The mission of the Oregon State Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale and distribution of drugs.

Monday, January 9, 2017
1891- Celebrating 125 Years of Excellence - 2016

MONDAY, JANUARY 9, 2017

I. 9:00 AM OPEN SESSION, Kate James, R.Ph, Presiding
   
   A. Roll Call

   B. Agenda Review and Approval
      9:15 AM

II. GENERAL ADMINISTRATION

   1. Rules
      
      1. Review Rulemaking Hearing Report & Comments – MacLean #A-A7
      2. Consider Adoption of Temporary Rules - none
      3. Consider Rules and send Rulemaking Hearing - none
      4. Consider Adoption of Rules
         
         Action Necessary
         Karbowicz/Miner/MacLean

         Note to the public – all proposed rules are on the Board’s website under the Laws and Rules link.
         a) Div 007 & 041 - Drug Room #A1 & A8
         b) Div 019 - Volunteer Limited Liability #A10
         c) Div 041 – Outlet Notification Requirement #A1 & A12
         d) Div 041 & 080 - Drug Take Back #A13
         e) Div 041 - Remote Dispensing Machines #A14
         f) Div 043 – Dispensing Practitioner Drug Outlets #A2-A7 & A15-revised
         g) Div 044 - Charitable Pharmacy Donations/Distribution #A7 & A16

   ≈ If special accommodations are needed for you to attend or participate in this Board Meeting, please contact Loretta Glenn at: (971) 673-0001. ≈
5. Policy Issues for Discussion – Miner
   - Depot rule intent

2. Discussion Items
   1. Waiver Requests – Karbowicz Action Necessary
      - Lane County Health Department request #B
   2. Oregon State Hospital – TCVP 1 yr report – Miner/Karbowicz #B1 Action Necessary
   4. Workplace Survey update- Watt/Miner #B3, B5
   5. Auto-refill update – Watt/Karbowicz #B4 and B4 revised 12.20.16
   6. Credentialing Issues – Watt/MacLean
   7. Compounding Update – Karbowicz/Wallace
   8. Multnomah County Health Department prescription pain pill campaign survey request #B6 Action Necessary

Noon - Lunch break

Resume outstanding Discussion items or move on to Issues and Activities

VII. ISSUES/ACTIVITIES

A. Reports:
   1. Board President/Members
   2. Executive Director
   3. Board Counsel
   4. Compliance Director
   5. Pharmacist Consultant
   6. Administrative Director
   7. Licensing Department Supervisor
   8. Project Manager

B. Board Member/Staff Presentations – James
   - Pharmacy Coalition – 10/18/16, 12/13/16, 2/7/17
   - Professional Practice Roundtable – 11/10/16, 1/12/17
   - Health System Outreach Meeting – none

C. Committees/Meetings
   1. OSPA Annual Mtg. 10/21-23,2016, Clackamas, OR – Karbowicz/Efremoff/Miner
   2. OSHP Mtg. 11/5/2016, Portland, OR - Wallace
   3. OSPA Lane Co. Mid-Winter Mtg. 2/18-19/2017, Eugene, OR–Wells/Efremoff/Fox
   4. NABP Annual Mtg. 5/20-23/2017, Orlando, FL - Action Necessary

D. Board Meeting Dates
   - February 8-9, 2017 Portland
   - April 5-6, 2017 Portland
   - June 7-8, 2017 Portland
   - August 9-11, 2017* Portland (*3 day meeting)
   - October 11-12, 2017 Portland
   - November 8-9, 2017 TBA (Strategic Planning)
• December 13-14, 2017  TBA
• February 7-9, 2018
• April 4-5, 2018
• June 6-7, 2018
• August 8-10, 2018
• October 3-4, 2018
• November 7-8, 2018
• December 12-13, 2018

*E. Rulemaking Hearing Dates
(The following dates are reserved for potential rulemaking hearings and identified only for planning purposes and approved by the Board. Actual Rulemaking Activities will be noticed as required by law and may deviate from this schedule as needed.)

• May 25, 2017
• November 29, 2017
• May 23, 2018
• November 27, 2018

*F. Financial/Budget Report – Watt/MacLean #C-C2

G. Legislative update – Watt (none)

H. Strategic Planning – MacLean
  • Updates

*I. 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.

  1. NAPLEX Scores – May 1 – Aug 31, 2016 – #D CONFIDENTIAL
  2. MPJE Scores – May 1 – Aug 31, 2016 - #D1 CONFIDENTIAL
  3. License/Registration Ratification - October 5, 2016 – December 6, 2016
  4. Extension Requests - none
  5. Approval of Board Meeting Minutes – August 10-12, 2016
  6. Approval of Board Meeting Minutes – October 5-6, 2016
  7. Approval of Board Meeting Minutes – December 7, 2016

VIII. OPEN FORUM At the completion of regular Board Business, any Board licensee or member of the public is invited to meet with the Board to discuss issues of interest (typically the last item of the meeting)

Adjourn
To: Board Members

From: Karen MacLean

Date: November 29, 2016

Subject: Hearing Officer’s Report for Proposed Rules in Divisions 007, 019, 041, 043, 044 and 080.

General Background:
A public hearing was held at the Portland State Office Building, located at 800 NE Oregon St. Conference Room 1A Portland, OR 97232 on November 22, 2016 at 9:30am.

Summary of Comments:
The Board received comments as follows:

Div 019 and 041 Naloxone
1) Lis Houchen on behalf of NACDS provided written and oral comment.
   Clarifications on how a pharmacist should identify - individuals who are authorized to conduct OHA approved training and ask the Board to clarify how pharmacists at the community pharmacy level can identify which individuals are authorized to conduct OHA approved training.

   Clarify inconsistent terminology in reference to “individual” and “OHA authorized person or organization”.

   Documentation requirements in 855-019-0460 – they ask for clarification regarding records retention and who is responsible, the outlet or the individual pharmacist.

   Opiate Overdose Treatment: Naloxone Training Protocol – the protocol is lengthy and may overwhelm laypersons receiving this training from pharmacists. They ask the Board to consider a more condensed version of the training protocol.

Div 041 – Pharmacy Outlet Notification Requirements OAR 855-041-1010.
NACDS also requests the Board revise the proposed rule to add the underlined text below re: terminations/resignations in lieu of termination where it is the result of actions by the licensee that would constitute a violation of federal or state laws or rules.

Div 041 Drug Rooms
1) Lauren Berton from CVS submitted written comment requesting to add language similar to Idaho as it relates to “Secured Delivery Area” for prescriptions not able to be delivered by the pharmacy or its agent or emergency kits being returned from licensed
Long Term Care facilities as outlined in IDAPA 27.01.604(04). Idaho allows a secured delivery area for prescriptions awaiting delivery; CVS is requesting consideration for items being returned to the pharmacy at this time.

This request is outside the intent of the Board’s proposed rules and in consulting with our Compliance Director, Gary Miner, although not specifically written in rule, this is currently permitted in Long Term Care settings as part of the pharmacy practice generally.

2) **Div 041 – Pharmacy Outlet Notification Requirements OAR 855-041-1010.** CVS also requested clarification from the Board on the definition of termination. **Does this include all terminations and resignations, or only those that result from diversion or grow violation of law, rule or policy, etc?**

**Div 043 – Dispensing Practitioner Drug Outlets**

We received a number of written comments and questions related to the proposed rules from the different health professions potentially affected.

**Naturopaths**

We received 3 written comments. Laurie Marzell N.D. submitted written comments and appeared to oppose the rules as written. She was a part of the original workgroup that worked on the 2014 draft concept that the various health boards and associations agreed to with the Board. She expressed concern that definitions for traditional and non-traditional dispensing, as well as the language re: FDA Human drugs being omitted. She does not think the Board should oversee homeopathic substances even though it’s part of the ORS 689 Pharmacy Practice definition of a drug. Her request is for the Board to identify what it considers a “drug” to be for the purposes of identifying offices as drug outlets. In addition, she asked to identify the terms traditional and non-traditional in the rules.

The other written comment highlighted that Naturethroid, a brand of natural thyroid supplementation, in various doses, that is not available at most pharmacies was the only thing she dispensed as a patient service. Her request was for the Board to consider adding an exclusion for practitioners who dispense 5 or less (3 or less?) non-controlled prescriptions in small volumes.

The Oregon Association of Naturopathic Physicians submitted a letter requesting the rules exempt homeopathic and thyroid glandular substances from the proposed rules.

One other ND appeared at the hearing with questions more than comments on the draft rules. His questions were similar to Laurie Marzell’s.

**Nurses**

We received written and oral testimony from the Oregon Board of Nursing’s Executive Director supporting the proposed rules highlighting that the rules only apply to the acquisition, storage, labeling and recordkeeping of drugs intended for dispensing and not the practice of dispensing. Their Board determined that these rules do not violate the Nursing statute ORS 678.390 (5) (e) re: inspecting the practice of dispensing without a formal complaint. Their Board also determined that this type of oversight is necessary due to the many different drug sources that can be accessed and may be outside of established safe procurement channels etc.
**Veterinarians**
We received 6 written comments (see attached) and numerous questions from various Veterinarians. No oral comments were presented.

Most individuals didn’t understand that the Veterinarians will primarily be carved out and that their Board will be conducting inspections of their own with input from the Board of Pharmacy, making the Board's rules best practices. Executive Director Marc Watt spoke to almost everyone that had questions or comments during the comment period.

**Dentists**
We received 1 question (see attached) from a Dentist asking about the applicability to their practice. Director Watt spoke to this person directly.

**Physicians/Physician Assistants** (see attached)
One oral comment along with a written letter was provided at the hearing from the Oregon Medical Association’s Courtni Dresser. The OMA opposes the rules. They do not see much change from the 2014 draft rules that they also opposed. She cited to an MOU from 2014 Legislative workgroup regarding outreach that was to delay any rules or legislation that would create “unnecessary and redundant oversight of drug dispensing and [that] does not create access barriers for patients”. They question whether the outreach was conducted; that OBOP actually has this authority to require outlets to register and oversight; that OMB has the laws and rules that cover dispensing; that this will be confusing to their members; that the Board of Pharmacy hasn’t proved there is a problem and why are these rules needed; the impact to rural Oregon patients and how this will improve patient care or make it more safe.

We received written comments from:
The Oregon Medical Board - they do not see that OBOP has the authority to oversee dispensing since OMB also has that oversight in their statute. They see no need for new, additional regulations. They do not see a pattern of complaints. They think the terms traditional and non-traditional are ambiguous and will lead to confusion. They think the fiscal is underestimated for the impact on small businesses, especially in regard to rural Oregon. They encourage the OBOP to take an educational approach rather than require registration and annual fee and submit to inspection. OMB supports a portion of the rules (855-043-0520 through 855-043-0555) minus references to registration OBOP.

The Oregon Society of Physician Assistants – they do not believe the Board’s rules do anything to improve patient safety and could be detrimental to patients in rural and underserved areas with limited access to store-front pharmacy service. They see this rule as redundant & burdensome. OMB requires PA’s to register as dispensing providers and they are tasked with overseeing that dispensing is in order to protect patient safety. They think this will create confusion to give OBOP authority over OMB’s licensees. They find the fiscal to be inadequate and a large fiscal impact for small business providers in rural and underserved areas. They question the Board’s authority for regulating rural and underserved dispensing practitioners, when 2012 legislation specifically related to PA’s. They believe this legislation exempts rural and
underserved areas. They find the rules to be ambiguous and some terms like traditional and non-traditional not well defined. They oppose the rules as written.

Hematology Oncology of Salem, LLP – They oppose the rules. They believe it would force them to hire and staff their dispensary with full-time pharmacists. They work with McKesson and follow their strict protocols. They request to the Board to exempt oncology practices and change the 72 hours to “course of therapy” as other states have done.

We received one question from a Surgery Center manager, Director Watt responded to the questions.

**Div 044 Charitable Pharmacy Donations/Distribution** (see attached)
George Wang from SIRUM wrote concerns regarding draft language in OAR 855-044-0030 (1) a charitable pharmacy may not accept (d) An FDA REMS (Risk Evaluation and Mitigation Strategy) drug and (e) A drug donated from another state.

**REMS** - he believes not allowing REMS drug from being accepted and unnecessary and more likely to harm patients than protect them.

**Donated drugs** - he believes the wording should more closely mirror statute regarding allowing donations from eligible out of state manufacturers and wholesalers.

*These rules are a result of 2016 SB 1514*

Based on the input received for Division 043 DPDO rules, staff will recommend some edits at the December Board meeting.

There were no comments – written or oral, received on the following rules:
- Div 019 Pharmacist Licensure Exams
- Div 019 Registration for Limited Liability for Volunteers
- Div 041 Remote Dispensing Machines
- Div 041 Drug Take Back
- Div 080 Synthetic Opioids / Fentanyl Derivatives

A copy of the written comment is included as part of the permanent rulemaking record.
November 22, 2016

Karen MacLean  
Rules Coordinator  
Oregon Board of Pharmacy  
800 NE Oregon St., # 150, Portland, OR 97232  
Via email: Karen.S.MacLean@state.or.us

Re: Proposed Rule Changes Under Divisions 019 & 041 – Pharmacist Prescribing of Naloxone, and Under Division 041 – Pharmacy Outlet Notification Requirements

Dear Ms. MacLean:

The National Association of Chain Drug Stores (“NACDS”) thanks the Oregon Board of Pharmacy (“Board”) for the opportunity to comment on the proposed rule changes under Divisions 019 & 041 – addressing requirements for pharmacist prescribing of naloxone, and under Division 041 – addressing requirements for pharmacy outlets to notify the Board upon the termination or resignation of employees. We appreciate the Board considering our input on these matters.

**Divisions 019 & 041 – Pharmacist Prescribing of Naloxone**

We thank the Board for its work in crafting rules to implement House Bill 4124 allowing pharmacists to prescribe unit-of-use packages of naloxone to individuals who conduct or complete training approved by the Oregon Health Authority (“OHA”). Pharmacists are recognized medication experts who are well-situated in local communities to improve access to naloxone for overdose prevention purposes. As such, the chain pharmacy community supports policies that leverage the accessibility of pharmacists for this purpose. In that spirit, we have the following comments and questions regarding the proposed new rules under Divisions 019 & 041 that outline requirements for pharmacist prescribing of naloxone:

- **No mechanism for pharmacists to identify individuals who are authorized to conduct OHA-approved training.** The proposed rules allow qualified pharmacists to prescribe unit-of-use naloxone and the necessary medical supplies to administer the naloxone to individuals who conduct OHA-approved training and may therefore possess and distribute naloxone to persons who successfully complete training. However, the proposed rules are not clear with respect to how pharmacists are to identify individuals who are authorized to conduct OHA-approved training. We ask the Board to clarify the mechanism by which pharmacists at the community pharmacy level can identify which individuals are authorized to conduct OHA-approved training.

- **Clarify inconsistent terminology.** The proposed rules reference both “an individual who... [c]onducts training that meets that criteria established by the [OHA]” and an “OHA
authorized person or organization”. Assuming that these terms share the same meaning, we ask the Board to use consistent terminology throughout the rule.

- **Documentation requirements.** The proposed rules require pharmacists that prescribe and dispense naloxone under 855-019-0460 to document the encounter and the prescription, and maintain records for three years. The proposed rule is not clear as to whether pharmacies must maintain these records separately, or if the prescription record would suffice as documentation of the encounter. We ask the Board to clarify this issue.

Additionally, we would like to take this opportunity to comment on the “Opiate Overdose Treatment: Naloxone Training Protocol” that has been developed and included in the “Toolkit Resources” for pharmacist prescribing of naloxone as posted on the Board’s website. We note that the training protocol is lengthy, and as such, may overwhelm laypersons receiving this training from pharmacists. We encourage the Board to consider whether a more condensed version of the training protocol may be appropriate.

**Division 041 – Pharmacy Outlet Notification Requirements**

Under 855-041-1010, the Board has proposed to require a pharmacy that terminates or allows a Board licensee to resign in lieu of termination to report the termination or resignation to the Board within 10 working days. So as not to overburden the Board with notifications when employment has been terminated because of retirement, or for reasons such as excessive tardiness, sick calls, violations of company policies or other employer/employee issues that are outside of the Board's purview, we respectfully request that the Board revise the rules and limit this requirement to instances where employee termination is due to a violation of state or federal laws or rules.

(2) A resident 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 if the termination or resignation in lieu of a termination is the result of actions by the licensee that would constitute a violation of federal or state laws or rules.

NACDS thanks the Board for considering our comments on this rulemaking. Please do not hesitate to contact me with any questions or for further assistance. I can be reached at: 360-480-6990 or lhouchen@nacds.org.

Sincerely,

Lis Houchen
Regional Director, State Government Affairs
November 18, 2016

Karen MacLean
Administrative Director, Rules Coordinator
Oregon Board of Pharmacy
800 NE Oregon St
Suite 150
Portland, OR 97232

Re: Proposed amendments to Oregon Administrative Rules Division 41 in regards to Drug Rooms and Outlet Notification Requirement

Dear Administrative Director MacLean:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies located across the state of Oregon. CVS Health appreciates the opportunity to submit comments on the proposed amendments to Division 41 regarding Drug Rooms and Outlet Notification Requirements. We would like to thank the Board for their continued vigilance to improve the laws and rules that guide pharmacists serving Oregon patients.

CVS Health supports the amendments related to Drug Rooms in OAR 855-041-1001 and 855-041-1036 which allows a retail drug outlet to store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements. We do request that the board consider adding language similar to Idaho as it relates to “Secured Delivery Area” for prescriptions not able to be delivered by the pharmacy or its agent or emergency kits being returned from licensed Long Term Care facilities as outlined in IDAPA 27.01.01.604(04). I have included language from Idaho below in regards to the requirements of this area as outlined in IDAPA 27.01.01.604(03). While Idaho allows a secured delivery area for prescriptions awaiting delivery, we are only requesting consideration for items being returned to the pharmacy at this time.

IDAPA 27.01.01.604. PHARMACY PRODUCT STORAGE AND REMOVAL.
03. Storage for Delivery.

b. The secured delivery area has walls that extend to the roof and solid core or metal doors, and all doors and other access points must be equipped with locking devices and be constructed in a manner so that the hinge hardware is tamper-proof when closed; (4-11-15)

c. The secured delivery area appropriately safeguards product integrity in accordance with USP-NF requirements; (3-20-14)

d. The secured delivery area is attached or located adjacent to the pharmacy that filled the prescriptions; (3-20-14)

e. The PIC, or a pharmacist designated by the PIC, and the approved transport agent solely have access to the secure delivery area. Two (2) factor credentialing is required for entry, which must include two (2) of the following: (3-20-14)

   i. Something known (a knowledge factor); (4-11-15)
   ii. Something possessed (a hard token stored separately from the computer being accessed); and (4-11-15)
   iii. Something biometric (fingerprint, retinal scan, etc.); (4-11-15)

f. The pharmacy has a means of recording the time of entry and the identity of all persons who access the secured delivery area; (3-20-14)
The pharmacy maintains immediately retrievable records of all persons who have accessed the secured delivery area and each prescription stored and removed for delivery; (3-20-14)

The pharmacy maintains written policies and procedures for secured delivery area storage and removal of prescriptions; and (3-20-14)

04. Qualified Returns to the Secured Delivery Area.
A pharmacist or a pharmacy, by means of its agent, may accept the return of the following drugs or devices to the secured delivery area: (3-20-14)
   a. Emergency kits; (3-20-14)
   b. Prescriptions that were unsuccessfully delivered by the pharmacy, a pharmacist, or its agent; and (3-20-14)
   c. Those deemed qualified for return pursuant to the Restricted Return of Drugs or Devices rule. (3-20-14)

In addition, we do request clarification from the board on the definition of termination as used in the proposed amended language in 855-041-1010(2) which requires a resident pharmacy that terminates or allows a Board licensee to resign in lieu of termination to report the termination or resignation to the Board within 10 working days. Does this include all terminations and resignations, or only those that result from diversion or gross violation of law, rule or policy, etc? We would appreciate clarification on the Board’s expectations for reporting with the proposed amendments.

CVS Health appreciates the opportunity to submit comments for the proposed amendment of this rule. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

Lauren Berton, PharmD.
Director, Pharmacy Regulatory Affairs
CVS Health
I worked with the pharmacy board and others in 2014 in regards to establishing language for the drug outlets. The final consensus was published in the “Non Pharmacy Dispensing Concept”, which was submitted to the Pharmacy Board and approved on 12/4/14. I expected the rules to be made using our final concepts, and be in effect starting in July of this year as planned.

I was quite surprised to discover the proposed administrative rules for OAR 855-043-0505, and OAR 855-043-0515 omitted some of the most important language from the Non Pharmacy Dispensing Concept.

The concept defines traditional and non-traditional dispensing of drugs. It states directly that the intension of the pharmacy board is not to regulate “traditional dispensing” of drugs by practitioners. The administrative rules submitted state that “a practitioner who participates in non-traditional dispensing must register the dispensing outlet with the Board (of pharmacy) as a Dispensing Practitioner Drug Outlet. What is non-traditional dispensing and what is traditional? It is very unclear. There are no definitions of these terms. In the dispensing concepts, several categories are listed to be exceptions to classification as a drug outlet. Some are provided, but the most important and specific from the dispensing concept is missing. That is “For the intention of this concept, “drug” shall specifically be defined as FDA-approved human prescription (legend) drugs.” Due to its absence, one is directed back to the definition of drugs under the pharmacy board, which includes such things as homeopathic substances. Does the Pharmacy board wish to oversee homeopaths? I do not think that was the intent, after speaking extensively with members of the pharmacy board and its representatives.

I hope that the pharmacy board will adjust the proposed administrative rule to include the agreed upon language used in the Non Pharmacy Dispensing Concept of 12/4/14 to identify what the pharmacy board considers “drugs” to be for the purpose of identifying offices as drug outlets. I hope the administrative rules will also be modified to a specific identification of the terms traditional and non-traditional.

Laurie Marzell, N.D.
15962 Boones Ferry Rd. #102
Lake Oswego, Oregon
97035
503-655-9493
lauriemarzellnd@gmail.com
Karen,

As a licensed Naturopathic Physician I have read the proposed Division 043 Dispensing Practitioner Drug Outlet rules. They would apply to me in that I dispense Naturethroid, a brand of natural thyroid supplementation, in various doses. Naturethroid is not available at most pharmacies. That is the one and only prescription medication that I ever dispense, as a service to patients, at a very economical price. These Rules would require an onerous level of administrative work that I think would mean I would stop dispensing Naturethroid, which would negatively affect several dozen patients. I would have to talk with pharmacies to see where I could get to stock it, and I am quite sure the price for patients would be at least double. While still a relatively inexpensive medication, I think some might stop taking it.

More paperwork does not guarantee safety. In general more paperwork contributes to practitioner burn-out. Please consider adding to these proposed Rules an exclusion for practitioners who dispense 5 or less (or 3 or less?) non-controlled prescription medications in small volumes!

Sincerely,
Sara Ohgushi ND
2207 NE Broadway Ste. 200
Portland OR 97232
503-236-6006
www.sarasfamilycare.com

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November 22, 2016

Karen MacLean
Hearings Officer
Karen.S.MacLean@state.or.us
Board of Pharmacy
800 NE Oregon St., # 150
Portland, OR 97232

Dear Karen,

We have been grateful to the Board of Pharmacy’s efforts to engage various stakeholders in the effort to put in place rules around Dispensing Practitioner Drug Outlets. Despite the lengthy process, we still hold several concerns that the proposed rules may inadvertently create unnecessary barriers to patients under the care of naturopathic doctors.

Specifically, we request that the rules exempt the following substances:

1. **Homeopathics** - it is unclear from the rules whether homeopathic substances would be considered as “drugs,” especially as there are many homeopathic products or combinations that have NDC numbers. As homeopathics are most certainly not what the Board of Pharmacy is concerned about in wanting to promulgate these rules, we respectfully request that the rules be amended to specifically exclude all homeopathics and homeopathic combinations.

2. **Thyroid glandular substances** – certain medications for thyroid diseases are required for ongoing – and, in some cases, lifelong – treatment of patients. The ability of patients to obtain these medications directly from their physician’s office increases adherence to treatment protocols, proper monitoring by the physician, and best outcomes for the patient.

We respectfully request that the rules be amended to reflect these two exemptions.

Sincerely,

Laura Farr
Executive Director
On November 10th, 2016 the Board of Nursing reviewed and discussed the proposed Dispensing Practitioner Drug Outlets rules. After discussion the Board clarified that these rules apply only to the acquisition, storage, labeling, and recordkeeping of drugs intended for dispensing and not the practice of dispensing. Inspecting the practice of dispensing without a formal complaint has restrictions as per ORS 678.390 5 (e) and OAR 851-056-0024 (8), the Board determined that these rules do not violate the referenced statute and rule. The Board also determined that this type of oversight is necessary due to the many different drug sources that could possibly be accessed, sources that may be outside of established safe procurement channels. Appropriate storage of drugs must be maintained to assure that the drug dispensed to a trusting public remains effective. Safe labeling practices assure that the patient understands the therapy and that the same safety warnings are present on a dispensing practitioner drug label as the public expects from a traditional retail pharmacy. Practitioners who dispense have a public safety obligation to demonstrate that the drugs procured are safe for the public, this demonstration is through adherence to the language contained in the proposed rules.

The actual practice of medication dispensing practices such as why the drug was dispensed, was it an appropriate drug, the assessment of the patient that warranted the dispensing of the drug, etc. fall under the purview of the Board of Nursing who will continue to work with our partners in the Board of Pharmacy to assure that at all times public safety is our utmost priority.
Hello,

Suffice to say I am a little confused at this message.

Does a dental practice that dispenses oral rinses such as chlorhexidine, toothpastes such as clinpro and mi paste, maintains an emergency medicine kit, and provide all the other aspects related to day to day basic general dentistry (provide OTC pain management when requested, provide topical and local anesthesia) have to be registered separately with the pharmacy board?

Prescriptions I provide for patients are to be filled at the pharmacy of their choosing. I'm just trying to learn if there is something different necessary with this most recent email...

Does dispensing narcotics, anxiolytics, sedatives, general anesthesia, and long term medicinal therapies, fall into a different category?

Thank you kindly!
Brandon White, DDS

On Nov 4, 2016, at 12:55 PM, OBD Info <obd.info@state.or.us> wrote:

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Oregon Board of Dentistry

Board of Pharmacy Proposed Rules & OBD Rule Changes

The Oregon Board of Pharmacy (OBP) has requested that the Oregon Board of Dentistry notify our licensees about their proposed rule changes regarding practitioners who participates in dispensing drugs from their practice location and who must register their dispensing outlet with the OBP. Following is OBP’s notice to our licensees:

Dear Practitioner:

The Board of Pharmacy has worked with your State Board and many of the Associations to craft the attached rules. These Division 043 Dispensing Practitioner Drug Outlet rules are intended to inform a practitioner who participates in dispensing drugs from their practice location and who must register their dispensing outlet with the Board.

Background for practitioners:

- These rules incorporate all elements negotiated with members from the state’s practitioner boards and associations to address the 2013 AAG opinion related the Oregon Board of Pharmacy’s oversight of drug distribution in the State.
- Stakeholders included the Oregon Medical Board, Oregon State Board of Nursing, Oregon Board of Pharmacy, Oregon Dental Board, Oregon Veterinary Board, Oregon Board of Naturopathic Medicine, Oregon Optometry Board, Oregon Medical Association, Oregon Nurses Association, Oregon State Pharmacy Association, Oregon Dental Association, Oregon Veterinary Medical Association, Oregon
Association of Naturopathic Physicians, Oregon Optometric Physicians Association, and the Drug Enforcement Agency (DEA).

- The Board plans a “soft-launch” of enforcement of these rules and, as always, plans to approach regulation per its “Compliance through Education” axiom.
- Once the Board has the opportunity to review public input, staff will complete the housekeeping and implementation details (fee, application, effective date).

The Pharmacy Board will conduct a Rulemaking Hearing on the attached rules, November 22, 2016 at 9:30 a.m. pursuant to the notice to that is also attached. To submit public comment in writing by mail or via email to:

Karen MacLean, Rules Coordinator
Oregon Board of Pharmacy
800 NE Oregon St., Suite 800
Portland, OR 97232
Email at: karen.s.maclean@state.or.us.

The deadline to receive written comment is: November 22, 2016 at 4:30PM

**OBD Rule Changes – Effective March 1, 2017**

The Board would also like to encourage all licensees to review all the rule changes that will go into effect on March 1, 2017. The information regarding these rule changes, which are effective March 1, 2017, can be viewed at this link [All Rules – Effective March 1- 2017](#).

Your opinion matters. Please complete our Customer Satisfaction Survey at [http://obd.oregonsurveys.com](http://obd.oregonsurveys.com)

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To Whom it may concern-

My name is Dr. Liana Barron, I am a veterinarian in Eagle Point, Oregon. I have practiced in Oregon for 11 years. The proposed DPDO in its entirety, is too general to be applied to veterinarians and veterinary medicine.

For example, there are many medications that are not dispensed in a unit dose or unit of use packaging (line 112/113 of proposed rules). Currently and traditionally veterinarians make smaller prescription bottles for each pet, dispensing from a 500-1000 count bottle. It unrealistic for veterinarians to act as a pharmacy and label each prescription as described in line 112/113 of proposed rules.

Prescriptions are generally made up and packaged by the veterinarian’s assistant. If this rule goes into effect, veterinarians could only have lay staff dispense unit of use packaging. Any other packaging would have to be done by the veterinarian (practitioner), a pharmacy, or a manufacturer registered with the board (i.e. a unit of use package that comes from the manufacturer) (line 130/131 of proposed rules). This will cause more harm than good, as some pets and their owners will get more medication than needed, just because it comes in a unit of use package. Some owners can only afford a small amount of medication each month, if they cannot afford the larger amount of medication, their pets will suffer.

Some veterinarians may choose to prescribe medications for owners to purchase at pharmacies. If this occurs, many animals will not get the medications they need. Many owners cannot afford the cost of prescriptions for themselves, let alone their pets. A recent example of this dichotomy is a client that had to get furosemide at the local pharmacy for his dog with heart failure. The dog would likely have life threatening complications of heart failure without this diuretic drug. Furosemide was on backorder from our manufacturer, we charge 5$ for the 100-count unit of use bottle of 20 mg furosemide. The owner paid 30$ for the same medication at the pharmacy. Situations like this, which may be created by the proposed DPDO will lead to a decreased standard of care for pets. Providing medications to the pet from the veterinary clinic, insures pets get the medications they need and improves owner compliance with administering the medications.

The proposed DPDO works well if you have a corporate clinic that is in a large store with it’s own pharmacy, like Walgreen’s “shotvet”. It doesn’t work well if you are a small business veterinarian in rural Oregon. Veterinarians are required to keep patient medical records for 3 years, these records include all medications sent out for each pet. Requiring veterinarians to keep a separate record of each and every prescription sent out is redundant. That information is located in each patient record.

Veterinary patients receive medications such as heartworm prevention, which is sold in a 6 or 12 month unit of use box. Heartworm prevention is very important for pets and people, as a few cases of human heartworm infection have been documented in recent years. A more specific description of animal medication in the DPDO is needed. Would heartworm prevention fall under line 25/26 in proposed rules? Would it be treated like a metered dose inhaler? How will medicated shampoos, topical skin medications and medicated ear flush be treated? Are these drugs? Will they have to be kept locked up as well as antibiotics? (line 77-79 of proposed rules). I feel that the proposed DPDO is unrealistic for veterinary medicine. I am opposed to its instatement, until these questions and concerns are resolved.

Sincerely, Liana M. Barron DVM, Oregon License #6023
Thank you Karen,

As a veterinary facility, the Portland Animal Welfare Team (PAW Team) is determined to live up to all standards and self-regulations and to use the next few years to come into complete compliance. As the managing practitioner at PAW Team, I personally agree that pharmaceuticals should be regulated in Oregon and support the extension of new standards to DPDOs like us. In fact, our goal is to get to the point where we could conduct a self-audit, using your form, sometime in the next 6 months, and pass before the veterinary board ever has occasion to come in and inspect us. However, we have a few urgent concerns about some of the details of these new rules, which I've listed below in hopes the Director could respond and I could share with our board. If, after reading below, you have further information that would help us transition more smoothly or if any of the below could inform future amendments, we would greatly appreciate it.

1. Regarding 855-043-0545 (4) drugs must be packaged by the practitioner, a pharmacy, or a manufacturer registered with the Board.

Very few veterinary facilities have a pharmacist on staff and very, very few pharmacists have been trained in, or properly understand, veterinary pharmacology. For this reason, our industry typically relies on registered veterinary technicians or experienced, trained veterinary assistants to fill prescriptions. Those of us who have sent prescriptions to human pharmacies have experienced mishaps and dangerous, sometimes fatal mistakes, irrelevant or misleading (i.e. human-species-specific) consultations from the pharmacist about side effects or route of administration, or often the pharmacy lacks availability of the drug type, form, or dosage our patients require.

More importantly, if it were required that the prescription be filled, labeled and packaged by the veterinarian (aka "practitioner") during the course of a veterinary visit, the average veterinary practice would require an additional 10-20 minutes of additional practitioner time dedicated to each patient. This would translate into the veterinarian scheduling anywhere from 6 to 10 less patients per day unless they plan to extend their work and business hours by up to 53%. In an industry where there is already a shortage of doctors, suffering the highest rates of compassion fatigue and suicide of all the professions, the latter would not be acceptable.

As for us at PAW Team, we are a non-profit charity providing free veterinary services to low-income families through the voluntary time of veterinarians and staff. This new regulation would create a "bottleneck" in our schedule which would cause us to cut our appointment schedule in half. This would mean more families evicted from low-income housing due lack of vaccinations and lack of spay/neuter. Not only would this add to an already growing homeless population in the Portland area, but it would increase public health crises due to the number of zoonotic diseases transmissable from pet animals to the human population.

At the same time, even for-profit veterinary clinics would be affected. The above requirement would, by my rough calculations, result in average daily revenue loss of around $1000 and annually around $500,000 for each individual veterinarian. Veterinarians already have the highest student debt to income ratio of all the professions and many would go out of
business to comply with this requirement.

For this reason, I take strong issue with the evaluation by the board that financial impact of these regulations is estimated to be low. In our industry, it will be anything but low.

- 855-043-0550 Drugs that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, or identified as suspect or illegitimate must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to the supplier.

With the exception of biologicals and many injectables (such as vaccines or controlled substances), the majority of pharmaceuticals we maintain in our pharmacy, and prescribe to our clients, are donated to us by the veterinary community after they've expired. While we are transparent about this with our clients, our entire pharmacy supply will be decimated if we aren't allowed to receive outdated drugs from donating veterinarians. As mentioned above, while we know we have the option to prescribe drugs via store pharmacy (e.g. sometimes we refer clients to Walmart pharmacy or others), our clients rarely have transportation or finances to be able to fill these prescriptions. An enormous number of pets would suffer and everything from skin conditions to intestinal illness, seizures, immune-mediated and endocrine disorders. Not to mention, parasites and other infections, often contagious to humans, would go completely untreated. While we've started to purchase some new medications through low-cost programs, we simply do not have the budget to purchase and maintain a pharmacy full of new, non-outdated pharmaceuticals and still serve our clients. To further illustrate this effect, I'd be happy to gather statistics and total number of clients and pets that rotate through our facility on an annual basis. My rough estimate is that the cost of pharmacy supply would exceed our entire annual operating budget by 25% and thus it would cause us to shut down entirely.

I admit I'm very worried about the future of PAW Team in the coming years and I'm hoping we could have some consideration in the above respects. I do understand that there are a few clauses exempting pharmacists performing charity work from certain standards. However, there are no exceptions to veterinary practitioners in these clauses/amendments and regardless, some of my concerns apply to the veterinary industry as a whole. Thank you for sharing and considering these points.

Sincerely,

Andrea Sanchez, DVM

On Mon, Nov 14, 2016 at 8:32 AM, Karen S MacLean <karen.s.maclean@state.or.us> wrote:

Hello Andrea,
Feel free to send questions or comments to me and I'll save them and forward questions to our Director for response.

Thank you.
Karen MacLean
Oregon Board of Pharmacy
Sent from my iPhone

On Nov 11, 2016, at 11:56 AM, Andrea Sanchez <sanchezchambers@gmail.com> wrote:
Dear Ms MacLean,

I have accepted responsibility as the managing practitioner of record for DPDO registration of the Portland Animal Welfare team, a non-profit veterinary provider which does not charge fees for prescriptions.

I have read the notice of rulemaking, proposed amendments and, in order to ensure we can meet standards of compliance, have carefully read all 855-043-0505 through 855-043-0560. We are beginning our review now. Should I direct comments and questions to you?

Sincerely,
Andrea Sanchez
Dear Ms Maclean:

As I read these regulations, as a rural practitioner, some of these rules are untenable. There is a large assortment of medications that do not require controlled access and are on open shelves in our treatment area (line 77): Is there going to be realistic latitude for interpretation of this rule? Overall, as an individual that feels that we already have enough rules to keep us honest (if we are interested in being so), this seems to be overkill and an additional step to drive small rural to semi-rural practitioners deeper into the cynicism brought on by unnecessary governmental oversight. The Oregon Board of Pharmacy seems to be operated in such a way that communicates to the vast majority of us who are trustworthy, that we are not so. The increasingly labor intensive requirements to be compliant continue to drive the cost of providing service up and ultimately do not inhibit those who are creative enough to work around them.

Regretfully,

Brian Reister, DVM
East Lane Veterinary Hospital
in practice for 35 years
Dear Pharmacy Board,

I am writing in regards to my concerns about the recently proposed rules imposed on veterinary clinics that dispense medications. Maintaining a high standard of care is of utmost importance in this profession, however these new rules would place an unnecessary burden on clinics already struggling to compete with the big box companies and online pharmacies.

Some of these proposed rules impart great cost for very little, if any benefit to those that are meant to be protected. A few of these examples include: keeping all medications locked away, only allowing practitioners to package medications, and maintaining additional extensive records on every script. To keep a clinic afloat, costs must then be transferred to the client, effectively pricing our pets out of the quality care that they deserve.

Sincerely,

D. Paul Bailey DVM
Blair Bailey DVM
Barry Downie DVM
Bailey Veterinary Clinic
248 Garden Valley Blvd
Roseburg, Oregon 97470
(541)673-4403
Dear Ms. MacLean:

I have reviewed the proposed DPDO rules. Whereas I understand the spirit in which the rules are being proposed to better regulate the distribution of drugs in Oregon by the Board of pharmacy, I feel that many of the statutes would place undue burden on small clinics including veterinary clinics. I would like to enter my feedback for consideration during the public comment period about specific proposed items in the statutes.

Many of the rules place undue and redundant burden on dispensers/veterinary clinics that are not set up with the infrastructure to be large pharmacies. Here are some examples of the proposed rules that would provide challenges for veterinarians to implement...

855-043-0540 (k) Any dispensed prescription medication, other than those in unit dose or unit of use packaging shall be labeled with it's physical description, including any identification code that may appear on the tablets and capsules. - This rule of course makes sense for pharmacies, however veterinarians source their pharmaceuticals through veterinary distributors with generic products that may be constantly changing. The same medication source from your same distributor may change its look and physical description. Although this can manually be implemented-there is no easy way to automate without investment in pharmacy management, barcoding and other software and hardware.

855-043-0545 (5) 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- For veterinarians this poses a significant problem. As you know, as veterinarians our clients rely on us to take back and safely dispose of drugs after a patient has passed away or been euthanized. As a referral clinic this request is even greater. To direct our clients to sites that will take the drug likely ensures that they will not take it to a disposal facility or be properly disposed of. In addition- in my past experience when clients have taken drugs prescribed for a pet to these locations they have been turned away. Many of these drug takeback sites are law enforcement locations - for a client to have to dispose of non-controlled drugs at these sites criminalizes the possession of innocuous drugs, and this is usually on top of the grief of losing a pet for which the drugs have been prescribed.

855-043-0555 (1-3) The record keeping burden with these proposed rules is immense such that dispensing records have be kept separate from the patient chart for three years after dispensing. As I read this effectively the label from each prescription would need to printed or stored in duplicate for 3 years meet this criteria. Inventory records would not suffice. Medical records would not be sufficient.

Thank you for reading through my concerns. I'm sure I'm not the only veterinarian or frankly practitioner who has concerns about how these DPDO rules would impact their practice. Please let me know if there is anything further that I can do ensure that our perspective is heard at the Board of Pharmacy.

Regards,
Lee V. Herold DVM, DACVECC
Chief Medical Officer
DoveLewis Emergency Animal Hospital
503-228-7281
10/23/2016

Dear Oregon Board of Pharmacy,

Regarding: Proposed rules for Dispensing Practitioner Drug Outlets

As a veterinarian who has been practicing in Oregon for 30 years and as a practice owner I would like to make some comments about the proposed rules and ask for some clarifications.

Lines 69 – 71 of the proposed rules. Is there an existing template these policies? How much detail needs to be included in the policies?

Lines 77 - 79. Veterinary clinics rather free standing or as tenant improvements in leased space are purpose designed for providing care based on how we have functioned for years. Most Veterinary facilities have open pharmacy shelves for filling prescriptions and storing drugs with the exception of controlled substances that are stored and locked up separately. The “pharmacy” area for storing and filling prescriptions is generally in an area of the hospital that is not assessable to clients but also is not in a separate room for this use only that can be locked up separately from the rest of the hospital. Would this suffice? Would it suffice to put locking cabinets on the shelving but not have it in a separate room? It would be a considerable building expense to build a separate room within the clinic. Is “when not in use” defined as when a medication is not being dispensed or when the hospital is closed?

Line 100. Our veterinary practice management software does not create a unique identifier number when we are creating a prescription. I believe that other veterinary practice management software does not create this number as well. Would not the prescription but unique and identifiable being labeled with the patient name, owner name, and date? This seems to me a requirement that does not benefit the patient or client and only creates another requirement to meet that would be very difficult to do until veterinary practice management software incorporates this. When that happens it would be an easy requirement to meet (if in fact it is important).

Line 109. Specifically, what would those cautionary statements required by law be to be?

Line 113 – 114. As an example would this say “blue capsule with a red D” or “square white tablet” or whatever the pill looked like?
Line 130 – 131. Would prescriptions need to be filled by the veterinarian or could someone be trained and designated to do this? Currently in our hospital staff are trained to do this and each prescription is checked to be correct by another trained person before being dispensed.

Lines 145 – 156. Our veterinary practice management software does not create a dispensing record separately from the patient chart. I don’t believe that other veterinary practice management software does this either. As all patients receiving prescriptions are patients of the practice that have a medical record, this seems to be busy work that serves no real purpose to patient care. I have to say that this makes no sense to me. In the future if and when veterinary practice management software incorporates this into their software then this would be easy to do.

Line 161. Do you have a copy of a Board Self Inspection Form that you could send to me?

As veterinarians we are trained about specie specific dosage requirements and specie specific side effects for those patients we treat. I could be wrong but to my knowledge human pharmacists have little to no training in this regard. I am assuming that all of the changes that the pharmacy board is recommending are only to ensure and improve the care of our patients and to help prevent mistakes. With the lobbying efforts of the big box stores like Walmart and others I hope these rule changes are not being made with the intent of pressuring veterinarians to send all of their prescriptions to these more politically connected and powerful businesses. Veterinary medical facilities have been sending home prescription medications for our patients for quite some time.

Sincerely,
Robert Merrill DVM
email: sherwoodfamilypetclinic@yahoo.com
phone 503-625-5664
where may one find definitions of traditional and nontraditional dispensing? what is the definition of drugs? the way it is written implies that i may not dispense more than a 72 hr supply of anything. more fees, more unnecessary costly duplicate record keeping. more bureaucracy and less care for patients. thank you in advance for answering my questions. Devon Trottier VMD
November 22, 2016

Karen MacLean
Rules Coordinator
Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland OR 97232

Re: Proposed rulemaking on Division 043, Dispensing Practitioner Drug Outlet

Dear Ms. MacLean,

The OMA appreciates the opportunity to comment on the proposed rules that create Dispensing Practitioner Drug Outlets (DPDO). The Oregon Medical Association (OMA) respectfully submits the following comments on the proposed rules.

In the 2014 legislative session, the OMA and additional professional associations, reached a memorandum of understanding with the Board of Pharmacy to delay any administrative rules or legislation that would create “unnecessary and redundant oversight of drug dispensing and [that] does not create access barriers for patients”. It was further agreed that if “legitimate concerns were brought forward, the Board of Pharmacy [would] collaborate with the licensing boards and professional associations to address those concerns through existing oversight structure”¹. In the two years since this understanding was reached, the OMA was not contacted nor made aware of any “legitimate concerns” with the current regulatory structure and therefore must remain must opposed to any duplicative regulations on our membership.

**Duplicative Regulations**

In a recent conversation with the Oregon Medical Board (OMB), the OMA learned that approximately 1,500 physicians and 50 physician assistants currently have the ability to dispense prescriptions in their clinical setting. The OMB regulates all 1,550 of these licensees through its own adopted administrative rules (OAR 847, Division 50), which, similar to the currently proposed rules by the Board of Pharmacy, include requirements on labeling, inventory and chart documentation. We find that the proposed rules would overlap and conflict with the existing OMB rules, thereby creating confusion for our members and increased likelihood they would give up dispensing all together. For example, the OMB rules require the dispensing of drugs must be documented in the chart and the proposed Board of Pharmacy rules state that a dispensing record must be maintained separately from the patient chart (OAR 855-043-0555).

Further, the OMA is concerned about the lack of clear definition between “traditional” and “non-traditional” dispensing. OAR 855-043-0515 (2)(D)(ii) relies on the “professional

¹ [https://olis.leg.state.or.us/liz/2014R1/Downloads/CommitteeMeetingDocument/35172](https://olis.leg.state.or.us/liz/2014R1/Downloads/CommitteeMeetingDocument/35172)
judgement of the practitioner” to allow a full course of therapy to be prescribed and exempted from registration as a DPDO. The standard of relying on a medical professionals’ judgement isn’t uncommon, however, without clearly defined parameters, it will be harder for practitioners to understand what, when and how they can dispense prescriptions and under which board they are obligated.

**Patient access to needed medications.**
The OMA is unclear about the Board of Pharmacy’s rationale for the need to regulate physician dispensing, evidence of “legitimate concerns,” or threats to patient safety. The OMB has not encountered any additional complaints about a practitioner’s dispensing practices, despite having seen an increase in the number of licensees registered to dispense. We know, based on a membership survey conducted in 2014, the dispensing by a physician is seen as a benefit by patients, often saving them time, giving them faster access to needed prescriptions (as not all pharmacies stock every prescription), lowering their cost and ensuring medication compliance is achieved. The unintended consequence of additional or duplicative regulation as proposed in these rules would be that the majority (49.1%) of practices currently dispensing would stop dispensing (in part due to the increased regulatory requirements as well as the additional fees to another regulatory body). Given that the OMB rules distinguish between general dispensing and underserved dispensing, the OMA is further concerned about the impact of these proposed rules on rural practices and their patients. The OMA encourages the Board of Pharmacy to consider conducting its own analysis of the fiscal and patient impacts of a decrease in dispensing practitioners before fully adopting these rules.

Thank you for your consideration of our comments. We would be glad to supplement our comment with discussion and further conversation with the Board of Pharmacy and any other appropriate partners.

Sincerely,

Mark Bonanno, JD  
General Counsel

Danielle Sobel, MPH  
Associate Director of Health Policy
November 22, 2016

Karen MacLean, Rules Coordinator
Oregon Board of Pharmacy
800 NE Oregon St. #150
Portland, OR  97232
karen.s.maclean@state.or.us


Dear Karen,

Thank you for the opportunity to provide written comments on the proposed new OARs 855-043-0505 through 855-043-0560. The Oregon Medical Board submits the following comments for consideration by the Board of Pharmacy. Many of these comments were shared at the June 30, 2016, workgroup but were not incorporated into the currently proposed draft.

Regulating dispensing physicians goes beyond the Board of Pharmacy’s statutory authority. While “dispensing” is within the definition of the practice of pharmacy in ORS chapter 689, it is also within the definition of the practice of medicine as stated in ORS 677.010, 677.085, and 677.089. The Medical Board already regulates dispensing physicians and physician assistants. When the Legislature intends to authorize more than one health professional regulatory board to regulate a particular practice, it clearly states that intent in the statute as shown in ORS 677.511(4).

There is no known need for new, additional regulations on dispensing physicians and physician assistants at this time. The Medical Board maintains a registry for dispensing physicians and physician assistants and does not charge additional fees for registering. The Medical Board has not seen a pattern of complaints related to dispensing that would warrant additional regulations of dispensing physicians and physician assistants.
“Traditional” and “non-traditional” are newly created distinctions in the practice of dispensing. These terms are ambiguous and will lead to confusion among dispensing physicians and physician assistants.

The fiscal impact statement underestimates the impact these new rules will have on small businesses and the public. Approximately 1500 physicians and physician assistants are registered as dispensing providers with the Medical Board. At $100 per year for each practice location, this has a potentially large fiscal impact to small businesses throughout Oregon. In many cases, these practice locations are more than 60 miles away from the nearest pharmacy. Often, these practices dispense medications at a reduced cost or at no cost to their patients. If these regulations cause small businesses to stop dispensing, the communities they serve would be negatively impacted.

The Medical Board encourages the Board of Pharmacy to take an educational approach rather than requiring physicians and physician assistants to register, pay an annual fee, and submit to annual inspections. The Medical Board supports the proposed rules OAR 855-043-0520 through 855-043-0555 after removing references to registration with the Board of Pharmacy. In addition, the Medical Board would be pleased to partner with the Board of Pharmacy to provide more outreach and educational materials to physicians and physician assistants who include dispensing as part of their practice of medicine.

Thank you for your consideration. We look forward to the next draft of these proposed rules.

Sincerely,

Nicole Krishnaswami, JD
Operations & Policy Analyst
Re: Proposed Rules for Dispensing Practitioner Drug Outlets

Ms. MacLean,

Thank you for the opportunity to submit comments on behalf of the Oregon Society of Physician Assistants (OSPA) for the Board of Pharmacy’s proposed rules for Dispensing Practitioner Drug Outlets.

OSPA is a member organization representing physician assistants across the state of Oregon. The Oregon Society of Physician Assistants seeks to promote quality, cost effective, and accessible health care; to support the professional and personal development of Physician Assistants; and to advance the PA profession as well as the PA/MD team approach to health care.

OSPA values the appropriate regulation of prescription drugs in order to limit the overuse and abuse which has led to addictions epidemics and drug resistance in recent years. However, we do not believe the Board’s rules do anything to improve patient safety, and in fact could be detrimental to patients in rural and underserved areas with limited access to store-front pharmacy service.

This regulation appears to duplicate oversight (ORS 677.515). Duplication is not helpful unless an actual identified problem exists. The proposal does increase both costs (in new fees) and oversight activity (potentially duplicative recordkeeping and inspections).

Currently, the licensing boards that oversee providers also regulate their dispensing, as the state recognizes that activity as within the scope of a licensed provider. Physicians and PAs must register with the Oregon Medical Board as dispensing providers, and the Board is tasked with overseeing that dispensing in order to protect patient safety.
The proposed rule creates redundant and burdensome new annual registration with a different cycle and expiration timelines than OMB license renewal and creates a new mandatory reporting requirement [Proposed OAR 855-043-0515(7)-(10)]. We are also concerned that the proposed regulations give the Board of Pharmacy authority over the Oregon Medical Board, thus creating a confusing chain of authority for practitioners [proposed OAR 855-043-0515(12)].

The rule doesn't necessarily appear to increase patient safety and/or access to care. It may, in fact, reduce access, as some providers may choose not to continue dispensing, even though they were doing it safely and appropriately.

The fiscal impact statement that accompanies these proposed rules says this will result in improved public safety, but the Board has not described the current public safety concern or provided any evidence that current dispensing regulations by providers’ boards is inadequate.

The fiscal impact statement also says there will be a minimal impact to dispensing practitioners, but we disagree. The Oregon Medical Board’s database shows that more than 1500 physicians and PAs are currently registered as dispensing providers, most of whom are located in rural and underserved areas. At $100/year for each practice, plus the paperwork and time taken for inspections – in addition to the compliance already required by the Oregon Medical Board – this poses a potentially large fiscal impact for those small businesses.

If a small rural practice decides that the fiscal impact and additional registration and compliance requirements are burdensome, they may end this part of their practice. OSPA is concerned that this will limit access in rural areas, where a dispensing provider often is the only access a patient has to prescription medicine within a reasonable travel distance.

That leads OSPA to also take issue with the fiscal impact statement’s claim that there will be no impact on the public. Many dispensing practices are located more than 60 miles from the nearest pharmacy. Should a practice stop dispensing, the time it takes to travel the distance to a pharmacy is not insignificant; therefore, we can assume there will be a negative impact on a patient in such a situation.

Additionally, we question the Board’s authority for regulating rural and underserved dispensing practitioners. 2012 legislation specifically related to PA dispensing clearly said that PAs not located in rural or underserved areas may only dispense if they register with the pharmacy board (ORS 677.515 and OAR 847-050-0041 vs. ORS 677.511). The legislature explicitly kept the exemption for rural and underserved areas in order to avoid unnecessary burdens on those populations. Legislative intent here is clear: rural and underserved practices that qualify should be able to dispense without additional oversight.

OSPA also has significant concerns with ambiguous language found in the rules. The proposed rules add a new distinction between “traditional” and “nontraditional”
dispensing, but those terms are not well-defined and leaves ambiguity for practices.

With the significant concerns about burden and ambiguity outlined here, OSPA is concerned enough with the proposed regulation to oppose the rules as written. We look forward to continuing this conversation about where the threat to patient safety might be and how to resolve it. We hope the Board of Pharmacy will look to OSPA as a resource in future discussions about the regulation of providers.

Sincerely,

Rachel Stappler, PA-C
President, Oregon Society of Physician Assistants
November 10, 2016

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232-2162

Dear Colleagues,

Thank you for the opportunity to comment on the proposed rule regarding Pharmacy practices in the State of Oregon.

As you may be aware, Hematology Oncology of Salem is the last free-standing privately-owned oncology practice in the State. As such, our prices to consumers and all payors are 30-100% less than institutionally based Oncology groups. Please see the attached article recently released nationally emphasizing this point.

Even though we appreciate your efforts to improve care for Oregon patients, we oppose the proposed rules for several reasons:

1. It would force us to hire and staff our oral oncologic dispensary with full-time pharmacists. This would add significant costs to our patients and all payor groups as well as disadvantaging our practice in the range of $200-300 thousand annually.

2. We operate as a physician owned dispensary and have done so successfully and without error for approximately 25 years. This arrangement allows our Physicians, APPs, and Nursing Staff to stay close and vigilant in the ongoing care of our patients.

3. Oral oncolytics have commensurate side effects with equivalent infuse drugs. This requires frequent connection and communication with our professional staff to ensure the quality of cancer care given. Your proposed rule will interfere with best practices in the cancer care arena.

4) Additionally, we work under the auspices of the McKesson Corporation which operates hundreds of oral pharmacies in the US. We follow their strict protocols for patient safety, ordering, dispensing, reconciliation, etc.

5) We only dispense oral oncolytics, supportive cared medications, and specialty drugs to our cancer and hematology patients. We do not serve or provide any drugs outside the Hematology Oncology arena or to patients outside our practice.

We are respectfully petitioning the board to exempt oncology practices from this modification and change 72 hours to ‘course of therapy’ as other States, including California, Utah and New York have done. Thank you for your consideration.

Sincerely,

[Signature]

Steven Taylor, CEO
William Pierce, M.D.
Charles Petrunin, M.D.
Natasha Tiffany, M.D.
John Strother, M.D.
Renee Prins, M.D.
Janelle Meyer, M.D.
Catherine O'Brien

Hematology/Medical Oncology
William C. Pierce, MD, PhD • Charles G. Petrunin, MD • Natasha M. Tiffany, MD • John M. Strother, MD • Renee C. Prins, MD • Catherine A. O'Brien, MD
Janelle M. Meyer, MD • Beth Dayton, MD • Steven Taylor, CEO • Sarah Daniel, PA • Sadie Blackhall, PA • Tabitha Phillips, PA • Jeffery Schwab, FNP
875 Oak Street SE, Suite 4030 • Salem, Oregon 97301 • 503.561.6444 • Fax: 503.561.6440 • www.hemoncofalem.com
Since 2010, the Community Oncology Alliance (COA) has prepared a Community Oncology Practice Impact Report, tracking the changing landscape of oncology practices in the United States. This is the sixth Community Oncology Practice Impact Report and covers activity for a nine-year period, from January 2008 to September 2016. Compiled from public and private data sources, the report provides a unique look at community oncology practice trends at both the national and state levels.

The 2016 Community Oncology Practice Impact Report shows that since 2008, 1,581 community practices and/or clinics nationally have been affected by closings, hospital acquisitions, and corporate mergers. This is a rate of 15.1 community practices affected per month during the observed period. Specifically, the data show:

- 380 Clinics closed — Denotes individual clinic treatment sites that have closed.
- 390 Practices struggling financially — Practices (typically comprised of multiple clinic sites) that have had financial difficulties, struggling to pay bills and/or stay open.
- 45 Practices sending patients elsewhere — Practices (typically comprised of multiple clinic sites) that are sending ALL of their Medicare patients elsewhere for chemotherapy.
- 609 Practices acquired by hospitals — Denotes practices (typically comprised of multiple clinic sites) that have been acquired by a hospital or, with less frequency, have entered into a contractual professional services agreement binding them to a hospital.
- 157 Practices merged or acquired — Practices (typically comprised of multiple clinic sites) that have merged or been acquired by a corporate entity.

Notably, the 2016 Community Oncology Practice Impact Report shows an increasing number of practice closures since the last report. The monthly rate of closures has increased 87% since the last report. Other trends COA notes are that since 2008:

- 121% increase in clinics closed.
- 21% increase in practices struggling financially.
- 2% increase in practices sending patients elsewhere.
- 172% increase in practices acquired by hospitals (or with a hospital agreement).
- 54% increase in practices merged or acquired by a corporate entity.

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Examining local trends in states, the report shows that the largest number of community oncology practice closures have been in Florida (37), Texas (36), and Michigan (34). The states with the most community oncology practices struggling financially are Michigan (43), New York (41), and California (40).
2016 Community Oncology Practice Impact Report: Tracking The Changing Landscape of Cancer Care

Historical Trend in the Changing Landscape of Cancer Care
(Derived from current and past reports)
### 2016 Community Oncology Practice Impact Report:
Tracking The Changing Landscape of Cancer Care

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<th>State</th>
<th>Total Sites/Practices</th>
<th>Clinics Closed</th>
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Hi Karen,

I am confused about a lot of the new changes that are coming up this next year. I was hoping that you would be able to simplify this for me. We are an oral surgery office, with an oral surgeon that performs all of the onsite anesthesia. We also administer medications to the patients during surgery such as versed and fentanyl along with dispensing of pain prescriptions for after surgery. We have a system in place with the drugs that we sell and dispense to the patients which includes a tracking form in the computer along with a log to the Pharmacy we buy from. Do we need to do anything different? We have gone through the print out and it looks like we are compliant with all the areas except I am not sure about the Naplex/Dug take back, and traditional vs nontraditional pharmacy. Do we need to fill out an application? Can you help explain this a little? Feel free to call me at 541-779-7799 thank you!

Dyan Dalton
Surgery Manager
Hi Karen, Gary and Fiona,

Thank you, Karen, for speaking with me on the phone yesterday and explaining the rulemaking timeline to me.

As background, SIRUM operates a Charitable Pharmacy in Hillsboro and we partner with most of the other Charitable Pharmacies throughout Oregon. SIRUM operates in several other states as well, running the largest drug redistribution program in the country. We worked with Senator Gelser and the Board of Pharmacy on SB 1514.

We understand the intent of the draft rules regarding Charitable Pharmacies on the October 6, 2016 agenda but have significant concerns over the scope and wording of these changes.

- **855-044-0030 (1) A charitable pharmacy may not accept: (d) An FDA REMS (Risk Evaluation and Mitigation Strategy) drug:**
  - We believe that this language, not allowing any REMS drug from being accepted, is unnecessary and precluding REMS drugs is more likely to harm patients than protect them. Charitable Pharmacies - like other pharmacies - should have the opportunity to dispense a donated REMS drug as long as they follow all REMS requirements. Importantly, disallowing REMS drugs would prevent uninsured and under-insured patients from receiving life-saving and often very expensive drugs - one such example is the pre-exposure HIV prophylaxis, Truvada, which can prevent a patient exposed to HIV from infection.

- **855-044-0030 (1) A charitable pharmacy may not accept: (e) A drug donated from another state.**
  - We believe the wording of this rule should more closely mirror statute which states that “The program may accept and distribute within this state”. We are aware of the Board’s stance on only distributing donated medicine within the state, however, as currently worded, this draft rule would essentially preclude all currently eligible donations of manufacturers and wholesalers from being accepted. If the intent of the Board is to limit these donor types, we would be happy to discuss working with the Board and any other stakeholders on statutory changes. If this is not the intent, we ask the Board to limit this rule to accepting and distributing medicines within the state as written in statute.

We look forward to further discussions in the rulemaking process. Please let us know if there is a possibility for a significant conversation on Thursday. We will gladly fly in if so, though based on our conversation, there was a limited opportunity to speak.

Thank you,
George

--

George Wang, PhD
Co-Founder & Director
The proposed rule amendments to Div 007 Public Health Emergency and 041 Operation of Pharmacies update rules related to the registration and regulation of Drug Rooms.

The rule (1) describes oversight of long-term storage of state and federal emergency medications in a Drug Room (2) clarifies that secondary storage areas related to Retail Pharmacies can register as a Drug Room; and (3) allows a Drug Room to be affiliated with an Institutional Pharmacy.

<table>
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### SNS and State Stockpile Emergency Drugs

(1) General: When drugs from the Strategic National Stockpile (SNS) are delivered to the state, the drugs may be delivered to a state Receipt, Staging and Storage center (RSS) for further distribution to Points of Dispensing (PODs) selected by OSPHD. State drugs (state stockpile) may also be delivered to the RSS.

(2) **Temporary** Storage of drugs from SNS or state stockpile:

(a) The RSS, PODs and local health departments (LHD) are authorized to store any drugs from the SNS or state stockpile prior to and during an emergency without any registration from the Board.

(b) All such drugs must be stored in accordance with manufacturers’ guidelines.

(c) This authority to possess drugs shall extend beyond the declared emergency until procedures issued by OSPHD for the return or destruction of unused drugs have been completed.

(3) **A long-term drug storage area for state and federal emergency medications not otherwise registered as a drug outlet must be approved by the Board, comply with storage and security requirements, and register as a Drug Room.**


Stats. Implemented: ORS 689.155
**Definitions**

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


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

(3) (4) “Interchangeable” means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. 262(k)(4).

(4) (5) “Reference biological product” means the biological product licensed pursuant to 42 U.S.C. 262(a) 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.


**Proper Storage of Drugs**

(1) A pharmacy must maintain proper storage of all drugs. This includes, but is not limited to the following:

(a) All drugs must be stored according to manufacturer’s published or USP guidelines.

(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.

(d) A pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect.

Cold Storage and Monitoring.
A pharmacy must store all drugs at the proper temperature according to manufacturer’s published guidelines (pursuant to FDA package insert or USP guidelines).

(a) All drug refrigeration systems must:

(A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.

(B) Utilize a centrally placed, accurate, and calibrated thermometer;

(C) Be dedicated to pharmaceuticals only; and

(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.

(b) A pharmacy must adhere to a monitoring plan, which includes, but is not limited to:

(A) Documentation of training of all personnel;

(B) Maintenance of manufacturer recommended calibration of thermometers;

(C) Maintenance of records of temperature logs for a minimum of three years;

(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;

(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan; and

(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment.

(3) Vaccine Drug Storage:

(a) A pharmacy that stores vaccines must comply with section two of this rule and the following:

(A) Vaccines must be stored in the temperature stable sections of the refrigerator;

(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 °C variance must be utilized;
(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;

(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and

(E) Must adhere to a written quality assurance process to avoid temperature excursions.

(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.

Stat. Auth.: ORS 689.205, 689.325
Stats. Implemented: ORS 689.155

855-041-5005

Definitions
For purposes of these rules, OAR 855-041-5000 through 855-041-9999 the following definitions apply:

(1) "Institutional Facility" means a hospital or other health care facility which is an inpatient care facility referred to in ORS 442.015, which includes long-term care facilities and special inpatient care facilities, and such facility is licensed by the appropriate state agency. For the purpose of this rule, an Institutional Facility is a Residential Drug Outlet.

(2) "Institutional Pharmacy" means a pharmacy where medications are dispensed to other health care professionals for administration to institutionalized patients served by an institutional facility, and which is:

(a) Located within the institutional facility;

(b) Located outside the facility but provides pharmaceutical services to institutionalized patients; and

(c) For the purpose of this rule, an Institutional Pharmacy is a Residential Pharmacy.

(3) "Drug Room" means a secure and lockable location within an inpatient care facility that does not have a pharmacy and is a Board approved location associated with a licensed institutional pharmacy.
The proposed rule amendment references new statewide laws related to limited liability for pharmacist volunteers, put forth by ORS 676.340 and ORS 676.345. A pharmacist who has registered and who provides health care services without compensation is not liable for any injury, death or other loss arising out of the provision of those services, unless the injury, death or other loss results from the gross negligence of the health practitioner.

The rule states that pharmacists may claim the state liability limitation upon registration with the Oregon Board of Pharmacy.

855-019-0123

Liability Limitations for Volunteers

1. A pharmacist may register with the Board for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services without compensation under the terms of the law.

2. A no cost registration may be issued by the Board upon receipt of a completed application. Registration requires submission of a signed form provided by the Board in accordance with ORS 676.345(2).

3. Registration will expire at the licensee’s next license renewal date and may be renewed biennially. It is the licensee’s responsibility to ensure his or her active registration in this program.

4. Nothing in this section relieves licensee from the responsibility to comply with Board regulations and still may be subject to disciplinary actions.

5. Pharmacists providing care under the provisions of ORS 676.340 and 676.345 remain subject to the Board complaint investigation process articulated in ORS 676.175.

Stat. Auth.: ORS 676.340, 689.205
Stats. Implemented: ORS 676.340, 676.345
The proposed rule amendments to *Div 041 Operation of Pharmacies* update regulations related to PIC expectations in Oregon Pharmacies.

The rule clarifies reporting requirements of an Oregon Pharmacy.

**855-041-1010**

**Personnel (Both Retail and Institutional Drug Outlets)**

(1) Each pharmacy must have one pharmacist-in-charge employed on a regular basis at that location who shall be responsible for the daily operation of the pharmacy. The pharmacist-in-charge shall be indicated on the application for a new or relocated pharmacy and for pharmacy renewal registration.

(2) A resident 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.

(3) The pharmacy must ensure that it 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 conformance with the keeping and inventory requirements of federal law and board rules.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155, 689.305
The proposed rule amendments to Div 041 Operation of Pharmacies and Div 080 Schedule of Controlled Substances put forth the requirements for a pharmacy to lawfully participate in Drug Take Back initiatives. Congress adopted the Secure & Responsible Drug Disposal act in 2010 and DEA published its Final Rule on Disposal of Controlled Substances in 2014. Additional information is available: http://www.deadiversion.usdoj.gov/drug_disposal/

The rule (1) states that a pharmacy must comply with all DEA regulations for secure and responsible drug disposal (2) directs a pharmacy to notify the Board of its Take Back program (3) outlines the minimum policies and procedures to be established by the pharmacy, including recordkeeping; and (4) prohibits pharmacy staff from handling collected drugs and using the receptacles to dispose of pharmacy stock.

855-041-1045

Returned Drugs and Devices

(1) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may only accept the return of controlled substances upon receiving a waiver from the Board of Pharmacy.

(2) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may accept the return of drugs or devices as defined by ORS 689.005 once the drugs or devices have been removed from the pharmacy only if;

(a) The drugs or devices are accepted for destruction or disposal and;

(b) The drugs or devices were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, were unable to be delivered to the patient, or are subject of a drug or device recall; or

(c) After consultation, a pharmacist determines that, in the pharmacist’s professional judgment, harm could result to the public or a patient if the drugs or devices were not accepted for return.

(3) Not withstanding section 2 of this rule, drugs or devices previously dispensed or distributed may be returned and redispensed or redistributed provided all the following conditions are met:

(a) The drug is in an unopened, tamper-evident unit;

(b) The drugs or devices have remained at all times in control of a person trained and knowledgeable in the storage and administration of drugs in long term care facilities or supervised living groups using the services of a consultant pharmacist;

(c) The drug or device has not been adulterated or misbranded and has been stored under conditions meeting United States Pharmacopeia standards.
Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 475 & 689 689.205
Stats. Implemented: ORS 689.305

Secure and Responsible Drug Disposal

(1) A pharmacy registered with the DEA as an authorized collector may collect controlled and non-controlled drugs for destruction in accordance with all applicable federal laws.

(2) A pharmacy that operates a drug take-back collection program shall notify the Board in writing prior to initiating the program and shall establish and enforce policies and procedures, including but not limited to:

(a) Provision of secure location of the collection receptacle, which must be accessible to the public and cannot be placed behind the pharmacy counter; and

(b) Provision of adequate security measures, including proper installation and maintenance of collection receptacle, tracking of liners, and key accountability; and

(c) Personnel training and accountability.

(3) Pharmacy personnel shall not count, sort, inventory, or otherwise handle drugs collected.

(4) A pharmacy shall not dispose of quarantined, recalled or outdated drugs from pharmacy stock in a collection receptacle.

(5) A pharmacy shall maintain disposal records for a minimum of 3 years.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305

Disposal of Drugs

(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.
(2) Controlled substances which are expired, deteriorated or unwanted shall be disposed of in conformance with 21 CFR 1307.21, 21 CFR 1317.

(3) Expired, deteriorated, discontinued, or unwanted controlled substances in a long-term care facility shall be destroyed and the destruction jointly witnessed on the premises by any two of the following:

(a) The consultant pharmacist or registered nurse designee.

(b) The Director of Nursing Services or supervising nurse designee.

(c) The administrator of the facility or an administrative designee.

(d) A Registered Nurse employed by the facility.

(4) The destruction shall be documented and signed by the witnesses and the document retained at the facility for a period of at least three years. Copies of the document shall be sent to the consultant pharmacist. Any destruction of controlled substances deviating from this procedure must be approved by the Board prior to implementation.

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

Stat. Auth.: ORS 475.035 & 689.205

Stats. Implemented: ORS 689.305
The proposed rule amendments to Div 041 Remote Dispensing Machine and Facilities allow use of emerging technology in licensed residential facilities. The rules clarify where RDM’s can exist and who can access and stock the machine.

855-041-4100

Definitions

(1) "Automated Pharmacy System" (APS) means a mechanical system that performs operations or activities, including but not limited to, those related to the storage, packaging, dispensing, or distribution of medications, but not including compounding or administration, and that collects, controls, and maintains all transaction information.

(2) "Remote Dispensing Facility" (RDF) means a facility where drugs are prepared for administration and where requisite pharmacist supervision is provided remotely as approved by the Board.

(3) "Remote Dispensing Machine" (RDM) means a component of an Automated Pharmacy System that contains prepackaged drugs for dispensing.

(4) "Responsible Pharmacy" means the licensed pharmacy that is responsible for the APS, and RDM.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155

855-041-4120

Drug Delivery and Control

(1) Each RDM must be registered with the Board, under the control of and connected via computer with a Responsible Pharmacy, but not located in a pharmacy. RDMs must be used only in settings with an established program of pharmaceutical care that ensures prescription orders are reviewed by a pharmacist before release to the patient. The Responsible Pharmacy must establish the policies and procedures necessary to fulfill the requirements of all applicable state and federal laws and regulations.

(2) The following must be conspicuously displayed at the site of the RDM:

(a) RDM license;

(b) DEA registration if required;

(c) A certified copy of the Responsible Pharmacy license; and

(d) A certified copy of the Pharmacist-In-Charge license.
(3) Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained in the pharmacy for review by the board. Such documentation must include, but is not limited to:

(a) Location of RDM(s);
(b) Manufacturer's name and model for each RDM;
(c) Description of how the RDM is used;
(d) Quality assurance procedures to determine continued appropriate use of the automated device; and
(e) Policies and procedures for training of appropriate personnel, system operation, safety, security, accuracy, patient confidentiality, oral counseling by a pharmacist or pharmacist-intern, access, and malfunction.

(4) Policies and procedures addressing the operation of the RDM must be maintained in the pharmacy responsible for the APS and at the location at which the RDM has been installed.

(5) All events involving the contents of the RDM must be recorded electronically. Records must be maintained by the pharmacy for a minimum of three years and must be readily available to the Board. Such records shall include:

(a) Identity of RDM accessed;
(b) Identification of the individual accessing the RDM;
(c) Type of transaction;
(d) Date and time of transaction;
(e) Name, strength, dosage form, and quantity of the drug accessed;
(f) Name of the patient for whom the drug was ordered;
(g) Name of the prescribing practitioner
(h) Such additional information as the pharmacist-in-charge may deem necessary; and
Only an Oregon registered technician or an Oregon licensed Pharmacist or Technician may have access to the RDM, except that a Registered Nurse, upon approval by the Board, may have access to the RDM.

Only an Oregon registered technician or an Oregon licensed Pharmacist or Technician may stock medications in the RDM, except that a Registered Nurse, upon approval by the Board, may stock medications in the RDM.

All containers of medications stored in the RDM shall be packaged and labeled in accordance with state and federal laws and regulations, including OAR 855-041-1130.

All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

Oral counseling, as required by OAR 855-019-0230, shall be provided by the pharmacist at the time of dispensing by a two-way audio and video hookup with the Responsible Pharmacy.

The Automated Pharmacy Systems shall provide a mechanism for securing and accounting for wasted, discarded or unused medications in accordance with existing state and federal laws and regulations.

The RDM must be clearly marked with the name, address, and phone number of the Responsible Pharmacy and Pharmacist-In-Charge.

A Responsible Pharmacy located outside of Oregon that operates a RDM in Oregon must be currently licensed and in good standing in Oregon. The Pharmacist-In-Charge must also be currently licensed and in good-standing both in Oregon and in the state in which the Responsible Pharmacy is located.

A Responsible Pharmacy may apply for the use of an RDM in a licensed residential facility that it provides services to, but only when the facility provides 24 hour nursing care.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.205
The proposed rules to \textit{Div 043 Dispensing Practitioner Drug Outlets} are intended to distinguish between traditional and non-traditional dispensing of drugs by a health care practitioner who has been granted dispensing privileges from their licensing board and dispenses from their practice location. A health care practitioner who participates in non-traditional dispensing must register the dispensing outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

The rule identifies purpose and scope, registration criteria and requirements, policies and procedures, security, drug acquisitions, drug storage, labeling, dispensing and drug delivery, disposal of drugs, recordkeeping, and inspections.

The Board plans a “soft-launch” of enforcement of these rules and, as always, plans to approach regulation per its “Compliance through Education” axiom.

The Board has worked with the following stakeholders in the development of these rules: Oregon Medical Board, Oregon State Board of Nursing, Oregon Board of Pharmacy, Oregon Dental Board, Oregon Veterinary Board, Oregon Board of Naturopathic Medicine, Oregon Optometry Board, Oregon Medical Association, Oregon Nurses Association, Oregon State Pharmacy Association, Oregon Dental Association, Oregon Veterinary Medical Association, Oregon Association of Naturopathic Physicians, Oregon Optometric Physicians Association, and the Drug Enforcement Agency (DEA).


\textbf{Dispensing Practitioner Drug Outlets}

\textbf{855-043-0505}

\textbf{Purpose and Scope}

These rules are intended to distinguish between traditional and non-traditional dispensing of drugs by a practitioner who has been granted dispensing privileges from their licensing board and dispenses from their practice location. A practitioner who participates in non-traditional dispensing must register the dispensing outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

\textbf{855-043-0515}

\textbf{Registration}

(1) A practitioner who engages in dispensing drug therapies greater than a 72 hours supply or any medication refill must register their dispensing site as a drug outlet with the Board as a DPDO on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.
(2) A practitioner is exempt from this registration requirement if the practitioner only engages in:

(A) Dispensing FDA approved drug samples; or

(B) Dispensing Medication Assistance Program (MAP) drugs; or

(C) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72 hour supply; or

(D) An amount greater than a 72 hour supply if the drug is:

(i) A drug in the manufacturer’s original unit-of-use packaging, such as a metered-dose-inhaler; or

(ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient’s best interest, such as a course of antibiotic therapy.

(3) The initial application must state the location of the DPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant’s affiliation with the owner.

(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.

(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation’s officers.

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

(5) An initial application must be accompanied by the fee established in division 110 of this chapter. The fee is not to exceed $100.

(6) A certificate of registration will be issued upon Board approval of the application.

(7) All registration renewal applications must be accompanied by the annual renewal fee established in Division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.
(8) The DPDO registration expires December 31, annually. If the annual renewal fee referred to in section (5) of this rule is not paid by November 30 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this chapter with the renewal application.

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

(10) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business name; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, consultant pharmacist or supervising physician.

(11) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in division 110 of this chapter within 15 days of the change.

(12) The Board may grant a time-limited waiver exempting DPDO registration when a practitioner licensing board submits a request to the Board with a plan to annually inspect the dispensing facility to the standards of the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

Policies and Procedures

855-043-0520

The registered DPDO must maintain written policies and procedures for the management of drugs intended for dispensing, to include security, acquisition, storage, dispensing and drug delivery, disposal and record keeping.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0525

Security
(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.

(2) A drug dispensing machine cannot be placed in a waiting room or an area that is accessible by the public.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305.

855-043-0530

Drug Acquisition

The registered DPDO must verify that all drugs are acquired from a registrant of the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305.

855-043-0535

Drug Storage

All drugs must be stored according to manufacturer’s published guidelines and be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305.

855-043-0540

Labeling

(1) A prescription must be labeled with the following information:

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

(b) Name of patient;

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

(e) Date of dispensing;

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

(g) Quantity dispensed;

(h) Directions for use;

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

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

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

(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the
practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-041-4000 through 4005, the name of the patient may be omitted.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0545

Dispensing and Drug Delivery

(1) Drugs dispensed from DPDO by a practitioner shall be dispensed in compliance with
the practitioner’s Board requirements.

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

(3) A DPDO must dispense a drug in a new container that complies with the current
provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S.
2162) and rules or regulations and with the current United States Pharmacopoeia/National
Formulary monographs for preservation, packaging, storage and labeling.
(4) Drugs must be packaged by the practitioner, a pharmacy, or a manufacturer registered with the Board.

(5) 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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0550

Disposal of Drugs

Drugs that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, or identified as suspect or illegitimate must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to the supplier.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0555

Record Keeping

(1) A dispensing record shall be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:

(a) Name of patient;

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

(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;

(d) Directions for use;

(e) Date of dispensing; and

(f) Initials of person dispensing the prescription.

(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.
(3) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0560

Inspections

(1) The DPDO must complete the Board Self Inspection Form by January 1, annually.

(2) Each DPDO will be inspected on a routine basis and shall be scheduled in advance with the practitioner, to occur during normal business hours.

(3) The inspection shall focus on the acquisition, storage, labeling and recordkeeping of drugs intended for dispensing and any violation will apply to the DPDO registration and not to the practitioner.

(4) The Board of Pharmacy shall refer any disciplinary action taken against a DPDO to the practitioner’s licensing Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305
These rules are intended to describe the Board’s registration and compliance expectations for a practitioner who has been granted dispensing privileges from their licensing board and engages in drug dispensing from their practice location. A practitioner who engages in dispensing certain FDA-approved human prescription drug therapies greater than a 72 hours supply or any medication refill must register their dispensing site as a drug outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

The rule (1) identifies purpose (2) registration criteria and requirements (3) policies and procedures, (4) security (5) drug acquisitions (6) drug storage (7) labeling (8) dispensing and drug delivery (9) disposal of drugs (10) recordkeeping and (11) inspections.

The Board plans a “soft-launch” of enforcement of these rules and, as always, plans to approach regulation per its “Compliance through Education” axiom.

The Board has worked with the following stakeholders in the development of these rules: Oregon Medical Board, Oregon State Board of Nursing, Oregon Board of Pharmacy, Oregon Dental Board, Oregon Veterinary Board, Oregon Board of Naturopathic Medicine, Oregon Optometry Board, Oregon Medical Association, Oregon Nurses Association, Oregon State Pharmacy Association, Oregon Dental Association, Oregon Veterinary Medical Association, Oregon Association of Naturopathic Physicians, Oregon Optometric Physicians Association, and the Drug Enforcement Agency (DEA).


Dispensing Practitioner Drug Outlets

855-043-0505

**Purpose and Scope**

These rules are intended to distinguish between traditional and non-traditional dispensing of drugs by a practitioner who has been granted dispensing privileges from their licensing board and dispenses from their practice location. A practitioner who participates in non-traditional dispensing must register the dispensing outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

A practitioner who engages in dispensing certain FDA-approved human prescription drug therapies greater than a 72 hours supply or any medication refill must register their dispensing site as a drug outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0515

Registration
A practitioner who engages in dispensing FDA-approved human prescription drug therapies greater than a 72 hours supply or any medication refill must register their dispensing site as a drug outlet with the Board as a DPDO on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.

A practitioner is exempt from this registration requirement if the practitioner only engages in:

(A) Dispensing FDA approved drug samples; or

(B) Dispensing Medication Assistance Program (MAP) drugs; or

(C) Dispensing homeopathic or natural thyroid supplemental products; or

(D) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72 hour supply; or

(E) An amount greater than a 72 hour supply if the drug is:

(i) A drug in the manufacturer’s original unit-of-use packaging, such as a metered-dose-inhaler; or

(ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient’s best interest, such as a course of antibiotic therapy.

The initial application must state the location of the DPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant’s affiliation with the owner.

(a) If more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site must be disclosed on the application.

(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation’s officers.

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

(5) An initial application must be accompanied by the fee established in division 110 of this chapter. The fee is not to exceed $100.
(6) A certificate of registration will be issued upon Board approval of the application.

(7) All registration renewal applications must be accompanied by the annual renewal fee established in Division 110 of this chapter and must contain the information required in sections (2) and (3) of this rule.

(8) The DPDO registration expires December 31, annually. If the annual renewal fee referred to in section (5) of this rule is not paid by November 30 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this chapter with the renewal application.

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

(10) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business name; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, consultant pharmacist or supervising physician practitioner.

(11) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in division 110 of this chapter within 15 days of the change.

(12) The Board may grant a time-limited waiver exempting DPDO registration when a practitioner licensing board submits a request to the Board with a plan to annually inspect the dispensing facility to the standards of the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

Policies and Procedures

855-043-0520

The registered DPDO must maintain written policies and procedures for the management of drugs intended for dispensing, to include security, acquisition, storage, dispensing and drug delivery, disposal and record keeping.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305
Security

(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.

(2) A drug dispensing machine cannot be placed in a waiting room or an area that is accessible by the public.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305.

Drug Acquisition

The registered DPDO must verify that all drugs are acquired from a registrant of the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305.

Drug Storage

All drugs must be stored according to manufacturer’s published guidelines and be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

Labeling

(1) A prescription must be labeled with the following information:

(a) Unique identifier (i.e. prescription number):
(b) Name of patient;

(c) Name of prescriber;

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

(e) Date of dispensing;

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

(g) Quantity dispensed;

(h) Directions for use;

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

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

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

(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the
practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-
041-4000 through 4005, the name of the patient may be omitted.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0545

Dispensing and Drug Delivery

(1) Drugs dispensed from DPDO by a practitioner shall be dispensed in compliance with
the practitioner’s Board requirements.

(2) A DPDO must comply with all requirements of State or federal law.
(3) A DPDO must dispense a drug in a new container that complies with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.

(4) Drugs must be packaged by the practitioner, a pharmacy, or a manufacturer registered with the Board.

(5) 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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305
855-043-0550

Disposal of Drugs

Drugs that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, or identified as suspect or illegitimate must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to the supplier.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305
855-043-0555

Record Keeping

(1) A dispensing record shall be maintained, be readily retrievable, separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:

(a) Name of patient;

(b) Unique identifier (i.e., prescription number);

(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;

(d) Directions for use:
(e) Date of dispensing; and

(f) Initials of person dispensing the prescription.

(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

(3) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0560

Inspections

(1) The DPDO must complete the Board Self Inspection Form by January 1, annually.

(2) Each DPDO will be inspected on a routine basis and shall be scheduled in advance with the practitioner, to occur during normal business hours.

(3) The inspection shall focus on the acquisition, storage, labeling and recordkeeping of drugs intended for dispensing and any violation will apply to the DPDO registration and not to the practitioner.

(4) The Board of Pharmacy shall refer any disciplinary action taken against a DPDO to the practitioner’s licensing Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

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

(1) Community Health Clinic. Expires March 31 annually — $75*. Delinquent renewal fee (postmarked after February 28) — $25. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

(2) Drug Distribution Agent. Expires September 30 annually — $400. Delinquent renewal fee (postmarked after August 31) — $100.

(3) Drug Room (including correctional facility). Expires March 31 annually — $75*. Delinquent renewal fee (postmarked after February 28) — $75. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

(4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually — $400. Delinquent renewal fee (postmarked after August 31) — $100.


(9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer — $50*. Expires December 31 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

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

(11) Retail or Institutional Drug Outlet. Expires March 31 annually — $175*. Delinquent renewal fee (postmarked after February 28) — $75. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.
(12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually — $400. Delinquent renewal fee (postmarked after August 31) — $100.


(15) Home Dialysis. Expires March 31 annually — $175*. Delinquent renewal fee (postmarked after February 28) — $75. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

(16) Supervising Physician Dispensing Outlet. Expires March 31 annually — $175*. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Delinquent renewal fee (postmarked after February 28) — $75.


Stat. Auth.: ORS 689.205 & 291.055
Stats. Implemented: ORS 689.135, 689.774 & 2689.305
The proposed rule amendments to Div 044 Charitable Pharmacies incorporate new statutory language put forth by Senate Bill 1514 (2016), available at this link: https://olis.leg.state.or.us/liz/2016R1/Downloads/MeasureDocument/SB1514/Enrolled

The rule (1) clarifies that this is an Oregon specific program that allows donations and distribution of donated drugs within Oregon; and (2) prohibits a Charitable Pharmacy from accepting an FDA REMS drug.

DIVISION 44
CHARITABLE PHARMACIES
855-044-0001

Purpose
The purpose of the program is to provide a process to make donated prescription drugs available to needy or uninsured individuals and those with limited access to pharmaceuticals. Under the rules in this Division, a Charitable Pharmacy that is registered with the Oregon Board of Pharmacy (Board) may accept donated drugs for donation and distribution within this state when the pharmacist can reasonably be assured of the purity and integrity of the drug. The program may not include categories of drugs specified by the Board as excluded from the program.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.772 & 689.774

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;

(d) An FDA REMS (Risk Evaluation and Mitigation Strategy) drug;

(e) A drug donated from another state.

(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
Board Conducts Survey on Working Conditions

The Board has continued to hear concerns regarding working conditions in the pharmacy from Oregon licensed pharmacists.

In July 2016, the Board conducted a follow-up Working Conditions Survey (a duplicate of the 2013 and 2011 survey) to solicit opinions from those pharmacists licensed in Oregon via an online survey. Over 1125 individuals responded to the survey with more than 678 providing one or more specific comments. The Board appreciates each person who took the time to participate in the survey and provide comment.

The Board of Pharmacy staff has summarized the results. This data will be statistically analyzed and compared to the survey results from the 2013 and 2011 survey.

The top four areas of concern expressed by the comments include:

- Staffing Conditions
- Meal Periods and Breaks
- Patient Safety
- Other Stressors

The data does not indicate whether these comments were positive or negative; it just indicates that comments were made.

The following are the initial survey results and additional sorted data for your information. The Board will continue to analyze the survey data results. The Board also expects to take future action to enhance patient safety and safe working conditions.
Pharmacy Working Conditions Survey Results - July 2016

Number of Active RPh: 7207
Number of RPh Email Addresses: 7207
Number of Undelivered Emails: -4
Number of Responses: 1130 (678 or 60% included written comments)
Response Rate: 15.69%

### Q.7 Years Licensed in Oregon (includes all out of state pharmacists):

<table>
<thead>
<tr>
<th>Years</th>
<th>Number of all OBOP licensed pharmacists</th>
<th>Percentage of all OBOP licensed pharmacists</th>
<th>Percentage that responded to survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Years</td>
<td>2279</td>
<td>31.6%</td>
<td>15.3%</td>
</tr>
<tr>
<td>5-10 Years</td>
<td>1623</td>
<td>22.5%</td>
<td>16.2%</td>
</tr>
<tr>
<td>10-15 Years</td>
<td>618</td>
<td>8.6%</td>
<td>8.0%</td>
</tr>
<tr>
<td>15-20 Years</td>
<td>683</td>
<td>9.5%</td>
<td>12.0%</td>
</tr>
<tr>
<td>20-25 Years</td>
<td>545</td>
<td>7.6%</td>
<td>11.4%</td>
</tr>
<tr>
<td>More than 25 Years</td>
<td>1459</td>
<td>20.2%</td>
<td>31.3%</td>
</tr>
</tbody>
</table>

### Q.2 Primary Role for Pharmacists Licensed:

<table>
<thead>
<tr>
<th>Years</th>
<th>Staff Pharmacist</th>
<th>Clinical/ Specialty Pharmacist</th>
<th>Pharmacy Manager/PIC</th>
<th>Regional Pharmacy Manager/VP</th>
<th>Relief Pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Years</td>
<td>85</td>
<td>27</td>
<td>53</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>5-10 Years</td>
<td>73</td>
<td>50</td>
<td>52</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>10-15 Years</td>
<td>32</td>
<td>24</td>
<td>30</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>15-20 Years</td>
<td>56</td>
<td>23</td>
<td>43</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>20-25 Years</td>
<td>59</td>
<td>22</td>
<td>40</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>More than 25 Years</td>
<td>162</td>
<td>37</td>
<td>104</td>
<td>7</td>
<td>44</td>
</tr>
</tbody>
</table>

### Q.3 Practice Setting for Pharmacist Licensed:

<table>
<thead>
<tr>
<th>Years</th>
<th>Community Pharmacy-Independent</th>
<th>Community Pharmacy-Chain</th>
<th>Mail Order Pharmacy</th>
<th>Out-Patient Hospital Pharmacy</th>
<th>In-Patient Hospital Pharmacy</th>
<th>Health Center Pharmacy</th>
<th>Long Term Care Pharmacy</th>
<th>Ambulatory Care</th>
<th>Compounding Pharmacy</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Years</td>
<td>7</td>
<td>116</td>
<td>0</td>
<td>4</td>
<td>18</td>
<td>2</td>
<td>1</td>
<td>13</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>5-10 Years</td>
<td>8</td>
<td>90</td>
<td>4</td>
<td>10</td>
<td>34</td>
<td>4</td>
<td>2</td>
<td>20</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>10-15 Years</td>
<td>6</td>
<td>36</td>
<td>7</td>
<td>1</td>
<td>17</td>
<td>5</td>
<td>1</td>
<td>6</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>15-20 Years</td>
<td>7</td>
<td>59</td>
<td>6</td>
<td>8</td>
<td>19</td>
<td>5</td>
<td>2</td>
<td>10</td>
<td>2</td>
<td>18</td>
</tr>
<tr>
<td>20-25 Years</td>
<td>9</td>
<td>59</td>
<td>3</td>
<td>5</td>
<td>24</td>
<td>6</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>More than 25 Years</td>
<td>49</td>
<td>141</td>
<td>17</td>
<td>7</td>
<td>63</td>
<td>12</td>
<td>12</td>
<td>7</td>
<td>6</td>
<td>42</td>
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</tbody>
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### Q.4 Shift Hours for Pharmacists Licensed:

<table>
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<tr>
<th></th>
<th>&lt; 4</th>
<th>4-5.9</th>
<th>6-7.9</th>
<th>8-9.9</th>
<th>10-11.9</th>
<th>12-13.9</th>
<th>&gt; 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Y</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>82</td>
<td>55</td>
<td>33</td>
<td>1</td>
</tr>
<tr>
<td>5-10 Yrs</td>
<td>2</td>
<td>1</td>
<td>9</td>
<td>100</td>
<td>57</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>10-15 Yrs</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>47</td>
<td>25</td>
<td>11</td>
<td>2</td>
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<tr>
<td>15-20 Yrs</td>
<td>0</td>
<td>3</td>
<td>7</td>
<td>70</td>
<td>47</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>20-25 Yrs</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>70</td>
<td>41</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>More than 25 Y</td>
<td>10</td>
<td>13</td>
<td>26</td>
<td>194</td>
<td>94</td>
<td>18</td>
<td>0</td>
</tr>
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</table>

### Q.5 Weekly Hours Worked for Pharmacists Licensed:

<table>
<thead>
<tr>
<th></th>
<th>&lt; 20</th>
<th>20-29.9</th>
<th>30-39.9</th>
<th>40-49.9</th>
<th>50-59.9</th>
<th>&gt; 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Y</td>
<td>0</td>
<td>4</td>
<td>30</td>
<td>123</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>5-10 Yrs</td>
<td>9</td>
<td>8</td>
<td>28</td>
<td>132</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>10-15 Yrs</td>
<td>3</td>
<td>1</td>
<td>19</td>
<td>59</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>15-20 Yrs</td>
<td>8</td>
<td>15</td>
<td>31</td>
<td>73</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>20-25 Yrs</td>
<td>5</td>
<td>10</td>
<td>30</td>
<td>77</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>More than 25 Y</td>
<td>53</td>
<td>52</td>
<td>56</td>
<td>170</td>
<td>21</td>
<td>3</td>
</tr>
</tbody>
</table>

### Q.6 Prescriptions per RPh for Pharmacist Licensed:

<table>
<thead>
<tr>
<th></th>
<th>&lt; 50</th>
<th>51-99</th>
<th>100-199</th>
<th>200-299</th>
<th>300-399</th>
<th>400-499</th>
<th>&gt; 500</th>
<th>Not Sure</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Y</td>
<td>4</td>
<td>6</td>
<td>74</td>
<td>44</td>
<td>8</td>
<td>3</td>
<td>4</td>
<td>13</td>
<td>18</td>
</tr>
<tr>
<td>5-10 Yrs</td>
<td>6</td>
<td>9</td>
<td>61</td>
<td>46</td>
<td>11</td>
<td>1</td>
<td>6</td>
<td>18</td>
<td>29</td>
</tr>
<tr>
<td>10-15 Yrs</td>
<td>5</td>
<td>1</td>
<td>23</td>
<td>27</td>
<td>2</td>
<td>1</td>
<td>6</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>15-20 Yrs</td>
<td>6</td>
<td>10</td>
<td>42</td>
<td>33</td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>13</td>
<td>22</td>
</tr>
<tr>
<td>20-25 Yrs</td>
<td>1</td>
<td>5</td>
<td>42</td>
<td>37</td>
<td>9</td>
<td>1</td>
<td>4</td>
<td>11</td>
<td>19</td>
</tr>
<tr>
<td>More than 25 Y</td>
<td>14</td>
<td>29</td>
<td>123</td>
<td>78</td>
<td>11</td>
<td>5</td>
<td>9</td>
<td>30</td>
<td>55</td>
</tr>
</tbody>
</table>

### Q.9 Gender of Responding Pharmacists Licensed:

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Y</td>
<td>75</td>
<td>97</td>
</tr>
<tr>
<td>5-10 Yrs</td>
<td>87</td>
<td>99</td>
</tr>
<tr>
<td>10-15 Yrs</td>
<td>27</td>
<td>62</td>
</tr>
<tr>
<td>15-20 Yrs</td>
<td>46</td>
<td>88</td>
</tr>
<tr>
<td>20-25 Yrs</td>
<td>52</td>
<td>76</td>
</tr>
<tr>
<td>More than 25 Y</td>
<td>227</td>
<td>131</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>1a. I have adequate time for breaks/lunches at my primary practice site.</strong></td>
<td><strong>1a. I have adequate time for breaks/lunches at my primary practice site.</strong></td>
<td><strong>1a. I have adequate time for breaks/lunches at my primary practice site.</strong></td>
</tr>
<tr>
<td></td>
<td>AGREE</td>
<td>DISAGREE</td>
</tr>
<tr>
<td>All Pharmacists</td>
<td>48.6%</td>
<td>51.4%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>44.9%</td>
<td>55.1%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>70.7%</td>
<td>29.3%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>49.0%</td>
<td>51.0%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>64.7%</td>
<td>35.3%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>20.0%</td>
<td>80.0%</td>
</tr>
<tr>
<td><strong>1b. I am satisfied with the amount of time I have to do my job.</strong></td>
<td><strong>1b. I am satisfied with the amount of time I have to do my job.</strong></td>
<td><strong>1b. I am satisfied with the amount of time I have to do my job.</strong></td>
</tr>
<tr>
<td></td>
<td>AGREE</td>
<td>DISAGREE</td>
</tr>
<tr>
<td>All Pharmacists</td>
<td>45.7%</td>
<td>54.3%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>41.9%</td>
<td>58.1%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>78.7%</td>
<td>21.3%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>44.9%</td>
<td>55.1%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>64.7%</td>
<td>35.3%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>30.3%</td>
<td>69.7%</td>
</tr>
<tr>
<td><strong>1c. My employer provides a work environment that is conducive to providing safe and effective patient care.</strong></td>
<td><strong>1c. My employer provides a work environment that is conducive to providing safe and effective patient care.</strong></td>
<td><strong>1c. My employer provides a work environment that is conducive to providing safe and effective patient care.</strong></td>
</tr>
<tr>
<td></td>
<td>AGREE</td>
<td>DISAGREE</td>
</tr>
<tr>
<td>All Pharmacists</td>
<td>58.8%</td>
<td>44.0%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>50.2%</td>
<td>49.8%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>78.7%</td>
<td>21.3%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>62.9%</td>
<td>37.1%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>75.0%</td>
<td>25.0%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>47.0%</td>
<td>53.0%</td>
</tr>
<tr>
<td><strong>1d. My site has adequate Pharmacist staff to provide safe and effective patient care.</strong></td>
<td><strong>1d. My site has adequate Pharmacist staff to provide safe and effective patient care.</strong></td>
<td><strong>1d. My site has adequate Pharmacist staff to provide safe and effective patient care.</strong></td>
</tr>
<tr>
<td></td>
<td>AGREE</td>
<td>DISAGREE</td>
</tr>
<tr>
<td>All Pharmacists</td>
<td>56.0%</td>
<td>44.0%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>49.3%</td>
<td>50.3%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>78.1%</td>
<td>21.9%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>58.4%</td>
<td>41.6%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>72.2%</td>
<td>27.8%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>39.7%</td>
<td>60.3%</td>
</tr>
<tr>
<td>----------------</td>
<td>---------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td><strong>1e. My site has adequate Technician staff to provide safe and effective patient care.</strong></td>
<td><strong>1e. My site has adequate Technician staff to provide safe and effective patient care.</strong></td>
<td><strong>1e. My site has adequate Technician staff to provide safe and effective patient care.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGREE</td>
<td>DISAGREE</td>
<td>AGREE</td>
</tr>
<tr>
<td>All Pharmacists</td>
<td>55.7%</td>
<td>44.3%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>49.7%</td>
<td>50.3%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>78.1%</td>
<td>21.9%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>58.4%</td>
<td>41.6%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>72.2%</td>
<td>27.8%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>39.7%</td>
<td>60.3%</td>
</tr>
<tr>
<td><strong>1f. My site has adequate Clerk staff to provide safe and effective patient care.</strong></td>
<td><strong>1f. My site has adequate Clerk staff to provide safe and effective patient care.</strong></td>
<td><strong>1f. My site has adequate Clerk staff to provide safe and effective patient care.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGREE</td>
<td>DISAGREE</td>
<td>AGREE</td>
</tr>
<tr>
<td>All Pharmacists</td>
<td>52.3%</td>
<td>47.8%</td>
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<tr>
<td>Staff Pharmacists</td>
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<td>54.9%</td>
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<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>79.5%</td>
<td>20.5%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>56.8%</td>
<td>43.2%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>66.7%</td>
<td>33.3%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>38.1%</td>
<td>61.9%</td>
</tr>
</tbody>
</table>
### Q.1

1a. I have adequate time for breaks/lunches at my practice site.

<table>
<thead>
<tr>
<th></th>
<th>AGREE</th>
<th>DISAGREE</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Pharmacists</td>
<td>55.7%</td>
<td>44.3%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>51.3%</td>
<td>48.7%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>71.2%</td>
<td>28.8%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>53.1%</td>
<td>46.9%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>86.4%</td>
<td>13.6%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>46.7%</td>
<td>53.3%</td>
</tr>
</tbody>
</table>

1b. I am satisfied with the amount of time I have to do my job.

<table>
<thead>
<tr>
<th></th>
<th>AGREE</th>
<th>DISAGREE</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Pharmacists</td>
<td>48.4%</td>
<td>51.6%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>41.4%</td>
<td>58.6%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>66.7%</td>
<td>33.3%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>47.1%</td>
<td>52.9%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>79.2%</td>
<td>20.8%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>44.1%</td>
<td>55.9%</td>
</tr>
</tbody>
</table>

1c. My employer provides a work environment that is conducive to providing safe and effective patient care.

<table>
<thead>
<tr>
<th></th>
<th>AGREE</th>
<th>DISAGREE</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Pharmacists</td>
<td>59.5%</td>
<td>40.5</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>48%</td>
<td>52%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>80.1%</td>
<td>19.9%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>62%</td>
<td>38%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>100%</td>
<td>0%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>51.9%</td>
<td>48.1%</td>
</tr>
</tbody>
</table>

1d. My site has adequate Pharmacist staff to provide safe and effective patient care.

<table>
<thead>
<tr>
<th></th>
<th>AGREE</th>
<th>DISAGREE</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Pharmacists</td>
<td>58.9%</td>
<td>41.1%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>52.9%</td>
<td>47.1%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>68.8%</td>
<td>31.2%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>62.4%</td>
<td>37.6%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>91.7%</td>
<td>8.3%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>44.1%</td>
<td>55.9%</td>
</tr>
</tbody>
</table>

1e. My site has adequate Technician staff to provide safe and effective patient care.

<table>
<thead>
<tr>
<th></th>
<th>AGREE</th>
<th>DISAGREE</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Pharmacists</td>
<td>57.3%</td>
<td>42.7%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>51.6%</td>
<td>48.4%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>76.1%</td>
<td>23.9%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>55.6%</td>
<td>44.4%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>85%</td>
<td>15%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>51.8%</td>
<td>48.2%</td>
</tr>
</tbody>
</table>

1f. My site has adequate Clerk staff to provide safe and effective patient care.

<table>
<thead>
<tr>
<th></th>
<th>AGREE</th>
<th>DISAGREE</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Pharmacists</td>
<td>53.8%</td>
<td>46.2%</td>
</tr>
<tr>
<td>Staff Pharmacists</td>
<td>44.6%</td>
<td>55.4%</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacists</td>
<td>83.6%</td>
<td>16.4%</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>55.5%</td>
<td>44.5%</td>
</tr>
<tr>
<td>Regional Manager/Director/VP</td>
<td>81.8%</td>
<td>18.2%</td>
</tr>
<tr>
<td>Relief Pharmacists</td>
<td>54%</td>
<td>46%</td>
</tr>
</tbody>
</table>
Oregon Board of Pharmacy
Pharmacy Working Conditions Survey Results July 2016

Q.1 ALL PHARMACISTS:
Please rate your level of agreement with the following statements:

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>N/A</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. I have adequate time for breaks/lunches at my primary site.</td>
<td>531</td>
<td>422</td>
<td>129</td>
<td>25</td>
<td>1,107</td>
</tr>
<tr>
<td>1b. I am satisfied with the amount of time I have to do my job.</td>
<td>447</td>
<td>476</td>
<td>161</td>
<td>20</td>
<td>1,104</td>
</tr>
<tr>
<td>1c. My employer provides a work environment that is conducive to providing safe and effective patient care.</td>
<td>514</td>
<td>350</td>
<td>212</td>
<td>29</td>
<td>1,105</td>
</tr>
<tr>
<td>1d. My site has adequate Pharmacist staff to provide safe and effective patient care.</td>
<td>525</td>
<td>367</td>
<td>177</td>
<td>36</td>
<td>1,105</td>
</tr>
<tr>
<td>1e. My site has adequate Technician staff to provide safe and effective patient care.</td>
<td>510</td>
<td>380</td>
<td>160</td>
<td>54</td>
<td>1,104</td>
</tr>
<tr>
<td>1f. My site has adequate Clerk staff to provide safe and effective patient care.</td>
<td>338</td>
<td>290</td>
<td>146</td>
<td>331</td>
<td>1,105</td>
</tr>
</tbody>
</table>

Answered question – 1,108

Skipped question - 1

All Pharmacists-Primary Practice Site
### Q.1 STAFF PHARMACISTS:

Please rate your level of agreement with the following statements:

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>N/A</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. I have adequate time for breaks/lunches at my primary site.</td>
<td>215</td>
<td>204</td>
<td>61</td>
<td>5</td>
<td>485</td>
</tr>
<tr>
<td>1b. I am satisfied with the amount of time I have to do my job.</td>
<td>165</td>
<td>234</td>
<td>81</td>
<td>4</td>
<td>484</td>
</tr>
<tr>
<td>1c. My employer provides a work environment that is conducive to providing safe and effective patient care.</td>
<td>180</td>
<td>195</td>
<td>104</td>
<td>5</td>
<td>484</td>
</tr>
<tr>
<td>1d. My site has adequate Pharmacist staff to provide safe and effective patient care.</td>
<td>207</td>
<td>184</td>
<td>86</td>
<td>7</td>
<td>484</td>
</tr>
<tr>
<td>1e. My site has adequate Technician staff to provide safe and effective patient care.</td>
<td>207</td>
<td>194</td>
<td>74</td>
<td>8</td>
<td>483</td>
</tr>
<tr>
<td>1f. My site has adequate Clerk staff to provide safe and effective patient care.</td>
<td>129</td>
<td>160</td>
<td>67</td>
<td>127</td>
<td>483</td>
</tr>
</tbody>
</table>

Answered question - 486  
Skipped question - 1

#### Staff Pharmacists-Primary Practice Site

- Other
- Compounding Pharmacy
- Ambulatory Care
- Long Term Care Pharmacy
- Health Center Pharmacy
- Out-Patient Hospital Pharmacy
- In-Patient Hospital Pharmacy
- Mail Order Pharmacy
- Community Pharmacy-Chain/Mass Merchandiser
- Community Pharmacy-Independent

![Staff Pharmacists-Primary Practice Site Chart](chart.png)
### Q.1 CLINICAL/SPECIALTY PHARMACISTS:

Please rate your level of agreement with the following statements:

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>N/A</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1a. I have adequate time for breaks/lunches at my primary site.</strong></td>
<td>114</td>
<td>46</td>
<td>21</td>
<td>8</td>
<td>189</td>
</tr>
<tr>
<td><strong>1b. I am satisfied with the amount of time I have to do my job.</strong></td>
<td>100</td>
<td>50</td>
<td>32</td>
<td>7</td>
<td>189</td>
</tr>
<tr>
<td><strong>1c. My employer provides a work environment that is conducive to providing safe and effective patient care.</strong></td>
<td>121</td>
<td>30</td>
<td>24</td>
<td>14</td>
<td>189</td>
</tr>
<tr>
<td><strong>1d. My site has adequate Pharmacist staff to provide safe and effective patient care.</strong></td>
<td>99</td>
<td>45</td>
<td>28</td>
<td>17</td>
<td>189</td>
</tr>
<tr>
<td><strong>1e. My site has adequate Technician staff to provide safe and effective patient care.</strong></td>
<td>102</td>
<td>32</td>
<td>29</td>
<td>26</td>
<td>189</td>
</tr>
<tr>
<td><strong>1f. My site has adequate Clerk staff to provide safe and effective patient care.</strong></td>
<td>56</td>
<td>11</td>
<td>27</td>
<td>95</td>
<td>189</td>
</tr>
</tbody>
</table>

Answered question - 189

Skipped question - 0

---

### Clinical/Specialty Pharmacist-Primary Practice Site

![Bar chart showing percentage of responses for different types of pharmacies and sites.](chart.png)

- Other
- Compounding Pharmacy
- Ambulatory Care
- Long Term Care Pharmacy
- Health Center Pharmacy
- Out-Patient Hospital Pharmacy
- In-Patient Hospital Pharmacy
- Mail Order Pharmacy
- Community Pharmacy-Chain/Mass Merchandiser
- Community Pharmacy-Independent

-10% 0% 10% 20% 30% 40% 50% 60%
Q.1 PHARMACY MANAGER/PIC:

Please rate your level of agreement with the following statements:

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>N/A</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. I have adequate time for breaks/lunches at my primary site.</td>
<td>155</td>
<td>137</td>
<td>36</td>
<td>2</td>
<td>330</td>
</tr>
<tr>
<td>1b. I am satisfied with the amount of time I have to do my job.</td>
<td>137</td>
<td>154</td>
<td>35</td>
<td>2</td>
<td>328</td>
</tr>
<tr>
<td>1c. My employer provides a work environment that is conducive to providing safe and effective patient care.</td>
<td>163</td>
<td>100</td>
<td>65</td>
<td>2</td>
<td>330</td>
</tr>
<tr>
<td>1d. My site has adequate Pharmacist staff to provide safe and effective patient care.</td>
<td>171</td>
<td>103</td>
<td>52</td>
<td>3</td>
<td>329</td>
</tr>
<tr>
<td>1e. My site has adequate Technician staff to provide safe and effective patient care.</td>
<td>155</td>
<td>124</td>
<td>44</td>
<td>6</td>
<td>329</td>
</tr>
<tr>
<td>1f. My site has adequate Clerk staff to provide safe and effective patient care.</td>
<td>117</td>
<td>94</td>
<td>37</td>
<td>82</td>
<td>330</td>
</tr>
</tbody>
</table>

Answered question - 330
Skipped question - 0

Pharmacy Manager/PIC-Primary Practice Site

- Community Pharmacy-Chain/Mass Merchandiser
- Community Pharmacy-Independent
- Mail Order Pharmacy
- In-Patient Hospital Pharmacy
- Out-Patient Hospital Pharmacy
- Health Center Pharmacy
- Long Term Care Pharmacy
- Ambulatory Care
- Compounding Pharmacy
- Other
## Q.1 REGIONAL MANAGER/DIRECTOR/VP:

Please rate your level of agreement with the following statements:

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>N/A</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. I have adequate time for breaks/lunches at my primary site.</td>
<td>19</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>27</td>
</tr>
<tr>
<td>1b. I am satisfied with the amount of time I have to do my job.</td>
<td>19</td>
<td>5</td>
<td>3</td>
<td>0</td>
<td>27</td>
</tr>
<tr>
<td>1c. My employer provides a work environment that is conducive to providing safe and effective patient care.</td>
<td>23</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>27</td>
</tr>
<tr>
<td>1d. My site has adequate Pharmacist staff to provide safe and effective patient care.</td>
<td>22</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>27</td>
</tr>
<tr>
<td>1e. My site has adequate Technician staff to provide safe and effective patient care.</td>
<td>17</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>27</td>
</tr>
<tr>
<td>1f. My site has adequate Clerk staff to provide safe and effective patient care.</td>
<td>9</td>
<td>2</td>
<td>4</td>
<td>12</td>
<td>27</td>
</tr>
</tbody>
</table>

Answered question - 27

Skipped question - 0

### Regional Pharmacy Manager/Director/VP-

**Primary Practice Site**

![Bar Chart](image_url)
Q.1 RELIEF PHARMACISTS:
Please rate your level of agreement with the following statements:

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Agree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>N/A</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. I have adequate time for breaks/lunches at my primary site.</td>
<td>28</td>
<td>32</td>
<td>8</td>
<td>8</td>
<td>76</td>
</tr>
<tr>
<td>1b. I am satisfied with the amount of time I have to do my job.</td>
<td>26</td>
<td>33</td>
<td>10</td>
<td>7</td>
<td>76</td>
</tr>
<tr>
<td>1c. My employer provides a work environment that is conducive to providing safe and effective patient care.</td>
<td>27</td>
<td>25</td>
<td>16</td>
<td>7</td>
<td>75</td>
</tr>
<tr>
<td>1d. My site has adequate Pharmacist staff to provide safe and effective patient care.</td>
<td>26</td>
<td>33</td>
<td>10</td>
<td>7</td>
<td>76</td>
</tr>
<tr>
<td>1e. My site has adequate Technician staff to provide safe and effective patient care.</td>
<td>29</td>
<td>27</td>
<td>11</td>
<td>9</td>
<td>76</td>
</tr>
<tr>
<td>1f. My site has adequate Clerk staff to provide safe and effective patient care.</td>
<td>27</td>
<td>23</td>
<td>11</td>
<td>15</td>
<td>76</td>
</tr>
</tbody>
</table>

Answered question - 76
Skipped question - 0

Relief Pharmacist-Primary Practice Site
Q8. Have you experienced any changes (positive or negative) in your work environment in the past 3 years?

Answered Question - 678

<table>
<thead>
<tr>
<th>Subcategory</th>
<th>Number of comments</th>
<th>Subcategory percentage of comments in category</th>
<th>Percentage of total submitted comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technician Related</td>
<td>225</td>
<td>-</td>
<td>33%</td>
</tr>
<tr>
<td>Reduced Staffing Hours</td>
<td>198</td>
<td>88%</td>
<td>29%</td>
</tr>
<tr>
<td>Lack Training</td>
<td>14</td>
<td>6%</td>
<td>2%</td>
</tr>
<tr>
<td>Limited Availability</td>
<td>22</td>
<td>10%</td>
<td>3%</td>
</tr>
<tr>
<td>Pharmacist Workload</td>
<td>348</td>
<td>-</td>
<td>51%</td>
</tr>
<tr>
<td>Pharmacist Schedule (extended hours, reduced overlap, mandatory OT, no OT, etc.)</td>
<td>197</td>
<td>57%</td>
<td>29%</td>
</tr>
<tr>
<td>Increase in Demands Placed on Pharmacist</td>
<td>293</td>
<td>84%</td>
<td>43%</td>
</tr>
<tr>
<td>Patient Safety Related</td>
<td>89</td>
<td>-</td>
<td>13%</td>
</tr>
<tr>
<td>Meal Periods and Breaks</td>
<td>63</td>
<td>-</td>
<td>9%</td>
</tr>
<tr>
<td>Able to Take Meal Periods and Breaks</td>
<td>31</td>
<td>49%</td>
<td>5%</td>
</tr>
<tr>
<td>Challenges Related to Taking Meal Periods and Breaks</td>
<td>38</td>
<td>60%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Q10. Please provide any additional comments you think would be helpful to the Board.

Answered Question - 311

Focus of the majority of comments mirrored Q8.

Other areas of concern included:

- Need for a pharmacist to technician ratio
- Need for a limit on how many prescriptions a pharmacist can do a day
- Non-clinical corporate supervisors making staffing decisions
- Insurance companies
- “Fast Food” style pharmacy services
## Pharmacy Working Conditions Survey Results Comparisons

### July 2016
Number of Active RPh: 7207  
Number of RPh Email Addresses: 7207  
Number of Undelivered Emails: 4  
Number of Responses: 1130 (678 or 60% included written comments)  
Response Rate: 15.69%  

<table>
<thead>
<tr>
<th>Q.7 Years Licensed in Oregon (includes all out of state pharmacists):</th>
<th>Number of all OBOP licensed pharmacists</th>
<th>Percentage of all OBOP licensed pharmacists</th>
<th>Percentage that responded to survey</th>
<th>Percentage that responded to survey compared to 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Years</td>
<td>2279</td>
<td>31.6%</td>
<td>15.3%</td>
<td>4.5%</td>
</tr>
<tr>
<td>5-10 Years</td>
<td>1623</td>
<td>22.5%</td>
<td>16.2%</td>
<td>-0.27%</td>
</tr>
<tr>
<td>10-15 Years</td>
<td>618</td>
<td>8.6%</td>
<td>8.0%</td>
<td>-28.38%</td>
</tr>
<tr>
<td>15-20 Years</td>
<td>683</td>
<td>9.5%</td>
<td>12.0%</td>
<td>-12.46%</td>
</tr>
<tr>
<td>20-25 Years</td>
<td>545</td>
<td>7.6%</td>
<td>11.4%</td>
<td>-16.76%</td>
</tr>
<tr>
<td>More than 25 Years</td>
<td>1459</td>
<td>20.2%</td>
<td>31.3%</td>
<td>-4.71%</td>
</tr>
</tbody>
</table>

### July 2013
Number of Active RPh: 5847  
Number of RPh Email Addresses: 5812  
Number of Undelivered Emails: 2  
Number of Responses: 1647 (492 or 30% included written comments)  
Response Rate: 28.35%  

<table>
<thead>
<tr>
<th>Q.7 Years Licensed in Oregon (includes all out of state pharmacists):</th>
<th>Number of all OBOP licensed pharmacists</th>
<th>Percentage of all OBOP licensed pharmacists</th>
<th>Percentage that responded to survey</th>
<th>Percentage that responded to survey compared to 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Years</td>
<td>1963</td>
<td>33.57%</td>
<td>10.80</td>
<td>-2.66%</td>
</tr>
<tr>
<td>5-10 Years</td>
<td>856</td>
<td>14.64%</td>
<td>16.47%</td>
<td>-4.86%</td>
</tr>
<tr>
<td>10-15 Years</td>
<td>580</td>
<td>9.92%</td>
<td>36.38%</td>
<td>6.95%</td>
</tr>
<tr>
<td>15-20 Years</td>
<td>646</td>
<td>11.05%</td>
<td>24.46%</td>
<td>-2.37%</td>
</tr>
<tr>
<td>20-25 Years</td>
<td>483</td>
<td>8.26%</td>
<td>28.16%</td>
<td>-3.54%</td>
</tr>
<tr>
<td>More than 25 Years</td>
<td>1319</td>
<td>22.56%</td>
<td>36.01%</td>
<td>0.70%</td>
</tr>
</tbody>
</table>

NOTE: There were 997 more email addresses in 2013 than 2011
### July 2011

Number of Active RPh 5316  
Number of RPh Email Addresses 4954  
Number of Undelivered Emails -141  

- **Number of Responses**: 1401 (518 or 37% included written comments)  
- **Response Rate**: 29.11%

<table>
<thead>
<tr>
<th>Q.7 Years Licensed in Oregon (includes all out of state pharmacists):</th>
<th>Number of all OBOP licensed pharmacists</th>
<th>Percentage of all OBOP licensed pharmacists</th>
<th>Percentage that responded to survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 5 Years</td>
<td>1575</td>
<td>29.63%</td>
<td>13.46%</td>
</tr>
<tr>
<td>5-10 Years</td>
<td>661</td>
<td>12.43%</td>
<td>21.33%</td>
</tr>
<tr>
<td>10-15 Years</td>
<td>717</td>
<td>13.49%</td>
<td>29.43%</td>
</tr>
<tr>
<td>15-20 Years</td>
<td>589</td>
<td>11.08%</td>
<td>26.83%</td>
</tr>
<tr>
<td>20-25 Years</td>
<td>429</td>
<td>8.07%</td>
<td>31.70%</td>
</tr>
<tr>
<td>More than 25 Years</td>
<td>1345</td>
<td>25.30%</td>
<td>35.32%</td>
</tr>
</tbody>
</table>

### Response Counts:

<table>
<thead>
<tr>
<th>Role</th>
<th>2011</th>
<th>2013</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Pharmacists</td>
<td>1393</td>
<td>1647</td>
<td>1130</td>
</tr>
<tr>
<td>Staff Pharmacist</td>
<td>652</td>
<td>760</td>
<td>486</td>
</tr>
<tr>
<td>Clinical/Specialty Pharmacist</td>
<td>173</td>
<td>255</td>
<td>186</td>
</tr>
<tr>
<td>Pharmacy Manager/PIC</td>
<td>403</td>
<td>452</td>
<td>330</td>
</tr>
<tr>
<td>Regional Pharmacy Manager/VP</td>
<td>42</td>
<td>36</td>
<td>27</td>
</tr>
<tr>
<td>Relief Pharmacist</td>
<td>90</td>
<td>107</td>
<td>76</td>
</tr>
</tbody>
</table>
Workplace related articles:

Tribune tests 255 pharmacies, find half say nothing about dangerous drug interactions

Two follow-ups:
Durbin, Chief of association of pharmacy boards call for changes following Tribune report

GOP Gov. Rauner, key House Dems move to protect consumers against drug interactions, seek accountability

Overall series, including stores about using big data to find drugs and effect of bad drug interaction on person:
(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient’s agent. A request specific to each unique medication is required, unless the requested refill is part of an auto-refill program.

(6) Auto-Refill Programs. A retail pharmacy may only use a program that automatically refills non-controlled prescriptions and controlled prescriptions for maintenance medications that have existing refills available and are consistent with the patient’s current medication therapy when the following conditions are met:

(a) A patient or patient’s agent must enroll each unique medication in an auto-refill program before a pharmacy can include the medication as part of the auto-refill program. Authorization for each prescription refill by a patient or patient’s agent is received before the pharmacy begins the filling process;

(b) The prescription is not a controlled substance; and

(c) The pharmacy must discontinue auto-refill program enrollment at the request of the patient or patient’s agent.

(7) An automated reminder cannot be used to generate an auto-refill prescription refill unless once the patient or patient’s agent has opted in to the pharmacy’s auto-refill program for that specific, unique medication; provides authorization for each individual prescription refill. The content of each reminder must include:

(a) Drug name and strength; and

(b) Date of last fill.

(d) Pick-up notification to a patient or patient’s agent may only be generated upon full completion of the prescription refill;

(e) When an auto-refill prescription is returned to stock that prescription medication is removed from the auto-refill program for that patient.
(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/refill is part of an auto-refill program.

(6) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may only use a program that automatically refills prescription medications, non-controlled prescriptions, and controlled substance prescriptions for maintenance medications that have existing refills available and are consistent with the patient’s current medication therapy when the following conditions are met:

(a) A patient or patient’s agent must enroll each prescription in an auto-refill program before a pharmacy can include the prescription medication as part of the auto-refill program; Authorization for each prescription refill by a patient or patient’s agent is received before the pharmacy begins the filling process;

(b) The prescription is not a controlled substance; and

(b) The pharmacy must discontinue auto-refill program enrollment at the request of the patient or patient’s agent.

(7) An automated reminder cannot be used to generate an auto-refill prescription refill unless once the patient or patient’s agent has opted in to the pharmacy’s auto-refill program for that specific prescription medication; provides authorization for each individual prescription refill. The content of each reminder must include:

   Note: This statement (c) is no longer needed. Propose to remove.

(a) Drug name and strength; and

(b) Date of last fill.

(8) Pick-up notification to a patient or patient’s agent may only be generated upon full completion of the 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.
For Public Information

At the Board’s December 7, 2016 meeting, the following rules were adopted and have since been filed with the Secretary of State and became effective on 12/14/16 due to timing needs.

December 2016

The Board permanently adopted the following rules at its December 7, 2016 Board meeting:

Changes to Division 019 - Reduce the number of days before eligibility to retake the NAPLEX. Limits the number of retakes on the NAPLEX and MPJE exams to no more than three times in one year for a lifetime maximum of five attempts. This change is consistent with the National Association of Boards of Pharmacy (NABP) new policy that changed on 11/1/16.

Changes to Divisions 019 & 041 - Permanently incorporates new statutory language put forth by House Bill 4124 (2016) related to Naloxone. The bill permits pharmacists to prescribe and distribute unit-of-dose packages of naloxone to individuals who conduct or complete OHA approved training. It allows a trainer to possess and distribute naloxone to trainees, and allows trainees to possess and administer naloxone to an individual experiencing an opiate overdose. The rule (1) gives the purpose; (2) specifies the qualifications of participating pharmacists and individuals; and (3) outlines the delivery of care expectations for the pharmacist and pharmacy, including documentation and recordkeeping. Changes for Division 080 - Permanently add illicit synthetic opioids/fentanyl derivatives (known as U-47700 and W-18) to Oregon Schedule CI drugs. Schedule I also includes any substituted derivatives of fentanyl that are not specifically listed, or are not FDA approved.

Certificate and Order for Permanent Rules - Effective 12/14/16 - Effective 12/14/16

- Division 019 - Pharmacists Licensure Exams
- Division 019 and 041 - Pharmacist Prescribing and Outlet Requirements for Naloxone
- Division 080 - Controlled Substance I – adds illicit synthetic opioids and fentanyl derivatives