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.

Wednesday, October 2, 2019 @ 8:30AM – Conference Room 1A
Thursday, October 3, 2019 @ 8:30AM – Conference Room 1A

≈ The meeting location is accessible to persons with disabilities. A request for hearing impaired assistance and accommodations for persons with disabilities should be made to Karen MacLean at 971-673-0001 at least 48 hours prior to the meeting. ≈

WEDNESDAY, October 2, 2019

I. OPEN SESSION, Cyndi Vipperman, CPhT, Presiding
   a. Roll Call
   b. Agenda Review and Approval
   c. Acknowledge Compliance Secretary, Annette Gearhart’s Retirement & 30 years of State Service

II. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (L).
    a. Deliberation on Disciplinary Cases and Investigations

III. Contested Case Deliberation pursuant to ORS 192.690(1) – Not open to the public

IV. OPEN SESSION – PUBLIC MAY ATTEND – At the conclusion of Executive Session, the Board may convene Open Session to begin some of the following scheduled agenda items - time permitting at approximately 4:00PM.

Adjourn

THURSDAY, October 3, 2019

V. OPEN SESSION, Cyndi Vipperman, CPhT, Presiding
   a. Roll Call
   b. Motions related to Disciplinary Actions – Efremoff

VI. GENERAL ADMINISTRATION
   a. Rules
      i. Review Rulemaking Hearing Report & Comments - #A-A2 Melvin Action Necessary

NOTE: The Board may rearrange its agenda to accommodate the Board or Members of the public.
ii. Consider Adoption of Rules – *Karbowicz*  
   1. Div 006 & 045 – Drug Compounding and Definitions #A3-A3.1  
   2. Div 019 & 020 – Prescribing Practices and Formulary #A4

iii. Consider Adoption of Temporary Rules – none

iv. Consider sending rules to Rulemaking Hearing - *Karbowicz*  
   2. Div 019 & 041 – Naloxone revisions - SB 910 #A6  
   3. Div 019 - Contraception Prescribing (age 18 law sunset) ORS 689.689 #A7  
   4. Div 019 & 031 – FPGEC – SB 855 #A8  
   5. Div 080 – Controlled Substances – Animal Euthanasia - SB 71 #A9

b. Public Health and Pharmacy Formulary Advisory Committee  
   i. Committee Meeting and Recommendations update #B  
   ii. Consider rules and sent to Rulemaking Hearing – see above

c. Discussion Items:  
   i. Policy Items for Discussion:  
      1. APhA Contraceptive Training Program – Update #C CONFIDENTIAL  
         *Karbowicz*  
      2. OSU Emergency Insulin Training Program #C1 revised CONFIDENTIAL-C2  
         CONFIDENTIAL – *Karbowicz*  
   
   ii. Waivers and Requests:  
      1. Petnet security request/waiver req. #D - *Karbowicz*/Efremoff  
      2. Bay Area Hospital request #D1 - Hennigan  
      3. TCVP – *Karbowicz*/Efremoff  
         a. Columbia Memorial Hospital – 1-year report #D2  
   
   iii. Other  
      1. Strategic Planning update – *Schnabel*/MacLean  
      2. 2019 Annual Key Performance Measure Report – *MacLean*/Melvin  

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

   i. Board Meeting Dates  
      • November 6-7, 2019  
      • December 11-12, 2019  
      • February 5-7, 2020*  
      • April 15-16, 2020  
      • June 17-18, 2020  
      • August 12-14, 2020*  
      • October 14-15, 2020  
      • November 18-19, 2020 TBA
• December 16-17, 2020 Portland

ii. Proposed Dates for 2021 - MacLean

• February 10-12, 2021* Portland (*3 day meeting)
• April 7-8, 2021 Portland
• June 9-10, 2021 Portland
• August 11-13, 2021* Portland (*3 day meeting)
• October 13-14, 2021 Portland
• November 3-4, 2021 TBA (Strategic Planning)
• December 8-9, 2021 Portland

iii. 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.)

• November 26, 2019

iv. Proposed Rulemaking Dates for 2020 and 2021

• May 27, 2020
• November 24, 2020
• May 26, 2021
• November 23, 2021

v. Conferences/Meetings

1. OSPA Annual Convention 10/5-6/2019 – Portland
2. NABP Executive Officers Forum 10/1-2/2019 – Chicago - Schnabel
3. NABP District VI-VIII Mtg. Boise, ID, 10/6-9/2019 - Schnabel/Beaman
4. FDA 50 State Meeting – DC, 10/10-11/2019 – Efremoff/Fox
5. OSHP Fall Seminar 11/16/19 – Portland (booth)
6. NABP Compliance Officer/Legal Counsel Forum -12/4-5/2019 - Efremoff

vi. Financial/Budget Report - MacLean

vii. Reports:

1. Board President/Members
2. Executive Director
3. Board Counsel
4. Compliance Director
5. Pharmacist Consultant
6. Administrative Director
7. Licensing Manager
VIII. Approve Consent Agenda*  
*Items listed under the consent agenda are considered to be routine agency matters and will be approved by a single motion of the Board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.

a. NAPLEX Scores – none  
b. MPJE Scores – none  
c. License/Registration Ratification July 23, 2019 – September 24, 2019 - CONSENT 1  
d. Pharmacy Technician Extensions – none  
e. Board Minutes – August 7-9, 2019 CONSENT 2  

IX. OPEN FORUM - At the completion of regular Board business, the Board provides an opportunity to make comments or present issues of general interest. The Board will not deliberate any issues or requests during Open Forum. Therefore, Open Forum should not be used to make formal requests to the Board, nor to address issues currently under investigation or requests pending before the Board. If you wish to be called upon, please sign up on the sheet at the podium in advance for inclusion.

Adjourn  

Action Necessary
Date: September 25, 2019
To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer’s Report on Rulemaking Hearing

Hearing Date: September 24, 2019
Hearing Location: Portland State Office Building, Room 1D

Title of Proposed Rules:
- Divisions 006 and 045 – Drug Compounding and Definitions
- Divisions 019 and 020 – Pharmacist Prescribing Authority & Formulary

The rulemaking hearing on the proposed rules was convened at 1:30PM. Nine people provided oral testimony on proposed rules; Divisions 006 and 045 Drug Compounding and no one appeared to provide comment on proposed rules, Divisions 019 and 020. The hearing was closed at 2:05PM. The hearing was recorded and copies of the proposed rules were available for attendees.

Attendance included 26 public, 4 OBOP Staff, and 3 OBOP Board members

Summary of Comments

- Karen Collell, Broadway Pharmacy, new independent pharmacy in Coos Bay – Would like the Board to consider that accreditation should be not required for “on-the-spot / just-in-time” traditional compounding in rural communities.
- The following people provided written testimony and utilized the open comment period to reiterate/emphasize certain points: Mike Millard (OSHP), Jackson Leong, Mark Cushing (Animal Policy Group), Tyler Trebarne, Natalie Gustafson, Michele Koder, Rob Geddes and Luke Eilers.

Items reiterated/emphasized include:
- Accreditation costs will limit patient access to medications
- Interprets the elimination of Shared Services agreements for humans as a requirement for registration as an FDA 503B Outsourcing Facility. This will impact small rural hospitals in Oregon and specialty clinics that may care for patients when patient specific pharmacy services are not available
• The need for OBOP to permit non-patient specific anticipatory “own-use” compounding, regardless of physical distance
• Inspection team is capable of identifying compliance with USP standards; accreditation is not necessary
• Legal concerns with excluding the non-resident pharmacies from providing non-patient specific veterinary medications, including lack of access. Of the 18 specifically identified veterinary drugs, there is not an Oregon pharmacy capable of providing all 18
• Favors accreditation for all locations as a way to ensure non-resident pharmacy safety
• Favors accreditation for locations to create a way to maintain a high level quality/safety
• Requiring accreditation for minimal amounts of simple compounding creates a barrier to access, especially to indigent patients
• Accreditation does not make sense for typical compounding at community pharmacies and accreditation entities do not actually have standards to address this type of traditional compounding
• Favors requiring non-resident compounding pharmacies to obtain 503B in order to provide non-patient specific drugs into Oregon; correction of the record provided by another testimony, Oregon pharmacies can provide those veterinary drugs

Summary of Written Comments

All written comments received by the public comment deadline date of 9/24/19 at 4:30PM have been provided in their entirety to the Board and are summarized below. 26 comments were received in response to the August 16, 2019 Notice of Proposed Rulemaking (sent via email, USPS mailed to all Rulemaking interested parties and posted on the Board’s website).

RULES PROPOSED: Compounding
AMEND: 855-006-0005

Luke Eilers, R.Ph
Commented in regards to a reasonable timeframe for accreditation and compliance enforcement. He provided background and suggestions.

Rob Geddes, Pharm D. – On behalf of Albertson’s Companies, Inc.
They are supportive of these regulations generally and they provided helpful background information from the standpoint of the community pharmacy setting, where simple, nonsterile compounds are provided routinely to patients in Oregon. They request the Board exclude community pharmacies from the accreditation requirement particularly due to costs. Additionally, they provided a number of suggestions for policy and rule language edits.
Michele Koder, Pharm D. - On behalf of Multnomah County Health Dept.
While they appreciate the intent and value of the proposed changes, they oppose the requirement for accreditation due to cost and Federally Qualified Health Center (FQHC) status.

Marc Rizzo, Pharm D.
He believes Compounding needs more oversight but strongly believes there should be exceptions and suggested replacing accreditation with mandatory training, similar to the contraceptive training and asked that we consider the patients in rural communities that will be negatively impacted by the current proposed rules.

Michael Blaire, R.Ph – On behalf of Wedgewood Pharmacy
Believes that purposed rules fail to address existing limitations on compounded office use dispensing for animal health, limiting veterinarians to in-state pharmacies only. Requests revised rules to allow any pharmacy that complies with regulations be permitted to provide compounded (non-patient specific) medications for veterinary office use.

Natalie Gustafson, R.Ph – On behalf of Lloyd Central Compounding Pharmacy
Supports accreditation requirement for standardization and safety and suggests up to 18 months lead-time for compliance. Additionally, she provided a number of suggestions for policy and rule language edits.

Eric Lintner, R.Ph- with Consonus Pharmacy Services
He applauds efforts to align rules more closely with USP, but has some concerns over wording and is opposed to additional requirements for compounding accreditation for pharmacies that are already in compliance with all existing rules. Additionally, he provided a number of suggestions for language edits and posed some questions for the Board to address.

OSHP Board of Directors
OSHP is in support of the proposed rules and feels that critical practices must be permitted under OAR to protect the health and safety of Oregonians receiving prescriptions for compounded drug products. They provided policy items for the Board’s consideration and are seeking clarification on a number of rules prior to Board adoption.

Lorri Walmsley, R.Ph- On behalf of Walgreens
They are supportive of the majority of the proposed rule language and provided a number of suggestions for language modifications for the Board’s consideration. They believe the cost of accreditation or inspection will limit patient access.

Lis Houchen, - On behalf of NACDS (National Association of Chain Drug Stores)
They provided specific details regarding their concerns with the proposed rule changes. They stated that USP announced plans to reconsider and potentially revise the standards due to the number of appeals and strongly encouraged the Board to delay making any revisions until USP completes their revision initiatives. They provided suggestions for language edits for the Board’s consideration. We believe the cost of accreditation or inspection by a board-approved
entity will create a significant cost barrier for pharmacies to participate in compounding of nonsterile preparations and will limit access to these products in Oregon.

Alan Matarasso – On behalf of the American Society of Plastic Surgeons (ASPS)  
They asked that the proposed rules be amended by allowing physicians to be exempt from recordkeeping requirements as well as more clarification around compounding in or outside of Oregon for those who plan to distribute in Oregon.

They share the Board’s concerns about safety of medications prepared and administered to patients and suggested that the Board set forth an exemption from requiring dermatologists to comply with Section 1.3 because they have engaged with USP regarding in-office preparation of drugs to establish a 12-hour exemption and pending testing results, state that USP will develop a monograph that would supersede Chapter 797.

Kevin Russell, R.Ph – On behalf of OSPA  
They give their full support to testimony submitted by OSHP and stated that their organization agrees with OSHP’s statements and take the same position on sterile compounding and shared services. They have some concerns related to non-sterile compounding in regards to regulatory burden, accreditation and added expenses and stated that it might lead pharmacies to discontinue compounding services and request that separate inspection or accreditation only be required for 503B outsourcing facilities.

Lauren Paul, PharmD – On behalf of CVS  
They have concerns with specific reference to multiple USP-NF chapters within the proposed rules regarding the expense and resources involved for accreditation for drug outlets that compound and believe that these rules will force some retail drug outlets to discontinue compounding services. They provided suggested language edits for the Board’s consideration.

John Girod M.D & Ryan Miller – On behalf of Cascade Infectious Diseases and Infusion, LLC.  
They stated that the proposed changes will have a significant negative effect on their patients and if the proposed rules are adopted in their current state, they might need to stop their infusion business.

Aaron Lopez- On behalf of Political Capital LLC.  
They provided reasons why the Board should consider requiring veterinarians to purchase their office-use stock from Oregon licensed, FDA registered outsourcing facilities regardless if the facility is located in state or out of state.

Kevin Smith, R.Ph  
They provided comments to current proposed language for the Board to consider and stated that adaptation of the Oregon compounding rules at this time may cause OR rules to not align with USP chapters, which was the intent of these rules. Additionally he is concerned about the
costs of implementation and provided a personal testimonial about the impact to rural communities.

Carrie Reedy, Pharmacy Manager – Works with Samaritan Ambulatory & Home Infusion Svs. She agrees with the plan to allow pharmacies to either pass a board of pharmacy inspection on compounding or to have outside accreditation from an approved entity, but has concerns regarding the inspections being performed every 3 years, as well as the expense for accreditation will cause small compounding pharmacies out of business limiting access to patients in rural communities.

Tabitha Fridriksson, R.Ph- On behalf of Kaiser Permanente Northwest Region Provided concerns regarding proposed language in Division 006, definitions and is asking for clarification to proposed language related to registrations and records proposed language in Division 045. They provided recommended language revisions for the Board to consider.

Jackson Leong, R.Ph.
He has concerns about the proposed language in regards to the inspection or accreditation portion of the language, as well as the costs involved with accreditation. He believes that Board’s current inspection process of using licensed pharmacists should be sufficient, whereas using an accredited 3rd party inspection will eliminate the important face to face relationship licensees currently have with the Board.

Tyler Treharne
He feels the upcoming proposed changes are very good and constructive and that compliance with USP 795, 797, and 800 is necessary to make sure all pharmacies are compliant. He stated that he is strongly in favor of all pharmacies being accredited or inspected to maintain continuity, quality and believes doing away with shared services for human use.

Christina Barry, Pharm.D.
Asked for clarification on several proposed language definitions. She asked for clarification on procedural processes and implementation timelines.

Ned Milenkovich – With Much Shelist, P.C. Attorneys at Law
He is concerned that USP 795 does not explicitly address or mention flavoring and that USP’s stance would place costly regulatory burdens on many community pharmacies in Oregon that offer the service and would effectively eliminate flavoring, which will negatively affect pediatric medication adherence. He proposed language for the Board to consider that would exclude flavoring from the definition of compounding.

**RULES PROPOSED: Prescribing**
855-019-0264, 855-019-0470, 855-020-0110, 855-020-0200, 855-020-0300
REPEAL: 855-019-0264
Lauren Paul, PharmD – On behalf of CVS
They continue to support the Board’s efforts in adopting new recommendations for the formulary and protocol compendium. They provided rule language edits for the Board’s consideration.

Tabitha Fridriksson R.Ph – On behalf of Kaiser Foundation Health Plan and Hospitals of the Northwest
Kaiser Permanente asks the Board to consider removing language “face to face” related to patient assessment to allow for telehealth services.

Lis Houchen, - On behalf of NACDS (National Association of Chain Drug Stores)
NACDS supports policies that give patients more options, including Oregon’s new law authorizing pharmacists to prescribe and dispense certain FDA-approved drugs and devices. They commend the Board and PHPFAC for their hard work on this regulatory initiative.
NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILING CAPTION: Revises Drug Compounding rules in Division 045 and repeals one definition in Division 006.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/24/2019 4:30 PM
The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@oregon.gov

FILED CAPTION: 08/16/2019

HEARING(S)
Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 09/24/2019
TIME: 1:30 PM
OFFICER: Portland State Office
Building - Conf. Rm 1D
ADDRESS: Portland State Office
Building - Conf. Rm 1D
800 NE Oregon St.
Portland, OR 97232

NEED FOR THE RULE(S):
Revised language related to drug compounding is proposed to address patient safety and incorporates FDA enforced national standards that become effective 12/1/2019. All drug compounding must adhere to the standards of United States Pharmacopoeia (USP) and USP-NF Chapters related to compounding practices at a location where drug compounding occurs. Existing rules no longer meet the acceptable standards for patient safety.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

FISCAL AND ECONOMIC IMPACT:
The fiscal impact for stakeholders associated with these rules is significant. Compliance costs can be placed into two major categories: initial costs, such as facility remodels and ongoing costs, such as gowning/garbing items and product testing needed for daily compounding activities. It is anticipated that the initial costs to comply are high, ranging
anywhere from an estimated $50,000 to more than $3,000,000 per location, depending on the current facility specifications and the type of compounding being performed. The Board is seeking stakeholder input specific to the Board’s proposed requirement for accreditation/certification. See OAR 855-045-0210 (1).

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

Hospital pharmacies and Community Retail Pharmacies (Chain and Independent) that perform non-sterile or sterile compounding will be affected by these rules differently, depending on the services they offer. The number of small businesses in Oregon is less than 200 and may include small hospitals and independent community pharmacies. Older buildings may be more expensive to remodel to satisfy these requirements. Both sterile compounding and non-sterile each have their own reporting records and administrative record keeping activities. Additionally, the cost of professional services, equipment supplies, labor and increased administration will vary depending on current readiness. See the Fiscal and Economic Impact information above.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):
Participants on the RAC included small business owners.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

AMEND: 855-006-0005

RULE SUMMARY: Removes "Shared Pharmacy Services" definition, which is no longer valid and renumbers definitions that followed.

CHANGES TO RULE:
855-006-0005
Definitions
As used in OAR chapter 855:
(1) “Board” means the Oregon Board of Pharmacy unless otherwise specified or required by the context.
(2) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the pharmacist are not considered pharmacy technicians.
(3) “Clinical Pharmacy Agreement” means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.
(4) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an
individual patient and:

(a) Is agreed to by one pharmacist and one practitioner; or
(b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.

(5) “Compounding” means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(a) As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the pharmacist and the patient, in the course of professional practice; or
(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or
(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns; or
(d) As a component of a Shared Pharmacy Service agreement as defined in section (21) of this rule.

(6) “Confidential Information” means any patient information obtained by a pharmacist or pharmacy.

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

(8) The “Container” is the device that holds the drug and that is or may be in direct contact with the drug.

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

(10) “Interpretation and evaluation of prescription orders” means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.

(11) “Labeling” means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.

(12) “Monitoring of therapeutic response or adverse effect of drug therapy” means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.

(13) “Medication Therapy Management (MTM)” means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.

(14) “Nationally Certified Exam” means an exam that is approved by the Board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible and valid.

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

(16) “Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy” means, among other things:

(a) The creation and retention of accurate and complete patient records;
(b) Assuming authority and responsibility for product selection of drugs and devices;
(c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the general public;
(d) Maintaining confidentiality of patient information.¶
(17) "Oral Counseling" means an oral communication process between a pharmacist and a patient or a patient’s agent in which the pharmacist obtains information from the patient (or agent) and the patient’s pharmacy records, assesses that information and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.¶
(18) Participation in Drug Selection and Drug Utilization Review:¶
(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.¶
(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review include, but are not limited to:¶
(A) Over-utilization or under-utilization;¶
(B) Therapeutic duplication;¶
(C) Drug-disease contraindications;¶
(D) Drug-drug interactions;¶
(E) Incorrect drug dosage;¶
(F) Incorrect duration of treatment;¶
(G) Drug-allergy interactions; and¶
(H) Clinical drug abuse or misuse.¶
(19) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life. These outcomes include:¶
(a) Cure of a disease;¶
(b) Elimination or reduction of a patient’s symptomatology;¶
(c) Arrest or slowing of a disease process; or¶
(d) Prevention of a disease or symptomatology.¶
(20) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the specialized education program pursuant to OAR 855-025-0012.¶
(21) "Practice of clinical pharmacy" means:¶
(a) The health science discipline in which, in conjunction with the patient’s other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient’s health and wellness;¶
(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and¶
(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.¶
(22) "Practice of pharmacy" is as defined in ORS 689.005.¶
(23) "Prescription released by the pharmacist" means, a prescription which has been reviewed by the pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.¶
(24) "Prohibited conduct" means conduct by a licensee that:¶
(a) Constitutes a criminal act against a patient or client; or¶
(b) Constitutes a criminal act that creates a risk of harm to a patient or client.¶
(25) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:¶
(a) Assure retention of their purity and potency;¶
(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;¶
(c) Assure security and minimize the risk of their loss through accident or theft;¶
(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;¶
(e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.¶

(26) “Quality Assurance Plan” is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.¶

(27) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication, the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.¶

(28) “Shared Pharmacy Service” means a written agreement, that has been approved in writing by the board, that exists for the processing by a pharmacy of a request from another pharmacy or a practitioner licensed to prescribe the drug, to fill or refill a prescription or a drug order, or to perform processing functions including but not limited to:

(a) Dispensing;¶
(b) Drug utilization review;¶
(c) Claims adjudication;¶
(d) Refill authorizations;¶
(e) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon for Oregon outlets and practitioners located in Oregon only; and¶
(f) Therapeutic interventions.¶

(29) “Specialized Education Program” means:

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

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

(A) An organization recognized by the board as representing pharmacists or pharmacy technicians;¶
(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or¶
(C) A trade association recognized by the board as representing pharmacies.¶

(30) “Supervision by a pharmacist” means being stationed within the same work area as the pharmacy technician or certified pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified pharmacy technician’s action.¶

(31) “Therapeutic substitution” means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.¶

(32) “Verification” means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified pharmacy technician.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.005, 689.151, 689.155, 689.305, 689.405 & 689.455, 689.645
855-045-0200

Application ¶

(1) These rules (OAR 855-045-0200 to 855-045-0270) apply to any person, including any business entity, located in or outside Oregon that engages in the practice of compounding drugs, or any person, including any business entity, located in any other state that compounds drugs for the use of patients located in Oregon. Compounding of radiopharmaceuticals is specifically exempted from these rules where these rules are in conflict with the rules or guidelines established by the Nuclear Regulatory Commission, the Radiation Protection Services of the Oregon Department of Human Services or any other applicable agency. Any person located outside Oregon that compounds drugs for the use of patients located in Oregon is expected to follow the compounding rules of their home state or these rules, whichever are more stringent.

(2) These rules apply to sterile and non-sterile compounding of medications that are prepared for a specific patient and that are prescribed or ordered subject to a valid practitioner-patient relationship.

(3) Whilst the Board does not insist on rigid application of, or distribution in Oregon shall register with the Board as a drug outlet and comply with these rules (OAR 855-045-0200 to 855-045-0270).

(2) These rules apply to sterile and non-sterile compounding of a drug.

(3) All drug compounding must adhere to all the guideline to standards of the current edition of the United States Pharmacopeia Chapters 795 (USP <795>) and 797 (USP <797>), it expects pharmacists engaging in compounding to adhere to those guidelines that apply to their practice setting and in all situations to comply with the spirit and 800 (USP <800>), as well as all Chapters of USP 795 and USP 797.

(4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for a specific patient is considered to be manufacturing, and any person engaged in manufacturing must be registered in accordance with OAR 855-060-0001, with the following exceptions:

(a) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon that is covered by a Shared Pharmacy Services agreement as defined in OAR 855-006-0005;

(b) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on a routine, regularly observed pattern;

(c) Notwithstanding any other provisions of this rule, the preparation of a patient specific product utilizing all non-sterile commercial components, as defined in these rules as Category 1 compounding, is not considered compounding under these rules provided that:

(A) Preparation of these products is an infrequent occurrence;

(B) Quantity of product prepared does not exceed the requirements of a single prescription except that small quantities can be prepared upon request for in-office use by licensed practitioners NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 825, 1072, 1116, 1160, 1163, 1211 and 1229.5.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
As used in this division of administrative rules:

1. "Airborne Particulate Cleanliness Classification" means the level of cleanliness defined by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). The levels used in these rules are:
   a. ISO Class 5 is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air.
   b. ISO Class 7 is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air.
   c. ISO Class 8 is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air.

2. Beyond Use Date (BUD) means the date after which the preparation may not be dispensed or administered to a patient. BUD has the same meaning as "Expiration Date".

3. "Biological Safety Cabinet" (BSC) means a ventilated cabinet with an inward airflow for personnel protection, a downward, High Efficiency Particulate Arresting (HEPA) filtered, laminar airflow for product protection, and a HEPA filtered exhaust system for environmental protection.

4. Categories of compounding: In these rules, compounding is defined as:
   a. Category 1: Nonsterile - Simple: Generally, the mixing of two or more commercial products. In these rules, this is not considered to be compounding.
   b. Category 2: Nonsterile - Complex: Generally, compounding with bulk drug substances or when calculations are required.
   c. Category 3: Sterile - Risk Level 1: Low-Risk, as defined in OAR 855-045-0250.
   d. Category 4: Sterile - Risk Level II: Medium-Risk, as defined in OAR 855-045-0250.
   e. Category 5: Sterile - Risk Level III: High-Risk, as defined in OAR 855-045-0250.

5. "A non-resident drug outlet that distributes a non-patient specific drug compound within Oregon" means a glove box isolator with a microbially retentive HEPA air filter that maintains an aseptic compounding environment. In Oregon, this must be registered within the isolator throughout the compounding and material transfer process.

6. "Compounded Sterile Preparation" (CSP) means:
   a. A preparation prepared according to the manufacturer's labeled instructions and other manipulations when preparing sterile products that expose the original contents to potential contamination, and includes all preparations compounded in IV rooms; or
   b. A preparation containing nonsterile ingredients, or employing nonsterile components and devices, that must be sterilized before administration; or
   c. Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the above two characteristics, and which include, but are not limited to, baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injections, irrigations, metered sprays, and ophthalmic and otic preparations.

7. "Compounding pharmacy" means any pharmacy where sterile or non-sterile compounding occurs on a regular basis.
“Parenteral Admixture” means a sterile preparation that is the combination of one or more sterile products with an appropriate admixture vehicle.

“Laminar Airflow Hood” (LAF) means a workspace where the work surface is subjected to a constant, HEPA filtered airflow that is directed towards the user. A resident drug outlet that distributes a non-patient specific human drug compound within or outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305
855-045-0220
Personnel and Responsibilities ¶

(1) Personnel who prepare compounded pharmaceuticals, both sterile and non-sterile, shall be provided with appropriate training before they begin to prepare such products including for CSPs, training in the theoretical principles. All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia Chapters 795 (USP <795>), 797 (USP <797>) and 800 (USP <800>), as well as all Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 1072, 1116, 1160, 1163, 1211 and 1229.5. ¶

(1) All personnel who prepare and supervise the preparation of compounded pharmaceuticals must complete appropriate training and be capable of practical skills of aseptic manipulation qualified to perform assigned duties. ¶

(2) The Pharmacist-in-Charge (PIC) shall establish pharmacy and the drug outlet shall establish, maintain and enforce policies and procedures that contain protocols in accordance with the guidelines in USP 797, for the initial training and testing of all personnel and for annual retesting in aseptic manipulative skills for those personnel involved in low and medium risk compounding standards in USP Chapters for all aspects and categories of the compounding operation of non-sterile and sterile preparations that include written procedures for: ¶

(3a) Personnel involved in high-risk compounding must be retested in aseptic manipulative skills at least semi-annually. qualifications, to include training, evaluation and requalification; ¶

(4b) The PIC shall ensure that training protocols are followed and records are kept for the training of all new personnel and for all continuing education and periodic testing that is completed. ¶

(5) The PIC is responsible for the procedures and the overall operation of all activities within the pharmacy and must: ¶

(a) Ensure all pharmacy personnel involved in preparing compounded pharmaceuticals are trained and have demonstrated skills commensurate with the complexity of the procedures they are performing; ¶

(b) Establish a procedure for verification by a pharmacist of the preparation of each completed compounded product. This verification shall be accommopny the preparation of each. ¶

(c) Components, addressing but not limited to selection, handling, and storage; ¶

(g) Creating Master Formulation Records; ¶

(h) Creating Compounding Records; ¶

(i) Establishes new compounded product that includes beyond-use dates (BUDs); ¶

(j) Continuous quality assurance program and quality controls, addressing but is not limited to: ¶

(A) Ensuring that the drug, dose and dosage form ordered are appropriate for the patient; ¶

(B) Verifying that the correct drugs and components were release testing, end-product evaluation, quantitative/qualitative testing; ¶

(k) Completed; ¶

(C) Confirming that the calculation and quantity of each drug and component is correct compounded preparations, to include handling, packaging, storage and transport; ¶

(D) Verifying the label is correct and the adverse event reporting process and recall procedure. The appropriate...
contains all the information specified in OAR 855-041-0065 and these rules.

(c) Document verification by the pharmacist responsible for the review, call procedure must include notification to the Board within 10 working days in the event of a patient-level recall of a compounded drug.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
A person licensed to practice pharmacy by the Oregon Board of Pharmacy who is working in a compounding pharmacy, including a pharmacy that only prepares sterile parenteral products, has the duty to exercise that degree of care, skill, diligence and professional judgment that is used by ordinarily competent, careful pharmacists in the same or similar circumstances in the community of the pharmacist or a similar community.

(1) A pharmacist engaged in compounding shall:
(a) Conform to all relevant federal laws and rules;
(b) Dispense a compounded product only subject to a valid prescription except as provided in OAR 855-045-0200(4), and only when, in their professional judgment, it results from a valid prescriber-patient relationship;
(c) Compound only products that are not commercially available except as allowed in OAR 855-045-0240(2), and, except that with the prior approval of the Board, a commercial product that is temporarily in short supply or otherwise unavailable, may be compounded subject to OAR 855-045-0200(4)(c);
(d) Maintain all records in accordance with OAR 855-045-0270;
(e) Perform final product verification.

(2) The pharmacist-in-charge of a compounding pharmacy including a pharmacy that only prepares sterile parenteral products shall ensure that policies and procedures for that pharmacy are reviewed not less than annually, are available for all staff to refer to, and are complied with by all staff. The policies and procedures for a compounding pharmacy shall include but are not limited to, the following:
(a) An organized index;
(b) Product formula information;
(c) Specifications for a compounding log book in compliance with OAR 855-045-0270;
(d) Conditions and surveillance of the compounding environment;
(e) Compounding procedures including requirements for use of gowns, shoe covers or dedicated shoes, hair covers, gloves and masks;
(f) Cleaning and equipment maintenance procedures;
(g) QA plan and documentation;
(h) Shipping and delivery procedures;
(i) Product labeling;
(j) Procedures for final product verification by the pharmacist;
(k) Compounded product quality procedures including procedures for establishing BUD;
(l) Training requirements for all staff;
(m) Safety procedures and training for personnel handling hazardous materials including:
(A) Use of personal protective equipment;
(B) Availability of Manufacturers’ Safety Data Sheets;
(C) Emergency procedures related to spills, fire, or exposure to hazardous materials;
(n) Requirements for availability of reference materials;

(3) Pharmacies that compound sterile products including parenteral products shall, when appropriate, also include in their policies and procedures:
(a) Establishment of BUD;
(b) End Product Testing;
(c) Random sampling of both the environment and CSPs;

(4) The pharmacist-in-charge of a compounding pharmacy shall ensure that a quality assurance plan is written for that pharmacy and that:
(a) It includes record keeping requirements for cleaning, testing and calibration of all equipment and devices;
(b) Pharmacies that compound sterile products shall additionally include:

(A) Schedules and protocols for End Product Testing. Pharmacies mixing High Risk Level CSPs or extending Beyond Use Dating (BUD), must establish an End Product Testing schedule that includes random sampling. End Product Testing of a mixing process must show an acceptable sampling of the total preparations prepared annually.

(B) Protocols for establishing BUDs. BUDs may not exceed those in USP 797 guidelines unless a quality assurance program is established that verifies End Product Testing beyond the dating established by USP 797. Records to verify sterility and pyrogenicity must be maintained and available for review for three years.

(5) Bulk chemicals require a certificate of analysis.

(6) The labeling of bulk chemical containers shall contain:

(a) The date obtained;

(b) The BUD, which shall be established as specified in the pharmacy policies and procedures but not more than five years after opening unless additional testing is conducted to extend that BUD by not more than one year.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
RULE SUMMARY: Rules revised to clearly articulate the Board's expectations for compliant labeling.

CHANGES TO RULE:

855-045-0240
Sterile Parenteral Products: Labeling ¶

(1) In addition to complying with all the other rules in this chapter of rules that are appropriate to their practice setting, pharmacists compounding sterile parenteral products must comply with the following specific rules. ¶
   (a) Establish the labeling requirements specified in Division 041, the label of a compounded drug dispensed or distributed must contain the following, at a minimum and enforce written policies and procedures associated with the pharmacy’s preparation and dispensing of parenteral products. Policies and procedures shall be available for inspection at the pharmacy. These policies and procedures shall include all requirements of OAR 855-045-0230 as appropriate to the practice setting: ¶
      (1) The generic or official name of each active ingredient; ¶
      (2) The strength or concentration of each active ingredient, to include primary solution for administration of sterile parenteral therapy preparation; ¶
      (3) Requirements for storage and maintenance of equipment and supplies. The name of the base, diluent, or primary excipient; ¶
   (b) Labeling: In addition to regular labeling requirements, the label shall include:
      (A) Requirements for compounding, labeling and storage of the products; ¶
      (B) Requirements to include primary solution for administration of sterile parenteral therapy preparation; ¶
      (C) Requirements for storage and maintenance of equipment and supplies. The name of the base, diluent, or primary excipient; ¶
   (c) Patient Care Services: Counseling shall be available to the patient or patient’s agent concerning proper use of parenterals and related supplies furnished by the pharmacy. ¶
      (1) A beyond-use date (BUD), complying with all the requirements in section (1) of this rule, licensed pharmacy personnel preparing parenteral admixtures as defined in OAR 855-045-0210 may: current USP standards; ¶
         (a) Prepare multiple source commercially available premixed parenteral admixtures; ¶
         (b) Prepare single source premix parenteral admixtures if the individual components of the premixed parenteral admixture, storage or drug specific instructions, caution are commercially available; ¶
         (c) Reassign a parenteral admixture to another patient if the admixture does not exceed the documented BUD for that admixture, and the parenteral admixture was prepared and dispensed for a patient specific order, and has been stored at all times under the control of a person trained and knowledgeable in the storage and administration of drugs; warnings as necessary or appropriate for proper use and patient safety; ¶
         (d) In the case of a patient specific parenteral admixture, the pharmacist does not need to comply with the worksheet and log requirements in these rules provided that a quality assurance process is in place to address drug recalls, and appropriate safeguards are in place dentity of the pharmacist who verified the accuracy of the completed product. ¶
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
Definitions of Risk Levels for Sterile Preparations

The three risk levels of CSPs recognized by USP 797 are based on the probability of contamination by microbial, chemical, or physical agents. Low-Risk and Medium-Risk Level CSPs are determined by the potential for microbial contamination during preparation, and High-Risk Level CSPs by the potential for not being properly sterilized before administration to patients. These risk levels are defined, and products must be prepared and managed as follows:

1. Low-Risk Conditions:
   (a) CSPs prepared using aseptic manipulation within an air quality environment that is equal to or better than ISO Class 5, using only sterile ingredients, products, components, and devices;
   (b) No more than three commercially manufactured sterile products and entries into one container of sterile product during preparation;
   (c) Manipulations limited to:
      (A) Aseptically opening ampoules;
      (B) Penetrating sterile stoppers on vials with sterile needles and syringes;
      (C) Transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and sterile containers for storage and dispensing;
   (d) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:
      (A) BUD less than or equal to 48 hours at controlled room temperature;
      (B) BUD up to 14 days: under refrigeration;
      (C) BUD up to 45 days: in solid frozen state at -20°C.

2. Medium-Risk Conditions:
   (a) CSPs compounded aseptically under Low-Risk Conditions but with the addition of one or more of the following conditions:
      (A) Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions;
      (B) The compounding process includes complex aseptic manipulations other than single-volume transfer;
      (C) The compounding process requires unusually long duration, such as that required to complete dissolution or homogenous mixing;
   (b) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:
      (A) BUD less than or equal to 30 hours: at controlled room temperature;
      (B) BUD up to 9 days: under refrigeration;
      (C) BUD up to 45 days: in solid frozen state at -20°C.

3. High-Risk Conditions:
   (a) CSPs compounded from non-sterile ingredients, including products manufactured for other routes of administration, or a non-sterile device is employed before terminal sterilization;
   (b) Exposure to an air quality environment that does not meet ISO 5 or better conditions for more than one hour for any of the following:
      (A) Sterile contents of commercially manufactured products;
      (B) CSPs that lack effective antimicrobial preservatives;
      (C) Sterile surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs;
   (c) Prior to terminal sterilization:
      (A) Nonsterile procedures including weighing and mixing occur in an air quality environment that does not meet ISO 7 or better conditions;
      (B) Compounding personnel are improperly gloved or garbed;
(C) Water-containing preparations are stored for more than 6 hours.

(d) In the absence of sterility testing:

(A) A preparation must be properly stored prior to administration as follows:

(i) For a BUD not to exceed 24 hours, at controlled room temperature;

(ii) For a BUD up to three days, under refrigeration;

(iii) For a BUD up to 45 days, in solid frozen state at -20°C.

(B) All nonsterile devices must be rinsed thoroughly with sterile, pyrogen-free water then thoroughly drained or dried immediately before use.

(C) Terminal sterilization is required as follows:

(i) CSP solutions passed through a filter with a nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter;

(ii) Sterilization of high-risk level CSPs by filtration must be performed with a sterile 0.22 micron porosity filter entirely within an air quality environment better than or equal to ISO 5.

(4) Immediate-use:

(a) A compounded preparation intended for immediate use may be prepared in an air quality environment that does not meet ISO 5 or better conditions and a preparer is not required to wear gloves or gown, provided that it is prepared using aseptic manipulation, only sterile ingredients, products, components and devices are used, and it meets all of the following conditions:

(A) No more than three sterile ingredients, products, components and devices are used;

(B) Only simple manipulation techniques employed;

(C) The preparer completes the preparation without interruption and with no direct contact contamination;

(D) Administration must begin within one hour of preparation;

(E) If prepared by someone other than the person who will administer the drug, labeling must include patient name, name and quantity of ingredients, name of person who prepared it, and exact one hour BUD.

(b) Provided that such preparations do not involve the use of hazardous materials, they are classified as "Low Risk".

(5) "Same-day-use": In this rule, the term "Same-day-use" means that the administration of the preparation shall commence within 24 hours from the time of preparation. A same-day-use product that is prepared using aseptic manipulation in a controlled environment with ISO 5 or better class air quality conditions, using only sterile, ingredients, products, components and devices, may be classified as Low or Medium risk provided that it meets all the following conditions:

(A) Only simple manipulation techniques employed;

(B) The environment meets or exceeds the following conditions:

(i) The mixing cabinet is located in an area that restricts airflow to prevent drafts and reduce particle counts;

(ii) There is a partitioned area around the mixing cabinet to create a buffer zone, which must be at least the width of the hood in front of the mixing cabinet;

(iii) The buffer zone must be clearly identified to prevent cardboard or outer packing material intruding into the buffer zone and to prevent any intrusion during the compounding process;

(iv) The environment is cleaned daily.

(C) The preparer completes the preparation without interruption and with no direct contact contamination;

(D) Batch preparation will not exceed eight CSPs;

(E) Administration of the preparation must begin within twenty-four hours of preparation;

(F) The preparer must use gloves, shoe covers or dedicated shoes, hair covers, gown and mask.

(6) Single-dose vial:

(a) The BUD shall be no greater than one hour from time of initial entry if accessed in an environment worse than ISO 5;

(b) The BUD may be up to 24 hours from time of initial entry if appropriately stored and accessed only in an environment better than or equal to ISO 5;

(c) Medications in a single dose ampoule may not be reused.
(7) Multi-dose vial. The BUD may be up to one month or the manufacturer's assigned BUD whichever is shorter, from time of initial entry, in accordance with the pharmacy policies and procedures.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
REPEAL: 855-045-0260

RULE SUMMARY: Division 45 is revised in its entirety.

CHANGES TO RULE:

855-045-0260
Pharmacies and Equipment
Minimum standards for pharmacies and equipment are dependent on the risk level of the products being prepared.¶

(1) Pharmacies and equipment for the preparation of immediate-use CSPs shall be in accordance with OAR 855-045-0250(4).¶

(2) Effective January 1, 2009, for preparation of low-risk level CSPs, an ISO 5 certified or better Biological Safety Cabinet (BSC), or a Compounding Aseptic Isolator (CAI), or a Laminar Airflow Hood (LAF) shall be used.¶

(3) Effective January 1, 2009, for preparation of medium-risk level CSPs, an ISO 5 certified or better BSC, CAI or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. These areas must have positive airflow unless used to prepare hazardous drugs. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.¶

(4) Effective January 1, 2009, for preparation of high-risk level CSPs, an ISO 5 certified or better BSC, CAI, or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. Unless used to prepare hazardous drugs, the buffer room or zone shall have a positive air pressure of 0.02 to 0.05 inch water column and may not contain a sink or drain. Surfaces and essential furniture in buffer rooms and zones and anterooms shall be nonporous, smooth, nonshedding, impermeable, cleanable and resistant to disinfectants. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.¶

(5) Hazardous drugs must be prepared in compliance with state and federal regulations.¶

(6) Radiopharmaceuticals must be prepared in accordance with OAR 855-042-0005 through 0025.¶

(7) Pharmacy policies and procedures must include protocols for cleaning and monitoring that include:
(a) A cleaning policy that requires the cleaning of all work surfaces in ISO 7 and 8 areas to be performed at least daily. Floors in ISO 7 and 8 areas cleaned at least monthly. Surfaces that are used to prepare CSPs must be cleaned either with a high-level disinfectant or with a medium-level disinfectant that is alternated regularly with another medium-level disinfectant. Empty shelving, walls and ceilings in anterooms and buffer rooms will be cleaned at least monthly with appropriate disinfectant solution;¶
(b) All ISO classified areas will be checked and certified by a qualified individual no less than every 6 months and whenever the LAF, BSC, or CAI is relocated or the physical structure of the buffer room or anteroom has been altered;¶
(c) Maintenance, and documentation of maintenance, of all equipment in accordance with manufacturer's specifications.¶

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
RULE SUMMARY: Revision to record keeping requirements to validate compliance with the rules and USP standards.

CHANGES TO RULE:

855-045-0270

Records ¶

(1) Except for products prepared subject to OAR 855-045-0200(4)(c), all appropriate compounding logs, formula worksheets, and documentation of the preparation must be maintained in written or electronic format, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board. Records must be stored on-site for at least one year and then may be stored in a secure off-site location if then retrievable within three business days. Required records include, but are not limited to:¶

(a) Standard operating procedures, including documented annual review;¶

(b) Personnel training, competency assessment, and qualification records, including corrective actions for any failures, including gloved fingertip and thumb sampling test and aseptic manipulation validation. The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations. At a minimum, the record must contain:¶

(A) Name and signature of the person receiving the training;¶

(B) Documentation of initial and continuing competency evaluation, to include dates and results of required elements outlined in the outlet’s policies and procedures; and¶

(C) Name and signature of the pharmacist who is designated as responsible for validation of the completion of all training.¶

(c) Engineering and environmental control records, including equipment, calibration, certification, dispensing or transfer of all compounded products must be stored in an organized manner, retained for a minimum of three years and be available for inspection. Environmental air and surface monitoring procedures and results, as well as documentation of any corrective actions taken; and¶

(d) Cleaning and disinfecting of all compounding areas and equipment.¶

(2) Records for compounding must utilize a master formulation record. All master formulation records must be approved by the pharmacist for compounded preparations, and records for all preparations, excluding those for patient specific IV admixture products, must contain, at a minimum:¶

(a) The name, strength and dosage form of the preparation;¶

(b) Physical description of the final preparation;¶

(c) Ingredient identities and amounts;¶

(d) Complete instructions for preparing the product, including equipment, supplies, and a description by the Board of compounding steps;¶

(e) The formula worksheets for compounding pharmacists. Calculations needed to determine and verify quantities of components and doses of ingredients;¶

(f) Compatibility and stability information, including references;¶

(g) Beyond-use date (BUD) assignment and storage requirements, excluding those for patient specific IV admixture products, reference source;¶

(h) Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration;¶

(i) Quality control procedures and expected results; and¶

(j) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.¶

(3) Each compounded product must be documented and the unique compounding record must include, but are not limited to, the following:¶

(a) Drug name and strength, strength and dosage form of the preparation;¶
(b) Physical description of the final preparation;

(c) Master formulation record reference for the preparation;

(d) Quantity prepared;

(e) Date and time prepared;

(f) Pharmacy unique lot number;

(g) Name, quantity and manufacturers’ lot numbers and expiration dates of all ingredients used to prepare compounded product;

(h) Beyond-use date;

(i) Name of verifying pharmacist;

(j) Names of all technicians involved in the process;

(k) Copy of the label used for the compounded product;

(l) Mixing instructions;

(k) Physical evidence of all personnel involved in each step of the process;

(l) Documentation of the proper weight of each dry chemical or drug used and measurement of each ingredient;

(m) Pharmacist documented verification that the correct formula, calculations and the correct weights or volumes of chemical or drugs were used;

(n) Total quantity compounded;

(o) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record;

(p) Certification of completion of any additional testing, including endotoxin, required by the pharmacy’s policies and procedures;

(q) Description of final preparation and Product Identification Label (PIL);

(r) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver or other person, to include corrective actions for any failures;

(s) Any other information required by the pharmacy’s policies and procedures.

(34) Record of maintenance and certifications for all equipment must be retained for a minimum of three years.

Patient-specific drug compounding is permitted for:

(a) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on routine, regularly observed patterns. Pharmacy shall retain documentation;

(b) Preparing veterinary non-patient-specific drug compounding by a pharmacy located in Oregon for a veterinary practitioner located in Oregon only. Pharmacy shall submit a request on a form prescribed by the Board and retain all documentation, including Board acknowledgment to be made available for upon inspection by the Board.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
Update on USP Compounding Standards

Esteemed Colleague,

We are writing to provide an update on the USP compounding standards.

On June 1, 2019, USP published revisions to <795> Pharmaceutical Compounding – Nonsterile Preparations and <797> Pharmaceutical Compounding – Sterile Preparations, as well as a new chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging. After publication of the revised and new compounding standards, USP received appeals on certain provisions in <795>, <797>, and <825>.

In accordance with USP’s Bylaws, the responsible Expert Committees worked with a sense of urgency to consider the information raised in the appeals and issued decisions on the appeals (see Decisions on Appeals to USP <795> and <797> and <825>). In accordance with USP’s formal appeals process, stakeholders who submitted appeals on the compounding chapters have requested further review by an appointed Panel.

USP’s Bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. In light of these appeals, USP is postponing the official dates of the revised <795> and <797> and the new chapter <825>. In the interim, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) including the section Radiopharmaceuticals as CSPs will remain official.

**General Chapter <800>** is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health.

USP plays no role in enforcement. State and other regulators may make their own determinations regarding the enforceability of <800>. USP remains committed to advancing public health and to promoting the quality of compounded preparations and the safe handling of hazardous drugs. USP will continue to communicate updates on the compounding chapters and the appeals process.

USP remains committed to advancing public health and to promoting the quality of compounded preparations and the safe handling of hazardous drugs. USP will continue to
communicate updates on the compounding standards and the appeals process. For any questions, please contact the Healthcare Quality & Safety Team at CompoundingSL@usp.org.

Sincerely,

Healthcare Quality & Safety Team
NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILING CAPTION: Prescribing practice rules updated to reflect statutory authority and incorporate Committee recommendations.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/24/2019 4:30 PM
The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@oregon.gov

800 NE Oregon St., Suite 150
Portland, OR 97232

FILED
08/13/2019 2:54 PM
ARCHIVES DIVISION
SECRETARY OF STATE

NEED FOR THE RULE(S):
ORS 689.645 and 689.649 describe intent and legal scope for the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) efforts. Per law, the Committee shall recommend a formulary of drug and devices that a pharmacist may prescribe and dispense to a patient; items must be pursuant to a diagnosis by a health care practitioner qualified to make the diagnosis and who has prescriptive authority. In Oregon, this includes physicians, nurse practitioners and PAs. The Committee shall periodically review the formulary and recommend revisions to the board and “The formulary may include post-diagnostic drugs and devices such as diabetic testing supplies, emergency refills of insulin, albuterol inhalers, epinephrine autoinjectors, smoking cessation aids, discharge medications for transitions of care, rapid strep tests and spacers.”

The law also states that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol, developed by the PHPFAC; and adopted by rule of the Board. These patient care services include smoking cessation and travel health services. For the purposes of the conversation and past minutes, a statewide protocol consists of a standardized patient assessment process and treatment care plan under which a pharmacist may prescribe and dispense a drug or device to a patient.
Rules have revisions (1) to appropriately reflect statutory authority, including repeal of OAR 855-019-0264; (2) provide clarity for documentation expectations; (3) incorporate recent PHPFAC recommendations; and (4) implement directives of 2019 SB 9.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:
2019 SB 9 (2019 OL Ch. 95)
Documents are available on the Boards website at:
https://www.oregon.gov/pharmacy/Pages/PharmacyFormularyAdvisoryCommittee.aspx

FISCAL AND ECONOMIC IMPACT:
The fiscal and economic impact is dependent upon whether or not a pharmacist chooses to participate in patient care and prescribing services, and if a pharmacy outlet chooses to offer these services. Participation is voluntary.

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

State agencies and local government are not impacted by these rules. Pharmacy stakeholders and the public may be impacted by these rules if utilized. Provision of formulary prescribing services by a pharmacist/pharmacy is voluntary.

2. a. Of the approximately 1500 pharmacy outlets registered in Oregon, about 50 to 100 are residential and may be considered small businesses. 2.b and c. The professional time to offer these services and comply with record keeping requirements may increase costs to the outlet, which may possibly be passed on to the public for prescribing services. Outlets will be required to establish and enforce policies and procedures and pharmacists must comply with the rules if they offer the services.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):
Participation is voluntary and a pharmacist is not mandated to offer patient care and prescribing services.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?
The statutorily mandated Public Health and Pharmacy Formulary Advisory Committee informed the content of these rules.

RULES PROPOSED:
855-019-0264, 855-019-0470, 855-020-0110, 855-020-0200, 855-020-0300
REPEAL: 855-019-0264
RULE SUMMARY: Repeals outdated language related to OHA protocols.
CHANGES TO RULE:
855-019-0264
State Drug Therapy Management Protocols
(1) A pharmacist may participate in statewide drug therapy management protocols developed by the Oregon
Health Authority to provide approved patient care services including but not limited to:

(a) Smoking cessation therapy;

(b) Travel health services; and

(c) Immunizations.

(2) The pharmacy must maintain written or electronic policies and procedures for each state drug therapy management protocol in which it participates.

(3) A pharmacist who participates in a state drug therapy management protocol must:

(a) Retain the required training documentation set forth by the protocol and make available to the Board upon request; and

(b) Document the prescription, administration, and patient interaction in the patient’s record, and provide notification to the patient’s primary care provider when available.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, 2015 OL Ch. 362
ADOPT: 855-019-0470

RULE SUMMARY: Implements 2019 SB 9 related to pharmacists prescribing emergency insulin.

CHANGES TO RULE:

855-019-0470
Emergency Insulin

Emergency Insulin. A pharmacist who has completed a Board approved ACPE accredited training program may prescribe and dispense emergency refills of insulin and associated insulin related devices and supplies, not including insulin pump devices, to a person who has evidence of a previous prescription from a licensed health care provider; in such cases, a pharmacist shall prescribe the lesser of a 30-day supply or the smallest available package size, and not more than three emergency refills and associated supplies in a calendar year.

Statutory/Other Authority: ORS 689 205
Statutes/Other Implemented: 2019 OL Ch. 95
AMEND: 855-020-0110

RULE SUMMARY: Rules have revisions to appropriately reflect statutory authority and to provide clarity for documentation expectations.

CHANGE TO RULE:

855-020-0110
Prescribing Practices

(1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist shall only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.

(2) A pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services via implementation of statewide drug therapy management protocols. The policies and procedures shall describe current and referenced clinical guidelines, and include but not be limited to:
   (a) Patient inclusion and exclusion criteria;
   (b) Explicit medical referral criteria;
   (c) Care plan preparation, implementation, and follow-up;
   (d) Prescribing drugs and devices pursuant to the formulary and protocol compendia;
   (e) Patient education; and
   (f) Provider notification.

(3) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond his or her pharmacist expertise by consulting with or referring patients to another health care provider.

(4) At a minimum, for each drug or device the pharmacist prescribes, the pharmacist must document the following, which constitutes the Visit Summary:
   (a) Create, approve, and maintain a drug therapy management protocol based on current and referenced clinical guidelines that must include:
      (A) Patient inclusion and exclusion criteria; and
      (B) Explicit medical referral criteria; and
   (b) Collect subjective and objective information
      (a) Assess patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient’s health history and clinical status. The pharmacist’s patient assessment shall be performed in a face-to-face, in-person interaction and not through electronic means; and
      (b) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the pharmacist’s established statewide drug therapy management protocol and policies and procedures; and
   (c) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and
   (d) Provide notification, preferably via an interoperable information technology system, to the patient’s identified primary care provider or other care providers when applicable, within five business days following the prescribing of a Compendia drug or device.

(5) The pharmacist shall maintain all records associated with prescribing for a minimum of 10 years, including but not limited to the drug therapy management protocol, the prescription record, consultation, and Visit Summary, and a copy must be made available to the patient, provider, and Board upon request and other related activities performed for a minimum of 10 years, and a copy must be made available to the patient and provider upon request. Pharmacy records must be retained and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

Statutory/Other Authority: ORS 689.205
AMEND: 855-020-0200

RULE SUMMARY: Rules have revisions to incorporate recent Public Health and Pharmacy Formulary Advisory Committee recommendations.

CHANGES TO RULE:

855-020-0200
Formulary Compendium

A pharmacist may prescribe, according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis must be documented on the Visit Summary.¶

(1) Devices and supplies:

(a1) Diabetic blood sugar testing supplies;¶
(b2) Pen needles;¶
(c3) Syringes;¶
(d4) Nebulizers and associated supplies;¶
(e5) Inhalation spacers;¶
(f6) Peak flow meters;¶
(g7) International Normalized Ratio (INR) testing supplies;¶
(h8) Enteral nutrition supplies; and ¶
(i8) Ostomy products and supplies.¶

(2) Placeholder

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649
RULE SUMMARY: Revisions incorporate recent Public Health and Pharmacy Formulary Advisory Committee recommendations.

CHANGES TO RULE:

855-020-0300
Protocol Compendium
A pharmacist may prescribe, via statewide drug therapy management protocol and according to regulations outlined in this Division, an FDA-approved drug and device listed in the following compendium:

1. Continuation of therapy
   a. A pharmacist may prescribe any non-controlled medication to extend a patient’s prescription therapy to avoid interruption of treatment; and
   b. In such cases, a pharmacist shall only prescribe a drug quantity sufficient for the circumstances, not to exceed a 60 day supply, and no more than two extensions in a 12 month period per medication.

2. Conditions
   a. Cough and cold symptom management
      A. Pseudoephedrine products for patients 18 years of age and older, verified by positive identification, not to exceed 3.6 grams or a 60 count quantity per prescription, whichever is less, or a total of three prescriptions in a 12 month period. Pharmacist must review PDMP prior to issuing prescription and retain documentation of PDMP review;
      B. Benzonatate, for the treatment of cough, not to exceed a 7 day supply;
      C. Short-acting beta agonists, not to exceed 1 inhaler with or without a spacer, or 1 box of nebulizer ampules, per year;
      D. Intranasal corticosteroids.

3. Preventative care
   a. Emergency Contraception, not including abortifacients
   b. Male and female condoms.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.645, ORS 689.649
New rules are proposed to Division 010 to address directives of 2019 HB 3030 and 2019 SB 688, to provide the spouse or domestic partner of a member of the U.S. Armed Forces stationed in Oregon a temporary authorization to practice their healthcare profession. The spouse or domestic partner must hold a current active license in good standing by another state with substantially similar requirements and must have demonstrated competency in the profession.

To implement the bills, the proposed language allows issuance of a temporary authorization for a license. The law is effective January 1, 2020.

2019 SB 688 also requires the Board to annually report to the legislature on the issuance of temporary authorization of military spouses and domestic partners. **ORS 192.245**

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**OAR 855-010-0130 Military Spouse or Domestic Partner**

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

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

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

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

   c. Applicant must complete an application for licensure, provide the Board with a valid email address, and complete and pass a national fingerprint-based criminal background check;

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

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

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

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

   A. Two years after the date of issuance;

   B. The date the spouse or domestic partner of the person to whom the authorization was issued completes the spouse’s term of service in this state; or
(C) The date the person’s authorization issued by the other state expires.

(4) A temporary authorization issued under this section is not renewable. A person may not continue to practice pharmacy unless the person is issued a license under OAR 855-019-0120, 855-019-0130, 855-025-0010 or 855-025-0012.

Statutory Authority: ORS 689.205

Statutes Implemented: ORS 689.151, 689.265, OL Ch. 142 and OL Ch. 626
Rule edits are proposed to Divisions 019 and 041 to address directives of 2019 SB 910, related to naloxone access in Oregon pharmacies. Statutory changes to Oregon’s naloxone laws intend to reduce barriers and increase access to naloxone, the life-saving opiate reversal drug.

Language in Division 019 is condensed (3 separate OARs combined into 1) and adds the new requirement for a pharmacist to offer naloxone to a patient when filling an opioid prescription for greater than a certain morphine milliequivalents (MME) per day dosage. Language in Division 041 adds requirement for written notice of naloxone availability.

Impacts: It is expected that patient awareness of and access to naloxone increases.

855-019-0450 – REPEAL

Purpose

The purpose of OAR 855-019-0450 through 855-019-0460 is to develop standard procedures for the prescribing and recordkeeping of naloxone by a pharmacist in Oregon.

855-019-0455 – REPEAL

Naloxone – Qualifications

A pharmacist acting in good faith, exercising reasonable care and who is educated in opiate overdose and naloxone rescue can prescribe naloxone and the necessary medical supplies to administer the naloxone.

855-019-0460

Naloxone – Delivery of Care and Prescribing

(1) A pharmacist acting in good faith, exercising reasonable care and who is educated in opiate overdose and naloxone rescue can prescribe naloxone and the necessary medical supplies to administer the naloxone for opiate overdose and opiate overdose training. A pharmacist using professional judgment when dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME) may offer to prescribe and provide naloxone.

(2) A pharmacist can prescribe naloxone and the necessary medical supplies to an individual or entity seeking naloxone.

(3) The pharmacist shall determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.

(4) The pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.

(5) The pharmacist shall dispense the naloxone product in a properly labeled container.
(6) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safety.

(7) The pharmacist must document the encounter and the prescription, and maintain records for three years.

(8) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.684, ORS 689.305, ORS 689.681 & ORS 689.682

855-041-2340
Naloxone - Pharmacist Prescribing of Naloxone
The pharmacy providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:

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

(2) Documentation and recordkeeping.

(3) A retail or hospital outpatient pharmacy shall provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, 689.681, 689.682, 2016 OL Ch. 100 & 2017 OL Ch. 683

855-041-2300 – REPEAL (no longer needed)

Purpose and Scope
The purpose of OAR 855-041-2300 through 855-041-2330 is to define the procedures for distributing emergency medication to certain authorized individuals for the use in emergency health circumstances. The authorized person is someone who has been trained under the guidelines set forth in 333-055-0110.20
CALCULATING TOTAL DAILY DOSE OF OPIOIDS FOR SAFER DOSAGE

Higher Dosage, Higher Risk.

Higher dosages of opioids are associated with higher risk of overdose and death—even relatively low dosages (20-50 morphine milligram equivalents (MME) per day) increase risk. Higher dosages haven’t been shown to reduce pain over the long term. One randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy (with average final dosage 52 MME) and maintenance of current dosage (average final dosage 40 MME).

WHY IS IT IMPORTANT TO CALCULATE THE TOTAL DAILY DOSAGE OF OPIOIDS?

Patients prescribed higher opioid dosages are at higher risk of overdose death.

In a national sample of Veterans Health Administration (VHA) patients with chronic pain receiving opioids from 2004–2009, patients who died of opioid overdose were prescribed an average of 98 MME/day, while other patients were prescribed an average of 48 MME/day.

Calculating the total daily dose of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose.

HOW MUCH IS 50 OR 90 MME/DAY FOR COMMONLY PRESCRIBED OPIOIDS?

50 MME/day:
- 50 mg of hydrocodone (10 tablets of hydrocodone/acetaminophen 5/300)
- 33 mg of oxycodone (~2 tablets of oxycodone sustained-release 15 mg)
- 12 mg of methadone (~3 tablets of methadone 5 mg)

90 MME/day:
- 90 mg of hydrocodone (9 tablets of hydrocodone/acetaminophen 10/325)
- 60 mg of oxycodone (~2 tablets of oxycodone sustained-release 30 mg)
- ~20 mg of methadone (4 tablets of methadone 5 mg)
HOW SHOULD THE TOTAL DAILY DOSE OF OPIOIDS BE CALCULATED?

1. **DETERMINE** the total daily amount of each opioid the patient takes.

2. **CONVERT** each to MMEs—multiply the dose for each opioid by the conversion factor. *(see table)*

3. **ADD** them together.

Calculating morphine milligram equivalents (MME)

<table>
<thead>
<tr>
<th>OPIOID (doses in mg/day except where noted)</th>
<th>CONVERSION FACTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>0.15</td>
</tr>
<tr>
<td>Fentanyl transdermal (in mcg/hr)</td>
<td>2.4</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>1</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>4</td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
</tr>
<tr>
<td>1-20 mg/day</td>
<td>4</td>
</tr>
<tr>
<td>21-40 mg/day</td>
<td>8</td>
</tr>
<tr>
<td>41-60 mg/day</td>
<td>10</td>
</tr>
<tr>
<td>≥ 61-80 mg/day</td>
<td>12</td>
</tr>
<tr>
<td>Morphine</td>
<td>1</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>1.5</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>3</td>
</tr>
</tbody>
</table>

These dose conversions are estimated and cannot account for all individual differences in genetics and pharmacokinetics.

**CAUTION:**
- Do not use the calculated dose in MMEs to determine dosage for converting one opioid to another—the new opioid should be lower to avoid unintentional overdose caused by incomplete cross-tolerance and individual differences in opioid pharmacokinetics. Consult the medication label.

**USE EXTRA CAUTION:**
- Methadone: the conversion factor increases at higher doses
- Fentanyl: dosed in mcg/hr instead of mg/day, and absorption is affected by heat and other factors

HOW SHOULD PROVIDERS USE THE TOTAL DAILY OPIOID DOSE IN CLINICAL PRACTICE?

- Use caution when prescribing opioids at any dosage and prescribe the lowest effective dose.
- Use extra precautions when increasing to ≥50 MME per day* such as:
  - Monitor and assess pain and function more frequently.
  - Discuss reducing dose or tapering and discontinuing opioids if benefits do not outweigh harms.
  - Consider offering naloxone.
- Avoid or carefully justify increasing dosage to ≥90 MME/day.*

* These dosage thresholds are based on overdose risk when opioids are prescribed for pain and should not guide dosing of medication-assisted treatment for opioid use disorder.

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html
RECOMMEND REPEAL OF 855-019-0420, PER ORS 689.689 “SUNSET” and change OAR 855-019-0400 through 0435 Statutes Implemented from ORS 689.683 to ORS 689.689

855-019-0420
Contraceptive - Delivery of Care: Age Requirements

A pharmacist may prescribe injectable hormonal contraceptives and self-administered hormonal contraceptives to a person who is:

(1) At least 18 years of age; or

(2) Under 18 years of age, only if the person has evidence of a previous prescription from a primary care practitioner or women’s health care practitioner for a hormonal contraceptive patch or self-administered oral hormonal contraceptive.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.005 & 689.683

689.689 Prescription and administration or dispensation of certain contraceptives; rules; insurance coverage. (1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may prescribe and administer injectable hormonal contraceptives and prescribe and dispense self-administered hormonal contraceptives to a person who is:

(a) At least 18 years of age, regardless of whether the person has evidence of a previous prescription from a primary care practitioner or women’s health care practitioner for an injectable hormonal contraceptive or a self-administered hormonal contraceptive; or

(b) Under 18 years of age, only if the person has evidence of a previous prescription from a primary care practitioner or women’s health care practitioner for an injectable hormonal contraceptive or a self-administered hormonal contraceptive.

(2) (a) The board shall adopt rules to establish, in consultation with the Oregon Medical Board, the Oregon State Board of Nursing and the Oregon Health Authority, and in consideration of guidelines established by the American Congress of Obstetricians and Gynecologists, standard procedures for the prescribing of injectable hormonal contraceptives and self-administered hormonal contraceptives by pharmacists.

Note: The amendments to 689.689 (formerly 689.683) by section 3, chapter 649, Oregon Laws 2015, become operative January 1, 2020. See section 6, chapter 649, Oregon Laws 2015. The text that is operative on and after January 1, 2020, including amendments by section 3, chapter 289, Oregon Laws 2017, is set forth for the user’s convenience.
Staff has identified the requirement to provide the original FPGEC certificate as a potential barrier to licensure for foreign pharmacy graduates and proposes these minor revisions to OAR 855-019-0150 and 855-031-0010 (see 2019 SB 855).

Additional background: The agency now utilizes NABP’s e-connect system to assist with licensure processes, including primary source verification. Foreign pharmacy graduates are only issued a single FPGEC certificate and it cannot be replaced.

Foreign Pharmacy Graduates

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

(a) Provide a copy of a valid visa permitting full time employment;
(b) Provide a copy of the original certificate issued by the NABP Foreign Pharmacy Graduate Examination Committee (FPGEC); and
(c) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 91 days. This score shall only be valid for one year unless the Board grants an extension;
(d) After having completed the required number of intern hours, pass the MPJE with a score of not less than 75. A candidate who does not attain this score may retake the exam after a minimum of 30 days. The MPJE score shall only be valid for 6 months unless extended by the Board.

Intern License Application

(1) Applications for licensure as an intern may be obtained from the Board office or from the Board web site at www.pharmacy.state.or.us.

(a) Failure to completely, accurately and honestly answer all questions on the application form for licensure or renewal of licensure is grounds for discipline;
(b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.

(2) The Board may issue a license to a qualified intern after the receipt of:

(a) A completed application;
(b) Payment of the fee prescribed in OAR 855-110-0005;
(c) A current, passport regulation size photograph (full front, head to shoulders);
(d) Any fingerprint card or other documentation required by the Board to conduct a criminal background check; and

(e) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study, except for foreign pharmacy graduates who must:

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

(B) Provide a copy of the original certificate issued by the Foreign Pharmacy Graduate Equivalency Examination Committee; and

(C) Provide evidence that they have passed the Test of English as a Foreign Language (TOEFL) Internet-based Test (IBT) with a minimum score of 26 in Speaking, 21 in Reading, 18 in Listening and 24 in Writing, however scores will be accepted until June 30, 2010 from candidates who have already passed or are scheduled to take the TOEFL and the Test of Spoken English (TSE)……
Revisions to Division 080 – Controlled Substances are provided to address directives of 2019 SB 71, which add sedatives and analgesic medications for use by a humane society or animal control agency personnel to humanely euthanize injured, sick, homeless or unwanted domestic pets and other animals. Registration with the Board as an Animal Euthanasia Drug Outlet will permits the utilization of a limited number of sedative and analgesic drugs for these purposes.

Drug outlet expectations for drugs being administered on-site include: (1) Proper acquisition of drugs, from Oregon registered distributors; (2) Proper and secure drug storage; and (3) Documentation. Recordkeeping requirements related to controlled substances must comply with all related federal and state regulations and are subject to state and federal regulatory oversight. Many sedative and analgesic drugs are “highly divertible”, therefore an outlet’s recordkeeping must be robust.

855-080-0100
Animal Euthanasia

(1) The following requirements shall be met in order for a humane society or animal control agency to be registered or registration renewed to allow the purchase, possession and administration of sodium pentobarbital and sedative and analgesic medications for euthanizing injured, sick, homeless or unwanted domestic pets and other animals:

(a) Registration as an animal euthanasia drug outlet is limited to animal control agencies and humane societies for the purpose of purchasing, possessing, or administering sodium pentobarbital and sedative and analgesic medications to euthanize animals. Registration requires submission of an application and a certificate of registration will be issued upon approval. All registrations and renewals shall be accompanied by an annual fee defined in Division 110 of this chapter.

Note: As written, the responsibility for CS security, oversight, etc. falls exclusively to the Animal Euthanasia Drug Outlet, not to a veterinarian. Staff recommends Board discussion, prior to sending to rulemaking hearing, due to the nature of drugs being added to their ‘formulary’. Options include the addition of a Designated Representative, Responsible Clinic Representative, etc. with articulated responsibilities.

(b) Drug Storage. All supplies of sodium pentobarbital and sedative and analgesic medications shall be acquired from an Oregon registered distributor, and kept in a locked cabinet. An assigned person designated in writing shall be responsible for the security of the sodium pentobarbital and sedative and analgesic medications. Such designated person shall allow withdrawal of the drug only to a person certified by the Oregon State Veterinary Medical Examining Board to administer sodium pentobarbital and sedative and analgesic medications;

(c) Records. The following records shall be made at the time of the occurrence and shall be maintained for a minimum of three years, available for inspection by the Board of Pharmacy and its agents:
(A) A record of the withdrawal of sodium pentobarbital **and sedative and analgesic medications**, signed by the person who takes possession of the sodium pentobarbital **and sedative and analgesic medications** for administration;

(B) A record of the weight, species of animal and dosage of each drug administered for euthanasia signed by the person who administers the drug and by the designated person responsible for security;

(C) A record of all wastage of each drug signed by the person administering the each drug and the designated person responsible for security; and

(D) A weekly record of verification of the stock of each drug on hand, minus the amounts withdrawn for administration, signed by the designated person responsible for security;

(E) A record of disposal of any expired or unwanted sodium pentobarbital and sedative and analgesic medications. Disposal shall be in a conformance with federal regulations 21 CFR 1307.21.

(F) **Complete and retain the annual Self-Inspection report by February 1 each year.**

**(c)(d)** Audits. The registrant shall submit to random audits of records and analysis of prepared solutions by the **DEA, and State Board of Pharmacy or its agents.**

(2) The humane society or animal control agency shall notify the Board in the event of a significant drug loss or violation related to drug theft within one (1) business day.

(3) At the time a Report of Theft or Loss of Controlled Substances (DEA Form 106) is sent to the Drug Enforcement Administration (DEA), a copy shall be sent to the Board.

(2) The fee for registration shall be paid as specified in division 110 of this chapter of rules.

(3) The Board will suspend or revoke the registration of any humane society or animal control agency **animal euthanasia drug outlet** which allows a person to administer sodium pentobarbital or sedative and analgesic medications who is not certified by the Oregon State Veterinary Medical Examining Board to administer such drug.

Statutory/Other Authority: ORS 475.095, 475.190 & 689.205

Statutes/Other Implemented: ORS 689.151 & 689.155
Committee Members

- Evon Anukam, RPh
- Kat Chinn, RN MSN
- Sean Jones, MD
- Amy Valdez, RPh
- Amy Burns, RPh
- Mark Helm, MD
- Helen Turner, DNP

OBOP Staff to Committee

- Joe Schnabel, Executive Director
- Fiona Karbowicz, Pharmacist Consultant
- Rachel Melvin, Operations Policy Analyst
- Karen MacLean, Administrative Director
- Brianne Efremoff, Compliance Director

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Desired Outcome</th>
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<tbody>
<tr>
<td>Welcome</td>
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</tr>
<tr>
<td></td>
<td>➢ Roll call, all Committee members present</td>
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<td></td>
<td>➢ Agenda review and approval</td>
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**Motion to approve agenda was made and unanimously carried (Motion by Helm, second by Chinn).**

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<tr>
<th></th>
<th>5.29.2019 Minutes review and approval</th>
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<tr>
<td>Motion to approve 5/29/19 Minutes was made and unanimously carried (Motion by Chinn, second by Jones).</td>
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</table>

Committee Business (times are approximate)

- High Priority Items – none
- Committee Protocol Development –
  - **NRT and Non-NRT Smoking Cessation**
    - Pharmacist Consultant Fiona Karbowicz introduced the subject matter experts to the Committee and provided background information related to the NRT and Non-NRT Smoking Cessation concept.
    - SMEs: Kiyomi Lehman – phone, Jennifer Davis, Sharon Rask – present
    - SMEs: Julie Himstreet, Laura Borgelt – not present
    - October 2018 meeting motion: RPH may prescribe individual or multiple NRT, OTC/Rx, for smoking cessation
    - January 2019 meeting minutes included details related to the creation of a standardized patient assessment process and treatment care plan for smoking cessation/prescribing of varenicline and bupropion. At that time, the Committee recommended a motion to include a number of patient safety elements, including the utilization of a standardized questionnaire with specific questions about mental health and suicide to assist with the pharmacist’s assessment and referrals. Also included specific inclusion criteria, such as 
      - age 18, prescribing limitations, mandated follow-up parameters, and a minimum education requirement of 2 hours CE.
    - Committee began work on finalizing the standardized questionnaire, with the assistance of SME Lehman. They determined that the questionnaire should be utilized
for all patients seeking tobacco cessation services, and therefore asked that it be edited to flow from NRT to non-NRT questions. They requested it be designed with a pharmacist reference guide to indicate clear referral points and cautionary information to assist with product selection and counseling.

- This concept, with finalized documents will be reviewed again at the next meeting, scheduled for October 25, 2019.

- **Pre-Travel Consult Medications**

- Fiona introduced the subject matter experts to the Committee and provided background information related to travel medications.

- SMEs: Kayla Hensley, Steve Nzele, Kaylie Yoon and Jennifer Davis – present

- January 2019 meeting minute highlights include:
  
  - Link to the CDC’s Health Information for International Travel, aka the Yellow Book, was provided for background.
  
  - The Committee discussed that a substantial amount of education would be needed for a pharmacist to prescribe in these circumstances and that ongoing education would be necessary. Committee’s motion recommended: completion of APhA immunization training or equivalent, plus 4 hour travel vaccination class or equivalent; and 1 hour travel medication related CE every 2 years.
  
  - This would be a valuable service in rural areas where travel services are not generally available.
  
  - The Committee stated that assessment regarding vaccination should be conducted at this time also.

- Motion to recommend addition of the four categories of Preventative Travel Medications including:
  
  - Malaria Prophylaxis (chloroquine, atovaquone/proguanil, mefloquine, doxycycline);
  
  - Traveler's Diarrhea Prevention and Treatment (ciprofloxacin, azithromycin);
  
  - Acute Mountain Sickness Prophylaxis (acetazolamide); and
  
  - Motion Sickness (Scopolamine patches, promethazine tablets/suppositories, meclizine)

- At the May 2019 meeting, the Committee discussed direction to build items into Statewide Drug Therapy Management Protocols for use by the ‘everyday pharmacist’. Therefore, Committee recommendations will be specific about the drugs that may be prescribed, and include the guidelines for therapy that are safe for patients. The CDC’s *Health Information for the International Traveler*, known as the Yellow Book, is the primary required source for pharmacists to use when providing travel health services.

- Committee began work on finalizing the standardized questionnaire and algorithmic patient assessment and treatment care plan process, with the assistance of subject matter experts.

- This concept, with finalized documents will be reviewed again at the next meeting, scheduled for October 25, 2019.
Committee Protocol Development (continued)

- Non-Occupational Post Exposure Prophylaxis
  - Fiona introduced the subject matter experts to the Committee and provided background information related to the non-occupational post exposure prophylaxis (n-PEP) concept.
    - SMEs: Jen Lee, Jenny Mappus, and Geoffrey L’Heureux - present
    - The SMEs provided a detailed summary of the draft protocol outline submitted, to help inform the Committee’s development of a standardized patient assessment process for a pharmacist to provide n-PEP services.
    - The Committee began work on finalizing the standardized questionnaire and algorithmic patient assessment and treatment care plan process, with the assistance of the SMEs.
    - This concept, with finalized documents, including a questionnaire, and decision-making process outlined with clear referral points and patient care follow-up requirements will be reviewed again at the next meeting, scheduled for October 25, 2019.
    - The SMEs strongly suggest additional continuing education to go along with this protocol. The Committee additionally discussed the importance of a pharmacist’s confidence in managing these sensitive patient consultations and motivational interviewing education is under consideration.

- Rules development / implementation update
  - It is anticipated that the Board will discuss edits to Division 020 rules that reflect Committee processes, expectations and compendia items at the August 8, 2019 meeting. (Note: Rules were noticed for a September 24, 2019 Rulemaking Hearing.)
  - The Committee reviewed the Statewide Protocol Draft Template as well as each of the draft for codified items. The Board will review and possibly approve these for publication at the August meeting.

- Items to explore
  - The Committee considered the two concepts received since the last meeting, Concept 2019-016 Condoms and Concept 2019-017 Female Condoms.

Motion to recommend adding male and female condoms to the Board’s Protocol/Formulary list, following established elements, including patient assessment, notification of provider upon prescribing, and documentation, among others was made and unanimously carried (Motion by Chinn, second by Anukam).

Upcoming Meeting Schedule – subject to change

- Next meeting
  - August 28, 2019 – (brief conference call to approve minutes)
    - October 25, 2019 – room 1D
  - November 20, 2019 - (brief conference call to approve minutes)
    - March 6, 2020 – room 1D

Motion to adjourn at 3:50pm was made and unanimously carried (Motion by Burns, second by Chinn).
**PETNET Solutions – Security Request**

**Situation:** Request  
PETNET Solutions (RP-0001824), a nuclear pharmacy located in Portland, Oregon is seeking review and approval of a long standing exception to pharmacy security rules.

**Background:**  
Details:  
- The PET radiopharmaceutical cyclotron is located in a secured room to minimize radiation exposure. Non-pharmacist personnel need access to the cyclotron at times when ambient radiation levels are lowest for maintenance and repair of the cyclotron after hours, when a pharmacist is not present.  
- Non-pharmacist personnel will not take part in the communication of prescription orders, will not prepare finished drugs, or perform any task considered a professional act subject to the practice of pharmacy. Pharmacy records and legend drugs are otherwise secured.  
- The Board has approved this specific request since at least 2001; most recent approval was granted in October 2014 for 5 years.

**Contact:** Melissa Leslie, Regulatory Affairs Specialist, 810 Innovation Drive, Knoxville, TN 37932

**Assessment:**  
Related rules:  
OAR 855-041-1020 Security of Prescription Area  
(3) When there is no pharmacist present, the pharmacy shall be secured to prevent entry. All entrances to the pharmacy shall be securely locked and any keys to the pharmacy shall remain in the possession of the pharmacist-in-charge and other employee pharmacists as authorized by the pharmacist-in-charge. When there is no pharmacist present, and it is necessary for non-pharmacist employees or owners to have access to the pharmacy, the prescription area shall be secured from entry as described in OAR 855-041-2100.  
(5) Any security system deviating from the requirements of this section, except as provided in OAR 855-041-6310, shall be approved by the Board prior to implementation. Requests for such approval shall be in writing and provide a detailed description of the proposed system. A written description of such security system, as approved by the Board, shall be maintained in the pharmacy.

**Recommendation:**  
Staff recommends granting approval of request for 5 years (return 10/2024)

**Date:** 7/3/2019
July 3, 2019

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

Re: Request for Exception, Pharmacy Permit RP0001824

To Whom It May Concern:

In correspondence dated November 20, 2014, the Oregon Board of Pharmacy granted PETNET Solutions, Inc. permission for after-hours access to the radiopharmacy area by cyclotron maintenance personnel. The request was signed and approved by Gary Minor, Compliance Director and expires October 8, 2019. A copy of the letter is included for convenience.

In a PET radiopharmacy, the cyclotron is stationed in a secured room or vault with a single access door to minimize radiation exposure to operating personnel. The computer control station, which operates the cyclotron, is located just outside the room in the pharmacy area. All cyclotron operation, maintenance, and repairs require access through the pharmacy area. As described in the original request, non-pharmacist personnel need access to the cyclotron at times when ambient radiation levels are lowest so that they can safely maintain, repair, and operate the machine and ensure that it is up and running when the pharmacist arrives.

In support of this request, as before, non-pharmacist personnel will not take part in the communication of prescription orders, will not prepare finished drugs, or perform any other task that may be construed as a professional act subject to the practice of pharmacy. Pharmacists will secure prescription records and legend drugs.

We are requesting that the previous exception be re-affirmed for the maximum period allowed by the Board to allow the maintenance and repair of the cyclotron after hours, when a pharmacist is not present.

Please contact me with questions or if further documentation is required to support this request.

Respectfully,

Melissa Leslie
Regulatory Affairs Specialist
melissa.leslie@petnetsolutions.com
865.218.2734, direct
November 20, 2014

PETNET Solutions, Inc
Attn: Doug Derry
810 Innovation Dr
Knoxville, TN 37932-2562

Re: Waiver

Dear Mr. Derry

At the Board’s October 2014 meeting, the Board reviewed the written materials requesting that the previous exception be re-affirmed for the purpose of allowing the maintenance and repair of the cyclotron after hours without the presence of a licensed pharmacist.

Based upon the information obtained, the Board has determined that this waiver has been approved.

This waiver is valid until October 8, 2019 (5 years from date of letter). After this date, a new waiver has to be requested. A copy of this notification should be kept with your Pharmacist-in-Charge self inspection report.

Sincerely,

[Signature]

Gary Miner
Compliance Director

Cc: Marcus Watt, R.Ph., Executive Director
Oregon Board of Pharmacy Licensing Representative
**SBAR:** Heather Loudon-Howley (RPH-0017301): Waiver Request – Bay Area Hospital

<table>
<thead>
<tr>
<th>Situation:</th>
<th>Waiver Request – PIC of multiple pharmacy drug outlets. At the June Board Meeting, the Board approved the waiver for Susanne McClelland, individually, of Bay Area Hospital to be the PIC and oversee three pharmacies. Heather Loudon-Howley has replaced Susanne McClelland as the PIC.</th>
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<tbody>
<tr>
<td>Background:</td>
<td>Regulations:</td>
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<td></td>
<td>• OAR 855-019-0300(3) A pharmacist may not be designated PIC of more than two pharmacies without prior written approval by the Board. If such approval is given, the pharmacist must comply with the requirements in sub-section (4)(e) of this rule.</td>
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<td>• OAR 855-019-0300(4)(e) The PIC must perform the following the duties and responsibilities: A pharmacist designated as PIC for more than one pharmacy shall personally conduct and document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC Compliance Audit Form provided by the Board.</td>
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<tr>
<td>Description:</td>
<td>• Nothing has changed in the hospital’s course of business and they understand that there is a quarterly compliance audit that must be conducted at both locations on the form provided by Board.</td>
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<td>• The Cancer Center registration change from a drug room registration to a pharmacy registration has been completed. The new license number is: RP-0003512.</td>
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<td>• PIC Loudon-Howley currently conducts daily huddle meetings to discuss operations/patient care and physically is present several time a month to oversee processes and general communication with the Cancer Center.</td>
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<tr>
<td>Contact information:</td>
<td>Heather Loudon-Howley, RPH-0017301 1775 Thompson Rd Coos Bay, OR 97420 Phone: 541-269-8490</td>
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<tr>
<td>Assessment:</td>
<td>Drug outlet registrations impacted are:</td>
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<tr>
<td></td>
<td>• IP-0000616 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay)</td>
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<td></td>
<td>• RP-0000822 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay)</td>
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<td>• RP-0003512 (Bay Area Hospital Pharmacy, 1775 Thompson Rd. Coos Bay)</td>
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<td>o Issue date: 9/5/19</td>
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<td>Recommendation:</td>
<td>Staff recommendation for approval to replace Susanne McClelland as PIC with Heather Loudon-Howley for Bay Area Hospital waiver: Grant (5 year; traditional language)</td>
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Inquiry Date: 7/26/2019
Board review: October 2019 meeting
Oregon Board of Pharmacy  
800 NE Oregon St. Suite 150  
Portland, OR 97232  

July 26, 2019

Dear Members of the Board

In section 855-019-0300 of Pharmacist-in-Charge, section (3) states “A pharmacist may not be designated PIC of more than two pharmacies without prior written approval by the board. If such approval is given, the pharmacist must comply with the requirements in sub-section (4)(e) of this rule.” I am writing to formally request a waiver for the PIC at Bay Area Hospital to oversee three pharmacies. Nothing has changed in the hospital’s course of business, however, we have been notified that our Cancer Center registration will need to change from a drug room over to retail drug outlet because we have a pharmacist at the center from open to close (7:00-17:30).

Currently, consulting pharmacist (Daniel Hendrickson; RPH – 0016051) along with a F/T pharmacist from the I/P side of the hospital staffs with 1.5 techs who assist with compounding, materials replenishment and inventory. We have daily huddle meetings to discuss operations/patient care and I am over there several times a month to follow up on staffing, processes and general communication with the Cancer Center. We have submitted a licensure request for Cancer Center pharmacy as the second retail drug outlet for the hospital and its’ third license. On the inpatient side, we are currently registered as both an institutional drug outlet with controlled substance registration and a retail drug outlet with controlled substance registration. We understand that if the Board gives Bay Area Hospital Pharmacist in Charge a waiver that a quarterly compliance audit must be conducted at both locations on the form provided by Board. Thank you in advance for your time and consideration.

Respectfully,

Heather Loudon-Howley (RPH-0017301)  
Bay Area Hospital Pharmacy  
1775 Thompson Rd  
Coos Bay, OR 97420  
541-269-8490
Columbia Memorial Hospital – TCVP 1 year Follow-Up

| S | Situation: PIC Nate Neremberg from Columbia Memorial Hospital (IP-0000112) implemented TCVP in August 2018 and has submitted their 1 year follow-up report for OBOP review and approval. |
| B/A | Background/Assessment: Report provided |
| R | Recommendation: Discuss report content and accept. Have Columbia Memorial Hospital report back in June 2023, based on original OBOP approval letter dated 9/12/2018. |

Date: 8/26/2019
September 12, 2018

Columbia Memorial Hospital
Attn: Nate Nerenberg, Pharm.D., BCPS
Pharmacy Manager
Inpatient Pharmacy Services
Nnerenberg@columbiamedical.org

Re: TCVP Program Request

Board of Pharmacy,

Please find the attached report in reference to this letter from one year ago.

Thank you,

Nate Nerenberg

At the Oregon Board of Pharmacy’s August 2018 Board meeting, the Board reviewed your request to implement TCVP at Columbia Memorial Hospital.

The Board approved your request to implement TCVP. This approval is valid for five (5) years, until June 2023. At that time, the request will need to be reviewed by the Board. The Board has requested an update on the program at their October 2019 meeting. The report must be received in the Board office by 9/1/2019. Please see the enclosed Questions that must be answered.

Please retain a copy of this letter in pharmacy records and ensure it is available for inspection.

If you have any questions, or if we can be of further assistance, please contact Compliance Director, Brianne Efremoff at Brianne.efremoff@oregon.gov. Please provide your name, your preferred contact method and information, and your concerns. Alternatively, you may contact our office at the address and phone number listed above.

Sincerely,

Karen S. MacLean
Administrative Director

CC: Oregon Board of Pharmacy Licensing file (IP-0000112)
Brianne Efremoff, Compliance Director
**Technician Checker Validation Program – Year One Questions**

1. Oregon Pharmacy Drug Outlet registration number to which this request relates: IP-0000112.

2. When was program implemented? - August of 2018

3. General comments on the program

   This program was considered at our facility because we had been attempting for several years to improve the quality of direct patient-care activities provided by our pharmacist team. In an effort to optimize workflows in the inpatient pharmacy, this program was assessed, developed, and implemented a year ago. Prior to implementation, we had hit a wall in the percentage of inpatients who received timely pharmacist mediated medication reconciliation. After implementation, the numbers steadily climbed from around 90% to nearly 99% of our inpatients receiving face-to-face pharmacist mediated medication reconciliation within 24 hours of their admission, with a decrease in average time from over 13 hours to about 10 hours.

   The program has also allowed for more consistent daily patient check-ins with our pharmacists, improved discharge counseling, and more collaboration between our outpatient and inpatient pharmacy departments with discharge prescription counseling of our surgical patients. The pharmacy staff also enjoys the improved workflow.

4. Quality Assurance/ Did you catch error?

   Since the inception of this program, our technicians routinely catch about one to three potential fill errors a month in our automated dispensing cabinets, which we document, correct, and then review to ensure accuracy and excellence in our pharmacy operations. We have also implemented mandatory barcode scanning upon filling of our automated dispensing cabinets as an additional safety check.

5. Did training program and materials work?

   Yes, the training program and materials were successful in giving our technician checkers an accurate understanding of their responsibilities, requirements of the program, and in ensuring compliance with it.

   a. Were any revisions needed for training program/materials?

   No. The training materials went through several revisions prior to implementation of the program. There has only been a minor change in format to the “Quality Assurance Check Form” to make documentation more consistent from the initial validation step onward.

6. Any problems with the rules and any recommended changes?

   I have none. I have polled my staff as well, and they are pleased with how the program is currently set up and did not have any suggestions for recommended changes.

7. Suggestions for others considering utilizing TCVP?

   I have polled my staff and they feel like the TCVP has been a good program for more fully utilizing the skillsets of all pharmacy staff. I would tend to agree, and would say that for facilities looking to optimize their workflows (especially smaller facilities with limited resources), it is a tremendously helpful program to adopt.
The technicians have further stated that they enjoy the responsibility and that they liked the length of the training process, and the consistent quality checks as it helped build their confidence in the new process for them.

My suggestions to others would be to make sure to reach out to other TCVP facilities in the beginning. Get help to make sure you have a well-developed plan in place, with all of the necessary training materials, quality assurance checks, and documentation forms prepared well in advance so when it is time to start your program, things go as smoothly as possible. This was a significant help to us in ensuring the success of our program.

8. Questions to Board of Pharmacy?

None at this time. Thank you!
State of Oregon
Oregon Board of Pharmacy

Policy: Licensee’s on Probation (Drug and alcohol violations)

Effective Date: Revised Pending Approval

Applicability: Board, Agency Staff, Pharmacists, Interns, Pharmacy Technicians

References: none

1) Purpose: To establish guidelines of what is expected of licensee’s on probation with Board screening and what will happen if they fail to meet those guidelines.

2) Policies:
   a) Toxicology Testing
      i) Licensee must register with Board’s designated testing facility within ten (10) days of their Consent Order becoming final.
      ii) Licensee must check-in with testing facility via internet or phone each day Monday – Saturday between 5 am and 2 pm
      iii) Licensee must test for the chosen panel option (given to them when they check-in daily). It is the licensee’s responsibility to ensure they are tested for the correct panel.
      iv) Licensee must be tested on the day they are chosen for testing.
      v) Licensee must notify the Board if finances, work, etc, have or will, result in lapsed testing (suspension)
      vi) Licensee may use outside service to complete their daily check-ins as long as they understand that it is their complete responsibility to ensure the check-in is made. If the service fails, it will count against the licensee.

   b) Vacations/Vacation Requests – see Toxicology Exemption Policy
      i) Licensee must provide a minimum of 14 day notice to testing facility prior to starting vacation
      ii) Licensee must be able to check-in and test if necessary
      iii) Licensee may not travel outside the country or anywhere that would restrict toxicology testing the first year of probation
      iv) Licensee must arrange for alternate testing site if out of area

   c) Employer notification forms
      i) Licensee must submit an Employer notification form at the beginning of probation, any time there is a change in management or a new PIC, and annually according to Consent Order

Last approved 12.17.15
d) Probation Violations
   i) Non-approved positive toxicology tests
      (1) Any positive test result in which the licensee has not provided a copy of a valid
          prescription prior to the test will be investigated by a Pharmacy Inspector and be
          reported to the Board
          (a) The frequency of toxicology testing will be increased to weekly during this period
   ii) Missed/Late Calls
      (1) Licensees are permitted 3 missed calls per 12 month period (January – December).
      (2) At the time of a fourth missed call; the licensee will be scheduled to test as soon as
          possible.
      (3) Licensees will be scheduled to test following each missed daily call after the fourth
          missed call.
      (4) Toxicology tests scheduled due to a missed daily call are not considered as part of or
          counted as part of the required annual testing frequency.
   iii) Missed Tests
      (1) If licensee fails to call in on a scheduled test day, their annual testing frequency will be
          increased by four (4) tests per year
      (2) If licensee fails to call on two (2) consecutive test days in a row, licensee will be
          interviewed by Board staff
      (3) If licensee calls, is informed it is a testing day but does not provide a sample on that
          day, they will be interviewed by Board staff and toxicology tests will be increased to
          weekly
iv) Dilute and/or Low Creatinine Samples
      (1) The Board defines a sample as dilute if the sample has a creatinine of less than 20mg/dl
          and a specific gravity less than 1.003. Low Creatinine is defined as a sample with a
          creatinine result of less than or equal to 20mg/dl.
      (2) At the time of a first dilute or low creatinine sample, the licensee will be sent a letter
          notifying them of the dilute sample and advising them to review their testing day
          procedures.
          (a) The licensee will be tested on the next available day.
      (3) At the time of a second dilute or low creatinine sample, the sample will be tested to the
          lowest level of detection (LLD) for drugs and/or alcohol. The additional charge
          associated with this is the licensee’s responsibility.
          (a) If the LLD is positive, the sample will follow the positive tests section of this
              policy.
          (b) The licensee will be sent a letter notifying them of the dilute sample and be required
              to submit an action plan to prevent further dilute or low creatinine samples.
          (c) The licensee will be recommended to have a medical evaluation to determine why
              they are producing dilute or low creatinine specimens.
          (d) The licensee will be tested on the next available day.
      (4) At the time of a third dilute or low creatinine sample within a one year period, the
          sample will be tested to the lowest level of detection (LLD) for drugs and/or alcohol.
          The additional charge associated with this is the licensee’s responsibility.
          (a) If the LLD is positive, the sample will follow the positive tests section of this
              policy.
          (b) The licensee will be required to have a medical evaluation to determine why they
              are producing dilute or low creatinine specimens.

Last approved 12.17.15
(c) The licensee will be tested on the next available day.
(5) If a medical problem is found to be causing the dilute or low creatinine samples, and cannot be reasonably resolved, it will be noted and further dilute or low creatinine samples will be randomly tested to LLD.
(6) If a medical problem is not found, and the dilute or low creatinine samples are negative when tested to LLD, the licensee’s probation compliance history will be reviewed for other violations. Licensee may be required to have increased toxicology testing frequency and/or a drug and alcohol evaluation.
(7) At the time of a fourth dilute or low creatinine sample within a one year period, the case will automatically be referred to the Board for review.

v) Suspension of account due to non-payment
(1) If licensee’s testing facility account is suspended due to non-payment, they shall contact the Board immediately
(2) Once their account is made active, they will be tested on the next possible day

e) Additional Tests
i) Any tests that are in addition to the annual frequency will be on the licensee’s current testing option

f) Requests for modification of probation requirements
i) Requests must comply with all restrictions in Licensee’s Order
ii) Requests will be presented to the Board at the next available meeting