Oregon Board of Pharmacy
***REVISED BOARD MEETING AGENDA**
June 8-10, 2022

The Portland State Office Building is now open to the public.
Meeting Location: 800 NE Oregon St. Conference Room 1A Portland, OR 97232

Click here to join virtually: June 8-10, 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.**

Public Attendance: Audio only (503) 446-4951 Phone Conference ID: 746 531 975 #

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, June 8, 2022 @ 8:30AM
Thursday, June 9, 2022 @ 8:30AM
Friday, June 10, 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 pharmacy.board@bop.oregon.gov by **12:00PM on 6/10/2022**.

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 pharmacy.board@bop.oregon.gov or by calling 971-673-0001 with at least 48 hours' notice.

WEDNESDAY, JUNE 8, 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)(i)(L), ORS 192.690(1) ORS 676.165, ORS 676.175.
- a. Employee Performance Review
- b. Legal Advice
- c. Deliberation on Disciplinary Cases and Investigations
- d. 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, JUNE 9, 2022

I. **OPEN SESSION, Wassim Ayoub RPh, Presiding**
***Please note that the board will meet in Executive Session immediately after roll call. If you plan on attending the meeting in person, the board anticipates resuming Open Session at 1:00PM and the public may attend.**
   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 006/041/043/045/080/139** - related to Standards Adopted by Reference & Definitions **#B** *Action Necessary*
         2. **Div 019/025/041 –** related to Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification - 2022 HB 4034 **#B1** *Action Necessary*
         3. **Div 019/041/139** – related to Interpreters – 2021 HB 2359 **#B2** *Action Necessary*
         4. **Div 019/143** – Pharmacy Prescription Lockers **#B3** *Action Necessary*
         5. **Div 020** – Pharmacist Prescriptive Authority – Tobacco Cessation & PrEP **#B4, B4a, B4b** *Action Necessary*
         6. **Div 031**- Public Health Emergency Rules sunset **#B5** *Action Necessary*
         7. **Div 041** – Telework – 2022 HB 4034 **#B6** *Action Necessary*
         8. **Div 041/139** – Permanent Pharmacy Closure Requirements **#B7** *Action Necessary*
         9. **Div 080** – Pseudoephedrine/Ephedrine & Interns – 2022 HB 4034 **#B8** *Action Necessary*
         10. **Div 110** – Drug Outlet Categories **#B9** *Action Necessary*
         11. **Div 139** – RDSP – 2022 HB 4034 **#B10** *Action Necessary*

      iii. Rules in Development – *Davis*
      iv. Consider Adoption of Temporary Rules – *Davis*
         1. **Div 019** – Duties of a Pharmacist – 2022 HB 4034 **#C**
         2. **Div 139** – RDSP Prohibited Practices - 2022 HB 4034 **#C1**

      v. Rulemaking Policy Discussion Items – *Davis*
         1. **Div 019** – Non-resident Volunteer Pharmacist - 2022 HB 4096 **#D**
         2. **Div 125** – Pharmacy Technicians Procedural Rule Review **#D1, #D1a**
         3. **Div 115** – Pharmacist Procedural Rule Review **#D2**
         4. **Div 021** – CE Procedural Rule Review **#D3**
         5. **Div 141** – Kiosks **#D4**

Adjourn *Action Necessary*

FRIDAY, JUNE 10, 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 **#E**

iii. Contraception CE Programs– *Davis* **#F** *Action Necessary*

iv. Strategic Plan Update – *Schnabel*

v. Waiver Request – *Efremoff*

1. Volunteers in Medicine **#G** *Action Necessary*

vi. Manufacturer Exemption Request – *Efremoff*

1. Acme United Corporation **#L** *Action Necessary*

vii. Well-being Index for Pharmacy Personnel – *Schnabel* **#H**

viii. Financial/Budget Report – *MacLean* **#I**

IV. ANNUAL BOARD BUSINESS MEETING

i. Update on Board & PHPFAC appointments/reappointments – *Schnabel*

ii. Election of New Officers – *Schnabel* *Action Necessary*

iii. Approval of ACPE Accredited schools & colleges of pharmacy and ACPE accredited providers of continuing pharmacy education – *Davis* **#J, #Ja** *Action Necessary*

iv. Bd. Best Practices Key Performance Measure Review – *MacLean* **#K**

v. Recognition of outgoing Board Member Wassim Ayoub – *Schnabel*

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

2022 Board Meeting Dates

• August 10-12, 2022	Portland	
• October 12-14, 2022*	Portland	
• November 10, 2022	Portland	(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.)

- November 22, 2022

Past Conferences/Meetings – *Schnabel*

1. OSHP 2022 Annual Seminar – April 22-24, 2022, Sunriver Resort
2. NABP Annual Meeting – May 19-21, 2022, Chandler, AZ

VI. 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 3/29/2022-5/23/2022 - **# CONSENT-1**
b. Board Meeting Minutes – April 2022 **# CONSENT-2**

VII. 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: May 25, 2022
To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer's Report on Rulemaking Hearing

Hearing Date: May 24, 2022

Hearing Location: Virtual via Teams

Proposed Rules:

- Divisions 006/041/043/045/139 - related to Standards Adopted by Reference & Definitions
- Divisions 019/025/041 – related to Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification
- Divisions 019/041/139 – related to Interpreters
- Divisions 019/143 – related to Pharmacy Prescription Lockers
- Division 020 – related to Pharmacist Prescriptive Authority – Tobacco Cessation & PrEP
- Division 031 – related to Public Health Emergency Rules sunset
- Division 041 – related to Telework
- Divisions 041/139 – related to Permanent Pharmacy Closure Requirements
- Divisions 080 – related to Pseudoephedrine/Ephedrine & Interns
- Division 110 – related to Drug Outlet Categories
- Division 139 related to RDSP

The rulemaking hearing convened at 9:31AM. There were no oral comments provided during the hearing and 16 written comments were received via pharmacy.rulemaking@bop.oregon.gov. The hearing adjourned at 9:43AM. 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 Davis
Staff Member Melvin
Staff Member Schnabel

Summary of Oral Testimony

RULES PROPOSED: Standards adopted by Reference & Definitions

AMEND: OAR 855-006-0005, OAR 855-041-1046, OAR 855-041-1145, OAR 855-041-7050, OAR 855-043-0545, OAR 855-043-0740, OAR 855-045-0200, OAR 855-080-0020, OAR 855-080-0021, OAR 855-080-0022, OAR 855-080-0023, OAR 855-080-0024, OAR 855-080-0028, OAR 855-080-0031, OAR 855-080-0065, OAR 855-080-0070, OAR 855-080-0075, OAR 855-080-0085, OAR 855-139-0350 & OAR 855-139-0460.

- No oral testimony was provided.

RULES PROPOSED: Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification
AMEND: OAR 855-019-0200, OAR 855-025-0040, OAR 855-041-1040 & OAR 855-041-6050.

ADOPT: OAR 855-025-0023 & OAR 855-041-0018.

- No oral testimony was provided.

RULES PROPOSED: Interpreters
AMEND: OAR 855-019-0230, OAR 855-041-1165 & OAR 855-139-0555.

ADOPT: OAR 855-041-1133 & OAR 855-139-0360.

- No oral testimony was provided.

RULES PROPOSED: Pharmacy Prescription Lockers
AMEND: OAR 855-019-0300, OAR 855-143-0155, OAR 855-143-0210 & OAR 855-143-0550.

- No oral testimony was provided.

RULES PROPOSED: Pharmacist Prescriptive Authority – Tobacco Cessation & PrEP
AMEND: OAR 855-020-0300

- No oral testimony was provided.

RULES PROPOSED: Public Health Emergency Rules sunset
AMEND: OAR 855-031-0026

- No oral testimony was provided.

RULES PROPOSED: Telework
AMEND: OAR 855-041-3205, OAR 855-041-3210, OAR 855-041-3215, OAR 855-041-3220, OAR 855-041-3225, OAR 855-041-3230, OAR 855-041-3235, OAR 855-041-3240, OAR 855-041-3245 & OAR 855-041-3250.

- No oral testimony was provided

RULES PROPOSED: Permanent Pharmacy Closure Requirements
AMEND: OAR 855-041-1090, OAR 855-041-1092, OAR 855-041-2115, OAR 855-139-0025, OAR 855-139-0145 & OAR 855-139-0325.

ADOPT: OAR 855-041-1167 & OAR 855-139-0560

- No oral testimony was provided.

RULES PROPOSED: Pseudoephedrine/Ephedrine & Interns
AMEND: OAR 855-080-0026

- No oral testimony was provided.

RULES PROPOSED: Drug Outlet Categories
AMEND: OAR 855-110-0007

- No oral testimony was provided.

RULES PROPOSED: RDSP
AMEND: OAR 855-139-0005, OAR 855-139-0010, OAR 855-139-0050, OAR 855-139-0100, OAR 855- 139-0150, OAR 855-139-0200, OAR 855-139-0210, OAR 855-139-0220, OAR 855-139-0315, OAR 855-139-0355, OAR 855-139-0455, OAR 855-139-0600, OAR 855-139-0715 & OAR 855-139-0730.

- No oral testimony was provided.

All written comments received by the public comment deadline date of 5/24/2022 at 4:30PM **have been provided in their entirety** to the board. Comments were received in response to the 4/25/2022 Notice of Proposed Rulemaking. The notices were sent via GovDelivery email to **1,1914** rulemaking/adopted rules recipients and **21,178** licensee/registrant recipients and by USPS mail as applicable. Notices with tracked changes were posted on the board's website.

From: DeClercque.Kevin
To: PHARMACY RULEMAKING * BOP
Subject: Comment to proposed rulemaking regarding interpreters
Date: Wednesday, April 27, 2022 2:00:55 PM
Attachments: image001.png

Hi,

I am in favor of having interpretive services for prescription counseling, but I would like to see options beyond only the OHA registered healthcare interpreters. Most health systems (ours included) have an expansive interpreter service already in place which our pharmacists utilize for counseling for patients with preferred languages other than English. These interpreters are amazing and the number of languages offered are incredible. We have been extremely satisfied with the service and feel that they are an appropriate alternative to the OHA registry. I would like the board to consider an option written into the OARs that allow for alternative interpreter services to be allowed. I echo the comments made by other pharmacies in the state in terms of the financial and contractual burden that would be imposed on organizations should we need to set up a new contract with an interpreter service.

Thank you for your consideration to this request

Kevin

Kevin DeClercque, PharmD
Pharmacist
Adventist Medical Center- Portland
10123 SE Market St Portland, OR 97216
P: (503) 251-6141 | F: (503) 261-6764
declerkm@ah.org

OHSUHealth
Adventist Health Portland

May 24, 2022

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

Re: Rulemaking changes 855-041-1165; 855-041-1092; Telework.

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.

We appreciate the conversation and opportunity to participate in a virtual manner during the last board of pharmacy meeting in April. This allowed participants to follow the conversation in real time, while viewing the same documents the Board Members had access to while facilitating their discussion. We believe this is essential to an open process and look forward to future meetings returning to full in person attendance. Thank you for your work during the pandemic and the emphasis on patient safety in the state of Oregon. This year has been a challenging year in Oregon for more reasons than COVID. This year has been a year were health equity has been decreased as state saw an unprecedented number of pharmacies close. Health equity is tied to patient safety by preserving access to care for underserved and disadvantaged members of the community. It is from this perspective that ACI will frame these comments.

855-041-1165 Healthcare Interpretation Patient Medical Record

With the passage of HB 2359 during the 2021 legislative session additional guardrails related to the use of healthcare interpreters were implemented in the statute. For the most part the rules being promulgated by the board line up with the statutory requirements as well as the recently released Administrative Order from the Oregon Health Authority ("OHA"). ACI supports access to interpretation for patients who have low English proficiency. We recently finished development and implementation of our language translation services and have long made available verbal interpretation available to patients by use of our language line. In review of these proposed rules, we identified one requirement that does not fall in line with the OHA Administrative Order, and that is the requirement to include in the patient's medical record their preferred language for communication. We would suggest removing this requirement or limiting to situations where the patient indicates their preference for a language other than English. This requirement is above what was required by both the statute and the OHA Administrative Order. While this requirement may seem to be menial, all menial tasks add up and become burdensome for pharmacists and technicians who are working tirelessly to serve in their communities. Additionally, as noted in the rulemaking notice related this rule change it was noted that only 1 of 17 individuals find themselves in the situation of needing interpretation. This means that 16 of 17 patient profiles will indicate their preference defaults to English.

Again, this seems to be an easy step, but to adequately document the patient profile the pharmacist or technician will have to inquire with each patient rather than allowing the patient to indicate when English is not their preferred language.

855-041-1092 Permanent Pharmacy Closures

As mentioned above Oregon experienced an unprecedented number of pharmacy closures in the past year. These closures have impacted our company, our pharmacy staff, and the patients we served both before and after the closures occurred. Closing a pharmacy is not a decision taken lightly and is a very complex decision to be made. One of the important aspects of closing a pharmacy is effectively managing the notification to patient. We appreciate the board members and staff for not requiring notification to be earlier than 15 days before the closing date of the pharmacy as this would have opened the door for a significant decrease in the financial value of the transaction between the closing and acquiring pharmacy. The one aspect of the proposed rule ACI would suggest changing is related to the methods of notification. In the proposed state there are three types of notifications that must be made: mail, newspaper, and physical notice on the building and phone message. We agree that patient notification and doing so in a timely and appropriate manner is extremely important, it is our opinion that flexibility should be provided in the method of notification. We generally send a letter to the patients and also post signs as indicated in the rule language. It would be out of the ordinary to post notice in the newspaper regarding the closure. We would suggest changing this to notification by letter OR in the newspaper AND posting signs on the physical building and forwarding the phone lines to the receiving pharmacy. This is customary practice in the industry and would be considered sufficient notice to the patient.

Telework

We appreciate the conversation that HB 4034 from the 2022 legislative session fostered during the last board meeting in April. However, we were under the impression that the bill was further reaching than just the act of remote access of the pharmacy database but rather encompassed the entirety of telework. We hope the board staff will honor the comments and commitment they made to the Board Members during that discussion to bring this important issue back in a future board meeting for a broader policy discussion. These regulations have proven to be restrictive and have further limited the ability to support pharmacies in the state. Please consider placing this policy discussion on a future board meeting to allow broad input from the board members to aid the staff in redrafting these regulations to allow for adequate support without administrative burden for our pharmacies in Oregon.

We appreciate this opportunity to provide feedback on these regulations and their significance to patient access to pharmacy care and health equity 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

From:	Rob Geddes
To:	PHARMACY RULEMAKING * BOP
Subject:	Rulemaking Comments 5/24/22 hearing
Date:	Tuesday, May 24, 2022 3:11:01 PM
Attachments:	Rulemaking comments 5-24-22 Hearing.pdf

Rachel,

Please accept my comments for the rulemaking hearing scheduled today 5/24/22.

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

From:	Lincoln Alexander
To:	PHARMACY RULEMAKING * BOP
Subject:	OAR 333-002 Comments
Date:	Monday, May 2, 2022 12:09:58 PM

Comments for proposed rules of OAR 333-002 requiring use of an Oregon certified interpreter for required Oregon languages and sign language:

Hello OBOP,

I know that you are directed by HB 2359 to require interpreters be licensed within Oregon. I am going to reach out to OHA to voice my concerns as well but I wanted to state them here as well. I feel that at my current site - Albertsons - we have an excellent interpreter system. Within a matter of 30 seconds, I can call our third party-provided interpreter service on the phone and have the correct language communicated to the patient soon after. I have never had an issue with a patient not understanding the interpreter and they always seem grateful that we offer this service.

I am concerned that with this mandate, it will actually decrease access of patient's ability to access interpreter services. I do not see third-party interpreter service companies complying with this mandate and may instead just not offer their services within Oregon in the future.

Thank you,

Lincoln Alexander

Lincoln Alexander, Pharm.D.
Oregon State University Alumnus '11/'15

Beaverton Pharmacy
Home Health Care Center
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www.beavertonpharmacy.com

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May 20, 2022

To whom it may concern:

My name is Wade Irby, I am a third-generation pharmacist and an independent pharmacy owner. I have practiced pharmacy for 25 years, with the last eight in Oregon. Many of the pharmacists in my family have served in government: my grandfather served in the Oklahoma state legislature and as a mayor in a town in New Mexico, my father is the longest serving school board member in the history of New Mexico and also served on the New Mexico Public School Insurance Authority, and my brother has served on the New Mexico Board of Pharmacy and Board of Nursing. This extensive family history and my personal experience have given me a deep understanding and respect for both pharmacy and public service. That being said, I thank the Oregon Board of Pharmacy for the consideration of my comments regarding Remote Dispensing Site Pharmacies (known widely as telepharmacy).

Telepharmacy has a proven history of safety and provides numerous benefits to patients and rural communities. I hope to use telepharmacy to bring pharmacy services to potentially two communities in Oregon that currently lack a pharmacy. As a business owner who is looking to help underserved communities in the state, I wanted to comment on a few items in Oregon's proposed permanent rules for telepharmacy.

First, I would like to thank the board for addressing the issue of technician ratio and allowing unlicensed personnel to staff a telepharmacy site, as this alleviates several concerns I had with implementing telepharmacy under the initial rules. However, the new language states that unlicensed personnel are not permitted to engage in "pharmacy services". I would like to request clarification on this terminology as "pharmacy services" is not a defined term and it is unclear what unlicensed personnel are permitted to do.

Next, I wanted to comment on the intent behind the proposed changes. The public notice for the remote dispensing site rules states the changes are to implement HB 4034. My understanding of this legislation is that it tasks the board of pharmacy with ensuring that the rules and regulations governing telepharmacy are not more restrictive than the regulations that govern traditional pharmacy practice. While the proposed changes will provide a benefit to

ensure the safe operation of telepharmacy, there are additional rules regarding telepharmacy that the board should consider.

The first regulation the board should consider is in section 855-139-0210(3) because it is more restrictive than what is required in a traditional pharmacy. This section requires a pharmacist to review, at minimum, 10% of all interactions between the technician and patients within 48 hours. This is not something that is required in my current operations of a traditional pharmacy. In this setting, when incidents occur outside of the involvement of the pharmacist, the situation is brought to the pharmacist's attention quickly by someone that is involved in the matter (a technician, a clerk, or a patient/customer). This can be similarly achieved in a telepharmacy setting utilizing the technology that locations must have according to other sections in the rules. This is also a requirement not seen in the laws or regulations of the 27 other states that allow telepharmacy.

The board should also address this section of rule, as it presents a hurdle in the operation of a telepharmacy. This requirement is not only time consuming, as it will add to an already heavy workload, but it is also difficult to achieve which will hinder operations. In implementing this requirement, I question how a pharmacist will accurately measure the total amount of interactions between licensees and patients per day in order to determine the number of interactions to count in the 10%.

Additionally, outside of these regulations, the board has already successfully created rules that ensure the practice of telepharmacy is provided safely, which is likely the intent behind this rule. Technicians are required to have extra training before staffing a telepharmacy. This ensures that they know how to properly operate the telepharmacy system which allows the supervising pharmacist to remain in contact with them. A supervising pharmacist is in constant contact with the technicians and is required to provide constant supervision utilizing the telepharmacy system and can intervene at any point, if needed.

The second regulation the board should consider is section 855-139-0550 for record retention requirements as the language provided for RDSPs in this section is stricter than the requirements for a traditional pharmacy. This section requires data (including data, telephone audio and surveillance system) be retained for 6 months. Similar to the 10% review requirement, this exceeds what is required in a traditional pharmacy as telephone audio and surveillance system footage is not required to be retained in any traditional pharmacy setting.

I worry that the low prescription volumes seen at telepharmacies will not offset the expenses associated with the setup, storage and maintenance needed to comply with this requirement and could prove to be a heavy financial burden. In addition, a supervising pharmacist has the opportunity to immediately address and correct any issues that arise. Coupled with the required monthly visits by pharmacists, where the supervising pharmacist can address the same concerns, there is little need for this long of a retention period. A long retention period may even encourage delayed investigations and resolutions to issues that occur.

On average, states that permit telepharmacy require retention of 30 to 90 days of security surveillance. These states have several years of history of providing telepharmacy safely, including Idaho which recently decreased their storage retention from 90 days to 30 days. The Idaho board of pharmacy recognized that the longer retention was not needed, as it was costly for licensees to implement and maintain, and it did not directly impact safety or security standards.

I would like to again thank the board for the opportunity to comment and ask for your consideration to ensure the rules align with the intent of HB 4034. I believe them to be crucial in the viability of telepharmacy for Oregon and their inclusion may render a telepharmacy operationally unachievable.

There are communities across the state in dire need of pharmacy services, one of which reached out to me personally for help. I see telepharmacy as a tool to provide that help. It would be unfortunate for us to not provide assistance and pharmacy services to these communities as a result of burdensome parameters established in rule, especially if they do not impact patient safety.

Thank you,

Wade Irby, RPh

From:	Thomas Irby
To:	PHARMACY RULEMAKING * BOP
Subject:	Written comment on rules for Division 139 - RDSP
Date:	Friday, May 20, 2022 4:02:44 PM
Attachments:	Letter comment on RDSP Rules 5.20.2022.pdf

Please find attached a letter commenting on the rules for Division 139. This is intended for the May 24, 2022 Rulemaking Hearing.

Thank you,

--
Wade Irby, RPh
Beaverton Pharmacy
12250 SW Canyon Rd.
Beaverton, OR 97005

Ph. (503) 644-2101
FAX (503) 376-6790

From:	Ian Black
To:	PHARMACY RULEMAKING * BOP
Subject:	Interpreter
Date:	Thursday, April 7, 2022 11:37:14 AM

Why are even discussing this issue? I believe anybody seeking help in the USA be prepared to do it in ENGLISH. It is our national language. No, Spanish is not an alternate national language anymore than Polish, German, Italian, etc. has been in the past.
Stop facilitating people who come here illegally and/or refuse to assimilate into our society. The first tenet of any society is to be able to communicate with every other person in that society in a shared language.
Ian L. Black R.Ph.

Sent from Mail for Windows

From:	PHARMACY BOARD * BOP
To:	PHARMACY RULEMAKING * BOP
Subject:	FW: FILING CAPTION: Technician final verification; General responsibilities of Pharmacists, Pharmacy Technicians and Drug Outlets
Date:	Tuesday, May 10, 2022 11:44:13 AM

From: kcoodley@yahoo.com <kcoodley@yahoo.com>
Sent: Tuesday, May 10, 2022 11:27 AM
To: PHARMACY BOARD * BOP <PHARMACY.BOARD@oregon.gov>
Subject: FILING CAPTION: Technician final verification; General responsibilities of Pharmacists, Pharmacy Technicians and Drug Outlets

Dear Members of the Board,

I would like to register my opposition to the above proposed rule letting pharmacy technicians be the final check and bypassing pharmacists.

I can comment further if necessary,

Karen Coodley
pharmacist
RPH 106090

CVSHealth

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

May 24, 2022

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

Re: Proposed Rules – Various Chapters

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 41 related to Telework

While the Board has made amendments to Division 41 related to telework as directed by HB 4034, the proposed amendments do not meet the full intent of the legislation. In Section 18 the directive reads "in adopting rules under this subsection, the Board may not establish standards for the remote access of a pharmacy's electronic database that are more restrictive than standards for accessing the electronic database from inside the pharmacy." Yet, the Board only focused on amending language to allow a pharmacy technician to telework and restricted the database from being duplicated, downloaded or removed in Division 41. The intent of the language in Section 18(2) was also removal of the additional onerous requirements that a pharmacist, intern, certified Oregon pharmacy technician or pharmacy technician must adhere to when working remotely, such as:

- Using real-time audiovisual communication for supervision
- Requiring "check-ins" at least once per work shift as well as documenting the interaction
- Reviewing and documenting a percentage of patient interactions performed by a technician within 48 hours
- Documentation within 24 hours of multiple data points of patient interactions the licensee has completed

Additionally, we request amendments be made to clarify that these rules do not apply to pharmacists, interns or pharmacy technicians working remotely for a drug outlet not located in Oregon as the laws and rules of the resident state in which the pharmacy is located would govern the practice of pharmacy and where it occurs in that state. CVS Health is providing Arizona Board of Pharmacy Rule R4-23-621 Shared Services for the Board's consideration to repeal the current rules and replace with the below language. Arizona rules are being provided as this language has been adopted by additional states and successfully operated in Arizona since 2007.

Suggested Language of Arizona for Review

Arizona Administrative Code R4-23-621. Shared Services

F. Nothing in this Section shall prohibit an individual pharmacist licensed in Arizona, who is an employee of or under contract with a pharmacy, or an Arizona-licensed graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the order processing functions permitted by the pharmacy act, if both of the following conditions are met:

1. The pharmacy establishes controls to protect the confidentiality and integrity of patient information; and
2. None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

CVSHealth

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

Division 139 related to Remote Dispensing Site Pharmacies (RDSP)

The Board has proposed amendments to Division 139 related to remote dispensing site pharmacies as directed by HB 4034 from the 2022 legislative session. However, we feel the amendments made do not meet the full intent of the legislation. In Section 19 the directive reads "in adopting rules under this section, the board may not establish standards for telepharmacy that are more restrictive than standards for the delivery of in-person pharmacy services, including standards regarding prescription and dispensation of drugs." While the Board is proposing amendments to remove requirements of work experience, pharmacist to technician ratio and allowing pharmacy technicians to work in a telepharmacy, additional onerous requirements preventing the operation of a remote dispensing site remain such as:

- Requiring the supervising pharmacist to review a percentage of patient interactions within 48 hours along with documentation of various requirements of the interactions
- Prohibition on delivery of a prescription from a RDSP

CVS Health requests the Board repeal the rule and consider language, such as what is provided below from Washington state, to adopt in its place which includes removal of duplicate sections from Division 41 placed in Division 139 in lieu of referencing back to Division 41.

Suggested Language of Washington for Review

WAC 246-945-430 Pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site.
(1) The following requirements apply to pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site and are in addition to applicable state and federal laws applying to pharmacies.
(2) The pharmacy is required to have adequate visual surveillance of the full pharmacy and retain a high-quality recording for a minimum of thirty calendar days.
(3) Access to a pharmacy by individuals must be limited, authorized, and regularly monitored.
(4) A visual and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA compliant.
(5) The responsible pharmacy manager, or designee, shall complete and retain, in accordance with WAC 246-945-005 a monthly in-person inspection of the pharmacy.
(6) A pharmacist must be capable of being on-site at the pharmacy within three hours if an emergency arises.
(7) The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning and remain closed until system corrections or repairs are completed or a pharmacist is on-site to oversee pharmacy operations.

Division 143 related to Pharmacy Prescription Lockers (PPLs)

CVS Health feels the proposed amendments to Division 143 related to Pharmacy Prescription Lockers (PPL) do not alleviate the onerous and unnecessary burden of operating a locker within Oregon, which will prevent utilization of a PPL to increase patient access by drug outlets. While the amendments allow for digital signage, returning to stock of medication not picked up by the patient and reducing the data surveillance requirement from 6 months to 30 days, these amendments do not go far enough for drug outlets to operate a PPL. A PPL, as defined by OAR 855-143-0005, is a mechanical system that securely stores completed patient-specific prescription and non-prescription drugs, devices, and related supplies for pick up. This machine is not dispensing but simply an alternative system provided for a patient to pick up prescriptions and non-prescription items. We request the Board repeal the rule in its entirety 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 has provided language from Illinois Board of Pharmacy Administrative Code 68-1440.510 as an example of operable requirements by a drug outlet to provide additional patient access through a locker system for patient pick up.

Suggested Language of Illinois for Review

IL ADC 68-1330.510

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2) Kiosk
A) A kiosk is a device that maintains individual patient prescription drugs that were verified and labeled at the home pharmacy.
B) A home pharmacy may only use the kiosk with prior approval of a patient.
C) A kiosk located on the same premises or campus of the home pharmacy shall operate under the same license as the home pharmacy. However, a kiosk must be licensed with the Division if it is not so located.
D) A kiosk shall:
i) When located on the same premises or campus as the pharmacy, inform a patient, if he or she is using the device when the pharmacy is open, that the patient may address questions and concerns regarding the prescription to a pharmacist at the pharmacy.
ii) When not located on the same premises or campus as the pharmacy, inform a patient, if he is using the device when the pharmacy is closed, that he or she may immediately direct any questions and concerns regarding the prescription to a licensed pharmacist via a pharmacy provided audio/video link;
iii) Inform a patient that a prescription is not available to be delivered by the device if the pharmacist has determined that he or she desires to counsel the patient in person regarding the prescription.

Division 041/139 related to Permanent Pharmacy Closure Requirements

CVS Health appreciates the Board's efforts to draft rules addressing requirements for pharmacy permanent closures. However, we feel the Board could streamline the rule for ease of licensees to follow the requirements while still notifying patients in an appropriate timeframe and manner. Therefore, CVS Health requests the Board not adopt the proposed amendments and review other state rules for permanent closure of a pharmacy, such as Washington provided below, to provide a concise and streamlined list of requirements for licensees to follow, which still provide for ample patient notification. We also suggest the Board adopt one rule in Division 41 to address permanent pharmacy closures and not repeat the language in Division 139 but refer to the rule in Division 41.

Suggested Language of Washington for Review

WAC 246-945-480 Facility reporting requirements.
(2) Unless otherwise specified, when permanently closing a facility, the facility must:
(a) Report to the commission in writing, no later than thirty calendar days prior to closing:
(i) The date the facility will close;
(ii) The names and addresses of the persons who shall have custody of the prescription files, bulk compounding records, repackaging records, invoices and controlled substances inventory records of the pharmacy to be closed; and
(iii) The names and addresses of any person(s) who will acquire any legend drugs from the facility to be closed, if known at the time the notification is filed.
(b) Provide notification to customers noting the last day the pharmacy will be open, name and address of the pharmacy to which prescription records will be transferred and instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice and the last day a transfer may be initiated. Notification should include:
(i) Distribution by direct mail; or
(ii) Public notice in a newspaper of general circulation in the area served by the pharmacy; and
(iii) Posting a closing notice sign in a conspicuous place in the public area of the pharmacy.
(c) No later than fifteen days after closing:
(i) Return the facility license;
(ii) Confirm that all legend drugs were transferred or destroyed.
If the legend drugs were transferred, provide the names and addresses of the person(s) to whom they were transferred;
(iii) Confirm if controlled substances were transferred, including the date of transfer, names, addresses, and a detailed inventory of the drugs transferred;

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(iv) Confirm return of DEA registration and all unused DEA 222 forms to the DEA;
(v) Confirm all pharmacy labels and blank prescriptions were destroyed; and
(vi) Confirm all signs and symbols indicating the presence of the pharmacy have been removed.
(3) The commission may conduct an inspection to verify all requirements in subsection (2) of this section have been completed.

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., 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:	Tuesday, May 24, 2022 8:28:51 AM
Attachments:	CVS Health Comments on Proposed Rules May 2022.pdf

Good Morning Rachel,

Please find attached comments from CVS Health on various proposed rules for the Board's consideration. Should the Board have any questions, please feel free to contact me directly.

Thanks,
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: Lori Goodrich
To: PHARMACY RULEMAKING * BOP
Subject: Technician Final Verification
Date: Monday, May 23, 2022 8:52:19 PM

To the board of pharmacy concerning final verification. I strongly oppose a change to allow technicians to execute the final verification of a prescription drug product.

My reason is in my 25 years experience as a retail pharmacist I do not think it is in the public's best interest. When I'm performing a final verification, I'm looking at the whole prescription with the drug product in hand (Is this appropriate for this person?). You might think That in Data Verification all of this is checked but we suffer from information overload with too many DUR's and an overload of information.

To a chain store boss it may look like we are only determining if the correct drug is in the correct vial but this is simply not the case. Many times, at the final verification, it becomes apparent that an error was made in the data verification that only a highly trained pharmacist would catch. The errors that I find are as complex as drug product selection to as simple as storage conditions. Pharmacist's need the actual box or package to look at instead of relying on a programmers description. So many times I have found an error in the programming on computer screens only to find the computer system is not accurate in the description of the product.

Strongly oppose Technician Final Verification!
Tyrell Goodrich RPH
License 9230

From: Ron Hogevoll
To: PHARMACY RULEMAKING * BOP
Subject: Technician final verification
Date: Saturday, May 7, 2022 11:16:46 AM

Hi,

I'm providing feedback on technician final verification. I am a pharmacist and I do not support technician final verification. At my practice site, we have pretty robust systems, processes and policies that help ensure accurate prescription filling. Even with those in place, I still find near misses (error that does not reach the patient) at product verification.

I feel that the course of providing pharmacy services to patients has been compromised over the years for reasons that are driven by motives that truly do not have patient safety as the core value or outcome. Allowing technicians to perform final verification seems to be in alignment with that assessment.

I'm also concerned that this is potentially happening at the same time as qualification requirements for technicians are being weakened.

Thank you for considering this input.

Ron Hogevoll
503-407-3297

From: Laura Hysen
To: PHARMACY RULEMAKING * BOP
Cc: Rose DIXON
Subject: Rule comments from Vetsource Pharmacy
Date: Monday, May 23, 2022 6:30:49 PM

Hello,

I wish to submit the following comments for the rulemaking committee that meets on 05/24/22:

- Telework
  - We support the changes to the pharmacist to technician ratio requirement. Our pharmacists will continue to safely supervise the appropriate number of technicians only within the scope of their capabilities. Each practice site is different and in our mail order setting, a ratio of four techs to one pharmacist is unreasonable and not sustainable from a staffing perspective. Our workflow is extremely streamlined compared to retail pharmacies, ensuring that we can achieve high quality supervision with a different but effective ratio.
  - We support the changes that now permit pharmacy technicians to perform telework. They perform consistently, are as capable of following all procedures and are easy to monitor and supervise.
  - We request that the Board consider eliminating the requirement to monitor a specific percentage of patient interactions, *855-041-3220(7)(a)- a minimum of 5% of patient interactions observed or reviewed.* Respectfully, please consider the following proposed rule language:
    - *(a) Uses reasonable professional judgment, to determine the appropriate percentage of patient interactions for each licensee that must be observed or reviewed to ensure public health and safety.* [Eliminates any specific quota, but must be in the pharmacist's determination and must be supported by the outlet, which is consistent with the other components of the supervision requirements in the rule]
    - This ensures that each outlet can set the number of observances and reviews of staff based on their functions and capabilities, and apply an appropriate level of monitoring that is not dependent on a fixed percentage.
    - Each outlet is unique. Vetsource will never compromise our quality standards and performance, especially since we are a leader in the veterinary industry.
    - Monitoring telework is absolutely necessary, but also requires quite a bit of pharmacist labor time as well. Telework supervision currently requires close to 8 hours of pharmacist time on top of the time required to perform other routine duties. And thus my pharmacist budget has to expand. As a business, we need to be capable of scaling our operation in a manner that preserves these high standards and maintains a fair and reasonable number of pharmacists compared to our competitors in similar settings. We of course will find ways to be more efficient but that also requires more capital investment in technologies to ensure this process is streamlined, effective and in compliance with these rules.
- Regarding *855-019-0200 Pharmacist General Responsibilities: (4)(d) Know the identity of each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction and control at all times*

    - We request that the Board consider clarifying this language. How would a pharmacist or an outlet confirm that the identity of each supervisee is "known" to the pharmacist? At the start of each work shift, pharmacists and technicians are immediately aware of who they are supervising and are continually monitoring their work. Documenting this acknowledgement would be time consuming and would not add to the quality of the supervision in a mail order dispensing environment where technicians and pharmacists are working side by side and can each readily identify the supervisors and supervisees. We request that the Board add clarifying language to help each outlet understand how to be in compliance with this rule.
- Counseling and language assistance - 855-019-0230
    - While this language is mostly determined by the ORS 413.558, please consider rule language that does not limit pharmacies with call centers. We wish to utilize a professional translation assistance company that is trained in ensuring a good customer experience for our pet owners and that can perform the duties as specified in ORS 413.558. We may be more limited if translation companies are not utilizing health care interpreters that are registered with the OHA.

Thank you so much for your time and consideration!

We greatly appreciate the efforts made by the Oregon Board and commend you and your team for the very thoughtful work that you are accomplishing.

Best regards,

Laura Hysen

Director of Pharmacy, Pharmacist in Charge

(503) 866-9653
Portland, Oregon

From:	jason melander
To:	PHARMACY RULEMAKING * BOP
Subject:	Proposed rule changes
Date:	Wednesday, April 27, 2022 3:46:48 PM

Hello,

I writing to gain more information about the rule change regarding technicians performing final verification. Does this mean a technician can fill a prescription, verify that it was filled correctly, and then dispense it to a patient?

The rule says the pharmacist is supervising the technician doing this, but I'm not clear what that entails. What is the role of the pharmacist in supervising the technician if the technician is verifying medications? Does a pharmacist just need to be present?

Many technicians don't have much experience with medication properties so I'm concerned about patient safety if a pharmacist is not directly involved in dispensing the physical drug or insuring it's dispensed correctly.

Thank your for any help you can provide explaining this rule change.

Jason Melander

From:	Fernanda Menda
To:	PHARMACY RULEMAKING * BOP
Subject:	Objection to pharmacy technicians doing final verification
Date:	Tuesday, May 10, 2022 2:11:03 PM

Dear members of the Board,

This rule isn't safe and if approved, employers will impose upon us to work in an environment we don't find safe and don't agree. The solution for overworked pharmacists is staffing. Not willing to pay a pharmacist in lieu of giving their task to a technician is a cheap way to go around a bigger issue.

Again, if this rule gets approved it will force pharmacists to follow instructions imposed by their employers that can be unsafe for the public. Plus, what if I'm forced to have a technician that I know to be sloppy to be verifying under my license? That's unacceptable.

To further move with this rule the Board needs to at least send an official survey to all Oregon pharmacists verifying their opinion on the subject.

A rule that will modify the conditions of work for the pharmacist cannot be changed without first their consent.

Thank you very much,

Fernanda Menda - RPH 0012136

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May 20, 2022

VIA EMAIL TRANSMISSION ONLY - pharmacy.rulemaking@bop.oregon.gov

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

RE: Proposal to Amend Chapter 855 of Oregon Regulations to Comply with House Bill 4034

Dear Board President Wassim Ayoub and Board Members:

Quarles & Brady LLP, on behalf of its Oregon pharmacy clients, submits this letter to comment on the Oregon Board of Pharmacy's proposed implementation of House Bill 4034 ("HB 4034" or the "Bill"). Specifically, Quarles & Brady LLP would like to suggest an approach to implementing the Telemedicine and Telepharmacy aspects of HB 4034 in a way that would ensure Oregon-based patients receive expanded access to quality pharmacy care as envisioned by the Oregon Legislature in a manner that is safe and efficient for those patients. Our recommendations are described below and the attached exhibit shows line-by-line proposed edits.

Section 14 of HB 4034 expands the manner in which health care services may be provided to a patient physically located in Oregon by allowing a physician or physician assistant to establish a patient-provider relationship, diagnose or treat a medical condition, or prescribe drugs to a patient via telemedicine. The term "telemedicine" is defined in HB 4034 as "the provision of health services to patients by physicians and health care practitioners from a distance using electronic communications, including synchronous technologies to facilitate an exchange of information between a patient and physician or health care practitioner in real time or asynchronous technologies to facilitate an exchange of information between a patient and a physician or health care practitioner in other than real time." H.B. 4034 § 15(26), 81st Leg. Assemb. (Or. 2022).

To comply with this bill, the Oregon Board of Pharmacy must amend Or. Admin. R. 855-019-0210(2)(a), which currently states the following:

> "The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their

> professional practice and not result solely from a questionnaire or an internet-based relationship."

As it stands, this language currently prohibits a pharmacy from accepting or dispensing prescription medication based upon a telemedicine visit that is compliant with the Bill. Therefore, we ask that the Board consider amending Or. Admin. R. 855-019-0210(2)(a) to state the following:

> "The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice."

Our proposed language maintains the protections espoused by the current language while also permitting prescriptions to be dispensed based on valid telemedicine visits. Instead of rewriting this entire provision, our proposal maintains the greatest degree of continuity for both physicians and pharmacists, and ensures prescriptions will continue to be dispensed only for legitimate medical purposes.

In addition to the expansion of telemedicine services, HB 4034 prohibits the State Board of Pharmacy from establishing standards for telepharmacy that are more restrictive than standards for activities conducted inside the pharmacy. *See* Sections 18(2) and 19(4)(b).

Compliance with HB 4034 will require the Board to amend their pharmacy telework rules in Division 41, which are currently more restrictive than the bill. Specifically, we are asking the Board to make the following changes to the telework rules in Division 41:

1. Remove the personal Oregon licensure requirement for all nonresident pharmacy staff performing telework (see Or. Admin. R. 855-041-3215(2)(a));

2. Revise the proposed supervision requirements in Or. Admin. R. 855-041-3220 currently requiring an Oregon-licensed pharmacist to monitor staff via video and to review phone and video recordings of each remote patient interaction, and replace these provisions with a requirement that pharmacies have the capability to communicate with staff using audio-visual means; and

3. Eliminate the requirement for a pharmacist to check-in on each supervised licensee once per work shift (see Or. Admin. R. 855-041-3220(4)). Or in lieu of eliminating this provision entirely, we propose revising it to permit the required check-in to be conducted by a manager instead of a pharmacist.

In adopting HB 4034, the Legislature intended to adopt the national standards for telework as contemplated by the National Association of Boards of Pharmacy ("NABP") model act. We commend the Board for adhering to this intent by removing the technician ratio and experience requirement from the proposed rule, as those requirements did not serve in the best interest of providing superior patient care and were not consistent with the onsite pharmacy standards.

However, more can be done truly effectuate the Legislature's intent, which is why we propose the aforementioned revisions.

Our proposals would keep intact the standards intended to ensure that pharmacies are taking the utmost precautions in protecting patient information. The superfluous requirements currently contained in the Board's current and proposed telework rules do not meaningfully advance these interests; they are unduly burdensome on pharmacists who would otherwise be focused on patient care, and they have no precedence in other states. In addition, the current requirements have no corollaries with onsite work. As the Legislature has made clear with its adoption of HB 4034, telepharmacy should be treated as an equally valid form of pharmacy practice as onsite work.

With that, we urge Oregon to take the progressive approach in understanding that nonresident pharmacy staff work remotely via telepharmacy in nonresident facilities licensed—and regulated—by the Oregon Board of Pharmacy. Thus, requiring these nonresident staff members to obtain personal licensure in Oregon to conduct telework remotely is unnecessary, burdensome, and counter to the Legislature's intent in HB 4034.

We also want to stress the importance of telework in improving workplace conditions and administrative burdens on pharmacists. Central to all of this is, and must always be, patient care. As pharmacists contend with heavier and heavier regulatory burdens related to the logistical and administrative aspects of their practice, more time and energy must be spent on navigating these regulatory hurdles, and subsequently less time can be spent focusing on the patients. When pharmacists are required to spend substantial amounts of their day checking in on licensees, reviewing all remote patient interactions, and monitoring staff via video, they cannot also be available to respond to patients' needs. If these onerous requirements were legitimately necessary, equivalent provisions would have been implemented for on-site pharmacy work as well. The fact that these requirements are not also being implemented inside the pharmacy speaks to how superfluous the current requirements are.

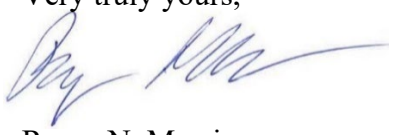
Finally, although the Board stated that pharmacies are not required to utilize telework, the pandemic has made clear that remote technology and associated telehealth services are going to become the new normal. More and more, pharmacies must contend with the reality that patients want (and often need) services provided to them remotely. Opening a new pharmacy without providing these services all but ensures that pharmacy will face serious challenges in providing adequate patient care. But unfortunately, the Board's proposed rule amendments, as they stand, add to the economic burden of providing these crucial telehealth services. The Board's proposed amendments have the tendency of requiring pharmacies to employ additional staff—and additional pharmacists—to review calls, manage the personal licensure of staff, monitor remote visits, and check in on licensees on a weekly basis.

Such economic barriers to opening new pharmacies (or to expanding telehealth services at existing pharmacies) have very real-world consequences on patient health. Often the pharmacies that are least capable of weathering these increased costs are the pharmacies serving the most

marginalized populations in rural or urban locations, thus directly contributing to decreases in health equity. The fundamental purpose of telehealth is to *expand* access to quality health care for individuals; the current and proposed changes to the telework rules have the exact opposite effect.

We hope you will agree with us that the revisions we propose are fundamentally in the best interest of permitting pharmacies to engage in the highest quality patient care for Oregon patients. For every hour a licensed pharmacist must spend on contending with unduly burdensome administrative regulations, an hour is taken that could have been used in the service of patients. As the Legislature has clearly recognized in HB 4034, telehealth (and specifically telepharmacy) services are equally as valid, safe, and effective as onsite pharmacy practice. Disparity in how the two forms of pharmacy practice are regulated serves no legitimate purpose in advancing the health outcomes of Oregon population, and we respectfully urge the Board to adopt our proposals to remedy that disparity.

Very truly yours,



Roger N. Morris
Susan Brichler Trujillo
Kaytie M. Ravega
Benjamin Lockwood

From:	Spinner, Kiara M.
To:	PHARMACY RULEMAKING * BOP
Cc:	Morris, Roger N.; Ravega, Kaytie M.; Trujillo, Susan Brichler; Lockwood, Ben A.
Subject:	Oregon Board of Pharmacy - Proposal to Amend Rule
Date:	Friday, May 20, 2022 1:15:49 PM
Attachments:	[Outgoing] 2022-05-20 Letter to OR BOP re Rule Amendments for HB 4034.pdf

Good afternoon,

Please see the attached correspondence on behalf of Quarles & Brady, LLP.

Thank you.

Kiara M. Spinner / Legal Secretary
Kiara.Spinner@quarles.com / LinkedIn
Quarles & Brady LLP
One Renaissance Square, Two North Central Avenue, Suite 600 / Phoenix, AZ 85004-2322
Office 602-229-5384 / quarles.com

VISIT our COVID-19: Guidance for Clients page for the latest updates from Q&B attorneys

From: Jason Smith
To: PHARMACY RULEMAKING * BOP
Subject: Written Comments May 24, 2022 Rulemaking Hearing
Date: Tuesday, May 24, 2022 2:52:55 PM

To the Oregon Board of Pharmacy,

After reviewing the proposed amendments to Divisions 019/25/041 related to Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification, I would like to provide written comments on the following section.

- (5) A Pharmacist may delegate final verification of drug and dosage form, device, or product to a Certified Oregon Pharmacy Technician or Pharmacy Technician per ORS 689.005 when the following conditions are met:¶ (a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification; ¶ (b) The Certified Oregon Pharmacy Technician or Pharmacy Technician does not use discretion in conducting final verification;¶ (c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and¶ (d) Ensure the Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.

I am concerned the above amendments to Divisions 019/25/041 will create a public health risk. As a pharmacist for the last eleven years, I have worked with countless pharmacy technicians in a variety of settings. I have seen experienced pharmacy technicians make mistakes that would have caused serious health outcomes had a pharmacist not caught the mistake. The final verification is more than a product check. The final verification, is another critical step in getting the right patient the right medication. I am concerned that pharmacists will be pressured to allow inexperienced technicians the ability to perform the final verification. If a pharmacist in a retail chain floats to another store, how will they determine if a technician is competent to perform a final verification? If a mistake is made, does liability fall on the pharmacy manager or the floating pharmacist? In regard to supervision, I do not see how a pharmacist can supervise a technician placing a product in a bag unless they are literally standing over the technician's shoulder verifying the product. I am concerned a pharmacist will be pressured to supervise an ever-increasing number of technicians performing a final verification. I am concerned that given current workloads in the retail sector, there will be an increase in mistakes resulting in patient harm. In response to these concerns, I would like to request the Oregon Board of Pharmacy not adopt the above proposed amendments to Division 019/25/041 related to Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification.

Thank you for your time,
Jason Smith PharmD

May 23, 2022

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

Re: Proposed rules related to Remote Dispensing Site Pharmacy

Dear Ms. Melvin:

TelePharm and Cardinal Health thank the Oregon Board of Pharmacy (OBoP) for the opportunity to comment regarding the amended rules for Remote Dispensing Site Pharmacies (RDSPs) resulting from the passage and implementation of HB 4034. These rules are pivotal to improving public health and increasing access to pharmacy services for patients in Oregon, and we are eager to see OBoP make the necessary changes as required by this legislation.

One of the directives detailed in HB 4034 requires the OBoP to ensure the rules for Remote Dispensing Site Pharmacies not be "more restrictive than the standards for the delivery of in-person pharmacy services, including standards regarding prescription and dispensation of drugs". In order to fully achieve the intent and direction outlined in HB 4034, we recommend a few minor revisions to the proposed rules.

855-139-0210 Outlet: Supervision

- This section requires a supervising pharmacist to record and review at least 10% of interactions and recorded telephone audio between a licensee and patients within 48 hours, and then document details of such review within 24 hours.
- The surveillance requirement, as outlined in this section, is more restrictive than the requirements for the delivery of pharmacy services in traditional pharmacy practice settings, as it does not exist in OBoP rule or law and is not required of pharmacists supervising in-person pharmacy services. This requirement should be removed in order to comply with HB 4034.
- A pharmacist review of interactions does not accomplish the intent of ensuring public health and safety as stated in 855-139-0210(3)(a), and the board has successfully implemented other safeguards and requirements to achieve this objective as addressed in other sections of the rules.
    - The requirement for continuous audiovisual surveillance already allows a supervising pharmacist the ability to hear and visually monitor interactions as they occur at the RDSP in real time.

    - In addition, a pharmacist is required to be on-site once every 28 days, which allows the pharmacist the ability to review any surveillance footage, if needed, and investigate and address any issues that have occurred and not already been resolved.
    - Calculating the number of interactions places an undue burden on pharmacy staff as there are no systems capable of measuring such interactions. Pharmacists would be required to make an arbitrary determination, resulting in a time-consuming process that ultimately increases workload and distracts pharmacists from providing actual care. This will negatively impact safety for patients at the RDSP and the affiliated pharmacy.
    - Like in a traditional retail drug outlet, a pharmacist is required to verify and counsel on all prescriptions dispensed from an RDSP, a requirement which adequately accomplishes the board's intent to ensure public health and safety.
- Of the 27 other states that permit remote dispensing pharmacies, Oregon is the only state with this requirement.
- ASHP, APhA and NABP all recognize telepharmacy or remote dispensing pharmacy as a means to provide access to pharmacy services, and none of these entities include this requirement in their guidance or language.
- We recommend removing this requirement from 855-139-0210 Outlet: Supervision, as it does not align with HB 4034, creates operational constraints for pharmacy staff and personnel, and can negatively impact patient safety. Our proposed revision is as follows:

  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 or Pharmacy Technician, and the surveillance system is fully operational;
  (2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Certified Oregon Pharmacy Technician or 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 the Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:~~
  ~~(a) Using reasonable 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 pPharmacist 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 pPharmacist is reviewing;~~
  ~~(C) Date and time of licensee patient interaction pPharmacist is reviewing;~~

~~*(D) Date and time of pPharmacist 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 pPharmacist'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 or Pharmacy Technician.*~~

(3)~~(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 or Pharmacy Technician at the RDSP.

855-139-0550 Records: General Requirements

- In addition to the requirement to record telephone audio, as similarly seen in section 855-139-0210(3)(a), this section requires that all surveillance records, including telephone audio recordings, and audio and video data be stored for a minimum of six months.
- These requirements directly conflict with federal standards regarding patient privacy, and do not align with HB 4034, as they are “more restrictive than the standards for the delivery of in-person pharmacy services, including standards regarding prescription and dispensation of drugs”.
    - There is no established standard regarding the retention of telephone audio and surveillance footage for traditional retail drug outlets in the state of Oregon.
    - HIPAA and other federal privacy regulations limit the recording and retention of telephone audio to permitted uses only. These uses do not include retention for the purposes of future audit and review to ensure personnel operate under appropriate supervision, direction and control.
    - A pharmacist can achieve the same level of oversight as seen in a traditional pharmacy by providing continuous audiovisual communication, as required and outlined in section 855-139-0100 for Remote Dispensing Site Pharmacies.
- The requirement for the retention of such recordings can increase the risk for accidental disclosures of patient information and result in impermissible use.
- Of the 27 other states that permit telepharmacy or remote dispensing, 25 states limit the requirement for storage of data as addressed in this section to 90 days or less. Additionally, Oregon is the only state that requires the recording of telephone audio. The other 27 states defer to federally recognized patient privacy guidelines and rules.
- The six-month retention period will be expensive for licensees to install and maintain in order to comply with the parameters as set forth in this rule.
- ASHP, APhA and NABP all recognize telepharmacy or remote dispensing pharmacy as a means to provide access to pharmacy services and none of these entities include the

requirements for recording telephone audio or six months of record retention in their guidance or language.

- We recommend the following edit, as this section conflicts with HB 4034 and federal privacy standards, and is cost prohibitive for pharmacy owners wishing to expand access to patients in underserved areas.

855-139-0550 Records: General Requirements
(1)-(2)
(3) Records retained by the Drug Outlet must include, but are not limited to:
(g) Still image capture and store and forward images must be retained according to (1);
(h) ~~*Data, telephone audio and s*~~*Surveillance system data must be retained for* ~~*6 months*~~ *90 days; and*
(i) Any errors or irregularities identified by the quality improvement program.

Thank you for your time and consideration, I can be reached at maimuna.bruce@telepharm.com or (847)-887-4891 for any questions you may have.

Sincerely,

Maimuna Bruce, PharmD, MBA
Manager, Regulatory Affairs

Jessica Adams, PharmD
Director, Regulatory Affairs

From:	PHARMACY RULEMAKING * BOP
To:	"Bruce, Maimuna"; PHARMACY RULEMAKING * BOP
Cc:	Adams, Jessica (Regulatory Affairs)
Subject:	RE: Division 139- Related to RDSP Comment Letter
Date:	Monday, May 23, 2022 1:13:17 PM
Attachments:	image004.png image005.png

Hello Bruce,

Thank you for your comments, they will be recorded into the Rulemaking Hearing Report and provided to the board at the June 8-10, 2022 Board Meeting.

Rulemaking Staff
Oregon Board of Pharmacy

pharmacy.rulemaking@bop.oregon.gov
(971) 673-0001 phone

www.Oregon.Gov/Pharmacy

From: Bruce, Maimuna <maimuna.bruce@telepharm.com>
Sent: Monday, May 23, 2022 12:43 PM
To: PHARMACY RULEMAKING * BOP <PHARMACY.RULEMAKING@bop.oregon.gov>
Cc: Adams, Jessica (Regulatory Affairs) <jessica.adams01@telepharm.com>
Subject: Division 139- Related to RDSP Comment Letter

Good Afternoon, Rachel,

Attached are comments for the proposed rules on Division 139- Related to RDSP

Please let me know if you have any questions.

Regards,

Maimuna Bruce-Uzzell, PharmD, MBA, MS
Manager, Regulatory Affairs, TelePharm
123 N Linn St Suite 2F, Iowa City, IA
847.887.4891 mobile

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

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

May 24, 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: Divisions 019/025/041 – related to Certified Oregon Pharmacy Technician/ Pharmacy Technician Final Verification

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 Certified Oregon Pharmacy Technician/ Pharmacy Technician Final Verification.

Walgreens supports allowing the Pharmacist on Duty to determine the maximum number of individuals they can supervise as outlined in current draft 855-019-0200(4)(e). However, we have concerns with the requirement as drafted in 855-041-0018(5). This would require a pharmacy outlet to comply with the Pharmacist's determination even if the outlet felt that that was an unsafe practice. If the Pharmacist is responsible for making the decision, they too should be accountable for their actions, not the permit holder. We respectfully request that the board strike 855-041-0018(5).

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
Phoenix, AZ 85034
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lorri.walmsley@walgreens.com

May 24, 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: Divisions 019/041/139 – related to Interpreters

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 Interpreters.

The Oregon Legislature passed 2021 HB 2359 related to healthcare interpreters, and OHA recently adopted many regulations to implement this new statute that will apply to pharmacies and other healthcare practitioners. The rules proposed by the Board are redundant and are not needed to implement the law. Walgreens strongly encourages the Board not to adopt the regulations proposed in 855-019-230, 855-041-1133, 855-041-1165, 855-139-0360, 855-139-0555.

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
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May 24, 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: Divisions 139 related to RDSP

Dear Dr. Schnabel,

Please accept these comments on behalf of all pharmacies owned and operated by Walgreen Co. located in Oregon. We thank the Board for your continued work to make pharmacy services broadly available for Oregonians; however, there are still several requirements within current regulations that are burdensome and will prevent implementation. Furthermore, we believe these regulations written are in direct conflict with the legislative intent of 2022 HB 4034.

855-139-0210 - Outlet: Supervision

The requirement for the surveillance system to record audio and video is extremely onerous and could pose patient HIPAA concerns. No other states require an audio recording for any telepharmacy system or surveillance components. Additionally, no other state requires the recording of telephone calls. The arbitrary requirement to have the pharmacist review percentage of interactions is very burdensome and impossible to comply with since it could not be easily measured. Furthermore, these requirements are in direct conflict with the legislative intent of 2022 HB2034 since these are not a requirement of a Drug Outlet. We respectfully request modifications to 855-139-0210 in accordance with the intent of the legislation passed by the Oregon Legislature.

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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May 24, 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: Divisions 006/041/043/045/080/139 – Standards Adopted by Reference

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 Standards Adopted by Reference.

To modernize Oregon's regulations, we respectfully request the following amendment to the definition of Final Verification. Most pharmacies now utilize a process for split verification of prescriptions; each step in the verification process; data, DUR and final product, maybe completed by multiple or different pharmacists. Each step of the process is documented to include, where, when and who completed the process. Many large facilities (i.e., mail-order pharmacies) utilize sophisticated robotic technologies to check the product at the canister level after filling, using a closed loop system.

(18) "Final Verification" means after the prescription is entered into a pharmacy's electronic system, a pharmacist is responsible for ensuring ~~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 correct drug ~~and dosage~~, device or product.

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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p: 602-214-6618
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May 24, 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: Divisions 041 related to 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 Oregon, the need for Telework promotes patient access. It 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 go unused, therefore ultimately hurting patient access largely. 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. Furthermore, as proposed, we believe these regulations are in direct conflict with the legislative intent of 2022 HB 4034.

The proposed definition in 855-041-3205(2) would require a technician working out-of-state supporting an in-state Oregon Pharmacy to hold an Oregon license. The requirement should be more broad to allow a technician licensed by another jurisdiction to perform these functions. In the event that the person performing work, whether a Pharmacist, Intern, Certified Pharmacy Technician, or Pharmacy Technician, is physically located in Oregon, those individuals should be required to hold the respective Oregon license. We respectfully request the following amendments and corresponding amendments throughout Division 41 striking all references to Oregon licensed, except the amendment as outlined below in 855-041-3215(1)(2).

855-041-3205(2) "Telework Site" means a location that is not a registered drug outlet where an Intern, Certified ~~Oregon~~ Pharmacy Technician or Pharmacy Technician may assist in the practice of pharmacy as contractors or employees of an Oregon registered drug outlet.

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, Certified ~~Oregon~~ Pharmacy Techncians, and Pharmacy Technicians working from a Telework Site work under the supervision, direction and control of a~~n Oregon~~ licensed Pharmacist.
(2) A Pharmacist that engages in the practice of pharmacy and an Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician that assists in the practice of pharmacy from a Telework Site physically located in Oregon for any person or facility locatated in Oregon must:

Walgreens

855-041-3200 Telework: Supervision Requirements

Drug outlets are not required to record, store and review conversations with patients on a routine basis. The current requirement in 855-041-3220 requiring that all telephone audio is recorded, stored, and a percentage is reviewed is not in compliance with the legislative intent of 2022 HB 4034. We respectfully request that the Board modify 855-041-3200 in compliance with 2022 HB 4034 and consistent with its legislative intent.

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

Sincerely,

Lorri Walmsley

Lorri Walmsley, RPh, FAzPA

From:	Walmsley, Lorri
To:	SCHNABEL Joseph * BOP; PHARMACY RULEMAKING * BOP
Subject:	Walgreens Comments
Date:	Tuesday, May 24, 2022 4:03:57 PM
Attachments:	OR Comment Letter_Standards Adopted by Reference.pdf OR Comment Letter_RDSP.pdf OR Comment Letter_Certified Oregon Pharmacy Technician Pharmacy Technician Final Verification_V!.pdf OR Comment Letter_Telework.pdf OR Comment Letter_Interpreters.pdf

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Hello Joe,

Please see attached comments on the proposed regulations.

Warm Regards,

Lorri

Lorri Walmsley, RPh, FAzPA
Director, Pharmacy Affairs

Walgreen Co.
Telephone 602-214-6618

Member of Walgreens Boots Alliance ¦ MyWalgreens.com

DIVISION 006
DEFINITIONS

855-006-0005

As used in OAR Chapter 855:

(1) “Adulterated” has the same meaning as set forth in 21 USC 351 (v. 3/15/2022)

(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) (03/15/2022).

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

(7) “Certified health care interpreter” has the meaning given that term in ORS 413.550.

(8) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the Pharmacist in the practice of pharmacy pursuant to rules of the board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the Pharmacist are not considered Certified Oregon Pharmacy Technicians or Pharmacy Technicians.

(9) “Clinical Pharmacy Agreement” means an agreement between a Pharmacist or pharmacy and a health care organization or a 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.

(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.

(11) "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.

(12) "Confidential Information" means any patient information obtained by a Pharmacist or pharmacy.

(13) "Consulting Pharmacist" means a Pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.

(14) 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 or registrant who is responsible for the maintenance, care or keeping of pharmacy records based on the services provided by the pharmacy, regardless of whether the records are in that person's actual physical custody and control.

(16) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

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

(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.

(19) "Health care interpreter" has the meaning given that term in ORS 413.550.

(20) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the Oregon Health Authority.

(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.

(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) (03/15/2022).

(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.

(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.

(25) “Misbranded” has the same definition as set forth in 21 USC 352 (v. 03/15/2022).

(26) "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.

(27) "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.

(28) "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.

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

(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.

(31) “Official compendium” means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP NF 2022, Issue 1), official Homeopathic Pharmacopoeia of the United States <HPUS> (v. 2022), or any supplement to any of these.

(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.

(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.

(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.

(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.

(36) “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.

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

(38) “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.

(39) "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.

(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.

(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.

(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 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.

(44) “Reference biological product” means the biological product licensed pursuant to 42 USC 262(a) (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.

(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.

(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.

(47) "Specialized Education Program" means;

(a) A program providing education for persons desiring licensure as Certified Oregon Pharmacy Technicians or Pharmacy Technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or

(b) A structured program approved by the board and designed to educate Certified Oregon Pharmacy Technicians or Pharmacy Technicians in one or more specific issues of patient health and safety that is offered by:

(A) An organization recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians;

(B) An employer recognized by the board as representing Pharmacists, Certified Oregon Pharmacy Technicians or Pharmacy Technicians; or

(C) A trade association recognized by the board as representing pharmacies.

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

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

(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, Certified Oregon Pharmacy Technician or Pharmacy Technician being supervised, coupled with the ability to control and be responsible for the Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician's action.

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

(52) "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.

(53) "Verification" means the confirmation by the Pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an Intern, a Certified Oregon Pharmacy Technician, or a Pharmacy Technician.

DIVISION 041
OPERATION OF PHARMACIES

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 (04/01/2021), 21 CFR 1317.35 (04/01/2021), 21 CFR 1317.40 (04/01/2021), 21 CFR 1317.55 (04/01/2021), 21 CFR 1317.60 (04/01/2021), 21 CFR 1317.65 (04/01/2021), 21 CFR 1317.70 (04/01/2021), 21 CFR 1317.75 (04/01/2021), 21 CFR 1317.80 (04/01/2021), and 21 CFR 1317.85 (04/01/2021); and

(d) 21 USC 822 (03/15/2022), 21 USC 822a (03/15/2022).

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 (01/01/2021), 16 CFR 1701 (01/01/2021), and 16 CFR 1702 (01/01/2021).

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

855-041-7050
Definitions- Long Term Care Pharmacy

As used in OAR 855-041-7000 through 855-041-7080:

(1) "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.

(2) For the purposes of Schedule II prescriptions in 21 CFR 1306.11 (04/01/2021), 21 CFR 1306.12 (04/01/2021), 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 (04/01/2021) includes "community-based care facilities."

(3) "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.

(4) "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.

DIVISION 043
Practitioner Dispensing

855-043-0545
Dispensing Practitioner Drug Outlets: Dispensing and Drug Delivery

(1) Prescription drugs must be personally dispensed by the practitioner unless otherwise authorized by the practitioner's licensing board.

(2) Drugs dispensed from the DPDO must be dispensed in compliance with the requirements of the practitioner's licensing board.

(3) A DPDO must comply with all requirements of State or federal law.

(4) A DPDO must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2021), 16 CFR 1701 (01/01/2021) and 16 CFR 1702 (01/01/2021).

(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.

855-043-0740
Community Health Clinic (CHC) – Dispensing and Drug Delivery

(1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.

(2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.

(3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.

(4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.

(6) A CHC must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2021), 16 CFR 1701 (01/01/2021) and 16 CFR 1702 (01/01/2021).

(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.

DIVISION 045
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 (12/01/2021), and 1821 (05/01/2017).

DIVISION 080
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 (03/15/2022), 21 USC 812 (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.

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 (04/01/2021), 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.

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) 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.

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).

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), unless specifically excepted or listed in another schedule.

855-080-0028
Excluded or Exempted Substances

(1) The board adopts the excluded substances list found in 21 CFR 1308.22 (04/01/2021).

(2) The board adopts the exempt chemical preparations list found in 21 CFR 1308.24 (04/01/2021).

(3) The board adopts the exempted prescription products list in the Table of Exempted Prescription Products (02/11/2022) pursuant to 21 CFR 1308.32 (04/01/2021).

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).

(3) The board adopts the exceptions to registration for the incidental manufacture of controlled substances pursuant to 21 CFR 1307.13 (04/01/2021).

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), 21 CFR 1301.02 (04/01/2021), 21 CFR 1301.71 (04/01/2021), 21 CFR 1301.72 (04/01/2021), 21 CFR 1301.73 (04/01/2021), 21 CFR 1301.74 (04/01/2021), 21 CFR 1301.75 (04/01/2021), 21 CFR 1301.76 (04/01/2021), 21 CFR 1301.77 (04/01/2021), 21 CFR 1301.90 (04/01/2021), 21 CFR 1301.91 (04/01/2021), 21 CFR 1301.92 (04/01/2021), and 21 CFR 1301.93 (04/01/2021).

(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.

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 (03/15/2022); 21 CFR 1304.01 (04/01/2021), 21 CFR 1304.02 (04/01/2021), 21 CFR 1304.03 (04/01/2021), 21 CFR 1304.04 (04/01/2021), 21 CFR 1304.05 (04/01/2021), 21 CFR 1304.06 (04/01/2021); 21 CFR 1304.11 (04/01/2021); 21 CFR 1304.21 (04/01/2021), 21 CFR 1304.22 (04/01/2021), 21 CFR 1304.23 (04/01/2021), 21 CFR 1304.24 (04/01/2021), 21 CFR 1304.25 (04/01/2021), 21 CFR 1304.26 (04/01/2021); 21 CFR 1304.31 (04/01/2021), 21 CFR 1304.32 (04/01/2021), 21 CFR 1304.33 (04/01/2021).

(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.

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 (03/15/2022) and 21 CFR 1305.01 (04/01/2021), 21 CFR 1305. 02 (04/01/2021), 21 CFR 1305.03 (04/01/2021), 21 CFR 1305.04 (04/01/2021), 21 CFR 1305.05 (04/01/2021), 21 CFR 1305.06 (04/01/2021), 21 CFR 1305.07 (04/01/2021); 21 CFR 1305.11 (04/01/2021), 21 CFR 1305.12 (04/01/2021), 21 CFR 1305.13 (04/01/2021), 21 CFR 1305.14 (04/01/2021), 21 CFR 1305.15 (04/01/2021), 21 CFR 1305.16 (04/01/2021), 21 CFR 1305.17 (04/01/2021), 21 CFR 1305.18 (04/01/2021), 21 CFR 1305.19 (04/01/2021), 21 CFR 1305.20 (04/01/2021); 21 CFR 1305.21 (04/01/2021), 21 CFR 1305.22 (04/01/2021), 21 CFR 1305.23 (04/01/2021), 21 CFR 1305.24 (04/01/2021), 21 CFR 1305.25 (04/01/2021), 21 CFR 1305.26 (04/01/2021), 21 CFR 1305.27 (04/01/2021), 21 CFR 1305.28 (04/01/2021), and 21 CFR 1305.29 (04/01/2021).

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 (04/01/2021), 21 CFR 1306.02 (04/01/2021), 21 CFR 1306.03 (04/01/2021), 21 CFR 1306.04 (04/01/2021), 21 CFR 1306.05 (04/01/2021), 21 CFR 1306.06 (04/01/2021), 21 CFR 1306.07 (04/01/2021), 21 CFR 1306.08 (04/01/2021), 21 CFR 1306.09 (04/01/2021); 21 CFR 1306.11 (04/01/2021), 21 CFR 1306.12 (04/01/2021), 21 CFR 1306.13 (04/01/2021), 21 CFR 1306.14 (04/01/2021), 21 CFR 1306.15 (04/01/2021); 21 CFR 1306.21 (04/01/2021), 21 CFR 1306.22 (04/01/2021); 21 CFR 1306.23 (04/01/2021), 21 CFR 1306.24 (04/01/2021), 21 CFR 1306.25 (04/01/2021), 21 CFR 1306.27 (04/01/2021); and 21 CFR 1304.03(d) (04/01/2021).

(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.

(b) Dispensed to patient pursuant to a prescription which must follow the provisions of 21 CFR 1306.21 (04/01/2021), 21 CFR 1306.22 (04/01/2021); 21 CFR 1306.23 (04/01/2021), 21 CFR 1306.24 (04/01/2021), 21 CFR 1306.25 (04/01/2021), and 21 CFR 1306.27 (04/01/2021).

DIVISION 139
REMOTE DISPENSING SITE PHARMACY

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 (01/01/2021), 16 CFR 1701 (01/01/2021), and 16 CFR 1702 (01/01/2021).

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

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 (04/01/2021), 21 CFR 1317.35 (04/01/2021), 21 CFR 1317.40 (04/01/2021), 21 CFR 1317.55 (04/01/2021), 21 CFR 1317.60 (04/01/2021), 21 CFR 1317.65 (04/01/2021), 21 CFR 1317.70 (04/01/2021), 21 CFR 1317.75 (04/01/2021), 21 CFR 1317.80 (04/01/2021), and 21 CFR 1317.85 (04/01/2021); and

(d) 21 USC 822 (03/15/2022), 21 USC 822a (03/15/2022).

DIVISION 19
PHARMACISTS

855-019-0200
Pharmacist: General Responsibilities

ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A Pharmacist licensed to practice pharmacy by the board has the duty to use that degree of care, skill, diligence and reasonable professional judgment that is exercised by an ordinarily careful Pharmacist in the same or similar circumstances.

(1) A Pharmacist is responsible for their own actions; however, this does not absolve the pharmacy from responsibility for the Pharmacist's actions.

(2) A Pharmacist and pharmacy are responsible for the actions of Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians.

(3) Only a Pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require reasonable professional judgment of a Pharmacist include but are not limited to:

(a) Drug Utilization Review;

(b) Counseling;

(c) Drug Regimen Review;

(d) Medication Therapy Management;

(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;

(f) Practice pursuant to State Drug Therapy Management Protocols;

(g) Prescribing a drug or device, as authorized by statute;

(h) Ordering, interpreting and monitoring of a laboratory test;

(i) Oral receipt or transfer of a prescription; and

(j) Verification of the work performed by those under their supervision.

(4) A Pharmacist must:

(a) Comply with all state and federal laws and rules governing the practice of pharmacy;

(b) 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 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 OAR 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 Certified Oregon Pharmacy Technician or Pharmacy Technician per ORS 689.005 when the following conditions are met:

(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;

(b) The Certified Oregon Pharmacy Technician or Pharmacy Technician does not use discretion in conducting final verification;

(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and

(d) Ensure the Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.

(6) A Pharmacist may permit and Intern under their direction and supervision to perform any task listed in OAR 855-019-0200(3), except that 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 final verification or verification as defined in OAR 855-006-0005.

DIVISION 025
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-025-0023
Certified Oregon Pharmacy Technician and Pharmacy Technician: General Responsibilities

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician is responsible for their own actions; however, this does not absolve the Pharmacist and the pharmacy from responsibility for the Certified Oregon Pharmacy Technician or Pharmacy Technician's actions.

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

(a) Comply with all state and federal laws and rules governing the practice of pharmacy;

(b) Only assist in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;

(c) Know the identity of the Pharmacist who is providing supervision, direction and control at all times;

(d) Only work within the scope of duties permitted by their license;

(e) Only perform duties they are trained to perform; and

(f) Only access the pharmacy area when a Pharmacist is on duty.

(3) A Certified Oregon Pharmacy Technician or Pharmacy Technician may not engage in the practice of pharmacy as defined in ORS 689.005.

(4) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification of the drug and dosage, device or product when:

(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;

(b) No discretion is needed;

(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and

(d) The Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.

855-025-0040
Certified Oregon Pharmacy Technician and Pharmacy Technician: Tasks and Guidelines

(1) Non-licensed pharmacy personnel may enter non-prescription information into a computer record system and may perform clerical duties such as filing prescriptions, delivery, housekeeping, and general record keeping, but the responsibility for the accuracy of the non-licensed pharmacy personnel's work lies with the Pharmacist.

(2) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician, acting in compliance with all applicable statutes and rules and under the supervision of a Pharmacist, may assist in the practice of pharmacy by the following:

(a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

(b) Reconstituting prescription medications. The supervising Pharmacist must verify the accuracy in all instances.

(c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.

(d) Entering information into the pharmacy computer. The Certified Oregon Pharmacy Technician or Pharmacy Technician shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising Pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.

(e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;

(f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The Pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.

(g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The Pharmacist must verify the accuracy of the finished task unless the requirements of OAR 855-025-0023(4) are met.

(h) Checking nursing units in a hospital or nursing home for nonjudgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a Pharmacist.

(i) Recording patient or medication information in computer systems for later verification by the Pharmacist.

(j) Bulk Compounding; Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.

(k) Preparation of parenteral products as follows:

(A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising Pharmacist must verify the accuracy in all instances.

(B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising Pharmacist must verify the accuracy in all instances.

(l) Performing related activities approved in writing by the board.

(3) In order to protect the public, safety, health and welfare, Certified Oregon Pharmacy Technicians or Pharmacy Technicians shall not:

(a) Communicate or accept by oral communication a new or transferred prescription of any nature;

(b) Receive or transfer a prescription to another pharmacy without the prior verification of a Pharmacist.

(c) Provide a prescription or medication to a patient without a Pharmacist's verification of the accuracy of the dispensed prescription;

(d) Counsel a patient on medications or perform a drug utilization review;

(e) Perform any task that requires the reasonable professional judgment of a Pharmacist; or

(f) Engage in the practice of pharmacy as defined in ORS 689.

DIVISION 041
OPERATION OF PHARMACIES

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 Certified Oregon Pharmacy Technicians or Pharmacy Technicians as required by OAR 855-025-0035;

(5) Comply with the Pharmacist's determination in OAR 855-019-0200(4)(e).

(6) 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.

855-041-1040
Outlet: Policies and Procedures

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

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

(a) Security;

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

(c) Sanitation;

(d) Storage of drugs;

(e) Dispensing;

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

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

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

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

(j) Drug and/or device procurement;

(k) Receiving of drugs and/or devices;

(l) Delivery of drugs and/or devices;

(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.

855-041-6050
Definitions – Automated Distribution Cabinet (ADC)

In these rules, OAR 855-041-6000 through 855-041-6999, the terms below have these meanings:

(1) “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;

(2) “Drug” means a drug, a prescription device, a biological medication, a chemical or any combination of these terms;

(3) “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;

(4) “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;

(5) “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;

(6) “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;

(7) “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;

(8) “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;

(9) “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;

(10) “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.

DIVISION 19
PHARMACISTS

855-019-0230
Counseling

(1) The Pharmacist or Intern must orally counsel the patient or patient's agent on the use of a drug or device as appropriate:

(a) The Pharmacist or Intern must counsel the patient on a new prescription and any changes in therapy, including but not limited to a change in directions or strength, or a prescription which is new to the pharmacy;

(b) Only the Pharmacist or Intern may accept a patient's or patient's agent's request not to be counseled. If, in their reasonable professional judgment, the Pharmacist or Intern believes that the patient's safety may be affected, the Pharmacist or Intern may choose not to release the prescription until counseling has been completed;

(c) The Pharmacist or Intern that provides counseling or accepts the request not to be counseled must document the interaction;

(d) A Pharmacist must not allow non-Pharmacist personnel to release a prescription that requires counseling, or accept the request not to be counseled;

(e) For a prescription delivered to a patient, except at a pharmacy or a pharmacy prescription locker, the Pharmacist must offer in writing, to provide direct counseling and information about the drug, including information on how to contact the Pharmacist;

(f) For each patient, the Pharmacist or Intern must determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(g) When communicating (e.g. counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the Pharmacist is proficient in the patient's preferred language.

(2) Counseling on a refill prescription must be such as a reasonable and prudent Pharmacist would provide including but not limited to changes in strength or directions.

(3) A Pharmacist may provide counseling in a form other than oral counseling when, in their reasonable professional judgment, a form of counseling other than oral counseling would be more effective.

(4) A Pharmacist or Intern must initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

(5) For a discharge prescription from a hospital, the Pharmacist must ensure that the patient receives appropriate counseling.

DIVISION 041
OPERATION OF PHARMACIES

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.

855-041-1165
Patient Medical Record

A patient record system must be maintained by pharmacies for all patients for whom prescription drug orders are dispensed. The patient record system 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 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 date of birth;

(4) Patient's gender;

(5) Patient's preferred language for communication and prescription labeling;

(6) Chronic medical conditions;

(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;

(8) Known allergies, drug reactions, and drug idiosyncrasies; and

(9) If deemed relevant in the Pharmacist's reasonable 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.

DIVISION 139
REMOTED DISPENSING SITE PHARMACY

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.

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 date of birth;

(4) Patient's gender;

(5) Patient’s preferred language for communication and prescription labeling;

(6) Chronic medical conditions;

(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;

(8) Known allergies, drug reactions, and drug idiosyncrasies; and

(9) If deemed relevant in the Oregon licensed Pharmacist's reasonable 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.

DIVISION 19
PHARMACISTS

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

(1) In accordance with OAR 855-041 and OAR 855-139, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) who is normally present in the pharmacy on a regular basis.

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

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

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

(3) A Pharmacist may not be designated PIC of more than three pharmacies without prior written approval by the board. If such approval is given, the Pharmacist must comply with the requirements in sub-section (4)(e) of this rule. A Pharmacy Prescription Locker in OAR 855-143 does not count toward this limit.

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

(a) When a change of PIC occurs, both the outgoing and incoming PICs must report the change to the board within 15 days of the occurrence, on a form provided by the board;

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

(c) The PIC may not authorize non-Pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a Pharmacist;

(e) A Pharmacist designated as PIC for more than one pharmacy must personally conduct and document a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit Form provided by the board;

(f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within:

(A) 15 days of receiving a deficiency notice; or

(B) 30 days of receiving a non-compliance notice.

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

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;

(g) Implementing a quality assurance plan for the pharmacy.

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

(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

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 acknowledge 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.

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 30 days except when 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.

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. 06/2022);

(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. 6/2022).

[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 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.

(3) With the written approval of a school of pharmacy, and when in their reasonable professional judgment it is appropriate, a preceptor may supervise up to 10 Interns at public-health outreach programs such as informational health fairs that provide general information but not direct patient care.

(4) For immunization clinics, an immunizing Pharmacist may supervise up to two immunizing interns.

(5) A licensed preceptor may delegate the preceptor responsibilities to another licensed Pharmacist or preceptor.

(6) The majority of an intern's overall experience must be with a licensed Pharmacist preceptor.

DIVISION 041
OPERATION OF PHARMACIES

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 Intern, Certified Oregon Pharmacy Technician, or Pharmacy Technician may assist in the practice of pharmacy as contractors or employees of an Oregon registered drug outlet.

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 assisting in the practice of pharmacy at Telework Sites.

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, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians working at 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, Certified Oregon Pharmacy Technician or Pharmacy Technician that assists in the practice of pharmacy at 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 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 via telework 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 reoccurrence;

(d) Develop, implement and enforce a procedure for identifying the Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician, and Pharmacy Technician responsible for each telework function;

(e) Develop, implement and enforce a process for a virtual inspection of 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.

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 and stored for all patient interactions completed by Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians;

(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern, Certified Oregon Pharmacy Technician, and Pharmacy Technician and that the audiovisual communication system is fully operational;

(4) Ensure that an Oregon licensed Pharmacist using reasonable 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, Certified Oregon Pharmacy Technician, or Pharmacy Technician knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction, and control at all times.

(7) Ensure the Oregon licensed Pharmacist who is supervising an Intern, Certified Oregon Pharmacy Technician, or Pharmacy Technician at a Telework Site:

(a) Uses reasonable 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) Reviews 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) Documents 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 has observed or reviewed;

(C) Date and time of licensee patient interaction Pharmacist has observed or reviewed;

(D) Date and time of Pharmacist observation or review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction observed or reviewed; and

(d) Reports 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) Employ adequate staff to allow for:

(a) Observation or review within 48 hours; and

(b) Create records; and

(10) Retain records.

855-041-3225
Telework: Confidentiality

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet Pharmacy, and the Pharmacist, Intern, Certified Oregon Pharmacy Technician, and 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, 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 each breach must be reported in writing to the board within ten days of discovery of the event.

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) Test the audiovisual communication system with the Telework Site and document that it operates properly before the Intern, Certified Oregon Pharmacy Technician, or Pharmacy Technician engages in telework at the Telework Site.

(2) 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, Certified Oregon Pharmacy Technician, and Pharmacy Technician at the Telework Site.

(3) 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.

(4) Train the Oregon licensed Pharmacists, Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians in the operation of the audiovisual communication system.

(5) For verification of prescriptions, use still image capture or store and forward 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.

855-041-3235
Telework: Personnel

(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 unlicensed personnel to engage in telework.

(3) Prior to working at a Telework Site, the Intern, Certified Oregon Pharmacy Technician, or 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: Security

(1) Telework Sites must be located in a designated area where:

(a) All equipment is stored;

(b) All work is performed; and

(2) Confidentiality must be maintained such that patient information cannot be viewed or overheard by anyone other than the Pharmacist, Intern, Certified Oregon Pharmacy Technician, or Pharmacy Technician.

(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.

(4) All computer equipment used for telework 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, Certified Oregon Pharmacy Technician, or Pharmacy Technician who is assisting in the practice of pharmacy at a Telework Site; or

(B) There is no Intern, Certified Oregon Pharmacy Technician, or Pharmacy Technician present at the Telework Site; or

(C) Any component of the audiovisual communication system with the Telework Site is not functioning;

(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

(e) Comply with all security and confidentiality requirements.

(5) A record must be maintained with the date, time and identification of the licensee accessing patient or pharmacy records at a Telework Site.

(6) Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians may only work at a Telework Site when authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the Telework Site.

(7) 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 via telework, the Drug Outlet Pharmacy and the Oregon licensed Pharmacist-in-charge are accountable for establishing, maintaining, and enforcing written policies and procedures for the licensees working via telework. 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, Certified Oregon Pharmacy Technicians, and 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 at a Telework Site;

(k) Written agreement with licensees engaging in telework outlining the specific functions performed and requirement to comply with telework policies and procedures; and

(l) Equipment.

855-041-3250
Telework: Records

(1) If a Drug Outlet Pharmacy utilizes licensees 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 of Telework Site addresses must be made available within 3 business days. Records created via telework must be stored 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 records may not be stored at the Telework Site.

(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.

(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;

(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 that includes:

(A) Name;

(B) License number and expiration date;

(C) Address of Telework Site; and

(D) Name of the Oregon licensed Pharmacist who:

(i) Verified (A-C);

(ii) Approved licensee to telework; and

(iii) 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.

DIVISION 041
OPERATION OF PHARMACIES

855-041-1090
Registration: Change of Business Name (Both Retail and Institutional Drug Outlets)

A pharmacy must notify the board 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.

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 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.

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

(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;

(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, inclement weather, 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.

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.

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 compromise patient safety or violate state or federal laws or rules; and

(b) By the end of the next business day of the request.

DIVISION 139
REMOTE DISPENSING SITE PHARMACY

855-139-0025
Registration: Change of Business Name

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.

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 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.

(3) Emergency closing. If the RDSP is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, 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.

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 licensed Pharmacist from the RDSP Affiliated Pharmacy must transfer a prescription:

(a) To a pharmacy requesting a transfer on behalf of the patient or patient's agent unless the transfer would compromise patient safety or violate state or federal laws or rules; and

(b) By the end of the next business day of the request.

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.

DIVISION 080
SCHEDULE OR 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 (04/01/2021); 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;

(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;

(d) Ensure that only a Pharmacist, Intern, Certified Oregon Pharmacy Technician or 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 pharmacy, Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician involved in the provision of pseudoephedrine or ephedrine to a purchaser must comply with the provisions of 21 CFR 1314.01 (04/01/2021), 21 CFR 1314.02 (04/01/2021), 21 CFR 1314.03 (04/01/2021), 21 CFR 1314.05 (04/01/2021), 21 CFR 1314.10 (04/01/2021), 21 CFR 1314.15 (04/01/2021), 21 CFR 1314.20 (04/01/2021), 21 CFR 1314.25, (04/01/2021); 21 CFR 1314.30 (04/01/2021), 21 CFR 1314.35 (04/01/2021), 21 CFR 1314.40 (04/01/2021), 21 CFR 1314.42 (04/01/2021), 21 CFR 1314.45 (04/01/2021); and 21 CFR 1314.50 (04/01/2021).

DIVISION 110
FEES

855-110-0007
Fees for Registration, Renewal, and Reinspection of Drug Outlets

(1) Drug Distribution Agent. Expires September 30 annually - $400. Late renewal fee (received after September 30) - $100.

(2) Drug Room (including Correctional Facility). Expires March 31 annually - $100. Late renewal fee (received after March 31) - $75.

(3) 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.

(4) Nonprescription Drug Outlet. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.

(a) This includes the following categories of registration:

(A) Nonprescription Class A.

(B) Nonprescription Class B.

(C) Medical Device, Equipment & Gas Class C.

(b) Other nonprescription Drug Outlet registration category fees are as follows:

(A) Nonprescription Class D. Expires January 31 annually - $100. Late renewal fee (received after January 31) - $25.

(B) Nonprescription Class E. Expires January 31 annually - $0. Late renewal fee (received after January 31) - $0.

(5) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - $50. Expires December 31 annually.

(6) Re-inspection fee - $100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.

(7) Retail or Institutional Drug Outlet Pharmacy. Expires March 31 annually - $225. Late renewal fee (received after March 31) - $75.

(a) This includes the following categories of registration:

(A) Consulting ”Drugless” Drug Outlet Pharmacy

(B) 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) Reserved.

(E) Prescription Lockers Retail Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(F) Remote Dispensing Machine Institutional Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(G) Remote Distribution Facility Institutional Drug Outlet Pharmacy. Expires March 31 annually - $120. Due by March 31 annually.

(8) 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.

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 or 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 or Pharmacy Technician.

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

855-139-0010
Registration: General

(1) A location in Oregon where the practice of pharmacy occurs by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician or 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.

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. Unlicensed personnel may not perform any pharmacy services.

(3) The Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy who is supervising a RDSP must determine how many licensed individuals the Pharmacist is capable of supervising, directing and controlling based on the services being provided.

(4) The RDSP Affiliated Pharmacy and the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy are required to comply with the Pharmacist's determination in (3) and retain records.

(5) The RDSP and RDSP Affiliated Pharmacy must ensure adequate staffing at both the RDSP and RDSP Affiliated Pharmacy.

(6) Prior to working at a RDSP, the RDSP Affiliated Pharmacy, and the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy are responsible for ensuring the Certified Oregon Pharmacy Technician or Pharmacy Technician and the Oregon licensed Pharmacist supervising the RDSP are adequately trained to perform their duties and have completed a training program on the proper use of the telepharmacy system.

(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.

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 or 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 or 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 or Pharmacy Technician working in the RDSP practices appropriate infection control.

855-139-0200
Outlet: General Requirements

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

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

(3) A RDSP and its RDSP Affiliated Pharmacy must:

(a) Have the same owner; or

(b) Have a written contract that specifies:

(A) The services to be provided by each licensee and registrant;

(B) The responsibilities of each licensee and registrant; and

(C) The accountabilities of each licensee and registrant;

(c) Ensure each prescription is dispensed in compliance with OAR 855-019, OAR 855-025 and OAR 855-139;

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

(e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians or Pharmacy Technicians authorized to access the RDSP and operate the telepharmacy system;

(f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians or 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.

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 or Pharmacy Technician, and the surveillance system is fully operational;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Certified Oregon Pharmacy Technician or 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 the Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:

(a) Using reasonable 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 or 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 or Pharmacy Technician at the RDSP.

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 or 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.

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 reasonable 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 or 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 or 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.

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 or 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 or 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.

855-139-0455
Drug and Devices: Return

A Certified Oregon Pharmacy Technician or 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.

855-139-0600
Prohibited Practices: General

A Retail Drug Outlet RDSP may not:

(1) Allow a Certified Oregon Pharmacy Technician or 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.

855-139-0715
Service: Epinephrine- General Requirements

(1) A Certified Oregon Pharmacy Technician or 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 or 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 or 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 or 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.

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.

(4) Prescription;

(a) 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:

(i) Write "for EPT," or a similar notation, on the face of the prescription;

(ii) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;

(iii) 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".

(b) An EPT Prescription expires 30 days after the date written;

(c) An EPT Prescription may not be refilled;

(d) 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.

(e) 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.

(5) Labeling;

(a) The Certified Oregon Pharmacy Technician or 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.

(b) The Oregon licensed Pharmacist must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.

(6) Counseling; 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.

(7) Records; 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.

Division 019: Pharmacists (Duties of a Pharmacist Receiving a Prescription; 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): Duties of a Pharmacist receiving a prescription; Telemedicine; 2022 HB 4034

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Section 14 of House Bill 4034 (2022) defines "telemedicine" as "the provision of health care services to a patient by a physician or physician assistant from a distance using electronic communications, including synchronous technologies to facilitate an exchange of information between a patient and physician or physician assistant in real time or asynchronous technologies to facilitate an exchange of information between a patient and a physician or physician assistant in other than real time." Modification to OAR 855-019-0210(2)(a) is necessary to eliminate conflict in Board of Pharmacy regulations with this new statute. Pharmacists must still ensure that prescriptions are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and issued pursuant to a valid patient-practitioner relationship.

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.

Optional: Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034; ORS 689.525

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments are necessary in order to remove conflict between Board of Pharmacy regulations and revised telemedicine statutes in 2022 HB 4034. Amendments include removing "not result solely from a questionnaire or an internet based relationship" and adding "issued pursuant to a valid patient-practitioner relationship" in OAR 855-019-0210(2)(a).

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

(1) A pharmacist must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed or prepared for administration in accordance with the prescribing practitioner's authorization.

(2) A pharmacist receiving a prescription is responsible for:

(a) Using professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist, in their professional judgment, believes that the prescription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner shall include a clinical associate of the practitioner or any other practitioner acting in the practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and **issued pursuant to a valid**

patient-practitioner relationship ~~not result solely from a questionnaire or an internet-based relationship~~; and

(b) Ensuring that the prescription contains all the information specified in Division 41 of this chapter of rules including the legible name and contact phone number of the prescribing practitioner for verification purposes.

(3) A pharmacist may refuse to dispense a prescription to any person who lacks proper identification.

(4) Oral Prescription: Upon receipt of an oral prescription, the pharmacist shall promptly reduce the oral prescription to writing or create a permanent electronic record by recording:

(a) The date when the oral prescription was received;

(b) The name of the patient for whom, or the owner of the animal for which, the drug is to be dispensed;

(c) The full name and, in the case of controlled substances, the address and the DEA registration number, of the practitioner, or other number as authorized under rules adopted by reference under Division 80 of this chapter of rules;

(d) If the oral prescription is for an animal, the species of the animal for which the drug is prescribed;

(e) The name, strength, dosage form of the substance, quantity prescribed;

(f) The direction for use;

(g) The total number of refills authorized by the prescribing practitioner;

(h) The written signature or initials or electronic identifier of the receiving pharmacist or intern and the identity of the person transmitting the prescription;

(i) The written or electronic record of the oral prescription must be retained on file as required by Division 41 of this chapter of rules, and in the case of controlled substances, under rules adopted by reference in Division 80 of this chapter of rules.

(5) Facsimile Prescription: Upon receipt of a facsimile prescription, the pharmacist must be confident that the prescription was sent by an authorized practitioner or practitioner's agent, and they must verify that:

(a) The facsimile contains all the information specified in division 41 and division 80 of this chapter of rules; and

(b) The facsimile prescription is not for a Schedule II controlled substance unless so permitted under federal regulations or division 80 of this chapter of rules; and

(c) If the facsimile prescription is for a controlled substance, the prescription contains an original, manually-signed signature of the prescriber. In this rule, manually-signed specifically excludes a signature stamp or any form of digital signature unless permitted under federal regulations.

(6) Electronic Prescription: Before filling a prescription that has been received electronically, the pharmacist must be confident that:

(a) The prescription was originated by an authorized practitioner or practitioner's agent;

(b) The prescription contains all the information specified in Division 41 of this chapter of rules.

(c) The prescription is not for a controlled substance unless permitted by federal regulations.

(7) The pharmacist must ensure that a written prescription that is hand-carried or mailed into the pharmacy contains an original manually-signed signature of the prescribing practitioner or practitioner's agent.

(8) Computer Transfer of Prescription Information between Pharmacies: A pharmacist that transmits or receives prescription information to or from another pharmacy electronically must ensure as appropriate:

(a) The accurate transfer of prescription information between pharmacies;

(b) The creation of an original prescription or image of an original prescription containing all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability and that the pharmacist will use in verifying the prescription;

(c) The prescription is invalidated at the sending pharmacy; and

(d) Compliance with all relevant state and federal laws and rules regarding the transfer of controlled substance prescriptions.

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

Division 139: Remote Dispensing Site Pharmacy (Prohibited Practices)

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 a Retail Drug Outlet RDSP to deliver a prescription

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Pursuant to Section 19 of 2022 HB 4034, a Retail Drug Outlet Pharmacy may deliver a prescription; thus, a Retail Drug Outlet RDSP may deliver a prescription.

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.

Optional: Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4034; ORS 689.005

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Removes language that states a Retail Drug Outlet RDSP may not "Deliver a prescription." Per 2022 HB 4034, the board may not establish standards for telepharmacy that are more restrictive than standards for the delivery of in-person pharmacy services, including standards regarding prescription and dispensation of drugs.

855-139-0600

Prohibited Practices: General

- NOTE: The rule package shown below are currently in rulemaking and have an impact on this rule. Changes made to this rule prior to adoption will be updated in this rule package before the motioning.
  - Division 139 - related to RDSP

A Retail Drug Outlet RDSP may not:

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

- NOTE: In rulemaking- Division 139 - related to RDSP

(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;~~

(43) Compound sterile preparations; or

(~~5~~4) Repackage drugs.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315, 2022 HB 4034
Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

Division 019: Pharmacists (2022 HB 4096: Non-Resident Volunteer RPH)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Allows a non-resident licensed Pharmacist to volunteer without compensation or licensure in Oregon

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Adopts language that would allow a non-resident licensed Pharmacist to volunteer without compensation in Oregon for 30 days each calendar year without being required to apply for licensure in Oregon and provides requirements needed to qualify as a non-resident volunteer Pharmacist. These rules are necessary pursuant to directives of 2022 HB 4096.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022 HB 4096

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 COVID-19 pandemic has exacerbated health care workforce shortages, leaving many health care facilities short-staffed. Appropriate staffing in health care facilities is essential to providing safe patient care and a safe work environment for health care providers. Volunteer health care providers provide services to people who might not otherwise have access, including rural areas bordering other states.

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The agency anticipates a minimal fiscal impact.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses: If a non-resident Pharmacist who is licensed in another state chooses to volunteer and qualifies, they may be subject to any fees charged by their state of residence associated with complying with the requirements.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No. Legislative mandate of 2022 HB 4096.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): The proposed rules create the necessary requirements for a Pharmacist to practice pharmacy in Oregon without compensation for a specified amount of time without being required to obtain licensure in Oregon. The proposed rules are necessary as a directive of 2022 HB 4096.

855-019-0124
Notification: Non-Resident Volunteer RPH

(1) A Pharmacist may, without compensation and in connection with a coordinating organization or other entity, practice pharmacy for 30 days each calendar year. A Pharmacist is not required to apply for licensure or other authorization from the board to practice pharmacy under this section.

(2) To practice pharmacy under this section, a Pharmacist must submit, at least 10 days prior to commencing practice in this state, to the board:

(a) Proof that the Pharmacist is in good standing and is not the subject of an active disciplinary action in any jurisdiction in which the Pharmacist is authorized to practice;

(b) An acknowledgement that the Pharmacist may provide services only within the scope of practice of pharmacy and will provide services pursuant to the scope of practice of this state or the health care practitioner's licensing agency, whichever is more restrictive;

(c) An attestation that the Pharmacist will not receive compensation for practice in this state;

(d) The name and contact information of the coordinating organization or other entity through which the Pharmacist will practice; and

(e) The dates on which the Pharmacist will practice in this state.

(3) Except as otherwise provided, a Pharmacist practicing under this section is subject to the laws and rules governing the pharmacy profession that the Pharmacist is authorized to practice and to disciplinary action by the appropriate health professional regulatory board.

Statutory/Other Authority: ORS 689.205, 2022 HB 4096
Statutes/Other Implemented: ORS 689.151, 2022 HB 4096

Division 125: Technicians (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; Technicians

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments are a result of the board's 2022-2026 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

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

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

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on 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 in the development of proposed revisions to these rules.

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

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed rule amendments include relocating and reorganizing existing rules from Division 025 to Division 125 in alignment with the board's strategy to systematically organize all Divisions. Amendments include revising titles, clarifying division applicability, definitions, general qualifications, licensure requirements, license renewal, license reinstatement, license surrender, license termination, general responsibilities, prohibited practices and grounds for discipline.

Division 125
CERTIFIED OREGON PHARMACY TECHNICIANS AND PHARMACY TECHNICIANS

855-~~025-0001~~125-0001
~~Purpose and Scope~~ Applicability

~~The purpose of the Pharmacy Technician (PT) license is to provide an opportunity for an individual to obtain competency in the role as a Pharmacy Technician. This license will allow an individual time to take and pass a national pharmacy technician certification examination, which is required to be eligible for licensure as a Certified Oregon Pharmacy Technician (CPT). These rules facilitate the initial licensure of a nationally certified Pharmacy Technician seeking licensure in Oregon.~~

(1) This Division applies to any individual who assists a Pharmacist in the practice of pharmacy.

(2) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may assist a Pharmacist in the practice of pharmacy and must act in compliance with statutes and rules under the supervision, direction, and control of a Pharmacist.

(3) Only persons licensed with the board as a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification when delegated to do so by a pharmacist and done in compliance with all applicable statutes and rules and under the supervision, direction, and control of that Pharmacist.

(4) Only a person licensed as a Certified Oregon Pharmacy Technician may use the titles "Certified Oregon Pharmacy Technician" and "COPT".

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-125-0005
Definitions
Note: Placeholder- No definitions specific to Division 125 at this time.

855-~~025-0005~~125-0010
Licensure: Qualifications - ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician or Pharmacy Technician

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

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

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

(b) National Healthcareer Association (NHA).

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

~~855-025-0010~~125-0020

Licensure: Application- Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) An application for licensure as a **Certified Oregon Pharmacy Technician or** 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~~**2**) The board may issue a license to a qualified applicant after the receipt of:

(a) A completed application **including:**~~;~~

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

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

(~~d~~**C**) Personal identification or proof of identity; ~~and~~

(~~e~~**D**) A completed national fingerprint-based background check~~.~~**; and**

(E) A completed moral turpitude statement or a written description and documentation regarding all conduct that required a yes answer to an application question.

(b) An applicant for a Certified Oregon Pharmacy Technician license, must provide a passing result from PTCB or NHA on a national pharmacy technician certification examination.

(3) A license may be denied and a civil penalty imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure;

(b) Failure to disclose any requested information on the application or requests resulting from the application; or

(c) Any other grounds found in ORS 689.405 and ORS 689.490.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

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

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

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

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

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

~~(a) A completed application;~~

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

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

~~(d) Personal identification or proof of identity;~~

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

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

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

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225 & ORS 689.486~~

855-~~025-0011~~125-0030
Licensure: Renewal or Reinstatement- Certified Oregon Pharmacy Technician or Pharmacy Technician

(1) An applicant for renewal of a **Certified Oregon Pharmacy Technician or** 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 **Certified Oregon Pharmacy Technician or** 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 **Certified Oregon Pharmacy Technician or** 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.

(4) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.

(5) Any person whose Certified Oregon Pharmacy Technician or Pharmacy Technician license has been suspended, revoked or restricted has the right, at reasonable intervals, to petition the board for reinstatement of such license pursuant to ORS 689.445 and in conjunction with the application process identified in OAR 855-125-0020.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, **ORS 689.445,** ORS 689.486 & ORS 413.450

~~**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.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225, ORS 689.486 & ORS 413.450~~

855-125-0040
Licensure: Lapse

(1) A Certified Oregon Pharmacy Technician or Pharmacy Technician may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not assist in the practice of pharmacy if the license is lapsed.

(d) A person may apply for renewal or reinstatement according to 855-125-0030.

(2) If a person requests lapse prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board will not accept the lapse if an investigation of or disciplinary action against the licensee is pending.

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-125-0046
Licensure: Voluntary Surrender

A Certified Oregon Pharmacy Technician or Pharmacy Technician may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a Board representative. The termination date is the date the licensee is sent the executed final order.

(4) The licensee must cease assisting in the practice of pharmacy from the date the license terminates.

(5) A voluntarily surrendered license may not be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-125-0030 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-~~025-0023~~125-0070

~~Certified Oregon Pharmacy Technician and Pharmacy Technician: General~~ Responsibilities: General-Certified Oregon Pharmacy Technician and Pharmacy Technician

- NOTE: In rulemaking- Divisions 019/025/041 - related to Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification

(1) ~~A~~ **Each** Certified Oregon Pharmacy Technician ~~or~~ **and** Pharmacy Technician is responsible for their own actions; however, this does not absolve the Pharmacist and the pharmacy from responsibility for the Certified Oregon Pharmacy Technician or Pharmacy Technician's actions.

(2) A Certified Oregon Pharmacy Technician ~~or~~ **and** 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 work within the scope of duties permitted by the Pharmacist providing supervision, direction and control;

(~~e~~**f**) Only perform duties they are trained to perform~~; and~~

(g) Appropriately perform the tasks permitted;

(~~f~~**h**) Only access the pharmacy area when a Pharmacist is on duty~~.~~**;**

(i) Be clearly identified as a Certified Oregon Pharmacy Technician or Pharmacy Technician in all interactions and communications (i.e., nametag, phone interaction, chart notations);

(j) Review pharmacy written procedures that describe the tasks that may be performed by Certified Oregon Pharmacy Technicians and Pharmacy Technicians in assistance in the practice of pharmacy every 12 months; and

(k) Dispense and deliver prescriptions accurately and to the correct party.

(3) A Certified Oregon Pharmacy Technician or Pharmacy Technician may not engage in the practice of pharmacy as defined in ORS 689.005.

(4) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification of the drug and dosage, device or product when:

(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification;

(b) No discretion is needed;

(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and

(d) The Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.

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

855-~~025-0030~~125-0072
Responsibilities: **Confidentiality**

(1) No licensee of the ~~B~~**b**oard who obtains any patient information ~~shall~~ **may** disclose that information to a third-party without the consent of the patient except as provided in ~~section two~~ **except as provided in (a)-(e)** of this rule.

~~(2)~~ A licensee may disclose patient information:

(a) To the ~~B~~**b**oard;

(b) To a practitioner, **Oregon licensed** Pharmacist, **Intern,** ~~Pharmacy Technician, or~~ Certified Oregon Pharmacy Technician **or Pharmacy Technician**, if disclosure is authorized by a Pharmacist ~~who reasonably believes that~~ **if** 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.

(2) A licensee or registrant of the board may not access or obtain any patient information unless it is accessed or obtained for the purpose of patient care or as allowed in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 689.205, **ORS 689.305, ORS 689.315**
Statutes/Other Implemented: ORS 689.155

855-~~025-0020~~125-0074
Responsibilities: **Duty to Report**

~~(1) Failure to answer completely, accurately and honestly, all questions on the application form for licensure or renewal of licensure is grounds for discipline.~~

~~(2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.~~

(~~3~~**1**) **Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each** ~~A Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **and Pharmacy Technician** must report to the board **without undue delay, but** within ~~10 days if they~~:

(a) 1 business day:

(A) Confirmed significant drug loss; or

(B) Any loss related to suspected drug theft of a controlled substance.

(b) 10 days if they:

(~~a~~**A**) Are ~~c~~**C**onvicted of a misdemeanor or a felony; or

(~~b~~**B**) ~~If they a~~**A**re arrested for a felony~~.~~**; or**

(C) Have reasonable cause to believe that any suspected violation of ORS 475, ORS 689 or OAR 855 has occurred.

(c) 10 working days if they:

(4**A**) ~~A Pharmacy Technician or Certified Oregon Pharmacy Technician who has~~ **Have** reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional conduct ~~as these terms are defined in OAR 855-006-0005, must report that conduct to the board responsible for the licensee who is believed to have engaged in the conduct. The reporting Pharmacy Technician or Certified Oregon Pharmacy Technician must report the conduct without undue delay, but in no event later than 10 working days after the reporting Pharmacy Technician or Certified Oregon Pharmacy Technician learns of the conduct unless federal laws relating to confidentiality or the protection of health information prohibit disclosure.~~ **to that licensee's board; or**

(B) Suspect records are lost or stolen.

(d) 15 days:

(A) Any change in legal name, name used when assisting in the practice of pharmacy, personal email address, personal phone number, personal physical address and personal mailing address;

POLICY DISCUSSION: Legal/used; required/optional

(B) Any change in employment location, employment physical address and employment phone number.

(C) A licensee who works at multiple locations of the same employer is required to only report the name, address and phone number for the primary location of employment.

(~~5~~**2**) A ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **or Pharmacy Technician** who reports to a board in good faith as required by **ORS 676.150** ~~section (4) of this rule~~ is immune from civil liability for making the report.

~~(6) A Pharmacy Technician or Certified Oregon Pharmacy Technician who has reasonable grounds to believe that prescription drugs or records have been lost or stolen, or any violation of these rules has occurred, must notify the board within 1 day.~~

~~(7) A Pharmacy Technician or Certified Oregon Pharmacy Technician must notify the board in writing, within 15 days, of any change in email address, employment location or residence address except that a Pharmacy Technician who is employed at more than one pharmacy need only report the name and address of the pharmacy at which the technician normally works the most hours.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: **ORS 676.150,** ORS 689.155**, ORS 689.455**~~, &~~ ORS 689.486

855-125-0076
Responsibilities: Training

Certified Oregon Pharmacy Technicians and Pharmacy Technicians must:

(1) Complete and document initial training that includes on-the-job and related education that is commensurate with the tasks that the Certified Oregon Pharmacy Technician or Pharmacy Technician will perform, prior to the performance of those tasks.

(2) Complete ongoing training to ensure continued competency in tasks that are performed.

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

~~**855-025-0025**~~
~~**Use of Pharmacy Technicians and Certified Oregon Pharmacy Technicians**~~

~~(1) A Pharmacist or pharmacy may use Pharmacy Technicians or Certified Oregon Pharmacy Technicians only as authorized by the rules of the Board.~~

~~(2) Pharmacy Technicians or Certified Oregon Pharmacy Technicians must be supervised by a Pharmacist.~~

~~(3) Pharmacists, Pharmacist Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians must be clearly identified as such to the public.~~

~~(4) Work performed by Pharmacy Technicians and Certified Oregon Pharmacy Technicians assisting the Pharmacist to prepare medications must be verified by a Pharmacist prior to release for patient use. Verification must be documented, available and consistent with the standard of practice.~~

~~(5) The pharmacist-in-charge must prepare and maintain in the pharmacy written procedures that describe the tasks performed by Pharmacy Technicians or Certified Oregon Pharmacy Technicians, and the methods of verification and documentation of work performed by Pharmacy Technicians or Certified Oregon Pharmacy Technicians. Written procedures must be available for inspection by the Board or its representatives. The pharmacist-in-charge must review written procedures annually and document that review on the annual pharmacist-in-charge inspection sheet.~~

~~(6) Training:~~

~~(a) The pharmacist-in-charge must outline, and each Pharmacy Technician or Certified Oregon Pharmacy Technician must complete initial training that includes on-the-job and related education that is commensurate with the tasks that the Pharmacy Technician or Certified Oregon Pharmacy Technician will perform, prior to the performance of those tasks.~~

~~(b) The pharmacist-in-charge must ensure the continuing competency of Pharmacy Technicians or Certified Oregon Pharmacy Technicians.~~
~~(c) The pharmacist-in-charge must document initial training of each Pharmacy Technician or Certified Oregon Pharmacy Technician and make that documentation available to the Board or its representatives upon request.~~

~~(7) Upon written request, the Board may waive any of the requirements of this rule upon a showing that a waiver will further public health or safety or the health or safety of a patient or other person. A waiver granted under this section is effective only when issued by the Board in writing.~~

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

~~855-025-0035~~
~~Pharmacy and Pharmacist Responsibility for Supervising Pharmacy Technicians and Certified Oregon Pharmacy Technicians~~

~~(1) The supervising Pharmacist and the pharmacist-in-charge are responsible for the actions of Pharmacy Technicians or Certified Oregon Pharmacy Technicians. The use of Pharmacy Technicians or Certified Oregon Pharmacy Technicians to perform tasks not included in written procedures maintained by the pharmacy constitutes unprofessional conduct on the part of the supervising Pharmacist and the pharmacist-in-charge.~~

~~(2) The pharmacy must maintain on file and post the current license of each Pharmacy Technician or Certified Oregon Pharmacy Technician.~~

~~(3) Before allowing any person to work as a Pharmacy Technician or Certified Oregon Pharmacy Technician, the pharmacy and Pharmacist shall verify that the person is currently licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician.~~

~~(4) Prior to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician, a person must provide to the Pharmacist or pharmacist-in-charge a copy of the person's current Pharmacy Technician license or current Certified Oregon Pharmacy Technician license.~~

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

855-~~025-0040~~125-0080

~~Certified Oregon Pharmacy Technician and Pharmacy Technician: Tasks and Guidelines~~
Responsibilities: Permitted Practices

(1) Non-licensed pharmacy personnel may **perform any function that does not constitute the practice of pharmacy as defined in ORS 689 or assistance in the practice of pharmacy** ~~enter non-prescription information into a computer record system and may perform clerical duties such as filing prescriptions, delivery, housekeeping, and general record keeping, but the responsibility for the accuracy of the non-licensed pharmacy personnel's work lies with the Pharmacist~~.

(2) ~~Only persons licensed with the board as a~~ Certified Oregon Pharmacy Technician**s** or Pharmacy Technician**s:** ~~, 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) May only assist in the practice of pharmacy as authorized by the rules of the board under the supervision, direction, and control of an Oregon licensed Pharmacist.

(b) Must ensure that work is verified by an Oregon licensed Pharmacist if independent judgement is utilized when assisting in the practice of pharmacy.

(c) May perform final verification as allowed under OAR 855-125-0070(5).

~~(a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.~~

~~(b) Reconstituting prescription medications. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.~~

~~(d) Entering information into the pharmacy computer. The Certified Oregon Pharmacy Technician or Pharmacy Technician shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising Pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.~~

- NOTE: In rulemaking- Divisions 019/025/041 - related to Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification

~~(e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;~~

~~(f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The Pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.~~

~~(g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The Pharmacist must verify the accuracy of the finished task unless the requirements of OAR 855-025-0023(4) are met.~~

- NOTE: In rulemaking- Divisions 019/025/041 - related to Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification

~~(h) Checking nursing units in a hospital or nursing home for nonjudgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a Pharmacist.~~

~~(i) Recording patient or medication information in computer systems for later verification by the Pharmacist.~~

~~(j) Bulk Compounding; Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(k) Preparation of parenteral products as follows:~~

~~(A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising Pharmacist must verify the accuracy in all instances.~~

~~(l) Performing related activities approved in writing by the board.~~

~~(3) In order to protect the public, safety, health and welfare, Certified Oregon Pharmacy Technicians or Pharmacy Technicians shall not:~~

- NOTE: In rulemaking- Divisions 019/025/041 - related to Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification

~~(a) Communicate or accept by oral communication a new or transferred prescription of any nature;~~

~~(b) Receive or transfer a prescription to another pharmacy without the prior verification of a Pharmacist.~~

~~(c) Provide a prescription or medication to a patient without a Pharmacist's verification of the accuracy of the dispensed prescription;~~

~~(d) Counsel a patient on medications or perform a drug utilization review;~~

~~(e) Perform any task that requires the reasonable professional judgment of a Pharmacist; or~~

- NOTE: In rulemaking- Divisions 019/025/041 - related to Certified Oregon Pharmacy Technician/Pharmacy Technician Final Verification

~~(f) Engage in the practice of pharmacy as defined in ORS 689.~~

855-125-0090
Prohibited Practices

In order to protect the public, safety, health and welfare, Certified Oregon Pharmacy Technicians and Pharmacy Technicians may not:

(1) Engage in the practice of pharmacy as defined in ORS 689.

(2) Ask questions of a patient or patient's agent which screen or limit interaction with the Oregon licensed Pharmacist;

(3) Perform any task that requires independent judgment without Pharmacist verification; or

(4) Perform any task that is not verifiable by a Pharmacist including but not limited to any task listed in OAR 855-019-0200(2);

(5) Assist in the practice of pharmacy when not under a Pharmacist's supervision, direction and control.

(6) Perform any task not permitted by the Pharmacist who is supervising, directing, and controlling the Certified Oregon Pharmacy Technician or Pharmacy Technician.

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

~~**855-025-0050**~~
~~**Grounds for Discipline of Pharmacy Technicians and Certified Oregon Pharmacy Technicians**~~

~~The State Board of Pharmacy may refuse to issue or renew; or may suspend, revoke, or restrict the license of a Pharmacy Technician or Certified Oregon Pharmacy Technician; or may impose a civil penalty upon a Pharmacy Technician or Certified Oregon Pharmacy Technician upon the following grounds including but not limited to:~~

~~(1) Unprofessional conduct as defined in OAR 855-006-0020;~~

~~(2) Repeated or gross negligence in performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician;~~

~~(3) Impairment, which means an inability to assist in the practice of pharmacy with reasonable competence and safety due to the habitual or excessive use of drugs or alcohol, other chemical dependency or a mental health condition;~~

~~(4) Being found guilty by the Board of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(5) Being found guilty by a court of competent jurisdiction of a felony as defined by the laws of this state;~~
~~(6) Being found guilty by a court of competent jurisdiction of a violation of the pharmacy or drug laws of this state or rules pertaining thereto or of statutes, rules or regulations of any other state or of the federal government;~~

~~(7) Fraud or intentional misrepresentation in securing or attempting to secure the issuance or renewal of a Pharmacy Technician or Certified Oregon Pharmacy Technician license;~~

~~(8) Allowing an individual to engage in the duties of a Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician without a license or to use falsely the title of Pharmacist, Pharmacy Technician or Certified Oregon Pharmacy Technician;~~

~~(9) Being found by the Board to be in violation of any violation of any of the provisions of ORS 435.010 to 435.130, 453.025, 453.045, 475.035 to 475.190, 475.805 to 475.995 or 689.005 to 689.995 or the rules adopted pursuant thereto;~~

~~(10) Failure to appropriately perform the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician as outlined in OAR 855-025-0040 while assisting a Pharmacist in the practice of pharmacy as defined in ORS 689.005;~~

~~(11) Any act or practice relating to performing the duties of a Pharmacy Technician or Certified Oregon Pharmacy Technician which is prohibited by state or federal law or regulation; or~~

~~(12) Any conduct or practice by a Pharmacy Technician, Certified Oregon Pharmacy Technician or pharmacy that the Board determines is contrary to the accepted standards of practice.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.405~~

JUNE 2022/D1a

Division Vision

Creating consistency in OAR 855- Licenses

June 2022

Goals and Objectives

- 2022-2026 Strategic Plan Regulation Goal:
  - Systematically refresh rules and standardize the rule development approach to improve clarity and compliance.

Division Vision- DRAFT

100	Definitions
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115	**Pharmacist**
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139	*DO Remote Dispensing Site Pharmacy (RP)*
141	**DO Kiosk (RP)**
143	*DO Locker (RP)*
144	DO Charitable Pharmacy (RP)
156	DO Pharmacy (IP)
159	DO Drug Room (IP)
161	DO RDF/RDM (IP)
164	DO Nuclear (IP)
167	DO LTC/Residential (IP)
170	DO Home Infusion (IP)
173	DO Home Dialysis (IP)
176	DO Home Health Care (IP)
177	DO Correctional Facility (IP)
180	Controlled Substances
183	Compounding

186	DO Nonprescription
189	DO Prophylactic
191	DO Devices
194	DO Practitioner Dispensing (RP)
197	DO CHC's
199	DO Animal Euthanasia
200	Facility- Manufacturer
203	Facility- Wholesaler
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Rule Number Order Licensees- DRAFT

COPT/PT

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5	Definitions
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30	Licensure: Renewal or Reinstatement: COPT/PT
40	Licensure: Lapse
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RPH

1	Applicability
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Division 115: Pharmacists (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; Pharmacists

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed amendments are a result of the board's 2022-2026 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

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

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

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on 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 in the development of proposed revisions to these rules.

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

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments include relocating and reorganizing existing rules for Pharmacists from Division 019 to Division 115 in alignment with the board's strategy to systematically organize all Divisions. Amendments include revising titles, clarifying requirements for applicability, definitions, general qualifications, licensure requirements, license renewal, license reinstatement and notification and registration requirements for licensed Pharmacists who volunteer.

Division ~~19~~**115**
PHARMACISTS

855-~~019-0100~~115-0001
Applica~~tion~~bility

(1) This Division applies to any ~~p~~**P**harmacist **who engages in the practice of pharmacy** ~~who is licensed to practice pharmacy in Oregon including any pharmacist located in another state who is consulting, or providing any other pharmacist service, for a patient, pharmacy or healthcare facility in Oregon~~.

~~(2) Where so indicated, these rules also apply to an intern who is licensed in Oregon.~~

(~~3~~**2**) ~~Any pharmacist who engages in the~~ **Only persons licensed with the board as a Pharmacist may** practice ~~of~~ pharmacy ~~in Oregon~~ **and** must ~~be licensed by the Board in accordance with the following~~ **act in compliance with statutes and** rules.

~~(4) A pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon, is not required to be licensed by the Board unless they are the pharmacist-in-charge (PIC).~~

~~(5) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.~~

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

855-~~019-0110~~115-0005
Definitions
Note: Placeholder- No definitions specific to Division 115 at this time.

~~In this Division of Rules:~~
~~(1) "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.~~

~~(2) "Collaborative Drug Therapy Management (CDTM)" has the same meaning as defined in OAR 855-006-0005.~~

~~(3) "Counseling" means an oral or other appropriate communication process between a pharmacist and a patient or a patient's agent in which the pharmacist obtains information from the patient or patient's agent, and, where appropriate, the patient's pharmacy records, assesses that information and provides the patient or patient's agent with professional advice regarding the safe and effective use of the drug or device for the purpose of assuring therapeutic appropriateness.~~

~~(4) "Drug Regimen Review (DRR)" means the process conducted by a pharmacist who is consulting for a long-term-care facility or other institution, either prior to dispensing or at a later time, with the goal of ensuring that optimal patient outcomes are achieved from the drug therapy.~~

~~(5) "Drug Utilization Review (DUR)" has the same meaning as defined in OAR 855-006-0005.~~

~~(6) "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.~~

~~(7) "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.~~

~~(8) "Practice of Pharmacy" is as defined in ORS 689.005.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.005, 689.151 & 689.155~~

855-115-0010
Licensure: Qualifications: General

(1) Before licensure as a Pharmacist, an applicant must meet the qualifications required that are applicable to their method of licensure;

(a) Examination or Score Transfer in OAR 855-115-0020; or

(c) Reciprocity in OAR 855-115-0025.

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

855-~~019-0150~~115-0013
Licensure: Qualifications: RPH- Foreign Pharmacy Graduates

(1) Foreign Pharmacy Graduates applying for licensure in Oregon must meet the following requirements:

(a) Provide a copy of a valid visa permitting full time employment;

(b) Provide a copy of the original certificate issued by the NABP Foreign Pharmacy Graduate Examination Committee (FPGEC); and

~~(c) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 91 days. This score shall only be valid for one year unless the Board grants an extension;~~

~~(d) After having completed the required number of intern hours, pass the MPJE with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 30 days. The MPJE score shall only be valid for 6 months unless extended by the Board.~~

(2) ~~An applicant must complete~~ **Submit evidence of** 1440 hours in pharmacy practice as an ~~i~~**I**ntern**.** ~~that must be certified to the Board by the preceptors.~~ **An applicant may not count internship hours or practice as a pharmacist toward Oregon's internship requirement that was completed:**

~~(3) An applicant may not count internship hours or practice as a pharmacist completed outside the United States toward Oregon's internship requirement.~~

(a) Outside the United States; or

~~(4) An applicant may not count internship hours or practice as a pharmacist that is completed before passing the Foreign Pharmacy Graduate Equivalency Examination (FPGEE), and either the TOEFL with TSE, or TOEFL (IBT) exams toward Oregon's internship requirement.~~

(b) Before obtaining the FPGEC certification.

(~~5~~**3**) The ~~B~~**b**oard may waive any requirement of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing.

POLICY DISCUSSION: Canadian graduates

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

855-~~019-0120~~115-0016
Licensure: Qualifications: RPH- Examination or Score Transfer

(1) ~~Before~~ **To receive** licensure as a ~~p~~**P**harmacist **by examination or score transfer**, an applicant must meet the following requirements:

(a) Provide evidence from a **board-approved** school or college of pharmacy ~~approved by the board~~ that**:** ~~they have successfully completed all the requirements for graduation and, starting with the graduating class of 2011, including not less than 1440 hours of School-based Rotational Internships as that term is defined in OAR 855-031-0005, and that~~

(**A**) ~~a~~**A** degree ~~will be~~ **has been** conferred; **and**

(B) The applicant has completed a minimum of 1440 hours of School-based Rotational Internships as that term is defined in OAR 855-120-0005.

(b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam**.** ~~with a score of not less than 75. This score~~ **A passing result** is valid for ~~only~~ one year ~~unless the board grants an extension~~. A candidate who does not ~~attain this score~~ **pass** may retake the exam after a minimum of 45 days with a

limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 **failed attempts** ~~times~~;

(c) Pass the **Oregon** Multistate Pharmacy Jurisprudence Examination (MPJE) exam**. A passing result is valid for 1 year** ~~with a score of not less than 75~~. ~~The applicant~~ **A candidate** may not take the **Oregon** MPJE until they have graduated from a **board-approved** school or college of pharmacy ~~approved by the board~~. A candidate who does not ~~attain this score~~ **pass** may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 **failed attempts**~~times~~. ~~The MPJE score is valid for 6 months unless extended by the board;~~

POLICY DISCUSSION: Validity length, Retake limits, Discipline

~~(d) Complete an application for licensure, provide the board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check; and~~

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

~~(2) A license, once obtained, will expire on June 30 in odd-numbered years and must be renewed biennially.~~

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

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151**, ORS 413.590** ~~& 2021 HB 2078~~

~~**855-019-0140**~~
~~**NAPLEX Score Transfer**~~

~~(1) An applicant for score transfer must be a graduate of a school or college of pharmacy approved by the Board and must have passed the NAPLEX or equivalent examination with a score of at least 75.~~

~~(2) Prior to taking the NAPLEX examination for their initial state of licensure, an applicant must have requested the National Association of Boards of Pharmacy to score transfer their NAPLEX score to Oregon.~~

~~(3) An applicant must provide the following documentation:~~

~~(a) Oregon Score Transfer Application;~~

~~(b) A passport regulation photograph;~~

~~(c) A copy of a birth certificate, US passport or naturalization documents, or a foreign passport endorsed with a US visa permitting full time employment;~~

~~(d) Evidence of successful completion of all graduation requirements from a school or college of pharmacy approved by the Board.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.151 & 689.265~~

855-~~019-0130~~115-0019
Licensure: Qualifications: RPH- ~~by~~ Reciprocity

(1) An applicant for licensure as a pharmacist by reciprocity must meet the requirements of ORS 689.265 and the following requirements:

(a) Be a graduate of a **board-approved** school or college of pharmacy ~~approved by the Board~~;

(b) Have passed the NAPLEX ~~or equivalent examination with a score of not less than 75~~;

(c) Have passed the **Oregon** MPJE~~. with a score of not less than 75;~~ **A passing result is valid for 1 year. A candidate may not take the Oregon MPJE until they have graduated from a board-approved school or college of pharmacy. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts;**

(d) ~~Be licensed and in good standing in the state from which the applicant bases the reciprocity application;~~ **Provide proof that each Pharmacist license granted to the applicant is not suspended, revoked, canceled or otherwise completely restricted from the practice of pharmacy for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the practice of pharmacy.**

(e) Have either:

(A) Been engaged in the practice of pharmacy for period of at least one year including a minimum of 1440 hours of work experience as a licensed ~~p~~**P**harmacist. Evidence supporting this work experience ~~shall~~ **must** be provided at time of application; or

(B) Met the internship requirements of this state within the one-year period immediately before the date of this application. Evidence from the school or college of pharmacy supporting this internship ~~shall~~ **must** be provided at time of application.

~~(2) Licensure as a pharmacist in another state precludes licensure to practice as an intern in the State of Oregon, except an applicant that has been accepted into an Oregon pharmacy residency program or for licensure by examination or by reciprocity who must acquire internship hours to become eligible for licensure, and then only until the required hours have been acquired.~~

POLICY DISCUSSION: Pharmacist license in another state; intern license exclusion

(~~3~~**2**) An applicant who has obtained their professional degree outside the United States is not eligible for licensure by reciprocity until they have met the requirements of OAR 855-~~019-0150~~**115-0015**.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151**,** ~~&~~ 689.265**, 689.405**

855-115-0020
Licensure: Application- Pharmacist

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

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

(a) Official transcript from a board-approved school or college of pharmacy;

(b) Passing result from NABP for the NAPLEX and MPJE;

(c) A completed application including:

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

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

(C) Personal identification or proof of identity;

(D) Certificate of completion for the one hour of continuing pharmacy education in pain management, provided by the Pain Management Commission of the Oregon Health Authority;

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

(e) A completed moral turpitude statement or a written description and documentation regarding all conduct that required a yes answer to an application question.

(3) A license may be denied and a civil penalty imposed for:

(a) Failure to completely and accurately answer each question on the application for licensure or renewal of licensure is grounds for discipline;

(b) Failure to disclose any requested information on the application or requests resulting from the application; or

(c) Any other grounds found in ORS 689.405 and ORS 689.490.

(4) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(5) The license of a Pharmacist expires June 30 in odd numbered years and may be renewed biennially.

855-~~019-0122~~115-0030

~~Renewal of~~ Licensure: Renewal or Reinstatement- ~~as a~~ Pharmacist

(1) An application for renewal of a ~~p~~**P**harmacist license must ~~include documentation of~~:

~~(a) Completion of continuing pharmacy education requirements as outlined in OAR 855-021; and~~

(~~b~~**a**) Pay~~ment of~~ the biennial license fee required in OAR 855-110;~~.~~

(b) Complete the continuing pharmacy education requirements as outlined in OAR 855-021; and

(~~2~~c) ~~A pharmacist will~~ ~~b~~Be subject to an annual criminal background check.

(2) A Pharmacist 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 Pharmacist 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:

~~**855-019-0170**~~

~~**Reinstatement of License**~~

~~(1) A pharmacist who fails to renew their license by the deadline may reinstate their license as follows:~~

(a) By payment of the license fees and ~~delinquency~~ **late** fees for all years during which the license was lapsed and for the current year~~; and~~

(b) By providing certification of completion of the continuing pharmacy education requirement in OAR 855-021 for all years in which the license was lapsed; and

(c) ~~If their license has been lapsed for more than one year, p~~**P**ass the **Oregon** MPJE**.** ~~with a score of not less than 75; and~~ **A passing result is valid for one year. A candidate who does not pass may retake the exam after a minimum of 30 days with a limit of three attempts in a 12 month period, not to exceed a lifetime maximum of 5 failed attempts; and**

(d) Complete an application for licensure **per OAR 855-115-0030**~~, provide the board with a valid e-mail address, and a fingerprint card or other documentation required to conduct a criminal background check~~.

POLICY DISCUSSION: Retain current requirements

(~~2~~**4**) A ~~p~~**P**harmacist in good standing who retired from the practice of pharmacy after having been licensed for ~~not less than~~ **a minimum of** 20 years need only pay the annual license fees for the year in which they seek a license, however they must provide certification of completion of continuing pharmacy education requirement in OAR 855-021 for all years since their retirement and pass the **Oregon** MPJE ~~with a score of not less than 75~~.

POLICY DISCUSSION: Retain CPE/MPJE

~~**855-019-0171**~~
~~**Reinstatement of a Revoked or Surrendered License**~~

(**5**~~3~~) A person whose pharmacist license has been **suspended,** revoked or surrendered ~~shall have~~ **has** the right, at reasonable intervals, to petition to the ~~B~~**b**oard in writing for reinstatement of such license. The written petition to the ~~B~~**b**oard shall be made in conjunction with the application process identified in OAR 855-~~019-0120~~**115-0030**.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151 & **ORS** 689.275**, ORS 689.445**

855-115-0040
Licensure: Lapse

(1) A Pharmacist may let their license lapse by failing to renew or request that the board accept the lapse of their license prior to the expiration date.

(a) Lapse of a license is not discipline.

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not practice pharmacy if the license is lapsed.

(d) A person may apply for renewal or reinstatement according to OAR 855-115-0030.

(2) If a person requests lapse prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the lapse.

(b) If the board accepts the lapse, the board will notify the licensee of the date the license terminates.

(c) The board will not accept the lapse if an investigation of or disciplinary action against the licensee is pending.

(d) The licensee must return the license to the board within 10 days of the board accepting the lapse.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0043
Licensure: Retirement

(1) A Pharmacist may request that the board accept the retirement of their license if the Pharmacist is in good standing, has been licensed as a Pharmacist for at least 20 years and is retired from the practice of pharmacy.

(a) Retirement of a license is not discipline;

(b) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

(c) A person may not practice pharmacy if the license is retired.

(d) A person may apply for renewal or reinstatement according to OAR 855-115-0030.

(2) If a person requests retirement prior to the expiration date of the license, the following applies:

(a) The license remains in effect until the board accepts the retirement.

(b) If the board accepts the retirement, the board will notify the licensee of the date the license terminates.

(c) The board will not accept the retirement if an investigation of or disciplinary action against the licensee is pending.

(d) The licensee must return the license to the board within 10 days of the board accepting the retirement.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-115-0046
Licensure: Voluntary Surrender

A Pharmacist may request that the board accept the voluntary surrender of their license.

(1) A voluntary surrender of a license is discipline.

(2) The license remains in effect until the board accepts the surrender.

(3) If the board accepts a request for voluntary surrender, the board will issue a final order terminating the license, signed by the licensee and a board representative. The termination date is the date the licensee is sent the executed final order.

(4) The licensee must cease practicing pharmacy from the date the license terminates.

(5) A voluntarily surrendered license may not be renewed. A former licensee who wants to obtain a license must apply for reinstatement per OAR 855-115-0030 unless the final order prohibits the licensee from doing so.

(6) The board has jurisdiction to proceed with any investigation or any action or disciplinary proceeding against the licensee.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.153

855-~~019-0123~~115-0060
~~Liability Limitations for Volunteers~~ Registration: Resident Volunteer Pharmacist

(1) A pharmacist may register with the ~~B~~**b**oard for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services without compensation under the terms of the law.

(2) A no cost registration may be issued by the ~~B~~**b**oard upon receipt of a completed application. Registration requires submission of a signed form provided by the ~~B~~**b**oard in accordance with ORS 676.345(2).

(3) Registration will expire at the licensee's next license renewal date and may be renewed biennially. It is the licensee's responsibility to ensure his or her active registration in this program.

(4) Nothing in this section relieves licensee from the responsibility to comply with ~~B~~**b**oard regulations and still may be subject to disciplinary actions.

(5) Pharmacists providing care under the provisions of ORS 676.340 and **ORS** 676.345 remain subject to the ~~B~~**b**oard complaint investigation process articulated in ORS 676.175.

Statutory/Other Authority: ORS 676.340 & **ORS** 689.205
Statutes/Other Implemented: ORS 676.340 & **ORS** 676.345

855-115-1165
Notification: Non-Resident Volunteer Pharmacist

NOTE: Will add new language once adopted by the board.

~~**855-019-0125**~~

~~**Coaching from Board and Staff**~~

~~No member or employee of the Board shall discuss the contents of an examination, its preparation or use with any candidate or other person. No member or employee of the Board shall coach a candidate or any other person on materials that may be used in the examination nor shall they accept any fees for any act of assistance that would bear on the examination.~~

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

855-~~019-0160~~-115-00XX

Nuclear Pharmacists

NOTE: Will be updated for future board review. No changes proposed at this time.

In order to qualify under these rules as a nuclear pharmacist, a pharmacist shall:

(1) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Protection Services of the Department of Human Services; and

(2) Be a pharmacist licensed to practice in Oregon; and

(3) Submit to the Board of Pharmacy either:

(a) Evidence of current certification in nuclear pharmacy by the Board of Pharmaceutical Specialties; or

(b) Evidence that they meet both the following:

(A) Certification of a minimum of six month on-the-job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radiopharmaceutical services; and

(B) Certification of completion of a nuclear pharmacy training program in a college of pharmacy or a nuclear pharmacy training program approved by the ~~B~~**b**oard.

(4) Receive a letter of notification from the ~~B~~**b**oard that the evidence submitted by the pharmacist meets the above requirements and has been accepted by the ~~B~~**b**oard.

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

Division 135- Continuing Pharmacy Education (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): Procedural rule review amending continuing education rules

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amending definitions, requirements for approved providers, applicants, instructors, renewal requirements for licensees and audits to reflect current requirements and standards.

Documents Relied Upon per ORS 183.335(2)(b)(D): Rules Advisory Committee- Continuing Pharmacy Education: May 2021 minutes, October 2021 minutes, and January 2022 minutes.

Resources: Other State Regulations: CA: CCR 1732**,** OH: OAC 4729:1-5**,**TX: TAC 295.8 Continuing Education Requirements, WA: WAC 246-861 Pharmacists—Professional Pharmaceutical Education

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): It is anticipated that state agencies, units of local government, licensees or the public will not be financially impacted by the proposed rules. Applicants and licensees are currently required by statute and rule to complete certain CE based on their license type.

Effect on Small Businesses? No effect anticipated for small businesses.

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): Yes, a RAC was consulted at three separate RAC meetings.

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 the proposed rules may increase patient safety for all Oregonians in every community by ensuring that all licensees continue to develop, maintain and enhance their competence in the practice or assistance of the practice of pharmacy.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): The proposed rules clarify definitions, incorporate universally acceptable CPE standards, amend outdated language and streamlines the process and requirements for providers and licensees applying for continuing pharmacy education credit.

NOTE: We will create a new Division 135 and expire Division 021. The following rule references will be corrected as a Statutory Minor Correction to reflect the new Division 135 after the rules have been permanently adopted.

855-019-0122(1)(a)	Renewal of Licensure as a Pharmacist
855-019-0170(1)(b) and (2)	Reinstatement of License
855-025-0011(1)(b)	Licensure: Renewal or Reinstatement- Pharmacy Technician
855-025-0015(2)(b)	Licensure: Renewal or Reinstatement- Certified Oregon Pharmacy Technician
855-031-0016(1)(a)	Renewal of Licensure as an Intern

Division ~~21~~**135**
CONTINUING PHARMACY EDUCATION

855-~~021~~135-0001

Continuing Pharmacy Education: Definitions

(1) "Accredited program" means a structured continuing pharmacy education (CPE) program which has been reviewed and approved by a provider of continuing pharmacy education that is accredited by the Accreditation Council on Pharmaceutical Education (ACPE) or approved by the American Medical Association (AMA).

(2) "AMA Category 1 Program" means a program reviewed and approved by the AMA as Category 1 Continuing Medical Education (CME) by a provider of continuing medical education accredited by the Accreditation Council for Continuing Medical Education (ACCME).

(3) "Approved provider" means any person, institution, organization, association, corporation, or agency approved either by the board or ACPE to conduct continuing pharmacy education programs.

(4) "Board-approved program" means a structured continuing pharmacy education which has been reviewed and approved by the board or a board-approved provider.

(5) "Certificate of completion" means a certificate or other official document issued to a participant certifying the successful completion of an approved continuing pharmacy education program.

(~~1~~**6**) "Continuing Pharmacy Education" or "CPE" **means an accredited or approved educational activity designed to support the continuing development of pharmacists, interns, or pharmacy technicians to maintain and enhance their competence applicable to the practice of pharmacy or the assistance of the practice of pharmacy**. ~~classes of post graduate studies, informal study group participation, institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, planned and professional meetings, self-study courses, cassette or audio visual tape/slides or materials, and other self-instruction units applicable to the practice of pharmacy~~.

(~~2~~**7**) "Contact hour" means ~~fifty~~ **sixty** minutes of continuing pharmacy education.

(8) "CPE Monitor" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy (NABP) for monitoring continuing pharmacy education that pharmacists, interns, and pharmacy technicians receive from participating providers;

(~~6~~**9**) "Cultural competence" means the lifelong process of examining the values and beliefs and developing and applying an inclusive approach to health care practice in a manner that recognizes the content and complexities of provider-patient communication and interaction and preserves the dignity of individuals, families, and communities.

(a) Cultural competence applies to all patients.

(b) Culturally competent providers do not make assumptions on the basis of an individual's actual or perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital status, socio-economic status, veteran's status, sexual orientation, gender identity, gender expression, gender transition status, level of formal education, physical or mental disability, medical condition or any consideration recognized under federal, state and local law.

(4**10**) “Medication error prevention” means **the prevention of events that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer** ~~systems, procedures and processes to prevent and avoid adverse events and to ensure that the correct patient receives the correct drug in the correct dose~~.

(~~3~~**11**) “Patient safety” means **the prevention of healthcare related errors or the elimination or mitigation of patient injury caused by healthcare related errors** ~~systems, procedures and processes that ensure that the correct patient receives the correct drug in the correct dose and is counseled appropriately~~.

(~~5~~**12**) "Pain management education program" means a specific one-hour web-based program developed by the Pain Management Commission of the Oregon Health Authority.

(13) “Pharmacy law” means the body of laws relating to pharmacy practice.

(14) “Structured continuing pharmacy education” or “Structured CPE” means education that includes defined learning objectives, qualified instructors, learning assessment, and a program evaluation.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: **ORS 689.255,** ORS 689.285, ORS 689.486, ORS 413.450**, ORS 689.490** & ORS 413.590

855-135-0010
Continuing Pharmacy Education Programs: General Requirements

(1) CPE programs must consist of subject matter pertinent to pharmacy including:

(a) Socio-economic aspects of healthcare;

(b) Legal aspects of healthcare;

(c) Properties and actions of drugs and dosage forms;

(d) Etiology, characteristics, therapeutics, and prevention of disease states; or

(e) General topics related to pharmacy.

(2) Time spent in the following activities may be included in the calculation of CPE credit:

(a) Content delivered by an instructor or a panel of instructors;

(b) The program is:

(A) A structured CPE discussion, workshop or demonstration;

(B) A structured CPE question and answer session; or
(C) An accredited or board-approved program; or

(D) Approved as an AMA Category 1 program. Licensees may earn a maximum of 10 hours of continuing pharmacy education for AMA Category 1 programs per renewal cycle.

(3) Time spent in the following activities may not be included in the calculation of CPE credit:

(a) Welcoming remarks;

(b) Time spent for meals or social functions;

(c) Business sessions (e.g. voting, treasury report, strategic plan);

(d) Unstructured discussion, workshops, and demonstrations;

(e) Unstructured question and answer sessions;

(f) Degree programs;

(g) Non-ACPE approved certificate programs;

(h) Licensing or certification examinations (e.g. MPJE, BCPS, CPhT-Adv);

(i) Skills training programs (e.g. CPR, ACLS);

(j) Software training programs (e.g. NPLEx, PDMP, ALERT-IIS, REMS);

(k) Learning assessments;

(l) Program evaluations; and

(m) Attending CPE programs for which credit was not granted by the provider.

(4) For each board-approved program, the licensee must retain a certificate of completion for each completed program that must include:

(a) Licensee name;

(b) Title, approval date, and activity number of the program;

(c) Topic designation (e.g. law, patient safety, pain);

(d) Name of the program provider;

(e) Date of completion of the program;

(f) Number of contact hours earned by topic designation; and

(g) Statement of credit granted to the participant.

(5) For each accredited or board-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or a certificate of completion is uploaded to the licensee's Oregon Board of Pharmacy e-Gov profile.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: **ORS 689.255,** ORS 689.285**, ORS 689.490**

855-135-0020
Continuing Pharmacy Education Programs: Approved Providers

(1) A CPE provider may apply to the board on forms provided by the board for qualification as an approved provider. If a provider is approved, the board will issue a certificate or other notification of qualification. The approval is effective for a period of two years. Providers who apply to the board for approved provider status must provide the following:

(a) Contact person for the providers' CPE program;

(b) Copies of CPE program material and information used by the provider in the previous two years with each renewal; and

(c) Procedures including:

(A) Educational goals and learning objectives for each program;

(B) Learning assessment component for each program; and

(C) Program evaluation component for each program.

(2) The provider must make available to each participant:

(a) A written program description which lists the topic(s) covered, an assigned activity number, names of instructors, time devoted to the program topic(s), and the learning objectives of the program. The program description must also bear a statement of the number of hours by topic designation of CPE credit assigned by the provider.

(b) A certificate of completion that must include:

(A) Licensee name;

(B) Title and activity number of the program;

(C) Topic designation (e.g. law, patient safety, pain);

(D) Name of the program provider;

(E) Date of completion of the program;

(F) Number of contact hours earned by topic designation; and

(G) Statement of credit granted.

(3) The provider must retain, for a period of six years, a list of persons to whom a certificate of completion was supplied in (2)(b).

(4) The board must establish the standards and specifications necessary for a provider to obtain approval.

(5) The board may revoke or suspend an approval of a provider if the provider fails to maintain the necessary standards and specifications required.

POLICY DISCUSSION: Provider-approval

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135, ORS 689.285

855-135-0030
Continuing Pharmacy Education Programs: Applications for Approval

(1) An application for approval of a CPE program which is not an accredited program or provided by an approved provider may apply for board approval using a form supplied for this purpose. A complete application includes:

(a) Program provider or sponsor name;

(b) Program name;

(c) Program topic designation(s);

(d) Licensee type(s);

(e) Total number of contact hours offered by topic designation;

(f) Description of program goal(s) and learning objective(s);

(g) Program format (e.g. interactive discussion, panel, speaker);

(h) Name and qualification(s) of each instructor;

(i) Date(s) and location(s) of program;

(j) Learning assessment; and

(k) Program evaluation

(2) The provider must submit an application form a minimum of forty-five days prior to the date the program will be held. Applications submitted less than forty-five days prior to the date the program will be held will not be approved.

(3) Incomplete applications will not be approved.

(4) An application for post-approval of a CPE program will not be approved.

POLICY DISCUSSION: Post-approval, accepting other state board approvals

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285

855-135-0040
Continuing Pharmacy Education Programs: Instructors' Credit Toward CPE Hours

(1) Any pharmacist whose primary responsibility is not the education of health professionals, who instructs a group of health professionals on pharmacy-related topics according to OAR 855-135-0010(1)(a)-(e) in structured CPE may be granted two hours of CPE credit for each hour spent in presenting the initial course or program which has been approved for CPE credit.

(2) Any pharmacist whose primary responsibility is the education of health professionals may be granted CPE credit as in (1) when instructing a group of health professionals on pharmacy-related topics unrelated to their formal course responsibilities in a learning institution.

(3) An instructor may only be granted credit for one presentation of the same program of CPE.

(4) An instructor may earn a maximum of 10 hours of CPE for instruction per renewal cycle.

(5) An instructor must submit an application form a minimum of forty-five days prior to the date the program will be held to apply for instructor credit toward CPE hours using a form provided for this purpose by the board. Applications submitted less than forty-five days prior to the date of the program will not be approved.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285

855-~~021-0005~~135-0050
Continuing Pharmacy Education: Requirements~~d~~ for Pharmacist License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a pharmacist must have satisfactorily completed at least 30 hours of ~~continuing pharmacy education~~ **CPE**. These hours must include at least:

(a) Two hours of ~~continuing pharmacy education~~ **CPE** in pharmacy law;

(b) Two hours of ~~continuing pharmacy education~~ **CPE** in patient safety or medication error prevention;

(c) Two hours of ~~continuing pharmacy education~~ **CPE** in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(d) One hour of ~~continuing pharmacy education~~ **CPE** in pain management, provided by the Pain Management Commission of the Oregon Health Authority; and

(e) Twenty-three additional hours of ~~continuing pharmacy education~~ **CPE in subjects pertinent to pharmacy per OAR 855-135-0010(1)(a)-(e)**.

(2) ~~Section (1) does not apply to p~~**P**harmacists 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~~.~~**, must have satisfactorily completed at least 15 hours of CPE. These hours must include at least:**

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

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

(D) Thirteen additional hours of CPE in subjects pertinent to pharmacy per OAR 855-135-0010(1)(a)-(e).

POLICY DISCUSSION: 15 hours, < 1 year

(3) A pharmacist must register with the CPE Monitor for tracking completed ACPE credit hours.

(4) For each ACPE-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor.

(5) For each board-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or uploaded to the licensee's Oregon Board of Pharmacy e-Gov profile.

(~~3~~**6**) A pharmacist must retain documentation of completed ~~continuing pharmacy education~~ **CPE** for six years and must provide this documentation if requested by the board.

(~~4~~**7**) ~~continuing pharmacy education~~ **CPE** credit accumulated in excess of the required 30 contact hours for biennial license renewal cannot be carried forward.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 689.285, **ORS 689.486,** ORS 413.450, ORS 413.590 ~~& 2021 HB 2078~~

855-~~021-0007~~135-0060

Continuing Pharmacy Education: Requirements~~d~~ for Intern License Renewal

(1) During each license renewal cycle, an intern must have satisfactorily completed 2 contact hours of approved ~~continuing pharmacy education~~ **CPE** in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(2) An intern must retain documentation of completed ~~continuing pharmacy education~~ **CPE** for six years and must provide this documentation if requested by the board.

(3) An intern must register with the CPE Monitor for tracking completed ACPE credit hours.

(4) For each ACPE-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor.

(5) For each board-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or uploaded to the licensee's Oregon Board of Pharmacy e-Gov profile.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: **ORS 413.450, ORS 689.151, ORS 689.255,** ORS 689.285, ORS 676.850~~, ORS 413.450 & ORS 689.151~~

855-~~021-0009~~135-0070

Continuing Pharmacy Education: Requirements~~d~~ for ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician or 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 **or Pharmacy Technician** must have satisfactorily completed 20 contact hours of ~~continuing pharmacy education~~ **CPE**. These hours must include:

(a) Two hours of ~~continuing pharmacy education~~ **CPE** in pharmacy law;

(b) Two hours of ~~continuing pharmacy education~~ **CPE** in patient safety or medication error prevention;

(c) Two hours of ~~continuing pharmacy education~~ **CPE** in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency effective July 1, 2023; and

(d) Fourteen additional hours of ~~continuing pharmacy education or documented onsite training approved by the board~~ **CPE in subjects pertinent to pharmacy per OAR 855-135-0010(1)(a)-(e)**.

(2) Section (1)(a)(b) and (d) do not apply to a ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **or 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) Certified Oregon Pharmacy Technicians and Pharmacy Technicians must register with the CPE Monitor for tracking completed ACPE credit hours.

(4) For each ACPE-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor.

(5) For each board-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or uploaded to the licensee's Oregon Board of Pharmacy e-Gov profile.

(~~3~~**6**) A ~~Pharmacy Technician or~~ Certified Oregon Pharmacy Technician **or Pharmacy Technician** must retain documentation of completed ~~continuing pharmacy education~~ **CPE** for six years and must provide this documentation if requested by the board.

(4**7**) ~~Continuing pharmacy education~~ **CPE** credit accumulated in excess of the required 20 contact hours for biennial license renewal cannot be carried forward.

(~~5~~**8**) If a license renewal is submitted after June 30th of the license renewal cycle, ~~continuing pharmacy education~~ **CPE** must be completed prior to submission of the license renewal.

(~~6~~**9**) 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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 676.850

~~**855-021-0010**~~
~~**Continuing Pharmacy Education Programs**~~

~~(1) A continuing pharmacy education program must consist of therapeutics, or pharmacy and drug law or other aspects of health care applicable to the practice of pharmacy.~~

~~(2) Programs must provide for examinations or other methods of evaluation to assure satisfactory completion by participants.~~

~~(3) The person or persons who are to instruct or who are responsible for the delivery or content of the program must be qualified in the subject matter by education and experience.~~

~~(4) Continuing pharmacy education programs must be approved by the Board of Pharmacy. Application for approval must be made on and in accordance with forms established by the board. The forms must require information relating to:~~

~~(a) Name of provider or sponsor;~~

~~(b) Type of program offered;~~

~~(c) Description of subject matter;~~

~~(d) Number of contact hours offered;~~

~~(e) Total number of contact hours in therapeutics or pharmacy and drug law or other aspects of health care applicable to the practice of pharmacy;~~

~~(f) Method of determining satisfactory completion of program;~~

~~(g) Dates and location of program;~~

~~(h) Name and qualification of instructors or other persons responsible for the delivery or content of the program.~~

~~(5) CE programs are not required to carry approval of American Council on Pharmaceutical Education (ACPE). Programs presented by providers approved by the American Council on Pharmacy Education (ACPE) are accepted.~~

~~(6) Providers must provide attendees with proof of attendance that shows the date and number of contact hours provided. Providers must maintain attendance lists for six years.~~

~~(7) A maximum of 10 contact hours may be earned in any licensing cycle by preparing and presenting CE programs. Pharmacists and Certified Oregon Pharmacy Technicians presenting CE programs may earn one contact hour for preparation time of one hour or more, plus credit for the actual contact hour time of the presentation. A pharmacist or Certified Oregon Pharmacy Technician must show content of the course, and a description of the intended audience (e.g., pharmacists, technicians, physicians, nurses). Public service programs, such as presentations to school children or service clubs, are not eligible for continuing education credit.~~

~~(8) Pharmacists or Certified Oregon Pharmacy Technicians taking post graduate studies applicable to graduate or professional degrees may submit the course syllabus and evidence of satisfactory completion of the course for continuing education credit approval by the board.~~

~~(9) The board may approve up to 26 contact hours of CE credit for pharmacists who have successfully completed nationally certified Disease State Management courses.~~

~~(10) Board members or staff may attend CE programs for the purpose of evaluating content, format and appropriateness of material for Continuing Pharmacy Education credit. Subsequent programs by CE providers whose current programs are deemed deficient by on-site evaluation may be required to obtain prior approval by the board. The board will provide feedback to CE providers regarding evaluated CE presentations.~~

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.285~~

855-135-0080

Continuing Pharmacy Education: Requirements for Licensees Licensed in Other Health Professions

A Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician who is licensed to practice another health profession must meet the same CPE requirements in the same manner as all other board licensees and must otherwise comply with this chapter.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.255, ORS 689.285, ORS 689.490

855-~~021-0045~~135-0085

Continuing Pharmacy Education: Notification of Biennial License Renewal

The board will send a biennial renewal notice to be issued to all licensed ~~p~~**P**harmacists, ~~i~~**I**nterns, ~~and~~ Certified Oregon Pharmacy Technicians**, and Pharmacy Technicians** at least 60 days prior to the license expiration date that states the biennial license fee, ~~continuing pharmacy education~~ **CPE** requirements and other information necessary for renewal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: **ORS 689.255,** ORS 689.275 & ORS 689.486**, ORS 689.490**

855-~~021-0050~~135-0090

Continuing Pharmacy Education: Audits

(1) The biennial renewal application must be submitted to the board with the appropriate fee and the licensee must attest that they have satisfactorily completed the ~~continuing pharmacy education~~ **CPE** requirements.

(2) The Board may randomly select and audit applications for renewal to verify completion of ~~continuing pharmacy education~~ **CPE** by ~~p~~**P**harmacists, ~~i~~**I**nterns, ~~and~~ Certified Oregon Pharmacy Technicians**, and Pharmacy Technicians** ~~or documented on-site training by Certified Oregon Pharmacy Technicians~~ reported on the application for renewal.

(a) Pharmacists whose applications for renewal are selected for audit must provide documentation of completion of the ~~continuing pharmacy education~~ **CPE** programs reported. A ~~p~~**P**harmacist who fails to provide the requested documentation to the board or who fails to complete the biennial ~~continuing pharmacy education~~ **CPE** requirement may be disciplined for unprofessional conduct.

(b) Interns whose applications for renewal are selected for audit must provide documentation of completion of the cultural competency ~~continuing pharmacy education~~ **CPE**. An ~~i~~**I**ntern who fails to provide the requested documentation to the board or who fails to complete the biennial ~~continuing education~~ **CPE** requirement may be disciplined for unprofessional conduct.

(c) Certified Oregon Pharmacy Technicians **and Pharmacy Technicians** whose applications for renewal are selected for audit must provide documentation of completion of the ~~continuing pharmacy education~~ **CPE** ~~or documented onsite training reported~~. A Certified Oregon Pharmacy Technician **or Pharmacy Technician** who fails to provide the requested documentation to the board or who fails to complete the biennial ~~continuing education~~ **CPE** requirement may be disciplined for unprofessional conduct.

(3) The board may utilize the National Association of Boards of Pharmacy CPE Monitor service **or the licensee's Oregon Board of Pharmacy e-Gov profile** when auditing licensees.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.275

POLICY DISCUSSION: Implementation with licensure cycles

Division 019/141: Pharmacists/Pharmacy Prescription Kiosk (PPK)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Establishes new registration for Pharmacy Prescription Kiosk

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposed rules that establish a new registration type for Pharmacy Prescription Kiosk. Adds new Division 141 which contains requirements for the operation of a Pharmacy Prescription Kiosk by a PPK Affiliated Pharmacy.

Documents Relied Upon per ORS 183.335(2)(b)(D): 2022-2026 Strategic Plan

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): TBD

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): Board staff will seek stakeholder/public input.

Cost of Compliance (OBOP/Other State Agencies/Units of Local Government/Public, Effect on Small Businesses): TBD

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

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): A RAC was not consulted for the development of these rules. The board held a technology forum during the August 2020 board meeting where vendors presented information and resources for the board's consideration prior to drafting proposed rules.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy.

Division 019
PHARMACISTS

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

(1) In accordance with OAR 855-041 and OAR 855-139, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) who is normally present in the pharmacy on a regular basis.

- NOTE: In rulemaking- Divisions 019/143 - related to Pharmacy Prescription Lockers

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

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

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

(3) A Pharmacist may not be designated PIC of more than three pharmacies without prior written approval by the board. If such approval is given, the Pharmacist must comply with the requirements in sub-section (4)(e) of this rule. **A Pharmacy Prescription Kiosk in OAR 855-141** and ~~a~~A Pharmacy Prescription Locker in OAR 855-143 do~~es~~ not count toward this limit.

- NOTE: In rulemaking- Divisions 019/143 - related to Pharmacy Prescription Lockers

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

(a) When a change of PIC occurs, both the outgoing and incoming PICs must report the change to the board within 15 days of the occurrence, on a form provided by the board;

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;

(c) The PIC may not authorize non-Pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;

(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a Pharmacist;

(e) A Pharmacist designated as PIC for more than one pharmacy must personally conduct and document a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit Form provided by the board;

(f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within 30 days of receiving notice.

- NOTE: In rulemaking- Divisions 019/143 - related to Pharmacy Prescription Lockers

(A) 15 days of receiving a deficiency notice; or

(B) 30 days of receiving a non-compliance notice.

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

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;

(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the board;

(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;

(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.

(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;

(g) Implementing a quality assurance plan for the pharmacy.

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

(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.

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

Division 141
PHARMACY PRESCRIPTION KIOSK

855-141-0001
Purpose and Scope

The purpose of OAR 855-141 is to provide minimum requirements for the operation of a Pharmacy Prescription Kiosk (PPK) by a PPK Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0005
Definitions

The following words and terms, when used in OAR 855-141, 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 Kiosk Affiliated Pharmacy" or "PPK Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon that operates a Pharmacy Prescription Kiosk.

(2) "Pharmacy Prescription Kiosk" or "PPK" means an Oregon location registered as a Retail Drug Outlet Pharmacy Prescription Kiosk using a mechanical system that stores and dispenses patient-specific prescription and non-prescription drugs, devices, and related supplies. ~~under the control of an Oregon licensed Pharmacist using a telepharmacy system~~.

(3) "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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0010
Registration: General

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

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

(3) A Retail Drug Outlet PPK application must specify the PPK Affiliated Pharmacy and cannot operate without a PPK 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 855-141-0015(2) and additional information requested by the board.

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

(6) A Retail Drug Outlet PPK 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 PPK may not operate until a certificate of registration has been issued by the board.

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.305 & ORS 689.527

855-141-0015

Registration: Application

(1) An application for registration of a PPK may be accessed on the board website.

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

(a) A completed application including;

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

(B) A floor plan drawn to scale with the location of the:

(i) PPK within the building;

(ii) Surveillance system cameras; and

(iii) Alarm system panel; and

(C A detailed explanation and supporting documentation relating to the PPK Affiliated Pharmacy regarding all conduct that required a yes answer to an application question; and

(c) The PPK Affiliated Pharmacy name, Retail Drug Outlet registration number and Pharmacist-in-Charge.

(d) 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; and

(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.

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

(4) A registration may be denied for:

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

(b) Failure to disclose any requested information on the application or requests resulting from the application; or

(c) Any other grounds found in ORS 689.405

(5) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.

(6) The certificate of registration for a PPK must be issued prior to opening.

(7) The registration for a PPK expires March 31 in each year and may be renewed annually.

Statutory/Other Authority: ORS 475.035 & ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 689.527

855-141-0020
Registration: Change of Owner, Location, or PPK Affiliated Pharmacy

(1) A change of location of the PPK Affiliated Pharmacy or location of the PPK requires:

(a) Submission of a new PPK 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 PPK Affiliated Pharmacy or ownership of the PPK requires:

(a) Submission of a new PPK 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 PPK that has changed location or ownership must not operate until the new certificate of registration has been approved and issued.

Statutory/Other Authority: ORS 475.035 & ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 689.527

855-141-0025
Registration: Change of Business Name

A PPK Affiliated Pharmacy must notify the board a minimum of 15 days prior to any change of business name of a Retail Drug Outlet PPK. The change must be reported by filing a new application for which no fee is required.

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

855-141-0030
Non-Resident PPK Affiliated Pharmacies

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

(2) Each non-resident PPK 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 PPK 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 PPK Affiliated Pharmacy is the PIC for each PPK.

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

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225 & ORS 689.527

855-141-0050
Personnel

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

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.527

855-141-0100
Security

(1) The PPK Affiliated Pharmacy, the PPK, Oregon licensed PIC of the PPK Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the PPK is responsible for the security of the PPK 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 PPK Affiliated Pharmacy must ensure the PPK:

(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 855-141-0125;

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

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

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

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

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

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

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

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

(a) Alarm system at the PPK and real-time notification to an Oregon licensed Pharmacist from the PPK 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 each access and securing the PPK;

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

(C) Date and time of each activity; and

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0120
Drug: Procurement

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

Statutory/Other Authority: ORS 475.035 & ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0125
Drug: Storage

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

(2) A PPK 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 PPK 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.

Statutory/Other Authority: ORS 689.205 & ORS 689.325
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0130
Drug: Loss

A PPK and its PPK 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.

Statutory/Other Authority: ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0145
Outlet: Closure

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

(1) Final disposition of drugs stored in the PPK 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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305 & ORS 689.527

855-141-0150
Outlet: Sanitation

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

Statutory/Other Authority: ORS 689.305
Statutes/Other Implemented: ORS 689.305 & ORS 689.527

855-141-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon PPK 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 PPK outlet;

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

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

(A) Stating "The (insert name of PPK 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 855-141-0410 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 Kiosk, supervised by an Oregon licensed Pharmacist from (insert name of PPK 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 PPK; and

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

(e) As an alternative to posting the required signage, PPK's that utilize an electronic video monitor that the patient is required to acknowledge prior to retrieving medication from the PPK may display the information required by sub-paragraphs (1)(c)(A) - (D) electronically.

- NOTE: In rulemaking Divisions 019/143 - related to Pharmacy Prescription Lockers

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

Statutory/Other Authority: ORS 689.205 & ORS 689.654
Statutes/Other Implemented: ORS 689.155, ORS 689.515, ORS 689.654 & ORS 689.527

855-141-0200
Outlet: General Requirements

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

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

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

(4) A PPK and its PPK 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 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 855-141;

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

(e) Comply with all applicable federal and state laws and rules; (f) Ensure that there is an Oregon licensed PIC who is responsible for all operations and enforcing all policies and procedures of the PPK;

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

(g) Utilize complete chain of custody tracking;

(h) Train the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system and PPK and document the training;

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

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

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0205
Outlet: Technology

A PPK and its PPK Affiliated Pharmacy must:

(1) Utilize a shared telepharmacy 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 PPK;

(3) Test the telepharmacy system and PPK 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 PPK 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 telepharmacy system and PPK.

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

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

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

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

(d) Completed prescription container including the label; and

(7) Utilize barcode, radio-frequency identification or quick response code technology to record information in (6) if available;

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0210
Outlet: Supervision

A PPK and its PPK Affiliated Pharmacy must:

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

(2) Ensure that stocking and destocking of prescription and non-prescription drugs, devices, and related supplies in a PPK is completed under the supervision, direction, and control of an Oregon licensed 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 PPK;

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

(c) Proper storage conditions were maintained during transfer per OAR 855-141-0125; and

(d) Records are maintained per OAR 855-141-0550.

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

- NOTE: In rulemaking Divisions 019/143 - related to Pharmacy Prescription Lockers

Statutory/Other Authority: ORS 689.205 & ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305 & ORS 689.527

855-141-0215
Outlet: Pharmacist Utilization

A PPK and its PPK Affiliated Pharmacy must ensure that a prescription drug or device is not released from the PPK 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.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0225
Outlet: Controlled Substances

Controlled substances may not be stored in the PPK.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0300

Prescription: General Requirements

(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization. When a prescription is transmitted orally, it must be transmitted to the Oregon licensed Pharmacist from the PPK Affiliated Pharmacy and both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.

(2) Each PPK Affiliated Pharmacy must document the following information for each prescription:

(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal.

(b) If for an animal, the name of the patient, name the owner and the species of the animal.

(c) The full name, address, and contact phone number of the practitioner.

(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

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

(f) The date of filling, and the total number of refills authorized by the prescribing practitioner.

(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, instruction may use any one of the following phrases or notations:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words with similar meaning.

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent must clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

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

(4) A PPK or Oregon licensed Pharmacist filling a prescription or order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:

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

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

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

(d) The PPK Affiliated Pharmacy or Oregon licensed Pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three (3) business days of dispensing the biosimilar product; and

(5) The PPK must dispense prescriptions accurately and to the correct party.

Statutory/Other Authority: ORS 689.205 & ORS 689.522
Statutes/Other Implemented: ORS 689.505, ORS 689.515 & ORS 689.522

855-141-0305
Prescription: Tamper-resistant

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

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

855-141-0310
Prescription: Verification of Authenticity

Alteration of a written prescription, other than by an Oregon licensed Pharmacist's or practitioner's authorization, in any manner constitutes an invalid order unless verified with the prescriber.

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

855-141-0315

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 reasonable professional judgment of the Oregon licensed Pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the Oregon licensed Pharmacist may authorize the Certified Oregon Pharmacy Technician to prepare for pharmacist verification a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner must be promptly notified of the emergency refill.

(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include;

(a) The identity of the Certified Oregon Pharmacy Technician and responsible Oregon licensed Pharmacist;

(b) Name of the patient;

(c) Name of the medication;

(d) Date of refill; and

(e) Quantity dispensed.

(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled substance or psychotherapeutic drug and the prescriber is notified of the change.

(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient's agent. A request specific to each prescription medication is required, unless the requested fill or refill is part of an auto-refill program and is a continuation of therapy.

(6) A prescription must be refilled in context with the approximate dosage schedule unless specifically authorized by the prescriber.

(7) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may use a program that automatically refills non-controlled prescription medications, that have existing refills available and are consistent with the patient's current medication therapy only when the following conditions are met:

(a) A patient or patient's agent must enroll each prescription medication in an auto-refill program before a pharmacy can include the prescription medication as part of the auto-refill program;

(b) The prescription is not a controlled substance;

(c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or patient's agent;

(d) Pick-up notification to a patient or patient's agent may be generated upon completion of a prescription refill; and

(e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription medication is removed from the auto-refill program for that patient.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-141-0320
Prescription: Expiration

This section of rule addresses the expiration date of the prescription and not the expiration date of the drug.

(1) After one year from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber.

(2) When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled substance means that the medication can be refilled in proper context for a period of one year.

(a) When this abbreviation is used alone as a means to authorize refills for a controlled substance, the medication can be refilled in proper context for a period of six months or five refills, whichever comes first.

(b) When this abbreviation is used in conjunction with a definite time period, or a specific number of refills, the non-controlled medication can be refilled in proper context for a period not to exceed one year.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-141-0325
Prescription: Transfers

(1) Prescriptions may be transferred between pharmacies for the purpose of an initial or refill dispensing provided that:

- NOTE: In rulemaking- Divisions 041/139 - related to Permanent Pharmacy Closure Requirements

(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 compromise patient safety or violate state or federal laws or rules; and

(b) By the end of the next business day of the request.

- NOTE: In rulemaking- Divisions 041/139 - related to Permanent Pharmacy Closure Requirements

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

855-141-0345
Dispensing: General Requirements

The PPK Affiliated Pharmacy must:

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

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0350
Dispensing: Containers

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

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

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

855-141-0400
Labeling: General Requirements

Prescriptions must be labeled with the following information:

(1) Name and address of the PPK.

(2) Date;

(3) Identifying number;

(4) Name of patient;

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

(6) Directions for use by the patient;

(7) Name of practitioner;

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

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

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

(11) Name, address and telephone number of the PPK Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505 & ORS 689.515

855-141-0405
Labeling: Prescription Reader Accessibility

(1) A PPK must notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request; a prescription reader is a device designed to audibly convey labeling information.

(2) If a person informs the PPK Affiliated Pharmacy that the person identifies as a person who is blind, the pharmacy must provide to the person a prescription reader that is available to the person for at least the duration of the prescription, must confirm it is appropriate to address the person's visual impairment, and must ensure that prescription labels are compatible with the prescription reader.

This requirement does not apply to an institutional drug outlet, dispensing a drug intended for administration by a healthcare provider.

(3) The PPK Affiliated Pharmacy must ensure an Oregon licensed Pharmacist verifies and documents that the correct electronic label was placed on each prescription container and that the audio information produced by the prescription reader is accurate prior to dispensing the prescription.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.561

855-141-0410
Labeling: Limited English Proficiency and Accessibility

(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide labels and informational inserts in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

855-141-0450
Drugs and Devices: Disposal

Drugs and devices that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155

855-141-0455
Drug and Devices: Return

A PPK or PPK Affiliated Pharmacy 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 PPK 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

855-141-0500
Policies and Procedures

(1) The Oregon licensed PIC of the PPK Affiliated Pharmacy and the PPK Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the PPK. The written policies and procedures must be maintained at the PPK 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 PPK Affiliated Pharmacy and each PPK including;

(a) Security;

(b) Operation, testing and maintenance of the telepharmacy system and the PPK;

(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 PPK;

(i) Documenting the identity, function, location, date and time of licensees engaging in telepharmacy and licensed personnel accessing the PPK;

(j) Utilization of Interns, Certified Oregon Pharmacy Technicians or Pharmacy Technicians;

(k) Utilization of Oregon licensed Pharmacist (e.g. Counseling);

(l) Drug and/or device procurement

(m) Receiving of drugs and/or devices;

(n) Delivery of drugs and/or devices;

(o) Recordkeeping;

(p) Patient confidentiality;

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

(r) Continuous quality improvement;

(s) Plan for discontinuing and recovering services if PPK disruption occurs;

(t) Training: initial and ongoing; and

(u) Interpretation, translation and prescription reader services.

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0550
Records: General Requirements

(1) The recordkeeping requirements OAR 855-141 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 PPK must be maintained by the PPK Affiliated Pharmacy.

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

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

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

(c) Telepharmacy system testing;

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

(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 PPK must include the:

(a) Physical location of the PPK;

(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 PPK 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

855-141-0555
Records: Patient

A patient record system must be maintained by the PPK Affiliated Pharmacy 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;

- NOTE: In rulemaking- Divisions 019/041/139 - related to Interpreters

(6) Chronic medical conditions;

(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;

(8) Known allergies, drug reactions, and drug idiosyncrasies; and

(9) If deemed relevant in the Oregon licensed Pharmacist's reasonable professional judgment:

- NOTE: In rulemaking- Divisions 019/041/139 - related to Interpreters

(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

855-141-0600
Prohibited Practices: General

A PPK may not:

(1) Allow unlicensed personnel, Certified Oregon Pharmacy Technicians or 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.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0602
Prohibited Practices: Disclosure of Patient Information

A PPK 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 (a)-(e) of this rule. A licensee may disclose patient information:

(a) To the board;

(b) To a practitioner, Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician or 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) 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 except as provided in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305 & ORS 689.315
Statutes/Other Implemented: ORS 689.155 & ORS 689.527

855-141-0650
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.

Statutory/Other Authority: ORS 689.151, ORS 689.155, ORS 689.205 & ORS 689.225
Statutes/Other Implemented: ORS 689.155, ORS 689.405 & ORS 689.527

JUNE 2022/ E

Safe Pharmacy Practice Conditions Survey

Final Results

Friday, April 15, 2022

2044

Total Responses

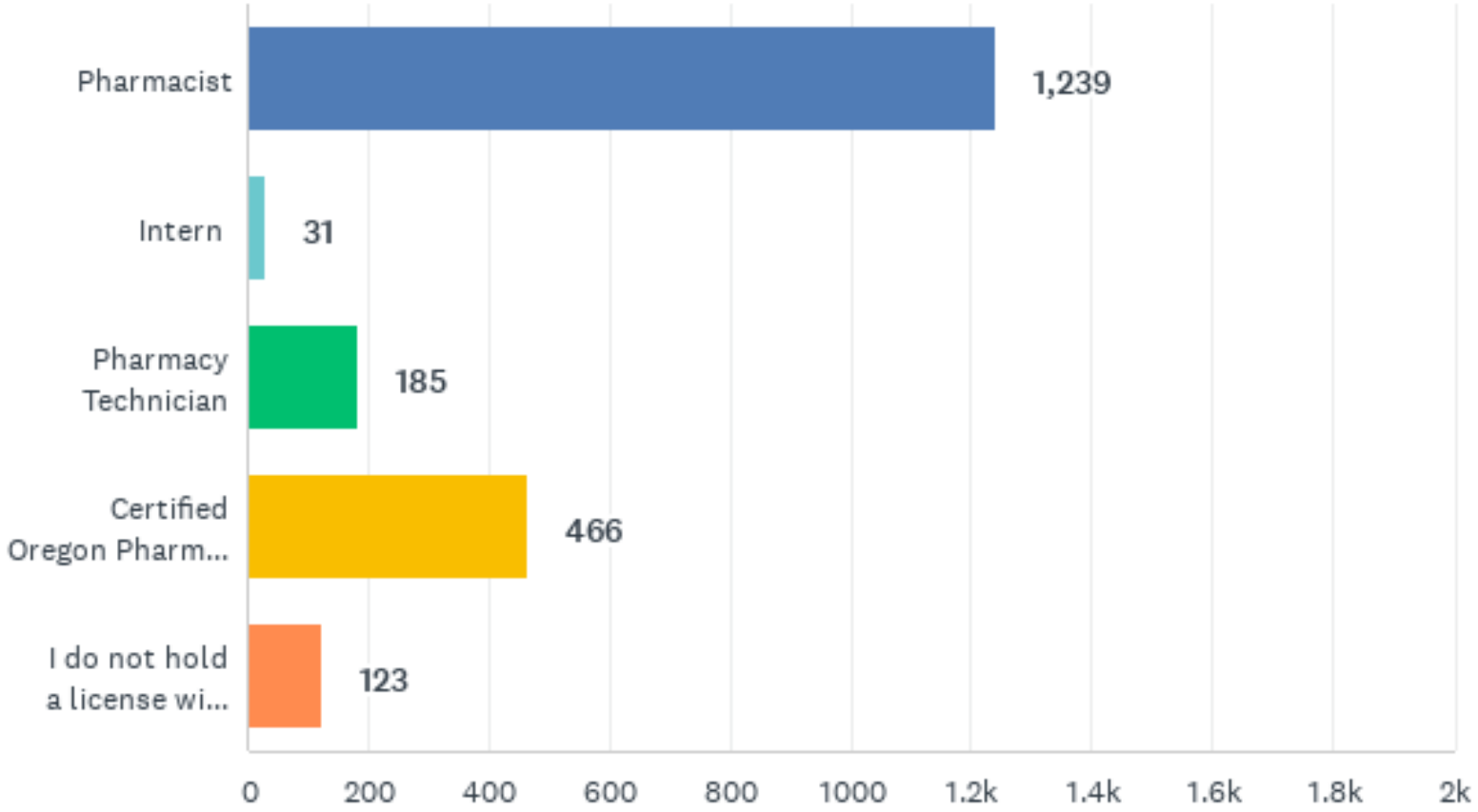
Date Opened: Wednesday, February 16, 2022

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



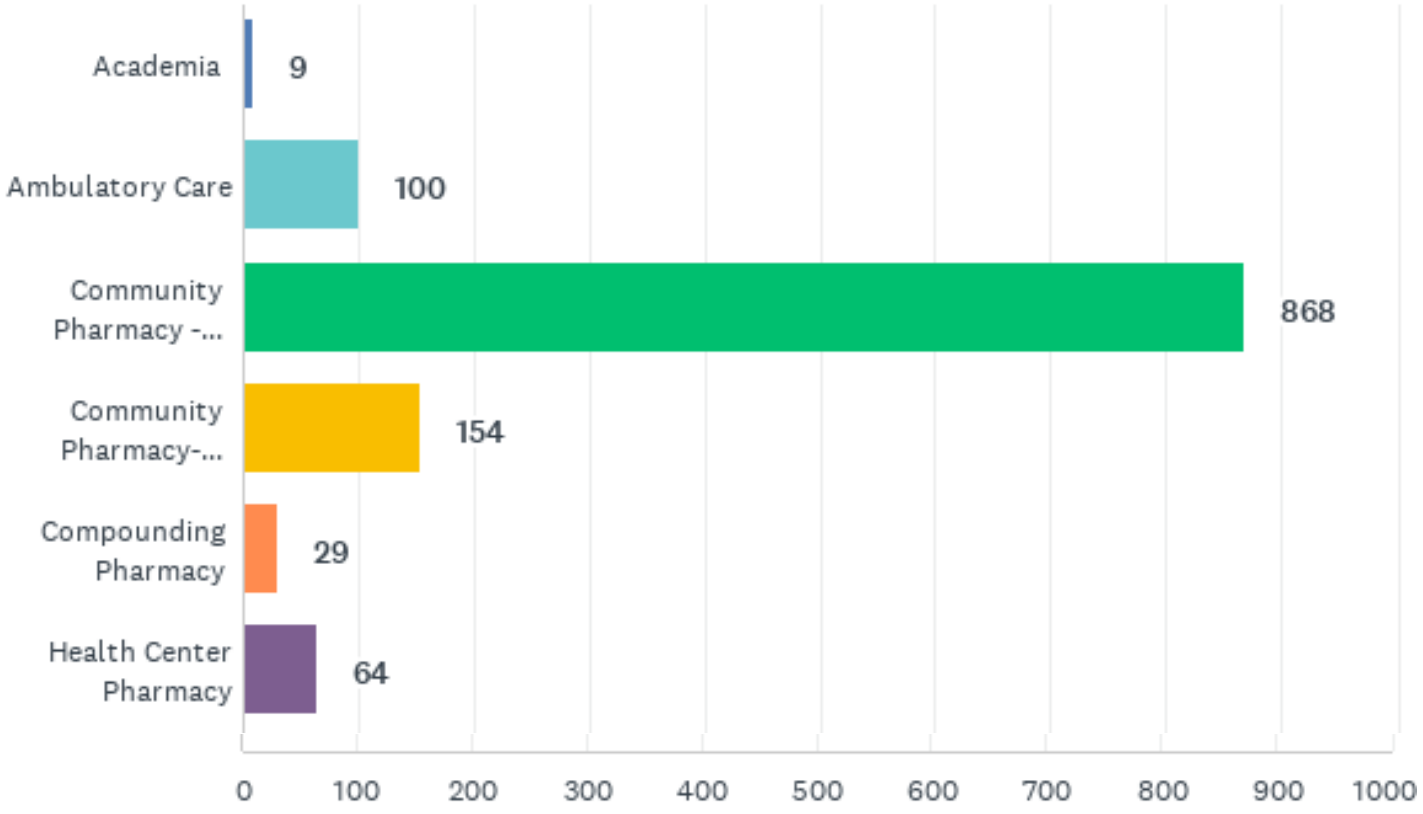
Q1: What type of license do you hold with the Oregon Board of Pharmacy?

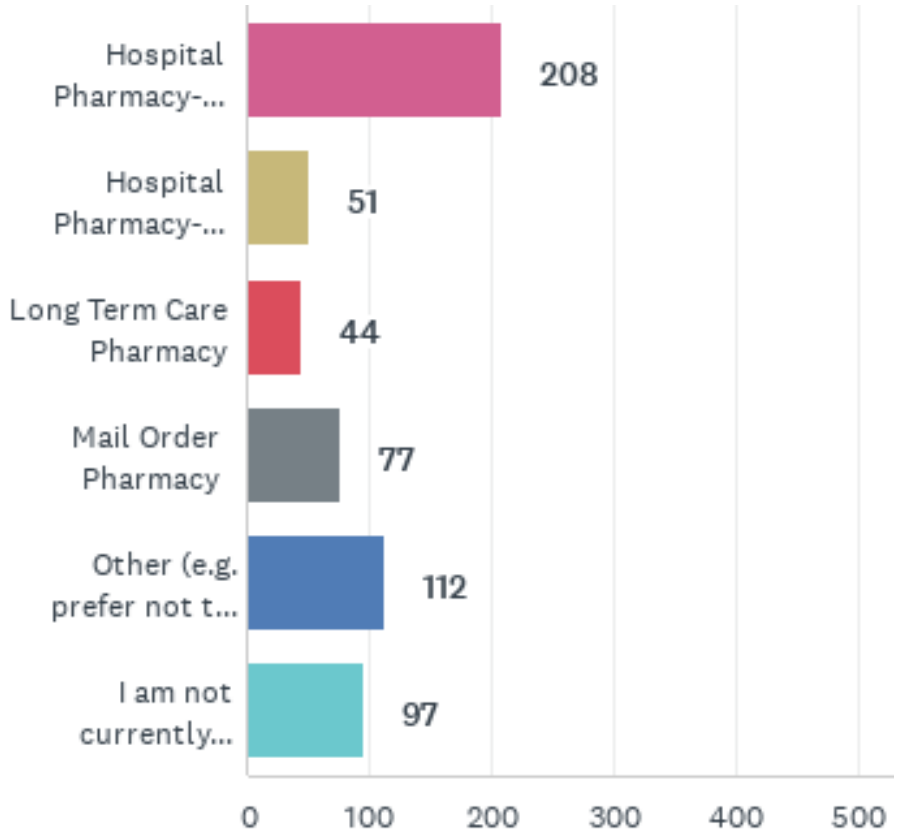
Answered: 2,044 Skipped: 0

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





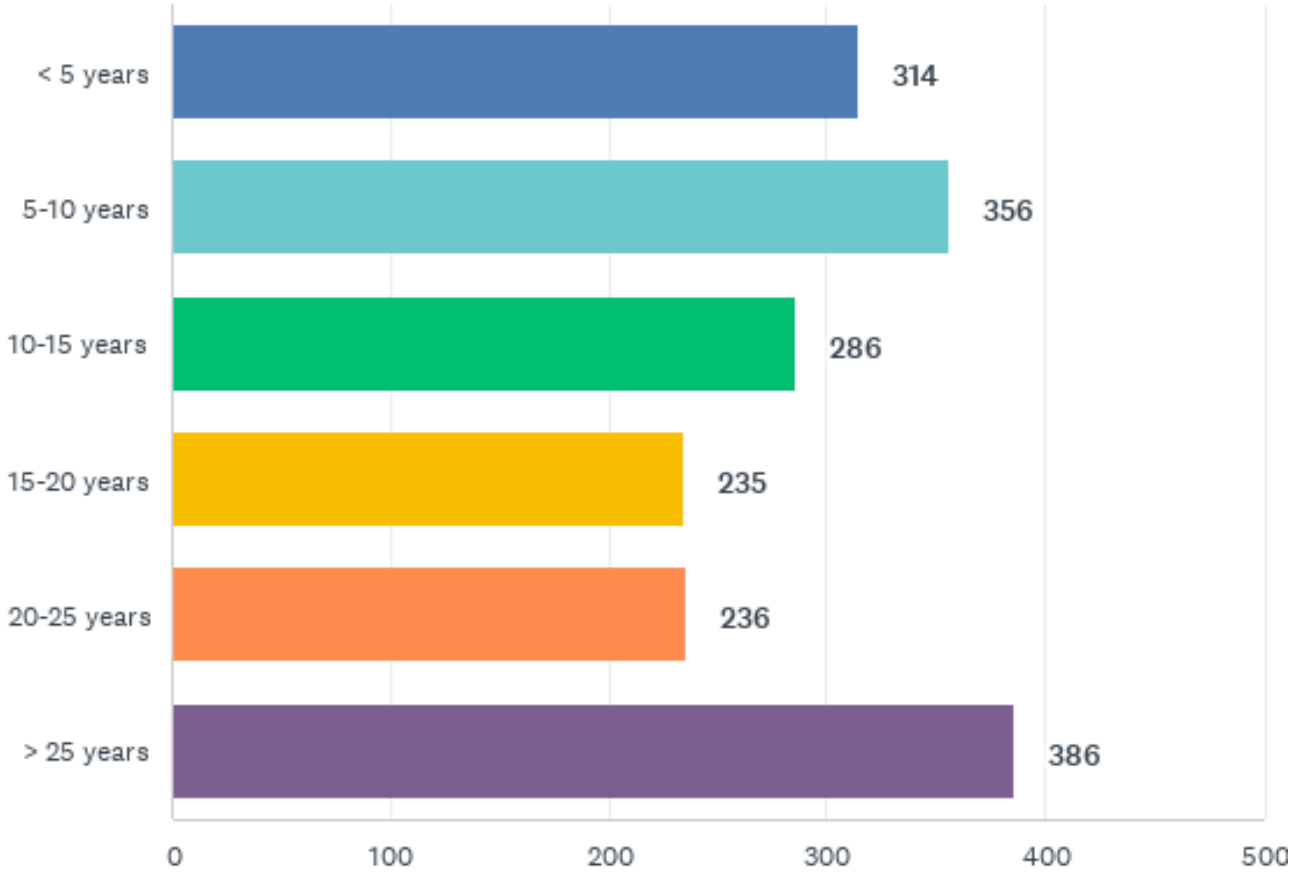
Q2: What is your primary pharmacy practice setting?NOTE: Students- Please select your primary pharmacy workplace outside of your IPPE/APPE. If you do not work outside of your required school IPPE/APPE, then please select "I am not currently working in/for a pharmacy"

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



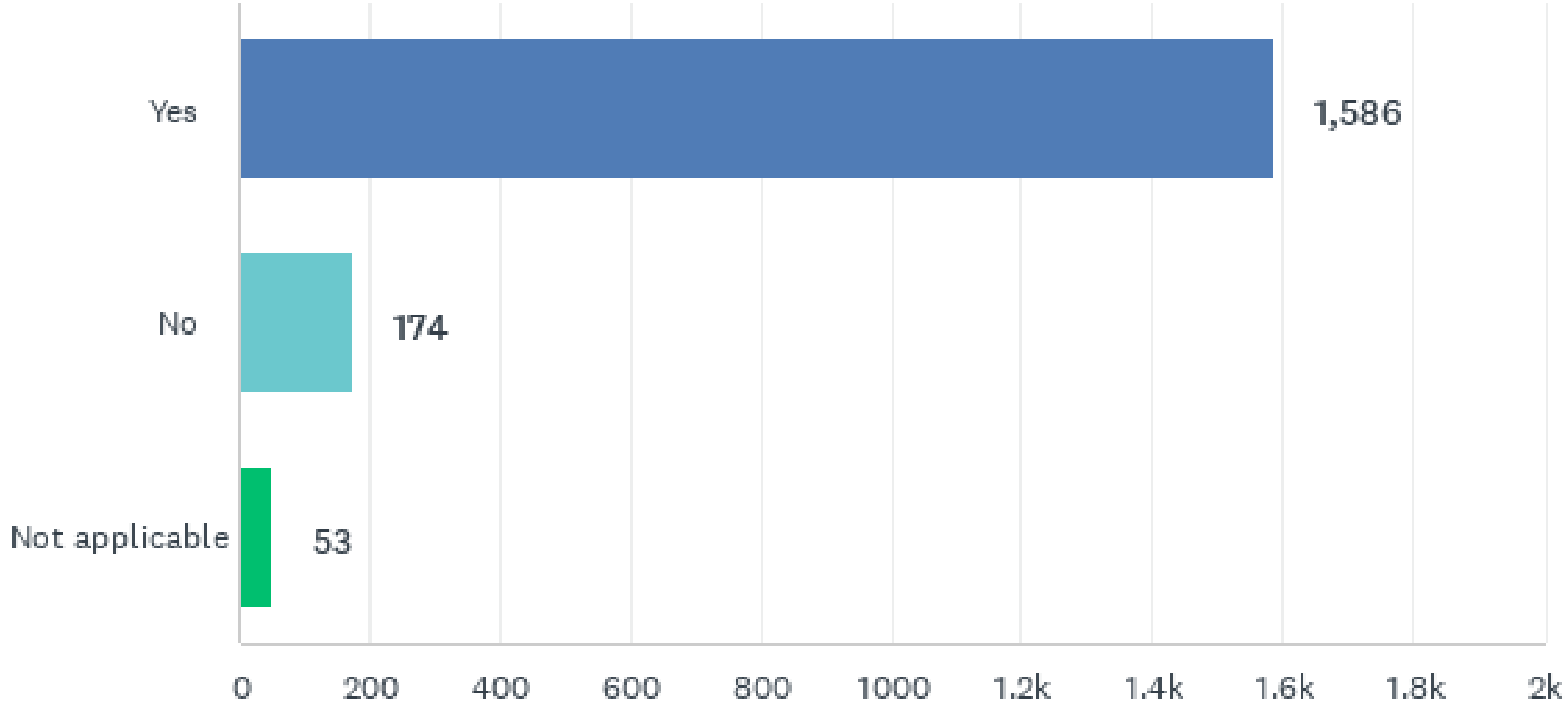
Q3: How many years have you practiced or assisted in the practice of pharmacy?

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



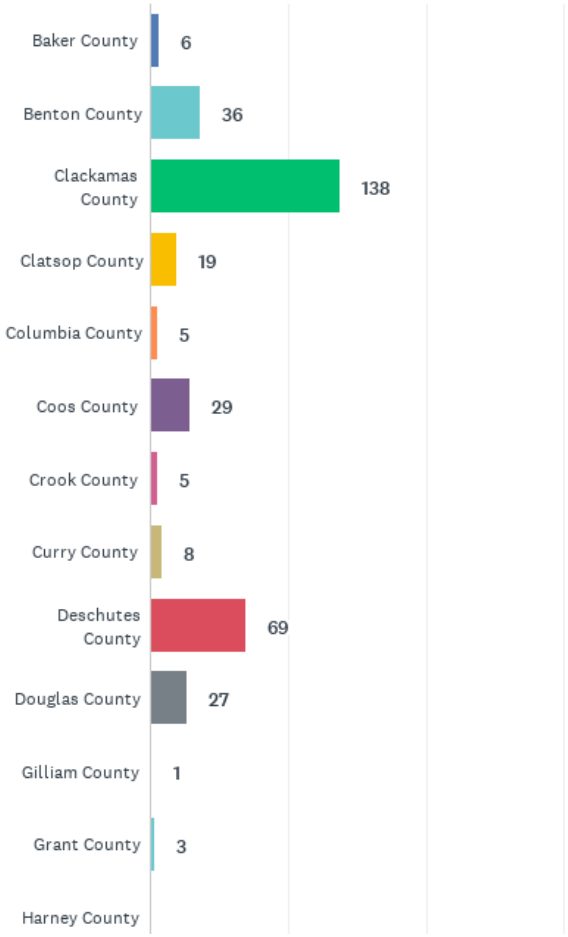
Q4: Is your primary practice setting located in Oregon?

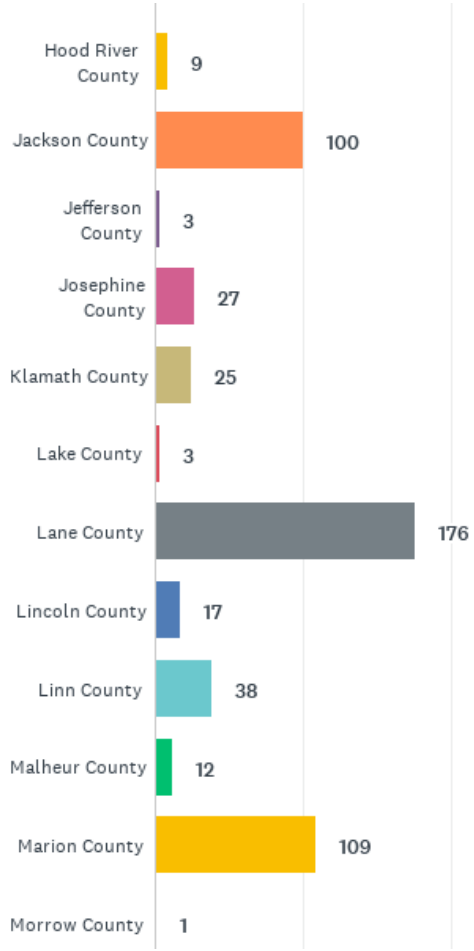
Answered: 1,813 Skipped: 231

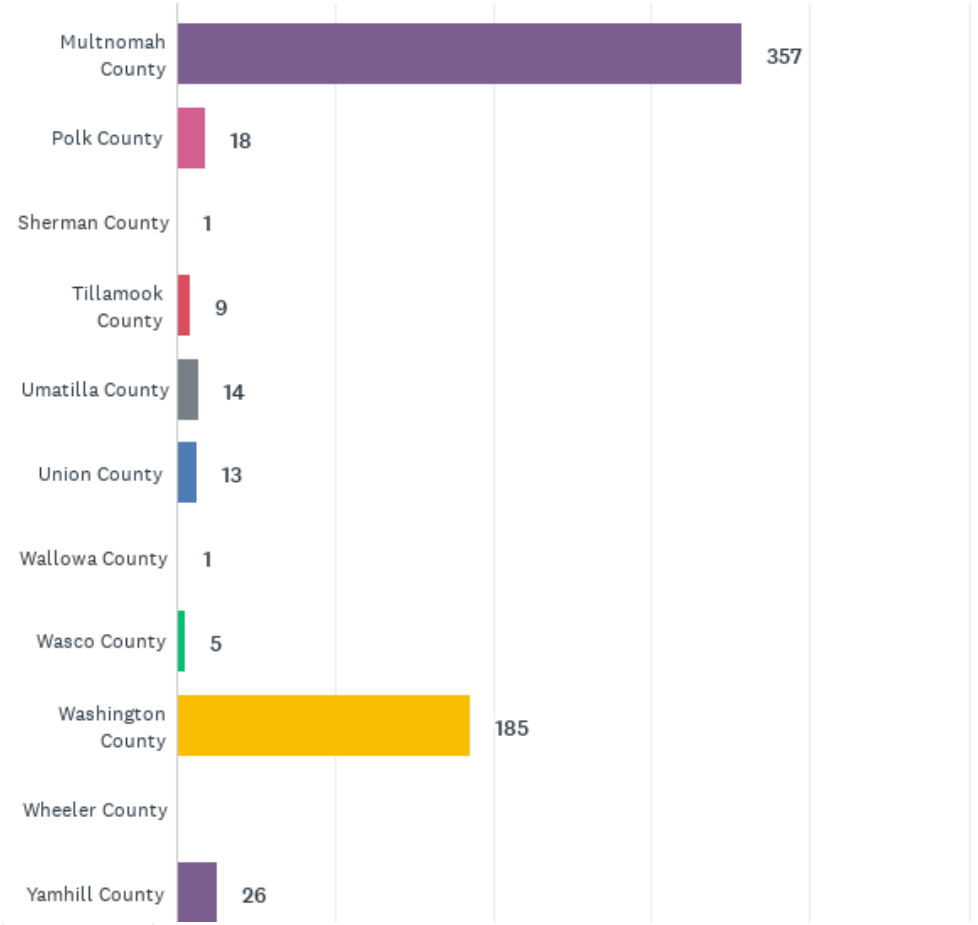
ANSWER CHOICES	RESPONSES	
Yes	87.48%	1,586
No	9.60%	174
Not applicable	2.92%	53
TOTAL		1,813

Q5: What county is your primary practice setting located?

Answered: 1,495 Skipped: 549







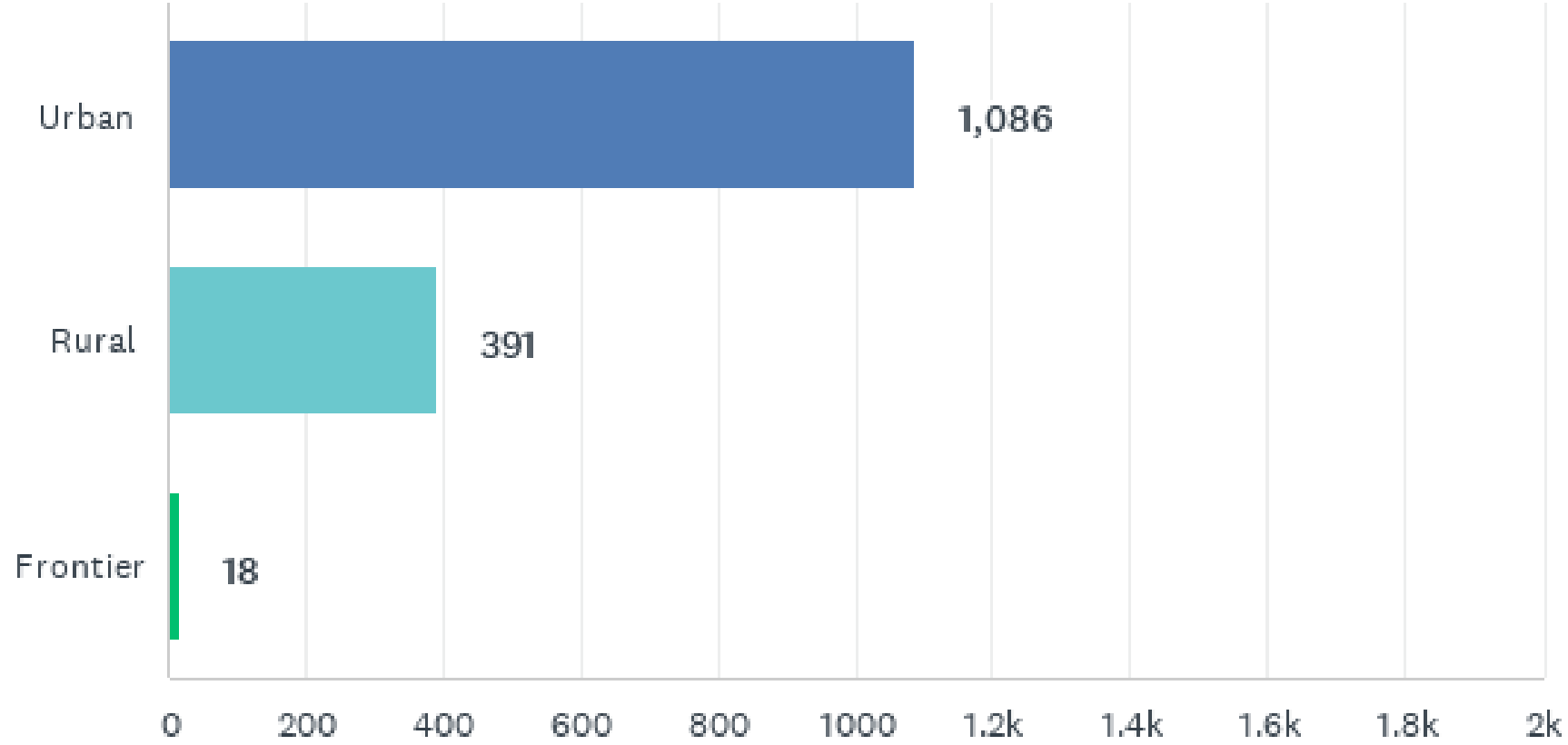
Q5: What county is your primary practice setting located?

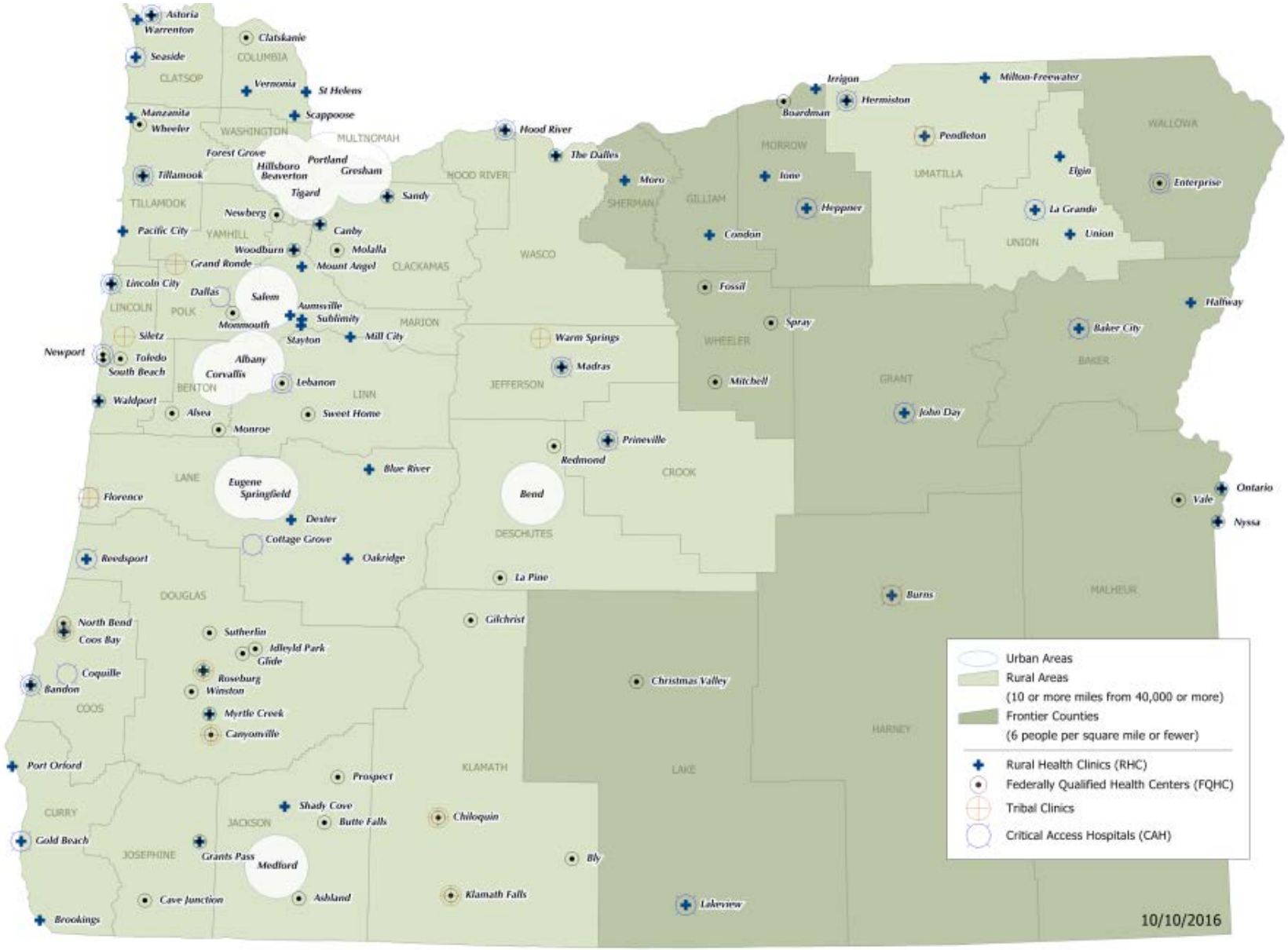
Answered: 1,495 Skipped: 549

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





Aging in Rural and Frontier Oregon. Oregon Office of Rural Health. Published September 2016. Accessed March 10, 2022. https://www.ohsu.edu/sites/default/files/2018-08/Aging%20in%20Rural%20and%20Frontier%20Oregon%202016.pdf

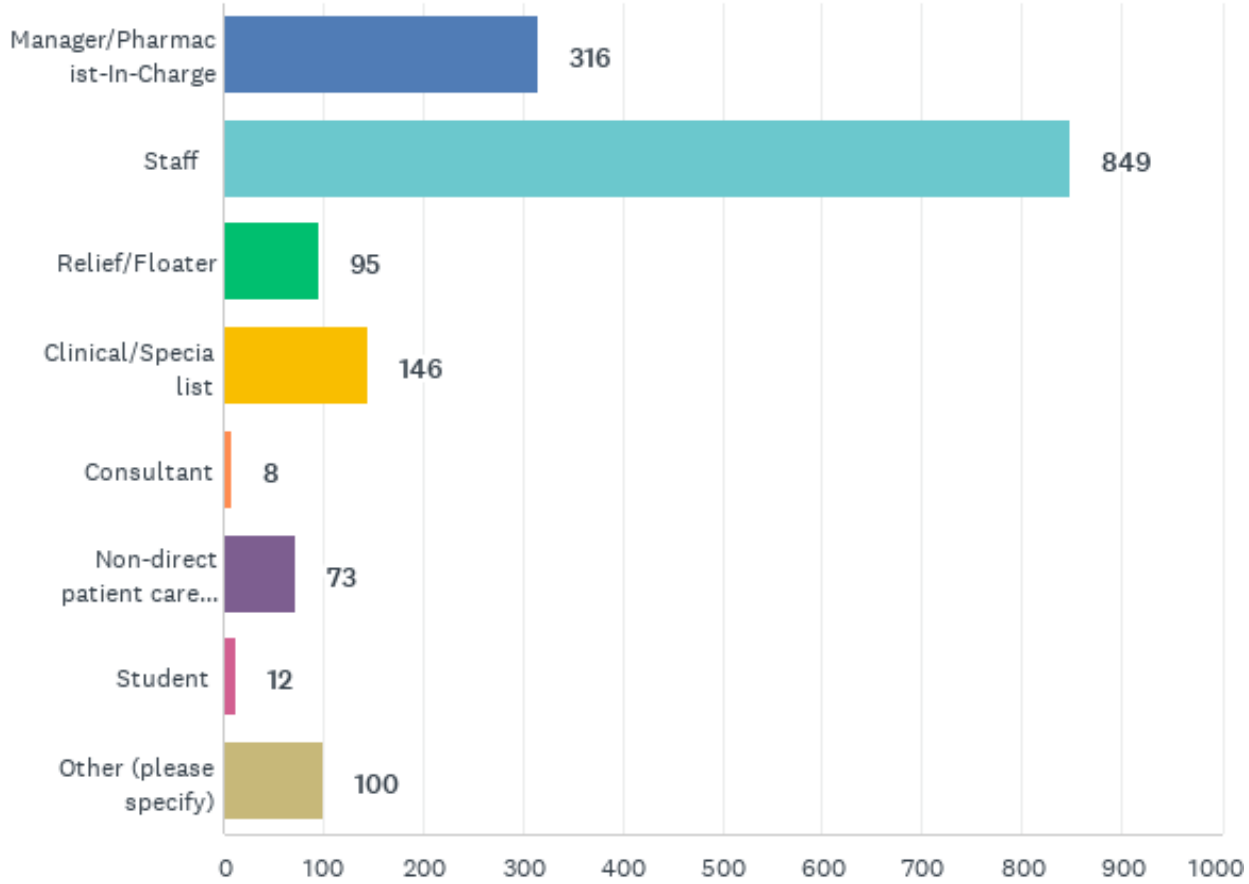
Q6: Before answering this question, please search for your practice site zip code here. Is your primary practice setting located in an urban, rural or frontier area?

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



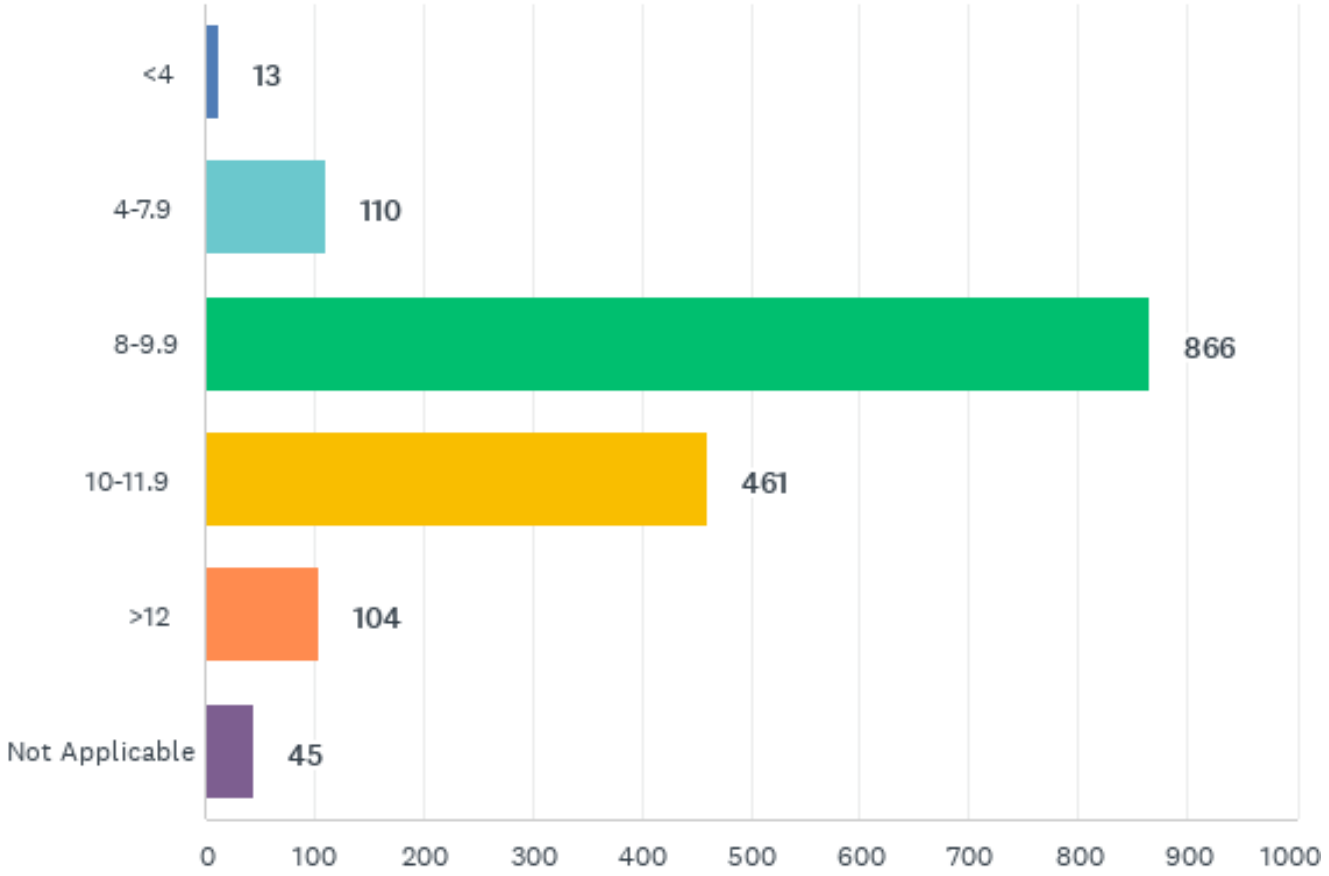
Q7: What is your primary role in your primary practice setting?

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



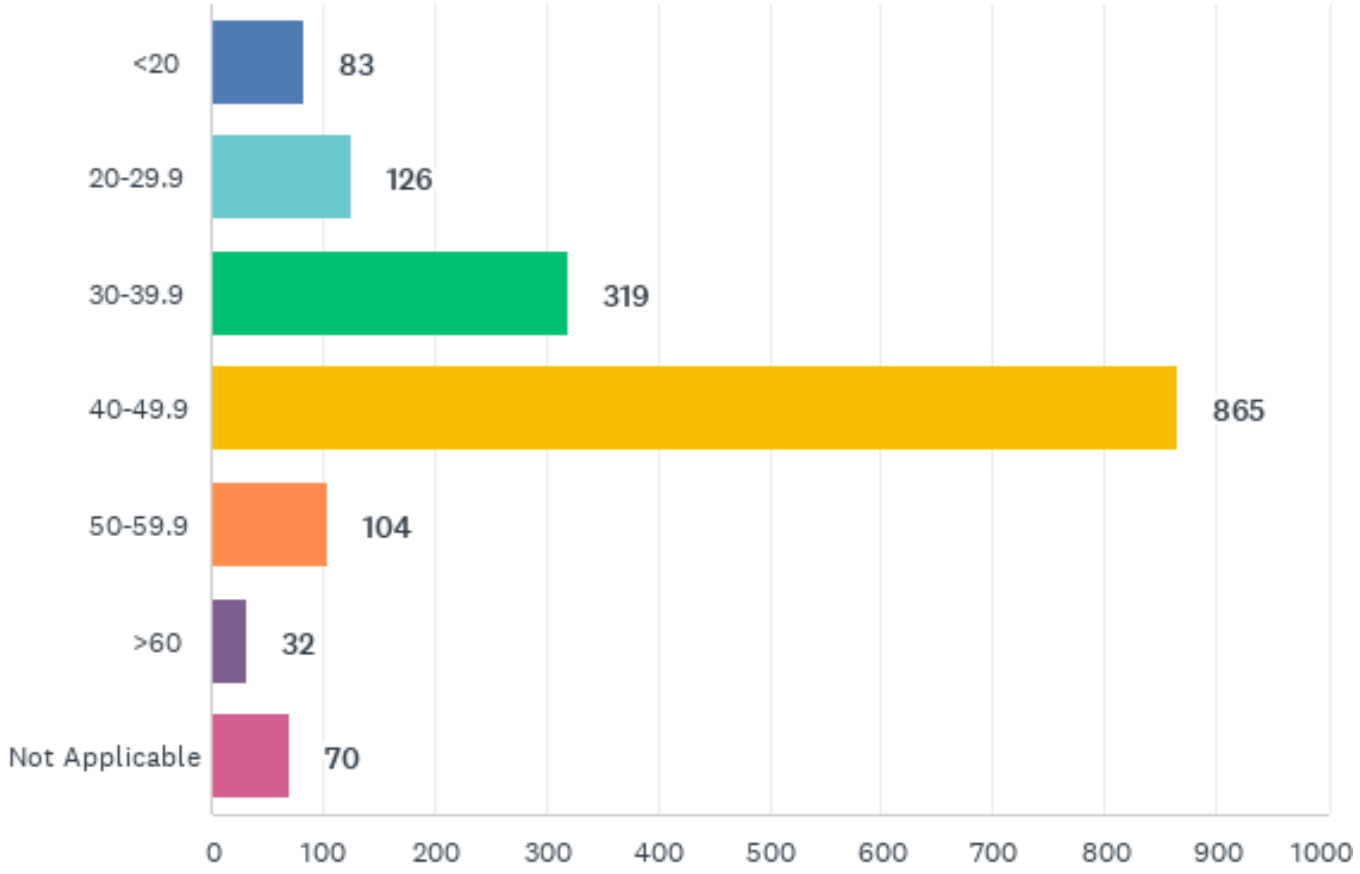
Q8: On average, how many hours do you work per shift?

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

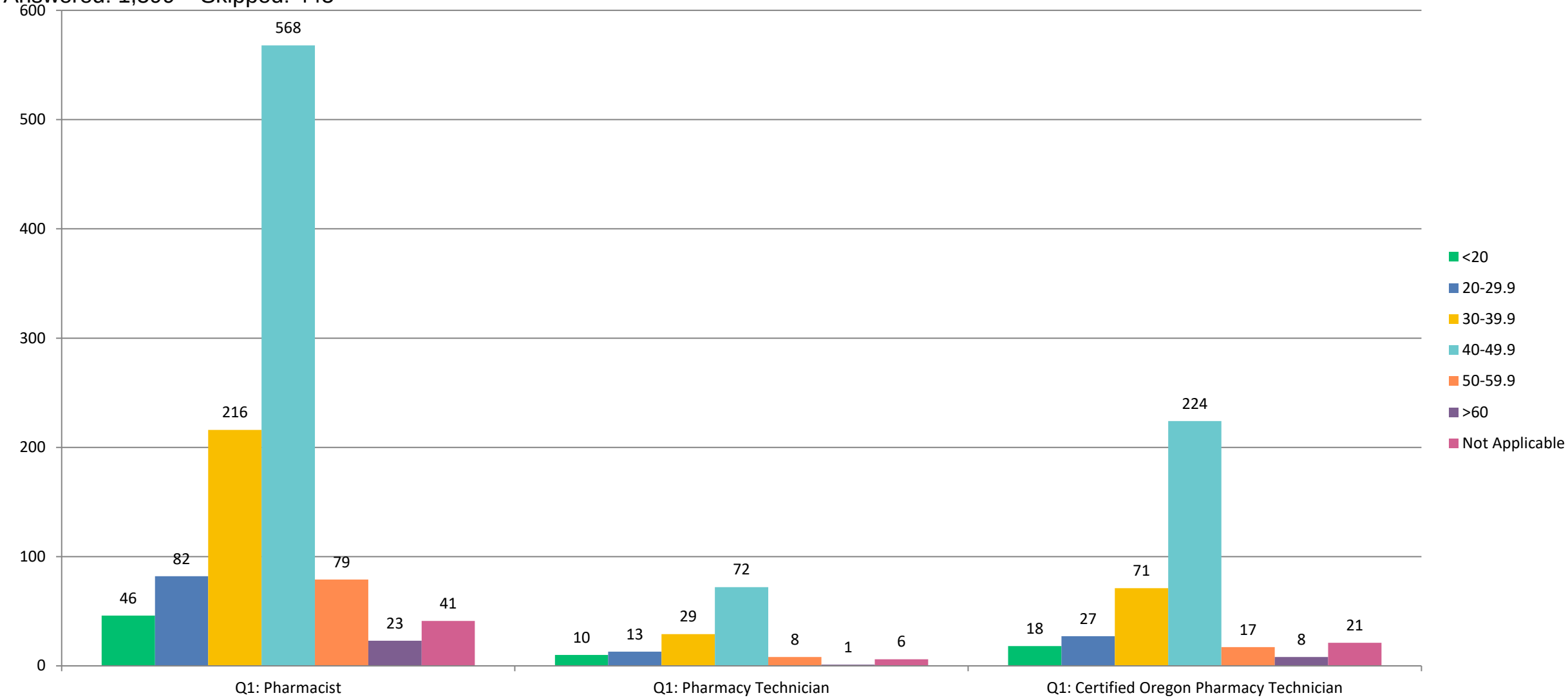
Q9: On average, how many hours do you work for a pharmacy per week?

Answered: 1,599 Skipped: 445



Q9: On average, how many hours do you work for a pharmacy per week?

Answered: 1,599 Skipped: 445



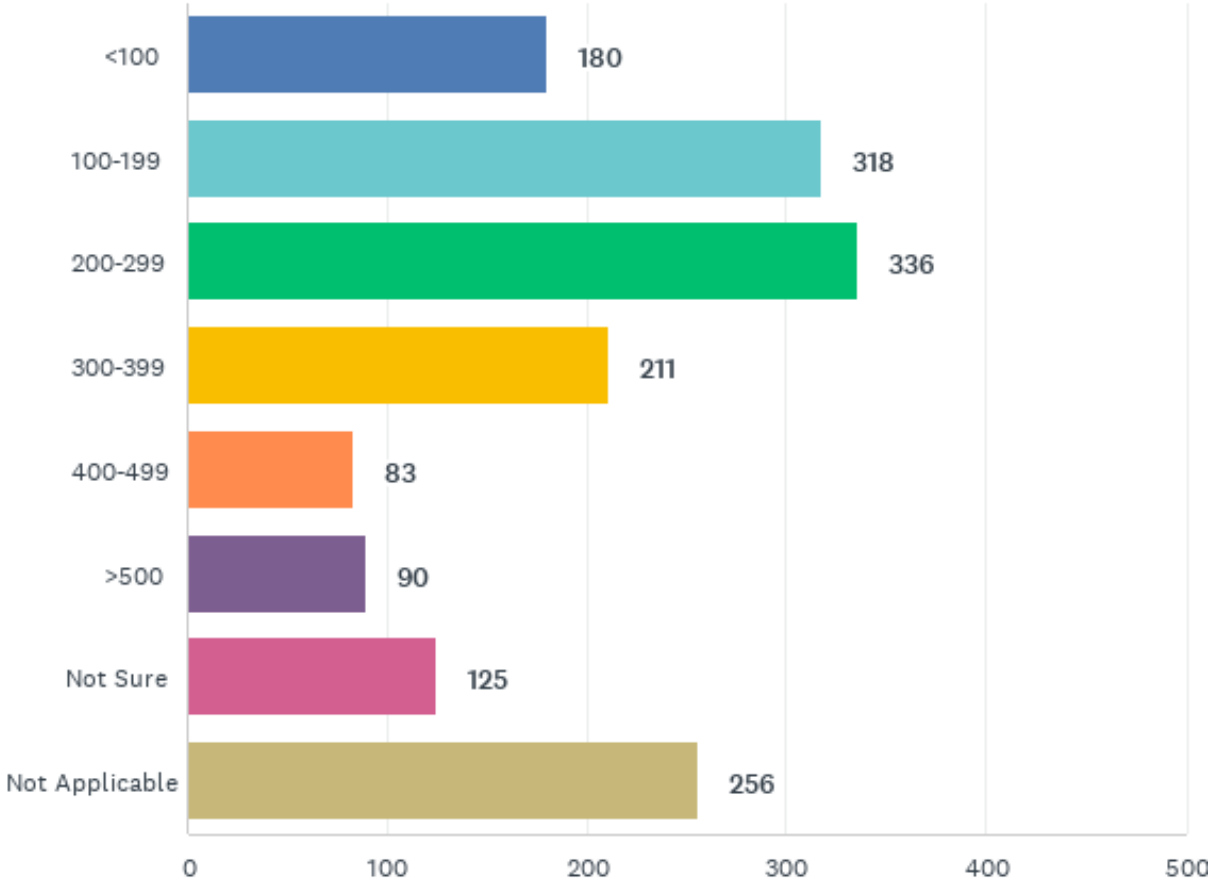
Q9: On average, how many hours do you work for a pharmacy per week?

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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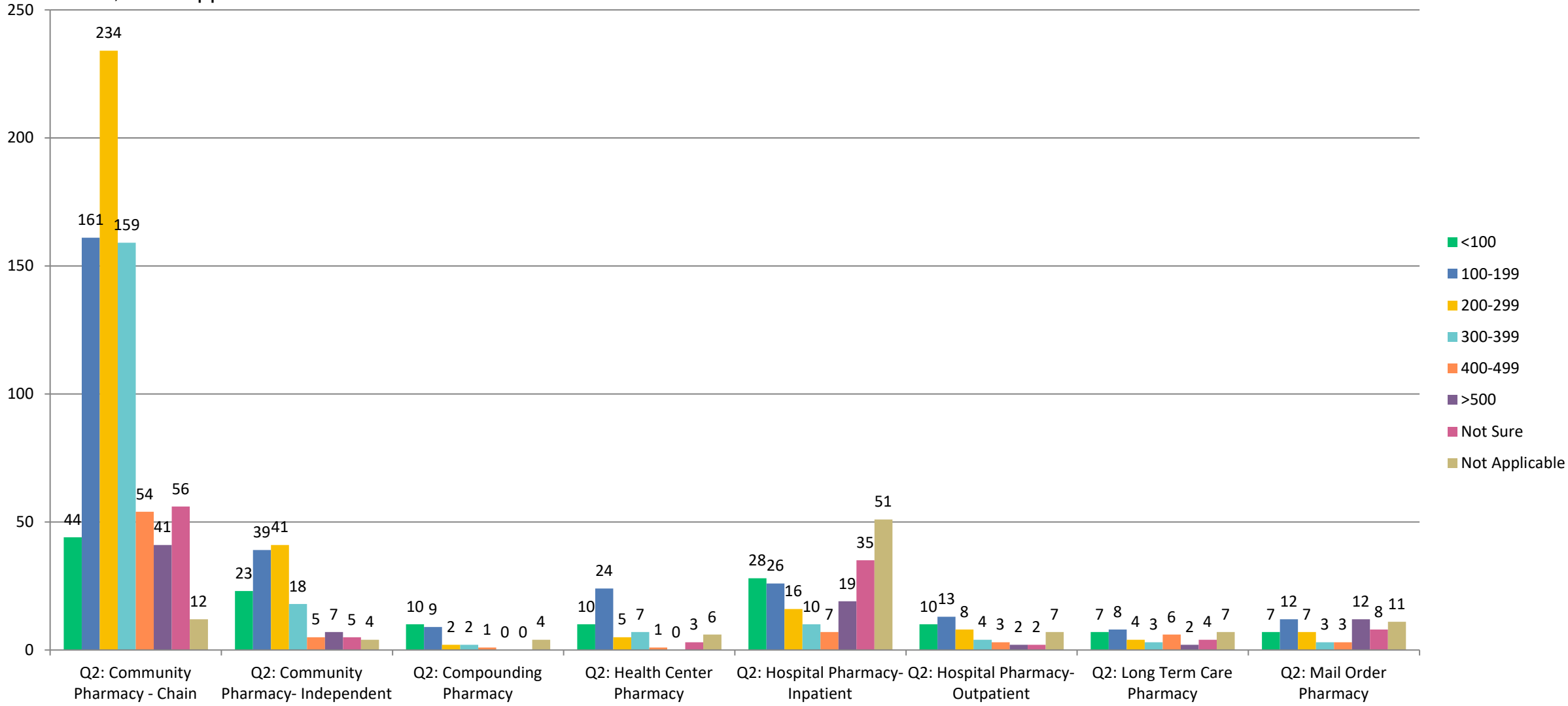
Answered: 1,599 Skipped: 445



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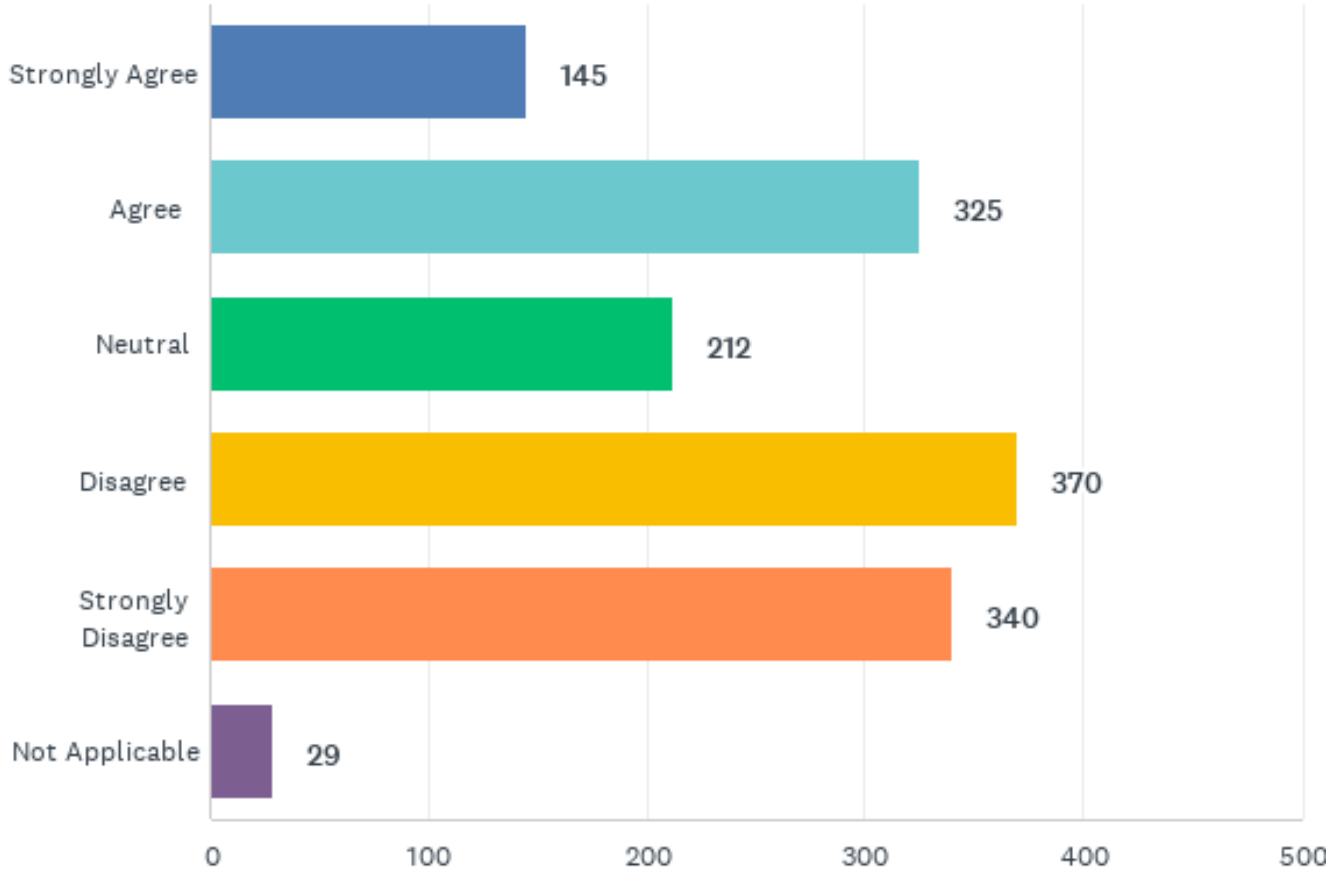
Answered: 1,599 Skipped: 445

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



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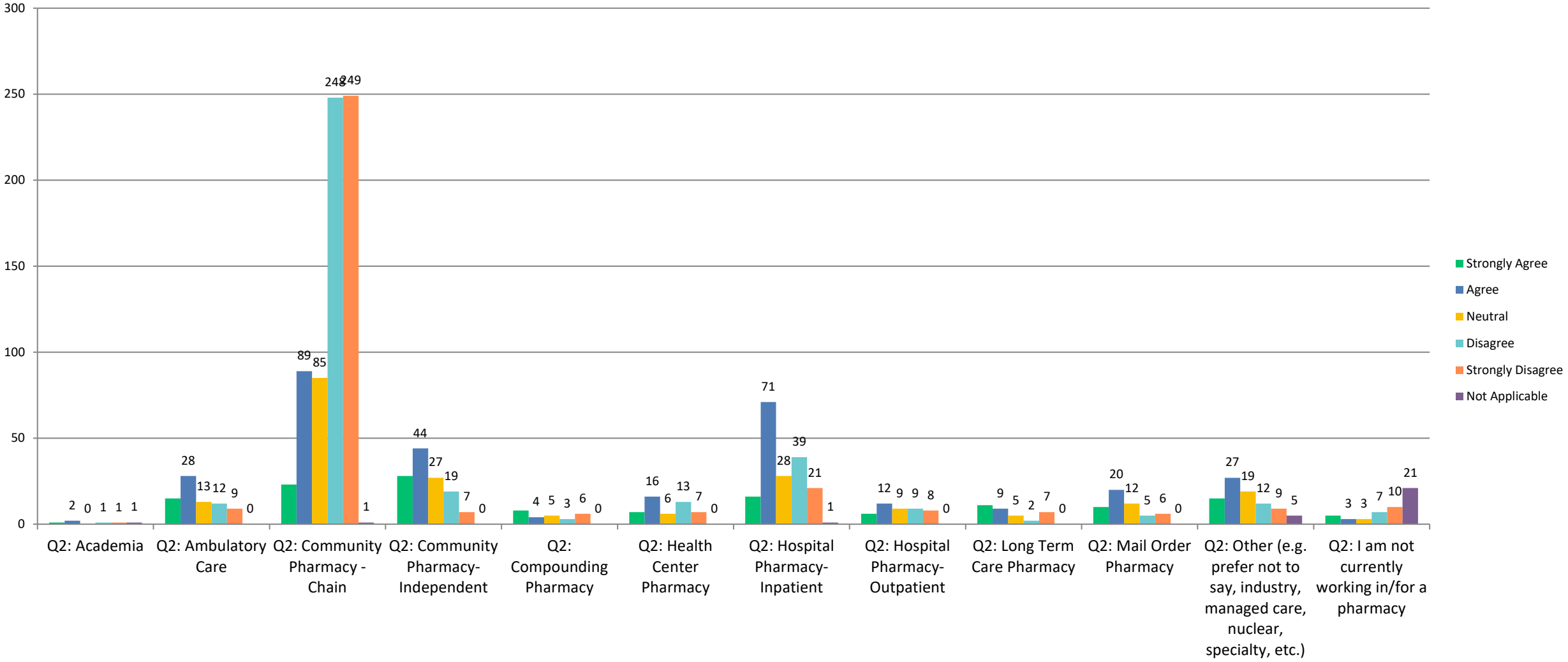
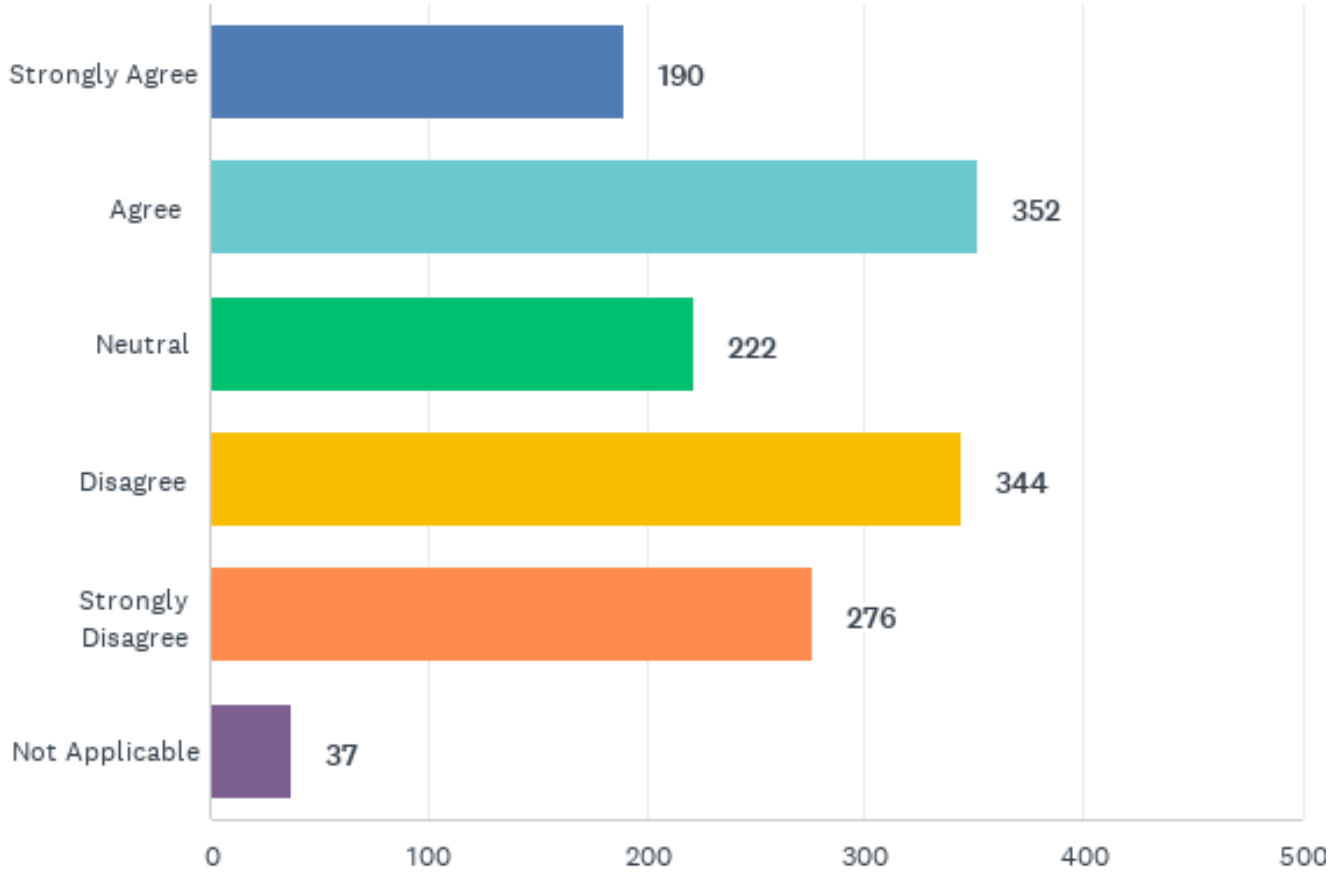


Q12: I feel that my employer provides a practice environment that allows for safe and effective patient care.

Answered: 1,421 Skipped: 623



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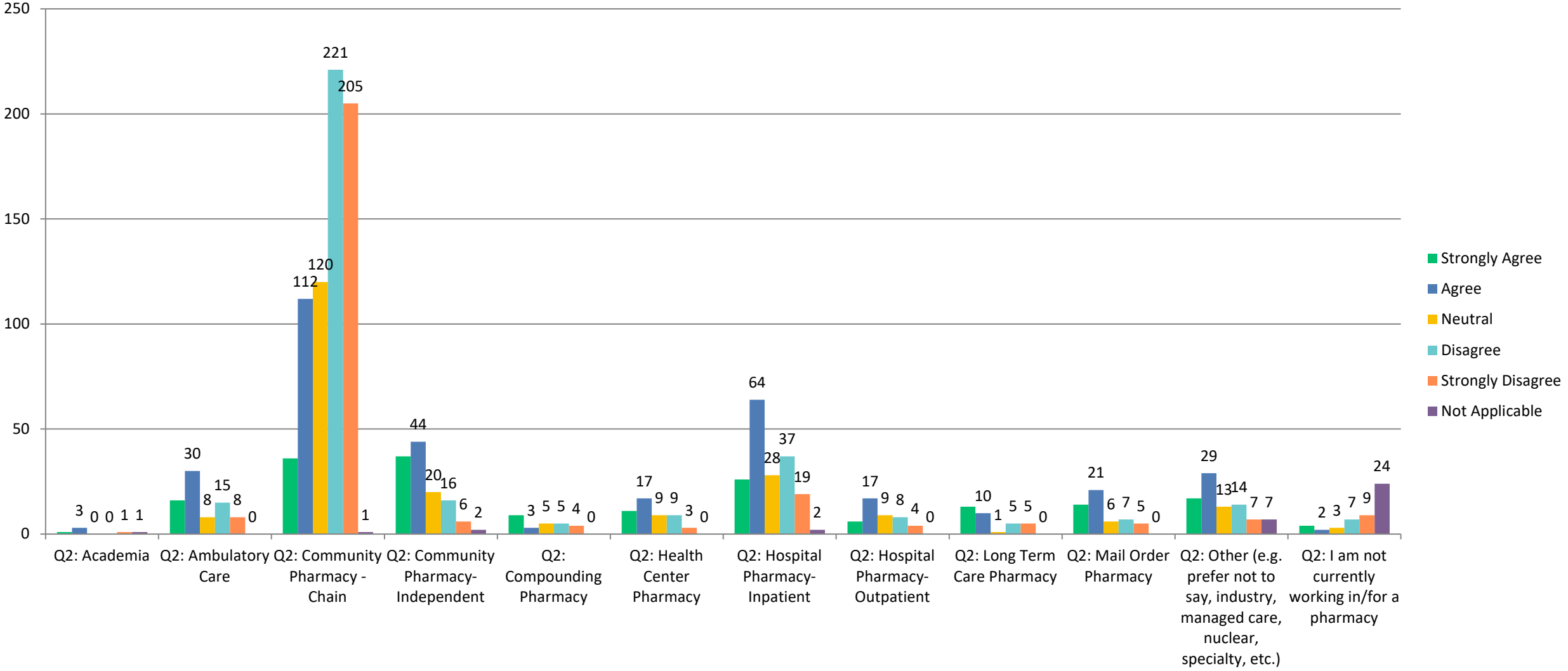
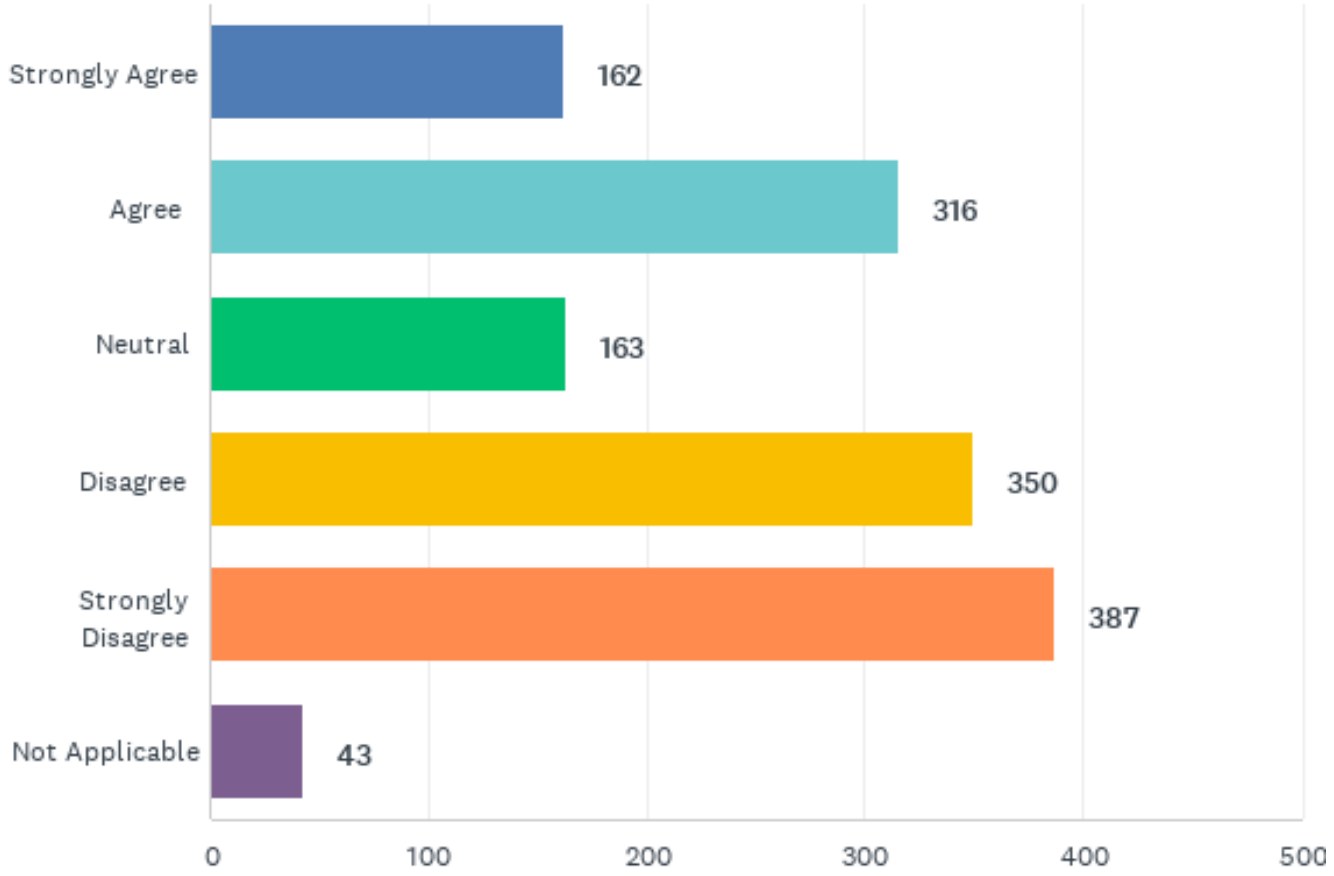


Q13: I feel that my practice environment utilizes sufficient pharmacist staffing that allows for safe, effective and timely patient care.

Answered: 1,421 Skipped: 623



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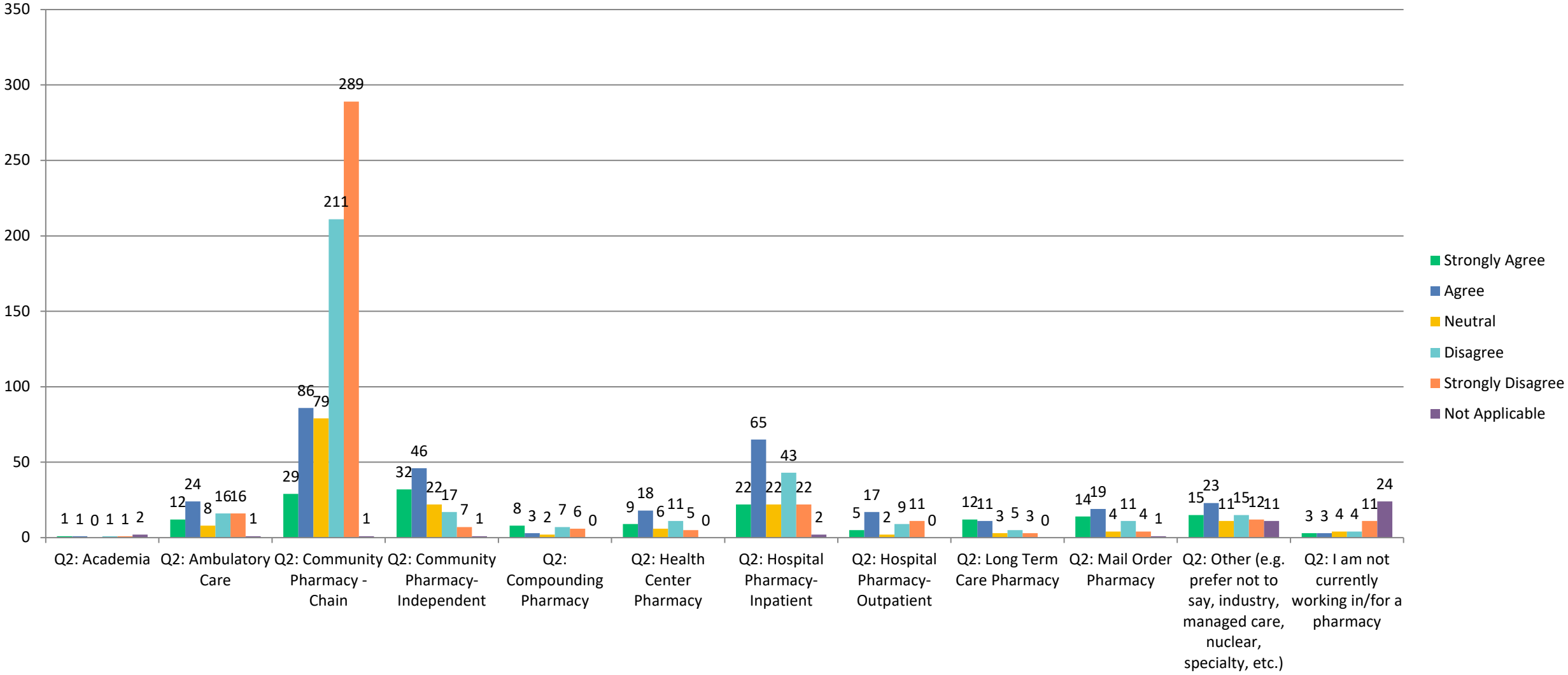
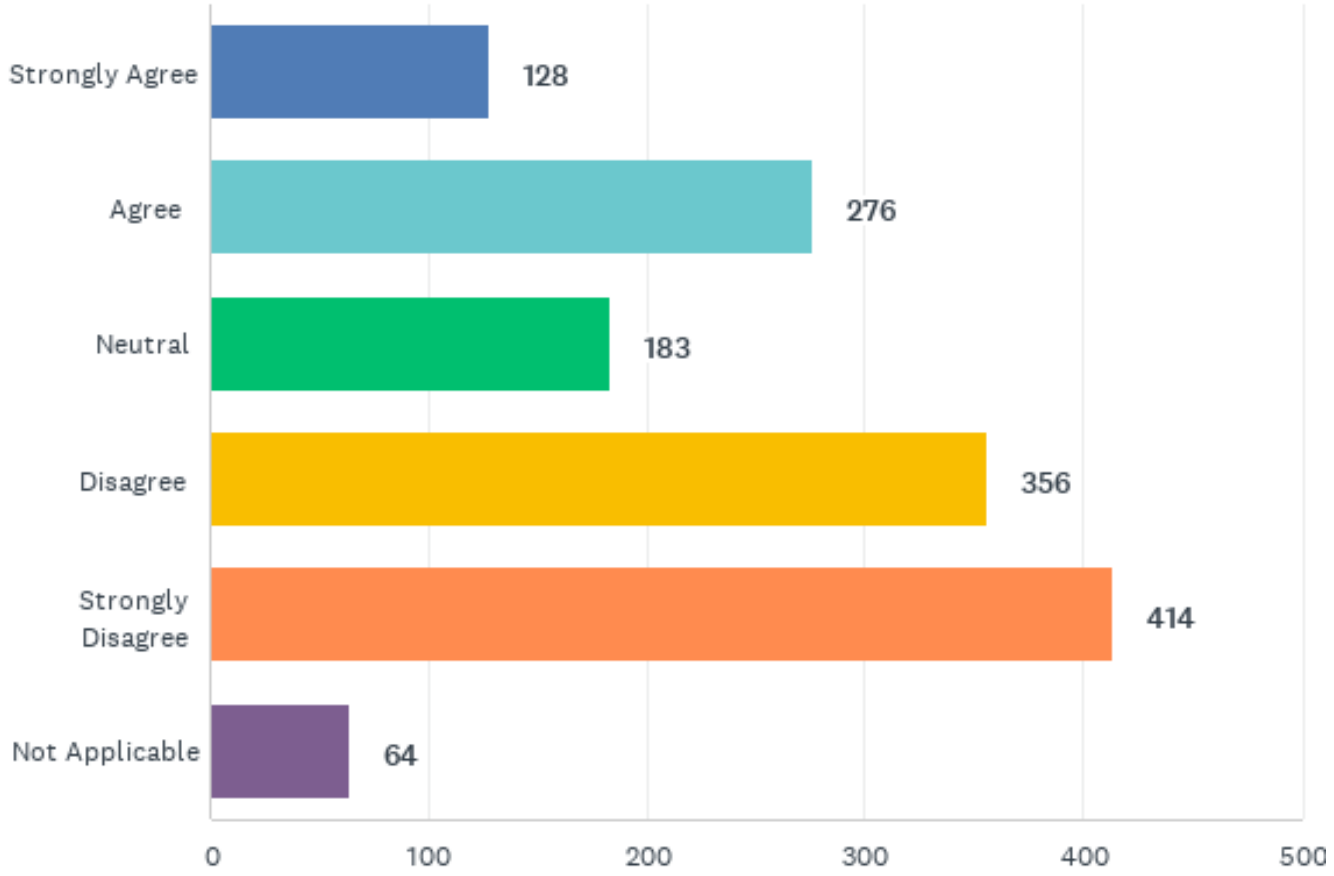


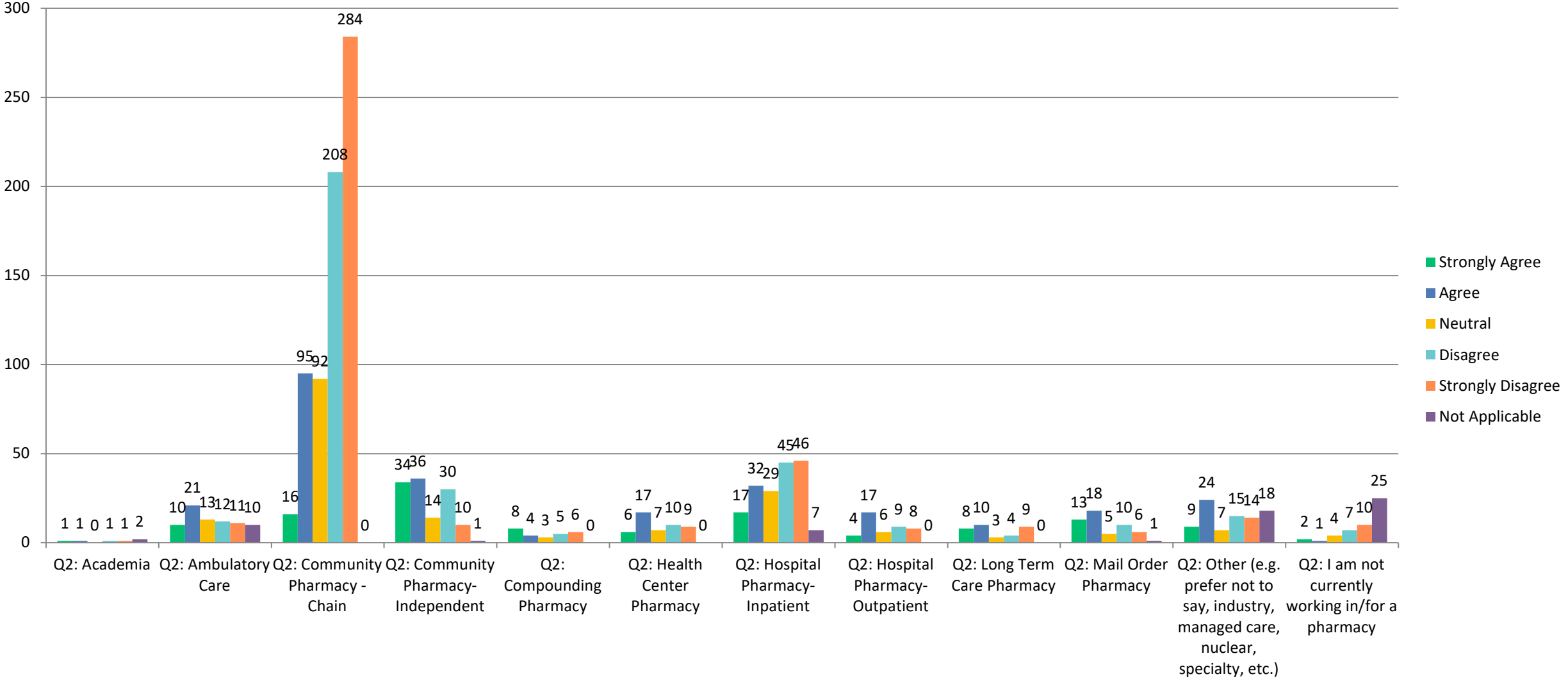
Q14: I feel that my practice environment utilizes sufficient pharmacy technician staffing that allows for safe and effective patient care

Answered: 1,421 Skipped: 623



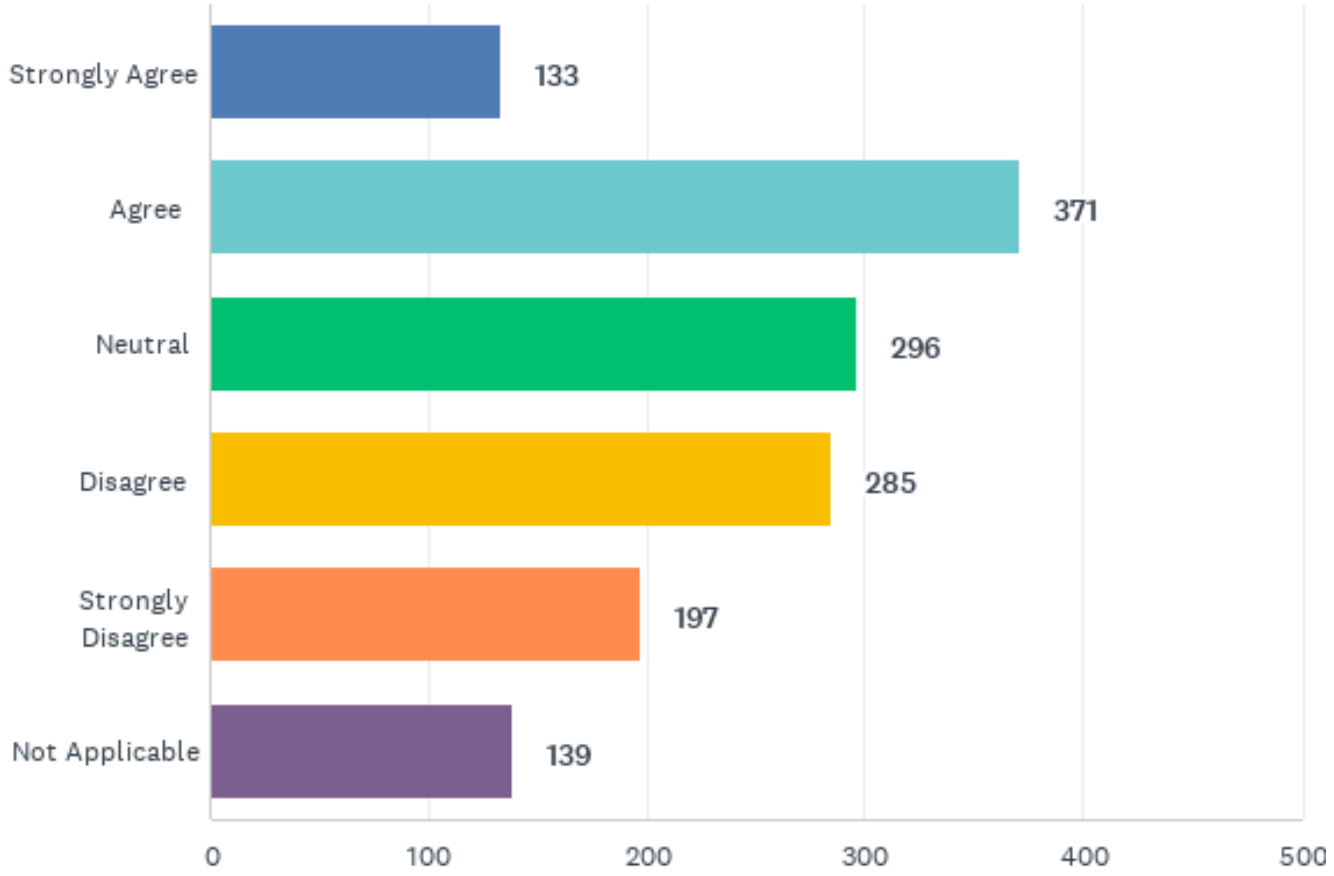
Q14: I feel that my practice environment utilizes sufficient pharmacy technician staffing that allows for safe and effective patient care

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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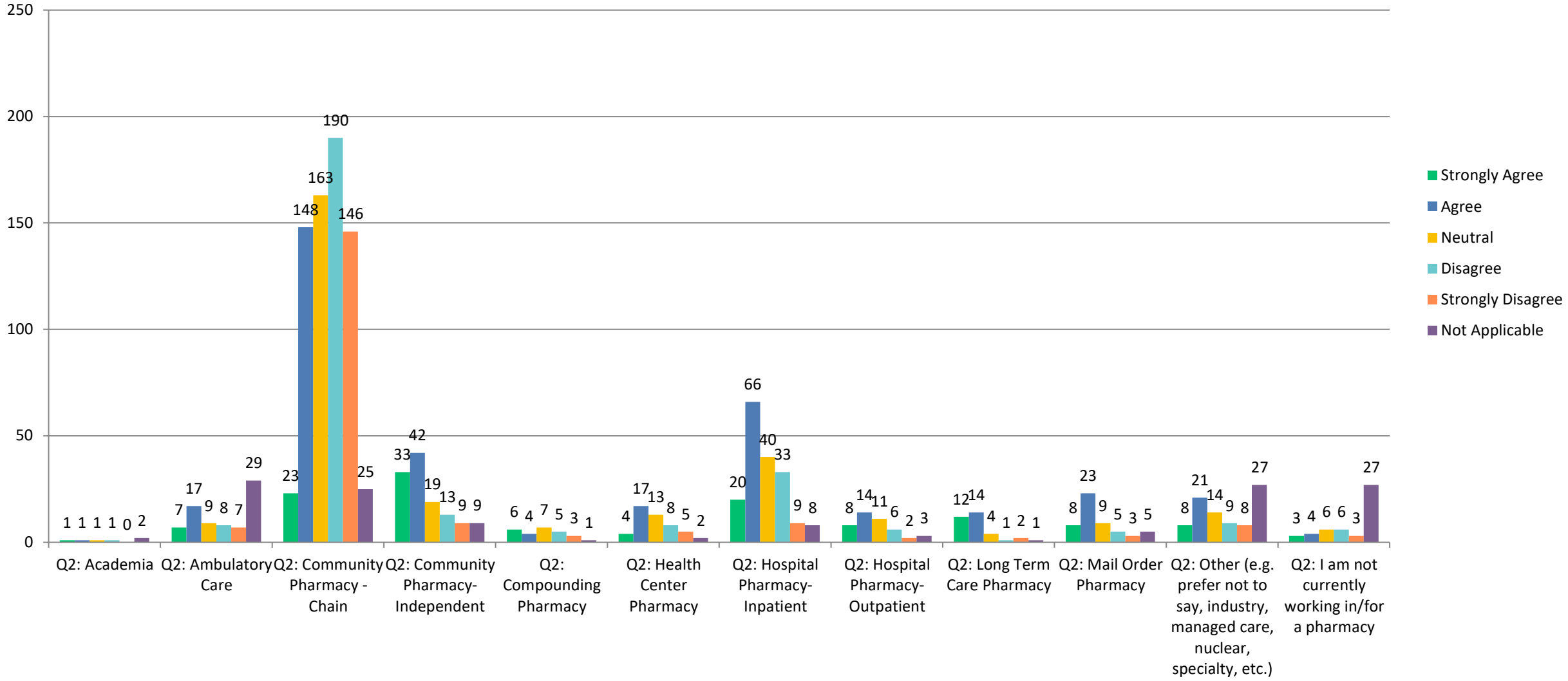
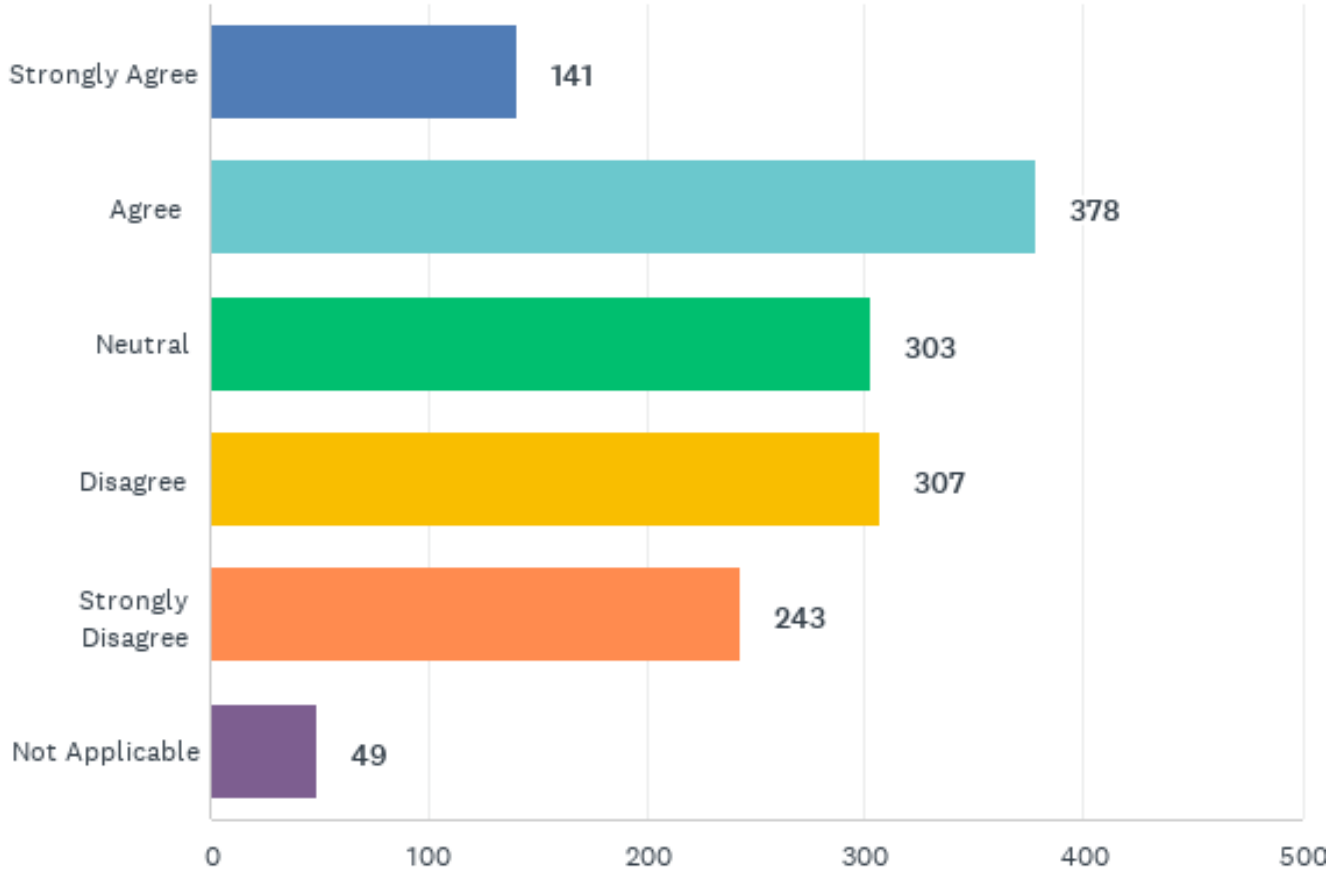


Q16: I feel that my practice environment utilizes staff training that is site-specific, thorough and prepares staff to provide safe and effective patient care.

Answered: 1,421 Skipped: 623



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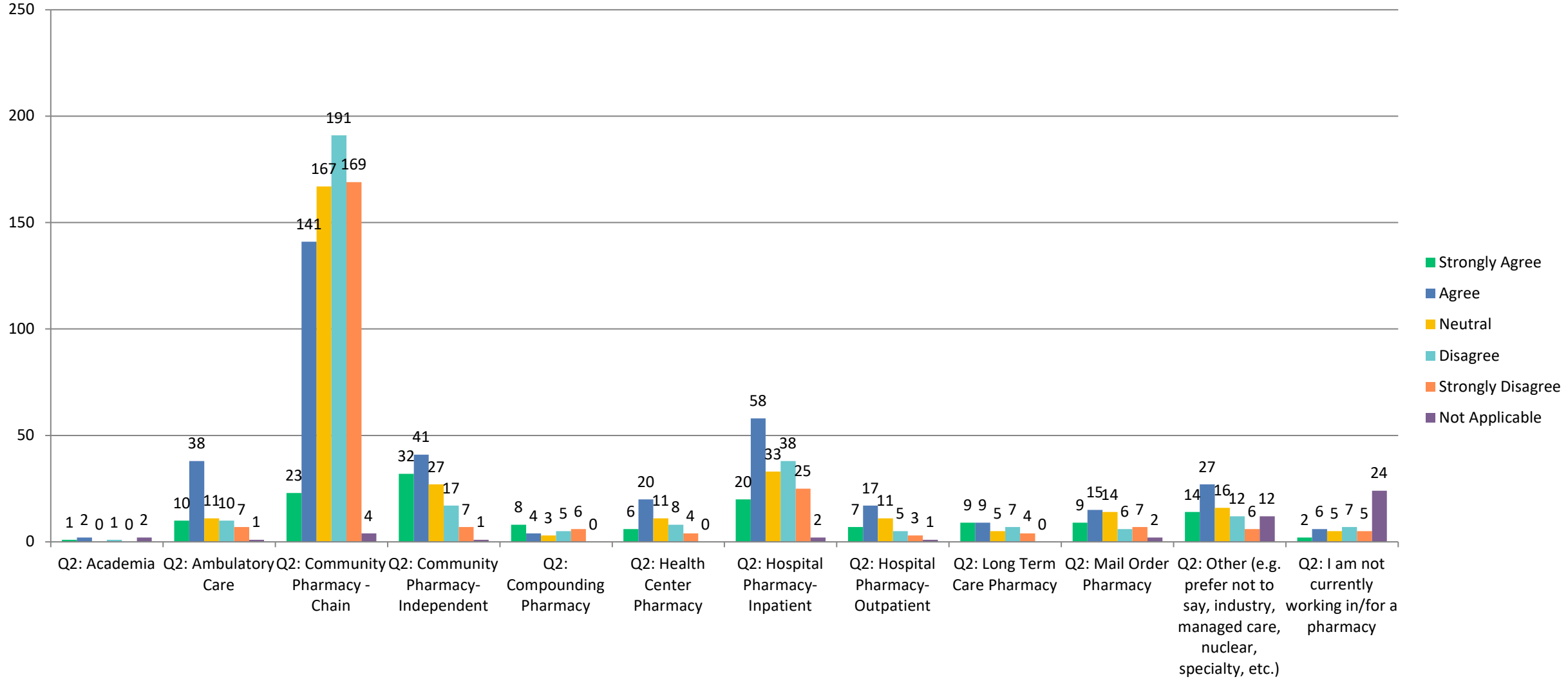
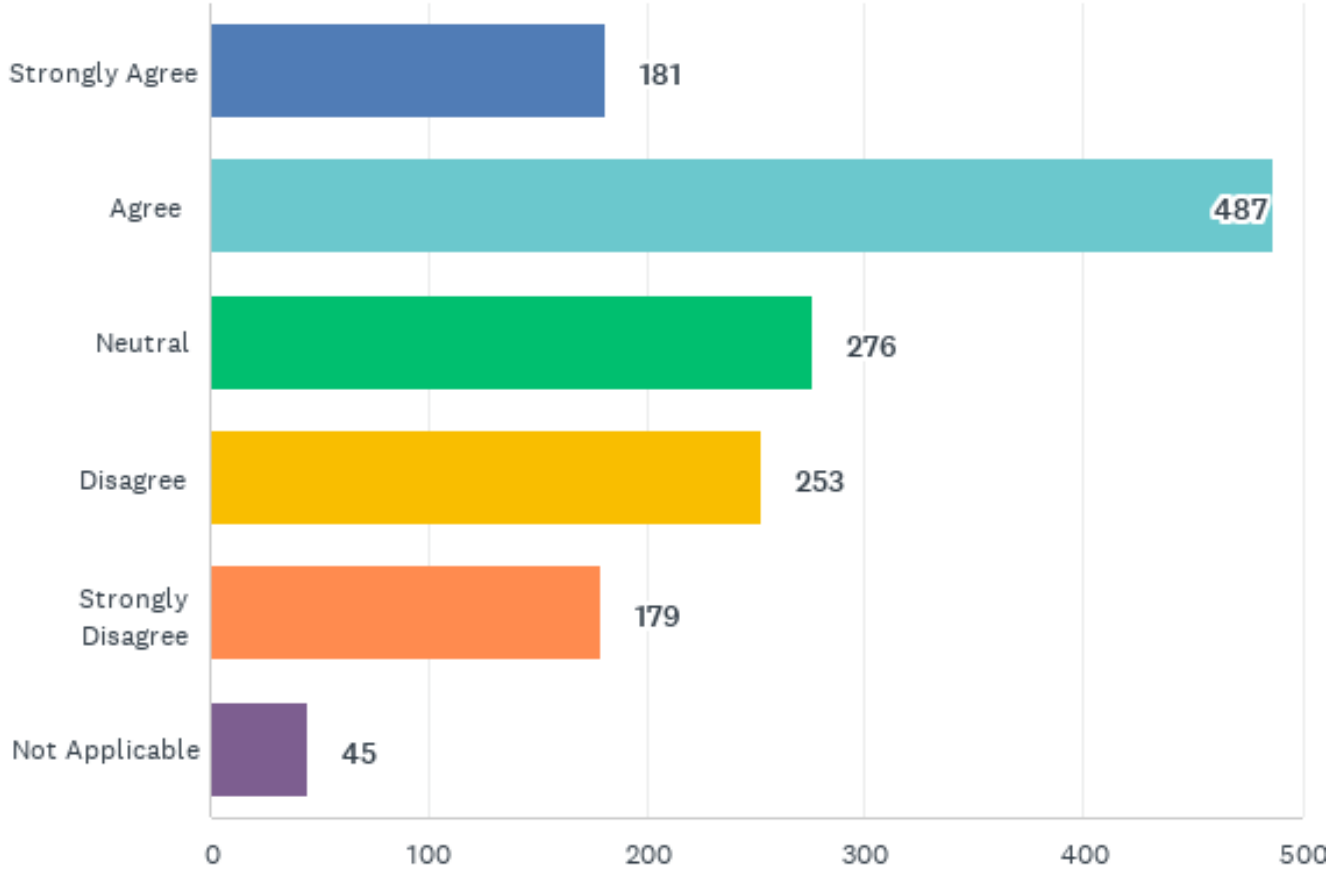


Q17: I feel that my practice environment has an organized workflow that promotes safe, effective and timely patient care.

Answered: 1,421 Skipped: 623



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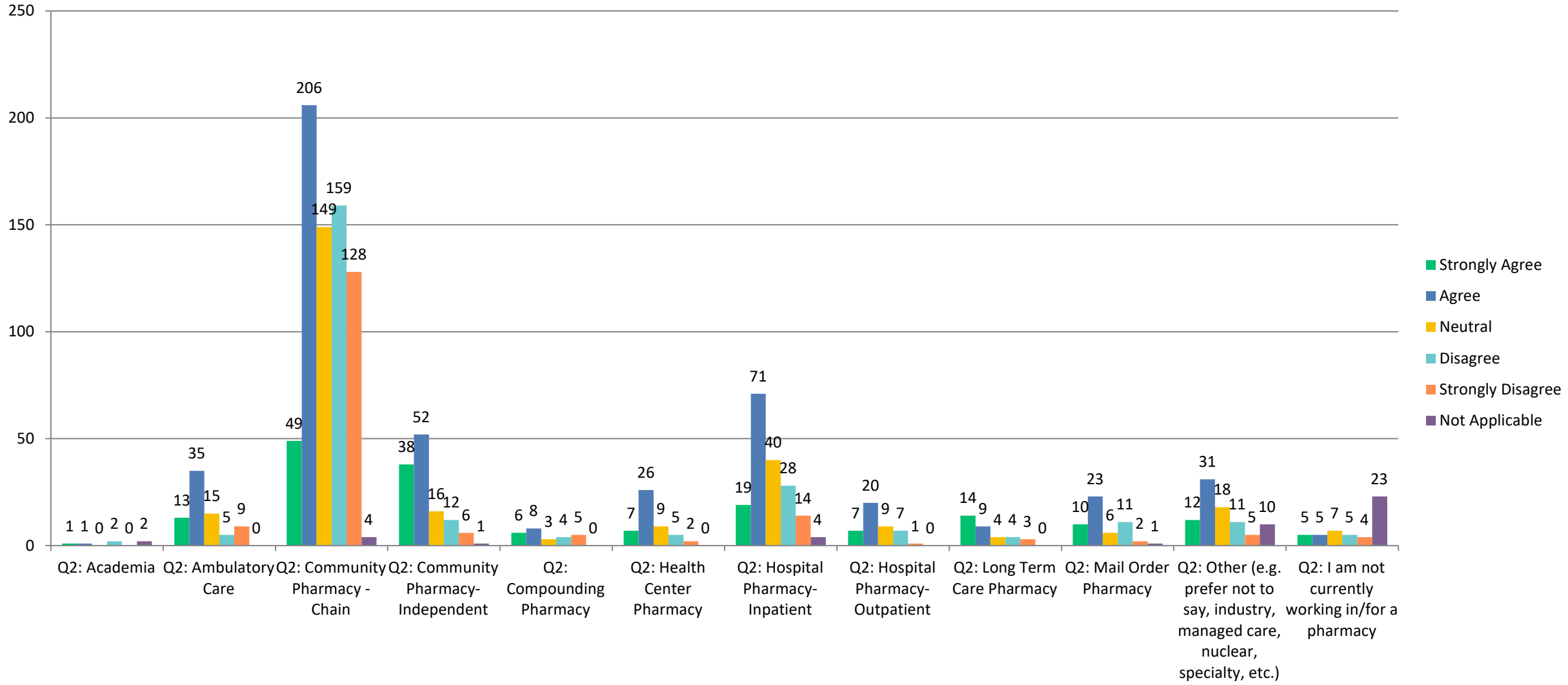
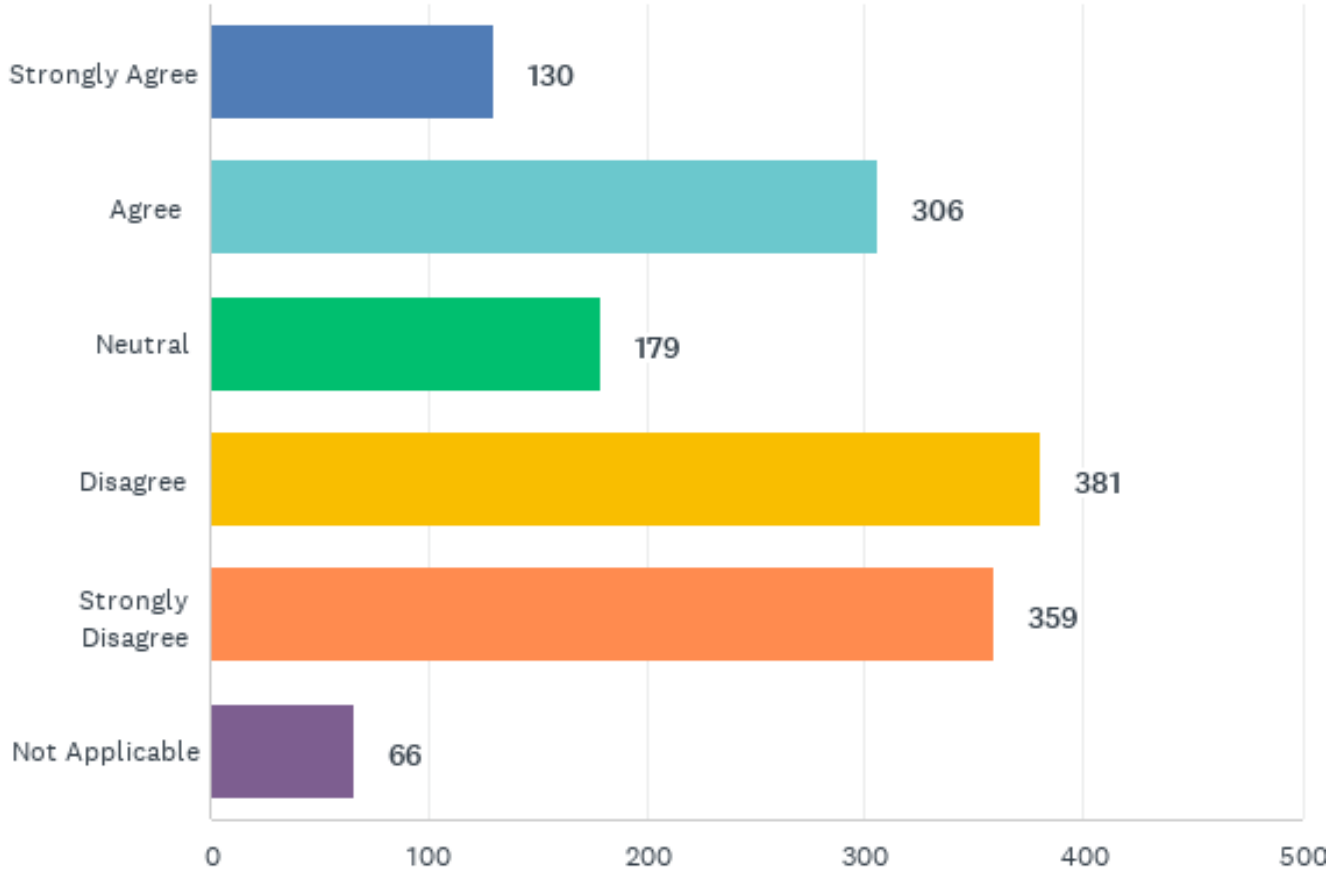


Q18: I feel that staffing in my practice environment is adequate and results in patients receiving their medication and consultation in a safe and timely manner.

Answered: 1,421 Skipped: 623



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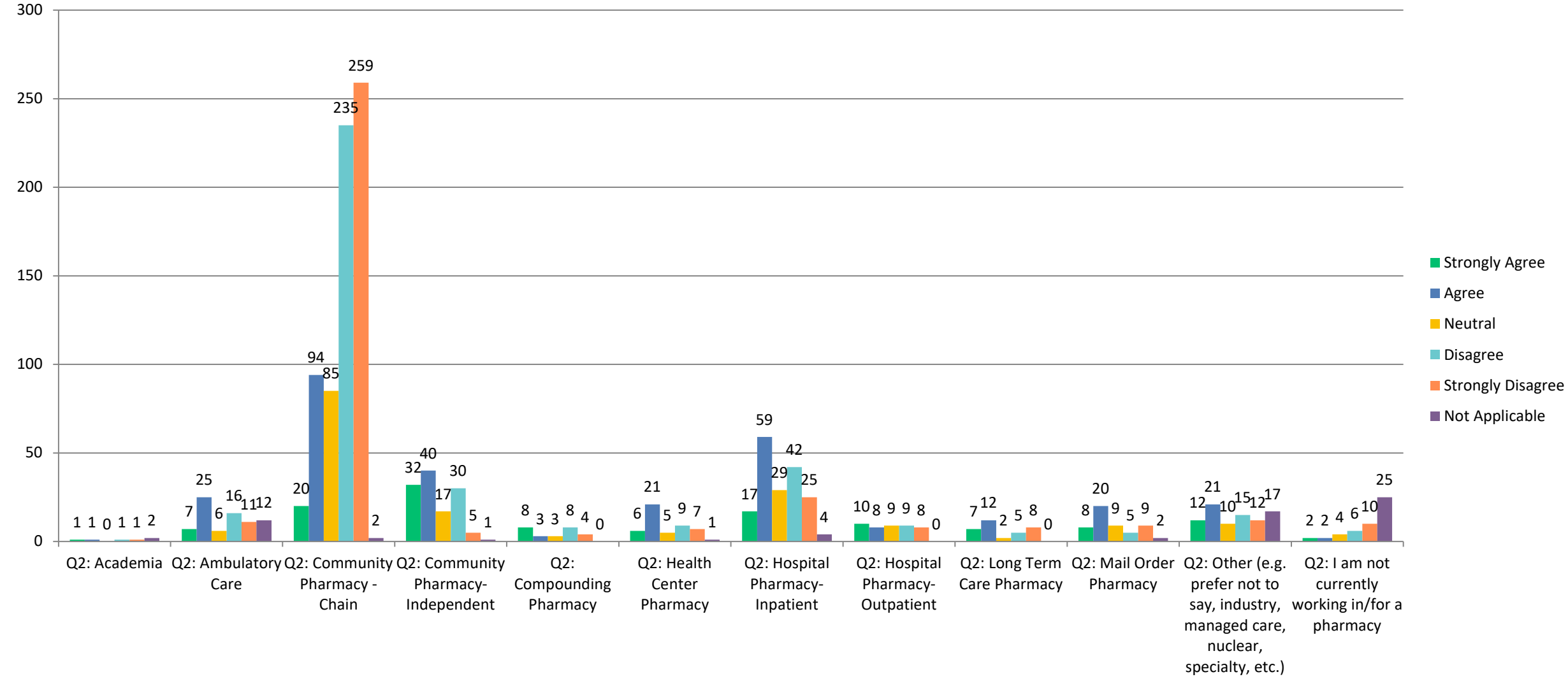
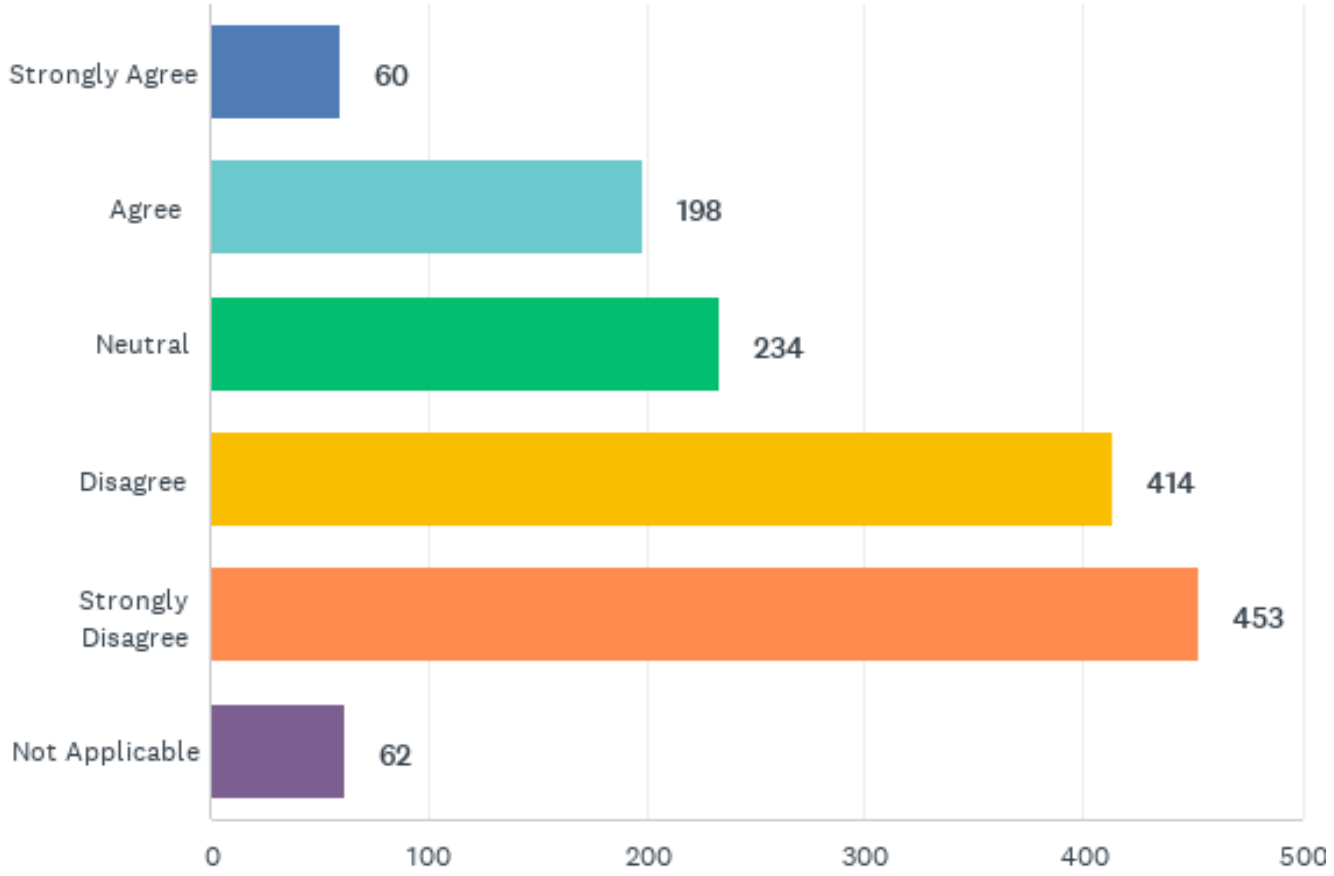


Q19: Job openings for my workplace are filled in a timely manner.

Answered: 1,421 Skipped: 623



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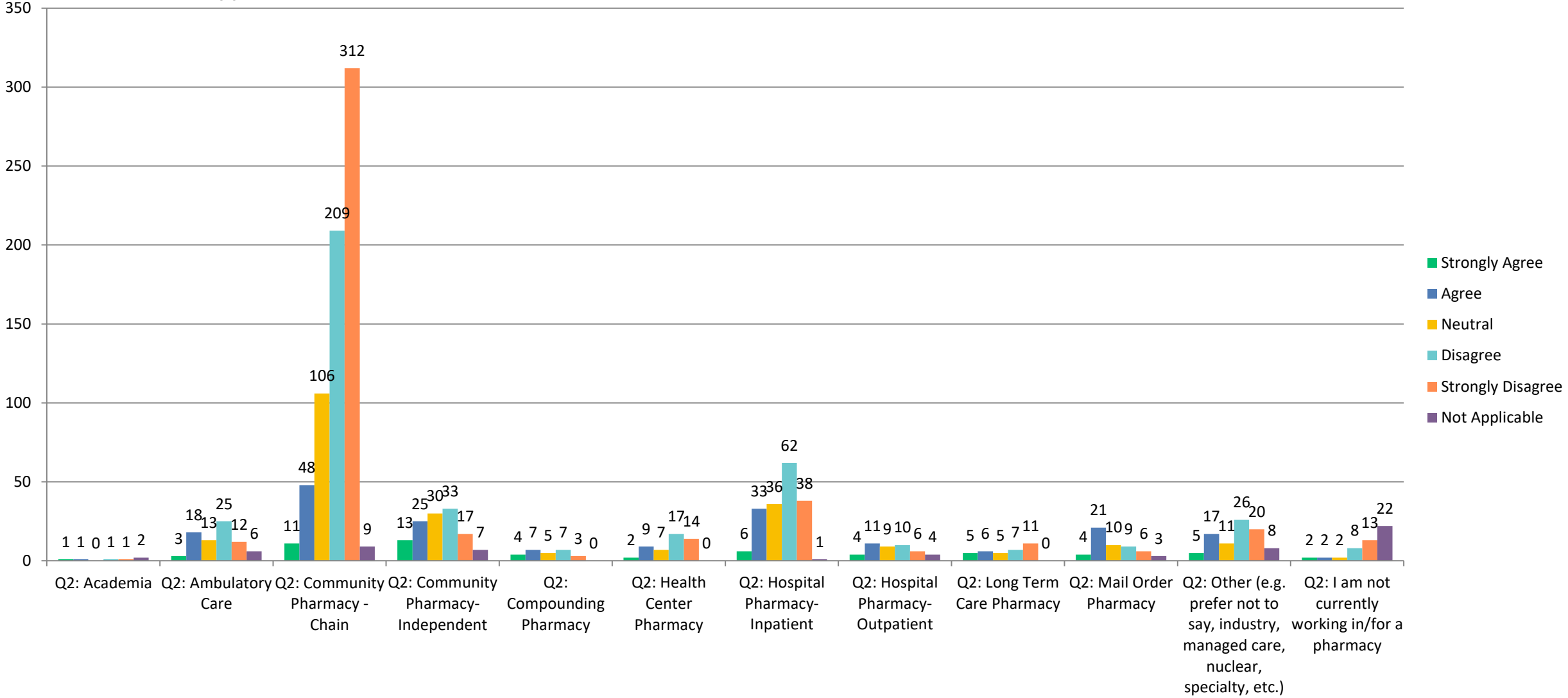
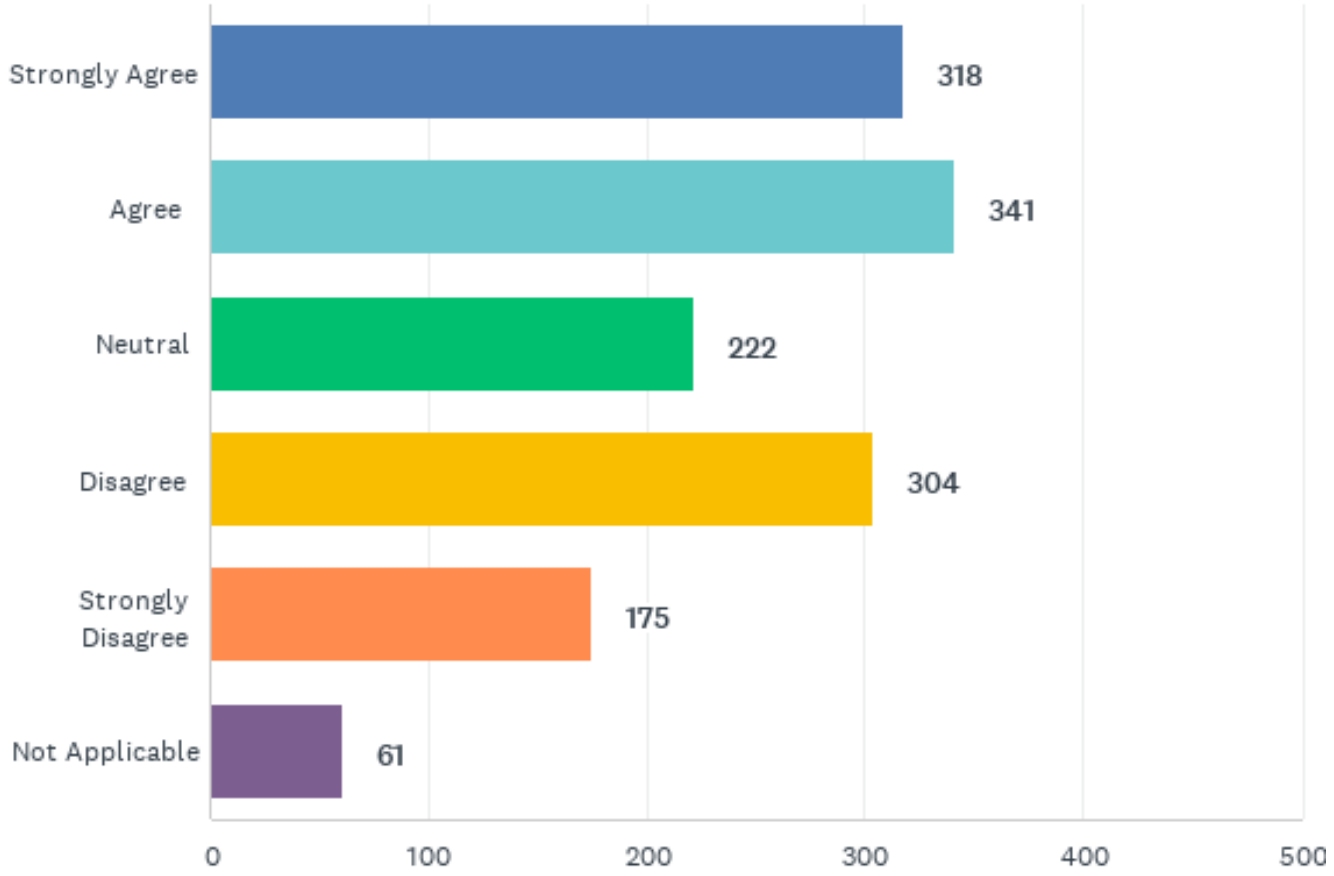


Q20: I feel pressure by my employer or supervisor to meet standards or metrics that may interfere with safe and effective patient care.

Answered: 1,421 Skipped: 623



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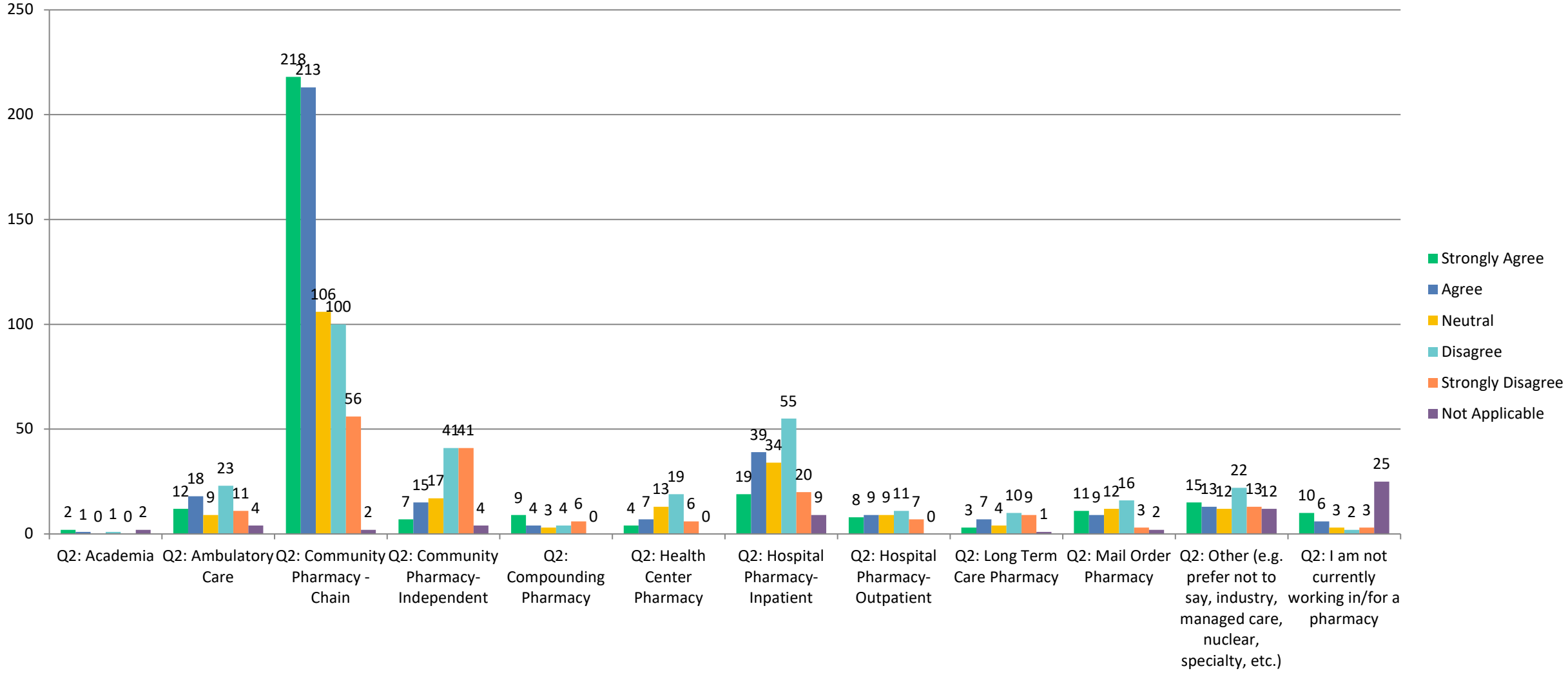
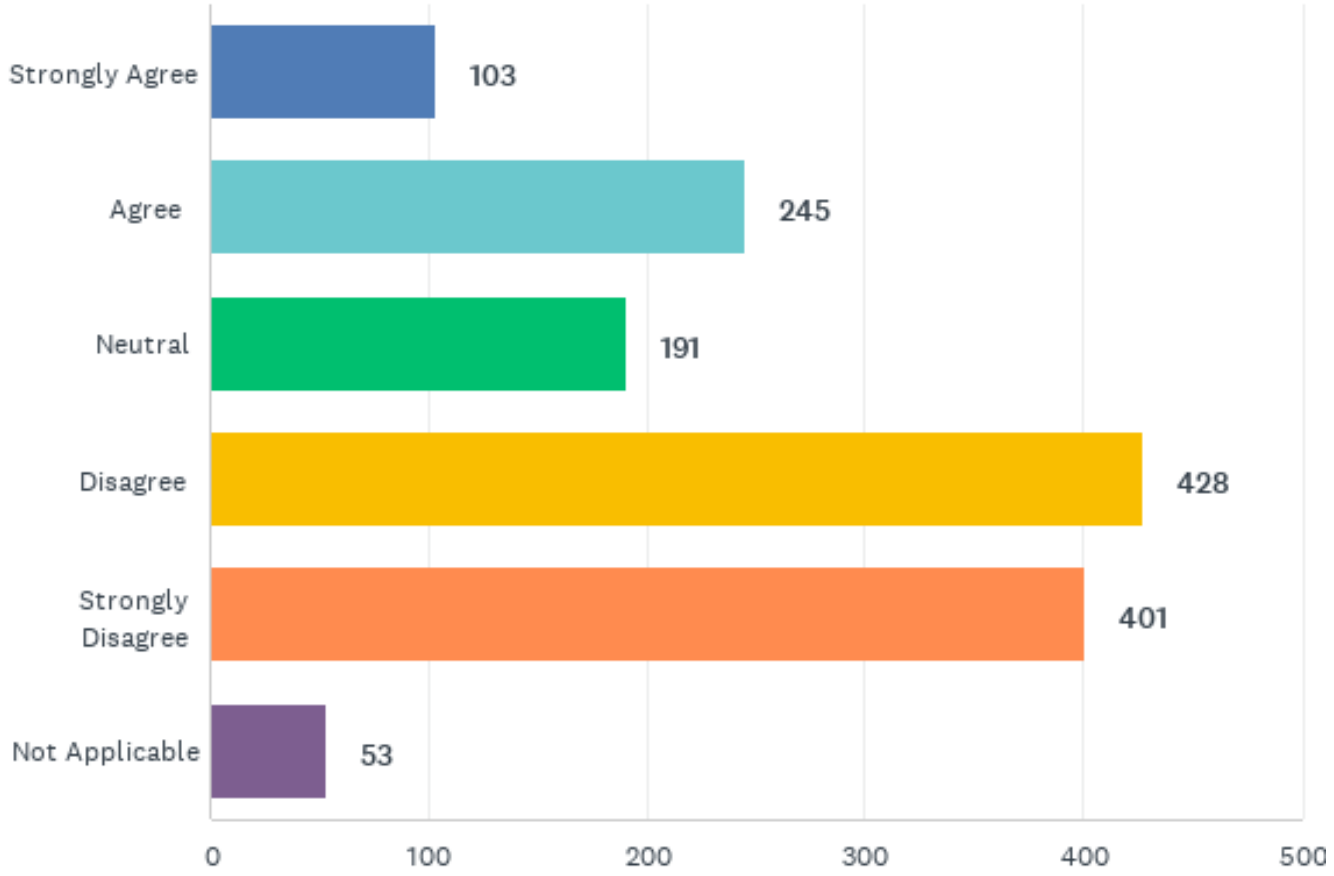


Q21: I feel that there are sufficient staff to manage the pharmacy's workload that allows me to provide safe and effective patient care.

Answered: 1,421 Skipped: 623



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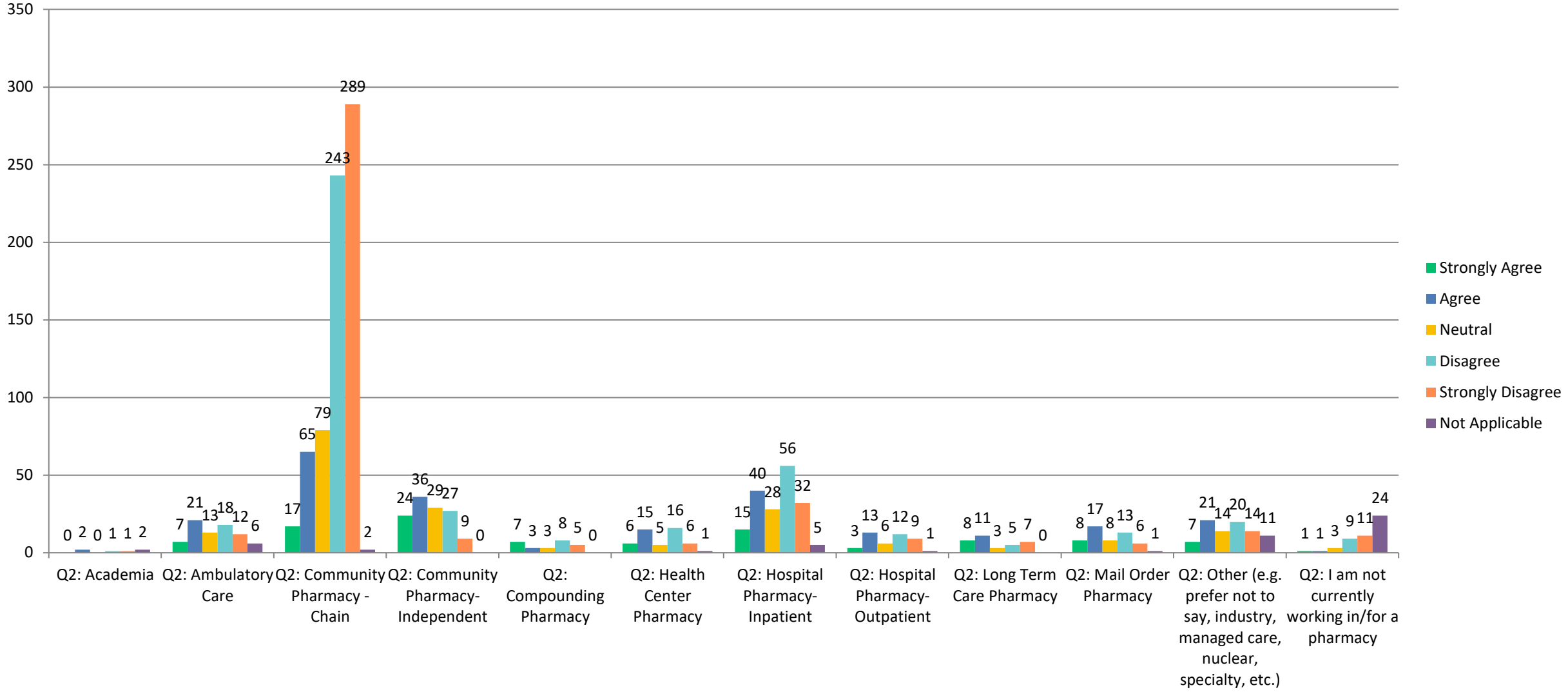
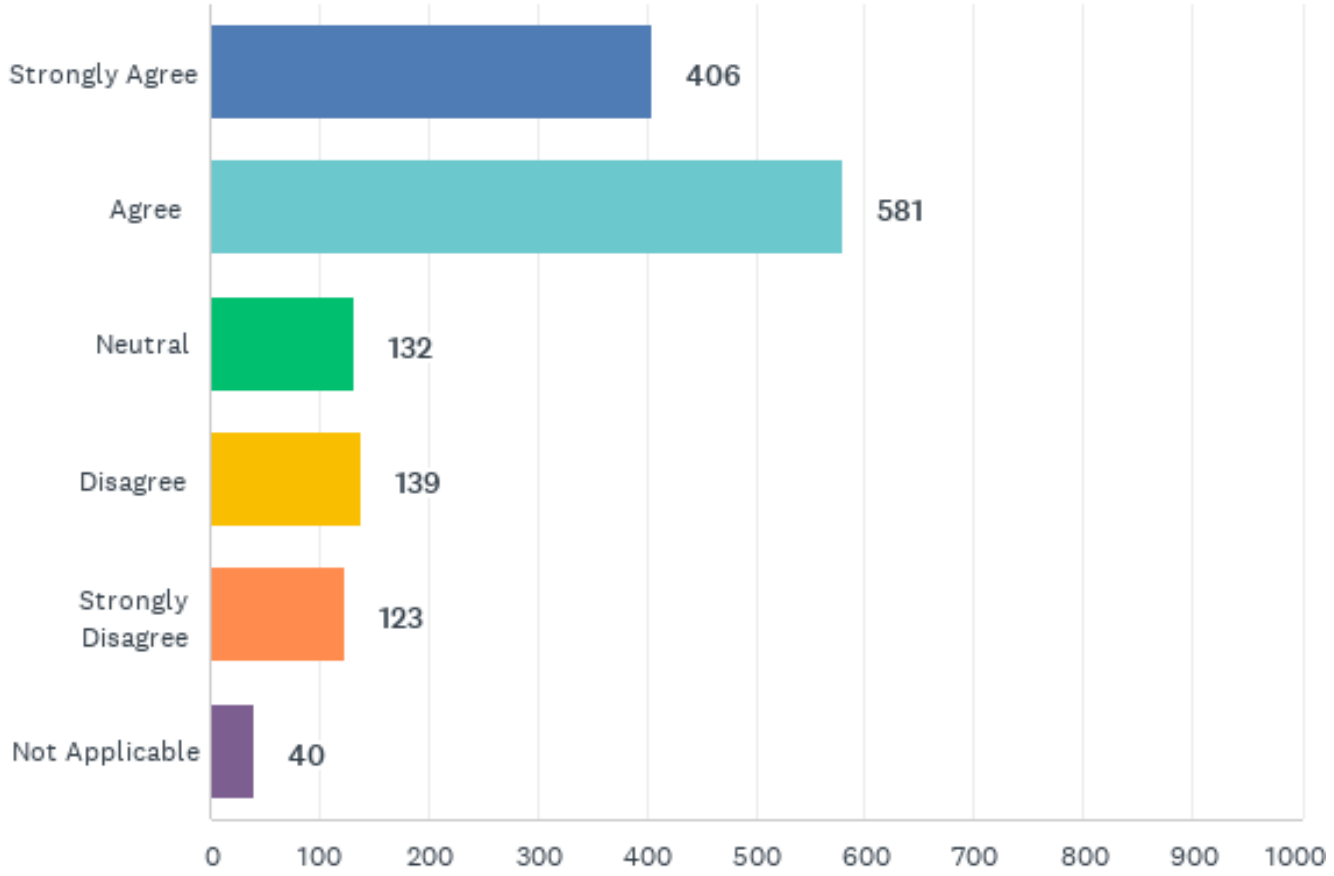


Q22: I am given the opportunity and am able to take meal breaks during the workday.

Answered: 1,421 Skipped: 623



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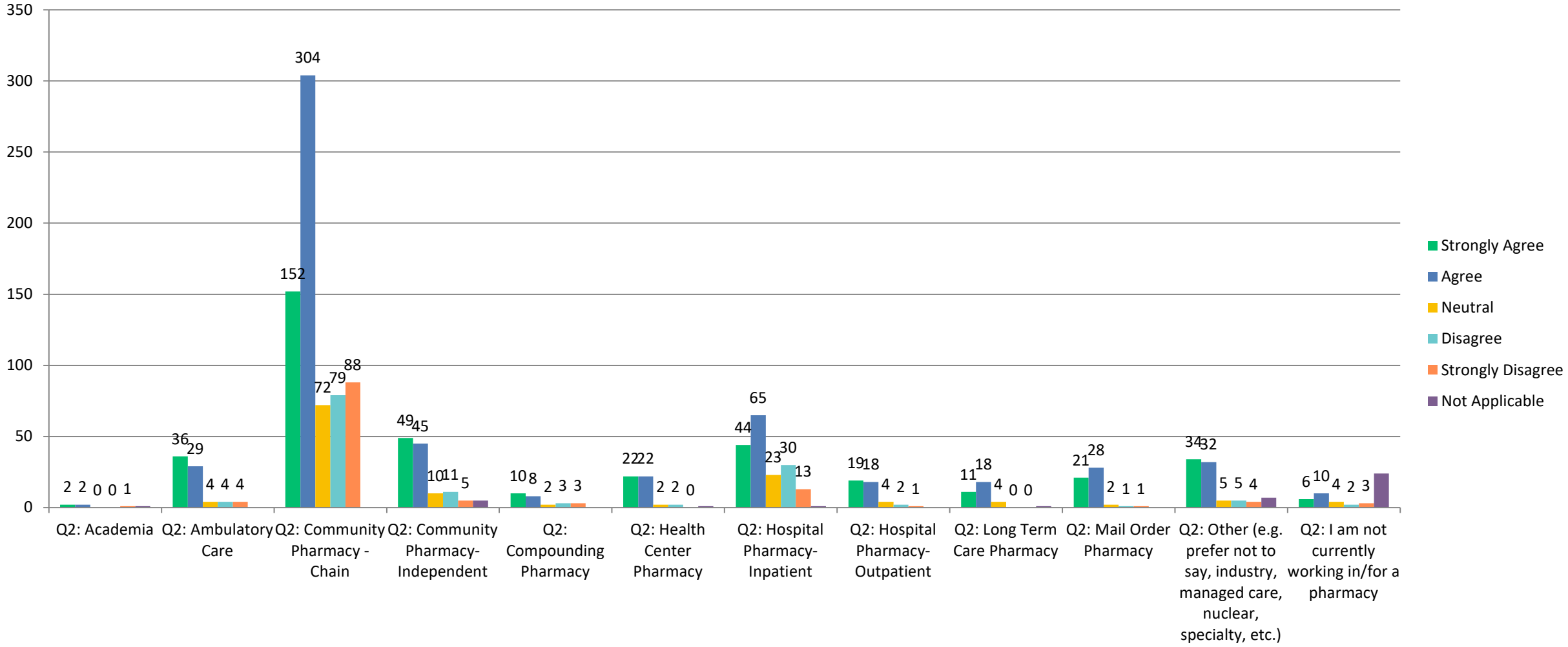
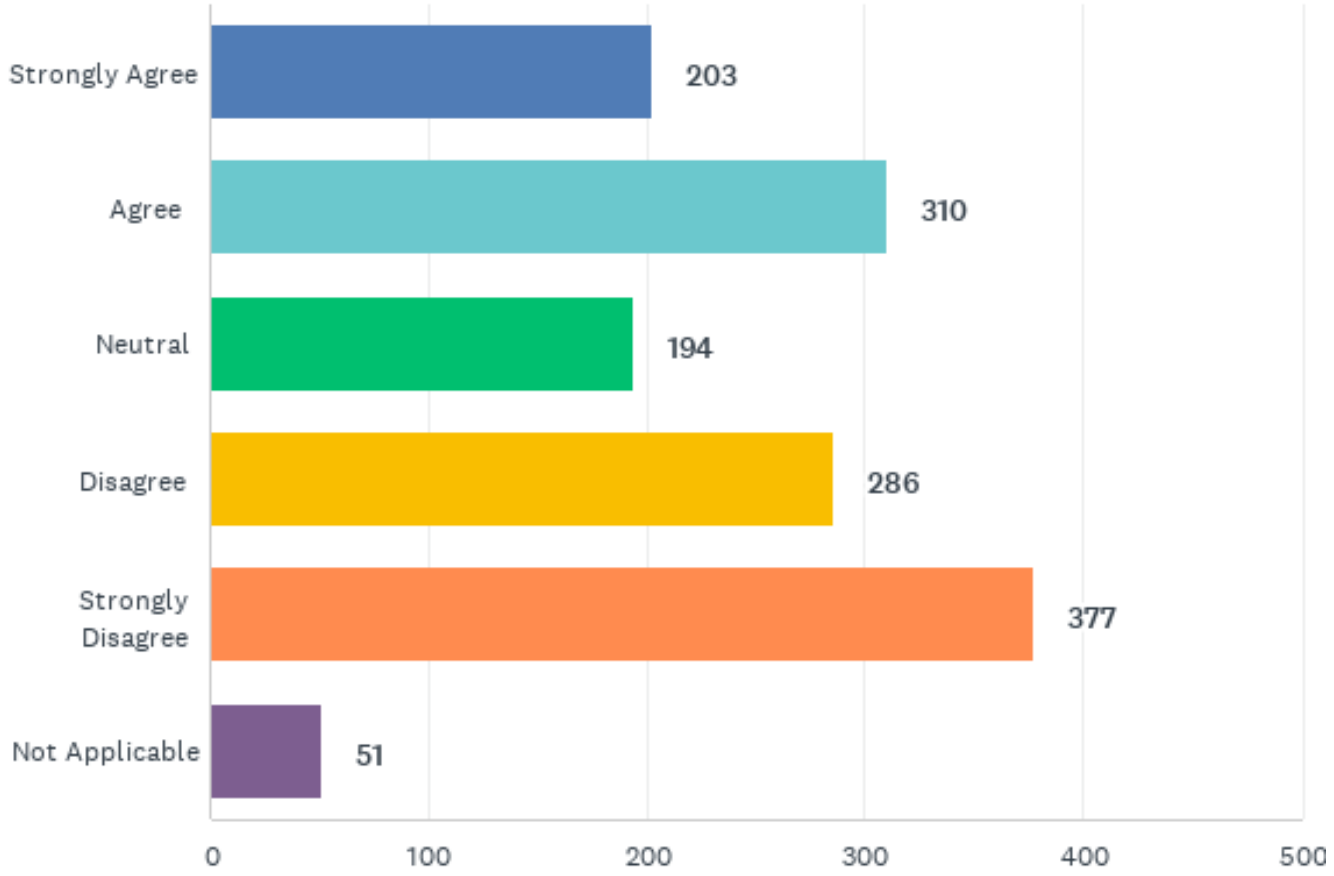
Answered: 1,421 Skipped: 623



Q23: I am given the opportunity and am able to take non-meal breaks throughout the workday.

Answered: 1,421 Skipped: 623



Q23: I am given the opportunity and am able to take non-meal breaks throughout the workday.

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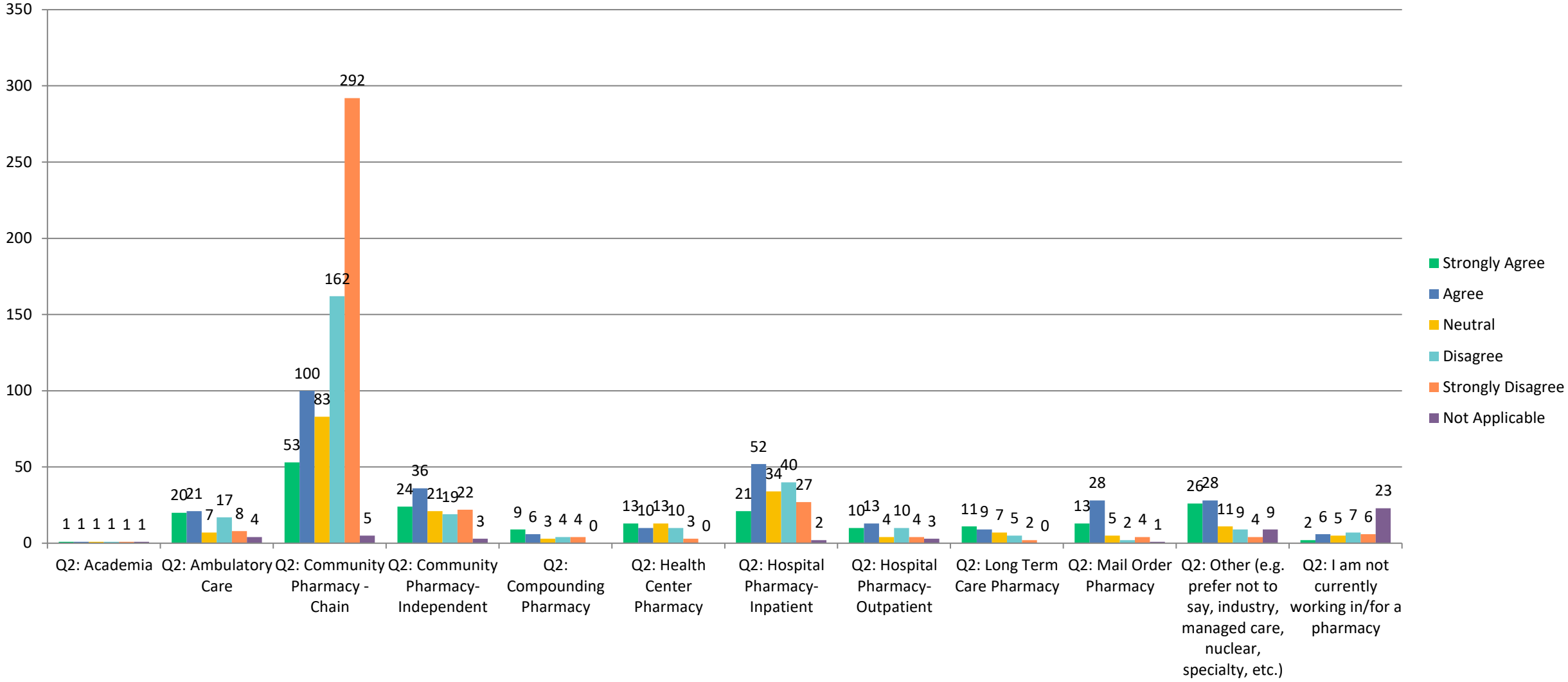
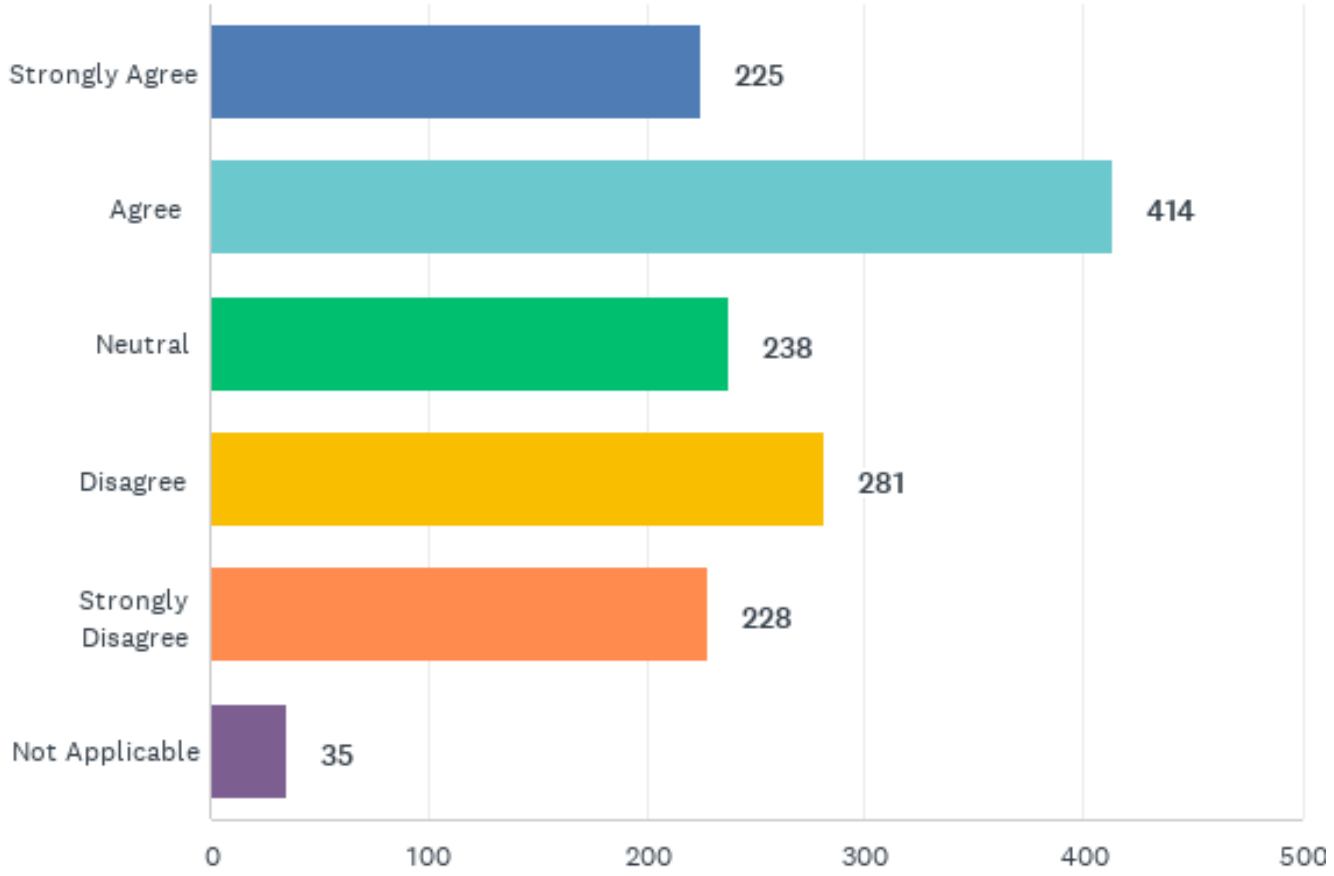


Q24: I feel safe voicing any workload concerns to my employer.

Answered: 1,421 Skipped: 623



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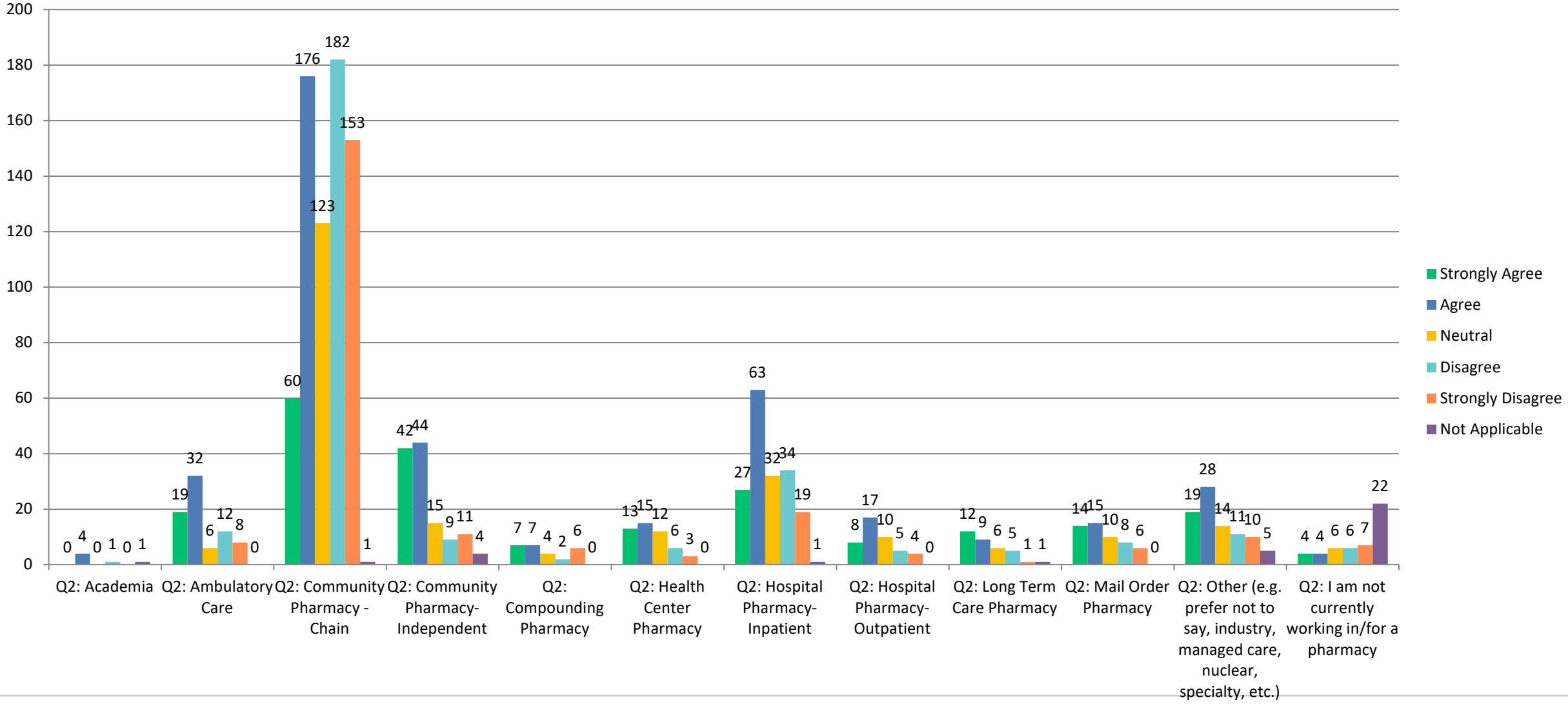
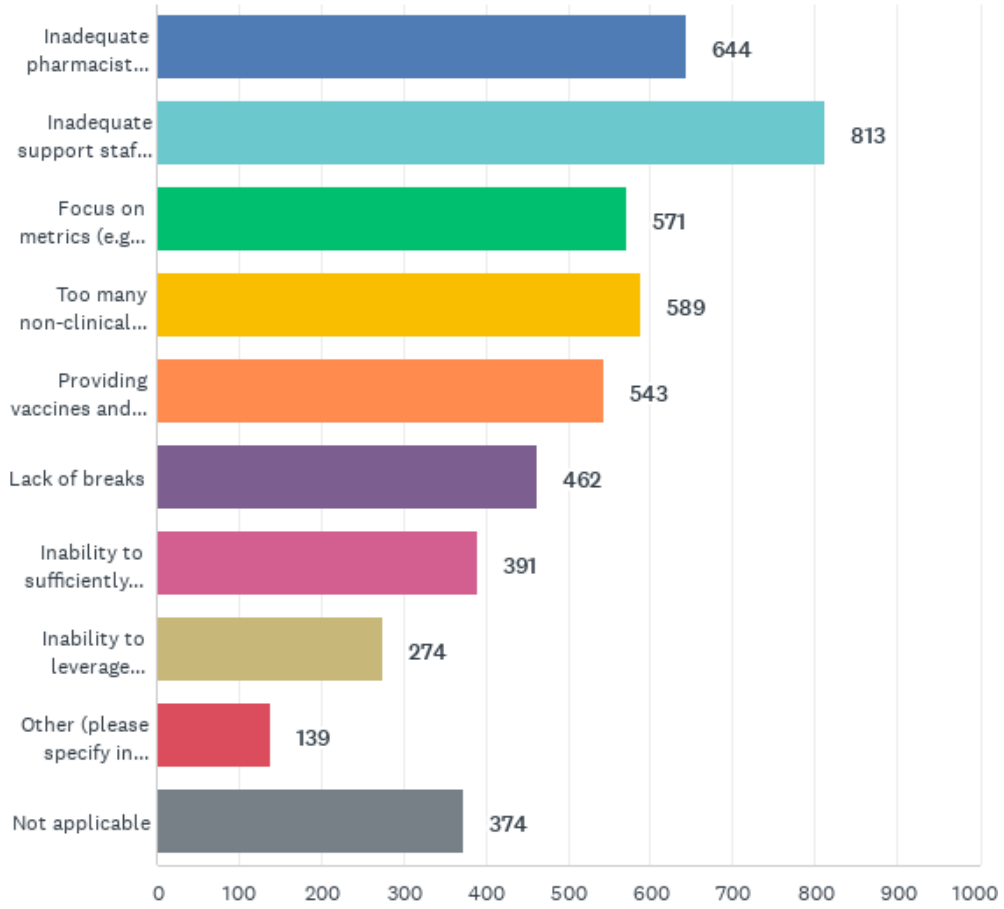


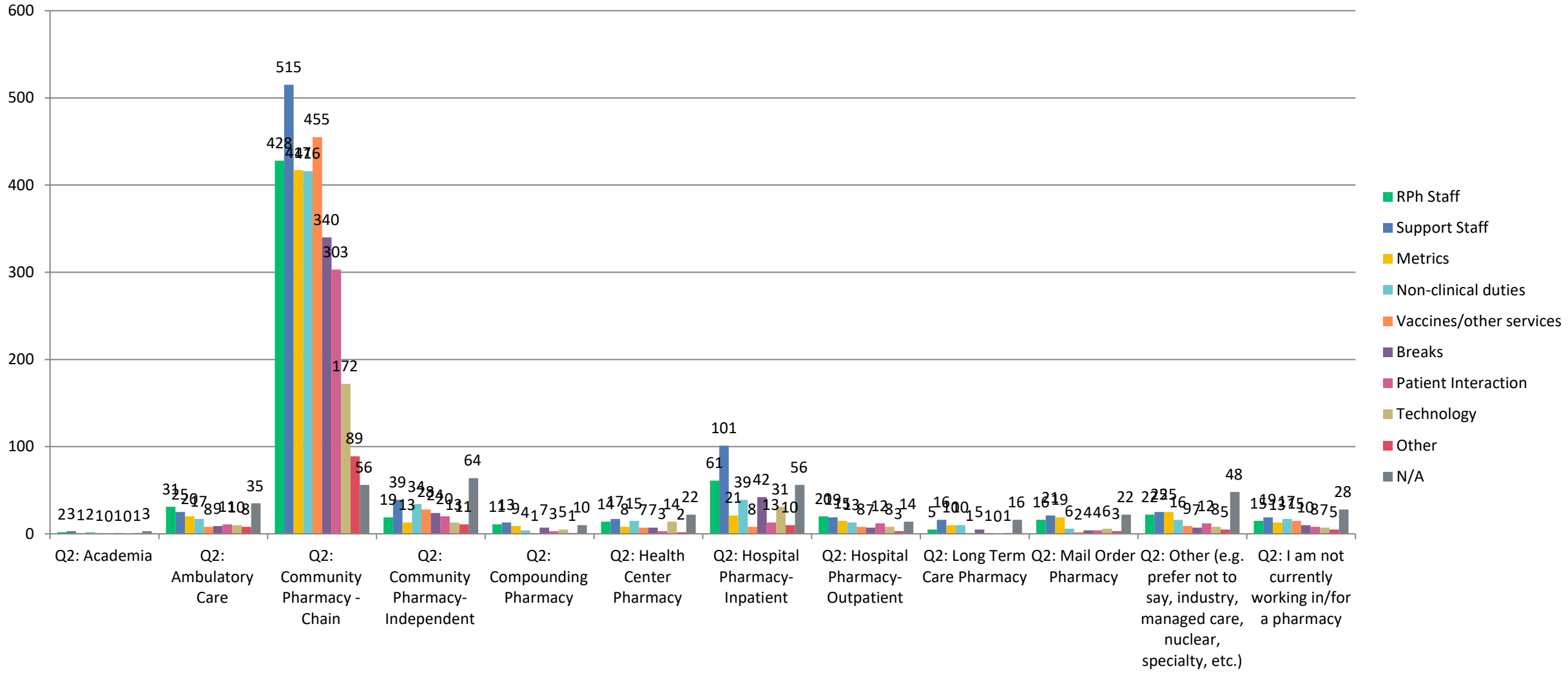
Q25: If you believe you are unable to practice or assist in the practice of pharmacy safely at your current practice setting, please select all that apply.

Answered: 1,421 Skipped: 623



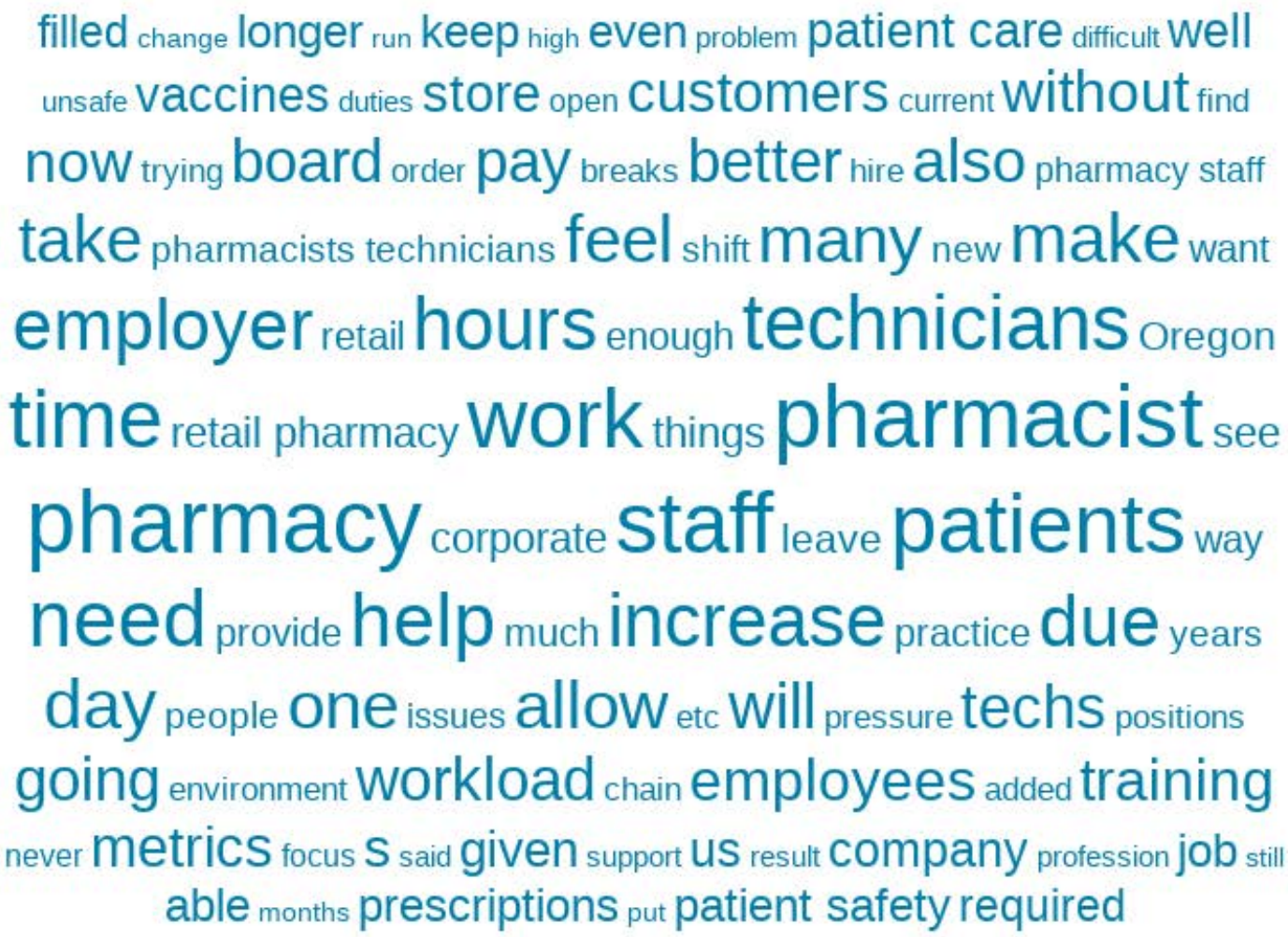
Q25: If you believe you are unable to practice or assist in the practice of pharmacy safely at your current practice setting, please select all that apply.

Answered: 1,421 Skipped: 623



Q26: Please provide any additional comments on this topic that you think would be helpful to the Board.

Answered: 533 Skipped: 1,511



JUNE 2022/F

Rite Aid

Hormonal Contraception: Pharmacist Management and Prescribing

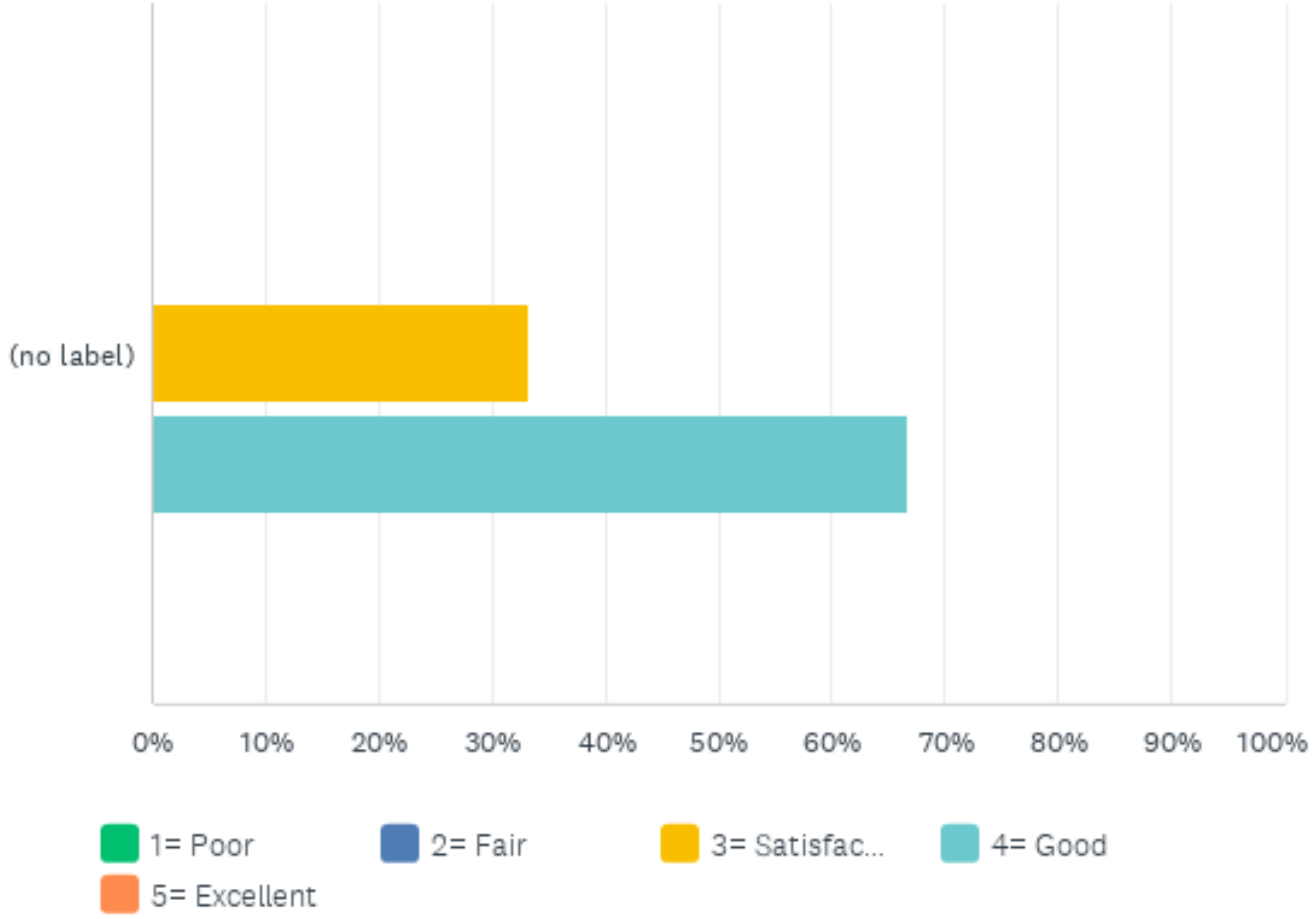
Oregon Board of Pharmacy Content Reviewer Results

5-24-2022

Content Reviewers

- Dr. Alison Edelman, M.D., M.P.H.
- Kayla Hensley, Pharm.D., RPH
- Christina Steurer, N.P., RN

Q1: This program provides a thorough review of women's reproductive health.



Q1: This program provides a thorough review of women's reproductive health.

- 2. Section: Hormonal Contraception: Women’s Health and Family Planning
  - Planning for pregnancy – “see a doctor” there are many different health professionals that prepare individuals for pregnancy than just a doctor.
  - Unplanned pregnancy – violence against individuals/lack of autonomy over their bodies is a major issue for unplanned pregnancies. This list is a little odd in its terms of phrasing and actually its not all true (an annual check up has not been linked to unplanned pregnancies). I would recommend the following: -lack of knowledge -contraceptive nonuse -inconsistent use -contraceptive failure -gender-based violence -lack of access to health care (costs, delays, and other barriers)
  - Socio-economic disparities I would delete the second slide reporting on the list since it helps perpetuate the racist infrastructure that access to medical health care and knowledge. You already report on unintended pregnancy in the beginning of the module. I think the first list makes the point without identifying issues that occur because of structural issues rather than true inherent causes. This second list is going to cause issues around diversity, equity, inclusion, and social justice issues. Easier just to delete it unless you want to get into health disparities.

Q1: This program provides a thorough review of women's reproductive health.

- 2. Section: Hormonal Contraception: Women’s Health and Family Planning
  - Women’s well visit Some programs are moving away from the word women or at the very least recognizing that some individuals seeking contraception may not identify as women and thus to be cognizant of that. Well-Women Visits Focus doesn’t seem to be grammatically correct? Would just label it again as Well-Women Visits or Preventative Health Visits.
  - Physician is again used here but a number of health care professionals provide these preventative health visits.
  - Menstrual cycle- International Federation of Gynecology & Obstetrics Classification of menstrual cycles is 24 to 38 days.
  - Knowledge check
    - Doctor is used instead of a more general health care provider term
    - I would change your second question again in order to avoid stereotypes and perpetuating health disparities.

Q1: This program provides a thorough review of women's reproductive health.

- 2. Section: Hormonal Contraception: Women’s Health and Family Planning
  - Estrogens –
    - Why is there so much information on estradiol valerate? Seems biased in terms of the other synthetic estrogens.
    - Clinically we consider any CHC 35mcg and under a low dose method. We do not differentiate between a low, moderate, and high dose in clinical practice.
    - Adverse events and side effects are different. This list is a mix of adverse events and side effects. Also many of these are temporary and rare to occur. This makes it look like they are all equal. You may want to consider changing this section.
  - Progestins –
    - The use of generations is outdated. It is a pharma- manufacturing classification and marketing scheme. It is fine to classify progestins from their derived source as you otherwise do here. https://www.contraceptionjournal.org/article/S0010-7824(20)30175-X/fulltext
    - Adverse events and side effects are different. Same statement around side effects and temporary.
    - Drosperinone does not appear to impact K levels in normal patients only those with possible K-level medication conditions or medications – so this statement is not entirely accurate. Androgenic activity is based off a rat receptor and not linked to human outcomes especially when combined with an estrogen and rates of sHBG increase which means free testosterone decrease. If it is of a concern – then sure fine to prescribed based on in vitro androgenicity. This is a controversial area.

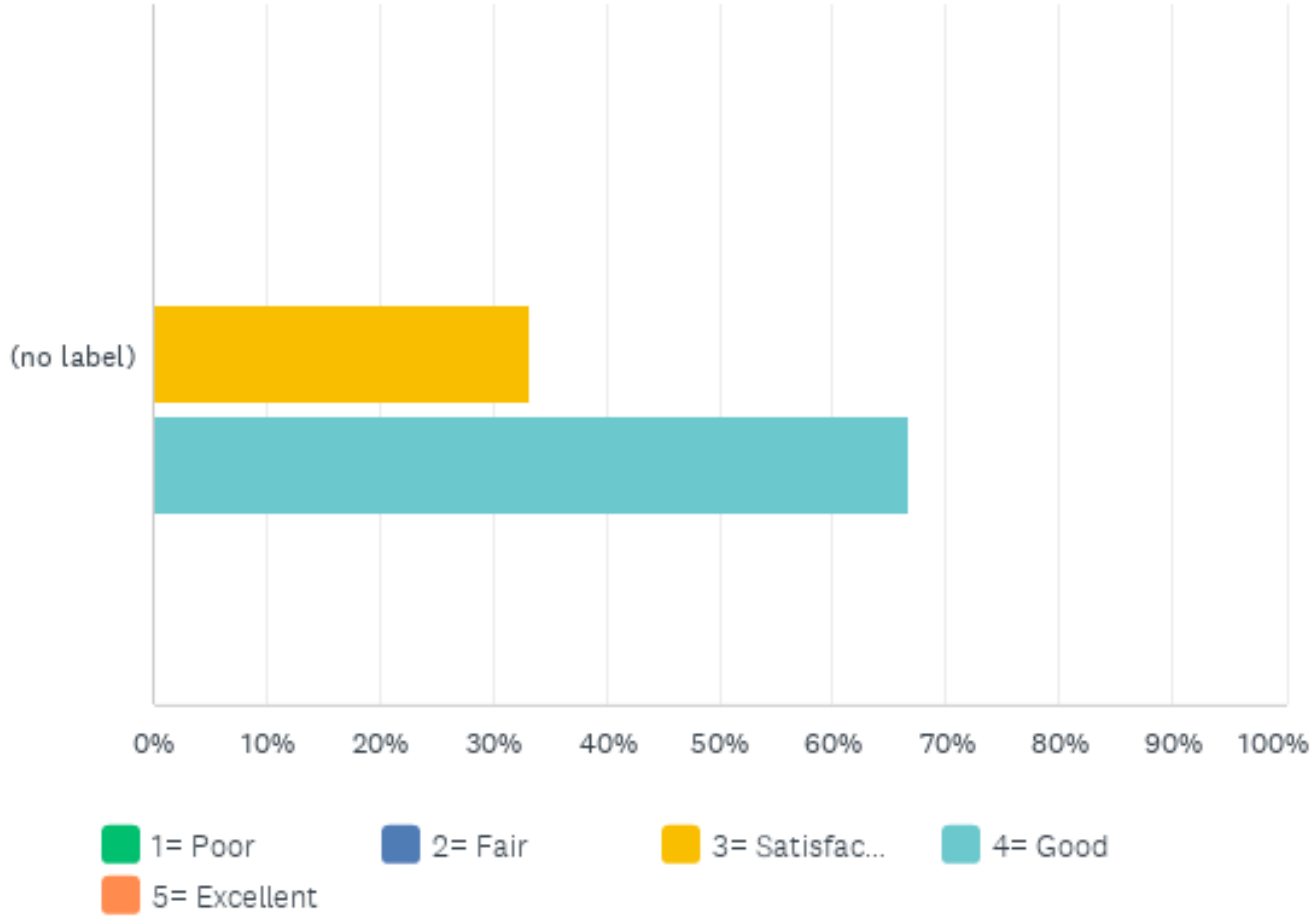
Q1: This program provides a thorough review of women's reproductive health.

- 2. Section: Hormonal Contraception: Women’s Health and Family Planning
  - Considerations for selecting a birth control
    - Preferences for a type of contraceptive – the examples include hirsuitism, acne, and PCOS. PCOS is not an example of adverse effects. It’s a medical condition where it might be good to have ovulation suppression etc.
    - Your list is supposed to include possible side effects. Common ones are acne, weight gain, and irregular bleeding.
    - Future intent of pregnancy – This is strong wording given that values and preferences are the core reasons for choosing a method plus. You might consider avoiding the word recommended. Additionally, sterilization is a term that the field is moving away from again because of its terrible history of forced sterilizations. I would reword this to: Individuals planning for a pregnancy in the next year should consider a method that is easily reversible for them. All methods are available to them except the injection which may take longer to reverse or permanent ones like a vasectomy or tubal ligation. They may want to choose an option that they can start and stop easily on their own, like a short acting-reversible method. For those who are done with childbearing, all methods are available to them. They may want to consider a method that has the best ability at preventing pregnancy like a permanent method or a long acting method (IUD or implant).

Q1: This program provides a thorough review of women's reproductive health.

- 2. Section: Hormonal Contraception: Women’s Health and Family Planning
  - Protection from STIs. I would recommend a language change to be less judgmental about sexual practices. Condoms are the one contraceptive method that prevents STIs and can be used with other methods. If a client is in need of STI protection, condoms can be provided. This is also a great time to discuss the availability of Prep and PEP!!! https://www.cdc.gov/hiv/clinicians/prevention/prep-and-pep.html Insurance coverage/cost.
  - You may want to put some state-based language in here. Oregon has a law that supports 13 cycles of coverage not just 3 months.
  - Knowledge based question – needs to be changed regarding generations
- 3. Section: Hormonal Contraception: Hormonal Contraceptives
  - Knowledge check question – if a woman is considering a pregnancy in the next 3 years. They can consider an IUD for use – the answer is totally wrong. This is a great patient for an IUD.

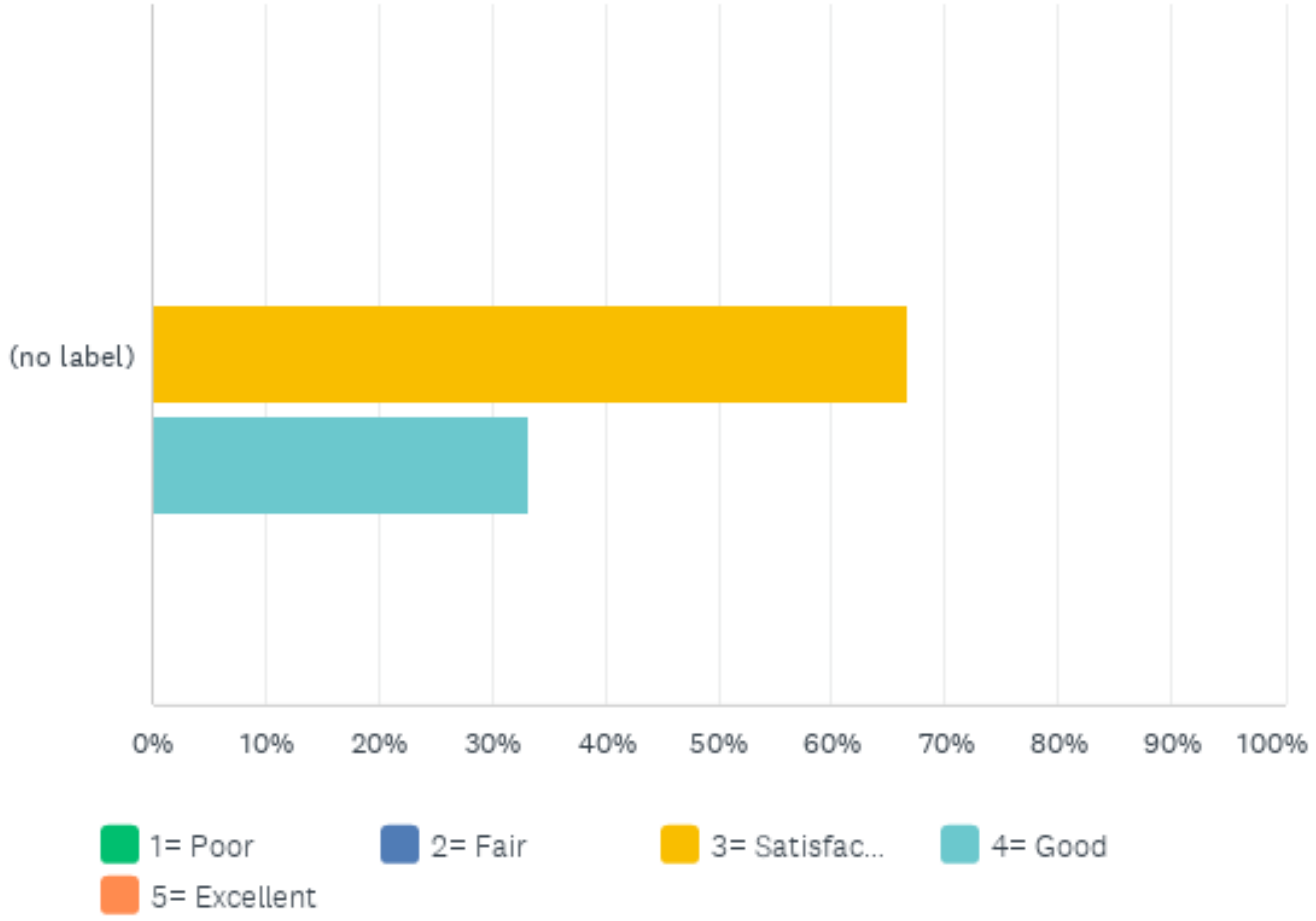
Q2: This program provides a robust therapeutics and pharmacologic review.



Q2: This program provides a robust therapeutics and pharmacologic review.

- 4. Hormonal Contraception: Therapeutics and Pharmacology
  - CHC pros/cons – for cons it says less effective with certain medications – while true, most of these medications are rare in reproductive age individuals – I don't know if you want to qualify that. Also the risk of clots, true, but rare and the risk of arterial clots related to CHCs is controversial - its venous thrombosis which is not controversial.
  - Patch pros/cons – I would make these very consistent for all the CHCs since that helps folks remember OR even make it all the same for all of them and then have a few things that are different about each formulation/delivery system. Here for patch it also says cycle return is 1-2 months. But that isn't listed for pills. Again, those are immediately reversible but sometimes can delay cycles for 1-3 months. Why are you calling this out specifically for the patch but not for the pill?
  - Ring pros/cons – TSS is qualified as a slight risk? This is extremely rare and not just a slight risk. Risk of DVT should probably be qualified as a slight risk.
  - DMPA – cons: it may cause irregular bleeding and spotting (not just spotting) especially during the first year

Q3: This program comprehensively teaches the "art" of patient assessment, evaluation and contraceptive product selection.



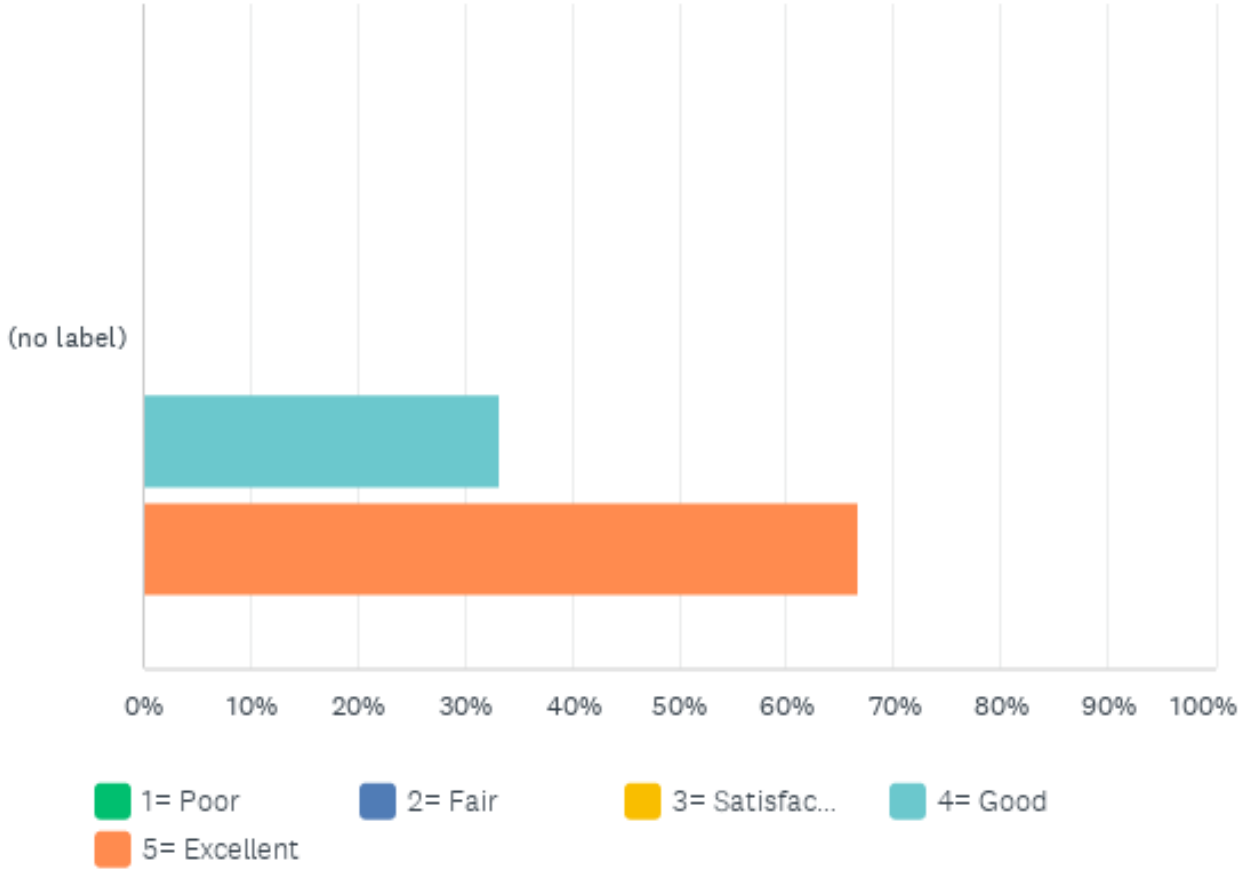
Q3: This program comprehensively teaches the "art" of patient assessment, evaluation and contraceptive product selection.

- I think this was satisfactory but not amazing. Teaching the art of patient assessment can be difficult through an online module.
- Some inaccurate/confusing information about the provision of certain contraceptives - for example:
  - 1. The knowledge check says an IUD cannot be considered if a person is planning to become pregnant in the next 3 years, but in fact an IUD may be the best option, and does not need to be kept for its entire lifespan.
  - 2. The Mirena IUD is FDA approved for up to 7 years, not 6 as stated in the materials
  - 3. There is information that Ella cannot be used more than once per menstrual cycle. This is not evidence-based. More concerning is that pharmacists may instead give a levonorgestrel-containing EC product if another dose of EC is warranted, which could decrease the effectiveness of the Ella which was taken previously. It would be much better to give a repeat dose of Ella in that situation.
  - 4. In the sections on contraindications for the different CHC products - there were different medical conditions listed for each, when in fact almost all of the contraindications apply to every type of CHC. (for example, Hep C medications was listed as a contraindication/consideration for the ring, but not for the patch or pills...)I think this is confusing.

Q3: This program comprehensively teaches the "art" of patient assessment, evaluation and contraceptive product selection.

- Hormonal Contraception: Prescribing Physician is used in this module but there are other contraceptive prescribers that aren't physicians. I would change to a broader term.
- HTN guidelines have changed a bit but I haven't seen any guidelines switch over from the screening of 140/90 (especially on one time point).
- Knowledge check 1. Actually the most common reason for breakthrough bleeding in the first 3 months is that its just a normal side effect and this isn't mentioned during the module

Q4: This program prepares the pharmacist to comply with all related Oregon laws and rules.

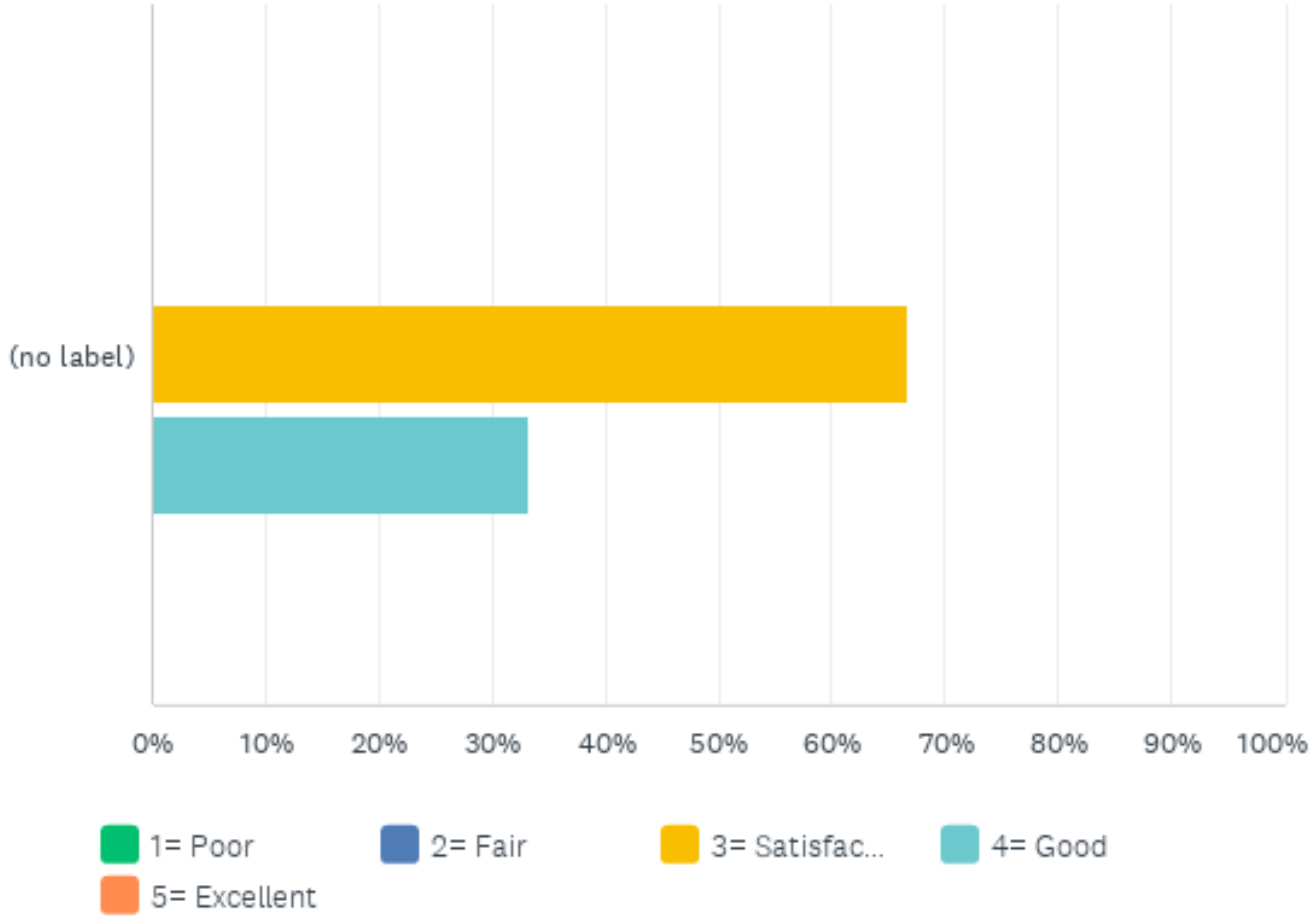


Q4: This program prepares the pharmacist to comply with all related Oregon laws and rules.

- The one thing I didn't see is that I know that initially the law was more restrictive around teens but I think that part has 'sundowned.' Might be good to ensure that pharmacists know that they can provide to this group.
- *The laws/rules section is not clear that:
  - A pharmacist is required to use the Oregon Self-Screening Risk Assessment Questionnaire and either the Oregon Standard Procedures Algorithm or DPMA Oregon Standard Procedures Algorithm
  - A pharmacist must follow the algorithm. Clinical judgement may only be utilized to determine the appropriate contraceptive option, not to determine if the patient qualifies under the protocol

*Board staff comment

Q5: This program is interactive and incorporates effective fundamentals of adult learning.



Q5: This program is interactive and incorporates effective fundamentals of adult learning.

- Overall the functionality of the program and the learning check questions were well placed.

Q6: Do you have any other comments, questions or concerns?

- Thank you for allowing me to review this program. I think it is well structured and will prepare Oregon pharmacists to safely and effectively provide hormonal contraception services to Oregonians.
- In the overview page 5 - I believe there is a typo. Should be "assess" not "access“

JUNE 2022/G

VOLUNTEERS IN MEDICINE
CLINIC OF THE CASCADES

2300 NE Neff Road Bend, Oregon 97701
P (541) 330-9001 F (541) 585-9002 vim-cascades.org

FAXED 3/7/22

3/7/2022

Dear Oregon Board of Pharmacy,

We are requesting one exception to Division 44, 855-044-0050 (j) Drug Distribution, (1) A charitable pharmacy may NOT distribute a donated prescription drug that: (j) "Requires refrigeration".

Refrigerated medications are vital to many of our client's health, and all too often they are prohibitively expensive when filled at community pharmacies at cash prices. For example, we have many diabetic patients who require insulin, GLP-1 agonists, and other refrigerated medications on an ongoing basis, but one month supply of Basaglar can cost as much as $300. Additionally, we serve patients who require Humira for Crohn's disease, or various vaccines including influenza, COVID-19, Prevnar-13, Tdap, etc. And we are able to source the above-mentioned refrigerated medications at no cost to the patient through manufacturer's patient assistance programs, or Direct Relief, AmeriCares, or other drug outlets licensed to distribute medication in Oregon.

These refrigerated medications arrive directly from the Drug Company's patient assistance programs, or from those company's partners, via insulated shipping boxes with cold packs and cold storage monitoring devices such as TempTale or similar. When these shipments arrive in refrigerated containers, we transfer them into either our Helmer medical grade refrigerator or Helmer medical grade freezer. Temperatures range between 2-8 degrees Celsius (refrigerator) or -20 - -30 degrees Celsius (freezer) inside our charitable pharmacy for secure storage and ongoing monitoring via Isensix.

Thank you for your consideration of these topics. Please feel free to contact me with any questions or clarifications.

Sincerely,

Alex Winn, PharmD
Consulting Pharmacist
Volunteers in Medicine – Clinic of the Cascades Charitable Pharmacy, License # CP-0000003
2300 NE Neff Rd.
Bend, Or. 97701
541-585-9010 phone
541-585-9002 fax

Oregon
John A. Kitzhaber, MD, Governor

Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971/673-0001
Fax: 971/673-0002
Email: pharmacy.board@state.or.us
Web: www.pharmacy.state.or.us

May 18, 2011

Alex Winn, PharmD
Dispensary Coordinator
Volunteers in Medicine – Clinic of the Cascades
2300 NE Neff Rd
Bend, OR 97701-6577

Re: Waiver Request

Dear Alex Winn,

The Oregon Board of Pharmacy has reviewed a waiver request for Volunteers in Medicine located in Bend. The request regarding OAR 855-044-0050(j) has been approved. The request regarding OAR 855-044-0050(d) cannot be approved as it is in statute ORS 689.722.

This waiver is valid until 5/18/2016 (5 years from date of letter). After this date, a new waiver has to be requested. A copy of this notification should be kept with your Pharmacist-in-Charge self inspection report.

Sincerely,

Gary Miner
Compliance Director

Cc: Gary Schnabel, R.Ph., Executive Director
Courtney Frank, Licensing Representative

VOLUNTEERS IN MEDICINE
CLINIC OF THE CASCADES

Providing Healthcare to the Medically Uninsured in Deschutes County

2/24/11

Requested Exceptions to Division 44

We are requesting two exceptions (d & j) to Division 44, 855-044-0050 Drug Distribution, (1) A charitable pharmacy may NOT distribute a donated prescription drug that: (d) "Bears an expiration date that is less than nine months from the date the drug is donated", or (j) "Requires refrigeration".

Expiration dating: VIM is often approached by local physician offices hoping to donate medications (usually samples) to our dispensary, and while these would be helpful to our patients, the expiration date is not always nine months in the future. Our inventory is carefully monitored for outdated medications, and expired medications are destroyed. Additionally, we would not dispense a medication if the expiration date would fall before the days supply of the medication being dispensed is used. We feel confident that a waiver to the nine-month rule would help more of our patients receive medication in a timely manner without posing any additional risks, while also minimizing waste.

Refrigerated medications: We have many diabetic patients who require insulin on an ongoing basis. Much of our insulin arrives directly from the Drug Company's patient assistance program, and also from those company's representatives. These shipments arrive in refrigerated containers and are immediately transferred to our refrigerator for storage. Periodically, our patients receiving medication through patient assistance become ineligible for services through our clinic. We would like to make their medications (including those properly stored under refrigeration) available to other eligible patients by receiving the medications from the "clinic" and donating them to the charitable pharmacy program according to policies and procedures.

Thank you for your consideration of these topics. Please feel free to contact me with any questions or clarifications.

Sincerely,

Alex Winn, PharmD
Dispensary Coordinator
Volunteers in Medicine – Clinic of the Cascades
2300 NE Neff Rd.
Bend, Or. 97701
541-585-9001 phone
541-585-4205 fax

Volunteers in Medicine Charitable Pharmacy

Good morning Gary,
I've included the new waiver request regarding using volunteer RN's and tacked on the waiver request I recently sent regarding using donated meds without lot numbers (thought it might be helpful to have both requests in one place).

Regarding OAR 855-044-0050 (3)-(3)(a) we seek a waiver to allow volunteer registered nurses as well as volunteer licensed pharmacists and practitioners with dispensing privileges to work in the lead role of the charitable pharmacy. This role includes the duties of final verify, dispensing and appropriate patient counseling as needed. The volunteer leads will always be working under either the staff pharmacist, the staff registered nurse, or both. Volunteers in Medicine relies on the use of volunteers to help keep costs low which allows the clinic to continue to give care to our patients who are unable to afford traditional medical care options. The largest pool of professional volunteer applicants are registered nurses, and the ability to use these volunteers as a lead in the pharmacy would greatly improve our ability to have the lead role filled by volunteers, which in turn allows the staff to be available to fill other needed roles in the pharmacy.
The volunteer leads will be trained by both the staff pharmacist and staff registered nurse, and will be closely supervised until training is complete. The lead will always have access to counseling cue cards and on-line clinical resources, and will be encouraged to pass problems on to a staff member.

Regarding ORS 689.772 (2)(a), OARs 855-044-0030 (2)(a) and 855-044-0070 (1)(b) we seek the following waiver from the Charitable Prescription Drug Program rules to increase access to donated prescription drugs and further public health: we request a waiver to allow the donation from other types of pharmacies, including, but not limited to long term care pharmacies, of repackaged medications that do not have a lot number, as long as the medicine has not left the control of a pharmacy or clinician. One example of this is a Medication Assistance Program (MAP) drug that is repackaged and sent from a mail order pharmacy to a safety-net pharmacy for a specific patient. When a patient does not pick-up this medicine, it is currently being destroyed even though the medicine has not left the control of the pharmacist. Drugs dispensed to patients are not required to have lot numbers on the medication label, which removes a large pool of medicine that would otherwise meet all the requirements of the Charitable Prescription Drug Program. We ask that this type of medicine be eligible for donation.

Thank you,
Laura Van Horn
Pharmacist and Point of Contact
Volunteers in Medicine Charitable Pharmacy

Exception and Waiver Requests April 2011 Board Meeting

Part 1
CardinalHealth Rxe-sourse

- Request – CardinalHealth is requesting a waiver for Board rules which relate to the storage, security and distribution of drugs.
- CardinalHealth is a consulting pharmacy which does not possess drugs and provides various consulting services
- They are aware of the requirements for licensure of the pharmacy as a retail drug outlet and an Oregon licensed PIC. All pharmacists who provide services to Oregon residents will be Oregon licensees.
- History – The Board has in the past granted this waiver request for the above activities.

No supporting letter from Gary Miner

Part 2
Volunteers in Medicine
Bend Oregon

- Request for waiver for OAR 855-044-0050 d and j related to dispensing of refrigerated items and the minimum nine month expiration date. See attached letter.
- This section does have a waiver clause and you can grant a waiver for each request.
- The waiver clause was placed in the rule to allow the Board to make exceptions on a case by case request.

- Board staff recommends granting the requests for the following reasons

The request to allow the dispensing of insulin which is donated by companies drug assistance programs would be reasonable as the dispensers will be a pharmacist, the clinic practitioners or nurse and proper storage can be maintained.

The second request also seems reasonable if proper save guards are added to their policy and procedures to make sure the stated and actual expiration date on the label reflect that the patient will receive a full course of therapy with good dated medications. This could be accomplished do to the use of trained medical personnel under the supervision of a pharmacist.

See supporting letter attached.

Volunteers in Medicine
Bend Oregon

End date Refrigeration

- Request for waiver for OAR 855-044-0050 d and j related to dispensing of refrigerated items and the minimum nine month expiration date. See attached letter.
- This section does have a waiver clause and you can grant a waiver for each request.
- The waiver clause was placed in the rule to allow the Board to make exceptions on a case by case request.

- Board staff recommends granting the requests for the following reasons

The request to allow the dispensing of insulin which is donated by companies' drug assistance programs would be reasonable as the dispensers will be a pharmacist, the clinic practitioners or nurse and proper storage can be maintained.

The second request also seems reasonable if proper save guards are added to their policy and procedures to make sure the stated and actual expiration date on the label reflect that the patient will receive a full course of therapy with good dated medications. This could be accomplished do to the use of trained medical personnel under the supervision of a pharmacist.
Note:

689.772 Establishment of program; immunity from liability. (1) There is created in the State Board of Pharmacy the Charitable Prescription Drug Program. The purpose of the program is to distribute donated prescription drugs to needy or uninsured individuals. Participation in the program is voluntary.

(2) The program may accept and distribute:

(a) Prescription drugs received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and

(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.

(3) The program may not distribute donated prescription drugs that:

(a) Fail to meet the requirements of this section;

(b) Bear an expiration date that is less than nine months from the date the drug is donated;

(c) Are adulterated or misbranded; or

(d) Belong to a category of controlled substances that may not be distributed under the program as adopted by the board by rule pursuant to ORS 689.774.

Oregon
Kate Brown, Governor

Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971/ 673-0001
Fax: 971/ 673-0002
Email: pharmacy.board@state.or.us
Web: www.pharmacy.state.or.us

August 30, 2016

Volunteers in Medicine Clinic
Attn: Laura Van Horn
2260 Marcola Rd
Springfield, OR 97477-2594

Re: Waiver Requests

At the Oregon Board of Pharmacy's August 2016 meeting, the Board reviewed two waiver requests for Volunteers in Medicine.

The Board approved a waiver request for the Drug Donation Rules in OAR 855-044-0030(2)(a) and Records rules in OAR 855-044-0070(1)(b). This waiver is valid for 5 years from date of letter. After this date, a new waiver must be requested. A copy of this notification should be kept with your files.

The Board denied a waiver request for the Drug Distribution Rules in OAR 855-044-0050(3)(a).

If you have any questions, or if we can be of further assistance, please contact Compliance Director, Gary Miner, at Gary.Miner@state.or.us. Please provide your name, your preferred contact method and information, and your concerns. Alternatively, you may contact our office at the address and phone number listed above.

Sincerely,

Marcus Watt, R.Ph
Executive Director

CC: Gary Miner, R.Ph., Compliance Director
Oregon Board of Pharmacy Licensing Department

June 29, 2016

Volunteers in Medicine Charitable Pharmacy waiver request

Volunteers in Medicine Charitable Pharmacy (VMCP) are requesting two waivers. One for the required lot number on accepted and donated drugs and allow donations from other health care provides other than LTC facilities {OAR855-044-0030(2)(a) and 855-044-0070(1)(b)}. The second request is to use volunteer nurses as the dispensing Registered Nurse {855-044-0050(3)(a)

Discussion:
The waiver for the lot number exception has been granted to other Charitable Pharmacies with the provision that if a recall occurs then all of the recalled drugs would be destroyed. A clarification in the waiver can include the appropriate donation of drugs in a partial manufacturer original container. The second part of this request does not need a waiver but maybe a clarification. We have allowed the donation of unused drugs from Medication Assistance programs and samples. This would include full or partial packets of drugs and full and drugs in manufacture original containers.

The waiver request for volunteer registered nurses to perform final verification, dispensing and appropriate patient counseling is the first time the Board has been asked for this waiver. The rule requires these functions should be performed by a Registered Nurse who is an employee of the pharmacy. The discussion about this section of rule when adopted centered on accountability and consistency using only RNs who are employed. A concern was creating a situation where there are several RNs working limited hours which would place public at a greater risk regarding dispensing errors.

Recommendation-

Approve the waiver for the lot numbers and use of drugs contained in partial bulk manufacturer original container. The use of other practitioners as a source for mediation donations has been allow as long as all the donation criteria is met.
Deny the waiver for use of non-employee RNs as dispensers but the Board can encourage the use of volunteer RNs to aid in the process but an employed RN would be responsible for the final verification and supervision of the dispensing.

855-044-0030

Drug Donation

(1) A charitable pharmacy may not accept:

(a) Any controlled substance or any kit, package or blister pack that contains any controlled substance;

(b) A non-prescription drug;

(c) A drug in a container or package that does not contain a product identification label (PIL), except that a drug in a manufacturer's original container or a manufacturer's blister pack does not need to bear a PIL.

(2) A charitable pharmacy may accept:

(a) A prescription drug received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; and

(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses.

(3) The following are examples of acceptable packaging:

(a) Manufacturer's original container;

(b) Single-dose blister packs in sealed outer package;

(c) Single-dose blister packs in opened outer package;

(d) Tamper-evident hospice kit containing manufacturer's original containers.

(4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be unsafe for re-dispensing must be stored separately from the drug supply until they can be destroyed.

(5) A charitable pharmacy may accept a drug from:

(a) An individual;

(b) A long-term care facility;

(c) A pharmacy;

(d) A practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice;

(e) Another registered charitable pharmacy;

(f) A medical clinic;

(g) A drug manufacturer or wholesaler;

(h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.

(6) The donor must certify on a Donor Form provided by the Board that the donated drug has been properly stored, in accordance with manufacturer's recommendations, and has never been opened, used, adulterated or misbranded.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0070

Records

(1) A charitable pharmacy must maintain a donation record of all drugs received that includes:

(a) Donor's name and address;

(b) Drug manufacturer, lot number, name and strength;

(c) Drug quantity;

(d) Expiration date of the drug;

(e) Date donated; and

(f) The unique identifier.

(2) A charitable pharmacy must maintain a distribution and dispensing record that includes:

(a) Drug name and strength;

(b) Quantity distributed;

(c) Name of manufacturer;

(d) Lot number and expiration date;

(e) Date of distribution or dispensing;

(f) Name and address of recipient.

(3) A charitable pharmacy must maintain a record of all drugs that are destroyed.

(4) In addition to the above records, a charitable pharmacy must cross-reference the donation record and the distribution and dispensing record with the appropriate donor and recipient forms.

(5) A charitable pharmacy must make an annual report to the Board by completing a form provided by the Board and submitting it with their application for renewal of registration.

(6) All records required by these rules must be retained for three years and made available to the Board upon request.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10; BP 9-2014, f. & cert. ef. 12-4-14

855-044-0050

Drug Distribution

(1) A charitable pharmacy may not distribute a donated prescription drug that:

(a) Fails to meet the requirements of the program;

(b) Has not been stored in accordance with manufacturer's recommendations;

(c) Has been repackaged, except that a drug that has been repackaged for a long-term care pharmacy may be distributed;

(d) Bears an expiration date that is less than nine months from the date the drug is donated;

(e) Is adulterated or misbranded;

(f) Is a controlled substance;

(g) Is a drug that requires a special registration for dispensing;

(h) Is an over-the-counter drug;

(i) Requires specialty storage or handling;

(j) Requires refrigeration;

(k) Is a compounded drug; or

(L) In the pharmacist's professional judgment, may be unfit for dispensing.

(2) A charitable pharmacy may only dispense a drug to a person who:

(a) Has a valid prescription for the drug; and

(b) Is a resident of Oregon; and

(c) Is underinsured or does not have adequate health insurance coverage for the prescription drug requested; or

(d) Is enrolled in a program of public assistance as defined in ORS 411.010;

(3) A drug may only be dispensed by a pharmacist or by a practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice, or by a registered nurse subject to the following:

(a) A registered nurse who is an employee of a charitable pharmacy may dispense a drug to a client of the charitable pharmacy; and

(b) Such dispensing by a registered nurse shall be pursuant to the order of a person authorized to prescribe the drug.

(4) The dispensing practitioner must provide the patient with appropriate counseling on the use of the drug and any potential side effects, and may provide written drug information;

(5) A recipient of a drug under this program must sign a Recipient Form, provided by the Board, that attests that the recipient has been notified that:

(a) The prescription drug was donated to the program;

(b) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging;

(c) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the Donor's Form and the visual inspection by the pharmacist;

(d) Participants in the program are immune from liability as provided in ORS 689.780; and

(e) That they are qualified to receive the drug as specified in section (2) of this rule.

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774
Hist.: BP 6-2010, f. & cert. ef. 6-29-10

SBAR: Volunteers in Medicine – Clinic of the Cascades Charitable Pharmacy Waiver Request

S	**Situation:** • Volunteers in Medicine – Clinic of the Cascades Charitable Pharmacy requests a waiver per OAR 855-044-0050(6) to permit dispensing of donated drugs that require refrigeration. o Registration: CP-0000003 2300 NE Neff Rd Bend Oregon
B	**Background:** • **OAR 855-044-0050 Drug Distribution** (1) A charitable pharmacy may not distribute a donated prescription drug that: (a) Fails to meet the requirements of the program; (b) Has not been stored in accordance with manufacturer's recommendations; (c) Has been repackaged, except that a drug that has been repackaged for a long-term care pharmacy may be distributed; (d) Bears an expiration date that is less than nine months from the date the drug is donated; (e) Is adulterated or misbranded; (f) Is a controlled substance; (g) Is a drug that requires a special registration for dispensing; (h) Is an over-the-counter drug; (i) Requires specialty storage or handling; (j) Requires refrigeration; (k) Is a compounded drug; or (L) In the pharmacist's professional judgment, may be unfit for dispensing. (2) A charitable pharmacy may only dispense a drug to a person who: (a) Has a valid prescription for the drug; and (b) Is a resident of Oregon; and (c) Is underinsured or does not have adequate health insurance coverage for the prescription drug requested; or (d) Is enrolled in a program of public assistance as defined in ORS 411.010; (3) A drug may only be dispensed by a pharmacist or by a practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice, or by a registered nurse subject to the following: (a) A registered nurse who is an employee of a charitable pharmacy may dispense a drug to a client of the charitable pharmacy; and (b) Such dispensing by a registered nurse shall be pursuant to the order of a person authorized to prescribe the drug. (4) The dispensing practitioner must provide the patient with appropriate counseling on the use of the drug and any potential side effects, and may provide written drug information; (5) A recipient of a drug under this program must sign a Recipient Form, provided by the Board, that attests that the recipient has been notified that:

	(a) The prescription drug was donated to the program; (b) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging; (c) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the Donor's Form and the visual inspection by the pharmacist; (d) Participants in the program are immune from liability as provided in ORS 689.780; and (e) That they are qualified to receive the drug as specified in section (2) of this rule. **(6) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing** • Past Board Meetings: o DCCT: June 19 Board Meeting reviewed requested waiver and requested additional information. August 19 Board meeting request to dispense donated refrigerated insulin approved. o Volunteers in Medicine: December 2014 Board Meeting request to accept and provide insulin and other cold storage drugs approved.
A	**Assessment:** • Per OAR 855-044-0050(6) Will this further public health or safety or the health and safety of a patient? o VIM stated that refrigerated medications are vital to many of their client's health and often too expensive when filled at community pharmacies. o They are ablet to provide refrigerated medications to their client's at no cost through manufacture patient assistance programs, Direct Relief, AmeriCares, or other drugs outlets licensed to distribute medication in Oregon. • VIM stated refrigerated medications arrive via insulated shipping boxes with cold package and cold drug storage monitoring devices such as TempTale or similar. They then transfer these shipments into their medical grade fridge or freezer. • List of location and registration # for manufacturers, wholesalers and pharmacy that would provide refrigerated drugs: o PFIZER 1855 SHELBY OAKS DR N MEMPHIS TN 38134 Registration #: M-0001757 o GSK CONSUMER HEALTH INC 10401 HWY #6 AND I-80 LINCOLN NE 68517 Registration #: M-0001052

	o NOVO NORDISK, INC 800 SCUDDERS MILL RD PLAINSBORO NJ 08536 Registration #: M-0001798 o MERCK SHARP & DOHME CORP 4633 MERCK RD WILSON NC 27893 Registration #: M-0003134 o NOVARTIS PHARMACEUTICALS CORP 59 ROUTE 10 EAST HANOVER NJ 07936 Registration #: M-0001068 o LILLY USA LLC ONE LILLY CORPORATE CENTER INDIANAPOLIS IN 46285 Registration #: M-0002089 o ABBVIE US LLC 1 N WAUKEGAN RD D-GS02, BLDG AP5 NORTH CHICAGO IL 60064 Registration #: M-0002418 o RX CROSSROADS BY MCKESSON 5101 JEFF COMMERCE DR STE A LOUISVILLE KY 40219 Registration #: RP-0001928 o DIRECT RELIEF 6100 WALLACE BECKNELL RD SANTA BARBARA CA 93117 Registration #: W1-0003221 o AMERICARES FOUNDATION INC 88 HAMILTON AVE STAMFORD CT 06902 Registration #: W3-0000071 o ST. CHARLES MEDICAL CENTER – BEND 2500 NE NEFF ROAD BEND OR 97701 Registration #: IP-0000012

	o How will the pharmacist assess and document assessment to determine and ensure integrity of drug product has been maintained? ▪ VIM stated that upon arrival refrigerated medications are removed from their insulated shipping boxes and scanned with an infrared thermometer (FLUKE 62 MAX, calibrated by GBARRY S/N 44842953WS), the temperature is recorded on the invoice along with the date and the receiver's initials. Invoices are stored on site by manufacturer/ wholesaler for 6 years. Any cold storage monitoring devices such as TempTale or Temptime TransTracker, or similar is inspected and handled per the manufacturer's recommendations. After inspection and documentation is complete, and the temperature of the medication is within the manufacturer's recommended storage temperature range, we then transfer them into either our Helmer medical grade refrigerator or Helmer medical grade freezer. Temperatures range between 2-8 degrees Celsius (refrigerator) or -20 - -30 degrees Celsius (freezer) inside our charitable pharmacy for secure storage and ongoing monitoring via Isensix.
R	**Recommendation:** • Grant for 3 years

Date: 6/2022

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WELL-BEING index

JUNE 2022/H

Well-being Index For Pharmacy Personnel

State Report for State Boards of Pharmacy

NABP District Seven States

MAY 2022

pharmacist.com

For Every Pharmacist. For All of Pharmacy.

DISTRESS PERCENT CHANGES

National and District

April 2022 versus May 2022

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Changes in Distress Levels

As of May 2022

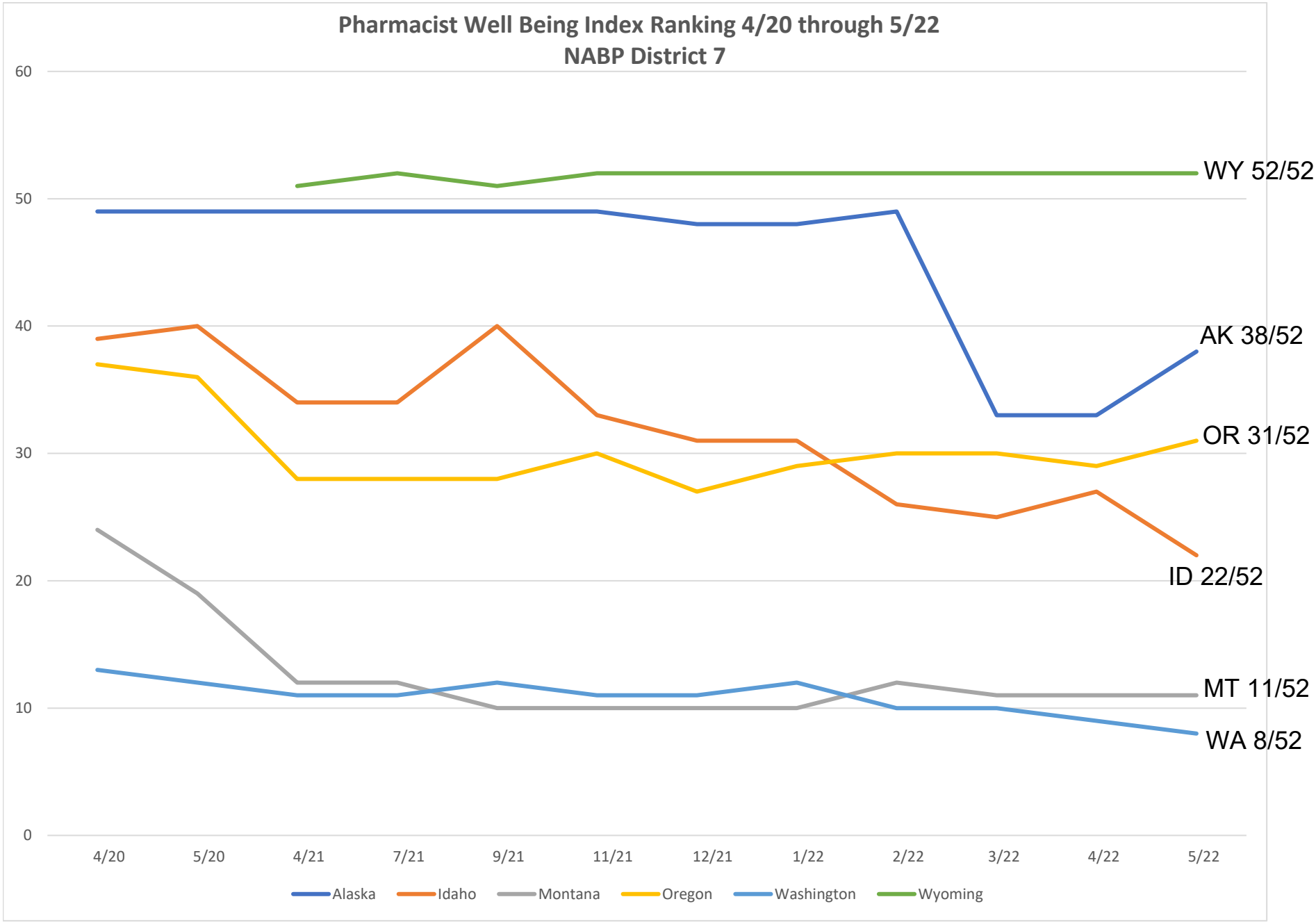
State	Change in Distress % April 2022 vs May 2022	Distress % May 2022	State Rank for Distress Percent May 2022
Largest Increase in Distress Percent			
Puerto Rico	2.93%	47.37%	4
District of Columbia	1.85%	31.58%	36
Idaho	1.15%	34.48%	22
New Jersey	0.94%	37.96%	16
Virginia	0.85%	40.81%	10
Largest Decrease in Distress Percent			
New Mexico	-0.72%	29.58%	130
Utah	-0.50%	29.75%	49
Hawaii	-0.47%	40.23%	28
Alaska	-0.45%	31.43%	64
Maryland	0.44%	33.19%	130
NATIONAL	0.06%	31.98%	----

Changes in Distress Levels – District Seven

As of May 2022

	Change in Distress % Apri22 Vs May 22	Distress % May 2022	Distress % State Rank May 2022	Change in Distress % Mar 22 Vs Apr 22	Distress % State Rank Apr 2022	Distress % State Rank Mar 2022	Distress % State Rank Feb 2022	Distress % State Rank Jan 2022	Distress % State Rank Dec 2021	Distress % State Rank Nov 2021	Distress % State Rank Sep 2021	Distress % State Rank Jul 2021	Distress % State Rank Apr 2021	Distress % State Rank May 2020	Distress % State Rank Apr 2020
Alaska	**-0.45%**	**31.43%**	**38**	-0.47%	33	33	49	48	48	49	49	49	49	49	49
Idaho	**1.15%**	**34.48%**	**22**	-0.30%	27	25	26	31	31	33	40	34	34	40	39
Montana	**No Change**	**40.63%**	**11**	No Change	11	11	12	10	10	10	10	12	12	19 (t)	24
Oregon	**-0.18%**	**32.98%**	**31**	0.01%	29	30	30	29	27 (t)	30	28	28	28	36	37
Washington	**0.51%**	**41.38%**	**8**	-0.28%	9	10	10	12	11	11	12	11	11	12	13
Wyoming	**No Change**	**17.39%**	**52**	-0.79%	52	52	52	52	52	52	51	52	51	~	~

Note: Historic data from 2020/2021 has been removed to allow space for current month.
Refer to previous months' reports or contact ashaughnessy@aphanet.org for data.


Pharmacist Well Being Index Ranking 4/20 through 5/22
NABP District 7
60
50
40
30
20
10
0
4/20
5/20
4/21
7/21
9/21
11/21
12/21
1/22
2/22
3/22
4/22
5/22
Alaska
Idaho
Montana
Oregon
Washington
Wyoming
WY 52/52
AK 38/52
OR 31/52
ID 22/52
MT 11/52
WA 8/52

DISTRESS PERCENT

Why does it change when the number of assessors stays the same? Reassessments!

WELL-BEING index
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NUMBER OF ASSESSMENTS, REASSESSMENT, and ASSESORS

As of May 2022

District Seven	Number of First Assessments	Number of Reassessments	Unique Number of Reassessment Assessors	Total Assessments
Alaska	46	21	8	70
Idaho	68	48	21	116
Montana	26	6	6	32
Oregon	94	97	36	191
Washington	151	81	22	232
Wyoming	15	8	6	23
National	8399	8080	2428	16479

DISTRESS PERCENT MONTHLY REPORTS
State-Specific
April 2022 versus May 2022

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

PHARMACISTS WELL-BEING INDEX

STATE DISTRESS PERCENT*

MAY 2022

As of May 6, 2022, the Alaska distress percent was 31.43% (ranked 38/52) with 49 assessors.

APRIL 2022

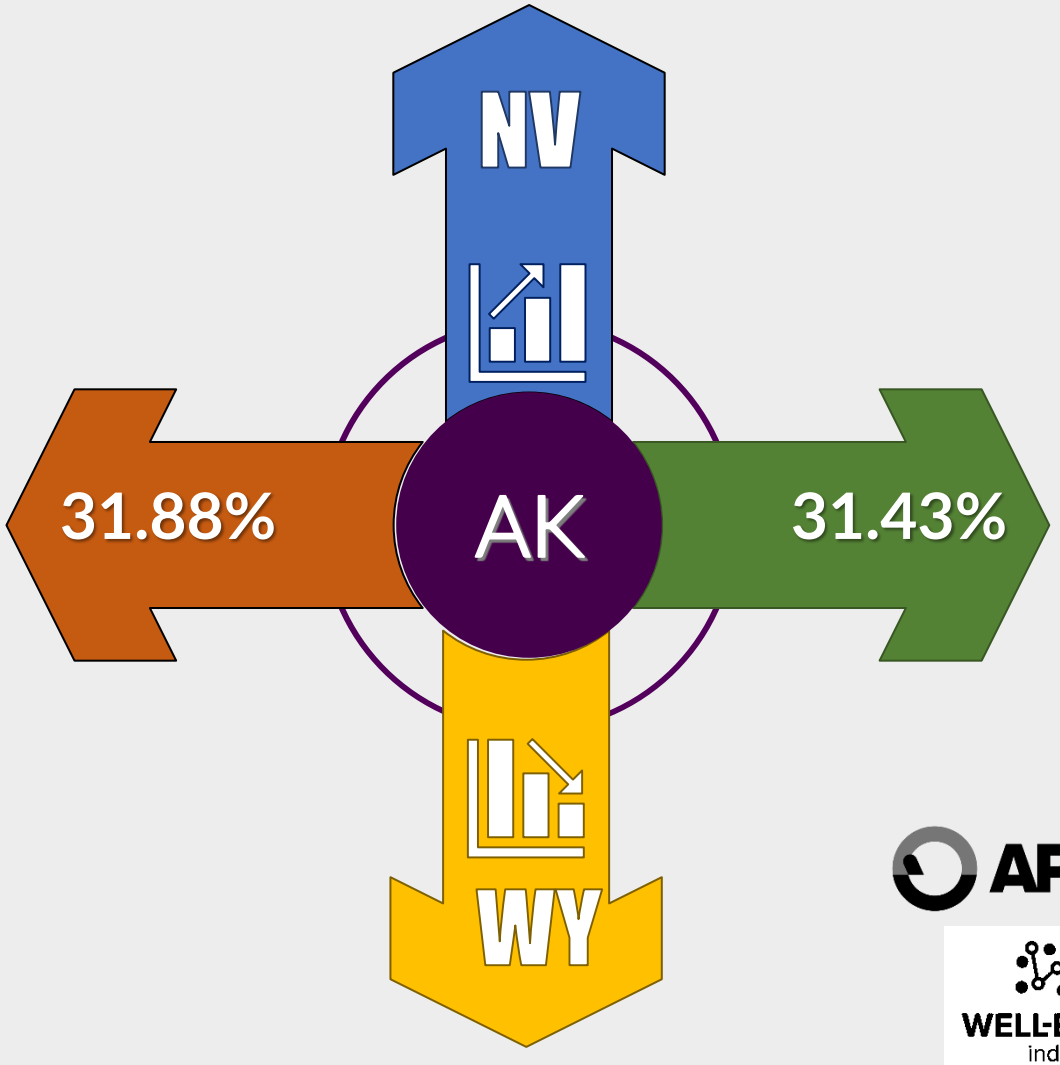
As of April 6, 2022, the Alaska distress percent was 31.88% (ranked 33/52) with 49 assessors.

STATE COMPARISON

As of May 6, 2022

Nevada is the highest at 57.81% (n=26)

Wyoming has the lowest 17.39% (n=16)



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WELL-BEING index
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Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

PHARMACISTS WELL-BEING INDEX

STATE DISTRESS PERCENT*

MAY 2022

As of May 6, 2022, the Idaho distress percent was 34.48% (ranked 22/52) with 68 assessors.

APRIL 2022

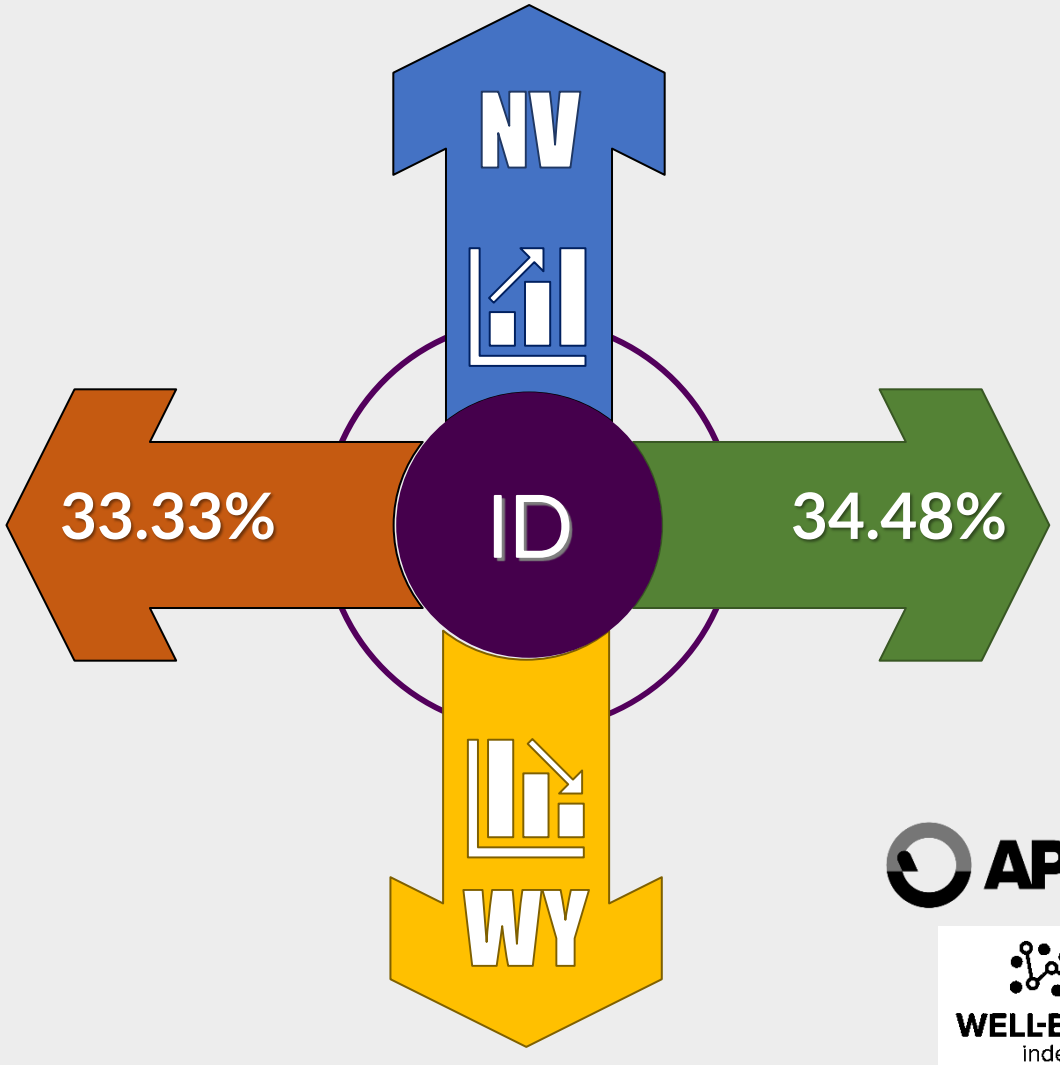
As of April 6, 2022, the Idaho distress percent was 33.33% (ranked 27/52) with 67 assessors.

STATE COMPARISON

As of May 6, 2022

Nevada is the highest at 57.81% (n=26)

Wyoming has the lowest 17.39% (n=16)



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WELL-BEING index
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PHARMACISTS WELL-BEING INDEX

STATE DISTRESS PERCENT*

MAY 2022

As of May 6, 2022, the Montana distress percent was 40.63% (ranked 11/52) with 26 assessors.

APRIL 2022

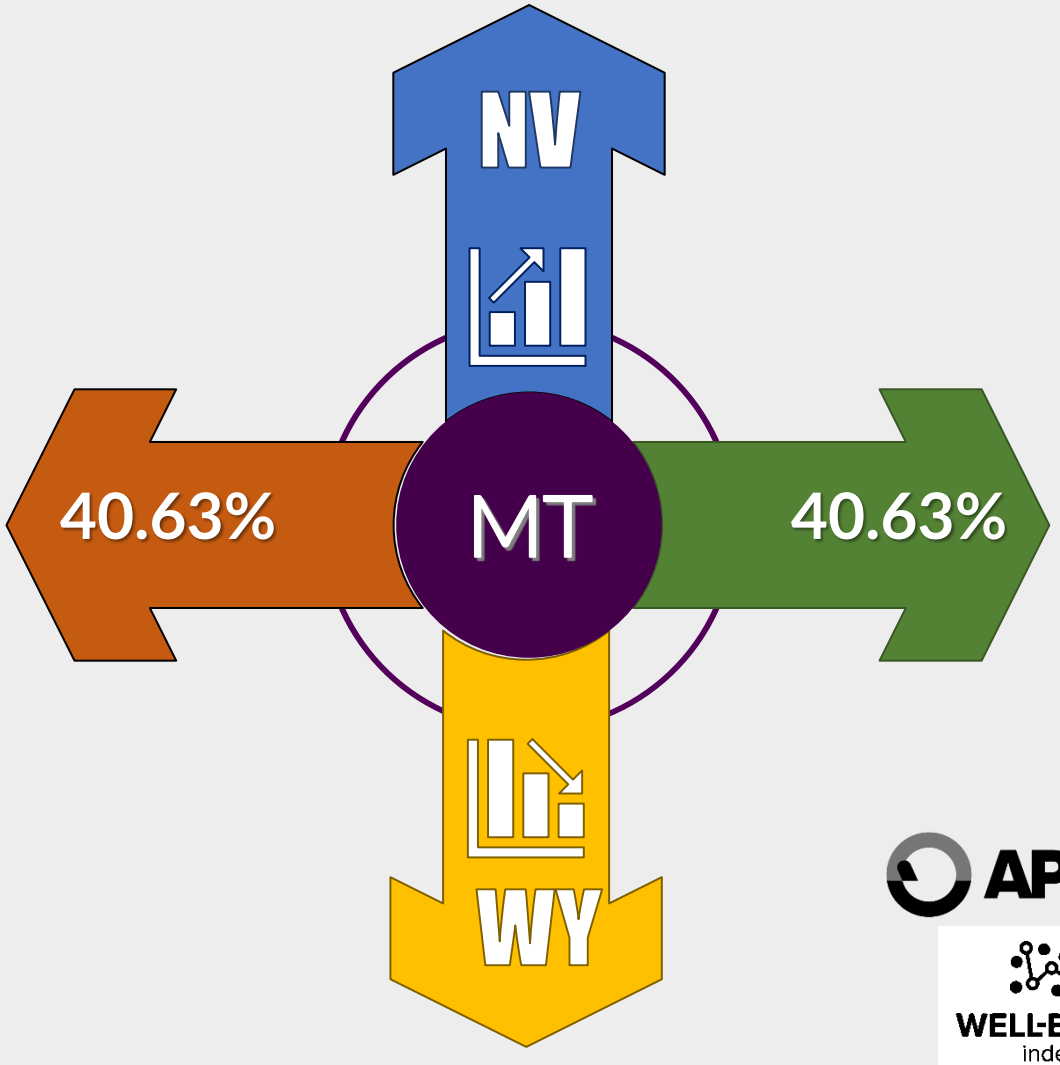
As of April 6, 2022, the Montana distress percent was 40.63% (ranked 11/52) with 26 assessors.

STATE COMPARISON

As of May 6, 2022

Nevada is the highest at 57.81% (n=26)

Wyoming has the lowest 17.39% (n=16)



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WELL-BEING index
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Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

PHARMACISTS WELL-BEING INDEX

STATE DISTRESS PERCENT*

MAY 2022

As of May6, 2022, the Oregon distress percent was 32.98% (ranked 31/52) with 94 assessors.

APRIL 2022

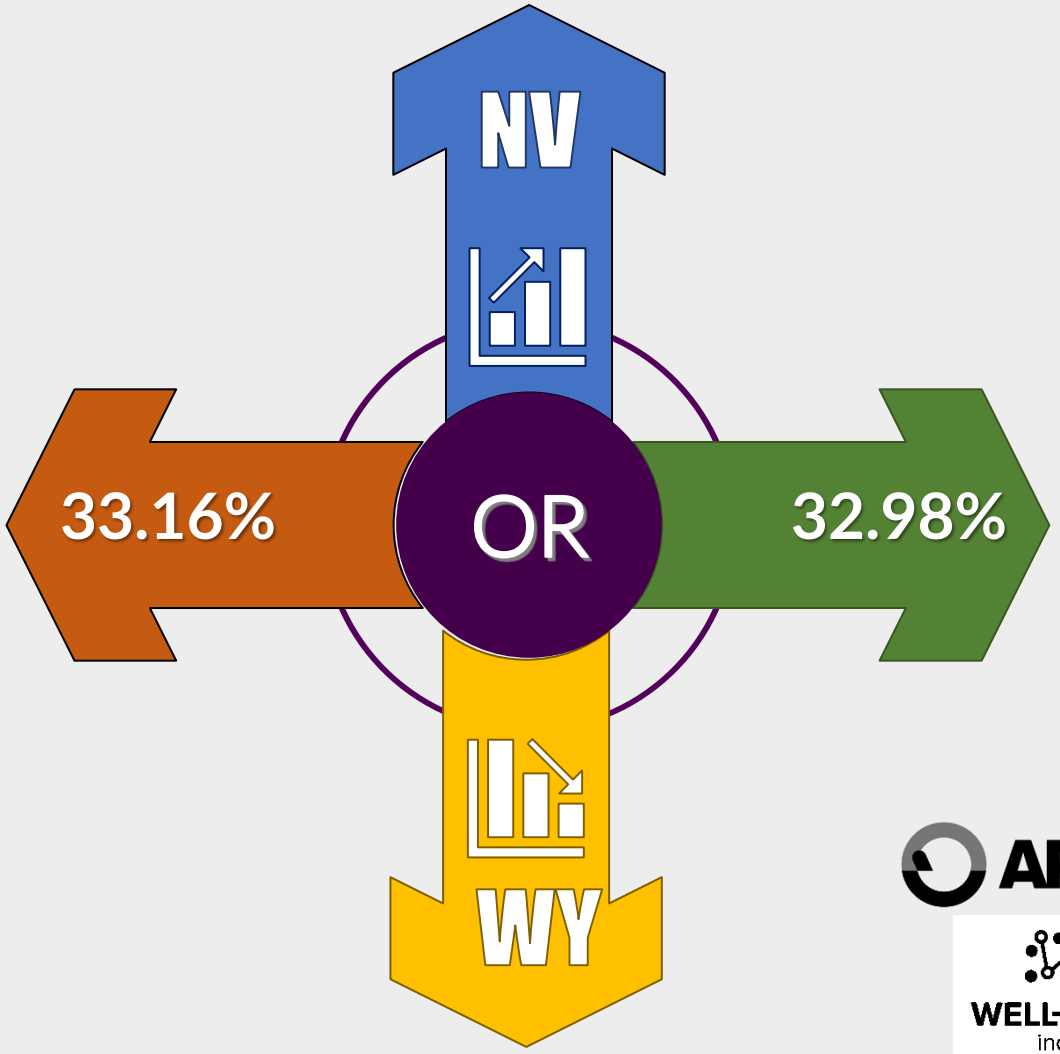
As of April 6, 2022, the Oregon distress percent was 33.16% (ranked 29/52) with 94 assessors.

STATE COMPARISON

As of May 6, 2022

Nevada is the highest at 57.81% (n=26)

Wyoming has the lowest 17.39% (n=16)



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Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

PHARMACISTS WELL-BEING INDEX

STATE DISTRESS PERCENT*

MAY 2022

As of May 6, 2022, the Washington distress percent was 41.38% (ranked 8/52) with 152 assessors.

APRIL 2022

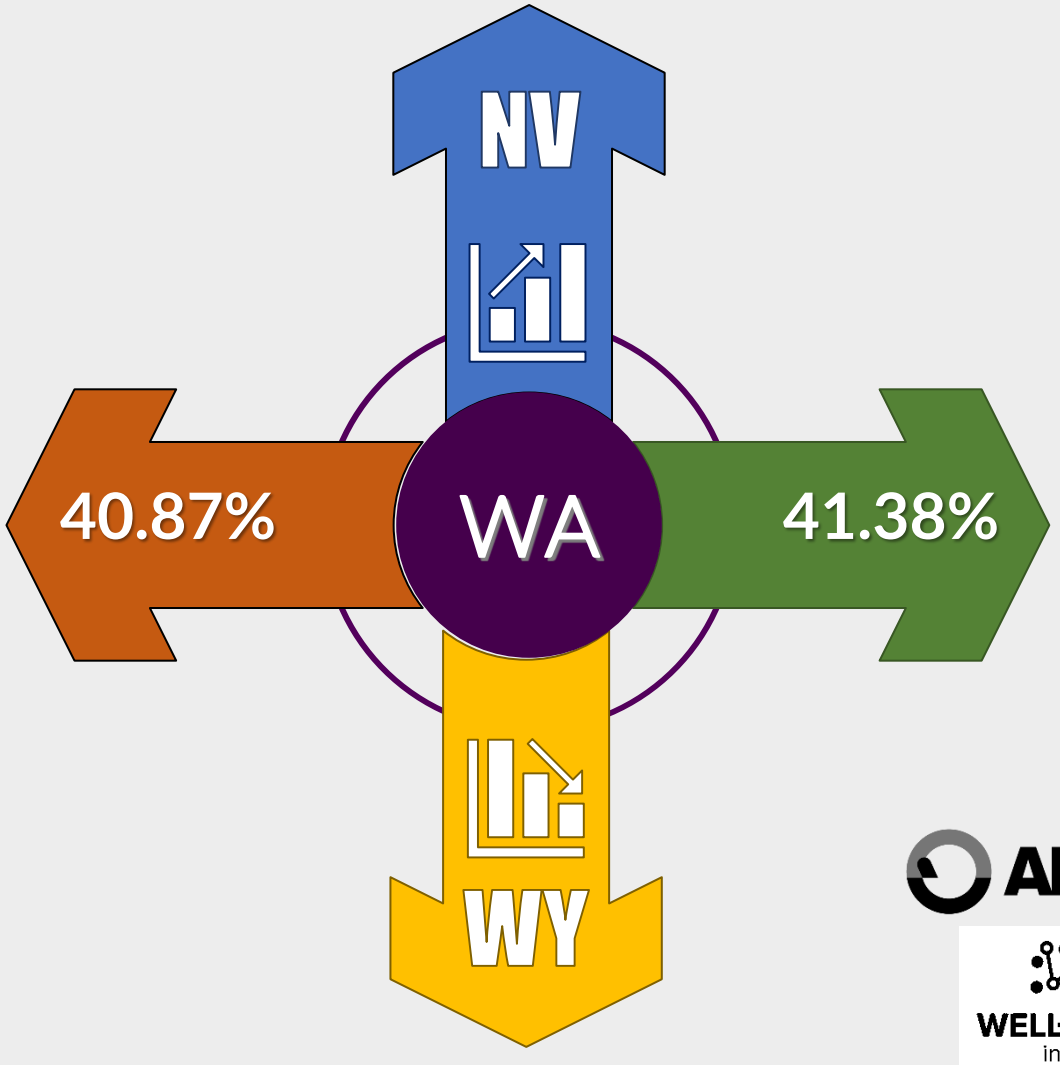
As of April 6, 2022, the Washington distress percent was 40.87% (ranked 9/52) with 152 assessors.

STATE COMPARISON

As of May 6, 2022

Nevada is the highest at 57.81% (n=26)

Wyoming has the lowest 17.39% (n=16)



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WELL-BEING index
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Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

PHARMACISTS WELL-BEING INDEX

STATE DISTRESS PERCENT*

MAY 2022

As of May 6, 2022, the Wyoming distress percent was 17.39% (ranked 52/52) with 16 assessors.

APRIL 2022

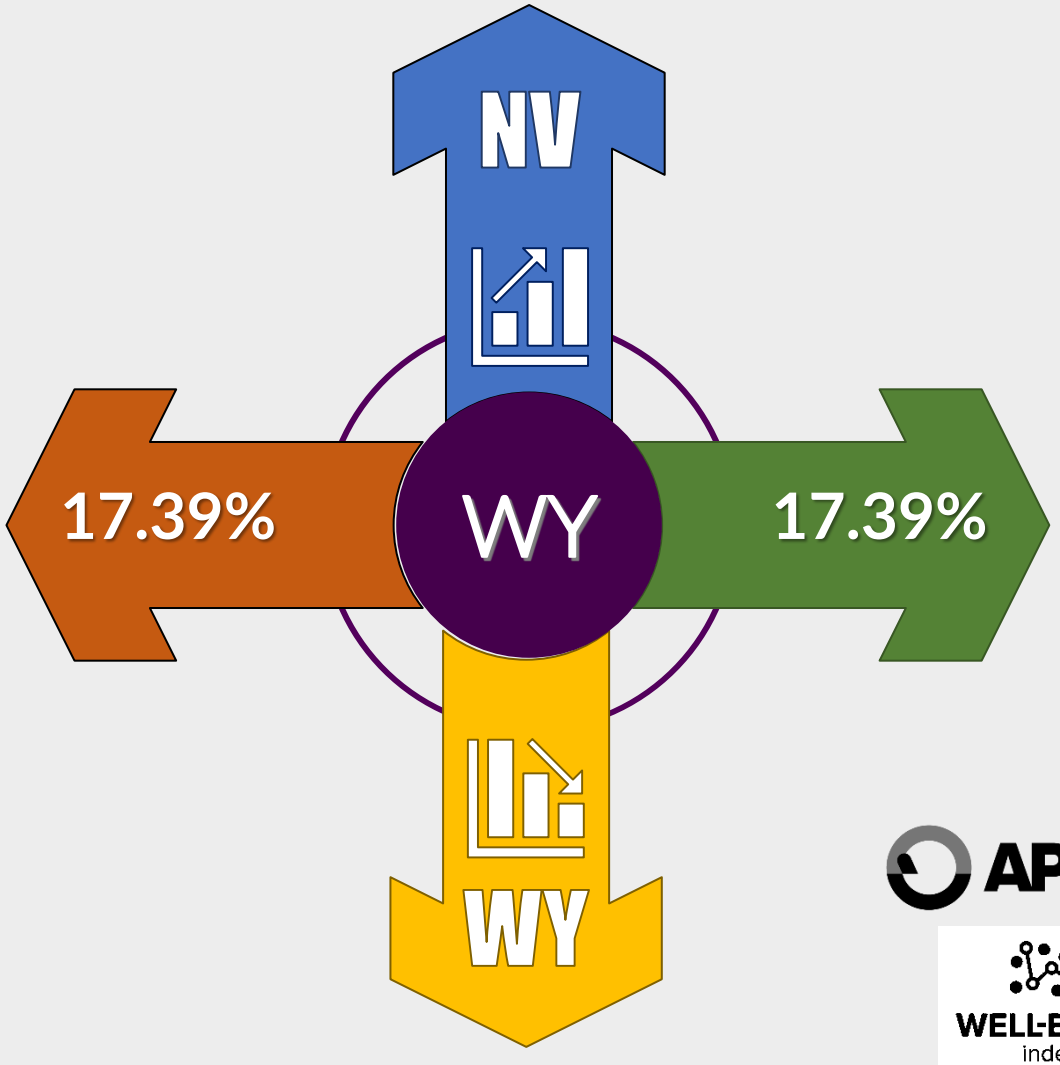
As of April 6, 2022, the Wyoming distress percent was 17.39% (ranked 52/52) with 16 assessors.

STATE COMPARISON

As of May 6, 2022

Nevada is the highest at 57.81% (n=26)

Wyoming has the lowest 17.39% (n=16)



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WELL-BEING index
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Distress Percent is the percentage of individuals with a Pharmacist Well-Being Index (WBI) score ≥5. It measures the percent of individuals that are at a high level of distress.

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Invitation Code: APhA

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We're committed to your well-being.
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Oregon Board of Pharmacy

Budget Report: March 2022 (Month 9)

Revenue:

Through March, revenue is $3,027,936 (-11.2%) **under** budget

Expenditures:

Through March, **total expenditures** are $3,170,257 (12.8%) **under** budget

Personal services are $2,341,614 (6.9%) **under** budget

Services and Supplies are $828,643 (34.3) **under** budget

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

Revenues less Expenditures: ($142,321)

Cash Balance:

Cash balance through March is $4,114,763 which represents (10.19) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through March 2022. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $5,108,808, which represents (13.75) months of operating expense*)

Cash balance target is $2,229,745, (6.0 months of operating expense)

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

Oregon Board of Pharmacy				
Total All Funds - LAB 2021-2023				
Actuals through MARCH 2022				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**3,679,852**	**4,714,145**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	8,716,500.00	8,981,156.50	(264,656.50)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	273,993.75	(80,998.75)
505	FINES AND FORFEITS	410,000.00	385,872.43	24,127.57
605	INTEREST AND INVESTMENTS	131,250.00	57,022.60	74,227.40
975	OTHER REVENUE	84,335.00	58,717.31	25,617.69
	TOTAL REVENUE	**9,535,080.00**	**9,756,762.59**	**(221,682.59)**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	443,120.00	443,120.00	-
	TOTAL TRANSFER OUT	**443,120.00**	**443,120.00**	**0.00**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,283,003.00	4,215,271.73	67,731.27
3160	TEMPORARY APPOINTMENTS	27,306.00	-	27,306.00
3170	OVERTIME PAYMENTS	-	1,542.57	(1,542.57)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	198,616.00	169,073.67	29,542.33
3210	ERB ASSESSMENT	1,276.00	1,252.80	23.20
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	760,737.00	774,547.43	(13,810.43)
3221	PENSION BOND CONTRIBUTION	236,241.00	239,994.79	(3,753.79)
3230	SOCIAL SECURITY TAX	334,236.00	327,627.60	6,608.40
3240	UNEMPLOYMENT ASSESSMENT	-	-	-
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	958.17	53.83
3260	MASS TRANSIT	27,053.00	26,057.67	995.33
3270	FLEXIBLE BENEFITS	841,104.00	777,164.03	63,939.97
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,710,584.00**	**6,533,490.47**	**177,093.53**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	16,988.84	98,905.16
4125	OUT-OF-STATE TRAVEL	17,024.00	1,032.87	15,991.13
4150	EMPLOYEE TRAINING	22,320.00	12,724.45	9,595.55
4175	OFFICE EXPENSES	134,566.00	65,996.66	68,569.34
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	58,214.36	(7,284.36)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	202,541.00	-
4250	DATA PROCESSING	318,678.00	357,904.32	(39,226.32)
4275	PUBLICITY & PUBLICATIONS	43,329.00	14,691.38	28,637.62
4300	PROFESSIONAL SERVICES	339,713.00	243,583.58	96,129.42
4315	IT PROFESSIONAL SERVICES	134,467.00	48,570.00	85,897.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	487,292.18	134,542.82
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	3,415.00	2,003.00
4425	FACILITIES RENT & TAXES	229,042.00	270,143.19	(41,101.19)
4475	FACILITIES MAINTENANCE	55.00	1,851.13	(1,796.13)
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	1,000.00	202.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	171,039.71	79,439.29
4650	OTHER SERVICES AND SUPPLIES	411,285.00	402,273.89	9,011.11
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	10,000.00	4,108.00
4715	IT EXPENDABLE PROPERTY	45,228.00	16,226.86	29,001.14
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,385,489.42**	**573,305.58**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,691,342.00**	**8,918,979.89**	**772,362.11**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,080,470**	**5,108,808**	
	End of biennium projected cash balance in months		13.75	
	Cash balance target of 6.0 months (working capital)		2,229,745	

JUNE 2022/J

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

Programs By Status

Programs By Status

ACPE requires the programs it accredits to meet the expectations of all 25 standards of ACPE's accreditation standards. Any standard the board finds to be partially compliant or non-compliant can be seen by clicking on the Detailed PharmD Accreditation History link for each College or School. The program has two years to bring the standard into compliance as per US Department of Regulation. If no standard is noted, the program is in compliance with all 25 ACPE Accreditation Standards.

Accredited (138)

School Name	
Albany College of Pharmacy and Health Sciences	View
Appalachian College of Pharmacy	View
Auburn University Harrison College of Pharmacy	View
Belmont University College of Pharmacy	View
Binghamton University State University of New York School of Pharmacy and Pharmaceutical Sciences	View
Butler University College of Pharmacy and Health Sciences	View
California Northstate University College of Pharmacy	View

Campbell University College of Pharmacy and Health Sciences	View
Cedarville University School of Pharmacy	View
Chapman University School of Pharmacy	View
Concordia University Wisconsin School of Pharmacy	View
Creighton University School of Pharmacy and Health Professions	View
Drake University College of Pharmacy and Health Sciences	View
Duquesne University School of Pharmacy	View
D'Youville University School of Pharmacy	View
East Tennessee State University Bill Gatton College of Pharmacy	View
Fairleigh Dickinson University School of Pharmacy & Health Sciences	View
Ferris State University College of Pharmacy	View
Florida A&M University College of Pharmacy and Pharmaceutical Sciences, Institute of Public Health	View
Harding University College of Pharmacy	View
High Point University Fred Wilson School of Pharmacy	View
Howard University College of Pharmacy	View
Husson University College of Health and Pharmacy School of Pharmacy	View
Idaho State University College of Pharmacy	View
Keck Graduate Institute (KGI) School of Pharmacy and Health Sciences	View
Lake Erie College of Osteopathic Medicine School of Pharmacy	View
Lebanese American University School of Pharmacy	View
Lipscomb University College of Pharmacy and Health Sciences	View
Loma Linda University School of Pharmacy	View
Long Island University Arnold and Marie Schwartz College of Pharmacy and Health Sciences	View
Manchester University College of Pharmacy, Natural and	View

Health Sciences	
Marshall B. Ketchum University College of Pharmacy	View
Marshall University School of Pharmacy	View
MCPHS University School of Pharmacy - Worcester	View
MCPHS University School of Pharmacy - Boston	View
Medical College of Wisconsin School of Pharmacy	View
Medical University of South Carolina College of Pharmacy	View
Mercer University College of Pharmacy	View
Midwestern University College of Pharmacy	View
North Dakota State University College of Health Professions School of Pharmacy	View
Northeast Ohio Medical University College of Pharmacy	View
Northeastern University Bouvé College of Health Sciences School of Pharmacy and Pharmaceutical Sciences	View
Notre Dame of Maryland University School of Pharmacy	View
Nova Southeastern University College of Pharmacy	View
Ohio Northern University Raabe College of Pharmacy	View
Ohio State University College of Pharmacy	View
Oregon State University College of Pharmacy	View
Pacific University School of Pharmacy	View
Palm Beach Atlantic University Lloyd L. Gregory School of Pharmacy	View
Philadelphia College of Osteopathic Medicine - Georgia School of Pharmacy	View
Presbyterian College School of Pharmacy	View
Purdue University College of Pharmacy	View
Regis University Rueckert-Hartman College for Health Professions School of Pharmacy	View
Roosevelt University College of Science, Health and Pharmacy	View
Rosalind Franklin University of Medicine and Science College of Pharmacy	View
Roseman University of Health Sciences College of Pharmacy	View

Rutgers, the State University of New Jersey Ernest Mario School of Pharmacy	View
Samford University McWhorter School of Pharmacy	View
Shenandoah University Bernard J. Dunn School of Pharmacy	View
South College School of Pharmacy	View
South Dakota State University College of Pharmacy and Allied Health Professions	View
South University School of Pharmacy	View
Southern Illinois University Edwardsville School of Pharmacy	View
Southwestern Oklahoma State University College of Pharmacy	View
St. John Fisher College Wegmans School of Pharmacy	View
St. John's University College of Pharmacy and Health Sciences	View
Sullivan University College of Pharmacy and Health Sciences	View
Temple University School of Pharmacy	View
Texas A & M University Health Science Center Irma Lerma Rangel College of Pharmacy	View
Texas Southern University Joan M. Lafleur College of Pharmacy and Health Sciences	View
Texas Tech University Health Sciences Center Jerry H. Hodge School of Pharmacy	View
Thomas Jefferson University Jefferson College of Pharmacy	View
Touro University Touro College of Pharmacy	View
Touro University - California College of Pharmacy	View
Union University College of Pharmacy	View
University at Buffalo The State University of New York School of Pharmacy & Pharmaceutical Sciences	View
University of Arizona R. Ken Coit College of Pharmacy	View
University of Arkansas for Medical Sciences College of Pharmacy	View
University of California, San Diego Skaggs School of	View

Pharmacy & Pharmaceutical Sciences	
University of California, San Francisco School of Pharmacy	View
University of Charleston School of Pharmacy	View
University of Cincinnati James L. Winkle College of Pharmacy	View
University of Colorado Anschutz Medical Campus Skaggs School of Pharmacy and Pharmaceutical Sciences	View
University of Connecticut School of Pharmacy	View
University of Findlay College of Pharmacy	View
University of Florida College of Pharmacy	View
University of Georgia College of Pharmacy	View
University of Hawaii at Hilo Daniel K. Inouye College of Pharmacy	View
University of Health Sciences and Pharmacy in St. Louis St. Louis College of Pharmacy	View
University of Houston College of Pharmacy	View
University of Illinois at Chicago College of Pharmacy	View
University of Iowa College of Pharmacy	View
University of Kansas School of Pharmacy	View
University of Kentucky College of Pharmacy	View
University of Louisiana at Monroe College of Pharmacy	View
University of Maryland School of Pharmacy	View
University of Maryland Eastern Shore School of Pharmacy and Health Professions	View
University of Michigan College of Pharmacy	View
University of Minnesota College of Pharmacy	View
University of Mississippi School of Pharmacy	View
University of Missouri-Kansas City School of Pharmacy	View
University of Montana College of Health Skaggs School of Pharmacy	View
University of Nebraska Medical Center College of Pharmacy	View
University of New England Westbrook College of Health Professions School of Pharmacy	View

University of New Mexico College of Pharmacy	View
University of North Carolina Eshelman School of Pharmacy	View
University of North Texas Health Science Center UNT System College of Pharmacy	View
University of Oklahoma Health Sciences Center College of Pharmacy	View
University of Pittsburgh School of Pharmacy	View
University of Puerto Rico Medical Sciences Campus School of Pharmacy	View
University of Rhode Island College of Pharmacy	View
University of Saint Joseph School of Pharmacy and Physician Assistant Studies	View
University of South Carolina College of Pharmacy	View
University of South Florida Health Taneja College of Pharmacy	View
University of Southern California School of Pharmacy	View
University of Tennessee Health Science Center College of Pharmacy	View
University of Texas at Austin College of Pharmacy	View
University of Texas at El Paso School of Pharmacy	View
University of Texas at Tyler Ben and Maytee Fisch College of Pharmacy	View
University of the Incarnate Word Feik School of Pharmacy	View
University of the Pacific Thomas J. Long School of Pharmacy	View
University of the Sciences Philadelphia College of Pharmacy	View
University of Toledo College of Pharmacy and Pharmaceutical Sciences	View
University of Utah College of Pharmacy	View
University of Washington School of Pharmacy	View
University of Wisconsin-Madison School of Pharmacy	View
University of Wyoming School of Pharmacy	View
Virginia Commonwealth University at the Medical College	View

of Virginia Campus School of Pharmacy	
Washington State University College of Pharmacy and Pharmaceutical Sciences	View
Wayne State University Eugene Applebaum College of Pharmacy and Health Sciences	View
West Coast University School of Pharmacy	View
West Virginia University School of Pharmacy	View
Western New England University College of Pharmacy	View
Western University of Health Sciences College of Pharmacy	View
Wilkes University Nesbitt School of Pharmacy	View
William Carey University School of Pharmacy	View
Wingate University School of Pharmacy	View
Xavier University of Louisiana College of Pharmacy	View

Accredited with Probation (1)

School Name	
Chicago State University College of Pharmacy	View

Candidate Status (2)

School Name	
American University of Health Sciences School of Pharmacy	View
Larkin University College of Pharmacy	View

Discontinued/Merged (3)

School Name	
Midwestern University - Chicago College of Pharmacy	View
Midwestern University - Glendale College of Pharmacy-Glendale	View
South Carolina College of Pharmacy	View

No Status Awarded (1)

School Name	
California Health Sciences University College of Pharmacy - 2021 Accreditation Application	View

Precandidate Status (1)

School Name	
University of California, Irvine School of Pharmacy & Pharmaceutical Sciences	View

Withdrawn (2)

School Name	
California Health Sciences University College of Pharmacy- 2013 Accreditation Application	View
Hampton University School of Pharmacy	View

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JUNE 2022/Ja

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

Accredited Providers By Name

Accredited Providers By Name

ACPE is the sole accreditation agency to accredit providers of continuing pharmacy education. ACPE's directory is the **only** recognized directory of accredited providers of continuing pharmacy education.Many providers are involved in activities and functions other than the provision of continuing education. However, any activity for which the provider is offering continuing pharmacy credit has been developed and presented in compliance with the Standards for Continuing Pharmacy Education.

These providers are continually monitored for maintenance of quality and efforts toward improvement. Participants in activities sponsored by these providers are encouraged to offer their comments and suggestions regarding activities to the provider and/or ACPE. The directory includes contact information and accreditation status and history for all ACPE-accredited providers. An (I) following a provider's name indicates that the Provider is on Inactive Status. An asterisk (*) following a provider's name indicates that the Provider is on probation as an accredited provider by the Accreditation Council for Pharmacy Education. Providers that have decided to discontinue or that their accreditation status has been withdrawn in the past three years may be found **here**. ACPE hereby authorizes reproduction of the following listing.

Accredited Providers By Name

Academy for Continued Healthcare Learning, The	**View**
Academy of Managed Care Pharmacy	**View**

Accredo Health Incorporated	View
AchieveCE	View
Acurity, Inc.	View
AdvanCE	View
Advocate Aurora Health, Department of Pharmacy	View
AffinityCE	View
Alabama Pharmacy Association Research & Education Foundation	View
Alabama Society of Health-System Pharmacists	View
Alaska Pharmacists Association	View
Albany College of Pharmacy and Health Sciences	View
Albertsons Companies, Inc.	View
Allegheny General Hospital Department of Pharmacy Services	View
Alpha Zeta Omega National Pharmaceutical Fraternity Philadelphia Alumni Chapter	View
Alpha Zeta Omega Pharmaceutical Fraternity New York Alumni Chapter	View
American Association of Colleges of Pharmacy	View
American College of Apothecaries, Inc.	View
American College of Clinical Pharmacology	View
American College of Clinical Pharmacy	View
American Pharmacists Association	View
American Society of Consultant Pharmacists	View
American Society of Health-System Pharmacists	View
Annenberg Center for Health Sciences at Eisenhower	View
Arizona Pharmacy Association	View
Arnold and Marie Schwartz College of Pharmacy and Health Sciences of Long Island University	View
Ascension Health Resource and Supply Management Group, LLC	View
Association for Medication Education, Inc.	View
Atlanta Academy of Institutional Pharmacists	View
Atrium Health Division of Pharmacy	View
Auburn University Harrison School of Pharmacy	View

Austin Community College Pharmacy Technician Program	View
Avant Institute	View
Banner Health	View
Baptist Memorial Health Care Corporation	View
Barnett International	View
Baylor Scott & White Health	View
Belmont University College of Pharmacy	View
BioMed General	View
Biomedical Learning Institute	View
Brigham and Women's Hospital Pharmacy	View
Brookdale Hospital Medical Center Department of Pharmacy Services	View
California Northstate University	View
California Pharmacists Association	View
California Society of Health-System Pharmacists	View
Cambridge Health Alliance (CHA) Department of Pharmacy	View
Campbell University College of Pharmacy and Health Sciences	View
Cardinal Health Pharmacy Services, LLC	View
CE Synergy, LLC.	View
CEimpact	View
Center for Independent Healthcare Education	View
Centers for Medicare and Medicaid Services	View
Chicago State University College of Pharmacy	View
Children’s National Medical Center	View
Children's Health	View
Children's Healthcare of Atlanta	View
City of Hope National Medical Center	View
Cleveland Clinic Abu Dhabi	View
CMEsolutions	View
Colegio de Farmaceuticos de Puerto Rico	View
College of Psychiatric and Neurologic Pharmacists	View
CompleteRx	View

Comprehensive Pharmacy Services, Inc.	View
Concordia University Wisconsin School of Pharmacy	View
Conduent Healthcare Knowledge Solutions, Inc.	View
Connecticut Pharmacists Association	View
Cook County Health	View
CPE Consultants, LLC	View
CVS Health	View
Dana-Farber Cancer Institute	View
Detroit Medical Center Department of Pharmacy Services, The	View
Drug Effectiveness Review Project	View
Drug Experts Inc.	View
Drug Information Association (DIA)	View
Duquesne University School of Pharmacy	View
D'Youville College School of Pharmacy	View
Educational Review Systems	View
Elite Healthcare	View
Elsevier Office of Continuing Medical Education	View
Emory University Hospital Department of Pharmaceutical Services	View
Essentia Health	View
European Association of Hospital Pharmacists (EAHP)	View
Florida A&M University College of Pharmacy and Pharmaceutical Sciences	View
Florida Pharmacy Association	View
Florida Society of Health-System Pharmacists, Inc.	View
France Foundation, The	View
Froedtert Hospital	View
Georgia Pharmacy Association, Inc.	View
Georgia Society of Health-System Pharmacists, Inc.	View
Global Education Group	View
Grady Health System Pharmacy	View
Hamad Medical Corporation	View

Harris Health System	View
Hematology/Oncology Pharmacy Association (HOPA)	View
HonorHealth	View
Houston Methodist Hospital	View
Howard University College of Pharmacy	View
Humana, Inc.	View
Idaho Society of Health-System Pharmacists	View
Illinois Council of Health-System Pharmacists	View
Illinois Pharmacists Association	View
Independent Pharmacy Alliance, Inc.	View
Indiana Pharmacists Association	View
Indiana University Health	View
Innovatix, LLC	View
Institute for Brain Potential	View
Institute for Natural Resources (INR)	View
Institute for Wellness and Education, Inc., The	View
Intermountain Healthcare	View
James A. Haley Veterans' Hospital	View
Jesse Brown VA Medical Center	View
Johns Hopkins Hospital Department of Pharmacy	View
JPS Health Network	View
Kaiser Permanente National Pharmacy	View
Karmanos Cancer Center	View
Kentucky Pharmacy Education and Research Foundation, Inc.	View
King Faisal Specialist Hospital & Research Center - Ryiadh	View
Korean American Pharmacists Association of U.S.A	View
Lee Health	View
Lehigh Valley Hospital Pharmacy Department	View
Lippincott Continuing Medical Education Institute, Inc.	View
Lone Star College - Tomball Pharmacy Technology	View
Louisiana Independent Pharmacies Association	View

Louisiana Pharmacists Association	View
Louisiana Society of Health-System Pharmacists	View
Lyceum, LLC	View
MAD-ID, Inc.	View
Marshall University School of Pharmacy	View
Marshfield Clinic Health System, Inc.	View
Massachusetts College of Pharmacy and Health Sciences	View
MED2000, Inc.	View
Medical Center of the Rockies Pharmacy University of Colorado Health - North	View
MediCom WorldWide, Inc.	View
MED-IQ	View
MedStar Washington Hospital Center	View
Memorial Hermann	View
Memorial Sloan-Kettering Cancer Center Division of Pharmacy Services	View
Michigan Pharmacists Association	View
Midwestern University College of Pharmacy	View
Missouri Pharmacy Association	View
National Association of Boards of Pharmacy and NABP Foundation, Inc.	View
National Community Pharmacists Association	View
National Jewish Health	View
National Pharmaceutical Association, Inc.	View
National Pharmacy Technician Association (NPTA)	View
NBLS, Inc.	View
NCODA, Inc.	View
Nebraska Pharmacists Association (NPA)	View
Nesbitt School of Pharmacy at Wilkes University	View
New Jersey Pharmacists Association	View
New Jersey Society of Health-System Pharmacists	View
New Mexico Pharmacists Association	View

New York Presbyterian Hospital Department of Pharmacy	View
New York State Council of Health-System Pharmacists	View
Northeast Kentucky Area Health Education Center	View
Northeastern University Bouve College of Health Sciences School of Pharmacy	View
Nova Southeastern University College of Pharmacy	View
Ochsner LSU Health Shreveport	View
Ohio Northern University College of Pharmacy	View
Ohio Pharmacists Foundation, Inc.	View
OhioHealth Pharmacy Services	View
Omnicare, Inc.	View
Oregon State University	View
Orlando Health, Inc.	View
Our Lady of the Lake	View
Palm Beach Atlantic University	View
PCMA	View
Pediatric Pharmacy Association	View
Penn State Milton S. Hershey Medical Center	View
Pennsylvania Pharmacists Association	View
PESI, Inc.	View
Pharmaceutical Education & Research Institute, Inc. (PERI)	View
Pharmacists Society of the State of New York	View
Pharmacy Institute (I)	View
Pharmacy Society of Wisconsin	View
Pharmacy Times Office of Continuing Professional Education	View
PharmCon	View
Philadelphia College of Pharmacy	View
Physicians' Education Resource, LLC	View
Postgraduate Healthcare Education, LLC	View
Potomac Center for Medical Education	View
Pro CE, LLC	View
Purdue University College of Pharmacy	View

Qatar University, College of Pharmacy	View
Rite Aid Hdqtrs. Corp.	View
Saint Thomas West Hospital	View
Samford University McWhorter School of Pharmacy	View
Saudi Society of Clinical Pharmacy (SSCP)	View
ScientiaCME	View
Select CE	View
Sharp HealthCare	View
Shenandoah University Bernard J. Dunn School of Pharmacy	View
Skaggs School of Pharmacy at the University of Montana	View
Society of Critical Care Medicine	View
Society of Nuclear Medicine and Molecular Imaging	View
South Carolina Pharmacy Association	View
South Dakota State University College of Pharmacy and Allied Health	View
South University School of Pharmacy	View
Southeastern Continuing Medical Education Consultants, LLC	View
Southeastern Michigan Society of Health-System Pharmacists	View
Southern Illinois University Edwardsville School of Pharmacy	View
Sparrow Hospital	View
Specialty Pharma Education Center	View
St. John Fisher College Wegmans School of Pharmacy	View
St. John's University College of Pharmacy and Health Sciences	View
St. Jude Children's Research Hospital Pharmaceutical Department MS150	View
St. Louis College of Pharmacy at University of Health Sciences and Pharmacy in St. Louis	View
Stony Brook University Medical Center	View
Swedish Medical Center Department of Pharmacy	View
Temple University School of Pharmacy	View
Tennessee Pharmacists Consortium for Education	View
Texas A&M Health Science Center Coastal Bend Health Education Center	View

Texas Children's Hospital Pharmacy	View
Texas Pharmacy Association	View
Texas Society of Health-System Pharmacists, The	View
Texas Southern University College of Pharmacy and Health Sciences	View
Texas Tech University Health Sciences Center School of Pharmacy	View
The George Washington University School of Medicine and Health Sciences	View
The Medical Letter, Inc.	View
The Ohio State University College of Pharmacy	View
The University of Texas at El Paso School of Pharmacy	View
The University of Texas MD Anderson Cancer Center	View
Tribune Group GmbH (I)	View
TRINU Corporation	View
UAB Hospital Department of Pharmacy	View
Union University College of Pharmacy	View
UnitedHealth Group Center for Clinician Advancement	View
University at Buffalo School of Pharmacy and Pharmaceutical Sciences	View
University Health System Department of Pharmacotherapy and Pharmacy Services	View
University Learning Systems, Inc.	View
University of California, San Francisco, School of Pharmacy	View
University of Cincinnati College of Pharmacy	View
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences	View
University of Connecticut School of Pharmacy	View
University of Florida College of Pharmacy	View
University of Hawaii at Hilo, Daniel K. Inouye College of Pharmacy	View
University of Illinois at Chicago College of Pharmacy	View
University of Maryland School of Pharmacy	View
University of Mississippi School of Pharmacy	View
University of New England School of Pharmacy	View

University of New Mexico College of Pharmacy	View
University of North Carolina Eshelman School of Pharmacy	View
University of North Texas Health Science Center	View
University of Oklahoma College of Pharmacy	View
University of Rhode Island College of Pharmacy	View
University of South Carolina College of Pharmacy	View
University of Southern California School of Pharmacy	View
University of Tennessee College of Pharmacy	View
University of Texas at Austin College of Pharmacy	View
University of the Incarnate Word, Feik School of Pharmacy	View
University of the Pacific, Thomas J. Long School of Pharmacy	View
University of Toledo College of Pharmacy	View
University of Utah College of Pharmacy	View
University of Wyoming, School of Pharmacy	View
USF Health	View
Utah Society of Health-System Pharmacists	View
VA Western New York Healthcare System	View
Vanderbilt University Hospital Department of Pharmaceutical Services	View
Vindico Medical Education	View
Virginia Pharmacists Association	View
Virginia Society of Health-System Pharmacists	View
Walgreens University	View
Washington State Pharmacy Association	View
Washington State University College of Pharmacy and Pharmaceutical Sciences	View
WellStar Health System Pharmacy	View
West Virginia University School of Pharmacy	View
Western New England University College of Pharmacy	View
Western University of Health Sciences, College of Pharmacy	View
Xavier University of Louisiana College of Pharmacy	View

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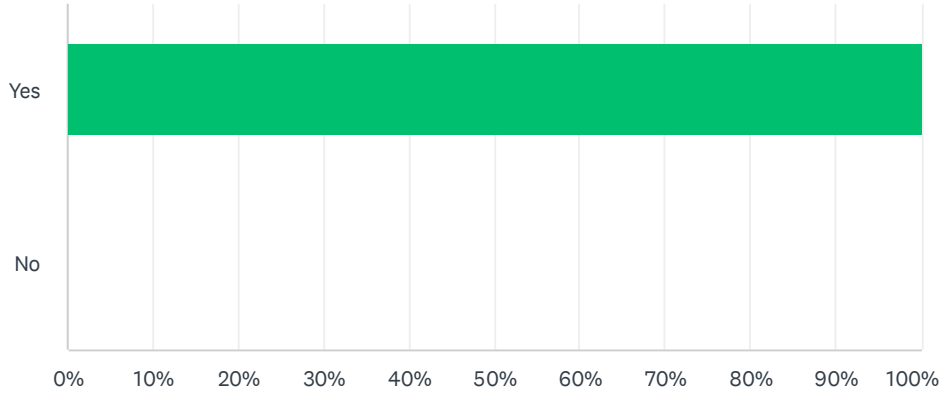
Q1 Executive Director's performance expectations are current.

Answered: 6 Skipped: 0

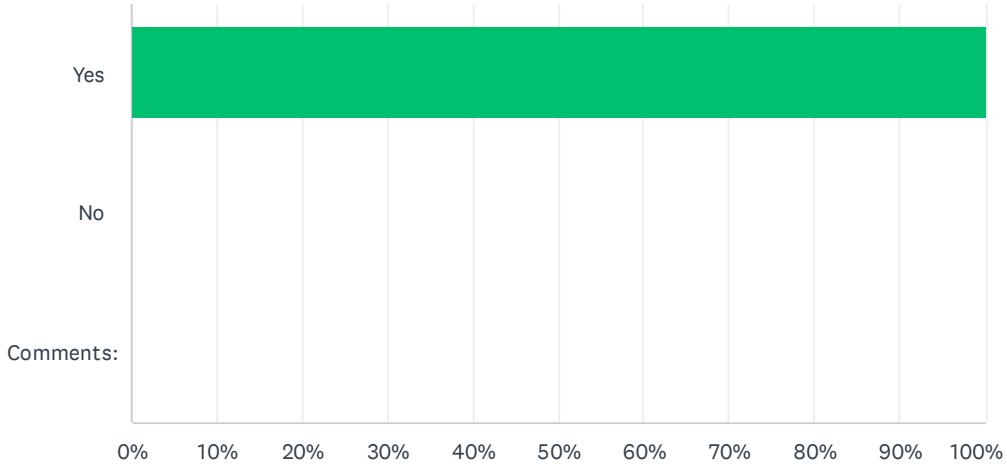


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
1	Clear, frequent communication. Open to feedback	5/10/2022 7:49 PM
2	Very good at communicating expectations and progress.	5/4/2022 4:01 PM

Q2 Executive Director receives annual performance feedback.

Answered: 6 Skipped: 0

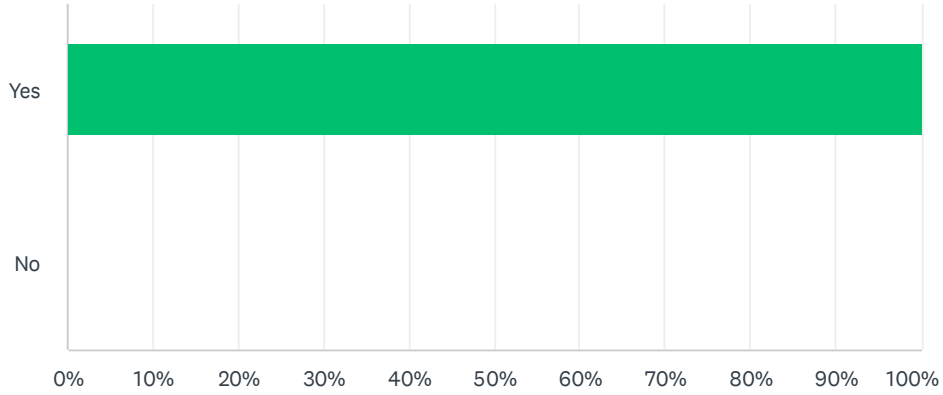


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
Comments:	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q3 The agency's mission and high-level goals are current and applicable.

Answered: 6 Skipped: 0

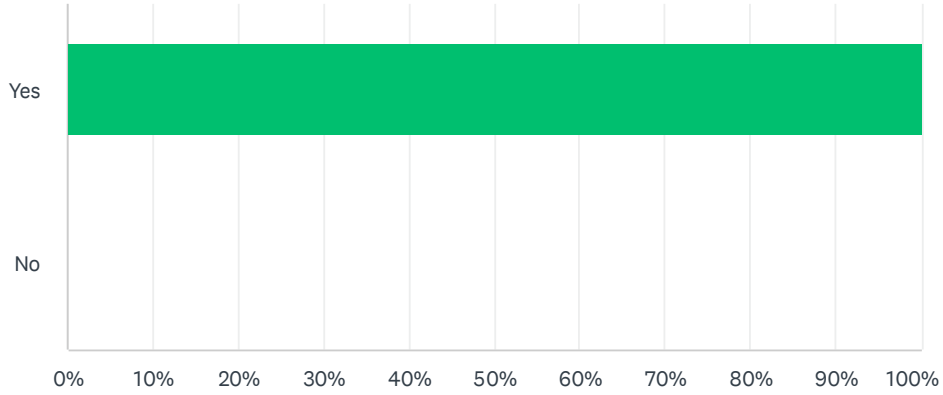


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q4 The board reviews the Annual Performance Progress Report.

Answered: 6 Skipped: 0

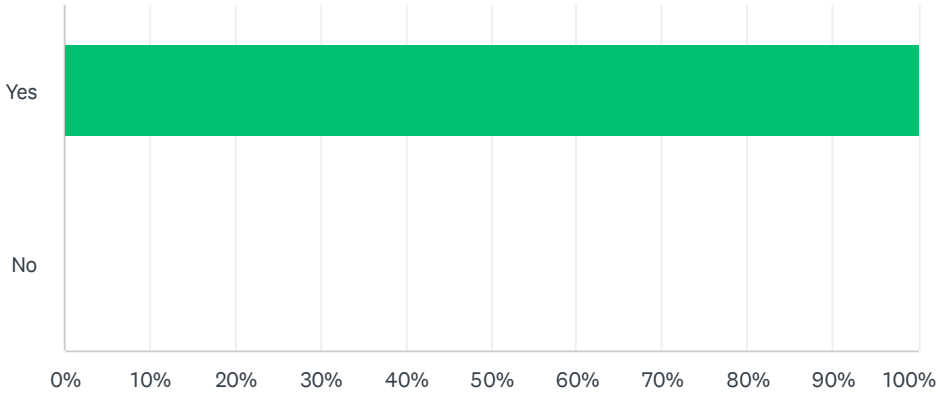


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q5 The board is appropriately involved in review of the agency's key communications.

Answered: 6 Skipped: 0

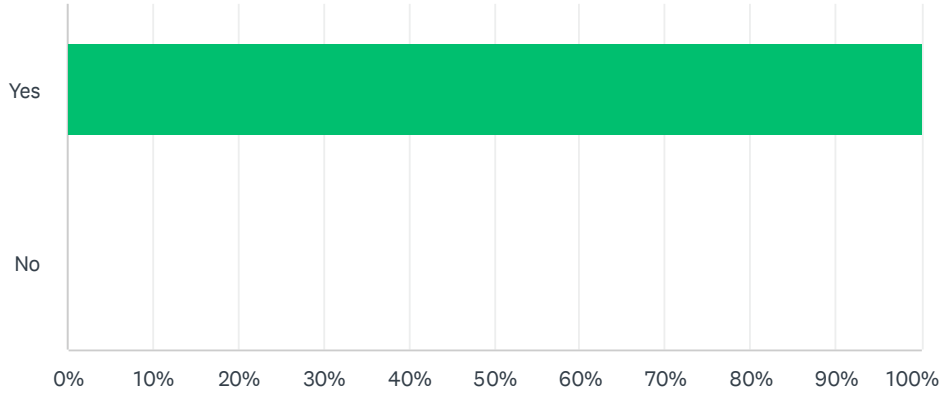


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q6 The board is appropriately involved with policy making activities.

Answered: 6 Skipped: 0

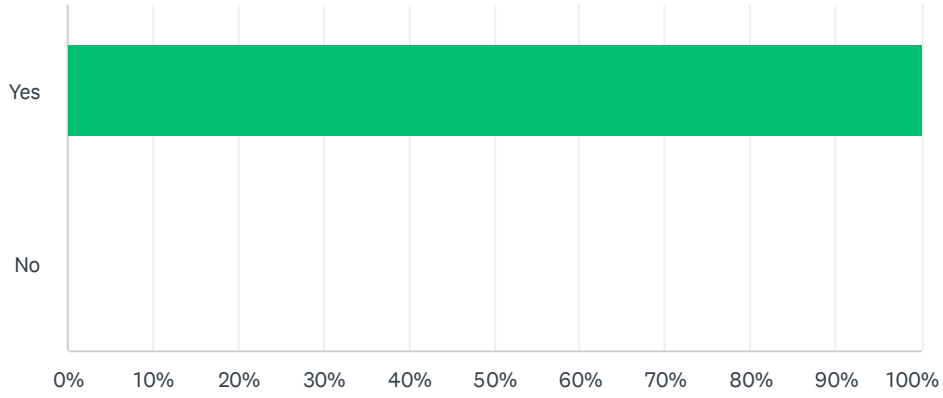


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q7 The agency's policy option packages are aligned with their mission and goals.

Answered: 6 Skipped: 0

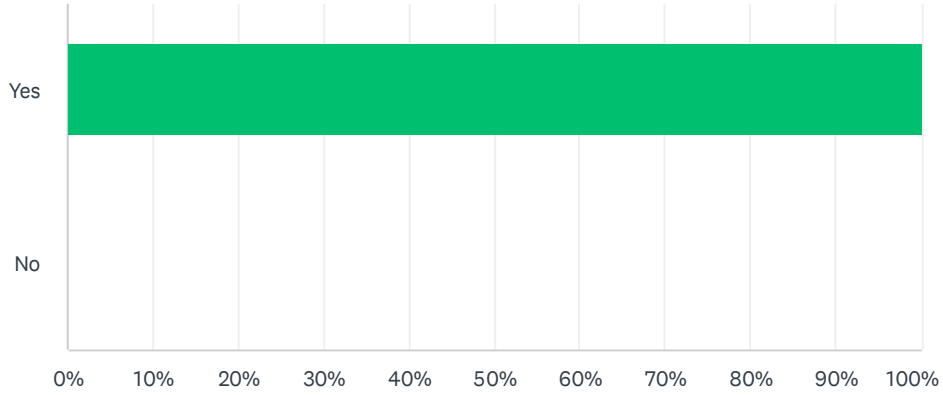


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q8 The board reviews all proposed budgets.

Answered: 6 Skipped: 0

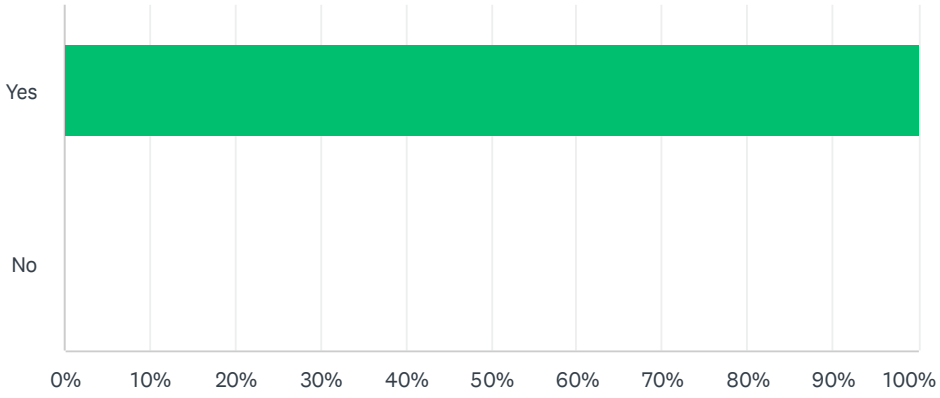


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
1	This has been made available to us but less time spent on review due to packed agendas	5/10/2022 7:49 PM

Q9 The board periodically reviews key financial information and audit findings.

Answered: 6 Skipped: 0

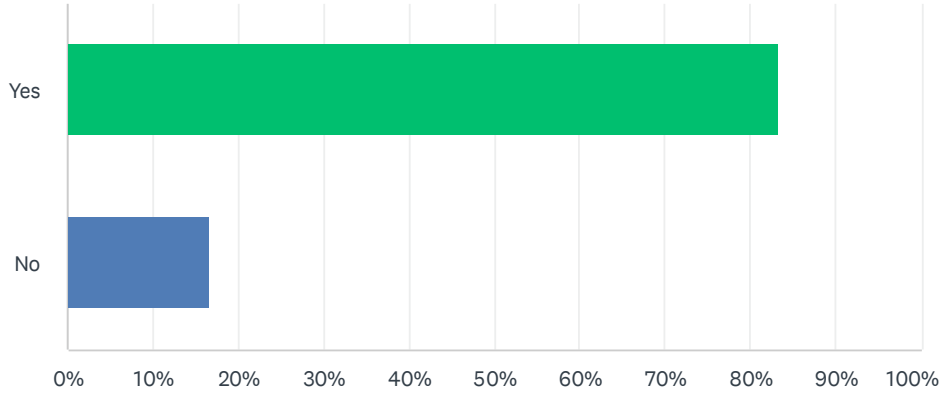


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q10 The board is appropriately accounting for resources.

Answered: 6 Skipped: 0

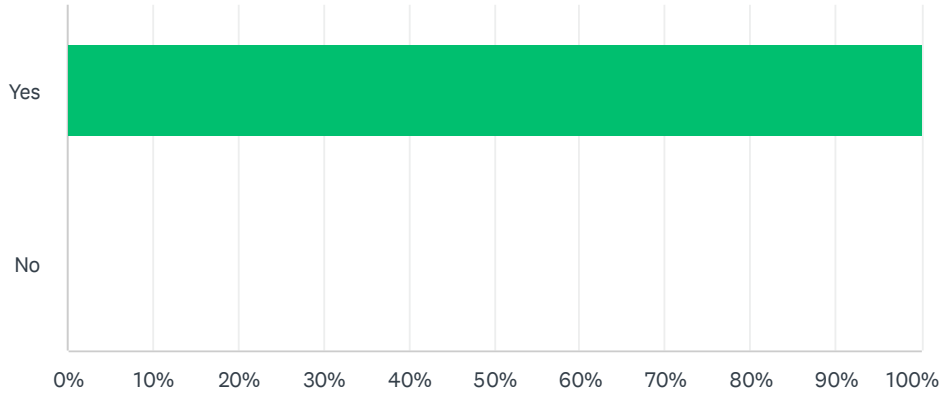


ANSWER CHOICES	RESPONSES	
Yes	83.33%	5
No	16.67%	1
TOTAL		6

#	COMMENTS:	DATE
1	I do not understand this statement	5/6/2022 8:46 AM

Q11 The agency adheres to accounting rules and other relevant financial controls.

Answered: 6 Skipped: 0

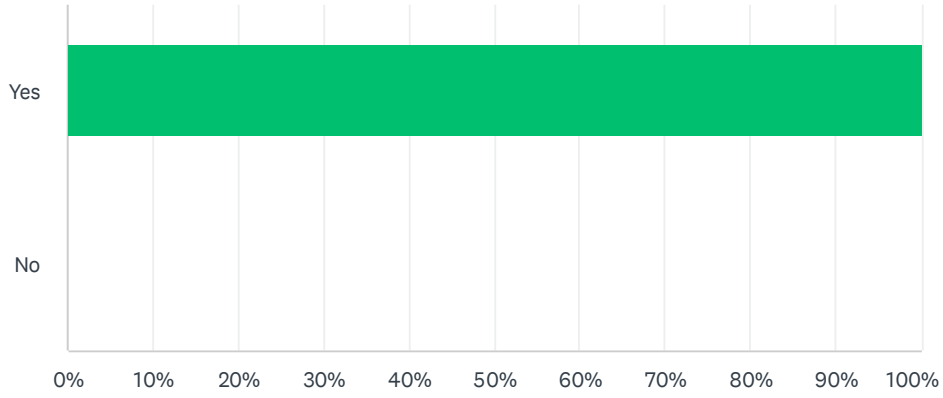


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q12 Board members act in accordance with their roles as public representatives.

Answered: 6 Skipped: 0

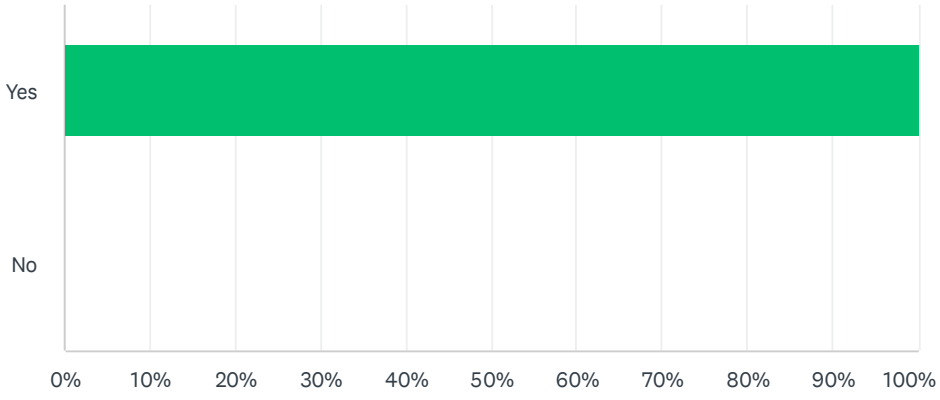


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q13 The board coordinates with others where responsibilities and interests overlap.

Answered: 6 Skipped: 0

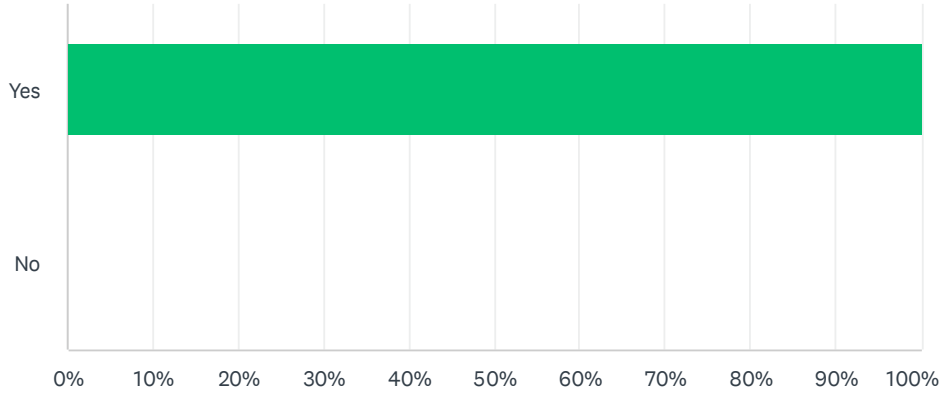


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
1	Definitely	5/4/2022 4:01 PM

Q14 The board members identify and attend appropriate training sessions.

Answered: 6 Skipped: 0

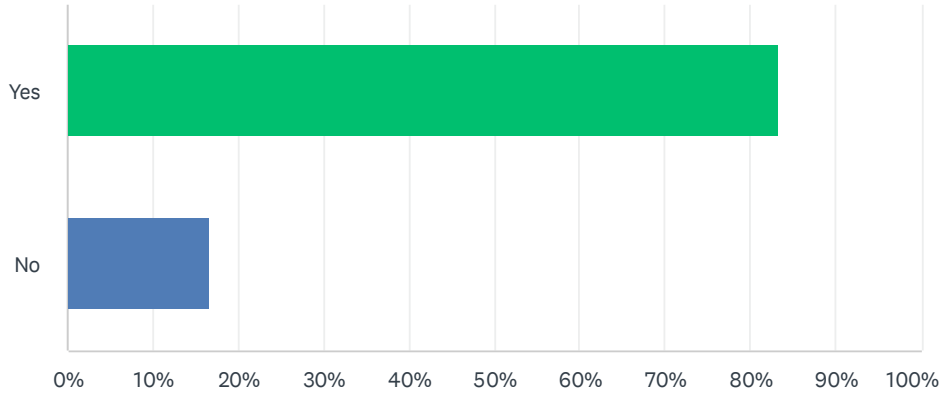


ANSWER CHOICES	RESPONSES	
Yes	100.00%	6
No	0.00%	0
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q15 The board reviews its management practices to ensure best practices are utilized.

Answered: 6 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	83.33%	5
No	16.67%	1
TOTAL		6

#	COMMENTS:	DATE
	There are no responses.	

Q16 General comments, observations or questions to discuss at the June 2022 Annual Board Business Meeting:

Answered: 2 Skipped: 4

#	RESPONSES	DATE
1	There are some impactful opportunities that will have to be addressed during feedback session with Joe since none of the 15 questions above are applicable.	5/4/2022 8:07 PM
2	None	5/4/2022 4:01 PM

SBAR: Acme United Corporation (M-0003028)

Manufacturer Request Exemption pursuant to ORS 689.527(7)

S	**Situation:** • Acme is requesting to sell to unlicensed resellers of first aid kits pursuant to the exemption provided in ORS 689.527(7)
B	**Background:** ORS 689.527 Prohibited practices; rules. (7) A manufacturer or wholesaler may not sell or otherwise distribute, or offer to sell or otherwise distribute, any drug or device except to a person legally authorized to resell, dispense or otherwise redistribute such drug or device. **The board may grant an exemption from the requirement of this subsection in the form of a special permit if the board finds that an exemption is in the best interest of the public health and safety**
A	**Assessment:** ORS 689.527(7) allows for an exemption if the board finds that an exemption is in the best interest of the public health and safety. • Is this exemption in the best interest of the public health and safety? • If the Board would like to proceed with the exemption request the following will need to occur: o Board will need to develop a special permit process. Board to determine expiration of special permit.
R	**Recommendation:** • Board discussion

Inquiry Date: 5/25/2022
Board review: June 2022 meeting