portland	
• November 10, 2022	TBA	(Strategic Planning)
• December 14-16, 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.)

- May 24, 2022
- November 22, 2022

Upcoming Conferences/Meetings – *Schnabel*

1. OSHP 2022 Annual Seminar – April 22-24, 2022 @ Sunriver Resort, Sunriver, OR

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 – February 2022 **# 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: March 29, 2022
To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: March 29, 2022

Hearing Location: Virtual via Teams

Proposed Rules:

- Divisions 006/041/139 - related to Definitions
- Division 020 - related to COVID-19 Antigen Self-Test Protocol
- Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems
- Divisions 021/025/110 - related to Pharmacy Technician & Certified Oregon Pharmacy Technician Licensure
- Division 041- related to Disclosure of Patient Information
- Divisions 041/139 - related to Accurate Pharmacy Hours & Temporary Pharmacy Closures
- Divisions 041/139 - related to Drug Storage
- Division 080 - related to Schedule I Exceptions
- Division 143 - related to Pharmacy Prescription Lockers (PPLs)

The rulemaking hearing on the proposed rules was convened at 9:30AM. There were four oral comments provided during the hearing and 32 written comments were received via pharmacy.rulemaking@bop.oregon.gov. The hearing adjourned at 10:00AM. 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 Joyce
Board Member Vipperman
Staff Member Ball
Staff Member Davis
Staff Member Efremoff
Staff Member Hennigan
Staff Member Melvin
Staff Member Schnabel

Summary of Oral Testimony

RULES PROPOSED: Definitions
AMEND: OAR 855-006-0005, OAR 855-041-1001 & OAR 855-139-0005.

- No oral testimony was provided.

RULES PROPOSED: COVID-19 Antigen Self-Test Protocol
AMEND: OAR 855-020-0300

- No oral testimony was provided.

RULES PROPOSED: Alarm, Audiovisual Communication, Entry & Surveillance Systems
AMEND: OAR 855-020-0110, OAR 855-041-1020, OAR 855-041-3220, OAR 855-041-3230, OAR 855-041-3235, OAR 855-041-3240, OAR 855-041-3245, OAR 855-041-3250, OAR 855-041-5055, OAR 855-041-6410, OAR 855-065-0012, OAR 855-139-0100, OAR 855-139-0210, OAR 855-139-0215, OAR 855-139-0230 & OAR 855-139-0550.

- No oral testimony was provided.

RULES PROPOSED: Pharmacy Technician & Certified Oregon Pharmacy Technician Licensure
AMEND: OAR 855-021-0009, OAR 855-025-0005, OAR 855-025-0010, OAR 855-025-0012, OAR 855-025-0015, OAR 855-110-0003 & OAR 855-110-0005.

ADOPT: 855-025-0011
REPEAL: 855-025-0060

- Senator Deb Patterson, District 10, Chair/Senate Health Care Committee is in strong support of making licensure accessible to entry level applicants, but also meet national standards. A 1-year limit on non-renewable PT licensure incentivizes a pharmacy technician to become Certified Oregon Pharmacy Technician, which meets national standards. Removing this requirement removes the incentive, which is needed to ensure that safety and national standards are met. Reducing continued education will result in a lower quality of care for Oregon patients. Agrees, we must increase access to the pharmacy technician profession but need to ensure the safety to patients and national standards are met.

- Madison Walters, UFCW 555, the largest labor union in Oregon, which includes pharmacy technicians. She is opposed to proposed rule changes because a renewable technician license will erode care and result in lowering the national standards. The PT license is good for entry level and 1-year limit creates incentive to become COPT. Removing the incentive and leads to lower level of education and lower level of care. 20 hours of continuing education is vital to keeping up to date. An increased CE requirement for initial licensure creates an additional administrative burden, suggests retaining pharmacy technician license as non-renewable and removing CE requirements.

RULES PROPOSED: Disclosure of Patient Information
AMEND: OAR 855-041-1055

- No oral testimony was provided.

RULES PROPOSED: Accurate Pharmacy Hours & Temporary Pharmacy Closures
AMEND: OAR 855-041-1015, OAR 855-041-1035 & OAR 855-139-0155

ADOPT: 855-041-1092. 855-139-0145

- No oral testimony was provided.

RULES PROPOSED: Drug Storage
AMEND: OAR 855-041-1036 & OAR 855-139-0125

- Natalie Gustafson, Lloyd Central Compounding Pharmacy, appreciates goal of proposed rules, patient safety is paramount, believes there are unintended consequences like restricted patient access, conflict with USP 797 & 659. Global supply chain crisis, challenges to replace drugs or receive answers from manufacturer. No variation between fridge and freezer storage- they are different in USP chapter and treated differently. Also difference in cold temperature vs room temperature. For controlled room temperature there is more temperature flexibility. Provided examples of how room temperatures are kept lower in compounding pharmacies related to different ISO rooms. Requests allotment related to room temperature excursions, inventory destruction could be costly and challenging and room temperature continuous monitoring is challenging.

RULES PROPOSED: Schedule I Exceptions
AMEND: OAR 855-080-0021

- No oral testimony was provided.

RULES PROPOSED: Pharmacy Prescription Lockers (PPLs)
ADOPT: OAR 855-143-0001, OAR 855-143-0005, OAR 855-143-0010, OAR 855-143-0015, OAR 855-143-0020, OAR 855-143-0025, OAR 855-143-0030, OAR 855-143-0050, OAR 855-143-0100, OAR 855-143-0120, OAR 855-143-0125, OAR 855-143-0130, OAR 855-143-0150, OAR 855-143-0155, OAR 855-143-0200, OAR 855-143-0205, OAR 855-143-0210, OAR 855-143-0215, OAR 855-143-0220, OAR 855-143-0225, OAR 855-143-0345, OAR 855-143-0500, OAR 855-143-0550, OAR 855-143-0600, OAR 855-143-0602 & OAR 855-143-0650.

- Sara Lake, Asteres commends the board for bringing rules forward. Asteres has had lockers in place since 2005, doing business in 33 states. 4 million prescriptions delivered, no diversion or break in attempts that she is aware of. Would like the board to consider allowing signage to be

configured and located on the screen of the locker that the patient interacts with vs. posting physically on the locker, consider allowing controlled substances for only hospital licensed pharmacies to allow CS in lockers for patients who are discharged and for hospital staff to utilize while the pharmacy is closed. The DEA does view lockers as an extension of their pharmacy DEA registration. Arizona has an issue in their statutes. Ohio is the only other state that has surveillance data retention requirements, asking board to consider 30 days for surveillance data retention, if issues pop-up such as patient didn't get their prescription from the locker, the pharmacy will be notified, return to stock occurs within 14 days and data can be tagged if any issues.

All written comments received by the public comment deadline date of 3/29/2022 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 2/23/2022 Notice of Proposed Rulemaking which was sent to rulemaking interested parties via GovDelivery email and USPS mail as applicable. All rulemaking notices in tracked changes were posted on board's website.

March 18, 2022

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

Re: Drug Storage Requirements 855-139-1036 and 855-139-0125

Dear Dr. Schnabel:

As you know, the Albertsons Companies Inc. ("ACI") 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."

ACI has grave concerns with the continued trend of overly prescriptive regulations, which are increasing the cost to operate a community retail pharmacy by increasing administrative burden required of pharmacy staff. These draft regulations are not unlike the recently approved telework regulations that have made it relatively impossible to support pharmacies from a remote unlicensed location, further exacerbating the significant staffing issues plaguing the industry within the state. These drug storage regulations have extensive unintended consequences that will lead to decreasing access to pharmacy services in a state that is still reeling from the recent closure of more than 40 BiMart pharmacies.

While the intention of these regulations is to ensure patients receive high quality pharmaceutical products that have not been compromised by extreme temperature excursions, they are overly prescriptive and further reaching than even universally accepted USP guidelines.[i] The established range for medication designated to be stored at room temperature according to USP is between 20º C and 25º C (68º F to 77º F) with excursions permitted between 15º C and 30º C (59º F to 86º F). In fact, USP allows brief exposure of temperatures up to 40º C (104º F). The FDA even defers to these USP established standards, which means the Oregon Board of Pharmacy is attempting to hold pharmacies to an even higher standard than the FDA expects of manufacturers of the very medications that are stored in our pharmacies.[ii] Based on this data a temporary excursion to acceptable levels would not warrant reaching out to a manufacturer to verify stability and safety of a medication prior to dispensing to a patient.

While 5º on either side of a room temperature range may seem minor, the overly prescriptive actions that the Board of Pharmacy requires a pharmacist to follow in the aftermath of an excursion are unnecessary and overly burdensome, which, in our experience, will result in unnecessary medication waste when even a manufacturer in unable to supply sufficient evidence to a Board Inspector's subjective standards that the medicine was safe to dispense to a patient. Our experience has shown that even medical grade refrigerators and freezers can briefly result in excursions just by accessing the unit frequently to stock or remove medication. When you consider the increased inefficiency of a commercial HVAC system, there will be variability in the ambient temperature of the pharmacy. The Oregon Board of Pharmacy requires continuous temperature monitoring which is defined as measuring the temperature at least every 15 minutes. The frequency of measurement results in identifying even a minor excursion lasting less than 15 minutes. This, in turn, requires an unnecessary investigation of each excursion to validate what we already know: the medication is safe to dispense. Minor natural variations in temperature are much different than a prolonged extreme excursion, which has been proven to degrade the stability of a medication and are not treated as minor. Not differentiating between a minor excursion in the same fashion as USP leads to unnecessary labor and administrative burden that should be reserved only for extreme excursions that have been proven to lead to degradation of medication active ingredients or expirations dates.

If there is an excursion experienced outside of the very narrow 20º C and 25º C (68º F to 77º F) range for medications stored at room temperature, these regulations will require the pharmacist to call each and every manufacturer to verify the medication is safe to dispense to a patient, document the evidence provided by the manufacturer, retention of a copy of the information provided by the manufacturer, and the reference number associated with manufacturer contact. This is an exhaustive lengthy process for the limited number of medications that would be contained within a refrigerator and, quite frankly, impossible to do for the thousands of medications that could be on the shelf of a standard community retail pharmacy at room temperature. We are concerned that these requirements have the potential to close a pharmacy for days to weeks while they perform this exhaustive analysis of their inventory following even a minor excursion resulting from the pharmacy reaching an ambient temperature of 26º C, which is 1º above the required range. The disruption to patient care outweighs the unlikely degradation of a medication subjected to a 1º deviation from acceptable ranges for less than 15 minutes. Pharmacies are already having to close temporarily due to the inability to staff them. This will only exacerbate the issue.

As mentioned, the pharmacy industry is suffering from an unprecedented staffing crisis throughout the country and in Oregon. Under these regulations as written, continuous temperature monitoring will be required to ensure proper storage during transfers between facilities and delivery to patients. This added cost may force pharmacies away from central fill support and may potentially require pharmacies to discontinue the home delivery option to patients. This will shift the work back into the dispensing pharmacy, resulting in an even larger gap in staffing to cover the needs of our Oregon patients. Additionally, minimizing home delivery will lead to increased pharmacy access issues for underserved home bound patients. Worst case scenario is that these regulations will cause additional pharmacy closures like BiMart, which will invariably further stress the market.

We cannot afford to regulate the practice of community pharmacy into nonexistence. For this reason, we ask that the Board consider rescinding these proposed regulations. Furthermore, we would recommend the

Board consider revising the temperature monitoring requirements to remove all continuous temperature monitoring and burdensome documentation requirements.

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

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[i] U.S. Pharmacopeia. <1079> Good storage and shipping practices. http://ftp.uspbpep.com/v29240/usp29nf24s0_c1079.html. Accessed March 15, 2022.

[ii] FDA Expiration Dating and Stability Testing for Human Drug Products. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-technical-guides/expiration-dating-and-stability-testing-human-drug-products#:~:text=The%20USP%20defines%20controlled%20room,at%20or%20near%2030%20C. Accessed March 15, 2022.

From: Rob Geddes
To: PHARMACY RULEMAKING * BOP
Subject: Emailing: Drug Storage Regulations Comments Final 3-18-22
Date: Friday, March 18, 2022 8:59:02 AM
Attachments: Drug Storage Regulations Comments Final 3-18-22.pdf

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Rachel,

Please accept my comments in advance of the 3/29/22 public hearing on the proposed Drug Storage regulations.

Rob Geddes, PharmD
Director, Pharmacy Legislative and Regulatory Affairs
Albertsons Companies, Inc.
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Rob.Geddes@albertsons.com

Your message is ready to be sent with the following file or link attachments:

Drug Storage Regulations Comments Final 3-18-22

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

March 25, 2022

Via email to: pharmacy.rulemaking@bop.oregon.gov

Joe Schnabel
Executive Director
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

Re: Oregon Board of Pharmacy — Notice of Proposed Rule Making, Chapter 855 Board of Pharmacy, Establishes New Registration for Pharmacy Prescription Lockers (PPLs)

Dear Mr. Schnabel:

I am writing on behalf of Asteres Inc. ("Asteres") to express support of the Oregon Board of Pharmacy's (the "Board") proposed rule, which establishes Pharmacy Prescription Lockers ("PPL") as a new drug outlet type, sets requirements for the operation of a PPL by a PPL Affiliated Pharmacy. We thank the Board for recognizing the patient care benefits associated with this type of technology and appreciate the opportunity to provide the following comments for the Board's consideration.

Background

Asteres® is the industry leader in 24/7 pharmacy automated storage and delivery systems, which are used by pharmacies to facilitate patient access to prescription medications which have already been prepared for dispensing by community and health system pharmacies. Its product, the ScriptCenter®, has safely and securely delivered more than 4 million prescriptions in 33 states across the country. The Asteres ScriptCenter has been used by patients in a variety of settings including retail pharmacies, healthcare facilities, clinics, corporate sites, and governmental locations.

Although we believe the proposed regulations appropriately address automated storage and delivery systems, there are a few sections that we believe require clarification or minor revisions, as follows.

Proposed Section 855-143-0210 - Clarification of Destocking Requirements

The term "destock" is used throughout the proposed regulation, but that term is not defined. For example, proposed section 855-143-0210 provides that a PPL and its PPL Affiliated Pharmacy must ensure that an Oregon licensed Pharmacist verifies and documents that all prescription and

non-prescription drugs, devices, and related supplies destocked from the PPL are returned to the PPL Affiliated Pharmacy. We have no issues with this language but are seeking confirmation that destocked drugs can be returned to stock at the Affiliated Pharmacy.

Specifically, we are concerned that language contained in Or. Admin. R. 855-041-1045(2), which states that a pharmacy may only accept returns in limited circumstances, and then only for purposes of destruction or disposal, may be conflated with the concept of destocking, and could be interpreted as requiring that destocked drugs be destroyed or disposed of by the Affiliated Pharmacy. We believe that the intent of the destock provision in the proposed rule is to treat drugs that are placed in a PPL as no different from drugs that are placed in the will call bin at a pharmacy, and if not picked up by the patient, can be returned to stock.

We request that the Board consider adding commentary to the record confirming that destocking is not considered to be the return to the pharmacy, and that destocked drugs may be returned to stock at the Affiliated Pharmacy. Alternatively, we request that proposed section 855-143-0210 be revised to add a new paragraph (4), as follows:

855-143-0210

Outlet: Supervision

A PPL and its PPL Affiliated Pharmacy must:

(1) Ensure prescription and non-prescription drugs, devices, and related supplies are only dispensed at the PPL if an Oregon licensed Pharmacist is available for patient consultation and the PPL is fully operational.

(2) Ensure that stocking and destocking of prescription and non-prescription drugs, devices, and related supplies in a PPL is completed under the supervision, direction and control of a pharmacist.

(3) Ensure that an Oregon licensed Pharmacist verifies and documents that:

(a) All prescription and non-prescription drugs, devices, and related supplies were correctly stocked into the PPL;

(b) All prescription and non-prescription drugs, devices, and related supplies destocked from the PPL were returned to the PPL Affiliated Pharmacy;

(c) Proper storage conditions were maintained during transfer per OAR 855-143-0125; and

(d) Records are maintained per OAR 855-143-0550.

(4) Drugs and devices destocked from a PPL that satisfy the requirements of this section may be returned to stock at the Affiliated Pharmacy.

Information Required to be Displayed on the PPL – Proposed Section 855-143-0155

Proposed section 855-143-0155(c) requires a significant quantity of text to be displayed on or at the location of a PPL. Although we agree that all of the information required is important for a patient to know, we believe that having signage surrounding the area of a PPL may not be the most effective way to communicate important information to a patient and propose that an alternative method of conveying the information, such as on a digital screen that the patient would be required to interact with before the PPL releases a medication, would be more effective.

When a patient approaches a pharmacy counter for the specific purpose of picking up a prescription medication, it is logical to place signage at the counter, since that is where the patient's attention will be directed at the time of dispensing. However, signage placed at or near, or as stated in the proposed regulation, "in a location easily seen by the public", may be missed by a patient who is interacting with the PPL for purposes of picking up a medication. We believe that some of the information required by the proposed regulation to be placed in signs that are visible to the *public*, would be more effectively communicated to a *patient* if displayed on such a screen. First, when a patient is at the screen, it is for the sole purpose of obtaining pharmacy services, and the information conveyed at that point is more likely to be effectively communicated to and received by the patient. Also, when a PPL is deployed in a clinic, or at a hospital, pharmacy specific signage placed near the PPL could compete for the patient's attention with other signage posted by the clinic or health system that are unrelated to the provision of pharmacy services.

We propose the following revisions to proposed section 855-143-0155(1)(c):

855-143-0155

Outlet: Minimum Equipment Requirements

(1) Each Oregon PPL must have the following:

* * * *

(c) Signage in a location easily seen by the public at the PPL where prescription and non-prescription drugs, devices, and related supplies are dispensed:

(A) Stating "The (insert name of PPL Affiliated 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 855-143-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Stating "This location is a Pharmacy Prescription Locker, supervised by an Oregon licensed Pharmacist from (insert name of PPL Affiliated Pharmacy, address, and telephone

number)." The printing on the sign must be in block letters not less than one inch in height; and

(D) Providing notification of accurate hours of operation at the PPL; and

(d) Additional equipment and supplies that are determined as necessary by the PPL Affiliated Pharmacy or PIC.

(e) As an alternative to posting the required signage, PPL's that utilize an electronic video monitor that the patient is required to interact with prior to retrieving medication from the PPL may display the information required by sub-paragraphs (A) – (D) electronically.

Delivering Controlled Substances from the PPL

As written, the proposed regulations prohibit using a PPL to deliver controlled substances to a patient. However, in certain settings, such as in a hospital that may choose to utilize PPL technology to deliver discharge medications to a patient following discharge, or in a hospital emergency department, a blanket prohibition against allowing delivery of controlled substances would interfere with the utility of the device.

Additionally, we believe that delivery of medications, including controlled substances, presents a safer and more secure method of delivering controlled substances when compared to leaving medication in a mailbox, delivery to a P.O. Box, or leaving a medication at a reception desk at a patient's home or place of business. All of those methods of delivery are presently allowed under Oregon law. Further, there is no reason to prohibit the use of a PPL to deliver controlled substances if the federal Drug Enforcement Administration ("DEA") allows it, particularly in locations that hold a DEA registration such as hospitals, or as an extension of the registration held by a DEA registrant.

We request the Board to consider revising the language in 855-143-0010, 855-143-0225, and 855-143-0225 to remove the prohibition against using a PPL to deliver controlled substances. Alternatively, we propose that the Board modify the language to state that controlled substances are prohibited "unless authorized by the U.S. Drug Enforcement Administration".

PPL Alarm Requirements - Proposed Section 855-143-0100

The proposed regulations require an alarm at the PPL to provide notification of unauthorized access. Rather than using an alarm (which suggests an audible method of alerting persons at or near the device), PPL-type technology presently in use across the country, including the Asteres ScriptCenter, utilize physical security measures, controls to prevent unauthorized access, and an alert functionality that ensures that instances of unauthorized access are communicated to appropriate personnel in real-time. We propose that the alarm requirement be revised to allow for this type of technology. Specifically, we propose the following revision:

855-143-0100

Security

(7) Minimum security methods must include a properly functioning:

(a) Alarm system at the PPL and real-time notification to an Oregon licensed Pharmacist of the PPL Affiliated Pharmacy if unauthorized access occurs**, or an alternative method of ensuring real-time alerts of unauthorized access to appropriate personnel.**

Surveillance System Data Storage – Proposed Regulation 855-143-0500

Proposed regulation 855-14-0500 as written requires storage of surveillance system data to be retained for six months. Storing surveillance data for that long of a period of time creates burdens that in our view are not necessary to protect the public. The need to retrieve information captured through a surveillance system would be apparent soon after, or at the longest, a few days after an event occur at the PPL that requires further investigation, including unauthorized access, a dispensing error, some other irregularity. Once retrieved, that information can be retained as long as needed to assist with the investigation. The costs associated with data storage, and the capacity to store such data for 6 months, could prove to be cost-prohibitive.

Requiring the PPL Affiliated Pharmacy to retain six months of surveillance system data is overly burdensome and extremely cost inefficient. Because prescriptions housed in the PPL are patient specific with pre-set Return to Stock timeframes of typically 7-10 days, it is our opinion that any unauthorized access, errors, or irregularities would be discovered within two weeks. The record requirements for retaining data and surveillance system data could be shortened to 30 days. We propose the following revision to the surveillance data retention requirement:

855-143-0500

Records: General Requirements

(3) Records retained by the PPL Affiliated Pharmacy must include, but are not limited to:

(f) Data and surveillance system data must be retained for **30 days. When an Affiliated Pharmacy becomes aware of an incident that requires review of surveillance data, the pharmacy must retain the data related to that incident until such time as an investigation into the incident has been completed.**

Again, we appreciate the opportunity to submit these comments for Board consideration. We will be available at the March 29 Board meeting to discuss these comments further and look forward to continuing to work with the Board on this and all future matters.

Respectfully,

Sara Lake
Director of Regulatory

From:	Sara Lake
To:	PHARMACY RULEMAKING * BOP
Cc:	Jeff Pinson
Subject:	Division 143 - Comments related to Pharmacy Prescription Lockers (PPLs)
Date:	Friday, March 25, 2022 1:57:49 PM
Attachments:	image001.png Asteres PPL Comments 3-25-22.pdf

Dear Mr. Schnabel:

I am writing on behalf of Asteres Inc. ("Asteres") to express support of the Oregon Board of Pharmacy's (the "Board") proposed rule, which establishes Pharmacy Prescription Lockers ("PPL") as a new drug outlet type, sets requirements for the operation of a PPL by a PPL Affiliated Pharmacy. We thank the Board for recognizing the patient care benefits associated with this type of technology and appreciate the opportunity to provide the following comments for the Board's consideration.

Background

Asteres® is the industry leader in 24/7 pharmacy automated storage and delivery systems, which are used by pharmacies to facilitate patient access to prescription medications which have already been prepared for dispensing by community and health system pharmacies. Its product, the ScriptCenter®, has safely and securely delivered more than 4 million prescriptions in 33 states across the country. The Asteres ScriptCenter has been used by patients in a variety of settings including retail pharmacies, healthcare facilities, clinics, corporate sites, and governmental locations.

Although we believe the proposed regulations appropriately address automated storage and delivery systems, there are a few sections that we believe require clarification or minor revisions, as follows.

Proposed Section 855-143-0210 - Clarification of Destocking Requirements

The term "destock" is used throughout the proposed regulation, but that term is not defined. For example, proposed section 855-143-0210 provides that a PPL and its PPL Affiliated Pharmacy must ensure that an Oregon licensed Pharmacist verifies and documents that all prescription and non-prescription drugs, devices, and related supplies destocked from the PPL are returned to the PPL Affiliated Pharmacy. We have no issues with this language but are seeking confirmation that destocked drugs can be returned to stock at the Affiliated Pharmacy.

Specifically, we are concerned that language contained in Or. Admin. R. 855-041-1045(2), which states that a pharmacy may only accept returns in limited circumstances, and then only for purposes of destruction or disposal, may be conflated with the concept of destocking, and could be interpreted as requiring that destocked drugs be destroyed or disposed of by the Affiliated Pharmacy. We believe that the intent of the destock provision in the proposed rule is to treat drugs that are placed in a PPL as no different from drugs that are placed in the will call bin at a pharmacy, and if not picked up by the patient, can be returned to stock.

We request that the Board consider adding commentary to the record confirming that destocking is not considered to be the return to the pharmacy, and that destocked drugs may be returned to stock at the Affiliated Pharmacy. Alternatively, we request that proposed section 855-143-0210 be revised to add a new paragraph (4), as follows:

855-143-0210

Outlet: Supervision

A PPL and its PPL Affiliated Pharmacy must:

(1) Ensure prescription and non-prescription drugs, devices, and related supplies are only dispensed at the PPL if an Oregon licensed Pharmacist is available for patient consultation and the PPL is fully operational.
(2) Ensure that stocking and destocking of prescription and non-prescription drugs, devices, and related supplies in a PPL is completed under the supervision, direction and control of a pharmacist.
(3) Ensure that an Oregon licensed Pharmacist verifies and documents that:
(a) All prescription and non-prescription drugs, devices, and related supplies were correctly stocked into the PPL;
(b) All prescription and non-prescription drugs, devices, and related supplies destocked from the PPL were returned to the PPL Affiliated Pharmacy;
(c) Proper storage conditions were maintained during transfer per OAR 855-143-0125; and
(d) Records are maintained per OAR 855-143-0550.
(4) Drugs and devices destocked from a PPL that satisfy the requirements of this section may be returned to stock at the Affiliated Pharmacy.

Information Required to be Displayed on the PPL – Proposed Section 855-143-0155

Proposed section 855-143-0155(c) requires a significant quantity of text to be displayed on or at the location of a PPL. Although we agree that all of the information required is important for a patient to know, we believe that having signage surrounding the area of a PPL may not be the most effective way to communicate important information to a patient and propose that an alternative method of conveying the information, such as on a digital screen that the patient would be required to interact with before the PPL releases a medication, would be more effective.

When a patient approaches a pharmacy counter for the specific purpose of picking up a prescription medication, it is logical to place signage at the counter, since that is where the patient's attention will be directed at the time of dispensing. However, signage placed at or near, or as stated in the proposed regulation, "in a location easily seen by the public", may be missed by a patient who is interacting with the PPL for purposes of picking up a medication. We believe that some of the information required by the proposed regulation to be placed in signs that are visible to the *public*, would be more effectively communicated to a *patient* if displayed on such a screen. First, when a patient is at the screen, it is for the sole purpose of obtaining pharmacy services, and the information conveyed at that point is more likely to be effectively communicated to and received by the patient. Also, when a PPL is deployed in a clinic, or at a hospital, pharmacy specific signage placed near the PPL could compete for the patient's attention with other signage posted by the clinic or health system that are unrelated to the provision of pharmacy services.

We propose the following revisions to proposed section 855-143-0155(1)(c):

855-143-0155
Outlet: Minimum Equipment Requirements
(1) Each Oregon PPL must have the following:
* * * *
(c) Signage in a location easily seen by the public at the PPL where prescription and non-prescription drugs, devices, and related supplies are dispensed:
(A) Stating "The (insert name of PPL Affiliated 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 855-143-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

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

(D) Providing notification of accurate hours of operation at the PPL; and

(d) Additional equipment and supplies that are determined as necessary by the PPL Affiliated Pharmacy or PIC.

(e) <u>As an alternative to posting the required signage, PPL's that utilize an electronic video monitor that the patient is required to interact with prior to retrieving medication from the PPL may display the information required by sub-paragraphs (A) – (D) electronically.</u>

Delivering Controlled Substances from the PPL

As written, the proposed regulations prohibit using a PPL to deliver controlled substances to a patient. However, in certain settings, <u>such as in a hospital</u> that may choose to utilize PPL technology to deliver discharge medications to a patient following discharge, or in a hospital emergency department, a blanket prohibition against allowing delivery of controlled substances would interfere with the utility of the device.

Additionally, we believe that delivery of medications, including controlled substances, presents a safer and more secure method of delivering controlled substances when compared to leaving medication in a mailbox, delivery to a P.O. Box, or leaving a medication at a reception desk at a patient's home or place of business. All of those methods of delivery are presently allowed under Oregon law. Further, there is no reason to prohibit the use of a PPL to deliver controlled substances if the federal Drug Enforcement Administration ("DEA") allows it, particularly in locations that hold a DEA registration such as hospitals, or as an extension of the registration held by a DEA registrant.

We request the Board to consider revising the language in 855-143-0010, 855-143-0225, and 855-143-0225 to remove the prohibition against using a PPL to deliver controlled substances. Alternatively, we propose that the Board modify the language to state that controlled substances are prohibited "unless authorized by the U.S. Drug Enforcement Administration".

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855-143-0100

Security

(7) Minimum security methods must include a properly functioning:

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Surveillance System Data Storage – Proposed Regulation 855-143-0500

Proposed regulation 855-14-0500 as written requires storage of surveillance system data to be retained for six months. Storing surveillance data for that long of a period of time creates burdens that in our view are not necessary to protect the public. The need to retrieve information captured through a surveillance system would be apparent soon after, or at the longest, a few days after an event occur at the PPL that requires further investigation, including unauthorized access, a dispensing error, some other irregularity. Once retrieved, that information can be retained as long as needed to assist with the investigation. The costs associated with data storage, and the capacity to store such data for 6 months, could prove to be cost-prohibitive.

Requiring the PPL Affiliated Pharmacy to retain six months of surveillance system data is overly burdensome and extremely cost inefficient. Because prescriptions housed in the PPL are patient specific with pre-set Return to Stock timeframes of typically 7-10 days, it is our opinion that any unauthorized access, errors, or irregularities would be discovered within two weeks. The record requirements for retaining data and surveillance system data could be shortened to 30 days. We propose the following revision to the surveillance data retention requirement:

855-143-0500

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(f) Data and surveillance system data must be retained for **30 days. When an Affiliated Pharmacy becomes aware of an incident that requires review of surveillance data, the pharmacy must retain the data related to that incident until such time as an investigation into the incident has been completed.**

Again, we appreciate the opportunity to submit these comments for Board consideration. We will be available at the March 29 Board meeting to discuss these comments further and look forward to continuing to work with the Board on this and all future matters.

Respectfully,
Sara

Sara Lake
Director of
Communications and
Regulatory Affairs

O (858) 777-8608
M (858) 603-2608
www.asteres.com

4110 Sorrento Valley Blvd
San Diego, CA 92121

Dear Oregon Board of Pharmacy,

Please consider the following comments when evaluating the proposed rules changes to 855-139-0125:

1. Continuous temperature monitoring devices: The current rule, as proposed, is not well defined regarding the transportation of medication between the pharmacy and facility or patient destination.
    - *Financial impact*: If a mail order, or long-term care pharmacy were to be required to institute continuous temperature monitors for items in-transit, this would create not only a tremendous amount of increased logistical support required but would also impose undue economic hardship on these businesses. For example, our Long Term Care pharmacy has over 400 shipping totes, so using the thermometer cost example listed in the rule, $1,429 x 400 thermometers would be a potential cost of $571,600 for procurement on room temperature drugs. Because we often send a refrigerated package on roughly 60% of totes, this would be an additional 240 thermometers, bringing the grand total to $914,560 for procurement alone. This would not account for the annual service fees and man hour costs that would go along with the addition of probes.
    - *Suggestion*: Add an exception for items deemed in-transit, or outside of pharmacy licensed space, "855-041-1036 (1)(a)- Drug Outlet and PIC should ensure proper manufacturer storage conditions are maintained during the transporting of drugs outside of pharmacy licensed space, however continuous temperature monitoring is not required in this setting."

2. 855-139-0125 (3)(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."
    - This review of data is an unnecessary addition to the rule, as the continuous monitoring system is already required to notify pharmacist of each temperature excursion in real-time. These notifications, combined with the requirement to validate the alarm functionality on a quarterly basis is already sufficient to prevent inaction during excursions. The addition of this requirement would create unneeded daily documentation that would pull a pharmacist from important patient care tasks, without a realized safety benefit.
    - *Suggestion*: Recommend removing this item from the rule.

3. (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.
    - This is overly prescriptive and does not allow for any professional judgement regarding excursions. As it is currently written, a 15 MINUTE temperature deviation even 1 degree above 77F would be treated the same as a 12 HOUR excursion at 105F. Both would require an intensive amount of pharmacist labor to investigate, however one of these is far more clinically significant than the other. We have over 3800 NDCs located in our

pharmacy. Were we to need to contact every manufacturer for a 1 degree temperature excursion for 15 minutes, we would have a very difficult time delivering medications safely to our patients.

- *Suggestion*: Change to, "Ensure that drugs exposed to significant excursion outside of the manufacturer's drug storage requirements" to allow for pharmacists clinical judgement in determining when common sense deviations are allowable.

Thank you,

Zack Korstian

RPH-0014986

From:	Zack D Korstian
To:	PHARMACY RULEMAKING * BOP
Subject:	Comments Rule 855-139-0125
Date:	Monday, March 28, 2022 9:32:43 PM
Attachments:	Comments on Proposed Rule 855-139-0125.pdf

Dear Oregon Board,

Please see attached comment for Rule 855-139-0125.

Thank you for your consideration.

Zack Korstian, PharmD
Director of Pharmacy
Consonus Pharmacy, Oregon

—
p. 971-206-2067
f. 503-652-0383
e. zdkorstian@consonushealth.com

CVSHealth

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

March 23, 2022

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

Re: Proposed Rules of Divisions 025 related to Pharmacy Technician and Certified Pharmacy Technician Licensure, Division 006 related to Definitions, Division 041/139 related to Drug Storage, Division 143 related to Pharmacy Prescription Lockers (PPLs)

Dear Executive Director Schnabel:

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

Division 025 related to Pharmacy Technician and Certified Pharmacy Technician Licensure
CVS Health appreciates the Board's recognition of staffing challenges due to a lack of renewal or reinstatement allowances for a pharmacy technician. We support and applaud the Board's efforts to amend Division 025 to allow for renewal or reinstatement of a pharmacy technician license, which may help to alleviate staffing shortages that pharmacies in Oregon are currently facing.

Division 006 related to Definitions and Division 041/139 related to Drug Storage
CVS Health has concerns with the proposed definition of temperature excursion. The proposed definition includes a **singular** event in which a drug is exposed to a temperature outside of a manufacture's required storage conditions. One event could include a door being open for stocking of new product, which does not lead to product degradation. The extent of physicochemical degradation of drug products depends on factors such as product stability, how a product is stored, and how it is packaged with temperatures likely to vary during the life of the product. The only true measurement to account for varying temperatures during the life of the product is Mean Kinetic Temperature ("MKT"), which defined as the single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures. Exclusion of the consideration of MKT in the proposed definition is concerning. MKT should be considered and used in evaluating and identifying the proper management of an excursion, as recommended by USP-NF Chapter 659. Therefore, we request the Board continue discussion on the definition of temperature excursion to include USP recommendations of evaluation of product degradation using MKT, which considers temperature **and time** of excursion to determine product degradation versus **one singular event**.

We are also concerned with the amendments to Division 41 and 139 related to drug storage, which utilize the definition of "temperature excursion." Pharmacies are currently required to use a temperature monitoring system that must be measured continuously and manually documented twice daily or be equipped with an automated system capable of producing a history of temperature readings. These proposed rules require a review of all temperature data, twice daily, from a continuous temperature monitoring device that records temperatures every 15 minutes, to ensure proper drug storage and identify potential excursions. In addition, the system is also required to notify the pharmacist of each temperature excursion in real time. Currently, there is a national as well as Oregon

specific discussion on pharmacy working conditions. Adding twice daily review of temperatures produced by a continuous monitoring system, which is required to notify a pharmacist in real time of excursions, is duplicative and adds unnecessary tasks, removing a pharmacist from clinical and professional activities. In conjunction with our concern over the definition of "temperature excursion", the management of an excursion does not consider official compendium guidance in determining degradation of the product, only relying on manufacture information, which is not often provided upon inquiry. We feel that a pharmacist should be able to use information in the package insert, official compendium recommendations using temperature and time of excursion (MKT), and professional judgement to determine if product degradation occurred, which prevents dispensing of the product. Finally, this proposed language would require the pharmacist to segregate all product and follow a temperature excursion protocol every time a refrigeration/freezer door is opened, again adding unnecessary tasks and burden to the pharmacist workload. CVS Health requests the Board not adopt this rule as proposed and continue discussion on potential amendments with stakeholders.

Division 143 related to Pharmacy Prescription Lockers (PPLs)

CVS Health feels the proposed new Division 143 related to Pharmacy Prescription Lockers (PPL) is onerous and unnecessarily burdensome, which will prevent utilization of a PPL to increase patient access by drug outlets. Requirements that we find burdensome include but are not limited to requiring: a locker to have a pharmacist in charge, an individual registration as opposed to being an extension of the current pharmacy outlet registration, certain equipment and supplies, multiple signs, and digital images of the individual to whom the prescription was dispensed. We request the Board not adopt the rule as proposed and continue discussion with stakeholders, while reviewing other state's laws, rules and/or regulations which address the use of a simple pharmacy pick up locker.

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

Sincerely,

Lauren Paul, PharmD

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

From:	Paul, Lauren N.
To:	PHARMACY RULEMAKING * BOP
Cc:	Paul, Lauren N.
Subject:	CVS Health comments on Proposed Rules
Date:	Wednesday, March 23, 2022 1:12:20 PM
Attachments:	CVS Health Comments on Proposed Rules.pdf

Please find attached comments on Proposed Rules of Divisions 025 related to Pharmacy Technician and Certified Pharmacy Technician Licensure, Division 006 related to Definitions, Division 041/139 related to Drug Storage, and Division 143 related to Pharmacy Prescription Lockers (PPLs). Should you have any questions, please contact me.

Warm Regards,
Lauren

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

From: PHARMACY BOARD * BOP
To: PHARMACY RULEMAKING * BOP
Subject: FW: Don"t reduce certification standards!
Date: Monday, March 21, 2022 8:33:36 AM

-----Original Message-----
From: Justin.M.Dalpez@kp.org <Justin.M.Dalpez@kp.org>
Sent: Sunday, March 20, 2022 5:05 PM
To: PHARMACY BOARD * BOP <PHARMACY.BOARD@oregon.gov>; PHARMACY RULEMAKING * BOP <PHARMACY.RULEMAKING@bop.oregon.gov>
Subject: Don't reduce certification standards!

Dear Board of Pharmacy,

Please vote NO on proposed changes to the pharmacy technician licensure requirements. Certified Oregon Pharmacy Technicians go through a rigorous national certification process in order to provide safe, quality care.

Allowing the creation of a renewable pharmacy technician license without this important certification requirement will disincentivize workers from applying for a Certified Oregon Pharmacy Technician license and result in a workforce that does not meet the national standard. Continuing education is vital to keep our workforce educated, culturally competent, and up to date on the latest changes in the profession. Reducing pharmacy technician hours to half of what national certification requires will surely result in a lower standard of education for Oregon's pharmacy technicians.

In times of emergency, it is understandable to want to increase staffing, but please don't do so at the expense of patient safety and workforce quality. Vote NO on the proposed changes to Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules.

From: Justin Dalpez

From: cdavis5717@gmail.com
To: PHARMACY BOARD * BOP; PHARMACY RULEMAKING * BOP
Subject: Don"t reduce certification standards!
Date: Thursday, March 17, 2022 10:27:59 PM

Dear Board of Pharmacy,

Please vote NO on proposed changes to the pharmacy technician licensure requirements. Certified Oregon Pharmacy Technicians go through a rigorous national certification process in order to provide safe, quality care.

Allowing the creation of a renewable pharmacy technician license without this important certification requirement will disincentivize workers from applying for a Certified Oregon Pharmacy Technician license and result in a workforce that does not meet the national standard. Continuing education is vital to keep our workforce educated, culturally competent, and up to date on the latest changes in the profession. Reducing pharmacy technician hours to half of what national certification requires will surely result in a lower standard of education for Oregon's pharmacy technicians.

In times of emergency, it is understandable to want to increase staffing, but please don't do so at the expense of patient safety and workforce quality. Vote NO on the proposed changes to Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules.

From: C. Davis

From:	chadangelahope@yahoo.com
To:	PHARMACY BOARD * BOP; PHARMACY RULEMAKING * BOP
Subject:	Don"t reduce certification standards!
Date:	Thursday, March 17, 2022 3:38:56 PM

Dear Board of Pharmacy,

Please vote NO on proposed changes to the pharmacy technician licensure requirements. Certified Oregon Pharmacy Technicians go through a rigorous national certification process in order to provide safe, quality care.

Allowing the creation of a renewable pharmacy technician license without this important certification requirement will disincentivize workers from applying for a Certified Oregon Pharmacy Technician license and result in a workforce that does not meet the national standard. Continuing education is vital to keep our workforce educated, culturally competent, and up to date on the latest changes in the profession. Reducing pharmacy technician hours to half of what national certification requires will surely result in a lower standard of education for Oregon's pharmacy technicians.

In times of emergency, it is understandable to want to increase staffing, but please don't do so at the expense of patient safety and workforce quality. Vote NO on the proposed changes to Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules.

From: Angela Edwards

From:	Amber Grant
To:	PHARMACY RULEMAKING * BOP
Subject:	obop temp rule
Date:	Monday, March 28, 2022 12:20:28 PM

To whom it may concern;
I am sending my concern over one more temp rule that you wish to enact. Pharmacies are working hard and having another log to check and maintain is not necessary nor welcome. We have no concerns over temp in our pharmacy or during delivery . We are also concerned over the cost of this new rule. The loggers are expensive to buy and to maintain. We are incurring costs on the refrigerator medications/vaccines loggers which makes sense since the range is more limited. we are finding all the expenses to pharmacy burdensome and we are not able to make any changes to many of the expenses although we fight the good fight and trying to stay in business is always a struggle. I do not feel like the cost and time for this new rule is over the top and pharmacies are asking OBOP to reconsider this ruling. Thanks for giving pharmacy an opportunity to respond to this ruling.
Amber Grant Rph

From:	Austin B.
To:	PHARMACY RULEMAKING * BOP
Subject:	Comments on Notice of Proposed Rulemaking
Date:	Tuesday, March 29, 2022 1:47:21 PM

To whom it may concern,

The proposed changes to rule 855-139-0125 state that a pharmacy must maintain drugs at temperature with continuous temperature monitoring device(s) that record the storage of each drug storage area at least every 15 minutes and notifies in real time of temperature excursions. It also requires that pharmacies maintain proper drug storage conditions between transfers to facilities and delivery to patients.

These requirements are significantly burdensome to our business as a whole and would significantly limit our ability to provide patient care. For instance, we would no longer be able to provide deliveries to our vulnerable retail, long-term care, and hospice patients due to the added cost of temperature monitoring while in the delivery vehicle. This rule threatens these patients' ability to receive timely care. Our pharmacies are mostly located in rural areas and some patients have no regular ability to come to the pharmacy. If they are outside our delivery area, we offer to mail the prescription to the patient. We do not have a way to monitor the temperature while it's in the mail. If this rule goes into effect, these patients will be stranded with no access to pharmacy care.

Machines generate heat. Where should we place a thermometer inside our robotic pill counting machine? If we are not able to have pill counting robots anymore, we are going to have to spend more money hiring pharmacy technicians at a time when they are in extremely short supply.

We would potentially be forced to spend a lot of money to remodel our pharmacy because the temperature can fluctuate throughout the day in different drug storage areas (i.e., pharmacy and OTC areas). If the sensor reads 0.5 degree above the acceptable temperature window for 30 minutes before the A/C kicks on again, should we call every manufacturer to verify product viability? This is all a significant time burden for pharmacy personnel.

I know one main goal is to prevent excursions. Are we expected to purchase a whole building generator to run the entire pharmacy? That purchase would be extremely expensive. How many temperature monitors do we need for a large pharmacy? Certainly not just 2 as mentioned in the proposed rule documents. We also have some pharmacies inside of other businesses (e.g., grocery store that we don't own). In this case, remodeling is not an option, we would be forced to close the business because we could not comply. Do these proposed rules require us to monitor temperature, humidity, etc for OTC drugs as well? If so, we would need additional probes for those areas in the front of the store.

Why should our pharmacies have to bear the cost burden to implement this program? We don't have a guarantee that the appropriate temperature, light, humidity, sanitation, ventilation, and space have been maintained from the time of manufacture to when the product is transported via plane, train, and automobile then ultimately enters our facility.

Implementation of this rule would be significantly burdensome in time and money and will hurt our ability to remain in business. Again, our pharmacies are in rural areas who are underserved in the first place. Our patients need access to our pharmacies in order to stay healthy. If we aren't there for them, Oregonians will suffer. We cannot afford to add this rule.

This rule will hurt Oregonians.

Thanks,

Hi-SCHOOL pharmacy®

Austin Blakeslee PharmD
Director of Pharmacy
916 W. Evergreen Blvd
Vancouver, WA 98660
P: 360-213-2236 | F: 360-213-2238

From: julia.chang842@gmail.com
To: PHARMACY BOARD * BOP; PHARMACY RULEMAKING * BOP
Subject: Don"t reduce certification standards!
Date: Friday, March 18, 2022 7:32:27 AM

Dear Board of Pharmacy,

Please vote NO on proposed changes to the pharmacy technician licensure requirements. Certified Oregon Pharmacy Technicians go through a rigorous national certification process in order to provide safe, quality care.

Allowing the creation of a renewable pharmacy technician license without this important certification requirement will disincentivize workers from applying for a Certified Oregon Pharmacy Technician license and result in a workforce that does not meet the national standard. Continuing education is vital to keep our workforce educated, culturally competent, and up to date on the latest changes in the profession. Reducing pharmacy technician hours to half of what national certification requires will surely result in a lower standard of education for Oregon's pharmacy technicians.

In times of emergency, it is understandable to want to increase staffing, but please don't do so at the expense of patient safety and workforce quality. Vote NO on the proposed changes to Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules.

From: Julia

KAISER PERMANENTE®

Pharmacy Administration

March 29, 2022

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

RE: Proposed Rules - Division 041 - related to Disclosure of Patient Information

Dear Officer Melvin:

Thank you for the opportunity to provide comment on the proposed rulemaking. Kaiser Permanente Northwest is requesting the Board reconsider the proposed language related to the disclosure of patient information.

855-041-1055(2) Proposed language

May not 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.

We would ask the Board to add additional exception language like 855-014-1055(1), something similar to "for the purpose of patient care or other activities as permitted pursuant to federal and state confidentiality laws" or combine the two subsections to read:

(1) May not allow a licensee or registrant of the board to access or disclose patient information to a third party without the consent of the patient except as provided in (a)-(e) of this rule. A licensee may access or disclose patient information:

Some examples, not having this exception language, could limit those who could access or obtain information related to a Board inquiry, pharmacy quality assurance reviews or pharmacy data analytic programs to just those who had access related to this patient's care and can now disclose the information.

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

5725 NE 138th Avenue
Portland, OR 97230-3409
503-261-7566
503-261-7567 - FAX

KAISER PERMANENTE®

Pharmacy Administration

March 29, 2022

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

RE: Proposed Rules - Division 041 - related to Drug Storage

Dear Officer Melvin:

Thank you for the opportunity to provide comment on the proposed rulemaking. Kaiser Permanente Northwest is requesting the Board reconsider the proposed language related to Drug Storage.

855-041-1036(3)(c) Proposed language

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.

This language is problematic for pharmacy locations that are not operational 7 days/week. It could be assumed a pharmacy staff member would be expected to log temperatures twice daily, even when the pharmacy is not open.

We recommend language similar to what is found in the CDC Vaccine Storage and Handling Toolkit, "Check and record minimum/maximum temperatures at the start of each workday". Once daily temperature review, in conjunction with a continuous temperature monitoring device, would provide regular review the system is working as designed without being administratively burdensome.

We would also ask the Board, if it is found necessary to keep language as prescriptive as currently proposed, to differentiate controlled room temperature monitoring from cold storage monitoring. USP<659> provides temperature and storage definitions, including allowable excursions for drugs stored at controlled room temperature. A definition of controlled room temperature, either matching or referencing USP<659> should be added for additional clarity.

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

5725 NE 138th Avenue
Portland, OR 97230-3409
503-261-7566
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KAISER PERMANENTE®

Pharmacy Administration

March 29, 2022

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

RE: Proposed Rules - Division 006 - related to definition of Telepharmacy System

Dear Officer Melvin:

Thank you for the opportunity to provide comment on the proposed rulemaking. Kaiser Permanente Northwest is requesting the Board reconsider the proposed language related to the definition of telepharmacy system.

855-006-0005(45) Proposed language

"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.

While Telepharmacy is defined in proposed rule 855-139-0005(3) and applies specifically to a remote dispensing site, including the definition of Telepharmacy System in Division 006 would indicate this applies to all practices.

Telepharmacy can be interpreted as the delivery of pharmaceutical care to patients at a distance through the use of telecommunication and other technologies. This could apply to pharmacists remotely completing drug utilization reviews, medication therapy management, or patient consultations.

While we believe it is not the intent for the telepharmacy definition to apply to practice settings other than a remote dispensing site, we are concerned the proposed definition of telepharmacy system would present a significant change for pharmacists who provide, and have been providing for years, services listed above. It could be interpreted that pharmacists/pharmacies providing remote pharmacy services to/for patients would be required to maintain audio and video recordings of their work. Not only is this well beyond what is expected of a pharmacist providing the same exact care from a brick and mortar pharmacy, it is impractical and personally invasive.

We recommend that the Board modify the definition or move it to division 139 where the definition of telepharmacy will reside.

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

5725 NE 138th Avenue
Portland, OR 97230-3409
503-261-7566
503-261-7567 - FAX

From:	Katie Jaeger
To:	PHARMACY RULEMAKING * BOP
Subject:	Kaiser Permanente comments for Rulemaking 3/29/22
Date:	Tuesday, March 29, 2022 11:13:11 AM
Attachments:	BOP ltr - Disclosure 2022.3.29.pdf BOP ltr - Drug Storage 2022.3.29.pdf BOP ltr - Telepharmacy 2022.3.29.pdf

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Please see attached comments from Kaiser Permanente.

Thank you,

Katie Jaeger, Pharmacy Regulatory

Kaiser Permanente Northwest Region

Cell: 503-758-6887

From: Oja, Mary K :LSO Pharmacy
To: PHARMACY RULEMAKING * BOP
Subject: Proposed Changes to Drug- Storage
Date: Tuesday, March 29, 2022 3:06:10 PM

Hello,

The Oregon Board of Pharmacy has helped improve practice around drug storage by requiring continuous temperature monitoring.
In addition to assuring safe med storage, pharmacies now have data to track potential issues with their refrigerators and freezers.
Testing of the temperature monitoring system and regular calibration help ensure accurate temperature data.
We understand the need to verify with drug manufacturers the safety of the affected product(s), but In the event of **any** (minor) temperature excursion the requirement to contact every drug manufacturer is burdensome. Our temperature monitoring systems work so well to notify us, the excursions experienced are most often less than 20 minutes with a minimal variance (< 0.5°C).
To contact all manufacturers is very time consuming, especially if we have previous data that states meds are safe to use after experiencing a minimal (variance and duration) excursion.

Thank you for your consideration,

Mary Oja, CPhT
Medication Safety & Compliance Pharmacy Technician | Legacy Health
2850 N.W 31st Ave | Portland, OR 97210 | ☎ (503) 944-4297 | ✉ moja@lhs.org

It is unclear how this would be maintained for prescriptions that are mailed or delivered to patients, including mail order or long-term care pharmacies. For central fill pharmacies, drugs must have continuous temperature monitoring during transport to ensure there are no excursions. If there is an excursion, **the manufacturer of every drug (INCLUDING ROOM TEMPERATURE DRUGS) must be contacted** to ensure it is safe for use and this contact must be documented.

From:	nancyhoward2002@yahoo.com
To:	PHARMACY BOARD * BOP; PHARMACY RULEMAKING * BOP
Subject:	Don"t reduce certification standards!
Date:	Friday, March 18, 2022 9:12:28 AM

Dear Board of Pharmacy,

Please vote NO on proposed changes to the pharmacy technician licensure requirements. Certified Oregon Pharmacy Technicians go through a rigorous national certification process in order to provide safe, quality care.

Allowing the creation of a renewable pharmacy technician license without this important certification requirement will disincentivize workers from applying for a Certified Oregon Pharmacy Technician license and result in a workforce that does not meet the national standard. Continuing education is vital to keep our workforce educated, culturally competent, and up to date on the latest changes in the profession. Reducing pharmacy technician hours to half of what national certification requires will surely result in a lower standard of education for Oregon's pharmacy technicians.

In times of emergency, it is understandable to want to increase staffing, but please don't do so at the expense of patient safety and workforce quality. Vote NO on the proposed changes to Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules.

In recent times, pharmacy technicians have become an even more essential partner in the patient care pharmacy setting, due to staffing shortages. It is important that they continue to have the highest level of training and competency, along with licensing, since their positions and job descriptions are being expanded, by necessity. They are vital professionals.
We do not want a lowering of standards or requirements, but an increase in recognition and moving towards a safe job expansion. As in all other healthcare professions, supporting technician staff has seen a development of education and duties, to enable their positions to grow as they help provide safer patient care and better outcomes. I don't think this new rulemaking proposal advances the position of pharmacy technicians or promotes greater patient safety. I recommend going back and putting together a proposal that expands technicians' position in the pharmacy setting, acknowledge their continuing education, and grow their recognition and professional contributions towards our establishing of stronger/safer patient care goals.

From: Nancy Levnetoff, Pharm.D.

Dear Oregon Board of Pharmacy,

Below please find our comments in response to the proposed rule change 855-041-1036, Proper Storage of Drugs. In general, the impact of this rule change is vast and we believe that there are unintended consequences specifically as they relate to controlled room temperature excursions. Below please find some of the specific challenges we identified. We believe that temperature excursions for controlled room temperatures need to be handled differently than excursions for fridge and freezer storage, and that these rules need to be reconciled with USP <659>.

We are happy to talk more about this in person. Please feel to reach out to me if you wish to discuss further. The ramifications of some of these points are difficult to describe in writing.

Best regards,

Natalie Gustafson
Director of Pharmacy
Lloyd Central Compounding Pharmacy
2606 NE Broadway St STE B
Portland, OR 97232

Rph.Natalie@LCRX.com
503-281-4161

Comments for Proposed Rule Change 855-041-1036 Proper Storage of Drugs

Summary of suggested changes

- In several ways, these temperature monitoring requirements are at odds with existing requirements for compounding pharmacies (including hospitals), specifically as it relates to USP chapters such as <797> and <659>. The regulations need to be reconciled, as USP <659> also can apply to commercially manufactured drugs and retail pharmacies, or compounding pharmacies need a carve out in these requirements.

- Bifurcate these temperature monitoring requirements into:
    - Drugs stored at controlled room temperature (or temperatures above refrigeration)
        - Less strict excursion documentation/quarantine requirements unless temperature is above the range for controlled room temperature for longer periods of time, following the parameters set in USP <659>
    - Drugs stored in refrigerator or in freezer
        - More strict excursion requirements if temperatures go above range for too much time

        - Most of the documents used as reference for the changes in this rule relate to cold chain storage or vaccine drug storage

- Allow controlled room temperature drugs/chemicals to be stored at colder temperatures than is the specified range, unless not allowed on the monograph or specified by the manufacturer
    - e.g. a drug that can be stored at controlled room temp can also be stored below room temp such as 15 C

- Follow existing USP <659> requirements for drug temperature and storage definitions, which also covers temperature excursions for controlled room temperature items

- Either adjust the definition of what a temperature excursion entails (proposed change to OAR 855-006-005 Definitions), or change language in this rule to allow for small periods of time and small deviations in temperature above the specified temperature range
    - For example, as written a temperature excursion for controlled room temperature could be 25.8 C for 1 minute and would require all of this documentation
    - There is no distinction between temperature excursions above or below the range of controlled room temperature
    - There is no distinction made between small or large temperature variances (e.g. 1 C vs 30 C)
    - There is no distinction made between small or large amount of time for an excursion (e.g. 5 minutes vs 2 days)

- Do not require all personnel be trained in how to use the temperature monitoring system
    - Burdensome and unnecessary for training, and increases security/safety risks

Dear Oregon Board of Pharmacy,

We would like to submit a short comment on the proposed rule change 55-041-1092 Pharmacy Closures: Temporary or Emergency.

There is some concern about the requirement to have notification posted on the pharmacy entrances within 2 hours of the temporary closure. While it is easy to change the phone message and website remotely, we physically have to be able to get to the pharmacy in an emergency to post a sign on the entrance. As the most common reason we have had to temporarily close in the past is due to severe ice and snow conditions in which none of my pharmacists can safely drive to the pharmacy, we worry that there may be times in which this requirement would be challenging to meet without endangering our employees.

Perhaps there could be a stipulation added given extreme extenuating circumstances to allow more time for this requirement?

Thank you for your consideration,

Natalie Gustafson
Director of Pharmacy
Lloyd Central Compounding Pharmacy
2606 NE Broadway St STE B
Portland, OR 97232

Rph.Natalie@LCRX.com
503-281-4161

855-041-1036 General Comments

- We believe the rule changes should be divided between controlled room temperature storage requirements, and fridge/freezer storage requirements, each with different excursion criteria and documentation requirements. As currently written, a temperature excursion for a room temperature drug/chemical is treated as severely as a temperature excursion for a fridge/freezer drug/chemical. Previously, this rule was focused on cold and vaccine drug storage requirements and has been expanded to include controlled room temperature storage without distinction.

- Patient access to medications will be adversely affected as written. For instance, a 1 degree "controlled room temperature" excursion will trigger quarantine requirements for all drugs affected. For all drugs/chemicals impacted by a temperature excursion, an analysis must be done that includes gathering information about drug stability, statements from manufacturers about determination of safety to keep using the drug following the temperature excursion, and a professional judgment by a pharmacist. All of this analysis must occur before any of those drugs can be released to a patient. In our experience, manufacturers may take weeks to respond to an inquiry of this nature. This means that a 1 degree temperature excursion from room temperature could cause hundreds to thousands of drugs to be quarantined at the same time until this analysis is completed. This causes a significant risk to patient access to their medications, as completing this analysis will take a significant amount of time, likely days to weeks.

- Existing HVAC in retail settings is probably inadequate for perfect, tight 24/7 regulation of controlled room temperature under continuous monitoring. Very few retail pharmacies currently have continuous monitoring of temperatures outside of refrigerators and freezers. Many retail pharmacies are in older buildings, or part of larger department stores, and rely on traditional HVAC systems that are likely not designed to keep their drug storage room in a consistent and narrow band of temperatures 24/7. Once the new prescription lockers are implemented, they are also unlikely to be able to meet these conditions perfectly. Making the HVAC upgrades to do this would be quite expensive if the existing system is not capable.

  It is our guess that once continuous monitoring is required in these "controlled room temperature" areas, retail pharmacies will have many temperature excursions outside of the room temperature ranges. However, it is quite likely that the majority of these excursions are small and for short periods of time, and therefore inconsequential for appropriate storage.

  As written, these new requirements will very likely cause significant labor by pharmacies quite often, as HVAC is unlikely to be able to perfectly keep controlled room temperatures in the correct range 24/7.

- Temperature excursions for controlled room temperature drug/chemical storage should be treated differently than temperature excursions for fridge/freezer

drug/chemical/vaccine storage. Drugs/chemicals that need to be stored in the fridge or freezer should be treated more carefully with temperature excursions than drugs/chemicals stored at controlled room temperature.

In general, the majority of drugs/chemicals that can be stored at controlled room temperature have a much wider range of safe storage temperatures. Having an excursion to, say, 19 C or 15 C would not be harmful and is allowed by USP <659> unless otherwise stated by the manufacturer or monograph. Similarly, the majority of drugs/chemicals stored at controlled room temperature are safe with small higher excursions, such as to 27 C or 30 C, assuming the mean kinetic temperature does not vary greatly, as per USP <659>.

In summer months, temperatures exceeding this range are commonly reached during shipping to the pharmacy, as is allowed by USP <659>. In winter months, temperatures below this range are commonly reached during shipping to the pharmacy, which is also allowed by USP <659> and is not considered an excursion unless specified so by the manufacturer or monograph. However, as the new regulations are written, if a temperature excursion occurs to 19 C or 26 C for one minute, all drugs/chemicals in that storage room (potentially hundreds to thousands of items) would need to undergo a labor intensive process to document this occurrence and verify safety with manufacturers. This is an excessive and expensive burden, and we guess this massive amount of extra labor in this example situation is an unintended consequence of this regulation.

- Temperature excursions to lower temperatures should be treated differently than excursions to higher temperatures. USP <659> does not consider temperatures below controlled room temperature to be excursions for controlled room temperature drugs. Unless specified by the manufacturer/monograph, it should not be considered a "temperature excursion" to store a controlled room temperature drug at a lower temperature. For example, it should be ok for a controlled room temperature drug/chemical to be stored in 17 C temperature, or in the fridge, unless the manufacturer/monograph says otherwise.

- Technicians performing compounding activities prefer working in colder environments because PPE is warm and their bodies get warm from labor intensive tasks. For the comfort of our technicians in our non-sterile compounding laboratory, who are in layers of PPE and performing what can be physically demanding labor, we try to keep the temp at the very low end of controlled room temperature. Our techs prefer cooler temps because they are moving a lot and their bodies get warm from labor. However, because of this, temps will occasionally go slightly colder than controlled room temperature for short periods of time as the HVAC is attempting to stay at the specified temperature. This challenge increases with the USP requirement for a certain number of air changes per hour. In this scenario, because some of our drugs/chemicals are stored in our non-sterile laboratory, whenever the temperature drops below controlled room temperature

range we would be required to do a labor intensive excursion report for all inventory in this room.

This is another reason why we request that storage in temperatures lower than specified for controlled room temperature should not be considered an excursion.

- The updated USP <797> states sterile compounding should be done at 20 C or below, which is inconsistent with OBoP requirements. In addition, the updated USP <797> chapter states that the cleanroom should be kept 20 C (68 F) or below, which is at the bottom of the range or below controlled room temperature. To maintain these temperatures, the cleanroom will need to be kept below controlled room temperature. The reason for this temperature range, per USP <797>, is to "reduce the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb." Of note, as specified previously, non-sterile technicians are garbed in similar PPE and work in similar conditions and also prefer cooler working environments. As Oregon rules require that sterile compounders follow USP <797>, the new rule as currently written will put all sterile facilities at direct conflict.

- USP <659> is already listed in an Oregon rule for compounding pharmacies, and specifies the temperature ranges that drugs/chemicals should be stored, and specifies how to handle excursions from controlled room temperature. USP <659> provides requirements for storage temperatures of drugs/chemicals, and also provides direction for temperature excursions outside of storage conditions, such as happens regularly during shipping to pharmacies. Compounding pharmacies are required to follow USP <659> as per OAR 855-045-0200.

  These new Oregon requirements are in conflict with existing USP <659> requirements. For example, USP <659> allows for room temperature drugs/chemicals to be stored/shipped at cooler temperatures, including refrigeration, unless specified otherwise by the manufacturer or monograph. As written, the new Oregon regulations do not allow this. USP <659> also has specifications for how to handle temperature excursions which are different from the requirements in the new Oregon regulations.

  Requiring pharmacies to document small excursions outside of normal room temperature is a burdensome and expensive requirement that is not backed by evidence for safety, and is not consistent with USP <659>.

- New changes to the rule will likely force compounding pharmacies to destroy most inventory following a temperature excursion of any kind. New rule language states that drugs/chemicals that have had a temperature excursion must be isolated until the pharmacy can get a statement from a manufacturer regarding safety to keep using.

  For compounding pharmacies, we can only get temperature excursion data on chemicals, if the manufacturer has tested as such, which not all have. No manufacturer

will make a determination “that the drug/chemical 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.” They will not take on this liability. At best, they give us temperature excursion data they have on the drug and tell us to use our professional judgment. So it will be virtually impossible for us to use most drugs/chemicals that have been in storage during a temperature excursion if we must have a statement.

- The training requirements, specifically that all pharmacy personnel be able to use the temperature monitoring system, is overly broad and challenging to implement. Key people need to know how to use the system, but all employees do not need this information. All employees undergo drug storage training and basic temperature monitoring, but do not know how to access/operate the monitoring system. Beyond training challenges, we do not want everybody to be able to have access to the continuous temperature monitoring and alert system for safety and liability reasons. Most employees should not have access to temperature settings or alerts.

855-041-1036 Additional Specific Comments/Clarifications

- **(3)(b)(A) Have a buffered probe (glycol, glass beads, or similar) that is centrally located**
    - We may be misunderstanding this requirement. It was our understanding that this type of probe is only used in refrigerators/freezers, as the probes that monitor room temperature are different. Typically, it’s not appropriate to have a room temperature monitor in a buffered solution, and they are often also monitoring humidity.

- **(3)(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 systems(s) for each storage area are recording temperature accurately and issuing appropriate alerts**
    - Clarification on this section of the rule is requested. The intent appears to be to check at least every 3 months that the continuous monitoring system is continuing to record temperatures and issue alerts when appropriate. The use of the term “accurately” is a little confusing as it could imply that the temperature sensors must be calibrated/certified every 3 months instead of every 2 years or per manufacturer’s specifications.

- **(3)(n)(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 drugs; (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**

- Clarification is requested for this section of the rule. For the analysis that occurs after a temperature excursion, it is unclear why an inventory count of each medication must be taken if each medication has to be labeled. In addition, is labeling required if there is no change to the expiration date?

From:	Natalie Gustafson
To:	PHARMACY RULEMAKING * BOP
Subject:	855-041-1036 proposed rule change comments
Date:	Friday, March 25, 2022 6:01:20 PM
Attachments:	LCRX Comments OBOP Rule 855-041-1036 Change 3.22.pdf

Hi Rachel,

Please see the attached for our comments on the proposed rule change for 855-041-1036 Proper Storage of Drugs.

Thanks so much!

--
Natalie Gustafson, PharmD (she/her)
Director of Pharmacy
Lloyd Central Compounding Pharmacy
2606 NE Broadway St, Suite B, Portland OR 97232
Phone: 503-281-4161
Fax: 503-281-1990

From:	Natalie Gustafson
To:	PHARMACY RULEMAKING * BOP
Subject:	Re: 855-041-1036 proposed rule change comments
Date:	Monday, March 28, 2022 9:05:25 AM
Attachments:	image001.png LCRX Comments OBOP Rule 855-041-1092 Change 3.22.pdf

---

Hi Rachel,

Thank you so much!

Two quick things - I also included a written comment on 855-041-1092 which is attached below. The second is that our comments submitted for 855-041-1036 are also applicable for 855-139-0125 Drug Storage. As they are submitted together and the language is so similar I didn't differentiate but thought I should mention that.

Thanks again,
Natalie

On Mon, Mar 28, 2022 at 8:01 AM PHARMACY RULEMAKING * BOP <PHARMACY.RULEMAKING@bop.oregon.gov> wrote:

> Hello Natalie,
>
> Thank you for your comments, they will be recorded into the Rulemaking Hearing Report and provided to the board at the April 13-15, 2022 Board Meeting. I also received your form to provide oral testimony during the hearing and will send you a Teams calendar invite shortly.
>
> Thanks!
> Rachel Melvin
>
> **Rulemaking Staff**
>
> **Oregon Board of Pharmacy**
>
> pharmacy.rulemaking@bop.oregon.gov
>
> (971) 673-0001 phone
>
> (971) 673-0002 fax
>
> www.Oregon.Gov/Pharmacy

From: Natalie Gustafson <rph.natalie@lcrx.com>
Sent: Friday, March 25, 2022 6:01 PM
To: PHARMACY RULEMAKING * BOP <PHARMACY.RULEMAKING@bop.oregon.gov>
Subject: 855-041-1036 proposed rule change comments

Hi Rachel,

Please see the attached for our comments on the proposed rule change for 855-041-1036 Proper Storage of Drugs.

Thanks so much!

--

Natalie Gustafson, PharmD (she/her)

Director of Pharmacy

Lloyd Central Compounding Pharmacy

2606 NE Broadway St, Suite B, Portland OR 97232

Phone: 503-281-4161

Fax: 503-281-1990

From:	Kelly A. Lund
To:	PHARMACY RULEMAKING * BOP
Cc:	Kelly Lund
Subject:	Regarding Pharmacy Technician Remote Work
Date:	Tuesday, March 1, 2022 11:16:06 AM

Hi Rachel,

My name is Kelly Lund and I am a Certified Pharmacy Technician with Kaiser Permanente currently working remotely and have been throughout this pandemic.

My question is, could the rules surrounding the technicians working remotely be written so that we can understand exactly what they mean? Kaiser is saying that we do not meet the requirements to continue to work remotely and we would like to be able to understand exactly why this is. We want to be able to read and understand clearly the rules as the board states as appose to what is told to us by our employer.

We are also curious if the way our job description states and or our titles play any part in us not falling into the remote work rules.

Thank you for your response in advance.

Kelly Lund

From: rodger.murry@gmail.com
To: PHARMACY BOARD * BOP; PHARMACY RULEMAKING * BOP
Subject: Don"t reduce certification standards!
Date: Friday, March 18, 2022 1:19:56 PM

Dear Board of Pharmacy,

I've worked at a pharmacy since shortly before the pandemic began. I've seen first hand the attrition on staff and the difficulty in retaining new hires. Reading the new proposal, I had one reaction.

Are you kidding me? The standards are already low enough that many workplaces require applicants to have several years experience OR to have recently completed a pharmacy technician training program like the one at OHSU. Making these changes will not significantly increase the number of pharmacy technicians. People do not want to be pharmacy techs because the job is hard, it's not well paid outside of hospitals, and because corporations refuse to hire enough pharmacists to keep pharmacies functioning well. We're hamstrung every day by the lack of pharmacists. Every tech and pharmacist I know has said the same: Some days we need another tech, but every day we need a 2nd pharmacist. Create rules that force companies to adequately provide the professional staff required to safely serve patients, stop lowering your standards and settling for less. There is a problem, it is within your power to fix it, but you're coming at it from the back-ass-wards direction of doing so. Demand more, not less.

Please vote NO on proposed changes to the pharmacy technician licensure requirements. Certified Oregon Pharmacy Technicians go through a rigorous national certification process in order to provide safe, quality care.

Allowing the creation of a renewable pharmacy technician license without this important certification requirement will disincentivize workers from applying for a Certified Oregon Pharmacy Technician license and result in a workforce that does not meet the national standard. Continuing education is vital to keep our workforce educated, culturally competent, and up to date on the latest changes in the profession. Reducing pharmacy technician hours to half of what national certification requires will surely result in a lower standard of education for Oregon’s pharmacy technicians.

In times of emergency, it is understandable to want to increase staffing, but please don’t do so at the expense of patient safety and workforce quality. Vote NO on the proposed changes to Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules.

From: Rodger

From: Naleway, Michael
To: PHARMACY RULEMAKING * BOP
Subject: Controlled Room Temperature Requirements and USP 797 Cleanroom Temperature Recommendations
Date: Friday, February 25, 2022 11:58:56 AM
Attachments: image001.png
image002.png
image003.png

In the proposed rule changes recently placed, controlled room temperature storage is listed as 20 to 25 degrees C:

855-041-1036
Proper Storage of Drugs ¶

(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~~store each drug according to the manufacturer's ~~published or USP guidelines.¶~~
~~(b) All drugs must be stored in appropriate conditions of~~storage requirements for temperature, light, humidity, sanitation, ventilation, and space.¶
(c2) ~~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~~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.¶
(~~2~~3) A~~Each~~ 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:¶~~
(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); ~~or as specified by the manufacturer.¶~~
~~(B) Utilize a~~¶
(b) Utilize continuous temperature monitoring device(s) that:¶
(A) Have a buffered probe (glycol, glass beads, or similar) that is 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~~

USP 797 (2008, first image below) and (2019, second image below) both recommend cleanrooms are maintained below 20 degrees C:

Figure 1. Conceptual representation of the placement of an ISO Class 5 PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD.

Figure 2 is a conceptual representation of the arrangement of a facility for preparation of CSPs

Facility Design and Environmental Controls

Compounding facilities are physically designed and environmentally controlled to minimize air-

borne contamination from contacting critical sites. These facilities shall also provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler, to maintain comfortable conditions for compounding personnel to perform flawlessly when attired in the required aseptic compounding garb. PECs typi-

compounding activities utilized during the preparation of the CSPs. The CSP work environment is designed to have the cleanest work surfaces (PEC) located in a buffer area. The buffer area shall maintain at least ISO Class 7 (see *Table 1*) conditions for 0.5-µm and larger particles under dynamic operating conditions. The room shall be

4.2 Facility Design and Environmental Controls

In addition to minimizing airborne contamination, sterile compounding facilities must be designed and controlled to provide a well-lighted and comfortable working environment (see *Physical Environments That Promote Safe Medication Use* ⟨1066⟩). The cleanroom suite should be maintained at a temperature of 20° or cooler and a relative humidity below 60% to minimize the risk for microbial proliferation and provide comfortable conditions for compounding personnel attired in the required garb. The temperature and humidity must be monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. The results of the temperature and humidity readings must be documented at least once daily or stored in the continuous recording device, and must be retrievable. The temperature and humidity readings must be reviewed as described in the facility's SOPs. Temperature and humidity in the cleanroom suite must be controlled through a heating, ventilation, and air conditioning (HVAC) system. Free-standing humidifiers/dehumidifiers and air conditioners must not be used within the classified area or within the perimeter of the SCA. Temperature and humidity monitoring devices must be verified for accuracy at least every 12 months or as required by the manufacturer.

The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities to be conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality.

Since both OBOP rules and regulations and USP 797 regulations are required for practice. **What temperature should an ISO 7 cleanroom or anteroom be maintained at?** 20-25 degrees C? Below 20 degrees C?

For reference, Simplifi 797 gives a ~16.6 degrees C to 20 degrees C range by default for temperature requirements for cleanrooms.

Thank you,
~Michael Naleway

Michael Naleway, PharmD, BCPS
ARRMC Heimann Cancer Center Pharmacy Supervisor
Non-Urgent: michael.naleway@asante.org, Heimann CTC Pharmacy: (541) 789-5547
Urgent: Doc Halo, Text: (541) 554-5777
| Excellence | Respect | Honesty | Service | Teamwork |

NEIGHBORHOOD HEALTH CENTER

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February 29, 2022

To: Oregon Board of Pharmacy

I have substantial concerns with the Board's proposed changes to OAR 855-041-1036. The current OARs in effect already require a pharmacy to ensure proper storage of drugs, inclusive of conditions of temperature. I believe further mandating precisely how a pharmacy must monitor this is likely to negatively impact the health, safety, and welfare of Oregonians rather than provide any discernable benefit. The proposed drug storage and drug storage monitoring rule changes require that a pharmacy:

(b) Utilize continuous temperature monitoring device(s) that:
(A) Have a buffered probe (glycol, glass beads, or similar) that is centrally placed, accurate, and calibrated thermometer;
(B) Records the temperature of each drug storage area at least every 15 minutes;

(d) Utilize a system that notifies a pharmacist of each temperature excursion in real-time.
(g) Maintain proper drug storage conditions during transfers between facilities and delivery to patients

As a pharmacy must 'Maintain proper drug storage conditions during transfers between facilities and delivery to patients,' any pharmacy providing mail order or delivery of a drug must have disposable or recoverable temperature monitoring devices that can report in real time during transit back to the dispensing pharmacy and packaging capable of centrally placing the device. This technology does not exist, and the Board would in effect be instituting a ban on mail order pharmacies as well as mail order and most delivery service operations from specialty pharmacies and walk in retail drug outlets. Of note, the Board of Pharmacy as recently as 03/23/2020 encouraged pharmacies to look to these specific delivery mechanisms to provide access to care during the COVID-19 pandemic. At a time when in state walk in retail drug outlet registrations as well as pharmacist and pharmacy technician licensees have been net negative in the state, access would be critically impacted by this ban on delivery and mail order. While this would have an impact on all of Oregon, underserved and rural communities and patients who often experience transportation insecurity or geographical barriers may see the greatest impact to access.

Further, if there is a substantial risk posed to the health, safety and welfare of Oregonians by leaving the specifics of the required temperature monitoring of drugs and devices up to Board licensees, why has the Board not proposed in kind changes to the rules for drug storage of non-pharmacist practitioners and licensees when issued a license as a Dispensing Practitioner Drug Outlet (OAR 855-043-0535), Drug Wholesaler (855-065-0012) or a Drug Manufacturer (855-060-0010)?

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CANBY MEDICAL CLINIC
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Canby, OR 97013
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HILLSBORO REPRODUCTIVE HEALTH CLINIC
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Hillsboro, OR 97213
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TUALATIN HS SBHC
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I encourage the Board to reconsider the need for and the impact of this proposed change.

Sincerely,

Zach Rosko, PharmD, BCPS
DIRECTOR OF PHARMACY AND CARE TEAMS
NEIGHBORHOOD HEALTH CENTER
ROSKOZ@NHCOREGON.ORG | 503-941-3131

From:	Zach Rosko
To:	PHARMACY RULEMAKING * BOP
Subject:	Comments for Rulemaking: Division 041/139 Drug Storage
Date:	Tuesday, March 29, 2022 12:04:31 PM
Attachments:	image001.png Rulemaking Comments Division 041 and 139 related to Drug Storage.docx

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Please see my attached statement for comments related to the proposed rules for Division 041/139 Drug Storage.

Thank you for your time,

Zach Rosko

Zach Rosko, PharmD, BCPS
DIRECTOR OF PHARMACY AND CARE TEAMS
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NEIGHBORHOOD HEALTH CENTER

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February 29, 2022

To: Oregon Board of Pharmacy

I am writing to express concerns with the Board's proposed changes to OAR 855-041-1035, specifically with the inclusion of 'at each building entrance' on (1) (E).

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

Not all pharmacy locations are able to place permanent signage at every building entrance due contractual restrictions in lease agreements. I am concerned that this requirement, if implemented, would force our pharmacy to find an alternative location, and may require temporary cessation of operations. Additionally, not all pharmacies operate on a walk-in basis or in locations where it makes sense from a drug security standpoint to post on the exterior of the building that drugs or a pharmacy are on site.

I ask that the Board consider as an alternative: (E) Providing notification of accurate hours of operation at each pharmacy entrance;

I am less concerned with the requirements of 855-041-1092 (1) (a) that only require temporary signage to be posted, though there may be other pharmacies that are also restricted from posting any signage rather than just permanent signage.

(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 notification of closure on each building entrance and each pharmacy entrance 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.

Sincerely,

Zach Rosko, PharmD, BCPS
DIRECTOR OF PHARMACY AND CARE TEAMS
NEIGHBORHOOD HEALTH CENTER
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TUALATIN HS SBHC
22300 SW Boones Ferry Rd
Rm #26A
Tualatin, OR 97062
Phone: 503.941.3180
Fax: 503.563.6969

From:	Zach Rosko
To:	PHARMACY RULEMAKING * BOP
Subject:	Comments for Rulemaking: Division 041/139 Pharmacy Hours
Date:	Tuesday, March 29, 2022 3:47:15 PM
Attachments:	image001.png Rulemaking Comments Division 041 and 139 related to Pharmacy Hours.docx

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Please see my attached statement for comments related to the proposed rules for Division 041/139 Pharmacy Hours

Thank you for your time,

Zach Rosko

Zach Rosko, PharmD, BCPS
DIRECTOR OF PHARMACY AND CARE TEAMS
NEIGHBORHOOD HEALTH CENTER
ROSKOZ@NHCOREGON.ORG | 503-941-3131

To: Oregon Board of Pharmacy Rulemaking Committee

From: Luke Eilers, PharmD, COO of Northwest Compounders

Date: 3/24/33

Re: Proposed rule changes to OAR 855-041-1036 and OAR 855-139-0125

Dear OBOP Rulemaking Committee,

Thank you for taking the time to review my comments about the proposed changes to 855-041-1036 Proper Storage of Drugs and 855-139-0125 Drug: Storage. I have listed my comments chronologically to match the organization of the notice of proposed rulemaking document.

Documents Relied Upon, and Where they are Available

Comments:

- There are no cited resources that provide reasoning for the necessity of proposed rules about drugs stored at room temperature.
- All cited resources support reasoning for proposed rules about vaccines, thermometers, and refrigerated drugs only.
- USP is cited as a reference but the proposed rules about storage of room temperature drugs clearly conflict with USP chapter <659> Packaging and Storage Requirements.
    - USP <659> clearly states that: "Excursions between 15° and 30° (59° and 86° F) that are experienced in pharmacies, hospitals, and warehouses, and during shipping are allowed. Provided the mean kinetic temperature does not exceed 25°, transient spikes up to 40° are permitted as long as they do not exceed 24 h. Spikes above 40° may be permitted only if the manufacturer so instructs."
    - If adopted as written, proposed rules would directly conflict with OAR 855-045-0200 as well, which states: "(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including: 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)."

Fiscal and Economic Impact

Comments:

- Proposed rules provide an estimated cost of $,2858 for each pharmacy to implement. This figure improperly assumes that pharmacies only store drugs in 2 areas.

- Here is a list of potential drug storage areas that the proposed rules would require pharmacies to monitor temperatures
    - Main inventory
    - Main refrigerated inventory
    - Will Call area
    - Will Call area refrigerator
    - Dedicated Vaccine Refrigerator
    - OTC area (many pharmacies have entire aisles of OTC drug products)
    - CII Safe
    - Bulk Storage/Shipping Area
    - Pyxis Machine/Automated Drug Dispensing Units
    - Hospital Med Carts
    - Hospital Satellite Pharmacy Locations
- Fiscal and Economic Impact does not consider the cost of professional recalibration services.
    - Current cost of recalibration services for our pharmacy's thermometers are the same cost as purchasing brand new thermometers.
    - Purchasing new thermometers capable of continuous monitoring, reporting capabilities, remote notification capabilities and with buffered probes for all areas that drugs are stored will be much more than $2,858
        - Using the proposed rule document's estimation, my pharmacy, which stores drugs in 7 locations, would incur a biennial cost of $10,003, assuming the cost of recalibration is the same as purchasing new equipment, as it is now.
- Fiscal and Economic Impact does not consider the additional cost of insulated/temperature-controlled packaging for mail order pharmacies.
    - Proposed rules (855-041-1036 (3)(G) state that drug storage conditions must be maintained during delivery to patients. This implies that drugs stored at room temperature would need to be kept at 68 to 77 degrees throughout the shipping process. This may be logistically impossible, especially during winter months.

855-041-1036 (2)

Comments:

- Rule does not state what to do if manufacturer does not include a storage requirement and no compendium exists.
    - Several API's used in pharmaceutical compounding do not come with a manufacturer storage recommendation nor do they exist in a compendium.

855-041-1036 (3)(A)

Comments:

- It is unclear if there is a precedent for using buffered probed thermometers to monitor room temperature. Typically buffered probed thermometers are used in refrigerators and freezers.

855-041-1036 (3)(n) Temperature Excursions

Comments:

- Temperature Excursions are not explicitly defined. For example, a room temperature of 67.5 degrees F would be considered an excursion even though a variance of up to 0.9 degrees F is permittable for the sensitivity of the thermometer
- Excursions should be treated differently based on variance and duration but they are not in the proposed rules.
    - For example, an excursion of 1 degree for 15 minutes is treated the same as an excursion of 10 degrees for 24 hours.
        - Both of these scenarios are common and should not be treated the same
- Proposed rules state that for each temperature excursion a list must be compiled for each drug involved in the excursion containing all of the following information:
    - Name
    - Quantity
    - NDC number
    - Lot Number
    - Exp Date
    - MFG
    - Dates of previous excursions experienced

    Additionally, for each excursion, a staff person must collect:

    - Drug manufacturer information utilized indicating drug is safe for use
    - Name of representative providing the information
    - Manufacturer contact information
    - Copy of information and case number if provided by manufacturer
    - Date and time information was obtained from manufacturer
    - Reference number associated with manufacturer contact
    - Name of the Oregon licensed pharmacist that reviewed the manufacturer data and confirmed the drug safe for continued use

    This is a total of 14 pieces of information for each drug involved in an excursion. My pharmacy has approximately 150 drugs stored at room temperature. This would equate to 2,100 pieces of information to collect in the event of an excursion. Collecting this information would involve an unbelievable amount of employee labor and many dozens of phone calls to drug manufacturers all over the world in varying time zones. Performing such a task would be nothing short of a logistical impossibility spanning the course of days, likely weeks and we don't even have that many drugs on the shelf. Conversely, it may take months to perform the same task for a big box retail store with hundreds if not thousands of Legend and OTC drug products stored at room temperature.

In closing, I would like to respectfully ask that the rule making committee consider striking any and all new language regarding the regulation of storage conditions for drugs stored at room temperature. The

proposed rules do not present any cited documentation for the necessity of these rules. The proposed rules clearly conflict with existing OAR rules. The proposed rules poorly define what excursions are and do not differentiate between types of excursions. The proposed rules would create a logistical nightmare for pharmacy personnel who already have too much on their plate following a pandemic and current global supply chain issues.

Thank you for your consideration.

Sincerely,

Luke Eilers, PharmD, COO
Northwest Compounders

From:	Luke Eilers
To:	PHARMACY RULEMAKING * BOP
Subject:	Providing Comment on Proposed Changes to Divisions 041/139 related to drug storage
Date:	Saturday, March 26, 2022 10:27:47 AM
Attachments:	Comments on Proposed Rule Changes to Drug Storage.docx

---

To whom it may concern,

Attached you will find my comments on the proposed rule changes to divisions 041/139 in relation to drug storage. Thank you for your time and consideration.

Sincerely,

Luke Eilers, PharmD, Owner
Northwest Compounders

March 29, 2022

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

RE: BOP Proposed Rules related to Drug Storage

Oregon Society of Health-System Pharmacists (OSHP), Oregon State Pharmacy Association (OSPA), The Oregon Pharmacy Coalition, Kaiser Permanente Northwest Region, Legacy Health, Oregon Health & Science University, Salem Health, Samaritan Health Services, St. Charles Health System, and Providence St. Joseph Health oppose the proposed rule changes 855-041-1036; Proper Storage of Drugs, and 855-139-0125; Drug Storage as they will cause challenging consequences that disrupt our pharmacy practice in Oregon.

- Temperature monitoring requirements conflict with USP temperature requirements.
- The revised diction emphasizes the usage of continuous temperature monitoring device for clarity to registrant but there are no current rules on proper documentation in the event of a downtime in the monitoring system.
- Adding controlled room temperature to the drug storage monitoring requirements will treat excursions for room temperature items the same as the excursions for the fridge or freezer. Having the same requirements may cause significant delay in patient care and risk to patient access.
- Buffered probes are not appropriate for room temperature monitoring and the containers available to store the probe for the purpose buffering will require an extensive amount of space relative to what is available.

In time of need to address post-pandemic workforce shortages and operational challenges, these requirements would hinder the momentum for us to tackle these immediate tasks.

Thank you for the opportunity to comment on the proposed rulemaking for your consideration. We look forward to opportunities for additional discussion to ensure safe and quality care for all Oregonians. OSHP will continue to collaborate with the Board to advocate for legislation to further advance the practice of pharmacy. We look forward to engaging with you in this matter to assess current rules 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

DocuSigned by:
Lincoln Alexander
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The Oregon Pharmacy Coalition
Joshua Free, PharmD, MBA
Chairman

DocuSigned by:
Joshua Free
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Asante
Amy Watson, PharmD, MBA, FACHE
Dir Pharmacy Services & Chief Pharmacy Officer

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Kaiser Permanente Northwest Region
Alfred Lyman, Jr., PharmD, BCPS
Executive Director, Regional Pharmacy Services

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Legacy Health System
Majid Tanas, PharmD, MHA, MS
VP, Pharmacy Services, Chief Pharmacy Officer

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Lloyd Central Compounding Pharmacy
Natalie Gustafson
Director of Pharmacy

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Oregon Health & Sciences University
Jennifer Zanon, RPh
Director, Pharmacy Services Regulatory Compliance & Supply Chain

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

DocuSigned by:
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Samaritan Health Services
Daniel M. Rackham, PharmD, BCPS
Chief Pharmacy Officer

St. Charles Health System
Michael Powell, RPh
Chief Pharmacy Officer

DocuSigned by:
Michael Powell
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From:	Tanas, Majid :LSO VP Chief Pharmacy Officer
To:	PHARMACY RULEMAKING * BOP
Cc:	Daniel Rackham; joshua.free@comcast.net; Amy.Watson@asante.org; cory.rahn@salemhealth.org; Jennifer Zanon; Steven Overby; Yen Pham; lincpalex@gmail.com; Hissam, Jennifer M; Jennifer Zanon; Junior Lyman; Michael Powell; Tanas, Majid :LSO VP Chief Pharmacy Officer; Trinh, Long D; Natalie Gustafson
Subject:	Oregon Hospital Letter of Opposition to Proposed Rule Changes 855-041-1036; Proper Storage of Drugs, and 855-139-0125
Date:	Tuesday, March 29, 2022 4:27:34 PM
Attachments:	Please DocuSign Opposition Response to Drug .pdf

To Whom it May Concern:

Please see the attached letter from the Oregon Hospitals.

Best,

Majid

Majid Tanas, PharmD, MHA, MS
Vice President, Pharmacy Services/
Chief Pharmacy Officer
Legacy Health System
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Portland, OR 97209

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(503) 415-5011

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www.legacyhealth.org

Oregon Society of Health-System Pharmacist's Comments on Drug Storage Requirements

OSHP is a professional organization affiliated with the American Society of Health-system Pharmacy (ASHP), which represents over 700 licensed practitioners by the Oregon Board of Pharmacy. OSHP is dedicated to the advancement of pharmacy practice in Oregon through education, collaboration and advocacy. We appreciate the Oregon Board of Pharmacy's focus 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 with respect to Drug Storage requirements found in proposed rules under **855-041-1036 (Proper Storage of Drugs) and 855-139-0125 (Drug: Storage.)** We join the Oregon State Pharmacy Association (OSPA) and many heatlth-systems in opposition to this rule change. We are opposed to the proposed regulation and ask the Board to instead state that non-compliance with community standards regarding drug storage conditions be regarded as unprofessional conduct. (see below)

Regulation to the Standard of Care

The proposed rules outline many steps in the process of documenting and responding to changes in the drug storage environment, especially refrigerated pharmaceuticals. These steps are clearly documented in the cited references and are part of professional practice. OSHP believes that there is no purpose in citing these well-known and specific steps in drug storage control in the OAR. This over-regulation causes unnecessary and duplicative work for the pharmacy workforce and does not result in greater safety for patients. Those outlets who do not comply with well known and documented community standards will continue to be non-compliant and should be disciplined by the Board for unprofessional conduct. The majority of outlets that adhere to proper procedures should not be punished by duplicative regulatory requirements.

CURRENT BOARD OF PHARMACY RULES:

855-041-1036 Proper Storage of Drugs and 855-139-0125 Drug: Storage

(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 the manufacturer's published or USP guidelines. (b) All drugs must be stored in appropriate conditions for temperature, light, humidity, sanitation, ventilation, and space.

(2) Failure to store drugs in appropriate conditions is considered unprofessional conduct. (855-026-0020) (855-041-1170)

From:	Millard, Michael
To:	PHARMACY RULEMAKING * BOP
Subject:	OSHP written testimony in opposition to drug storage requirement rules.
Date:	Tuesday, March 29, 2022 9:43:27 AM
Attachments:	Comment to OBOP re drug storage requirements.docx

Hello all,
Please find attached, the written testimony of the Oregon Society of Health-System Pharmacists with regard to the rules hearing on Div 41 and 139 pertaining to drug storage requirements. We are in opposition to the approval of these rules.

--
"A lie is not the truth because you believe it"
Michael Millard B.Pharm MS FOSHP
Professor Emeritus
Pacific University School of Pharmacy
millard@pacificu.edu | 971-998-8838

March 29, 2022

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

RE: BOP Proposed Rules related to Drug Storage

Oregon Society of Health-System Pharmacists (OSHP), Oregon State Pharmacy Association (OSPA), The Oregon Pharmacy Coalition, Kaiser Permanente Northwest Region, Legacy Health, Oregon Health & Science University, Salem Health, Samaritan Health Services, St. Charles Health System, and Providence St. Joseph Health oppose the proposed rule changes 855-041-1036; Proper Storage of Drugs, and 855-139-0125; Drug Storage as they will cause challenging consequences that disrupt our pharmacy practice in Oregon.

- Temperature monitoring requirements conflict with USP temperature requirements.
- The revised diction emphasizes the usage of continuous temperature monitoring device for clarity to registrant but there are no current rules on proper documentation in the event of a downtime in the monitoring system.
- Adding controlled room temperature to the drug storage monitoring requirements will treat excursions for room temperature items the same as the excursions for the fridge or freezer. Having the same requirements may cause significant delay in patient care and risk to patient access.
- Buffered probes are not appropriate for room temperature monitoring and the containers available to store the probe for the purpose buffering will require an extensive amount of space relative to what is available.

In time of need to address post-pandemic workforce shortages and operational challenges, these requirements would hinder the momentum for us to tackle these immediate tasks.

Thank you for the opportunity to comment on the proposed rulemaking for your consideration. We look forward to opportunities for additional discussion to ensure safe and quality care for all Oregonians. OSHP will continue to collaborate with the Board to advocate for legislation to further advance the practice of pharmacy. We look forward to engaging with you in this matter to assess current rules 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

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Lincoln Alexander
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The Oregon Pharmacy Coalition
Joshua Free, PharmD, MBA
Chairman

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Joshua Free
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Asante
Amy Watson, PharmD, MBA, FACHE
Dir Pharmacy Services & Chief Pharmacy Officer

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Amy Watson
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Kaiser Permanente Northwest Region
Alfred Lyman, Jr., PharmD, BCPS
Executive Director, Regional Pharmacy Services

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Alfred Lyman, Jr.
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Legacy Health System
Majid Tanas, PharmD, MHA, MS
VP, Pharmacy Services, Chief Pharmacy Officer

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Lloyd Central Compounding Pharmacy
Natalie Gustafson
Director of Pharmacy

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Natalie Gustafson
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Oregon Health & Sciences University
Jennifer Zanon, RPh
Director, Pharmacy Services Regulatory Compliance & Supply Chain

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Jennifer Zanon
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Providence St. Joseph Health
Jennifer M. Hissam, RPH, MHA
Executive Director, Chief Pharmacy Officer/Oregon

DocuSigned by:
Jennifer Hissam
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Salem Health
Corey Rahn, PharmD, BCPS
System Director of Pharmacy

DocuSigned by:
Cory Rahn
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Samaritan Health Services
Daniel M. Rackham, PharmD, BCPS
Chief Pharmacy Officer

St. Charles Health System
Michael Powell, RPh
Chief Pharmacy Officer

DocuSigned by:
Michael Powell
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From:	Chae, Hyesoo
To:	PHARMACY RULEMAKING * BOP
Subject:	Oregon Health-System Comment on Proposed Rules: Drug Storage
Date:	Tuesday, March 29, 2022 4:20:40 PM
Attachments:	Opposition_Response_to_Drug_ Storage.pdf

Hi All,

Please see attached for a written comment from OSHP, OSPA, and multiple Oregon Health-Systems in regard to opposition of the proposed rule changes 855-041-1036 and 855-139-0125.

Please let me know if you have any questions or concerns.

Warmly,
Hyesoo

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

March 28, 2022

Oregon Board of Pharmacy
c/o Joe Schnabel
Executive Director
800 NE Oregon St. Suite 150
Portland, OR 97232
pharmacy.rulemaking@bop.oregon.gov

Dear Director Schnable,

The Oregon State Pharmacy Association would like to submit comments on rule changes proposed by the Board of Pharmacy for drug storage requirements for pharmacies.

We are requesting that the Board not adopt the proposed rule changes for Proper Storage of Drugs and instead revise the proposed changes for future rulemaking so that rules allow for practical compliance while maintaining drug integrity.

Compliance with current temperature monitoring rules is a known issue. Part of the problem is that rules are excessively complex and difficult to administer daily in a busy practice setting. There are elements of the proposed changes which bring needed clarity and direction; however, many changes significantly add to the complexity and administrative burden. The changes also add new questions and uncertainty as to when to apply the rules and to what extent.

Problematic sections include:
(3)(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."

- Other sections of the rules require a continuous temperature monitoring system which alerts for all excursions. A review of temperatures would not be necessary with such a system, only a check that the system is working and that there are no alerts. Pharmacies must be able to utilize technology to replace manual work. This increases compliance and decreases administrative burden.
- Once daily checking is adequate to assure the system is working. Twice daily is unnecessary.
- Review should only be required on days the pharmacy is open

(3)(n) "Document the following for each temperature excursion"

- This whole section is beyond what is necessary to document. There needs to be trust that licensed and educated professionals are obtaining the information necessary to determine drug integrity and safety. That is our jobs. Requiring case numbers, manufacturer contact names, and copies of communication or documents reviewed only serves the purpose of Board auditing to prove a pharmacist did what they said they did.
- There are 23 data points required to document with each excursion, most of these for each drug. That is too many. Every recorded data point costs money and time away from patient care. Imagine having 100 NDC/lots in a refrigerator- that is 2,300 pieces of data that must be recorded!

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- The critical missing piece of these rules is: "What constitutes an excursion for when these documentation requirements apply?" Without such language, the rules appear to apply to every excursion of greater than one minute or one degree. That is completely impractical and unnecessary. There should be language to exercise pharmacist professional judgement; that the documentation requirement applies when a pharmacist judges that a drug may have been therapeutically compromised or expiration date shortened.

In general, Drug Storage Requirement rules need to be rewritten to answer what to do in real world situations of temperature variation to assure the public has safe and therapeutically viable drugs. We recommend the Board take into account the numerous studies showing drug safety and unchanged therapeutic effect when drugs are used beyond their recommended storage or expiration dates. Rules must also consider the limitations of staff resources and drug access problems that can be created when drugs are quarantined. It would be unacceptable if rules require documentation and contact of every manufacturer, for every drug in the pharmacy, for every minor storage variation.

We request that rules provide guidance on how to use professional judgement in real world situations:

- What to do if the power went out last night for two hours and the refrigerator temperature showed a 7-degree excursion and was back in range 20 minutes later?
- What to do if the air conditioning went out for several days in the pharmacy and the daily peak temperature in the pharmacy went up to 80 degrees and was out of range 4 hours per day?

We appreciate the work of the Board and Board Staff to revise and modernize rules for rapidly changing pharmacy practice settings. We ask that when writing or revising rules, the Board keep rules simple and practical while allowing pharmacists to exercise professional judgment and keep their focus on providing great care for patients.

Sincerely,
OSPA Board of Directors

From:	Brian Mayo
To:	PHARMACY RULEMAKING * BOP
Cc:	SCHNABEL Joseph * BOP; DAVIS Jen * BOP
Subject:	OSPA Comments of Rulemaking for Drug Storage Requirements
Date:	Monday, March 28, 2022 8:36:45 AM
Attachments:	Drug Storage Requirements rulemaking comments.pdf

Hello,

The Oregon State Pharmacy Association would like to submit comments on rulemaking for drug storage requirements. Please see the attached letter and let me know if you have any questions.

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

DEB PATTERSON
STATE SENATOR
DISTRICT 10

OREGON STATE SENATE

March 29, 2022

Dear Chair Ayoub and Members of the Board of Pharmacy,

Good morning. My name is Deb Patterson. I am State Senator from South Salem, and Chair of the Senate Health Care Committee. Thank you for the opportunity to testify today.

I am in strong support of making the Pharmacy Technician (PT) licensure accessible to entry level applicants, while protecting public safety and keeping our standards in Oregon for all professions up to national standards. This is why I add my concerns about making permanent a rule which allows a PT to continue to work without meeting national certification standards.

The current Pharmacy Technician license is an excellent avenue for students, entry level workers, and out of state workers to transition into an Oregon pharmacy license while they pursue national certification. The one-year limit on the non-renewable Pharmacy Technician (PT) license ensures that Oregon's pharmacy technicians are incentivized to reach national certification and obtain their COPT license in a reasonable amount of time, while also giving them a head start in the workforce. The proposed rule changes erode the quality of the Pharmacy Technician profession by removing that incentive to pursue national certification.

National certification is key to ensuring Oregon's pharmacy technicians operate at a competitive standard. The required 20 hours of continuing education is vital to keep our workforce educated, culturally competent, and up-to-date on the latest changes in the profession. Reducing required CE hours to half of what national certification requires will result in a lower standard of education for Oregon's Pharmacy Technicians, and a lower quality of care for patients.

I agree that we must work to increase access to the pharmacy technician profession, but we cannot do so at the expense of patient care standards and workforce quality. I urge you to vote NO on this proposed rule change.

Thank you for your time and service.

Sincerely yours,

Deb Patterson

Deb Patterson
Senator, District 10

900 Court St. NE, S-215, Salem, OR 97301 - (503) 986-1710 - sen.debpatterson@oregonlegislature.gov

From: Sen Patterson
To: PHARMACY RULEMAKING * BOP
Cc: Mooney Emily
Subject: RE: Testimony re: Rulemaking on PTs
Date: Monday, March 28, 2022 1:03:05 PM
Attachments: PT Rule Testimony - Deb Patterson.pdf

Dear Rachel,
Attached please find my testimony for tomorrow to submit for the record. I would still like to testify during the meeting as well, if I may. Many thanks!
Deb

Deb Patterson
Senator / District 10
Chair / Senate Health Care Committee
Address: 900 State Street, S-215, Salem, OR 97301
Phone: 503-986-1710

From:	Melissa Netland
To:	PHARMACY RULEMAKING * BOP
Subject:	Temperature monitoring
Date:	Monday, March 28, 2022 8:30:21 PM

To Whom it May Concern,
The proposed rule changes regarding continuous temperature monitoring during transport to ensure there are no excursions is absurd. Pharmacies do not receive the products from manufacturers or wholesalers with the assurance that an excursion did not occur.
Pharmacies are prudent and take into consideration extreme weather conditions for the safety of all.
This proposed rule will not allow pharmacies to provide the simplest of deliveries that may be minutes away from the pharmacy without requiring the most extreme of burdens put upon them. Most room temperature medications have a large range of acceptable temperatures, and refrigerated products can be very safely transported with a cooling system that is adequate to meet the manufacturer's standards. Multiple delivery drivers with multiple monitoring systems??
Pharmacies are increasingly burdened with unnecessary costly regulations that get in the way of providing quality patient care. Please vote this down!
Respectfully,
Melissa Netland, RPh
Stayton and Sublimity Pharmacy

From: ktibby1@gmail.com
To: PHARMACY BOARD * BOP; PHARMACY RULEMAKING * BOP
Subject: Don"t reduce certification standards!
Date: Tuesday, March 22, 2022 1:22:15 PM

Dear Board of Pharmacy,

Please vote NO on proposed changes to the pharmacy technician licensure requirements. Certified Oregon Pharmacy Technicians go through a rigorous national certification process in order to provide safe, quality care.

Allowing the creation of a renewable pharmacy technician license without this important certification requirement will disincentivize workers from applying for a Certified Oregon Pharmacy Technician license and result in a workforce that does not meet the national standard. Continuing education is vital to keep our workforce educated, culturally competent, and up to date on the latest changes in the profession. Reducing pharmacy technician hours to half of what national

certification requires will surely result in a lower standard of education for Oregon’s pharmacy technicians.

In times of emergency, it is understandable to want to increase staffing, but please don’t do so at the expense of patient safety and workforce quality. Vote NO on the proposed changes to Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules.

From: Karen Thibodeau

Dan Clay, President Sandy Humphrey, Secretary-Treasurer

STATEMENT IN OPPOSITION TO THE PROPOSED RULES ON PHARMACY TECHNICIAN LICENSURE

To: Oregon Board of Pharmacy
From: United Food and Commercial Workers Local 555
3/29/2022

Dear Chair and members of the board:

We thank you for the opportunity to testify in opposition to the proposed rules in Divisions 021/025/110 related to Pharmacy Technician & Certified Oregon Pharmacy Technician Licensure.

UFCW Local 555 is the largest private sector labor union in Oregon. Our members come from a number of industries, including grocery, retail, food processing, manufacturing, and healthcare– including some pharmacy technicians. We are a diverse group of workers who take pride in acting as a strong collective voice for working people. We are opposed to the proposed changes to the Pharmacy Technician licensure. Creating a new, renewable license with reduced standards will erode the current profession, resulting in a lower quality of care for patients across Oregon.

The current Pharmacy Technician license is an excellent avenue for students, entry level workers, and out of state workers to transition into an Oregon pharmacy license while they pursue national certification. The one year limit on the non-renewable Pharmacy Technician license ensures that Oregon's pharmacy technicians are incentivized to reach national certification and obtain their Certified Oregon Pharmacy Technician license in a reasonable amount of time, while also giving them a headstart in the workplace.

National certification is key to ensuring Oregon's pharmacy technicians operate at a competitive standard. The required 20 hours of continuing education is vital to keep our workforce educated, culturally competent, and up to date on the latest changes in the profession. Reducing required continuing education hours to half of what national certification requires will result in a lower standard of education for Oregon's Pharmacy Technicians, and a lower quality of care for patients.

At the same time, these proposed rules increase the hourly continuing education requirement for the entry level pharmacy technician licensure, increasing the barrier to entry for those new to the profession. Healthcare workers are exhausted and leaving the workforce in droves. We are concerned that adding on additional administrative burdens in the licensure process may discourage many potential pharmacy technicians from pursuing a license.

In summation, this proposed rule would create a middle ground license that is both more difficult to apply for at the onset, but also encourages no progression to the Certified Oregon Pharmacy Technician license, resulting

in a workforce that is undereducated and cheaper to maintain, without increasing access to the qualified, higher paying jobs workers are looking for.

UFCW 555 agrees that we must work to increase access to the pharmacy technician profession, which provides a strong job in the healthcare workforce for our members. However, we cannot do so at the expense of patient care standards and workforce quality.

If we are to update the pharmacy technician licensure, we must retain the entry level nonrenewable license for greatest access, and provide incentives to encourage pharmacy technicians to continue to pursue a certified Oregon pharmacy technician license that meets the requirements set by the National Board of Pharmacy. For pharmacy technicians that are having trouble meeting that one year deadline to complete certification, let's find other opportunities for training programs, informational flyers, or other deadline extensions that can be offered to help get these workers over the finish line.

We commend the board for their work to increase access to pharmacy jobs in the midst of the COVID-19 pandemic, and ask that you reconsider the ramifications of these proposed rules and work to find a solution that does not undermine the existing workforce. We urge your NO vote.

Sincerely,

Madison Walters,
Political Liaison,
UFCW Local 555

From:	Madison Walters
To:	PHARMACY RULEMAKING * BOP
Subject:	Rulemaking Testimony
Date:	Tuesday, March 29, 2022 4:26:02 PM
Attachments:	Board of Pharmacy UFCW555 Testimony.pdf

Good afternoon,

Attached is UFCW 555's testimony in opposition to the proposed rules in Divisions 021/025/110 related to Pharmacy Technician & Certified Oregon Pharmacy Technician Licensure.

Thank you very much for your consideration. If you have any questions, please don't hesitate to reach out to me via email or phone.

Sincerely,

Madison Walters

--
Madison Walters (she/they)
Political Liaison
UFCW Local 555
(503) 708-3489

From:	April Von Allmen, PharmD, BCACP
To:	PHARMACY RULEMAKING * BOP
Subject:	Proposed changes to rule 855-139-0125
Date:	Thursday, March 24, 2022 2:43:33 PM
Attachments:	MMlogosignature_4a573b52-1cc1-4ca4-9c82-d9829aacb407.png FB_651c4cb6-129b-47f3-b8aa-7319521648cb.png IG_86320df1-e4a1-4100-a485-c34566b98142.png LI_1669a809-50d4-4b49-924a-3e01793f3431.png

I oppose the segment of the rule that indicates that if there is an excursion, the manufacturer of every drug (including room temperature drugs) must be contacted to ensure it is safe for use and this contact must be documented particularly in the setting of mail order or long-term care pharmacies.

Unless there has been documented harm of the current practice for **room temperature** medications regarding temperature excursions or studies indicating they lose potency after temporary excursions I do not see the value in requiring a pharmacy to call manufacturers for potentially hundreds of medications.

Warm regards,
April Von Allmen, PharmD, BCACP

Mosaic Medical

April Von Allmen, PharmD, BCACP
Pharmacy Manager, Clinical
Pronouns: She/Her/Hers
Why Pronouns Matter
Direct: 541-408-9488

Bend-Madras-Prineville-Redmond
Phone: 541-383-3005
Fax: 541-383-1883
Website: www.mosaicmedical.org

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

March 29, 2022

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: Accurate Pharmacy Hours and Temporary Pharmacy Closures.

Dear Dr. Schnabel,

Please accept these comments on behalf of all pharmacies owned and operated by Walgreen Co. in Oregon. We appreciate the opportunity to submit comments for the Board's careful deliberation of these important topics.

Walgreens acknowledges the challenges patients have faced during the pandemic with access to pharmacy services due to unexpected closures. The Board contemplated these rules at the right time as the Omicron variant was ravaging our communities and causing many unavoidable and unanticipated team member illnesses. As the pandemic has waned and Governors' are removing executive orders and declarations of emergency, life is beginning to return to normal. We are experiencing far fewer closures that limit patient access. Walgreens strongly urges the Board **not to permanently adopt** the rules related to temporary or emergency closures in 855-041-1092 and 855-139-0145, as we feel that they are unnecessary and create an additional burden on pharmacist's time and company resources.

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.
5330 E. Washington St, Ste. 105
Phoenix, AZ 85034
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lorri.walmsley@walgreens.com

March 28, 2022

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: Drug Storage

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 Drug Storage.

As the Board contemplates safe pharmacy practice conditions and the Board's role in ensuring patient safety, these updates are a perfect example of regulations creating additional demands on pharmacists' time without significant impact on patient safety. As proposed, Walgreens has many concerns that will impact both our business and our pharmacists, and most importantly patients.

- Real-time alerts: While well-intentioned, they will create many distractions for our pharmacists. An excellent example of this is when putting away deliveries or if a prescription is misplaced and takes time to find in the refrigerator. Temperature excursions are very common in the pharmacy for very short periods. An alert and the associated actions would be tremendously burdensome on our pharmacist's time without having any real impact on patient safety or product integrity. At a minimum we would request to change the interval for monitoring to 45 minutes versus the currently proposed 15 minutes.
- Documentation and actions for excursions: The proposed requirement for pharmacists to document each product, NDC, lot, expiration, etc., as well as the information from the manufacturer is far too onerous and would take time away from direct patient care or cause pharmacies to stock quantities of refrigerated or frozen products. The requirement for a pharmacist to call each manufacturer is far more restrictive than any other state and would take hours, if not days resulting in delays in patient care as this process is completed. Additionally, these proposed regulations are likely to result in additional waste of medications due to the time it would take to comply, resulting in financial losses of potentially hundreds of thousands of dollars for pharmacies.

We believe that the Board has not provided sufficient evidence to amend these regulations. Walgreens, strongly encourages the Board **not to adopt** these regulations as proposed and **retain** the current version of the regulations related to Drug Storage, as these rules are far to onerous for both the business and our team members. Every regulation change a board considers should be directed at improving patient care, not diminishing it. There is no evidence to support the added work by pharmacists required to comply with these regulations. The additional steps that would be required by Pharmacists will take time away from patient care and add additional stress and workload for the personnel in the store.

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
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5330 E. Washington St, Ste. 105
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lorri.walmsley@walgreens.com

March 28, 2022

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: Pharmacy Prescription Lockers (PPLs)

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 Pharmacy Prescription Lockers.

Walgreens appreciates the Board's willingness to consider Pharmacy Prescription Lockers as an alternative form of delivery for patients' however, these rules are far too specific and onerous for businesses to comply, thereby limiting the utility of these good-intentioned regulations. We strongly encourage the Board **does not adopt** these regulations and send them back to a RAC with the appropriate industry stakeholders to promulgate rules that are more in line with industry standards.

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.
5330 E. Washington St, Ste. 105
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March 28, 2022

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 opportunity to submit comments for the Board's careful deliberation of these important topics. We believe the Board is well-intentioned in the promulgation of the Telework rules below. With the understanding of the healthcare crisis in the US and in Oregon, the need for telework promotes patient access and is most critical to populations of patients that have many limitations when it comes to pharmacy choices. As outlined below, many of the requirements articulated in the regulations are highly burdensome and unfortunately, we believe will cause telework to largely go unused, therefore ultimately hurting patient access. We believe Boards of pharmacy should create regulations based on facts and/or data. Many of the requirements outlined are not backed by data or facts to support the basis for inclusion within these rules.

855-041-3220 – Telework: Supervision Requirements

While we appreciate the Board's continued work to address stakeholder feedback related to the Telework, provisions, these rules are still too onerous for efficient use in practice. These rules are more restrictive than any other remote work provisions in the country. As the Board continues to deliberate and discuss safe pharmacy practice conditions, appropriate telework provisions will be key to offer both alternative work environments for team members and to allow alternative solutions to support traditional dispensing pharmacies. 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 and respectfully request the amendments as outline below.

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 a real-time connection and have appropriate technology or interface to allow access to information required

to complete assigned duties;¶

(2) Ensure telephone audio is recorded, ~~reviewed~~ and stored for all patient interactions completed by Certified Oregon Pharmacy Technicians and Interns;¶

(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon

Pharmacy Technician and that the continuous ~~audio/visual connectionmmunication~~ system 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 connectionaudiovisual communication system 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~~ PIC 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 5% of patient interactions observed or 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~~ ¶

(a~~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 48 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 audiovisual communication system~~ 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 audiovisual communication system~~.

855-041-3235 - Telework: Personnel

The requirement for audiovisual 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 audiovisual communication system~~ 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.

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 audiovisual communication system~~ 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 audiovisual communication system~~ 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~~ ~~audtiovisual communication system~~ 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 audiovisual communication system~~ testing and training;

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, RPh, FAzPA

From:	Walmsley, Lorri
To:	PHARMACY RULEMAKING * BOP; SCHNABEL Joseph * BOP
Cc:	Aytay, Michelle
Subject:	Walgreens Comments
Date:	Monday, March 28, 2022 3:26:36 PM
Attachments:	OR Comments_Telework March 2022.pdf OR Comment Letter_Drug Storage.pdf OR Comment Letter_Pharmacy Prescription Lockers.pdf OR Comments_Accurate Pharmacy Hours and Temporary closures.pdf

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Hello,

Please accept the attached comments on behalf of Walgreens regarding the proposed rules for the hearing tomorrow.

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs

Walgreen Co.
Telephone 602-214-6618

Member of Walgreens Boots Alliance ¦ MyWalgreens.com

From: PHARMACY RAC * BOP
To: PHARMACY RULEMAKING * BOP
Subject: FW: EXTERNAL EMAIL: Safe Pharmacy Conditions Workgroup Meeting Pre-Work - Review Required
Date: Friday, March 25, 2022 11:11:00 AM
Attachments: image002.png
image004.png
image005.png

Hello,

Was hoping I could offer a couple of suggestions below for the rulemaking committee. While pharmacy workload has decreased recently with less vaccine demand, I'm appreciative of any rule changes that would help address issues we dealt with over the winter. Thank you for your time and consideration.

Christopher Ward

Pharmacy Field Evaluator

Portland Division

Albertsons SAFEWAY Working together to be the "favorite local supermarket"

503-319-8721 (mobile)

christopher.ward@albertsons.com

From: Christopher Ward <Christopher.Ward@albertsons.com>
Sent: Friday, March 11, 2022 11:41 AM
To: PHARMACY RAC * BOP <PHARMACY.RAC@bop.oregon.gov>
Subject: Re: EXTERNAL EMAIL: Safe Pharmacy Conditions Workgroup Meeting Pre-Work - Review Required

Thank you for the opportunity to help our colleagues. Was hoping I could forward a couple thoughts that I wanted to relay as time seemed to get away from us. Not familiar with the fishbone process but seemed like a very structured way of resolution. However we didn't get a chance to problem solve what I think we all agree were the critical issues, namely increasing the supply of qualified technicians in the area and the availability of telework. Seemed to get hung up on topics that couldn't be resolved legislatively (phones, receipts?).

Regarding the Technician shortage. Someone touched on licensing clerks, similar to the Pharmacy Assistant license in WA. Would like to propose, at least temporarily, dropping the fee for the first year Technician license. As mentioned, technician wages have been stagnant compared to opening positions in other retail work. The fee creates a barrier for individuals who are interested in the position, but are unwilling to pay for the opportunity. Also agreed that expanding Certified Technician duties can alleviate RPh workload in any way the Board see's as appropriate. In my opinion this would be a quick fix and help with recruiting. Also any way we can expedite the application process would be helpful.

Regarding telework, OR requirements are currently arduous. As it stands my company legal department will not allow us to work remotely unless at the office or another store location, which is

very limiting for both RPh's and Technicians. Recorded audio, four tech oversight limit, continuous check in. As a technician licensed both in OR and WA, I am allowed to help remotely our Washington stores with data entry. In Oregon I am not able to.

Hopefully these suggestions are helpful and added to the notes for the Members who will be creating legislation from our recommendations. Thank you.

Christopher Ward

Pharmacy Field Evaluator

Portland Division

503-319-8721 (mobile)

christopher.ward@albertsons.com

From: PHARMACY RAC * BOP <PHARMACY.RAC@bop.oregon.gov>
Sent: Friday, March 4, 2022 4:22 PM
To: PHARMACY RAC * BOP <PHARMACY.RAC@bop.oregon.gov>
Subject: EXTERNAL EMAIL: Safe Pharmacy Conditions Workgroup Meeting Pre-Work - Review Required

Dear Workgroup Members,

Thank you for confirming your participation in Oregon Board of Pharmacy's upcoming Safe Pharmacy Practice Conditions Workgroup meeting on **March 10 from 1-4PM**.
Prior to the meeting, please review the attached "Safe Pharmacy Practice Conditions Workgroup Pre-Work" pdf, which we will reference during the meeting. It is very important that you take the time to read over the survey data and comments. During the upcoming meeting, the workgroup will participate in a fishbone exercise to identify possible causes of unsafe pharmacy practice conditions based on the survey data and comments.

Thank you again for volunteering your time and expertise. If you have any questions or would like to see the data in a different format, please email us at pharmacy.RAC@bop.oregon.gov.

FYI, the January 2022 Safe Pharmacy Practice Conditions Workgroup Meeting Minutes are now available on our website.

HOW TO JOIN THE WORKGROUP MEETING USING TEAMS:

You do not need to have a Microsoft account to join the Teams meeting, however if you use a smart phone or tablet, you will need to download the app.

To join a Teams meeting you will simply open the invitation and choose “click here to join the meeting”
Here’s an **example**:

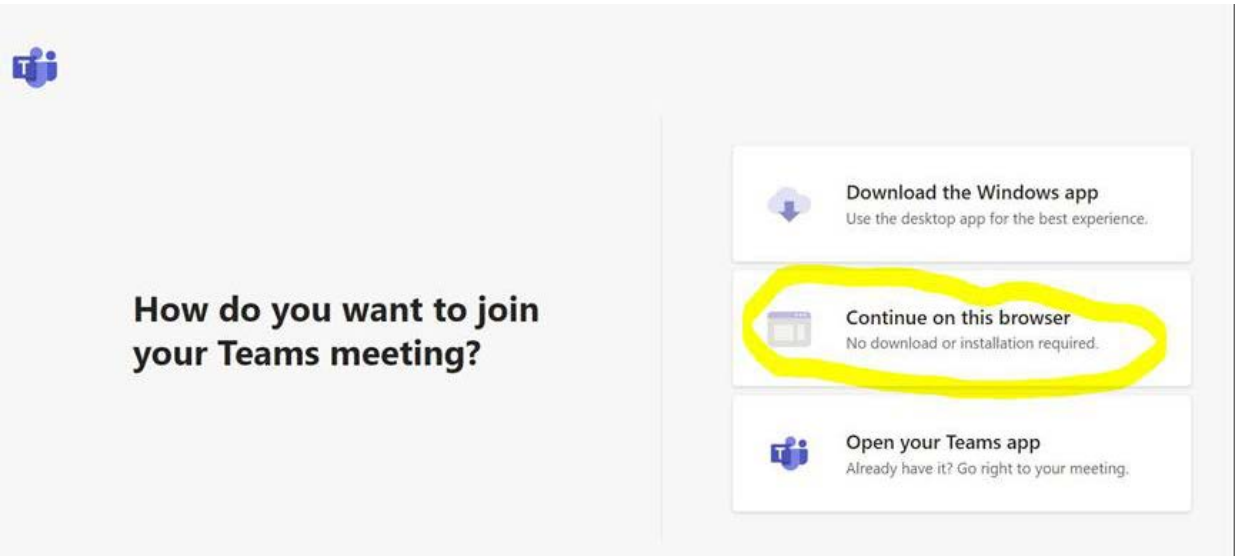
Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting

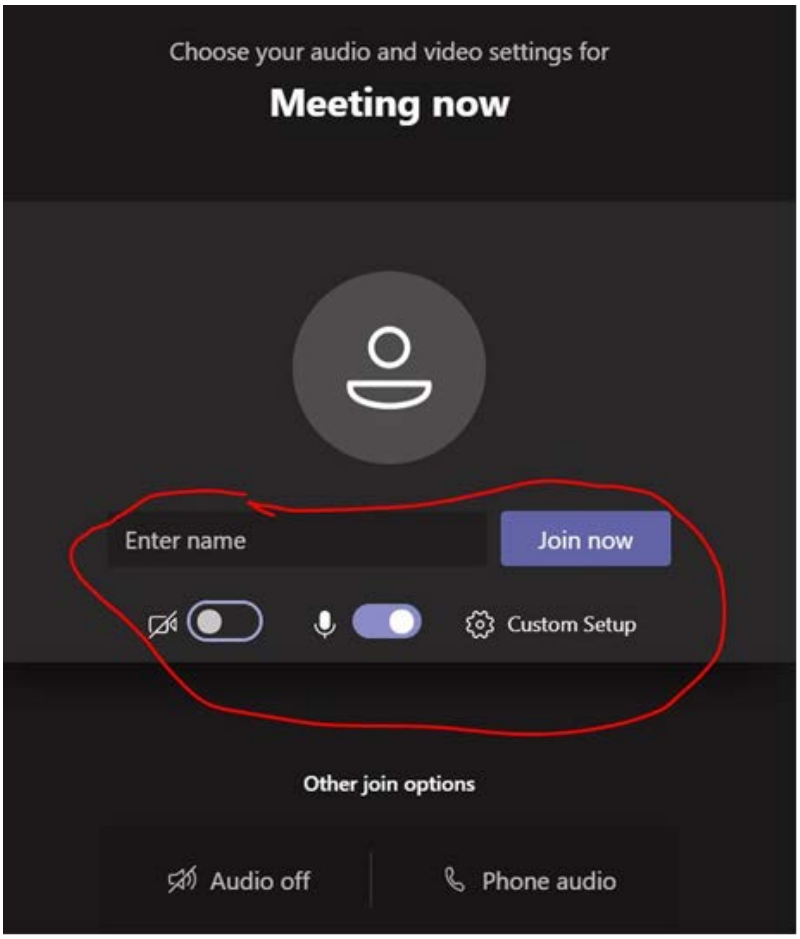
Or call in (audio only)
+1 503-446-4951,,618960603# United States, Portland
Phone Conference ID: 618 960 603#
Find a local number | Reset PIN

Learn More | Meeting options

If you are joining from a laptop, this is the prompt you will see after choosing “join the meeting”



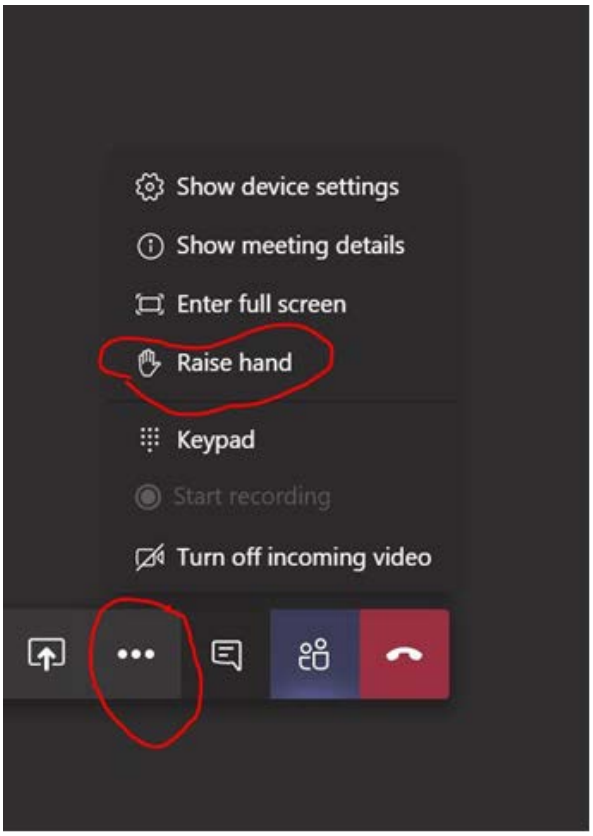
After you choose “Continue in this browser” or have opened the meeting in the Teams app, you will see a black prompt box where you will be able to enable the video and microphone, click “join now” to join the meeting.



You may have a brief pause and or see a prompt letting you know that the host will admit you to the meeting.

Once you are in the meeting, please mute your microphone.

When you need to speak, use the “raise your hand” feature so everyone has an opportunity to speak. This also key for the meeting minutes which allows us to capture the audio clearly.
Click on the three … to engage:



Rulemaking Staff
Oregon Board of Pharmacy
(971) 673-0001 phone
pharmacy.RAC@bop.oregon.gov

Oregon.Gov/Pharmacy

From: Lincoln Wright
To: PHARMACY RULEMAKING * BOP
Subject: Division143 rulemaking comments
Date: Wednesday, March 2, 2022 11:39:54 AM
Attachments: image001.png

Greetings,

You should consider two different definitions of PPLs. Some PPLs are treated like a PO Box and not stored in a pharmacy area. While they may only have prescriptions in them, they may not even be owned by a pharmacy. In this case, the drugs delivered to these devices are out of the pharmacy custody similar to something that is mailed to a patient via USPS. Even if the PPL is owned by a pharmacy, these deliveries should be considered dispensed, and these medications cannot be returned to the pharmacy's stock. In this case you would want regulations that do not require the PPLs to be locked when the pharmacy is closed or require the observation of a PIC or other pharmacist 24/7. The requirements for drug storage also shouldn't apply as if the locker was an extension of the pharmacy. You might suggest or that this type of PPL be kept in an indoor temperature controlled environment but not require a pharmacy that delivers to the PPL to monitor the temperature as if the locker area was part of the pharmacy. In fact, in this case since the PPL is similar to any other PO box for UPS, FedEx, USPS, or other private company, I can't see it being required to be licensed with the state or be under the jurisdiction of OBOP. It would be different if the pharmacy would want to return the orders to their stock if the orders sit too long. Otherwise, how is this type of PPL any different from a delivery service or mailing a prescription to a patient's mailbox? The pharmacy is already required to ensure that the patient receives orders in a way that ensures drug stability, so as long as the drugs delivered to a PPL never go back into the pharmacy stock, why would these types of PPLs need registration and extra regulations?

Thank you for your attention,

Dr. Lincoln Wright, PharmD
Director of Pharmacy
Confederated Tribes of Grand Ronde
Health and Wellness Center
503-879-2299 - office
503-879-2030 - fax

From:	jeannettezimmer@gmail.com
To:	PHARMACY BOARD * BOP; PHARMACY RULEMAKING * BOP
Subject:	Don"t reduce certification standards!
Date:	Tuesday, March 29, 2022 4:03:51 PM

Dear Board of Pharmacy,

Please vote NO on proposed changes to the pharmacy technician licensure requirements. Certified Oregon Pharmacy Technicians go through a rigorous national certification process in order to provide safe, quality care.

Allowing the creation of a renewable pharmacy technician license without this important certification requirement will disincentivize workers from applying for a Certified Oregon Pharmacy Technician license and result in a workforce that does not meet the national standard. Continuing education is vital to keep our workforce educated, culturally competent, and up to date on the latest changes in the profession. Reducing pharmacy technician hours to half of what national certification requires will surely result in a lower standard of education for Oregon's pharmacy technicians.

In times of emergency, it is understandable to want to increase staffing, but please don't do so at the expense of patient safety and workforce quality. Vote NO on the proposed changes to Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules.

From: Jeannette Zimmer

Division 006
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. 12/09/2021)

(2) “Alarm system” means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.

(3) “Audiovisual communication system” means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.

(4) “Biological product” means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

(5) "Biosimilar" product means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (12/1/2021).

(6) “Board” means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(7) "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.

(8) “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.

(9) "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.

(10) "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.

(11) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(12) "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.

(13) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(14) "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.

(15) "Entry system" enables control of access to a secured area.

(16) "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).

(17) "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.

(18) "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.

(19) "Misbranded" has the same definition as set forth in 21 USC 352 (v. 12/09/2021).

(20) "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.

(21) "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.

(22) "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.

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

(24) "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.

(25) “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.

(26) "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.

(27) 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.

(28) "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.

(29) "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.

(30) “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.

(31) “Practice of pharmacy” is as defined in ORS 689.005.

(32) “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.

(33) "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.

(34) “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.

(35) "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.

(36) “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.

(37) “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.

(38) “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.

(39) "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.

(40) "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.

(41) “Still image capture” means a specific image captured electronically from a video or other image capture device.

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

(43) "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.

(44) “Surveillance system” means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

(45) “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.

(46) “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.

(47) "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.

(48) "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.

Division 041
OPERATION OF PHARMACIES

855-041-1001
Definitions

"Drug room" is a drug storage area registered with the board which is secure and lockable.

Division 139
REMOTE DISPENSING SITE PHARMACY

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) "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.

(3) "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.

DETECTION OF SARS-CoV-2 ANTIGEN: OTC COVID-19 ANTIGEN SELF-TEST

STATEWIDE PATIENT CARE SERVICE 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 OTC COVID-19 Antigen Self-Tests.

PRESCRIBING PARAMETERS:

- Product: OTC COVID-19 Antigen Self-Tests listed on either of the following sites:
  - FDA *In Vitro Diagnostics EUAs* - Antigen Diagnostic Tests for SARS-CoV-2 webpage
    - Must have "OTC" designation
  - FDA *Approved OTC Devices* database
- Indication: Must be consistent with the Emergency Use Authorization or FDA approval for the specific product prescribed (e.g. age, symptom onset)

Division 020
PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0300
Protocol Compendium

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

(1) Continuation of therapy (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)

(D) Intranasal corticosteroids (v. 06/2021);

(b) Vulvovaginal candidiasis (VVC) Protocol (v. 06/2021);

(c) COVID-19 Monoclonal Antibody (mAb) Protocol (v.12/2021); and

(d) COVID-19 Antigen Self-Test 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.]

Division 020
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 an audiovisual communication system to conduct the consultation.

Division 041
OPERATION OF PHARMACIES

855-041-1020
Security of Prescription Area

(1) The area in a registered pharmacy where legend and/or controlled substances are stored, possessed, prepared, manufactured, compounded, or repackaged shall be restricted in access, in such a manner as to ensure the security of those drugs.

(2) The pharmacist-in-charge and each pharmacist while on duty shall be responsible for the security of the prescription area including provisions for adequate safeguards against theft or diversion of prescription drugs, and records for such drugs.

(3) When there is no pharmacist present, the pharmacy shall be secured to prevent entry. All entrances to the pharmacy shall be securely locked and any keys to the pharmacy shall remain in the possession of the pharmacist-in-charge and other employee pharmacists as authorized by the pharmacist-in-charge. When there is no pharmacist present, and it is necessary for non-pharmacist employees or owners to have access to the pharmacy, the prescription area shall be secured from entry as described in OAR 855-041- 2100.

(4) Prescription drugs and devices and non-prescription Schedule V controlled substances shall be stored within the prescription area or a secured storage area.

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 an audiovisual communication system and have appropriate technology or interface to allow access to information required to complete assigned duties;

(2) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by Certified Oregon Pharmacy Technicians and Interns;

(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon Pharmacy Technician and that the audiovisual communication system 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 audiovisual communication system 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 5% of patient interactions observed or 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 48 hours, and retain records.

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 audiovisual communication system 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 audiovisual communication system.

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 audiovisual communication system 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.

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 audiovisual communication system 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.

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 audiovisual communication;

(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 the audiovisual communication system is disrupted;

(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) Audiovisual communication system testing and training;

(g) Still image capture and store and forward images must be retained according to (1);

(h) Data and telephone audio must be retained for 6 months; and

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

855-041-5055
Remote Distribution Facility (RDF)

The purpose of these rules is to provide for the use of a Certified Oregon Pharmacy Technician functioning outside of a pharmacy to prepare drugs only for administration to a patient by another healthcare provider, and where requisite pharmacist supervision and verification is provided remotely by an Oregon licensed pharmacist via an audiovisual communication system.

(1) A pharmacy physically located in Oregon may make written application to operate a RDF.

(2) The board may approve an application for registration as a RDF which includes the following:

(a) An operation plan;

(b) Policies and Procedures;

(c) A training plan;

(d) A quality assurance plan for ensuring that there is a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems; and

(e) The fee specified in Division 110.

(3) Notwithstanding the definition of “supervision by a pharmacist” in Division 006, supervision in a RDF may be accomplished by a pharmacist via an audiovisual communication system from the applying pharmacy.

(4) Notwithstanding rules in this Division and in Divisions 019 and 025, a Certified Oregon Pharmacy Technician who works in a RDF may have access to the facility without the physical presence of a pharmacist, but may only perform Board approved functions when under the supervision of a pharmacist.

855-041-6410
Emergency Department Distribution

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

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

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

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

(d) The drug is in a manufacturer's unit-of-use container, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:

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

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

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

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

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

(e) The following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

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

(E) Name of prescribing practitioner; and

(F) Initials of the dispensing nurse or practitioner.

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

(A) Name of patient;

(B) Date of issuance;

(C) Drug name and strength distributed;

(D) Units issued;

(E) Name of practitioner;

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

(G) Instructions given to the patient as labeled.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Division 065
WHOLESALE DRUG OUTLETS

855-065-0012
Storage of Drugs

(1) As a condition for receiving and retaining a wholesale distributor registration issued under these rules, an applicant must satisfy the Board that the applicant has and will continuously maintain acceptable storage and handling conditions and facilities standards for each facility at which drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which drugs are transported, including:

(a) Suitable construction of the facility and appropriate monitoring equipment to ensure that drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards.

(b) Suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations.

(c) Adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

(d) A quarantine area for the separate storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened.

(e) Maintenance of the facility in a clean and orderly condition.

(f) Maintenance of the facility in a commercial, nonresidential building.

(g) Freedom of the facility from infestation by insects, rodents, birds or vermin of any kind.

(2) The facility must be equipped with appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of drugs.

(3) The facility must meet security standards including but not limited to:

(a) An entry system that restricts access to areas where drugs are held, to authorized personnel.

(b) An after-hours central alarm system or a comparable entry detection system.

(c) Adequate outside perimeter lighting.

(d) Safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records.

Division 139
REMOTE DISPENSING SITE PHARMACY

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 alarm system armed to prevent, deter and detect 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 surveillance 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 at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy if unauthorized access occurs;

(b) Electronic entry system that is controlled by an Oregon licensed Pharmacist and 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 video 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.

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, and the surveillance system is fully operational;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Certified Oregon Pharmacy Technician at the RDSP using an audiovisual communication system. All patient interactions 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 10% of patient interactions observed or 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 48 hours, and retain records.

(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician.

(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.

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 an audiovisual communication system 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.

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 an audiovisual communication system all steps of the compounding; and

(b) Documents and visually verifies each item required in OAR 855-139-0205.

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) Audiovisual communication system testing and individual training on use of the audiovisual communication system;

(g) Still image capture and store and forward images must be retained according to (1);

(h) Data, telephone audio and surveillance system data must be retained for 6 months; and

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

Division 021
CONTINUING PHARMACY EDUCATION

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 effective July 1, 2023; and

(d) Fourteen additional hours of continuing pharmacy education or documented onsite training approved by the board.

(2) Section (1)(a)(b) and (d) do 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. Section (1)(c) is required.

(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)(a)(b) and (d) do not apply to a Pharmacy Technician applying for the first renewal of their license prior to July 1, 2023. Section (1)(c) is required.

Division 025
PHARMACY TECHNICIANS AND CERTIFIED OREGON PHARMACY TECHNICIANS

855-025-0005
Licensure: Qualifications - Pharmacy Technician or Certified Oregon Pharmacy Technician

(1) To qualify for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician, an applicant must demonstrate that the applicant is at least 18 years of age and has completed high school (or equivalent).

(2) To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must also demonstrate that the applicant has taken and passed a national pharmacy technician certification examination offered by:

(a) Pharmacy Technician Certification Board (PTCB); or

(b) National Healthcareer Association (NHA).

(3) No person whose license has been denied, revoked, suspended or restricted by any healthcare professional regulatory board may be licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician unless the board determines that licensure will pose no danger to patients or to the public interest.

855-025-0010
Licensure: Application- Pharmacy Technician

(1) An application for licensure as a Pharmacy Technician may be accessed on the board website.

(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline;

(3) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.

(4) The board may issue a license to a qualified applicant after the receipt of:

(a) A completed application;

(b) Payment of the fee prescribed in OAR 855-110;

(c) A current, passport regulation size photograph (full front, head to shoulders);

(d) Personal identification or proof of identity; and

(e) A completed national fingerprint-based background check.

(5) The license of a Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.

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 earned in the prior 12 months. These hours may not be counted toward a future renewal; and must include:

(A) One hour of continuing pharmacy education in pharmacy law;

(B) One hour of continuing pharmacy education in patient safety or error prevention; and

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

855-025-0012
Licensure: Application- Certified Oregon Pharmacy Technician

(1) An application for licensure as a Certified Oregon Pharmacy Technician may be accessed on the board website.

(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline.

(3) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.

(4) The board may issue a license to a qualified applicant after the receipt of:

(a) A completed application;

(b) Payment of the fee prescribed in OAR 855-110;

(c) A current, passport regulation size photograph (full front, head to shoulders);

(d) Personal identification or proof of identity;

(e) A completed national fingerprint-based background check; and

(f) Proof that the applicant has taken and passed a national pharmacy technician certification offered by the PTCB or the NHA.

(5) The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.

855-025-0015

Licensure: Renewal or Reinstatement- Certified Oregon Pharmacy Technician

(1) A person who has taken and passed a national pharmacy technician certification examination listed in OAR 855-025-0012(1)(a)–(b) may use the following title, and is referred to in these rules as, and is licensed as a "Certified Oregon Pharmacy Technician."

(2) An applicant for renewal of a Certified Oregon Pharmacy Technician license must:

(a) Pay the biennial license fee required in OAR 855-110;

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-021; 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 their license by the expiration date and whose license has been lapsed for one year or less may renew their license and must pay a late fee required in OAR 855-110.

(5) A Certified Oregon Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-025-0010; and

(b) Provide certification of completion of 10 continuing education hours earned in the prior 12 months. These hours may not be counted toward a future renewal; and must include:

(A) One hour of continuing pharmacy education in pharmacy law;

(B) One hour of continuing pharmacy education in patient safety or error prevention; and

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

855-025-0060
Reinstatement of a Certified Oregon Pharmacy Technician License

(1) A Certified Oregon Pharmacy Technician who fails to renew their license by the deadline and whose license has been lapsed for greater than one year may reinstate their license as follows:

(a) Complete a new application for licensure and provide the board with a valid e-mail address;

(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).

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, Pharmacy Technician or Certified Oregon Pharmacy Technician 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 fee may be assessed when an application is submitted incomplete and the board requests the missing information.

855-110-0005
Licensing Fees

(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:

(a) Expires June 30 each even numbered year. The biennial license fee is - $100. Late renewal fee (received after June 30) - $20. For Pharmacy Technician licenses that expire on June 30, 2023, a late renewal fee will not be assessed.

(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.)

Division 041
OPERATION OF PHARMACIES

855-041-1055
Prohibited Practices: Disclosure of Patient Information

A Retail Drug Outlet or Institutional Drug Outlet:

(1) May not 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 (a)-(e) of this rule. 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 wellbeing; 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.

(2) May not 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.

Division 041
OPERATION OF PHARMACIES

855-041-1015
Operation of Pharmacy (Both Retail and Institutional Drug Outlets)

(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.

855-041-1035
Minimum Equipment Requirements

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

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

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

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

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

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

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

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

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

(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for

patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

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

(D) Providing written notice in a conspicuous manner that 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; and

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

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

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

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

855-041-1092
Pharmacy Closures: Temporary or Emergency

(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 notification of closure on each building entrance and each pharmacy entrance 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) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the pharmacy is temporarily closed greater than 2 consecutive business days, 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 the temporary closure.

(2) Federal and state holidays are exempt from the requirements of (1).

(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.

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0145
Outlet: Closure- Temporary or Emergency

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a RDSP is temporarily closed to the public the RDSP must:

(a) Post notification of closure on each building entrance and each RDSP entrance as soon as the need to deviate from the posted hours is known by the RDSP, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the RDSP is temporarily closed greater than 2 consecutive business days, 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 the temporary closure.

(2) Federal and state holidays are exempt from the requirements of (1).

(3) Emergency closing. If RDSP 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.

855-139-0155

Outlet: Minimum Equipment Requirements

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

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

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

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

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

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

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

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

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

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

(C) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-139-0720;

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

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

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

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

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

Division 041
OPERATION OF PHARMACIES

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:

(A) Have a buffered probe (glycol, glass beads, or similar) that is centrally located;

(B) Records the temperature of each drug storage area at least every 15 minutes; and

(C) Accurate and calibrated on a schedule determined by the manufacturer within a plus or minus 0.5°C (0.9 °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.

Division 139
REMOTE DISPENSING SITE PHARMACY

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:

(A) Has a buffered probe (glycol, glass beads, or similar) that is centrally located;

(B) Records the temperature of each drug storage area at least every 15 minutes; and

(C) Accurate and calibrated on a schedule determined by the manufacturer within a plus or minus 0.5°C (0.9 °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.

Division 080
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0021
Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.11 (04/01/2020), and unless specifically exempt or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;

(b) Gamma-butyrolactone

(c) Methamphetamine, except as listed in OAR 855-080-0022;

(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)

(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.

(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,

(A) Methylmethcathinone (Mephedrone);

(B) Methylenedioxypyrovalerone (MDPV);

(C) Methylenedioxymethylcathinone (Methylone);

(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);

(E) Fluoromethcathinone (Flephedrone);

(F) 4-Methoxymethcathinone (Methedrone).

(2) Schedule I also includes any compounds in the following structural classes (2a–2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);

(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;

(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and

(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) is not an FDA approved drug or is exempted from the definition of controlled substance in ORS 475.005(6)(b)(A)-(E).

(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.

(5) Schedule I also includes any compounds in the following structural classes (a – b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Benzodiazepine class: A fused 1,4-diazepine and benzene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Clonazolam, Flualprazolam

(b) Thienodiazepine class: A fused 1,4-diazepine and thiophene ring structure with a phenyl connected to the 1,-4-diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Etizolam

(6) Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;

(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;

(c) The following substances per ORS 475.005(6)(b):

(A) The plant Cannabis family Cannabaceae;

(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;

(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;

(D) The seeds of the plant Cannabis family Cannabaceae; or

(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph.

Division 143
PHARMACY PRESCRIPTION LOCKER

855-143-0001
Purpose and Scope

The purpose of OAR 855-143 is to provide minimum requirements for the operation of a Pharmacy Prescription Locker (PPL) by a PPL Affiliated Pharmacy.

855-143-0005
Definitions

The following words and terms, when used in OAR 855-143, 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) "Pharmacy Prescription Locker Affiliated Pharmacy" or "PPL Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon that operates a Pharmacy Prescription Locker.

(2) "Pharmacy Prescription Locker" or "PPL" means an Oregon location registered as a Retail Drug Outlet Pharmacy Prescription Locker using a mechanical system that securely stores completed patient-specific prescription and non-prescription drugs, devices, and related supplies for pick up.

855-143-0010
Registration: General

(1) Each PPL located in Oregon must be registered as a Retail Drug Outlet PPL.

(2) A controlled substance registration will not be issued for a Retail Drug Outlet PPL.

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

(4) Each registration renewal application must be accompanied by the annual fee and must contain the same information required in OAR 855-143-0015(2) and additional information requested by the board.

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

(6) A Retail Drug Outlet PPL 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.

(8) The registration fee cannot be prorated.

(9) A PPL may not operate until a certificate of registration has been issued by the board.

(10) The PPL Affiliated Pharmacy registration and PPL registration must be on display at both the PPL Affiliated Pharmacy and at the PPL.

855-143-0015
Registration: Application

(1) An application for registration of a new PPL must include a floor plan drawn to scale with the location of the:

(a) PPL at the facility;

(b) Surveillance system cameras; and

(c) Alarm system panel.

(2) The certificate of registration for a PPL must be issued prior to opening.

(3) The application must specify the location of the PPL 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, if applicable, who own the five largest interests must be indicated on the application.

(4) 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.

855-143-0020
Registration: Change of Owner, Location, or PPL Affiliated Pharmacy
(1) A change of location of the PPL Affiliated Pharmacy or location of the PPL requires:

(a) Submission of a new PPL application a minimum of 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the board; and

(d) New certificate of registration.

(2) A change in the PPL Affiliated Pharmacy or ownership of the PPL requires:

(a) Submission of a new PPL application a minimum of 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.

(5) A PPL that has changed location or ownership must not operate until the new certificate of registration has been approved and issued.

855-143-0025
Registration: Closure

A PPL Affiliated Pharmacy must notify the board a minimum of 15 days prior to discontinuing operation of a PPL. Notification must include the:

(1) Final disposition of drugs stored in the PPL 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;

(2) Provide the board with:

(a) Oregon Board of Pharmacy state license(s); and

(b) Signed statement giving the effective date of closure.

855-143-0030
Non-Resident Affiliated Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes a PPL Affiliated Pharmacy located outside of Oregon and providing pharmacy services to a PPL located in Oregon.

(2) Each non-resident PPL Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy as a Retail Drug Outlet Pharmacy.

(3) To qualify for registration under these rules, every non-resident PPL Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) The Oregon licensed Pharmacist-in-Charge (PIC) of the non-resident PPL Affiliated Pharmacy is the PIC for each PPL.

(5) The PIC is responsible for ensuring that the PPL PIC self-inspection form is completed prior to February 1 each year.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

855-143-0050
Personnel

(1) A PPL must have an Oregon licensed PIC at all times.

(2) Prior to utilizing a PPL, the Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician must have completed a training program on the proper use of the PPL.

855-143-0100
Security

(1) The PPL Affiliated Pharmacy, the PPL, Oregon licensed PIC of the PPL Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the PPL is responsible for the security of the PPL including provisions for adequate safeguards against loss, theft or diversion of prescription and non-prescription drugs, devices, and related supplies, and records for such drugs, devices and related supplies.

(2) The PPL Affiliated Pharmacy must ensure the PPL:

(a) Is placed in a secure indoor location that is climate controlled and protected from the elements;

(b) Is securely fastened to a permanent structure so that it cannot be removed;

(c) Stores prescription and non-prescription drugs, devices, and related supplies in compliance with the provisions of OAR 855-143-0125;

(3) The PPL must be secured to prevent access when:

(a) There is no Oregon licensed Pharmacist supervising and authorizing access in real-time to the PPL; or

(b) There is no Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician employed by the PPL Affiliated Pharmacy present at the PPL; or

(c) Any component of the PPL is not functioning.

(4) A record must be maintained with the name and Oregon license number of each person accessing the PPL.

(5) An Intern, Certified Oregon Pharmacy Technician, and Pharmacy Technician may only access the PPL when an Oregon licensed Pharmacist is supervising the licensee and has authorized access to the PPL in real-time.

(6) Unlicensed personnel (e.g. vendor) may only access the PPL when escorted and continuously observed by a licensee who is authorized by the Oregon licensed Pharmacist who is supervising and authorizing access to the PPL in real-time.

(7) Minimum security methods must include a properly functioning:

(a) Alarm system at the PPL and real-time notification to an Oregon licensed Pharmacist of the PPL Affiliated Pharmacy if unauthorized access occurs;

(b) Electronic entry system that is controlled by an Oregon licensed Pharmacist and records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the PPL;

(B) Identification of the Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician accessing and securing the PPL; and

(C) Date and time of each activity; and

(c) Surveillance system that utilizes continuously accessible and recorded video between the PPL Affiliated Pharmacy and the PPL. The system must provide a clear view of the entire PPL including its access points.

855-143-0120
Drug: Procurement

A PPL may only receive prescription, non-prescription drugs, devices, and related supplies from the PPL Affiliated Pharmacy.

855-143-0125
Drug: Storage

(1) A PPL 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 PPL must quarantine drugs which are outdated, adulterated, misbranded or suspect.

(2) A PPL 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 (35.6 to 46.4°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 PPL 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.

855-143-0130
Drug: Loss

A PPL and its PPL 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 is reported to the board within one business day.

855-143-0150
Outlet: Sanitation

A PPL and its PPL Affiliated Pharmacy must ensure the PPL is kept clean.

855-143-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon PPL must have the following:

(a) 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 PPL outlet;

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

(c) Signage in a location easily seen by the public at the PPL where prescription and non-prescription drugs, devices, and related supplies are dispensed:

(A) Stating “The (insert name of PPL Affiliated 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 855-143-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

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

(D) Providing notification of accurate hours of operation at the PPL; and

(d) Additional equipment and supplies that are determined as necessary by the PPL Affiliated Pharmacy or PIC.

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

855-143-0200
Outlet: General Requirements

(1) The PPL Affiliated Pharmacy and its PIC are responsible for all operations and enforcing all policies and procedures of the PPL.

(2) A PPL Affiliated Pharmacy may operate more than one PPL.

(3) A PPL Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the PPL.

(4) A PPL and its PPL 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 and non-prescription drugs, devices, and related supplies are dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, OAR 855-041 and OAR 855-143;

(d) Ensure that the PPL Affiliated Pharmacy prevents duplicate dispensing of a prescription;

(e) Comply with all applicable federal and state laws and rules;

(f) Ensure that PPL Affiliated Pharmacy has received and documented consent by the patient or patient's agent for the patient's prescription and non-prescription drugs, devices, and related supplies to be placed in the PPL;

(g) Ensure that there is an Oregon licensed PIC who is responsible for all operations and enforcing all policies and procedures of the PPL;

(h) Designate in writing the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians authorized to access the PPL;

(i) Utilize complete chain of custody tracking;
(j) Train the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians in the operation of the PPL and document the training;

(k) Develop, implement and enforce a continuous quality improvement program for dispensing services from a PPL 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;

(l) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Oregon licensed Pharmacist from the PPL Affiliated Pharmacy; and

(m) Develop, implement and enforce a process for an in person physical inspection of the PPL by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed PIC of the PPL Affiliated Pharmacy. The inspection must utilize the PPL self-inspection form, be documented, and records retained.

855-143-0205
Outlet: Technology

A PPL and its PPL Affiliated Pharmacy must:

(1) Utilize a shared computer system and have appropriate technology or interface to allow access to information required to dispense prescription and non-prescription drugs, devices, and related supplies and counsel the patient or patient's agent;

(2) Utilize barcode, radio-frequency identification or quick response code technology for stocking, destocking and dispensing at the PPL;

(3) Test the PPL and verify the unit is operable and functioning in all aspects in accordance with minimum acceptable system or unit design specifications before dispensing prescription and non-prescription drugs, devices, and related supplies and after an upgrade or change is made to the system. The PPL Affiliated Pharmacy must make the results of such testing available to the board upon request; and

(4) Develop, implement and enforce a plan for routine maintenance of the PPL.

(5) Develop, implement and enforce a plan for responding to and recovering from an interruption of service where the PPL is not fully operational and functioning.

855-143-0210
Outlet: Supervision

A PPL and its PPL Affiliated Pharmacy must:

(1) Ensure prescription and non-prescription drugs, devices, and related supplies are only dispensed at the PPL if an Oregon licensed Pharmacist is available for patient consultation and the PPL is fully operational.

(2) Ensure that stocking and destocking of prescription and non-prescription drugs, devices, and related supplies in a PPL is completed under the supervision, direction and control of a pharmacist.

(3) Ensure that an Oregon licensed Pharmacist verifies and documents that:

(a) All prescription and non-prescription drugs, devices, and related supplies were correctly stocked into the PPL;

(b) All prescription and non-prescription drugs, devices, and related supplies destocked from the PPL were returned to the PPL Affiliated Pharmacy;

(c) Proper storage conditions were maintained during transfer per OAR 855-143-0125; and

(d) Records are maintained per OAR 855-143-0550.

855-143-0215
Outlet: Pharmacist Utilization

A PPL and its PPL Affiliated Pharmacy must ensure that a prescription drug or device is not released from the PPL until the Oregon licensed Pharmacist or Intern has:

(1) Provided counseling when required under OAR 855-019-0230 or when requested by the patient or patient's agent; and

(2) Documented the interaction.

855-143-0220
Outlet: Non-Prescription Drugs and Supplies

If non-prescription drugs and related supplies are placed in the PPL, the PPL and its PPL Affiliated Pharmacy must ensure that only an Oregon licensed Pharmacist verifies non-prescription drugs and related supplies that will be placed in the PPL.

855-143-0225
Outlet: Controlled Substances

Controlled substances may not be stored in the PPL.

855-143-0345
Dispensing: General Requirements

The PPL Affiliated Pharmacy must:

(1) Ensure each prescription, prescription refill, and drug order is correctly dispensed by the PPL in accordance with the prescribing practitioner's authorization; and

(2) Ensure the PPL dispenses prescriptions accurately and to the correct party.

855-143-0500

Policies and Procedures

(1) The Oregon licensed PIC of the PPL Affiliated Pharmacy and the PPL Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the PPL. The written policies and procedures must be maintained at the PPL Affiliated Pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the responsibilities of the PPL Affiliated Pharmacy and each PPL including;

(a) Security;

(b) Operation, testing and maintenance of the PPL;

(c) Sanitation and cleaning;

(d) Storage of drugs;

(e) Stocking and destocking;

(f) Dispensing;

(g) Preventing duplicate dispensing;

(h) Oregon licensed Pharmacist supervision, direction and control of and licensed personnel accessing the PPL;

(i) Documenting the identity, function, location, date and time of the licensed personnel accessing the PPL;

(j) Utilization of Oregon licensed Pharmacist (i.e. Counseling);

(k) Recordkeeping;

(l) Patient consent and confidentiality;

(m) On-site inspection by an Oregon licensed Pharmacist;

(n) Continuous quality improvement;

(o) Plan for discontinuing and recovering services if PPL disruption occurs;

(p) Training: initial and ongoing; and

(q) Interpretation, translation and prescription reader services.

(3) If compounded preparations are compounded at the PPL Affiliated Pharmacy and placed in the PPL the policies and procedures must meet the requirements of OAR 855-045.

(4) A PPL Affiliated Pharmacy that provides prescription and non-prescription drugs, devices, and related supplies through a PPL must review its written policies and procedures every 12 months, revise them if necessary, and document the review.

855-143-0550

Records: General Requirements

(1) The recordkeeping requirements OAR 855-143 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) All required records for the Drug Outlet PPL must be maintained by the PPL Affiliated Pharmacy.

(3) Records retained by the PPL Affiliated Pharmacy must include, but are not limited to:

(a) Date, time and identification of each individual and activity or function performed on the PPL;

(b) Oregon licensed Pharmacist physical inspection of the PPL;

(c) Audiovisual communication system testing;

(d) Licensee training on the proper use of the PPL;

(e) Still image capture and store and forward images must be retained according to (1);

(f) Data and surveillance system data must be retained for 6 months; and

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

(4) Records of dispensing from a PPL must include the:

(a) Physical location of the PPL;

(b) Identification of the patient or patient's agent retrieving the prescription, non-prescription drugs, and supplies;

(c) A digital image of the individual to whom the prescription was dispensed.

(d) Date and time of transaction;

(e) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;

(f) Each non-prescription drug and supply name, UPC or NDC number, and quantity; and

(g) Name of Oregon licensed Pharmacist or Oregon licensed Intern who provided counseling to the patient or patient's agent, if required, documentation that the counseling was performed or that the Pharmacist or Intern accepted the patient or patient's agent request not to be counseled.

(5) Records of stocking and destocking of prescriptions into or from a PPL must include the:

(a) Date and time;

(b) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;

(c) Each non-prescription drug and supply name, UPC or NDC number, and quantity;

(d) Name and Oregon license number of the person stocking or destocking prescription, non-prescription drugs and supplies from the system; and

(e) Identity of the Oregon licensed Pharmacist who verifies that the system has been accurately stocked or destocked.

855-143-0600
Prohibited Practices: General

A PPL may not:

(1) Allow unlicensed personnel, Oregon licensed Pharmacy Technicians or Certified Oregon Pharmacy Technicians to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;
(2) Utilize a person to dispense or deliver a prescription and non-prescription drugs, devices, and related supplies directly to the patient;

(3) Dispense drugs that require further manipulation prior to administration or dispensing (e.g. reconstitution, compounding, vaccines); and

(4) Store or dispense controlled substances.

855-143-0602
Prohibited Practices: Disclosure of Patient Information

A Retail Drug Outlet PPL 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.

855-143-0650
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) Any of the grounds listed in ORS 689.405.

(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.

Division 006/019/025/041: Technician Final Verification (2022 HB 4034)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds final verification definition; Amends pharmacist general responsibilities

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments include adding "final verification" to definitions, adds additional requirements for pharmacists and strikes language that is no longer relevant to automated distribution cabinet (ADC).

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): 2022 HB 4034 is currently operative, a temporary rule is required to remove conflicts in rule with the directives of 2022 HB 4034.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Adds "final verification" to definitions, adds language related to general responsibilities of a pharmacist including tasks that cannot be performed by an Intern, Certified Oregon Pharmacy Technician or pharmacy technician and removes language no longer relevant related to ADC.

Division 6
DEFINITIONS

855-006-0005
Definitions

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 006/041/139 - related to Definitions

As used in OAR Chapter 855:

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. 12/09/2021)

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(2) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(3) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(4) “Biological product” means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(5) "Biosimilar" product means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (12/1/2021).

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(6) “Board” means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(7) "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.

(8) “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.

(9) "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.

(10) "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.

(11) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(12) "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.

(13) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(14) "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.

(15) "Entry system" enables control of access to a secured area.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(16) "Final verification" means after prescription information is entered into a pharmacy's electronic system and reviewed by a pharmacist for accuracy, a physical verification that the drug and drug dosage, device or product selected from a pharmacy's inventory pursuant to the electronic system entry is the prescribed drug and drug dosage, device or product.

(16~~7~~) "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).

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(17~~8~~) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.

(18~~9~~) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.

(19~~20~~) "Misbranded" has the same definition as set forth in 21 USC 352 (v. 12/09/2021).

(20~~1~~) "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.

(2~~1~~**2**) "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.

(2~~2~~**3**) "Nationally Certified Exam" means an exam that is approved by the board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible and valid.

(2~~3~~**4**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(2~~4~~**5**) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:

(a) The creation and retention of accurate and complete patient records;

(b) Assuming authority and responsibility for product selection of drugs and devices;

(c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the general public;

(d) Maintaining confidentiality of patient information.

(2~~5~~**6**) “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.

(2~~6~~**7**) "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.

(2~~7~~**8**) 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.

(2~~8~~**9**) "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.

(~~29~~**30**) "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.

(3~~0~~**1**) “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.

(3~~1~~**2**) “Practice of pharmacy” is as defined in ORS 689.005.

(3~~2~~**3**) “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.

(3~~3~~**4**) "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.

(34~~5~~) “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.

(35~~6~~) "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.

(36~~7~~) “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.

(37~~8~~) “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.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(38~~9~~) “Repackage” means the act of taking a drug from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(39~~40~~) "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.

(40~~1~~) "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.

(4~~1~~2) "Still image capture" means a specific image captured electronically from a video or other image capture device.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(4~~2~~3) "Store and forward" means a video or still image record which is saved electronically for future review.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(4~~3~~4) "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.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(4~~4~~5) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(4~~5~~6) "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.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(4~~6~~7) "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.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 041/139 - related to Drug Storage

(4~~7~~**8**) "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.

(4~~8~~**9**) "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 19
PHARMACISTS

855-019-0200
General Responsibilities of a Pharmacist

ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A pharmacist licensed to practice pharmacy by the Board has the duty to use that degree of care, skill, diligence and professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances.

(1) A pharmacist while on duty must ensure that the pharmacy complies with all state and federal laws and rules governing the practice of pharmacy.

(2) Only a pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require the professional judgment of a pharmacist include but are not limited to:

(a) Drug Utilization Review;

(b) Counseling;

(c) Drug Regimen Review;

(d) Medication Therapy Management;

(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;

(f) Practice pursuant to State Drug Therapy Management Protocols;

(g) Prescribing a drug or device, as authorized by statute;

(h) Ordering, interpreting and monitoring of a laboratory test;

(i) Oral receipt or transfer of a prescription; and

(j) ~~Final v~~**V**erification of the work performed by those under their supervision.

(3) A pharmacist may not delegate any task listed in OAR 855-019-0200(2), except that a pharmacist may permit an intern to perform the duties of a pharmacist under their direction and supervision, after the intern has successfully completed his or her first academic year, and only after successful completion of coursework corresponding to those duties.

(4) An intern cannot prescribe a drug or device and cannot perform **confirmation of the correctness, exactness, accuracy and completeness of a prescription or medication order prior to dispensing to the patient** ~~final verification~~.

(5) A pharmacist who is supervising an intern is responsible for the actions of that intern; however, this does not absolve the intern from responsibility for their own actions.

(6) A pharmacist on duty is responsible for supervising all pharmacy personnel, and ensuring that pharmacy personnel only work within the scope of duties allowed by the Board.

(7) A pharmacist may not permit non-pharmacist personnel to perform any duty they are not licensed and trained to perform.

(8) A pharmacist while on duty is responsible for the security of the pharmacy area including:

(a) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;

(b) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;

(c) Ensuring that only a pharmacist has access to the pharmacy when the pharmacy is closed.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.025, ORS 689.151, ORS 689.155, ORS 689.645, ORS 689.682 & ORS 689.689

Division 25
PHARMACY TECHNICIANS AND CERTIFIED OREGON PHARMACY TECHNICIANS

855-025-0040
Certified Oregon Pharmacy Technician and Pharmacy Technician Tasks and Guidelines

(1) Non-licensed pharmacy personnel may enter non-prescription information into a computer record system and may perform clerical duties such as filing prescriptions, delivery, housekeeping, and general record keeping, but the responsibility for the accuracy of the non-licensed pharmacy personnel's work lies with the Pharmacist.

(2) Only persons licensed with the Board as a Pharmacy Technician or Certified Oregon Pharmacy Technician, acting in compliance with all applicable statutes and rules and under the supervision of a Pharmacist, may assist in the practice of pharmacy by the following:

(a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

(b) Reconstituting prescription medications. The supervising Pharmacist must verify the accuracy in all instances.

(c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.

(d) Entering information into the pharmacy computer. The Pharmacy Technician or Certified Oregon Pharmacy Technician shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising Pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.

(e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;

(f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The Pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.

(g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The Pharmacist must verify the accuracy of the finished task **unless the requirements of Section 24 of 2021 HB 4034 are met.**

(h) Checking nursing units in a hospital or nursing home for nonjudgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a Pharmacist.

(i) Recording patient or medication information in computer systems for later verification by the Pharmacist.

(j) Bulk Compounding. Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.

(k) Preparation of parenteral products as follows:

(A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising Pharmacist must verify the accuracy in all instances.

(B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising Pharmacist must verify the accuracy in all instances.

(l) Performing related activities approved in writing by the Board.

(3) In order to protect the public, safety, health and welfare, Pharmacy Technicians or Certified Oregon Pharmacy Technicians shall not:

(a) Communicate or accept by oral communication a new or transferred prescription of any nature;

(b) Receive or transfer a prescription to another pharmacy without the prior verification of a Pharmacist.

(c) Provide a prescription or medication to a patient without a Pharmacist's verification of the accuracy of the dispensed ~~medication~~ **prescription**;

(d) Counsel a patient on medications or perform a drug utilization review;

(e) Perform any task that requires the professional judgment of a Pharmacist; or

(f) Engage in the practice of pharmacy as defined in ORS 689.

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

Division 41
OPERATION OF PHARMACIES

855-041-6050
Definitions - Automated Distribution Cabinet (ADC)

~~(1)~~ In these rules, OAR 855-041-6000 through 855-041-6999, the terms below have these meanings:

(a) “Automated Distribution Cabinet” (ADC) means a computerized drug storage device or cabinet that allows a drug to be stored and dispensed near the point-of-care, while controlling and tracking drug distribution;

(b) “Drug” means a drug, a prescription device, a biological medication, a chemical or any combination of these terms;

(c) “Central pharmacy” means a pharmacy within a licensed hospital with a single location and inventory, which prepares and distributes drugs to secondary storage areas in the facility, and remote locations;

(d) “Chief Pharmacy Officer” (CPO) means an Oregon licensed pharmacist who supervises the pharmacy operations in a hospital. The CPO may hold the title of Pharmacy Manager, Pharmacy Director, Director of Pharmacy, Pharmacy Administrator or other pharmacy supervisory management title within the organization. The PIC may also be the CPO if there is only one pharmacy in the hospital;

(e) “Drug profile” means a complete and comprehensive summary of a patient's current drugs and details of each drug including information such as active ingredient, strength and form, dose and directions for use, and other supplementary information;

(f) “Licensed Independent Practitioner” (LIP) means an individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license;

(g) “Out-patient” means a person who is not residing in the facility but who is registered with the facility and is using the facility for treatment or diagnostic services;

(h) “Remote storage area” means a patient care area which is part of the hospital that is under the supervision and control of the hospital's central pharmacy but is not located in the same building as the central pharmacy;

(i) “Secondary drug storage area” means an area in a hospital or licensed residential facility, which is supplied by a central pharmacy and may include facilities such as a drug room, a distribution cabinet or a hospital department;

(j) “Unit-dose” means a quantity of a drug designed to be administered to a patient, such as:

(A) An oral solid individually packaged or re-packaged;

(B) An oral liquid drawn up in a labeled oral syringe;

(C) An injectable product; or

(D) A pre-mixed IV product.

~~(2) Not withstanding 855-006-0005 and 855-019-0200(2) and (3), for the purpose of these rules, OAR 855-041-6000 through 855-041-6999, verification or final verification means the confirmation by a pharmacist of the correctness, exactness and accuracy of the act, tasks, or function as specified elsewhere in this Division of rules.~~

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

Division 080: Controlled Substances (PSE/EPH Sale by Interns- 2022 HB 4034)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): 2022 HB 4034 allows an intern to transfer pseudoephedrine or ephedrine without prescription

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amends rule by adding "intern" as required by 2022 HB 4034.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): 2022 HB 4034 mandate, effective upon passage.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034 Engrossed

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): OAR 855-080-0026 proposed amendments include adding "intern" as mandated in 2022 HB 4034, which allows an intern to transfer a drug containing pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine without a prescription from a practitioner to a person who is 18 years of age or older and who provides to the pharmacist, intern or pharmacy technician the person's valid government-issued photo identification.

Division 80
SCHEDULE OF CONTROLLED SUBSTANCES

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, **Intern,** 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, **Intern,** 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) **Each** ~~P~~**p**harmac~~y~~**y**~~ies~~, Pharmacist~~s~~, **Intern,** Certified Oregon Pharmacy Technician~~s~~ and Pharmacy Technician~~s~~ 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, **ORS 475.230**, ~~2021 HB 2648~~, 2022 HB 4034
Statutes/Other Implemented: ORS 475.035, ORS 475.230, ~~2021 HB 2648~~, 2022 HB 4034

Division 041: Operation of Pharmacies (Telework/2022 HB 4034)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Telework rules pursuant to 2022 HB 4034

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments add configuration and records requirements for telework.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): 2022 HB 4034 is currently operative, a temporary rule is required to allow licensees/registrants to utilize telework if applicable while remaining in compliance with state laws and rules.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments include adding configuration and records requirements for telework to prevent patient and pharmacy records from being duplicated or downloaded when a pharmacy database is accessed remotely. Revisions are necessary pursuant to directives of 2022 HB 4034.

Division 041
OPERATION OF PHARMACIES

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 audiovisual communication system is not functioning; ~~and~~

(d) Be configured so information from any patient or pharmacy records are not duplicated, downloaded or removed from the electronic database when an electronic database is accessed remotely; and

(~~d~~**e**) 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

855-041-3250
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 may not be duplicated, downloaded or removed when accessed via telework.

(4) Records must be stored in a manner that prevents unauthorized access.

(~~3~~**5**) 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) Audiovisual communication system testing and training;

(g) Still image capture and store and forward images must be retained according to (1);

(h) Data and telephone audio must be retained for 6 months; and

(i) 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

Division 139: Remote Dispensing Site Pharmacy (2022 HB 4034)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Removes certain personnel and ratio requirements for Remote Dispensing Site Pharmacies per 2022 HB 4034.

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments include adding 'pharmacy technician' and striking Certified Oregon Pharmacy Technician pursuant to directives of 2022 HB 4034. A 'pharmacy technician' includes both the 'Pharmacy Technician' and 'Certified Oregon Pharmacy Technician' licensure categories. Removes requirement for similar work experience and pharmacist to technician ratio pursuant to directives of 2022 HB 4034.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): 2022 HB 4034 is currently operative, a temporary rule is required to remove conflicts in rule with the directives of 2022 HB 4034.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Adds 'pharmacy technician', strikes 'Certified Oregon Pharmacy Technician, and removes requirement for similar work experience and pharmacist to technician ratio pursuant to directives of 2022 HB 4034.

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0005
Definitions

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 006/041/139 - related to 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) "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~~ **pharmacy technician** under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.

(3) "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~~ **pharmacy technician**.

Statutory/Other Authority: ORS 689.205, ORS 689.522, 2021 SB 629
Statutes/Other Implemented: 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 a ~~Certified Oregon Pharmacy Technician~~ **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) The 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 855-139-0015(2).

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

(6) The 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

855-139-0050
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~~**3**) 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~~**4**) The RDSP Affiliated Pharmacy **and the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy** is required to comply with the pharmacist's determination in (~~4~~**3**) and retain records.

(~~7~~**5**) The RDSP and RDSP Affiliated Pharmacy must ensure adequate staffing at both the RDSP and RDSP Affiliated Pharmacy.

(~~8~~**6**) Prior to working at a RDSP, **the RDSP Affiliated Pharmacy, the RDSP, Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy is responsible for ensuring** the ~~Certified Oregon Pharmacy Technician~~ **pharmacy technician** and the Oregon licensed Pharmacist supervising the RDSP ~~must~~ **are adequately trained to perform their duties and** have completed a training program on the proper use of the telepharmacy system.

(~~9~~**7**) 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

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(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 alarm system armed to prevent, deter and detect 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~~ **pharmacy technician** present in the RDSP; or

(c) Any component of the surveillance 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 at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy if unauthorized access occurs;

(b) Electronic entry system that is controlled by an Oregon licensed Pharmacist and records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the RDSP;

(B) Identification of the ~~Certified Oregon Pharmacy Technician~~ **pharmacy technician** accessing and securing the RDSP; and

(C) Date and time of each activity.

(c) Surveillance system that utilizes continuously accessible and recorded video 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.

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~~ **pharmacy technician** working in the RDSP practices appropriate infection control.

Statutory/Other Authority: ORS 689.305
Statutes/Other Implemented: ORS 689.305

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 Technician~~ **pharmacy technicians** authorized to access the RDSP and operate the telepharmacy system;

(f) Train the Oregon licensed Pharmacists and ~~Certified Oregon Pharmacy Technician~~ **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: 2021 SB 629 & ORS 689.155

855-139-0210
Outlet: Supervision

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
    - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

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~~ **pharmacy technician**, and the surveillance system is fully operational;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each ~~Certified Oregon Pharmacy Technician~~ **pharmacy technician** at the RDSP using an audiovisual communication system. All patient interactions must be recorded, reviewed and stored;

(3) The Oregon licensed Pharmacist who is supervising ~~Certified Oregon Pharmacy Technician~~ **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 10% of patient interactions observed or 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 48 hours, and retain records.

(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the ~~Certified Oregon Pharmacy Technician~~ **pharmacy technician**.

(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~~ **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

855-139-0220
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~~ **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

855-139-0315
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~~ **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~~ **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

855-139-0355
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~~ **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~~ **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 855-139-0205 for each individual dosage unit in the med pak.

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

855-139-0455
Drug and Devices: Return

A ~~Certified Oregon Pharmacy Technician~~ **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:

(1) An Oregon licensed Pharmacist has approved the return;

(2) The drugs or devices are accepted for destruction or disposal; and

(3) An Oregon licensed Pharmacist verifies the destruction or disposal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet RDSP may not:

(1) Allow a ~~Certified Oregon Pharmacy Technician~~ **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) Compound sterile preparations; or

(5) Repackage drugs.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0715
Service: Epinephrine- General Requirements

(1) A ~~Certified Oregon Pharmacy Technician~~ **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~~ **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~~ **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~~ **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

855-139-0730
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~~ **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

Division: 006/019/025/041: Technician Final Verification (2022 HB 4034)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Final verification; Drug Outlet and Pharmacist general responsibilities

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments include adding "final verification" to definitions, adds additional requirements for a drug outlet and pharmacist, adds additional general responsibilities and strikes language that is no longer relevant.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Proposed amendments provide clarity, transparency for licensees/registrants and promotes patient safety, no effects on racial equity are anticipated.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal impact anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): A Drug Outlet may need to amend current policies and procedures in order to be in compliance with the proposed rules.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rules, amendments are directives of 2022 HB 4034.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Directives of 2022 HB 4034.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Adds "final verification" to definitions, adds new language related to general responsibilities of a pharmacist and pharmacy including being responsible for not only their own actions, but those of an Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician. Adds additional pharmacist responsibilities related to compliance, assisting in the practice of pharmacy, supervision of pharmacy personnel, policy enforcement, security, maintaining records and access to the pharmacy.

Adds general responsibilities for Certified Oregon Pharmacy Technician and Pharmacy Technician related to compliance, assist and working within the scope of the practice of pharmacy, performing duties trained for, access to the pharmacy and final verification.

Adds procedural requirements for the Drug Outlet and PIC related to establishing, maintaining and enforcing policies and procedures, security, maintaining and testing pharmacy system equipment, sanitation, drug storage, dispensing, pharmacist supervision of personnel, drug and device procurement related to receiving and delivery, utilization of pharmacy technicians and Oregon licensed pharmacist, recordkeeping, patient confidentiality, continuous quality improvement, pharmacy closure plans, training and interpretation, translation and prescription reader services. Proposed amendments are directives of 2022 HB 4034.

Removes language no longer relevant to ADC.

Division 6
DEFINITIONS
855-006-0005
Definitions

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 006/041/139 - related to Definitions
- NOTE: The rule packages shown below is currently proposed to send to rulemaking. If changes are made prior to sending to rulemaking they will need to be reflected here.
  - Div 006/041/043/045/080/139 Adopted Standards by Reference
  - Div 006/031 PHE Rules Sunset
  - Div 006/019/041/139/143 Interpreters
- NOTE: The rule package shown below is currently proposed as a temporary rule. If changes are made prior to adopting the temporary rule, it will need to be reflected here.
  - Div 006/019/025/041 Tech Final Verification HB 4034 TEMP

(16) "Final verification" means after prescription information is entered into a pharmacy's electronic system and reviewed by a pharmacist for accuracy, a physical verification that the drug and drug dosage, device or product selected from a pharmacy's inventory pursuant to the electronic system entry is the prescribed drug and drug dosage, device or product.

- NOTE: In Temporary Rules- Div 006 019 025 041 Tech Final Verification HB 4034 TEMP

(X) "Reasonable professional judgment" means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities, qualifications and/or competencies, after careful review, analysis and consideration of the relevant subject matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion or conclusion.

(48) "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.

- NOTE: Only shown here for quick reference. No amendments are proposed.

Division 19
PHARMACISTS

855-019-0200
General Responsibilities of a Pharmacist

ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A pharmacist licensed to practice pharmacy by the Board has the duty to use that degree of care, skill, diligence and professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances.

(1) ~~A pharmacist while on duty must ensure that the pharmacy complies with all state and federal laws and rules governing the practice of pharmacy.~~ **A pharmacist is responsible for their own actions; however, this does not absolve the pharmacy from responsibility for the pharmacist's actions.**

(2) A Pharmacist and pharmacy are responsible for the actions of Interns, Pharmacy Technicians, and Certified Oregon Pharmacy Technicians.

(~~2~~**3**) Only a ~~p~~**P**harmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require the professional judgment of a pharmacist include but are not limited to:

(a) Drug Utilization Review;

(b) Counseling;

(c) Drug Regimen Review;

(d) Medication Therapy Management;

(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;

(f) Practice pursuant to State Drug Therapy Management Protocols;

(g) Prescribing a drug or device, as authorized by statute;

(h) Ordering, interpreting and monitoring of a laboratory test;

(i) Oral receipt or transfer of a prescription; and

(j) ~~Final v~~**V**erification of the work performed by those under their supervision.

(4) A Pharmacist must:

(a) Comply with all state and federal laws and rules governing the practice of pharmacy;

(b) Ensure each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a pharmacist;

(c) Ensure non-pharmacist personnel only perform duties they are licensed and trained to perform.

(d) Know the identity of each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction and control at all times;

(e) When supervising an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, determine and document how many licensed individuals the Pharmacist is capable of supervising, directing and controlling based on the services being provided.

(f) Ensure and enforce the drug outlet written procedures for use of Certified Oregon Pharmacy Technicians and Pharmacy Technicians as required by 855-025-0035;

(g) Ensure the security of the pharmacy area including:

(A) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;

(B) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;

(C) Ensuring that only a pharmacist has access to the pharmacy when the pharmacy is closed.

(5) A pharmacist may delegate final verification of drug and dosage form, device, or product to a pharmacy technician per ORS 689.005 when the following conditions are met:

(a) The pharmacist utilities reasonable professional judgment to determine that a pharmacy technician may perform final verification;

(b) The technician does not use discretion in conducting final verification;

(c) The pharmacist delegating final verification is supervising the technician; and

(d) Ensure the pharmacy technician is performing a physical final verification.

(3**6**) A pharmacist may ~~not delegate~~ **permit an Intern under their direction and supervision to perform** any task listed in OAR 855-019-0200(~~2~~**3**), except that ~~a pharmacist may permit an intern to perform the duties of a pharmacist under their direction and supervision, after the intern has successfully completed his or her first academic year, and only after successful completion of coursework corresponding to those duties.~~ **an Intern may not**:

(a) Perform the duties of a pharmacist until after the Intern has successfully completed their first academic year, and only after successful completion of coursework corresponding to those duties;

(b) Prescribe a drug or device; or

(c) Perform confirmation of the correctness, exactness, accuracy and completeness of a prescription or medication order prior to dispensing to the patient.

~~(4) An intern cannot prescribe a drug or device and cannot perform final verification.~~

~~(5) A pharmacist who is supervising an intern is responsible for the actions of that intern; however, this does not absolve the intern from responsibility for their own actions.~~

~~(6) A pharmacist on duty is responsible for supervising all pharmacy personnel, and ensuring that pharmacy personnel only work within the scope of duties allowed by the Board.~~

~~(7) A pharmacist may not permit non-pharmacist personnel to perform any duty they are not licensed and trained to perform.~~

~~(8) A pharmacist while on duty is responsible for the security of the pharmacy area including:~~

~~(a) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;~~

~~(b) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;~~

~~(c) Ensuring that only a pharmacist has access to the pharmacy when the pharmacy is closed.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.025, ORS 689.151, ORS 689.155, ORS 689.645, ORS 689.682, ORS 689.689

Division 25
PHARMACY TECHNICIANS AND CERTIFIED OREGON PHARMACY TECHNICIANS

855-025-0023
Responsibilities: General

(1) A pharmacy technician is responsible for their own actions; however, this does not absolve the pharmacist and the pharmacy from responsibility for the pharmacy technician's actions.

(2) A pharmacy technician must:

(a) Comply with all state and federal laws and rules governing the practice of pharmacy;

(b) Only assist in the practice of pharmacy under the supervision, direction, and control of a pharmacist;

(c) Know the identity of the pharmacist who is providing supervision, direction and control at all times;

(d) Only work within the scope of duties permitted by their license;

(e) Only perform duties they trained to perform; and

(f) Only access the pharmacy area when a pharmacist is on duty.

(3) A pharmacy technician may not engage in the practice of pharmacy as defined in ORS 689.005.

(4) A pharmacy technician may perform final verification of the drug and dosage, device or product when:

(a) The pharmacist utilities reasonable professional judgment to determine that a pharmacy technician may perform final verification;

(b) No discretion is needed;

(c) The pharmacist delegating final verification is supervising the pharmacy technician; and

(d) The pharmacy technician is performing a physical final verification.

855-025-0040

Certified Oregon Pharmacy Technician and Pharmacy Technician Tasks and Guidelines

(1) Non-licensed pharmacy personnel may enter non-prescription information into a computer record system and may perform clerical duties such as filing prescriptions, delivery, housekeeping, and general record keeping, but the responsibility for the accuracy of the non-licensed pharmacy personnel's work lies with the Pharmacist.

(2) Only persons licensed with the Board as a Pharmacy Technician or Certified Oregon Pharmacy Technician, acting in compliance with all applicable statutes and rules and under the supervision of a Pharmacist, may assist in the practice of pharmacy by the following:

(a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

(b) Reconstituting prescription medications. The supervising Pharmacist must verify the accuracy in all instances.

(c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.

(d) Entering information into the pharmacy computer. The Pharmacy Technician or Certified Oregon Pharmacy Technician shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising Pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.

(e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;

(f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The Pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.

(g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The Pharmacist must verify the accuracy of the finished task **unless the requirements of OAR 825-025-0023(4) are met.**

(h) Checking nursing units in a hospital or nursing home for nonjudgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a Pharmacist.

(i) Recording patient or medication information in computer systems for later verification by the Pharmacist.

(j) Bulk Compounding. Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.

(k) Preparation of parenteral products as follows:

(A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising Pharmacist must verify the accuracy in all instances.

(B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising Pharmacist must verify the accuracy in all instances.

(l) Performing related activities approved in writing by the Board.

(3) In order to protect the public, safety, health and welfare, Pharmacy Technicians or Certified Oregon Pharmacy Technicians shall not:

(a) Communicate or accept by oral communication a new or transferred prescription of any nature;

(b) Receive or transfer a prescription to another pharmacy without the prior verification of a Pharmacist.

(c) Provide a prescription or medication to a patient without a Pharmacist's verification of the accuracy of the dispensed ~~medication~~ **prescription**;

(d) Counsel a patient on medications or perform a drug utilization review;

(e) Perform any task that requires the professional judgment of a Pharmacist; or

(f) Engage in the practice of pharmacy as defined in ORS 689.

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

Division 41
OPERATION OF PHARMACIES

855-041-1040

Drug Outlet Procedures

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

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

(a) Security;

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

(c) Sanitation;

(d) Storage of drugs;

(e) Dispensing;

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

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

(h) Technician final verification, if utilized;

(i) Drug and/or device procurement;

(j) Receiving of drugs and/or devices;

(k) Delivery of drugs and/or devices;

(l) Utilization of pharmacy technicians;

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

(n) Recordkeeping;

(o) Patient confidentiality;

(p) Continuous quality improvement;

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

(r) Training: initial and ongoing; and

(s) Interpretation, translation and prescription reader services.

~~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; and~~

~~(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

855-041-0018
Outlet: General Requirements

A drug outlet pharmacy must:

(1) Ensure each prescription is dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031 and OAR 855-041;

(2) Comply with all applicable federal and state laws and rules;

(3) Ensure all licensees are trained to appropriately perform their duties prior to engaging or assisting in the practice of pharmacy.

(4) Ensure and enforce the drug outlet written procedures for use of pharmacy technicians as required by 855-025-0035;

(5) Develop, implement and enforce a continuous quality improvement program for dispensing services from a drug outlet pharmacy designed to objectively and systematically:

(a) Monitor, evaluate, document the quality and appropriateness of patient care;

(b) Improve patient care; and

(c) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence.

855-041-6050

Definitions - Automated Distribution Cabinet (ADC)

~~(1)~~ In these rules, OAR 855-041-6000 through 855-041-6999, the terms below have these meanings:

(a) "Automated Distribution Cabinet" (ADC) means a computerized drug storage device or cabinet that allows a drug to be stored and dispensed near the point-of-care, while controlling and tracking drug distribution;

(b) "Drug" means a drug, a prescription device, a biological medication, a chemical or any combination of these terms;

(c) "Central pharmacy" means a pharmacy within a licensed hospital with a single location and inventory, which prepares and distributes drugs to secondary storage areas in the facility, and remote locations;

(d) "Chief Pharmacy Officer" (CPO) means an Oregon licensed pharmacist who supervises the pharmacy operations in a hospital. The CPO may hold the title of Pharmacy Manager, Pharmacy Director, Director of Pharmacy, Pharmacy Administrator or other pharmacy supervisory management title within the organization. The PIC may also be the CPO if there is only one pharmacy in the hospital;

(e) "Drug profile" means a complete and comprehensive summary of a patient's current drugs and details of each drug including information such as active ingredient, strength and form, dose and directions for use, and other supplementary information;

(f) "Licensed Independent Practitioner" (LIP) means an individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license;

(g) "Out-patient" means a person who is not residing in the facility but who is registered with the facility and is using the facility for treatment or diagnostic services;

(h) “Remote storage area” means a patient care area which is part of the hospital that is under the supervision and control of the hospital's central pharmacy but is not located in the same building as the central pharmacy;

(i) “Secondary drug storage area” means an area in a hospital or licensed residential facility, which is supplied by a central pharmacy and may include facilities such as a drug room, a distribution cabinet or a hospital department;

(j) “Unit-dose” means a quantity of a drug designed to be administered to a patient, such as:

(A) An oral solid individually packaged or re-packaged;

(B) An oral liquid drawn up in a labeled oral syringe;

(C) An injectable product; or

(D) A pre-mixed IV product.

~~(2) Not withstanding 855-006-0005 and 855-019-0200(2) and (3), for the purpose of these rules, OAR 855-041-6000 through 855-041-6999, verification or final verification means the confirmation by a pharmacist of the correctness, exactness and accuracy of the act, tasks, or function as specified elsewhere in this Division of rules.~~

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

Division 080: Controlled Substances (PSE/EPH Sale by Interns- 2022 HB 4034)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): 2022 HB 4034 allows an intern to transfer pseudoephedrine or ephedrine without prescription

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amends rule by adding "intern" as required by 2022 HB 4034.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034 Engrossed

Racial Equity Statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Adopting proposed amendments will increase patient access to drugs containing pseudoephedrine or ephedrine by reducing barriers for pharmacy staff and the patient.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): No fiscal anticipated.

Cost of Compliance (including small businesses OBOP/Other State Agencies/Units of Local Government/Public: There are no known economic impacts to the Oregon Board of Pharmacy, small businesses, or members of the public.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Legislative directive of 2022 HB 4034.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): OAR 855-080-0026 proposed amendments include adding "intern" as mandated in 2022 HB 4034, which allows an intern to transfer a drug containing pseudoephedrine or ephedrine or a salt, isomer or salt of an isomer of pseudoephedrine or ephedrine without a prescription from a practitioner to a person who is 18 years of age or older and who provides to the pharmacist, intern or pharmacy technician the person's valid government-issued photo identification.

Division 80
SCHEDULE OF CONTROLLED SUBSTANCES

NOTE: The rule package shown below is currently proposed to send to rulemaking. If changes are made prior to sending to rulemaking they will need to be reflected here.

- Div 006 041 043 045 080 139 Adopted Standards by Reference

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 (04/01/2021~~0~~); 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 **ORS 475.230** ~~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 **ORS 475.230** ~~2021 HB 2648~~;

(d) Ensure that only a Pharmacist, **Intern,** 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, **Intern,** 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) **Each** ~~P~~**p**harmac**y**~~ies~~, Pharmacist~~s~~, **Intern,** Certified Oregon Pharmacy Technician~~s~~ and Pharmacy Technician~~s~~ involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/202**1**~~0~~), 21 CFR 1314.02 (04/01/202**1**~~0~~), 21 CFR 1314.03 (04/01/202**1**~~0~~), 21 CFR 1314.05 (04/01/202**1**~~0~~), 21 CFR 1314.10 (04/01/202**1**~~0~~), 21 CFR 1314.15 (04/01/202**1**~~0~~), 21 CFR 1314.20 (04/01/202**1**~~0~~), 21 CFR 1314.25, (04/01/202**1**~~0~~); 21 CFR 1314.30 (04/01/202**1**~~0~~), 21 CFR 1314.35 (04/01/202**1**~~0~~), 21 CFR 1314.40 (04/01/202**1**~~0~~), 21 CFR 1314.42 (04/01/202**1**~~0~~), 21 CFR 1314.45 (04/01/202**1**~~0~~); and 21 CFR 1314.50 (04/01/202**1**~~0~~).

Statutory/Other Authority: **ORS 475.230,** ORS 689.205~~,~~ & **2022 HB 4034** ~~2021 HB 2648~~
Statutes/Other Implemented: ORS 475.035, **ORS 475.230** & **2022 HB 4034** ~~2021 HB 2648~~

Division 041: Operation of Pharmacies (Telework- Procedural Rule Review/2022 HB 4034)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Telework rules pursuant to 2022 HB 4034

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Clarifies licensees who can work from a telework site. Incorporates directives of 2022 HB 4034 related to duplication, downloading or removal of records from an electronic database.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): The proposed rules provide clarity for currently promulgated rules, no effects on racial equity are anticipated.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): Pharmacies are not required to utilize telework, no fiscal impact is anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses): There are no known economic impacts to the Oregon Board of Pharmacy or other local government agencies. Pharmacies are not required to utilize telework.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of the rules, proposed amendments are directives of 2022 HB 4034.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Directives of 2022 HB 4034.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Amends the definition of Non-Resident Pharmacy in 855-041-1060 to eliminate conflict with telework rules. Proposes amending current Telework rules OAR 855-041-3205 – OAR 855-041-3250 to comply with the directives of 2022 HB 4034. Proposed amendments include amending definitions, striking language that is no longer relevant, amending general requirements, amending supervision requirements, adding new citation to confidentiality rules, amending technology testing requirements, proposing minor amendments in personnel, removing "environment" from the rule title in 855-041-3240, adding language around configuration to protect patient records, proposing small amendments to policies and procedures, clarifying licensees that can work from telework site, and adding language specific to how records are stored and accessed.

Division 041
OPERATION OF PHARMACIES

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 ~~shall~~ **must** be registered with the Oregon Board of Pharmacy.

(3) To qualify for registration under these rules, every non-resident pharmacy ~~shall~~ **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 ~~shall~~ **must** designate an Oregon licensed Pharmacist-in-Charge (PIC), who ~~shall~~ **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~~**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 ~~B~~**b**oard 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 ~~B~~**b**oard correspondence and inquiries.

(7) A new Pharmacist-in-Charge must be appointed, and communication made to the ~~B~~**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

855-041-3205
Telework: Definitions

(1) "Telework" means the practice or assistance in the practice of pharmacy physically located outside of a registered drug outlet when working as **a contractor or** an employee of an Oregon 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 **contractors or** 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~~,~~ and phone number ~~where 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~~ **via** ~~T~~**t**elework ~~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

(D) **Implement measures to** 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~~ **each** 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

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

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 an audiovisual communication system and have appropriate technology or interface to allow access to information required to complete assigned duties;

(2) Ensure telephone audio is recorded~~, reviewed~~ and stored for all patient interactions completed by Certified Oregon Pharmacy Technicians and Interns;

(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon Pharmacy Technician and that the audiovisual communication system 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 audiovisual communication system 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) **Ensure** ~~T~~**t**he Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy Technician at a Telework Site ~~must~~:

(a) Us**es**~~ing~~ professional judgment~~,~~ **to** determine the percentage of patient interactions for each licensee that must be **observed or** reviewed to ensure public health and safety with a minimum of 5% of patient interactions observed or reviewed;

(b) Review**s** 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**s** the following within 24 hours of the **observation or** review in (b):

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

(B) Number of each licensee's patient interactions pharmacist ~~is~~ **has observed and** review**ed**~~ing~~;

(C) Date and time of licensee patient interaction pharmacist ~~is~~ **has observed and** review**ed**~~ing~~;

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

(E) Pharmacist notes of each interaction **observed or** reviewed; and

(d) Report**s** 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)~~,~~**; and**

(9) E~~e~~mploy adequate staff to allow for:

(a) ~~completion of the~~ **Observation and** review within 48 hours~~,~~**; and**

(b) Create records; and

(10) ~~r~~**R**etain records.

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 855-020,** OAR 855-025, OAR 855-031, ~~and~~ OAR 855-041 **and OAR 855-139**.

(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 breach of confidentiality. Report of ~~the~~ **each** 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

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

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 audiovisual communication system w**ith the Telework Site** and document that it operates properly before **the Intern or Certified Oregon Pharmacy Technician** engage**s**~~ing~~ in telework **at the Telework Site**.

(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 audiovisual communication system.

Statutory/Other Authority: ORS 689.135, ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3235
Telework: Personnel

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all operations at **the** Drug Outlet Pharmacy including responsibility for the audiovisual communication system and enforcing policies and procedures.

(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel to engage in ~~at T~~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

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(1) Telework Sites must be located in a designated area where:

(a) All equipment is stored;

(b) All work is performed; and

(~~c~~**2**) Confidentiality ~~is~~ **must be** maintained such that patient information cannot be viewed or overheard by anyone other than the Pharmacist, Intern or Certified Oregon Pharmacy Technician.

(~~2~~**3**) 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~~**4**) All computer equipment used ~~at the~~ **for** ~~T~~**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 audiovisual communication system **with the Telework Site** is not functioning; ~~and~~

(d) Be configured so information from any patient or pharmacy records are not duplicated, downloaded or removed from the electronic database when an electronic database is accessed remotely; and

(~~d~~**e**) Comply with all security and confidentiality requirements.

(**4**~~5~~) A record must be maintained with the date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site.

(~~5~~**6**) 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~~**7**) 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

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(1) If a Drug Outlet Pharmacy utilizes licensees **via telework** ~~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 **via telework** ~~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 audiovisual communication;

(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 the audiovisual communication system is disrupted;

(i) Confirmation of dedicated, secure Telework Sites;

(j) Documenting the identity, function, location, date and time of the licensees engaging in telework from **a Telework Site**;

(k) Written agreement with licensees engaging in telework outlining **the** specific functions performed~~,~~ **and requirement to comply with telework** ~~conditions and~~ policies and procedures ~~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

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(1) If a Drug Outlet Pharmacy utilizes licensees ~~at Telework Sites~~ **via telework** 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~~ **via telework** must be stored ~~at~~ **by** 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) **Physical** ~~R~~records ~~must~~ **may not** be stored at the Telework ~~s~~**S**ite ~~in a manner that prevents unauthorized access.~~

(3) Records may not be duplicated, downloaded or removed when accessed via telework.

(4) Records must be stored in a manner that prevents unauthorized access.

(~~3~~**5**) 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 **performing telework** ~~working from Telework Sites~~ that includes:

(A) Name;

(B) License number **and expiration date**;

~~(C) Verification of each license;~~

(~~D~~**C**) Address of Telework Site; and

(~~E~~**D**) Name of the Oregon licensed Pharmacist who**:**

(i) ~~v~~**V**erified **(A)-(C)** ~~each licensure,~~**;**

(ii) ~~a~~**A**pproved licensee to telework**;** and

(iii) ~~a~~**A**pproved each Telework Site;

(f) Audiovisual communication system testing and training;

(g) Still image capture and store and forward images must be retained according to (1);

(h) Data and telephone audio must be retained for 6 months; and

(i) 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

Division 139: Remote Dispensing Site Pharmacy (2022 HB 4034)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Removes certain personnel and ratio requirements for Remote Dispensing Site Pharmacies

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments include adding 'pharmacy technician' and striking Certified Oregon Pharmacy Technician pursuant to directives of 2022 HB 4034. A 'pharmacy technician' includes both the 'Pharmacy Technician' and 'Certified Oregon Pharmacy Technician' licensure categories. Removes requirement for similar work experience and pharmacist to technician ratio pursuant to directives of 2022 HB 4034.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): There are racial and ethnic disparities in geographic access to pharmacies. Remote Dispensing Site Pharmacies are an option to add pharmacy access in current pharmacy deserts. Given the critical role of prescription medications in the prevention and treatment of chronic conditions, ensuring access to pharmacies has implications for population health and health disparities. By permitting both Pharmacy Technicians and Certified Oregon Pharmacy Technicians to work in a RSDP, removing the work experience and ratio requirements for this setting more RDSPs may be able to open and Oregonians may have increased access to pharmacy services.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): Pharmacies are not required to operate a Remote Dispensing Site Pharmacy. No fiscal impact is anticipated.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There are no known economic impacts to the Oregon Board of Pharmacy, small businesses or members of the public. If a pharmacy chooses to operate a Remote Dispensing Site Pharmacy via telepharmacy, the pharmacy will be required to apply and pay a registration fee for the Remote Dispensing Site Pharmacy as well as required to comply with all Oregon Administrative Rules and Oregon Revised Statutes.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Proposed amendments are directives of 2022 HB 4034.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Adds 'pharmacy technician', strikes 'Certified Oregon Pharmacy Technician, and removes requirement for similar work experience and pharmacist to technician ratio pursuant to directives of 2022 HB 4034.

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0005

Definitions

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 006/041/139 - related to 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) "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~~ **pharmacy technician** under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.

(3) "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~~ **pharmacy technician**.

Statutory/Other Authority: ORS 689.205, ORS 689.522, 2021 SB 629
Statutes/Other Implemented: 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 a ~~Certified Oregon Pharmacy Technician~~ **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) The 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 855-139-0015(2).

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

(6) The 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

855-139-0050
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~~**3**) 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~~**4**) The RDSP Affiliated Pharmacy **and the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy** is required to comply with the pharmacist's determination in (~~4~~**3**) and retain records.

(~~7~~**5**) The RDSP and RDSP Affiliated Pharmacy must ensure adequate staffing at both the RDSP and RDSP Affiliated Pharmacy.

(~~8~~**6**) Prior to working at a RDSP, **the RDSP Affiliated Pharmacy, the RDSP, Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy is responsible for ensuring** the ~~Certified Oregon Pharmacy Technician~~ **pharmacy technician** and the Oregon licensed Pharmacist supervising the RDSP ~~must~~ **are adequately trained to perform their duties and** have completed a training program on the proper use of the telepharmacy system.

(~~9~~**7**) 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

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(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 alarm system armed to prevent, deter and detect 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~~ **pharmacy technician** present in the RDSP; or

(c) Any component of the surveillance 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 at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy if unauthorized access occurs;

(b) Electronic entry system that is controlled by an Oregon licensed Pharmacist and records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the RDSP;

(B) Identification of the ~~Certified Oregon Pharmacy Technician~~ **pharmacy technician** accessing and securing the RDSP; and

(C) Date and time of each activity.

(c) Surveillance system that utilizes continuously accessible and recorded video 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.

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~~ **pharmacy technician** working in the RDSP practices appropriate infection control.

Statutory/Other Authority: ORS 689.305
Statutes/Other Implemented: ORS 689.305

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 Technician~~ **pharmacy technicians** authorized to access the RDSP and operate the telepharmacy system;

(f) Train the Oregon licensed Pharmacists and ~~Certified Oregon Pharmacy Technician~~ **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: 2021 SB 629 & ORS 689.155

855-139-0210
Outlet: Supervision

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
    - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

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~~ **pharmacy technician**, and the surveillance system is fully operational;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each ~~Certified Oregon Pharmacy Technician~~ **pharmacy technician** at the RDSP using an audiovisual communication system. All patient interactions must be recorded, reviewed and stored;

(3) The Oregon licensed Pharmacist who is supervising ~~Certified Oregon Pharmacy Technician~~ **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 10% of patient interactions observed or 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 48 hours, and retain records.

(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the ~~Certified Oregon Pharmacy Technician~~ **pharmacy technician**.

(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~~ **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

855-139-0220

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~~ **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

855-139-0315

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~~ **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~~ **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

855-139-0355
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~~ **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~~ **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 855-139-0205 for each individual dosage unit in the med pak.

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

855-139-0455
Drug and Devices: Return

A ~~Certified Oregon Pharmacy Technician~~ **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:

(1) An Oregon licensed Pharmacist has approved the return;

(2) The drugs or devices are accepted for destruction or disposal; and

(3) An Oregon licensed Pharmacist verifies the destruction or disposal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet RDSP may not:

(1) Allow a ~~Certified Oregon Pharmacy Technician~~ **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) Compound sterile preparations; or

(5) Repackage drugs.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-139-0715
Service: Epinephrine- General Requirements

(1) A ~~Certified Oregon Pharmacy Technician~~ **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~~ **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~~ **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~~ **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

855-139-0730

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~~ **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

Division 006/031: Definitions/Interns (PHE Rules Sunset)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Supervision by a pharmacist and preceptor supervision of Interns

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Removes language that is no longer relevant due to the end of the declared public health emergency.

Documents Relied Upon per ORS 183.335(2)(b)(D): https://www.oregon.gov/gov/Pages/executive-orders.aspx

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Removing language that is no longer relevant may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated.

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

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Effect on Small Businesses): There are no known fiscal impacts to the agency or the public.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff recommends striking language that is no longer relevant due to the end of the public health emergency related to COVID-19.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): In March 2020, the Governor declared a public health emergency related to COVID-19 pandemic. The board received input from Oregon pharmacy school programs that due to social distancing requirements, they needed to create remote School-based Rotational Internships (SRIs) opportunities that would permit non-direct patient internships for the 2020-2021 academic year. In September 2020 the board adopted permanent rules in Div 006 and Div 031 that allowed preceptors to monitor as many interns & technicians as they believed was appropriate in their professional judgement during the declared public health emergency.

Removes language in Div 006 related to the definition of "supervision of a pharmacist" regarding pharmacist monitoring of technicians and interns for remote processing functions as defined during the declared public health emergency. Removes language in Div 031 that allowed a preceptor to monitor as many interns as they believed was appropriate in their professional judgement during the public health emergency.

Division 006
DEFINITIONS

855-006-0005
Definitions

- NOTE: The rule packages shown below is currently proposed to send to rulemaking. If changes are made prior to sending to rulemaking they will need to be reflected here.
    - Div 006/041/045/080/139- Adoption of Standards by Reference

(43) "Supervision by a pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the **Intern,** ~~p~~**P**harmacy ~~t~~**T**echnician or ~~c~~**C**ertified Oregon ~~p~~**P**harmacy ~~t~~**T**echnician being supervised, coupled with the ability to control and be responsible for the **Intern,** ~~p~~**P**harmacy ~~t~~**T**echnician or ~~c~~**C**ertified Oregon ~~p~~**P**harmacy ~~t~~**T**echnician'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.~~

Division 031
INTERNS

855-031-0026
Ratio & Supervision

(1) A pharmacist may not supervise more than one intern at a time at a TPI site who performs the duties of an intern as listed in OAR 855-019-0200(3)(g). A pharmacist may supervise more than one intern if only one intern performs the duties of an intern as listed in OAR 855-019-0200(3)(g) and if other interns supervised by the pharmacist perform the duties listed in OAR 855-025-0040.

(2) A preceptor may not supervise more than two interns simultaneously during a shift at an SRI site where patient specific recommendations for care or medications are provided without prior written authorization of the board. ~~Through the 2020-2021 academic year, a preceptor may monitor as many interns as they believe in their professional judgement is appropriate to achieve desired experiential outcomes for non-direct patient care learning opportunities only, while also preserving and assuring patient safety. The preceptor must retain documentation of all interns monitored during this timeframe.~~

(3) With the written approval of a school of pharmacy, and when in their professional judgment it is appropriate, a preceptor may supervise up to 10 interns at public-health outreach programs such as informational health fairs that provide general information but not direct patient care.

(4) For immunization clinics, an immunizing pharmacist may supervise up to two immunizing interns.

(5) A licensed preceptor may delegate the preceptor responsibilities to another licensed pharmacist or preceptor.

(6) The majority of an intern's overall experience must be with a licensed pharmacist preceptor.

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

Division 006/019/041/139– Definitions/RPH/Operation of a Pharmacy/RDSP (Interpreters/Patient Records)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds requirements for use of interpreters and modifies patient record requirements

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Revisions to Division 006/019/041/139/143 are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Per 2021 HB 2359, pharmacists and interns must work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services. Modifies patient records requirements to include patient's preferred language for communication and prescription labeling.

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

- Oregon regulations: 2021 HB 2359; ORS 413.550 and ORS 413.558 related to health care interpreters; OAR 333-002 related to health care interpreters

- Federal Regulations: Title VI of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, and national origin in programs and activities receiving federal financial assistance; Section 1557 of the Affordable Care Act prohibits discrimination on the basis of race, color, national origin, age, disability, or sex, in covered health programs or activities; 42 USC 18116 Nondiscrimination and 45 CFR Part 92 Nondiscrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities receiving federal financial assistance and programs or activities administered by the Department of Health and Human Services under Title I of the Patient Protection and Affordable Care Act or by entities established under such title.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Patients from a variety of racial and ethnic backgrounds are of Limited English Proficiency. Approximately 222,000 Oregonians (1 out of every 17) cannot read the directions for their prescription medications provided in English and approximately 4,000 Oregonians communicate via American Sign Language (ASL). Interpreters offer a language and cultural bridge between a Pharmacist and a LEP patient or and those who prefer to communicate in a language other than English, including American Sign Language and other signed languages. Utilizing qualified interpreters will ensure that proper communication occurs to allow the LEP patient and those who prefer to communicate in a language other than English, including American Sign Language and other signed languages, to achieve desired health outcomes. The ability to access an interpreter who can communicate in the patient's preferred language will have a positive impact on patients from a variety of racial and ethnic backgrounds who may have barriers to oral communication.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): To be determined

OBOP/Other State Agencies/Units of Local Government/Public: No anticipated fiscal impact is expected for the agency, other state agencies, units of local government or the public.

Cost of Compliance (including small businesses): To be determined

Number/Type: To be determined

Reporting, Recordkeeping and Administrative Activities Cost: To be determined

Professional Services, Equipment/ Supplies, Labor Cost: To be determined

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, A RAC was not consulted, proposed rules are a legislative directive of 2021 HB 2359 related to health care interpreters.

Rules Summary per ORS 183.335(2)(a)(B) (Indicates the change to the rule and why): Proposed amendments are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Requires pharmacists and interns to work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services. Modifies patient records requirements to include patient's preferred language for communication and prescription labeling.

Division 6
DEFINITIONS

855-006-0005
Definitions

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
  - Divisions 006/041/139 - related to Definitions
- NOTE: The rule packages shown below is currently proposed to send to rulemaking. If changes are made prior to sending to rulemaking they will need to be reflected here.
  - Div 006 041 043 045 080 139- Adopted Standards by Reference
  - Div 006/031- PHE Sunset
  - Div 006/019/041/139/143 Interpreters

(x) "Certified health care interpreter" has the meaning given that term in ORS 413.550.

(x) "Health care interpreter" has the meaning given that term in ORS 413.550.

(x) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.

(x) "Individual with limited English proficiency" means a person who, by reason of place of birth or culture, communicates in a language other than English and does not communicate in English with adequate ability to communicate effectively with a health care provider.

NOTE: Board will motion all changes to Div 006 Definitions in one motion at end of policy discussions.

Division 19
PHARMACISTS

855-019-0230
Counseling

(1) The pharmacist or intern ~~shall~~ **must** orally counsel the patient or patient's agent on the use of a drug or device as appropriate:

(a) The pharmacist or intern ~~shall~~ **must** counsel the patient on a new prescription and any changes in therapy, including but not limited to a change in directions or strength, or a prescription which is new to the pharmacy;

(b) Only the pharmacist or intern may accept a patient's or patient's agent's request not to be counseled. If, in their professional judgment, the pharmacist or intern believes that the patient's safety may be affected, the pharmacist or intern may choose not to release the prescription until counseling has been completed;

(c) ~~Effective July 1, 2008,~~ ~~t~~**T**he pharmacist or intern that provides counseling or accepts the request not to be counseled ~~shall~~ **must** document the interaction;

(d) A pharmacist ~~shall~~ **must** not allow non-pharmacist personnel to release a prescription that requires counseling, or accept the request not to be counseled;

(e) For a prescription delivered to a patient, except at a pharmacy or a pharmacy prescription locker, the pharmacist ~~shall~~ **must** offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist;

(f) For each patient, the pharmacist or intern ~~shall~~ **must** determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient; and

(g) When communicating (e.g. counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the Pharmacist is proficient in the patient's preferred language.

(2) Counseling on a refill prescription ~~shall~~ **must** be such as a reasonable and prudent pharmacist would provide.

(3) A pharmacist may provide counseling in a form other than oral counseling when, in their professional judgment, a form of counseling other than oral counseling would be more effective.

(4) A pharmacist or intern ~~shall~~ **must** initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

(5) For a discharge prescription from a hospital, the pharmacist must ensure that the patient receives appropriate counseling.

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

Division 41

OPERATION OF PHARMACIES

855-041-1165

Patient Medical Record

A patient record system shall be maintained by pharmacies for all patients for whom prescription drug orders are dispensed~~, except for those patients who the pharmacist has good reason to believe will not return to that pharmacy to obtain drugs~~. The patient record system ~~shall~~ **must** provide for readily retrievable information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist ~~shall~~ **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) Patient's preferred language for communication and prescription labeling;

(~~5~~**6**) Chronic medical conditions;

(~~6~~**7**) 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~~**8**) Known allergies, drug reactions, and drug idiosyncrasies; and

(~~8~~**9**) If deemed relevant in the pharmacist's professional judgment:

(a) 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, 689.155 & 689.508

855-041-1133

Dispensing: Interpretation

(1) Except as provided in subsection (2) of this section, a Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 when communicating with a patient who prefers to communicate in a language other than English or who communicates in signed language, unless the Pharmacist is proficient in the preferred language of the person with limited English proficiency. The Pharmacist or drug outlet may not charge for these services.

(2) A Pharmacist or Intern who is otherwise required to work with a health care interpreter from the health care interpreter registry may work with a health care interpreter who is not listed on the health care interpreter registry only if the Pharmacist or Intern:

(a) Verifies that the Pharmacist or Intern has made a good faith effort needed to obtain a health care interpreter from the health care interpreter registry in accordance with rules adopted by the authority under ORS 413.558 and has found that none are available to provide interpretation; or

(b) Has offered the patient the services of a health care interpreter from the health care interpreter registry and the patient declined the offer and chose a different interpreter.

(3) A Pharmacist or Intern must provide personal protective equipment, consistent with established national standards, to health care interpreters providing services on-site at no cost to the health care interpreter and may not suggest to the health care interpreter that the health care interpreter should procure the health care interpreter's own personal protective equipment as a condition of working with the Pharmacist or Intern.

(4) A Pharmacist or Intern must maintain records of:

(a) Each patient encounter in which the Pharmacist or Intern worked with a health care interpreter from the health care interpreter registry; or

(b) Each good faith effort to utilize a health care interpreter from the health care registry for each patient encounter in which the Pharmacist or Intern worked with an interpreter not on the health care interpreter registry and met one of the exceptions in (2) of this rule.

(5) The records required in (4) must include:

(a) The full name of the health care interpreter;

(b) The health care interpreter's registry number, if applicable; and

(c) The language interpreted.

(6) Pharmacists, Interns, Certified Oregon Pharmacy Technicians, Pharmacy Technicians and Pharmacies are required to comply with ORS 413.559.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359
Statutes/Other Implemented: ORS 689.155, 2021 HB 2359

Division 139
REMOTE DISPENSING SITE PHARMACY

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) Patient's preferred language for communication and prescription labeling;

(~~5~~**6**) Chronic medical conditions;

(~~6~~**7**) 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~~**8**) Known allergies, drug reactions, and drug idiosyncrasies; and

(~~8~~**9**) If deemed relevant in the 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

855-139-0360
Dispensing: Interpretation

(1) Except as provided in subsection (2) of this section, a Pharmacist or Intern from the RDSP Affiliated Pharmacy must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 when communicating with a patient who prefers to communicate in a language other than English or who communicates in signed language, unless the Pharmacist is proficient in the preferred language of the person with limited English proficiency. The Pharmacist or drug outlet may not charge for these services.

(2) A Pharmacist or Intern who is otherwise required to work with a health care interpreter from the health care interpreter registry may work with a health care interpreter who is not listed on the health care interpreter registry only if the Pharmacist or Intern:

(a) Verifies that the Pharmacist or Intern has made a good faith effort needed to obtain a health care interpreter from the health care interpreter registry in accordance with rules adopted by the authority under ORS 413.558 and has found that none are available to provide interpretation; or

(b) Has offered the patient the services of a health care interpreter from the health care interpreter registry and the patient declined the offer and chose a different interpreter.

(3) A Pharmacist or Intern must provide personal protective equipment, consistent with established national standards, to health care interpreters providing services on-site at no cost to the health care interpreter and may not suggest to the health care interpreter that the health care interpreter should procure the health care interpreter's own personal protective equipment as a condition of working with the Pharmacist or Intern.

(4) A Pharmacist or Intern must maintain records of:

(a) Each patient encounter in which the Pharmacist or Intern worked with a health care interpreter from the health care interpreter registry; or

(b) Each good faith effort to utilize a health care interpreter from the health care registry for each patient encounter in which the Pharmacist or Intern worked with an interpreter not on the health care interpreter registry and met one of the exceptions in (2) of this rule.

(5) The records required in (4) must include:

(a) The full name of the health care interpreter;

(b) The health care interpreter's registry number, if applicable; and

(c) The language interpreted.

(6) Pharmacists, Interns, Certified Oregon Pharmacy Technicians, Pharmacy Technicians and Pharmacies are required to comply with ORS 413.559.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359
Statutes/Other Implemented: ORS 689.155, 2021 HB 2359

Division 020: Pharmacist Prescribing (Tobacco Cessation & PrEP Protocol Amendments)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Compendia updated with new protocol versions for Tobacco Cessation and PrEP

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Permanently adopts amended statewide drug therapy management protocol for Tobacco Cessation – NRT (Nicotine Replacement Therapy) and Non-NRT v.6/2022 and statewide drug therapy management protocol for HIV Pre-Exposure Prophylaxis (PrEP) v.6/2022 as recommended by the Public Health and Pharmacy Formulary Advisory Committee.

Documents Relied Upon per ORS 183.335(2)(b)(D): Tobacco Cessation protocol v.6/2021, HIV Pre-Exposure Prophylaxis (PrEP) protocol v.12/2021

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Although tobacco use has declined significantly since 1964, disparities in tobacco use remain across groups defined by race, ethnicity, educational level, and socioeconomic status and across regions of the country. In 2015, 16.8% of African-Americans, 21.9% of American Indians/Alaska Natives, 7% of Asian-Americans, 10.1% of Hispanics and 16.6% of non-Hispanic Whites used tobacco. Although African Americans usually smoke fewer cigarettes and start smoking cigarettes at an older age, they are more likely to die from smoking-related diseases than Whites. During 2010–2015, racial/ethnic disparities in HIV incidence increased among men who have sex with men (MSM); in 2015, rates among black and Hispanic MSM were 10.5 and 4.9 times as high, respectively, as the rate among white MSM (compared with 9.2 and 3.8 times as high, respectively, in 2010). Preexposure prophylaxis (PrEP) reduces the risk for sexual human immunodeficiency virus transmission by approximately 99%. By making tobacco cessation and PrEP therapies easily accessible to patients at their local pharmacy, it may improve access for patients who may not be able to otherwise access these services.

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

Cost of Compliance OBOP/Other State Agencies/Units of Local Government/Public, Effect on small businesses: State agencies and local government are not impacted by proposed protocols or the draft rule. Pharmacy stakeholders and the public may be impacted by these rules if utilized. Provision of formulary prescribing services by a pharmacist/pharmacy is voluntary. The professional time to offer these services and comply with record keeping requirements may increase costs to the outlet, which may possibly be passed on to the public for prescribing services. Outlets will be required to establish and enforce policies and procedures and pharmacists must comply with the rules if they offer the services.

Describe how small businesses were involved in development of the rules: Participation is voluntary, and a pharmacist is not mandated to offer patient care and prescribing services.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. The statutorily mandated Public Health and Pharmacy Formulary Advisory Committee informed the content of the amended protocols.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Minor edits to Tobacco Cessation Assessment and Treatment Care Pathway for clarity. Edits to PrEP Patient Intake Form, Assessment and Treatment Care Pathway and Provider Fax documents to align with CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline.

Division 020
PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0300
Protocol Compendium

NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.

- Division 020 - related to COVID-19 Antigen Self-Test Protocol

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)

(D) Intranasal corticosteroids (v. 06/2021);

(b) Vulvovaginal candidiasis (VVC) Protocol (v. 06/2021);

(c) COVID-19 Monoclonal Antibody (mAb) Protocol (v. 12/2021); and

(d) COVID-19 Antigen Self-Test 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. 06/2022~~1~~);

(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~~**06/2022**).

[Publications referenced are available for inspection in the office of the Board of Pharmacy per OAR 855-010-0021.]

PREVENTIVE CARE

TOBACCO CESSATION – NRT (Nicotine Replacement Therapy) and Non-NRT

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 individual or multiple Nicotine Replacement Therapy (NRT) OTC and Rx for tobacco cessation.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe non-NRT medications for tobacco cessation.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Tobacco Cessation Patient Intake Form (pg. 2-4)
- Utilize the standardized Tobacco Cessation Assessment and Treatment Care Pathway (pg. 5-6)

PHARMACIST TRAINING/EDUCATION:

- Minimum 2 hours of documented ACPE CE related to pharmacist prescribing of tobacco cessation products

Tobacco Cessation 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 _____
Any allergies to foods (ex. menthol/soy)? Yes / No If yes, please list _____
List of medicine(s) you take:_____

_____

_____

Do you have a preferred tobacco cessation product you would like to use?_____
Have you tried quitting smoking in the past? If so, please describe _____
What best describes how you have tried to stop smoking in the past?

- ☐ "Cold turkey"
- ☐ Tapering or slowly reducing the number of cigarettes you smoke a day
- ☐ Medicine
  - o Nicotine replacement (like patches, gum, inhalers, lozenges, etc.)
  - o Prescription medications (ex. bupropion [Zyban®, Wellbutrin®], varenicline [Chantix®])
- ☐ Other_____

Health and History Screen – Background Information:

1.	Are you under 18 years old?	□ Yes □ No
2.	Are you pregnant, nursing, or planning on getting pregnant or nursing in the next 6 months?	□ Yes □ No □ Not sure
3.	Are you currently using and trying to quit non-cigarette products (ex. Chewing tobacco, vaping, e-cigarettes, Juul)?	□ Yes □ No

Medical History:

4.	Have you ever had a heart attack, irregular heartbeat or angina, or chest pains in the past two weeks?	□ Yes □ No □ Not sure
5.	Do you have stomach ulcers?	□ Yes □ No □ Not sure
6.	Do you wear dentures or have TMJ (temporomandibular joint disease)?	□ Yes □ No □ Not sure
7.	Do you have a chronic nasal disorder (ex. nasal polyps, sinusitis, rhinitis)?	□ Yes □ No □ Not sure
8.	Do you have asthma or another chronic lung disorder (ex. COPD, emphysema, chronic bronchitis)?	□ Yes □ No □ Not sure

Tobacco History:

9.	Do you smoke fewer than 10 cigarettes a day?	□ Yes □ No

Blood Pressure Reading _____/_____ mmHg (**Note: Must be taken by a pharmacist*)

Stop here if patient and pharmacist are considering nicotine replacement therapy or blood pressure is ≥ 160/100 mmHg.

If patient and pharmacist are considering non-nicotine replacement therapy (ex. varenicline or bupropion) and blood pressure is < 160/100mmHg continue to answer the questions below.

Tobacco Cessation Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

Medical History Continued:

10.	Have you ever had an eating disorder such as anorexia or bulimia?	□ Yes □ No □ Not sure
11.	Have you ever had a seizure, convulsion, significant head trauma, brain surgery, history of stroke, or a diagnosis of epilepsy?	□ Yes □ No □ Not sure
12.	Have you ever been diagnosed with chronic kidney disease?	□ Yes □ No □ Not sure
13.	Have you ever been diagnosed with liver disease?	□ Yes □ No □ Not sure
14.	Have you been diagnosed with or treated for a mental health illness in the past 2 years? (ex. depression, anxiety, bipolar disorder, schizophrenia)?	□ Yes □ No □ Not sure

Medication History:

15.	Do you take a monoamine oxidase inhibitor (MAOI) antidepressant? (ex. selegiline [Emsam®, Zelapar®], Phenelzine [Nardil®], Isocarboxazid [Marplan®], Tranylcypromine [Parnate®], Rasagiline [Azilect®])	□ Yes □ No □ Not sure
16.	Do you take linezolid?	□ Yes □ No □ Not sure
17.	Do you use alcohol or have you recently stopped taking sedatives? (ex. Benzodiazepines)	□ Yes □ No □ Not sure

The Patient Health Questionnaire 2 (PHQ 2):

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not At All	Several Days	More Than Half the Days	Nearly Every Day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3

Suicide Screening:

Over the last 2 weeks, how often have you had thoughts that you would be better off dead, or have you hurt yourself or had thoughts of hurting yourself in some way?	0	1	2	3

Patient Signature_____Date_____

Tobacco Cessation Assessment & Treatment Care Pathway

STEP 1: Health and History Screen Part 1 Review Tobacco Cessation Patient Questionnaire (Questions 1 -2)	No = No Contraindicating Conditions. Continue to step 2	Yes/Not sure = Contraindicating Conditions. Refer	Refer to PCP and/or Oregon Quit Line 1-800-QUIT-NOW
STEP 2: Health and History Screen Part 2 Review Tobacco Cessation Patient Questionnaire (Question 3)	Smoking Cigarettes. Continue to step 3	Yes to question 3 Refer	Refer to Oregon Quit Line 1-800-QUIT-NOW to receive counseling and NRT
STEP 3: Blood Pressure Screen Take and document patient's current blood pressure. (Note: RPh may choose to take a second reading if initial is high)	BP < 160/100. Continue to step 4	BP ≥ 160/100 Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW
STEP 4: Medical History Nicotine Replacement Therapy Questions (Questions 4-5)	No, to question 4 and 5. Continue to step 5	Yes, to question 4 and/or 5 Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW

STEP 5: Medical History Nicotine Replacement Therapy Questions (Questions 6-8) Question 6 = if Yes, avoid using nicotine gum Question 7 = if Yes, avoid using nicotine nasal spray Question 8 = if Yes, avoid using nicotine inhaler	If patient wants NRT, prescribe NRT*	If patient wants bupropion or varenicline, continue to step 6.

Prescribing NRT*(pg.6): • Combination NRT is preferred (Nicotine patch + Acute NRT) • Acute NRT = Nicotine gum, Nicotine lozenge, Nicotine nasal spray, Nicotine inhaler	**Tobacco History (Question 9 on questionnaire)** If Yes to smoking </=10 cigs/day, start with nicotine patch 14mg/day If No to smoking > 10 cigs/day start with nicotine patch 21mg/day

STEP 6: Medical History Bupropion and varenicline screening Questions 10-14	Consider NRT* if yes to any question from 10-14	
	a) If yes to any question → avoid bupropion. If patient still wants bupropion, refer. Refer	Refer to PCP **AND** Oregon Quit Line 1-800-QUIT-NOW; NRT* can be considered
	b) If yes to any questions from 12-14→ avoid varenicline. If patient still wants varenicline, refer. Refer	
	If patient answered no to questions 10 – 14, continue to step 7. If patient answered no to questions 12-14, but yes to question 10 and/or 11, AND wants varenicline (but not bupropion), skip to step 8	

STEP 7: Medication History Questions 15-17 on questionnaire.	If patient answered no to questions 15-17, review depression screening step 8.	If patient answered yes to any question from 15-17 → Avoid bupropion. Refer - Refer if patient still wants bupropion. - If patient wants varenicline, continue to depression screening step 8.	Refer to PCP if patient wants bupropion; NRT* can be considered
STEP 8: The Patient Health Questionnaire 2 (PHQ 2): Depression Screening	Score < 3 on PHQ2. Review Suicide Screening in step 9.	Score ≥ 3 on PHQ. Refer Avoid bupropion and varenicline, refer to PCP for treatment. NRT* can be offered.	Refer to PCP; NRT* can be considered
STEP 9: Suicide Screening	Score of 0 on suicide screening. May prescribe bupropion or varenicline.	Score ≥ 1 on suicide screening. Refer **Immediate** referral to PCP.	Call PCP office to notify them of positive suicide screening and determine next steps. After hours, refer to suicide hotline 1-800-273-8255

Prescribing Bupropion:	**Prescribing Varenicline:**
150mg SR daily for 3 days then 150mg SR twice daily for 8 weeks or longer. Quit day after day 7. Consider combining with Nicotine patch or Nicotine lozenge or Nicotine gum for increased efficacy.* For patients who do not tolerate titration to the full dose, consider continuing 150mg once daily as the lower dose has shown efficacy.	0.5mg daily for 3 days then 0.5mg twice daily for 4 days then 1mg twice daily for 12 to 24 weeks. Quit day after day 7 or alternatively quit date up to 35 days after initiation of varenicline. Generally not used in combination with other smoking cessation medications as first line therapy.

Tobacco Cessation Assessment & Treatment Care Pathway

*Nicotine Replacement Dosing:

	Dose
Long Acting NRT	
Nicotine Patches	• Patients smoking >10 cigarettes/day: begin with 21mg/day for 6 weeks, followed by 14mg/day for 2 weeks, finish with 7mg/day for 2 weeks • Patients smoking ≤ 10 cigarettes/day: begin with 14mg/day for 6 weeks, followed by 7mg/day for 2 weeks • **Note:** Adjustment may be required during initial treatment (move to higher dose if experiencing withdrawal symptoms; lower dose if side effects are experienced).
Acute NRT	
Nicotine Gum	• Chew 1 piece of gum when urge to smoke occurs. If strong or frequent cravings are present after 1 piece of gum, may use a second piece within the hour (do not continuously use one piece after the other). • Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended. • Use according to the following 12-week dosing schedule: o Weeks 1 to 6: Chew 1 piece of gum every 1 to 2 hours (maximum: 24 pieces/day); if using nicotine gum alone without nicotine patches, to increase chances of quitting, chew at least 9 pieces/day during the first 6 weeks o Weeks 7 to 9: Chew 1 piece of gum every 2 to 4 hours (maximum: 24 pieces/day) o Weeks 10 to 12: Chew 1 piece of gum every 4 to 8 hours (maximum: 24 pieces/day)
Nicotine Lozenges	• 1 lozenge when urge to smoke occurs; do not use more than 1 lozenge at a time • Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended. • Use according to the following 12-week dosing schedule: o Weeks 1 to 6: 1 lozenge every 1 to 2 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day); if using nicotine lozenges alone without nicotine patches, to increase chances of quitting, use at least 9 lozenges/day during the first 6 weeks o Weeks 7 to 9: 1 lozenge every 2 to 4 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day) o Weeks 10 to 12: 1 lozenge every 4 to 8 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day)
Nicotine Inhaler	• *Initial treatment*: 6 to 16 cartridges/day for up to 12 weeks; maximum: 16 cartridges/day • Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation. • *Discontinuation of therapy:* After initial treatment, gradually reduce daily dose over 6 to 12 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.
Nicotine Nasal Spray	• Initial: 1 to 2 doses/hour (each dose [2 sprays, one in each nostril] contains 1 mg of nicotine) • Adjust dose as needed based on patient response; do not exceed more than 5 doses (10 sprays) per hour [maximum: 40 mg/day (80 sprays)] or 3 months of treatment • If using nicotine nasal spray alone without nicotine patches, for best results, use at least the recommended minimum of 8 doses per day (less is likely to be effective). • Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation. • *Discontinuation of therapy:* Discontinue over 4 to 6 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.

Oregon licensed pharmacist must adhere to Prescribing Parameters, when issuing any prescription for tobacco cessation.

PRESCRIBING PARAMETERS:

- 1st prescription(s) up to 30 days
- Maximum duration = 12 weeks
- Maximum frequency = 2x in a rolling 12-month period

TREATMENT CARE PLAN:

- Documented follow-up: within 7-21 days, phone consultation permitted

Tobacco Cessation 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
- ☐ Referred patient to Oregon Quit Line (1-800-QUIT-NOW or www.quitnow.net/oregon)
- ☐ BP Reading: ____/____ mmHg *must be taken by a RPh

Note: RPh must refer patient if blood pressure ≥ 160/100

Rx

Written Date: _____

Prescriber Name:_____Prescriber Signature: _____

Pharmacy Address:_____Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____
_____

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.4-8)
  - Utilize the standardized PrEP Provider Fax (pg.10)

  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_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
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 want to start or continue PrEP?
2. Do you sexually partner with men, women, transgender, or non-binary people?
3. 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
4. Do you have oral sex? • Giving- you perform oral sex on someone else • Receiving- someone performs oral sex on you
5. 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
6. 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
7. Do you inject drugs?
8. Are you in a relationship with an HIV-positive partner?
9. Do you exchange sex for money or goods? (includes paying for sex)
10. 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. Have you had any of the following in the last 4 weeks: fever, feeling very tired, muscle or joint aches or pain, rash, sore throat, headache, night sweats, swollen lymph nodes, diarrhea, general flu-like symptoms?	□ yes □ no
3. When was your last possible HIV exposure?	□ < 72 hrs ago □ 72 hrs - 2 weeks ago □ 2 – 4 weeks ago □ > 4 weeks ago
4. Do you see a (healthcare provider) for management of Hepatitis B?	□ yes □ no
5. 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 __/__/__

Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

6. Do you see a healthcare provider for problems with your kidneys?	□ yes □ no
7. Do you take non-steroid anti-inflammatory drugs (NSAIDS)? • Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen)	□ yes □ no
8. Are you currently or planning to become pregnant or breastfeeding?	□ yes □ no
9. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____	□ yes □ no

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. Patient requests PrEP	• Patient may not be comfortable sharing detailed sexual history per CDC PrEP guidelines, if a patient requests PrEP, the recommendation is to prescribe it regardless of identified HIV exposure risk.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. Injection drug use	• Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes.
8. 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.
9. Exchanging sex for money or goods	• People who buy or sell sex are at high risk for HIV.
10. 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 (recommended, optional)*:	____/____/_____	□ *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. If planning to monitor for Hep C, order lab at initial intake and at least annually thereafter.

• Gonorrhea/Chlamydia:	____/____/_____		□ *Yes*

Urinalysis result:	Pharyngeal test result:	Rectal test result:
□ *reactive* □ *indeterminate*	□ *reactive* □ *indeterminate*	□ *reactive* □ *indeterminate*
□ non-reactive	□ non-reactive	□ 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):	____/____/_____	_____ mL/min	□ *Yes*
SCr _____mg/dL		□ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min*	

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; if over 50 years old and on emtricitabine/tenofovir DF (Truvada) PrEP order every 6 months.

- Signs/symptoms of acute retroviral syndrome AND potential HIV exposure in the last 4 weeks AND not on PrEP? □ *Present* □ Not Present □ Yes
- Exposure risk less than 72 hours ago? □ *Yes* □ No

2. Is HIV ab/ag 4th gen test resulted? □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes and non-reactive: Proceed to question #3
- *If yes and reactive or indeterminate: Do NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, do NOT prescribe PrEP, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

3a. If initial visit: Are syphilis, gonorrhea, chlamydia, Hepatitis B serologies (if no documentation of complete vaccination), and serum creatinine resulted? □ **yes** □ ***no***

- If yes, RPH may prescribe up to a 90 day supply of PrEP. Proceed to next section: Medical History.
- If no, RPH may prescribe PrEP for up to a 30 day supply and the patient needs to complete all required labs and bring them in within 30 days before next refill. 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 resulted? □ **yes** □ ***no***

- □ Every 90 days- HIV
- □ Every 90-180 days- Syphilis/Treponemal antibody and Gonorrhea/Chlamydia; Renal function if > 50 yrs old and on emtricitabine/tenofovir DF (Truvada)
- □ Annually - 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. Symptoms of acute retroviral syndrome in last 4 weeks □ *yes* □ no	• Could have acute HIV with negative screening HIV Ag/Ab result. • Order HIV RNA and/or refer to PrEP provider or Infectious Disease provider for further evaluation.
3. Exposure risk was < 72 hrs ago □ *yes* □ no	• Screen for eligibility for PEP (see OBOP Protocol for PEP Prescribing) OR refer to urgent care or ED for further evaluation and possible PEP initiation. • If exposure 72 hours – 2 weeks ago, defer testing and PrEP until at least 2 weeks post exposure and proceed with PrEP according to the result.
4. 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.
5. 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.
6. 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.
7. 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
8. 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.
9. 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.
10. 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

☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
- Take one tablet by mouth daily

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): ☐ CrCl >60mL/min	____/____/_____ _____ mL/min ☐ CrCl 30mL/min - 60mL/min	☐ *CrCl <30mL/min*	☐ *Yes*
• Signs/symptoms of acute retroviral syndrome AND potential HIV exposure in the last 4 weeks AND **not** on PrEP?	☐ *present* ☐ not present		☐ *Yes*
• Exposure risk less than 72 hours ago?	☐ yes ☐ no		☐ *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:

- PrEP is prescribed for up to a 90 day supply for each prescription to align with appropriate lab monitoring guidelines.
- 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.

Pharmacist monitoring of HIV PrEP and transition of care:

- The pharmacist prescribing and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and other baseline and treatment monitoring lab results 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 006/041/139: Operation of Pharmacies (Permanent Pharmacy Closures)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Updates transfer requirements; Creates pharmacy permanent closure requirements; Requires patient access to pharmacy records

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Modifies transfer requirements allowing a prescription transfer for the initial filling of a prescription and requires pharmacies to respond to transfer requests; Provides a list of items that must be completed prior to, within 24 hours, and within 30 days of a permanent pharmacy closure; requires pharmacies to make protected health information in the pharmacy record available to the patient or the patient's representative upon their request.

Documents Relied Upon per ORS 183.335(2)(b)(D): ORS 192.553, ORS 192.556, ORS 192.558, ORS 192.563, ORS 192.566 Protected Health Information

Resources:

Other State Regulations: ME 392-13-9 Permanent Closing of a Pharmacy; TX 291.5 Closing a Pharmacy; WA 246-945-480 Facility Reporting Requirements; TX 291.34 Records; TX Rule 291.104 Operational Standards; MO Rule 20 CSR 2220-2.120 Transfer of Prescription or Medication Order Information.

Oregon Medical Board: OAR 847-012-0000 Patient's Access to Medical Records; Philosophy: Ending the Patient-Physician Relationship; Topic: Ending Oregon Practice

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): The proposed rule will positively impact people in both urban and rural areas of Oregon by mitigating multiple issues identified via complaints received by the agency. All communities regardless of race have been negatively impacted statewide due to issues such as pharmacies closing without notification or not having an alternate process in place for patients to access medication from another source. The proposed rule will allow patients from all communities to be informed in a timely manner and make alternative arrangements to access medication if the pharmacy permanently closes.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): On 1/4/2022 the agency sent out a fiscal impact request to 1,261 interested party email addresses, and 17,645 licensee/registrant email addresses. We asked for an estimate of costs associated with compliance, implementation and operation related to both temporary and permanent closure for items such as: displaying accurate hours, updating telephone greeting or website, etc. We received 2 responses; one registrant estimated costs for some items to be $0 or no additional cost while another licensee estimated each of the costs ranging from $800,000 to $1,000,000 but did not provide an explanation on how costs were calculated. See detailed information:

• Estimate of fiscal impact associated with compliance implementation & operation related to:

• Displaying accurate hours of operation at each building and pharmacy entrance = $0 "Internal process, supported locally. A change can be made and uploaded within minutes, provided the owners of this work are available." = $800 no explanation provided.

• Indicating accurate hours of operation on each pharmacy telephone greeting = $0 no additional cost, and = $3500 “time and paying someone to re-record voicemail due to changing seasonal hours etc.”

• Indicating accurate hours of operation on pharmacy-operated internet (e.g. website, social media, mobile applications) = $0 “No additional cost, this is internal and supported at the national level (weekdays/regular business hours). A change can be made within 1-2 days of request.” = $100,000 “develop and maintain website, social media, mobile app that would otherwise be unnecessary for pharmacy operations”

• Fiscal impact associated with notifying patients with of a temporary pharmacy closure by:

• Displaying accurate hours of operation at each building and pharmacy entrance that provides:

• The estimated period of time the pharmacy will be closed = $2800 no explanation provided.

• Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions). = $9500 “waiting on hold with pharmacies that may also be closed, waiting on hold with prescribers’ offices, having to hire pharmacists to come onsite so prescriptions can be reversed etc.”

• Updating each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) with:

• The estimated period of time the pharmacy will be closed = $7500 no explanation provided.

• Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions). = $0 “No additional cost, IVR phone broadcast messaging (telephone greeting) can be made and uploaded within minutes, provided the owners of this work are available, informing phone-in members of closure(s) as well as other pharmacy options.” = $0 “No additional cost, Website/Social Media/Apps is internal and supported at the national level (weekdays/regular business hours). A message can be added within 1-2 days of request. Depending on the type of message to be conveyed via this means, what is included may be limited by space available.” = $12,500 no explanation provided.

• Indicate if additional fees would be incurred if the above must be completed within 2, 4, 8, 12 or 24 hours = N/A and = 2-24 hours: $155,000 “hiring pharmacist to be on call all year to make sure employees can access pharmacy at will based on closure”.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): May have a fiscal impact for all Oregon pharmacies. Because all Oregon pharmacies are required to comply with these rules, small businesses are impacted including independently owned pharmacies; however, no fiscal impact was received from these outlets or licensees upon request.

- Number/Type: 113 independently owned pharmacies.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Rules are straightforward and necessary to provide the public with accurate information to access medication from alternate sources if a pharmacy permanently closes.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): During the COVID-19 pandemic, there has been an increase in permanent pharmacy closures. Registrants need clear direction on orderly disposition of pharmacy records and drugs when a pharmacy permanently closes. The patients and the public need advance notice of the pharmacy closure to determine where they would like their pharmacy records sent. The proposed rules require pharmacies to respond to transfer requests in a timely manner, to notify the public and patients in the event of a permanent closure, to complete a list of items prior to, within 24 hours, and within 30 days of a permanent pharmacy closure, and to make protected health information in the pharmacy record available to the patient or the patient's representative upon their request.

Division 006
DEFINITIONS
855-006-0005
Definitions

- NOTE: The rule package shown below is currently proposed to send to rulemaking. If changes are made prior to sending to rulemaking they will need to be reflected here.
    - Div 006 041 043 045 080 139 Adopted Standards by Reference

(x) "Custodian of pharmacy records" means a Board licensee who is responsible for the maintenance, care or keeping of pharmacy records based on the services provided by the pharmacy, regardless of whether the records are in that person's actual physical custody and control.

855-041-2115
Transfer of Prescription Information Between Pharmacies

(1) Prescriptions may be transferred between pharmacies for the purpose of **an initial or** refill dispensing provided that:

(a) The prescription is invalidated at the sending pharmacy; and

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.

(2) Prescriptions for controlled substances can only be transferred one time.

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

(4) An Oregon registered pharmacy must transfer a prescription:

(a) To a pharmacy requesting a transfer on behalf of the patient or patient's agent unless the transfer would violate state or federal laws or rules; and

(b) Within 1 business day of the request.

POLICY DISCUSSION: Length of time

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

855-041-1090
Registration: Change of Business Name~~, or Closure~~ (Both Retail and Institutional Drug Outlets)

~~(1)~~ A A~~ny change of business name of a~~ pharmacy must ~~be reported to~~ **notify** the board ~~within~~ **a minimum of** 15 days **prior to any change of business name of a pharmacy. The change must be reported** 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.~~

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

855-041-1092
Retail Drug Outlet Pharmacy Closures: Temporary, Permanent and Emergency

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a **Retail Drug Outlet** pharmacy is temporarily closed to the public the pharmacy must:

(a) Post notification of closure on each building entrance and each pharmacy entrance 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) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the pharmacy is temporarily closed greater than 2 consecutive business days, 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 the temporary closure.

~~(2)~~ **(d)** Federal and state holidays are exempt from the requirements of (1).

~~(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.~~

(2) Permanent Closing. If a Retail Drug Outlet 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 each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:

(i) The last day the pharmacy will be open;

(ii) Name, address and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records;

POLICY DISCUSSION: Custodian licensure, Records to be maintained

(iii) Instructions on how patients can arrange for transfer of their pharmacy 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 or written notice with each prescription dispensed;

(ii) Public notice in a newspaper of general circulation, if available, in the area served by the pharmacy; and

(iii) Posting a closing notice on 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.

(C) Provide any new patients filling prescriptions during the 15 calendar 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 pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records;

(iii) Instructions on how patients can arrange for transfer of their pharmacy 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 (04/01/2021).

(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:

(A) Complete and document an inventory of all controlled substances.

(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 30 calendar days after the closing of the pharmacy, the pharmacist-in-charge must:

(A) Complete and document an inventory of all non-controlled drugs and devices.

(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the pharmacy by one or a combination of the following methods:

(i) Return to manufacturer or supplier (credit or disposal);

(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or

(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (4/1/2021), 21 CFR 1304.22 (4/1/2021), 21 CFR 1317.05 (4/1/2021), 21 CFR 1317.90 (4/1/2021) and 21 CFR 1317.95 (4/1/2021).

(C) 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 who 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 (04/01/2021) for discontinuing operation as a pharmacy that dispenses controlled substances.

(vi) The name, address and phone number of the pharmacy that took possession of the pharmacy records or the Oregon licensed pharmacist who is serve as the custodian of pharmacy records which must be maintained according to OAR 855-041-1160;

(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.

(D) 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.

(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.

(3) Emergency closing. If a Retail Drug Outlet 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 Retail Drug Outlet 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 30 calendar 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.

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

855-041-1167
Patient's Access to Pharmacy Records

(1) Licensees and registrants of the board must make protected health information in the pharmacy record available to the patient or the patient's representative upon their request, to inspect and obtain a copy of protected health information about the individual, except as provided by law and this rule. The patient may request all or part of the record. A summary may substitute for the actual record only if the patient agrees to the substitution. Board licensees and registrants are encouraged to use the written authorization form provided by ORS 192.566.

(2) For the purpose of this rule, "health information in the pharmacy record" means any oral, written or electronic information in any form or medium that is created or received and relates to:

(a) The past, present, or future physical or mental health of the patient.

(b) The provision of healthcare to the patient.

(c) The past, present, or future payment for the provision of healthcare to the patient.

(3) Upon request, the entire health information record in the possession of the Board licensee will be provided to the patient. This includes records from other healthcare providers. Information which may be withheld includes:

(a) Information which was obtained from someone other than a healthcare provider under a promise of confidentiality and access to the information would likely reveal the source of the information;

(b) Psychotherapy notes;

(c) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(d) Other reasons specified by federal regulation.

(4) Registrants who have permanently closed must notify patients according to OAR 855-041-1092.

(5) A reasonable cost may be imposed for the costs incurred in complying with the patient's request for health information pursuant to ORS 192.563.

(6) A patient may not be denied summaries or copies of pharmacy records because of inability to pay.

(7) Requests for pharmacy records must be complied with within a reasonable amount of time not to exceed 30 days from the receipt of the request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 192.553, ORS 192.556, ORS 192.558, ORS 192.563, ORS 192.566 & ORS 689.155

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0025
Registration: Change of Business Name

~~(1)~~ A RDSP Affiliated Pharmacy must notify the board **a minimum of** 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

855-139-0145
Outlet: Closure- Temporary, Permanent and Emergency

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a RDSP is temporarily closed to the public the RDSP must:

(a) Post notification of closure on each building entrance and each RDSP entrance as soon as the need to deviate from the posted hours is known by the RDSP, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the RDSP is temporarily closed greater than 2 consecutive business days, 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 the temporary closure.

(d) Federal and state holidays are exempt from the requirements of (1).

(2) Permanent Closing. If a RDSP is permanently closing to the public, the RDSP must:

(a) Prior to closing, the RDSP must comply with the following:

(A) Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 15 calendar days prior to closing and must include:

(i) The last day the RDSP will be open;

(ii) Name, address and telephone number of the pharmacy to which pharmacy 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 pharmacy 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 or written notification with each prescription dispensed;

(ii) Public notice in a newspaper of general circulation, if available, in the area served by the RDSP; and

(iii) Posting a closing notice at each building and each RDSP 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 RDSP may also provide notification via email or text.

(C) Provide any new patients filling prescriptions during the 15-calendar day period prior to the RDSP closing with written notification that includes:

(i) The last day the RDSP will be open;

(ii) Name, address and telephone number of the pharmacy to which pharmacy 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 pharmacy 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 (04/01/2021).

(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:

(A) Complete and document an inventory of all controlled substances.

(B) If the RDSP 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 RDSP operating status with each electronic prescribing vendor; and

(iii) Remove all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications).

(c) After closing. Within 30 calendar days after the closing of the RDSP, the pharmacist-in-charge must:

(A) Complete and document an inventory of all non-controlled drugs and devices.

(B) Remove all prescription and non-prescription drugs, devices, and related supplies from the RDSP by one or a combination of the following methods:

(i) Return to manufacturer or supplier (credit or disposal);

(ii) Transfer (sell or give away) to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or

(iii) Destroy and document the destruction by two board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21 (4/1/2021), 21 1304.22 (4/1/2021), 21 CFR 1317.05 (4/1/2021), 21 CFR 1317.90 (4/1/2021) and 21 CFR 1317.95 (4/1/2021).

(C) 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 RDSP were transferred or disposed;

(iv) If drugs were destroyed, name and license numbers of individuals who witnessed the destruction;

(v) If the RDSP is registered to possess controlled substances, confirmation that the RDSP complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2021) for discontinuing operation as a RDSP that dispenses controlled substances.

(vi) If the RDSP dispenses prescriptions, the name, address and phone number of the RDSP 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 RDSP labels and blank prescriptions were destroyed;

(viii) Confirmation all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and

(ix) Confirmation that each registration certificate issued to the RDSP by the board has been mailed to the board office.

(D) Once the RDSP has notified the board that the RDSP is permanently closed, the license may not be renewed. The RDSP may apply for a new license as specified in OAR 855-139-0015.

(E) Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.

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(3) Emergency closing. If RDSP 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) The board may conduct an inspection to verify all requirements in subsection (1), (2), and (3) of this section have been completed.

Statutory/Other Authority: ORS 475.035, ORS 689.205 & 2021 SB 629
Statutes/Other Implemented: ORS 689.155 & 2021 SB 629

855-139-0325
Prescription: Transfers

(1) Prescriptions may be transferred between pharmacies for the purpose of **an initial or** refill dispensing provided that:

(a) The prescription is invalidated at the sending pharmacy; and

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.

(2) Prescriptions for controlled substances can only be transferred one time.

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

(4) An Oregon registered pharmacy must transfer a prescription:

(a) To a pharmacy requesting a transfer on behalf of the patient or patient's agent unless the transfer would violate state or federal laws or rules; and

(b) Within 1 business day of the request.

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

855-139-0560
Patient's Access to Pharmacy Records

(1) Licensees and registrants of the board must make protected health information in the pharmacy record available to the patient or the patient's representative upon their request, to inspect and obtain a copy of protected health information about the individual, except as provided by law and this rule. The patient may request all or part of the record. A summary may substitute for the actual record only if the patient agrees to the substitution. Board licensees and registrants are encouraged to use the written authorization form provided by ORS 192.566.

(2) For the purpose of this rule, "health information in the pharmacy record" means any oral, written or electronic information in any form or medium that is created or received and relates to:

(a) The past, present, or future physical or mental health of the patient.

(b) The provision of healthcare to the patient.

(c) The past, present, or future payment for the provision of healthcare to the patient.

(3) Upon request, the entire health information record in the possession of the board licensee will be provided to the patient. This includes records from other healthcare providers. Information which may be withheld includes:

(a) Information which was obtained from someone other than a healthcare provider under a promise of confidentiality and access to the information would likely reveal the source of the information;

(b) Psychotherapy notes;

(c) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(d) Other reasons specified by federal regulation.

(4) Registrants who have permanently closed must notify patients according to OAR 855-041-1092.

(5) A reasonable cost may be imposed for the costs incurred in complying with the patient's request for health information pursuant to ORS 192.563.

(6) A patient may not be denied summaries or copies of pharmacy records because of inability to pay.

(7) Requests for pharmacy records must be complied with within a reasonable amount of time not to exceed 30 days from the receipt of the request.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 192.553, ORS 192.556, ORS 192.558, ORS 192.563, ORS 192.566 & ORS 689.155

Division 110: Fees (Procedural Rule Review/Lockers/RDSP)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Reorganizes drug outlet categories by registration type

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments will reorganize drug outlet categories in OAR 855-110-0007 by itemizing by registration type and removes outdated language

Documents Relied Upon per ORS 183.335(2)(b)(D): None available.

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

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): Minimal fiscal impact is anticipated by adding Remote Dispensing Site Retail Drug Outlet Pharmacy and Prescription Lockers Retail Drug Outlet Pharmacy; registrant categories are being reorganized.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses: No anticipated costs to the agency or small businesses. Proposed amendments impose no additional mandatory reporting, recordkeeping, or other administrative requirements on small businesses.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not consulted. Board staff suggests amending the current rule for transparency and clarity for registrants.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments add Remote Dispensing Site Retail Drug Outlet Pharmacy and Prescription Lockers Retail Drug Outlet Pharmacy registration types. By reorganizing each registration type and category for nonprescription drug outlets and retail drug outlets by registration type, When applying for a new registration or when renewing their existing registration, registrants will be able to easily find and comprehend which fee registration type is applicable.

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~~**1**) Drug Distribution Agent. Expires September 30 annually - $400. Late renewal fee (received after September 30) - $100.

(~~3~~**2**) Drug Room (including Correctional Facility). Expires March 31 annually - $100. Late renewal fee (received after March 31) - $75.

(4**3**) 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~~**4**) **Nonprescription Drug Outlet. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.** ~~Medical Device, Equipment & Gas Class C. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.~~

(a) This includes the following categories of registration:

(~~6~~**A**) Nonprescription Class A. ~~Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.~~

(~~7~~**B**) Nonprescription Class B. ~~Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.~~

(C) Medical Device, Equipment & Gas Class C.

(**b**) **Other Nonprescription Drug Outlet registration category fees are as follows:**

(~~8~~**A**) Nonprescription Class D. Expires January 31 annually - $100. Late renewal fee (received after January 31) - $25.

(B) Nonprescription Class E. Expires January 31 annually - $0. Late renewal fee (received after January 31) - $0.

(~~9~~**5**) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - $50. Expires December 31 annually.

(~~10~~**6**) Re-inspection fee - $100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.

(~~11~~**7**) Retail~~,~~ **or** Institutional~~, or Consulting/"Drugless"~~ Pharmacy Drug Outlet. Expires March 31 annually - $225. Late renewal fee (received after March 31) - $75.

(a) This includes the following categories of registration:

(A) Consulting/"Drugless" Drug Outlet Pharmacy

(B) Home Dialysis Retail Drug Outlet Pharmacy

(C) Institutional Drug Outlet Pharmacy

(D) Remote Dispensing Site Retail Drug Outlet Pharmacy

(E) Retail Drug Outlet Pharmacy

(b) Other Retail/Institutional Drug Outlet registration category fees are as follows:

(A) Charitable Retail Drug Outlet Pharmacy. Expires March 31 annually - $75. Late renewal fee (received after March 31) - $25.

(B) Community Health Clinic (CHC) Retail Drug Outlet Pharmacy. Expires March 31 annually - $100. Late renewal fee (received after March 31) - $25.

(C) Dispensing Practitioner Drug Outlet (DPDO) Retail Drug Outlet Pharmacy. Expires March 31 annually - $100. Late renewal fee (received after March 31) - $25.

(D) Prescription Lockers Retail Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(E) Reserved.

(F) Remote Dispensing Machine Institutional Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(G) Remote Distribution Facility Institutional Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(~~12~~**8**) 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.~~

~~(17) Dispensing Practitioner Drug Outlet. Expires March 31 annually - $100. Late renewal fee (received after March 31) — $25.~~

Division 006/041/043/045/080/139: Definitions/Drug Disposal/Closures/Containers/Dispensing/Application/Schedules/RDSP

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Updates incorporated standards adopted by reference

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments incorporate updated standards adopted by reference as required the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019).

Documents Relied Upon per ORS 183.335(2)(b)(D): 16 CFR (1/1/2021), 21 CFR (4/1/2021), 21 USC (3/15/2022), 42 USC (3/15/2022), United States Pharmacopeia <USP> and National Formulary <NF> (USP NF 2022, Issue 1 38 v. 2022), Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2022), USP <1231> (12/1/2021) and DEA Table of Exempted Prescription Products (2/11/2022), ORS 475.035, ORS 475.055, ORS 183.337

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

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

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

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Amendments are required per ORS 475.035, ORS 475.055 and ORS 183.337.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments include revised reference versions of 16 CFR (1/1/2021), 21 CFR (4/1/2021), 21 USC (3/15/2022), 42 USC (3/15/2022), United States Pharmacopeia <USP> and National Formulary <NF> (USP NF 2022, Issue 1 38 v. 2022), Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2022), USP <1231> (12/1/2021) and DEA Table of Exempted Prescription Products (2/11/2022). Revisions are necessary in order to be in compliance with ORS 475.035, ORS 475.055 and ORS 183.337.

Division 006
DEFINITIONS

855-006-0005
Definitions

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 006. If changes are made prior to adopting the permanent rule they will need to be reflected here.
    - Divisions 006/041/139 - related to Definitions
    - Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems
    - Divisions 041/139 - related to Drug Storage
    - Division 080 - related to Schedule I Exceptions
- NOTE: The rule packages shown below is currently proposed to send to rulemaking. If changes are made prior to sending to rulemaking they will need to be reflected here.
    - Div 006/031- related to PHE Sunset
    - Div 006/019/041/139/143 Interpreters
    - Div 006 019 025 041 Tech Final Verification HB 4034 TEMP
    -
- NOTE: The rule package shown below is currently proposed as a temporary rule. If changes are made prior to adopting the temporary rule, it will need to be reflected here.
- Div 006 019 025 041 Tech Final Verification HB 4034 TEMP

As used in OAR Chapter 855:

(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (~~v. 12/09/2021~~**03/15/2022**)
- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(2) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.
- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(3) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.
- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(4) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.
- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(5) "Biosimilar" product means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (~~12/1/2021~~**03/15/2022**).

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(6) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(7) "Certified health care interpreter" has the meaning given that term in ORS 413.550.

- NOTE: In proposed rules- Div 006/019/041/139 Interpreters/Patient Records

(~~7~~**8**) "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~~ **taken and passed a national pharmacy technician certification examination** 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.

(~~8~~**9**) "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.

(~~9~~**10**) "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.

(1~~0~~**1**) "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.

(1~~1~~**2**) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(12**3**) "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.

(13**4**) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(15) "Custodian of pharmacy records" means a board licensee who is responsible for the maintenance, care or keeping of pharmacy records based on the services provided by the pharmacy, regardless of whether the records are in that person's actual physical custody and control.

- NOTE: In proposed rules- Div 041 139 Permanent Pharmacy Closure PERM

(14**6**) "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.

(15**7**) "Entry system" enables control of access to a secured area.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(18) "Final verification" means after prescription information is entered into a pharmacy's electronic system and reviewed by a pharmacist for accuracy, a physical verification that the drug and drug dosage, device or product selected from a pharmacy's inventory pursuant to the electronic system entry is the prescribed drug and drug dosage, device or product.

- NOTE: In proposed TEMP rule- Div 006/019/025/041 Technician Final Verification

(19) "Health care interpreter" has the meaning given that term in ORS 413.550.

- NOTE: In proposed rules- Div 006/019/041/139 Interpreters/Patient Records

(20) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.

- NOTE: In proposed rules- Div 006/019/041/139 Interpreters/Patient Records

(21) "Individual with limited English proficiency" means a person who, by reason of place of birth or culture, communicates in a language other than English and does not communicate in English with adequate ability to communicate effectively with a health care provider.

- NOTE: In proposed rules- Div 006/019/041/139 Interpreters/Patient Records

(~~16~~**22**) "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~~**03/15/2022**).

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(~~17~~**23**) "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.

(~~18~~**24**) "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.

(~~19~~**25**) “Misbranded” has the same definition as set forth in 21 USC 352 (~~v. 12/09/2021~~**03/15/2022**).

(2~~0~~**6**) "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.

(2~~1~~**7**) "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.

(2~~2~~**8**) "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.

(2~~3~~**9**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(~~24~~**30**) "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.

(~~25~~**31**) “Official compendium” means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP ~~43~~ NF **2022, Issue 1** ~~38 v. 2021~~), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 202~~1~~**2**), or any supplement to any of these.

(~~26~~**32**) "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.

(~~27~~**33**) 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.

(~~28~~**34**) "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.

(~~29~~**35**) "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.

(3~~0~~**6**) “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.

(3~~1~~**7**) "Practice of pharmacy" is as defined in ORS 689.005.

(3~~2~~**8**) "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.

(3~~3~~**9**) "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.

(3~~4~~**40**) "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.

(3~~5~~**41**) "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.

(3~~6~~**42**) "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.

(43) "Reasonable professional judgment" means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities, qualifications and/or competencies, after careful review, analysis and consideration of

the relevant subject matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion or conclusion.

- NOTE: In rulemaking- Div 006 019 025 041 Tech Final Verification HB 4034 TEMP

(~~37~~**44**) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (~~12/01/2021~~**03/15/2022**) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(~~38~~**45**) "Repackage" means the act of taking a drug from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(~~39~~**46**) "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.

(4~~0~~**7**) "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.

(4~~1~~**8**) "Still image capture" means a specific image captured electronically from a video or other image capture device.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(4~~2~~**9**) "Store and forward" means a video or still image record which is saved electronically for future review.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(~~43~~**50**) "Supervision by a pharmacist" means being stationed within the same work area, except as authorized under OAR 855-041-3200 through OAR 855-041-3250, as the **Intern,** ~~p~~**P**harmacy ~~t~~**T**echnician or ~~c~~**C**ertified Oregon ~~p~~**P**harmacy ~~t~~**T**echnician being supervised, coupled with the ability to control and be

responsible for the **Intern,** ~~p~~**P**harmacy ~~t~~**T**echnician or ~~c~~**C**ertified Oregon ~~p~~**P**harmacy ~~t~~**T**echnician'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.~~

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In proposed rules- Division 006/031: Definitions/Interns (PHE Rules Sunset)

(~~44~~**51**) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 020/041/065/139 - related to Alarm, Audiovisual Communication, Entry & Surveillance Systems

(~~45~~**52**) "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.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions

(~~46~~**53**) "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.

- NOTE: In rulemaking- Divisions 006/041/139 - related to Definitions
- NOTE: In rulemaking- Divisions 041/139 - related to Drug Storage

(~~47~~**54**) "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.

(~~48~~**55**) "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.

Division 41
OPERATION OF PHARMACIES

855-041-1001
Definitions

- NOTE: The rule packages shown below are currently in rulemaking and have an impact on Division 041. If board does not motion to move definitions from Div 041 to Div 006 as noticed (2), (4) and (5) will need to be added here with updated references.

- Divisions 006/041/139 - related to Definitions

855-041-1046

Secure and Responsible Drug Disposal

(1) A pharmacy 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 pharmacy 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 pharmacy 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 pharmacy 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 pharmacy 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 (04/01/202~~0~~**1**), 21 CFR 1317.35 (04/01/202~~0~~**1**), 21 CFR 1317.40 (04/01/202~~0~~**1**), 21 CFR 1317.55 (04/01/202~~0~~**1**), 21 CFR 1317.60 (04/01/202~~0~~**1**), 21 CFR 1317.65 (04/01/202~~0~~**1**), 21 CFR 1317.70 (04/01/202~~0~~**1**), 21 CFR 1317.75 (04/01/202~~0~~**1**), 21 CFR 1317.80 (04/01/202~~0~~**1**), and 21 CFR 1317.85 (04/01/202~~0~~**1**); and

(d) 21 USC 822 (~~04/01/2021~~**03/15/2022**), 21 USC 822a (~~04/01/2021~~**03/15/2022**).

855-041-1092

Retail Drug Outlet Pharmacy Closures: Temporary, Permanent and Emergency

- NOTE: This rule package is currently proposed to send to rulemaking. If changes are made prior to sending to rulemaking they will need to be added to this package and reflected here.
    - Div 041/139 Permanent Pharmacy Closures

855-041-1145

New 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 (0**1**~~4~~/01/2021), 16 CFR 1701 (0**1**~~4~~/01/2021), and 16 CFR 1702 (0**1**~~4~~/01/2021).

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

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

855-041-7050

Definitions - Long Term Care Pharmacy

As used in OAR 855-041–7000 through 855-041-–7080:

(1)(a) "Long term care facility" means a facility with permanent facilities that include inpatient beds, providing medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the director, to provide treatment for two or more unrelated patients. "Long Term Care facility" includes skilled nursing facilities and intermediate care facilities but may not be construed to include facilities licensed and operated pursuant to ORS 443.400 to 443.455.

(b) For the purposes of Schedule II prescriptions in 21 CFR 1306.11 **(04/01/2021)**, 21 CFR 1306.12 **(04/01/2021)**, **and 21 CFR** 1306.13 **(04/01/2021)**, **21 CFR 1306.14 (04/01/2021), and 21 CFR 1306.15**

(04/01/2021), the DEA definition of "long term care facility" as defined in 21 CFR 1300.01(~~25~~**04/01/2021**) includes "community-based care facilities."

(2) "Community Based Care Facility" means a home, facility or supervised living environment licensed or certified or otherwise recognized by an agency of the state of Oregon which provides 24-hour care, supervision, and assistance with medication administration. These include but are not limited to Adult Foster Homes, Residential Care Facilities (RCF), Assisted Living Facilities (ALF), Group Homes for the Developmentally Disabled and Mentally Retarded and Inpatient Hospice.

(3) "Pharmaceutical Care" means the responsible provision of any or all of the following services by the pharmacist:

(a) Develop and maintain policies and procedures for pharmaceutical services;

(b) Provide direction and oversight regarding all aspects of the acquisition, disposition, handling, storage, and administration of drugs including but not limited to the following:

(A) Receipt and interpretation of physician's orders;

(B) Ordering and receiving of medications;

(C) Handling of emergency drugs and supplies;

(D) Labeling of all drugs;

(E) Selection of drug delivery systems;

(F) Development of systems to provide timely delivery of drugs and supplies;

(G) Monitoring of drug storage conditions and expiration dates;

(H) Monitoring accuracy and efficiency of medication administration and compliance with physician's orders;

(I) Establishing and monitoring of appropriate record keeping;

(J) Accountability of controlled substances;

(K) Return, release, and/or destruction of discontinued or outdated drugs; and

(L) Compliance with state and federal laws and regulations related to pharmaceutical services and medication management.

(c) Provide training and in-service education to facility staff;

(d) Perform drug regimen review for each resident on a regularly scheduled basis for the purpose of promoting therapeutic appropriateness and achieving the desired drug therapy outcomes by identifying issues such as:

(A) Over-utilization or underutilization;

(B) Therapeutic duplication;

(C) Drug-disease contraindications;

(D) Drug-drug interactions;

(E) Incorrect drug, drug dosage or duration of drug treatment;

(F) Drug-allergy interaction;

(G) Clinical abuse/misuse;

(H) Untreated indication;

(I) Monitoring and assessing of drug therapy outcomes;

(e) Communicate effectively with residents' physicians and facility staff; and

(f) Participate in resident care planning.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.~~0~~305

Division 43
PRACTITIONER DISPENSING

855-043-0545
Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery

(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by the practitioner's licensing board.

(2) Drugs dispensed from the DPDO must be dispensing in compliance with the requirements of the practitioner's licensing board.

(3) A DPDO must comply with all requirements of State or federal law.

(4) A DPDO must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (0**1**~~4~~/01/2021), 16 CFR 1701 (0**1**~~4~~/01/2021) and 16 CFR 1702 (0**1**~~4~~/01/2021).

(5) Dispensed drugs must be packaged by the DPDO, a pharmacy, or a manufacturer registered with the board.

(6) A DPDO may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(7) A DPDO may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The DPDO offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(8) The DPDO must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(9) 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

855-043-0740
Community Health Clinic (CHC) - Dispensing and Drug Delivery

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.

(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.

(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.

(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.

(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01**4**/01/2021), 16 CFR 1701 (01**4**/01/2021) and 16 CFR 1702 (01**4**/01/2021).

(7) Dispensed drugs must be packaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the board.

(8) A CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed.

(9) A CHC must have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

(10) A CHC may deliver or mail prescription to the patient if:

(a) Proper drug storage conditions are maintained; and

(b) The CHC offers in writing, to provide direct counseling, information on how to contact the practitioner, and information about the drug, including, but not limited to:

(A) Drug name, class and indications;

(B) Proper use and storage;

(C) Common side effects;

(D) Precautions and contraindications; and

(E) Significant drug interactions.

(11) The CHC must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law.

(12) 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 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 board as a drug outlet and comply with board regulations.

(2) These rules apply to sterile and non-sterile compounding of a drug.

(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia (USP) and the National Formulary (NF) including:

(a) USP <795> Pharmaceutical Compounding- Non-Sterile Preparations (05/01/2020 v. 2014);

(b) USP <797> Pharmaceutical Compounding—Sterile Preparations (05/01/2020 v. 2008);

(c) USP <800> Hazardous Drugs—Handling in Healthcare Settings (07/01/2020 v. 2020);

(d) USP <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging (12/01/2020 v. 2020); and

(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018), 151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2016), 1231 (~~08/01/2018~~**12/01/2021**), and 1821 (05/01/2017).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

Division 80
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0020
Schedules

Pursuant to ORS 475.005(6) those drugs and their immediate precursors classified in Schedules I through V under the Federal Controlled Substances Act, 21 USC 811 (~~04/01/2021~~**03/15/2022**), 21 USC 812 (~~04/01/2021~~**03/15/2022**) and as amended by the Board pursuant to ORS 475.035 are the controlled substances for purposes of regulation and control under the Act. Those schedules are set out in OAR 855-080-0021 through 855-080-0026.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

855-080-0021
Schedule I

- NOTE: The rule package shown below is currently in rulemaking and will have an impact on Division 080. If changes are made prior to adopting the permanent rule they will need to be reflected here.
    - Division 080 - related to Schedule I Exceptions

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.11 (04/01/2021~~0~~), and unless specifically exempt or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;

(b) Gamma-butyrolactone

(c) Methamphetamine, except as listed in OAR 855-080-0022;

(d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)

(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.

(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,

(A) Methylmethcathinone (Mephedrone);

(B) Methylenedioxypyrovalerone (MDPV);

(C) Methylenedioxymethylcathinone (Methylone);

(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);

(E) Fluoromethcathinone (Flephedrone);

(F) 4-Methoxymethcathinone (Methedrone).

(2) Schedule I also includes any compounds in the following structural classes (2a-2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);

(e) Naphthylmethylindoles: Any compound containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(f) Naphthoylpyrroles: Any compound containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(g) Naphthylmethylindenes: Any compound containing a 1-(1-naphthylmethyl) indene structure with substitution at the 3-position of the indene ring whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent;

(h) Cyclopropanoylindoles: Any compound containing an 3-(cyclopropylmethanoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the cyclopropyl ring to any extent. Examples of this structural class include but are not limited to: UR-144, XLR-11 and A-796,260;

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;

(j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: STS-135 and 2NE1; and

(k) Adamantylindazolecarboxamides: Any compound containing an N-adamantyl-1-indazole-3-carboxamide with substitution at the nitrogen atom of the indazole ring, whether or not further substituted in the indazole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AKB48.

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or is not an FDA approved drug.

(4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are derived from fentanyl by any substitution on or replacement of the phenethyl group, any substitution on the piperidine ring, any substitution on or replacement of the propanamide group, any substitution on the phenyl group, or any combination of the above.

(5) Schedule I also includes any compounds in the following structural classes (a - b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Benzodiazepine class: A fused 1,4-diazepine and benzene ring structure with a phenyl connected to the diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or benzene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Clonazolam, Flualprazolam

(b) Thienodiazepine class: A fused 1,4-diazepine and thiophene ring structure with a phenyl connected to the 1,-4-diazepine ring, with any substitution(s) or replacement(s) on the 1,4-diazepine or thiophene ring, any substitution(s) on the phenyl ring, or any combination thereof. Examples of this structural class include but are not limited to: Etizolam

(6) Exceptions. The following are exceptions to subsection (1) of this rule:

(a) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of its sale to a legitimate manufacturer of industrial products and the person is in compliance with the Drug Enforcement Administration requirements for List I Chemicals;

(b) 1, 4-butanediol and gamma-butyrolactone when in the possession of a person for the purpose of the legitimate manufacture of industrial products;

(c) The following substances per ORS 475.005(6)(b):

(A) The plant Cannabis family Cannabaceae;

(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;

(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;

(D) The seeds of the plant Cannabis family Cannabaceae; or

(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.005, ORS 475.035, ORS 475.055, ORS 475.065

855-080-0022
Schedule II

Schedule II consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.12 (04/01/2021~~0~~) and any quantity of methamphetamine, when in the form of a FDA approved product containing methamphetamine, its salts, isomers and salts of its isomers as an active ingredient for the purposes of currently accepted medical use.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035, ORS 475.055, ORS 475.065, ORS 475.005

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 (04/01/2021~~0~~).

Statutory/Other Authority: ORS 689.205, ORS 475.973
Statutes/Other Implemented: ORS 475.035

855-080-0024
Schedule IV

Schedule IV consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.14 (04/01/2021~~0~~), unless specifically excepted or listed in another schedule.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.035

855-080-0026
Schedule V

- NOTE: The rule package shown below is currently proposed to send to rulemaking. If changes are made prior to sending to rulemaking they will need to be reflected here.
    - Div 080- PSE/EPH Interns

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 (04/01/2021~~0~~); 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 **ORS 475.230** ~~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 **ORS 475.230** ~~2021 HB 2648~~;

(d) Ensure that only a Pharmacist, **Intern,** 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, **Intern,** 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) **Each** ~~P~~**p**harmac**y**~~ies~~, Pharmacist~~s~~, **Intern,** Certified Oregon Pharmacy Technician~~s~~ and Pharmacy Technician~~s~~ involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/202**1**~~0~~), 21 CFR 1314.02 (04/01/202**1**~~0~~), 21 CFR 1314.03 (04/01/202**1**~~0~~), 21 CFR 1314.05 (04/01/202**1**~~0~~), 21 CFR 1314.10 (04/01/202**1**~~0~~), 21 CFR 1314.15 (04/01/202**1**~~0~~), 21 CFR 1314.20 (04/01/202**1**~~0~~), 21 CFR 1314.25, (04/01/202**1**~~0~~); 21 CFR 1314.30 (04/01/202**1**~~0~~), 21 CFR 1314.35 (04/01/202**1**~~0~~), 21 CFR 1314.40 (04/01/202**1**~~0~~), 21 CFR 1314.42 (04/01/202**1**~~0~~), 21 CFR 1314.45 (04/01/202**1**~~0~~); and 21 CFR 1314.50 (04/01/202**1**~~0~~).

Statutory/Other Authority: **ORS 475.230,** ORS 689.205~~,~~ & **2022 HB 4034** ~~2021 HB 2648~~
Statutes/Other Implemented: ORS 475.035, **ORS 475.230** & **2022 HB 4034** ~~2021 HB 2648~~

855-080-0028
Excluded or Exempted Substances

(1) The board adopts the excluded substances list found in 21 CFR 1308.22 (04/01/202**1**~~0~~).

(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/202**1**~~0~~).

(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (~~06/26/2021~~**02/11/2022**) pursuant to 21 CFR 1308.32 (04/01/202**1**~~0~~).

Statutory/Other Authority: ORS 689.205, ORS 475.035
Statutes/Other Implemented: ORS 689.155, ORS 475.035

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 (04/01/2021~~0~~).

(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/2021~~0~~).

Statutory/Other Authority: ORS 689.155, ORS 689.205
Statutes/Other Implemented: ORS 475.125

855-080-0065
Security

(1) All applicants and registrants as applicable to the registration classification must comply with the security requirements of 21 CFR 1301.01 (04/01/2021~~0~~), 21 CFR 1301.02 (04/01/2021~~0~~), 21 CFR 1301.71 (04/01/2021~~0~~), 21 CFR 1301.72 (04/01/2021~~0~~), 21 CFR 1301.73 (04/01/2021~~0~~), 21 CFR 1301.74 (04/01/2021~~0~~), 21 CFR 1301.75 (04/01/2021~~0~~), 21 CFR 1301.76 (04/01/2021~~0~~), 21 CFR 1301.77 (04/01/2021~~0~~), 21 CFR 1301.90 (04/01/2021~~0~~), 21 CFR 1301.91 (04/01/2021~~0~~), 21 CFR 1301.92 (04/01/2021~~0~~), and 21 CFR 1301.93 (04/01/2021~~0~~).

(2) The security requirements of (1) of this rule apply to all controlled substances, as defined in these rules, including ephedrine, pseudoephedrine and phenylpropanolamine.

(3) Applicants and registrants must guard against theft and diversion of ephedrine, pseudoephedrine and phenylpropanolamine.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.135, ORS 475.125

855-080-0070
Records and Inventory

(1) All registrants must, as applicable to the registration classification, keep records and maintain inventories in compliance with 21 USC 827 (~~04/01/2021~~**03/15/2022**); 21 CFR 1304.01 (04/01/2021~~0~~), 21 CFR 1304.02 (04/01/2021~~0~~), 21 CFR 1304. 03 (04/01/2021~~0~~), 21 CFR 1304.04 (04/01/2021~~0~~), 21 CFR 1304.05 (04/01/2021~~0~~), 21 CFR 1304.06 (04/01/2021~~0~~); 21 CFR 1304.11 (04/01/2021~~0~~); 21 CFR 1304.21 (04/01/2021~~0~~), 21 CFR 1304.22 (04/01/2021~~0~~), 21 CFR 1304.23 (04/01/2021~~0~~), 21 CFR 1304.24 (04/01/2021~~0~~), 21 CFR 1304.25 (04/01/2021~~0~~), 21 CFR 1304.26 (04/01/2021~~0~~); 21 CFR 1304.31 (04/01/2021~~0~~), 21 CFR 1304.32 (04/01/2021~~0~~), 21 CFR 1304.33 (04/01/2021~~0~~).

(2) A written inventory of all controlled substances must be taken by registrants annually within 367 days of the last written inventory.

(3) All such records must be maintained for a period of three years.

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 475.165

855-080-0075
Orders for Schedule I and II Controlled Substances

Controlled substances in Schedules I and II must be distributed by a registrant to another registrant only pursuant to an order form or electronic order in compliance with 21 USC 828 (~~04/01/2021~~**03/15/2022**) and 21 CFR 1305.01 (04/01/202**1**~~0~~), 21 CFR 1305. 02 (04/01/202**1**~~0~~), 21 CFR 1305.03 (04/01/202**1**~~0~~), 21 CFR 1305.04 (04/01/202**1**~~0~~), 21 CFR 1305.05 (04/01/202**1**~~0~~), 21 CFR 1305.06 (04/01/202**1**~~0~~), 21 CFR 1305.07 (04/01/202**1**~~0~~); 21 CFR 1305.11 (04/01/202**1**~~0~~), 21 CFR 1305.12 (04/01/202**1**~~0~~), 21 CFR 1305.13 (04/01/202**1**~~0~~), 21 CFR 1305.14 (04/01/202**1**~~0~~), 21 CFR 1305.15 (04/01/202**1**~~0~~), 21 CFR 1305.16 (04/01/202**1**~~0~~), 21 CFR 1305.17 (04/01/202**1**~~0~~), 21 CFR 1305.18 (04/01/202**1**~~0~~), 21 CFR 1305.19 (04/01/202**1**~~0~~), 21 CFR 1305.20 (04/01/202**1**~~0~~); 21 CFR 1305.21 (04/01/202**1**~~0~~), 21 CFR 1305.22 (04/01/202**1**~~0~~), 21 CFR 1305.23 (04/01/202**1**~~0~~), 21 CFR 1305.24 (04/01/202**1**~~0~~), 21 CFR 1305.25 (04/01/202**1**~~0~~), 21 CFR 1305.26 (04/01/202**1**~~0~~), 21 CFR 1305.27 (04/01/202**1**~~0~~), 21 CFR 1305.28 (04/01/202**1**~~0~~), and 21 CFR 1305.29 (04/01/202**1**~~0~~).

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 475.175

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 (04/01/202**1**~~0~~), 21 CFR 1306.02 (04/01/202**1**~~0~~), 21 CFR 1306.03 (04/01/202**1**~~0~~), 21 CFR 1306.04 (04/01/202**1**~~0~~), 21 CFR 1306.05 (04/01/202**1**~~0~~), 21 CFR 1306.06 (04/01/202**1**~~0~~), 21 CFR 1306.07 (04/01/202**1**~~0~~), 21 CFR 1306.08 (04/01/202**1**~~0~~), 21 CFR 1306.09 (04/01/202**1**~~0~~); 21 CFR 1306.11 (04/01/202**1**~~0~~), 21 CFR 1306.12 (04/01/202**1**~~0~~), 21 CFR 1306.13 (04/01/202**1**~~0~~), 21 CFR 1306.14 (04/01/202**1**~~0~~), 21 CFR 1306.15 (04/01/202**1**~~0~~); 21 CFR 1306.21 (04/01/202**1**~~0~~), 21 CFR 1306.22 (04/01/202**1**~~0~~); 21 CFR 1306.23 (04/01/202**1**~~0~~), 21 CFR 1306.24 (04/01/202**1**~~0~~), 21 CFR 1306.25 (04/01/202**1**~~0~~), 21 CFR 1306.27 (04/01/202**1**~~0~~); and 21 CFR 1304.03(d) (04/01/202**1**~~0~~).
(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 **ORS 475.230** ~~section 2 of HB 2648 (2021)~~.

(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/202**1**~~0~~), 21 CFR 1306.22 (04/01/202**1**~~0~~); 21 CFR 1306.23 (04/01/202**1**~~0~~), 21 CFR 1306.24 (04/01/202**1**~~0~~), 21 CFR 1306.25 (04/01/202**1**~~0~~), and 21 CFR 1306.27 (04/01/202**1**~~0~~).

Statutory/Other Authority: **ORS 475.230,** ORS 689.205
Statutes/Other Implemented: ORS 475.185, ORS 475.188

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0005
Definitions

- NOTE: The rule package shown below is currently in rulemaking and has an impact on Division 139. If board does not motion to move definitions from Div 041 to Div 006 as noticed (2), (3) and (5) will need to be added here with updated references.
    - Divisions 006/041/139 - related to Definitions

855-139-0145
Outlet: Closure- Temporary, Permanent and Emergency

- NOTE: This rule package is currently proposed to send to rulemaking. If changes are made prior to sending to rulemaking they will need to be added and reflected here.
    - Div 041/139 Permanent Pharmacy Closures

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 (01**1**4/01/2021), 16 CFR 1701 (01**1**4/01/2021), and 16 CFR 1702 (01**1**4/01/2021).

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

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

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 (04/01/202~~0~~**1**), 21 CFR 1317.35 (04/01/202~~0~~**1**), 21 CFR 1317.40 (04/01/202~~0~~**1**), 21 CFR 1317.55 (04/01/202~~0~~**1**), 21 CFR 1317.60 (04/01/202~~0~~**1**), 21 CFR 1317.65 (04/01/202~~0~~**1**), 21 CFR 1317.70 (04/01/202~~0~~**1**), 21 CFR 1317.75 (04/01/202~~0~~**1**), 21 CFR 1317.80 (04/01/202~~0~~**1**), and 21 CFR 1317.85 (04/01/202~~0~~**1**); and

(d) 21 USC 822 (~~04/01/2021~~**03/15/2022**), 21 USC 822a (~~04/01/2021~~**03/15/2022**).

Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218

Division 143: Pharmacy Prescription Lockers (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Proactive procedural rule review; Pharmacy Prescription Lockers

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments are a result of public comments received during March 2022 rulemaking. Revisions include amending the signage requirements, clarifying that destocked drugs may be returned to the PPL Affiliated Pharmacy and clarifying surveillance data requirements.

Documents Relied Upon per ORS 183.335(2)(b)(D): None

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

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): Pharmacies are not required to operate a Pharmacy Prescription Locker (PPL).

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public/Small Businesses): There is no anticipated fiscal impact to other state agencies, units of local government or the public.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Board staff proposes amendments based on feedback received during the public comment period.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments include permitting an electronic signage option, allowing destocked drugs to be restocked at the PPL Affiliated Pharmacy if certain requirements are met, retaining data and surveillance data for 30 days and retaining data due to an incident for 6 months from the date of review.

Division 143
PHARMACY PRESCRIPTION LOCKER

855-143-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon PPL must have the following:

(a) 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 PPL outlet;

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

(c) Signage in a location easily seen by the public at the PPL where prescription and non-prescription drugs, devices, and related supplies are dispensed:

(A) Stating "The (insert name of PPL Affiliated 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 855-143-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

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

(D) Providing notification of accurate hours of operation at the PPL; and

(d) Additional equipment and supplies that are determined as necessary by the PPL Affiliated Pharmacy or PIC.

(e) As an alternative to posting the required signage, PPL's that utilize an electronic video monitor that the patient is required to interact with prior to retrieving medication from the PPL may display the information required by sub-paragraphs (1)(c)(A) – (D) electronically.

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

855-143-0210
Outlet: Supervision

A PPL and its PPL Affiliated Pharmacy must:

(1) Ensure prescription and non-prescription drugs, devices, and related supplies are only dispensed at the PPL if an Oregon licensed Pharmacist is available for patient consultation and the PPL is fully operational.

(2) Ensure that stocking and destocking of prescription and non-prescription drugs, devices, and related supplies in a PPL is completed under the supervision, direction and control of a pharmacist.

(3) Ensure that an Oregon licensed Pharmacist verifies and documents that:
(a) All prescription and non-prescription drugs, devices, and related supplies were correctly stocked into the PPL;

(b) All prescription and non-prescription drugs, devices, and related supplies destocked from the PPL were returned to the PPL Affiliated Pharmacy;

(c) Proper storage conditions were maintained during transfer per OAR 855-143-0125; and

(d) Records are maintained per OAR 855-143-0550.

(4) Drugs and devices destocked from a PPL that satisfy the requirements of this section may be returned to stock at the PPL Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305, ORS 689.527

855-143-0550
Records: General Requirements

(1) The recordkeeping requirements OAR 855-143 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) All required records for the Drug Outlet PPL must be maintained by the PPL Affiliated Pharmacy.

(3) Records retained by the PPL Affiliated Pharmacy must include, but are not limited to:

(a) Date, time and identification of each individual and activity or function performed on the PPL;

(b) Oregon licensed Pharmacist physical inspection of the PPL;

(c) Audiovisual communication system testing;

(d) Licensee training on the proper use of the PPL;

(e) Still image capture and store and forward images must be retained according to (1);

(f) Data and surveillance system data must be retained for ~~6 months~~**30 days** ~~except wh~~**en a PPL Affiliated Pharmacy becomes aware of an incident that requires review of surveillance data, the PPL Affiliated Pharmacy must retain the data related to that incident for 6 months from the date of review**; and

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

(4) Records of dispensing from a PPL must include the:

(a) Physical location of the PPL;

(b) Identification of the patient or patient's agent retrieving the prescription, non-prescription drugs, and supplies;

(c) A digital image of the individual to whom the prescription was dispensed~~.~~**;**

(d) Date and time of transaction;

(e) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;

(f) Each non-prescription drug and supply name, UPC or NDC number, and quantity; and

(g) Name of Oregon licensed Pharmacist or Oregon licensed Intern who provided counseling to the patient or patient's agent, if required, documentation that the counseling was performed or that the Pharmacist or Intern accepted the patient or patient's agent request not to be counseled.

(5) Records of stocking and destocking of prescriptions into or from a PPL must include the:

(a) Date and time;

(b) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;

(c) Each non-prescription drug and supply name, UPC or NDC number, and quantity;

(d) Name and Oregon license number of the person stocking or destocking prescription, non-prescription drugs and supplies from the system; and

(e) Identity of the Oregon licensed Pharmacist who verifies that the system has been accurately stocked or destocked.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508, ORS 689.527

APRIL 2022/E

Safe Pharmacy Practice Conditions Survey

Final Results

Friday, April 15, 2022

2044

Total Responses

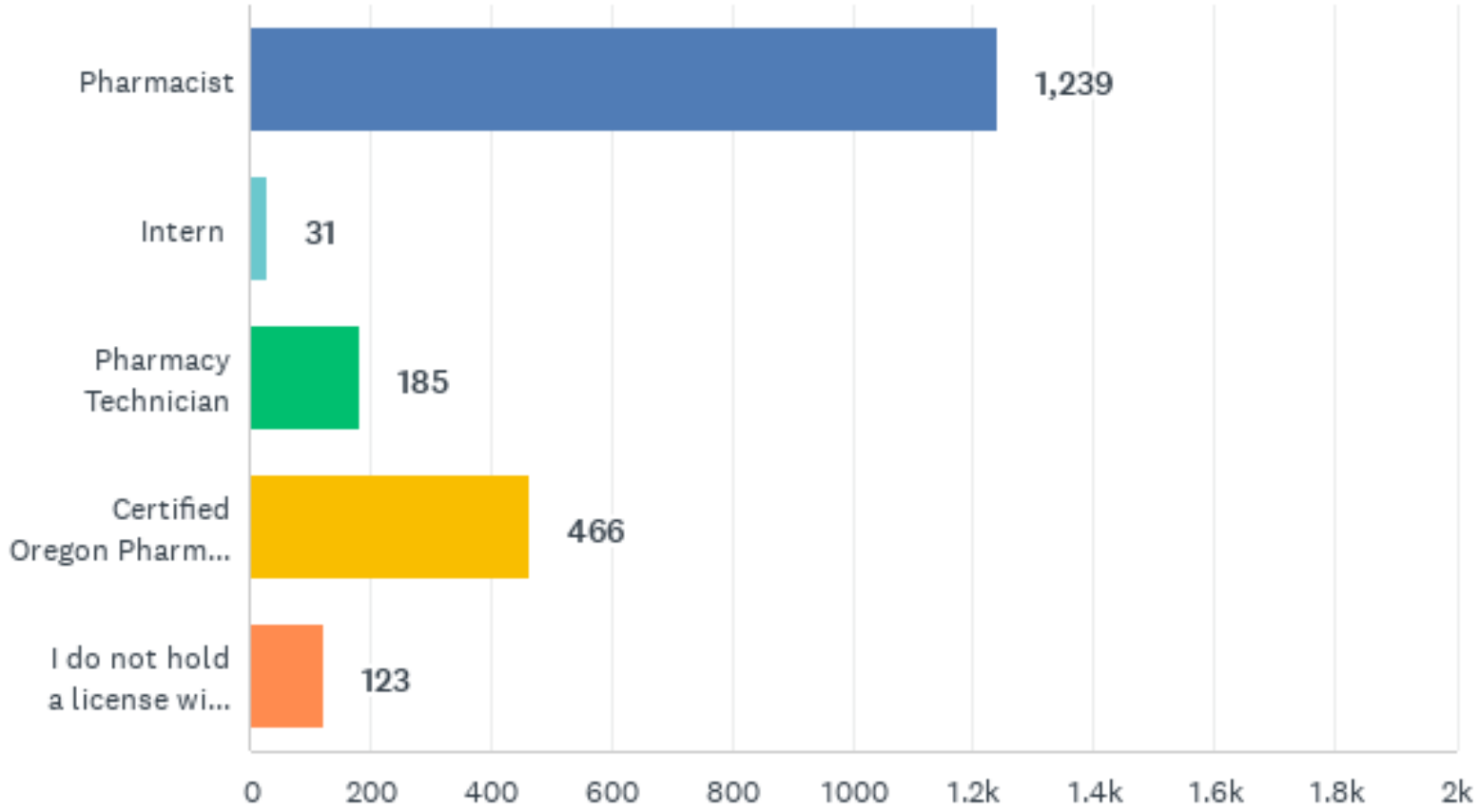
Date Opened: Wednesday, February 16, 2022

Date Closed: Wednesday, March 2, 2022

Complete Responses: 2044

Q1: What type of license do you hold with the Oregon Board of Pharmacy?

Answered: 2,044 Skipped: 0



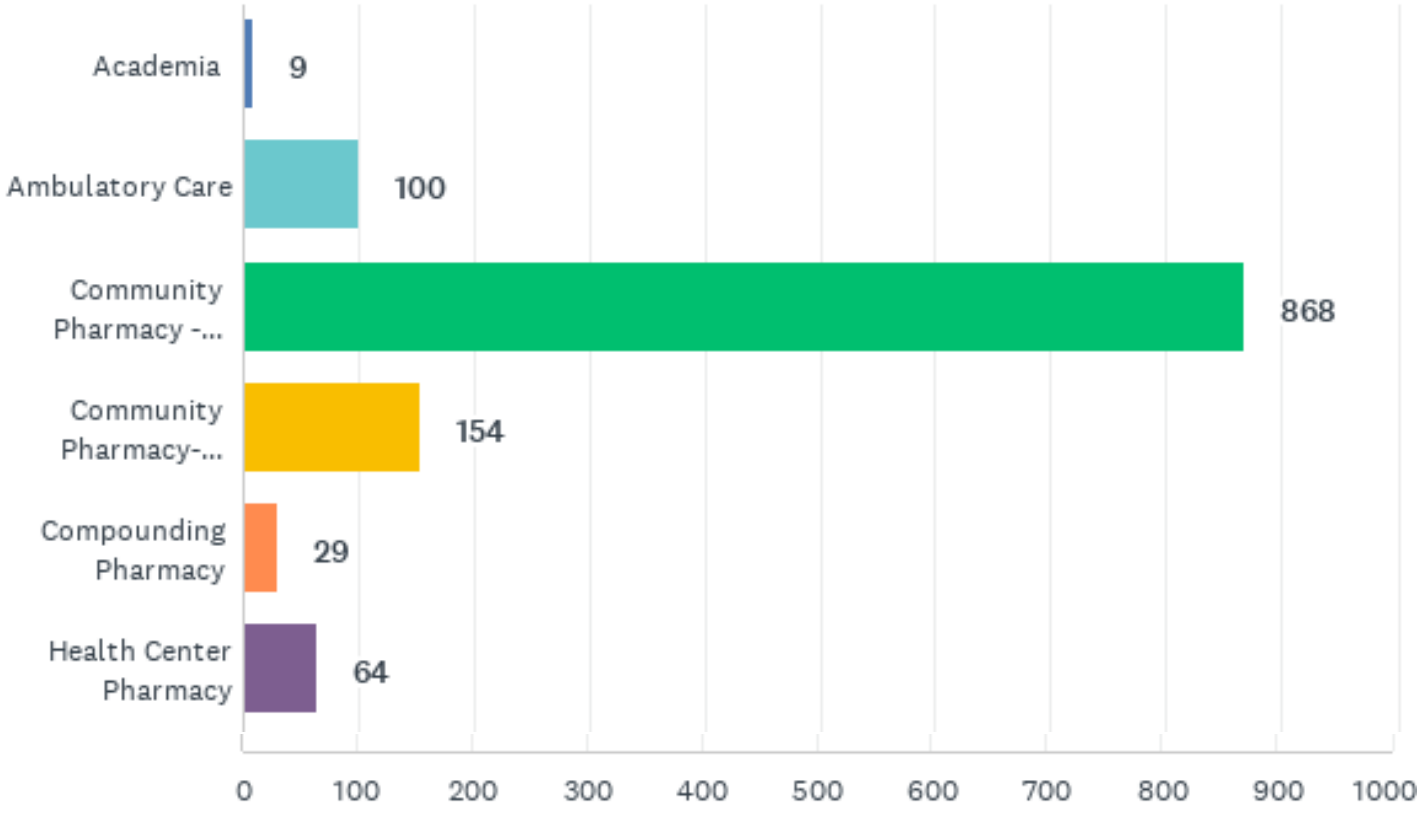
Q1: What type of license do you hold with the Oregon Board of Pharmacy?

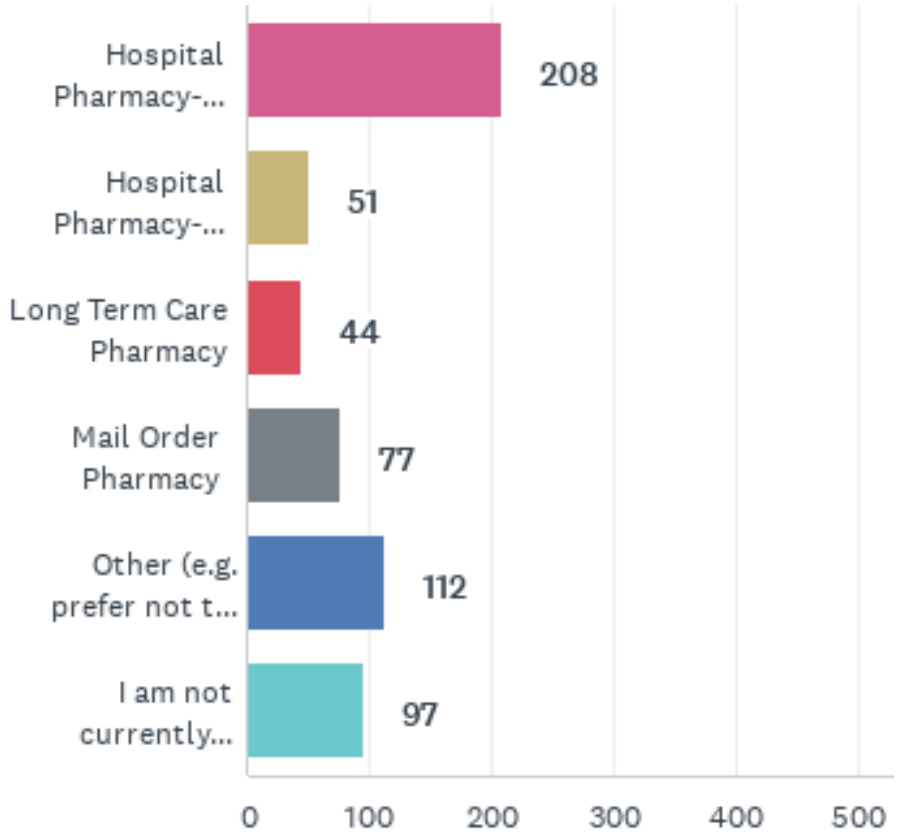
Answered: 2,044 Skipped: 0

ANSWER CHOICES	RESPONSES	
Pharmacist	60.62%	1,239
Intern	1.52%	31
Pharmacy Technician	9.05%	185
Certified Oregon Pharmacy Technician	22.80%	466
I do not hold a license with the Oregon Board of Pharmacy	6.02%	123
TOTAL		2,044

Q2: What is your primary pharmacy practice setting?NOTE: Students- Please select your primary pharmacy workplace outside of your IPPE/APPE. If you do not work outside of your required school IPPE/APPE, then please select "I am not currently working in/for a pharmacy"

Answered: 1,813 Skipped: 231





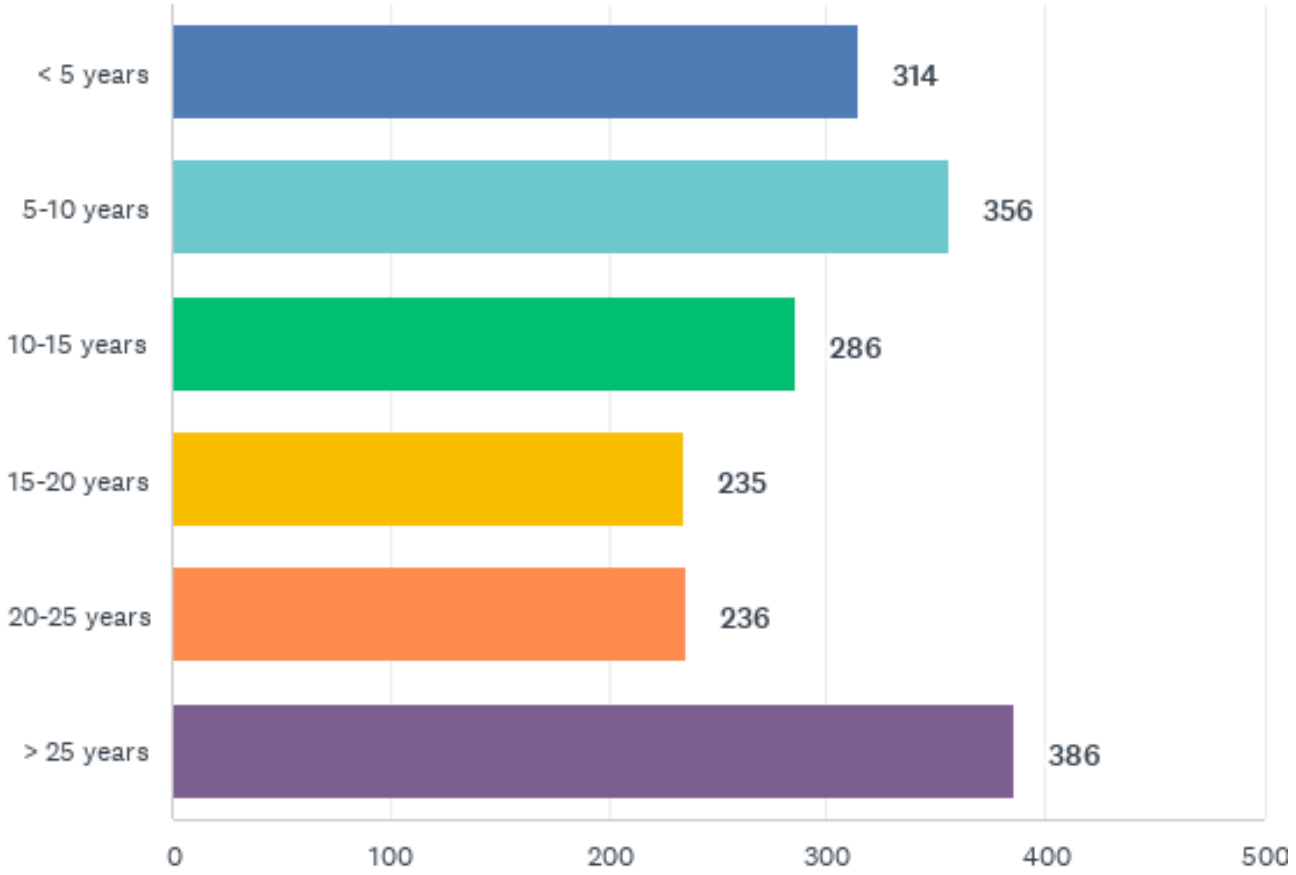
Q2: What is your primary pharmacy practice setting?NOTE: Students- Please select your primary pharmacy workplace outside of your IPPE/APPE. If you do not work outside of your required school IPPE/APPE, then please select "I am not currently working in/for a pharmacy"

Answered: 1,813 Skipped: 231

ANSWER CHOICES	RESPONSES	
Academia	0.50%	9
Ambulatory Care	5.52%	100
Community Pharmacy - Chain	47.88%	868
Community Pharmacy- Independent	8.49%	154
Compounding Pharmacy	1.60%	29
Health Center Pharmacy	3.53%	64
Hospital Pharmacy- Inpatient	11.47%	208
Hospital Pharmacy- Outpatient	2.81%	51
Long Term Care Pharmacy	2.43%	44
Mail Order Pharmacy	4.25%	77
Other (e.g. prefer not to say, industry, managed care, nuclear, specialty, etc.)	6.18%	112
I am not currently working in/for a pharmacy	5.35%	97
TOTAL		1,813

Q3: How many years have you practiced or assisted in the practice of pharmacy?

Answered: 1,813 Skipped: 231



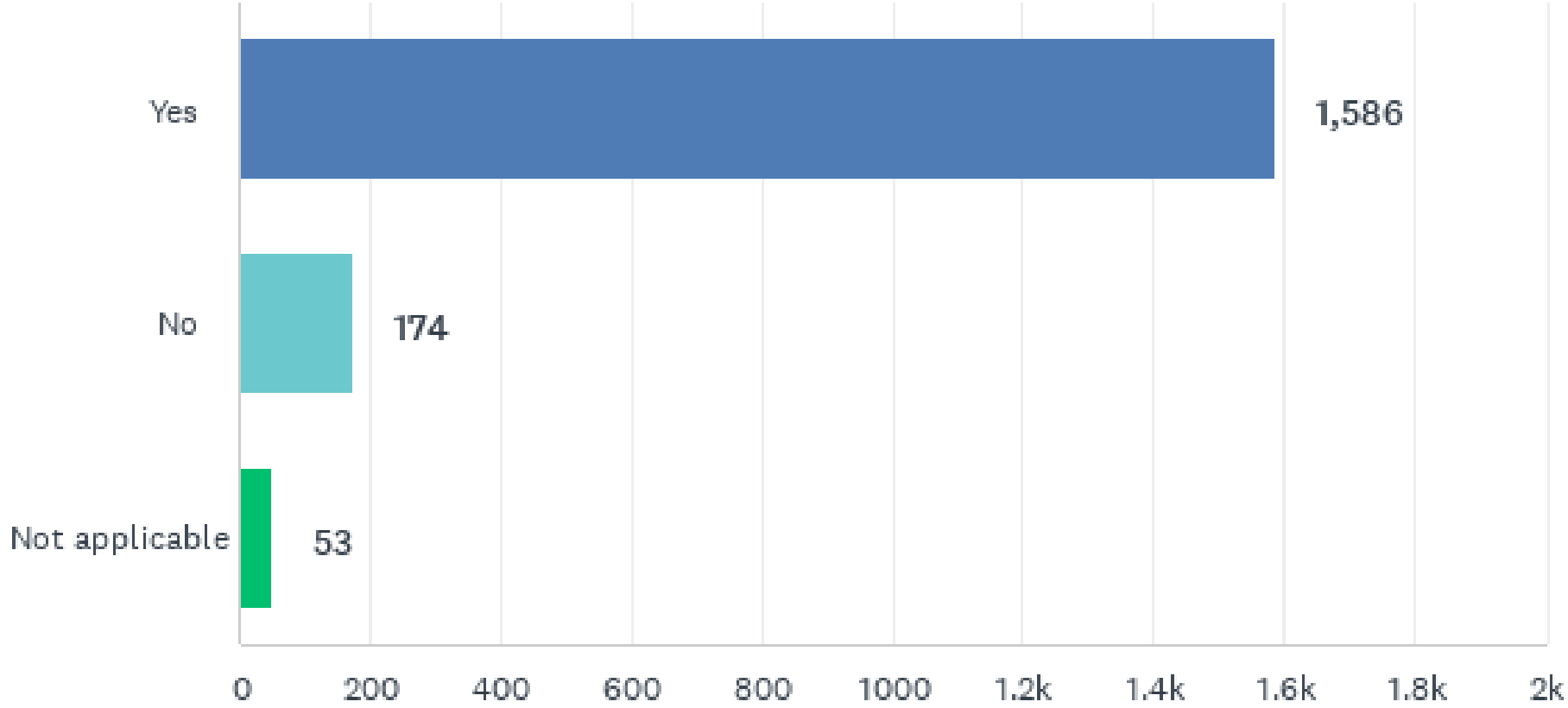
Q3: How many years have you practiced or assisted in the practice of pharmacy?

Answered: 1,813 Skipped: 231

ANSWER CHOICES	RESPONSES	
< 5 years	17.32%	314
5-10 years	19.64%	356
10-15 years	15.77%	286
15-20 years	12.96%	235
20-25 years	13.02%	236
> 25 years	21.29%	386
TOTAL		1,813

Q4: Is your primary practice setting located in Oregon?

Answered: 1,813 Skipped: 231



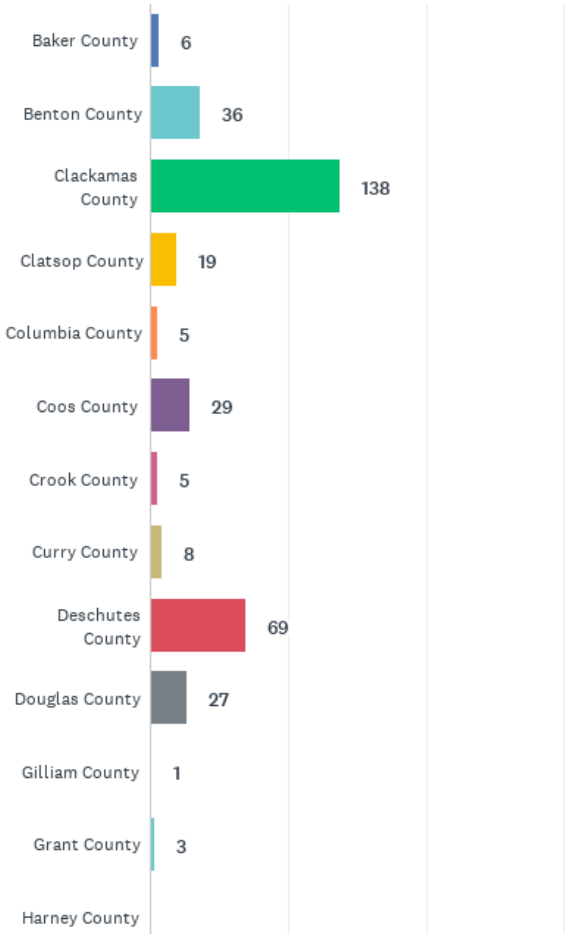
Q4: Is your primary practice setting located in Oregon?

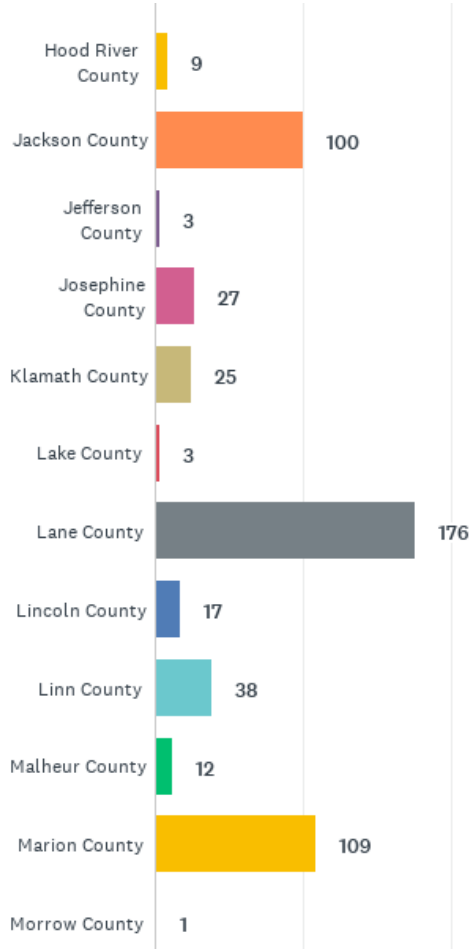
Answered: 1,813 Skipped: 231

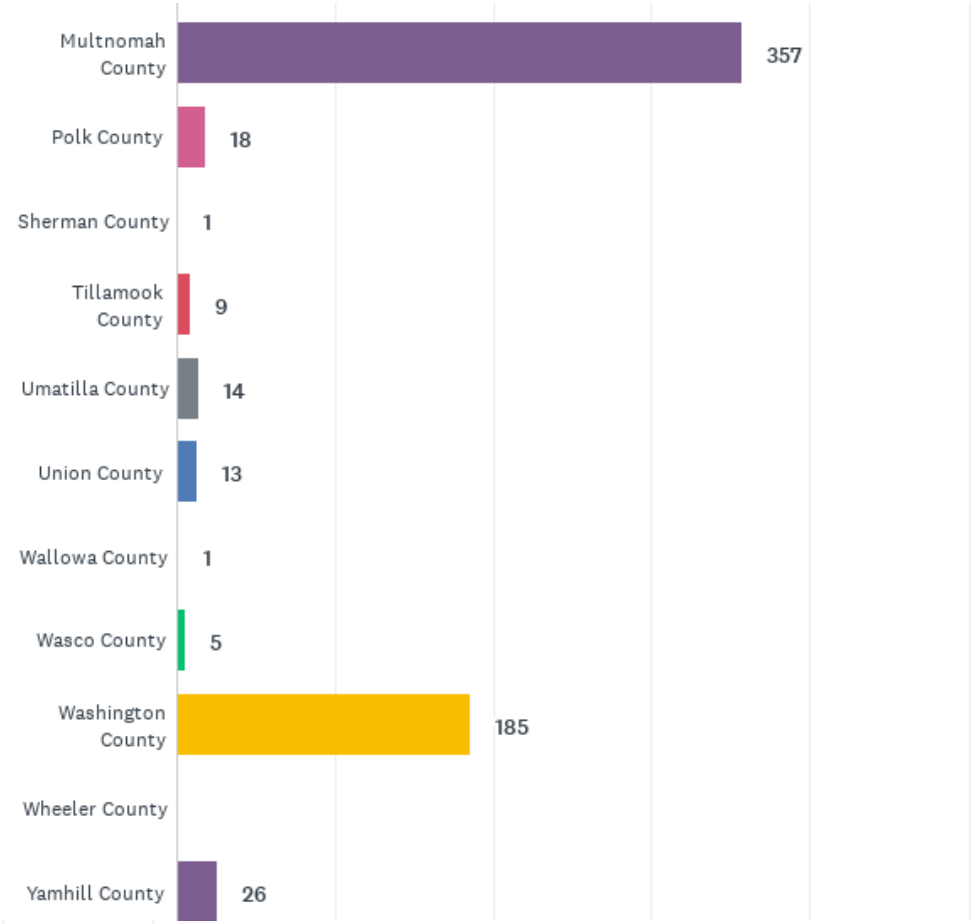
ANSWER CHOICES	RESPONSES	
Yes	87.48%	1,586
No	9.60%	174
Not applicable	2.92%	53
TOTAL		1,813

Q5: What county is your primary practice setting located?

Answered: 1,495 Skipped: 549







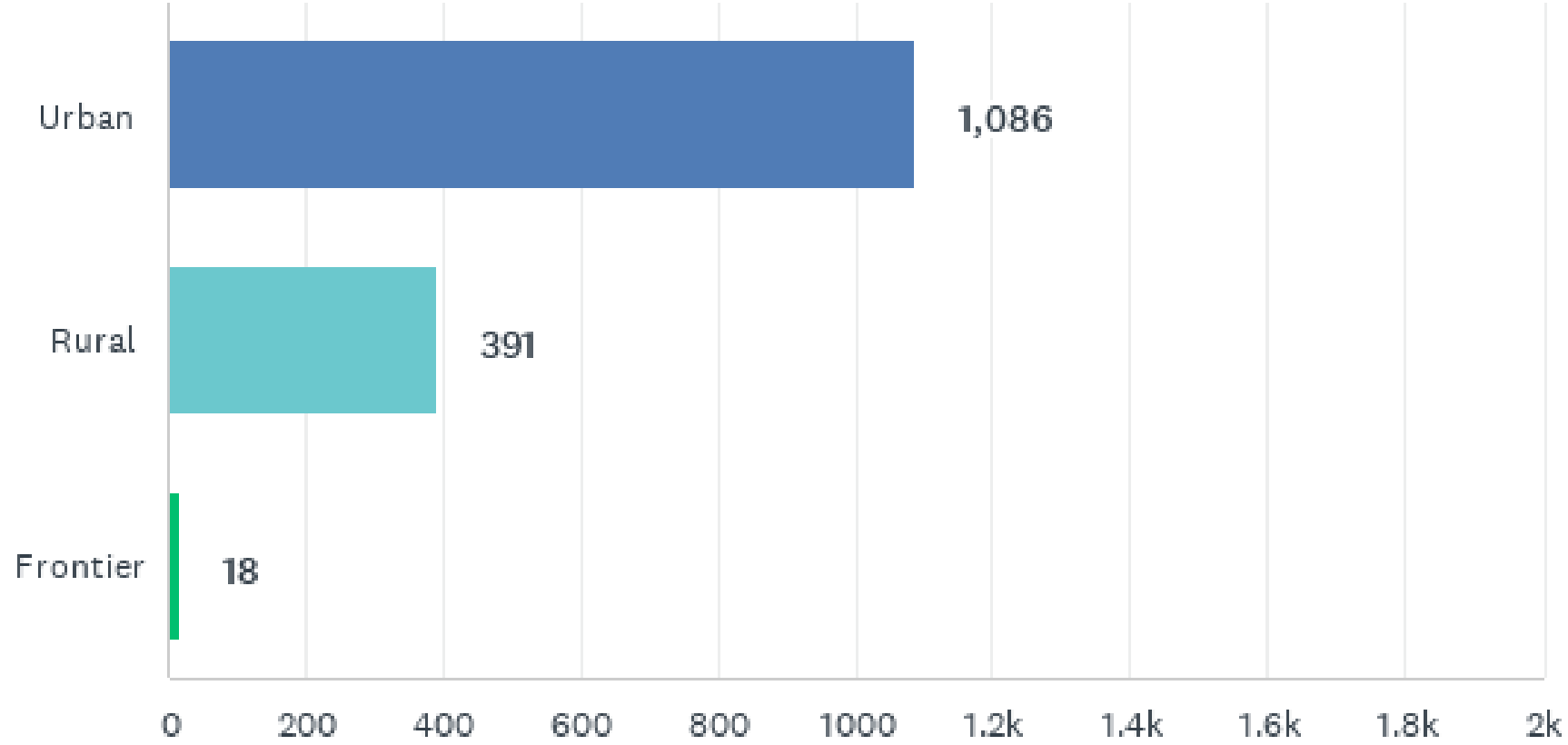
Q5: What county is your primary practice setting located?

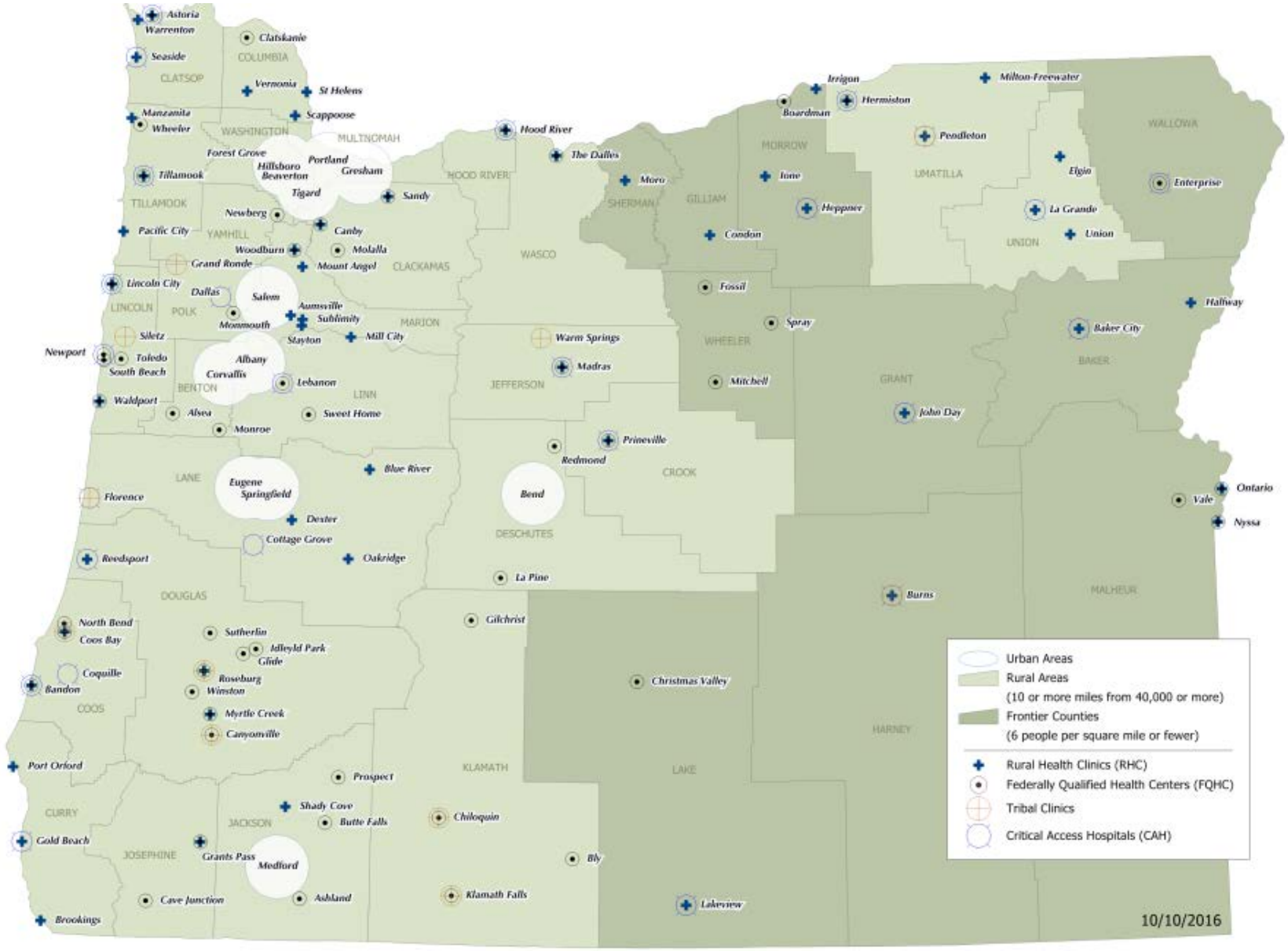
Answered: 1,495 Skipped: 549

ANSWER CHOICES	RESPONSES	
Baker County	0.40%	6
Benton County	2.41%	36
Clackamas County	9.23%	138
Clatsop County	1.27%	19
Columbia County	0.33%	5
Coos County	1.94%	29
Crook County	0.33%	5
Curry County	0.54%	8
Deschutes County	4.62%	69
Douglas County	1.81%	27
Gilliam County	0.07%	1
Grant County	0.20%	3
Harney County	0.00%	0
Hood River County	0.60%	9
Jackson County	6.69%	100
Jefferson County	0.20%	3
Josephine County	1.81%	27
Klamath County	1.67%	25
Lake County	0.20%	3
Lane County	11.77%	176
Lincoln County	1.14%	17
Linn County	2.54%	38
Malheur County	0.80%	12
Marion County	7.29%	109
Morrow County	0.07%	1
Multnomah County	23.88%	357
Polk County	1.20%	18
Sherman County	0.07%	1
Tillamook County	0.60%	9
Umatilla County	0.94%	14
Union County	0.87%	13
Wallowa County	0.07%	1
Wasco County	0.33%	5
Washington County	12.37%	185
Wheeler County	0.00%	0
Yamhill County	1.74%	26
TOTAL		1,495

Q6: Before answering this question, please search for your practice site zip code here. Is your primary practice setting located in an urban, rural or frontier area?

Answered: 1,495 Skipped: 549




Astoria
Warrenton
Clatskanie
Seaside
COLUMBIA
CLATSOP
Vernonia
St Helens
Manzanita
Wheeler
Scappoose
WASHINGTON
MULTNOMAH
Forest Grove
Hillsboro
Beaverton
Portland
Gresham
Tillamook
Tigard
Sandy
TILLAMOOK
Newberg
Canby
Pacific City
YAMHILL
Woodburn
Molalla
Grand Ronde
Mount Angel
CLACKAMAS
Lincoln City
Dallas
Salem
LINCOLN
POLK
Aumsville
Sublimity
Monmouth
MARION
Siletz
Stayton
Mill City
Newport
Toledo
South Beach
Albany
Corvallis
BENTON
Lebanon
LINN
Waldport
Alsea
Sweet Home
Monroe
LANE
Eugene
Springfield
Florence
Dexter
Cottage Grove
Reedsport
Oakridge
DOUGLAS
North Bend
Coos Bay
Sutherlin
Idleyld Park
Glide
Coquille
Roseburg
Bandon
Winston
COOS
Myrtle Creek
Canyonville
Port Orford
CURRY
Gold Beach
JOSEPHINE
Grants Pass
Medford
Cave Junction
Ashland
Brookings
Hood River
The Dalles
HOOD RIVER
Sandy
WASCO
Warm Springs
Madras
JEFFERSON
Primeville
Redmond
Blue River
Bend
DESCHUTES
La Pine
Gilchrist
Prospect
KLAMATH
Shady Cove
Butte Falls
Chiloquin
JACKSON
Klamath Falls
Bly
Irrigon
Hermiston
Boardman
Milton-Freewater
Pendleton
MORROW
UMATILLA
WALLOWA
Elgin
Enterprise
Ione
Moro
SHERMAN
GILLIAM
Heppner
La Grande
Condon
Union
UNION
Fossil
Spray
WHEELER
Mitchell
Baker City
Halfway
BAKER
GRANT
John Day
Burns
MALHEUR
Ontario
Vale
Nyssa
Christmas Valley
HARNEY
LAKE
Lakeview
Urban Areas
Rural Areas
(10 or more miles from 40,000 or more)
Frontier Counties
(6 people per square mile or fewer)
Rural Health Clinics (RHC)
Federally Qualified Health Centers (FQHC)
Tribal Clinics
Critical Access Hospitals (CAH)
10/10/2016

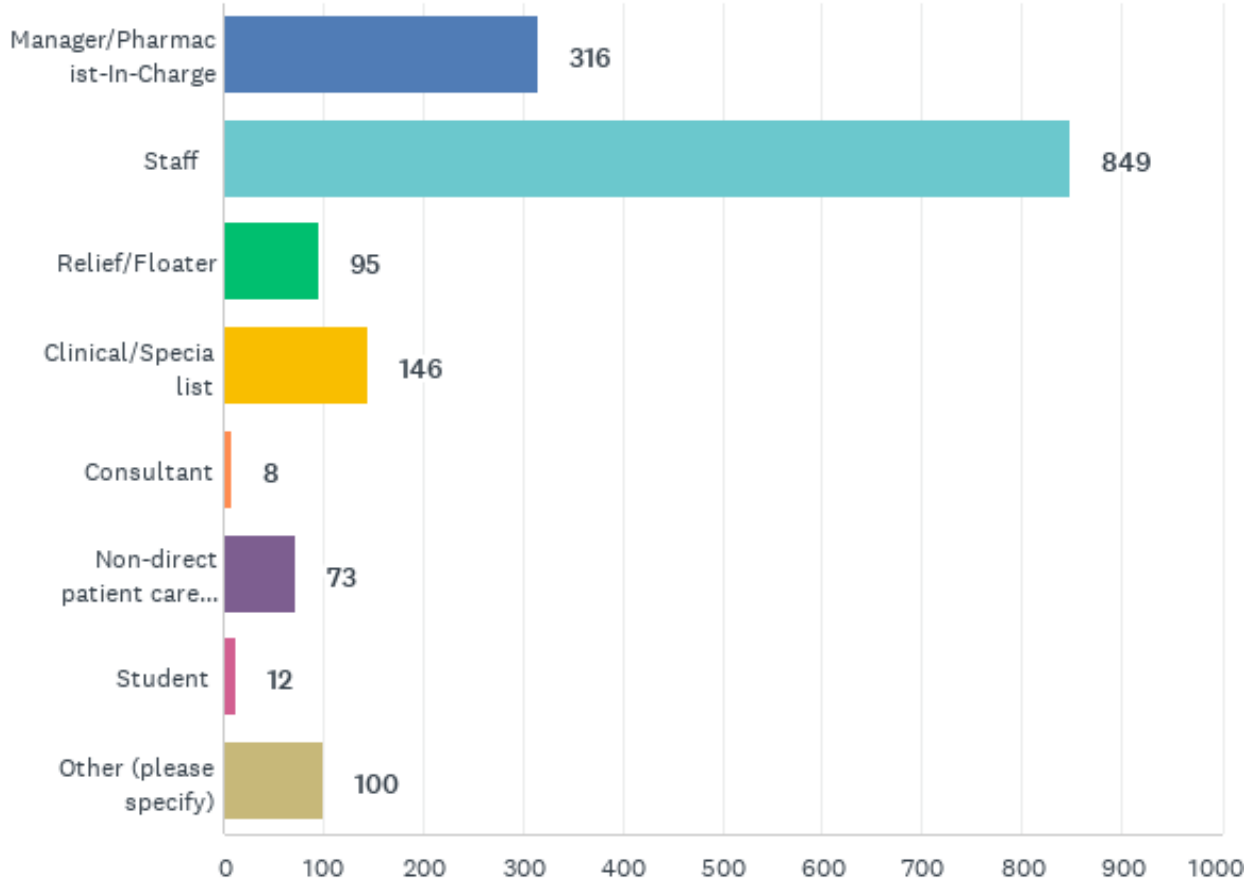
Q6: Before answering this question, please search for your practice site zip code here. Is your primary practice setting located in an urban, rural or frontier area?

Answered: 1,495 Skipped: 549

ANSWER CHOICES	RESPONSES	
Urban	72.64%	1,086
Rural	26.15%	391
Frontier	1.20%	18
TOTAL		1,495

Q7: What is your primary role in your primary practice setting?

Answered: 1,599 Skipped: 445



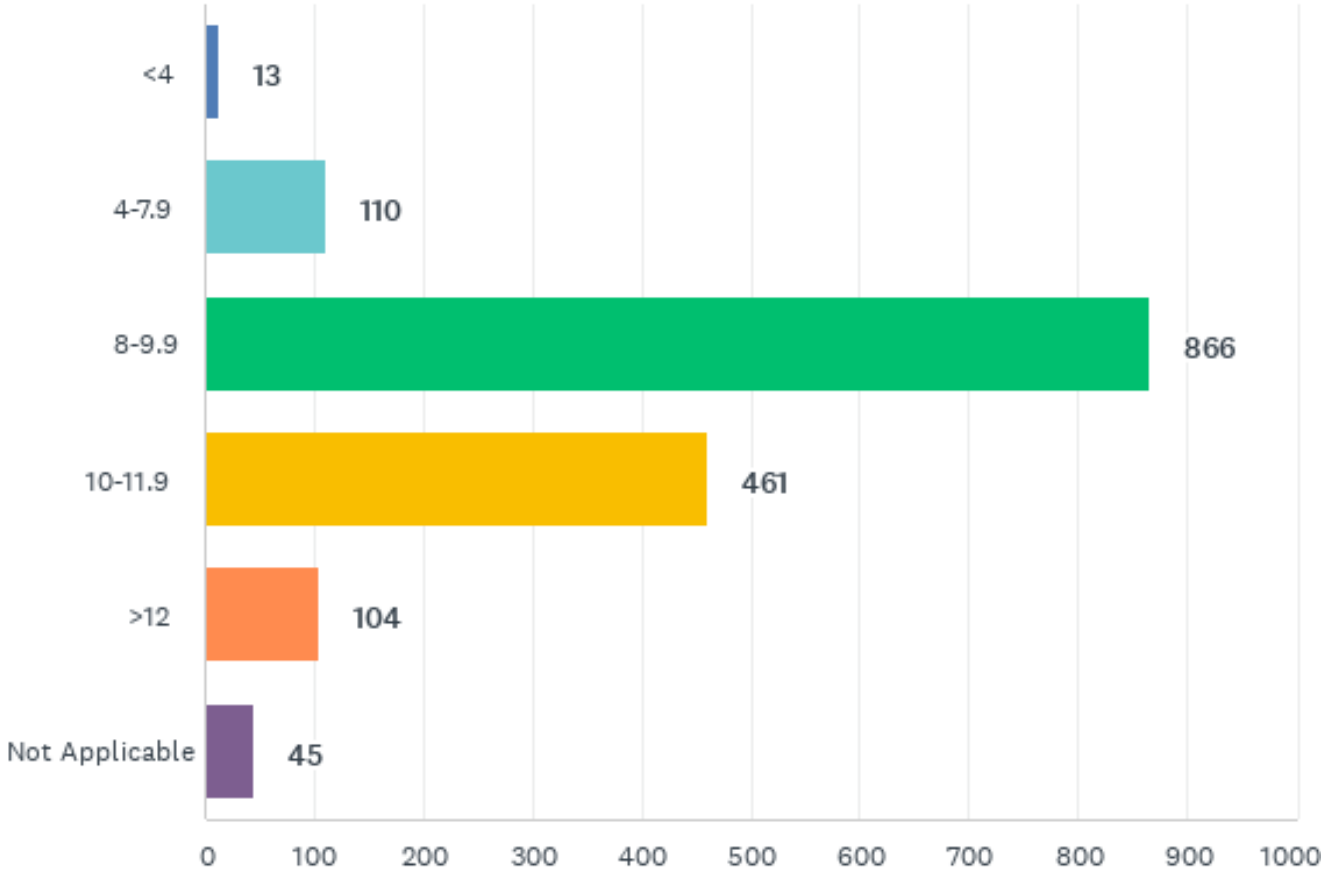
Q7: What is your primary role in your primary practice setting?

Answered: 1,599 Skipped: 445

ANSWER CHOICES	RESPONSES	
Manager/Pharmacist-In-Charge	19.76%	316
Staff	53.10%	849
Relief/Floater	5.94%	95
Clinical/Specialist	9.13%	146
Consultant	0.50%	8
Non-direct patient care administrative / supervisory / leadership position (e.g. Operations Manager, Regional Manager, VP)	4.57%	73
Student	0.75%	12
Other (please specify)	6.25%	100
TOTAL		1,599

Q8: On average, how many hours do you work per shift?

Answered: 1,599 Skipped: 445



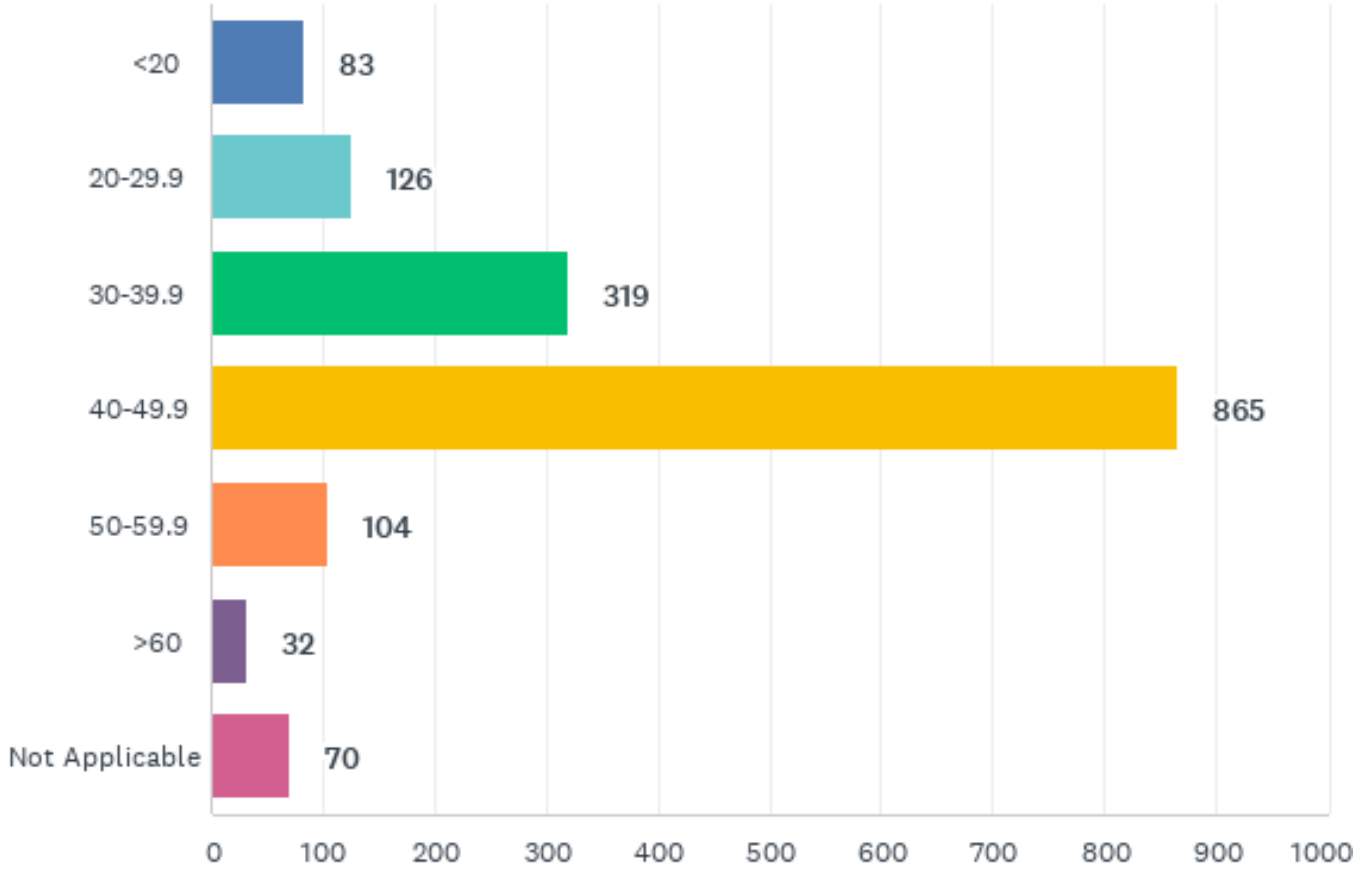
Q8: On average, how many hours do you work per shift?

Answered: 1,599 Skipped: 445

ANSWER CHOICES	RESPONSES	
<4	0.81%	13
4-7.9	6.88%	110
8-9.9	54.16%	866
10-11.9	28.83%	461
>12	6.50%	104
Not Applicable	2.81%	45
TOTAL		1,599

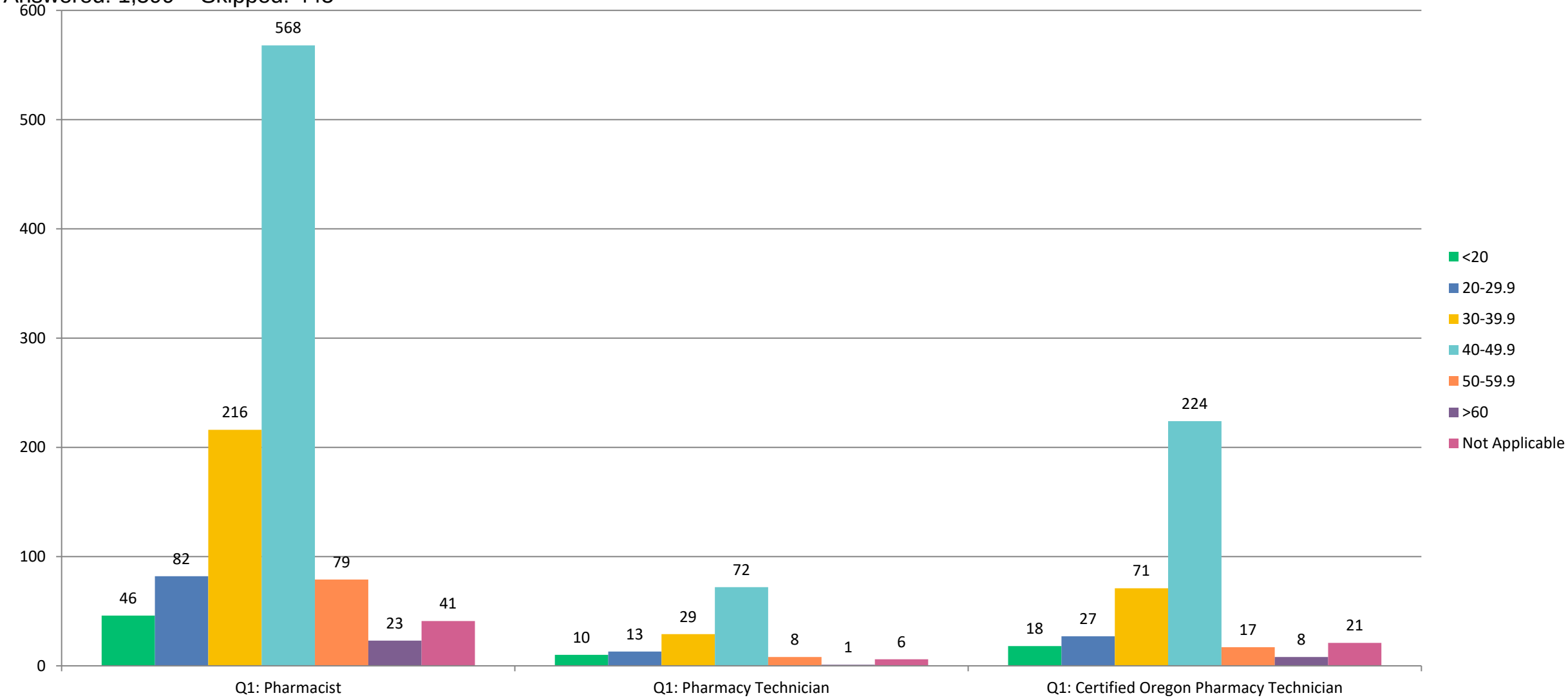
Q9: On average, how many hours do you work for a pharmacy per week?

Answered: 1,599 Skipped: 445



Q9: On average, how many hours do you work for a pharmacy per week?

Answered: 1,599 Skipped: 445



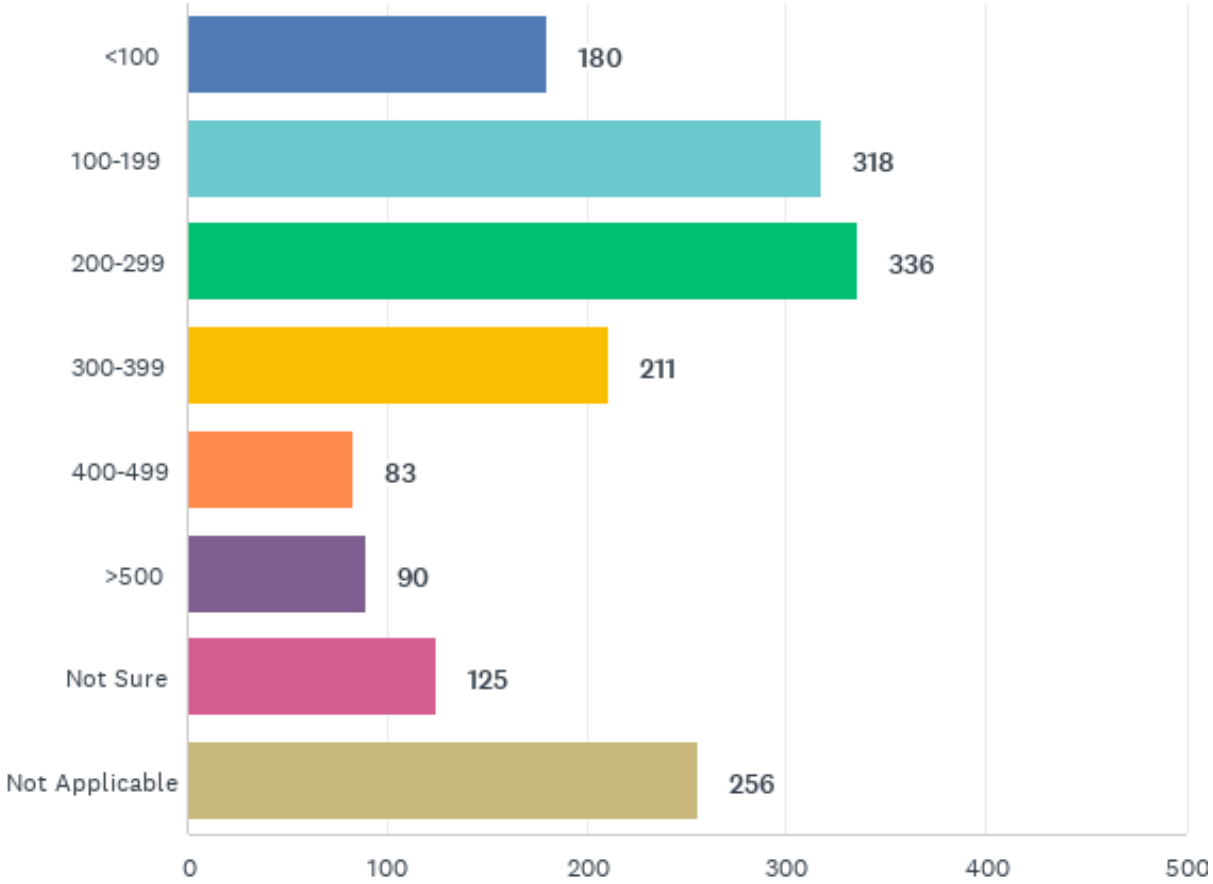
Q9: On average, how many hours do you work for a pharmacy per week?

Answered: 1,599 Skipped: 445

ANSWER CHOICES	RESPONSES	
<20	5.19%	83
20-29.9	7.88%	126
30-39.9	19.95%	319
40-49.9	54.10%	865
50-59.9	6.50%	104
>60	2.00%	32
Not Applicable	4.38%	70
TOTAL		1,599

Q10: On average, how many prescriptions or medication orders: Pharmacists- Do you personally verify (e.g. data verification, DUR, final verification) per shift? Technicians/Interns- Do you personally process (e.g. data entry, insurance processing, count/label) per shift?

Answered: 1,599 Skipped: 445



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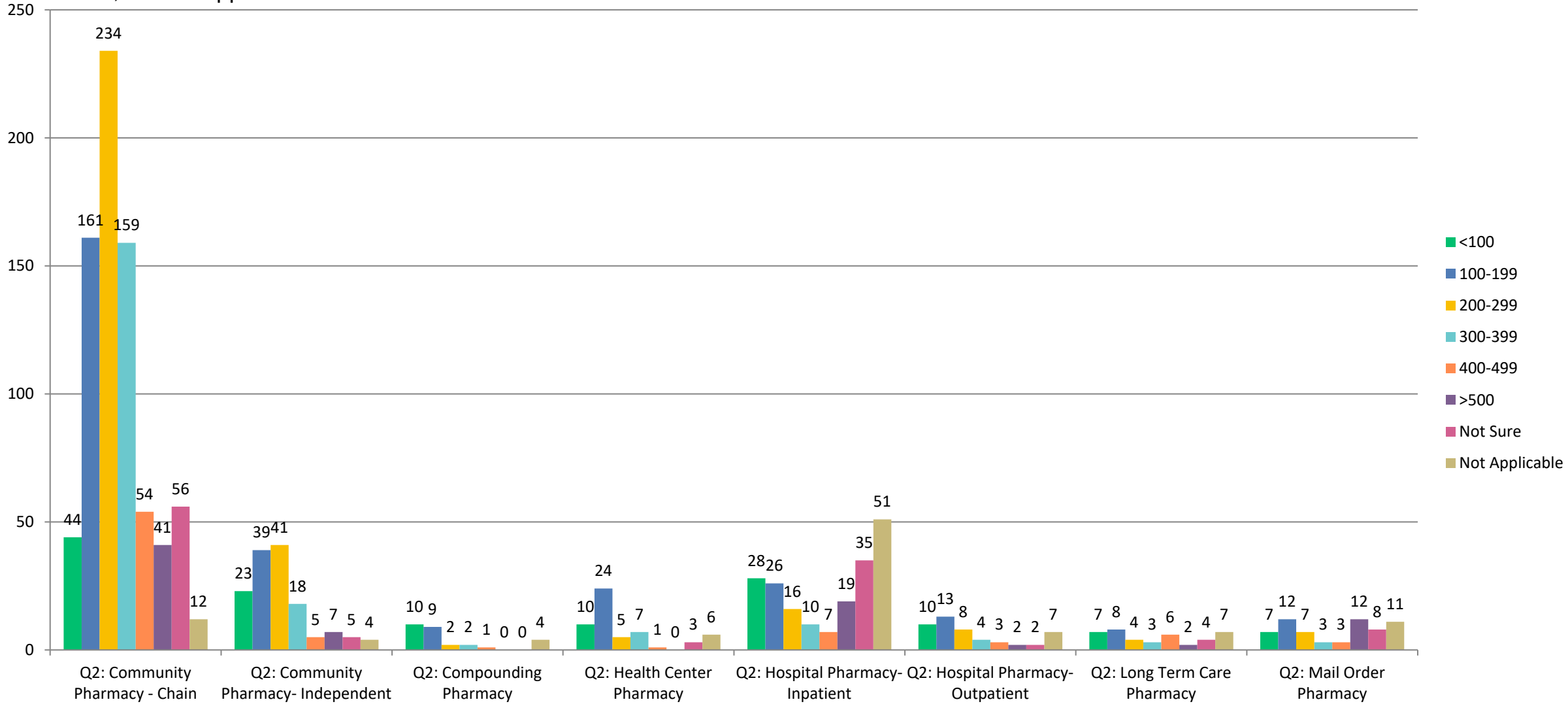
Answered: 1,599 Skipped: 445



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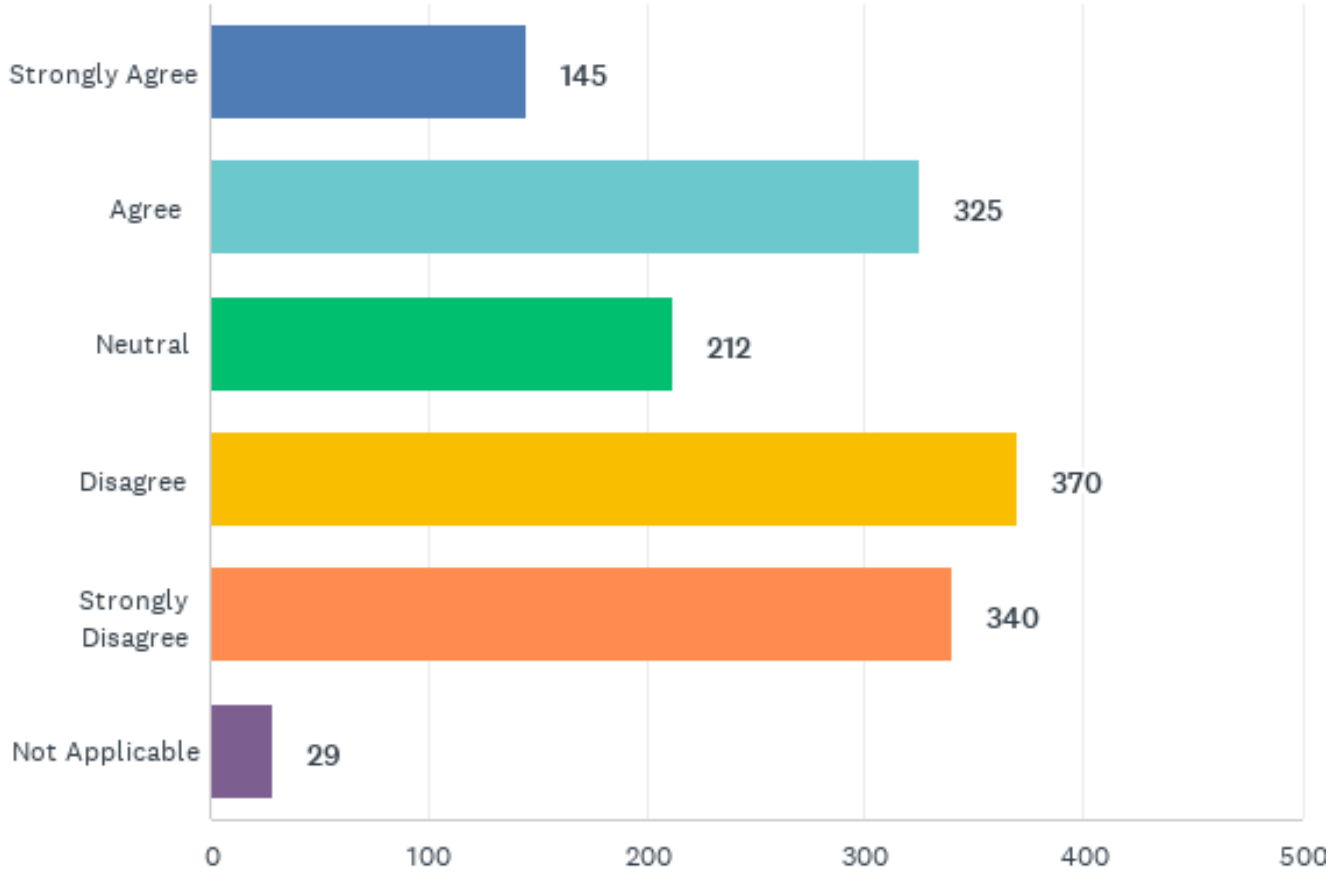
Answered: 1,599 Skipped: 445

ANSWER CHOICES	RESPONSES	
<100	11.26%	180
100-199	19.89%	318
200-299	21.01%	336
300-399	13.20%	211
400-499	5.19%	83
>500	5.63%	90
Not Sure	7.82%	125
Not Applicable	16.01%	256
TOTAL		1,599

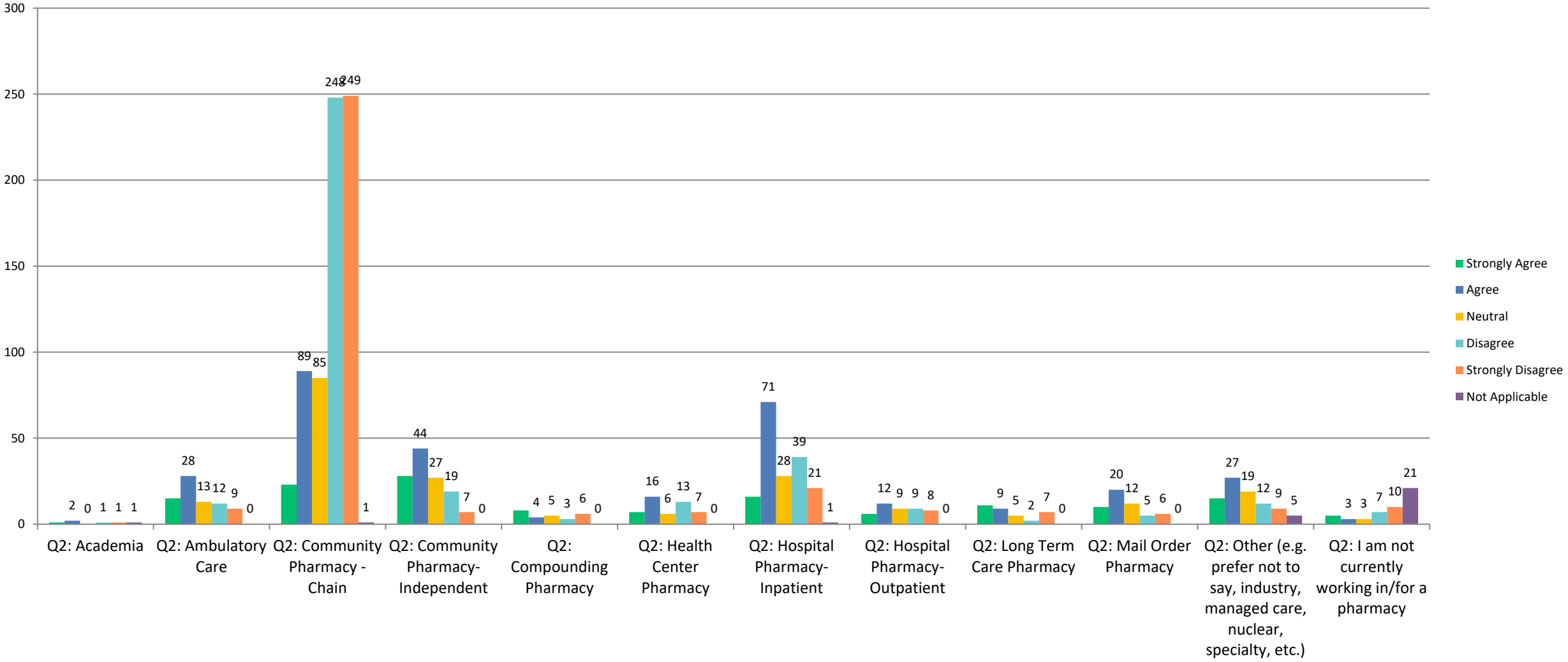
Q11: I feel that I have adequate time to complete my job in a safe and effective manner.

Answered: 1,421 Skipped: 623



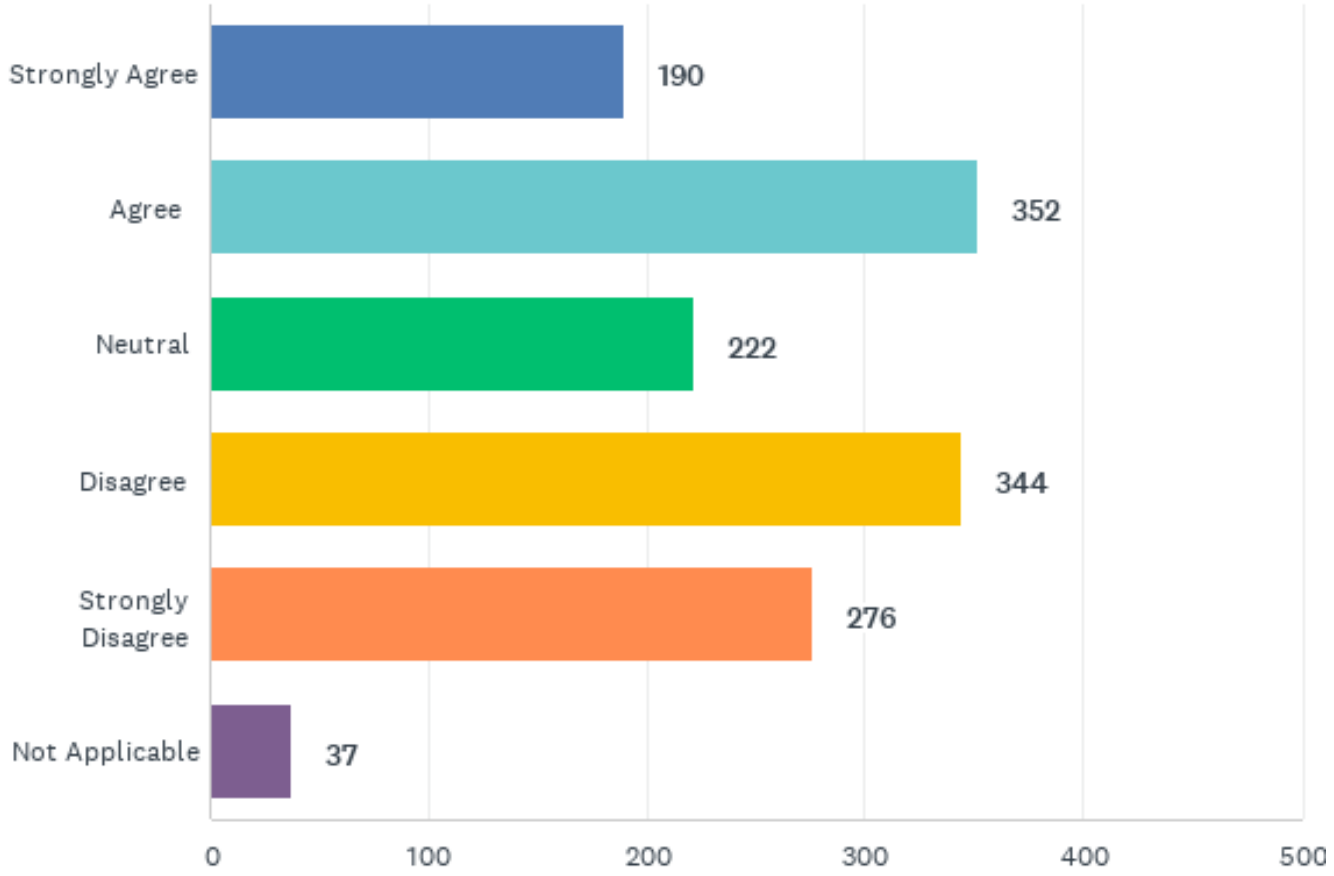
Q11: I feel that I have adequate time to complete my job in a safe and effective manner.

Answered: 1,421 Skipped: 392



Q12: I feel that my employer provides a practice environment that allows for safe and effective patient care.

Answered: 1,421 Skipped: 623



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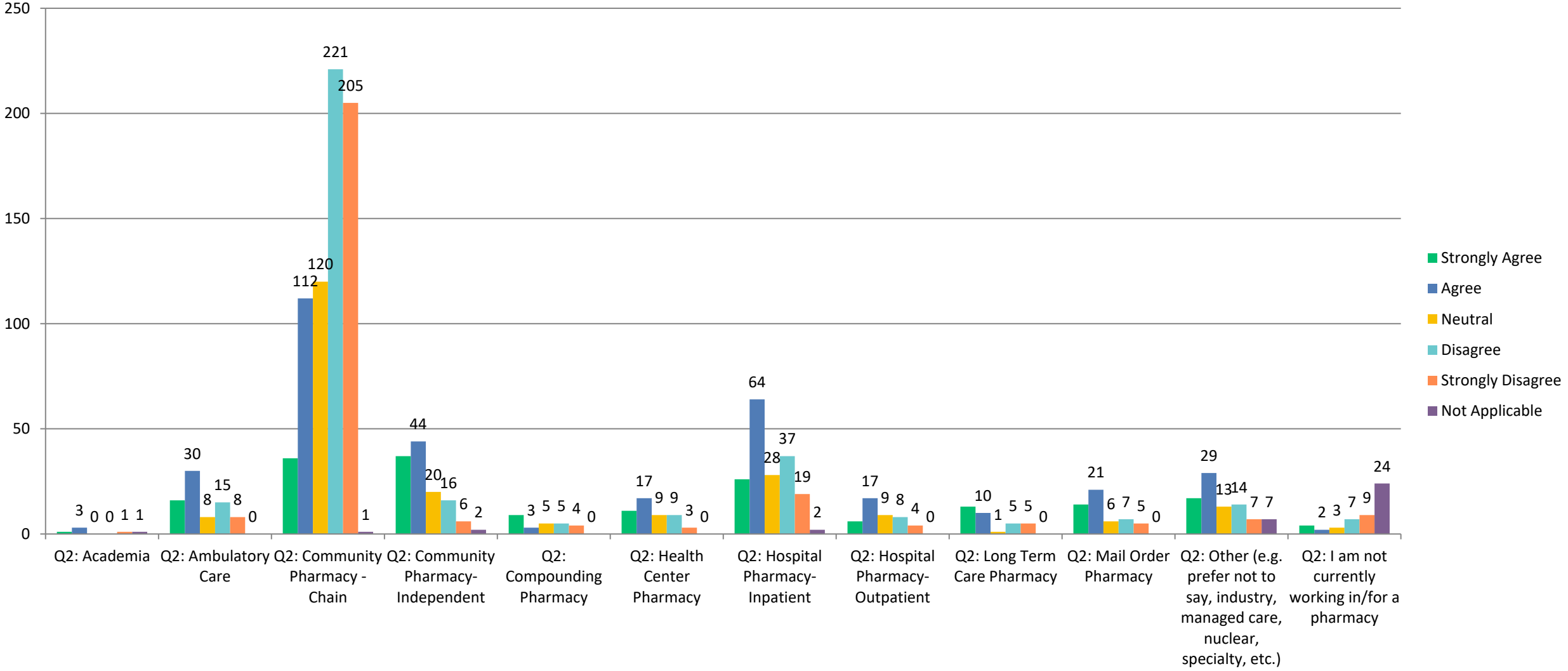
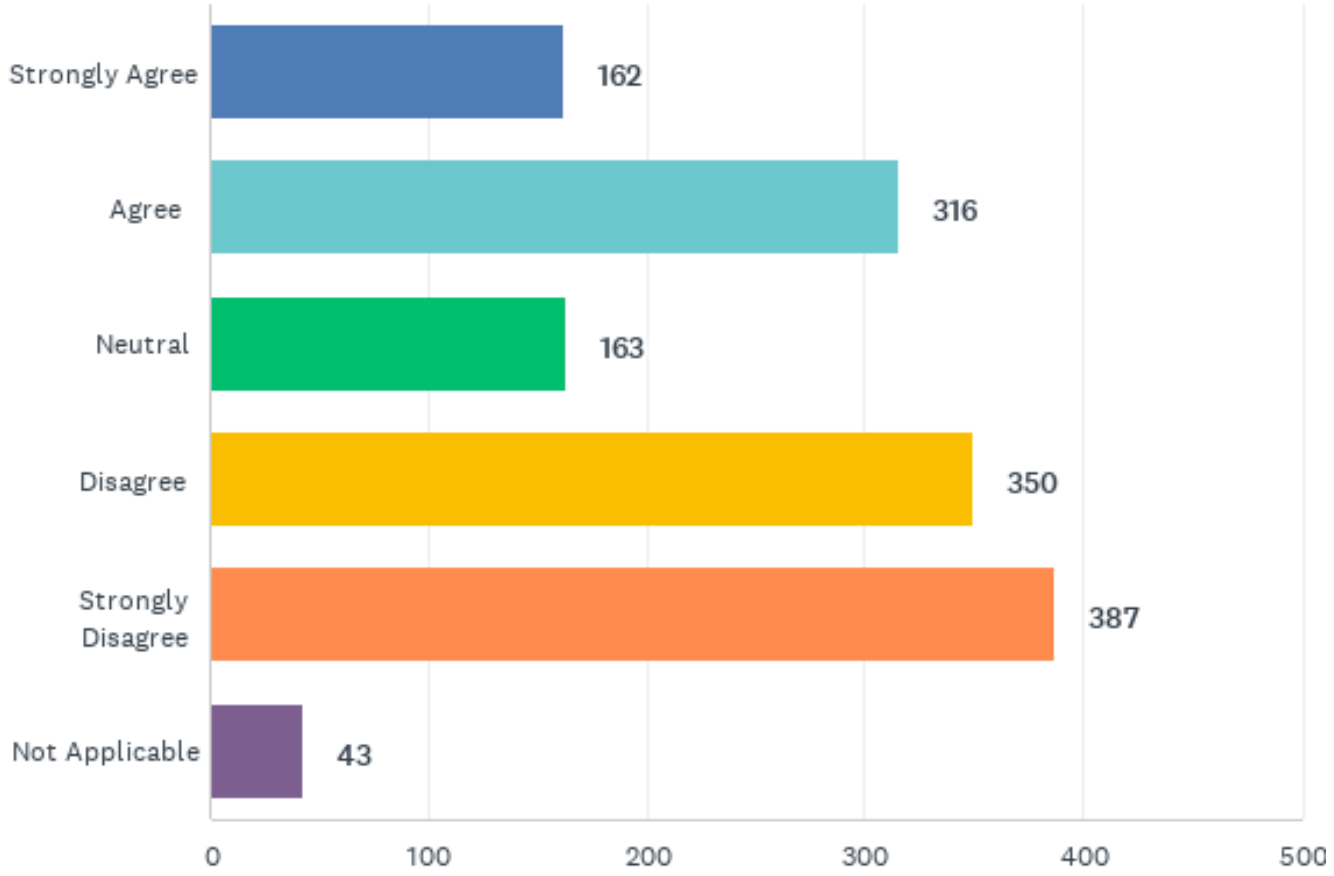


Q13: I feel that my practice environment utilizes sufficient pharmacist staffing that allows for safe, effective and timely patient care.

Answered: 1,421 Skipped: 623



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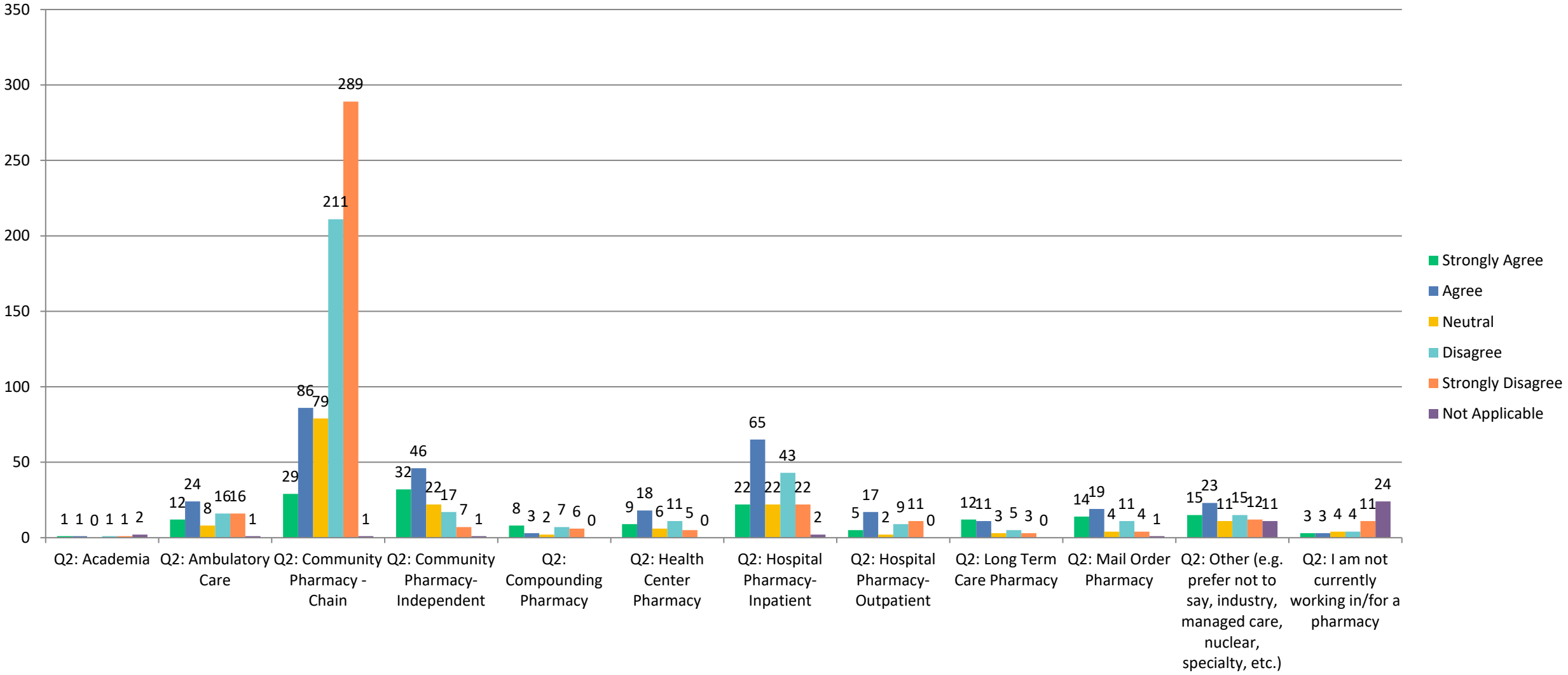
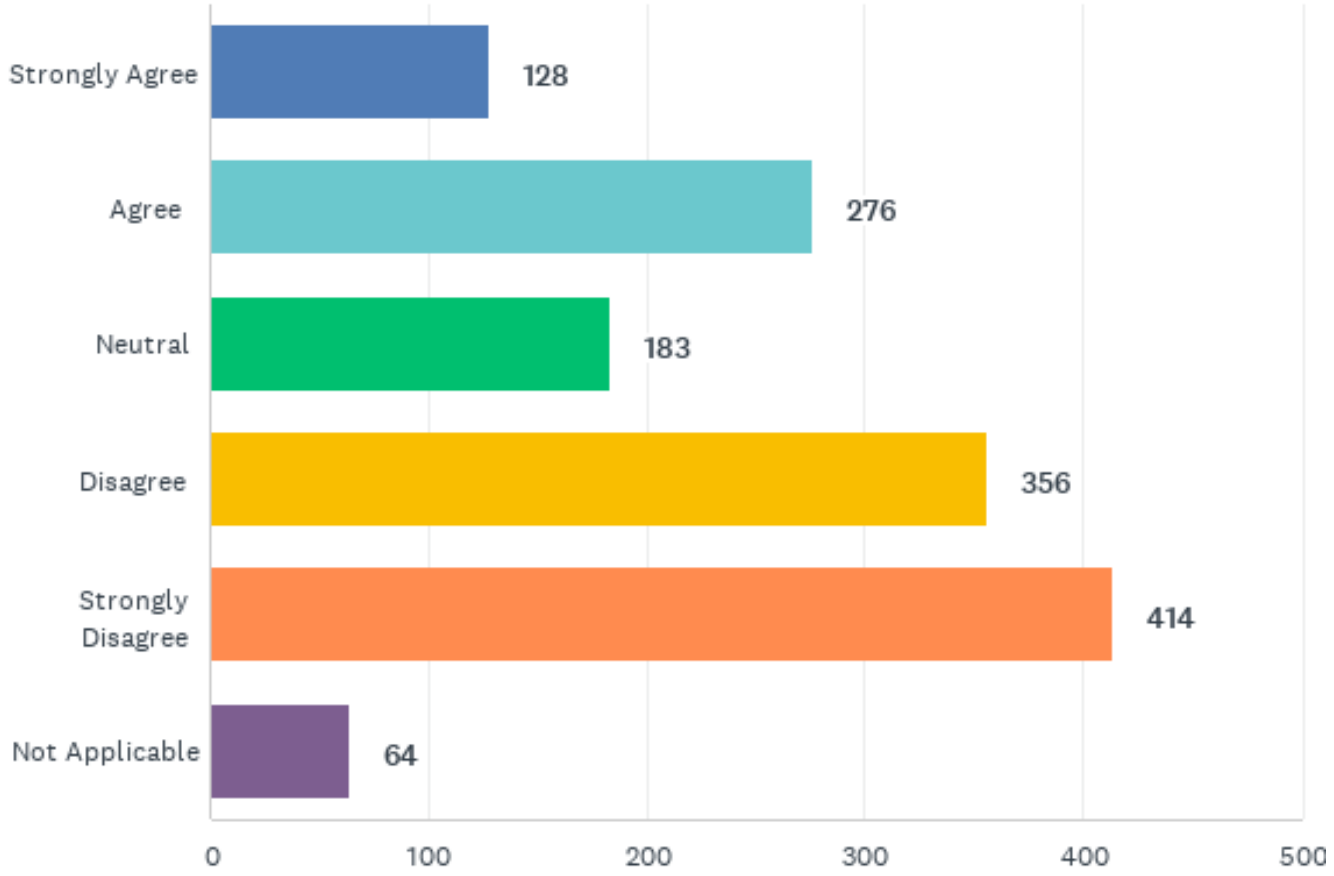


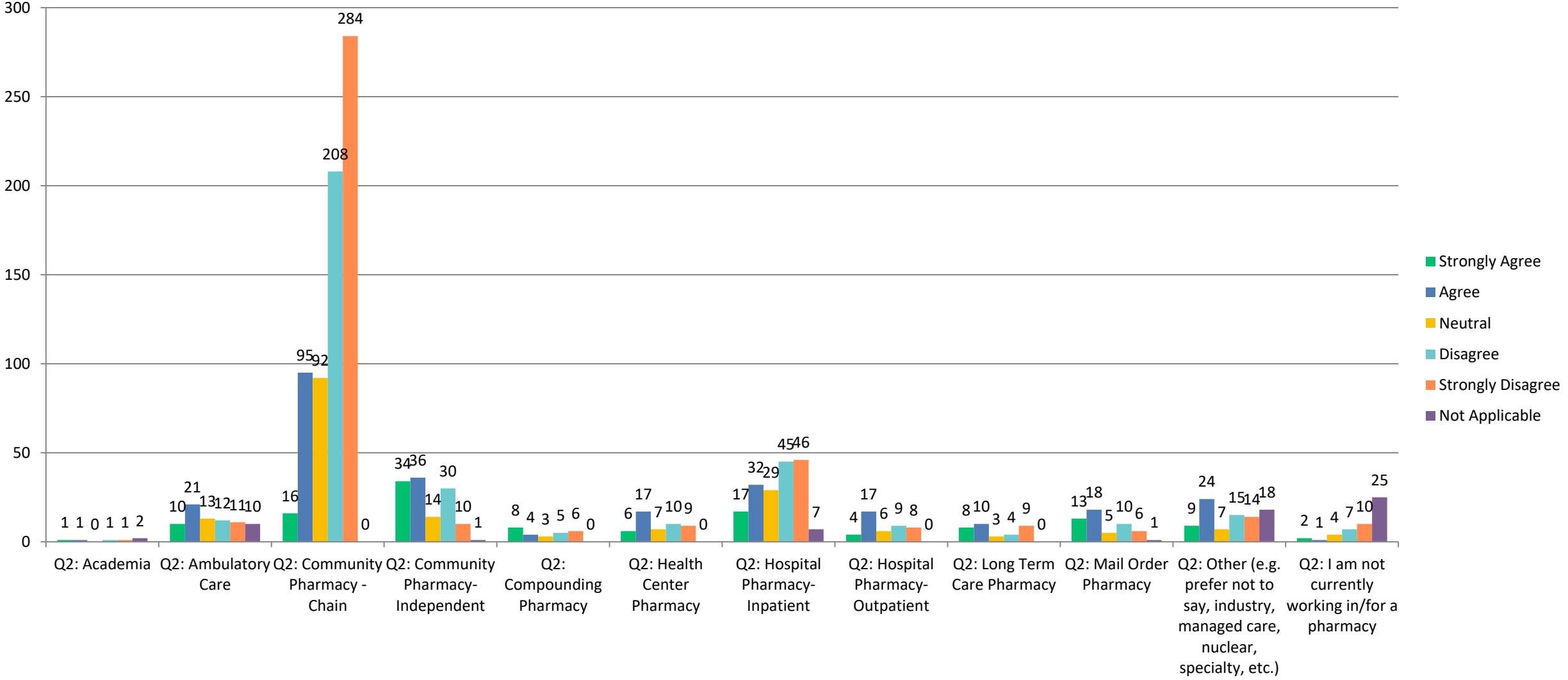
Q14: I feel that my practice environment utilizes sufficient pharmacy technician staffing that allows for safe and effective patient care

Answered: 1,421 Skipped: 623



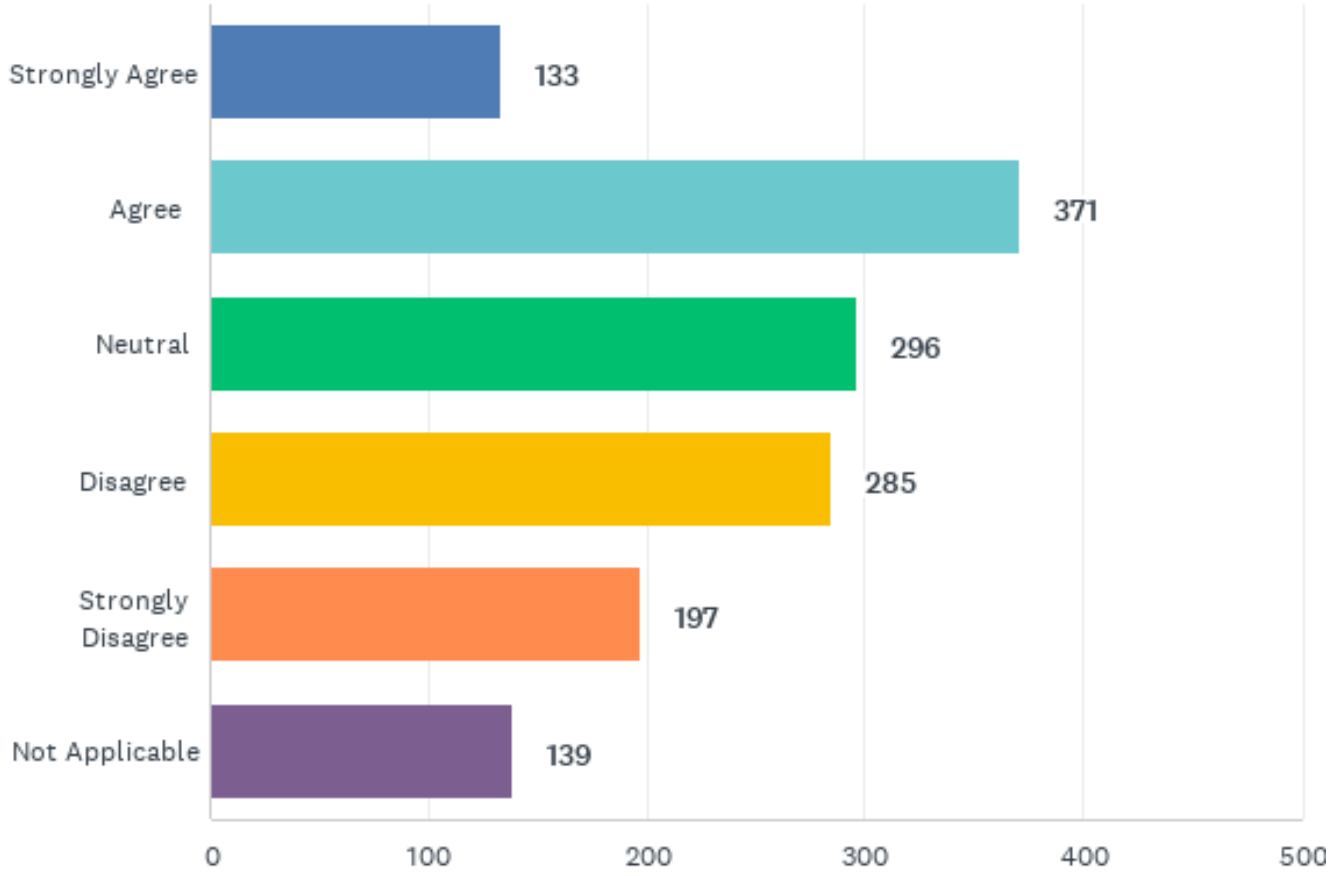
Q14: I feel that my practice environment utilizes sufficient pharmacy technician staffing that allows for safe and effective patient care

Answered: 1,421 Skipped: 623



Q15: I feel that my practice environment utilizes automation, professional and technical equipment (e.g. counting machines, central fill, phone systems) that allows for safe, effective and timely patient care.

Answered: 1,421 Skipped: 623



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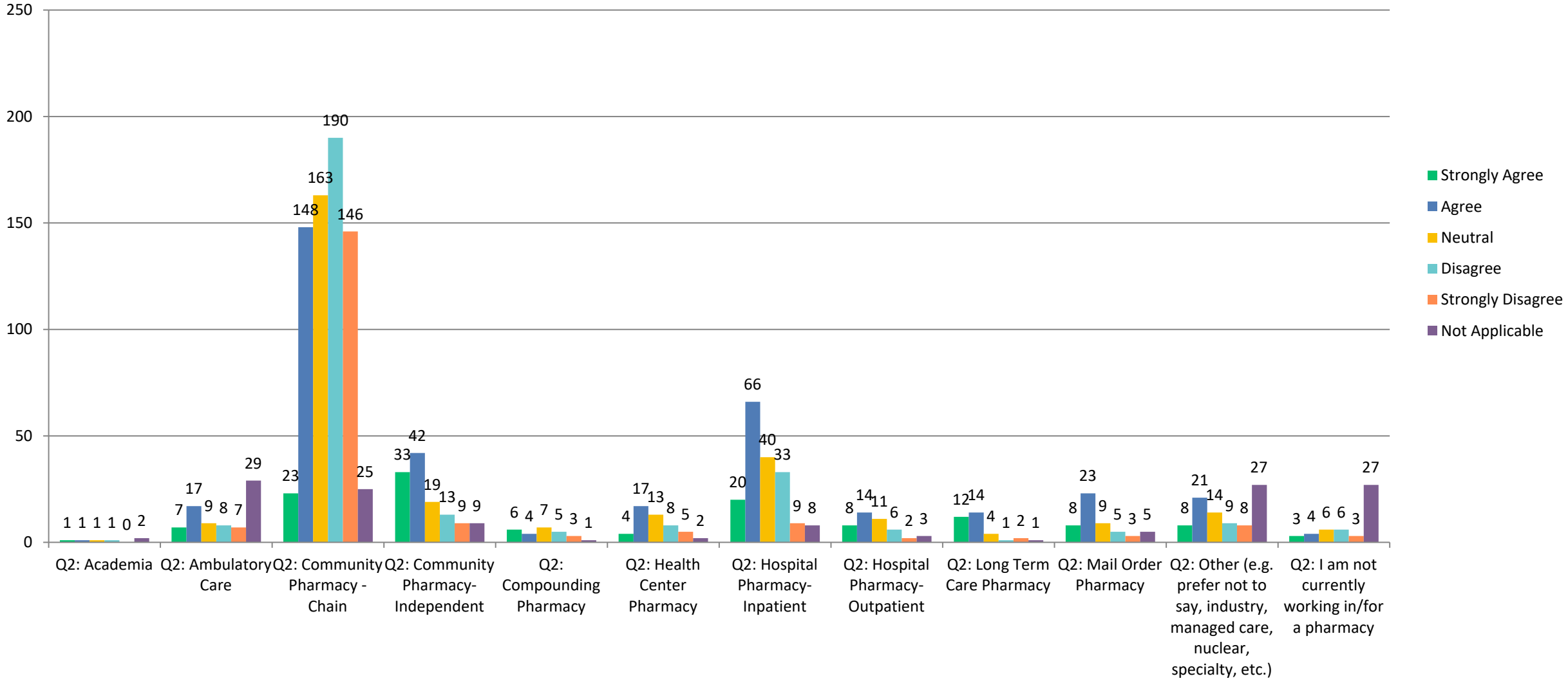
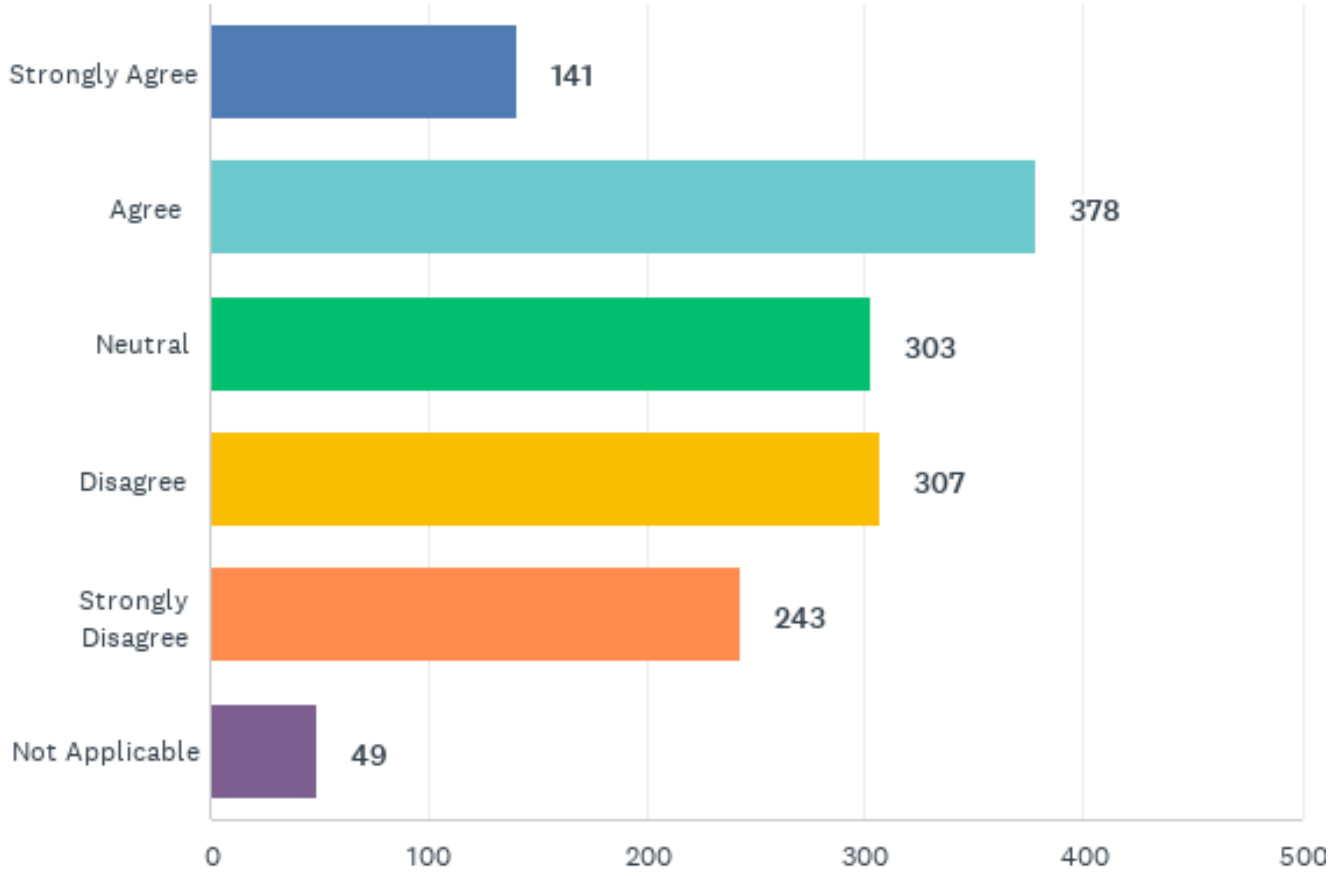


Q16: I feel that my practice environment utilizes staff training that is site-specific, thorough and prepares staff to provide safe and effective patient care.

Answered: 1,421 Skipped: 623



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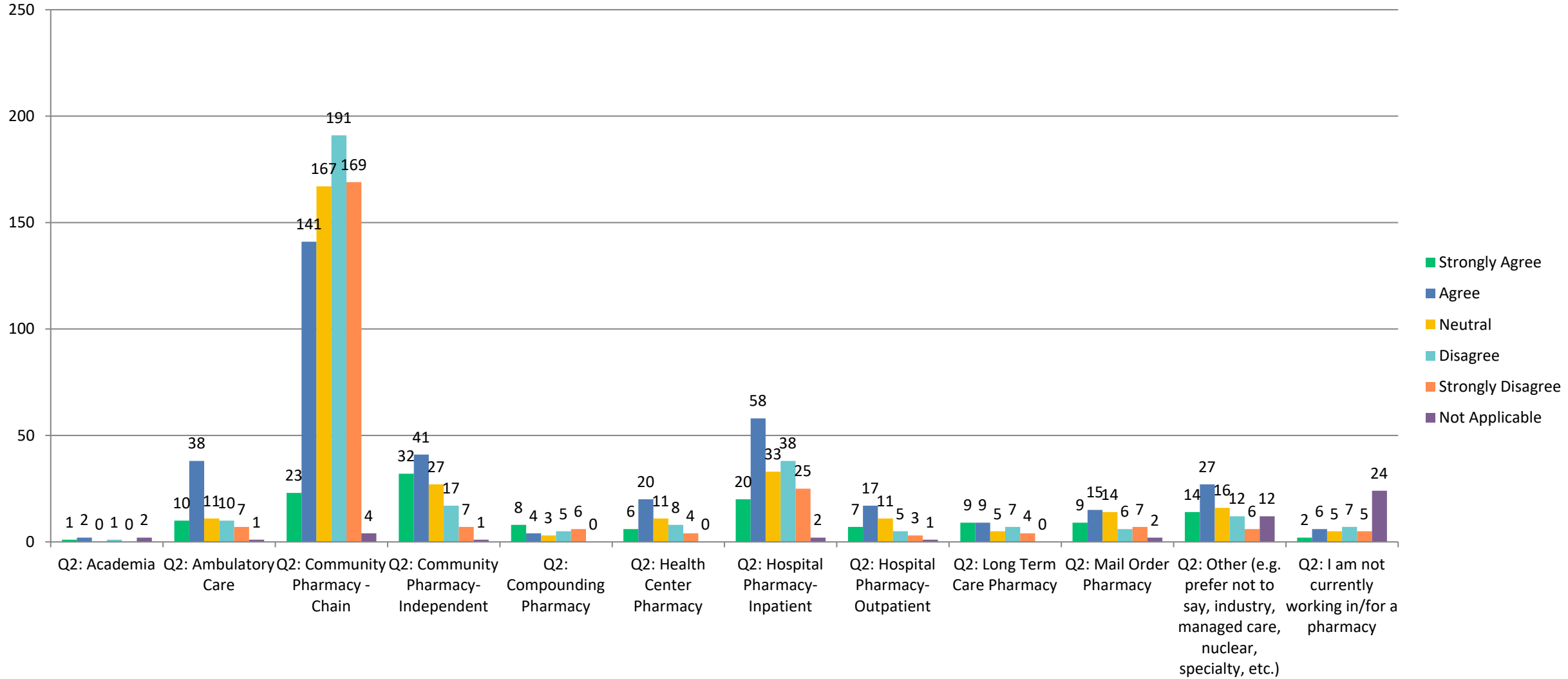
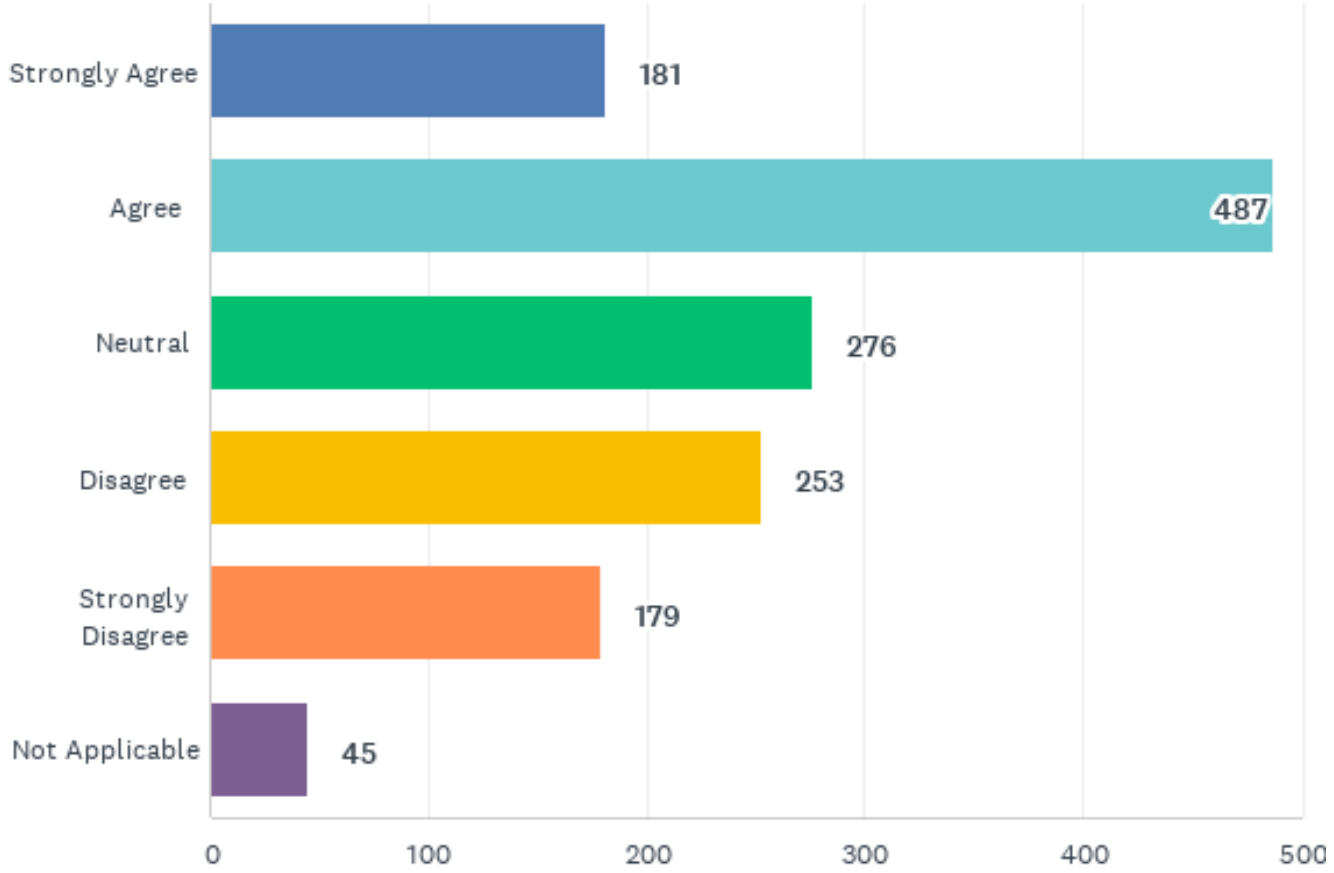


Q17: I feel that my practice environment has an organized workflow that promotes safe, effective and timely patient care.

Answered: 1,421 Skipped: 623



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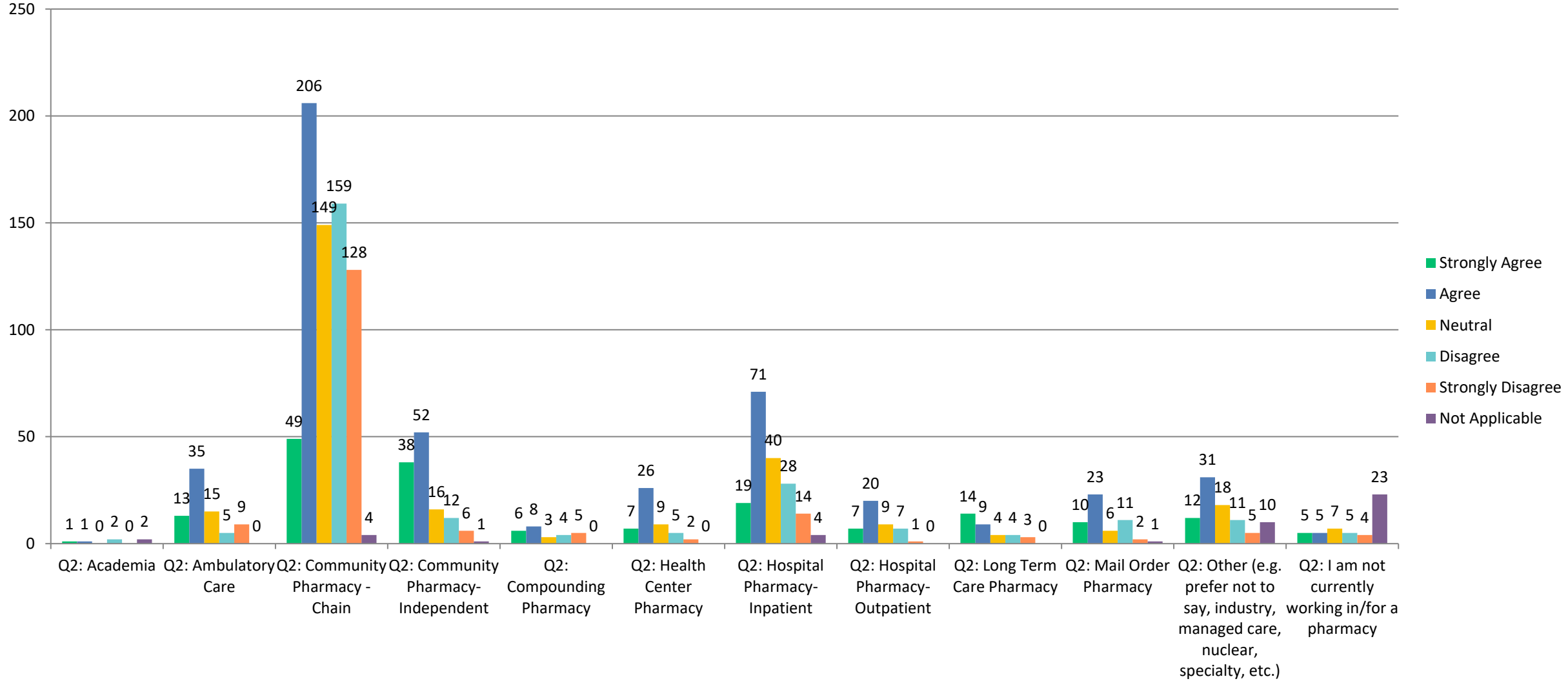
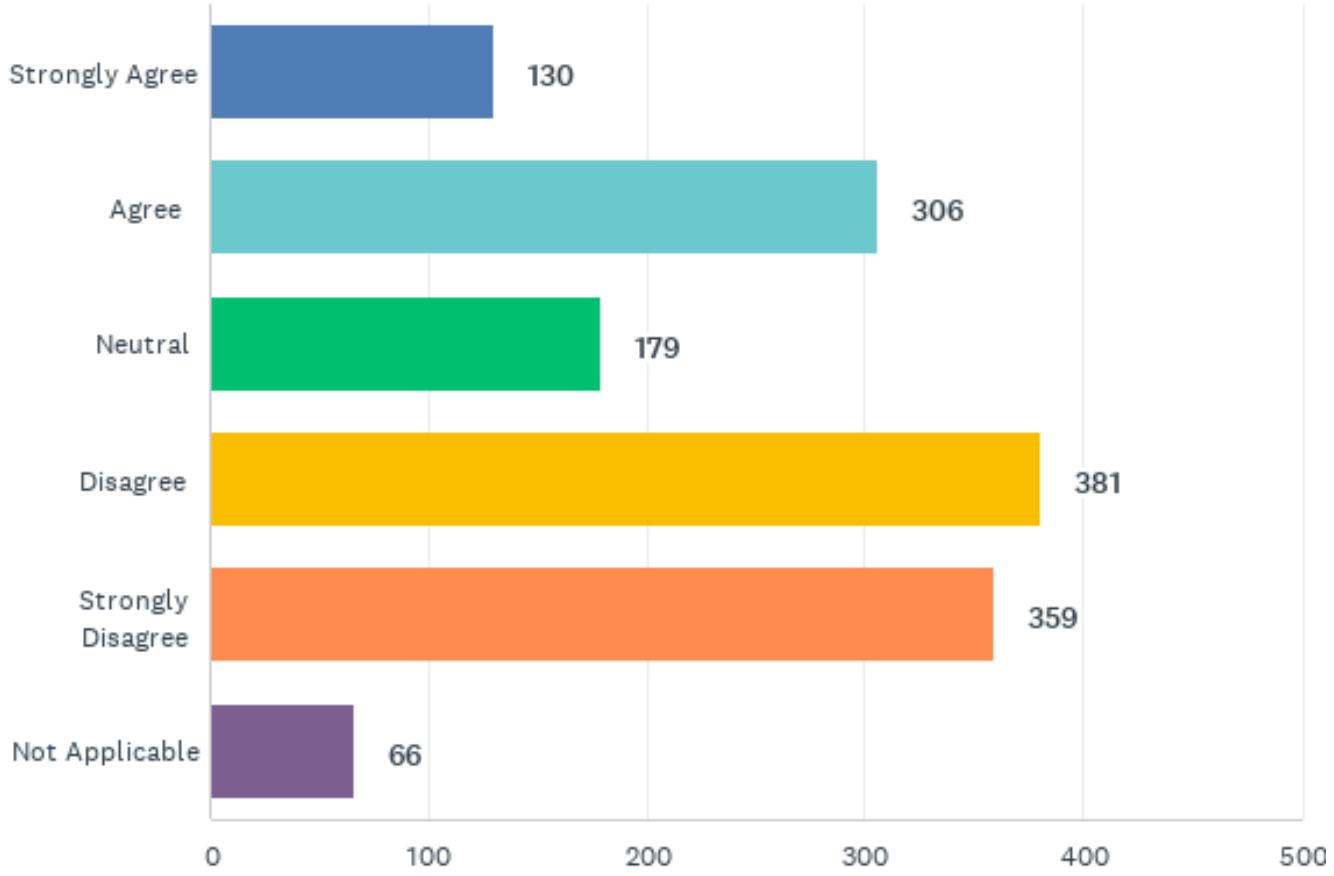


Q18: I feel that staffing in my practice environment is adequate and results in patients receiving their medication and consultation in a safe and timely manner.

Answered: 1,421 Skipped: 623



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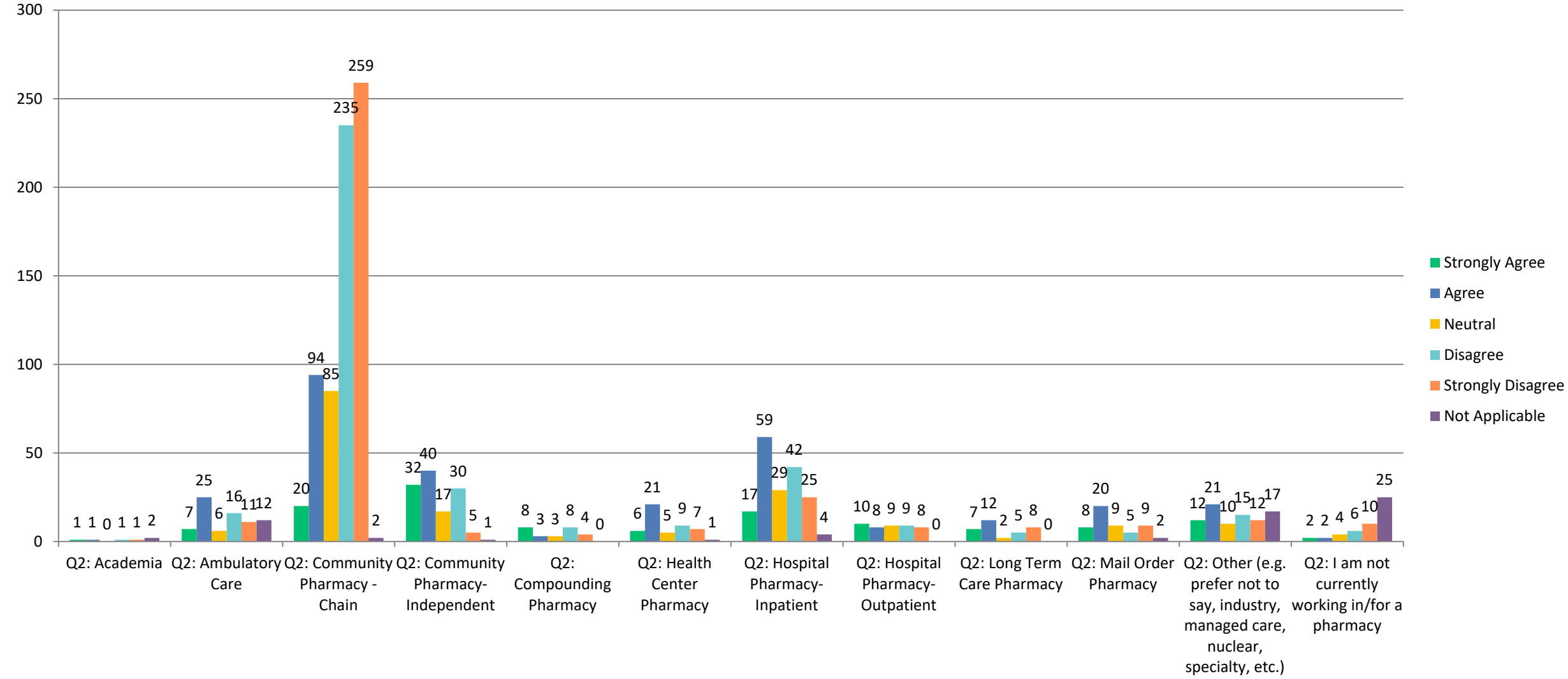
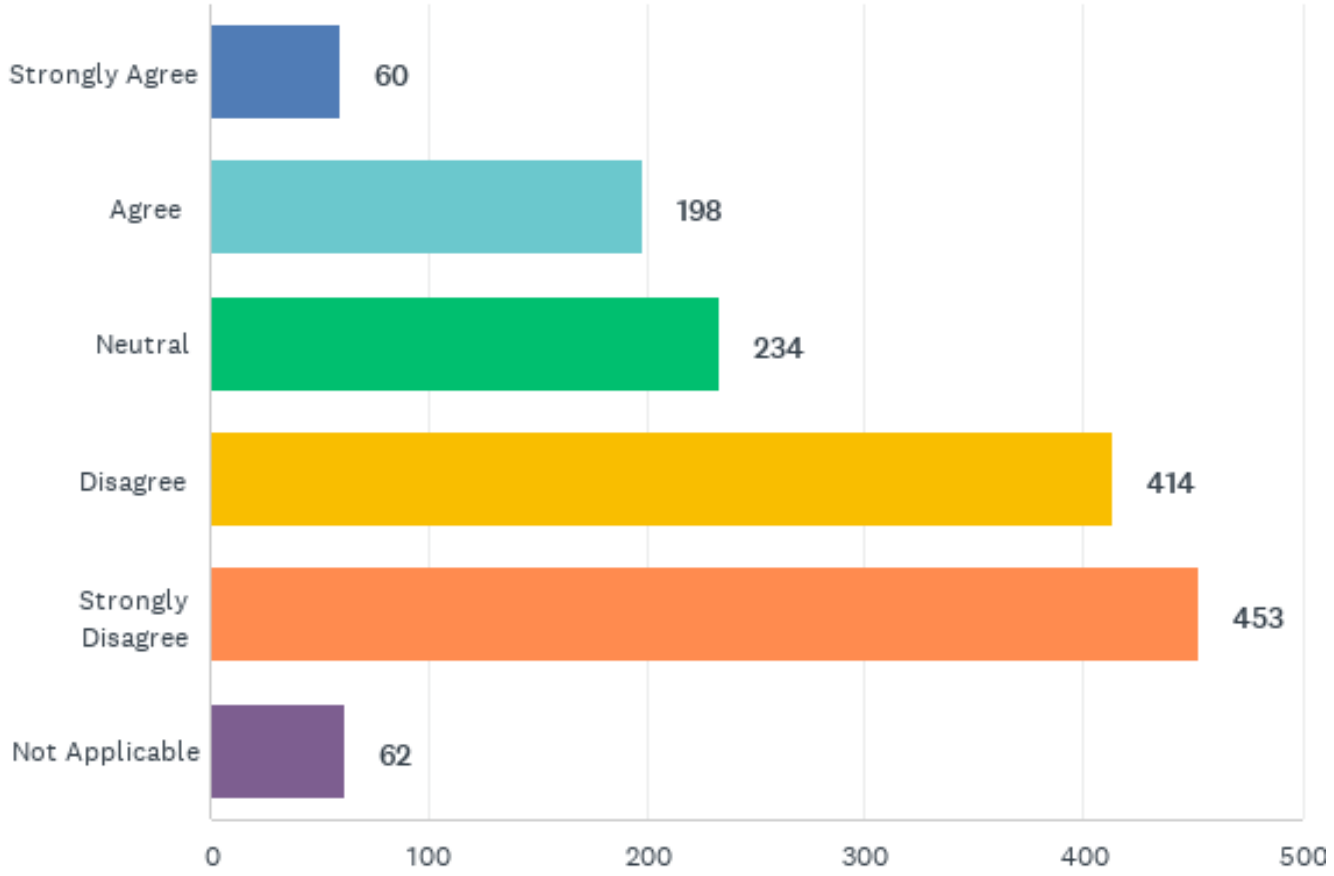


Q19: Job openings for my workplace are filled in a timely manner.

Answered: 1,421 Skipped: 623



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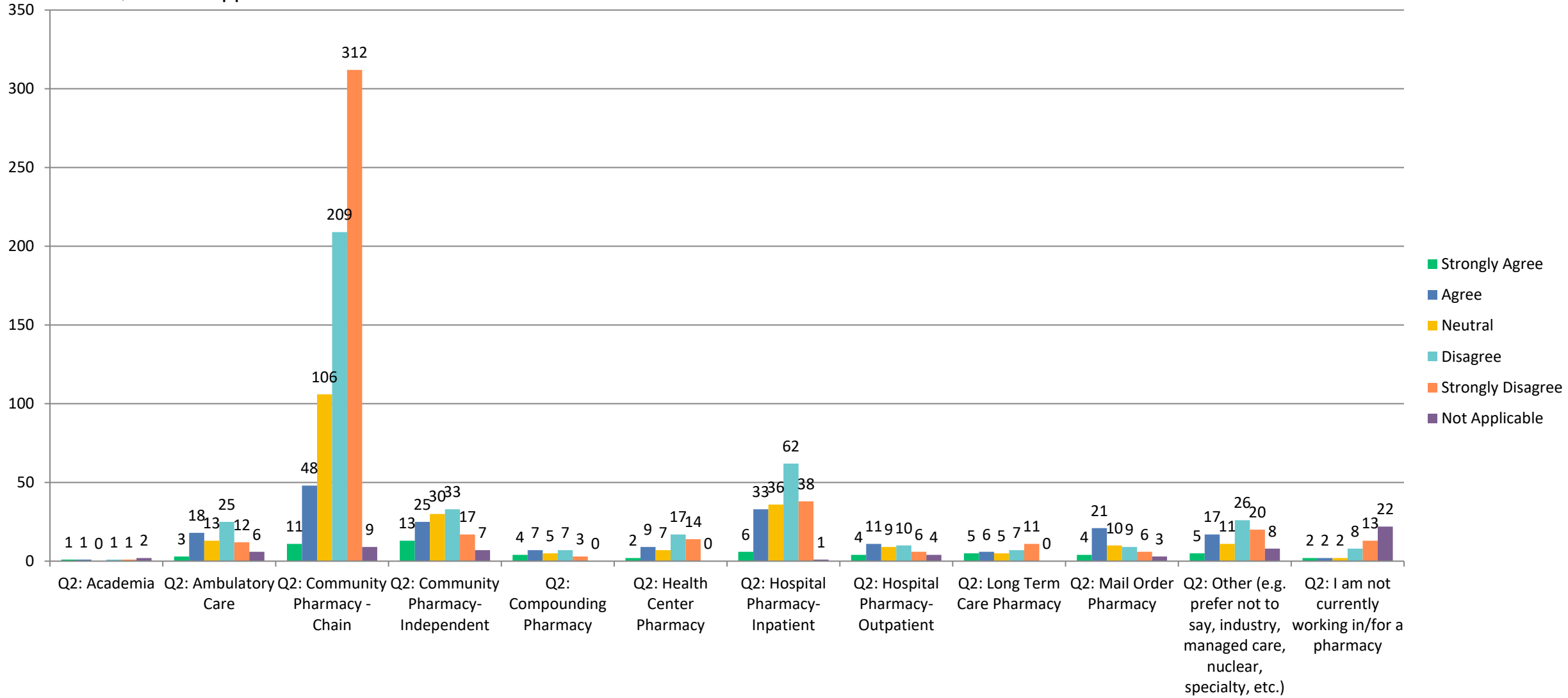
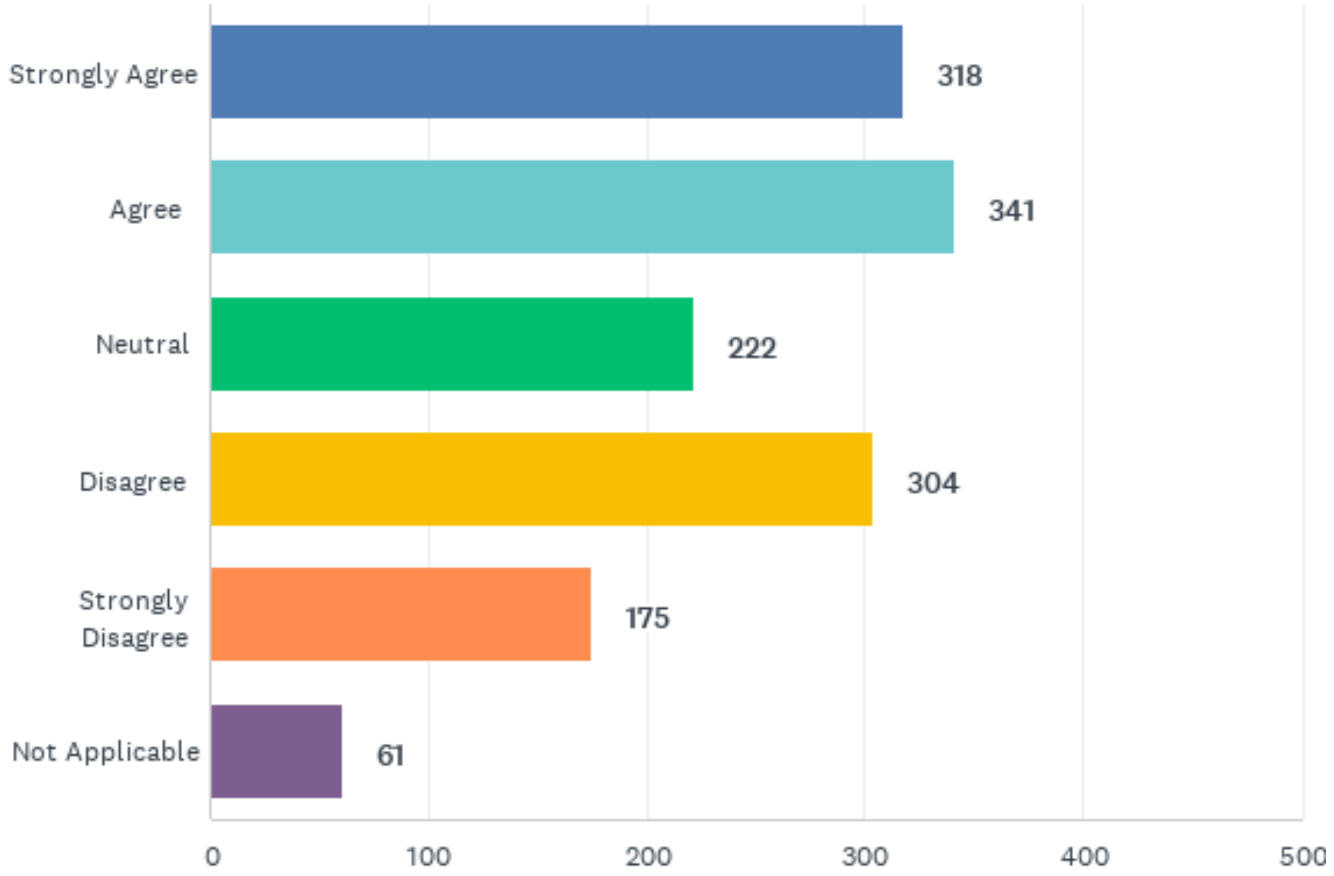
Answered: 1,421 Skipped: 623



Q20: I feel pressure by my employer or supervisor to meet standards or metrics that may interfere with safe and effective patient care.

Answered: 1,421 Skipped: 623



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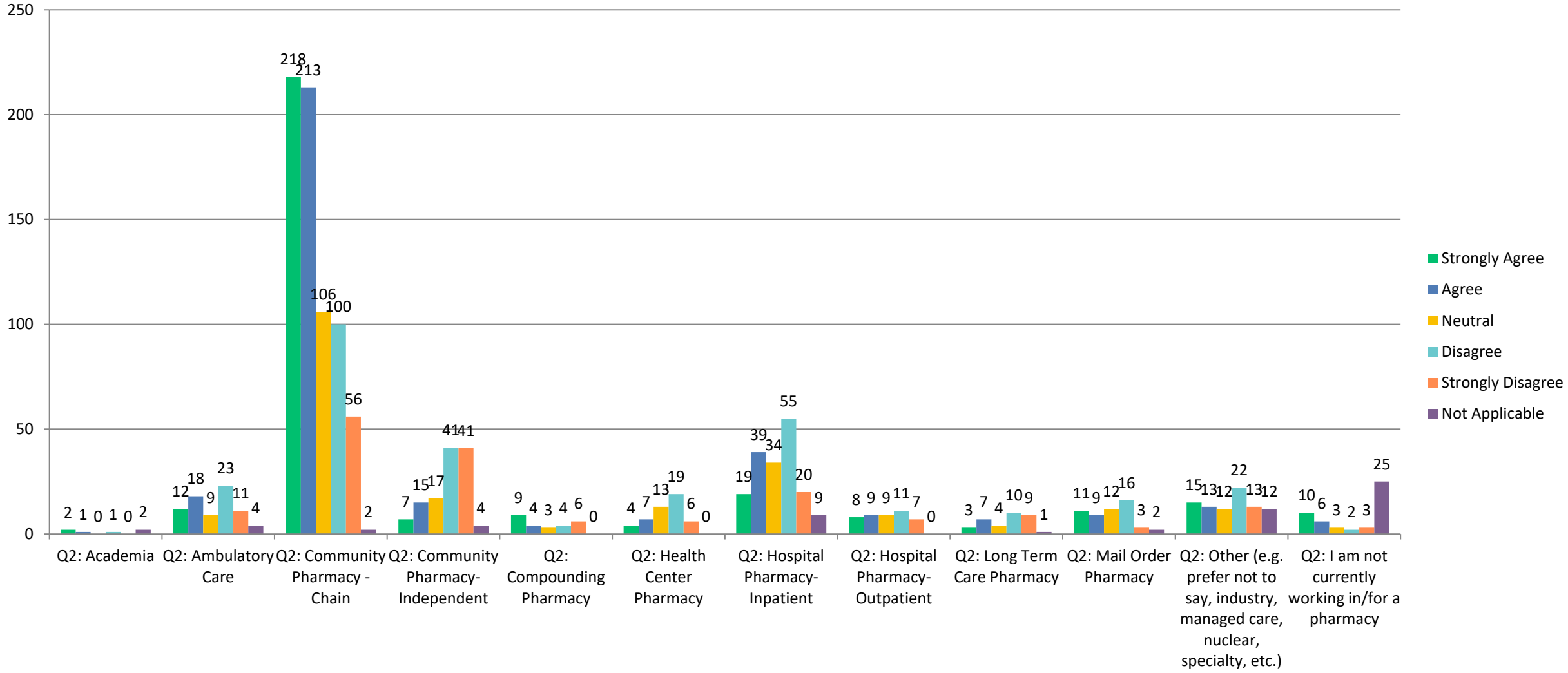
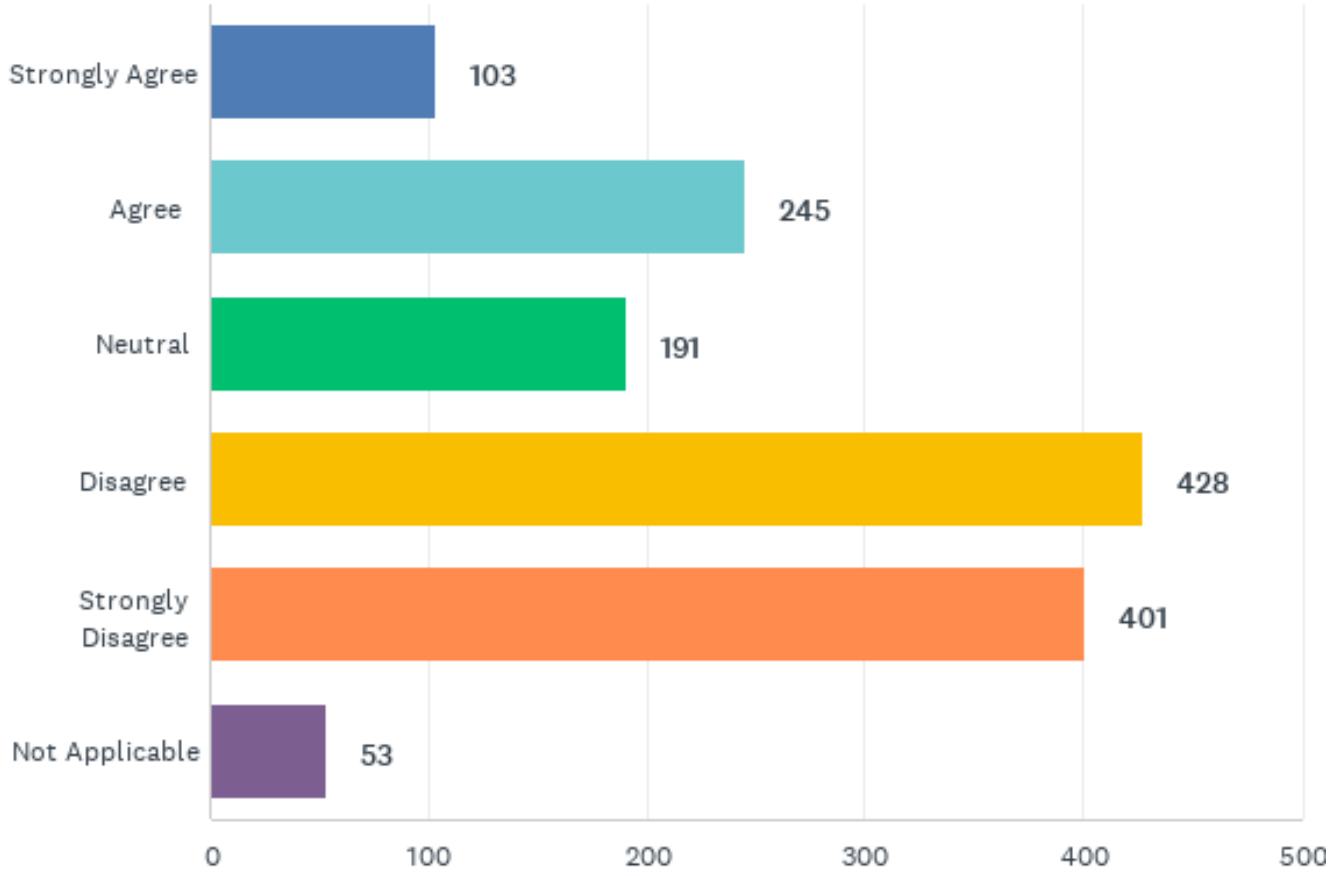
Answered: 1,421 Skipped: 623



Q21: I feel that there are sufficient staff to manage the pharmacy's workload that allows me to provide safe and effective patient care.

Answered: 1,421 Skipped: 623



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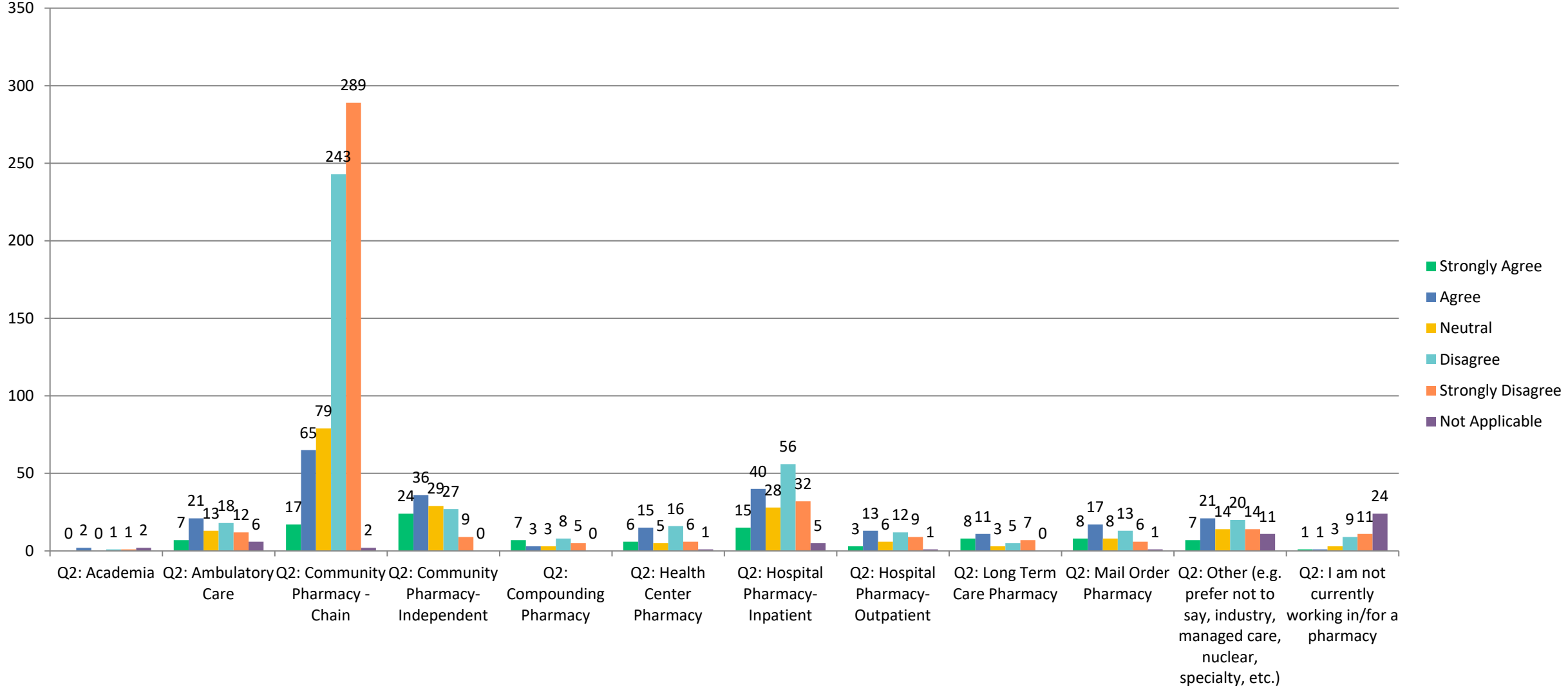
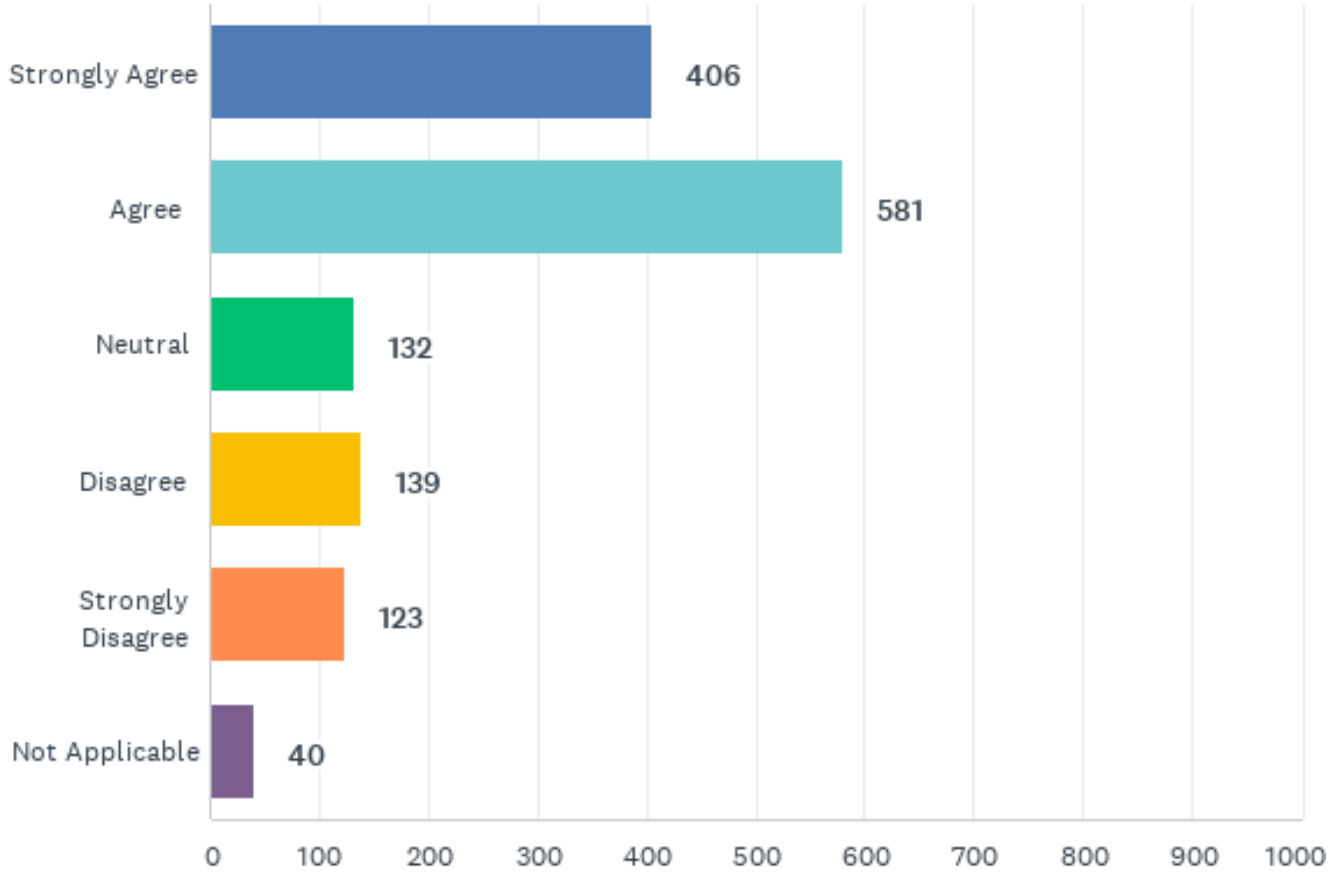


Q22: I am given the opportunity and am able to take meal breaks during the workday.

Answered: 1,421 Skipped: 623



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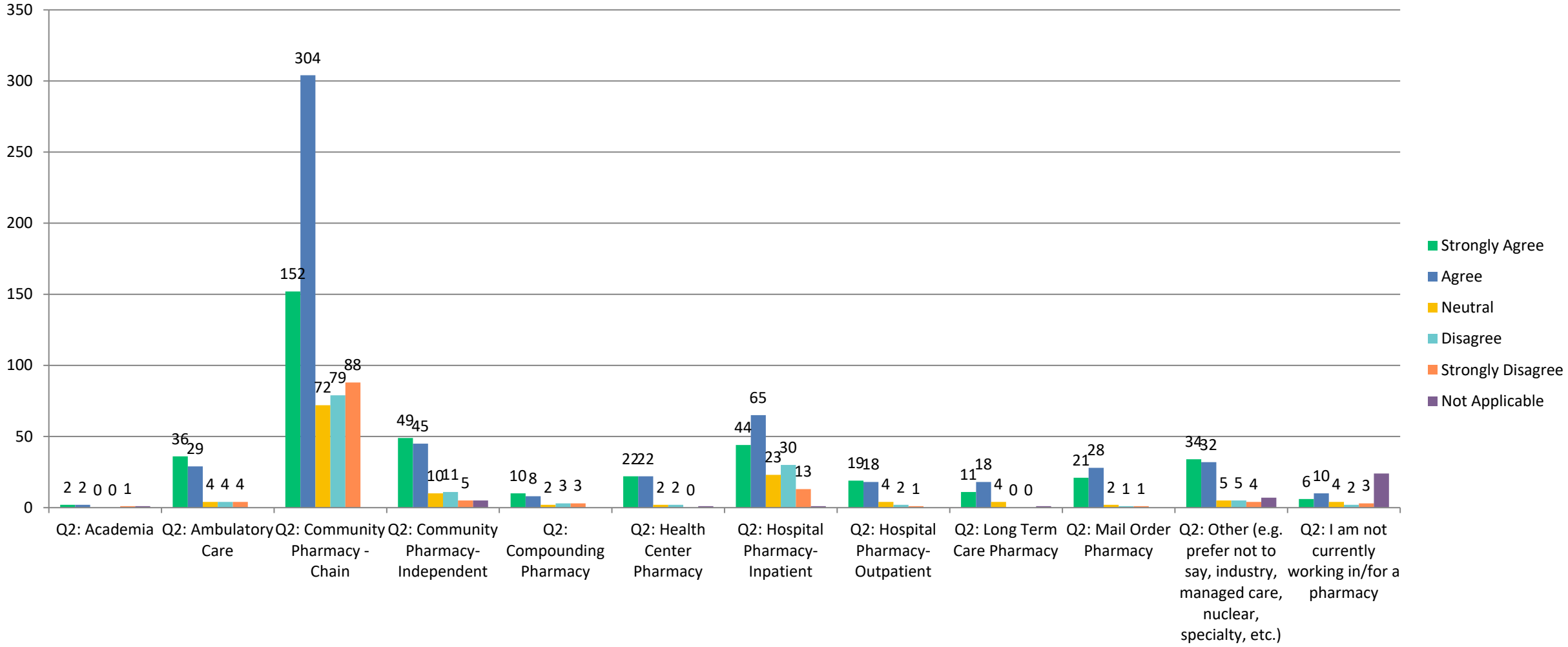
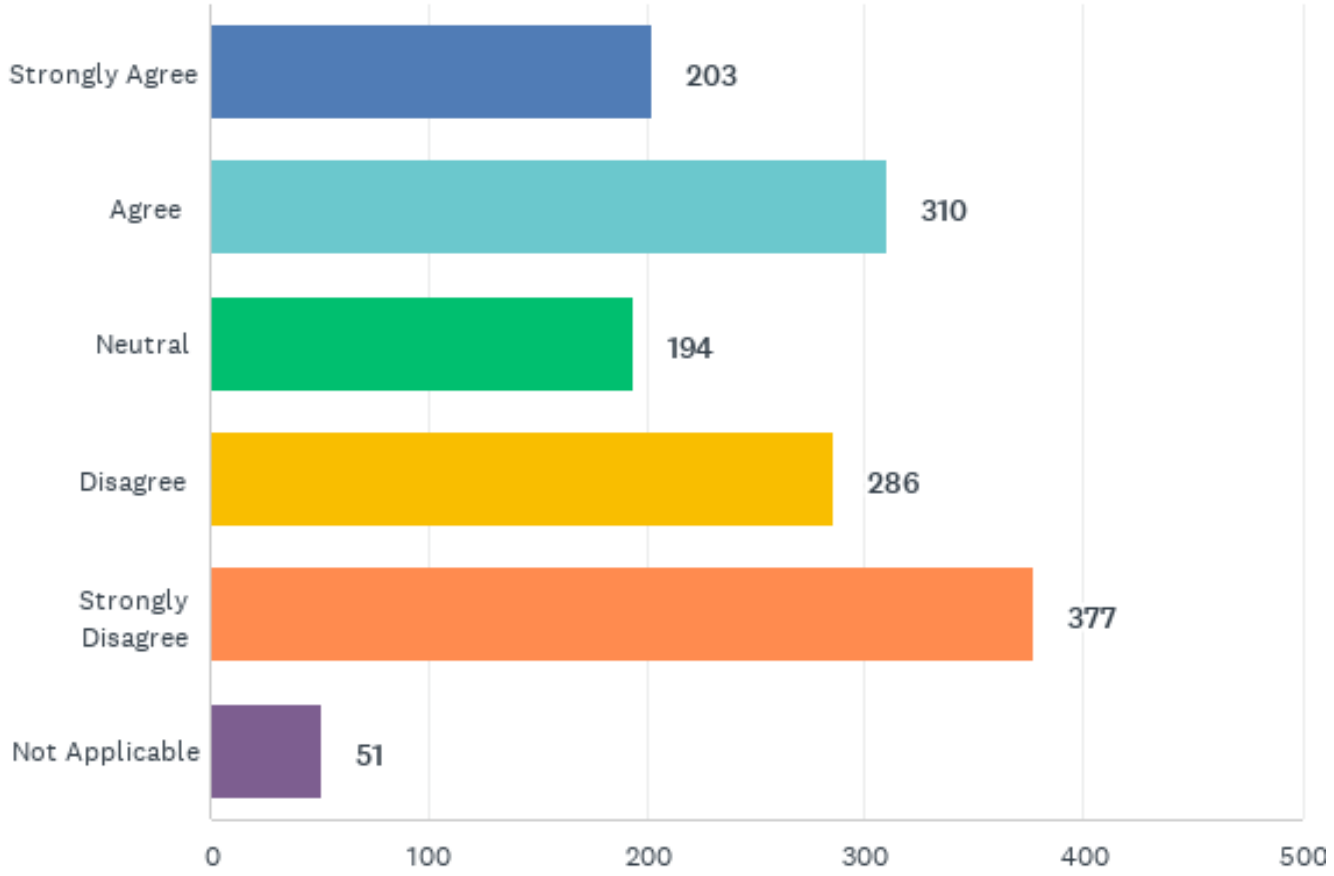
Answered: 1,421 Skipped: 623



Q23: I am given the opportunity and am able to take non-meal breaks throughout the workday.

Answered: 1,421 Skipped: 623



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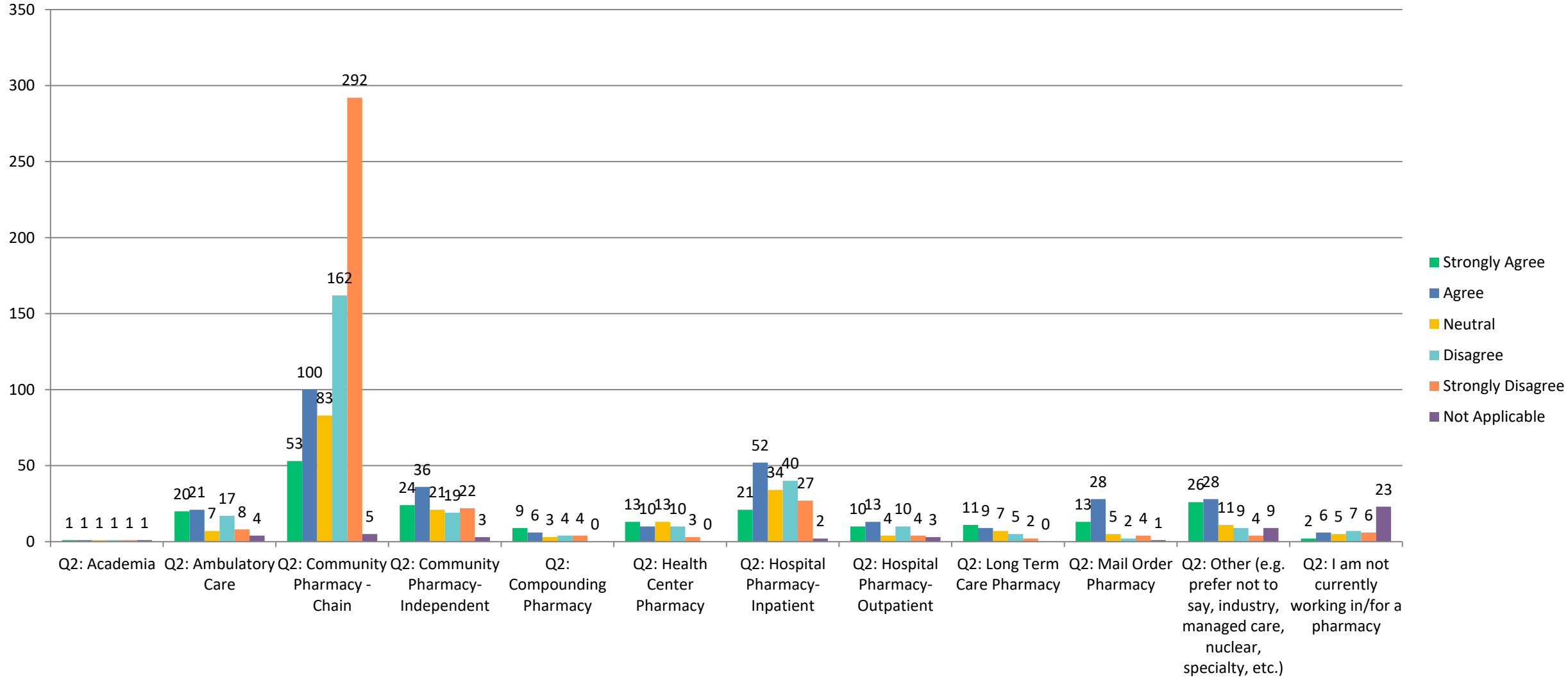
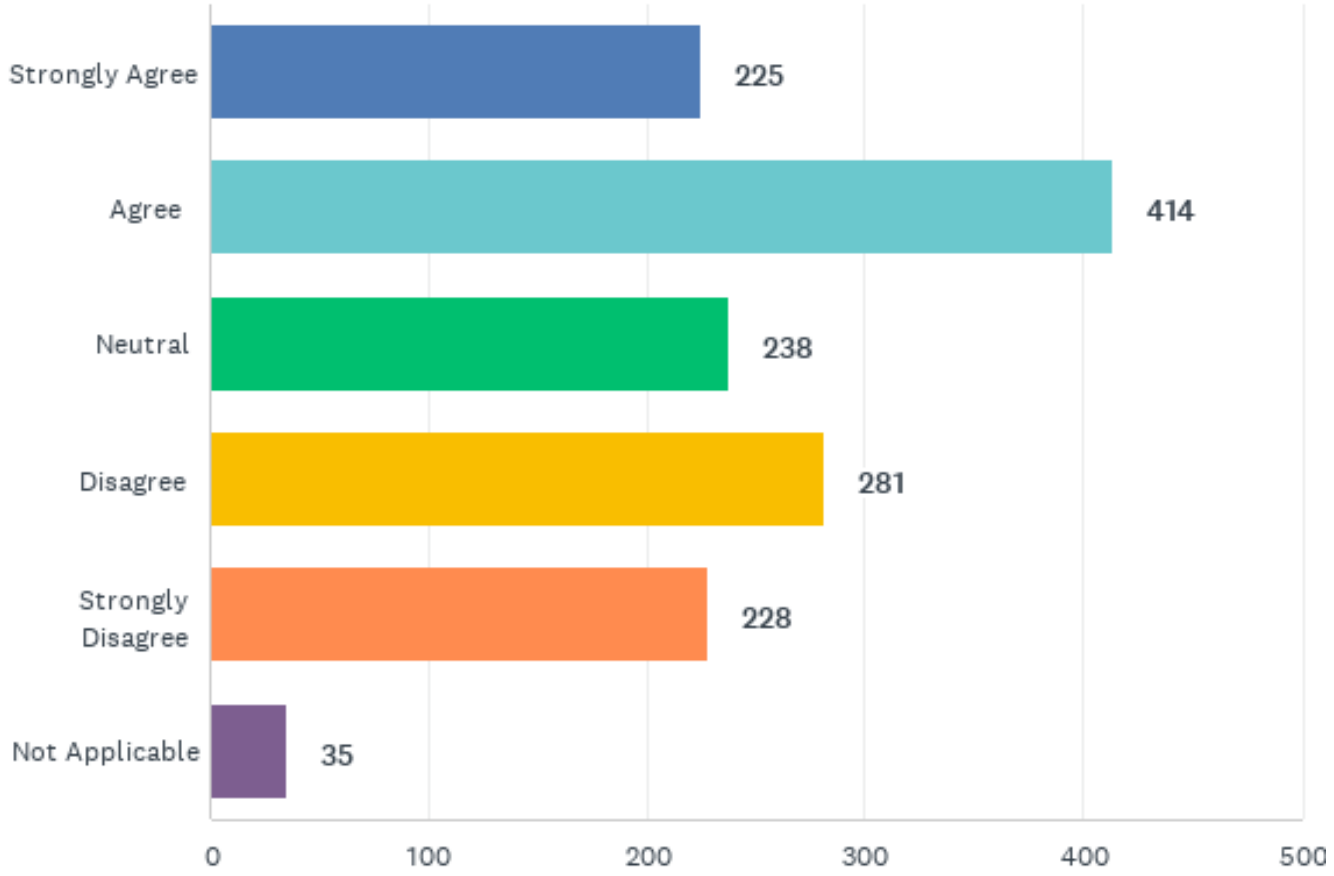
Answered: 1,421 Skipped: 623



Q24: I feel safe voicing any workload concerns to my employer.

Answered: 1,421 Skipped: 623



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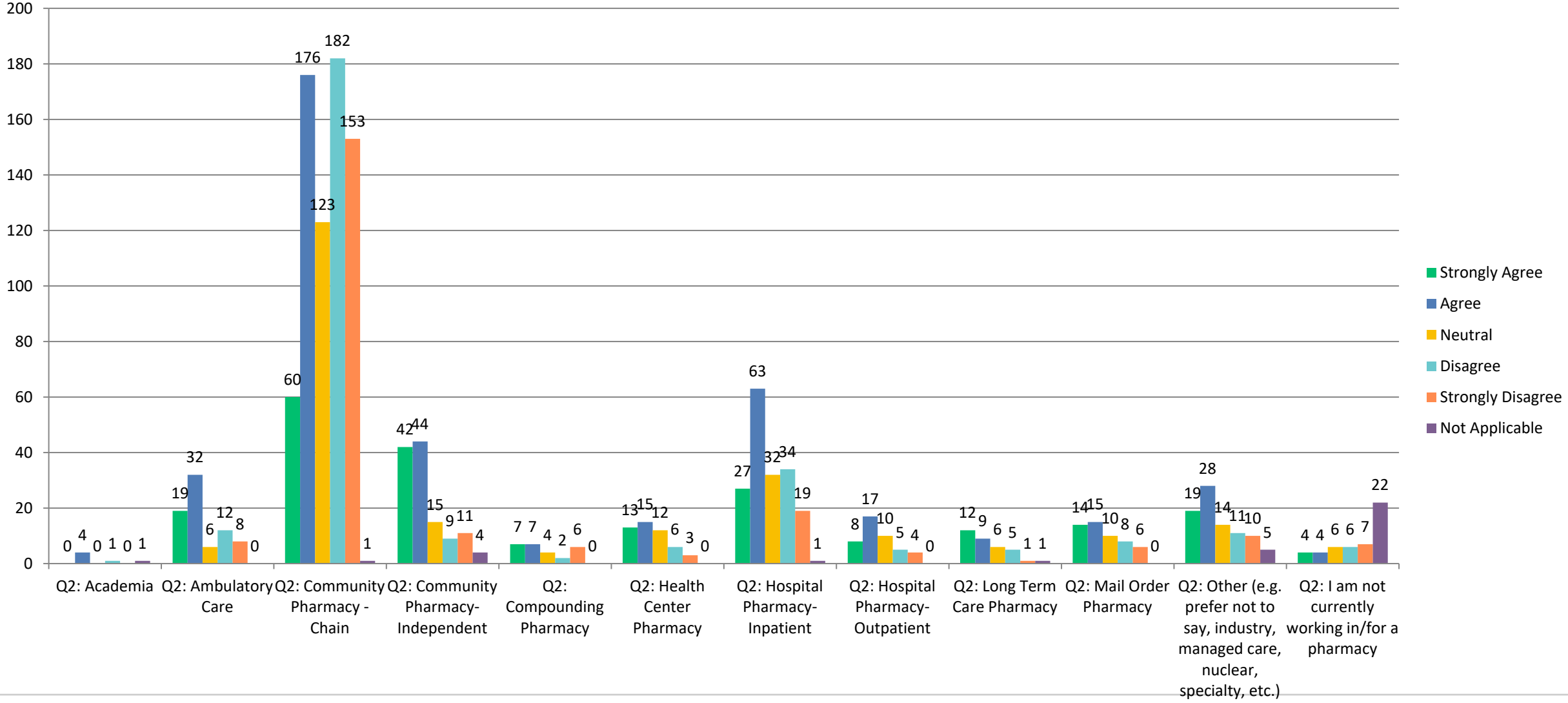
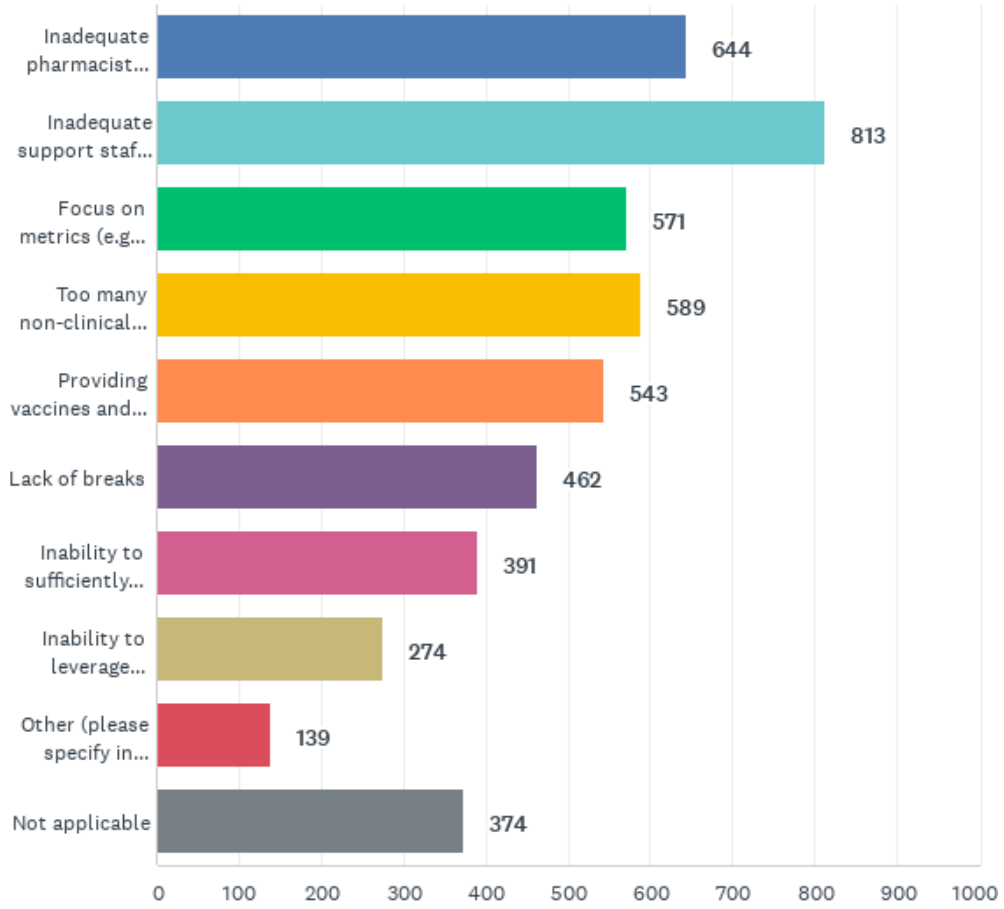


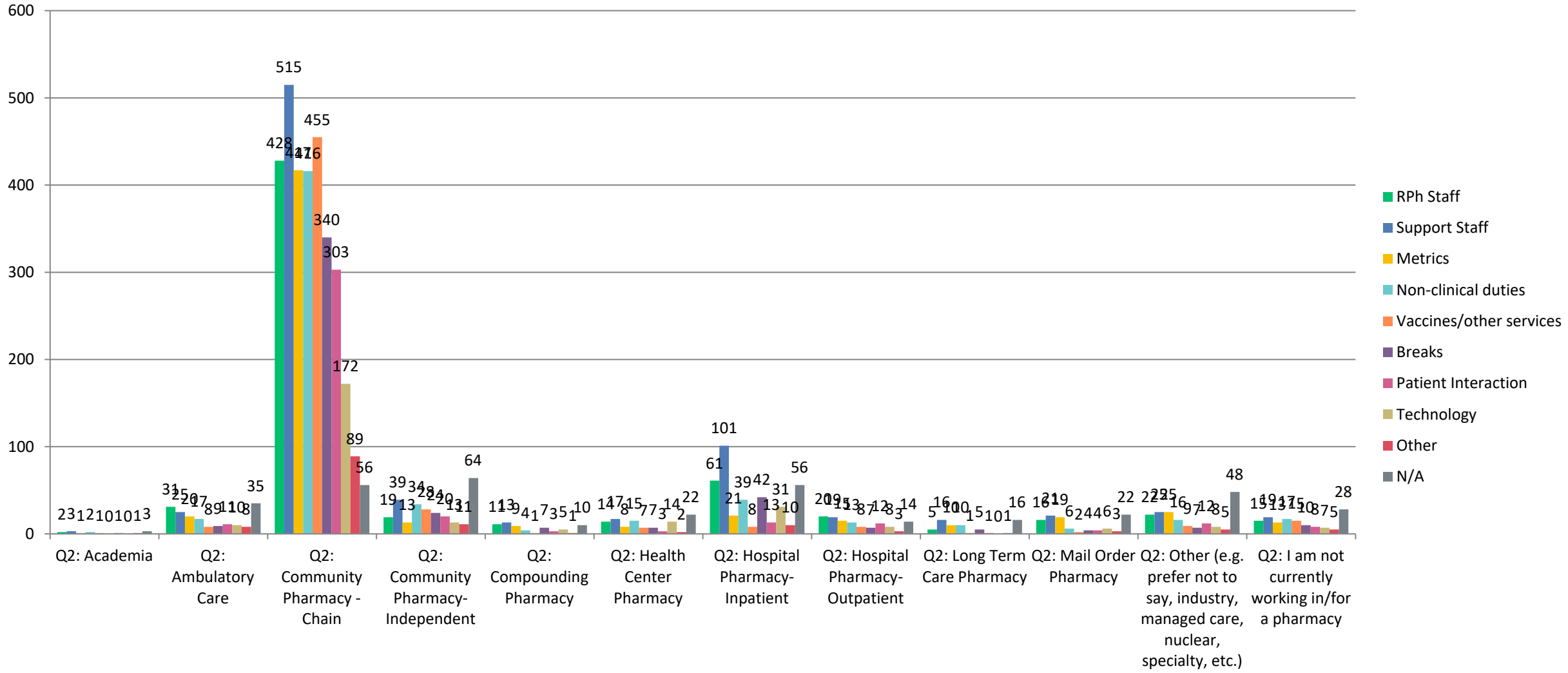
Q25: If you believe you are unable to practice or assist in the practice of pharmacy safely at your current practice setting, please select all that apply.

Answered: 1,421 Skipped: 623



Q25: If you believe you are unable to practice or assist in the practice of pharmacy safely at your current practice setting, please select all that apply.

Answered: 1,421 Skipped: 623



Q26 Optional - Please provide any additional comments on this topic that you think would be helpful to the Board.

Answered: 533 Skipped: 1,511

#	RESPONSES	DATE
1	with vaccines, testing and consultation etc, 1 pharmacist through out the whole day slows down our workflow	3/2/2022 8:39 PM
2	NA	3/2/2022 8:00 PM
3	We only have 1 pharmacist per day. There is no pharmacist overlap which causes the pharmacist to not be able to do job properly. Corporations keep cutting hours while expecting us to stay on top of everything with less hours and less techs. With increase in volume of tests/shots/vaccines with little staff, it makes it hard to properly take care of our patients when we also have 500+ scripts to catch up on	3/2/2022 6:32 PM
4	Adopt better rules for COPT so we can easily work from home. There is a shortage after all.	3/2/2022 4:56 PM
5	Severely underpaid technicians and interns, inaccurate text/call notifications to patients about the status of their prescriptions, unreasonable verified by promised times	3/2/2022 3:03 PM
6	Answering a survey is a low priority for so many of us pharmacists after working a dumpster fire every day. There is such a high turnover of staff and so many collapsed or stretched duties that when coupled with brand new travel agents in multiple disciplines, there is a deep-seated fear that we are days away from a serious medical error. Doing the job of 2-3 pharmacists and training up brand new RNs, CNAs, MDs on the phone on correct treatment/administration/timing/technique with little reprieve as administration sees us mostly as a cost and not a benefit is deeply discouraging.	3/2/2022 1:43 PM
7	We are having to hire non certified technicians who are in their first year becoming technicians. The seasoned technicians are stressed trying to train and still keep up with the demands. We live in a community with a community college. I'd like to see the chain pharmacies find a way to partnership for better training. Rather than hiring someone off the street let's find a way to help them get some in class training. I was able to do in person 6 weeks through a major retailer training program in Houston Instead, under the current climate, we're burning out potential really good candidates because everyone is overwhelmed .	3/2/2022 12:25 PM
8	As an employee at a chain pharmacy, Walgreens, there is a constant pressure that never gives up. Metrics about how fast phones need to be answered, an unreasonable number of vaccine and tests performed daily with little or no extra staff. I worked in a tier 5 pharmacy where we filled over a thousand prescriptions daily and on a Monday I was all by myself closing from 4pm to 10pm by myself. I had no other staff beside me other than pharmacy manager for 6 hours. No breaks, no dinner break, literally running from the front counter to the drive thru none stop. This went on for months. I asked the store manager and upper management for aid and they said and I quote, "tough beans" and "every where is short staffed". I could barely catch my breath because of my mask was soaked with sweat. I finally called in sick one Monday and they had to close the pharmacy and because I called out sick I received a written reprimand. Covid has push pharmacist and technicians to beyond the breaking point. Safety has been sacrificed because there isn't enough staff to complete daily tasks. Either they need to increase the staff or lower the daily extra tasks. I personally one day gave over 300 covid vaccines in a 12 hour shift because we were accepting walk ins for all vaccines. On that day I didn't get a single break. Things have to change and the pay should be equivalent to the work you do. It is not fair that someone that does a quarter of the work makes 5 cents less then you do. There should be a way to mandate more pay for more work. Safety in the chain pharmacy since covid started has been getting worse by the day and now almost marks 2 year of some the mandates being put in place. More meaningful mandates of compensation because of pain and suffering should be put on corporations who have made billions because of the pandemic. This is simply wrong and unsafe on so many levels. Patient safety and timeliness should be the pharmacies' number one priority and unfortunately in has not and does not look like it will change. Covid has changed pharmacies, corporation should	3/2/2022 10:21 AM

	enable them, not line their pockets with more money then we can imagine. This needs to change now or lives will be lost. Sincerely, Concerned Technician	
9	Something needs to change. Corporate people who are not pharmacists have not provided help or support to pharmacies. Working like this is not safe for patients. Corporate has done nothing to promote patient safety and continues to require increased Covid testing and vaccines while cutting technician hours. Open pharmacist positions have not been filled, even with sign-on bonuses. This means huge pharmacist workloads and is not safe for patients. Please do something to help the pharmacists and technicians who are left. We are the hardest workers and genuinely care about our patients.	3/2/2022 10:19 AM
10	I feel my employer is trying to address the staffing shortage we have, but we still don't have adequate staffing when employees are out sick or on vacation. We also have trouble taking breaks due to the lack of staffing. We frequently work late and skip breaks to avoid falling behind which creates a snowball effect on patient wait times. Providing clinical services (ie prescribing birth control, covid testing etc), in a retail setting with only one pharmacist on duty is extremely difficult and stretches the pharmacist and staff too thin	3/2/2022 10:02 AM
11	It is my opinion that everyone in the pharmacy is doing the best they can with a difficult situation.	3/2/2022 2:18 AM
12	Inadequate staffing at retail pharmacies impedes our ability to assist in compiling patients' best possible medication list. Pharmacies are unable to return requests for patient fill history in a timely fashion due to their overwhelming prescription and vaccine volume.	3/1/2022 11:51 PM
13	Retired-provide information on request	3/1/2022 9:12 PM
14	With the BiMart closure most stores meet their narcotic order thresholds early in the month… some store just 10 days into February. The DEA is extremely slow to correct for this and our customers are angry and inconvenienced. They are forced to pharmacy hop to fill their routine monthly prescriptions. This is very stressful for us to have to deal with on top of everything else.	3/1/2022 5:58 PM
15	Overly-punitive actions on behalf of the board of pharmacy	3/1/2022 9:04 AM
16	My answers to this survey are based on my current employment. I previously worked in a retail setting for a chain pharmacy and left due to adverse working conditions and the impact the job had on my mental health and work life balance. I hope this survey results in changes to make working environments better for others in the community setting.	3/1/2022 8:40 AM
17	more & more clinical services are being put into the pharmacy setting without a corresponding increase in time, space and labor need to adequately perform these services. pharmacists are also not being adequately compensated for these services in increased wages.	2/28/2022 7:27 AM
18	As pharmacists, we are continued to be expected to provide superior care and speedy transactions but are doing so with fewer and fewer labor resources and staff. We have been pressed into providing just a bottle with pills in it instead of providing a trusted and comprehensive service.	2/27/2022 9:14 PM
19	Feel like this survey is looking to place blame on employers rather than trying to understand the true barriers to patient care. Patients post Covid are increasingly more demanding, rude, and many mentally ill patients have gone without usual treatment over the past two years. Those factors, along with many exiting the workforce have created a completely nee environment. I personally work for a large chain pharmacy and feel I am taken care of as much as possible from my bosses. I feel that the BOP could support more by issuing licenses quicker for perspective technicians. It would also be helpful if the board handled complaints in a manner that is more supportive of RPHs. I actually operate in fear due to the Board, not of my employer.	2/27/2022 8:28 PM
20	Current turn around time for technician licenses has greatly impacted the ability to get technicians fully trained, as I often have to wait 6-8 weeks before a new employee is licensed. This makes it difficult to replace a technician when they leave.	2/27/2022 8:19 PM
21	Not having enough workspace and too many interruptions without enough help.	2/27/2022 3:56 PM
22	I recently watched an interview on PBS news from a few weeks ago. This pharmacist who was interviewed said it perfectly. He stated that "If you had a doctor working on a loved one or a family member performing surgery, would you want the phone ringing in the background while the doctor's providing surgery to your loved one? [Would] you want that doctor having	2/27/2022 3:51 PM

	questions thrown at them, having the drive-thru being wrung, having emails pop up at you, having customers waving at you? So, it's challenging." Please feel free to watch the short video from PBS news: https://youtu.be/4LvlqpGW_hQ Another individual, who, until the end of last year, was a pharmacy manager at a big drug chain, said, "I felt like I was an octopus pulled in eight different directions and one of them is having to give vaccines. Now I'm even concerned that I might give the wrong vaccine at the wrong time. The white coat that I would wear became so heavy to put on every day in the fear that I might be a danger to my patients instead of that safety net that they need." Another said "Having about 30 or 40 vaccines on top of your daily work with the same amount of people for my store was overwhelming," said one former chain pharmacist who now runs an independent drug store in Oklahoma City. "I felt that I was not living up to the oath that I took as a pharmacist to take care of my patients, but also to take care of my staff." ALL of these statements are so true to the word. While I don't currently practice in Oregon (I'm in NY), I continue to keep my Oregon pharmacist license up in case of moving back. I do wholeheartedly wish that the New York State board of Pharmacy was as progressive as the Oregon board of Pharmacy is and has been about patient safety and work conditions for pharmacists!! Thank you!	
23	We are feeling the effects on the inpatient side from over worked outpatient retail pharmacies. The work load is causing our patients to not get the medications they need to treat acute infections in a timely manner. It is unacceptable. Patients can't get their medications and are flooding the hospitals with unnecssary visits!!! Do something to help those poor retail pharmacist and technicians, before patients die!!	2/27/2022 3:47 PM
24	Unfortunately, PBM reimbursement adversely affects my ability to afford staff that would truly make me feel comfortable that we are providing superior pharmaceutical care	2/27/2022 1:43 PM
25	PBM regulation priority	2/27/2022 9:08 AM
26	My employer's top priority is volume and earnings. Work flow conditions and requests for help are ignored.	2/26/2022 4:28 PM
27	I did not feel that we had a safe practice environment with my employer mandated vaccines for all employees. This created a situation where we had to hire new pharmacists, new technicians as well as other new healthcare workers (ie MDs, and RNs') This was all occurring as we headed into a COVID-19 surge of patients. This was definitely not a safe working environment.	2/26/2022 4:19 PM
28	Employer pressure to do training tasks without time in the workforce metrics force staff to race through continuing training. Employer sends too much information from too many sources to follow in a manner to allow compliance with company programs puts strain on pharmacists.	2/26/2022 2:57 PM
29	The culmination of the afore mentioned issues in question 25 is a common place issue in many retail and independent pharmacies directly contributing to staffing shortages and degredation in patient care. The retail sphere has a profit motive that far out weighs it's concern for patient safety and that sentiment is trained into regional "leaders" by their corporation and its profit only interest.	2/26/2022 2:23 PM
30	Priority is always metrics & false narrative to satisfy corporate meddling.	2/26/2022 11:20 AM
31	Due to lack of time and staffing, it is difficult to consult patients in any meaningful way	2/26/2022 10:58 AM
32	There are too many things being added to the pharmacy staffs to do list including testing, immunizations, and metrics. Patient safety is being sacrificed in order to do all of the extra things with less staff than we had before everything was added. Patients are not getting their medication in a timely manner, and in order to keep up with the workload employees are working outside of their schedule including before and after opening and closing. My store is now cutting technician hours so we will get in trouble for going over the budgeted hours but we also get in trouble for not keeping up with the workload when we are understaffed.	2/26/2022 9:33 AM
33	Currently taking a break from pharmacy, looking for employment other than as a technician after 20 years. Independent pharmacies that focus on patient care/customer service can no longer afford to operate within the current system. The large chain pharmacies do not seem to focus on patient care and definitely not on employee well being, both of which seem like a safety issue.	2/26/2022 9:30 AM
34	The main problem is the staffing hours are all over the place. There isn't consistency to be able to write a schedule. Out corporate tells us to hire staff then cuts hours right after.	2/26/2022 6:40 AM
35	Our pharmacy is short staffed and has been for about 9 months. Our script count has	2/26/2022 5:45 AM

	increased due to Bi-Mart closing and Walgreens taking over. There is no extra help to be had within our company and we are struggling. We are frazzled and do not feel we can provide good patient care for our customers. Some days we are hundreds behind because we do not have adequate staffing. Because of this, we can't spend time answering our phones and really helping customers. It's very frustrating.	
36	treat hospitals and community the same. whole floors are closed in hospitals because of lack of staff.	2/25/2022 3:25 PM
37	We really need to figure out how to recruit and retain high quality candidates to the pharmacy technician industry.	2/25/2022 11:42 AM
38	With multiple pharmacy shut downs in my area it has been difficult to get the patient their medication when it is billed to another pharmacy. Also, I have never been threatened by customer as I have in the last 6 months. People verbally and legally intimidating me and my staff. I have had customers threaten to run over employees in the drive thru, people banging on our plexiglass. This is the least safe I have ever felt in my 15+ years of pharmacy	2/25/2022 8:16 AM
39	In order to address patient safety pharmacies need to be reimbursed fairly for their services even if it is "just" and accurately filled rx screened for drug interactions and appropriateness. Pharmacies should be considered a part of our emergency response network. We supply much needed services during events that disrupt supply chain issues. Independent pharmacies have more ability to located backordered product quickly. We take up slack from chains unable to address the needs of more complex patients which take more time. For example finding products without certain dyes for patients with color additive allergies. While this takes a great deal of labor dollars the resulting order may be less profitable. Overtime as we see with BiMart these individualized activities result in lower profits and potential continued pharmacy closure. Less access to hight quality pharmacy care can result in overall increased healthcare costs. I am a former BiMart employee. I take my position very seriously. I treat every patient as I would want to be treated. My actions resulted in lower profit margins in my work because that was not my goal. My goal is to provide patient centered healthcare. I am now considering leaving the field if I am able to get retrained. I hope to enter a career in social work. My salary will decrease but I hope to truely be able to help my community without the pressure of profit margins.	2/25/2022 7:02 AM
40	I have a few suggestions. 1st, Pharmacy should close down for half an hour lunch break each day. 2nd, Each shift should not be more than 8 hours. 3nd, if it possible, all prescriptions should be sent in electronically. That way it would save us a lot of time and make our work flow become more efficient.	2/24/2022 11:00 PM
41	I think it would be helpful for the OBOP of pharmacy to examine what a safe pharmacist to patient ratio would be for inpatient clinical pharmacists and set standards for hospitals to follow	2/24/2022 9:36 PM
42	Once we get behind due to staffing ,it creates more customer calls, which puts entering orders behind which causes more calls	2/24/2022 9:07 PM
43	Understaffed.	2/24/2022 8:18 PM
44	Masks! Since we do not have direct physical contact with patients I don't feel we should be wearing masks when the mandate lifts. The drop off window is covered in plexiglass, the counsel window is covered in plexiglass, the registers are covered in plexiglass, we're basically in a box now surrounded by, plexiglass. What little interaction we do have with patients is no more than a few minutes behind, plexiglass.	2/24/2022 7:40 PM
45	We work with a skeleton crew on weekends. Its over whelming most weekends for 2 techs and 2 pharmacists.	2/24/2022 7:26 PM
46	Surveys are one thing, but nothing ever happens. Unless there is enforcement forcing the pharmacy license holder responsible, the chains will just burn people out and sign up someone to be the fall guy. Chains have control over payroll, not PIC. It	2/24/2022 7:24 PM
47	Our pharmacy is under-staffed, with no full-time pharmacist and less-than-adequate training for technicians.	2/24/2022 6:41 PM
48	At my location I work 12hr/shift 2-3 day straight, which is very tiring and towards the end of my shift I feel exhausted which compromises patient's safety. All my requests to have shorter shifts and have some overlap between pharmacists are denied. My staff pharmacist showed symptoms at work and had a positive COVID test next day. Even though I was working with	2/24/2022 6:20 PM

	her that day, and according to CDC guidelines I fell into category of an exposure, my superiors forced me to come to work stating that pharmacy had to be open. I also had two call-outs that day and had to work by myself with no tech support. When I expressed my concerns that it is not safe for me to be in a pharmacy for a 10 hour shift alone and I didn't feel comfortable doing that, I was told to open pharmacy and wait for them to find some coverage; it wasn't done. Due to lack of support I have to work lots of overtime (50-60hrs/week) which causes a lot of stress to the point when I had nervous breakdown in a pharmacy when dealing with a difficult patient. Only after I had such incident I finally got some help. I hear a lot of promises from higher-ups and little actual support when it comes to staffing or training. When hired I was promised after 2 weeks of general training to have 3 months of additional training as PIC and to be assigned to a mentoring PIC. None of this was done. Being constantly understaffed, overstressed, and overworked has affect of my health and mental well-being. I believe there should be a law that puts restrictions on employers, and regulates the amount of work that a single pharmacist can do alone.	
49	There needs to be a max on how many tranfer pt can go to a pharmacy or how man pt we can have at one small pharmacy	2/24/2022 4:17 PM
50	Long work hours on top of a large workload is further taxing and increases the risk of mental fatigue which could result in errors. Creating rules regarding max hours per shift (such as 10 hour maximum) may be a useful tool in increasing patient safety.	2/24/2022 4:15 PM
51	I think after probation period with the board is up the board record should be expunged. Then maybe there wouldn't be so many staffing issues. I've been trying to find a new job for 3 years but because of my record nobody will hire me. My offense I feel was minor compared to other I know about so I can only imagine what others are going through finding work.	2/24/2022 2:39 PM
52	i feel my company gives us the resources to hire appropriately but staff is just unavailable also extending ditiea to include curbside/mailout and walkup vaccinations have been overwhelming the staff we have. we have been fortunate to have 1/3 of our ataff willing to take on extra hours	2/24/2022 1:50 PM
53	Change the Oregon law on consultation, other states do not require the pharmacist to use time unnecessarily because a prescription is marked “new.” If the patient says they have no questions because the doctor spoke with the them about the prescription or it’s a refill the pharmacist should not have to sign it out to them each time on a log. Allow certified pharmacy technicians to take in new prescriptions or transfers verbally over the phone as some states allow to save the workload on the pharmacist. Also allow technicians to give all immunizations, not just COVID and flu.	2/24/2022 1:45 PM
54	Walgreens in[redacted] something needs to change	2/24/2022 1:30 PM
55	It’s a tough environment to both give shots AND provide safe/timely outpatient prescriptions	2/24/2022 1:16 PM
56	NA	2/24/2022 12:41 PM
57	Staffing shortages in a retail setting are extreme. Some locations of my chain have little to no technicians left. The salary for technicians is drastically to low for the amount of stress and work that is expected. As the cost of living increases and our paychecks remain the same while the work load increases is making the shortage worse. Long time well trained technicians are leaving and new hires are not staying long enough to become well trained. Implementing central fill, counting machines, and new clinical plans that should make things more efficient are actually doing the opposite because there is no time train anyone properly on how these systems need to be managed to optimize them. Without a significant wage increases for technicians and proper time to train I don’t think this problem will resolve. The only reason I am still at my job is because I am able to have the flexibility to work part time and still receive benefits.	2/24/2022 11:31 AM
58	The chain that I work with has multiple stores without any tech. I find myself doing all the duties by myself. I try my best to take my time and make sure my patients are safe but there’s backlash from stores saying they fall behind. The focus is too much on phone calls and things that I cannot do without harming my patients so I choose my patients and make sure they are safe. I work 12+ hours without any lunch or other breaks throughout the day. Sometimes it is hard to even use the restroom because that would mean closing the pharmacy since the RPh is the only person working.	2/24/2022 11:30 AM
59	Why are we monitoring Sudafed sales in Oregon when it is legal to have small amounts of hard street drug on you ie. meth? This is the biggest waste of my time…adding pointless regulations like this just take away from me performing my job as a pharmacist.	2/24/2022 11:25 AM

60	Inadequate competitive options for retention of help and on boarding new help with sufficient ability	2/24/2022 11:20 AM
61	I feel that I can safely provide quality patient care, but I often work many unpaid extra hours and sacrifice family time to do so.	2/24/2022 10:52 AM
62	I really think the biggest issue with my company is the lack of adequate technician staffing whether that's float staff or store staff. At my site, my strong technician quit and we have had the position remain open since then so far. I think the biggest issue with technicians at our company is the lack of appropriate training. We have no special extra hours dedicated to training new technicians. They are supposed to do 'on-the-job' training in the pharmacy and so you can imagine how this does not work effectively.	2/24/2022 10:40 AM
63	Every pharmacy that I have ever worked in, has trouble keeping adequate staffing and has completely unrealistic expectation from their employees. This was BEFORE Covid! Now, with increased cleaning expectations, constant sick calls and ever increasing patient load, it’s really scary.	2/24/2022 10:24 AM
64	My employer consistently governs with a "do more with less" strategy. In the same month they will increase responsibilities and duties while simultaneously cutting hours. We are being heavily communicated to (not open communication, but one way only) about meeting goals and metrics, and those goals are constantly increasing. To say "here is an extra duty" but to avoid providing additional resources to accomplish the additional workload is asinine. Sometimes it feels like it is a grand experiment to see how far they can push their employees before they snap. One of the most frustrating corporate ideas is the gift cards they would like us to give out at every opportunity. Years ago the Oregon BOP passed rules forbidding the act of incentivizing transfers and around the same time tried to adopt rules to limit "work place distractions." This was commendable and in the interest of patient safety, but while my employer follows the letter of the law they completely disregard the spirit of the law. We are not allowed to offer incentives to transfer, but everyone understands the loophole and instead will have their doctor send a new prescription to our pharmacy so that they qualify. If it were a one time deal it would be problematic enough, but they have structured it so that people can ask for giftcards at every transaction, requiring additional steps from pharmacy staff, more documentation, and more time that is desperately needed to accomplish the workload we did not have the time to complete in the first place. The gift card situation is a HUGE distraction in the pharmacy that has nothing to do with patient care and robs us of valuable time. We have voiced repeated concerns to management about the situation but those concerns fall on deaf ears. Unless the board prohibits giftcards from being issued by the pharmacy I feel this situation will only get worse.	2/24/2022 10:21 AM
65	During the worst of Covid the corporation I work for had me (as the only pharmacist on staff) doing tests every 15-30 minutes with multiple vaccinations every hour plus trying to verify all scripts for the day. The pharmacy I work at has been short staffed for over a year with our 2 technicians working 60+ hour weeks. At one point we were 21 days behind in our work queue because corporate was, and still is, more interested in vaccinations and testing than getting prescriptions out to our patients. Thankfully, our new PDM pushed for reduced hours, testing and vaccinations so we are finally caught up. But now corporate is breathing down her neck about all the overtime being paid for in her district because we still don’t have sufficient staff to cover the hours we are open.	2/24/2022 10:06 AM
66	Main issue is understaffed for the work load	2/24/2022 9:50 AM
67	I work in home infusion pharmacy. The lack of understanding from the board of pharmacy and others of how our setting functions is detrimental when rules are put in place. We follow both retail and compounding rules. Retail rules put in place have made our setting have made so we lack support that is needed. We need more staffing. We also need a way to bill for clinical services that are provided, so that we are able to increase staffing. Otherwise we could go under. The board of pharmacy has overstepped in making rules without considering different pharmacy workflows.	2/24/2022 9:05 AM
68	It doesn't feel like the BOP is here to assist or protect pharmacists. It is as if there are designed to police pharmacy practice and often decline to answer questions about the law and suggest RPHs consult an attorney rather than help us understand and do things correctly. We should be on the SAME team with the SAME goals of patient care and safety but that is not the impression given. While the the primary focus of the BOP should be to protect patients if they also looked out for pharmacists they would be more successful in that mission.	2/24/2022 8:12 AM

69	I have been working for Safeway since December 2021 and in that short time they care more about vaccines and covid tests. Safeway just signed up to give covid test's and we don't have time to do those and be able to fill prescriptions. We don't have 2 pharmacist everyday, so doing those tests are going to cause us to fall behind. We also need more cashiers, but Safeway says we don't do enough prescriptions per day to have 2 fulltime cashiers. So what happens is a technician ends up being a cashier for the day instead of processing prescriptions. I would like to see better staffing in pharmacies so that way customers can be helped quickly and efficiently.	2/24/2022 7:24 AM
70	most concerns are from non pharmacy duties vaccinatons (primarily covid), birth control, adherence, insurance billing etc. These duties require lots of tech time in data input which takes away from other duties filling, input etc. This causes delays in regular patients receiving their prescriptions which causes people to get hostile which adds more stress on staff which leads to more mistakes. just a vicious cycle	2/24/2022 7:17 AM
71	Lack of support staff and other techs at the site is counter productive. A corporation should not be able to pull covering techs from a site to go elsewhere when said site is down a vital staff member.	2/24/2022 7:00 AM
72	A well staffed oharm. Cashier +	2/24/2022 12:30 AM
73	Pharmacists are required to staff as technicians in order to make up for short staffing in those departments while keeping up with our own work. Being constantly pulled away is very distracting and increases the potential for errors. Mandatory overtime ranges from 1-4 hours per night causing significant staff burnout and exhaustion. Staff is asked to come in earlier, but is still staying way past shift. Management says there is, “No good solution.” to our staffing issues which has been going on for months.	2/23/2022 11:26 PM
74	Too many sick calls and not enough people that can come work on short notice	2/23/2022 11:08 PM
75	I feel that it is completely unfair that pharmacists have nobody backing them for their complaints in the situation’s. It feels as though the parent companies are not liable, responsible in anyway and have no repercussions for providing an unsafe work environment.	2/23/2022 10:51 PM
76	This is site specific to my current location. Other stores in my same chain are struggling a lot. I feel lucky we have managed the workload as a cohesive team and weathered the storm that is pharmacy very well. This has more to do with my technicians and staff pharmacist and me advocating heavily than offers for help/mitigation of workload from my employer. I will say that overtime has been paid for pharmacists working more than 40 hours, which is not normally the case. Labor budgets have not been held to, we’ve been able to use whatever hours we need to get the job done. This is also not the case with other chains.	2/23/2022 10:38 PM
77	Low paid and inadequate staffing led to many technicians quitting or calling out sick daily. The working environment is toxic with frustrated staffs and customers. Everyone is exhausted.	2/23/2022 10:27 PM
78	Personnel shortages, extra work load caused by the pandemic (vaccines, boosters, testing, etc), a major wildfire, the closing of BiMart, impossibly difficult patient expectations, etc have greatly impacted workload and safety of retail pharmacy in our area for the past 2+ years. I do, however, believe my employer has tried to address the issues as soon as they are aware of a problem. They have dropped any emphasis on metrics, tried everything possible to hire staff, even formed a team to help catch up work backlogs during dark hours. There just are not enough resources to do all of the things. In particular, so many experienced staff have left retail pharmacy. Without experienced staff, everything is slower, more difficult and requires a higher level of supervision. Time, however, seems to be the solution. We are finally seeing better staffing levels and those staff are getting trained, most patients who are interested have been vaccinated and boosted, workload from the Bimart closure is settling down, and it finally feels like we may be reaching the end of the chaos. I believe the problems were relatively transient (2 years) and are now getting dramatically better.	2/23/2022 9:40 PM
79	Don't have a voice in staffing levels. If complain just label a trouble maker or not a team player with a bad attitude	2/23/2022 9:37 PM
80	The covid booster shots took many pharmacies in our area by surprise and contributed to the difficult challenges we faced during the last several months. This survey seems ill timed, as things are starting to return to normal.	2/23/2022 9:30 PM
81	New USP800 standards have increased workload significantly, but our technician staffing has not increased. We were already understaffed with respect to technicians, and now this has hit	2/23/2022 9:14 PM

	a critical level. Pharmacists are doing many things that technicians would normally do in addition to the high pharmacist workload. This increases the interruptions to pharmacist work that requires concentration and deep thought and is resulting in an increase in errors.	
82	We are being driven into the ground with an ever increasing workload. Vaccinations are the bane of our work now. They are not being given to protect the community but are forced on us for the larger profit gap for our employers. The community pharmacist role is no longer a enjoyable profession largely in part from lack of intervention by the OBOP. You are doing too little too late!	2/23/2022 9:11 PM
83	The staffing issue was very bad for about 3 months, but we are well staffed now.	2/23/2022 9:05 PM
84	As of now, with high amounts of people coming into the hospital, there are not enough technicians to help deliver all the meds that need to be taken on time. Almost every shift there are medications that are late to patients. This creates lots of stress for technicians and unsafe care for patients.	2/23/2022 7:36 PM
85	Get rid of Action OI (use to compare other workplace metrics) to reduce staff.	2/23/2022 7:22 PM
86	Lack of Pharmacy technicians will be a crisis for pharmacy's for years to come. They need better pay to keep them in this field of work.	2/23/2022 7:13 PM
87	I work for a mail order specialty pharmacy out of state. Oregon does not allow pharmacists who work at a site that is not licensed to ship to Oregon to participate in prescription processing or verification remotely. This slows the process for Oregon patients since only certain pharmacists can verify order entry on these prescriptions	2/23/2022 6:50 PM
88	Most of these problems have been exaggerated due to the pandemic and other natural disasters that had happened at the same time (ie. wild fires). Since the pandemic started the shear volume of responsibility has increased to an unsafe level at every pharmacy. Not just one specific chain or type from what we have heard and experienced.	2/23/2022 6:29 PM
89	I don't work retail but the amount of work given to retail pharmacists is ridiculous! It affects my job because they send work over to us that they should be able to handle, and it is definitely not safe. Our patients are greatly affected with meds going missing, meds not being filled, no counseling provided. It is not sustainable and there is a downhill effect on the entire clinic.	2/23/2022 6:00 PM
90	The requirement to constantly do more with less help and be timed on how long it takes to get patients in and out of our pharmacy is crazy and stressful. Makes too much room for errors to occur, and when they do occur its not the company held responsible its the individual/employee. Yet this is the standards and requirements we are held to by the company we work for.	2/23/2022 5:57 PM
91	The staffing issues that Oregon pharmacies are experiencing are a direct result of Covid-19 vaccine mandates. Stop ignoring the elephant in the room. Many pharmacy techs and pharmacists have either been terminated or forced to resign due to the Covid-19 vaccine mandate. My previous employer in Oregon terminated me after refusing to honor my request for religious exemption from Covid-19 vaccination (even if they did "honor" my request I would have been placed on unpaid leave). This is the crux of the issue and the reason for the staffing crisis. Oregon legislature needs to represent their constituents by protecting them from unlawful medical discrimination. I've since relocated to Montana (a state that recently passed a law which prevents discrimination based on vaccination status) and I don't plan to return to Oregon unless a similar law is passed/upheld. I would like to note that Montana is not experiencing the staffing crisis that Oregon is. This is because the "crisis" is a self-inflicted wound.	2/23/2022 5:36 PM
92	Recently have 4 new employees still in training but getting so much better.	2/23/2022 5:14 PM
93	We have grave difficulty finding quality applicants in this area and being able to provide wages that are attractive.	2/23/2022 5:03 PM
94	Staff shortages in retail pharmacies and reduced open hours in rural areas has impacted LTC nursing home residents as LTC pharmacies often collaborate with retail for emergency new order fills. I see a trend in reatails ability to dispense, which impacts senior living residents and their access to critical new medications- this creates a patient safety concern.	2/23/2022 4:20 PM
95	Lots of technology but it does not work correctly	2/23/2022 3:28 PM
96	Our workload increased immensely and suddenly when BiMart shut down. The only other retail	2/23/2022 3:28 PM

	pharmacies nearby are Rite Aids (one is severely behind, patients wait for days for prescription fills, and the other is closed most of the time) and another small independent store in the same boat as us. We do not have the staff to keep up with the increased work load and it's very very difficult to hire technicians with any amount of experience. We could hire a new technician but there is no time/staff available for adequate training.	
97	Pharmacy practice has become inhumane to pharmacists	2/23/2022 3:23 PM
98	I'm not sure what can be done but the way insurance and PBMs work together to squeeze pharmacies has created a dangerous and untenable situation. Combined with the fact we have more people taking more drugs which requires more staff that the current profit margins can't support it is going to result in increased morbidity and mortality for patients because they will not be able to get their medications in a safe and timely matter. Our healthcare system is broken.	2/23/2022 2:54 PM
99	Leadership focuses on quantity over quality, has created a hostile and inefficient workflow and work environment, and the staff feel unsupported and without concern of staff or patient safety.	2/23/2022 2:53 PM
100	My co-workers in retail were drowning. This survey should have happened months ago.	2/23/2022 2:46 PM
101	I work in a cancer center. There are services that are basic that are not being offered and would result in safer and better outcomes	2/23/2022 1:54 PM
102	Unnecessary Computer overrides - by pharmacist? Making less time for noticing significantly clinical ones to keep up dispensing metrics. Placing LEAST capable person @ initial customer pt of contact w no prob solving skills.	2/23/2022 12:28 PM
103	Training is not given uniformly to all our techs, only the young favorite techs	2/23/2022 12:27 PM
104	I enjoyed my job before Covid. The mandates (which were fine for 2 weeks) have affected patient care. Patients can't understand counseling with masks on and barriers.Major RX chains aren't answering phones due to being overburdened with tasks and low help. Dr offices aren't answering phones and taking way to long to respond to concerns and refills. Administering shots can not be done with proper consulting, informed consent, with the loads we have had. Dr offices and other providers are filling prescriptions now with out proper standards and knowledge and aren't held accountable. Mail order leaves patients confused and often over prescribed. PDM's are robbing the pharmacies. The board seems to keep making decisions, rules, that affect retail pharmacy the most-the publics trusted and 1st resource available. This harms the public. To be told the board is there to protect the public has become a complete joke.	2/23/2022 12:25 PM
105	I think it's a bad idea to take away the Technician check technician program; it works in my facility quite well. Discontinuing this program adds more to the pharmacists duties that can be done by a technician.	2/23/2022 12:23 PM
106	My company 1. Under utilizes the pharmacy clerk position by not having any. 2. Would there be any value to bring back the pharmacist to tech ratio? 3. Company utilizes service companies to maintain the database who regularly delete or inactivate files because a dr has an additional address that doesn't match npi or DEA databases or delete active insurances without the ability to reactivate. 4. Other locations inability to answer their phones is having a negative impact on our store due to the increased call volume. 5. Some dr offices are now not answering their phones. 5. Inability to get transfers in a timely manner is causing an increase in lag time to get patients their medicine. Random pharmacy closures is causing an inconsistent increase in volume at our store making scheduling a more difficult task. Pharmacies are not 'accepting new patients' making it harder for patients to fill prescriptions from urgent care. Drive thrus are backing up on to major roads causing traffic issues.	2/23/2022 11:47 AM
107	Employer is very non-communicative on changes in procedures or policies. Often find out through the grapevine. Communication from management is very poor.	2/23/2022 11:44 AM
108	Pharmacy is seen as the most accessible of health care settings. However, as more duties are allowed, employers are expecting pharmacists to perform these new tasks while completing all old expectations and at the same or faster speed with less staff. It's become unreasonable and is leading to mistakes. Not to mention the toll on staff mental health.	2/23/2022 11:28 AM
109	Too many techs to 1 rph to keep track of	2/23/2022 11:20 AM
110	The facility itself is not adequate to handle the increased staff due to increased volume. The privacy area for vaccines is inadequate. The turnover of support staff means we always have	2/23/2022 10:57 AM

	new persons trying to cashier, and their training is also being done mostly by new people so pharmacist is constantly interrupted by questions from cashiers. Computer system and other devices used to perform job functions often do not work properly. Company seems to tolerate abuse of employees by patients/customers requiring more of pharmacist time to resolve. I do not believe this to be the company I work for as much as the entire industry. Pharmacist are being treated quite badly all over the state. Unacceptable, unsafe, unprofessional.	
111	N/A	2/23/2022 10:50 AM
112	We're in a tough situation. There are not enough staff to help. I think the public would be shocked to see how many different tasks a single pharmacist handles currently vs having the time to focus on patient safety. Pharmacies do NOT need to be offering immunizations. That, in itself, is the largest drain on pharmacy personnel time. When pharmacies are 3 and 4 days behind in filling prescriptions, that's a huge issue. We literally just do what we can to make it through the day. There is no possibility of getting ahead and being proactive. It's very, very frustrating.	2/23/2022 10:49 AM
113	n/a	2/23/2022 10:46 AM
114	Consolidate pharmacies to have more personal for better work enviroment	2/23/2022 10:31 AM
115	All pharmacies are over worked and of course the techs are way under paid. Data person has to deal phone calls non stop all day plus type all rx's and handle all insurance problems. Pharmacist over see everything. They too are too over whelmed. I retired 5 years early just to get out of such a stressful situation. I was worried about my Heath.	2/23/2022 10:25 AM
116	It’s very frustrating that my current and past employers tell us to slow down and focus on patient safety, and that errors are on the pharmacist—yet when concerns are brought up due to staffing/etc, those pharmacists are told they are too slow/some other excuse and driven out or fired, then replaced by cheaper new grads desperate to pay student loans (the price of which are insane for pharmacy school—another concern the BOP should comment on). So essentially, we voice our opinion and get fired. Or keep working and pray no mistake is made. If we slow down, then we get in trouble for metrics and driven out/fired.	2/23/2022 10:18 AM
117	I think the timing of this survey is unfortunate. Vaccines have waned. At the height of covid and flu vaccinations from February 2021 through the end of 2021 and even a bit beyond our workload was unsustainable. I frequently wondered what the board of pharmacy was doing in their efforts to support pharmacists and technicians in Oregon. We need help to make sure our situation does not return to that again. Please do something to help us. The safety of the staff and patients will depend on how this gets addressed going forward.	2/23/2022 10:04 AM
118	My employer laid off employees due to the pandemic then we experienced Covid surge and they were scrambling to fill shifts and we are still short.	2/23/2022 9:56 AM
119	THE RATIO OF TECHS TO PHARMACISTS NEEDS TO BE INCREASED. THE IDEA THAT THE BOP HAS TO ENFORCE A LAW ON SUCH A BUSINESS DECISION TAKES AWAY FROM MY PROFESSIONAL JUDGEMENT. TELL ME WHAT OTHER PROFESSION LIMITS THE NUMBER OF SUPPORT PERSONNEL BY A RATIO. THIS IS NUTS	2/23/2022 9:55 AM
120	We are can only work on business hours.. we would like to start early before customers come and pick up their prescriptions…and Doctors will send ADHD medications ahead of time..3 to 4 months and that takes our time to reschedule everything…I hope that will change! I should be every month..we won’t get paid ahead by doing early prescriptions..beside under-staff..patients will bounce back and forth to pharmacies in order to get their drugs faster. Our phone system is not very efficient..filling their prescriptions over the phone is a struggle..it still direct the call to us ..which is a waste of time.	2/23/2022 9:47 AM
121	I chose none applicable on most because I am in clinical pharmacy and do not have face to face with patients	2/23/2022 9:32 AM
122	N/a	2/23/2022 9:26 AM
123	Pharmacists are burnt out and no one is helping, just adding more responsibilities with less staff and less pay	2/23/2022 9:11 AM
124	This survey was based on my previous employer. I left chain retail because of these working conditionas after developing stress-induced medical conditions	2/23/2022 9:06 AM
125	I'm deeply concerned about employers taking advantage of remote work for positions that need	2/23/2022 9:04 AM

	to be in person. While I am supportive of persons protecting their health, I remain deeply concerned about employers taking advantage of loose rules regarding remote work and the end result on patient care.	
126	I also help very part time at a retail environment and the answers would be dramatically different for that environment.	2/23/2022 9:03 AM
127	COVID testing and COVID vaccination duties are on TOP of what we already do. Nothing else is (or could be) taken away, and it seems endless. A COVID team needs to be hired to deal with the crisis at the very least. We are swabbing noses and delivering vaccines and manning clinics to draw up doses sometimes on weekends or holidays and since I am at the pay cap at our facility, no extra pay is given for the extra hours. It is extremely arduous even to get gas money when you drive your personal car for these events which can be 50 to >100 miles away.	2/23/2022 8:59 AM
128	We are in a lot better shape than many other pharmacies in our area.	2/23/2022 8:57 AM
129	Mist have better closing procedures, if they get a license they shud be open during posted hours	2/23/2022 8:57 AM
130	If you want survey to be anonymous, consider not requiring county.	2/23/2022 8:55 AM
131	I don't understand why he majority of pharmacists are either 84 hrs/2weeks or 64hrs/2weeks only. We need more pharmacist overlap during the day	2/23/2022 8:50 AM
132	In the work setting, the focus is on performance matrix measures, numbers and decreasing times so by default, patient care (consult time, safety reviews sacrificed). The environment and focus have flip flopped making the work day at times, hazardous and unpleasant.	2/23/2022 8:45 AM
133	Our staff is very new and not a lot of time to train. Our pharmacy is very small and we are walking all over each other all day.	2/23/2022 8:44 AM
134	As an independent in a frontier community it is the inability to find staffing. The staff we have is great and we have a workflow that allows for safe work even being short handed	2/23/2022 8:43 AM
135	Since so many pharmacy closed there are only one FT RPH with floating rest and they are doin best they can but too short staff and everyone just felling burt out but a wonderful team doin best we can.. Tired of the customers complaint on things we cant change. Some days we have close pharmacy bc there is only 1 RPh so they can eat.. It horrible in all retail So hard find people who wants to work there for burning out those who are working	2/23/2022 8:37 AM
136	Better pay for the technicians with the workload and performance straining to breaking points. Allow more hours and team to disperse the work instead relying on one to two techs to perform the majority of the work. Place value on their work instead of denying vacation requests, burning them out faster. In essence more pay for those that are performing in the daily workload not metrics. Not one tech cares about metrics when we are struggling to perform safely in the daily workload.	2/23/2022 8:34 AM
137	12-hourshift is too long	2/23/2022 8:33 AM
138	In regards to the retail setting, the lack of store pharmacists has a big impact on how much we can do as well as having to reach chain metrics such as At Home COVID-19 tests. Since our store only has one pharmacist (our PIC) most days it is hard to manage a reasonable amount of vaccines as well as have him available for counsel, approvals, talking to providers. Because of that we don't do walk in vaccines and limit them to at max 10 a day.	2/23/2022 8:32 AM
139	I've been voicing my concerns for YEARS- they don't listen! Staffing keeps getting cut, tech pay isn't competitive. Management doesn't care	2/23/2022 8:31 AM
140	I used to work for a chain pharmacy in Oregon. The only reason I left Oregon to practice in another state is I was tired of the workload put on me. I now work for an independent pharmacy out of state and have a much better quality of life. Chain pharmacies do not staff their pharmacies with enough personal to be safe. They do not pay their employees enough.	2/23/2022 8:28 AM
141	A system that looks into shared workload would be better. Some pharmacists are doing more than double the work of other pharmacists at my work site which causes fatigue.	2/23/2022 8:27 AM
142	My setting in a retail pharmacy. We have a major influx of new patients from pharmacy's closing. We don't have enough staff to keep up with the workload, have time to train new staff, which leaves everyone overwhelmed and stressed. We are getting new people to start	2/23/2022 8:24 AM

	however, there isn't time for training. People are trying to figure out stuff by asking questions every time a problem arises but then it slow down workflow for us and for patients as well.	
143	We cannot keep going forward assuming that patient safety is a secondary concern. Some strict rules for production maximums would allow pharmacists to tell patients they can only do X, Y, and Z because the Board allows 200 verified prescriptions and 20 immunizations per day MAX (or other similar things). Employers won't protect us, so the Board must protect the public and we will then tell the public we have been given limits.	2/23/2022 8:21 AM
144	I understand that there is a shortage in tech help. But shortages should only span a month and if the employer cannot hire adequate help, someone needs to regulate them to make the choice to close the pharmacy until adequate help is sufficient to properly and safely run the pharmacy. It should be illegal to continue to operate a pharmacy with this level of shortage. Companies have refused to hire clerks, would not pay them competitive pay so our site is left without help for >6 months. I have been staffed solo so while breaks are allowed we have to close the pharmacy. I am terrified on weekends when I have my menstrual cycle because no one is available to relieve me for bathroom breaks and when I close the pharmacy I get build up of a line and customers yelling at me. My periods are impacted by the vaccine. We can't pick up the phones anymore as there are no help. How long will the board allow a pharmacy to run with these working conditions	2/23/2022 8:20 AM
145	Patient safety has been a low priority for Walgreens for years, second only to stagnate wages and stressful work conditions that have resulted in a max exodus of trained and talented staff. The problems have been magnified by the Covid-19 pandemic and most recently, the acquisition of all Bi-Mart pharmacies. Pharmacists are regularly working alone for 10-14 hour shifts, with only a 30 minute lunch break. During this time, they are responsible for overseeing all technicians, as well as monitoring as many as 800+ prescriptions. Medication errors have skyrocketed, incorrect vaccines have been administered, and burnout has resulted in staffing shortages that leave patients without access to medications for hours to days on end. Additionally, district supervisors encourage unsafe practices in order to boost metrics and revenue, including extending operating hours but reducing budget hours, staging prescription fill processes, and reducing an already short training period for new licensed pharmacists.	2/23/2022 7:55 AM
146	Why are Technician hours / staffing always being cut, but yet workload and duties increase, without wage increase?	2/23/2022 7:48 AM
147	Technician pay has lagged and as a result we have had significant turnover the last couple years which has hurt efficiency	2/23/2022 7:42 AM
148	The board has become more of a source for punishment than support for pharmacy workers. It would be nice to see the board be more supportive and less punishment oriented when we need answers to questions. It's got to the point where we are scared to call and ask questions for fear of repercussions.	2/23/2022 7:25 AM
149	Employers make every effort, but struggle, to provide staff, equipment, and a safe environment for everyone. It is our government that has allowed uncontrolled greed of the insurance companies via very low reimbursement and "claw-back" in the form of DIR fees that create unsafe practices in pharmacy settings.	2/23/2022 7:21 AM
150	technicians are not getting paid fairly, so they quit. leaving pharmacists to do technician work, such as being first-line option for answering phone calls on refill requests, billing insurances. this takes away pharmacists from practicing at the top of their license and importantly- providing better care for the patients.	2/23/2022 7:15 AM
151	Maintenance on necessary office equipment like printers is lacking. Getting new equipment such as printers and installing pneumatic tube systems not being done	2/23/2022 6:59 AM
152	No concern by my employer to staff adequately. I am told I will be subject to disciplinary action if I do not take a lunch break but have worked 12 hour shifts with no ancillary staff. Have been informed that I will not get a bonus as I have finally refused to do vaccinations due to being severely under staffed.	2/23/2022 6:55 AM
153	Last minute scheduling	2/23/2022 6:49 AM
154	there are no technicians to fill open job positions nobody wants to work we are under paid !	2/23/2022 6:43 AM
155	The vaccines have taken away the ability to do our jobs. To safety get patients their medications in a timely manner. The focus and priorities of the pharmacy are out of order.	2/23/2022 6:33 AM

	Because of this there is a shortage of staff and the desire to work in the pharmacy is low. Therefore this shortage is making it unsafe to get life saving medications at the pharmacy.	
156	Any rules or supportive/guidance statement that we can utilize to influence the corporations to provide better staffing will be greatly appreciated. Thank you	2/23/2022 6:26 AM
157	Thank you	2/23/2022 6:13 AM
158	Staffing is a huge concern. My Hospital has not been able to fill positions that have been open for long periods of time. This leads to open shifts that are filled by techs that are doubling or working > 50 hours a week. we will have 100+ open sifts per schedule cycle, Month. This is not safe and causes burn out and techs to leave the industry. We need the board to set staffing rules for hospitals eg. # of scripts to number of techs. or something similar	2/23/2022 6:12 AM
159	Great pharmacy environment	2/23/2022 6:06 AM
160	Unsafe working conditions is one of the reasons I left Walgreens about a year ago. Now I work in managed care and have no workplace safety concerns.	2/23/2022 5:56 AM
161	No time off if sick due to lack of staffing	2/23/2022 5:55 AM
162	My workload is IV chemotherapy. 60+ IVs with two techs is a busy day. With the recent holidays that number grew to almost 90. That is too much for one pharmacist. Plus, keeping 6-7 RNs happy is stressful. RNs	2/23/2022 5:50 AM
163	As more responsibilities are put upon the pharmacist in terms of meeting metrics, vaccinations, MTM's, performing clerical & technician duties and the increase in pharmacists providing additional clinical functions such as Prescriptive Authority, etc due to the changing environment in the Healthcare Field there needs to be an increase in guidelines for staffing ratios to ensure corporate businesses comply with appropriate staffing models. In pharmacies with corporate management the focus is financial with meeting metrics, budget, etc and part of this is management of labor, and as pharmacists salaries are higher in comparison to other staff, the corporate expectation is to do more with less staff and minimize increases in annual compensation. All of these issues lead to inadequate staffing, less access to provide patient care at the top of your license, and burnout of staff as well as decreased interest in the pharmacy profession.	2/23/2022 5:25 AM
164	When BiMart pharmacies closed it put an enormous strain on all retail pharmacies across the state.	2/23/2022 4:47 AM
165	The primary problem with chain pharmacy staffing, i.e. CVS/Kroger/Walgreens, is that decisions about staffing levels and pay are made at the corporate level, with the primary concern being increasing profits by limiting labor costs. I personally am concerned it took this long for the Board to take an interest in the problem.	2/23/2022 4:34 AM
166	Product Verification Expectation= 500 to 700+ Rx's/hr. Data Verification Expectation= 175 - 200 Rx's per hour. Employee Evaluations based on these Performance Standard Expectations. Treatment and Satisfaction and Scheduling based on Employer Assessment of Employee Performance per Metric Data. Metric Data is sent out on a daily basis for Performance for all RPh's and Techs to view at once, to include Data Verification metrics, # of Phone Calls taken per hour, and for Technicians, also Data Entry and # of Phone Calls per hr.	2/23/2022 4:13 AM
167	N/A	2/23/2022 3:46 AM
168	Na	2/23/2022 2:46 AM
169	To many vaccine goals,ie. mandatory flu goals per season which seem unrealistic. Right now is Pfizer pneumococcal goals of 1 per day. Then next month will be another vaccine rollout that will have goals to meet, etc..Im all for helping patients with there needs, but it is bottom line for this chain pharmacy. If you dont make your goals on script count they cut staff pharmacist hours to 32 and manager to 38 hours. They also cut down tech hours. How can you build more scripts with less hours? They have now cut all staff hours twice within the last year and a half. Im lucky to still have my staff pharmacist this long, and this person is again applying to other practice setting.	2/23/2022 1:46 AM
170	I currently work at a very rare pharmacy environment. Where I feel respected and valued. I recently left a hospital setting where although I loved the job and duties required, it was NOT a healthy or safe work environment. Understaffed, poorly managed, and we were not given the breaks and support we needed. I feel fortunate to of found my current employment but this	2/23/2022 1:10 AM

	opportunity is extremely rare and on a large scale the issues in pharmacy are real and need to be addressed.	
171	No	2/23/2022 12:00 AM
172	Retail chains don't pay their pharmacist well so they never stay. On top of that, the environment is unsafe to practice in. Lack of pharmacist overlap leads to pharmacist fatigue, especially when they're pulled in all directions (ex: verifying a typed prescription while a tech is asking a question while a patient is waiting consultation while someone is checking in for a vaccine)	2/22/2022 11:51 PM
173	Underappreciated and overworked seems to the constant, especially in these past couple years. We can only schedule at or under our budgeted ours which always seem to be under estimated. Then you throw in the occasional call out (which has been happening more often since COVID) and that just adds more fuel to the fire. Now, add closing pharmacies and their upset customers calling your store demanding to know what's going on and when they can get their Rxs and no one at your pharmacy even knew that pharmacy was closed and you work for the same company. All these means for communication an no one who knows what's going on can bother to call or send an email letting us know what to tell their customers. Communication? ...	2/22/2022 11:46 PM
174	Help us	2/22/2022 11:43 PM
175	Frequent internet based phone system problems. Unable to hear or be heard frequently. Other broken or poorly operating technology that makes staff work hard at things that should be a given to run a pharmacy smoothly and safely. Lack of support by non-pharmacy management: demands to "just fill the rx" without consideration of the circumstances. This all puts unnecessary stress and pressure on pharmacy employees.	2/22/2022 11:37 PM
176	Adequate staffing is everything. If you have enough people on shift, everything can run smoothly. It's especially difficult if 1 pharmacist has to work over 12 hours without another pharmacist.	2/22/2022 11:28 PM
177	practice in ca bear or boder. health providers medford, grants pass fail to inform patients that they may have trouble accessing non emergency non electronic c2 meds in ca putting them at risk of going back up to [redacted] and getting their script filled at Fred Meyers (long wait times, no rx coverage) or Rite Aid(shortened store hours). believe me, lots of unhappy patients who often forgo pain treatment, yet get the antibiotics	2/22/2022 11:27 PM
178	A general feeling that the board of pharmacy is not acting in our best interest. Margins are so low that volume and vaccinations and labor are the controlling forces that drive our industry right now.	2/22/2022 11:25 PM
179	Retail chains are having trouble keeping the best pharmacists for the job due to stress and low pay for pharmacists and technicians. No one wants to be a technician for such low pay and during the training they realize the stress is not worth the pay. It takes months to hire new technicians and most of them do not make it past training. Pharmacists and interns are tasked with not only doing their jobs as a clinician but also having to perform technician tasks due to technician and pharmacist shortages. On top of all the daily workload, we have to answer all questions from phones and in person regarding covid-19 vaccines and testing without any additional help. I feel like all of the staff are significantly burnt out due to working extremely hard over the years in the pharmacy and not being properly compensated. Instead, it feels like we are doing more work with less staff and seeing our pay decrease by roughly 15%. We have worked hard throughout the pandemic and it feels like we are underappreciated and management can never find and train staff proactively to avoid staff shortages. Until proper pay for pharmacist and technicians can be obtained, I do not see retail pharmacy being a safe place to practice and provide optimal patient care. It's sad to see bakeries being more staffed than a pharmacy.	2/22/2022 11:20 PM
180	We need refrigerators- can't get 'em	2/22/2022 11:16 PM
181	Please address PBMs	2/22/2022 11:16 PM
182	The most unsafe I have seen pharmacy in my 13 years of practice. Technician shortages due to low pay. Never time anymore for maintenance duties, like pulling expired drugs.	2/22/2022 11:15 PM
183	2 years of On the job training should suffice for certification instead of taking the exam. Too much work load and not enough time to study.	2/22/2022 11:03 PM

184	The [redacted] phone system is antiquated and crap. It bounces holds to other departments in the store and we cannot update our phones with location-specific information.	2/22/2022 10:41 PM
185	Todays pharmacy expectations are unattainable, growing work flow requires added staffing hrs and staff. From my experience employers are not willing to hire more staff to meet the growing demands.	2/22/2022 10:29 PM
186	Regarding my pharmacy: I wish this survey was sent months ago. It was absolutely horrible. The work load was tremendous with vaccinations and prescriptions transferred from other pharmacies. We had staff out due to COVID, plus we had to send our staff to other pharmacies to cover their short(skeleton) crew. Our team was so exhausted, driving home about to cry. We have finally slowed down, fortunately, however our affiliates are in dire straits. With Bi-Mart and other pharmacies closing it's becoming a nightmare for businesses who remain open. Some pharmacies do not answer their phones, because they are so short staffed. Patients can't get through, so they just call their doctor and have them send in all new prescriptions because it's impossible to have things transferred because they can't talk to anyone! I Have have talked to many patients who have expressed their frustrations. There are cities that have only a couple pharmacies still operating, and can barely answer their phone,and have patients waiting for an hour in drive up, only to find something missing or a problem. These people get furious! It's not their fault, and certainly not the fault of the pharmacy employees. If this survey was sent earlier, some of my questions would be very different. I believe that big chains, should have a ratio of employees to prescriptions processed. I realize this is a very complex issue, however, there is much that can be learned. Foremost, during this difficult time, I understand that many people who cannot easily seek health care, will also not get much needed prescriptions. Thank you. This survey monkey app. won't let me view or edit my comments, so I apologize for duplicate or disjointed sentences.	2/22/2022 10:29 PM
187	Working 50 plus hours a week from almost every tech is breaking our staff and is exhausting . Can't hire techs for any help and always feeling like nobody cares how hard we work to keep it together . All out techs have no time for anything other work and we might loose good employees this way. Im the top tech in the pharmacy and Im about to throw in the towel for being over worked . It's time to make a change as a company to save employee that's actually like their job. We shouldn't be aloud to work over a certain amount of hours a week . Unstaffed pharmacy need better operating hours . raises to those have suffered the past 2 year of hell!	2/22/2022 10:16 PM
188	Patients do not wear masks in pharmacy and it provides an unsafe work environment for staff and other patients in pharmacy. Even with signage and free masks. Employers do not want staff asking patients to wear masks	2/22/2022 10:04 PM
189	For all the reasons written in question 25 are why I do not feel comfortable in a retail practice setting at this time. Corporate offices are trying to offset the high price of medications and the low reimbursement rates from insurance companies by cutting staffing costs. Pharmacies are understaffed and overworked which, in my opinion, leads to poor patient care, longer rx wait times and and increase in the likelihood of mistakes occurring. The current climate of the retail industry is not the setting I went to school for 7 years to be in. I want to be able to take care of patients; know them by name without needing to look them up in a computer first and be an accessible healthcare provider. I hope this survey will change what retail pharmacy has become. Best of luck to those reviewing these surveys; I truly hope they are informative and actionable. Thank you for your time and efforts!	2/22/2022 9:57 PM
190	Pharmacists do not feel like we have support from chain retailers OR the board of pharmacy. The board is there to protect patients, prosecute pharmacists, not support the profession.	2/22/2022 9:49 PM
191	living and working in a rural area, it appears that we are overlooked compared to some urban areas. It is very difficult to get extra help (i.e. float RPhs or Float CPhT) when needed.	2/22/2022 9:47 PM
192	Pharmacy should be closed during rph lunch break by board rule! Enough staffing is very important for patient safety and pharmacy staff's healthy work environment as well.	2/22/2022 9:42 PM
193	All of my answers are based on the fact I work night shift at the hospital. Day shift and evening shift usually have adequate staffing but there are only 4 technicians staffed on nights. We need at least one more tech and we have voiced this to our manager. We work 10 hour shifts and the workload is a lot. We barely get everything done in time. And because we are constantly on the go, we rarely get a full 30 minute lunch break. There's just too much to do.	2/22/2022 9:39 PM
194	I am making arrangements to leave the profession altogether due to unsafe pharmacy staffing and expectations.	2/22/2022 9:34 PM

195	We miss [redacted]	2/22/2022 9:34 PM
196	To many phone calls and clients and not enough workers! New workers don't have enough training.	2/22/2022 9:32 PM
197	The extra load of administering vaccines especially during the pandemic has really interfered with the work flow of getting prescriptions to patients and adequate time to counsel.	2/22/2022 9:31 PM
198	I am still waiting to be trained by my company, and for my 500 hours toward certified Pharmacy Technician might be over a year, to test, due to lack of staffing a second pharmacist. I am looking at over 6 months to be able to qualify to be a certified Pharmacy Technician. I am eager and ready to learn, but can not financially wait.	2/22/2022 9:30 PM
199	Please help our patients get medications timely manner by tell company to hiring more staffs and pay them well . Many patients go days with their medications because they cannot get a hold of pharmacy. Corporate only cares about metrics and prescriptions volume not care about patients safety and get medication on time. We are as pharmacists and technicians are burn out and exhausted. We cannot don't time for break and cannot even go pee or take a sip of water.	2/22/2022 9:30 PM
200	It is getting better	2/22/2022 9:29 PM
201	This is such a wonderful profession. I was proud to provide focus patient centered health care. That feels so long ago and so out of reach now. I feel like I can't catch my breath. I refuse to rush despite the pressure for fear of harming someone. I have stepped away from the bench. I cannot do it full time anymore. It doesn't feel like i am providing care anymore.	2/22/2022 9:27 PM
202	As before (the last survey regarding pharmacist workload issues) the assumption is that pharmacists are at the same level of power as the employer and as such can negotiate at a level playing field. Well, honestly it is if a woman sexually harassed by a C E O of her corporation should have felt comfortable telling the Individual to stop. The staff has no agency. It is a matter of feeding your family or loosing your job. How would most humans respond? I love my profession. I am absolutely genuine in my response. However, I have told my son (who is really smart and one of the most generous humans I know) not to consider pharmacy as a career. Thank you O B O P for considering my comment. May this and other comments shock the board and others into real action. Sincerely, a pharmacist that has reached the end of their rope BEFORE COVID.	2/22/2022 9:18 PM
203	With my experience any pharmacy work load that exceeds 220 prescriptions daily should have more than one pharmacist on duty, and not be reliant on that sole pharmacist.	2/22/2022 9:16 PM
204	Anticoag clinic	2/22/2022 9:08 PM
205	It is unacceptable of corporate to put money before patients and employees. This has to stop with corporate.	2/22/2022 9:07 PM
206	Na	2/22/2022 8:54 PM
207	Our company has a online vaccine appointment portal that allows people to make vaccine appointments every 15 minutes 7 days a week not realizing that due to lack of staff the pharmacist is all by himself on weekends. Completely unable to manage vaccines, prescriptions and endless people picking up prescriptions. With the pharmacy closures in our area our pharmacy has tripled its volume since last November. We are barely able to get prescriptions filled let alone spare one of the two pharmacists we have to do vaccines. All of our pharmacy staff have been working upwards of 50 hours a week or more just trying to keep up with the workload. Tripled prescription volume with the same amount of staff with the expectation todo any and all vaccines every 15 minutes is completely unreasonable.	2/22/2022 8:50 PM
208	As long as corporate members are on the board, work conditions will not improve. Technicians deserve much better compensation and all staff deserve adequate breaks. And the board should also help protect Pharmacy staff from abusive patients. Workload far exceeds staff capacity in Central Oregon and patient safety is at risk. We cannot be chastised into providing better care when there is not enough time or staff. Happy employees = happy customers.	2/22/2022 8:48 PM
209	Finding CPhT available and willing to work has been extremely difficult during and post COVID apocalypse. Many other professions either shutdown or are forgiven to have lack of labor support. However, the public has no patience or forgiveness for the overwhelmed fatigued pharmacy staff.	2/22/2022 8:48 PM

210	[redacted]pharmacy is negligent. As a pregnant female I was denied breaks, a place to sit, no access to a fridge or microwave. Pharmacist staffing was cut in half and work load was increased ie more vaccines, more clinical assignment's and are script volume continues to grow annually. It's a conflict of interest to have[redacted]at the OBOP.	2/22/2022 8:43 PM
211	Labor hour cut to meet profit margin. Scheduling long pharmacist hours with inadequate break and meal time.	2/22/2022 8:41 PM
212	Recent closures from Rite Aid have strained our resources and we still aren't able to keep up with the patients that are leaving them. Its very fristrating that their inadequate staffing is adversely affecting our pharmacy.	2/22/2022 8:39 PM
213	In my experience with past jobs I definitely believe myself to be in the minority having adaquite staff at my current job. This is the only job I have ever had where my employwr seemed to be concerned primarily about staff working conditions and patient safety.	2/22/2022 8:38 PM
214	We have needed help throughout the entirety of this pandemic. Vaccination rollout was poorly handled, and I'm appalled that the vaccine has driven profits for some health care settings.	2/22/2022 8:37 PM
215	Something is constantly being added on without additional help. You want something mailed? Sure, we can mail that to you and take time away from filing RX. You want something delivered, let me do that and spend the 10-15 minutes doing that for you away from filling these urgent RX. You want curbside pick up, sure! There are only two of us here and the pharmacist is doing a vaccine and I have a line of customers at the register. When does it stop?	2/22/2022 8:35 PM
216	Since the COVID pandemeic, it has been nearly impossible to obtain adequate help in the pharmacy. Only recently have I been able to hire sufficient technician help to be safe and effective. Hopefully this will continue to improve.	2/22/2022 8:33 PM
217	Continue to allow work from home. For rph and techs too	2/22/2022 8:31 PM
218	The expectations are unsafe, unfair, unachievable. Lack of staff and workload are completely out of control.	2/22/2022 8:29 PM
219	When are you going to lift the mask mandates.Can we not wear masks at our desks.Provide more hand sanitizers to employees.Are we going to get paid hazard pay for working during the corona virus.	2/22/2022 8:16 PM
220	It is crazy unsafe out there. How have we allowed big business to dictate how we practice? How is this the first time I've been asked about this? Please take this seriously and really do the hard work. Without mandates on safe staffing ratios, big business will just continue to squeeze every last dollar out of the business with no regard to safety or patient care.	2/22/2022 8:14 PM
221	Pharmacy chains have obsolete dispensing software that does not allow technology checks , barcode scans to verify RXs and rely on Rph checking NDC'S etc for accuracy , no software engineering to match a medication vial with a patient leaflet electronically , often 20 -30 consults per 4 -5 minutes , bare minimum instruction for patients . I'm leaving OREGON state to find safer work environments after Gov Kate Brown forced mandates on healthcare workers and pharmacists creating a shortage and a division amongst healthcare workers themselves , their communities and quality of care Oregonians now receive due to corporate and government pressures and mandates . I will happily hang my Oregon license up after 31 years in pharmacy and search a safer work environment in another state .	2/22/2022 8:09 PM
222	routine need to have overtime 8-12hrs/wk per R.Ph. to keep up with demand for filling prescriptions. Lots of technician turnover and re-hiring/re-training.	2/22/2022 8:07 PM
223	Finding employees is at its most difficult in over 20 years!	2/22/2022 8:05 PM
224	Never ending phone calls. The phone is always ringing.	2/22/2022 7:57 PM
225	Inadequate education, training of technicians	2/22/2022 7:55 PM
226	The lack of adequate staffing is not allowing us to take a lot of things that are important to get done and settled from day to day. Would be more helpful to have another staff member to help, etc.	2/22/2022 7:55 PM
227	Fortunate to work where technician and non-licensed staffing levels are good. Due to pharmacy closures and covid vaccination efforts, our daily prescription count has increased by about 50% without an increase in pharmacist staffing.	2/22/2022 7:53 PM

228	Na	2/22/2022 7:40 PM
229	My role is unusual: pharmacy administrative specialist responsible for drug shortages, inventory management, revenue integrity, month-end accounting closing, and added on top of this has been managing COVID-19 vaccine receipt and distribution across an 8-hospital system. Nothing is directly patient-care related, but my responsibilities are more than one person should have to bear.	2/22/2022 7:40 PM
230	None	2/22/2022 7:38 PM
231	With respect, I think the boards previously released statement on safety is completely ineffective. The only action that will solve this situation is mandatory limits on number of Rxs / technician hour.	2/22/2022 7:37 PM
232	Slow system and process of flow. some automation not available and creates extra steps	2/22/2022 7:31 PM
233	From a clinical perspective, working remotely for a telephonic based clinic has improved work-life balance and decreased stressors during the pandemic. Our clinic maintained effective management of our patients working remotely.	2/22/2022 7:29 PM
234	Corporate does not care. New grads and old pharmacists are being paid very low with no chance of raise. The workload has tripled since the pandemic and RPH get pay $50an hour? Unsafe work environment and damaging to my mental health	2/22/2022 7:18 PM
235	State Board(s) of Pharmacy and Dep’t(s) of Health have failed and/or are missing in their leadership/inspection position. If you are perplexed or at a loss to understand this comment, please review your Mission Statement.	2/22/2022 7:16 PM
236	Pharmacy staff wages are godawful low. And we need a better pharmacist to tech ratio, say 4 techs per pharmacist (and interns don't count towards ether one of those).	2/22/2022 7:16 PM
237	Due to the closure of Bimart in our area and the subsequent overflow from Walgreens we are continuing to struggle to maintain against the pressures of over three thousand rxs per week. I know it is unrealistic but I would like to see another option for a pharmacy in our area to come in and take off some of the load.	2/22/2022 7:12 PM
238	Opiates are often filled early with no documentation or review or reason	2/22/2022 7:11 PM
239	Way more work than can possibly ever get done, and pressure to work so quickly that there's not enough adequate time to even the no and do a safe and good job. Retired and lost employees are not replaced and we are told to be work more efficiently. The problem is the executive director of Kaiser.	2/22/2022 7:11 PM
240	Lately communication with doctors offices and other pharmacies to resolve safety issues has been a huge problem. Over 2 hours on hold to talk to a provider about drug interactions or to transfer a medication from another pharmacy. This has been the biggest barrier over the last 6+ months.	2/22/2022 7:10 PM
241	Inadequate staffing is the elephant in the room. Not being addressed or discussed. Techs need to be paid a living wage. C-suite just cares about profit margin and pleasing shareholders.	2/22/2022 7:10 PM
242	Our employer has no clue or doesn't care about the safety of our staff and members in regards to staffing. Our managers are feeling the brunt of having to cut hours and schedule a skeleton crew just to satisfy budgets created by those who have never stepped into our workplace. Pharmacists are doing tech work which cuts into our roles to consult due to short staffing and this needs to stop. Just because other workplaces are suffering staff shortages, pharmacies should not be suffering the same. Please enforce some rules to eliminate the stress of working in a pharmacy. We need more staff, better equipment (automated counters that constantly need pampering, better computer systems)	2/22/2022 7:10 PM
243	We are in a hard to staff area but we always are short staffed & given max technician/pharmicist hours even though we cannot get caught up. Another major issue is our chain does not hire clerks, they expect technicians to work drop off, fill & pick up, lots of times with 3 techs.	2/22/2022 7:07 PM
244	Inadequate space to efficiently process and fill the qty of prescriptions required on any given day.	2/22/2022 7:06 PM
245	I have recently changed employers so I feel I have a much better work load than I did, so I	2/22/2022 7:05 PM

	tried to answer honestly with that it mind, but had I been evaluating my old employer my answers would have been much harsher	
246	I exited retail pharmacy in 2018 due to workplace pressure that made my practice as a pharmacist unsafe. I voiced concerns to management but they were ignored. I felt I had no choice but to quit. I can't imagine what it is like now with the pandemic. I'd like to return to retail pharmacy work to help out, but I am afraid of being put into unsafe working conditions. It breaks my heart because although I love teaching, I miss retail pharmacy, and teaching does not pay very well	2/22/2022 7:00 PM
247	We are forced to concentrate on MTM to decrease DIR fees which makes it difficult to concentrate on the patient in the store.	2/22/2022 6:59 PM
248	Vaccines and covid tests take priority over over getting prescriptions safely to patients.	2/22/2022 6:57 PM
249	New Technician's need time for training not to be rush. Staff needs to be able to have time to make sure the safety of filling a prescription than just getting numbers done	2/22/2022 6:56 PM
250	This survey should have ended when I said I was retired and not working. Future surveys should be formatted so I don't have to answer unnecessary questions	2/22/2022 6:55 PM
251	Though my current workplace (urban outpatient) allows for arguably sufficient staffing, etc., my prior workplace (rural chain pharmacy) did not have adequate staffing due to too many nonclinical duties and vaccinations, leading to feeling rushed all the time and lack of breaks.	2/22/2022 6:51 PM
252	How allowing wait time metrics to be tied to manager bonuses can possibly be legal is beyond my understanding. We are berated to no end over these metrics, including unfavorable shifts being given to pharmacists as punishment for not making wait time metrics.	2/22/2022 6:50 PM
253	I feel that for right now it you should help technicians get there licenses easier	2/22/2022 6:49 PM
254	Immunization function is not feasible in retail setting. This is a function of pharmacy that has gone haywire!!!	2/22/2022 6:49 PM
255	Oregon Pharmacy Licences Are Mainly a Burocracy	2/22/2022 6:46 PM
256	I think as a technician we are put to do more than is capable. We are just barely getting by and especially at my pharmacy we have 1 pharmacist that is amazing and on that is incompetent. I have no idea how is even a pharmacist	2/22/2022 6:46 PM
257	The answers to the questions asked speak well.	2/22/2022 6:43 PM
258	In the case of my employer, I feel that the lack of staff is primarily due to the lack of qualified applicants.	2/22/2022 6:39 PM
259	Retail chains have cut pharmacist staff to the bone, to the point that it is impossible to keep up with workflow, counsel patients appropriately, complete the myriad of clinical tasks expected of us, and keep the pharmacy Board-compliant. Pharmacists need to be given fair hours and fair wages to compete these tasks, and to help combat fatigue and burnout that have become a critical issue in this profession. If pharmacist working conditions are not drastically improved, I do not see how safe practices can become the norm.	2/22/2022 6:38 PM
260	At this time, I feel the largest problem is finding quality technicians that stay and show-up for their shifts. This seems to be due to poor compensation in combination with the immense amount of stress and workload put on the shoulders of technicians. For instance, I know of one technician that refilled the automated dispensing machines by themselves for an entire hospital because someone else who normally partnered with them had to call out. Redundancy is extremely important in safety checks and thus staffing redundancy should also be at the forethought of managing entities especially as large as a hospital. If these aren't addressed then it will be difficult to retain qualified and experienced technicians, which is important since they are much less prone to making errors.	2/22/2022 6:38 PM
261	Volume of work . With closings of stores the increased volume has been difficult to provide service as quickly as patients are used to. We are having to change their expectations.	2/22/2022 6:32 PM
262	Very grateful to practice in a rural independent pharmacy. Cash flow due to pbm’s is making life very difficult for all of us. My career spans 40 years. I have watched the antics of this group destroy this great profession. Very disheartening!!	2/22/2022 6:32 PM
263	I have retired early due to the stress of work overload.	2/22/2022 6:30 PM

264	Overworked and under paid. Not enough reliable staff, and to much focus on vaccines, tests, and masks which takes away from time spent on accurately filling prescriptions in a timely matter	2/22/2022 6:21 PM
265	AN	2/22/2022 6:14 PM
266	Regional and senior leaders care more about metrics than patient care . Their pressuring to meet metrics pushes people to take unsafe shortcuts for fear of discipline if they don't meet the numbers	2/22/2022 6:13 PM
267	Medications are being coming more complicated with more interactions or dosing specific requirements. it takes time to lean about new medications and new workflows. That time is rarely provided by employers. Patients get short changed because interventions pharmacists could identify, or medication narrowing does is not maximized as there is not enough time provided to really review med profiles.	2/22/2022 6:12 PM
268	Please lower the age requirement for technicians to 16 years. The wages for most chains cannot compete with other businesses' compensation.	2/22/2022 6:11 PM
269	Our new priority has become administrating vaccines and Covid-19 tests. Our pharmacy and many like ours will have 300-400 prescriptions that need to be filled, but we're stuck giving vaccines and tests. So now I've got dozens of pissed off patients who called their prescriptions in for refill 7 days ago and their not done. I don't have enough staff to answer the phones because it's either help the line of 20 of people in front of me or answer the phone. Take a guess which one we choose? We've already had to alter our hours of operation due to pharmacist shortage, which pisses off patients and pisses off the OBOP. We get yelled at and mistreated by corporate and patients. The shortages aren't just in OR either. It's become increasingly evident that pharmacists and technicians are getting tired of this garbage. Why OBOP is even bothering to do a survey beats me. You'll never do anything about it.	2/22/2022 6:08 PM
270	WE HAVE BEEN SEXUALLY AND VERBALLY HARASSSED BY THE MANAGER! AND CUSTOMERS!	2/22/2022 6:07 PM
271	I work in the clinic not in the actual pharmacy	2/22/2022 6:03 PM
272	As a Pharmacist I have been told by my district Pharmacy Manager, when calling in sick with an illness, 1. I am responsible to find my own coverage when I am sick. 2. A single sick day (one in a row without a previous sick day taken in over a year) requires a note from a doctor. 3. If I am unable to do 1 or 2 I am required to come into work sick or not. I actually kept screen shots of the text messages from the district manager telling me this. I reported it to the Oregon Bureau of Labor and Industries, but they stated they could only take action if I was punished for not showing up. I, however, went to work sick from fear of punishment. During a period of time around 4 months, previously in my career, I was literally the only person employed in my retail chain pharmacy. This pharmacy averaged about 1600 prescriptions per week and as a pharmacist I was the only human in the pharmacy from 9am to 8pm. Things got so bad one day someone called the police because they were unable to get a hold of anyone in the pharmacy. The police officer showed up to my pharmacy I was the only one there, many people in line and waiting around the area, many people trying to get through on the phone lines. This was before COVID. The suggested staffing from the company was 1 pharmacist per day and 12 hours of pharmacy technician. During this time there was an opening for a pharmacist and 2 technicians at that pharmacy. Those positions stayed open for 4 months, then I left the company. In another instance during a time while I was a pharmacy manager, my colleague had requested I sit in on a meeting with my district pharmacy manager to discuss some mental health issues they had been going through. During this meeting the District Pharmacy Manager made it clear that "there is no such thing as a mental health day" and that they could not take a sick day due to mental health. I reported this as well, but unfortunately this former colleague quit shortly after that meeting. I'll go ahead and name the "mental health sick day is not real" district manager because he is no longer in Oregon and is now[redacted] [redacted]at Rite Aid[redacted]Just sad.	2/22/2022 5:58 PM
273	Lack of centralized medical records/information. Unable to get patient history.	2/22/2022 5:57 PM
274	When I worked in pharmacy we were pressured to make decisions that were profit based and not safety based. Techs are overworked and underpaid. It is the last profession to recognize professionals to assist doctorates . Technicians are grossly underpaid for doing the pharmacists job. We ARE smart and educated but do not get paid what we are worth and there	2/22/2022 5:49 PM

	is little room for advancement. This is why I left pharmacy after 36 yrs to work at a shipyard in data entry.. I get paid more and it's way less stress!k	
275	I feel sorry for anyone that is currently working in a retail pharmacy setting. It doesn't take a "rocket scientist" to see that the system is broken! I have been a pharmacist for almost 30 years and many of that was in a retail setting. It has progressively gotten worse and continues to decline for customer satisfaction. Rite-Aid is providing a new low to our practice, but some of the other chains shouldn't give themselves a pat on the back either. The labor models that these stores are using are extremely short in staff and while the closure of Bi-Mart and COVID has increased this pressure, it would be foolish to not recognize that we were already heading down this path over the past several years.	2/22/2022 5:46 PM
276	I have given notice. I can no longer take the verbal abuse, name calling, bullying, physical threats, and worse, have to answer to be board and be under investigation every time a disgruntled customer files a complaint full of lies, and I feel like a criminal trying to defend myself over perceived customer service issues. Every day I work, I fear for my life. Not sure when the next person is going to explode. I wish you all would take certain areas into consideration. Customers are losing it and we are in the receiving end. I am done.	2/22/2022 5:44 PM
277	The metrics just keep getting greater and the staffing fewer and fewer with more and more patients. This is a broken system. We need to return pharmacies to being healthcare facilities, be able to focus on patient care, and get rid of the fast food mentality.	2/22/2022 5:43 PM
278	When am I going to stop taking ridiculous surveys and see some change in this industry. I know pharmacists who have walked out mid shift and will never return to pharmacy. How am I supposed to want to continue being a pharmacist when the board of pharmacy won’t do anything. I’m sick of feeling unwanted by my employer and the board of pharmacy. What are you doing all day? Maybe make some change before there’s no pharmacists or technicians at all. It’s so disappointing waking up and going to work every day knowing nobody gives a shit about us. I’m about a week from quitting pharmacy and working at McDonald’s because at least they care about their employees.	2/22/2022 5:42 PM
279	I think CPhT’s need to be able to handle more responsibilities. We should be able to administer vaccines more openly a freely exactly how RPh’s are able to. Oregon needs to step up it’s game like other states are allowing. Be more progressive, a leader in what’s new. I’m also a contract technician here in Oregon so I work at 5 different hospital inpatient pharmacies and I see a lot of what’s wrong with different places and they’re all different.	2/22/2022 5:41 PM
280	Allow for more time to finish ce	2/22/2022 5:40 PM
281	Company policies over complicate the filling process making it so I must focus on documentation of tasks unrelated to patient care. Additionally some policies intentionally bypass safety measures put in place to prevent medication errors. My company has acknowledged that 20% of all medication errors are the direct result of this policy but has done nothing to address the bad policy and instead has decided to focus on the punishment of pharmacists for errors that occur while following company policy	2/22/2022 5:39 PM
282	Because of staffing shortages, we are unable to cover vacations/days off/sick days. We all work overtime every week, and are asked to go to other stores before/after work to help. We've had 2 staff out with covid, in the last month. Because we're in the back of a retail store, and company policy discourages asking customers to wear masks, we are constantly having customers refuse to wear them while in line, sometimes becoming angry and occasionally verbally abusive. I have not seen other pharmacies enforcing the mask mandate in a health care setting, and have been told by management that we cannot "refuse care" to people who refuse to wear masks. This creates extreme anxiety and unsafe conditions for those customers who are immunocompromised and those who are getting vaccinated.	2/22/2022 5:37 PM
283	I’m not currently working as a technician due to workplace practices.	2/22/2022 5:35 PM
284	Thank you. I fear for patients because of permanent staffing issues.	2/22/2022 5:34 PM
285	I don't practice in a dispensing pharmacy, however occasionally need to collaborate with a dispensing pharmacy (eg clarify a prescription sent by myself or other provider, resolve prescription barriers/issues by telephone, etc). It has been increasingly difficult to reach someone due to long call wait times, pharmacies not answering phones, or finding someone who can help with simple requests (eg take a verbal order to update a quantity on a prescription, etc).	2/22/2022 5:33 PM

286	Pharmacy that I work for needs equipment like pump repeater to help with the workload	2/22/2022 5:31 PM
287	I work at the VA, and I hope that I never need to go back to retail. The demands placed on retail staff are unsustainable.	2/22/2022 5:30 PM
288	The only healthcare field where professionals are expected to serve patients and corporate interests at their own emotional, mental and physical expense.	2/22/2022 5:29 PM
289	Covid shots appointments were over 120 shots per day(within 6 hours windows) with no extra help	2/22/2022 5:28 PM
290	Being able to work from home has allowed my pharmacy to run more effectively due to space limitations at the physical location. The restrictions put in place to remain at home are too substantial unless we hire an absurd amount of pharmacists. Please reconsider your guidelines. I	2/22/2022 5:25 PM
291	The metric demands need to go away.	2/22/2022 5:22 PM
292	My location is well taken care of and practices very safe and timely patient care. I am concerned only in that other locations in my chain are not set up this way and lean on my staff and time constantly in order to barely get by. The reasons for this are mostly due to the quality of technicians that are hired due to the low rate of pay compared to other jobs like fast food for example. Industry standard needs to rise to pay both technicians and pharmacists better so they can retain top talent for the stress load we are under.	2/22/2022 5:18 PM
293	Patient expectations aka 10-15 min wait time is unrealistic	2/22/2022 5:16 PM
294	The board of pharmacy needs to mandate more pharmacist and more technician hours based on number of prescriptions filled. Right now we are SERIOUSLY understaffed. Patient safety is at great risk. We are doing the best we can with what we've got, but it's not nearly enough and patient care and safety (which is what the board of pharmacy needs to address) is suffering greatly. Patient care abs safety have been on a downward slide for quite a while. Please help us provide adequate care by mandating a minimum number of man hours (pharmacist and technician) based on number of prescriptions filled. We're drowning.	2/22/2022 5:16 PM
295	na	2/22/2022 5:15 PM
296	My pharmacy is one of the few in Jackson County that can keep up with the work, I believe it is because it is very well managed. Other pharmacies are making their patients wait for their medications.	2/22/2022 5:13 PM
297	I would have checked all of the options in question 25 if I was still practicing. All of those questions were applicable at the time I retired 8 years ago and it appears that things have gotten worse. Now as a customer I can see that pharmacies are just overloaded with work and lack of employees to do the work. Waiting 45 minutes in line just to get a refill is unacceptable. I have always been against mail order but I may be forced into it. Like I said these were all problems 8 years ago when I gave up hoping for a better work environment.	2/22/2022 5:02 PM
298	not enough staff and to little technicians	2/22/2022 5:01 PM
299	This lack of staffing and pushing pharmacy staff to the point of exhaustion is nothing new. It is more apparent during COVID but it has been happening for year. Employers have always asked us to do more and more with less, creating a dangerous environment for patients. Many Walgreen pharmacists in Central Oregon were very vocal to upper management about this and they do not seem to care. It goes beyond the employers though, they are also strapped because of low reimbursement rates from PBMs. Employers can't adequately staff when they lose money for health care services. It goes far beyond COVID. I filled this survey out based on me still working at Walgreens. I have recently left. I'll chat about this anytime if it helps to make changes [redacted]	2/22/2022 4:57 PM
300	Pharmacist shifts should not be longer than 8 hours.	2/22/2022 4:56 PM
301	It is hard to get good new employees for non-technical support staff.	2/22/2022 4:55 PM
302	Walgreens	2/22/2022 4:54 PM
303	Please implement new rules and save this profession	2/22/2022 4:53 PM
304	I am not sure how we would get more pharmacy technicians to get certified and or joing the phqrmacy practise. It is about time to think about ways to incentivice technicians or expedite	2/22/2022 4:50 PM

	their certification process.	
305	The sheer amount of verbal abuse endured by the pharmacy staff creates a rather unsafe work environment	2/22/2022 4:48 PM
306	The lack of technicians is putting stress on pharmacists and technicians are choosing to work at fast food chains where they get very similar if not more pay for less abuse from patients via phone and at the counter. Please help change the way technicians perceive this very important and valuable role.	2/22/2022 4:48 PM
307	New rules such as licensed professionals must sell Sudafed makes our workload higher and takes away from professional duties.	2/22/2022 4:43 PM
308	I believe my staff can use more training besides CEs	2/22/2022 4:42 PM
309	Please help us. We need some kind of protocol that outlines certain # staff per number of prescriptions.	2/22/2022 4:41 PM
310	More pharmacies should remain 24 hours	2/22/2022 4:39 PM
311	Our pay is too low	2/22/2022 4:38 PM
312	We allow our pharmacist to work a hybrid remote shift but not technicians. I think if we allowed technicians to work remotely like all other call centers we could hire more technicians. Also we only have full time employees. Offer part time.	2/22/2022 4:38 PM
313	Lack of technicians to fill open positions	2/22/2022 4:37 PM
314	the current operational practice does not allow for safe pt care. The board is not licensing rapidly enough to meet the demands. Our staff is overworked and there are to many parameters put in place to work against pharmacists. The Board investigates pt claims and make the pharmacists take additional time to respond to pt complaints that are unfounded. If the board would like to see the current operations they may want to start doing in-person visits. It seems the BOP has lost touch with the current practice.... i.e. pharmacist and technicians have been working in the Covid environment from the start and the board has not stepped into a pharmacy.	2/22/2022 4:37 PM
315	No masking would increase communication efficiency.	2/22/2022 4:35 PM
316	If something can be done to decrease mandatory counsels (like a dosage change that is not really a dosage change -- ie worded differently) it would be helpful	2/22/2022 4:35 PM
317	Most of questions in this survey are not applicable and do not address the real issues that has lead to unsafe work environments in Oregon pharmacies. Please allow me to clear this up for you. In Oregon pharmacist are walking off the job due to unsafe practice environments and most that I know of are leaving Oregon all together or pursuing a different career choice. In my opinion and the current situation cannot be blamed on the chains and supermarket corporate leadership. The blame falls solely on the current Oregon Board of Pharmacy, poor/horrific under reimbursement from health plans/PBMs, and unethical practices of pharmacy benefit managers. Even if we could hire more staff there is no way to afford additional FTE under the current reimbursement in Oregon. The amount administrative burden, unnecessary regulation, lack of support, and outdated practice standards the current Oregon Board of Pharmacy staff are promoting is not reflective of today's practices and cause public harm by standing in the pharmacists and their patients. We spending far too much time trying to protect our licenses and understand memorize game of thrones novel that is the OBOP OARS that no patient is able to spend time with a pharmacist. How can we increase staff when you cant afford them? Even the chains and supermarkets are unable to afford the FTE needed to staff appropriately for their standards of care! Five years ago we used to limit the number of prescriptions to 120 per pharmacist per shift. I left my old position in November because due to poor reimbursement and VERY high administrative cost we were told by corporate that we had to check 300 prescriptions between 2 pharmacist and 2.5 technicians. That is insanity, and does not include the additional clinical services, and compliance activities that have to be completed. Pharmacist are being punished and fined by the OBOP for trivial and foolish reasons. OBOP holds us accountable for the unethical practices and working environments we are forced to work in due to large corporate pharmacy chains, and pharmacy benefit managers. I hope you read this and understand that OBOP is just as big of problem and poses just much of safety risk as pharmacy benefit managers in Oregon. We need to de-regulate Oregon's outdated and archaic OARs. We are qualified health care providers and not high school	2/22/2022 4:35 PM

	teenagers. When you current OARs are similar to a game of throne novel how can any of us hope to ever be compliant. We would ask for help understanding the OARs but unfortunately not all of us can utilize tax payor dollars to pay for a lawyer to play babysitter for us any time we have a question. Better yet lets propose another 56 pages of temperature monitoring rules even though our current OARs are already to bloated with requirements. Why don't you try out follow CDC guidelines and the pharmacist professional judgement or did you forget that pharmacist have to go to school for 8 years in order to practice pharmacy in Oregon?	
318	I work for a small chain and firmly and STRONGLY believe my positive responses is unique in pharmacy today. Large corporations are providing terrible working conditions. I can attest to several patients leaving their current pharmacies and willing to drive 30+ minutes just to avoid their previous larger chain pharmacies.	2/22/2022 4:33 PM
319	N/a	2/22/2022 4:32 PM
320	We are under paid and understaffed	2/22/2022 4:31 PM
321	I have found at least 2 shots almost given to minors that were adult vaccinations. My daughters included. The pharmacist grabbed the wrong vial and was using it. I was able to stop them before it was injected. On top of rx requirements from corporate and vaccines. We are car salesmen now not healthcare workers. I have also seen wrong RXs get out.	2/22/2022 4:30 PM
322	My role is not in patient care/in a pharmacy. I work in healthcare IT industry.	2/22/2022 4:28 PM
323	If the BOP really cared about the safety of patients they would care about the toxic pharmacy environments and standards emposed on pharmacist by employers and their henchman directors. start passing laws to protect pharmacist and the profession.	2/22/2022 4:26 PM
324	I am concerned that the Board thinks central fill and automation is an always helpful solution. In my experience it ends up pulling staffing from the store, I.e. pulls staff from patient contact without providing a sufficient increase in efficiency or accuracy. Furthermore, I am excited that the board is initiating this survey and am hopeful the board realizes in their goal to promote patient safety that poor staffing is one of the most important issues to address. Not increasing requirements for checking. Not adding new rules and regulations regarding what can and can't be done. Not increasing audits. If the board truly promotes patient safety the board must take responsibility for understanding that pharmacists are professionals who also care about patient safety number one. The board needs to focus on how to improve pharmacy staffing if the board wants to increase patient safety. Be this a grant to increase technician interest, or some way of improving the turn around time for background checks and licensure through the board. I very much look forward to the result of this survey which I have faith the board will make public as well as what the board hopes to do with the findings to improve patient safety. Again, because this was quite long, I do not see central fill or robots as great patient safety improvers as they inevitably lead to staff being pulled from the pharmacy to pay for them.	2/22/2022 4:26 PM
325	Patient safety is more important than metrics. Provide enough staff to help customers effectively, and you make them happy; they will give better surveys.	2/22/2022 4:25 PM
326	My particular location does 75%-80% new prescriptions and may not take into account the increased workload to compensate the workflow. It is also mostly dependent on the pharmacist to operate the phones as well.	2/22/2022 4:24 PM
327	We just need more people. We pay well	2/22/2022 4:23 PM
328	Less complicated rules to allow tech to work from home when not able to go into pharmacy	2/22/2022 4:21 PM
329	Lack of regular raises, dwindling benefit packages yet increasing need for retail pharmacists . There should be incentives to help attract and keep what seems to be a valuable commodity. The profession is hailed for its attributes and contributions to local communities yet the employees are treated like cannery workers on a line . There needs to be change if retail is expected to thrive	2/22/2022 4:21 PM
330	There are too many other things that are required to do that are time consuming and it is known by corporate that they are being done on days off by the pharmacy manager in order for them to get done.	2/22/2022 4:20 PM
331	Pharmacies are too busy, not enough staffing, very stressful and overwhelming environment to work in.	2/22/2022 4:19 PM
332	Lack of margins from payers had really compounded the issue of being able to provide	2/22/2022 4:19 PM

	adequate clinical care and time to patients as pharmacies can not afford to staff at the levels required due to reimbursement rates from PBM's, Medicaid, Medicare. So it is not just the employer squeezing but the demands put on the employer to stay in business at rates that are unacceptable to patient care. This is across healthcare but even worse in pharmacy because of the payor contracting practices.	
333	The root of the problem is PBMs gutting reimbursement rates so in order to remain profitable most chains have to cut labor. CVS and Owns their own PBM and manipulates the markets to the disadvantage of pharmacies that don't, they also own a large share of insurance companies confounding their market control. Walgreens is in a similar boat. Until these oligopolies are broken up and regulated the pharmacy profession will continue to deteriorate. It doesn't help that they have large presences with multiple state boards and massive lobbying power.	2/22/2022 4:18 PM
334	I work outside retail and as an ambulatory care pharmacist in chronic disease state management at an FQHC.	2/22/2022 4:17 PM
335	Need to get rid of masks!!! We do not touch people or get very close at all. Pharmacists can wear one when giving vaccines but otherwise it is not needed. Hard to hear people through mask and plexiglass. Plus people are angry and sick of wearing them!!!! I'm tired of getting yelled at about it!!!	2/22/2022 4:17 PM
336	Extra workload with covid without added staff or pay. 20 plus covid injections a day. Curb Side without added staff or reimbursement. Many prescriptions filled at negative reimbursement.	2/22/2022 4:17 PM
337	My pharmacy has worked hard to develop work-flows using one simple principle: If a pharmacists must do something, then that is what a pharmacist must do; Everything else needs to be done by technicians. I am sick of hearing about pharmacists working too hard, when they spend most of the day doing the work of technicians. Employers should be intelligent enough to recognize that it is stupid to have a row of pharmacists counting pills when techs could do the same thing for a lot less money. When techs are doing what they can do, then the work-load of a pharmacist is realistic even given higher script counts now then when I began in the 1980s.	2/22/2022 4:17 PM
338	I believe some employers expect the current level of staffing for support positions (technicians) to be able to keep pre-covid standards while adding a large amount of vaccinations and testing to the workload, bit not increasing available scheduling hours to be able to justify hiring more technicians to help with the work load.	2/22/2022 4:15 PM
339	If I hadn't retired a year ago, I would have answered disagree or stongly disagree to most of the questions instead of not applicable. I was employed by Bi-Mart which has exited the pharmacy business. They treated pharmacists much better than most employers, but were unable to be profitable because of PBM and expecially Oregon's Corporate Activities Tax. In the last 2 years Newberg has lost 3 of its 7 pharmacies. Board of Pharmacy has done too little too late.	2/22/2022 4:15 PM
340	I quit retail pharmacy because my answers would be inverse of these. Metrics driven, short staffed, no breaks, no patient care. Just numbers, not even safety for the patients or staff was considered.	2/22/2022 4:14 PM
341	Pharmacy Technician pay is a big factor in the inability of employers to obtain and keep staff, but the ratio of techs to pharmacists is an even larger problem at some of the larger chains. One Pharmacist cannot adequately supervise and check the work of more than 2 technicians.	2/22/2022 4:12 PM
342	There are 3 main reasons staffing and patient care at pharmacies is so poor. 1) Reimbursement from third parties, especially Medicare Part D DIR fees, do not allow enough profit to sufficinetly staff for the workload. 2) Oregon's Gross Receipts Tax has further eroded profits for pharmacies. 3) Onerous regulation from the Board of Pharmacy and legislature places an undo burden on the daily workflow, thus reducing time for patient care.	2/22/2022 4:12 PM
343	We are short staffed, but no fault of staff or employer, but lack of applicants for clerical and technicians.	2/22/2022 4:11 PM
344	I work remote technical support for our hospital system so this survey is not applicable for me. I am supported in my role and do not feel any safety concerns. I appreciate you doing this survey. Our local retail pharmacies are are really struggling and I am concerned for the staff. We have 2 pharmacies that have shut down in our community so those pharmacies that are left to take on the burden of all the patients are overworked, stressed, constantly being yelled	2/22/2022 4:11 PM

	at by their customers because they do not understand the struggle to obtain medications and get authorizations and transfer prescriptions and get responses from providers, etc. They are doing a phenomenal job and probably sill making mistakes as it is just a very unsafe environment due to the constant stress and pressure they are under. The staff need to be recognized and praised for everything they are doing to take care of our community. I try to say thank you every time I go there but it just isn't enough.	
345	Retail seems like literal hell.	2/22/2022 4:10 PM
346	How automation is too dusty. There is a concern of pill dust cross contamination. Also, the machines do not operate correctly with all of the pill dust	2/22/2022 4:10 PM
347	Our staffing is shrinking by the day. We have a severe shortage of technicians throughout the company I work for. There are also places where the pharmacist has zero staffing on the weekends for support and we are running the entire pharmacy alone, from open to close. Not only is it mentally and emotionally frustrating to have no help, but easy to get distracted, overwhelmed and make errors.	2/22/2022 4:08 PM
348	we really need more pharmacists interns and technicians	2/22/2022 4:08 PM
349	As A retail pharmacy we need to concentrate back on filling prescriptions instead of offering vaccinations. We do not have adequate staffing to be doing vaccinations.	2/22/2022 4:07 PM
350	The vaccines really impacted our ability to do our primary job of filling prescriptions. A separate specific person should be tasked with only the precessional of vaccines. Every vaccine done in our pharmacy took the data entry person away from typing up prescriptions. We had were running a constant 800 RX’s everyday to type up . Couldn’t get ahead. Vaccines should be offered at doctors offices and health clinics. Not pharmacy’s	2/22/2022 4:07 PM
351	I like working at the pharmacy	2/22/2022 4:05 PM
352	Too many board regulations. I think most of the problems we face in pharmacy are due to overregulating every aspect of pharmacy. Mandatory counsels do not benefit patients in 99% of circumstances and pharmacists should be able to use their professional judgement in other situations. Opening independent pharmacies requires specialists due to the immense number of laws that the board enforces more harshly than any other health profession. Pharmacy suffers from a lack of entrepreneurship and over abundance of corporate oligopolies that do not focus on quality and instead focus on metrics. There needs to be safe guards for independent pharmacies against overwhelming regulation and chokehold contracts that manipulate pharmacist behavior into actions that produce the best results for the benefit managers. If more pharmacist were able to open up their own practices we would face less of these systemic issues that stem from a clear lack of diversity in the market.	2/22/2022 4:05 PM
353	NA	2/22/2022 4:04 PM
354	Some shift sites are better than others with regard to meal breaks. Some shift locations have specific lunch coverage and others do not (or the timing is poor; like working 6hrs then getting lunch).I do know the pharmacy management is working on break coverage and has improved. There were times this last year where pharmacists were doing tech duties bc of lack of staffing. Normally, in the shifts I am scheduled I do not even have time to complete CE which is required by employer. Sometimes I don't take breaks or stay late due to the workload. Lack of techs has drastic effect on workload and workflow. This was all before covid19, but was definitely exacerbated by covid19. Not idea when all surrounding departments are stressed for time and staff as well.	2/22/2022 4:03 PM
355	Inpatient hospital pharmacy is dedicated in patient care and does not overburden employees to maintain safe practices and efficiency.	2/22/2022 4:01 PM
356	My employer is one of the higher paying do technicians, but they still are generally underpaid for the type of work they do and the demands made upon them. They could make similar wages doing so many other less stressful jobs.	2/22/2022 3:58 PM
357	Pharmacists and technicians have had to take on more and more duties the past two years with little support from upper management and with the expectation to just absorb these additional duties with inadequate support and training. We’ve reached a breaking point with many staff members quitting and still very little help from the employer.	2/22/2022 3:58 PM
358	I believe retail chain practice has been diluted to a customer service oriented business instead of focusing on providing quality patient care.	2/22/2022 3:57 PM

359	Recently started at Mosaic Medical Pharmacy which is amazing. I worked at Walgreens before this and it was absolutely unsafe. I felt my license was at risk working at Walgreens, and the pressure to meet certain metrics, with inadequate staffing, was unsafe. I am so thankful that I was hired at Mosaic, because I now know what it is like to work for a company that appreciates its employees, and correctly staffs the pharmacy.	2/22/2022 3:57 PM
360	Na	2/22/2022 3:56 PM
361	In most pharmacies, there is 3 to 5 techs needed to type, bill, request, and fill medications. But typically there is only 1 pharmacist to review, verify, and consult on all those meds. How is 1 pharmacist supposed to process what 3 to 5 techs input/output?? That ration is absolutely a recipe for disaster.	2/22/2022 3:56 PM
362	I mainly practiced in Colorado but still hold my Oregon license. The issues are universal for retail pharmacy regardless of state. I have been retired for 2 years but keep up with current conditions from coworkers.	2/22/2022 3:56 PM
363	Extremely heavy workload not enough staffing. Push for higher volume and not able to keep up with phone calls, rxs, patient demands,	2/22/2022 3:54 PM
364	Turnover is very high so when we get people trained, they then leave to work at another pharmacy that is less stressful and busy. We are paid such a small amount compared to other pharmacy no one stays because of the workload. If my schedule allowed I would have left 7 years ago once I was trained.	2/22/2022 3:54 PM
365	The workload varies significantly throughout the year. During peak Covid vaccinations our prescription wait times and my ability to focus on other essential tasks suffered. As vaccination rates drop our pharmacist staffing feels adequate. Technician staffing could always be better. First we need more tech hours. And more importantly better pay to attract and retain competent techs. We nearly always run short due to sick calls, no shows and lack of coverage for leave.	2/22/2022 3:54 PM
366	Over the years, I have brought up to my supervisors the idea of taking a paycut myself in order to pay technicians more (to reduce turnover) or to increase tech hours for my store, but the idea has always been quickly dismissed. I don't know what else to do that is within my power to help fix this staff shortage problem. I have decided to switch careers and go into computer programming as I don't feel safe practicing retail pharmacy anymore.	2/22/2022 3:53 PM
367	I have worked in ambcare and tele clinical consultation for last 10years but I have seen my peers suffering under warehouse style working conditions. No time to eat, rest or go to the restroom. I am thankful everyday I do not have to work in that	2/22/2022 3:53 PM
368	[redacted]Telepharmacy, [redacted]California	2/22/2022 3:52 PM
369	Inability to hire qualified staff to fill staff positions leaving me as a float as the main tech	2/22/2022 3:52 PM
370	When giving more than 20 vaccines per day we needed additional staff. The pharmacy hired nurses and that helped. Overtime has been required to keep up with tasks,especially when shot volume was over 40 per day.	2/22/2022 3:52 PM
371	Great job OBOP	2/22/2022 3:52 PM
372	even before the bi mart pharmacy closures the pressure was too much. frequently I worked as the only RPh with 1 or 2 technicians for multiple days in a row. Customers do not care that you are not adequately staffed. Over all quality of the facility I work in is very poor. Everything from poor phone lines to tepid hot water. District/regional managers are out of touch with front line employees. We have recently gone to central fill... while this has "helped" ease the filling process the product leaves much to be desired. we have found vials with more broken tablets than whole ones, hair in multiple vials etc so central fill just makes us look like there is zero value. as a 25+ year veteran pharmacist THIS IS NOT WHAT I SIGNED UP TO DO!	2/22/2022 3:50 PM
373	The state makes it too expensive to acquire licensure. Outrageous costs.	2/22/2022 3:49 PM
374	Inadequate pay for the staff that does show up	2/22/2022 3:46 PM
375	Government intervention is the biggest cause of unsafe conditions. The State of Oregon does more harm than good	2/22/2022 3:46 PM
376	The chain I work for had a record year in sales, yet we run around doing the absolute minimum	2/22/2022 3:45 PM

	to fill as many Rx as we can. DUR's are a joke, counseling is a joke, oral contraceptive prescribing is a joke, etc.	
377	Providing pediatric vaccines (covid) caused stress for the pharmacists, techs, and customers. Many children scream and cry loudly making it difficult to care for other patients who need consultations in an already compromised consultation environment due to masks (hearing / seeing faces). Pediatric vaccinations require on average double the amount of time in providing them. Some days were chaos with kids.	2/22/2022 3:45 PM
378	Help the pharmacy professionals	2/22/2022 3:42 PM
379	We could use another pharmacist. Often there is only one pharmacist on duty and there is high demand for vaccinations and consultations	2/22/2022 3:40 PM
380	There are times when staffing becomes an issue, due to illnesses scheduled time offs, or when other pharmacies in area are closed due to staffing issues. Most of the time we have sufficient staffing to adequately care for patients in a safe manner.	2/22/2022 3:37 PM
381	Please encourage companies to pay technicians a living wage. Pharmacy technicians are essential to proper pharmacy functions and are barely compensated fairly. Many of my technician friends and I are having to work 2 jobs to make ends meet.	2/22/2022 3:36 PM
382	I have left retail pharmacy after 12 years. Although my former employer offered a $50,000 retention bonus, I declined because conditions are terrible and I have no faith that the chain would improve them. My replacement quit after 1 month, and told me he "was taking a break from pharmacy." He was a twenty year veteran. To my knowledge, that position has been unfilled for the last 3 months.	2/22/2022 3:36 PM
383	Labor laws around hours are not safe for the pharmacist position in most settings. Over 8 hours in a workday for most people at most sittings is dangerous. Many are working through breaks and meal periods as some companies are somehow able to classify these pharmacists as salaried. In most settings the pharmacist is required to be there for certain time periods, so the line is very blurred here for certain pharmacists in these salaried positions. Fixing current labor laws to not exceed 8 hours in a workday without overtime pay and making it clear what a salary position versus an hourly position is for a pharmacist is a start. There may be some exceptions where a hospital or 24 hour facility could negotiate 10 hour shifts without overtime through a union, but in general this is unsafe. Also, standing for long periods of time for anyone is unhealthy and this needs to change in many settings. But the issues I raise here, mental focusing ability and standing in place have plenty of data that would actually support an environment with reduced hours and varied physical positioning.	2/22/2022 3:36 PM
384	Hours allowed are based too heavily on metrics/numbers. Each pharmacy has a different situation to deal with(customer base, phone calls,language barriers,staff experience/work speed etc. I feel it is unfair to have one set rule to base hours allowed when there are many different factors that can vary the functioning /flow of a pharmacy. Obviously a store with little turnover more experienced staff will run a lot more smoother than one that has a majority of new techs and older customers that need more one on one attention (detailed counseling and longer phone service). There are a lot of unfair aspects and expectations that increase stress and increase risk of errors.	2/22/2022 3:36 PM
385	Non pharmacists should not be in charge of pharmacies. They simply don’t understand what all goes into providing good pharmaceutical care.	2/22/2022 3:35 PM
386	I have over heard pharmacists talking about extended work hours. The last time they had work hours like that the pharmacists were exhausted and made mistakes.	2/22/2022 3:35 PM
387	Make it to where we no longer have to wear masks at work!!!!	2/22/2022 3:33 PM
388	The Board contributes to ALL of these issues extensively in some form or another either directly or indirectly.	2/22/2022 3:33 PM
389	Help!	2/22/2022 3:32 PM
390	If we could get rid of half of the Rules laws and regulations like Idaho did, it would be a lot easier to do our jobs. A sage work place is one thing. Too much regulation needs to be addressed as well.	2/22/2022 3:32 PM
391	This problem has been overlooked far too long. The big chains are in a race to the bottom when it comes to patient care/safety in the name of maximizing profits/efficiency. The board	2/22/2022 3:32 PM

	needs to take strong action to correct these problems and protect patients	
392	I work in CCO adminstration. In the future can you create a choice for Health Benefit Administrators??	2/22/2022 3:32 PM
393	The Board staff is getting in the way of patient safety. Stop intimidating pharmacists and let us practice as medical professionals or pay my student loans so I can go do something else	2/22/2022 3:30 PM
394	we dont get paid enough from krogers	2/22/2022 3:30 PM
395	The lack of applicants at our location has been out biggest problem. We have staff willing to pick up extra shifts here and there but we just need more applicants.	2/22/2022 3:30 PM
396	The board adds additional pressure and unnecessary stress on the pharmacy teams. Their investigative staff are aggressive and adds additional burdens on the pharmacists. The administrative requirements of the boards to adopt technology that would make pharmacy working conditions better are prohibitive to actually adopting the technology. The BOP is also a part of the problem and needs to look at their staff and how they interact with the pharmacists and the rules they write. Pharmacists don't want to work in Oregon because of the board staff.	2/22/2022 3:30 PM
397	Inadequate technology to do the job timely and well	2/22/2022 3:30 PM
398	There aren't any techs to hire!	2/22/2022 3:29 PM
399	I ask for help from the board of pharmacy to provide baseline standards for pharmacy companies such as instituting a pharmacist:tech ratio or cannot have more than X number of orders without X staff, or some means of regulating the number of orders flowing through the pharmacy. Staff are overworked, we have low morale, and are burning out Due to an adequate staffing. We've had openings for over a year that have not been filled and the remaining staff here are looking to leave since they are losing sleep and their families due to the stress of the work environment. We are at a critical point in pharmacy and I strongly request the boards assistance in creating a safe and better work environment so we can adequately take care of our patients.	2/22/2022 3:29 PM
400	Pay techs more	2/22/2022 3:28 PM
401	Need some incentivizing for pharmacy technicians to take the job. We cannot convince people to get into the profession due to poor conditions as pharmacy technicians.	2/22/2022 3:26 PM
402	As the PIC I have to try to make the best of a bad situation and it is getting exhausting. I am not allowed to have enough staff to see to the needs of the patients in a safe and effective, non-rushed manner. I fear that we miss things and the patients will come to harm. It is difficult to get the corporate leadership to understand the level of staffing that is needed.	2/22/2022 8:07 AM
403	Some state boards allow technicians to help ease the workload on pharmacists by allowing them to take in new prescriptions verbally. Our pharmacists are overworked and can use extra help. Helping give vaccines to patients has greatly helped the workload on the pharmacists. Technicians should be approved for all vaccine types, not just COVID and flu. Also, technicians should be allowed to verbally take in new prescriptions as some states allow. The consultation law in Oregon is extreme, making the pharmacist go to each patient and then initial a paper after each one. If the patient does not want a consult or says they have had the medication before, the pharmacist should not have to be forced to give a convict anyways simply because the prescription is marked "new." Other states don't have such extreme consultation laws and free the pharmacists up more.	2/22/2022 5:18 AM
404	I feel the pharmacy profession has been in the frontlines accessible and available for the public with very little support from the board and our employer. Secondary to mandate, we had no second tech. I close and open alone, the bring fourth more work load like testing now before hiring sufficient staff to do it?? It's the only department where I see the pharmacist is a rph, clerk and tech. Even a restaurant doesn't allow the cook to be the hosts, waitress and cook? Yet here we are. There's no enough employees and our hours are the same. If the chains refuse to hire enough staff to support a safe environment for patients they should not be allowed to remain open. Throughout pandemic, never seen my dr check me in instead of her MA to get height and weight. Zoom care PA never have to check in patients upon arrival or even when they are dispensing drugs. Somehow, maybe our board can help learn from the PAs? They seem to be more professional industry? Also, nurses seem to have more support than pharmacist . Not sure when and how our profession became unprofessional and work environment so hostile. Pharmacy just appears and is ran unprofessionally. We are so	2/21/2022 8:51 AM

	desperate and burned out I am positive if we didn't have student loans to pay most of us would be out by now. The way it's being ran, it appears that perhaps we can really do without pharmacy and just hand over our responsibilities to the PAs since they appear more professional and better staff better outcomes to the patients and their work setting appears more encouraging and has the publics best interest. Pharmacy department across the healthcare system just appears to be poorly ran to the public and it's very transparent. It's not healthy and very much embarrassing	
405	Employer hires poor workers. Employer underpays me. Employer has poor leadership. Employer makes paid time off most difficult. Employer needs better workflow.	2/21/2022 12:11 AM
406	Things were terrible and unsafe prepandemic. My employer has no meal policies. If two pharmacists work, we get a lunch, but there is pressure to not take breaks. If you're alone, you must make time and there is no way to redirect customers well. Now, since pandemic, it has become downright unsafe and awful, both from personal physical and mental health to patient safety and health.	2/20/2022 9:36 PM
407	There needs to always be a ratio of having a technician on duty at all times and never a pharmacist by themselves	2/20/2022 1:23 PM
408	Pharmacy Interns(Foregin pharmacy graduate) urgently need training on vaccine administration since they did not have been trained on it outside USA, and they will be a great help in their pharmacies with increased demand for vaccination. There is no distinction offers this training. Neigther the American Pharmacist Association nor Oregon board of Pharmacy does this training for Foreign Pharmacy Graduate as interns. Also, all Pharmacy schools in Oregon do not offer such training, but do offer it only for their students.	2/20/2022 8:59 AM
409	Corporate will tell us they are sending us help to cover a shift but then they don't so we are not even given the opportunity to find our own coverage until it's too late. They also don't approve/deny our vacation request till the last minute. And it's usually a denial, so we never get to plan or even use our earned vacation time for the year. And they don't always post our open shifts for people to pick up so we end up covering our own staffs shifts pushing us to work full 8 to 12 hour shifs 7 days a week sometimes. And often times they only schedule a floater for 4 hour shifts so we get 3 a day or only partial coverage for the day and are expected to cover our own shift or not get it off	2/20/2022 8:17 AM
410	The only treason I disagree with the hiring of employees in a timely manner is the nationwide shortage of technicians. It has nothing to do with my employer wanting and trying to hire new employees.	2/19/2022 7:39 PM
411	I may have filled out the survey differently during the height of Covid vaccinations mid last year. Currently my pharmacy is calm	2/19/2022 7:10 PM
412	I frequently work alone in pharmacies. No techs, no clerks, just me as the float pharmacist. I am expected to type and fill all the prescriptions, ring people out at the register, answer phone calls, accommodate appointments & walk-ins for all vaccines, and do multiple MTMs a day. Plus all the extraneous tasks like pulling expired & recalled drugs, taking out the trash, submitting the next days order, general cleaning & restocking. Most stores I go to are multiple days behind because we can't keep up so I spend most of the day getting screamed at by customers too & have been physically threatened on the job as well. I've had patient complaints because I went to the bathroom & for asking someone to wear a mask in the immunization room. I've also worked through 2 miscarriages for this company. I'm tired of being asked to do the impossible for the ungrateful.	2/19/2022 4:35 PM
413	for the most part, safe place; have been unable to find a COPT to replace one that recently retired from full-time work; however, he is willing to fill in on 2 saturdays a month to relieve the one COPT	2/19/2022 4:02 PM
414	None	2/19/2022 11:46 AM
415	Over scheduled Ambulatory with IV's and chemo's at the same time but only one technician to make everything that day including inpatient and ER IV's making it potentially unsafe for patient's when ambulatory over books even though they have 5 nurses that day to handle the load we only run IV rooms with 1 Technician	2/19/2022 10:19 AM
416	Rate of pay does not reflect the critical nature of the role nor the training and education required to perform said role safely. Lack of pharmacy technicians due to no applicants and due to multiple consistent callouts per week creates an unsafe environment for both patients	2/19/2022 1:00 AM

	and staff. There is greater risk of errors in medications released to patients as seen by our metrics. There is greater risk for staff due to constant berating by patients who are needing their meds and not receiving them.	
417	They keep extending our hours open but reducing the labor we can use. It's not possible to keep stretching farther. When I started 19 years ago we filled 300 with 3 pharmacists, had 5 techs, and cashiers. We were open 9-7 weekdays and 9-6 on Sat. Now we have 1 RPh, and sometimes only 2 techs to fill 350 in a day. We are suppose to be open 8-8 weekdays and all weekend. It just doesn't work.	2/18/2022 9:31 PM
418	i am very disappointed in how my new employer is handling the staffing concerns that we have after the closing of 2 of the 5 pharmacies in our town of 10k ! i have expressed my concerns and am asking for special consideration to their requests for no overtime, but am met with attitudes from the corporate office that are so out-of-touch-with -reality that I have considered other places of employment. I remain here out of great concern for my community. We simply cannot have another pharmacy close here !	2/18/2022 7:00 PM
419	Everything I answered was for my present job. If I had continued in my previous job (grocery store pharmacy) I would have been very worried about my mental and physical health. I was routinely working 14 hour days with no real breaks. I am extremely happy with my situation, but feel for many of my retail compatriots	2/18/2022 6:26 PM
420	We are performing under pressure and pushing ourselves at the same wages prior to Covid 19. A wage increase needs to be discussed	2/18/2022 6:24 PM
421	Hi turnover of support staff, constantly in training mode	2/18/2022 6:08 PM
422	The only thing that will decrease the workload and increase patient care is to limit the number of prescriptions a pharmacist is required to check per hour. Pharmacy owners are in it to make money, not to allow extra time to help a patient. The law that says a pharmacist will only take on a workload that is safe, is not effective because as long as patients aren't dying the situation is deemed as safe. The board must put in a law on a prescription limit per pharmacist in order for anything to change.	2/18/2022 1:58 PM
423	I have been working for different independent retail pharmacies in southern Oregon for the last 4 years. Prior to that I worked for chain retail corporations for 2-3 years. There is a grand canyon of difference between the work environments of the two. When I worked for Safeway (even before the pandemic) both pharmacist hours and tech hours were cut to the bone so we had the bear minimum staff we needed to get the work done at all, certainly not in a safe or effective manner. While not having enough hours to get the work done I was told by corporate to cut 30 more tech hours. I refused and told my DM he could come fire someone personally if that was the decision but I wasn't going to do it and I never heard about it again. I fear this is a tactic used by chain corporations to pressure pharmacies into operating at unsafe staffing levels - especially pressuring younger graduates with less experience or confidence to say no to their employer in order to maintain patient safety. While I was at Safeway my direct [redacted] (who is not a licensed pharmacist in Oregon by the way) would tell me to do things that I was not comfortable doing. Of course never in writing because the company LOVED pushing responsibility and liability onto the individual, but I remember the time he called me on my cell phone at work and told me to fill a fentanyl script for an opioid naiive patient because the patient was complaining to corporate. Overall in my time with Safeway I felt that I had no support from the company, and in fact they would do anything and everything to increase the profitability of my store - even sacrificing patient safety. I couldn't take it anymore and quit after a little over a year in the PIC position. I never reported anything or told many people out of fear of retaliation - I'm sure you're aware that pharmacy is a very small world, especially in [redacted]Oregon.	2/18/2022 11:24 AM
424	Can't find people to even interview for a position. Tech's working 50+ hours a week to keep things going. Many clinical services suffering due to pharmacists having to do tech work due to technician shortage.	2/18/2022 7:52 AM
425	I hope someone will be the voice for all of pharmacy personnel who has no voice in big corporations	2/17/2022 11:24 PM
426	Current problems interfering with pharmacy workflow and safety :. Extreme increase in rx count, staff burn out and shortage due to increase workload demand, hostility from patients due to long wait times and mask wearing requirements. It is exhausting, and sometimes frightening, being yelled at for trying to enforce a mask mandate to customers. This is going to	2/17/2022 11:03 PM

	be VERY difficult when the indoor mask mandate is lifted. The noise in busy pharmacies has reached unsafe levels, with staff and customers all speaking side by side at the counter, staff on multiple phone lines, phones constantly ringing, refrigerator alarms, store pa announcements and and music blaring... Patients can't hear us and we can't here them. Privacy is not even possible when you have to shout to be heard. Patients nod they they understand, say they don't need counsel just to get out of the pharmacy quicker. Mask burnout is a real thing. It's uncomfortable and exhausting to wear one for 10+ hours per day. I understand masking up for direct patient contact like vaccines but once the indoor mandate is gone retail employees and customers should not be burdened with this. I challenge you to come and work side by side with us, day after day, and explain to a customer in the store why they will need to wear a mask to stand in the pharmacy line but not in the grocery line... In the same building.	
427	District Manager holds unpaid mandatory conference call each week. Pharmacist manager is required to attend on their regular day off to discuss vaccine and company target goal which is metric. This is not professional conduct for healthcare personnel. California law prohibits such act. I hope Oregon can protect pharmacist from unpaid calls or metric stress.	2/17/2022 10:10 PM
428	Decisions no longer seems to be made based on patient care or clinical benefit, it is purely money/ profit and having metrics that must fit no matter what practice variation exist	2/17/2022 10:06 PM
429	Pressure to complete mundane tasks through OutcomesMTM to prevent dir fees etc but not actually adding value to patient adherence	2/17/2022 9:49 PM
430	Pharmacists SHOULD be able to get mandatory breaks and scheduled lunches. If there is no pharmacist overlap, then pharmacies should CLOSE for lunch. Please protect pharmacists and technicians. We are overworked and burnt out, especially during the COVID-19 pandemic. Ultimately, patient safety will be negatively affected.	2/17/2022 9:42 PM
431	ask us what we think about the boards mask mandate	2/17/2022 7:41 PM
432	I have floated to stores that do not have a full time PIC and I worry that some of these stores lack the leadership and staffing to remain compliant with BOP requirements. Managers have been leaving my company at a very high rate and I worry that the new PIC's are inexperienced and unprepared to handle the current demands in pharmacy.	2/17/2022 6:54 PM
433	Unreasonable metrics	2/17/2022 6:39 PM
434	We have been required to work 13 hour shifts throughout Covid and I feel my ability to provide safe work has been compromised. I do not have the mental or physical capacity to continue at that level.	2/17/2022 6:11 PM
435	Wages are too low for pharmacy staffing.	2/17/2022 5:54 PM
436	in my experience this site does not reflect the current norms. I was previously at a large chain community pharmacy where any breaks were discouraged, vaccines were out of control, metrics ruled the pharmacy, and we were chronically understaffed. I am extremely grateful for the position I hold due to the ability to practice safely during these times	2/17/2022 3:56 PM
437	I am filling this out in regards to the previous pharmacy I worked at. I've been gone for 3 months now and can not believe I stayed as long as I did. We are supposed to be in the medical field. We are supposed to care for our patients. I can guarantee that is not happening at most of the local pharmacy's in my area.	2/17/2022 3:46 PM
438	Shifts longer than 8 hours promote errors and is NOT an ideal employment standard. Stores are focused on finances and not staff or safety. The reports of staff abuse and inability to fill in a timely manner have been escalating for years. Vacant positions are not filled because of poor pay, shockingly poor workplace causing "burnout" and resignations. Corporate do NOTHING to address the problems. Additional workload has been added to pharmacies without any additional staff or change in store design or workflow. Numerous associations have been pointing out these and other deficiencies for years now without any change. Pharmacies are closing and staff leaving the profession resulting in failure to provide necessary care. PBM are remotely practising medicine WITHOUT a license - non-payment and underpayment plays a key role in the failure pharmacies and healthcare without consequences or malpractice litigation.	2/17/2022 3:17 PM
439	The requests to meet clinical metrics such as completing MTM interventions such as CMR and other targeted reviews on the fly (i.e., when patient picks up meds) which is not logistical	2/17/2022 3:14 PM

	with the time given for counseling and number of patients in line/staffing etc. Especially a CMR which should take at a minimum 20-30 minutes of review time with patients on multiple medications as well as additional time for documentation, provider communication, etc. These "CMRs" completed during patient Rx pick-up and billed to insurance as "completed" is fraudulent in my opinion, and although we aren't directed to be fraudulent...our supervisors simply say "it's completely possible to complete these interactions during Rx counseling if you're prepared) but their pressures and expectations directly contradict reality and the limited staffing doesn't allow for adequate prep-time to supposedly facilitate this ridiculous method. These problems are all pre-COVID related issues, but we continue to be understaffed and under-supported being asked to complete multiple other clinical and non-clinical tasks while somehow managing to safely and effectively review and dispense prescriptions. It's absolutely ridiculous and it does nothing to promote our profession forward or support the clinical services we offer if we can't deliver them effectively or efficiently. All we end up doing is providing sub-par clinical service and sub-par dispensing/counseling services and both patients and practitioners are suffering because of these practices. It's undermining our healthcare system completely. Not to mention how many prescribers I speak with on a regular basis that are under the impression the pharmacist is reviewing these medications with their patients when it reality they may get read the directions on the bottle and asked if they have questions at the most. I feel like we are all struggling but not feeling confident or comfortable enough to speak out because we're treated as dispensable.	
440	As a direct result of the working conditions faced during this ongoing health crisis, I developed mental health issues which forced me to leave a role that I excelled at (RXM) and take a pay cut with my company to become a staff pharmacist. The workload is immense, the pressure from corporate was too great, and I was left feeling like my pharmacy was a danger to the public. I know I am not alone in these thoughts, as I have read many articles from pharmacists across the US detailing the same conditions. It is time that the BOP steps up and stands up for the pharmacists and technicians in this state to ensure we can safely maintain our work environments for our patients.	2/17/2022 3:10 PM
441	Working over 8-10 hrs few days in a raw makes it very difficult to focus and perform duties safely. After 8 hrs, I am physically and mentally exhausted and same task takes me 3 times longer to perform. As a result we are falling behind and may start cutting corners to speed up and make the metrics. When I'm trying to ask to reduce hrs per shift and have overlapping shifts with a second pharmacist, the answer I'd that our volume is not large enough (300-350 rxs per day) in addition to other clinical and non-clinical daily duties to have more pharmacist per day.	2/17/2022 2:44 PM
442	The lack of pharmacists on staff could be partly resolved by increasing the number of technicians on staff. As it is now, I'm often performing many technician tasks in order to take care of patients in a timely manner. This takes away from my pharmacist duties and results in more pressure to get things done faster. Patient expectations are generally unrealistic. Pharmacies would work better in a closed environment. Pharmacists are interrupted way too often. The lack of concentration is a huge barrier to getting prescriptions and vaccines done safely and in a timely manner.	2/17/2022 2:23 PM
443	Stop adding so many duties to pharmacy staff!! Allow cashiers to do methcheck. Allow techs to give vaccines. Remove having pharmacies give vaccines under 11 (very time consuming due to children throwing fits). Minimize phone lines within a pharmacy (causes too many distractions). Only allow vaccines by appointment to help with daily workflow.	2/17/2022 2:00 PM
444	There is a giant lack of understanding from patients as well that perpetuates this cycle. There is also issues recieving things from providers in a timely manner that can hinder the process as well. Most companies these days are focused on doing more with less. They are cutting pay and hours and conditions get frightening fast. There is a lack of compassion, and especially in the corporate environment, a lack of caring. They wantore profits and it doesn't matter how. Unfortunately, 2ith how bent over a barrel we are with insurances as well, this also is unlikely to end soon. There needs to be a change. Our profession is being degraded before our very eyes.	2/17/2022 1:40 PM
445	Not enough technicians to hire in the market to fill all positions timely.	2/17/2022 11:38 AM
446	Printed patient education on drugs too generic and need major improvements.	2/17/2022 11:34 AM
447	Lack of appropriate training and treatment of staff. Changing job duties that are outside the scope of hire. Useless metrics used to shame employees with no constructive feedback. General lack of humanity towards patients and staff.	2/17/2022 11:33 AM

448	I am retired, I volunteer at a vaccine clinic	2/17/2022 10:40 AM
449	I am shocked the OBOP allows chain pharmacies to disregard patient safety for profit.	2/17/2022 10:17 AM
450	Vaccinations and non-clinical tasks (3rd party mainly) are taking more and more time with little to no added help	2/17/2022 9:54 AM
451	Drug shortages/backorders and provider unwillingness to adapt has been a problem at my hospital inpatient workplace. A significant amount of time has been spent trying to communicate shortages to nursing staff and the pharmacy is criticized for putting patient care in jeopardy when we are unable to provide medication that is unavailable from any source.	2/17/2022 9:38 AM
452	I think that some pharmacies should go back to having clerks to ring up patients so that pharmacists and technicians can focus on the pharmacy aspects of the job. Also the computer programs are not user friendly. Our employer just went to central fill for some sites and it made our on site process more time consuming when we are trying to get caught up. PBMs and insurances should be doing more to help pharmacies from closing and losing money.	2/17/2022 9:35 AM
453	12 HOUR DAYS AS THE ONLY PHARMACIST WITH 1/2 HOUR LUNCH BREAK IS ROUGH	2/17/2022 9:00 AM
454	Inadequate computer systems that do not provide for safe working conditions. No magnification of computer systems that lead to eye fatigue, eye strain, and increased risk of errors due to unacceptable font size. Poor lighting or harsh lighting and no magnification devices provided to help with properly identifying pill imprints, lot numbers, etc. How many errors are caused by inadequate technology that places patients at risk and increases pharmacy error rates? No pharmacy employee should have to work in a situation where they can't properly see, through no fault of their own, such small print that mistakes are occurring. We wouldn't expect a surgeon to operate in dim light with no magnification, why are pharmacy personnel being asked to take unnecessary risk?	2/17/2022 8:17 AM
455	1) multiple technicians with leave of absence, both continuous and intermittent, and accommodations for reduced work schedules limit ability to keep up with volumes as we are unable to replace these positions or take disciplinary action against those who overuse/abuse their FMLA. 2) company questioning that our standards for accuracy/safety are too high and asking us to reexamine our expectations	2/17/2022 8:09 AM
456	My specific pharmacy is being impacted by local pharmacy closures and the complete inability of my competitors to fill a prescription in a timely fashion or even answer the phone. Low tech wages prevent me from being able to hire talent and my current employees are burnt out.	2/17/2022 5:34 AM
457	Retail pharmacy customer mask wearing in the building and at pharmacy counter and lobby area is not enforced when they drop general mask mandates. Lots of customers there for shots etc for healthcare needs plus pharmacy staff that is supposedly healthcare and needs to wear masks but hundreds across counter and in store do not?	2/17/2022 1:29 AM
458	LTC does not have as hard of a time as retail right now. It's almost impossible for us to satellite to retail pharmacies right now for filling in a timely manner, let alone getting through to them on the phone. Retail is struggling bad.	2/17/2022 12:01 AM
459	staffing only tied to script count not other tasks which also must be completed, resulting in pharmacist doing clerk or tech duties and not enough time to perform additional services such as MTM etc as they should be everything is rushed do not feel patients are getting the best care	2/16/2022 11:44 PM
460	I am looking for a new career.	2/16/2022 11:37 PM
461	Co-workers cry daily. It’s been terrible.	2/16/2022 11:26 PM
462	I have to spend a lot of extra time dealing with angry patients, who are angry for things outside of my control (being behind because of staffing, being mad because we don’t have COVID tests). So I can’t spend my time filling prescriptions.	2/16/2022 11:10 PM
463	Increased qualified staffing would resolve most issues	2/16/2022 11:08 PM
464	We need more technicians!	2/16/2022 10:52 PM
465	Regulations set such has med b and now pa from my corporate requirements prevent patients from getting medication in a timely manner and are focused more on making money than	2/16/2022 10:43 PM

	providing a safe effective service for patients all pharmacy's closeting early instead of some opening later put more strain on ers and urgent cares	
466	It has been a literal nightmare. We are on average 800 prescriptions behind . It seems silly techs aren't able to data entry from home.	2/16/2022 10:28 PM
467	Someone needs to stop by the [redacted]CVS in Target [redacted]Or) for observation. This pharmacy is extremely unsafe and understaffed needs immediate attention.	2/16/2022 10:25 PM
468	It seemed evident that our upper pharmacy management was more interested in pushing us to absolute above maximum work load than trying to supplement staff and relieve these insane working conditions that we went through. An ineffective and poor scheduling system for vaccinations using multiple platforms that don't communicate with each other resulting in multiple overlap appointments causing stress and anger at the pharmacy. Sometimes we would have up to 5 people schedule at a single time slot. This was one of many things that caused stress and tuff working conditions. They would tell us we are looking to hire more support staff, ie techs and clerks. That never happened. All our open tech shifts are being filled by pharmacists.	2/16/2022 10:17 PM
469	Lack of quality career technicians	2/16/2022 10:11 PM
470	Workload is way too high for staffing. Wages have not increased while CEO income grossly increasing. No time to call on drug interactions/clarification, little patient privacy for actual consultation.	2/16/2022 10:06 PM
471	Inability to find and hire new pharmacists and technicians to provide adequate staffing shortage by the leadership of chain community pharmacy	2/16/2022 9:58 PM
472	I believe Covid test should NOT be administered in/around/near the pharmacy.	2/16/2022 9:46 PM
473	I've decided I'd like to leave the field of pharmacy but don't want to leave my pharmacy even more short staffed.	2/16/2022 9:38 PM
474	Survey should have been delivered when vaccine surge first happened, when pharmacies were really busy with vaccines and with a work load to do.	2/16/2022 9:22 PM
475	It takes way too long to initially license a pharmacy technician	2/16/2022 9:21 PM
476	Retail pharmacies, Walgreens in particular, had metrics for everything in the pharmacy. As a technician I am responsible for working the counter, drive thru, answering phones, giving vaccines, administering Covid tests, making 50+ phone calls daily offering med sync and pickup reminders, filling rx's, putting up the warehouse order, and basically keeping the pharmacy from burning down. Logging about 20,000 steps per day.All while the pharmacist gets to stand at the computer all day	2/16/2022 9:12 PM
477	Staffing issue and increased work load have significantly impact my ability to safely and adequately provide patient care. It also negatively impact my mental and physical health.	2/16/2022 8:59 PM
478	I work inpatient hospital setting. I have worked in retail setting before and if I had to answer the same questions for retail my answers would have been totally different. Some/ most retail settings are not safe! Staff (pharmacists and techs) are treated like slave labor. Pharmacists treated the worst. It's horrible in retail. We all know it is. It's unsafe, demeaning, thoughtless about the staff or patients. Something has to change. PBM's must be stopped. Pharmacists are brilliant people snd should be treated as such. Not like disposable garbage!	2/16/2022 8:44 PM
479	Retail chains do not allocate enough labor to do our jobs safely and do not pay technicians a wage that is sufficient for their level of skill and training. This leads to high technician and pharmacist burnout and the inability to staff vacant positions. Performance bonuses are offered to pharmacy managers, district pharmacy managers and even store managers to increase our prescription count beyond a point that we can safely handle. Meanwhile we are told that corporate cannot afford to pay technicians more. These staffing shortages are severely impacting patient safety. It is no longer a matter of if we will make critical errors, but when.	2/16/2022 8:11 PM
480	Significant increase in ex's due to closure of multiple area pharmacies.	2/16/2022 8:02 PM
481	safety for employees. I have been assaulted by customers. our staff needs more protection such as bank teller protection, especially in the high C2 dispensing locations. it's becoming increasingly dangerous.	2/16/2022 8:01 PM

482	The past year has been unbelievably stressful and miserable in retail pharmacy. I have on many, many days been the only person in my pharmacy and expected to give dozens of vaccines that were scheduled online without my consent. We gave so many vaccines that we could not fill medications, and patients suffered and took it out on staff. I legitimately feel that many of us who survived this time in the pharmacy without quitting will suffer from PTSD.	2/16/2022 7:46 PM
483	Very toxic work environment, especially when salary pharmacist regularly perform “shift work”. Lack of patient safety from leadership and more focus on profits and reducing FTE if it is not directly creating profit.	2/16/2022 7:23 PM
484	Technicians are fleeing retail pharmacy for less stressful jobs with better hours.	2/16/2022 7:19 PM
485	I have left retail pharmacy for the hospital setting. I am on one hand unhappy about this situation, as I felt that serving my community directly was my calling. Yet at the same time I am grateful for the opportunity to expand my professional skills in a new direction. I wanted to serve my communities as a retail pharmacist and pharmacy manager because I cherish the direct interaction with patients. I have left retail pharmacy because the profession is unmanageable and is literally falling apart due to the short sighted, profit driven behaviors of retail chains. It used to be Walgreens and rite aid that were horrible employers, and other companies (Kroger, Safeway, Albertsons, Costco, Target) were decent places to work. Now, in my opinion due to the first two corporations being left unchecked, now almost all of the decent places to work have followed the bad example of the bigger chains and are actively cutting staffing and overburdening pharmacists to the same degree. Add to this the fact that these large corporations have successfully run almost all the independently owned pharmacies out of the marketplace and you have the current, extremely unhealthy and potentially dangerous situation. I feel the board of pharmacy has been implicitly involved in the creation of this situation. You start literally every conversation concerning work conditions with the statement that you are not here to protect pharmacists. I feel this statement has been used to justify inaction which has allowed our profession to decline in quality under your watch. I do not feel this statement or the sentiment behind it admonishes you in any way from your responsibility to proactively monitor our profession and act in meaningful ways to ensure the professional environment remains safe. In addition, the board actively promotes an agenda that overburdens retail pharmacists under the guise of expanding the profession. An appropriate analogy is building a higher and taller building that appears grand and sophisticated upon an unstable foundation. You have failed to shore up the foundational activities of our profession and have instead focused on expanding our professional duties in a manner that encourages the propagation of chaotic and unsafe retail workplaces lorded over by absentee management. All the citizens of this state now experience difficulty managing their medical needs because you've allowed corporations to walk you down the primrose path that has enriched a small number of executives and shareholders that do not even reside in our state. You've let the enrichment of these few people take away from the safety and wellbeing of the public and you still act as though you've done a service to our communities. Healthcare in America is a mess and will continue to be an expanding and worsening mess until you and the other regulatory boards stop turning a blind eye to the significant detrimental impact unchecked greed can have on the delivery of Healthcare goods and services and start acting appropriately to keep these selfish interests in check.	2/16/2022 7:06 PM
486	though I am not working at this time, …as a customer, I find the pharmacist rarely seems to have time for much patient interaction.	2/16/2022 6:56 PM
487	Too much emphasis on metrics is by far the worst contributing factor	2/16/2022 6:51 PM
488	Pharmacy is in a difficult position as a business. Lack of profitability and appropriate reimbursement is a big issue which usually results in cutting labor costs to remain profitable. Therefore this puts more pressure and workload on existing staff.	2/16/2022 6:47 PM
489	Na	2/16/2022 6:37 PM
490	The retail pharmacy I work in has gone from 1000-1100 prescriptions per week to 1600-1800 per week in the last 2 years. We have no additional pharmacists and the addition of 1 CPhT for approx. 24-32 hours per week. Our pharmacy is one of the few we know of that is caught up at the end of the day because as a crew, we stay until the work is done each day, no matter what that takes. The pharmacists easily work 5 -10 hours a week that are not compensated, and more if a member of the staff is out for vacation, medical, etc. I mention this because my company has weekly conference calls to cover upcoming policies, metrics, and current items of business. The last few months these conference calls are calling on pharmacy managers to	2/16/2022 6:23 PM

	cut hours in the pharmacy. The pharmacists are doing so many tasks at once it is bound to lead to an increase in errors and the company would like us to cut hours.	
491	Company focus too much on metrics and not patients care, also staff has been reduced significantly compared to five years ago	2/16/2022 6:19 PM
492	Too many requirements. Fills, vaccines, not enough staff. We cannot keep up	2/16/2022 5:57 PM
493	Chain pharmacies are making huge profits by understaffing. Metrics were bad enough before COVID, then they add COVID vaccinations with no additional help. Employees can't take it so they quit, and the chains take their time filling the spots. Pharmacists are pressured into working overtime without pay - because we actually care about the well-being of our patients. The staffing problem is entirely the creation of chain pharmacies not adequately staffing pharmacies and not offering equitable pay (ESPECIALLY techs! but pharmacists too). One small thing - it would be helpful if the pharmacist didn't have to drop everything to personally offer counseling to every patient with a new prescription - the law has good intent, but it is incredibly disruptive to workflow and doesn't actually result in more patients asking for/receiving counseling.	2/16/2022 5:52 PM
494	[redacted] in Portland, OR practice poor practice where it is unsafe for employee managed by [redacted] We are to meet deadlines that is nearly impossible to meet and techs have been injured on the job due to this lack of management.	2/16/2022 5:49 PM
495	Pharmacies have been seriously struggling for over the last year; why is the board only addressing this now?	2/16/2022 5:46 PM
496	Staff must work overtime every day in order to keep up with workload. If a worker calls in sick, there is no replacement. Workers are pressured to return to work when not fully recovered from covid.	2/16/2022 5:45 PM
497	We are tired of pizza breaks and stale cookies as incentives. We need more staff and we need people who can handle clerical work so we can focus on tasks related to our license. Vaccines and tests are swamping us. My pharmacist works with no breaks at all. They are often solo on their shifts and they look exhausted. Mistakes get made due to this. Please stop allowing tests and vaccines in big pharmacies... We can't keep up.	2/16/2022 5:37 PM
498	Not given adequate shift changes, was placed in an IV sterile compounding role consecutively for months, I'm now waiting for surgery for nerve damage in my wrist. When speaking up to management, nothing was done, until I got HR involved.	2/16/2022 4:51 PM
499	The phones ring off the hook and it's been stated you have to answer the phone by the second ring. And they want people that are assembling prescriptions to take phone calls to. That is a medication error waiting to happen	2/16/2022 4:50 PM
500	I previously worked for Walgreens and we were overloaded with meeting metrics instead of helping patients right in front of us. To many tentacles - such as Covid testing, covid shots, covid clinics off sight.	2/16/2022 4:45 PM
501	Not enough help, overworking staff, and zero help coming from corporate leaves us struggling to provide any kind of patient care. We are burned out. Adding Covid vaccinations and the lengthy paperwork/insurance to the process compounds the problem. A pharmacy filling more and more prescriptions every day with other pharmacies shutting down means inadequate patient care for the thousands of incoming patients and little patient care for the existing patients. We need help. We need mandatory breaks. We need the unobtainable matrixes gone. We need to be able to be patient-centered healthcare centers not fast-food restaurants slinging the latest products that will make a corporation more money. I WANT to take care of my patients without the constant threat of job loss if we don't fill enough prescriptions in a day and if we don't bring in even more patients to add to the already overwhelming workload. Our patients deserve better then to be treated as numbers on a corporate spreadsheet. They deserve pharmacists and technicians who are at the top of their game not exhausted from overwork and overwhelmed by the metrics. They DESERVE better!	2/16/2022 4:42 PM
502	Higher management hired anyone they could, 5 people within a month with no experience or experienced staff to train them and only 1 pharmacist to staff the pharmacy with over 600 rx's per day. All experienced staff quit due to mismanagement from store and corporate entities. PIC finally quit due to fear of liabilities beyond their control.	2/16/2022 4:39 PM
503	One rph for 700-1000 rxs in 10 hours and sometimes only 3 techs is beyond unsafe. Those	2/16/2022 4:29 PM

	who do work usually don't get breaks and some don't get lunches. Over 1000 to fill is extreme and hard to catch up from. The amount of hours required to work to partially meet demand is unsafe and unreasonable.	
504	The amount of work being done by 1 pharmacist & a few techs everyday is just too much. When Walgreens is pushing Covid shots & testing along with other vaccines they want us to push. Not to mention all the phone calls we have to make, the metics we need to meet. Oh and did I mention they cut our pharmacy Technician hours down so we have even less hours to work now & more too do!	2/16/2022 4:17 PM
505	I got of retail after 3 year of absolute hell in retail. I remember working 6-7 days per week to keep my store open. I NEVER took a 30 minute lunch or 10 minute breaks. I once counseled a patient with while I had a bloody nose bc they couldn't wait for their prescription any longer. I was thankfully able to get out of retail after three years of torture. After 6 months I saw a hair dresser that noticed I had all of this new hair growth. Did you come out of a stressful situation she asked? I said oh I quit my retail pharmacy job. RETAIL PHARMACY WAS CAUSING MY HAIR TO FALL OUT. I remember wishing I could be a tech bc at least they were able to clock out for 30 minutes and go to the back. The expectations are unrealistic and unfair to any human. I felt like I was in a country that didn't have workers rights. I have a doctorate and yet I felt this way. I know mandated lunches are a start for pharmacists but I am absolutely certain pharmacists are working through their lunches to catch up. I hope conditions improve for my retail pharmacists. I have heard work has gotten worse since Covid testing and Covid vaccines started. I can't even imagine. And you want them to prescribe birth control on top of that?	2/16/2022 4:08 PM
506	I think I big misconception is that pharmacists just verify scripts. At my location I was often the ONLY employee in the pharmacy for a 12 hour shift and thus responsible for EVERY single task. On top of the short staffing challenges we have taken on full burden of the covid pandemic having to vaccinate more customers than we have capacity for while still trying to manage the workload of the entire pharmacy. I feel like there is a ton of pressure to push out scripts and vaccinations without regard to the safety of the pharmacy staff or the patients. My personal level of stress had increased to the point it had started to affect my life outside of work. I have seen no indication of improvement in workload from my employer or the board and don't feel like pharmacist voices are heard. I really hope this survey can serve as a wake up call to the terrible work conditions in pharmacies.	2/16/2022 4:03 PM
507	CE burden. My work already provides cultural training, yet I have two do extra CE as a requirement for Oregon. Patient safety requirement CE is vague at best. Again we are required to review patient safety yearly in our employment. I agree with CE, but putting specific reqduirements that need to be done as apposed to not be able to target the CE that best fits my needs in taking care of patients.	2/16/2022 4:01 PM
508	I feel the mask mandate is causing more problems than safety, employees and patients can't safely communicate with mask. drug names are hard enough then to muffle someone with a mask. Most patients you can tell no longer listen to you counseling.	2/16/2022 4:01 PM
509	Regarding the metrics, corporate has recently and probably temporarily backed off, beginning when the board started looking into the safety issue. I still believe the OBOP should require a district pharmacy manager to hold an Oregon pharmacist license in good standing in order to be held accountable for the consequences of ill-conceived corporate initiatives.	2/16/2022 4:01 PM
510	I think you should also focus on the pay that the abused and burnt out pharmacy staff are making. Not worth what we are being put through.	2/16/2022 3:56 PM
511	A current issue we have dealt with in rural locations has been the permanent or temporary closure of other pharmacies. These pharmacies leave their own patients without options, provide no to little notice and continue to put the burden on pharmacies still trying to practice safely. They have often brought in additional staff to fill prescriptions without providing sufficient time for patients to obtain their prescriptions. They also create issues for other pharmacies trying to fill these prescriptions which are filled at the other pharmacy, which won't answer phone calls to return prescriptions to allow for insurance billing. This creates further burden on the pharmacies continuing to operate and attempting to assist patients.	2/16/2022 3:55 PM
512	I work as a remote specialist but my specialty pharmacy employer does not provide a safe environment with adequate PPE training staffing etc.	2/16/2022 3:54 PM
513	Operating at 30% staffing for almost a year and no end in sight. The company response was "nobody is applying"	2/16/2022 3:52 PM

514	The increased demands - vaccines, covid testing, amount of phone calls about these things - severely limit my ability to fill prescriptions. Tech vaccinating is nice but that still comes back on me, and corporate is pushing every tech to get certified, even if they're not an appropriate choice in my eyes	2/16/2022 3:50 PM
515	My answers are based off of the questionnaire at this time. If this was given at an earlier date, my answers would have been different. I only speak for my pharmacy. That being said, I also float due to lack of personnel at other locations. I do enjoy learning more while helping other pharmacies.	2/16/2022 3:50 PM
516	I think that you should have not mandated proof of vaccine and then you wouldn't be dealing with such a big staffing shortage. I was an amazing technician for nearly 8 years and I was never asked to show proof of my personal health information until now. My personal health info is none of my employers or the pharmacy boards business. Thank you.	2/16/2022 3:43 PM
517	One pharmacist on duty from open to close with only 4 hours of overlap with another another pharmacist	2/16/2022 3:38 PM
518	I am satisfied with support from my employer.	2/16/2022 3:38 PM
519	You need to do something to help pharmacy staff. We are drowning. Companies are taking advantage of staff, and they need more protections. Pharmacies should be adequately staffed and paid so they can focus on prescriptions and patients and not pleasing store managers and ringing up groceries and those stupid metrics.	2/16/2022 3:37 PM
520	Special rules need to be had for infusion centers regarding patient load to technicians staffing.	2/16/2022 3:35 PM
521	My location has never had pharmacist lunch breaks on weekends prior to COVID. The increased volume makes a bathroom break almost impossible due to over 50 foot walk to the employee restroom and only one male restroom for all store employees. When I have voiced my concerns (2 times thus far) I have been written up for doing so. Non pharmacy management have more say on how the pharmacy is to run than I do. To a point we have had management breach the pharmacy (already reported) due to not listening to a technician that they weren't allowed access to the pharmacy when no pharmacist was on duty. I know the situation is bad but I find myself wanting to leave pharmacy after 12 years of being a pharmacist due to not wanting the harm or death of a patient on my conscious. Currently looking at reorganizing my finances to do so.	2/16/2022 3:31 PM
522	I love giving vaccines--I just wish my employer would not schedule so many of them in one day.	2/16/2022 3:27 PM
523	Our hospital pharmacy management department will not deal with an impaired pharmacist on staff 02/13/22	2/16/2022 3:26 PM
524	The Board should mandate AND enforce pharmacist non-meal breaks especially when working alone or longer than 10 hours. Also consultations on every prescription should be changed to OPTIONAL of the patient's choosing, that way the pharmacist can spend adequate time with patients that actually DO want to receive one. Most people are just picking up refills, and it is a waste of time for the pharmacist to walk back and forth ALL DAY just to release a refill. This is not efficient and prevents one from performing meaningful consults.	2/16/2022 3:26 PM
525	Clarification by the Board for "inappropriate dispensing" as it relates to ivermectin prescriptions similar to that provided for hydroxychloroquine would be supportive. Reimbursement is abysmal and negatively impacts the ability of independent pharmacies to staff appropriately.	2/16/2022 3:25 PM
526	#1 Curbside is a huge PIA; not enough staff to deal with it and customers are not prepared. #2 Pharmacists and Staff need to be rid of the masks once and for all. Infectious viruses and bacteria have been floating around in the air long before covid showed up. #3 E-script mistakes are pathetic and prolific. Sooo much time is wasted contacting ill-trained staff at prescriber's offices and then waiting forever for an answer.	2/16/2022 3:24 PM
527	State run by thoughtless leaders who don't think things through, who are focused on image more than reality	2/16/2022 3:16 PM
528	None	2/16/2022 3:09 PM
529	None	2/16/2022 3:07 PM
530	Patients have to wait 2 to 3 days for a new prescription. Patient also have to wait in line for	2/16/2022 2:55 PM

	hours to pick up their medication's. We are unable to answer our phones do to inadequate staffing. The situation is bad for staff and for customers.	
531	Not enough staff and Bi mart closing has made it difficult. Pharmacist is cashier, technician, vaccinator and lastly pharmacist.	2/16/2022 2:55 PM
532	Due to the conditions in retail pharmacies, we are receiving numerous inquiries about opportunities to work in our health system. I am very concerned at the working conditions that currently exist in some of these pharmacies and the impact on patient care.	2/16/2022 2:54 PM
533	our motto: scripts, scripts, scripts!	2/16/2022 2:51 PM

End of Session Report

Report Date: March 28, 2022

Oregon Board of Pharmacy

N/A

Bill #	Status	Effective Date	Last Three Actions
HB 4034 EN	Passed		3/23/2022 - Governor signed. 3/8/2022 - President signed. 3/4/2022 - Speaker signed.
Allows pharmacy intern to transfer drug containing pseudoephedrine or ephedrine to person 18 years of age or older without prescription.			
HB 4068 EN	Passed		3/23/2022 - Governor signed. 3/8/2022 - President signed. 3/8/2022 - Speaker signed.
Transfers Oregon Homeland Security Council to Oregon Department of Emergency Management.			
HB 4096 EN	Passed		3/23/2022 - Governor signed. 3/2/2022 - President signed. 3/2/2022 - Speaker signed.
Authorizes health care practitioner authorized in another state or United States territory to practice in this state without compensation for specified number of days without obtaining licensure in this state.			
SB 1529 EN	Passed		3/17/2022 - Governor signed. 3/8/2022 - Speaker signed. 3/4/2022 - President signed.
Allows Public Health Director to direct and deploy volunteer emergency health care providers under specified circumstances.			
SB 1560 EN	Passed		3/24/2022 - Governor signed. 3/8/2022 - Speaker signed. 3/8/2022 - President signed.
Updates statutory references to individual who is not citizen or national of United States to replace "alien" with "noncitizen." Directs state agencies to use "noncitizen" in rules and regulations to reference individual who is not citizen or national of United States and to update rules and regulations that use "alien" to use "noncitizen." Authorizes agencies to amend rule without prior notice or hearing for purpose of changing term or phrase in order to conform with change made by law.			
SB 1586 EN	Passed		3/24/2022 - Governor signed. 3/2/2022 - Speaker signed. 3/2/2022 - President signed.
Clarifies prohibitions regarding provisions that may not be included in agreements between employers and former, current or prospective employees.			

End of Session Report

Report Date: March 28, 2022

Oregon Board of Pharmacy

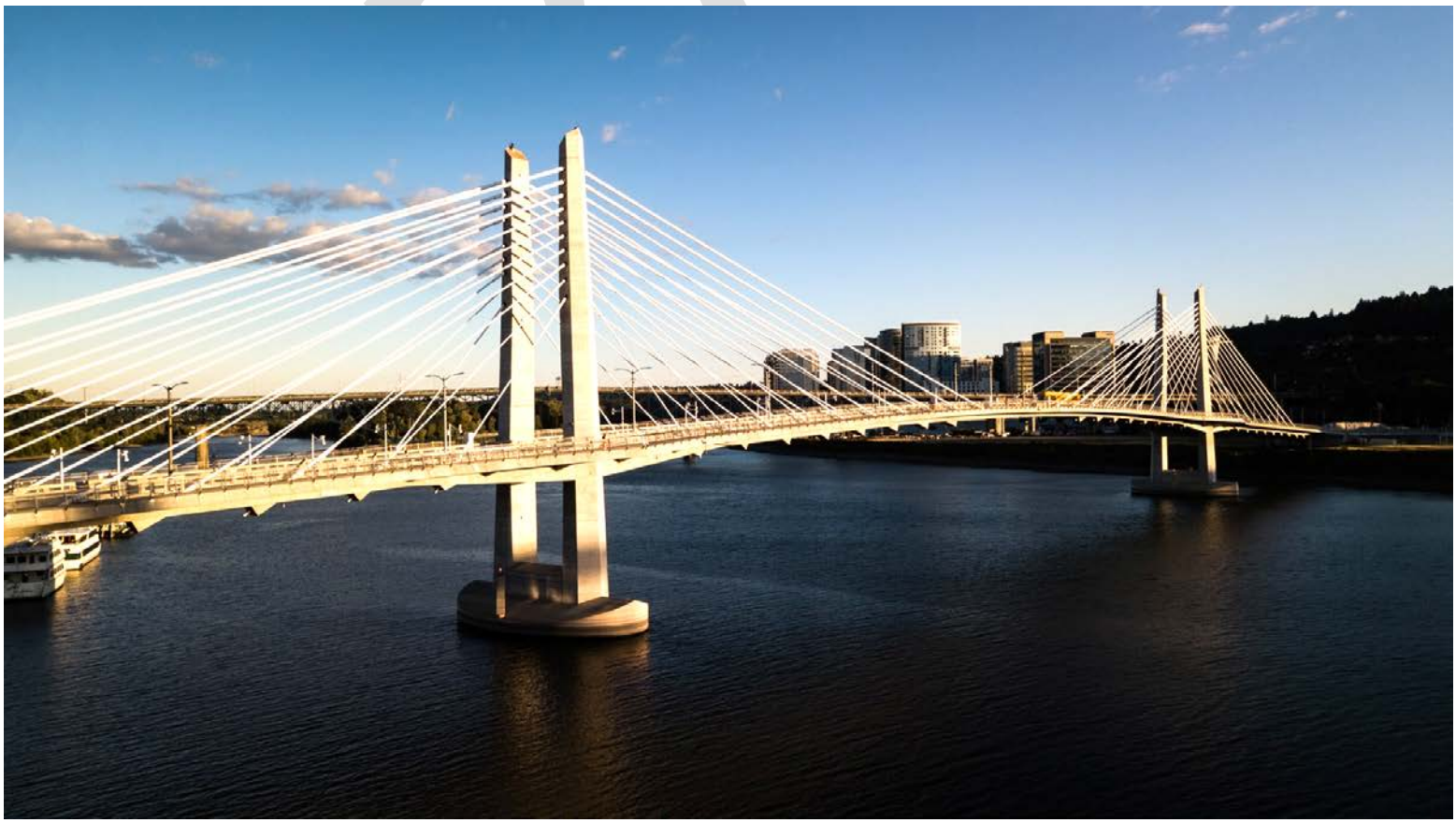
N/A

Bill #	Status	Effective Date	Last Three Actions

APRIL 2022/ G

Oregon Board of Pharmacy

Strategic Plan 2022-2026



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CONTENTS

INTRODUCTION

On behalf of the Board members and staff of the Oregon State Board of Pharmacy, I am pleased to present the Board's Strategic Plan for 2022-2026. The purpose of this plan is to outline the direction and priorities which have been established by the Board and which will ensure that pharmacy practice is regulated in the interest of public health and safety, result in exceptional service to our licensees and registrants, and advance the health of Oregonians.

Over the past two years, the board and staff have been working to implement the 2020-2024 Strategic Plan that was adopted in early 2020. Little did we know at that time, a global pandemic was beginning that would present extraordinary challenges to the public and the profession and would change pharmacy practice in significant ways. In addition, 2020 brought devastating wildfires to several areas in Oregon that further impacted the public and profession. Pharmacists, interns and pharmacy technicians throughout the state have been asked to go above and beyond their already demanding roles to provide vaccinations, testing, and prescription services. The board and staff are extremely appreciative of the extraordinary professionalism and selflessness of pharmacists and technicians in serving the needs of Oregonians during the ongoing pandemic.

We would like to acknowledge the input of stakeholders who share their views on priorities for pharmacy regulation that allows pharmacists, pharmacy technicians and drug outlets to provide the best possible care to all Oregonians. The practice of pharmacy and pharmaceutical supply chain have continued to undergo profound change due to technological advances, changes in healthcare delivery, increasing complexity in the supply chain, fragmentation of care, remote practice, social and political shifts, drug shortages, health disparities, access issues, opioid abuse, compounding and medication safety, natural disasters, and a variety of political and economic forces. We are committed to continuing to assure that pharmacy services are provided in a way that prevents healthcare disparities and to continue our affirmative action, diversity, equity and inclusion efforts in recruitment and retention of Board and Committee members and staff.

The five strategic goal areas outlined in this Strategic Plan will continue to guide the work of the Board and staff to create the regulatory structure necessary to incorporate and encourage the best pharmacy practices to ensure public health and safety. This plan will be reviewed and updated annually to assess progress and to encourage safe and equitable delivery of pharmacy services. The five strategic goal areas include:

- **Technicians**
- **Technology**
- **Licensing and Registration**
- **Regulation**
- **Communication**

As we begin to implement these initiatives, we encourage continued active engagement with the Board and participation in Board Meetings, Committee Meetings, Rules Hearings, and other Board activities.

Joe Schnabel, Pharm.D., R.Ph.
Executive Director

OUR PURPOSE

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.

Vision

Partners for a Healthy Oregon

Values

These values reflect both how our Board and staff strive to conduct ourselves, and the behaviors we seek to instill across the practice of pharmacy in Oregon.

Integrity

We meet commitments to public health & safety and are accountable for our words and actions

Includes …

- Honesty
- Ethics
- Respect

Quality

We strive to deliver a consistent standard of excellence

Includes …

- Excellence
- Value
- Worth

Safety

We are committed to protecting the health, safety and welfare of the public

Includes …

- Protection
- Security
- Care

Accountability

We accept responsibility for our actions, products, decisions and policies

Includes …

- Trust
- Responsibility
- Transparency

Professionalism

We are committed to promoting excellence in pharmacy practice

Includes …

- Expertise
- Commitment
- Competence

PHARMACY STRATEGIC LANDSCAPE

Transformation of healthcare, pharmacy practice and society has occurred since early 2020 due to the COVID-19 pandemic. This will likely be a profoundly pivotal event in each of our lives and will have far-reaching consequences on the delivery healthcare, pharmacy practice, and our way of life.

A variety of changes in how pharmacy services are delivered is impacting the Board's regulatory activities, daily work and strategic priorities. Many of these changes offer potential benefits to the public, the pharmacy profession and health care while others pose clear risks. All, however, require careful monitoring and response from the Board to ensure public safety is maintained and that licensing, regulation, enforcement and outreach efforts reflect the evolving landscape.

Some of the issues facing the Board of Pharmacy include:

Access and distribution: The COVID-19 pandemic has demonstrated the value of pharmacists, pharmacy interns, and pharmacy technicians as the most accessible healthcare professionals able to deliver essential services, such as vaccinations, testing, and therapeutics.

Economic and social impacts: The economics of pharmacy along with pharmacists and pharmacy technicians leaving the profession has resulted in challenges for the public seeking pharmacy services. Pharmacies have been closing and staff have been resigning in numbers that are impacting access to pharmacy services, particularly in rural Oregon.

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

STRATEGIC PRIORITIES

At its Strategic Planning meeting in November 2021, the Board, Executive Director and the staff leadership team identified and evaluated a wide range of trends and challenges facing the practice of pharmacy and our agency. This process and deliberation led to agreement that the five critical Strategic Areas of focus identified in 2019 will remain the same for the 2022-2026 period and upon which the board's attention and resources will be focused.

TECHNICIANS

Goal: *Articulate the regulatory structure where the accountabilities of pharmacists and the role of pharmacy technicians are aligned to enhance safety, access, service and efficiency*

TECHNOLOGY

Goal: *Articulate the regulatory structure where the accountabilities of pharmacists and the use of technology are aligned to enhance safety, access, service and efficiency*

LICENSING and REGISTRATION

Goal: *Clarify licensing and registration categories to promote appropriate professional licensure and drug outlet registration*

REGULATION

Goal: *Systematically refresh rules and standardize the rule development approach to improve clarity and compliance*

COMMUNICATION

Goal: *Improve and maintain stakeholder and public engagement through proactive communication strategies*

The Board indicated that meaningful progress has been made in each goal area and additional work remains to be completed over the next two to four years. We will regularly assess progress and refine our goals and resource commitments as we work to achieve these key objectives.

TECHNICIANS

Goal: Articulate the regulatory structure where the accountabilities of pharmacists and the role of pharmacy technicians are aligned to enhance safety, access, service and efficiency

The Board seeks to develop clear rules to ensure that pharmacists understand their legal scope of practice and their accountability to provide patient care services and safe pharmacy practices. Permitting pharmacists to more fully and effectively utilize technician support must be structured to improve safety, access and patient care services.

The Board seeks rule alignment to clearly describe the role of pharmacy technicians and how they assist the pharmacist in the practice of pharmacy. Regulatory structures developed for technician roles should delineate requirements for training, quality assurance, and pharmacist supervision.

Key Actions:

1. Revise rules to make Pharmacy Technician (PT) license renewable indefinitely and remove five-year waiting period for reapplication of lapsed PT licenses. (June 2022)
2. Review technician licensing and training rules to remove barriers to licensure for those wishing to become licensed and renew their license.
3. Evaluate the impact of a single, renewable pharmacy technician license.
4. Evaluate role of national certification as a requirement for licensure and assess those pharmacy technician functions in the assistance of the practice of pharmacy for which national certification would enhance public health and safety.
5. Review and assess applicable statutes for the development of rules that clearly articulate the responsibilities of a pharmacist and functions that only a pharmacist may perform.

Outcome Conditions:

- Adoption of revised rules for pharmacy technician licensure.
- Adoption of revised rules for pharmacy technician training.
- Adoption of revised rules for pharmacist supervision, direction and control of pharmacy technicians
- Evaluation and board decision on the role of national certification in the licensing process.
- Enhanced capacity for pharmacist provision of patient care services while maintaining safety in dispensing services.

TECHNOLOGY

Goal: Articulate the regulatory structure where the accountabilities of pharmacists and the use of technology are aligned to enhance safety, access, service and efficiency

The Board seeks to develop clear rules to ensure that pharmacists understand their scope of practice and their accountability to provide patient care services and safe pharmacy practices while permitting the use of technologies that improve safety, access, service and efficiency. Regulatory structures developed for use of technology should be function-based and delineate pharmacist and drug outlet accountabilities for each critical stage of automated processes.

Key Actions:

1. Implement Remote Dispensing Site Pharmacy (RDSP) rules and amend them as more is learned from experiences of pharmacists, Certified Oregon Pharmacy Technicians, and the public about their effectiveness at maintaining public health and safety while improving access to pharmacy services.
2. Draft and adopt rules for Pharmacy Prescription Lockers (PPL). Amend the PPL rules as more is learned from experiences of pharmacists, technicians, and the public about their effectiveness at maintaining public health and safety while improving access to medications and supplies.
3. Draft and adopt rules for kiosks. Amend the kiosk rules as more is learned from experiences of pharmacists, technicians, and the public about their effectiveness at maintaining public health and safety while improving access to medications and supplies.
4. Amend Remote Dispensing Machine (RDM) and Remote Distribution Facility (RDF) rules to align with RDSP and PPL rules.

Outcome Conditions:

- Number of RDSPs registered in Oregon each year.
- Compliance cases involving RDSPs and their affiliated pharmacies.
- Number of PPLs registered in Oregon each year.
- Compliance cases involving PPLs and their affiliated pharmacies.
- Draft rules for Board consideration that clearly delineate the use of new technology and pharmacist accountabilities in the practice of pharmacy.
- Defined accountabilities for each critical step in automated processes.
- Enhanced capacity for pharmacist provision of patient care services while maintaining safety in dispensing services.
- Effective quality assurance plan applied to all automated pharmacy processes.

LICENSING and REGISTRATION

Goal: Clarify licensing and registration categories to promote appropriate professional licensure and drug outlet registration

The Board promotes patient safety through appropriate licensing and registration of all licensees and drug outlets engaged in the practice of pharmacy or assistance in the practice of pharmacy and in the manufacture, dispensing, delivery or distribution of drugs, devices and supplies. License and registration categories should clearly guide applicants to the appropriate license type.

Key Actions:

1. Review technician licensing and training rules to remove barriers to licensure for those wishing to become licensed and renew their license.
2. Create and implement a consistent, ongoing process to evaluate applicable statutes for each drug outlet registration type and develop rules that clearly outline the appropriate registration type for each outlet.
3. Evaluate legislative and budgetary considerations that may be required to implement changes to drug outlet registration types.

Outcome Conditions:

- Draft rules for Board consideration that clarify the appropriate registration type for each drug outlet.
- Decrease in questions from applicants regarding appropriate registration type for which to apply.

REGULATION

Goal: Systematically refresh rules and standardize rule development to improve clarity and longevity

The Board proactively reviews and updates rules to provide clear expectations to licensees and registrants to promote compliance and patient safety. Rule updates should emphasize clarity and longevity that allows practice variation that improves safety, access, service and efficiency.

Key Actions:

1. Identify and complete process for submitting a legislative concept for board to compel licensees to undergo substance use disorder evaluation for compliance cases involving substance use (June 2023).
2. Update Continuing Pharmacy Education rules to create clear expectations that guide licensees in professional development that improves their ability to safely engage in contemporary pharmacy practice (June 2022).
3. Evaluate current state of pharmacy practice in Oregon and convene Safe Pharmacy Practice Conditions workgroup to develop rules to assure that clearly outline requirements for safe pharmacy practice in all pharmacy settings (December 2023).
4. Create standard procedures and schedule to accomplish five-year rule review that emphasizes clarity and durability.
5. Conduct routine, scheduled, and systematic review of Board of Pharmacy rules by Division and draft revisions for Board consideration.

Outcome Conditions:

- Legislative concept submitted for substance use disorder evaluations for 2023 legislative session.
- Improved compliance rate with Continuing Education audits and reduce resources used to conduct such audits.
- Improved safe pharmacy practice conditions in all pharmacy settings and reduced licensee and public complaints regarding pharmacy practice conditions and services.
- At least four divisions are reviewed, updated and presented to Board for consideration annually.

COMMUNICATION

Goal: Improve and maintain stakeholder and public engagement through proactive communication strategies

The Board communicates through multiple platforms to collaborate, educate, promote patient safety and enhance consumer protection.

Key Actions:

1. Execute the agency's communication plan at all levels to improve access to relevant information and encourage stakeholder engagement.
2. Utilize public records request process to respond to inquiries for agency records and provide training to agency staff to respond in compliance to state law.
3. Continue regular outreach to stakeholder groups, including schools and colleges of pharmacy, pharmacy associations, and the public.
4. Utilize analytics from agency website and listserv platform to improve agency communications.

Outcome Conditions:

- Modern materials for agency communications, including branding and plain language used for presentations and other public documents.
- Agency website updated and maintained to provide current information and focused content, including forms and reference documents.