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

<table>
<thead>
<tr>
<th>Wednesday, December 11, 2019</th>
<th>Thursday, December 12, 2019 @ 8:30AM – Conference Room 1A</th>
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</thead>
<tbody>
<tr>
<td>OPEN SESSION, Cyndi Vipperman, CPhT, Presiding</td>
<td>Menu Items</td>
</tr>
<tr>
<td>Roll Call</td>
<td>Action Necessary</td>
</tr>
<tr>
<td>Agenda Review and Approval</td>
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<tr>
<td>EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (L).</td>
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<tr>
<td>Deliberation on Disciplinary Cases and Investigations</td>
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<tr>
<td>Contested Case Deliberation pursuant to ORS 192.690(1) – Not open to the public</td>
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<tr>
<td>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.</td>
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<td>Adjourn</td>
<td>Action Necessary</td>
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THURSDAY, December 12, 2019

| OPEN SESSION, Cyndi Vipperman, CPhT, Presiding | Action Necessary |
| Roll Call |  |
| Motions related to Disciplinary Actions – Efremoff |  |
| Acknowledge Tom Cowan Sr Assistant Attorney General - 15 yrs with the Board |  |

VI. GENERAL ADMINISTRATION

| Policy Discussion re SB 9 – Schnabel/Karbowicz |  |
| Rules | Action Necessary |
| Review Rulemaking Hearing Report & Comments - #A-A2 Melvin |  |
ii. Consider Adoption of Rules – *Karbowicz*  
   1. Div 006 & 045 – Drug Compounding and Definitions  
   3. Div 019 & 041 – Naloxone revisions -  
   4. Div 019 - Contraception Prescribing (age 18 law sunset) ORS 689.689  
   5. Div 019 & 031 – FPGEC –  
   6. Div 080 – Controlled Substances – Animal Euthanasia -  

iii. Consider Adoption of Temporary Rules – *Karbowicz*  
   1. Div 041 Prescription readers  

iv. Consider sending rules to Rulemaking Hearing – *none*  

**c. Public Health and Pharmacy Formulary Advisory Committee - *Karbowicz***  
   i. Committee Meeting and Recommendations update  

**d. Discussion Items:**  
   i. Policy Items for Discussion:  
      1. Cultural Competency CE (2019 HB 2011) and OBOP CE  
      2. OSU Emergency Insulin Training Program  
   (topic to occur after 1:00PM) 
   
   ii. Waivers and Requests:  
      1. TCVP – *None*  
      2. Request to schedule Clonazolam – *Schnabel/Karbowicz*  
   iii. Other  
      1. Strategic Planning update – *Schnabel/MacLean*  
      2. OR Opioid Tapering Guidelines – *Schnabel*  
      3. CBD Update – *Efremoff*  
      4. Drug Outlet Inspections – *Efremoff*  
      5. Possible OVMEB appearance approx. 11:00  

**VII. ISSUES AND ACTIVITIES* (Items in this section may occur anytime during the meeting as time allows)**  
   i. Reports:  
      1. Board President/Members  
      2. Executive Director  
      3. Board Counsel  
      4. Compliance Director  
      5. Pharmacist Consultant  
      6. Administrative Director  
      7. Licensing Manager  

   ii. Financial/Budget Report - *F-F2 MacLean*  

   iii. Board Meeting Dates  

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*NOTE: The Board may rearrange its agenda to accommodate the Board or Members of the public.*
iv. Rulemaking Hearing Dates
(The following dates are reserved for potential rulemaking hearings and identified only for planning purposes and approved by the Board. Actual Rulemaking Activities will be noticed as required by law and may deviate from this schedule as needed.)

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

v. Conferences/Meetings

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

FUTURE MEETINGS
7. NABP Board Member Forum – Jan 28-29, 2020 – Vipperman

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 – yes add dates – #CONSENT 1
b. MPJE Scores – yes add dates - #CONSENT 2
c. License/Registration Ratification September 25, 2019 – December 4, 2019 - #CONSENT 3
d. Pharmacy Technician Extensions – none
e. Board Minutes – October 2-3, 2019 - #CONSENT 4
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: November 26, 2019
To: Oregon Board of Pharmacy
From: Rachel Melvin, Hearings Officer

Subject: Hearings Officer’s Report on Rulemaking Hearing

Hearing Date: November 26, 2019
Hearing Location: Portland State Office Building, Room 1A

Title of Proposed Rules:
- Divisions 045 & 006 – Drug Compounding and Definitions
- Division 080 – Animal Euthanasia Drug Outlet Requirements
- Divisions 010, 019, 031 & 041 – Military Spouse/Domestic Partner, Foreign Pharmacy Grads, Naloxone and Intern License Application

The rulemaking hearing on the proposed rules was convened at 9:31AM. No oral testimony was provided on the proposed rules. The hearing adjourned at 9:50AM. The hearing was recorded and copies of the proposed rules were available for attendees.

Attendance included 9 public, 4 OBOP Staff & 1 OBOP Intern, OBOP Board Member DeBarmore and 7 OBOP Board Members participated via teleconference.

Summary of Comments

None received.

Summary of Written Comments

All written comments received by the public comment deadline date of 11/26/19 at 4:30PM have been provided in their entirety to the Board and are summarized below. Comments were received in response to the October 21, 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
William Cover, R.Ph. – On behalf of NABP
NABP is requesting that the Board reconsider the addition of an inspection requirement for out of state pharmacies that compound sterile drug products (855-045-0200). They stated that their VPP program inspects large numbers of sterile compounding pharmacies in the US and provided data as an example of deficiencies they have found. They stated that Oregon citizens could be at risk without requiring out of state inspections.

Lauren Paul, PharmD.- On behalf of CVS Health
CVS Health has concerns regarding multiple references to USP-NF chapters and suggested removing redundant language. They also have concerns in regards to elements required in procedures to address sterile compounding requirements vs non-sterile requirements and suggest allowing elements of the policies & procedures be included according to the type of compounding performed. Lastly, they stated that they appreciate the removal of the accreditation requirements and labeling requirements.

RULES PROPOSED: Animal Euthanasia Drug Outlet requirements
855-080-0100

No comments received.

RULES PROPOSED: Military Spouse/Domestic Partner, Foreign Pharmacy Grads, Naloxone & Intern Application.

William Cover, R.Ph. – On behalf of NABP
NABP stated that the proposed rule language allowing a copy of the FPGEC certificate to be submitted by the applicant has the potential for the submission of fraudulent documentation. They are suggesting that the Board consider requesting the FPGEC copy directly from NABP staff instead of the applicant.

William Cover, R.Ph. – On behalf of NABP
NABP requested that the Board clarify language in ORS 689.265 that would allow for the continued utilization of the NABP Electronic Licensure Transfer Program, which verifies the status of all license held by an applicant as well as searches the NABP Clearinghouse for any disciplinary actions against the applicant across all of the states.
November 25, 2019

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

Dear Oregon Board Members:

I am writing today in regard to rule changes to section 855-045-0200 that require adherence to USP standards for drug compounding.

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP is the only professional association that represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Australia, and 10 Canadian provinces.

Following a review of the most recent version of rule amendments to section 855-045-0200 it was noted that all inspection requirements had been removed from the original amendment version. Based on patient safety risk, NABP respectfully requests that you reconsider the addition of an inspection requirement for out of state pharmacies that compound sterile drug product.

Recently the State of Michigan contracted with NABP to identify and inspect high risk sterile compounding pharmacies within the state. Prior to this time limited resources were available to adequately inspect these more complex pharmacies. Below is a list of findings from these eighty inspections.

- Improper temp/humidity monitoring – Not 24/7; No max/min; No plan for excursions
- Certifications of ISO rooms and PECs performed at REST
- Sprinkler heads not flush with the ceiling; ledges in ISO areas including viewing windows
- Pressure gauges not calibrated annually
- Return ducts located in the ceiling
- No smoke testing of rooms and/or PECS
- Personnel not garbed correctly – wearing makeup, jewelry, fingernail polish, hair not under head cover
- Handwashing – not using nail picks; using brushes which are not permitted.
• Missing certificate of analysis on media/APIs
• Automated compounding devices not used in Media Fill
• Hazardous compounding in the same area as nonhazardous compounding; room not under negative pressure.
• Batches not marked as hazardous.
• Preparations not being checked against a light and dark background for particulates
• Lack of understanding of first air
• No genus determination of CFUs
• Lack of understanding of certification reports
• Sparse training documentation
• Improper room type for High Risk Compounding

The NABP Verified Pharmacy Program or VPP® continues to inspect a large number of sterile compounding pharmacies across the United States. Many of these pharmacies demonstrate deficiencies like those noted above which could potentially put Oregon Citizens at risk. Michigan, as do many of the other states in which we see deficiencies, require adherence to USP Chapter 797.

With this in mind, NABP respectfully requests that you consider the addition of language in section 855-045-0200:

(4) Any person, including any business entity, located outside Oregon that engages in the practice of sterile compounding of a drug must submit an inspection conducted within the past two years by the resident state or a board approved third party inspection entity.

Thank you for your consideration of these changes to the current amended rule language.

Sincerely,

[Signature]

William J. Cover, RPh
Member Relations and Government Affairs Director
November 26, 2019

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

Re: Proposed Changes to Division 45 Rule – Drug Compounding

Dear Executive Director Schnabel:

I am writing to you in my capacity as Sr. Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide care with diverse access points to patients in the state of Oregon through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments to the Board pertaining to drug compounding.

**Application**

CVS Health appreciates the time and consideration the Board has taken in amending their compounding rules. However, we have concerns with specific reference to multiple USP-NF chapters within the draft rules. While we understand the intention for adherence to the standards of current edition of USP-NF relating to compounding, the second sentence in OAR 855-045-0200(3) is redundant and not needed. Therefore, we suggest removal.

**Suggested Language**

OAR 855-045-0200
Application
(2) 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, 825, 1072, 1116, 1160, 1163, 1211 and 1229.5

**Personnel and Responsibilities**

While we appreciate the Board amending the language for policies and procedures to reflect the type of compounding performed, we have concerns with the elements required in procedures continue to address sterile compounding requirements vs non-sterile requirements. As an example, the continuous quality assurance program and controls section which includes release testing, end-product validation along with quantitative/qualitative testing should be required only when performing sterile compounding. This is common practice for sterile compounding and would impact patient care by delaying therapy in retail drug outlets that occasionally prepare non-sterile compounded preparations as they perform this testing. We suggest amending this policy and procedure section to allow elements of the policies and procedures be included according to the type of compounding performed.

**Registration**

CVS Health appreciates the removal of the requirement mandating that all drug outlets that compound undergo an inspection or accreditation by a Board approved entity every 3 years in order to dispense compounded preparations into and within Oregon. The removal will allow the citizens of Oregon continued access to compounded medications.
**Labeling**

Finally, we appreciate the Board’s understanding and removal of label requirements as requested in our previous letter. The Institute for Safe Medication Practices published recommended industry guidelines for medication labels for community and mail order pharmacies on December 30, 2014\(^1\) in which they suggest maximizing the use of white space on a label to improve medication adherence and reduce inadvertent medication errors. By removing additional requirements to the label of compounded preparations, especially non-sterile, there will be a patient friendly label, maximizing white space.

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

Sincerely,

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

**References:**

November 25, 2019

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

Dear Oregon Board Members:

I am writing today in regard to rule changes to section 855-019-0150 which outlines the requirements for licensure of Foreign Pharmacy Graduates.

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP is the only professional association that represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Australia, and 10 Canadian provinces.

The amended rule language in Section 855-019-0150 allows for the Foreign Pharmacy Graduate to be able to provide a copy of the original certificate issued by the NABP Foreign Pharmacy Graduate Examination Committee. The practice of allowing a copy of the FPGEC certificate to be submitted by the applicant has the potential for the submission of fraudulent documentation.

Due to this concern, NABP respectfully requests that the board request a copy of the FPGEC from NABP staff. If a copy of the FPGEC is allowed to be submitted by the applicant, NABP requests that the board verify the certification by use of the NABP eProfile Connect portal.

Thank you for your review and clarification as part of changes to section 855-019-0150.

Sincerely,

William J. Cover, RPh
Member Relations and Government Affairs Director
November 25, 2019

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

Dear Oregon Board Members:

I am writing today in regard to rule changes to section 855-010-0130 that allows for a temporary authorization to practice for military spouses or domestic partners.

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP is the only professional association that represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Australia, and 10 Canadian provinces.

Section 855-010-0130 states that an applicant for licensure as a pharmacist by reciprocity must meet the requirements of ORS 689.265. ORS 689.265 outlines the requirements an applicant must adhere to in order to obtain a license as a pharmacist by reciprocity.

In section (f) of ORS 689.265 it states that an applicant for licensure by reciprocity “shall have presented to the board proof of initial licensure by examination and proof that such license and any other licenses granted to the applicant by another state or states have not been suspended, revoked, canceled or otherwise restricted for any reason…”

NABP respectfully requests that the Oregon Board of Pharmacy clarify that this section in ORS 689.265 would allow for the continued utilization of the NABP Electronic Licensure Transfer Program (eLTP®) for these military spouses and domestic partners. The NABP eLTP program verifies the status of all license held by an applicant as well as searches the NABP Clearinghouse for any disciplinary actions against the applicant across all of the states.

NABP certainly understands the concern and desire to eliminate any unnecessary obstacles for our military members and their dependents which are frequently moved to various state. However, the NABP eLTP program is an important tool to objectively review applicants for licensure by reciprocity. In addition, the fees related to eLTP are discounted for military members and the eLTP applications are reviewed and completed typically within 1 to 2 days.

Thank you for your review and clarification as part of changes to section 855-010-0130.
Sincerely,

William J. Cover, RPh

Member Relations and Government Affairs Director
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: 11/26/2019  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 By:
Rachel Melvin
Rules Coordinator

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

DATE: 11/26/2019
TIME: 9:30 AM
OFFICER: Rachel Melvin
ADDRESS: Portland State Office
Building - Conf. Rm 1A
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. 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, in registered Oregon drug outlets. Certain drug compounding by other licensed practitioners is subject to jurisdiction and other agencies, such as the FDA and state health regulatory boards. 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 dependent on current facility specifications, compliance readiness and the type of compounding being performed.

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 and they type of compounding performed. The number of pharmacy related small businesses in Oregon is estimated to be less than 50 and may include small hospitals and independent community pharmacies. Additionally, the cost of professional services, equipment supplies, labor and increased administration will vary depending on current readiness.

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: Updated definitions; removed Shared Pharmacy Service.

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
(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 Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action.¶

(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 Oregon pharmacy technician.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.005, 689.151, 689.155, 689.305, 689.405 & 689.455, 689.64151, ORS 689.155
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 Board regulations.¶

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

(3) All drug compounding must adhere to all the guidelines 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
AMEND: 855-045-0210

RULE SUMMARY: Revisions require adherence to USP standards for drug compounding.

CHANGES TO RULE:

855-045-0210

Definitions

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. "Compounding Aseptic Isolator" (CAI) means a glove box isolator with a microbially retentive HEPA air filter that maintains an aseptic compounding environment 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.

8. "Parenteral Admixture" means a sterile preparation that is the combination of one or more sterile products with:
   (1) A non-resident drug outlet that distributes a non-patient specific compounded drug into Oregon must be registered with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.
   (2) A resident drug outlet that distributes a non-patient specific human compounded drug within or outside of
Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a
appropriate admixture vehicle.¶

(9) "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 manufacturer drug outlet.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
AMEND: 855-045-0220

RULE SUMMARY: Revisions require adherence to USP standards for drug compounding.

CHANGES TO RULE:

855-045-0220

Personnel and Responsibilities

(1) All 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 and practical skills of aseptic manipulation and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties.

(2) The Pharmacist-in-Charge (PIC) shall establish pharmacy 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.

(3) Personnel involved in high-risk compounding must be retested in aseptic manipulative skills at least semi-annually.

(4) 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 in accordance with the standards in USP Chapters for all aspects of the compounding operation according to the type of compounding performed and shall include written procedures for:

(b) Personnel qualifications, to include training, evaluation and requalification;

(c) Hand hygiene;

(d) Garbing;

(e) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;

(f) Cleaning activities, to include sanitizing and disinfecting, including those compounded products are trained personnel and have demonstrated skills commensurate with the complexity of the procedures they are performing or other staff responsible for cleaning;

(g) Components, to include selection, handling, and storage;

(b) Establish a procedure for verification by a pharmacist of the preparation of each completed compounded product. This verification shall be accomplished by a review of each compounded product that includes but is not limited to:

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

(B) Creating master formulation records, with documented pharmacist approval;

(h) Creating compounding records;

(i) Establishing beyond-use-dates (BUDs);

(j) Continuous quality assurance program and quality controls, to include release testing, end-product evaluation, and quantitative/qualitative testing;

(B) Verifying that the correct drugs and components were selected;

(C) Confirming that the calculation and quantity of each drug and component is correct;

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

(e) Document verification by the pharmacist responsible for the review. This 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
855-045-0230

General Requirements

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
(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, maintain 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 and:

(A) Requirements for compounding, labeling and storage of the products;

(B) Requirements for administration of parenteral therapy;

(C) Requirements for storage and maintenance of equipment and supplies.

(b1) Labeling: In addition to regular labeling requirements, the label shall include:

(A) Rate of infusion, as appropriate;

(B) Beyond Use Date;

(C) Storage requirements or special conditions, if applicable

The generic or official name of each active ingredient;

(D2) Name, quantity and the strength or concentration of all ingredients contained in the product, each active ingredient, to include the primary solution;

(E) Initials of the pharmacist who verified the accuracy of the completed product.

(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.

(2) In addition to 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:

(a) Prepare multiple source commercially available premixed parenteral admixtures for a sterile parenteral preparation;

(b5) Prepare single source premix parenteral admixtures if the individual components of the premixed parenteral solution are commercially available

The total quantity of the drug product;

(e6) Reassign a parenteral admixture to another patient if the admixture does not exceed the documented BUD for that admixture, and the parenteral admixture that 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;

(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

A beyond-use-date (BUD), compliant with current USP standards; and

(7) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
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
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 daily. 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
AMEND: 855-045-0270

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, verification, dispens All records 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 onsite 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 according to the type of compounding performed, including 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 or the transfer of all compounded products must be stored in an organized manner, retained for a minimum of three years and be available for inspection; and
(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;
(d) Cleaning and disinfecting of all compounding areas and equipment;
(2) Master formulation records, including as appropriate:
(a) The name, strength and dosage form of the preparation;
(b) Physical description by of the Board final preparation;
(c) Ingredient identities and amounts;
(2d) The formula worksheets for compounding pharmacies, including equipment, supplies, and a description of the compounding steps;
(e) 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;
(b) Strength and dosage form of the preparation;
(b) Physical description of the final preparation, when dispensed to a patient for self-administration;
(c) Master formulation record reference for the preparation, when applicable;
(d) Quantity prepared;
(ee) Date and time prepared;
(df) Pharmacy unique lot number;
(e) M Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient;
(fh) Beyond Use Date;
(gi) Name of verifying pharmacist. Pharmacist documented verification of order accuracy;
(hj) Names of all technicians involved in the process;
(li) Copy of the label used for the compounded product;
(jj) Mixing instructions;
(k) Physical evidence of identity 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 of compounded product accuracy including the correct formula, calculations, and the correct weights or volumes of chemical or measurements and drugs were used;
(n) Certification of completion of any additional testing, including endotoxin, required by the pharmacy's policies and procedures;
(o) Total quantity compounded;
(n) BUD assignment and storage requirements, including reference source, if differs from master formulation record;
(no) Any other information required by the pharmacy's policies and procedures;
(3) Record of maintenance and certifications for all equipment must be retained for a minimum of three years and be available for inspection by the Board. 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 failure;
(p) Records of dispensing or transfer of all compounded preparations; and
(q) Any other information required by the pharmacy's policies and procedures.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155
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WHAT IS THE EXPOSURE?

Drugs are classified as hazardous when they possess any of these characteristics:

- Impact or damage DNA/genes
- Cause cancer
- Contribute to infertility
- Impact a developing embryo or fetus
- Cause developmental abnormalities
- Cause organ damage
- Have a similar structure or function to drugs that are determined to be hazardous

WHAT ARE THE POTENTIAL RISKS?

Acute and long term effects

- Hair Loss
- Cardiac Toxicity
- Kidney Damage
- Hearing Loss
- Nausea
- Rashes
- Cancer
- Infertility

WHO IS AT RISK?

Anyone handling hazardous drugs is at risk of exposure.

1. https://www.cdc.gov/niosh/topics/hazdrug
2. IMS Data 2016 data and analysis
6. USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings
   https://www.usp.org/usp-chapter-800-download

Download the USP <800> HazRx™ mobile app
Help minimize your risk with the USP <800> HazRx™ mobile app

WHERE CAN EXPOSURE OCCUR?
Exposure can take place in any healthcare setting1,6

1. Hospitals
2. Surgical Centers
3. Veterinary Hospitals and Clinics
4. Pharmacies
5. Home Health Care
6. Skilled Nursing Facilities

HOW CAN EXPOSURE OCCUR?
Every aspect of handling hazardous drugs may result in exposure if proper precautions are not taken1,6

1. https://www.cdc.gov/niosh/topics/hazdrug
2. IMS Data 2016 data and analysis
6. USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings https://www.usp.org/usp-chapter-800-download

Download the USP <800> HazRx™ mobile app
November 25, 2019

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

Dear Oregon Board Members:

I am writing today in regard to rule changes to section 855-019-0150 which outlines the requirements for licensure of Foreign Pharmacy Graduates.

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP is the only professional association that represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Australia, and 10 Canadian provinces.

The amended rule language in Section 855-019-0150 allows for the Foreign Pharmacy Graduate to be able to provide a copy of the original certificate issued by the NABP Foreign Pharmacy Graduate Examination Committee. The practice of allowing a copy of the FPGEC certificate to be submitted by the applicant has the potential for the submission of fraudulent documentation.

Due to this concern, NABP respectfully requests that the board request a copy of the FPGEC from NABP staff. If a copy of the FPGEC is allowed to be submitted by the applicant, NABP requests that the board verify the certification by use of the NABP eProfile Connect portal.

Thank you for your review and clarification as part of changes to section 855-019-0150.

Sincerely,

William J. Cover, RPh
Member Relations and Government Affairs Director
November 25, 2019

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

Dear Oregon Board Members:

I am writing today in regard to rule changes to section 855-010-0130 that allows for a temporary authorization to practice for military spouses or domestic partners.

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP is the only professional association that represents the state boards of pharmacy in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Australia, and 10 Canadian provinces.

Section 855-010-0130 states that an applicant for licensure as a pharmacist by reciprocity must meet the requirements of ORS 689.265. ORS 689.265 outlines the requirements an applicant must adhere to in order to obtain a license as a pharmacist by reciprocity.

In section (f) of ORS 689.265 it states that an applicant for licensure by reciprocity “shall have presented to the board proof of initial licensure by examination and proof that such license and any other licenses granted to the applicant by another state or states have not been suspended, revoked, canceled or otherwise restricted for any reason…”

NABP respectfully requests that the Oregon Board of Pharmacy clarify that this section in ORS 689.265 would allow for the continued utilization of the NABP Electronic Licensure Transfer Program (eLTP®) for these military spouses and domestic partners. The NABP eLTP program verifies the status of all license held by an applicant as well as searches the NABP Clearinghouse for any disciplinary actions against the applicant across all of the states.

NABP certainly understands the concern and desire to eliminate any unnecessary obstacles for our military members and their dependents which are frequently moved to various states. However, the NABP eLTP program is an important tool to objectively review applicants for licensure by reciprocity. In addition, the fees related to eLTP are discounted for military members and the eLTP applications are reviewed and completed typically within 1 to 2 days.

Thank you for your review and clarification as part of changes to section 855-010-0130.
Sincerely,

[Signature]

William J. Cover, RPh
Member Relations and Government Affairs Director
NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILING CAPTION: Implements legislative changes for various rules by adoption, amend or repeal.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2019 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 By:
Rachel Melvin
Rules Coordinator

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

DATE: 11/26/2019
TIME: 9:30 AM
OFFICER: Rachel Melvin
ADDRESS: Portland State Office Building - Conf. Rm 1A
800 NE Oregon St.
Portland, OR 97232

NEED FOR THE RULE(S):

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

FISCAL AND ECONOMIC IMPACT:
The military spouse/domestic partner temporary authorization will not generate an additional fiscal impact to the licensing fees required by individuals. Foreign Pharmacy Graduates will no longer have to mail their original certificate to the Board, this is a cost savings. There is no negative fiscal impact on outlets that offer contraceptive services. Pharmacies providing naloxone services shall provide written notice in a conspicuous manner that the drug and medical supplies are available; dispensing and prescribing costs associated with this drug could be impacted.

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).

There are less than 200 pharmacy outlets that report as a small business in Oregon. New naloxone requirements may result in additional costs to provide notice as required by 2019 SB 910.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):
Small businesses were not involved in the development of these rules; revisions are legislatively required.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?
Revisions are legislatively required.

RULES PROPOSED:

ADOPT: 855-010-0130

RULE SUMMARY: 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.

CHANGES TO RULE:

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 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 their term of service in this state; or
(c) The date the person’s authorization issued by the other state expires.
(4) A temporary authorization issued under this section is not renewable.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.265, 2019 OL Ch. 142, 2019 OL Ch. 626
RULE SUMMARY: The requirement to provide the original FPGEC certificate is a potential barrier to licensure for foreign pharmacy graduates (who could be immigrants or refugees).

CHANGES TO RULE:

855-019-0150
Foreign Pharmacy Graduates

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

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

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

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

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

(2) An applicant must complete 1440 hours in pharmacy practice as an intern that must be certified to the Board by the preceptors.

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

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

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.255
REPEAL: 855-019-0420

RULE SUMMARY: Repeal due to ORS 689.689 sunset provision effective 1/1/2020 which restricted prescribing to a person younger than 18 years old.

CHANGES TO RULE:

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
CHANGES TO RULE:

855-019-0450

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.

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, 689.681, 2016 OL Ch. 100, 2017 OL Ch. 683
AMEND: 855-019-0460

RULE SUMMARY: Rule edits are proposed to Divisions 019 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 and allows for a pharmacist to offer naloxone to a patient when filling an opioid prescription for greater than 50 morphine milligram equivalents (MME) per day dosage.

CHANGES TO RULE:

855-019-0460
Naloxone - Delivery of Care and Prescribing ¶

(1) A pharmacist, having determined that there is an identified medical need, can prescribe naloxone and the necessary medical supplies for opiate overdose training. ¶
(2) A pharmacist can prescribe naloxone and the necessary medical supplies to an individual or to administer naloxone for opiate overdose: ¶ (a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME); ¶ (b) To an individual seeking naloxone; ¶ (c) To an 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, 2019 OL Ch. 470
AMEND: 855-031-0010

RULE SUMMARY: The requirement to provide the original FPGEC certificate is a potential barrier to licensure for foreign pharmacy graduates (who could be immigrants or refugees).

CHANGES TO RULE:

855-031-0010
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 national fingerprint 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). ¶
(3) The Board may issue an intern license after processing the application, however unless the applicant is a foreign graduate or an applicant for licensure by reciprocity, it is not valid until the intern has started a course of study. For licenses issued after May 1, 2010, the initial license is valid until the last day of November following the second anniversary of issue unless terminated automatically by any one of the following events. Renewed licenses are valid for two years unless terminated automatically by any one of the following events: ¶
(a) Licensure to practice pharmacy is granted in any state; or ¶
(b) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, fails to maintain enrollment or active registration in a pharmacy degree program for a period greater than one year; or ¶
(c) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by reciprocity, has been graduated from a school of pharmacy for 12 months; ¶
(d) The intern is dismissed, terminated or expelled by the school of pharmacy, or withdraws from the program. ¶
(4) An intern must surrender their license to the Board within 30 days of one of the above events. ¶
(5) Notwithstanding the requirements of section (3) above, upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing. ¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.207, ORS 689.255, 2009 OL Ch. 536 ORS 689.455
855-041-2300

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.

Statutory/Other Authority: ORS 689.205, 2013 OL Ch. 340
Statutes/Other Implemented: ORS 689.155, 2013 OL Ch. 34
RULE SUMMARY: Rule edits are proposed to Division 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 adds legislatively mandated requirement for written notice of naloxone availability.

CHANGES TO RULE:

855-041-2340
Naloxone - Pharmacist Prescribing of Naloxone ¶

Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:

1. Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; and
2. Documentation and recordkeeping; and
3. Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, ORS 689.681, 2016 OL Ch. 100, ORS 689.682, 2017 OL Ch. 683.
NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILING CAPTION: Revises Animal Euthanasia Drug Outlet requirements, adds sedatives and analgesic medications and expectations.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/26/2019 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

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

DATE: 11/26/2019
TIME: 9:30 AM
OFFICER: Rachel Melvin
ADDRESS: Portland State Office Building - Conf. Rm 1A
800 NE Oregon St.
Portland, OR 97232

NEED FOR THE RULE(S):
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 permit 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. Record keeping 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 have a high abuse potential therefore an outlet's record keeping must be robust.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:
2019 SB 71

FISCAL AND ECONOMIC IMPACT:
Any humane society or animal control agency that euthanizes animals must be registered by the Board of Pharmacy as a
drug outlet and comply with requirements, including: drug storage, record keeping, completion of self inspection report and reporting all controlled substance drug losses.

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).

There are currently 28 local animal control agencies or humane societies registered with the Board. Some are public entities and some may be considered small business.

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

Small businesses were not involved in the development of these rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

The Board worked with the Oregon State Veterinary Medical Examining Board and the Oregon Veterinary Medical Association to incorporate the changes in 2019 SB 71.

AMEND: 855-080-0100

RULE SUMMARY: Rules are revised to incorporate 2019 SB 71 which adds 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.

CHANGES TO RULE:

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) Storage. All supplies of sodium pentobarbital shall be 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 access to and 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.

(b) 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 each drug and the designated person responsible for security; and

(D) A weekly record of verification of the stock amount 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 conformance with 21 CFR 1307.21 federal regulations.

(F) Complete the annual Self-Inspection Report by February 1 each year, and retain for Board inspection.

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

(2) The fee for registration shall be paid as specified in division 110 of this chapter of rules Drug Enforcement Administration (DEA), and Board of Pharmacy or its agents.

(2) The outlet shall notify the Board of Pharmacy 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 DEA, a copy shall be sent to the Board of Pharmacy.

(34) The Board of Pharmacy 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 and sedative or analgesic medications who is not certified by the Oregon State Veterinary Medical Examining Board to administer such drug.

Statutory/Other Authority: ORS 475.095, ORS 475.190, ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, 2019 OL Ch. 126
Temporary rule is proposed to Divisions 041 to address directives of 2019 HB 2935 which require accessibility services for visually impaired patients. These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

Impacts: In Oregon, it is estimated that 104,500 patients are visually impaired

Justification: Operative date is January 1, 2020

Documents relied upon include: Title VI of the Civil Rights Act of 1964 (42 USC 2000d)

OAR 855-041-1131 Prescription Reader Accessibility

A pharmacy shall notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request; a prescription reader is a device designed to audibly convey labeling information. A pharmacy that provides a prescription reader shall make it available to the person for at least the duration of the prescription, shall confirm it is appropriate to address the person’s visual impairment, and shall ensure that prescription labels are compatible with the prescription reader. This requirement does not apply to an institutional drug outlet, dispensing a drug intended for administration by a healthcare provider.
Treatment and Management of Pain

Adopted June 2006

Healthcare leaders and patient advocates have come together in a legislatively mandated pain commission to work toward providing well managed and adequate pain control to the citizens of Oregon. Involvement with The Oregon Pain Commission has prompted the Board of Pharmacy to take a leadership role in promoting the effective management of pain for the state’s citizens. The mission of the Oregon Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by regulating the practice of pharmacy and the distribution of drugs within and into the state. As a part of that endeavor, the Board strives to ensure that all Oregonians have access to appropriate pain relief. Appropriate and effective pain therapies, including the use of controlled substance medications, can greatly improve a patient’s quality of life and reduce unnecessary morbidity and cost associated with inadequate treatment of pain.

Inadequate pain control, in some cases, may result from a lack of knowledge or understanding of proper pain management by health care professionals and patients. Under-treatment of pain can also be the result of fear or misunderstanding of the position of regulatory boards or law enforcement agencies regarding the use of controlled substances in the treatment and management of pain. This statement is intended to clarify the Board of Pharmacy’s position regarding pain management in the practice of pharmacy.

The Oregon Board of Pharmacy recognizes that the use of controlled substances, including opioid analgesics, is often essential for the treatment and management of both acute and chronic pain of any origin. A pharmacist involved in the care of a patient undergoing treatment for pain should not fear disciplinary action from the board for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose as defined in the state of Oregon. Pharmacists’ involvement with pain management in the usual course of their professional practice should be based upon accepted scientific knowledge and sound clinical judgment.

The Board of Pharmacy also recognizes that controlled substances, by their nature, carry with them a risk of abuse or misuse. All health care professionals must remain alert to the fact that these drugs are subject to abuse and that some people will seek them for inappropriate uses. Care must be taken to balance this risk with the desired outcome of effective pain control for all who are in need.

Dispensing of controlled substances for the treatment of pain must be based upon a valid prescription issued within currently accepted standards. All pharmacists are encouraged to increase their knowledge of current medical standards for the treatment of pain and develop effective strategies for delivering pharmaceutical care to patients suffering with pain. Pharmacists should actively participate on the health care team by providing expertise to the patient, physician, nurse and hospice provider or other care giver. As a member of the health care team, pharmacists can contribute to positive therapeutic outcomes for patients suffering from pain and can reduce the potential for drug abuse. Detailed documentation of the patient’s medical condition and clinical response to treatment provides the strongest foundation for providing optimal patient care.

The Board acknowledges the review of position statements from the Iowa, Michigan, Wisconsin, and Texas Boards of Pharmacy as well as the Oregon Board of Nursing and the Oregon Board of Medical Examiners and the Oregon Pain Commission in developing this Position Statement on the Treatment and Management of Pain.
### 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
- Jane Gin, Inspector/Investigator

### Agenda Item
<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Desired Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome</td>
<td>Roll call</td>
</tr>
<tr>
<td></td>
<td>Agenda review and approval</td>
</tr>
<tr>
<td>Motion to approve agenda was made and unanimously carried (Motion by Chinn, seconded Burns).</td>
<td></td>
</tr>
<tr>
<td>8.28.19 Minutes review and approval</td>
<td>Motion to approve 8/28/19 Minutes was made and unanimously carried (Motion by Jones, seconded by Burns).</td>
</tr>
<tr>
<td>Committee Business (times are approximate)</td>
<td>High Priority Items – none</td>
</tr>
<tr>
<td></td>
<td>Committee Protocol Development</td>
</tr>
</tbody>
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**NRT and Non-NRT Smoking Cessation**

SMEs: Julie Himstreet and Sharon Rask – present
SMEs: Kiyomi Lehman – phone, Laura Borgelt – not present

- Pharmacist Consultant Fiona Karbowicz provided a summary of the history of this concept, which was originally submitted and discussed at the Committee’s October 2018 meeting.

- The subject matter experts (SMEs) lead a thorough review of the related forms for this concept, highlighting the edits incorporated from the July 2019 meeting discussions.
  - The Committee reviewed the Self-Screening Questionnaire intended to be completed by a patient seeking smoking cessation services and with the assistance of the SMEs, finalized the form with minor edits.
  - The Committee reviewed the Assessment and Prescribing Algorithm that facilitates the pharmacist’s assessment and professional determinations for whether the patient meets the criteria for NRT or non-NRT tobacco cessation products and medications. It was determined that the evidence supports the use of the NRT/non-NRT products to quit tobacco products. With the assistance of the SMEs, the Committee finalized the algorithm with minor edits.
Motion was made and unanimously carried (Motion by Burns, second by Anukam) to recommend NRT and non-NRT Tobacco Cessation Statewide Drug Therapy Management Protocol “package” to the OR Board of Pharmacy for review. This includes:

- Adherence to elements outlined in OAR 855-020-0110 (core elements);
- Standardized patient assessment process elements and treatment care plan algorithm;
- Prescribing parameters: 1st rx up to 30 days, max duration 12 weeks, max frequency 2x in rolling 12 months; Dosages outlined;
- Mandated follow-up: RPH consultation within 7-21 days (phone consult permitted); and
- A one-time minimum of 2 hours of smoking cessation-related continuing education (CE).

- On behalf of board staff, Karbowicz thanked the SMEs for their ongoing efforts over these many months preparing form drafts and guidance to the Committee’s development of the Tobacco Cessation protocol package.

Travel Consult Medications

SMEs: Kayla Hensley, Kaylie Yoon, and Claire Rutledge – present

- Karbowicz provided a summary of the history of this concept, which was originally submitted and discussed at the Committee’s January 2019 meeting.
- The subject matter experts (SMEs) lead a thorough review of the related forms for this concept, highlighting the edits incorporated from the July 2019 meeting discussions.
  - The Committee reviewed the Self-Screening Questionnaire intended to be completed by a patient seeking pre-travel medication services. The Committee finalized the form, utilizing the assistance of the SMEs.
  - The Committee reviewed the Assessment and Prescribing Algorithm that facilitates the pharmacist’s assessment and professional determinations related to travel itinerary, particularly aligned with the CDC’s references, including but not limited to the “Yellow Book”. With the assistance of the SMEs, the Committee finalized the algorithm with minor edits.
  - The Committee discussed the importance of the pharmacist to provide all necessary vaccination(s) in conjunction with medications potentially needed (for Travelers Diarrhea (TD), Malaria prevention, Altitude sickness, and Motion Sickness). Regarding medications, note that while the CDC still recommends ciprofloxacin for TD, SMEs advise azithromycin only, due to complicated drug interactions as well as resistance in various locales.
  - The Committee discussed the importance of a patient having clear instructions on how to take medications, particularly when traveling internationally. They agreed that the recommendation shall include providing each patient with the individualized care plan created by the pharmacist. This ‘visit summary’ will facilitate safe and proper medication use.
  - Proper and comprehensive documentation by the pharmacist when prescribing according to this protocol is essential.
  - The Committee discussed the appropriate minimum age for this recommendation, concluding that down to (and including) age 7 is consistent with the state’s immunization protocols and will incorporate pediatric dosing.
MOTION was made and unanimously carried (Motion by Turner, seconded by Chinn) to recommend the Pre-Travel Consult Medications Statewide Drug Therapy Management Protocol “package” to the OR Board of Pharmacy for review. This includes:

- Adherence to the CDC’s *Health Information for International Travel* (“Yellow Book”), with the exception of recommending azithromycin for TD rather than ciprofloxacin;
- Adherence to elements outlined in OAR 855-020-0110 (core elements);
- Standardized patient assessment process elements and treatment care plan algorithm, including prescribing parameters; and
- Provision of individualized care plan to each patient.

Committee recommends the following education:

- APhA Immunization Training Program certificate (or equivalent); and
- Minimum of 4 hour certificate related to travel medicine intended for the pharmacist (or equivalent); and
- A minimum of 1 hour of travel medication related continuing education (CE) every 2 years was made and unanimously carried (Motion by Turner, second by Chinn).

On behalf of board staff, Karbowicz thanked the SMEs for their ongoing efforts over these many months preparing form drafts and guidance to the Committee’s development of the Pre-Travel Medications protocol package.

*(Non-Occupational) Post Exposure Prophylaxis*

SMEs: Jen Lee, Geoffrey L’Heureux, and Rebekah Bartholomew, Jenny Mappus-phone

- Karbowicz provided a summary of the history of this concept, which was originally submitted and discussed at the Committee’s January 2019 meeting.
- The subject matter experts (SMEs) lead a thorough review of the related forms for this concept, highlighting the edits incorporated from the July 2019 meeting discussions.

- The Committee reviewed the Self-Screening Questionnaire intended to be completed by a patient seeking Post Exposure Prophylaxis (PEP) services. The Committee worked with the SMEs to finalize the form. With discussion, it was determined that it is not necessary to prohibit a pharmacist from assessing and providing treatment to a person who has experienced occupational exposure (such as a “needle stick”), therefore the questionnaire was edited accordingly and the title of this protocol was updated to PEP.
- The Committee discussed the sensitive nature of these conversations and suggests that the Board of Pharmacy should expect a drug outlet providing these services to provide for a confidential assessment and consultation location.
- The Committee reviewed the Assessment and Prescribing Algorithm that facilitates the pharmacist’s assessment and professional determinations related to initiating medication treatment for PEP. Questions that have answers of “not sure” shall be handled appropriately by the pharmacist seeking additional information from the patient during the assessment.
  - Algorithm edits were made to provide clarity to the pharmacist, to include specific “hard halts”, with defined exclusion criteria
  - Algorithm to include direction to the pharmacist when the patient has experienced a sexual assault.
Committee discussed the appropriate age and final algorithm to reflect the clinical and legal determination. (Note: CDC recommends a different treatment regimen for patients under age 13)

- The Committee discussed the importance of the intentional “hand-off” of each PEP patient to their PCP or other care provider; the SMEs offered to create a template provider notification form, to include suggested labs and follow-up. Additionally, the Committee discussed the importance of a patient having clear instructions on how to take prescribed PEP treatment. They agreed that the recommendation shall include providing each patient with the individualized care plan created by the pharmacist. The SMEs will create a template ‘visit summary’ to facilitate safe and proper medication use and address options for any patient experiencing “start-up syndrome”.

- Proper and comprehensive documentation by the pharmacist when prescribing according to this protocol is essential.

- Educational training program provides the foundational knowledge and how to apply this algorithmic decision-making; training program is also incorporating important elements for pharmacists to understand and be comfortable with Trauma Informed Care concepts and its application to PEP; training program to include a slide about referral expectations “warm referral”/”linkage to care”

**MOTION** was made and unanimously carried (Motion by Chinn, seconded by Helm) to recommend the Post Exposure Prophylaxis (PEP) Statewide Drug Therapy Management Protocol “package” to the OR Board of Pharmacy for review. This includes:

- Adherence to elements outlined in OAR 855-020-0110 (core elements);
- Standardized patient assessment process elements and treatment care plan algorithm, including prescribing parameters; and
- Provision of standardized notification to provider AND provision of individualized care plan to each patient.
- Committee recommends a training program to be completed by the pharmacist, related to PEP and Trauma Informed Care, prior to providing PEP services.

**Rules development / implementation update**

- Staff provided a rules update. At their October 2019 meeting, the Board adopted rules to better reflect statutory authority and make language more clear. Additionally, the Protocol list was reorganized and categorized to adapt to future additions. Male and female condoms were added.

- Items to explore -

**Housekeeping Issues** – Staff and Committee members briefly discussed reappointment applications and state mandatory trainings, with the reminder of upcoming deadlines.

**Upcoming Meeting Schedule** – subject to change

- Next meetings - November 20 (brief conference call to approve minutes)
  - March 6, 2020 – room 1D
  - September 11, 2020 – room 1D

Chair Valdez adjourned the meeting at 3:19PM.
Statement Regarding Cultural Competency Continuing Education

Adopted August 2014

The Oregon Board of Pharmacy is charged with preserving and protecting the health of our state’s citizens in the delivery of pharmacy related healthcare. Oregonians are growing increasingly diverse, and inequities in access to quality health care are apparent according to the Oregon Health Authority’s Office of Equity and Inclusion. The Office has identified that racial and ethnic populations, lesbian, gay, bisexual and transgender communities, low literacy level individuals and rural Oregonians experience health disparities. The Board believes that increasing understanding and awareness of the necessity to provide culturally competent health care is a patient safety priority.

The National Institutes of Health (NIH) speaks to the critical importance of healthcare practitioner’s awareness and competency in equal care given to patients across cultural lines. The NIH provides the following background to define Cultural Competence: *Culture is often described as the combination of a body of knowledge, a body of belief and a body of behavior. It involves a number of elements, including personal identification, language, thoughts, communications, actions, customs, beliefs, values, and institutions that are often specific to ethnic, racial, religious, geographic, or social groups. For the provider of health information or health care, these elements influence beliefs and belief systems surrounding health, healing, wellness, illness, disease, and delivery of health services. The concept of cultural competency has a positive effect on patient care delivery by enabling providers to deliver services that are respectful of and responsive to the health beliefs, practices and cultural and linguistic needs of diverse patients.*

Cultural competency continuing education is a life-long process of examining values and beliefs while developing and applying an inclusive approach to health care practice in a manner that recognizes the context and complexities of provider-patient interactions and preserves the dignity of individuals, families and communities. Continuing education in cultural competency should teach attitudes, knowledge and skills to care effectively for patients from diverse cultures, groups and communities. The Office of Equity and Inclusion states that such training enables health care providers to work effectively in cross-cultural situations.

The Board recommends and encourages licensees to pursue ongoing continuing education opportunities for cultural competency. For purposes of maintenance of licensure, the Board considers continuing education (CE) in cultural competency to be relevant to the current practice of all licensees, and licensees may use this type of continuing education toward satisfying the required CE hours for license renewal. The Board will document licensees’ voluntary participation in cultural competency CE through the license renewal process beginning in 2015.

In order for Oregon to achieve the triple aim of improving health, improving care, and lowering cost, providers must be responsive to the needs of diverse populations. Cultural competency training for health care providers is one method for helping Board licensees adapt to the needs of Oregon’s socially and culturally diverse communities.

(U) Clonazolam Identified in Overdose Incidents in Oregon and Idaho

(U) Recent reports of non-fatal overdose incidents have been reported in the Portland area. Clonazolam, a chemical sold as a designer drug online and part of the benzodiazepine drug class, was identified in these cases in Oregon and Idaho. In Portland, OR the drug was in liquid form and referred to as "liquid benzos" found in small vials similar to those in photo 1. In Idaho, law enforcement agencies have reported seizures of counterfeit "Xanax" bars, in which the clonazolam was in pressed into crude counterfeit Xanax pills, similar to those seen in photo 2.

INDICATORS
(U) Clonazolam is a psychoactive research chemical that acts as a sedative and muscle relaxant. It is a derivative of clonazepam and alprazolam, which are used to often treat anxiety and insomnia, among other medical uses. According to open sources, clonazolam has been reported to be fast-acting and its effects can be felt within 20-60 minutes. Due to its high potency it can produce heavy sedation and effects even when ingested in low doses such as 0.5mg. 1 Because of its high potency, it may be more dangerous than other benzodiazepines available on the market, especially when taken in higher doses. 2

(U) Currently there is limited regulation on clonazolam and it is uncontrolled in most of the United States. Virginia and Louisiana are the only states that currently have clonazolam listed as a schedule I substance under their state's controlled substance laws. This lack of regulation allows for the product to be openly sold on the internet and easy to obtain in its various forms to include liquid (photo 3), pellets/pills, blotters and powder.

CONCERNS
(U) Overdoses related to clonazolam are being reported as presenting with symptoms similar to an opiate related overdose. The symptoms often include slurred speech, lack of coordination, drowsiness and profoundly altered mental status. A high level of toxicity can cause a patient to become comatose and need immediate airway management. Fatal overdoses are rare but can occur with high level doses or if mixing benzodiazepines with other depressants such as alcohol, barbiturates or opioid painkillers. 4 Although the symptoms are similar to an opioid overdose, the use of naloxone is not effective in reversing benzodiazepine overdoses. 5

REQUEST FOR INFORMATION
(U) The Oregon-Idaho HIDTA Investigative Support Center is interested in reports involving clonazolam or other designer benzodiazepines to assess the emerging trend and public safety impact for our communities. Information can be sent to OrIdHIDTA@doj.state.or.us.

1 https://testcountry.com/pages/all-you-need-to-know-about-clonazolam
2 https://www.serenityatsummit.com/research-chemicals/clonazolam/
3 https://www.reddit.com/r/benzodiazepines/comments/a5msln/clonazolam_solution_just_came_in_today/
4 https://drugabuse.com/benzodiazepines/overdose/
5 https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone
The Online Sale of Opioids Continues to Put Lives at Risk

National Association of Boards of Pharmacy®

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1 Summary
NABP Not Recommended List Findings

2 Continued Online Availability of Opioids Perpetuates Public Health Crisis
Opioid Epidemic Persists
Regulators and Enforcement Authorities Recognize the Internet’s Role in the Crisis
Hidden Fentanyl Involved in Many Overdose Deaths
Latest NABP Findings Confirm Easy Online Access to CS

3 Regulators and Stakeholders Call for Coordinated Action
Authorities Target Illegal Online Drug Sellers
Solutions Require Action by Public and Private Entities
Internet Stakeholders Step Up

5 Conclusion

6 Resources
Summary

The opioid epidemic continues to devastate the nation. According to the Centers for Disease Control and Prevention (CDC), 46 Americans die every day from overdoses involving prescription opioids. The National Safety Council reports that, in 2017, opioid overdose deaths surpassed traffic-related fatalities. The culprit in many opioid-related overdoses is fentanyl, a potent synthetic opioid that is often used in the illicit manufacture of look-alike or falsified medicines. According to regulators and enforcement authorities, the epidemic is exacerbated by the fact that prescription opioids are readily available online – generally without a prescription – from websites masquerading as pharmacies. Research performed by the National Association of Boards of Pharmacy® (NABP®) confirms the continued online availability of controlled substances (CS), including opioids. During the first half of 2019, NABP identified more than 1,500 websites operating out of compliance with pharmacy laws or patient safety standards. Nearly a third of these websites offered or facilitated the sale of opioids or other CS.

The government has worked hard to reduce the online supply of opioids but recognizes the greater need for private sector action. Food and Drug Administration (FDA) has called on internet companies and domain name service providers to remove opioid sellers from social media platforms and take down websites that facilitate the illegal sale of opioids. Likewise, members of Congress have asked that internet search engines direct users to legitimate pharmacies and disable the ability to search for illicit drugs.

In response to such prompts, internet companies – including search engines, social media, and domain name registries – have taken some steps to protect patients. However, as evidenced by recent NABP findings, CS – including opioids – are still readily available online.
To reduce the online sale of opioids and other CS, NABP calls for additional voluntary action by internet stakeholders, including: deindexing websites of illegal drug sellers; directing users to legitimate pharmacies when they search for medicines; and reporting to law enforcement those entities that want to advertise the sale of CS via the internet platform.

**Continued Online Availability of Opioids Perpetuates Public Health Crisis**

**Opioid Epidemic Persists:**

The opioid epidemic is far from over. According to the CDC, from 2013 to 2017, the number of opioid-related overdose deaths in the United States increased 90%, from 25,052 to 47,600. Although there was a 5% overall decline in opioid deaths between 2017 and 2018, this decline does not appear to be uniform: 18 states saw increases in overdose deaths in 2018. Among them are Delaware, Missouri, and Vermont, which experienced double-digit increases. In addition, deaths attributed to illicitly manufactured fentanyl increased by 11%.

**Regulators and Enforcement Authorities Recognize the Internet’s Role in the Crisis:**

FDA is intensely attuned to the opioid epidemic and its impact on public health, as well as the role of illegal online drug sellers in perpetuating the crisis. “The rise in illegal sales of opioids over the internet is a critical public health concern and major focus of attention by the FDA,” then-FDA Commissioner Scott Gottlieb, MD, said in an April 2, 2019 news release. “These drugs are highly addictive and can be deadly when used without a doctor’s supervision.”

The Department of Justice (DOJ) has also focused on the internet as a significant player in the opioid epidemic. In January 2018, DOJ announced the creation of the Joint Criminal Opioid Darknet Enforcement (J-CODE) team, which focuses on shutting down illegal online drug marketplaces. According to then-Attorney General Jeff Sessions, “The J-CODE team will help us continue to shut down the online marketplaces that drug traffickers use and ultimately that will help us reduce addiction and overdoses across the nation.”

Likewise, the Office of National Drug Control Policy (ONDCP) noted that the internet has expanded the market for opioids. According to the ONDCP’s 21st Century Drug Trafficking: “Marketing Advisory” on Fentanyl and Other Synthetic Opioids (Tab B), “Today, fentanyl, fentanyl analogues, and other synthetic opioids are marketed to consumers in several ways, most notably via online platforms like social media and special interest online forums.”

**Hidden Fentanyl Involved in Many Overdose Deaths:**

Fentanyl often reaches consumers by way of falsified medicines. Law enforcement authorities have seen an influx of falsified drugs where fentanyl is an adulterant. Fentanyl is 50 times stronger than heroin and up to 100 times more potent than morphine, making even small amounts potentially fatal. Drug Enforcement Administration (DEA)
finds that “fentanyl in counterfeit pill form still represents a significant public health risk and law enforcement challenge.”

In New York City, overdose deaths have reached record levels, and fentanyl is involved in over half of these deaths. Throughout New York City, we have seen a spate of cases involving tens of thousands of potentially lethal fentanyl pills masquerading as oxycodone,” New York City Special Narcotics Prosecutor Bridget G. Brennan said in a news release. “Just because black market pills have the same color and design as legitimate pills, it does not mean they are safe. The ingredients and potency are all unknown, and minuscule amounts of fentanyl can cause overdose or death.”

In San Diego County, US Attorney Robert Brewer warned the public to be aware of pills made with fentanyl disguised as oxycodone. DEA’s El Paso Division issued a similar alert.

If someone is accustomed to taking a less potent drug, unknowingly taking a look-alike drug made with fentanyl can, and does, cause accidental overdose. These falsified drugs are often purchased online.

Latest NABP Findings Confirm Easy Online Access to CS: NABP’s recent findings corroborate regulator and enforcement authority assertions that illicit distributors of opioids and other CS are actively using the internet to reach customers. NABP routinely calls out those websites that endanger patient health and safety by including these domain names on its Not Recommended List. In the first half of 2019, NABP placed 1,543 new websites on its Not Recommended List. Of those, nearly a third (471, or 31%) offered opioids such as codeine, fentanyl, and oxycodone; or other CS, such as Adderall®, Valium®, and Xanax®. Nearly all of these websites (465, or 99%) offered CS without requiring a prescription, and 94% (441 websites) offered drugs that lacked required FDA approval. NABP research has consistently shown that 95-96% of websites selling prescription-only drugs are doing so illegally and endangering patient health.

Regulators and Stakeholders Call for Coordinated Action

Authorities Target Illegal Online Drug Sellers:
To curb the online sale of opioids and other CS, regulators and enforcement authorities have aggressively investigated and prosecuted the illegal actors behind these sales. Since September 2017, FDA has issued 25 warning letters identifying more than 450 illegally operating websites. On the enforcement side, the J-CODE team has completed two operations aimed at reducing the sale of opioids: Operation Disarray and Operation SaboTor. As part of Operation SaboTor, US and international law enforcement agencies shut down 50 darknet accounts and seized 299.5 kilograms of drugs, 51 firearms, and more than $7 million.

Solutions Require Action by Public and Private Entities:
While federal agencies have been actively targeting illegal online drug sellers, they have also acknowledged the need for action by private sector partners. According to FDA, “Stopping these websites from illegally offering opioids for sale will require a broad collaboration across the internet community.”
Federal legislators agree with FDA’s statement. In early 2018, a group of senators wrote to Google, Microsoft, Yahoo!, and Pinterest, expressing concern about the role that these companies play in facilitating the sale of opioids. 21 While acknowledging that these companies have compliance policies in place regarding online pharmacies, the senators urged these stakeholders to take additional steps, including: directing users to legitimate pharmacies that require a valid prescription as a condition of sale; disabling the ability to search for illicit drugs through each platform; and requiring each platform to report to law enforcement when it receives information indicating that it has been used to advertise or sell narcotics.

In April 2019, FDA convened an Online Opioid Summit to bring together regulators, patient safety advocates, and industry stakeholders. In an April 2 news release regarding the summit, FDA noted that the agency is “committed to targeting these illegal sales and working with internet stakeholders to advance a proactive approach to cracking down on internet traffic in illicit drugs to address this public health emergency.” 22 One summit attendee, registry services provider Neustar, concurred that the opioid crisis is exacerbated by online drug sellers. “While opioids are of course taken in the offline world,” an article in Neustar’s June 2019 Safer Domains newsletter states, “there is no question that the online distribution of opioids is a huge contributor to the current crisis.” 23

The federal government continues to call on internet stakeholders to help stem the tide of illegal online opioid sales. In August 2019, the ONDCP issued an advisory to digital platforms, which was intended to raise awareness about the “marketing and sale of illicit fentanyl via [. . .] social media, ecommerce websites, and online forums.” 24

**Internet Stakeholders Step Up:**

Recently, major internet players have begun to take action. Bing began by expanding its consumer warning banners from websites that received FDA warning letters to all websites on NABP’s Not Recommended List. It then blocked all rogue online pharmacies listed on FDA’s Internet Pharmacy Warning Letters site from its US search results. 25 Google has similarly begun to deindex illegally operating websites named in FDA warning letters. Social media platforms, including Facebook and Instagram, have begun redirecting users looking for opioids to a government helpline. “We’re committed to doing our part to help combat the opioid crisis,” a Facebook spokesperson said. “This is one of a number of ways we are helping connect people with resources and communities to support them.” 26

Domain name registries have also taken affirmative action to combat the crisis. For instance, Neustar reported that, in response to an FDA alert, it suspended multiple .biz and .us domain names linked to the illegal sale of opioids. Then, using certain keywords related to pharmaceuticals, Neustar proactively searched for domain names in the .us Top-Level Domain (TLD). It placed illicit actors on server hold to deactivate their websites. Furthermore, Neustar took independent voluntary steps to begin policing other TLDs that it administers. Neustar’s newsletter article states, “We firmly believe that both domain Registries and Registrars have an important role to play in protecting U.S. consumers from the scourge of illicit opioids by proactively taking action against websites that deliberately break the law by marketing and distributing opioids.” 27
Conclusion

Every half hour, another American dies as a result of an opioid-related overdose. Meanwhile, public health regulators and law enforcement authorities continue to grapple with this epidemic that, according to DEA, is “spreading like wildfire devastating our communities.” NABP research supports stakeholder and regulator assertions that illegal online drug sellers fuel the flames of the opioid crisis. In the first half of 2019, NABP identified more than 1,500 active sites as Not Recommended. Nearly a third of these websites offered opioids or other CS. Of those, nearly all (99%) did not require a prescription, and 94% offered drugs illegally.

To address the opioid epidemic effectively, stakeholders must work collaboratively to approach it from multiple angles. FDA and patient safety advocates have called on internet companies to take a more active role in eliminating illegal sellers from their platforms, and some have taken steps to do so. NABP applauds the efforts of regulators, enforcement authorities, and private sector stakeholders. However, we can and must do more to halt the opioid epidemic and reverse the damage it has caused. NABP calls on internet stakeholders to take additional proactive steps, including: deindexing websites of known illegal online drug sellers; reporting to law enforcement those entities that want to advertise the sale of CS via the internet platform; and directing users to legitimate pharmacies when users search for medicines via an internet platform.

*For information about NABP’s Rogue Rx: Activity Report, or the Association’s research and reporting capabilities, please contact Policy and Communications Director Melissa Madigan via email at mmadigan@nabp.pharmacy.*
Resources


20 FDA takes new enforcement actions as part of the agency’s ongoing effort to combat the illegal online sales of opioids [news release].
FDA; April 2, 2019.

21 Grassley, Feinstein, Colleagues Urge Tech Companies to Clamp Down on Illegal Online Drug Sales and Advertising [news release].

22 FDA takes new enforcement actions as part of the agency’s ongoing effort to combat the illegal online sales of opioids [news release].
FDA; April 2, 2019.


24 ONDCP. 21st Century Drug Trafficking: “Marketing Advisory” on Fentanyl and Other Synthetic Opioids (Tab B).

25 Bing to warn customers about the threats of fake online pharmacies. Bing Blogs.

26 Kozlowska H. Facebook now shows users trying to buy opioids a government helpline number. Quartz.


28 CDC. Overdose Death Maps.

NABP Mission Statement
NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions for the purpose of protecting the public health.

Vision Statement
Innovating and collaborating today for a safer public health tomorrow.

NABP Member Boards of Pharmacy

Alabama State Board of Pharmacy
Alaska Board of Pharmacy
Arizona State Board of Pharmacy
Arkansas State Board of Pharmacy
California State Board of Pharmacy
Colorado State Board of Pharmacy
Connecticut Commission of Pharmacy
Delaware State Board of Pharmacy
District of Columbia Board of Pharmacy
Florida Board of Pharmacy
Georgia State Board of Pharmacy
Guam Board of Examiners for Pharmacy
Hawaii State Board of Pharmacy
Idaho State Board of Pharmacy
Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy
Indiana Board of Pharmacy
Iowa Board of Pharmacy
Kansas State Board of Pharmacy
Kentucky Board of Pharmacy
Louisiana Board of Pharmacy
Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation – Board of Pharmacy
Maryland Board of Pharmacy
Massachusetts Board of Registration in Pharmacy
Michigan Board of Pharmacy
Minnesota Board of Pharmacy
Mississippi Board of Pharmacy
Missouri Board of Pharmacy
Montana Board of Pharmacy
Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit
Nevada State Board of Pharmacy
New Hampshire Board of Pharmacy
New Jersey State Board of Pharmacy
New Mexico Board of Pharmacy
New York State Board of Pharmacy
North Carolina Board of Pharmacy
North Dakota State Board of Pharmacy
State of Ohio Board of Pharmacy
Oklahoma State Board of Pharmacy
Oregon State Board of Pharmacy
Pennsylvania State Board of Pharmacy
Puerto Rico Board of Pharmacy
Rhode Island Board of Pharmacy
South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy
South Dakota State Board of Pharmacy
Tennessee Board of Pharmacy
Texas State Board of Pharmacy
Utah Board of Pharmacy
Vermont Board of Pharmacy
Virgin Islands Board of Pharmacy
Virginia Board of Pharmacy
Washington State Pharmacy Quality Assurance Commission
West Virginia Board of Pharmacy
Wisconsin Pharmacy Examining Board
Wyoming State Board of Pharmacy

The Bahamas:
Bahamas Pharmacy Council*

Canada:
Alberta College of Pharmacy*
College of Pharmacists of British Columbia*
College of Pharmacists of Manitoba*
New Brunswick College of Pharmacists*
Newfoundland and Labrador Pharmacy Board*
Nova Scotia College of Pharmacists*
Ontario College of Pharmacists*
Prince Edward Island College of Pharmacists*
Quebec Order of Pharmacists*
Saskatchewan College of Pharmacy Professionals*

* Associate Member
Diversifying your pharmacy portfolio for prime performance

If 100 percent of your investments for retirement were in one stock, a financial adviser would be appalled. Studies show that a diversified portfolio is going to make more money over the long haul, and comes with significantly less financial risk. The same goes for your pharmacy. Diversifying your revenue sources will make more money over time and reduce risk.

This month America’s Pharmacist® highlights two exciting new NCPA resources to help you make sure your business is primed for optimal performance. In this issue, we introduce the SurThrival series for pharmacy owners (page 32). The SurThrival series has been developed to help pharmacy owners to not only survive but — you guessed it — to thrive. In talking with thousands of pharmacy owners, there are attributes that the most successful share. Each topic in the series covers one of these successful attributes and helps you evaluate it for your pharmacy.

One of the topics in the SurThrival series will focus on how important it is to get out from behind the counter and develop niches that complement your pharmacy’s position as a community health care resource. A product that has generated more excitement — and more misinformation — in many years is CBD, short for cannabidiol. Oils, capsules, tinctures, bath bombs, lotions, and even gummies! are just a few of the numerous products that many consumers are asking about these days. Some have claimed that CBD can treat a long list of conditions, including inflammation, migraines, insomnia, anxiety, depression, nausea, and cancer. Though evidence of actual clinical efficacy is still inconclusive, consumers aren’t waiting for official studies. Some analysts say the sales of CBD will grow 107 percent annually into $18 billion by sales by 2025. If those predictions are true, why shouldn’t those purchases be at your pharmacy versus the “head shop” that just popped up down the road?

The good news about the explosive growth of CBD in health care is that there is an abundance of information about CBD online. The bad news is much of the online information comes from less than reliable sources. That’s where community pharmacists come into play. Who better than the local pharmacist to serve as the source for truth in their community? Not only is there an overwhelming amount of CBD information to process, community pharmacies want to be confident that they are recommending products that are high in quality ingredients.

At last month’s NCPA Annual Convention, we unveiled the NCPA CBD Source powered by PRS (www.ncpacobdsource.com), an online resource for CBD products and general information about CBD as a whole. The mission of this initiative is simple — help community pharmacists be the source of truth for their communities. (See page 24 for more on this new program.)

What’s more, NCPA knows how essential it is for community pharmacists to believe that the products they are recommending are high quality and trustworthy. So all companies in the Source must provide their certificate of analysis (COA). Products in the Source have also been tested by a third-party lab. This step holds CBD companies accountable for the active ingredients label, and verifies that the components in the CBD product, including potency, are as advertised.

Diversifying business revenue sources is an important strategy to protect and grow the investment you have in your business. The SurThrival series and NCPA’s CBD Source powered by PRS were created to help pharmacy owners do just that.

Best,

B. Douglas Hooy, Pharmacist, MBA
NCPA Chief Executive Officer

America’s PHARMACIST | November 2019
NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 137
DEPARTMENT OF JUSTICE

FILING CAPTION: Representations Regarding Health Benefits of Goods

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/14/2019 5:00 PM

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

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Filed By:
Angie Emmert
Rules Coordinator

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

DATE: 11/14/2019
TIME: 10:00 AM - 12:00 PM
OFFICER: Cheryl Hiemstra
ADDRESS: Department of Justice
1162 Court St. NE
Salem, OR 97301-4096

SPECIAL INSTRUCTIONS:
Kulongoski Conference Room

NEED FOR THE RULE(S):
The rule is necessary to protect consumers and provide a level playing field for advertisers and sellers. Many goods claim to have health benefits. However, some claims are not substantiated by competent and reliable scientific evidence, and thus may be deceiving consumers and inducing consumer to purchase goods that will not provide the health benefits as described. This deception not only leads consumers to lose money on fruitless goods, but could also lead to adverse health consequences: if a consumer is using an unsubstantiated good, the consumer might be missing out on the health benefits of a different, substantiated good. Advertisers and sellers of goods with substantiated claims could be harmed by losing business to deceitful advertisers and sellers.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:
Documents relied upon include news articles, (See examples submitted, including:
https://www.thelundreport.org/content/dollars-docs-database-shows-oregon-doctors-have-accepted-428-million-gifts-payments-industry;
https://www.newyorker.com/news/news-desk/the-birth-tissue-profiteers), the current text of the Oregon Revised Statutes 646.608(4) and ORS 646.608(1)(u), and information regarding the Federal Trade Commission’s advertising substantiation requirements (in place since at least 1983, some discussion available at: https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation).
FISCAL AND ECONOMIC IMPACT:
The fiscal impact to state agencies is minimal to none.
The estimated economic impact to sellers and advertisers of health goods is mixed.
There is positive economic impact to some sellers and advertisers, of national breadth, who expressed appreciation that
this rule would put Oregon on par with the Federal Trade Commission and most other states that require claimed health
benefits to be supported by competent and reliable scientific evidence, allowing for a more even playing field for
businesses. The rule would also reward advertisers and sellers, regardless of size, who substantiated health benefits
and thereby saved money for the consumers. These cost savings to consumers will be for consumers who could spend
their funds on substantiated health goods, instead of having to purchase an unsubstantiated good and keep searching
for relief elsewhere if the unsubstantiated good fails to deliver on its claims.
The negative economic impact to some sellers and advertisers would be to spend more time to substantiate health
benefits. However, the impact is mitigated because the Federal Trade Commission, who has national enforcement, uses
the same standard as in the proposed rule, and thus would not create a unique burden.

COST OF COMPLIANCE:
(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the
rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the
expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost
of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).
1. Units of state or local government that receive complaints from the public regarding unsubstantiated health goods
would send complaints to the Department of Justice for consideration of enforcement. Members of the public who buy
goods for health benefits are likely to be economically affected positively, as the public would be buying more goods
with substantiated health benefit claims.
2a. The identified types of small businesses subject to the rule include: pharmacy, vitamin shops, retail establishments,
manufacturers of tinctures, CBD sellers, and the like. Certain professions might also be included: naturopaths,
chiropractors, ophthalmologists, and massage therapists (when selling goods, but the rule does not cover the services of
these practitioners). The number of businesses was unable to be estimated by business groups and others in a
Rulemaking Advisory Committee. The stakeholders in the Rules Advisory Committee, including those representing
small business, were asked to estimate the number of small businesses that would be subject to the rule, but they were
unable to provide an estimate of the number.
2b. There would be a cost associated with this recordkeeping and administrative activities, but not regular reporting.
There would be a cost to business for having to review advertisements with claims of health benefits before they are
published, perhaps and added cost for some small businesses that currently subcontract advertising tasks and do not
already review advertisements before publication. However, as this is currently the requirement nationally, most
businesses probably do review their advertisements. Small businesses need to have substantiation for their health
benefit claims, however, the small businesses would not need to conduct the research and studies themselves. For
example, small businesses could keep on file some websites and research conducted by others and that are publicly
available. Also, some of the cost would be perhaps mitigated: if businesses can provide more evidence that the
advertised good is beneficial, this could eventually establish claims and good reputation. The amount of net cost for the
businesses was difficult to quantify or measure, due to the fact that it will depend on the type of business, the product
for sale, and these factors could vary greatly from business to business.
2c. There would perhaps be a cost associated with establishing marketing guidelines, and perhaps discussions with an
attorney if enforcement actions were pursued. No fiscal impact due to the need for extra equipment, supplies, or labor
was identified.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):
Small businesses were consulted in 2015-2016 with an earlier version of the text of the rule that applied to both goods and services. After substantial concerns about the inclusion of services raised by many small health practitioners (chiropractors, naturopaths, etc), the decision was made to remove services from the text of the rule. In 2019, a Rulemaking Advisory Committee was consulted regarding the impact of the advertisers and sellers of goods only, as the text stands now. The discussion included a representative from Main Street Alliance, a group of small business owners, Oregon Business and Industry, an association for businesses both large and small, Oregon Health and Science University, the Consumer Healthcare Products Association, who represents manufacturers and sellers of many goods with health benefit claims, the Oregon Trial Lawyers Association, and the Oregon State Public Interest Research Group. Members of the Pharmaceutical Research and Manufacturers of America were also in attendance at the Rulemaking Advisory Committee meeting. It was discussed that pharmaceuticals are required to meet a more rigorous standard than the proposed rule; thus there was little to no impact for pharmaceuticals.

**WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES**

**ADOPT: 137-020-0900**

**RULE SUMMARY:** Makes it an unfair and deceptive practice to represent, without competent and reliable scientific evidence, that a good has a health benefit.

**CHANGES TO RULE:**

**137-020-0900**

Representations Regarding Health Benefits of Goods

It is unfair and deceptive for an advertiser or seller to make a representation of fact about a health benefit of a good without first having competent and reliable scientific evidence upon which to base a reasonable belief in the truth of the representation.

Statutory/Other Authority: ORS 646.608(4), ORS 646.608(1)(u)

Statutes/Other Implemented:
BACKGROUND
In the U.S., the 2018 Farm Bill removed industrial hemp (and its extracts) from the Controlled Substances Act and legalized hemp to be considered as an agricultural product. It has had a wide range of practical uses including the production of fibers, textiles, cosmetics, foods, beverages, oils and more.

Like marijuana, hemp is a variety of the *Cannabis sativa* plant species. However, it is typically distinguished by its lower concentration of tetrahydrocannabinol (THC) which is the main psychoactive component of cannabinoids (i.e. marijuana, hemp). Legally, industrial hemp cannot contain >0.3% THC on a dry weight basis. With its fast-growing popularity, hemp has also become a primary source of CBD which like THC is a major component of cannabinoids but has no psychoactive (“high”) effects.

In Oregon, cannabis is divided into 2 categories: industrial hemp and marijuana. If hemp-made, a license or registration is not required for a business to sell CBD products under the state’s Hemp Program as long as the product has <0.3% THC and is not advertised as a dietary supplement. Testing requirements are implemented and enforced by the Oregon Department of Agriculture (ODA) to ensure growers and handlers are in compliance prior to sale or transfer to consumers. Overall, there is no legal prohibition against the sale of CBD products to individuals who are <21 years of age (unless it is used for the sale of inhalant delivery systems and their components) or limitations on purchases from retail locations.

Per the Oregon Board of Pharmacy, CBD products can be sold at the pharmacy register by any staff, but all questions related to CBD products must be directed to the pharmacist. CBD products should not be stored in the pharmacy or ordered through the pharmacy. (source: April 2019 Board meeting minutes)

FAQs
The following FAQs are provided to address pharmacy involvement in the sales of CBD products. The Oregon Board of Pharmacy does not have jurisdictional oversight over the regulation of industrial hemp and CBD products in Oregon.

Q. Are pharmacy locations permitted to sell CBD products at the retail (front-end) of the store and if so does this require registration with a regulatory body?
A. Per the 2018 Farm Bill, which legalized industrial hemp (including its extracted products such as CBD), it is legal to sell hemp derived CBD products at a retail location as long as they are: 1) not advertised as a dietary supplement, and 2) provided that their THC concentration is <0.3%.

Currently, there is no requirement for a license or registration for a business to sell CBD products under ODA’s Hemp Program.

Q. Who regulates CBD products and verifies that the amount of THC is within legal concentrations, per 2018 Farm Bill, THC level <0.3%?
A. In Oregon, testing requirements are implemented and enforced by the ODA to ensure growers and processors of industrial hemp are in compliance prior to sale or transfer to consumers.

Q. Are there any restrictions to sale; age restriction, limit in quantity, delivery mechanism?
A. No, as long as the CBD product is derived from industrial hemp and meets federal requirements.

Q. Can CBD be sold as a dietary supplement?
A. No. According to the FDA, under the FD&C Act, it is illegal to market CBD as a dietary supplement.
Q. Can CBD products be sold at the pharmacy register?
A. Yes.

Q. Who can answer health-related questions about CBD?
A. Pharmacists, when the pharmacy is open.

Q. Can a CBD product user test positive for a marijuana drug screen?
A. Yes, it is possible. The test does not distinguish between THC derived from hemp product or marijuana product. The test may be dependent on how much individuals take, when they use it and the frequency in which they consume it. (Note: Drug tests do not test for CBD, but do detect THC. The test cannot distinguish whether detectable THC metabolites is the result of CBD use or the use of marijuana.)

OREGON LAWS AND RULES

The laws and rules applicable to the retail sales of CBD in Oregon include:

2018 OR SB 1544. Requires that products sold in an Oregon Liquor Control Commission (OLCC) retailer (recreational marijuana) must have a label that clearly identifies the source of the CBD – hemp vs marijuana.

ORS 571.303. Industrial hemp is an agricultural product that is subject to regulation by ODA.

ORS 571.333. ODA may enter an agreement with the Oregon Health Authority (OHA) to ensure that hemp crops contain THC concentrations <0.3% on a dry weight basis and are tested by a laboratory licensed by OLCC and accredited by OHA.

REGULATORY OVERSIGHT

<table>
<thead>
<tr>
<th>Product</th>
<th>Medical Marijuana</th>
<th>Recreational Marijuana</th>
<th>Industrial Hemp</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Marijuana</td>
<td>Marijuana products and CBD products derived from marijuana or industrial hemp.</td>
<td>CBD products derived from industrial hemp containing &lt;0.3% THC.</td>
</tr>
<tr>
<td>Location of Sales</td>
<td>Designated growers or medical marijuana dispensaries.</td>
<td>Licensed OLCC recreational marijuana dispensaries.</td>
<td>Any retail location.</td>
</tr>
<tr>
<td>Restriction on Sales</td>
<td>Must have a medical marijuana card. Individuals with a qualifying medical condition and a recommendation for medical marijuana from an attending physician may apply for a medical marijuana card.</td>
<td>Must be ≥21 years of age or older. Source of CBD must be labeled – hemp or marijuana.</td>
<td>None. Unless the product is used for the sale of inhalant delivery systems and their components, then must be ≥21 years of age or older.</td>
</tr>
<tr>
<td>Regulatory Body</td>
<td>OHA</td>
<td>OLCC</td>
<td>ODA</td>
</tr>
</tbody>
</table>

FDA Regulation of Cannabis: Q&A (posted 4/2/2019)
Veterinary Medical Examining Board

The Oregon Veterinary Medical Examining Board’s Monitoring of Controlled Substances Needs to Be Strengthened

November 2019
2019-40
Veterinary Medical Examining Board

The Oregon Veterinary Medical Examining Board’s Monitoring of Controlled Substances Needs to Be Strengthened

What We Found

1. The Oregon Veterinary Medical Examining Board’s inspections of veterinary facilities do not include verification that the federal Drug Enforcement Agency’s requirements for controlled substances are being followed. These medications are known contributors to Oregon’s opioid crisis. (pg. 6)

2. The board did not conduct background checks on new or renewing licensees, despite a 2014 board resolution to begin doing so. This is in contrast to other health licensing boards in Oregon and other state veterinary boards, which perform background checks. Subsequent to our inquiries, the board adopted rules on October 28, 2019, to conduct background checks. (pg. 10)

3. Veterinarians are exempt from participation in Oregon’s Prescription Drug Monitoring Program (PDMP). Their inclusion would contribute to a more complete database of opioid prescribers and could provide useful information to the Oregon Health Authority. Our office issued a performance audit in December 2018 examining the state’s PDMP in detail. (pg. 12)

What We Recommend

The board should take action to ensure administrative rules allow for inspections of veterinary facilities to monitor the use of controlled substances; complete the implementation of administrative rules and begin conducting background checks; and work with both the Oregon Health Authority and the state Legislature to require that veterinarians participate in the state PDMP.

The board agreed with all of our recommendations and has recently initiated rule changes to implement changes. Their response can be found at the end of the report.
Introduction

The Oregon Veterinary Medical Examining Board is responsible for regulating veterinarians and veterinary facilities. The board’s mission is to protect animal health and welfare, public health, and consumers of veterinary services.

Veterinary clinics range from large hospitals to single-veterinarian mobile practices, the majority of which prescribe and dispense drugs that are controlled substances. These drugs are used for surgical procedures, administered during in-clinic treatments, or dispensed for animal patient home use.

Oregon is in the midst of an opioid epidemic and the Governor has indicated that addressing the issue is a high state priority. While much of the focus has been on medical doctors and pharmacists, doctors of veterinary medicine prescribe and dispense many of the same controlled substances used by human practitioners, including opioids.

This audit focused on whether the board is meeting its mission to protect the public health with regard to controlled substances.

The board licenses and regulates veterinary professionals

The board was established in 1903 to test, license, monitor, and regulate practitioners of veterinary medicine in the state. The board consists of eight members, appointed by the Governor and approved by the Senate. Five of the eight board members are licensed veterinarians, one is a certified veterinary technician, and the remaining two are public members.

The board is one of six independent health-related licensing boards. Each board operates in essentially the same manner, issuing and regulating their particular licenses according to their statutory guidelines. The other five boards are the Board of Examiners for Speech Pathology and Audiology, the Board of Naturopathic Medicine, the Mortuary and Cemetery Board, the Occupational Therapy Licensing Board, and the Board of Medical Imaging.

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1 Office of the Governor, State of Oregon; Executive Order No. 18-01, "Building Oregon’s Commitment to Addiction Prevention, Treatment, and Recovery Priorities, and Setting Deadlines for Statutory Requirements, and Declaring a Public Health Crisis"; signed March 27, 2018.

2 These boards, because of their size and similar nature, are grouped together in one agency. Other health-related boards, such as the Oregon Medical Board and the Oregon Board of Dentistry, operate as individual agencies.
The board’s 2017-19 legislatively adopted budget includes four budgeted positions: an executive director, a facility inspector, an investigator, and a part-time administrative staff. For 2017-19 the board is funded by approximately $973,220 in annual revenue from veterinarian license, application, and examination fees, and veterinary facility registration fees.

Primary board functions include the licensing of veterinary professionals and facilities, investigating public complaints against licensees, and inspecting veterinary facilities for compliance with state and federal requirements. The board currently licenses more than 650 veterinary facilities and approximately 4,000 veterinarians and certified veterinary technicians.

The board’s authority comes from the Veterinary Practice Act. The act defines who is required to be licensed, what constitutes the practice of veterinary medicine, qualifications for licensing, and continuing education requirements. The act also defines unprofessional or dishonorable conduct and states that the board may discipline any permit or license holder for such acts. The board develops and maintains rules under which licensees practice, codified under Oregon Administrative Rules chapter 875.

Several stakeholders play a role in board operations

Several entities play a role in the board’s mission to protect the public health with regard to controlled substances as shown in Figure 1. Two of the board’s main stakeholders include the federal Drug Enforcement Administration (DEA) and the Oregon Veterinary Medical Association (OVMA).

Figure 1: Several stakeholders play a role in board operations

ORS 686.210 establishes the Oregon State Veterinary Medical Examining Board. Chapter 686 of Oregon law more generally is referred to as the Veterinary Practice Act.
The DEA’s primary responsibility is to enforce the Controlled Substances Act. One of the responsibilities of the DEA Office of Diversion is to investigate complaints of suspected diversion of controlled substances; they receive about eight to ten complaints each month of which two to three pertain to veterinarians and veterinarian practices. Diversion with respect to controlled substances is re-routing these drugs from their intended, legal purpose to other uses. Diversion occurs when a person fakes illness or injury or intentionally injures themselves or others to obtain a prescription. The board has a responsibility to ensure DEA regulations over controlled substances are followed.

As a regulatory entity, the board has a relationship with and is influenced by the OVMA, a professional association that exists to promote and protect the interests of the veterinary profession. The OVMA seeks to influence legislation to benefit their members. According to the OVMA website, 80% of Oregon veterinarians in active practice are members of the organization.

**Oregon’s opioid crisis has focused attention on medical doctors and pharmacists, but veterinarians also prescribe controlled substances**

**Opioids are extremely addictive and opioid-related deaths are still rising**

Opioids are controlled substances that act on receptors in the brain and are widely used to control pain; however, they are also highly addictive and pose significant danger when misused. Heroin, morphine, and opium are natural opiates derived from the poppy plant. Synthetic opioids are made in a laboratory and include drugs such as fentanyl and tramadol. Some opioids, such as heroin, have no currently accepted medical use and a high potential for abuse and are therefore illegal. Others, such as oxycodone or fentanyl, can be legally prescribed, but are often sold or obtained illegally.

Widespread misuse and abuse of opioids has led to a public health crisis in the United States. The National Center for Health Statistics reported 341 opioid-related deaths in Oregon from November 2017 to November 2018, which translates to 28 Oregonians dying from opioids every month. According to the Centers for Disease Control and Prevention, drug overdose deaths, including those involving opioids, continue to increase in the United States. The rate of opioid overdose deaths has more than doubled since 2007 (see Figure 2).

Addiction is a public safety issue that continues to plague Oregon. Three out of every five prescriptions written in the state, or 60%, are for schedule II-IV opioids. In addition, Oregon has some of the highest rates in the country of addiction involving vulnerable populations, including teens, seniors, and those with mental health issues. Addiction has been shown to exacerbate homelessness and crime. Drug addiction is also expensive. In 2015, annual costs related to opioid addiction were $1,413 per Oregonian, or 2.46% of Oregon’s gross domestic product.

Executives, legislators, and state agencies have issued declarations, passed laws, and strengthened guidelines in an attempt to stem the tide of opioid addiction. The Oregon Prescription Drug Monitoring Program (PDMP) is one component of the Oregon Health Authority’s “Opioid Initiative,” launched in 2015, to address the opioid crisis.

The PDMP facilitates collection of drug prescribing data that can be used by the Oregon Health Authority to develop strategies and policies, allowing the agency to determine whether their

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4 The Controlled Substances Act of 1970 is codified in Title 21 of the United States Code, Chapter 13. Related regulations are in the Code of Federal Regulations, Title 21, Chapter II, Parts 1300-1399.
5 Controlled substances are drugs and other substances, including opioids, identified with potential for abuse or dependence, and as a result their manufacture, distribution, and use is highly restricted or illegal under the Controlled Substances Act.
actions are effective. The PDMP is a tool used by pharmacists and other medical professionals to identify unusual prescribing patterns and prevent individuals from obtaining prescriptions for illicit use.

**Figure 2: The rate of opioid overdose deaths has more than doubled since 2007**

![Opioid Overdose Deaths Chart](image)

Source: Centers for Disease Control and Prevention, Opioid Data Analysis and Resources

Veterinarians purchase their controlled substances directly from suppliers and manufacturers, much like pharmacists. However, unlike pharmacists, they are not required to independently report this information to the PDMP or query the data in PDMP when dispensing prescription drugs. Our office issued a performance audit in December 2018 examining the state’s PDMP system; in that audit, we recommended including veterinarian prescriptions in the information to be collected by the PDMP.8

**Diversion of controlled substances can occur through veterinary practices**

Those who prescribe, dispense, and administer controlled substances are required to register with the DEA and maintain a strict accounting for all distributions. Logs should include the drug type, dosage, patient name, and number of pills dispensed. Controlled substances must be stored in a locked cabinet and a detailed physical inventory should be performed at least every two years. The drug dispensing information should correspond to patient records. For a minimum of two years, practitioners must maintain copies of DEA order forms (used to order controlled substances from distributors), copies of invoices for drug orders, and records of transfers of controlled substances to other DEA registered practitioners.

Those who work in occupations with access to controlled substances can steal drugs, write fake prescriptions, and alter records to hide missing inventory if internal controls are not sufficient to prevent or detect such actions. All of these diversion activities have been known to occur in the veterinary field.

Veterinary practices often function as both doctor and pharmacy. Drugs are stored on site for surgical procedures administered in the clinic, or dispensed for clients to take home for their pet. Veterinary practices, which can range from large hospital settings to single-veterinarian mobile practices, vary in their capacity to meet the DEA requirements. Small practices may only have one person ordering the drugs, entering them into logs, and recording use of the drugs on a

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8 Report no. 2018-40: “Constraints on Oregon’s Prescription Drug Monitoring Program Limit the State’s Ability to Help Address Opioid Misuse and Abuse,” December 2018; recommendation no. 12(c)
pet’s medical chart. In some cases, DEA regulation may not be followed at all. There is little hands-on training available on the subject, compliance with regulations is not monitored on a consistent basis, and some practices find the regulations cumbersome and view them as unnecessary.

Controlled substances prescribed in veterinary medicine are identical to those used in human medicine, even though differences exist between animal and human physiology. Tramadol and fentanyl, for example, are used to treat moderate to severe pain in many species of animals. Ketamine is used as an anesthetic agent. Hydrocodone can be used to treat coughing in dogs. Alprazolam (Xanax®) and diazepam (Valium®) are used to treat anxiety, panic disorders, and seizures. These are all drugs used for human medical treatments and favored by drug addicts. According to the Centers for Disease Control and Prevention, overdose deaths from synthetic opioids (e.g., tramadol and fentanyl) have had the sharpest rise in recent years.

Since many dogs, cats, and other animals have lower weights and higher metabolisms, they may require lower drug strengths, or dosages of drugs, than humans. However, smaller dosages can be combined to provide enough strength to get a human high.

We conducted a survey of veterinary facilities that showed that over 23% of respondents have seen an increase in the number of customers exhibiting doctor shopping behaviors in the last three years, including suspicious pet injuries. The survey results mirrored those of a survey conducted by the Colorado School of Public Health. Just over 15% of respondents suspected a co-worker of having a controlled substance issue or of diverting medications to themselves or others in the last three years. Additional survey results are covered in greater detail later in this report.

According to the president of the National Alliance for Model State Drug Laws: “Those misusing or selling drugs for nonmedical purposes tend to take the path of least resistance. As states close routes to obtaining medications, addicts and sellers will choose others.” One such route could be the veterinary industry, where insufficient controls and lax monitoring increase the risk of diversion occurring. Therefore, if a significant veterinary diversion problem does not exist now, the risk is high that one will develop in the current climate, with the advent of the PDMP and other barriers to obtaining opioids.

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Audit Results

We found the Oregon Veterinary Medical Examining Board is not proactively managing the risk of controlled substance diversion in Oregon. We identified three main areas for the board to address. To begin with, the board needs to improve its inspection process. The board developed veterinary facility inspection rules, but neither the rules nor the inspection process includes a review of invoices for drug orders, patient records, or other required DEA documentation. The board only investigates if there are complaints involving diversion, but has few processes in place to identify risks involving inappropriate use of controlled substances. During the course of the audit, the board had not determined what action it would take against a fast approaching deadline pertaining to Board of Pharmacy rules over inspections.

Second, although background check rules were proposed and approved by the board in 2014, rules were not adopted until October 28, 2019. Lastly, the board has not taken a position on whether to include veterinarians in the PDMP.

Without proactive measures, the board’s mission is undermined and the possibility of controlled substance diversion is heightened, putting both the public health and the welfare of animals at increased risk.

Incomplete inspections of veterinary facilities increase the risk of diversion

The board established its current facility inspection process as a result of amendments the Legislature made to the Oregon Veterinary Practice Act in 2015. Prior to this, the board only conducted inspections in response to complaints. The board recognized that without inspections, facilities could fall short of minimum cleanliness and safety standards, so the board requested these statutory changes.

Over the years, non-veterinary ownership of facilities has become more prevalent as it allows greater opportunity for veterinarians wishing to expand ownership or sell their practices upon retirement. By requiring all veterinary practices to register as facilities, the board has the authority to regulate all facilities, whether or not they are owned by a veterinarian.

The 2015 amendments enabled the board to conduct regular facility inspections and investigate issues or complaints against facilities that were not owned by veterinarians. Prior to the amendment, the board could enforce rules against veterinarians but had no ability to enforce rules against a facility owned by a non-veterinarian. In 2017, the board hired a facility inspector and began inspections of veterinary facilities.

Inspections of veterinary facilities focus on safety, cleanliness, and sanitation, but do not include review of controlled substance logs

The board used an inspection checklist from the state of Virginia as a model for its own checklist, but did not include Virginia’s detailed steps related to controlled substance and patient record review. The board excluded these steps because it believes they are not within its authority. The current checklist focuses primarily on best practices for safety, cleanliness, and sanitation, which includes verifying controlled substances are properly stored in a locking cabinet and that expired drugs are separated and not sold. The board’s inspection procedures are not designed to detect diversion, which is known to be a problem with some Oregon veterinarians.

The DEA enforces the Controlled Substance Act, which requires strict accounting for controlled substances. According to the DEA, they do not have the resources to perform regular facility inspections to ensure compliance, so they rely on the states to conduct regular inspections. In relation to veterinary practices, the DEA’s role is to investigate only if they have reason to believe a violation has occurred (i.e., a public complaint or report from the board). Only 3% of
our survey respondents indicated they have had a facility inspection by the DEA in the last three years.

Since the board determined it does not have authority to monitor for controlled substances, board inspections do not include compliance with all DEA requirements. The board’s inspector must adhere to the limited checklist and is at a distinct disadvantage to discover, note, or address controlled substance violations or irregularities. For example, if during an inspection the inspector suspected the veterinarian was hiding or manipulating the opioid stock, the board contends its inspector would not be able to comment on or note this suspicious behavior for further follow up because of specific instructions to focus only on verifying that controlled substances were locked up. In addition, the inspector would not be allowed to review controlled substance documentation that would have shown if there were any missing pharmaceuticals.

**The board has not taken sufficient action to ensure its authority allows for inspection of controlled substances**

The board contends its current inspection authority, as spelled out in law and rule, does not allow inspecting veterinary facilities for DEA requirements related to handling of controlled substances. Yet the board has not taken action to amend its administrative rules to permit inspections of controlled substances.

Current law allows the board to adopt certain rules for facility registration and renewal procedures, to establish fees, and to define health and safety standards, which includes rules for monitoring of controlled substances. Current administrative rules for veterinarians and veterinary facilities state “all biological substances shall be stored, maintained, administered, dispensed and prescribed in compliance with federal and state laws and manufacturers’ recommendations.” The board contends that since this requirement is included in a rule for veterinary practice standards and not specifically stated in the rule for veterinary facilities and licensees, the board would assume legal risk if it inspected facilities for controlled substances.

As a result, the board specifically scopes inspections so that the inspector adheres to a checklist that does not allow for monitoring of controlled substances (see Appendix B). Because the board is not seeking amendments to its rules so they align with federal requirements for administering, dispensing, and prescribing controlled substances, it is not meeting its mission to protect the public.

Amending administrative rules to enhance inspections takes time, as it involves writing proposed rules, holding a hearing, obtaining feedback from interested parties, making any necessary revisions, and implementing the rules. However, in this particular instance, the process is even more onerous due to a recent requirement to involve a specially formed rules advisory committee.

When the Legislature was considering granting authority to the board to register and regulate veterinary facilities as part of the 2017 amendment process, the OVMA successfully presented testimony to have the bill amended to require convening a rules advisory committee to approve any addition or change to facility inspection rules. The advisory committee requirement is in place until January 2020 and mandates the committee consist of a diverse group of 11 veterinarians. Due to the 2017 legislative amendments, the board has not taken action to

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10 Oregon Administrative Rule 875-015-0030(7)(a)
11 Oregon Administrative Rule 875-015-0020
12 Oregon Revised Statutes 686.210, Section 7, requires that the advisory committee include representatives of the following: a rural veterinary facility, an urban veterinary facility, a mixed animal practice, a large animal practice, a nonprofit animal shelter, a nonprofit caring for indigent animals, the OSU College of Veterinary Medicine, a certified veterinary technician (or individual who represents a veterinary technology program offered in the state and accredited by the American Veterinary Medical Association), two current members of the board, and one former member of the board.
revise its administrative rules to include administering, dispensing, and prescribing controlled substances.

Since 2017, the board has initiated 78 investigations in response to complaints. At least seven of those investigations, or 9%, involved diversion of controlled substances by veterinarians or veterinary staff. When conducting an investigation where the board inspector suspects diversion has occurred, the inspector passes that information to a local DEA agent in Portland to investigate and determine whether diversion did occur. The agent estimates that 20% to 30% of their caseload is veterinary-practice related.

A more robust inspection process would help the board identify diverters so they could be investigated and disciplined. In addition, if record keeping deficiencies are found, the inspection process provides an opportunity to educate veterinary facility personnel on proper practices for maintaining DEA required records.

The board must change its inspection processes by 2021 or become subject to the Board of Pharmacy’s inspections

The board’s inspection process also falls short of the more rigorous inspections conducted by the Board of Pharmacy for controlled substances. The board has until June 2021 to align its rules and controlled substance inspection process with the Board of Pharmacy or its controlled substance inspection responsibilities could be transferred to the Board of Pharmacy. During the course of the audit, the veterinary board had not determined what action it plans to take.

In 2013, the state Department of Justice issued a final opinion that medical practice sites with dispensing practitioners (such as veterinary clinics) are subject to Oregon Board of Pharmacy dispensing practitioner drug outlet (DPDO) registration requirement. The Board of Pharmacy began working with other agencies and stakeholders to establish rules to regulate DPDOs. The Notice of Proposed Rule-making, filed in January 2017, provides an explanation for these new rules:

“Prescription drug dispensing has changed significantly in the last 5 years with increased access outside the pharmacy model. The process is also more sophisticated around the access to drugs, compounded drugs, supply and the chain of custody; i.e. how drugs are acquired, stored, labeled, when they expire etc. The Board of Pharmacy is charged with the regulation of the practice of pharmacy, as well as the risks and public safety related to the distribution of prescription drugs. Practitioner Dispensing Drug Outlets are not currently regulated or inspected as all other dispensing locations. The Board wants to facilitate and ensure safe dispensing practices occur for the public.”

The rules became effective December 1, 2017, and require DPDOs to register and be inspected on an annual basis.

Based on the Department of Justice opinion, since veterinary facilities dispense controlled substances, they meet the definition of a DPDO and would be subject to these rules and inspections. However, veterinarians expressed concerns to the Board of Pharmacy during the rule-making process that the DPDO rules would constitute an undue burden on their practices, such as additional fees and inspections. The board requested a waiver, and was allowed an

exemption from the registration requirements on the condition that the board’s controlled substance inspection process mirror the Board of Pharmacy’s.

The board has until June 2021 to comply. At the time of this report, the board’s inspection process encompassed only a few limited portions of two of the Board of Pharmacy’s 11 specific areas of compliance related to controlled substances, which are documented in Appendix B. The new administrative rules need to be written and approved, and an inspector needs to be trained in DEA controlled substance requirements by the June deadline.

In May 2019, the board’s executive director stated they had not determined what action to take and indicated it might be easier if the responsibility for controlled substance inspections was transferred to the Board of Pharmacy, as their inspectors are registered pharmacists trained to monitor DEA documents and review patient records for compliance and signs of diversion. However, the shift would mean veterinary facilities would have to register separately with the Board of Pharmacy and have a separate facility inspection on an annual basis — resulting in additional costs and inspections for veterinarians and veterinary facilities. Meanwhile, veterinary practices are not being monitored for compliance with controlled substance requirements by the veterinary board, the DEA, or the Board of Pharmacy.

Many other states inspect for controlled substances as part of their facility monitoring process

California has extensive inspection procedures that apply to veterinarians handling controlled substances. Their inspection process covers 42 areas, including drug security controls and drug logs. In addition, California requires that veterinary assistants who have access to controlled substances hold a Veterinary Assistance Controlled Substance Permit. The permit holder is required to wear a badge displaying the required information.

In addition to keeping controlled substances in a secure location, Arizona inspects the facility’s dispensing logs, and requires separate inventory logs of each substance linking purchases to specific invoice numbers. The logs are required to contain the drug name, strength, and amount of each substance; the name of the animal and owner; who dispensed or administered and when; and a running balance of the controlled substance available. The latter requirement in particular makes it very easy to verify the accuracy of the facility’s recordkeeping.

We found similar facility inspection processes in Florida, Nevada, New Mexico, North Carolina, Virginia, and West Virginia.

Strengthened inspections are a proactive and effective way for the board to combat diversion

Controlled substance diversion is a problem in the veterinary industry, one that is compounded by a lack of oversight related to diversion. In October 2018, an Oregon veterinarian was arrested on charges of menacing and coercion. The charges stemmed from threatening an employee with a gun and tampering with drug records. The DEA and other authorities also investigated allegations of diverting opioids, falsifying drug records, and being abusive to animals under
veterinary care. The board subsequently denied the veterinarian’s 2019 license renewal pending resolution of the criminal charges. Had a thorough inspection of drug ordering and dispensing records occurred, the diversion activity may have been detected sooner.

Responses to our survey indicated diversion related to client doctor shopping is likely occurring; however, the larger risk of diversion appears to be through veterinarians and their staff. Almost 9% of the complaints brought to the board in the past three years were related to controlled substance diversion by veterinarian staff.

A thorough and periodic inspection of DEA required documentation would bring a multitude of benefits. It would highlight areas where veterinary practice training is needed in documenting controlled substances. It could uncover current diversion and could deter further diversion by making it more difficult for diversion to continue without being detected.

**The board recently initiated action for more thorough inspections**

Despite the board’s opinion that they could not change the administrative rules related to facility inspections without convening an 11-member rules advisory committee, rules were drafted and proposed on October 29, 2019. On the proposed rules notice, it indicates that input from the OVMA was sufficient to justify not consulting with a rules advisory committee.

**The board does not require criminal background checks**

*Unlike other health licensing boards in Oregon, the Veterinary Board only requires self-reporting of criminal history*

Criminal background checks can help protect public safety and animal welfare by alerting the board to applicants that have drug-related arrests and convictions prior to issuing or renewing a veterinary license. Of the six health-related licensing boards, the Veterinary Medical Examining Board is the only board that does not require background checks.

Instead, the board requires licensees to indicate on their license applications and renewals if they have been charged or convicted of a crime. A positive response triggers a review of the applicant’s background to determine whether the license should be renewed or other action taken. Those who fail to self-report a conviction are subject to civil penalties or other sanctions.

The American Association of Veterinary State Boards created a Practice Act Model, which recommends boards require veterinary licensee applicants provide a full set of fingerprints for the purpose of obtaining criminal records checks.

To date, 17 states, including Washington and California, require background checks on veterinary licensees. These are primarily states that, like Oregon, have significant issues with opioid addiction.

**Despite earlier opposition, the board recently initiated action to conduct background checks**

The board voted unanimously to adopt rule amendments for criminal background checks on October 14, 2014, after considering audit recommendations in a report our office released earlier that year.\(^{14}\) The 2014 rules were never adopted.

According to the board’s executive director, the board did not initiate background checks in 2014 because of the “negative feedback” received from respondents in the public comments.

stage of rule-making. We examined the public comments and found that out of twelve responses, five respondents opposed the rule change, four were in favor, and three had questions about the proposed rules or unrelated comments.

The OVMA also opposed the rule amendments to adopt criminal background checks, stating that online comments received by OVMA did not support adoption. During interviews with board members and staff, some indicated that conducting background checks on veterinarians and their staff was either not necessary because veterinarians go through four years of schooling and there are very few problems in the veterinary industry; or, in the case of veterinary technicians, it is the responsibility of the employer.

In contrast, our survey found widespread support among veterinarians and veterinary technicians for background checks. When asked whether they believed that veterinarians should be subject to a criminal background check before beginning practice in Oregon, 72% of respondents said yes. With respect to background checks for veterinary technicians, 70% of respondents said yes. In addition, the majority of respondents (59%) said they believed it was the responsibility of the board to conduct those background checks.

Survey respondents support background checks

Our survey found 72% of respondents supported criminal background checks for veterinarians and 70% support for background checks for veterinary technicians.

The need for background checks becomes even more important considering the fact that the DEA issues controlled substance registration numbers based on whether the board issued a license to the veterinarian. The DEA assumes that the applicant has been properly vetted by the board and found to have no history of controlled substance diversion. The DEA looks into an applicant’s background only if they self-disclose a felony drug charge or conviction.

Not performing due diligence, including background checks, increases the risk of noncompliant veterinarians and diversion of opioids. Given the board’s application process, individuals who engage in these activities could gain a professional license that allows them to apply for DEA registration. That, in turn, would enable them to prescribe, dispense, and directly order controlled substances, thereby increasing the risk of controlled substance diversion to the public.

The board recently took action to address this concern. On July 23, 2019, the board filed proposed administrative rules to implement background checks for veterinarians and veterinary technicians.\(^\text{15}\) As proposed, the rules will allow the board to conduct background checks on initial and renewing applicants and require applicants to provide any police and court records for any arrests and convictions. The rules were adopted on October 28, 2019. The new rules state the board may conduct background checks on intern, initial, and renewing license applicants and on initial and renewing CVT license applicants. According to board management, staff were instructed to begin conducting background checks on new applicants in November 2019.

\(^{15}\) Notice of Proposed Rulemaking, Chapter 875, Veterinary Medical Examining Board, published in the Oregon Bulletin for August 2019. ([https://secure.sos.state.or.us/oard/displayBulletins.action](https://secure.sos.state.or.us/oard/displayBulletins.action))
Veterinarians are exempted from participating in Oregon’s Prescription Drug Monitoring Program

Oregon’s PDMP is designed to promote public health and safety and help improve patient care by providing information to better manage patients’ prescriptions. It was also developed to help ensure the appropriate use of prescription drugs. During the course of the audit, the board had not taken a position on whether to include veterinarians in the PDMP. Currently, veterinarians are not required to participate or query the data when dispensing prescription drugs, although they may voluntarily participate.

Prescription monitoring programs are in place in 49 states, Puerto Rico, Guam, and the District of Columbia. While all states with programs require pharmacies to report, as of July 2019, just 19 required dispensing veterinarians to report controlled substances. Oregon is not among them.

Our survey of veterinarians and veterinary technicians found the majority of respondents were in favor of some level of involvement with the PDMP. Slightly more than half of survey respondents said they would be willing to report dispensed controlled substances to the PDMP and 89% said they would be willing to query the PDMP if they suspected a customer may be diverting controlled substances from their animal. Additionally, 74% said they would be willing to write prescriptions for scheduled drugs in lieu of directly dispensing them, which would result in the filling pharmacy entering the information the PDMP.

*Participation in PDMP aids in gathering more complete data on controlled substances*

Adding veterinarian prescriptions to the PDMP will improve its usefulness as a complete database of prescribers of controlled substances. Although this requirement may not deter all diversion and may require more effort by veterinarians, it will help determine the prescribed controlled substance volume, identify potential prescribing and dispensing issues, and contribute to the board’s mission of protecting public health.

The addition of veterinarians would give the Oregon Health Authority a clearer picture of controlled substances being prescribed and dispensed in the state, and provide a tool for veterinarians to detect and prevent drug diversion through their practices. Our office issued a performance audit examining the state’s PDMP system in detail, in which we recommended including veterinarian prescriptions in the information to be collected by the PDMP.16

When implementing any new process, there may be inefficiencies and challenges. However, when considering public health and the extent of the opioid crisis in Oregon, all reasonable efforts to thwart the epidemic should be seriously considered. The board and its stakeholders need to consider the needs of Oregonians in addition to the impact to their specific responsibilities.

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16 Report no. 2018-40; “Constraints on Oregon’s Prescription Drug Monitoring Program Limit the State’s Ability to Help Address Opioid Misuse and Abuse,” December 2018; recommendation no. 12(c)
**Recommendations**

Strengthened inspections, background checking licensees, and helping to provide more complete PDMP data is the most effective course of action for addressing controlled substance diversion in the veterinary community.

Strengthening inspections would put an emphasis on controlled substance monitoring in the practice setting, allowing veterinarians and managers to identify diversion sooner. This would also allow the inspector to proactively identify diversion, rather than the more reactive method of responding to a complaint.

Background checks in and of themselves may prevent those with arrests or convictions from even applying for a license and would eliminate the risk of someone with a diversion-related felony arrest or conviction being licensed and having access to controlled substances. Adding veterinarian prescriptions to the PDMP would improve its usefulness as a complete database.

We recommend the Oregon Veterinary Medical Examining Board take the following actions to more effectively monitor controlled substances:

1. Take action to ensure administrative rules allow the board to inspect veterinary facilities to monitor controlled substances, ensuring inspections comply with required DEA documentation.

2. Complete the implementation of proposed administrative rules and begin conducting background checks on all new and renewing veterinary and certified veterinary technician licensees.

3. Work with the Oregon Health Authority and the state Legislature to require veterinarians to participate in the state PDMP.
Objective

The objective of this audit was to determine whether the Oregon Veterinary Medical Examining board is upholding the tenets of its mission: to protect animal health and welfare, public health, and consumers of veterinary services.

Scope

This audit focused on proper inspection and monitoring of veterinary controlled substance prescribing and dispensing.

Methodology

To address our objective, we interviewed key staff and members of the board, including the executive director, several board members, the investigator, and the inspector. We also interviewed the executive director of the OVMA, a Portland DEA Diversion Agent who works with the board, a practicing veterinarian, and the compliance director from the Oregon Board of Pharmacy. We developed a survey of questions to elicit the opinions of Oregon veterinarians about the board’s processes. We also requested their views on whether veterinarians and technicians should be subject to background checks, the extent of the veterinary role in the opioid crisis, and use of the PDMP.

We accompanied the facilities inspector on inspections of a nonprofit practice affiliated with an animal rescue and a small veterinary practice. We obtained information from other states regarding their practices for facility inspections to establish best practices nationwide. We also traced the development and implementation of House Bill 2474 (2015 legislation), which established facility registrations, and reviewed the board’s presentation to the legislature and testimony made during that process.

We attended a board meeting, reviewed minutes of board meetings, board policies and procedures, Oregon Revised Statutes, and Oregon Administrative Rules that relate to the board. We traced the history of background check discussions during board meetings, proposed administrative rules, and public comments regarding rule changes.

Our team also reviewed complaint files processed since 2017, documenting the total number of complaints, type of complaint, and how each was resolved. We identified which complaints were specifically related to controlled substance abuse or diversion.

We developed and emailed a survey to 623 licensed veterinarians and veterinary technicians. We received 222 responses to our survey, which is documented in appendix A. We also received numerous written comments that help explain some of the respondents’ concerns.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained and reported provides a reasonable basis to achieve our audit objective.

We sincerely appreciate the courtesies and cooperation extended by members and employees of the Oregon Veterinary Medical Examining Board during the course of this audit.
Appendix A: Survey Results in Detail

The audit team developed a survey to inquire about the following topics:

- Licensee Type
- New license application process
- Renewal license application process
- Complaint process
- Accessibility and user friendliness of the Board’s Website
- Background checks
- Controlled substances and diversion
- Prescription Drug Monitoring Program usage
- Board inspections

Auditors used SurveyMonkey to develop and complete the survey. Using a list of facility emails provided by the Oregon Veterinary Medical Examining Board, we sent the survey to 623 facilities. We received 222 responses, a 35.6% response rate. Of the total responses, 211 were licensed veterinarians and 11 were certified veterinary technicians. The survey included 38 questions, six of which required open-ended responses. To preserve the anonymity of the respondents, the open-ended responses have not been included.

**Question 1:** I am a:

- Licensed veterinarian: 95%
- Certified veterinary technician: 5%

**Question 2:** I have gone through the veterinarian or certified veterinary technician initial licensing process in Oregon.

- Yes: 88%
- No: 12%

**Question 3:** I found the initial licensing process easy to complete.

![Bar chart showing the responses to Question 3]

**Question 4:** I have renewed my veterinarian or certified veterinary technician license in Oregon.

- Yes: 99%
- No: 1%
Question 5: I found the renewal process easy to complete.

![Bar chart showing the distribution of responses to Question 5. 71% agreed, 20% somewhat agreed, 8% neutral, 1% somewhat disagreed, and 0% disagreed.](image)

Question 6: I have been involved in the Oregon Veterinary Medical Examining Board complaint process.

Yes: 30%
No: 70%

Question 7: I felt the complaint process was easy to complete.

![Bar chart showing the distribution of responses to Question 7. 26% agreed, 20% somewhat agreed, 32% neutral, 11% somewhat disagreed, and 11% disagreed.](image)

Question 8: I felt the person taking my complaint understood my concerns.

![Bar chart showing the distribution of responses to Question 8. 36% agreed, 11% somewhat agreed, 29% neutral, 13% somewhat disagreed, and 11% disagreed.](image)
Question 9: I felt that the Oregon Veterinary Medical Examining Board handled my complaint appropriately.

Question 11: I have visited the Oregon Veterinary Medical Examining Board’s website within the last year.

Yes: 85%
No: 15%

Question 12: I found the following section(s) of the website to be helpful, easy to understand, and easy to navigate. (Select all that apply)

- Licensing Information: 31%
- Continuing education: 22%
- License application: 17%
- Laws, rules, and regulations: 17%
- Board information: 5%
- Complaint information: 4%
- None of the above: 4%

Question 13: I found the following section(s) of the website to be confusing, incomplete, or frustrating to navigate. (Select all that apply)

- Licensing Information: 55%
- Continuing education: 8%
- License application: 4%
- Laws, rules, and regulations: 15%
- Board information: 7%
- Complaint information: 6%
- None of the above: 5%
Question 15: I believe that veterinarians should be subject to a criminal background check before beginning to practice in Oregon.

Yes: 72%
No: 10%
Unsure/No opinion: 18%

Question 16: I believe that certified veterinary technicians should be subject to a criminal background check before beginning to practice in Oregon.

Yes: 70%
No: 11%
Unsure/No opinion: 19%

Question 17: I believe that it is the responsibility of the Oregon Veterinary Medical Examining Board to administer criminal background checks on all new license applicants.

Yes: 59%
No: 15%
Unsure/No opinion: 26%

Question 18: I believe it is the responsibility of the Oregon employer to run criminal background checks on prospective employees.

Yes: 33%
No: 35%
Unsure/No opinion: 32%

Question 20: Please rate how large of a role you believe veterinarians and certified veterinary technicians play in the opioid crisis.

A large part 5%
Some part 66%
Unsure 11%
No part 18%

Question 21: In the last three years, I have seen an increase in the number of customers exhibiting “vet shopping” behaviors (i.e., suspect injuries, asking for medications by name, asking for early refills, etc.).

Yes: 24%
No: 76%
Question 22: In the last three years, I have suspected a co-worker of having a controlled substance abuse issue and/or diverting medications to themselves or others.

Yes: 15%
No: 85%

Question 23: My workplace has an FDA-recommended safety plan in place to handle instances of abuse related to controlled substances.

Yes: 29%
No: 31%
Unsure: 40%

Question 25: I have my own Drug Enforcement Agency (DEA) identification number, which allows me to prescribe and dispense controlled substances.

Yes: 90%
No: 10%

Question 26: I think the PDMP could be useful in the detection and prevention of controlled substance abuse and diversion.

Yes: 27%
No: 25%
Unsure/No opinion: 48%

Question 27: I am willing to report dispensed schedule II-IV drugs to Oregon’s PDMP.

Yes: 53%
No: 47%

Question 28: I am willing to query the PDMP if I suspect a customer may be diverting schedule II-IV drugs from their animal.

Yes: 89%
No: 11%

Question 29: I am willing to provide my clients with written prescriptions (as opposed to direct dispensing) for schedule II-IV drugs.

Yes: 74%
No: 26%

Question 30: Out of the options below, I believe this option would be the most effective in helping control the diversion of schedule II-IV drugs.

- Veterinarians providing written prescriptions for all schedule II-IV drugs: 16%
- Veterinarians reporting to and querying the PDMP: 28%
- Unsure/No opinion: 56%
**Question 31:** Of the options below, I believe this option would be the most *efficient* in helping control the diversion of schedule II-IV drugs.

- [Bar Chart]
  - Unsure/No opinion: 49%
  - Veterinarians providing written prescription for all schedule II-IV drugs: 24%
  - Veterinarians reporting to and querying the PDMP: 27%

**Question 33:** Are you the managing veterinarian at your workplace?

- Yes: 81%
- No: 19%

**Question 34:** My facility has had an Oregon Veterinary Medical Examining Board inspection in the last three years.

- Yes: 42%
- No: 58%

**Question 35:** I found the inspection to be efficient.

- [Bar Chart]
  - Disagree: 0%
  - Somewhat Disagree: 1%
  - Neutral: 13%
  - Somewhat Agree: 18%
  - Agree: 67%

**Question 36:** I found the inspection to be thorough.

- [Bar Chart]
  - Disagree: 0%
  - Somewhat Disagree: 3%
  - Neutral: 15%
  - Somewhat Agree: 16%
  - Agree: 66%

**Question 37:** My facility has had an inspection by the Federal Drug Enforcement Agency (DEA) in the last three years.

- Yes: 3%
- No: 97%
## Appendix B: Comparison of Facility Inspection Checklists for Controlled Substances

The table below compares inspection points related to DEA required controlled substance requirements. The table includes excerpts from the Oregon Veterinary Medical Examining Board’s facilities inspection checklist and the Oregon Board of Pharmacy’s Dispensing Practitioner Drug Outlet Self-Inspection report, which encompasses steps to comply with DEA regulations.

<table>
<thead>
<tr>
<th>Oregon Veterinary Medical Examining Board – Veterinary Facility Inspection Report</th>
<th>Oregon Board of Pharmacy – Dispensing Practitioner Drug Outlet Self-Inspection Report</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4. Guidance:</strong> Controlled and legend substances must be purchased, stored, secured, inventoried, logged and dispensed according to DEA, FDA and manufacturers’ requirements.</td>
<td><strong>1.</strong> Does the outlet have policies and procedures for drug management, including security, acquisition, storage, labeling, disposal, record keeping?</td>
</tr>
<tr>
<td><strong>5.</strong> Expired drugs must be clearly marked or segregated to ensure no fee is charged.</td>
<td><strong>2.</strong> Are drugs kept in a locked drug cabinet or drug storage area that sufficiently denies access to unauthorized persons?</td>
</tr>
<tr>
<td><em>In regards to above, the board’s current checklist only includes verifying controlled substances are properly stored in a locking cabinet, adequate refrigeration is provided for perishable drugs, and that expired drugs are separated and not sold.</em></td>
<td><strong>3.</strong> Have you verified the pharmacy, wholesaler(s), manufacturer(s), that the outlet purchases medication from is registered in Oregon with the Board of Pharmacy? You may verify licenses and registrations on the Board website <a href="http://www.oregon.gov/pharmacy">www.oregon.gov/pharmacy</a>. Where are invoices kept?</td>
</tr>
<tr>
<td><strong>4.</strong> Are all drugs stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space?</td>
<td><strong>5.</strong> Are recalled, outdated, damaged, deteriorated, misbranded, identified as suspect/illegitimate, or adulterated medications documented and physically separated from other drugs? Where are they stored prior to being destroyed or returned to the supplier?</td>
</tr>
<tr>
<td><strong>6.</strong> Are prescriptions properly labeled?</td>
<td><strong>7.</strong> Are drugs dispensed in compliance with current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162 [Poison Prevention Act])?</td>
</tr>
<tr>
<td><strong>8.</strong> Does the outlet maintain a list of sites in Oregon where drugs may be disposed?</td>
<td></td>
</tr>
<tr>
<td>Oregon Veterinary Medical Examining Board – Veterinary Facility Inspection Report</td>
<td>Oregon Board of Pharmacy – Dispensing Practitioner Drug Outlet Self-Inspection Report</td>
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</tbody>
</table>
| 9. Is a unique dispensing record maintained separately from the patient chart and kept for a minimum of 3 years? | **10.** Does the dispensing record contain;  
- Name of patient  
- Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor  
- Directions for use  
- Date of dispensing  
- And Initials of person dispensing the prescription |
| 11. Is the dispensing record readily retrievable and available for inspection? |
November 12, 2019

Kip Memmott, Director
Secretary of State, Audits Division
255 Capitol St. NE, Suite 500
Salem, OR 97310

Dear Mr. Memmott,

This letter provides a written response to the Audits Division’s final draft audit report titled “The Oregon Veterinary Medical Examining Board’s Monitoring of Controlled Substances Needs to be Strengthened.”

The Board is in agreement with the Audit Division’s recommendations. We note that the recommendations are subject to current statutory limitations. We appreciate that the Audit recognizes that the Board follows the current statutes and rules in the Veterinary Practice Act. Additional oversight authority may require legislative approval. To the greatest extent possible, the Board will consider rules and policies consistent with Audit recommendations.

The Board wishes to acknowledge the Auditors for their diligence and professional courtesies. We appreciate the work that went into this Audit and are grateful for its fresh perspectives and policy recommendations. Thank you for the opportunity to respond.

Below is our detailed response to each recommendation in the audit.

<table>
<thead>
<tr>
<th>RECOMMENDATION 1</th>
</tr>
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<tbody>
<tr>
<td>We recommend the board take action to ensure administrative rules allow the board to inspect veterinary facilities to monitor the use of controlled substances, ensuring inspections comply with required Drug Enforcement Agency documentation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agree or Disagree with Recommendation</th>
<th>Target date to complete implementation activities</th>
<th>Name and phone number of specific point of contact for implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agree</td>
<td>Already in progress, implementation upon adoption of final rules.</td>
<td>Lori Makinen 971-673-0223</td>
</tr>
</tbody>
</table>
Narrative for Recommendation 1

The Board has proposed new administrative rules for veterinary drugs and biologicals that incorporate monitoring requirements of the Board of Pharmacy Drug Practitioner Dispensing Outlet (DPDO) program. The proposed rules have been published for public comment. Inspections would include monitoring for compliance with both Board of Pharmacy and DEA requirements.

The Board has inspected for compliance with basic DEA regulations for securing drugs and maintaining drug logs. In 388 inspections completed since December 2018, nine facilities appeared to have one of the following minor DEA noncompliance issues:

- Controlled substances at location other than DEA registrant.
- Expired controlled substances not separated from non-expired drugs.
- Controlled substance logs missing required information.
- No controlled substance logs available for review.
- Facility needs to add additional information to the drug logs.
- Expired controlled substances not separated from other expired meds, not locked.

During each inspection, the Managing Veterinarian is informed that the facility must maintain controlled substances in compliance with all federal and state laws, and should obtain exact requirements directly from the controlling authority. The inspector reviews basic DEA requirements and suggests further resources, such as manufacturers’ guidelines. Managing Veterinarians are provided with the DEA ‘hotline’ for follow-up.

Should the inspector encounter what appears to be a violation of the Veterinary Practice Act, or significant noncompliance with DEA regulations, they would immediately contact the Board investigator or executive director for instructions. Should the inspector encounter an immediate, potential criminal activity taking place, law enforcement would be contacted.

The Board will make a policy decision as to whether and to what extent other agencies’ regulations should be monitored and enforced by the Veterinary Board.

<table>
<thead>
<tr>
<th>RECOMMENDATION 2</th>
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<tbody>
<tr>
<td>We recommend the board complete the implementation of administrative rules and begin conducting background checks on all new and renewing veterinary and certified veterinary technician licensees.</td>
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</tr>
</thead>
<tbody>
<tr>
<td>Agree</td>
<td>Completed</td>
<td>Lori Makenen 971-673-0227</td>
</tr>
</tbody>
</table>
Narrative for Recommendation 2

The Board has adopted rules authorizing, and has begun performing, background checks for new and renewing license applicants.

It should be noted that a background check is a snapshot in time and will only provide the Board grounds to deny an application for cause if the conduct has a direct nexus to the practice of veterinary medicine.

Available data from six other health related licensing boards shows that since 2012, two license applications were denied based on actionable information obtained through background checks.

RECOMMENDATION 3
We recommend the board work with the Oregon Health Authority and the state legislature to require veterinarians to participate in the state PDMP.

<table>
<thead>
<tr>
<th>Agree or Disagree with Recommendation</th>
<th>Target date to complete implementation activities</th>
<th>Name and phone number of specific point of contact for implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agree</td>
<td>Unknown</td>
<td>Lori Makinen 971-673-0223</td>
</tr>
</tbody>
</table>

Narrative for Recommendation 3

Consistent with the best interests of animal health care and public protection, the Board will actively support efforts by the Legislature and/or Oregon Health Authority to include veterinarians in state PDMP reporting requirements.

Please contact me at 971-673-0223 with any questions.

On behalf of the Board,

Lori Makinen
Executive Director
About the Secretary of State Audits Division

The Oregon Constitution provides that the Secretary of State shall be, by virtue of the office, Auditor of Public Accounts. The Audits Division performs this duty. The division reports to the elected Secretary of State and is independent of other agencies within the Executive, Legislative, and Judicial branches of Oregon government. The division has constitutional authority to audit all state officers, agencies, boards and commissions as well as administer municipal audit law.

This report is intended to promote the best possible management of public resources.

Copies may be obtained from:

Oregon Audits Division
255 Capitol St NE, Suite 500 | Salem | OR | 97310
(503) 986-2255
sos.oregon.gov/audits
<table>
<thead>
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<th>Budget Objects</th>
<th>REVENUE</th>
<th>EXPENDITURES</th>
<th>TOTAL</th>
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<tr>
<td></td>
<td>LAB</td>
<td>ORBITS</td>
<td>SUBTOTAL</td>
<td>To Date</td>
<td>Balance</td>
</tr>
<tr>
<td></td>
<td>BUDGET</td>
<td>BUDGET</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LAB</td>
<td>ORBITS</td>
<td>TOTAL</td>
<td>LAB</td>
<td>ORBITS</td>
</tr>
<tr>
<td></td>
<td>BUDGET</td>
<td>BUDGET</td>
<td>EXPENDED</td>
<td>EXPENDED</td>
<td>EXPENDED</td>
</tr>
<tr>
<td></td>
<td>Revenue</td>
<td>Expenditures</td>
<td>Revenue</td>
<td>Expenditures</td>
<td>Revenue</td>
</tr>
<tr>
<td></td>
<td>Through</td>
<td>Through</td>
<td>through</td>
<td>through</td>
<td>through</td>
</tr>
<tr>
<td></td>
<td>Month 13</td>
<td>Month 13</td>
<td>Month 13</td>
<td>Month 13</td>
<td>Month 13</td>
</tr>
<tr>
<td></td>
<td>2019</td>
<td>2019</td>
<td>2019</td>
<td>2019</td>
<td>2019</td>
</tr>
<tr>
<td></td>
<td>$330,000</td>
<td>$330,000</td>
<td>$660,000</td>
<td>$660,000</td>
<td>$660,000</td>
</tr>
<tr>
<td></td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
</tr>
</tbody>
</table>

**Revenue: Sunday, 08/03/2020**

**expenses through month 13, 2019**

**Publicity & Publications**

**Revenue & Expenditures**

**Attorney General**

0% 0%

**Other Special Payments**

11,991 11,991 11,991 - 11,991 0%

**Data Processing Software**

0 - 0 - 0%

**Social Security Taxes**

256,020 256,020 256,020 244,571 11,449 96%

**Other NonBusiness Licenses and Fees**

(409,357) (409,357) 56,241 (465,598) -14%

**Flexible Benefits**

666,720 666,720 24,720 691,440 627,544 63,896 91%

**Medical Supplies and Services**

ORBITS Financial Adj Budget or Financial ACTUALS

Unobligated

2,448,136

Agency Program Related S&S

183,457

- 0 -

5,444,919 5,444,919 0 5,444,919 6,323,414 (878,495) 116%

66% 67% Target 100%

**Other Revenue**

39,700 39,700 39,700 95,914 (56,214) 242%

**504,012**

InState Travel

Workers' Compensation Assessment

Overtime Payments

- 0 3,100 (3,100) 0%

Data Processing Hardware

Interest and Investments

48,000 48,000 48,000 181,656 (133,656) 378%

Pension Bond Contribution

195,224 195,224 (3,502) 191,722 196,583 (4,861) 103%

IT Expendable Property

3,597,493 (498,517)

Public Employees Retirement Contributions

1,380 1,380 1,380 949 431 69%

4,875,272 1,29,211 5,004,483 4,927,566 76,917 98% $ 76,917

**SubTotal Personal Services**

4,875,272 5,004,483 2,038,527 409,609 83% $ 409,609

**Transfer out to OHA—Workforce/PS**

(409,357) (409,357) 0 (409,357) 56,241 (465,598) -14%

**Total Revenue & Transfers**

5,035,563 5,035,563 0 5,035,563 6,187,173 (412,927) 116%
<table>
<thead>
<tr>
<th>Budget Object</th>
<th>REVENUE</th>
<th>EXPENDITURES</th>
<th>Services and Supplies</th>
<th>Personal Services</th>
<th>Transfers</th>
<th>Special Payments</th>
<th>TOTAL Revenue &amp; Transfer</th>
<th>Revenue %</th>
<th>2019 Est.</th>
<th>2019 Est.</th>
<th>2019 Est.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$2,777,070</td>
<td>$1,929,859</td>
<td>$4,706,929</td>
<td>$1,797,070</td>
<td>$1,929,859</td>
<td>$4,706,929</td>
<td>$8,641,978</td>
<td>11%</td>
<td>$8,641,978</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAB % PS</td>
<td>66%</td>
<td>66%</td>
<td>-</td>
<td>Target</td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAB % S/S</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAB % SP</td>
<td>0%</td>
<td>0%</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Board of Pharmacy
### ACTUALS THROUGH OCTOBER 2019 MONTH-END CLOSE

### REVENUE & EXPENDITURES

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dues &amp; Subscriptions</strong></td>
<td>7,146,250</td>
<td>7,146,250</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Workers' Compensation Assessments</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Revenue received</strong> is more than budgeted so zero is not yet received**</td>
<td>0%</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Revenue</strong></td>
<td>7,146,250</td>
<td>7,146,250</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### State Govt. Service Chgs.

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>State Govt. Service Chgs.</strong></td>
<td>1,700,083</td>
<td>1,700,083</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### Other Revenue

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Other Revenue</strong></td>
<td>57,090</td>
<td>57,090</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### Total Revenue & Transfers

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Revenue &amp; Transfers</strong></td>
<td>7,792,362</td>
<td>7,792,362</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### PERSONAL SERVICES

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regular Employees</strong></td>
<td>3,663,668</td>
<td>3,663,668</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Board Member Expenses</strong></td>
<td>0</td>
<td>0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Temporary Appointments</strong></td>
<td>26,180</td>
<td>26,180</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Overnight Payments</strong></td>
<td>26,180</td>
<td>26,180</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Shift Differential</strong></td>
<td>0</td>
<td>0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Alt Other Differential</strong></td>
<td>190,428</td>
<td>190,428</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>ERB Assessment</strong></td>
<td>1,261</td>
<td>1,261</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Public Employees' Retirement System</strong></td>
<td>647,442</td>
<td>647,442</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Pension Benefit</strong></td>
<td>200,306</td>
<td>200,306</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Social Security Tax</strong></td>
<td>296,540</td>
<td>296,540</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Unemployment Assessment</strong></td>
<td>0</td>
<td>0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Workers' Compensation Assessment</strong></td>
<td>1,276</td>
<td>1,276</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Max Travel Taxes</strong></td>
<td>23,248</td>
<td>23,248</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Employee Recruitment &amp; Development</strong></td>
<td>774,048</td>
<td>774,048</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### Services and Supplies

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Instate Travel</strong></td>
<td>113,572</td>
<td>113,572</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Out of State Travel</strong></td>
<td>16,322</td>
<td>16,322</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Employee Training</strong></td>
<td>21,400</td>
<td>21,400</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Office Expenses</strong></td>
<td>139,018</td>
<td>139,018</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Telecommunications</strong></td>
<td>48,830</td>
<td>48,830</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>State Govt. Service Chgs.</strong></td>
<td>163,176</td>
<td>163,176</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Data Processing</strong></td>
<td>80,540</td>
<td>80,540</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Publicity &amp; Publications</strong></td>
<td>39,983</td>
<td>39,983</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Professional Services</strong></td>
<td>321,394</td>
<td>321,394</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>IT Professional Services</strong></td>
<td>652,149</td>
<td>652,149</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Attorney General</strong></td>
<td>551,381</td>
<td>551,381</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Employee Recruitment &amp; Develop</strong></td>
<td>653</td>
<td>653</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Dues &amp; Subscriptions</strong></td>
<td>5,195</td>
<td>5,195</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Facilities Rent &amp; Taxes</strong></td>
<td>210,941</td>
<td>210,941</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Facilities Maintenance</strong></td>
<td>53</td>
<td>53</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Medical Supplies and Services</strong></td>
<td>1,152</td>
<td>1,152</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Agency Program Related SAS</strong></td>
<td>240,152</td>
<td>240,152</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Other Services &amp; Supplies</strong></td>
<td>284,656</td>
<td>284,656</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Expansible Property</strong></td>
<td>13,526</td>
<td>13,526</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>IT Expansible Property</strong></td>
<td>43,363</td>
<td>43,363</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Board Equipment &amp; Software</strong></td>
<td>8,611</td>
<td>8,611</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Other Capital Outlay</strong></td>
<td>0</td>
<td>0</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

### Special Payments

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Special Payments</strong></td>
<td>12,447</td>
<td>12,447</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### Total Expenditures Budget

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Expenditures</strong></td>
<td>7,057,070</td>
<td>7,057,070</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### Additional Information

- **LAB % PS:** 66%
- **LAB % SSS:** 44%
- **LAB % SP:** 0%

###AY21 Ending Cash Balance

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AY21 Ending Cash Balance</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

### Revenue less Expenditures

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue less Expenditures</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

### Total Revenue & Transfers

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Revenue &amp; Transfers</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

### Total Payroll & Benefits less Expenditures

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Payroll &amp; Benefits less Expenditures</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

###AY21 Cash Balance after the Fiscal Month Closed

<table>
<thead>
<tr>
<th>Category</th>
<th>2019 Budget</th>
<th>2019 Actuals</th>
<th>Revenue %</th>
<th>Expenses %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AY21 Cash Balance after the Fiscal Month Closed</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

---

**AY21 Estimated Cash Balance**

- **AY21 Estimated Cash Balance:** 6,604,394
  - **Cash Balance Contingency (Months):** (7.34 months)