Oregon Board of Pharmacy  
BOARD MEETING AGENDA  
Meeting Location:  
Portland State Office Building  
800 NE Oregon Street, Portland, OR 97232  
December 13-14, 2017  
(Updated 12/13/17)

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

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WEDNESDAY, DECEMBER 13, 2017

I. 8:30AM OPEN SESSION, Penny Reher, R.Ph, Presiding

   A. Roll Call
   B. Agenda Review and Approval  
      Action Necessary
   C. Public Meeting Update - Cowan

II. Contested Case Deliberation pursuant to ORS 192.690(1) - Not Open to the Public

III. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (k).

   A. Items for Consideration and Discussion:
      1. Deliberation on Disciplinary Cases and Investigations
      2. Personal Appearances
      3. Deficiency Notifications
      4. Case Review

IV. OPEN SESSION - PUBLIC MAY ATTEND - At the conclusion of Executive Session, the Board may convene Open Session to begin some of the following scheduled agenda items if time permits.

V. Approve Consent Agenda*  
   Action Necessary

   *Items listed under the consent agenda are considered to be routine agency matters and will be approved by a single motion of the Board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.

   1. NAPLEX Scores – none
   2. MPJE Scores – none
   3. License/Registration Ratification – September 27, 2017-November 28, 2017
   4. Pharmacy Technician Extensions – none
5. Board Minutes – October 11-12, 2017

VI. ISSUES/ACTIVITIES

A. Board Meeting Dates

- February 7-9, 2018  Portland (*3 day meeting)
- April 4-5, 2018  Portland
- June 6-7, 2018  Portland
- August 8-10, 2018*  Portland (*3 day meeting)
- October 3-4, 2018  Portland
- November 7-8, 2018  Portland (*Strategic Planning)
- December 12-13, 2018  Portland
- February 6-8, 2019*  Portland (*3 day meeting)
- April 10-11, 2019  Portland
- June 5-6, 2019  Portland
- August 7-9, 2019*  Portland (*3 day meeting)
- October 9-10, 2019  Portland
- November 6-7, 2019  Portland (*Strategic Planning)
- December 11-12, 2019  Portland

B. 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 23, 2018
- November 27, 2018
- May 22, 2019
- November 26, 2019

C. Committees/Meetings

2. BPA Medication Outreach – 11/15/17 – Karbowicz/Frost
3. OSHP Fall Seminar – 11/18/2017, Portland – Karbowicz/Frost
4. NABP Interactive Compliance Officer/Legal Counsel Forum 11/29-30/2017 – Efremoff
5. OSPA Lane County – 2/17-18/2018 – Eugene
6. NABP District VI-VIII, meeting Kansas City, KS 9/23-26/2018

D. Board Member/Staff Presentations – Reher

- Pharmacy Coalition – 10/11/17, 11/14/17
- Professional Practice Roundtable – 9/20/17, 1/23/18

E. Financial/Budget Report – Watt/MacLean #A-A1

F. Legislative update – Watt

G. Reports:

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

Adjourn

THURSDAY, DECEMBER 14, 2017

8:30AM
VII. OPEN SESSION, Penny Reher, R.Ph, Presiding

A. Roll Call
B. Motions for Contested Cases & Disciplinary Action  Action Necessary

9:00 AM
VIII. GENERAL ADMINISTRATION

A. Rules  
*First Look
1. Review Rulemaking Hearing Report & Comments – Klein #B
2. Consider Adoption of Rules – Karbowicz/MacLean
   • Div 010 – Board Member Compensation #B1
   • Div 010 – Criminal Background Checks #B2
   • Div 019 and 041 – Contraceptive update #B3
   • Div 019 and 041 – Naloxone #B4
   • Div 041 – Remote Distribution Facility #B5
   • Div 080 – Controlled Substances #B6

3. Consider Adoption of Temporary Rules
   • Div 019 – Naloxone* #B7

4. Consider Rules and send to Rulemaking Hearing – None

5. Policy Issues for Discussion – Karbowicz/Efremoff
   • Div 019 & 041 – Community Pharmacy Personnel/PIC #B8

Noon – Lunch break
(Some of the items below may occur before or after lunch depending on the length of the Board’s discussions.)

B. Discussion Items
1. Kratom – Watt #C7-C7a
2. Waiver Requests #C
   a. Providence Labeling Requirement waiver request renewal – Karbowicz  Action Necessary

NOTE: The Board may rearrange its agenda to accommodate the Board or members of the public.
3. Contraceptive Prescribing Update – Watt/Karbowicz #C1 Action Necessary
4. Public Health and Pharmacy Formulary Advisory Committee Update - Watt/Frost #C2-C5
5. Per Diem Policy – Watt/MacLean #C6 Action Necessary

C. Strategic Planning – Watt/MacLean
   • 2017 meeting update

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
<table>
<thead>
<tr>
<th>Item</th>
<th>Budgeted Expenditures</th>
<th>Actual Expenditures</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office Supplies &amp; Equipment</td>
<td>6443</td>
<td>4715</td>
<td>73%</td>
</tr>
<tr>
<td>Facilities Maintenance</td>
<td>4650</td>
<td>229,434</td>
<td>51%</td>
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<tr>
<td>EMS</td>
<td>4575</td>
<td>219,519</td>
<td>42%</td>
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<tr>
<td>Social Security</td>
<td>3991</td>
<td>119,969</td>
<td>31%</td>
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<tr>
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<td>3470</td>
<td>3465</td>
<td>100%</td>
</tr>
<tr>
<td>Board Member Stipends</td>
<td>3465</td>
<td>19,101</td>
<td>100%</td>
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<tr>
<td>Attorney General</td>
<td>3230</td>
<td>1,100</td>
<td>15%</td>
</tr>
<tr>
<td>Attorney General</td>
<td>3225</td>
<td>933</td>
<td>76%</td>
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<tr>
<td>Board Member Stipends</td>
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<td>167</td>
<td>15%</td>
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<td><strong>Total</strong></td>
<td><strong>2,468,135</strong></td>
<td><strong>2,468,135</strong></td>
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**Special Payments**

<table>
<thead>
<tr>
<th>Item</th>
<th>Budgeted Expenditures</th>
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<th>% Expended</th>
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<tbody>
<tr>
<td>Other Special Payments</td>
<td>11,991</td>
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<td>Other Special Payments</td>
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**Total Expenses**

<table>
<thead>
<tr>
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<th>Actual Expenditures</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Expenses</td>
<td>7,294,257</td>
<td>7,294,257</td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Unbudgeted Activities</td>
<td>1,349,204</td>
<td>1,349,204</td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Total Expenditures</td>
<td><strong>8,643,461</strong></td>
<td><strong>8,643,461</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Operating Cash Flow**

<table>
<thead>
<tr>
<th>Items</th>
<th>Budgeted Expenditures</th>
<th>Actual Expenditures</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
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<td><strong>100%</strong></td>
</tr>
<tr>
<td>Unbudgeted Activities</td>
<td>1,349,204</td>
<td>1,349,204</td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Total Expenditures</td>
<td><strong>8,643,461</strong></td>
<td><strong>8,643,461</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Total Revenues**

<table>
<thead>
<tr>
<th>Items</th>
<th>Budgeted Expenditures</th>
<th>Actual Expenditures</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>1,349,204</td>
<td>1,349,204</td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Total Revenues</td>
<td><strong>1,349,204</strong></td>
<td><strong>1,349,204</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
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<table>
<thead>
<tr>
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<th>% Expended</th>
</tr>
</thead>
<tbody>
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<td>1,349,204</td>
<td>1,349,204</td>
<td><strong>100%</strong></td>
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<tr>
<td><strong>Cash</strong></td>
<td><strong>1,349,204</strong></td>
<td><strong>1,349,204</strong></td>
<td><strong>100%</strong></td>
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**Administrative Services and Supplies**

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<th>Actual Expenditures</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budgeted Expenditures</td>
<td>7,294,257</td>
<td>7,294,257</td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Unbudgeted Activities</td>
<td>1,349,204</td>
<td>1,349,204</td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Total Expenditures</td>
<td><strong>8,643,461</strong></td>
<td><strong>8,643,461</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

**Operating Cash Flow**

<table>
<thead>
<tr>
<th>Items</th>
<th>Budgeted Expenditures</th>
<th>Actual Expenditures</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Revenues</td>
<td>1,349,204</td>
<td>1,349,204</td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td><strong>Cash</strong></td>
<td><strong>1,349,204</strong></td>
<td><strong>1,349,204</strong></td>
<td><strong>100%</strong></td>
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</tbody>
</table>

**Revenue less Expenditures**

<table>
<thead>
<tr>
<th>Items</th>
<th>Budgeted Expenditures</th>
<th>Actual Expenditures</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Revenue less Expenditures</td>
<td>1,349,204</td>
<td>1,349,204</td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td><strong>Cash</strong></td>
<td><strong>1,349,204</strong></td>
<td><strong>1,349,204</strong></td>
<td><strong>100%</strong></td>
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<tr>
<td>Object</td>
<td>ORBITS Budget</td>
<td>ORBITS Financial Plan</td>
<td>Adj. Budget or Activity Plan</td>
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<tr>
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<td>-----------------------</td>
<td>----------------------------</td>
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<tr>
<td>REVENUE</td>
<td></td>
<td></td>
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<tr>
<td>0100</td>
<td>Other Business Licenses</td>
<td>4,431,667</td>
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<td>0110</td>
<td>Other Nonbusiness Licenses and Fees</td>
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<td>0200</td>
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<td>0300</td>
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<td>0700</td>
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<td>EXPENSES</td>
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<tr>
<td>0101</td>
<td>Board Member Stipends</td>
<td>20,223</td>
<td>20,223</td>
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<tr>
<td>0115</td>
<td>Overtime Payments</td>
<td>0</td>
<td>0</td>
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<tr>
<td>1100</td>
<td>All Other Differential O/Class Lead Work</td>
<td>193,457</td>
<td>193,457</td>
</tr>
<tr>
<td>3220</td>
<td>Public Employee Retirement Control</td>
<td>254,012</td>
<td>254,012</td>
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<tr>
<td>3231</td>
<td>Pension Bond Contribution</td>
<td>195,224</td>
<td>195,224</td>
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<tr>
<td>3250</td>
<td>Social Security Taxes</td>
<td>256,030</td>
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<td>3240</td>
<td>Unemployment Assessment</td>
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<td>3260</td>
<td>Workers’ Compensation Assessments</td>
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<tr>
<td>3500</td>
<td>Mass Transit Tax</td>
<td>20,334</td>
<td>20,433</td>
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<td>4,389,155</td>
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<tr>
<td>TOTAL REVENUES &amp; EXPENSES</td>
<td>5,444,919</td>
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<td>ASSETS</td>
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<tr>
<td>0500</td>
<td>Regular Employees</td>
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<tr>
<td>4000</td>
<td>Transfer out to OHA--PDMP program</td>
<td>0</td>
<td>0</td>
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<tr>
<td>5000</td>
<td>Transfer out to OHA--Workforce Data</td>
<td>(409,357)</td>
<td>(409,357)</td>
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<tr>
<td>TOTAL ASSETS</td>
<td>202,745</td>
<td>202,745</td>
<td>202,745</td>
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**AY19 Cash Balance Contingency (Months)**

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>Board Member Stipends</td>
<td>20,223</td>
</tr>
<tr>
<td>Overtime Payments</td>
<td>0</td>
</tr>
<tr>
<td>All Other Differential O/Class Lead Work</td>
<td>193,457</td>
</tr>
<tr>
<td>Public Employee Retirement Control</td>
<td>254,012</td>
</tr>
<tr>
<td>Pension Bond Contribution</td>
<td>195,224</td>
</tr>
<tr>
<td>Social Security Taxes</td>
<td>256,030</td>
</tr>
<tr>
<td>Unemployment Assessment</td>
<td>0</td>
</tr>
<tr>
<td>Workers’ Compensation Assessments</td>
<td>1,380</td>
</tr>
<tr>
<td>Mass Transit Tax</td>
<td>20,334</td>
</tr>
<tr>
<td>Special Payments to OHA-HPSP</td>
<td>176,899</td>
</tr>
<tr>
<td>Transfer out to OHA--PDMP program</td>
<td>0</td>
</tr>
<tr>
<td>Transfer out to OHA--Workforce Data</td>
<td>(409,357)</td>
</tr>
<tr>
<td>TOTAL ASSETS</td>
<td>202,745</td>
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</table>

**AY17 Ending Cash Balance**

<table>
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<tr>
<th>Description</th>
<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>Revenue less Expenditures</td>
<td>$4,765,938</td>
</tr>
<tr>
<td>Total Revenue &amp; Transfers</td>
<td>$4,765,938</td>
</tr>
<tr>
<td>Total Expenditures</td>
<td>$1,055,764</td>
</tr>
<tr>
<td>Total Revenue &amp; Transfers less Expenditures</td>
<td>$3,710,174</td>
</tr>
<tr>
<td>Total Revenue &amp; Transfers less Expenditures to be made ($3,440,049)</td>
<td>$270,125</td>
</tr>
<tr>
<td>Cash Balance at Fiscal Month Closed</td>
<td>$2,507,749</td>
</tr>
</tbody>
</table>

**AY19 Cash Balance after the Fiscal Month Closed**

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue received</td>
<td>$2,712,109</td>
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</tbody>
</table>

**Special Payments and Services**

<table>
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<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab S &amp; Q</td>
<td>68%</td>
</tr>
<tr>
<td>Lab S &amp; S</td>
<td>32%</td>
</tr>
<tr>
<td>Lab S &amp; F</td>
<td>0%</td>
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</table>

**AY19 Estimated Cash Balance**

<table>
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<tr>
<th>Description</th>
<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>Revenue received</td>
<td>$2,712,109</td>
</tr>
<tr>
<td>Budgeted Expenditures not yet received (zero) less Estimated Transfers to OHA-HPSP &amp; Workforce Data program to be made ($3,440,049)</td>
<td>$270,125</td>
</tr>
<tr>
<td>Budgeted Expenditures net yet received</td>
<td>$4,765,938</td>
</tr>
<tr>
<td>Income not recognized</td>
<td>$2,712,109</td>
</tr>
</tbody>
</table>

**AY19 Estimated Cash Balance**

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue received</td>
<td>$2,712,109</td>
</tr>
<tr>
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<td>$270,125</td>
</tr>
<tr>
<td>Budgeted Expenditures net yet received</td>
<td>$4,765,938</td>
</tr>
<tr>
<td>Income not recognized</td>
<td>$2,712,109</td>
</tr>
</tbody>
</table>
The rulemaking hearing on the proposed rules was convened at 9:30 a.m. People were asked to sign the registration list if they wished to comment on the proposed rules and were informed of the procedures for making comments. They were also told that the hearing was being recorded.

Copies of the proposed rules were available for attendees.

Attendance included 8 public, 6 OBOP Staff, 6 OBOP Board members

**Summary of Oral Comments**

There were no oral comments.
Summary of Written Comments

Three written comments received during the public comment period are as follows, the full text of comments as received by OBOP are attached:

1. Lauren Berton, PharmD
   Director, Pharmacy Regulatory Affairs
   CVS Health
   (November 22, 2017);
   CVS Health supports the rule changes regarding expanding access to naloxone, and the prescribing of and administering of hormonal contraceptives. CVS Health is concerned that OBOP is restricting the use of RDFs, which in turn may restrict access to pharmaceutical care for patients in medically underserved areas.

2. Adam Chesler, PharmD
   On behalf of TelePharm
   (November 10, 2017)
   TelePharm is concerned that the proposed changed in rules regarding RDF may restrict access to healthcare in Oregon.

3. Liz Houchen
   Regional Director, State Government Affairs
   National Association of Chain Drug Stores
   NACDS supports the updated requirements for hormonal contraceptives and naloxone. They provided a minor edit to the text regarding hormonal contraceptives.

The agency evaluation of public comments is contained in Attachment 1.

Written comments are in Attachment 2.
Remote Distribution Facility

The rationale for this current rule edit is to clearly articulate the purpose and allowance of the use of an RDF (Remote Distribution Facility); there is no new content added.

Moving the rule to the 5000s section of Division 041 helps further define this outlet type.

Hormonal Contraception

Staff appreciates the text edits provided by NACDS.
November 20, 2017

Marcus Watt, R.Ph.
Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232-2162
Via email: Pharmacy.exec@obop.net

Re: Draft Proposed Rule Changes Under Division 019 and 041

Dear Mr. Watt:

The National Association of Chain Drug Stores (NACDS) thanks the Oregon Board of Pharmacy (Board) for the opportunity to comment on the proposed rules under OAR 855-019-0400 through -0435 and OAR 855-019-0455, -019-0460, -041-2310, -041-2330, and -041-2340 updating requirements for pharmacists to prescribe, administer and dispense hormonal contraceptives and pharmacists prescribing naloxone respectively. We strongly support these proposed rule changes which broaden pharmacists’ ability to provide important healthcare services to patients in Oregon.

We do have one suggested minor change in OAR 855-019-0415.

Training Program

(1) Only a pharmacist, who has completed a Board approved Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may prescribe injectable hormonal contraceptives patches and self-administered oral hormonal contraceptives for a patient.

We believe the changes above would bring consistency with the other changes being made to the rule.

Pharmacists are highly educated, trusted healthcare professionals who play an important role in improving access to patient care services. In recent years, community pharmacists have provided a growing number of convenient, accessible and cost-effective health services such as health and wellness testing, managing chronic disease, performing medication therapy management (MTM) services, administering immunizations, and otherwise working in partnership healthcare entities and other providers to improve health outcomes.

Community pharmacists are well-situated in local communities, and are oftentimes the most readily accessible healthcare provider. Research has shown that nearly all Americans (88.8%) live within five miles of a community retail pharmacy. Such access is especially critical in reaching the medically underserved and patients in rural communities. From helping patients take their medications effectively and safely, to providing preventative services, pharmacist services help keep people healthier and reduce costs.
NACDS thanks the Board for considering our comments on this rulemaking. Please do not hesitate to contact me with any questions or for further assistance. I can be reached at: 360.480.6990 or lhouchen@nacds.org.

Sincerely,

[Signature]

Lis Houchen
Regional Director, State Government Affairs
lhouchen@nacds.org
November 27, 2017

Marcus Watt, RPh
Executive Director
Oregon State Board of Pharmacy
800 NE Oregon Street; Suite 150
Portland, OR 97232

Re: Proposed Rule Amendments in Division 019 and 041 pertaining to Naloxone, Hormonal Contraceptive Prescribing and Remote Distribution Facility

Dear Executive Director Watt:

I am writing to you in my capacity as Director of 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 diverse access points to care 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 on the Oregon State Board of Pharmacy proposed rule amendments in Division 019 and 041 pertaining to naloxone, hormonal contraceptive prescribing and remote distribution facilities. We would also like to thank the Board for their vigilance in continuously improve the laws and regulations that guide pharmacists, pharmacy interns and pharmacy technicians serving Oregon patients.

Pharmacists are highly educated and trained professionals who have become an integral part of the healthcare team, often being ranked at or near the top of public surveys of the most trusted professionals. With the shortage of primary care providers looming, pharmacists are poised to fill the gaps for delivery of patient care. Thus, CVS Health is in support of amendments made in Divisions 019 and 041 which conform to HB 3440 and HB 2527 passed in 2017, which expand access to naloxone and additional hormonal contraceptive products for Oregon patients. The proposed amendments remove Oregon Health Authority Training previously required to prescribe and be dispensed naloxone along with the allowance for a pharmacist to prescribe injectable and all self-administered hormonal contraceptives. Removal of previous barriers provides the patients of Oregon greater access through our pharmacists in retail drug outlets.

While the amendments regarding naloxone and hormonal contraceptive prescribing expand access, CVS Health is concerned that amendments to remote distribution facility (RDF) rules in Division 041, clarifying that RDFs may only be utilized by institutional pharmacies, may further restrict access. RDFs provide access to pharmaceutical care for Oregon patients in medically underserved areas, which can be rural or urban. We encourage the Board to further review the amendments to ensure that access is being expanded in Oregon and not restricted. Additionally, we request that the Board consider adding an amendment for dispensing directly to the patient at RDFs in lieu of preparation of administration to the patient only. We have provided suggested language below for the Board’s consideration.

Suggested Language:

855-041-5050 Definitions

(2) "Remote Distribution Facility" (RDF) means an in-state/resident facility where drugs are prepared for administration and or dispensing, where requisite pharmacist supervision is provided remotely as approved by the Board.
855-041-5055 Remote Distribution Facility (RDF) The purpose of these rules is to provide for the use of a Certified Oregon Pharmacy Technician functioning outside of a pharmacy to prepare drugs only for administration to a patient by another healthcare provider or dispensing directly to the patient, and where requisite pharmacist supervision and verification is provided remotely by an Oregon licensed pharmacist via real-time audio-visual technology.

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

Sincerely,

Lauren Berton, PharmD
Director, Pharmacy Regulatory Affairs
CVS Health
November 10th, 2017

Mo Klein
800 NE Oregon Street;
Suite 150
Portland, OR 97232

Via email: pharmacy.rulemaking@state.or.us
Cc: Karen.S.MacLean@state.or.us

Re: Remote Distribution Facilities (855-041-4200)

Dear Ms. Klein:

On behalf of TelePharm, I would like to thank the Oregon Board of Pharmacy for the opportunity to comment on the proposed repeal of OAR 855-041-4200, and its replacement with OAR 855-041-5050 and 855-041-5055. We appreciate the Board’s consideration of our views on this matter.

At TelePharm, a Cardinal Health company, we have long supported the benefits of Remote Distribution Facilities (RDFs), or telepharmacy, as a means to provide pharmaceutical care to medically underserved areas. Telepharmacy can help safely improve patient adherence, increase local jobs, and provide local access to a pharmacist’s expertise. A “pharmacy desert” is defined as an area where patients travel greater than 20 miles round trip in order to have access to pharmacy services. In Oregon, there are 31 pharmacy deserts, comprising over 41,000 residents. There are also 44 “at-risk communities”, which if they lose their only pharmacy, would become a pharmacy desert. Additionally, Oregon has 61 designated health professional shortage areas, meaning there is a lack of primary medical care, according to the U.S. Department of Health and Human Services.

Based on the proposed language in OAR 855-041-5050 and 855-041-5055, we fear that without certain key revisions, these rules could have a significant impact on access to healthcare for the residents of Oregon. TelePharm encourages the Oregon Board of Pharmacy to reconsider the proposal of OAR 855-041-5050 and 855-041-5055, to include dispensing of medications in addition to administration. Specifically, we suggest the following changes for the Board’s consideration:

- (855-041-5050) (2) "Remote Distribution Facility" (RDF) means an in-state/resident facility where drugs are prepared for dispensing or administration and where requisite pharmacist supervision is provided remotely as approved by the Board.
- (855-041-5055) Remote Distribution Facility (RDF) The purpose of these rules is to provide for the use of a Certified Oregon Pharmacy Technician functioning outside of a pharmacy to prepare drugs for administration to a patient by another healthcare provider or for dispensing directly to a patient, and where requisite pharmacist supervision and verification is provided remotely by an Oregon licensed pharmacist via real-time audio-visual technology.

RDFs (or similar facilities) are currently being utilized in 22 states for much more than administration of medication in an institutional setting. States such as North Dakota have been utilizing RDFs to dispense...
medications for over 15 years. Studies conducted at North Dakota State University have proven a lower error rate than traditional pharmacy services, as well as the creation of 80-100 jobs and 26.2 million dollars in economic growth. In 2017 alone, Wyoming, New Mexico, Iowa, Idaho, California, Texas, and Indiana have all updated their statutes and/or regulations to allow dispensing of medication at remote sites using a telepharmacy model. We expect this trend to continue in 2018, with Florida, Arizona, Kansas, Nebraska and Washington already expressing interest to do the same.

RDFs are not just being utilized in rural areas; they can also help with access to a pharmacist in urban areas. The University of Illinois at Chicago recently released a study which shows patients with transportation issues, such as the elderly, students, or those with low vehicle ownership rates, have difficulty accessing a pharmacy just 0.5 mile away. We are seeing organizations in Illinois use RDFs to dispense medication at the point of care to improve adherence by increasing access to a pharmacist even in urban settings. Customers are also using RDFs to insert a pharmacist, through audio-visual technology, in areas where it was previously not economically feasible to hire or staff a pharmacist. When patients are discharged from 24-hour clinics and hospitals, they would be able to access RDFs with medications immediately without having to wait or travel a far distance, which significantly helps improve outcomes and reduce readmission rates. RDFs can allow pharmacist access to patients in specialty clinics, such as an HIV clinic, to provide a more thorough consultation and to allow the patient to start therapy sooner.

TelePharm thanks the Oregon Board of Pharmacy for considering our comments on this matter. We hope that the Board will reconsider its proposed language to align with the public’s best interest and safety. We have served as subject matter experts across the United States, including as members of the 2016 NABP Telepharmacy Task Force and as speakers at the APhA, NCPA, and ASPL annual meetings on the topic of RDFs and telepharmacy. Additionally, we have worked with many states, most of which we referenced above, with drafting their current statutory and regulatory language to ensure RDFs are a safe practice of pharmacy for their patients.

Thank you for your consideration, and please do not hesitate to contact me with any questions or for further assistance. I can be reached at: 319-774-7725 or adam.chesler@cardinalhealth.com.

Respectfully,

Adam Chesler, PharmD
DIVISION 10

BOARD ADMINISTRATION AND POLICIES

This rulemaking is authorized by the Board’s 2017-19 Legislatively Adopted Budget where funding was sought under the 2009 statutory change to ORS 689.115(4) which allows more than $30, the rate provided in ORS 292.495. Any increase is required to be adopted by rule.

With the addition of Pharmacy Technicians to the Board, members felt it was time to address this issue.

The new Public Health and Pharmacy Formulary Advisory Committee effective 1/1/18 allows for compensation, and is included here. (HB 2397 - 2017 OL Ch. 106)

Pharmacy Board Member or Formal Advisory Committee Member Compensation

(1) A board member or member of an advisory committee of the Oregon Board of Pharmacy who is entitled to compensation under ORS 292.495 is eligible to receive up to $100 compensation when engaged in the performance of official duties for each day, calculated as whichever amount is the greater of:

(a) $50 after a minimum of three hours of service; or

(b) $100 after a minimum of six hours of service.

(2) For the purpose of compensation, a board member or member of an advisory committee is considered engaged in the performance of official duties when:

(a) The activity furthers the Board’s mission, such as attending a board meeting;

(b) Engaged in an activity at the request of the board chair or authorized by a vote of the board in advance of the activity; or

(c) Attending an official advisory committee, such as the Public Health & Pharmacy Formulary Committee meeting.

(3) Except as otherwise provided by law, all members, including those employed in full-time public service, may receive actual and necessary travel or other expenses actually incurred in the performance of their official duties within the limits provided by law or by the Oregon Department of Administrative services under ORS 292.210 – 292.250.

(4) No board or committee member shall be required to accept compensation or reimbursement of travel expenses while performing their official duties as a board or committee member.
Stat. Auth.: ORS 689.115, 689.205
Stats. Implemented: ORS 292.495, 689.115, 689.175, 689.645, 2017 OL Ch. 106
The proposed rule amendments reference new statewide rules on criminal records checks recently adopted by the Department of Administrative Services (DAS), and incorporate language specific to the Oregon Board of Pharmacy that is consistent with ORS chapter 181A and the DAS rules. Lines 47-95 are a combination of OBOPs existing rules, with additions from the DAS rules.

This rulemaking is required by House Bill 3168 (2013) and House Bill 2250 (2015), which gave the Department of Administrative Services the authority to adopt statewide administrative rules for criminal records checks and required other agencies to repeal or amend existing rules as needed in order to be consistent with the statewide rules.

The rule (1) gives the purpose, (2) specifies the individuals subject to the criminal records check under this rule includes all applicants and licensees as well as Board employees, volunteers and applicants, (3) incorporates the statewide rules on how a criminal records check is conducted, (4) provides the factors the Board will consider when making a fitness determination, (5) provides the potential fitness determination outcomes and their consequences, (6) maintains that criminal records information is confidential, (7) requires the Board to provide criminal records information to the individual subject to the check, (8) provides the appeals process, and (9) maintains the fee charged to the individual for criminal records checks.

The proposed rulemaking also repeals the Oregon Board of Pharmacy’s conflicting procedural rules related to criminal background checks.

855-010-0100

State and Nationwide Criminal Background Checks for Licensure

(1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure; directors, officers and designated representatives of drug outlets applying for registration; and individuals subject to investigation by the Board, in order to determine if they have a history of criminal behavior such that they are not fit to be granted or retain a license or registration issued by the Board.

(2) "Subject individual" means a person from whom the Board may require legible fingerprints for the purpose of a state or nationwide criminal records check and fitness determination. In this rule, subject individual means: applicants for licensure or renewal of a license; directors, officers and designated representatives of drug outlets applying for registration or renewal of a registration; and individuals subject to an investigation by the Board.

(3) Criminal records checks and fitness determinations are conducted according to ORS 181A.170 to 181A.215, ORS 670.280, OR 676.303, and OAR 125-007-0200 to 125-007-0310.
(a) The Board will request that the Oregon Department of State Police conduct a state and
nationwide criminal records check, using fingerprint identification of subject individuals.

The Board may conduct state criminal records checks on subject individuals and any licensee
through the Law Enforcement Data System maintained by the Department of State Police in
accordance with rules adopted, and procedures established, by the Department of State
Police. Criminal history information obtained from the Law Enforcement Data System must
be handled in accordance with ORS Chapter 181A, OAR 257-010 to 257-015 and applicable
Oregon State Police procedures.

(b) The applicant or licensee must disclose all arrests, charges, and convictions regardless of
the outcome or date of occurrence. Disclosure includes any military or criminal records.

(c) The Board may require additional information from the applicant or licensee, such as,
but not limited to, proof of identity, previous names, residential history or additional
criminal, judicial or other background information.

(4) In making licensing fitness determinations, the Board will consider the following:

(a) The nature of any criminal record that reflects:

(A) Drug or alcohol offense;

(B) Felony;

(C) Misdemeanor;

(D) U.S. military or international crime;

(E) Offense involving fraud, theft, identity theft or other instance of dishonesty;

(F) Offense involving violation of federal importation or customs laws or rules;

(G) Offense requiring registration as a sex offender;

(H) Condition of parole, probation, or diversion program, or

(I) Unresolved arrest, charge, pending indictment or outstanding warrant.

(b) Intervening circumstances relevant to the responsibilities and circumstances of the
license or registration. Intervening circumstances include but are not limited to:

(A) The passage of time since the commission of the crime;

(B) The age of the subject individual at the time of the crime;

(C) The likelihood of a repetition of offenses or of the commission of another crime;

(D) The subsequent commission of another relevant crime;

(E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and

(F) A recommendation of an employer.

(c) The facts that support the conviction or indictment, or that indicate the making of a
false statement;

(d) The relevancy, if any, of the crime or the false statement to the specific requirements of
the subject individual's license or registration; and

(e) Any false statement or omission made to the Board regarding the individual’s criminal
history.
(f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint identification;

(g) Any other pertinent information obtained as part of an investigation.

(h) The Board shall evaluate a crime or offense on the basis of the law of the jurisdiction in which the crime or offense occurred.

(i) The following are examples of crimes likely to result in denial unless there are significant mitigating circumstances:

(A) Aggravated murder;

(B) Murder;

(C) Rape I;

(D) Sodomy I;

(E) Unlawful sexual penetration I;

(F) Sexual abuse I;

(j) Under no circumstances shall an applicant be denied under these rules because of a juvenile record that has been expunged or set aside pursuant to ORS 419A.260 to 419A.262.

(k) Under no circumstances shall an applicant be denied under these rules due to the existence or contents of an adult record that has been set aside pursuant to ORS 137.225.

(5) Criminal offender information is confidential. Dissemination of information received under this rule may only be made to people with a demonstrated and legitimate need to know the information. When the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS 676.175. Any fingerprint cards used to conduct a check shall be destroyed by either the Federal Bureau of Investigation or the Department of State Police as specified in ORS 181A.195.

(6) The Board will permit the subject individual for whom a fingerprint-based criminal records check was conducted to inspect the individual's own state and national criminal offender records and, if requested by the subject individual, provide the individual with a copy of the individual's own state and national criminal offender records.

(7) If an applicant, licensee or registrant is denied a license, they are entitled to a contested case hearing pursuant to ORS 183.413 to 470 and in accordance with OAR 855-001-0005 to 0017.

(8) A challenge to the accuracy or completeness of information provided by the Department of State Police, Federal Bureau of Investigation and agencies reporting information must be made through the Department of State Police, Federal Bureau of Investigation or reporting agency and not through the contested case process.

(9) Request for re-evaluation following correction. If the subject individual successfully contests the accuracy or completeness of information provided by the Oregon State Police,
the Federal Bureau of Investigation or other agency reporting information to the Board, the Board will conduct a new criminal history check and re-evaluate the criminal history upon submission of a new criminal history request form.

(10) The applicant or licensee must pay a criminal records check fee for the actual cost of acquiring and furnishing the criminal offender information.

State and Nationwide Criminal Background Checks for Employees, Volunteers and Employment Applicants

(1) The Board requires a criminal records check and fitness determination for Board employees, volunteers or applicants for employment with the Board.

(2) Criminal records checks and fitness determinations are conducted pursuant to ORS 181A.170 to 181A.215 and OAR 125-007-0200 to 125-007-0310.

(a) To complete the criminal records check and fitness determination, the Board may require additional information from the employee, volunteer or applicant, such as, but not limited to, proof of identity or additional criminal, judicial or other background information.

(b) If the employee, volunteer or applicant has potentially disqualifying criminal offender information, the Board will consider factors listed in ORS 181A.195 before making a fitness determination.

(c) An approved fitness determination does not guarantee employment.

(d) An incomplete fitness determination does not entitle the employee, volunteer or applicant the right to appeal under OAR 125-007-0300.

(3) Pursuant to ORS 181A.195, and OAR 125-007-0310, information obtained in the criminal records check is confidential and will not be disseminated by the Board except to persons with a demonstrated and legitimate need to know the information.

Fees

(1) The applicant or licensee must pay a criminal records check fee for the actual cost of acquiring and furnishing the criminal offender information. The fee will not exceed the cost
to the Board to obtain such information, including fees charged to the Board by the OSP and the FBI.

Stat. Auth.: ORS 676.303, 689.205

Stats. Implemented: ORS 181A, 676.303, 689.207

REPEAL ALL OLD RELATED RULES

State and Nationwide Criminal Background Checks

(1) The purpose of this rule is to provide for the reasonable screening of: applicants for licensure; directors, officers and designated representatives of drug outlets applying for registration; and individuals subject to investigation by the Board, in order to determine if they have a history of criminal behavior such that they are not fit to be granted or retain a license or registration issued by the Board.

(2) "Subject individual" means a person from whom the Board may require fingerprints for the purpose of enabling the Board to request a state or nationwide criminal records check. In this rule, subject individual means: applicants for licensure or renewal of a license; directors, officers and designated representatives of drug outlets applying for registration or renewal of a registration; and individuals subject to an investigation by the Board.

(3) This rule is to be applied when evaluating the criminal history of a subject individual and conducting fitness determinations based upon such history. The fact that a subject individual does not have an adverse criminal history does not guarantee the granting or renewal of a license, or registration.

(4) The Board may request that the Department of State Police conduct a state criminal history check and a national criminal history check, using fingerprint identification of subject individuals. The Board may conduct state criminal records checks on subject individuals and any licensee through the Law Enforcement Data System maintained by the Department of State Police in accordance with rules adopted, and procedures established, by the Department of State Police. Criminal history information obtained from the Law Enforcement Data System must be handled in accordance with ORS Chapter 181, OAR 257-010 to 257-015 and applicable Oregon State Police procedures.

(5) Additional Information Required. In order to conduct a state and national criminal history check and fitness determination, the Board may require additional information from the subject individual as necessary. Additional information may include but is not limited to, proof of identity; residential history; names used while living at each residence; or additional criminal, judicial, or other background information.
(6) In making the fitness determination, the Board may consider:

(a) The nature of any record that may include but is not limited to any record of arrest or conviction for:

(A) Any drug or alcohol offence;

(B) Any felony;

(C) Any offence involving fraud, theft, identity theft or other instance of dishonesty;

(D) Any offence involving violation of federal importation or customs laws or rules;

(E) Any offence requiring registration as a sex offender.

(b) The facts that support the conviction or indictment or that indicate the making of the false statement;

(c) The relevancy, if any, of the crime or the false statement to the specific requirements of the subject individual's license or registration; and

(d) Intervening circumstances relevant to the responsibilities and circumstances of the license or registration. Intervening circumstances include but are not limited to:

(A) The passage of time since the commission of the crime;

(B) The age of the subject individual at the time of the crime;

(C) The likelihood of a repetition of offenses or of the commission of another crime;

(D) The subsequent commission of another relevant crime;

(E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and

(F) A recommendation of an employer.

(e) Any false statement made by the individual regarding the criminal history of the individual;

(f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint identification;

(g) Any other pertinent information obtained as part of an investigation.

(7) If a subject individual is determined to be unfit, then the individual may not be granted a license or registration or a renewal of a license or registration. The Board may make a fitness determination conditional upon applicant's acceptance of probation, conditions, limitations, or other restrictions upon licensure or registration.
(8) All background checks shall be requested to include available state and national data, unless obtaining one or the other is an acceptable alternative.

(9) Criminal offender information is confidential. Dissemination of information received under this rule may only be made to people with a demonstrated and legitimate need to know the information. When the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS 676.175. Any fingerprint cards used to conduct a check shall be destroyed by either the Federal Bureau of Investigation or the Department of State Police as specified in ORS 181.534.

(10) The Board will permit the subject individual for whom a fingerprint-based criminal records check was conducted to inspect the individual's own state and national criminal offender records and, if requested by the subject individual, provide the individual with a copy of the individual's own state and national criminal offender records.

(11) If an applicant, licensee or certificate holder is determined not to be fit for a license or registration, they are entitled to a contested case hearing pursuant to ORS 183.413 to 470 and in accordance with OAR 855-001-0005 to 0017.

(12) A challenge to the accuracy or completeness of information provided by the Department of State Police, Federal Bureau of Investigation and agencies reporting information must be made through the Department of State Police, Federal Bureau of Investigation or reporting agency and not through the contested case process.

(13) Request for re-evaluation following correction. If the subject individual successfully contests the accuracy or completeness of information provided by the Oregon State Police, the Federal Bureau of Investigation or other agency reporting information to the Board, the Board will conduct a new criminal history check and re-evaluate the criminal history upon submission of a new criminal history request form.

(14) If the subject individual discontinues the application or fails to cooperate with the criminal history check process then the application is considered incomplete.

(15) Subject individuals will be required to pay the actual costs charged by the Department of State Police for the state and national criminal background check.

Stat. Auth.: ORS 181.534, 689.205
Stats. Implemented: ORS 689.207
Hist.: BP 2-2008, f. & cert. ef. 2-20-08

Criminal Background Checks
Employees, Applicants for Employment and Volunteers

855-010-0050
Purpose

The purpose of these rules is to provide for the reasonable screening of subject individuals to determine if they have a history of criminal behavior such that they are not fit to work or volunteer for the Board. The fact that the Board determines that a subject individual is fit does not guarantee the individual a position as a Board employee, volunteer, or that the individual will be hired by the Board.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11
855-010-0055

Definitions

As used in OAR 855-010-0050 through 855-010-0086, unless the context of the rule requires otherwise, the following definitions apply:

(1) Conviction: A final judgment on a verdict or finding of guilty, a plea of guilty, or a plea of nolo contendere (no contest) or any determination of guilt entered by a court of law against a subject individual in a criminal case, unless that judgment has been reversed or set aside by a subsequent court decision.

(2) Fitness determination: A determination made by the Board, pursuant to the process established under OAR 855-010-0060, that a subject individual is fit or not fit to be a Board employee or volunteer.

(3) Criminal offender information: Records and related data concerning physical description and vital statistics, fingerprints received and compiled by the Oregon State Police (OSP) to identify criminal offenders and alleged offenders, records of arrests and the nature and disposition of criminal charges, including sentencing, confinement, parole and release records.

(4) Criminal records check: One or more of the following three processes undertaken by the Board to check the criminal history of a subject individual:

(a) A name-based check of criminal offender information conducted through the Law enforcement Data System (LEDS) maintained by the OSP, in accordance with the rules adopted and procedures established by the OSP;

(b) A check of Oregon criminal offender information, through fingerprint identification and other means, conducted by the OSP at the Board's request (Oregon Criminal Records Check); or
(e) A nationwide check of federal criminal offender information, through fingerprint identification and other means, conducted by the OSP through the FBI or otherwise at the Board’s request (Nationwide Criminal Records Check).

(5) Criminal Records Request form: A Board-approved form, completed by a subject individual, requesting the Board to conduct a criminal records check.

(6) False statement: In association with an activity governed by these rules, a subject individual either:

(a) Provided the Board with false information about the subject individual’s criminal history, including but not limited to false information about the individual’s identity or conviction record; or

(b) Failed to provide the Board information material to determining the individual’s criminal history.

(7) Subject Individual: An individual identified in OAR 855-010-0057 as someone from whom the Board may require a criminal records check.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0057

Subject Individual

The Board may require a subject individual to complete a criminal records check pursuant to these rules because the person is:

(1) A Board employee

(2) A Board volunteer; or

(3) An applicant for employment with the Board.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0060

Criminal Records Check Process

Oregon Board of Pharmacy 10.12.17
(1) Disclosure of Information by Subject Individual.

(a) Preliminary to a criminal records check, a subject individual must complete and sign the Board Criminal Records Request form and a fingerprint card. Both forms ask for identifying information (e.g., name, birth date, social security number, physical characteristics, driver's license or identification card number and current address of the subject individual). The Board Criminal Records Request form also requires information about the subject individual’s prior residences in other states and any other identifying information deemed necessary by the Board.

(b) A subject individual must complete and submit to the Board the Criminal Records Request form and, if requested, a fingerprint card within five business days of receiving the forms. The Board may extend the deadline for good cause.

(c) The Board may require additional information from the subject individual as necessary to complete the criminal records check and fitness determination, such as, but not limited to, proof of identity, or additional criminal, judicial, or other background information.

(d) The Board shall not request a fingerprint card from a subject individual under the age of 18 years unless the subject individual is emancipated pursuant to ORS 419B.550 et seq., or unless the Board also requests the written consent of a parent or guardian. In such case, such parent or guardian and youth must be informed that they are not required to consent. Notwithstanding, failure to consent may be construed as a refusal to consent under OAR 855-010-0065(3).

(2) When a Criminal Records Check is required. The Board may conduct, or request the OSP to conduct, a criminal record check when:

(a) An individual meets the definition of a subject individual; or

(b) Required by federal law or regulation, by state statute or administrative rule, or by contract or written agreement with the Board.

(3) Which Criminal Records Check is conducted. When the Board determines under section (2) of this rule that a criminal records check is needed, the Board may request or conduct a LEDS Criminal Records Check, an Oregon Criminal Records Check, a Nationwide Criminal Records Check, or any combination thereof.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11
855-010-0065
Final Fitness Determination
(1) If the Board elects to conduct a criminal records check, the Board shall make a fitness determination about a subject individual based on information provided by the subject individual under OAR 855-010-0060(1), any criminal records check conducted, and any false statement made by the subject individual.

(2) In making a fitness determination about a subject individual, the Board will also consider the factors in subsections (a) through (f) below in relation to information provided by the subject individual under OAR 855-010-0060(1), any LEDS report or criminal offender information obtained through a criminal records check, and other information known by the Board. To assist in considering these factors, the Board may obtain any other information deemed relevant from the subject individual or any other source, including law enforcement and criminal justice agencies or courts within or outside of Oregon. To acquire other criminal offender information from the subject individual, the Board may request to meet with the subject individual, and may request to receive written materials or authorization to obtain other relevant information, from the subject individual. The subject individual shall meet with the Board if requested and provide additional information or authorization within a reasonable period of time, as established by the Board. The Board will use all collected information in considering:

(a) Whether the subject individual has been convicted, found guilty except for insanity (or a comparable disposition), or has a pending indictment for a crime listed in OAR 855-010-0067;

(b) The nature of any crime identified under section (2)(a) of this rule;

(c) The facts that support the conviction, finding of guilty except for insanity, or pending indictment;

(d) Any facts that indicate the subject individual made a false statement;

(e) The relevance, if any, of a crime identified under section (2)(a) of this rule or of a false statement made by the subject individual to the specific requirements of the subject individual's present or proposed position, services or employment; and

(f) The following intervening circumstances, to the extent that they are relevant to the responsibilities and circumstances of the services or employment for which the fitness determination is being made:

(A) The passage of time since the commission or alleged commission of a crime identified under section (2)(a) of this rule;

(B) The age of the subject individual at the time of the commission or alleged commission of a crime identified under section (2)(a) of this rule;

(C) The likelihood of a repetition of offenses or of the commission of another crime;

(D) The subsequent commission of another crime listed in OAR 855-010-0067;
(E) Whether a conviction identified under section (2)(a) of this rule has been set aside, and the legal effect of setting aside the conviction;

(F) A recommendation of an employer;

(G) The disposition of a pending indictment identified under section (2)(a) of this rule;

(H) Whether the subject individual has been arrested for or charged with a crime listed under OAR 855-010-0067;

(I) Whether the subject individual is being investigated, or has an outstanding warrant, for a crime listed under OAR 855-010-0067;

(J) Whether the subject individual is currently on probation, parole or another form of post-prison supervision for a crime listed under 855-010-0067;

(K) Whether the subject individual has a deferred sentence or conditional discharge in connection with a crime listed under OAR 855-010-0067;

(L) Whether the subject individual has been adjudicated in a juvenile court and found to be within the court's jurisdiction for an offense that would have constituted a crime listed in OAR 855-010-0067 if committed by an adult;

(M) Periods of incarceration of the subject individual;

(N) The education and work history (paid or volunteer) of the subject individual since the commission or alleged commission of a crime.

(3) Refusal to Consent. If a subject individual refuses to submit or consent to a criminal records check including fingerprint identification, the Board will deny the employment of the subject individual or deny any applicable position or authority to provide services. A person may not appeal any determination made based on a refusal to consent.

(4) If a subject individual is determined to be not fit, the subject individual may not be employed by or provide services as a volunteer to the Board.

(5) Final Order. A completed final fitness determination is a final order of the Board unless the affected subject individual appeals the determination by requesting a contested case hearing as provided by OAR 855-010-0080(2) or an alternative appeals process as provided by OAR 855-010-0080(6).

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11
Potentially Disqualifying Crimes

(1) Crimes Relevant to a Fitness Determination:
(a) All felonies;
(b) All misdemeanors;
(c) Any United States Military crime or international crime;

(2) Evaluation of Crimes. The Board shall evaluate a crime on the basis of the law of the jurisdiction in which the crime or offense occurred, as those laws are in effect at the time of the fitness determination.

(3) Expunged Juvenile Record. Under no circumstances shall a subject individual be determined to be not fit under these rules on the basis of the existence or contents of a juvenile record that has been expunged pursuant to ORS 419A.260 and ORS 419A.262.

Incomplete Fitness Determination

(1) The Board will close a preliminary or final fitness determination as incomplete when:
(a) Circumstances change so that a person no longer meets the definition of a "subject individual" under OAR 855-010-0057;
(b) The subject individual does not submit materials or information within the time required under OAR 855-010-0060;
(c) The Board cannot locate or contact the subject individual;
(d) The subject individual fails or refuses to cooperate with the Board's attempts to acquire other criminal records information under OAR 855-010-0065; or
(e) The Board determines that the subject individual is not eligible or not qualified for the position of employee or volunteer, for a reason unrelated to the fitness determination process.
(f) The position is no longer open.
(2) A subject individual does not have a right to a contested case hearing under OAR 855-010-0080(2) or a right to an alternative appeals process under OAR 855-010-0080(6) to challenge the closing of a fitness determination as incomplete.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

Notice to Subject Individual of Fitness Determination

The Board shall inform the subject individual who has been determined not to be fit on the basis of a criminal records check, via personal service, or registered or certified mail to the most current address provided by the subject individual, of such disqualification.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

Appealing a Fitness Determination

(1) Purpose: Sections (2) to (5) of this rule set forth the contested case hearing process a subject individual must use to appeal a completed final fitness determination made under OAR 855-010-0065 that the individual is not fit to hold a position with, or provide services to the Board as an employee or volunteer. Section (6) of this rule identifies an alternative appeal process available only to current Board employees.

(2) Appeal process.

(a) To request a contested case hearing, the subject individual or the subject individual's legal representative must submit a written request for a contested case hearing to the address specified in the notice provided under OAR 855-010-0075. To be timely, the request must be received by the Board at the specified address within 14 calendar days of the date stated on the notice. The Board shall address a request received after expiration of the deadline as provided under OAR 137-003-0528.

(b) When a timely request is received by the Board under subsection (a), a contested case hearing shall be conducted by an administrative law judge assigned by the Office of Administrative Hearings, pursuant to the Attorney General's Uniform and Model Rules, “Procedural Rules,
Office of Administrative Hearings OAR 137-003-0501 to 137-003-0700, as supplemented by the provisions of this rule.

(3) Discovery. The Board or the administrative law judge may protect information made confidential by ORS 181.534(15) or other applicable law as provided under OAR 137-003-0570(7) or (8).

(4) No Public Attendance. Contested case hearings on fitness determinations are closed to non-participants.

(5) Proposed and Final Order:

(a) Proposed Order. After a hearing, the administrative law judge will issue a proposed order.

(b) Exceptions. Exceptions, if any, shall be filed within 14 calendar days after service of the proposed order. The proposed order shall provide an address to which exceptions must be sent.

(c) Default. A completed final fitness determination made under OAR 855-010-0065 becomes final:

(A) Unless the subject individual makes a timely request for a hearing; or

(B) When a party withdraws a hearing request, notifies the Board or the ALJ that the party will not appear, or fails to appear at the hearing.

(6) Alternative Process. A subject individual currently employed by the Board may choose to appeal a fitness determination either under the process made available by this rule or through a process made available by applicable personnel rules, policies and collective bargaining provisions. A subject individual's decision to appeal a fitness determination through applicable personnel rules, policies, and collective bargaining provisions is an election of remedies as to the rights of the individual with respect to the fitness determination and is a waiver of the contested case process made available by this rule.

(7) Remedy. The only remedy that may be awarded is a determination that the subject individual is fit or not fit. Under no circumstances shall the Board be required to place a subject individual in any position, nor shall the Board be required to accept services or enter into a contractual agreement with a subject individual.

(8) Challenging Criminal Offender Information. A subject individual may not use the appeals process established by this rule to challenge the accuracy or completeness of information provided by the OSP, the FBI, or agencies reporting information to the OSP or the FBI.

(a) To challenge information identified in this section of the rule, a subject individual may use any process made available by the agency that provided the information.
(b) If the subject individual successfully challenges the accuracy or completeness of information provided by the OSP, the FBI, or an agency reporting information to the OSP or the FBI, the subject individual may request that the Board conduct a new criminal records check and re-evaluate the original fitness determination made under OAR 855-010-0065 by submitting a new Board Criminal Records Request form. This provision only applies if the position for which the original criminal history check was conducted is vacant and available.

(9) Appealing a fitness determination under section (2) or section (6) of this rule, challenging criminal offender information with the agency that provided the information, or requesting a new criminal records check and re-evaluation of the original fitness determination under section (8)(b) of this rule, will not delay or postpone the Board’s hiring process or employment decisions.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0085

Recordkeeping and Confidentiality

Any information obtained in the criminal records check is confidential. The Board must restrict the dissemination of information obtained in the criminal records check. Only those persons, as identified by the Board, with a demonstrated and legitimate need to know the information, may have access to criminal records check records.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11

855-010-0087

Fees

(1) The Board may charge a fee for acquiring criminal offender information for use in making a fitness determination that will not exceed the fee charged the Board by the OSP and the FBI to obtain such information.

(2) The Board may charge the fee to the subject individual on whom criminal offender information is sought.

Stat. Auth.: ORS 181.534, 676.303, 689.205
Stats. Implemented: ORS 181.534

Oregon Board of Pharmacy
Hist.: BP 1-2011(Temp), f. & cert. ef. 2-8-11 thru 6-30-11; BP 4-2011, f. 6-24-11, cert. ef. 7-1-11.
The proposed rule amendment incorporates edits put forth in 2017 HB 2527, signed by Governor Kate Brown on 6-14-2017.

A trained pharmacist may prescribe and administer injectable hormonal contraceptives and prescribe and dispense self-administered hormonal contraceptives. These include injectable, patch, vaginal ring and oral hormonal contraceptives. Note: A new module related depomedroxyprogesterone will be made available and must be completed prior to engaging in prescribing.

These amendments become operative on or after January 1, 2018.

855-019-0400

Purpose

The purpose of rules OAR 855-019-0400 through 855-019-0435, operative January 1, 2016, is to develop standard procedures for the prescribing of injectable hormonal contraceptives, patches and oral self-administered hormonal contraceptives by an Oregon licensed pharmacist, providing timely access to care. To ensure public safety and provide a consistent level of care, a pharmacist may participate upon completion of a Board approved training program. Under the rules of this section, a qualified pharmacist may prescribe hormonal contraceptives to a patient pursuant to a self-screening risk assessment questionnaire and standard procedural algorithm.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 689.683

855-019-0405

Definitions

In OAR 855-019-0400 through 855-019-0435:

1. “Clinical visit” means a consultation with a healthcare provider, other than a pharmacist, for women’s health, which should address contraception and age-appropriate screening.

2. “Hormonal contraceptive patch” means a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.

3. “Injectable hormonal contraceptive” means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that a health care practitioner administers to the patient by injection.

4. “Self-administered Oral hormonal contraceptive” means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that a health care practitioner administers to the patient by injection.
Administration to prevent pregnancy and that the patient to whom the drug is prescribed may administer to oneself take orally.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 689.683

**855-019-0410**

**Prescriptive Practice Consultation**

In an effort to clarify, improve, and support appropriate pharmacist prescribing, the Board shall periodically review prescribing standards, practices, and scope in consultation with designated representatives from the Oregon Medical Board, Oregon State Board of Nursing, and Oregon Health Authority. The Board will seek recommendations from these representatives to be considered in conjunction with American Congress of Obstetricians and Gynecologists (ACOG) guidelines and other evidence-based standards, as it seeks to evaluate and improve prescribing practices within pharmacy. To the extent that developed standards are incorporated into practice, the forms, screening tools, or requisite training materials shall be prepared by the Board in consultation with these designated representatives.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 689.683

**855-019-0415**

**Training Program**

(1) Only a pharmacist, who has completed a Board approved Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist, may prescribe injectable hormonal contraceptives patches and self-administered oral hormonal contraceptives for a patient.

(2) A pharmacist must submit a copy of the certificate of completion of training to the Board within 15 days of completion.

(3) A pharmacist must maintain the certificate of completion and make available upon request.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 689.683

**Delivery of Care**

**855-019-0420**

**Age Requirements**
A pharmacist may prescribe injectable hormonal contraceptives patches and self-administered oral 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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 689.683

855-019-0425
Procedural Mandates

1. For each new patient requesting contraceptive services and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:
   a. Obtain a completed Oregon Self-Screening Risk Assessment Questionnaire; and
   b. Utilize and follow the Oregon Standard Procedures Algorithm to perform the patient assessment; and
   c. Prescribe, if clinically appropriate, the hormonal contraceptive patch or self-administered or injectable oral hormonal contraceptive, or refer to a healthcare practitioner; and
   d. Provide the patient with a Visit Summary; and
   e. Advise the patient to consult with a primary care practitioner or women’s health care practitioner; and
   f. Document the encounter and maintain records pursuant to OAR 855-019-0435.

2. If the hormonal contraceptive patch or self-administered oral hormonal contraceptive is dispensed or the injectable hormonal contraceptive is administered, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.

3. Nothing in this rule shall prohibit the partial filling or transferring of a drug prescribed pursuant to this process, per the request of the patient.

4. A pharmacy must:
   a. Keep records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years; and
   b. Keep records of the medication dispensed for a minimum of three years; and
(c) Establish, maintain and enforce written procedures for the provision of care under this section, including, but not limited to:

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

(B) Documentation and recordkeeping.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 689.683

855-019-0430

Prohibited Practices

A pharmacist must not:

(1) Require a patient to schedule an appointment with the pharmacist for the prescribing, administering or dispensing of a hormonal contraceptive patch or self-administered oral hormonal contraceptive;

(2) Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit;

(3) Prescribe in instances that the Oregon Standard Procedures Algorithm requires referral to a provider; and

(4) Prescribe to self or immediate family members.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 689.683

855-019-0435

Records

(1) A pharmacist must document the encounter and the prescription, and maintain records of drug dispensing.

(2) A pharmacy must maintain records of the encounter, including but not limited to, the Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years and maintain records of the medication administered or dispensed for a minimum of three years.

(3) Prescriptions are valid for one year pursuant to OAR 855-041-1125.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.005 & 689.683
The proposed rule amendments in Div 019 and Div 041 incorporate edits put forth in 2017 HB 3440. The new law removes all previous Oregon Health Authority (OHA) training mandates. Edits clarify that a pharmacist can prescribe naloxone to an entity or an individual seeking naloxone and any necessary supplies to administer the naloxone.

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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100

855-019-0455

Qualifications

A pharmacist acting in good faith, exercising reasonable care and who is educated in opiate overdose and naloxone rescue can prescribe unit-of-use naloxone and the necessary medical supplies to administer the naloxone for an individual who:

1. Conducts training that meets that criteria established by the Oregon Health Authority (OHA) so that the person may possess and distribute naloxone and the necessary medical supplies to persons who successfully complete the training; or
2. Has successfully completed training that meets criteria established by the OHA allowing the person to possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100 & 2017 OL Ch. 683

855-019-0460

Delivery of Care

1. A pharmacist can prescribe naloxone and the necessary medical supplies for opiate overdose training to an OHA authorized person or organization.
2. A pharmacist can prescribe naloxone and the necessary medical supplies to an individual or entity seeking naloxone who has successfully completed an OHA approved training. The pharmacist shall determine that the individual seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.
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.

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

The pharmacist shall dispense the naloxone product in a properly labeled container identifying the authorized recipient.

Naloxone may not be dispensed without providing oral counseling to the authorized recipient, to include dose, effectiveness, adverse effects, storage conditions, and safety.

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

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

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

(b) Documentation and recordkeeping.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100
Definitions

The following words and terms, when used in OAR 855-041-2300 through 855-041-2330 shall have the following meanings, unless the context clearly indicates otherwise.

(1) “Allergic reaction” means a medical condition caused by exposure to an allergen, with physical symptoms that may be life threatening, ranging from localized itching to severe anaphylactic shock and death.

(2) “Authorization to Obtain Epinephrine” means a certificate that contains the name, signature, and license number of the supervising professional authorizing the dispensing of epinephrine to the individual whose name appears on the certificate. Additionally, the certificate contains a record of the number of epinephrine orders filled to date.

(3) “Authorization to Obtain Naloxone” means a certificate that contains the name, signature, and license number of the supervising professional authorizing the dispensing of naloxone to the individual whose name appears on the certificate. Additionally, the certificate contains a record of the number of naloxone orders filled to date.

(4) “Opiate” means a narcotic drug that contains: opium, any chemical derivative of opium, or any synthetic or semi-synthetic drug with opium-like effects.

(5) “Opiate overdose” means a medical condition that causes depressed consciousness and mental functioning, decreased movement, depressed respiratory function, and the impairment of vital functions as a result of ingesting opiates in any amount larger than can be physically tolerated.

(6) “Statement of Completion” means a certificate that states the specific type of emergency the trainee was trained to respond to, the trainee’s name and address, the name of the authorized trainer and the date that the training was completed.

(7) “Supervising Professional” means a physician or nurse practitioner licensed to practice in this state who has prescription writing authority.

(8) “Trainee” means an individual who has attended and successfully completed the formal training pursuant to the protocols and criteria established by the Oregon Health Authority, Public Health Division.

(9) “Trainer” means an individual conducting the formal training as directed by the supervising professional and in accordance with the protocols and criteria established by the Oregon Health Authority, Public Health Division.

Stats. Implemented: ORS 689.155 & 2013 OL Ch. 340
Hist.: BP 6-2013(Temp), f. 9-23-13, cert. ef. 9-24-13 thru 3-23-14; BP 2-2014, f. & cert. ef. 1-24-14
(1) A Pharmacy may fill orders for unit-of-use naloxone to be used by trainees for opiate overdose emergencies. Individuals must successfully complete a training program approved by the Oregon Health Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:

(a) Statement of Completion; and

(b) Authorization to Obtain Naloxone.

(2) Distribution of naloxone from a pharmacy to be used for opiate overdose emergencies may occur in the following ways:

(a) A supervising professional may obtain a supply of naloxone for a program pursuant to a request by the supervising professional and a pharmacy sale by invoice. The pharmacy shall keep the invoice on record for three (3) years.

(b) A trainee may obtain naloxone upon presentation of the Statement of Completion and Authorization to Obtain Naloxone certificate to a pharmacy which:

(A) A pharmacist may generate a prescription for, and dispense up to two (2) unit-of-use doses of naloxone as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Naloxone certificate.

(B) The pharmacist who generates the hardcopy prescription for naloxone in this manner shall reduce the prescription to writing and file the prescription in a manner appropriate for a non-controlled substance.

(C) Once the pharmacist generates the naloxone prescription, the pharmacist shall write in the appropriate space provided on the Authorization to Obtain Naloxone certificate the date and the number of doses dispensed, and return the certificate to the trainee.

(3) The Statement of Completion and Authorization to Obtain Naloxone certificate may be used to obtain naloxone up to six (6) times within three (3) years from the date of the initial training:

(a) Both the Statement of Completion and the Authorization to Obtain Naloxone certificate expire three (3) years from the date of the trainee’s last Oregon Health Authority, Public Health Division approved naloxone training.

(b) Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Naloxone, with a valid duration of three (3) years.

(4) The naloxone container must be labeled with the following information:

(a) A statement that the naloxone is intended for use in the Oregon Opiate Overdose Treatment program;
(b) Trainees name; and
(c) Trainer; or
(d) Supervising Professional.
Hist.: BP 6-2013(Temp), f. 9-23-13, cert. ef. 9-24-13 thru 3-23-14; BP 2-2014, f. & cert. ef. 1-24-14
855-041-2340

Pharmacist Prescribing of Naloxone

(1) A pharmacist educated in opiate overdose and naloxone rescue may prescribe unit-of-use naloxone and the necessary medical supplies to administer the naloxone to an individual who:

(a) Conducts training that meets criteria established by the Oregon Health Authority (OHA) so that the person may possess and distribute naloxone and the necessary medical supplies to persons who successfully complete the training; or

(b) Has successfully completed training that meets criteria established by the OHA allowing the person to possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

(2) The pharmacy providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:

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

(b) Documentation and recordkeeping.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100
These proposed changes clarify the intent and utilization of a Remote Distribution Facility (RDF) by an Oregon Institutional Pharmacy (IP).

RDF rules are moved to the 5000 section of Div 041 so that it is clear this is linked to INSTITUTIONAL pharmacies (IPs) only.

855-041-4200

Remote Distribution Facility (RDF)

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

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

(a) An operation plan;

(b) Policies and Procedures;

(c) A training plan;

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

(e) The fee specified in OAR 855-110.

(3) Notwithstanding the definition of “supervision by a pharmacist” in OAR 855-006-0005, supervision in an RDF may be accomplished by a pharmacist via an audio-visual technology from the applying pharmacy.

(4) Notwithstanding rules in this division and in divisions 19 and 25, a Certified Oregon Pharmacy Technician who works in an RDF may have access to the facility without the physical presence of a pharmacist, but may only perform Board approved functions when under the supervision of a pharmacist.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 3-2011, f. & cert. ef. 4-18-11; Renumbered from 855-041-0645, BP 7-2012, f. & cert. ef. 12-17-12; BP 1-2014, f. & cert. ef. 1-3-14; BP 2-2016, f. 6-30-16, cert. ef. 7-1-16

OAR 855-041-5050

Definitions

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

(2) "Remote Distribution Facility" (RDF) means an in-state/resident facility where
drugs are prepared for administration and where requisite pharmacist supervision
is provided remotely as approved by the Board.

(3) "Responsible Pharmacy" means the licensed resident pharmacy that is
responsible for the RDF.

Remote Distribution Facility (RDF)

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

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

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

(a) An operation plan;
(b) Policies and Procedures;
(c) A training plan;
(d) A quality assurance plan for ensuring that there is a planned and systematic
process for the monitoring and evaluation of the quality and appropriateness of
pharmacy services and for identifying and resolving problems; and
(e) The fee specified in Division 110.

(3) Notwithstanding the definition of “supervision by a pharmacist” in Division 006,
supervision in a RDF may be accomplished by a pharmacist via an audio-visual
technology from the applying pharmacy.

(4) Notwithstanding rules in this Division and in Divisions 019 and 025, a Certified
Oregon Pharmacy Technician who works in a RDF may have access to the facility
without the physical presence of a pharmacist, but may only perform Board
approved functions when under the supervision of a pharmacist.
The proposed rule amendment incorporates edits put forth in 2017 SB 302. It was signed into law on 4-21-2017, and essentially de-classifies cannabis as a controlled substance in Oregon.

855-080-0022

Schedule II

Schedule II consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.12 and any quantity of the following substances:

1. Marijuana and delta-9-tetrahydrocannabinol (THC).
2. Methamphetamine, when in the form of an FDA approved product containing methamphetamine, its salts, isomers and salts of its isomers as an active ingredient for the purposes of currently accepted medical use.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 475.035, 475.059 & 475.065
Hist.: PB 4-1987, f. & ef. 3-30-87; PB 8-1987, f. & ef. 9-30-87; PB 10-1987, f. & ef. 12-8-87; PB 15-1989, f. & cert. ef. 12-26-89; PB 9-1990, f. & cert. ef. 12-5-90; PB 5-1991, f. & cert. ef. 9-19-91; PB 1-1992, f. & cert. ef. 1-31-92 (and corrected 2-7-92); PB 1-1994, f. & cert. ef. 2-2-94; PB 1-1996, f. & cert. ef. 4-5-96; PB 1-1997, f. & cert. ef. 9-22-97; BP 3-1999(Temp), f. & cert. ef. 8-9-99 thru 1-17-00; BP 4-2000, f. & cert. ef. 2-16-00; BP 4-2006, f. 6-9-06, cert. ef. 7-1-06; BP 1-2007, f. & cert. ef. 6-29-07; BP 8-2010, f. & cert. ef. 6-29-10; BP 10-2014, f. 12-30-14, cert. ef. 1-1-15
The proposed amendments in OAR 855-019-0460 are provided for the Board’s review for a temp rule.

ORS 689.681(4) states “Notwithstanding any other provision of law, a pharmacy, a health care professional with prescription and dispensing privileges or any other person designated by the State Board of Pharmacy by rule may distribute unit-of-use packages of naloxone, and the necessary medical supplies to administer the naloxone.

Certain entities are in the position to provide naloxone distribution within their agency. In order to allow this to occur, sub (8) is proposed.

Another question: Now that the mandate to provide training is removed, does the Board find it necessary to mandate counseling on all naloxone prescriptions a pharmacist prescribes? See proposed sub (6) edits.

855-019-0460

Delivery of Care

1) A pharmacist 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 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 dispensed prescribed without offering to providing oral counseling to the authorized recipient, to 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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100
Edits to Div 041 and Div 019 are proposed to address Retail Drug Outlet (RP)/Community Pharmacy personnel and compliance requirements.

These edits (1) Add a requirement to an Oregon community pharmacy outlet that each Pharmacist-in-Charge (PIC) shall report directly to an Oregon licensed pharmacist; (2) Update the PIC rules to clarify the role of a PIC; and (3) Incorporate general/housekeeping edits for the PIC duties and responsibilities.

“Model” language from 6000s (Hospital) section of Div 041:

(d) “Chief Pharmacy Officer” (CPO) means an Oregon licensed pharmacist who supervises the pharmacy operations in a hospital. The CPO may hold the title of Pharmacy Manager, Pharmacy Director, Director of Pharmacy, Pharmacy Administrator or other pharmacy supervisory management title within the organization. The PIC may also be the CPO if there is only one pharmacy in the hospital;

(2) A hospital that has more than one pharmacy must designate an Oregon licensed pharmacist as CPO or an equivalent position who has responsibility for directing pharmacy services in the hospital. The CPO may also be the PIC of one of the pharmacies.

“Model” language from OAR 855-041-1060:

(5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within four months of initial licensure of the pharmacy.

(6) When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the Board within ten business days and identify a contact person. The pharmacy will have an Oregon licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the pharmacy’s state of residence and is responsible for the following:

(a) Supervision of pharmacy staff and ensuring compliance with laws and rules; and

(b) Responding to Board correspondence and inquiries.

(7) A new Pharmacist-in-Charge must be appointed, and communication made to the Board within 90 days, or the non-resident pharmacy will cease drug distribution and provision of pharmacy services in Oregon.

General Community Pharmacy

855-041-2105 Personnel

(1) Each community pharmacy drug outlet (RP) must have an Oregon licensed pharmacist designated as Pharmacist-in-Charge (PIC) who is responsible for the daily operations of
the pharmacy. The PIC is responsible for exercising professional judgment and discretion to ensure a pharmacy environment that is safe and effective, and fulfils the responsibilities listed in Div 019.

(2) Each resident community pharmacy that employs a person who directs the professional activities of multiple PICs shall ensure that the person is an Oregon licensed pharmacist.

(3) When a change of the direct supervisor occurs, the pharmacy will notify the Board within ten business days, and will have an Oregon licensed direct supervisor within 90/120 days.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Pharmacist-in-Charge

855-019-0300

Duties of a Pharmacist-in-Charge

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis at that location who is responsible for the daily operation of the pharmacy.

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

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

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

(3) A pharmacist may not be designated PIC of more than two pharmacies without prior written approval by the Board. If such approval is given, the pharmacist must comply with the requirements in sub-section (4)(e) of this rule. A pharmacist may be designated as a PIC of up to two Oregon licensed pharmacies only upon notification of the second site to the Board in writing within 15 days.

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

(a) Exercising professional judgment and discretion to ensure a pharmacy environment that is safe and effective, to include:

(A) Assessing pharmacy demand, and workload;

(B) Evaluating pharmacy staffing, inventory, resources, and capacity;

(C) Prioritizing pharmacy tasks, responsibilities, and assignments; and

(D) Modifying pharmacy workflow and services provided.

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

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

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

(c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120-6310;
(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;

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

(f) If a discrepancy is noted on a Board inspection, the PIC must submit a plan of correction within **15 days for a Non-Compliance Notification and 30 days of receiving a Deficiency Notice.**

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

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

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

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

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

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

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

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

(g) Implementing a **Maintaining the continuous quality assurance plan program** for the pharmacy;

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

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.151, 689.155
Date:
9/18/2017

Request/Inquiry Type:
Waiver Extension

Question(s):
Providence Investigational Drug Services Pharmacy (RP-0002790) requests an extension of their waiver, related to components of prescription labeling, OAR 855-041-1130.

Related ORS/OARs:

855-041-1130 Prescription Labeling
(1) Prescriptions must be labeled with the following information:
   (a) Name, address and telephone number of the pharmacy;
   (b) Date;
   (c) Identifying number;
   (d) Name of patient;
   (e) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;
   (f) Directions for use by the patient;
   (g) Name of practitioner;
   (h) Required precautionary information regarding controlled substances;
   (i) Such other and further accessory cautionary information as required for patient safety;
   (j) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container unless, in the pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an expiration date shall not be dispensed beyond the said expiration date of the drug; and
   (k) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.
   (l) Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

855-041-6260 Investigational Drugs
(1) All in-patient investigational drugs must be stored in the pharmacy and may only be distributed from the pharmacy when properly labeled.
(2) Information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity of such drugs must be available in the pharmacy.
(3) Investigational drugs may only be ordered by a designated physician-investigator or their authorized clinician, subject to the prior approval of the appropriate hospital committee.
(4) Each order must include the appropriate protocol number.
Discussion:
- This waiver was initially granted in 2012; this is a “re-up” request.
- The pharmacy follows the FDA approved investigational protocols and the FDA requirements for labeling investigational drugs.
- This waiver only pertains to those dispensed by the Providence Investigational Drug Pharmacy.

Contact Info:
Danielle Mackey, PIC
Providence Investigational Drug Pharmacy

Staff Recommendation:
Approve waiver extension for 5 years (to 2022).
September 18, 2017

To the Oregon Board of Pharmacy:

The Investigational Drug Services pharmacy has operated with a waiver for the labeling requirements outlined in 855-041-1130, which requires a pill description on the prescription labeling. This waiver was granted because the FDA requirements for labeling an investigational drug vary from the Oregon Board’s rule.

I am writing to request that this waiver continue to be in effect for this pharmacy, as it pertains to investigational (research) agents. These are agents that are being dispensed pursuant to the guidelines of investigational protocols that are open to our pharmacy.

While some protocols may describe the contents of the packages, not all do. In addition, most of our studies are double blind, in which we (the onsite research staff) are not privy as to whether the patient is receiving active treatment, or placebo. Because it is sometimes impossible to conceal the actual identity of the contents, research staff does not view the active and placebo products together. Therefore, the exact contents and description of the product are not always known.

The labeling for investigational drugs will include both the labeling from the manufacturer, which includes the protocol name and number, and usually the drug name and/or investigational number. The label from the manufacturer may or may not include the patient’s name (some products are shipped for specific patients). In addition, a prescription label from the IDS pharmacy will be applied as per usual dispensing practice. The directions for use are applied to the product as directed in the protocol.

Again, I would like to reiterate that this request only pertains to the Investigational Drug Services Pharmacy, in regard to the dispensing of agents that are being used under FDA approved investigational protocols.

Please don’t hesitate to contact me if you have questions in regard to this request.

Regards,

Danielle Mackey, PharmD
Pharmacist in Charge, Investigational Drug Pharmacy
Providence Portland Medical Center Campus
4805 NE Glisan Street, Suite 6N-45
Portland, OR 97213
August 30, 2012

Danielle Mackey, PharmD
Pharmacist in Charge
Investigational Drug Pharmacy Services
Suite 6N-45
Providence Portland Medical Center Campus
4805 NE Glisan St
Portland, OR 97213-2933

Re: Waiver

Dear Danielle Mackey, PharmD,

At the Board’s June 2012 meeting, the Board reviewed and approved a waiver for labeling requirements in 855-041-0065 when the Board’s rule varies from FDA requirements for labeling an investigational drug to be dispensed to an outpatient at Providence Portland Medical Center.

This waiver is valid until 8/30/2017 (5 years from date of letter). After this date, a new waiver has to be requested. A copy of this notification should be kept with your Pharmacist-in-Charge self inspection report.

Sincerely,

Gary Miner
Compliance Director

Cc: Gary Schnabel, R.Ph., Executive Director
   Oregon Board of Pharmacy Licensing Representative
Exception and Waiver Request

Providence Portland Medical Center
Investigational Drug Pharmacy Services

- Request – Providence Investigational Drug Pharmacy is requesting a waiver from the Board’s labeling requirements in 855-041-0065 when the Board’s rule varies from FDA requirements for labeling an investigational drug to be dispensed to an outpatient.
- Investigational drugs for use by inpatients is addressed in OAR 855-041-6260 (Investigational Drugs) in the hospital section but current rules are silent on dispensing and labeling for outpatients receiving investigational drugs.
- Providence Investigational Drug Pharmacy is a new licensee who will be storing and dispensing investigational drugs.
- Investigational drugs may come in ready to use packaging or ready to dispense packaging and need to be dispensed as provided by the study to maintain the integrity of the study.
- The requirement for the Product Identification Label is problematic as the packaging cannot be open to obtain the necessary information to include with the prescription label and could bias the assessment of the drug particularly in the double-blind studies.
- All prescriptions will be dispensed under the FDA approved investigational drug protocols and labeling requirements.
- The OAR 855-041-0065(8) allows the Board to grant a waiver for this section of rules.
- The Staff considers this an appropriate use the waiver and recommends granting the waiver.

OAR 855-041-0065

Requirements for Prescriptions — Prescription Refills

Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner’s authorization. When a prescription is transmitted orally, both the receiving pharmacist’s name or initials and the name of the person transmitting must be noted on the prescription.

(1) Each pharmacy must document the following information:

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

(b) The full name and, in the case of controlled substances, the address and the Drug Enforcement Administration registration number of the practitioner or other number as authorized under rules adopted by reference under rule OAR 855-080-0085;

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

(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

(e) The directions for use, if given by the practitioner;

(f) The date of filling, and the total number of refills authorized by the prescribing practitioner; and
(2) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, this instruction may use any one of the following phrases or notations:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words with similar meaning.

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent shall clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

(c) Such instructions shall not be default values on the prescription.

(3) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III and IV are limited to five refills or six months from date of issue, whichever comes first.

(4) If the practitioner is not available and in the professional judgment of the pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the pharmacist may dispense a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner shall be promptly notified of the emergency refill.

(5) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include:

(a) The identity of the responsible pharmacist;

(b) Name of the patient;

(c) Name of the medication;

(d) Date of refill; and

(e) Quantity dispensed.
(6) After two years from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber. When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled substance means that the medication can be refilled in proper context for a period of one year. When this abbreviation is used alone as a means to authorize refills for a controlled substance, the medication can be refilled in proper context for a period of six months or five refills, whichever comes first. When this abbreviation is used in conjunction with a definite time period, or a specific number of refills, the non-controlled medication can be refilled in proper context for a period not to exceed two years. The prescription shall not be refilled out of context with the approximate dosage schedule unless specifically authorized by the prescriber. A "non-controlled substance" means those drugs defined as "legend" pursuant to ORS 689.005(29) but does not include those drugs or substances controlled under the jurisdiction of the United States Department of Justice Drug Enforcement Administration.

(7) Prescriptions must be labeled with the following information:

(a) Name, address and telephone number of the pharmacy;

(b) Date;

(c) Identifying number;

(d) Name of patient;

(e) Name of drug, strength, and quantity dispensed; when a generic name is used, the label shall also contain the name of the manufacturer or distributor;

(f) Directions for use by the patient;

(g) Name of practitioner;

(h) Required precautionary information regarding controlled substances;

(i) Such other and further accessory cautionary information as required for patient safety;

(j) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container unless, in the pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an expiration date shall not be dispensed beyond the said expiration date of the drug; and

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

(8) Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.
Oregon Pharmacists,

The 2017 Oregon Legislature passed legislation adding the vaginal ring and depot medroxyprogesterone acetate (DMPA) injection administration to the list of contraceptives methods that certified Oregon pharmacists can prescribe and administer.

As directed by the Oregon Board of Pharmacy, on October 10th, 2017, a letter written by Dr. Lorinda Anderson was emailed by Oregon State University’s Professional and Continuing Education Department (PACE) to all pharmacists who had registered for the Comprehensive Contraceptive Education and Training for the Prescribing Oregon Pharmacist. The email included details on how to access the new DMPA module, which is provided to you at no charge. Only pharmacists who completed the original course can access the new DMPA module.

Pharmacists must complete the new module by December 31st, 2017 or their name will be removed from the list of pharmacists certified to prescribe and administer hormonal contraceptive therapies in Oregon. Beginning on January 1, 2017 there will only be access to the entire program which includes the additional module.

To ensure a smooth transition, each week Oregon State University College of Pharmacy provides a list to the corporations of their pharmacists who have completed the DMPA module. The Oregon State Board of Pharmacy will receive on Friday, December 15th, 2017, a preliminary list and on Tuesday, January 2nd, 2018, the final list of those pharmacists who have completed the DMPA module, and the entire course.

If you have not yet registered and/or completed the DMPA module, it is imperative that you complete the module, as soon as possible. As of December 31st, 2017, you will have had a minimum of seven (7) weeks to have completed the DMPA module, at no additional charge. To be certified to prescribe and administer hormonal contraceptive therapies in Oregon, those pharmacists who choose not to complete the DMPA module prior to December 31st, 2017 deadline, will need to register and take the new Oregon Contraceptive Course, which includes the DMPA module.

If you have any questions, please feel free to contact me at:

kenneth.wells@oregonstate.edu

Thanks,
Ken Wells, RPh
Corporate Business Development Manager
Professional and Continuing Education (PACE)
Oregon State University
Hello,

You are receiving this message as our records indicate that you’ve taken the Board approved contraceptive prescribing training program.

Regarding the email sent to you on November 18th, while the Board strongly recommends that all complete the additional DMPA module as soon as possible, be aware that the Board is working on the logistics of this transition of adding the new module to the certification program.

This topic will be discussed at the upcoming December 14, 2017 meeting. You will receive an updated email providing the important details on or about the week of December 18th.

Regards and Best Wishes for a Happy Thanksgiving,
Fiona

Fiona Karbowicz, R.Ph. | Pharmacist Consultant
Oregon Board of Pharmacy | 800 NE Oregon Street; Suite 150, Portland OR 97232
Office 971-673-0009 | Mobile 971-254-6098

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Oregon Pharmacists,

Hello,

While the Oregon Board of Pharmacy strongly recommends that all pharmacists complete the additional DMPA module as soon as possible, be aware that the Board is working on the logistics of this transition of adding the new module to the certification program.

This topic will be discussed at the upcoming December 14, 2017 meeting. You will receive an updated email from both the Board and the Program providing the important details on or about the week of December 18th.

Ken
Kenneth Wells, RPh
Corporate Business Development Manager
Professional and Continuing Education (PACE)
Oregon State University
Corvallis, OR 97331
kenneth.wells@oregonstate.edu
Public Health and Pharmacy Formulary Advisory Committee

Appointed 11/28/17 – 11/28/19

Physicians

Mark Helm MD, Salem
Sean Jones MD, Portland

Advanced Practice Nurses

Helen Turner DNP, Portland
Kathleen Chinn RN MSN, Eugene

Pharmacists

Amy Valdez RPh, Portland
Amy Burns Pharm D, Grants Pass
Evon Anukam Pharm D MPH, Clackamas
## Scoping Review of Nurse Practitioner Standards of Care for Prescribing

<table>
<thead>
<tr>
<th>Prescribing Scope of Practice</th>
<th>Oregon</th>
<th>Washington</th>
<th>Idaho</th>
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<tbody>
<tr>
<td>851-050-0005</td>
<td>Nurse Practitioner Scope of Practice</td>
<td>WAC 246-840-300 ARNP scope of practice.</td>
<td>Chapter 280. STANDARDS OF PRACTICE FOR ADVANCED PRACTICE REGISTERED NURSING</td>
</tr>
<tr>
<td>(4) Within his or her specialty, the nurse practitioner is responsible for managing health problems encountered by the client and is accountable for health outcomes. This process includes: (I) Prescribing, dispensing, and administration of therapeutic devices and measures, including legend drugs and controlled substances as provided in Division 56 of the Oregon Nurse Practice Act, consistent with the definition of the practitioner’s specialty category and scope of practice.</td>
<td>(1) The ARNP is prepared and qualified to assume primary responsibility and accountability for the care of patients. (2) ARNP practice is grounded in nursing process and incorporates the use of independent judgment. Practice includes collaborative interaction with other health care professionals in the assessment and management of wellness and health conditions. (3) The ARNP functions within his or her scope of practice following the standards of care defined by the applicable certifying body as defined in WAC 246-840-302.</td>
<td>02. Core Standards for All Roles of Advanced Practice Registered Nursing. The advanced practice registered nurse is a licensed independent practitioner who shall practice consistent with the definition of advanced practice registered nursing, recognized national standards and the standards set forth in these rules.</td>
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<td>05. Certified Nurse Practitioner. In addition to core standards, the advanced practice registered nurse in the role of certified nurse practitioner provides initial and ongoing comprehensive primary care services to clients including, but not limited to, diagnosis and management of acute and chronic disease, and health promotion, disease prevention, health education counseling, and identification and management of the effects of illness on clients and their families.</td>
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</tbody>
</table>

Chapter 400. DECISION-MAKING MODEL f. Performance of the act is within the accepted standard of care that would be provided in a similar situation by a reasonable and prudent nurse with similar education and experience and the nurse is prepared to accept the consequences of the act.
### Defined Clinical Guidelines

None explicitly specified

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### Nurse Practitioner Scope of Practice

**851-050-0005**

(4) Within his or her specialty, the nurse practitioner is responsible for managing health problems encountered by the client and is accountable for health outcomes. This process includes:

(i) Use of research skills;

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### Additional Education to Prescribe Drugs and Devices

**851-050-0005**

Nurse Practitioner Scope of Practice

(8) The nurse practitioner will only provide health care services within the nurse practitioner's scope of practice for which he/she is educationally prepared and for which competency has been established and maintained. Educational preparation includes academic coursework, workshops or seminars, provided both theory and clinical experience are included.

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### Patient Assessment

**851-050-0000**

Definitions

(1) “Assessment” means a process of collecting information regarding a client’s health status including, but not limited to, illness; response to illness; health risks of individuals, families and groups; resources; strengths and weaknesses, coping behaviors; and the environment. The skills employed during the assessment process may include, but are not limited to: obtaining client histories, conducting physical examinations, ordering, interpreting and conducting a broad

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WAC 246-840-300

ARNP scope of practice.

(4) An ARNP shall obtain instruction, supervision, and consultation as necessary before implementing new or unfamiliar techniques or practices.

(5) Performing within the scope of the ARNP's knowledge, experience and practice, the licensed ARNP may perform the following:

(a) Examine patients and establish diagnoses by patient history, physical examination, and other methods of assessment;

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Chapter 280. STANDARDS OF PRACTICE FOR ADVANCED PRACTICE REGISTERED NURSING

c. The advanced practice registered nurse shall evaluate and apply current evidence-based research findings relevant to the advanced nursing practice role.

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Chapter 280. STANDARDS OF PRACTICE FOR ADVANCED PRACTICE REGISTERED NURSING

a. The advanced practice registered nurse shall provide client services for which the advanced practice registered nurse is educationally prepared and for which competence has been achieved and maintained.

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Chapter 280. STANDARDS OF PRACTICE FOR ADVANCED PRACTICE REGISTERED NURSING

d. The advanced practice registered nurse shall assume responsibility and accountability for health promotion and maintenance as well as the assessment, diagnosis and management of client conditions to include the use of pharmacologic and non-pharmacologic interventions and the prescribing and dispensing of pharmacologic and non-pharmacologic agents.
851-050-0005
Nurse Practitioner Scope of Practice
(4) Within his or her specialty, the nurse practitioner is responsible for managing health problems encountered by the client and is accountable for health outcomes. This process includes:
(a) Assessment;
(g) Consultation and/or collaboration with other health care providers and community resources;
(h) Referral to other health care providers and community resources;
(7) The nurse practitioner is responsible for recognizing limits of knowledge and experience, and for resolving situations beyond his/her nurse practitioner expertise by consulting with or referring clients to other health care providers.

Referral to more appropriate health care venue

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<th>Nurse Practitioner Scope of Practice</th>
<th>851-050-0005 ARNP scope of practice. (5) Performing within the scope of the ARNP's knowledge, experience and practice, the licensed ARNP may perform the following: (g) Refer patients to other health care practitioners, services, or facilities;</th>
<th>Chapter 280. STANDARDS OF PRACTICE FOR ADVANCED PRACTICE REGISTERED NURSING b. The advanced practice registered nurse shall recognize his limits of knowledge and experience and shall consult and collaborate with and refer to other health care professionals as appropriate</th>
</tr>
</thead>
</table>

WAC 246-840-300
### Follow-up Care Plan

<table>
<thead>
<tr>
<th>Requirement to notify the primary care provider upon prescribing</th>
<th>None</th>
<th>None</th>
<th>None</th>
</tr>
</thead>
</table>

### Documentation

<table>
<thead>
<tr>
<th>Prescription record – 3 years</th>
<th>Prescription record – 2 years</th>
<th>Prescription record – 3 years</th>
</tr>
</thead>
</table>

### Discipline

<table>
<thead>
<tr>
<th>Conduct Derogatory to the Standards for Prescriptive or Dispensing Authority</th>
<th>Violations of standards of nursing conduct or practice.</th>
</tr>
</thead>
<tbody>
<tr>
<td>WAC 246-840-710 Violations of standards of nursing conduct or practice.</td>
<td>Chapter 306. DISCIPLINARY ENFORCEMENT. The Board may revoke, suspend or otherwise discipline the advanced practice registered nurse license of a licensee who fails to comply with current recognized scope and standards of practice, who fails to maintain national certification or competency requirements, or who violates the provisions of the Nursing Practice Act or rules of the Board.</td>
</tr>
<tr>
<td>Conduct Derogatory to the Standards for Prescriptive or Dispensing Authority</td>
<td>WAC 246-840-700 Standards of nursing conduct or practice.</td>
</tr>
<tr>
<td>Conduct Derogatory to the Standards for Prescriptive or Dispensing Authority</td>
<td>(2) Failure to adhere to the standards enumerated in WAC 246-840-700 which may include, but are not limited to:</td>
</tr>
<tr>
<td>(2) Failure to adhere to the standards enumerated in WAC 246-840-700 which may include, but are not limited to:</td>
<td>WAC 246-840-700 Standards of nursing conduct or practice.</td>
</tr>
<tr>
<td>(2) Failure to adhere to the standards enumerated in WAC 246-840-700 which may include, but are not limited to:</td>
<td>(1) The purpose of defining standards of nursing conduct or practice through WAC 246-840-700 and 246-840-710 is to identify responsibilities of the professional registered nurse and the licensed practical nurse in health care settings and as provided in the Nursing Practice Act, chapter 18.79 RCW.</td>
</tr>
<tr>
<td>(2) Failure to adhere to the standards enumerated in WAC 246-840-700 which may include, but are not limited to:</td>
<td>316. GROUNDS FOR DISCIPLINE OF AN ADVANCED PRACTICE REGISTERED NURSE LICENSE. In addition to the grounds set forth in Section 54-1413, Idaho Code, and Section 100 of these rules, an advanced practice registered nurse license of a licensee who fails to comply with current recognized scope and standards of practice, who fails to maintain national certification or competency requirements, or who violates the provisions of the Nursing Practice Act or rules of the Board.</td>
</tr>
</tbody>
</table>

### Nurse Practitioner Scope of Practice

(4) Within his or her specialty, the nurse practitioner is responsible for managing health problems encountered by the client and is accountable for health outcomes. This process includes:

(c) Development of a plan;

(i) Management and coordination of care;

(5) Performing within the scope of the ARNP's knowledge, experience and practice, the licensed ARNP may perform the following:

(d) Manage health care by identifying, developing, implementing, and evaluating a plan of care and treatment for patients;
(g) Prescribing, dispensing, administering, or distributing drugs in an unsafe or unlawful manner or without adequate instructions to the client according to acceptable and prevailing standards or practice;

(i) Failure to properly assess and document client assessment when prescribing, dispensing, administering, or distributing drugs;

Violation of these standards may be grounds for disciplinary action under chapter 18.130 RCW. Each individual, upon entering the practice of nursing, assumes a measure of responsibility and public trust and the corresponding obligation to adhere to the professional and ethical standards of nursing practice. The nurse shall be responsible and accountable for the quality of nursing care given to clients. This responsibility cannot be avoided by accepting the orders or directions of another person. The standards of nursing conduct or practice include, but are not limited to the following;

(2) The nursing process is defined as a systematic problem solving approach to nursing care which has the goal of facilitating an optimal level of functioning and health for the client, recognizing diversity. It consists of a series of phases: Assessment and planning, intervention and evaluation with each phase building upon the preceding phases.

nursing license may be suspended, revoked, placed upon probation, or other disciplinary sanctions imposed by the Board on the following grounds:

03. Outside Scope of Practice. Prescribing or dispensing outside the scope of the advanced practice registered nurse’s practice.

Areas of note **NOT required** for nurse practitioners in OR, WA, and ID state law:

- Mandated universal electronic medical record (EMR)
- Specified education program for each drug, drug category, or device the practitioner may prescribe
- Mandated participation in the state health data exchange
- Requirement in law to follow specified clinical guidelines (e.g. AHA/ACC, JNC 8) when prescribing each drug or device
- Requirement to notify the primary care physician when prescribing each drug or device
- Codified statewide protocols or algorithms for all practitioners to make prescribing decisions
Extraction of the Core Elements of Prescribing Standards: Considerations for Pharmacists

- Prescribing Scope of Practice
- Education
- Patient Assessment (not including diagnosis)
- Referral to more appropriate venue of care
- Follow-up Patient Care Plan
- Documentation
- Notifying providers upon prescribing
- Standard for Discipline

References:
1. Oregon Board of Nursing – Division 50 https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=16
New pharmacy board rules could provide life-saving option for Oregon diabetics

Sen. Peter Courtney, Guest Opinion Published 4:02 p.m. PT Oct. 13, 2017

If you are a diabetic, you require insulin to live. Without it, your blood sugars will go dangerously high. You will fall into a diabetic coma. You could die.

These are the terrifying facts for thousands of insulin-dependent diabetics in Oregon. Most of the time, they live regular lives like you and me. They take regular shots or use a pump to receive proper doses of insulin daily. But when something disrupts their insulin supply, it creates a life or death emergency.

In 2017, we hope diabetics who need emergency insulin can make it to a hospital for life-saving treatment, but that can be expensive. In 2012 diabetes was responsible for over 4,000 hospitalizations with an average cost of $10,000. It would be better to allow people to access insulin before turning to the emergency room – to give them other life-saving options.
Consider the recent experience one of my constituents shared with me. Her daughter is a Type 1 diabetic who was diagnosed at 18, right before leaving for college in Arizona. While she was home in Salem for a recent visit, the pump she was using to inject her insulin failed and most of the insulin was wasted.

She needed to get more insulin. It was a Thursday. Her local doctor was not available. The quickest she could get a prescription was after the weekend. The pharmacy wouldn’t provide her insulin without a prescription. The insurance company would not authorize insulin without a prescription. My constituent and her daughter were facing an expensive emergency room visit for treatment that should have been routine.

Luckily my constituent’s daughter found some insulin at the last minute. Many people aren’t that lucky.

Last session the legislature gave the Board of Pharmacy the authority through HB 2397 to write rules for emergency access to life-saving treatment without prescriptions. After hearing this story, I wrote to the board – along with Secretary of State Dennis Richardson and Senator Linthicum (both of whom are insulin dependent). We requested that they prioritize access to insulin in its rule-making process.

We are expecting emergency access to insulin to be available by July of 2018. It will give insulin-dependent diabetics peace of mind. It will save money. It will save lives.

Peter Courtney, D-Salem, is president of the Oregon Senate. Contact him at sen.petercourtney@state.or.us.
AN ACT

Relating to pharmacists; creating new provisions; amending ORS 689.645; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 689.645 is amended to read:

689.645. (1) In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may:

(a) Administer vaccines:

(A) To persons who are seven years of age or older; or

(B) If authorized by the Governor under ORS 433.441 or the Public Health Director under ORS 433.443 or 433.444, to a person three years of age or older.

(b) Pursuant to a statewide drug therapy management protocol developed by the [Oregon Health Authority] Public Health and Pharmacy Formulary Advisory Committee convened under section 2 of this 2017 Act and adopted by rule of the board, provide approved patient care services including smoking cessation therapy and travel health services.

(c) Using a form prescribed by the board, submit a concept for the development of a protocol, other than the protocols pharmacists may establish under subsection (5) of this section, to the committee for consideration by the committee and recommendation to the board for adoption by rule of the board.

(d) Prescribe and dispense a drug or device included on the formulary established under subsection (6) of this section if the prescription and dispensation is pursuant to a diagnosis by a health care practitioner who has prescriptive authority and is qualified to make the diagnosis.

(2) The board may adopt rules allowing a pharmacist to prescribe vaccines, [and] provide patient care services and submit protocol concepts under subsection (1) of this section. The rules related to the prescription of vaccines may be only as broad as necessary to enable pharmacists to enroll and participate in the Vaccines for Children Program administered by the Centers for Disease Control and Prevention.

(3) The board is authorized to issue, to licensed pharmacists who have completed training accredited by the Centers for Disease Control and Prevention, the American Council on Pharmaceutical Education or a similar health authority or professional body, certificates of special competency in the prescription and administration of vaccines.
(4) The board shall adopt rules relating to the reporting of the prescription and administration of vaccines to a patient's primary health care provider and to the Oregon Health Authority.

(5) The board shall adopt rules requiring pharmacists to establish protocols for the prescription and administration of vaccines and the provision of patient care services under subsection (1) of this section.

(6) The board shall convene a volunteer Public Health Advisory Committee consisting of no more than nine members for the purpose of advising the board in promulgating rules under this section. The committee shall consist of one representative from the Oregon Health Authority, two representatives from the Oregon Medical Board, two representatives from the Oregon State Board of Nursing and two representatives from the State Board of Pharmacy. The committee may not include more than two pharmacists other than the representatives from the State Board of Pharmacy.

(6)(a) The board shall establish by rule a formulary of drugs and devices, as recommended by the committee, that a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis.

(b) The formulary may include post-diagnostic drugs and devices such as diabetic testing supplies, emergency refills of insulin, albuterol inhalers, epinephrine autoinjectors, smoking cessation aids, discharge medications for transitions of care, rapid strep tests and spacers.

SECTION 2.

(1) The State Board of Pharmacy shall convene a Public Health and Pharmacy Formulary Advisory Committee consisting of seven members, appointed by the Governor, for the purpose of advising the board in promulgating rules under ORS 689.645. The committee shall consist of:

(a) Two physicians licensed to practice medicine under ORS 677.100 to 677.228;

(b) Two advanced practice registered nurses who have prescriptive authority and who are licensed by the Oregon State Board of Nursing; and

(c) Three pharmacists licensed by the State Board of Pharmacy, at least one of whom is employed as a community pharmacist and one of whom is employed as a health system pharmacist.

(2) The Oregon Medical Board, the Oregon State Board of Nursing and the State Board of Pharmacy may each submit to the Governor a list of up to three names of individuals to be considered for membership for each of the vacancies required to be filled by licensees of each board.

(3) The term of each member of the committee is two years. A member whose term has expired shall continue to serve until a successor is appointed. If a vacancy occurs, a person who is a representative of the same state agency as the departing member shall serve for the remainder of the term.

(4) The committee shall elect one of its members to serve as chairperson.

(5) Members of the committee are entitled to compensation and expenses as provided in ORS 292.495, to be paid by the State Board of Pharmacy.

(6) A member of the committee who fails to attend two consecutive meetings of the committee shall be removed from the committee unless the failure to attend was because of a serious health condition of the member or a family member of the member.

(7) The committee shall recommend to the State Board of Pharmacy for adoption by rule of the board a formulary of drugs and devices that a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a health care practitioner qualified to make the diagnosis. The committee shall periodically review the formulary and recommend the revisions to the board for adoption by rule.

(8) A pharmacist may request that the committee add a drug or device to the formulary by submitting to the committee a request form prescribed by the State Board of Pharmacy. The addition to the formulary of a drug or device under this subsection shall be considered a revision to the formulary that the committee may recommend to the board for adoption by rule.
SECTION 3. The name of the Public Health Advisory Committee is changed to the Public Health and Pharmacy Formulary Advisory Committee. The Public Health and Pharmacy Formulary Advisory Committee is a continuation of the Public Health Advisory Committee.

SECTION 4. (1) Sections 2 and 3 of this 2017 Act and the amendments to ORS 689.645 by section 1 of this 2017 Act become operative on January 1, 2018.

(2) The State Board of Pharmacy and the Public Health and Pharmacy Formulary Advisory Committee may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the board and the committee to exercise, on or after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the board and the committee by sections 2 and 3 of this 2017 Act and the amendments to ORS 689.645 by section 1 of this 2017 Act.

SECTION 5. This 2017 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2017 Act takes effect on its passage.
PER DIEM AND EXPENSES
The following Oregon Statutes (ORS) guide the Board’s policy for Per Diem compensation and reimbursement for expenses - ORS 292.210 - 292.250, 292.495, 689.115(4), 689.175(1), ORS, 689.645, 2017 OL Ch. 106:

292.495 Compensation and expenses of members of state boards and commissions. (1) Subject to the availability of funds therefor in the budget of the state board or commission, and except as otherwise provided by law, any member of a state board or commission, other than a member who is employed in full-time public service, who is authorized by law to receive compensation for time spent in performance of official duties, shall receive a payment of $30 for each day or portion thereof during which the member is actually engaged in the performance of official duties.

(2) Except as otherwise provided by law, all members of state boards and commissions, including those employed in full-time public service, may receive actual and necessary travel or other expenses actually incurred in the performance of their official duties within the limits provided by law or by the Oregon Department of Administrative Services under ORS 292.210 to 292.250.

(3) As used in subsection (2) of this section, “other expenses” includes expenses incurred by a member of a state board or commission in employing a substitute to perform duties, including personal, normally performed by the member which the member is unable to perform because of the performance of official duties and which by the nature of such duties cannot be delayed without risk to health or safety. No member shall be reimbursed for expenses incurred in employing a substitute in excess of $25 per day. [1969 c.314 §1; 1973 c.224 §2; 1975 c.441 §1; 1979 c.616 §1]

689.115(4) OBOP Compensation
(4) Members of the board are entitled to compensation and expenses as provided in ORS 292.495. The board may provide by rule for compensation to board members for the performance of official duties at a rate that is greater than the rate provided in ORS 292.495. [1979 c.777 §§7,8,9,11; 1987 c.108 §2; 2009 c.535 §29]

689.175 Compensation of board members (1) Each member of the State Board of Pharmacy shall receive compensation for each day on which the member is engaged in performance of the official duties of the board, and reimbursement for all expenses incurred in connection with the discharge of such official duties as provided in ORS 292.495.

2017 OL Ch. 106 – Public Health and Pharmacy Formulary Advisory Committee
(5) Members of the committee are entitled to compensation and expenses as provided in ORS 292.495, to be paid by the State Board of Pharmacy.

COMPENSATION
Board members and Public Health and Pharmacy Formulary Advisory Committee appointees authorized by ORS 292.495(1) may choose if eligible, to receive up to $100 daily allowable per diem adopted under OAR 855-010-0020 when attending a Board of Pharmacy Board or Public Health and Pharmacy Formulary Advisory Committee meeting that lasts a minimum of three hours. Travel time and preparation time for meetings will not be compensated other than when there is an allowable expense reimbursement.

For the purpose of compensation, a board member or Public Health and Pharmacy Formulary Advisory Committee appointee is considered engaged in the performance of official duties when:

- The activity furthers the Board’s mission; and
- Attending a board meeting; or
- Attending a Public Health & Pharmacy Formulary Advisory Committee meeting; or
- Engaged in an activity which is either at the request of the board chair or authorized by a vote of the board in advance of the activity.
- All per diem shall be calculated as whichever amount is the greater of:
  a) $50 after a minimum of three hours of service daily; or
  b) $100 after a minimum of six hours of service.

Note -1 : 292.495(1) does not allow a member who is employed in full-time public service to receive compensation.

Note -2 : The Board has elected to adopt a rule as 689.115(4) allows to be compensated at a rate that is greater than the $30 listed in ORS 292.495.

Board/Committee members will report meetings and activities to staff and they will process per diem assignments monthly. In the interest of efficiency and cost savings, all members have been asked to set up direct deposit for per diem.

EXPENSE REIMBURSEMENT
Expenses incurred in the course of a Board/Committee Member’s official duties will be reimbursed pursuant to ORS 292.210-292.250 and the Department of Administrative Services Fiscal Policies and Procedures identified in the Oregon Accounting Manual (OAM).

Reimbursements typically include mileage and hotel/meal reimbursement for individuals that have to travel to the Board office for Board/Committee meetings and require an overnight stay or anytime a member is required to travel to an out of state meeting to represent the Board.

Reimbursements are calculated based on the OAM allowable or actual and necessary if receipts are submitted.

Board/Committee Members are asked to submit reimbursement requests in a timely manner. Staff prepares the paperwork for signature and sends it to member’s following each meeting or official activity. All members have been asked to set up direct deposit for reimbursements to reduce the overall cost to the agency.

Hi Marc—
As you know, the FDA just issued a warning related to the negative health effects of Kratom. 
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584970.htm

CDC has written about an increase number of calls to poison control centers related to the negative health effects of Kratom. 
https://www.cdc.gov/mmwr/volumes/65/wr/mm6529a4.htm

Since dietary supplements are not regulated at the federal level, would the Oregon Board of Pharmacy consider scheduling Kratom in Oregon?

Thanks. --Katrina

Katrina Hedberg, MD, MPH
Health Officer & State Epidemiologist
OREGON HEALTH AUTHORITY
Public Health Division
desk: 971-673-1050
Katrina.hedberg@state.or.us

The following additional article came out 11/14/17:

Link:

**FDA warns on use of kratom to treat opioid addiction amid links to 36 deaths**

Fox News
Kratom is an unapproved substance touted as a treatment for depression, pain, anxiety and even opioid addiction. (iStock)

The FDA issued a public health advisory on Tuesday over the use of kratom, an unapproved botanical substance that originates from Thailand, Malaysia, Indonesia and Papua New Guinea. The warning comes amid an increase in popularity in the U.S., where kratom is touted as a treatment for pain, anxiety, depression and even as an opioid alternative.

“It’s very troubling to the FDA that patients believe they can use kratom to treat opioid withdrawal symptoms,” said FDA commissioner Scott Gottlieb, in part. “There is no reliable evidence to support the use of kratom as a treatment for opioid use disorder. Patients addicted to opioids are using kratom without dependable instructions for use and more importantly, without consultation with a licensed health care provider about the product’s dangers, potential side effects or iterations with other drugs.”
The advisory warned that kratom produced similar effects to narcotics, carrying the risk of abuse, addiction and even death. The FDA noted a 10-fold increase in calls made to U.S. poison control centers regarding kratom from 2010 to 2015, and reports of 36 deaths linked to the substance.

**'NUTRIBULLET’ USERS CLAIM DEVICES 'BURST’ CAUSING BURNS, LACERATIONS**

“There have been reports of kratom being laced with other opioids like hydrocodone. The use of kratom is also associated with serious side effects like seizures, liver damage and withdrawal symptoms,” Gottlieb said.

Additionally, the FDA said it has identified kratom products on two import alerts, and is working to prevent shipments of the substance from entering the U.S., as well as detained hundreds of shipments at international mail facilities.

“We’ve learned a tragic lesson from the opioid crisis: that we must pay early attention to the potential for new products to cause addiction and we must take strong, decisive measures to intervene,” Gottlieb said. “From the outset, the FDA must use its authority to protect the public from addictive substances like kratom, both as part of our commitment to stemming the opioid epidemic and preventing another from taking hold.”
The U.S. Food and Drug Administration is actively working with drug manufacturers to address critical shortages of IV fluids aggravated by Hurricane Maria’s impact on Puerto Rican drug manufacturing facilities.

Because the hurricane disrupted Baxter International’s IV fluid production facilities in Puerto Rico, FDA has not objected to the temporary import from Baxter facilities in Ireland, Australia, Mexico and Canada and from B. Braun in Germany. B. Braun recently announced they were slowing production. It is important to note that when FDA exercises regulatory discretion with respect to importation of a medically necessary drug from another country, the agency evaluates the foreign firms and drug products to ensure they are of adequate quality and do not pose undo risks to patients. A letter from the company explaining that the drug is being imported to address a shortage is posted on the FDA Drug Shortages webpage and accompanies the drug when it is shipped.

In addition to the temporary imports, FDA continues to expedite review of drug applications that may help relieve shortages. The agency recently approved Fresenius Kabi and Laboratorios Grifols saline products and anticipates that availability of these products will help address the shortage.

Although Hurricane Maria affected Baxter’s facilities in Puerto Rico, there have been limited supplies of IV fluids since 2014. Since that time, the approved manufacturers Pfizer/Hospira and now ICU Medical, Baxter and B. Braun, have worked with FDA to meet steadily increasing demand for IV fluids.

Since 2014, FDA has encouraged the firms with FDA-approved saline products to add capacity to meet increased U.S. demand and has searched for additional manufacturers to help prevent future shortages. The agency anticipates this situation will improve over time and will continue to address this shortage.

For more information, please visit: IV Fluid Shortages.

This is an automated message delivery system. Replying to this message will not reach DDI staff. If you have comments or questions, please contact us at: 1-888-INFO FDA (1-888-463-6332) or (301) 796-3400 from 8:00 am - 4:30 pm ET
Monday - Friday. You can also email us at druginfo@fda.hhs.gov.

- For additional drug information, please visit the DDI Web page.
- For up-to-date drug information, follow the FDA’s Division of Drug Information on Twitter: FDA_Drug_Info.
- This service is provided to you at no charge by the U.S. Food & Drug Administration (FDA).