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

WEDNESDAY, APRIL 5, 2017

I. 11:00 AM OPEN SESSION, Kate James, R.Ph, Presiding
   A. Roll Call
   B. Agenda Review and Approval  Action Necessary

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. Warning Notices
      4. Case Review
   B. Employee Performance Review pursuant to ORS 192.660(2)(i).

IV. OPEN SESSION - PUBLIC MAY ATTEND - At the conclusion of Executive Session, the Board may convene Open Session to begin the scheduled agenda for April 6, 2017.

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 - February 7, 2017 - April 4, 2017
4. Extension Requests – none
5. Board Minutes – January 9, 2017 and February 8-9, 2017

Adjourn

THURSDAY, APRIL 6, 2017

8:30AM
VI. OPEN SESSION, Kate James, R.Ph, Presiding

A. Roll Call
B. Agenda Review and Approval Action Necessary
C. Motions for Contested Cases & Disciplinary Action Action Necessary

9:00 AM
VII. GENERAL ADMINISTRATION

1. Rules
   1. Review Rulemaking Hearing Report & Comments – MacLean #A
      Action Necessary
   2. Consider Adoption of Temporary Rules - none
   3. Consider Rules and send Rulemaking Hearing
      • Div 010 – Criminal Background Checks - MacLean #A1
        Action Necessary
      • Div 041 – Auto Refill – Karbowicz #A2
        Action Necessary
      • Div 065 - Wholesaler reporting requirement – Watt/Karbowicz #A3
        Action Necessary
   4. Consider Adoption of Rules - none
   5. Policy Issues for Discussion – Karbowicz/Efremoff/MacLean
      • TCVP Rule Change Request #A4
        Action Necessary

2. Discussion Items
   1. Waiver Requests – none
   2. Tri-County Opioid Trends – Watt #B-B1
   3. Open Forum procedural discussion – James/Watt #B2
      Action Necessary
   4. Board meeting start time discussion – Watt

11:00 Appearance – Christopher Hamilton, PhD, MPA,
Monitoring Programs Director, Reliant Behavioral Health
Health Professional Services Program update - (1 hour)

Noon – Lunch break

Resume outstanding Discussion items or Issues and Activities depending on when we break.

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

B. Board Member/Staff Presentations – James
- Pharmacy Coalition – 3/14/17, 4/11/17
- Professional Practice Roundtable – 3/9/17
- Health System Outreach Meeting – none
- Health Futures – Eugene – 2/17/17 - Karbowicz/Efremoff
- Douglas Co. Pain Summit, Roseburg - 3/21/17 –Karbowicz
- Southern OR CCO’s Naloxone & Drug Take Back Outreach:
  i. to Grants Pass, Medford - March 21-22, 2017 - Karbowicz
  ii. to Gold Beach and Coos Bay - April 11-12, 2017) - Karbowicz
- Marion Polk Yamhill Pharmacy Association – Law Update 4/6/17 - Karbowicz
- PRN Annual Conference –Law Update/Naloxone – April 8, 2017- Fox/Gin/Murch
- OSPA Procrastrinators Seminar – April 15, 2017 – Wells/Efremoff
- Linn Benton Pharmacy Association – Law Update 4/19/17 - Karbowicz

C. Committees/Meetings
1. OSPA Lane Co. Mid-Winter Mtg. 2/18-19/2017, Eugene, OR–Wells/Efremoff/Fox/Baldwin
   - NABP – Resolutions & Task Force Volunteers #D-CONFIDENTIAL & D2
   - Executive Committee Candidates for Consideration #D1
4. APhA Institute on Alcoholism and Drug Dependencies 6/1-4/2017, Salt Lake City, UT - Murch

D. Board Meeting Dates
- June 7-8, 2017 Portland
- August 9-11, 2017* Portland (*3 day meeting)
- October 11-12, 2017 Portland
- November 8-9, 2017 Silverton (Strategic Planning)
- December 13-14, 2017 Portland
- 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
- December 12-13, 2018 Portland

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

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

F. Financial/Budget Report – Watt/MacLean #E-E2

G. Legislative update – Watt #F-F1
   - Bill tracking
   - SB 50 Pain Management CE

H. Strategic Planning – MacLean
   - Facilitator for 2017

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

Adjourn
To: Board Members

From: Karen MacLean

Date: March 29, 2017

Subject: Hearing Officer’s Report for Proposed Rules in Divisions 043 and 110.

General Background:
A public hearing was held at the Portland State Office Building, located at 800 NE Oregon St. Conference Room 1E Portland, OR 97232 on March 7, 2017.

Summary of Comments:
The Board received comments as follows:

- One written comment related to the proposed rules from a pharmacist about a concern with a practitioner drug outlet. One written comment from a Board in support of the current proposed rules and three comments, plus two supplemental comments after the hearing on 3/7/17. All written comments are attached to this report.

Div 043 – Dispensing Practitioner Drug Outlets; and
Div 110 - Fees

Pharmacist - comment
We received an e-mail about a provider dispensing issue re: an unlabeled bottle of tablets that a patient brought in to the hospital upon admission for dispensing. This was for a cancer related drug. After contacting the practitioner's office to confirm the indicated use, were told by the Oral Medication Coordinator, a CPhT, that they “don’t have to follow Board of Pharmacy rules” for dispensing. The hospital is concerned about the safety of this situation and provided pictures of what they received.

Nurses - comment
We received an e-mail from the Oregon Board of Nursing’s Executive Director Ruby Jason, indicating that she could not attend, but they were fine with the proposed rule changes. They also had previously supported the proposed rules in November 2016.

Dentists - comment/testimony
Board of Dentistry, Executive Director Stephen Prisby provided written comments and oral testimony. The Dental Board requests the Board to consider incorporating additional language to better reflect the skills and professional judgement that licensed Oregon Dentists and Hygienists have obtained through their education, training and work experience. They suggest more clarification and that specific dental therapy not be itemized in the proposed rules, offering suggestions for OAR 855-043-0505 and OAR 855-043-0515 2(E)(iii).
Physicians/Physician Assistants – comment/testimony
Danielle Sobel, Associate Director of Health Policy for Oregon Medical Association, provided written comment and oral testimony at the hearing. The OMA acknowledged the changes and appreciates the clarification of traditional vs non-traditional dispensing, however they have two concerns, continued or loss of access in rural areas and the fiscal impact. Her testimony, which was clarified later in the day with additional written comment, focused on access for the underserved and the Medical Board’s (OMB) statutory authority in ORS 677.515, relating to how the OMB regulates individual practitioner dispensing and how it does differ by licensee and geographic area. They also believe the fiscal is wrong, citing to input from a member in a specialty clinic who provides oral oncologic drugs to their patients, who would need to hire additional staff ($200,000 annually) to meet the Boards dispensing requirements. They also cited to a 2014 survey of clinics that dispense fertility drugs that have similar cost concerns and availability to drug product at retail pharmacies. Overall, they believe the proposed rules are duplicative of existing rules the OMB has in place, they do not know of any complications or patient safety issues and are confident in the OMB’s oversight. They also do not see a need for an outlet registration fee.

Nicole Krishnaswami, Operations and Policy Analyst for The Oregon Medical Board, provided written comment and oral testimony at the hearing. She commented that the OMB believes the rules are headed in the right direction and submitted concerns about OAR 855-043-0505, the and OAR 855-043-0515(1)-(2), Notice of Proposed Rulemaking Hearing and Statement of Need and Fiscal Impact references to a healthcare practitioner vs a facility. They request language be edited to focus on the facility.

They highlighted discrepancies in the dates associated with the fee and renewal in OAR 855-043-0510(8) and 855-110-0007, these were acknowledged as typos. They raised concerns about the impact of the registration and annual renewal fees on healthcare practices and Oregon patients, particularly those in rural or underserved communities. They are concerned that providers may discontinue dispensing due to the additional fees. They request the Board engage with the Office of Rural Health, the Oregon Primary Care Association and other stakeholders and associations to determine the impact the fee may have on small businesses that provide healthcare to these communities.

Nicole later submitted clarification regarding ORS 677.515(4) and the OMB’s statutory direction about not limiting the privilege of administering, dispensing and prescribing to population groups federally designated as underserved, or to geographic areas of the state…

Based on the input received for Division 043 DPDO rules, staff will recommend further revisions for the Board to consider at the June 2017 Board meeting after additional research can be completed.

A copy of the written comment is included as part of the permanent rulemaking record.
From: Joseph G. Schnabel [mailto:Joseph.Schnabel@salemhealth.org]
Sent: Wednesday, March 1, 2017 8:59 AM
To: Pharmacy Board <Pharmacy.Board@obop.net>
Subject: Provider Dispensing Issue

Hello –

We received an unlabeled bottle of tablets from a patient who was admitted to the Hospital on 02/27/2017. We were asked to dispense them as a “patient’s own medication”. Without any labeling, we contacted the provider’s office for additional information. Our pharmacist was given the lot # and Expiration date from the source container, positively identified the tablets from MicroMedex as ruxolitinib (Jakafi®) 5 mg, and labeled them for inpatient use. The CPhT (“Oral Medication Coordinator”) at the provider’s office (there is no pharmacy there) indicated that they “don’t have to follow Board of Pharmacy rules” for dispensing. We are concerned about the safety of this situation.

Images below include: the container given to us by the patient; a close-up of the tablets; the clarifying FAX from the CPhT; a Xerox of the source container; and the MicroMedex ID.

I would be happy to provide additional information.

Thanks! Joe

Joe Schnabel, Pharm.D., BCPS
Director of Pharmacy

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Karen:
We are fine with these changes, I will be out of town on the 7th of March but Sarah Wickenhagen may attend but we believe that the changes are fine.

Ruby R. Jason, MSN, RN, NEA-BC  
Executive Director  
Oregon State Board of Nursing  
17938 SW Upper Boone’s Ferry Rd  
Portland, Oregon 97224-7012  
Phone: 971-673-0639  
Fax: 971-673-0681  
Executive Assistant: Peggy Lightfoot  
Phone: 971-673-0638

Notice to All Stakeholders of the following Health Boards and Associations, please forward this to all of your Licensees or Interested Parties, thank you.

- Stakeholders included the Oregon Medical Board, Oregon State Board of Nursing, Oregon Board of Pharmacy, Oregon Dental Board, Oregon Veterinary Board, Oregon Board of Naturopathic Medicine, Oregon Optometry Board, Oregon Medical Association, Oregon Nurses Association, Oregon State Pharmacy Association, Oregon Dental Association, Oregon Veterinary Medical Association, Oregon Association of Naturopathic Physicians, Oregon Optometric Physicians Association, and the Drug Enforcement
The Board of Pharmacy has worked with your State Board and many of the Associations to craft the attached rules. The attachments will be made available on the Board’s website: http://www.oregon.gov/pharmacy/Pages/index.aspx

Background for practitioners:

- These rules are intended to describe the Board’s registration and compliance expectations for a practitioner who has been granted dispensing privileges from their licensing board and engages in drug dispensing from their practice location. A practitioner who engages in dispensing certain FDA-approved human prescription drug therapies greater than a 72 hours supply or any medication refill must register their dispensing site as a drug outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).
- These rules incorporate all elements negotiated with members from the state’s practitioner boards and associations to address the 2013 AAG opinion related the Oregon Board of Pharmacy’s oversight of drug distribution in the State.
- Stakeholders included the Oregon Medical Board, Oregon State Board of Nursing, Oregon Board of Pharmacy, Oregon Dental Board, Oregon Veterinary Board, Oregon Board of Naturopathic Medicine, Oregon Optometry Board, Oregon Medical Association, Oregon Nurses Association, Oregon State Pharmacy Association, Oregon Dental Association, Oregon Veterinary Medical Association, Oregon Association of Naturopathic Physicians, Oregon Optometric Physicians Association, and the Drug Enforcement Agency (DEA).
- The Board plans a “soft-launch” of enforcement of these rules and, as always, plans to approach regulation per its “Compliance through Education” axiom.
- This is the second rulemaking hearing on this subject. Changes from the November 2016 rulemaking hearing are highlighted in yellow on the attached proposed rule, including language that has been removed or replaced in the interest of transparency.
  - Changes include:
    - Clarification of intent.
    - Exemption of homeopathic products, natural thyroid supplements and veterinary only drugs.
    - Removal of the unique identifier requirement.
    - Edits to recordkeeping requirements.
    - Incorporation of fee in OAR 855 Division 110.

The Board will conduct a Rulemaking Hearing on the attached rules, **March 7, 2017 at 9:30am** pursuant to the notice to that is also attached. To submit public comment in writing by mail or via email to:
Karen MacLean Rules Coordinator
Oregon Board of Pharmacy
800 NE Oregon St., Suite 800
Portland, OR 97232

Email at: karen.s.maclean@state.or.us

The deadline to receive written comment is: March 7, 2017 at 4:30PM
On behalf of the Oregon Board of Dentistry, I want to thank you for this opportunity to testify regarding the Pharmacy Board’s proposed rules regarding Dispensing Practitioner Drug Outlets. The Oregon Board of Dentistry enjoys a good relationship with your Board's Executive Director, Mr. Watt and other members of the Pharmacy Board’s staff.

The Oregon Board of Dentistry reviewed your proposed rules at its Board meeting on February 24, 2017. Our Board would like the Pharmacy Board to consider incorporating additional language into your new rules, to better reflect the skills and professional judgement that licensed Oregon Dentists and Hygienists have obtained through their education, training and work experience.

The rules proposed appear to give practitioners some latitude as written, which the Board supports. However, the Board noted that dispensing fluoride gel, or Peridex rinse might not necessarily be defined as a full course of therapy, per your proposed rule language. In addition, prescribing and dispensing teeth whitening gels, might not be addressed in the proposed rule language as well as other commonly used dental therapies.

The Board of Dentistry would prefer more clarity and that specific dental therapies not be itemized in the proposed rules, as this could be problematic to keep up to date with appropriate prescribing and dispensing practices, which change over time.

The Board of Dentistry suggests that sentences like the following could be incorporated into the rules in the appropriate places:

**OAR 855-043-0505**
whom dispenses non-opioid medications relating to the practice of dentistry...

**OAR 855-043-0515 2(E)(iii)**
Dispensing non-opioid medications relating to the practice of dentistry.

I am happy to work with Mr. Watt and the Pharmacy Board to help refine and develop language that will support the intended outcomes of these new proposed rules.

Thank you for your time and for letting the Board of Dentistry share this with you. Please let me know if you have any questions.
March 7, 2017

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

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

Dear Ms. MacLean,

The Oregon Medical Association (OMA) appreciates the opportunity to comment on the changes to the proposed rules that create Dispensing Practitioner Drug Outlets (DPDO). While we do appreciate the removal of traditional v. non-traditional dispensing for the purposes of clarity of regulation, we still have concerns with the rules as written. The OMA respectfully submits the following comments on the proposed rules.

**Patient access to needed medications.**

We know, based on a membership survey conducted in 2014, dispensing by a physician is seen as a benefit by patients, as it saves them time, gives them faster access to needed prescriptions, lowers out-of-pocket costs and increases medication adherence. This is especially true for medical practices whose nearest pharmacy may be more than 60 miles away. Without any exemption or acknowledgement of the burden these rules could place on rural clinics or clinics in underserved areas (OMB rules distinguish between general and underserved dispensing), rural patients could lose access to needed medications that are for longer than a 72-hour period or that need regular refills, because their practices would give up dispensing altogether (49.1% of those members surveyed in 2014 indicated they would cease dispensing at their clinic due to regulatory increases and fee increases). Many clinics operate on a tight budgets and an added regulatory program, even if the direct fee cost is minimal but requires monitoring and FTE time to administer, will be viewed as too great a financial burden to maintain. In short, the OMA supports patient access to needed medications and the ability to directly access medication from the doctor's office directly translates to better health and increased productivity (less time away from work to pick up medications, etc.).
Fiscal Impact
According to Oregon Medical Board (OMB) data, approximately 1,500 physicians and physician assistants currently have the ability to dispense prescriptions in their clinical setting. A loss of any one of these dispensing physicians could have a negative or fiscal impact on the public and/or their small business (as physicians often own and/or oversee clinics). We know firsthand that for one of our member’s clinics, the cost to maintain their dispensary under these rules, would require additional FTE time and cost the clinic (and their patients and insurers) over $200,000 annually. Whether the physician elects to eliminate dispensing or pay the fee and task a staff member with compliance, the impact on the public (aka, their patients) is not minimal or none. Consequently, we urge the Board of Pharmacy to reconsider its fiscal statement and engage with organizations who can speak for small businesses that provide health care.

Finally, we remain unclear about the Board of Pharmacy’s rationale for the need to regulate physician dispensing, without evidence of “legitimate concerns,” or threats to patient safety. The OMB has not encountered any additional complaints about a practitioner’s dispensing practices and, in the event of a complaint, would investigate and appropriately sanction any offending providers. We are confident in their ability to ensure the public’s safety through the careful oversight of their licensees without a need to duplicate the oversight of the provider.

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

Sincerely,

Mark Bonanno, JD, MPH
General Counsel and
Vice President of Health Policy

Danielle Sobel, MPH
Associate Director of Health Policy
MEMORANDUM

To: The Oregon Board of Pharmacy

From: Danielle Sobel, MPH Associate Director of Health Policy
        Mark Bonanno, JD, MPH, General Counsel and Vice President of Health Policy

Date: March 7, 2017

Re: Addendum to OMA comments on the proposed rulemaking on Division 043, Dispensing Practitioner Drug Outlets

Ms. MacLean,

In follow up to our testimony at the rules hearing this morning on Division 043, the OMA would like to clarify our reference to general v. underserved dispensing privileges for physician assistants defined by the Oregon Medical Board. OAR 847-050-0041 (statutory authority is ORS 677.515) further defines how the OMB regulates individual practitioner dispensing and how it does differ by licensee and geographic area. The careful regulation and oversight by the OMB has kept patient's safe and ensured their licensees are both prescribing and dispensing appropriately, without complaint.

We would like to further clarify the reference to the high cost of maintaining existing practitioner dispensing under the proposed rules. As a specialty clinic who provides oral oncologic drugs to their patients onsite through their physicians, their estimate of the “cost” of these proposed regulations was based on the loss of revenue this would be for the clinic if they didn’t dispense. The actual cost to the clinic to provide these cancer drugs onsite is expensive (over $200,000 annually), however, they balance this cost with the benefits it brings their patients (including direct patient interaction with the physician, whether at the time of dispensing or when they come back in to the dispensary) and the minimal revenue it generates for the clinic. This particular clinic is the only remaining independent oncology practice in Oregon, however, it’s analysis of the rules is not unique—we know from our 2014 survey that clinics who dispense fertility drugs (which often aren’t carried in local/chain pharmacies and are higher cost) shared similar predictions if regulations and fees increased on practitioners. Additionally, the proposed rules reference individual practitioners and not the facility at which practitioners practice, which is an additional reason why the rules could be financially and administratively burdensome.

Thank you for the opportunity to clarify our testimony and we are happy to be a contributing resource on these rules as they continue to move through your Board processes.
March 2, 2017

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


Dear Karen,

Thank you for the opportunity to provide comments on the proposed new OARs 855-043-0505 through 855-043-0560 and the proposed amendment to OAR 855-110-0007. The Oregon Medical Board believes the drafting process for these rules is heading in the right direction and submits the following comments for the Board of Pharmacy’s consideration.

The Medical Board shares the goal of ensuring safety in medication dispensing practices. To that end, the Medical Board supports the proposed new rules OAR 855-043-0520 through 855-043-0560, which provide guidelines for healthcare facilities on policies and procedures, security, drug acquisition, drug storage, prescription labeling, dispensing and drug delivery, drug disposal, record keeping, and inspections.

The Medical Board remains concerned, however, that the proposed rules regulate licensed healthcare providers. These rules place new registration and compliance requirements on the healthcare providers themselves rather than the facilities where the dispensing occurs, see 2013 DOJ Opinion OP-2013-1.

1. **OAR 855-043-0505** as proposed regulates the healthcare practitioner. The Medical Board requests that this language be amended to regulate the **facility**.

2. **OAR 855-043-0515(1)-(2)** as proposed regulates the healthcare practitioner. The Medical Board requests that this language be amended to regulate the **facility**.

3. **Notice of Proposed Rulemaking Hearing** states that the rules are intended to set forth registration and compliance expectations for healthcare **practitioners**. (See Rule Summary, paragraph 4.) The Medical Board requests that this language be changed to clarify that these rules will regulate **facilities**.
4. **Statement of Need and Fiscal Impact** again provides the intention to set forth registration and compliance expectations for healthcare practitioners. (See Need for the Rules, paragraph 3.) The Medical Board requests that this language be changed to clarify that these rules will regulate *facilities*.

5. **Staff Summary** again states that the practitioners are regulated by these rules. (See paragraph 1.) The Medical Board requests that this language be changed to clarify that these rules regulate *facilities*.

As currently written, the annual registration renewal requirements are unclear.

1. **OAR 847-043-0510(8)** describes a renewal fee “referred to in section (5).” However, the renewal fee is actually described in section (7). It appears this may be a simple typo.

2. **OAR 847-110-0007** provides a March 31 expiration date and requires fee payment by February 28. However, OAR 847-043-0510(8) states that DPDO registration expires December 31 and the renewal fee must be paid by November 30. The Medical Board requests clarification on the registration expiration date and payment deadline.

Finally, the registration and annual renewal fees raise concern about the impact this may have on healthcare practices and Oregon patients, particularly those in rural or underserved communities.

1. **Fiscal Impact on the Public** is described in the Statement of Need and Fiscal Impact as having no negative or fiscal impact on the public. However, physicians and physician assistants who include dispensing as part of their medical practice are often more than 60 miles away from the nearest pharmacy. If these healthcare providers were to no longer include dispensing in their medical practice due to these additional fees, the patients they serve will be negatively and fiscally impacted.

2. **Fiscal Impact on Small Businesses** in the Statement of Need and Fiscal Impact is described as not expected to affect a high number of practitioner facilities. However, the Medical Board provided data in November 2016 that approximately 1500 physicians and physician assistants are registered as dispensing providers with the Medical Board. The Medical Board requests that the Board of Pharmacy engage the Office of Rural Health, the Oregon Primary Care Association, and other stakeholders and associations to determine the impact these fees may have on the small businesses that provide healthcare to these communities.

The Medical Board thanks the Board of Pharmacy for considering these comments and looks forward to contributing to the continued improvement of these rules.

Sincerely,

Nicole Krishnaswami
Operations & Policy Analyst
March 7, 2017

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


Dear Karen,

It was a pleasure to testify at the Board of Pharmacy’s rulemaking hearing this morning. Ms. Heather Anderson, public member, requested information on the term “rural or underserved area.” I am happy to provide the following statutory information.

ORS 677.515(4) states in part:
“The [medical] board may not limit the privilege of administering, dispensing and prescribing to population groups federally designated as underserved, or to geographic areas of the state that are federally designated health professional shortage areas, federally designated medically underserved areas or areas designated as medically disadvantaged and in need of primary health care providers by the Director of the Oregon Health Authority or the Office of Rural Health.”

The Medical Board does not place additional regulatory barriers on dispensing in these areas. Instead, physicians and physician assistants register with the Board as dispensing providers; the Board then grants those providers dispensing privileges if qualified and in good standing with the Board. If concerns were to arise based on a licensee’s dispensing practices, the Board would investigate as required by Oregon law and would discipline when appropriate.

Thank you for requesting this additional information.

Sincerely,

Nicole Krishnaswami
Operations & Policy Analyst
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.

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 Board considers the following criminal conduct grounds for presumptive disciplinary action:

(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.

Stat. Auth.: ORS 676.303, 689.205 181A.195
Stats. Implemented: 181A.170, 181A.195, 181A.215, 676.175, 676.303

855-010-0110

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.

Stat. Auth.: ORS 676.303, 689.205, 181A.195
Stats. Implemented: ORS 181A.170, 181A.195, 181A.215 and 676.303

855-010-0120

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
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 offense;
(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

(c) 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

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

Criminal Records Check Process

(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.

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

855-010-0067

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.

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

855-010-0070

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.
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.

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
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 amendments to Div 041 Prescription Refills update rules related to the auto-refilling of prescriptions by pharmacy outlets. Auto-refill programs are allowed under the conditions outlined by the rule.

The Oregon Board plans to make these rules effective on July 1, 2017 and plans a 12-month delay in enforcement to allow time for pharmacy systems to comply.

855-041-1120 Prescription Refills

(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient’s agent. A request specific to each prescription medication is required, unless the requested fill or refill is part of an auto-refill program and is a continuation of therapy.

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

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

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

(c) The pharmacy must discontinue auto-refill program enrollment at the when requested of by the patient or patient’s agent; and

(7) An automated reminder cannot be used to generate a prescription refill unless the patient or patient’s agent provides authorization for each individual prescription refill. The content of each reminder must include:

(a) Drug name and strength; and

(b) Date of last fill.

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

(e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription medication is removed from the auto-refill program for that patient.
Minimum Requirements for Reporting, Record Keeping and Inventory Management

(1) A Wholesale distributor must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records must comply with all federal drug laws and regulations unless exempted.

(2) Inventories and records required by this rule must be made available for inspection and copying by any authorized official of the Drug Enforcement Agency, the Food and Drug Administration, the Department of Agriculture, law enforcement agencies, and this Board.

(3) Inventories and records required under these rules must be maintained for a minimum of three years following disposition of the drugs.

(4) Records described in this section that are less than 13 months old must be kept at the inspection site or be immediately retrievable by computer or other electronic means, and must be immediately available for inspection. All other records required by this rule must be made available for inspection within three business days of a request.

(5) A wholesale distributor must establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping and distribution of drugs, including policies and procedures for identifying, recording, and reporting any loss, theft, counterfeiting or diversion of any drug and for correcting all errors and inaccuracies in inventories. A wholesale distributor must include in its written policies and procedures the following:

(a) A procedure whereby the oldest approved stock of a drug is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling a recall or withdrawal of a drug. Such procedure must be adequate to deal with a recall or withdrawal due to:

(A) Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board;

(B) Any voluntary action by the manufacturer to remove a defective or potentially defective drug from the market; or

(C) Any action undertaken to promote public health and safety by replacing an existing drug with an improved product or new package design.

(c) A procedure to prepare for, protect against, and handle any crisis that affects the security or operation of the facility in the event of strike, fire, flood, or other natural disaster, or other local, state, or national emergencies.

(d) A procedure to ensure that any outdated drug is segregated from other drugs and either returned to the manufacturer or destroyed. This procedure must provide for written
documentation of the disposition of an outdated drug. This documentation must be maintained for three years after disposition of the outdated drug.

(e) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

(f) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband drugs and reporting of discrepancies within three business days to the Board and any other appropriate state or federal agency.

(g) Reporting of criminal or suspected criminal activities involving the inventory of drugs to the Board within three business days.

(h) Conducting for cause authentication as required under section (7) of this rule.

(i) Procedures for accurately documenting the temperature and humidity conditions of the storage facility.

(6) A wholesale distributor must maintain and adhere to written policies and procedures for all incoming and outgoing product shipments, including but not limited to the following:

(a) Upon receipt, visual examination of each shipping container sufficient to identify the drugs in the container and to determine whether the drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution.

(b) Upon receipt, review of records for accuracy and completeness, considering the:

(A) Total facts and circumstances surrounding each transaction involving the drugs; and

(B) Wholesale distributors involved.

(c) Quarantine of a drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution until:

(A) Examination and a determination is made that the drug is fit for distribution; or

(B) The drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired.

(d) If the wholesale distributor identifies a suspect product, the wholesale distributor must quarantine the product and promptly conduct an investigation to determine whether the suspect product is illegitimate. If it is determined to be an illegitimate product the wholesale distributor must provide notice to the Board, the Food and Drug Administration, and the trading partners involved in the transaction, within 24 hours.

(e) If the immediate or sealed outer or secondary container or labeling of a drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale distributor must:
(A) Quarantine the drug until the drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired; and

(B) Provide notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the Board, the Food and Drug Administration, and the manufacturer or wholesale distributor from which the drug was acquired, within 24 hours.

(f) A drug that is not adulterated, misbranded, counterfeit, or suspected counterfeit, but has been opened or used, is identified as such and quarantined until the drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired.

(g) A drug that will be returned to a manufacturer or wholesale distributor is stored, handled and transported under proper conditions before the return, and documentation showing that proper conditions were maintained must be provided to the manufacturer or wholesale distributor to which the drug is returned.

(h) Inspection of each outgoing shipment to verify the identity of each drug and to ensure that each drug has not been damaged in storage or held under improper conditions.

(i) Contraband, counterfeit, or suspected counterfeit drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the Board or the Food and Drug Administration.

(j) Any sealed outer or secondary shipping container or labeling, and accompanying documentation, for a drug that is suspected to be counterfeit or fraudulent, is retained until a disposition is authorized by the Board and the Food and Drug Administration.

(k) Operations comply with all state and federal laws, rules and regulations applicable to wholesale drug distribution.

(l) All confidential information is stored in an area with restricted access and in such a way as to protect the integrity and confidentiality of the information.

(7) A wholesale distributor must maintain pedigree records for a minimum of three years.

(8) If the wholesale distributor is involved in the distribution of controlled substances, the distributor must register with the Drug Enforcement Administration and the Board, and comply with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances including, but not limited to, the isolation of controlled substances from non-controlled substances and storage of the controlled substances in a secure area in accordance with Drug Enforcement Administration security requirements and standards.

(9) A wholesale distributor must notify the Board in writing of suspicious orders upon discovery. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
BACKGROUND – DEA LAW:

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

SECURITY REQUIREMENTS

§1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
FOR IMMEDIATE RELEASE

Contact: DEA Public Affairs

(202) 307-7977

Press Release

MCKESSON AGREES TO PAY RECORD $150 MILLION SETTLEMENT FOR FAILURE TO REPORT SUSPICIOUS ORDERS OF PHARMACEUTICAL DRUGS

JAN 17 - (Washington, DC) – McKesson Corporation (McKesson), one of the nation’s largest distributors of pharmaceutical drugs, agreed to pay a record $150 million civil penalty for alleged violations of the Controlled Substances Act (CSA), the U.S. Drug Enforcement Administration (DEA) announced today.

The nationwide settlement requires McKesson to suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan and Florida for multiple years. The staged suspensions are among the most severe sanctions ever agreed to by a DEA-registered distributor. The settlement also imposes new and enhanced compliance obligations on McKesson’s distribution system.

In 2008, McKesson agreed to a $13.25 million civil penalty and administrative agreement for similar violations. In this case, the government alleged again that McKesson failed to design and implement an effective system to detect and report “suspicious orders” for controlled substances distributed to its independent and small chain pharmacy customers—i.e. orders that are unusual in their frequency, size, or other patterns. From 2008 until 2013, McKesson supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills, frequently misused products that are part of the current opioid epidemic.

The government’s investigation developed evidence that even after designing a compliance program after the 2008 settlement, McKesson did not fully implement or adhere to its own program. In Colorado, for example,
McKesson processed more than 1.6 million orders for controlled substances from June 2008 through May 2013, but reported just 16 orders as suspicious, all connected to one instance related to a recently terminated customer.

“This groundbreaking resolution is tough and appropriate and underscores our commitment to hold accountable all DEA registrants, including those who distribute controlled substances,” said DEA Acting Administrator Chuck Rosenberg. “DEA is committed to fighting the opioid epidemic with all of the tools at our disposal.”

In addition to the monetary penalties and suspensions, the government and McKesson agreed to enhanced compliance terms for the next five years. Among other things, McKesson has agreed to specific, rigorous staffing and organizational improvements; periodic auditing; and stipulated financial penalties for failing to adhere to the compliance terms. Critically, the settlement will require McKesson to engage an independent monitor to assess compliance – the first independent monitor of its kind in a CSA civil penalty settlement.

This was a multi-district investigation that involved the following DEA Field Divisions: Boston Field Division, Chicago Field Division, Denver Field Division, Detroit Field Division, Miami Field Division, New Jersey Field Division, San Francisco Field Division, St. Louis Field Division, and Washington Division Office. The following U.S. Attorneys’ Offices participated in the case: Central District of California, Eastern District of California, District of Colorado, Middle District of Florida, Eastern District of Kentucky, Northern District of Illinois, District of Massachusetts, Eastern District of Michigan, District of Nebraska, District of New Jersey, Northern District of West Virginia, and Western District of Wisconsin.

U.S. Attorneys’ Offices for the District of Colorado and the Northern District of West Virginia, along with DEA’s Office of Chief Counsel and its Diversion Control Division, led the civil settlement negotiations. DEA’s Denver, Detroit and Miami Field Divisions and its Washington Division Office led the administrative and civil investigation. The U.S. Department of Justice Criminal Division’s Narcotic and Dangerous Drug Section (NDDS) also coordinated and assisted in negotiating certain portions of the settlement. Assistant United States Attorneys Amanda Rocque (Colorado) and Alan McGonigal (NDIW) represented the United States in the civil penalty investigations and negotiations. Associate Chief Counsel Lee Reeves and Senior Attorneys Dedra Curteman, Dana Hill and Krista Tongring represented DEA in the investigations and negotiations. Trial Attorneys Harry Matz and Kirtland Marsh were involved for NDDS.

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Date: 3.10.2017

Request/Inquiry Type: Request for rule changes, related to TCVP

Question: Is the Board willing to make edits to the Technician Checking Validation Program at this time?

Background: On behalf of Asante Rogue Regional Medical Center as well as the OSHP Legal and Regulatory Committee and Joint Legislative Committee Matthew White, RPH has submitted a request for expanding the TCVP regulations.

Decision/Response:
Suggestion #1: Reduce the number of doses required for initial validation process.

“Currently, rural hospitals have a hard time meeting the requirement of 1,500 doses for initial validation of unit of use checking. I would therefore propose that we make the number 500 doses, matching the number of line-items required for ADC checking, due to the idea that a single unit-of-use item used in cart fill takes the same skill to check as a line item in ADC checking (ie. 500 individual items require the same skill as 500 line items, the only difference being that the quantity on cart fill is 1 (daily), 2 (BID), etc.”

• These rules were intended to be utilized by specific sites, where volume (based on size) warrants the use of TCVP.
• Another way to look at this, is when a hospital is TOO SMALL, would the TCVP regulations really have a measurable impact to “free up the RPHs”?
• OBOP Staff recommends no change in the 1500 doses required for initial validation.

Suggestion #2: Add technician checking of patient specific unit dose packs that are not part of ADC restocking to list of eligible specialized functions.

“Additionally, larger hospitals with ADCs, who do not perform cart fill, do not have the opportunity to check batches of unit-of-use medications via cart fill, and therefore are unable to certify technicians to check individual line items that are not included in ADCs. This creates a missed opportunity of reducing distractions for central pharmacy pharmacists who interrupt their concentration to check these single line items. I would therefore propose that we add language to the ADC and non-emergent trays and kits portion of the TCVP rules that allows for technicians to check these individual unit dose items, which are not included in the ADCs and dispensed throughout the day.”

Proposed language for OAR 855-041-5160:

   Eligible Specialized Functions
(1) The following specialized functions are eligible for participation in the TCVP:
   (a) Cart fill;
   (b) ADC batch replacement; and
   (c) Patient specific unit dose packs not part of ADC restocking; and
   (d) Non-Emergent kits and trays.

• This would mean NO Pharmacist final verification of patient-specific prescriptions.
• Rules do not allow an intern or technician to perform final verification (see OAR 855-019-0200).
• OBOP Staff recommends retaining the requirement for pharmacist final verification of patient specific medications.
Suggestion #3: Remove requirement for QA checks to be random and unannounced.

“I do not believe that it would reduce the efficacy of QA checks if the technicians know when they are scheduled, but would make the TCVP program much easier to administer, therefore, I propose that we eliminate the requirement of unannounced QA checks.”

- OBOP Compliance philosophy is that pharmacy processes are ongoing and performing random auditing of those processes provides the best insight in to the actual realities occurring.
- OBOP Staff recommends retaining current language for OAR 855-041-5140(2)(b) (see line 39).

Contact:
Matthew M. White, PharmD, MHA
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Related ORS/OARs:

Technician Checking Validation Program (TCVP)

NOTE: The TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients. The development of individualized training programs is the responsibility of each pharmacy in order to tailor the program to the patient population and medication distribution system of the institution. Assessment questions must be tailored to the site and be changed periodically as appropriate. It is the responsibility of the pharmacist-in-charge to ensure that all training is completed and documented prior to a technician performing as a technician checker.

855-041-5100

Definitions
(1) “Error” in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item counts as one error.
(2) “Error” in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date. All errors in any single dose count as one error.
(3) “Line Item” is a checking unit for ADC restocking (example: one specific drug and dose, regardless of quantity).
(4) “Technician Checker” is an Oregon certified technician who has completed the TCVP validation process and is currently authorized to check another technician’s work.
(5) “Technician Checking Validation Program (TCVP)” is a program that uses a technician checker to check functions completed by another technician.
(6) “Unit Dose” is the physical quantity of a drug product designed to be administered to a patient specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged, oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed IV products.
Hospital and Pharmacist in Charge Requirements

(1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital pharmacy must meet the following requirements:
(a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be available in the pharmacy for board inspectors.
(b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can be implemented;
(c) The hospital pharmacy must have a drug distribution system that is structured to allow for one additional check of the distributed medications by a licensed nurse or other licensed health care professional with authority to administer medications after the delivery of checked medications; and
(d) The Pharmacist-in-Charge is responsible for the TCVP and will document any error, or irregularity in the quality assurance documentation records.

(2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of Pharmacy. To apply for approval, the hospital must submit the following to the Board:
(a) Copies of written training material that will be used to train technicians as technician checkers;
(b) Copies of quality assurance documentation records and forms that will be used to evaluate the technician checkers and the proposed TCVP;
(c) Copies of the policy and procedures for the proposed TCVP; and
(d) A description of how the proposed TVCP will improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.
(e) Other items as requested by the Board.

Technician Eligibility and Training

(1) Only Oregon certified technicians who undergo specific training may work as technician checkers. The training must include the following:
(a) A minimum of one year of drug distribution experience;
(b) Didactic lecture or equivalent training with a self-learning packet;
(c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a pharmacist; and
(d) Initial Validation Process as described in OAR 855-041-5140(1).

(2) The practical training sessions must include:
(a) The trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning;
(b) The trainee performing the initial check with a pharmacist verifying all doses;
(c) The trainee completing the validation process with a pharmacist verifying all doses;
(d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors. Artificial errors introduced into the live environment, which are not corrected by the technician, must be removed.
(e) The pharmacist must document and notify a technician checker of any errors found during training.

(3) If at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.
Initial Validation Process and Quality Assurance Process

(1) Initial Validation Process: The initial process to validate a trainee’s ability to accurately check another technician’s work must include:

(a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who makes more than three errors in 1500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.

(A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.

(B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.

(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.

(b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.

(A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.

(B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.

(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.

(2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of technician checkers must include:

(a) Quality checks conducted in the same manner as the applicable initial validation process described in section one of this rule, except that the quality check sample must consist of at least 300 doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.

(b) The quality checks must occur on random and unannounced dates and times.

(c) A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.

(d) The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.

(3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks
must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.

(4) A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.

(5) A description of the quality assurance process must be included in the hospital’s and the pharmacy’s quality assurance program and error reporting system.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5150

Checking Procedure

(1) A technician checker must use the following procedure when checking another technician’s work:
(a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits.
(b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.
(c) If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction. A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker.
(d) If a technician checker is not available, then all doses must be checked by a pharmacist.

(2) This checking process continues until all doses have been checked and determined to be correct.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5160

Eligible Specialized Functions

(1) The following specialized functions are eligible for participation in the TCVP:
(a) Cart fill;
(b) ADC batch replacement; and
(c) Non-Emergent kits and trays.

(2) Upon written request, the Board may permit additional specialized functions if to do so will further public health or safety. A waiver granted under this section shall be effective only when issued in writing and approved by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5170

Records

(1) Unless specified otherwise, all records and documentation required by these rules must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:
(a) Technician checker training documents;
(b) List of high risk medications;
(c) Documentation of any errors, irregularities and results of each initial validation check.
(d) Documentation of quality assurance and forms used to evaluate the technician checker including:
(A) Total number of doses or line item checks;
(B) Description of errors;
(C) Total number of errors; and
(D) Percent error rate.
(e) Documentation of the initial validation check.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-019-0200
General Responsibilities of a Pharmacist
ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A pharmacist licensed to practice pharmacy by the Board has the duty to use that degree of care, skill, diligence and professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances.
(1) A pharmacist while on duty must ensure that the pharmacy complies with all state and federal laws and rules governing the practice of pharmacy.
(2) Only a pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require the professional judgment of a pharmacist include but are not limited to:
(a) Drug Utilization Review;
(b) Counseling;
(c) Drug Regimen Review;
(d) Medication Therapy Management;
(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement;
(f) Practice pursuant to State Drug Therapy Management Protocols;
(g) Ordering, interpreting and monitoring of a laboratory test;
(h) Oral receipt or transfer of a prescription; and
(i) Final verification of the work performed by those under their supervision.
(3) A pharmacist may not delegate any task listed in OAR 855-019-0200(2), except that a pharmacist may permit an intern to perform the duties of a pharmacist under their direction and supervision, after the intern has successfully completed his or her first academic year, and only after successful completion of coursework corresponding to those duties.
(4) An intern cannot perform final verification.
(5) A pharmacist who is supervising an intern is responsible for the actions of that intern; however, this does not absolve the intern from responsibility for their own actions.
(6) A pharmacist on duty is responsible for supervising all pharmacy personnel, and ensuring that pharmacy personnel only work within the scope of duties allowed by the Board.
(7) A pharmacist may not permit non-pharmacist personnel to perform any duty they are not licensed and trained to perform.
(8) A pharmacist while on duty is responsible for the security of the pharmacy area including:
(a) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;
(b) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;
(c) Ensuring that only a pharmacist has access to the pharmacy when the pharmacy is closed.
Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.025, 689.151, 689.155
Oregon Board of Pharmacy,

In 2012, the Oregon Board of Pharmacy adopted OAR 855-041-5100 to 855-041-5170 ‘Technician Checking Validation Program (TCVP)’. The program has been overwhelmingly successful at meeting the mission allowing “the re-direction of a pharmacist from a distributive task to a cognitive task... and allowing a pharmacist to improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.”

While the program has been highly impactful, there are a few areas that can be improved upon to make the program (1) more accessible to rural, smaller hospitals that use cart fill, and (2) to make it feasible for larger hospitals with Automatic dispensing cabinets (ADC) to have technicians check single unit doses that are not included in the ADCs.

Currently, rural hospitals have a hard time meeting the requirement of 1,500 doses for initial validation of unit of use checking. I would therefore propose that we make the number 500 doses, matching the number of line-items required for ADC checking, due to the idea that a single unit-of-use item used in cart fill takes the same skill to check as a line item in ADC checking (ie. 500 individual items requires the same skill as 500 line items, the only difference being that the quantity on cart fill is 1 (daily), 2 (BID), etc.).

Additionally, larger hospitals with ADCs, who do not perform cart fill, do not have the opportunity to check batches of unit-of-use medications via cart fill, and therefore are unable to certify technicians to check individual line items that are not included in ADCs. This creates a missed opportunity of reducing distractions for central pharmacy pharmacists who interrupt their concentration to check these single line items. I would therefore propose that we add language to the ADC and non-emergent trays and kits portion of the TCVP rules that allows for technicians to check these individual unit dose items, which are not included in the ADCs and dispensed throughout the day.

Lastly, I do not believe that it would reduce the efficacy of QA checks if the technicians know when they are scheduled, but would make the TCVP program much easier to administer, therefore, I propose that we eliminate the requirement of unannounced QA checks.

Please see the proposed revisions to OAR 855-041-5140 ‘Initial Validation Process and Quality Assurance Process’ that meets the two objectives of improving access to the TCVP program for all hospitals, and subsequently improve patient safety.

Sincerely,

Matthew M. White, PharmD, MHA
matthew.white@asante.org | (541)829-9936
Initial Validation Process and Quality Assurance Process

(1) Initial Validation Process: The initial process to validate a trainee’s ability to accurately check another technician’s work must include:

(a) Unit of Use (Cart Fill): For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 500 total doses, divided among five separate training checks. A trainee who makes more than one error in 500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.

(A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.

(B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.

(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.

(b) ADC, non-emergent trays and kits, and patient specific unit dose packs not part of ADC restocking: For initial validation of a trainee to fill ADC, non-emergent trays and kits, and patient specific unit dose packs not part of ADC restocking, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.

(A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.

(B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.

(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.

(2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of technician checkers must include:
(a) Quality checks conducted in the same manner as the applicable initial validation process described in section one of this rule, except that the quality check sample must consist of at least **100** doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.

(b) The quality checks must occur on random and unannounced dates and times.

(c) A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.

(d) The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.

(3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.

(4) A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.

(5) A description of the quality assurance process must be included in the hospital’s and the pharmacy’s quality assurance program and error reporting system.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5150

Checking Procedure
(1) A technician checker must use the following procedure when checking another technician’s work:
(a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits **and patient specific unit dose packs not part of ADC restocking**.
(b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits **and patient specific unit dose packs not part of ADC restocking**. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.
(c) If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check
the correction. A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker.
(d) If a technician checker is not available, then all doses must be checked by a pharmacist.
(2) This checking process continues until all doses have been checked and determined to be correct.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12

855-041-5160

Eligible Specialized Functions
(1) The following specialized functions are eligible for participation in the TCVP:
(a) Cart fill;
(b) ADC batch replacement
(c) Patient specific unit dose packs not part of ADC restocking; and
(d) Non-Emergent kits and trays.
(2) Upon written request, the Board may permit additional specialized functions if to do so will further public health or safety. A waiver granted under this section shall be effective only when issued in writing and approved by the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155
Hist.: BP 1-2012, f. 4-26-12, cert. ef. 5-1-12
Executive Summary
“20.8 million people in the United States have a substance use disorder (not limited to opioids), equivalent to the number of Americans with diabetes.¹

We have to help the country see that addiction is a chronic disease like diabetes or heart disease. If we help people see that it will make it easier for folks to come forward. It will make it easier for communities to support treatment programs in their neighborhoods.”

--Dr. Vivek Murthy, United States Surgeon General

Staff from the public health departments of Clackamas, Multnomah, and Washington counties produced the content of this special report in collaboration with the Oregon Public Health Division of the Oregon Health Authority and Health Share of Oregon.

Contact:
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Multnomah County Health Department
Tri-County Opioid Safety Coalition
christine.e.sorvari@multco.us
503-.988.8692

Executive Summary

The purpose of the 2016 Tri-County Region Opioid Trends report is to provide the public, community advocates, physical and behavioral health providers, and policy makers with accurate quantitative data about a pervasive problem. The report is organized in five chapters: fatal overdoses, 9-1-1 overdose responses (non-fatal overdoses), opioid prescribing trends, syringe exchange trends and client survey, and substance use treatment. This document presents the key points from each chapter of the report alongside considerations for future policy. More analysis, data gaps, and analytic challenges are discussed in the full report.

While deaths have diminished since the peak in 2011, we are disappointed to report there has been little decrease in fatal overdoses in the Tri-County region over the last three years. Although half of all opioid deaths are caused by prescription pain pills, legal opioid prescribing remains persistently high; more than one in five people in the region receives an opioid prescription every year. Although our efforts at harm reduction through syringe exchange prevent the spread of HIV and hepatitis C, the high demand for syringes suggests that injection drug use may be increasing. Finally, we are deeply concerned that many of those suffering from addiction want treatment to reach long-term recovery but do not receive it.

Fatal Overdose

Both Oregon Medical Examiner records and National Vital Statistics analysis show that total opioid deaths in the Tri-County peaked in 2011 but remain stubbornly elevated. In 2015, prescription opioids and heroin killed similar numbers of people in our region but, in contrast to national trends, heroin deaths here have not increased. Deaths from pain pills remain persistently elevated.

---

Across the Tri-County region in 2015 there were:

- 159 fatal opioid overdoses; two thirds occurred in Multnomah County.
- Deaths occur at younger ages among males than females in all three counties.
- Deaths from heroin occur at younger ages than from prescription opioids in all three counties.
- Over 90% of opioid deaths occurred among those of white race.

### 9-1-1 Overdose Responses (Non-Fatal Overdose)

Naloxone is the antidote for opioid overdose and can prevent death if given early after respiratory depression begins. One measure of the frequency of non-fatal opioid overdose is how often paramedics successfully use naloxone to revive patients. From 2014 to 2015, we noted a substantial decline in such ambulance naloxone responses. The decreased need for naloxone after 9-1-1 response may reflect either fewer overdoses or more frequent bystander administration of naloxone.

American Medical Response ambulances provided service in Clackamas and Multnomah Counties; in 2015:

- There were over 600 overdose responses in Clackamas and Multnomah counties, with 88% of these occurring in Multnomah.
- In Multnomah County, over half of responses occurred in public places or businesses; most of the remainder occurred in private residences.
- In Clackamas County, two thirds overdose responses were to private residences.
- Data were available for Washington County but were not comparable to Clackamas and Multnomah because there is a different ambulance company operating in that county.
Overdose Policy Considerations

This report illustrates that opioid deaths in the region have declined from a peak in 2011-2012, but that progress in preventing fatal overdose has slowed. While we are pleased to report a trend toward slightly fewer EMS responses to opioid overdose, our optimism is tempered because more widespread use of naloxone by the public may cause EMS records to underestimate the true number.

Decreasing the number of opioid users, providing better treatment for chronic pain, and providing more high quality addiction treatment will be needed to turn the tide on overdose fatalities. In the short run, better data and increased access to the antidote naloxone can prevent fatal overdose among opioid users. To do so, policy makers may wish to consider:

- Changing naloxone to over-the-counter status because it is not a drug of abuse.
- Adopting lessons learned from State and National evaluations of successful naloxone programs.
- Promoting state, local, and health-insurer policies that include naloxone prescription coverage for members, and encourage community pharmacies to stock naloxone.
- Providing incentives and support for law enforcement and other community first responders to understand, carry, and use naloxone.
- Linking naloxone administration to recovery treatment.
- Developing media campaigns for the public to learn about fatal overdose prevention with naloxone.
- Facilitating bulk purchasing of naloxone to decrease cost.
- Disseminating regular, detailed reporting of fatal and non-fatal overdoses by county.

Opioid Prescribing

Prescription opioids can be used appropriately for pain, misused by the intended patient, misused by others, or diverted for illegal sale. Excessive prescribing is likely to be an important driver of the opioid epidemic in Oregon for several reasons.

*Excludes tramadol which was added to PDMP in mid 2014.
First, the higher rates of opioid prescribing are tightly correlated with fatal overdose and substance use treatment admissions. Second, in national polls, 75% of current heroin users report first becoming addicted to prescription pain pills; a 2016 survey at our regional syringe exchanges found more than 50% of heroin users reported getting hooked on pain pills before switching to heroin. Finally, compared with other states, Oregon has consistently high rates of opioid prescribing, especially for long-acting versions of these drugs.

Analysis of de-identified data from the Oregon Prescription Drug Monitoring Program (PDMP) showed that:

- There has been little decrease in the number of total opioid prescriptions and total opioid prescription recipients from 2012 through 2015.
- In each county, more than 20 of every 100 residents received an opioid prescription in 2015.
- While Clackamas County has the highest prescribing rate in the region, residents of all three counties frequently receive opioids.
- In 2015, retail pharmacies dispensed over 1.4 million opioid prescriptions to residents of the region which has a total population of approximately 1.7 million.
- The rate of prescribing increases steeply after age 15 and is highest in those ages 65-74.
- The overall rate of prescribing is higher in Clackamas County and higher in younger age groups compared with Multnomah and Washington counties.
- Females are prescribed opioids at a higher rate than males in all three counties.

**Prescribing Policy Considerations**

Although the misuse of prescription opioids has been widely publicized, this new analysis shows that through the end of 2015, the medical community in our region continues to dispense opioids at a high rate. In 2015, doctors, nurses, physician assistants, naturopaths, and dentists wrote nearly as many as many opioid prescriptions as there are people alive in the region. While there are many appropriate uses of opioids, our region’s volume of prescribing per capita is beyond many other states and far in excess of the rate of prescribing in other countries. Policy options for addressing excess prescribing include:

- Encouraging Oregon licensing boards to include PDMP registration as part of licensure.
- Enhancing Oregon’s PDMP to provide alerts to practitioners for possible unsafe prescribing.
- Allowing the PDMP program to partner with licensing boards to provide education to providers prescribing outside of the state-adopted CDC guidelines.
- Partnering of Oregon with neighboring states to provide cross border sharing of prescribing information.
- Developing metrics with insurers and health systems to monitor prescribing patterns.
- Enhancing links from the PDMP to electronic medical records to increase safety and decrease burden on providers.
- Providing incentives for free drug disposal to decrease the quantity of unused opioid pills
- Evaluating safe prescribing programs from other states.
Syringe Exchange

Syringe exchange is one part of a comprehensive public health approach to prevent the spread of HIV/AIDS, hepatitis C, and other blood-borne pathogens among injection drug users. Because most syringe exchange clients report using heroin, the clients of these programs can provide insight into the population suffering from opioid addiction and the need for substance use disorder treatment.

The syringe exchange programs run by Outside In and Multnomah County report:

- More than 3 million syringes exchanged in 2015, a 59% increase since 2012.
- More than 6,000 unique clients served in 2015; 70% were male, 78% white non-Hispanic race.
- 63% of first time clients in 2016 reported injecting heroin as the primary drug.
- Methamphetamine use among syringe exchange clients has increased from 38% in 2010 to 83% in 2016.
- In 2015, 40% of syringe exchange clients were homeless; an additional 27% reported an unstable housing situation.
- Among heroin users, 51% reported first being hooked on prescription pain pills.
- More than half of heroin users surveyed wanted to quit or cut down but report many barriers to treatment.

Substance Use Disorder Treatment

Comprehensive substance use disorder data are not available for the Tri-County region. In light of this limitation, Health Share of Oregon (Health Share), the state’s largest Coordinated Care Organization serving 220,000 low income members, provided information as a proxy for the Tri-County; the Tri-County region also has Medicaid members served by FamilyCare. Analysis of Health Share of Oregon data shows:

![Syringes Exchanged, Visits, and Unique Clients](chart)

**Syringes Exchanged, Visits, and Unique Clients**

- **Syringes distributed x 1 million**
- **Total visits x 10,000**
- **Total unique clients x 1000**

**Multnomah County and Outside In**

- **2012**
- **2013**
- **2014**
- **2015**

- **Number**
- **2012**
- **2013**
- **2014**
- **2015**

- **Syringes distributed x 1 million**
- **Total visits x 10,000**
- **Total unique clients x 1000**
Opioid use disorder accounted for approximately 40% of all substance use disorder claims (other substance use disorders include alcohol, amphetamines, cocaine, marijuana, etc.).

In 2015, nearly 5,000 Health Share members had a primary opioid substance use disorder claim.

Comparison between the three metro area counties suggests possible gaps in the continuum of care, especially in Clackamas and Washington counties.

### Opioid Substance Use Treatment Policy Considerations

Physical dependence and addiction to opioids is difficult to accurately measure. Our partnership Health Share provides some insight from medical claims into the magnitude of the problem, the services currently provided, and the characteristics of those in treatment. These data also suggest that there are geographic gaps in the availability of recovery services even in the most populated region in the state. This analysis also finds that among Medicaid clients, opioid drugs are the most frequent reason for substance use disorder treatment in our region. Between analysis of Health Share claims data and responses to the survey conducted at syringe exchange sites, we worry that treatment is not uniformly accessible and many receive no treatment at all in a given year. Despite the limitations of our methods, our local observations are broadly consistent with recent findings from the 2013 National Survey on Drug Use and Health that found that more than 75% of those with prescription opioid use disorders received no treatment in the previous year.³

Policy options to consider include:

- Updating and sharing a regional inventory of substance use disorder treatment options.
- Identifying gaps in substance use disorder treatment capacity.
- Eliminating or decreasing barriers to accessing opioid use disorder treatment.
- Requiring payers to use consistent criteria for level of addiction treatment.
- Eliminating payer policies that require clients to ‘fail first’ at one treatment before having access to other options.
- Requiring all payers and providers to support medication assisted opioid addiction treatments.
- Providing incentives for prompt treatment after overdose reversal by naloxone.
- Convening health care payers and treatment providers to collaborate on quality, metrics, and reimbursement for addiction treatment.
- Providing incentives for primary care office-based opioid use disorder treatment.

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For Board Consideration –

Board Counsel suggests establishing a more limited approach to Open Forum. This would include announcing the guidelines during the opening speech of each meeting such as:

*OPEN FORUM note (to be added to the opening speech)* - At the completion of regular Board business, the Board provides an opportunity to make comments or present issues of general interest during Open Forum. The Board will not deliberate any issues or requests during this time. 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.

Here is an example of the sign-up sheet specifically for Open Forum. When it’s time, the Board President will review the list and call those with applicable Open Forum topics.

**PHARMACY BOARD MEETING**  
**OPEN FORUM**  
**SIGN UP SHEET**  
**THURSDAY, DATE**

*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.*

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Similar language will be edited onto the Agenda for public notice if this is approved.

For discussion.
Let's make it an informational mailer,

Marcus Watt, R.Ph.
Executive Director
Oregon Board of Pharmacy
Marcus.Watt@state.or.us
971-673-0001 fax 971-673-0002

From: Penny Reher [mailto:PennyR@samhealth.org]
Sent: Thursday, March 23, 2017 8:56 AM
To: Marcus Watt <Marcus.Watt@obop.net>; Kate James - Email <kate@broadwayapothecary.com>
Subject: FW: Mar. 23: Former Compounding Pharmacy Owner Acquitted Of Murder, Convicted On Racketeering Charges

Is the lead article worthy of an update for the pharmacy board members in the mailings?
Thanks,
Penny

From: ASHP Daily Briefing [mailto:ashp_daily_briefing@ashp.custombriefings.com]
Sent: Thursday, March 23, 2017 6:07 AM
To: Penny Reher
Subject: Mar. 23: Former Compounding Pharmacy Owner Acquitted Of Murder, Convicted On Racketeering Charges

WARNING: This email originated from outside of SHS. DO NOT CLICK ANY LINKS OR OPEN ATTACHMENTS unless you recognize the sender and know the contents are safe.

Please add ashp_daily_briefing@ashp.bulletinhealthcare.com to your address book

Good morning Penny Reher

Leading the News

Former Compounding Pharmacy Owner Acquitted Of Murder, Convicted On Racketeering Charges.
The CBS Evening News (3/22, story 11, 0:30, Pelley) reported, "In Boston a pharmacist blamed for a deadly meningitis outbreak beat a murder charge today." The outbreak was "traced to fungus in drugs mixed in filthy conditions by the New England compounding pharmacy which Cadden owned."

The New York Times (3/22, A10, Bidgood, Subscription Publication) reports that former New England Compounding Center owner Barry Cadden "was convicted Wednesday of racketeering charges but acquitted of 25 counts of second-degree murder" stemming from a "meningitis outbreak in 2012 that killed more than 60 people and sickened 700 others."

USA Today (3/22, MacDonald, Bacon) reports that some of the counts Cadden was convicted on "could bring a maximum sentence of 20 years." Sentencing "was set for June 21."

The Wall Street Journal (3/22, Loftus, Subscription Publication) reports that while awaiting sentencing, Cadden has been released to home confinement, according to his attorney.

The Boston Globe (3/22, Valencia, Lazar) reports that the trial "lasted more than nine weeks, and featured more than 60 witnesses." According to the Globe, "a majority of jurors sided with prosecutors and voted to find Cadden responsible for 23 out of the 25 deaths authorities linked to the tainted drugs, but the jury could not reach the necessary unanimity to rule him responsible."

According to a separate Boston Globe (3/22, Lazar) piece, "to family members whose relatives died from tainted drugs or to people left with unremitting pain," the March 22 verdict convicting Cadden "of racketeering and mail fraud was small comfort. Barry Cadden, they said, should have been convicted of murder."

Fierce Pharma (3/22, Palmer) reports that the outbreak "shined a spotlight on the rapid growth of the drug compounding industry" and "led to the passage of the Drug Quality and Security Act, which gives the FDA new, but limited, powers to oversee compounding pharmacies that volunteer to be regulated."

Also covering the story are the AP (3/22, Lavoie), Reuters (3/22, Raymond), CNN (3/22, Johnston, Boyette), the NPR (3/22, Wamsley) "The Two-Way" blog, the CBS News (3/22) website, and the Boston Herald (3/22, Graham).

From ASHP

ASHP To Host Twitter Chat on Residency Education

Join us next Tuesday, March 28, at 6 p.m. ET for a live Twitter chat on residency education. Moderated by Nadia Awad, Emergency Medicine Pharmacist at the Robert Wood Johnson University Hospital in New Brunswick, N.J., the chat will look at the state of pharmacy residency education — where it is now and where it is headed. To jump-start your thinking, view AJHP’s special theme issue on innovations in residency education.

Medication Use

Pregabalin May Be No Better Than Placebo For Relieving The Leg Pain Associated With Sciatica, Study Suggests.

In "To Your Health," the Washington Post (3/22, Naqvi) reports that research suggests pregabalin, which is "frequently prescribed for pain, is no more effective than a placebo at controlling sciatica." The findings were published in the New England Journal of Medicine.

Reuters (3/22, Emery) reports that "volunteers tested after eight weeks of therapy and again at the 52-week mark were just as likely to report improvement whether they received" pregabalin or a placebo.

Additionally, MedPage Today (3/22, Fiore) reports, "there were...significantly more adverse events" among those who received pregabalin. HealthDay (3/22, Norton) also covers the story.

Quality and Safety
Mylan Announces Precautionary Recall Of 81,000 EpiPens Outside US.

Reuters (3/22, Grover) reports Mylan NV said it had recalled 81,000 of its EpiPens outside the US after two reports of incidents in which the allergy shot device failed to work. According to Reuters, the recalls applied to Australia, New Zealand, Europe, and Japan, and Mylan said it is working with regulators in those places, "where appropriate."

CBS News (3/22, Sherter) reports Mylan said that for some EpiPens, "a defective part could cause them to malfunction," according to the article. Mylan’s Australian subsidiary AlphaPharm “said it was recalling the product, which was made by Meridian Medical Technologies in St. Louis, Missouri, as a precautionary measure.” STAT (3/21) also reported on the recall.

Regulatory

GAO To Investigate Possible Orphan Drug Program Abuses.

In its "Fortune Brainstorm Health Daily" briefing, Fortune (3/22, Mukherjee) continues coverage of reports the GAO agreed to officially investigate possible abuse of the FDA’s orphan drug designation. Fortune cites “a growing chorus of complaints that some pharma companies are gaming the system to rake in profits.” Fierce Pharma (3/22, Sagonowsky) reports similarly.

Appeals Court Revives Alendronate Claims Against Merck.

Reuters (3/22, Stempel) reports that on Wednesday, a federal appeals court revived claims accusing Merck of failing to provide an adequate warning about the risks of thigh bone fractures from osteoporosis drug Fosamax (alendronate). The Philadelphia court enabled plaintiffs to proceed with the trial, while Merck said that a judge should decide the pre-emption question. Merck also said it remains “confident” in the safety and effectiveness of the drug.

Sanders, Cummings Seek Pricing Info On PTC Therapeutics’ Deflazacort.

Reuters (3/22) reports Sen. Bernie Sanders (I-VT) and Rep. Elijah Cummings (D-MD) sent a letter Wednesday to PTC Therapeutics Inc. asking for "information about the drugmaker’s pricing strategy for its recently acquired” Duchenne muscular dystrophy drug, Emflaza (deflazacort). PTC announced last week that it intended to buy the drug from Marathon Pharmaceuticals LLC, and the company “promised to re-examine the hefty U.S. price tag for the treatment.” In their letter, Sanders and Cummings urged PTC Chief Executive Stuart Peltz "to keep the price of this relatively common steroid at its current importation cost."

Health Coverage and Access

Uncertainty Surrounds AHCA Vote Today.

The Washington Post (3/22, Somashekhar) reports the House is expected on Thursday to vote on the American Health Care Act, which “is intended to supplant the 2010 Affordable Care Act.”

CNBC (3/22, Mangan) reports the odds of getting the AHCA "passed by the House of Representatives improved late Wednesday as the White House reportedly offered to tweak the plan by getting rid of the set of minimum benefits health insurers are now required to provide customers.” A source in the House Freedom Caucus "which has been seen as the biggest remaining stumbling block for the bill, told CNBC that chances for passage of the plan during Thursday’s scheduled vote increased with the offer.”

In an interview on Fox News’ Hannity (3/22) Wednesday night, House Freedom Caucus Chairman Mark Meadows (R-NC) said, “I’m really optimistic that we can get there. There’s still a lot of details to work out, and so to say that we got a deal that wouldn’t be accurate.” He added, “The President and I came to an agreement in principle. I think what we're trying to do now is make sure that our agreement is actually something that can be executed in a way that passes the Senate. ... So there’s still work to be done."

CNN (3/23, Luhby) reports that House leadership “did not originally include” the change to the minimum benefits requirement “because doing so would likely run afoul of Senate rules governing budget reconciliation.” Members of the Freedom Caucus argue guaranteeing certain benefits has driven up the cost of insurance plans for those who do not need coverage in those areas.

The potential deal comes as a separate article in the Washington Post (3/22, Debonis, Snell, Costa) reports that the bill “suffered a significant setback Wednesday, as personal appeals by both the
president and vice president failed to sway conservatives to back the bill.” In what the Post describes as “a last-ditch effort to persuade key GOP opponents of the bill to stand down,” Pence met in his office with members of the House Freedom Caucus, while Trump met at the White House with 18 House Republicans. While Rep. Steve King left the White House meeting in favor of the bill, “that single switch was not enough to put the measure over the top.”

The New York Times (3/22, Pear, Kaplan, Subscription Publication) says the “small but potentially pivotal group of House conservatives were largely unmoved” by the appeals from Trump and Pence, and the Wall Street Journal (3/22, Peterson, Radnofsky, Subscription Publication) likewise says most members were not swayed by the meetings, which left the outcome of Thursday’s vote uncertain Wednesday night.

Prior to talk of a potential deal, the Los Angeles Times (3/22, Mascaro) reported “more than 30 GOP House members – more than enough to sink it – [are] refusing to back the proposal.”

Research

Serelaxin Fails To Meet Goals Of Late-Stage Clinical Trial.

Bloomberg News (3/22, Serafino) reports Novartis AG said in a statement Wednesday that its serelaxin compound failed to meet the goals of a late-stage clinical trial known as RELAX-AHF-2. The drug neither lowered cardiovascular deaths nor reduced worsening heart failure, and Novartis has said it will further analyze the trial results to assess the next step for development. Reuters (3/22, Revill) reports serelaxin’s failure marks the drugs “likely demise,” and analysts believe the results “will put pressure on Novartis to ramp up sales of its Entresto heart failure drug that has got off to a slow start.”

Fierce Biotech (3/22, Taylor) reports Novartis enrolled 6,600 patients with acute heart failure for the trial and then “randomized them to receive either placebo or the recombinant peptide vasodilator serelaxin.” Patients were assessed against the endpoints of “reduction in cardiovascular death over 180 days” and “occurrence of worsening heart failure over five days.” According to the article, serelaxin “failed to move the needle on either count.” Healia (3/22) also reports.

FDA Clears Akashi To Resume Clinical Development Of HT-100.

The Boston Business Journal (3/22, Stendahl, Subscription Publication) reports, “More than a year after Akashi Therapeutics was forced to halt” an early-stage trial of HT-100, a drug meant to improve muscle strength in patients with Duchenne muscular dystrophy, “following the death of one patient, the Cambridge biotech has received clearance from the FDA to launch a new study.” The company will now resume clinical develop of HT-100, and “said Wednesday that patients in the new trial would get a lower dose of the drug, and would not use anti-nausea treatments, which can sometimes hide life-threatening symptoms.”

Fierce Biotech (3/22, Adams) reports HT-100 “is being researched for its ability to reduce fibrosis (scarring) and inflammation, while also boosting healthy muscle fiber regeneration in DMD patients.”

Neurocrine Posts Full Phase 3 Valbenazine Data, Showing Positive Results.

Fierce Biotech (3/22, Taylor) reports, “Neurocrine Biosciences has published a journal paper about its phase 3 trial of tardive dyskinesia candidate Ingrezza,” which “linked 80 mg per day doses of Ingrezza (valbenazine) to statistically-significant changes over placebo in scores on the Abnormal Involuntary Movement Scale (AIMS), resulting in it hitting its primary endpoint.” The company also “reported a significant difference in the proportion of patients in the drug and placebo arms whose AIMS score improved by 50% or more over the course of the study,” while “the only adverse events to affect more than 5% of patients in the treatment arms were drowsiness and dry mouth.”

Ultragrenyx Drug To Treat Mucopolysaccharidosis Seizures Fails Mid-Stage Study.

Reuters (3/22, Mukhopadhyay) reports, “Ultragrenyx Pharmaceutical Inc said its drug to treat” seizures in patients with mucopolysaccharidosis “did not meet the main goal in a mid-stage study” after it failed to “show statistical significance in reducing the frequency of seizures among patients treated with the drug compared to a placebo.”

Wednesday’s Lead Stories

• AHCA Faces “Strong Opposition” Ahead Of Thursday Vote.
• **FDA Approves Safinamide As Add-On Treatment For Parkinson’s.**

• **Secukinumab May Modify The Course Of Psoriasis, Study Suggests.**

• **Study Ties 2011 Norepinephrine Shortage To Increased Deaths.**

• **Judge In Cadden Trial Says Verdict May Be Near.**

• **NYTimes: GOP Plan Would Insure Fewer Than Full Obamacare Repeal.**

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March 6, 2017

Dear Friends:

I am Lee Ann Bundrick. Since 2002, I have served as South Carolina's Chief Drug Inspector and Administrator of the State Board of Pharmacy. I want to fill the Open Member Position on the NABP Executive Committee representing District III. The election will take place at the Annual NABP Meeting in Orlando this May.

There are many crucial issues facing NABP and the profession of pharmacy. I have the background and experience to ensure we maintain patient safety as it relates to the profession of pharmacy. Each state has one vote. I would sincerely appreciate your state's vote at the 2017 Annual Meeting.

I joined the South Carolina Board of Pharmacy staff in December 1997. I have had experience in various roles including compliance manager and pharmacist investigator/inspector. Currently, I am responsible for all aspects of the Board to include licensing, permitting, inspections, investigations and discipline. I have actively advocated for many legislative issues through the years that include compounding, pharmacy technician ratio, immunizations and naloxone protocol. I have also worked with the HealthCare Collaborative Committee to address pertinent compliance issues and interaction between Boards, Agencies and Institutions responsible for the public’s general health. Our agency has worked directly with the Governor's Prescription Drug Abuse Prevention Council. In 2005, I was honored by our profession in South Carolina by being named Pharmacist of the Year.

I served on the District III Board of Directors in 2013 and was also on the Auditing Committee and the Resolutions Committee. Additionally, I have participated on many NABP Committees and Task Forces since 2008. I was chairperson of the Committee on Constitution and Bylaws and the Task Force on the Regulation of Telepharmacy Practice. This service has given me the opportunity to come to know and work with many of you.

If you will give me your support, I promise you my best effort and will professionally represent all states within District III, as well as working in a collaborative effort with all district representatives and the executive committee officers, to promote NABP's mission.

I sincerely ask for your support at the May NABP meeting. Thank you for your consideration and I look forward to seeing you in Orlando!

Please call me or email me if you have any questions or if you would like to share your ideas of how I could best serve as the District III member of NABP. 803-206-6132, Leeann.bundrick@llr.sc.gov

Best Regards,

Lee Ann F. Bundrick, RPh
February 23, 2017

Dear State Board Members,

My name is Reggie Dilliard and I will be a candidate for election to the District III position on the NABP Executive Committee at the Annual NABP Meeting this May in Orlando, Florida.

I was appointed to serve as the Executive Director of the Tennessee Board of Pharmacy in 2013 after serving a 6 year term as a member of the board. I served as President of that board in 2005-2006. I also was fortunate to have served 1 term as the District III representative on the Executive Committee during that time.

After a career in community pharmacy, I feel that I now have the job that my career and time as a board member have prepared me for and it has been a joy to serve in this capacity. Even though I was honored to have served on the Executive Committee, I have always felt that there was work left undone there.

As director of the Tennessee Board my passion for patient safety and regulation that promotes safe practice has been re-kindled. I see so many opportunities for boards to move forward in areas of regulation for technology and collaboration with other professional regulatory boards. We can’t continue to operate in our own silos if we want to move the regulatory processes forward efficiently. Boards also need to become more diligent in the area of opioid abuse and overdose prevention and give our licensees the tools they need to combat this epidemic. As we strive to stem the flow of drug abuse in the nation, we have to collaborate with all stakeholders to pass rules that make sense and will have impact on the problem.

These efforts may require some “out of the box” thinking as to how we move the needle to keep our rules adaptive rather than reactive and hopefully as a member of the Executive Committee, I can contribute to the process.

Please consider my candidacy for District III and if you have any questions or wish to talk to me, please do not hesitate to reach out to me between now and convention. Thank you for the opportunity and I hope you will support me in May.

With utmost respect for what you do,

Reggie Dilliard
January 20, 2017

Dear Board Members,

My name is Richard Mazzoni and I am a candidate for re-election to the District 8 position on the NABP Executive Committee. As you know, the election will be held at the Annual Meeting in Orlando this May.

I am currently a member and chairman of the New Mexico Board of Pharmacy, and have also served in the past on the California Board of Pharmacy, including one term as president of that Board.

I retired from a 25-year career at a major pharmacy company, where I was employed in Pharmacy Operations, Professional Services, Government Affairs, and finally in Regulatory Compliance. During my tenure, I had the privilege of working with many of you. I currently operate a consulting business providing regulatory guidance to select clients.

The practice of pharmacy is rapidly changing and evolving, along with our entire healthcare delivery system. Practice settings, technologies, and modalities exist today that we couldn’t even have imagined as recently as last year. Federal agencies are inserting themselves into pharmacy practice in unprecedented fashion. Boards of Pharmacy are challenged with keeping up with these changes. Regulating appropriately to protect the safety of our citizens, while not impeding genuine progress is a major current challenge. NABP serves a vital purpose in providing insight, services and coordination to the member Boards.

If re-elected, I pledged to serve NABP and your Board with energy and integrity. I respectfully ask for your vote at the upcoming Annual Meeting. Thank you for your consideration.

Warm regards,

Richard Mazzoni, R.Ph.
Oregon Board of Pharmacy performance in protecting Oregonians

OSPA and OSHP would like to take a moment to note the performance and service to its licensees over the last several years.

- The Oregon Board of Pharmacy has consistently communicated clearly with its licensees on upcoming regulatory requirements. These communications occur during the two periodic meetings with leaders of the pharmacy stakeholders that the Board has created and continued. In these roundtable meetings stakeholders can hear from the Board about current issues, and provide input regarding patient safety concerns of the profession.
- The Board has constituted various task force meetings on specific topics to gain the expertise and insight of practicing pharmacists.
- The Board has been proactive in implementing legislative changes, providing the necessary certifications, regulations and guidelines needed to safely provide for the legislative intent (Examples include recent Hormonal Contraceptive and naloxone prescribing)
- The Board has worked with legislators and the profession to draft need legislation to protect the Oregon consumer. (Examples include recent regulatory efforts for Pharmacy Benefit Managers)
- The Board is responsive to new practitioners, pharmacy interns, and pharmacy graduates in examinations and licensing requirements. New practitioners can reach the Board staff and resolve questions in an efficient manner.
- The Board maintains an informative website, where regulatory information can be readily found and current events can be communicated.
- The Board is fair and just in its discipline of licensees, and follows Oregon Administrative rules.

The professional organizations have the responsibility to advance the profession of pharmacy and improve the health of all Oregonians through effective medication use. We find a strong partner in these endeavors in the Oregon Board of Pharmacy and the Executive Director, Marcus Watt.
<table>
<thead>
<tr>
<th>Budget Object</th>
<th>Revenue &amp; Expenditures</th>
<th>LAB</th>
<th>ORBITS</th>
<th>Financial Plan</th>
<th>Adjusted Financial Plan</th>
<th>ACTUALS To Date</th>
<th>Unobligated Balance</th>
<th>% Expended</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0205</strong> Other Business Licenses</td>
<td>4,924,832</td>
<td>5,012,583</td>
<td>5,012,583</td>
<td>3,687,106</td>
<td>1,405,478</td>
<td>72%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>0210</strong> Other Nonbusiness Licenses and Fees</td>
<td>65,855</td>
<td>127,584</td>
<td>127,584</td>
<td>227,086</td>
<td>(99,502)</td>
<td>178%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>0505</strong> Fines and Forfeits</td>
<td>270,000</td>
<td>360,573</td>
<td>360,573</td>
<td>466,746</td>
<td>(106,174)</td>
<td>129%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>0605</strong> Interest and Investments</td>
<td>35,000</td>
<td>43,095</td>
<td>43,095</td>
<td>63,701</td>
<td>(20,606)</td>
<td>148%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>0975</strong> Other Revenue</td>
<td>29,700</td>
<td>37,811</td>
<td>37,811</td>
<td>49,245</td>
<td>(11,434)</td>
<td>130%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SubTotal Revenue</strong></td>
<td>5,325,387</td>
<td>5,581,646</td>
<td>0</td>
<td>5,581,646</td>
<td>4,143,833</td>
<td>1,167,762</td>
<td>79%</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL REVENUE &amp; TRANSFERS</strong></td>
<td>5,674,832</td>
<td>5,931,091</td>
<td>0</td>
<td>5,931,091</td>
<td>4,364,311</td>
<td>867,890</td>
<td>74%</td>
<td></td>
</tr>
<tr>
<td><strong>PERSONAL SERVICES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3110</strong> Regular Employees</td>
<td>2,872,872</td>
<td>2,812,213</td>
<td>142,105</td>
<td>2,954,195</td>
<td>808,233</td>
<td>74%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3160</strong> Temporary Appointments</td>
<td>24,322</td>
<td>-</td>
<td></td>
<td>24,322</td>
<td>0</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3170</strong> Overtime Payments</td>
<td>-</td>
<td>0</td>
<td>770</td>
<td>(770)</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3210</strong> All Other Differential O/Class Lead Work</td>
<td>176,911</td>
<td>209,963</td>
<td>148,830</td>
<td>209,963</td>
<td>113,333</td>
<td>71%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3220</strong> Employment Relations Board Assessment</td>
<td>880</td>
<td>885</td>
<td>95</td>
<td>885</td>
<td>90</td>
<td>79%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3221</strong> Public Employee Retirement Contrib</td>
<td>478,038</td>
<td>393,047</td>
<td>22,438</td>
<td>415,485</td>
<td>317,413</td>
<td>76%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3222</strong> Pension Bond Contribution</td>
<td>176,574</td>
<td>178,285</td>
<td>2,678</td>
<td>181,233</td>
<td>136,099</td>
<td>75%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3230</strong> Social Security Taxes</td>
<td>235,168</td>
<td>224,276</td>
<td>10,871</td>
<td>235,168</td>
<td>168,398</td>
<td>74%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3240</strong> Unemployment Assessment</td>
<td>1,380</td>
<td>1,227</td>
<td>1,227</td>
<td>930</td>
<td>297</td>
<td>76%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3250</strong> Workers' Compensation Assessments</td>
<td>18,445</td>
<td>18,133</td>
<td>853</td>
<td>18,986</td>
<td>13,895</td>
<td>73%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3260</strong> Mass Transit Tax</td>
<td>4,632,972</td>
<td>200,825</td>
<td>4,833,797</td>
<td>3,395,126</td>
<td>1,438,671</td>
<td>70%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3270</strong> Flexible Benefits</td>
<td>610,560</td>
<td>560,967</td>
<td>21,680</td>
<td>582,647</td>
<td>429,663</td>
<td>73%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3455</strong> Vacancy Savings-ORBITS only</td>
<td>0</td>
<td>-</td>
<td></td>
<td>0</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3465</strong> Reconciliation Adjustment-ORBITS only</td>
<td>0</td>
<td>-</td>
<td></td>
<td>0</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3470</strong> Undistributed Personal Services-ORBITS</td>
<td>157,704</td>
<td></td>
<td></td>
<td>204,746</td>
<td>204,746</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3991</strong> PERS Policy Adjustment-ORBITS</td>
<td>0</td>
<td>-</td>
<td></td>
<td>0</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SubTotal Personal Services</strong></td>
<td>4,595,150</td>
<td>4,632,872</td>
<td>200,825</td>
<td>4,833,797</td>
<td>3,395,126</td>
<td>1,438,671</td>
<td>70%</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL REVENUE &amp; TRANSFERS</strong></td>
<td>5,674,832</td>
<td>5,931,091</td>
<td>0</td>
<td>5,931,091</td>
<td>4,364,311</td>
<td>867,890</td>
<td>74%</td>
<td></td>
</tr>
</tbody>
</table>

### Reconciliation of Budget Plan and Actuals
- **AY15 Ending Cash Balance**: 5,094,726
- **Revenue less Expenditures**: 4,364,311
- **Total Revenues & Transfers**: 4,888,233
- **Total Revenues & Transfers less Expenditures**: 4,888,233
- **AY17 Cash Balance after the Fiscal Month Closed**: 4,606,503
- **AY17 Estimated Cash Balance**: 3,227,396
- **Cash Balance Contingency (Months)**: 11.30 months
<table>
<thead>
<tr>
<th>PERSONAL SERVICES</th>
<th>$</th>
<th>%</th>
<th>$</th>
<th>%</th>
<th>$</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Board Member Stipends</td>
<td>2,872,633</td>
<td>142,105</td>
<td>2,890,231</td>
<td>142,155</td>
<td>635,228,88</td>
<td>79%</td>
</tr>
<tr>
<td>Temporary Appointments</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Overtime Payments</td>
<td>793</td>
<td>793</td>
<td>1,700</td>
<td>1,700</td>
<td>3,500</td>
<td>78%</td>
</tr>
<tr>
<td>Other Differential O/Class Lead Work</td>
<td>176,911</td>
<td>176,911</td>
<td>176,911</td>
<td>176,911</td>
<td>32,166</td>
<td>83%</td>
</tr>
<tr>
<td>Employment Relations Board Assessment</td>
<td>883</td>
<td>883</td>
<td>1,150</td>
<td>1,150</td>
<td>2,450</td>
<td>83%</td>
</tr>
<tr>
<td>Public Employees Retirement Contrb</td>
<td>478,038</td>
<td>23,488</td>
<td>407,709</td>
<td>20,306</td>
<td>77,040</td>
<td>81%</td>
</tr>
<tr>
<td>Pension Bond Contribution</td>
<td>176,574</td>
<td>1,750</td>
<td>176,066</td>
<td>1,750</td>
<td>32,276</td>
<td>81%</td>
</tr>
<tr>
<td>Security Taxes</td>
<td>235,168</td>
<td>10,871</td>
<td>228,297</td>
<td>10,871</td>
<td>71,996</td>
<td>78%</td>
</tr>
<tr>
<td>Unemployment Assessment</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2,398</td>
<td>0%</td>
</tr>
<tr>
<td>Workers' Compensation Assessments</td>
<td>1,800</td>
<td>1,215</td>
<td>1,215</td>
<td>1,215</td>
<td>2,420</td>
<td>80%</td>
</tr>
<tr>
<td>Mass Transit Tax</td>
<td>18,445</td>
<td>853</td>
<td>18,445</td>
<td>853</td>
<td>3,881</td>
<td>79%</td>
</tr>
<tr>
<td>Flexible Benefits</td>
<td>610,560</td>
<td>21,680</td>
<td>571,804</td>
<td>21,680</td>
<td>121,240</td>
<td>79%</td>
</tr>
<tr>
<td>Pension Bond Contribution</td>
<td>176,574</td>
<td>1,878</td>
<td>176,754</td>
<td>1,878</td>
<td>32,276</td>
<td>81%</td>
</tr>
<tr>
<td>Other Flexible Benefits</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Pension Bond Contribution</td>
<td>322,148</td>
<td>47,946</td>
<td>274,202</td>
<td>47,946</td>
<td>49,236</td>
<td>39%</td>
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<tr>
<td>Professional Services</td>
<td>78,096</td>
<td>78,096</td>
<td>78,096</td>
<td>78,096</td>
<td>49,236</td>
<td>62%</td>
</tr>
<tr>
<td>Attorney General</td>
<td>314,038</td>
<td>267,602</td>
<td>314,038</td>
<td>267,602</td>
<td>44,436</td>
<td>85%</td>
</tr>
<tr>
<td>Employee Recruitment &amp; Develop</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>13</td>
<td>0%</td>
</tr>
<tr>
<td>Dues &amp; Subscriptions</td>
<td>4,419</td>
<td>4,419</td>
<td>4,419</td>
<td>4,419</td>
<td>5,056</td>
<td>113%</td>
</tr>
<tr>
<td>Facilities Rent &amp; Taxes</td>
<td>217,606</td>
<td>152,755</td>
<td>217,606</td>
<td>152,755</td>
<td>64,851</td>
<td>70%</td>
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<tr>
<td>Facilities Maintenance</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>49</td>
<td>0%</td>
</tr>
<tr>
<td>Medical Supplies and Services</td>
<td>1,070</td>
<td>1,070</td>
<td>1,070</td>
<td>1,070</td>
<td>273</td>
<td>126%</td>
</tr>
<tr>
<td>Other Special Payments</td>
<td>58,880</td>
<td>40,285</td>
<td>58,880</td>
<td>40,285</td>
<td>18,595</td>
<td>65%</td>
</tr>
<tr>
<td>Data Processing Software</td>
<td>271,077</td>
<td>271,077</td>
<td>271,077</td>
<td>271,077</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Data Processing Hardware</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Subtotal Services and Supplies</td>
<td>2,072,633</td>
<td>2,077,271</td>
<td>1,922,535</td>
<td>1,922,535</td>
<td>664,736</td>
<td>81%</td>
</tr>
</tbody>
</table>

**TOTAL REVENUE & TRANSFERS**

<table>
<thead>
<tr>
<th>$</th>
<th>$</th>
<th>$</th>
<th>$</th>
<th>$</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>4,595,150</td>
<td>4,516,774</td>
<td>208,825</td>
<td>4,727,592</td>
<td>3,561,725</td>
<td>1,155,828</td>
</tr>
</tbody>
</table>

**AY17 Estimated Cash Balance**

<table>
<thead>
<tr>
<th>$</th>
<th>$</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,243,631</td>
<td>3,243,631</td>
<td>3,243,631</td>
</tr>
</tbody>
</table>

**AY17 Estimated Cash Balance as of 1/31/16**

<table>
<thead>
<tr>
<th>$</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td>11,70</td>
<td>11,70</td>
</tr>
</tbody>
</table>
**OBOP Priority Bills**

Report Date: March 16, 2017

**Oregon Board of Pharmacy**

<table>
<thead>
<tr>
<th>Bill Name</th>
<th>Priority</th>
<th>Next Hearing</th>
</tr>
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<tbody>
<tr>
<td>HB 2044 INTRO</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>HB 2101 INTRO</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>HB 2114 INTRO</td>
<td>2</td>
<td>3:00PM 03/20/2017 House Committee Health Care Work Session HR E</td>
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<tr>
<td>HB 2116 INTRO</td>
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<td></td>
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<tr>
<td>HB 2128 INTRO</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>HB 2232 INTRO</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

**HB 2044 INTRO**

Relating to overpayments of medical assistance.

Prohibits Oregon Health Authority from recovering state's share of overpayment of medical assistance for prescription drug unless overpayment resulted from fraud.

**HB 2101 INTRO**

Relating to public records.

Sunsets certain exemptions from disclosure for public records. Requires Legislative Assembly to review exemptions prior to sunset. Requires future exemptions to sunset within six years of date of enactment.

**HB 2114 INTRO**

Relating to prescription drugs.

Prohibits issuing initial prescription for opioids or opiates to adults for outpatient use in quantity exceeding seven-day supply.

Prohibits issuing initial and refill prescription for opioids or opiates to minors for outpatient use in quantity exceeding seven-day supply.

Creates exceptions.

**HB 2116 INTRO**

Relating to reducing the high costs of pharmaceutical products.

Creates Help In Cutting Costs for Unusual Pharmaceuticals program in Oregon Health Authority to reimburse high costs incurred by persons in this state to purchase certain pharmaceutical products. Requires Department of Revenue to transfer specified amount of corporate excise taxes paid on Oregon sales of pharmaceutical products by pharmaceutical manufacturers doing business in Oregon to pay for administration of program.

**HB 2128 INTRO**

Relating to pseudoephedrine; prescribing an effective date.

Deletes requirement that pseudoephedrine be classified as Schedule III controlled substance.

Directs State Board of Pharmacy to adopt rules for dispensing pseudoephedrine. Requires rules to be consistent with provisions of federal Controlled Substances Act that are related to dispensing of pseudoephedrine and federal regulations that implement those provisions. Punishes violation of rules by five years' imprisonment, $125,000 fine, or both.

Becomes operative January 1, 2018.

Takes effect on 91st day following adjournment sine die.

**HB 2232 INTRO**

Relating to reproductive health care; declaring an emergency.

Requires health benefit plan coverage of specified health care services, drugs, devices, products and procedures related to reproductive health. Allows exemption for plans sold to religious employers.

Requires Oregon Health Authority to implement program to reimburse costs of services, drugs, devices, products and procedures related to reproductive health provided to individuals who can become pregnant and who would be eligible for medical assistance if not for certain federal requirements.

Prohibits discrimination in provision of health care coverage.

Declares emergency, effective on passage.
## OBOP Priority Bills

**Report Date:** March 16, 2017

### Oregon Board of Pharmacy

<table>
<thead>
<tr>
<th>Bill Name</th>
<th>Priority</th>
<th>Next Hearing</th>
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<tbody>
<tr>
<td><strong>HB 2386</strong></td>
<td>1</td>
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<tr>
<td>INTRO</td>
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<tr>
<td>Relating to drugs; prescribing an effective date.</td>
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<tr>
<td>Directs each manufacturer of certain types of drugs that are sold within this state to develop and implement drug take-back program for purpose of collecting from individuals and nonbusiness entities those types of drugs for disposal.</td>
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<tr>
<td>Directs State Board of Pharmacy to administer Act. Requires manufacturers subject to Act to first submit plan for developing and implementing drug take-back program on or before December 31, 2018.</td>
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<tr>
<td>Becomes operative January 1, 2018.</td>
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<tr>
<td>Takes effect on 91st day following adjournment sine die.</td>
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<tr>
<td><strong>HB 2387</strong></td>
<td>4</td>
<td>3:00PM 03/22/2017</td>
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<tr>
<td>INTRO</td>
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<td>House Committee</td>
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<td>Health Care</td>
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<td></td>
<td></td>
<td>Work Session</td>
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<td></td>
<td></td>
<td>HR 50</td>
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<tr>
<td>Relating to prescription drugs.</td>
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<tr>
<td>Requires pharmaceutical manufacturer to reimburse payers for cost of prescription drug that exceeds specified threshold. Requires pharmaceutical manufacturer to provide 60 days' advance notice of increase in cost of prescription drug that exceeds 3.4 percent over 12-month period.</td>
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<tr>
<td>Prohibits Public Employees' Benefit Board, Oregon Educators Benefit Board, health care service contractors, multiple employer welfare arrangements and carriers for small employer, group or individual health benefit plans from requiring enrollees to incur out-of-pocket costs for prescription drugs that exceed specified maximums.</td>
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<tr>
<td>Requires pharmaceutical manufacturers to report to Department of Consumer and Business Services specified information about prescription drug costs and about patient assistance programs. Authorizes civil penalties for failing to report.</td>
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<tr>
<td>Requires Public Employees' Benefit Board, Oregon Educators Benefit Board, health care service contractors, multiple employer welfare arrangements and carriers for small employer, group or individual health benefit plans to make available online specified information about prescription drug coverage and costs.</td>
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<tr>
<td>Requires Public Employees' Benefit Board, Oregon Educators Benefit Board, health care service contractors, multiple employer welfare arrangements and carriers for small employer, group or individual health benefit plans to offer at least one health benefit plan that has no deductible or coinsurance requirement for prescription drugs.</td>
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<td><strong>HB 2388</strong></td>
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<td>INTRO</td>
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<tr>
<td>Relating to pharmacy benefit managers; declaring an emergency.</td>
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<tr>
<td>Requires Department of Consumer and Business Services to deny, revoke or suspend authority of pharmacy benefit manager to conduct business in Oregon if pharmacy benefit manager fails to comply with applicable statutes, rules or orders.</td>
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<tr>
<td>Declares emergency, effective on passage.</td>
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<tr>
<td><strong>HB 2394</strong></td>
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<tr>
<td>INTRO</td>
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<tr>
<td>Relating to impaired health professionals; declaring an emergency.</td>
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<tr>
<td>Allows participating health profession licensing boards to refer to impaired health professional program for monitoring licensees who have been convicted of certain alcohol- or drug-related crimes. Includes for purposes of definition of &quot;impaired health professional&quot; physical health conditions deemed appropriate for inclusion in program by Oregon Health Authority.</td>
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<tr>
<td>Declares emergency, effective July 1, 2017.</td>
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<td>Bill Name</td>
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<td>Next Hearing</td>
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<tr>
<td>HB 2395 INTRO</td>
<td>1</td>
<td>8:00AM 03/17/2017 House Committee Health Care Work Session HR E</td>
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</tbody>
</table>

Relating to prescription labels; declaring an emergency.
Directs State Board of Pharmacy to adopt rules related to prescription drug labels.
Declares emergency, effective on passage.

<table>
<thead>
<tr>
<th>Bill Name</th>
<th>Priority</th>
<th>Next Hearing</th>
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<tbody>
<tr>
<td>HB 2397 A</td>
<td>1</td>
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</tbody>
</table>

Relating to pharmacists; declaring an emergency.
Changes name of Public Health Advisory Committee to Public Health and Pharmacy Formulary Advisory Committee.
Limits term of committee members to two years. Directs State Board of Pharmacy to establish by rule formulary of drugs and devices that pharmacists may prescribe and dispense to patients under specified conditions. Directs committee to recommend drugs and devices for inclusion on formulary.
Declares emergency, effective on passage.

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<tr>
<th>Bill Name</th>
<th>Priority</th>
<th>Next Hearing</th>
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<tbody>
<tr>
<td>HB 2517 INTRO</td>
<td>2</td>
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</table>

Relating to programs used to monitor the dispensing of prescription drugs; declaring an emergency.
Provides that Director of the Oregon Health Authority may enter into agreements governing sharing and use of information reported to prescription monitoring program with regulatory authorities of other states that administer prescription monitoring programs.
Becomes operative January 1, 2018.
Declares emergency, effective on passage.

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<tr>
<th>Bill Name</th>
<th>Priority</th>
<th>Next Hearing</th>
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<tr>
<td>HB 2518 INTRO</td>
<td>2</td>
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</table>

Relating to programs used to monitor the dispensing of prescription drugs; declaring an emergency.
Requires pharmacy to report de-identified information to prescription monitoring program upon dispensing prescribed naloxone.
Requires pharmacy to report certain other identifying information to prescription monitoring program upon dispensing prescribed controlled substance classified in schedules II through IV.
Requires information to be disclosed from prescription monitoring program to medical director or pharmacy director.
Requires information to be disclosed from prescription monitoring program for certain other purposes.
Requires licensing information of licensees who are authorized to prescribe or dispense controlled substances to be provided to Oregon Health Authority for purpose of qualifying licensees to report information to, or receive information from, prescription monitoring program.
Provides that Director of the Oregon Health Authority may enter into agreements governing sharing and use of information reported to prescription monitoring program with regulatory authorities of other states that administer prescription monitoring programs.
Becomes operative January 1, 2018.
Declares emergency, effective on passage.
## OBOP Priority Bills

Report Date: March 16, 2017

### Oregon Board of Pharmacy

<table>
<thead>
<tr>
<th>Bill Name</th>
<th>Priority</th>
<th>Next Hearing</th>
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<tbody>
<tr>
<td>HB 2519 INTRO</td>
<td>2</td>
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</tbody>
</table>

Relating to the program used to monitor the dispensing of prescription drugs; declaring an emergency.

- Requires pharmacy to report de-identified information to prescription monitoring program upon dispensing prescribed naloxone.
- Requires pharmacy to report certain other identifying information to prescription monitoring program upon dispensing prescribed controlled substance classified in schedules II through IV.
- Requires information to be disclosed from prescription monitoring program to medical director or pharmacy director.
- Requires information to be disclosed from prescription monitoring program for certain other purposes.
- Requires licensing information of licensees who are authorized to prescribe or dispense controlled substances to be provided to Oregon Health Authority for purpose of qualifying licensees to report information to, or receive information from, prescription monitoring program.

Becomes operative January 1, 2018.

Declares emergency, effective on passage.

| HB 2527 INTRO | 3:00PM 03/20/2017 House Committee Health Care Public Hearing HR E |

Relating to contraceptives; declaring an emergency.

- Allows pharmacists to prescribe and dispense self-administered hormonal contraceptives. Defines "self-administered hormonal contraceptive."

Declares emergency, effective on passage.

| HB 2645 INTRO | | |

Relating to drugs; prescribing an effective date.

- Directs each manufacturer of certain types of drugs that are sold within this state to develop and implement drug take-back program for purpose of collecting from individuals and nonbusiness entities those types of drugs for disposal.
- Directs State Board of Pharmacy to administer Act. Requires manufacturers subject to Act to first submit plan for developing and implementing drug take-back program on or before December 31, 2018.

Becomes operative January 1, 2018.

Takes effect on 91st day following adjournment sine die.

| HB 2897 INTRO | 3 | |

Relating to health insurance.

- Prohibits insurer that offers health benefit plan in state from restricting covered services to in-network providers, imposing higher deductible, copayment or out-of-pocket maximum for out-of-network physicians than for in-network physicians, requiring prior authorization for physician ordered prescription drugs, laboratory tests or physician referrals, requiring generic drugs, except for controlled substances, to be filled at in-network pharmacies and requiring physicians licensed by Oregon Medical Board to be credentialed. Requires insurer that offers health benefit plan to reimburse immunization at same rate across all providers and to reimburse all drugs within same class in same amount.

| HB 2923 INTRO | 4 | |

Relating to English as the official language of Oregon.

- Makes English official language of state.
# Oregon Board of Pharmacy

## Report Date: March 16, 2017

### OBOP Priority Bills

<table>
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<tr>
<th>Bill Name</th>
<th>Priority</th>
<th>Next Hearing</th>
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</thead>
</table>
| HB 3262 INTRO | 3 | 8:00AM 03/16/2017  
House Committee  
Human Services and Housing  
Public Hearing  
HR E |

Relating to psychotropic medication; declaring an emergency.

Requires Department of Human Services, in collaboration with other agencies, to adopt rules related to prescription of psychotropic medications to elderly persons and persons with disabilities.

Declares emergency, effective on passage.

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<table>
<thead>
<tr>
<th>Bill Name</th>
<th>Priority</th>
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<tbody>
<tr>
<td>HB 3315 INTRO</td>
<td>2</td>
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</tbody>
</table>

Relating to drugs; prescribing an effective date.

Directs Oregon Health Authority to establish program under which authority oversees establishment of kiosks for purpose of collecting from consumers and disposing of certain drugs.

Becomes operative January 1, 2018.

Takes effect on 91st day following adjournment sine die.

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<table>
<thead>
<tr>
<th>Bill Name</th>
<th>Priority</th>
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<tbody>
<tr>
<td>SB 50 INTRO</td>
<td>2</td>
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</table>

Relating to pain management.

Requires certain health care professionals and persons holding certificate of certified alcohol drug counselor to complete pain management education once every four years.

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<tr>
<th>Bill Name</th>
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<tbody>
<tr>
<td>SB 72 INTRO</td>
<td>2</td>
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</table>

Relating to nursing.

Removes outdated application requirement for certain nurses applying to Oregon State Board of Nursing for authority to dispense prescription drugs.

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<tr>
<th>Bill Name</th>
<th>Priority</th>
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<tbody>
<tr>
<td>SB 270 INTRO</td>
<td>2</td>
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</tbody>
</table>

Relating to prescription drugs.

Prohibits issuing initial prescription for opiates to adults for outpatient use in quantity exceeding seven-day supply.

Prohibits issuing initial and refill prescription for opiates to minors for outpatient use in quantity exceeding seven-day supply.

Creates exceptions.

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<thead>
<tr>
<th>Bill Name</th>
<th>Priority</th>
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<tbody>
<tr>
<td>SB 272 INTRO</td>
<td>3</td>
</tr>
</tbody>
</table>

Relating to insurance coverage of prescription drugs.

Defines "prescription drug formulary" for purposes of Insurance Code.

Requires carrier offering health benefit plan to small employers, groups or individuals to make specified information about prescription drug formularies available on carrier's website and through toll-free telephone number. Prohibits carrier from making changes to prescription drug formulary more than once every 12-month period unless based on alert issued by United States Food and Drug Administration.
## Oregon Board of Pharmacy

### Bill Name Priority Next Hearing

<table>
<thead>
<tr>
<th>Bill Name</th>
<th>Priority</th>
<th>Next Hearing</th>
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<tbody>
<tr>
<td>SB 423 INTRO</td>
<td>3</td>
<td>1:00PM 03/23/2017 Senate Committee Health Care Work Session HR B</td>
</tr>
</tbody>
</table>

Relating to physician assistants.  
Allows physician assistants to dispense controlled substances in schedules III and IV under federal Controlled Substances Act.

<table>
<thead>
<tr>
<th>SB 518 INTRO</th>
<th>2</th>
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</thead>
</table>

Relating to kratom; declaring an emergency.  
Directs State Board of Pharmacy to conduct study for purpose of determining whether plant mitragyna speciosa and drug derivatives of plant should be scheduled as controlled substance.  
Sunsets January 2, 2019.  
Declares emergency, effective on passage.

<table>
<thead>
<tr>
<th>SB 743 INTRO</th>
<th>1</th>
<th>1:00PM 03/16/2017 Senate Committee Health Care Work Session HR B</th>
</tr>
</thead>
</table>

Relating to dextromethorphan.  
Creates violation prohibiting business that makes retail sales of product containing dextromethorphan, or employee of business, from selling or delivering product to individual 17 years of age or younger unless individual has valid prescription.  
Creates violation prohibiting individual who is 17 years of age or younger from purchasing or receiving product containing dextromethorphan unless individual has valid prescription.  
Preempts local governments from further regulating sale, delivery, purchase, receipt or possession of product containing dextromethorphan, except as is necessary to enforce Act.

<table>
<thead>
<tr>
<th>SB 786 INTRO</th>
<th>1</th>
<th>1:00PM 03/23/2017 Senate Committee Health Care Public Hearing HR B</th>
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</thead>
</table>

Relating to telehealth.  
Requires health care regulatory boards to allow health care practitioner to use telehealth when health care practitioner determines telehealth is appropriate.

<table>
<thead>
<tr>
<th>SB 792 INTRO</th>
<th>3</th>
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</table>

Relating to prescription drug advertising.  
Requires manufacturer to disclose in any advertisement for prescription drug wholesale price for prescription drug in Oregon.  
Imposes civil penalty for violation of requirement.

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<tr>
<th>SB 793 INTRO</th>
<th>3</th>
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</table>

Relating to the price of prescription drugs; declaring an emergency.  
Requires prescription drug manufacturer to report to Department of Consumer and Business Services prices and increases in prices of manufacturer's prescription drugs sold in Oregon.  
Requires manufacturer to provide justification for increase in price greater than 3.4 percent for prescription drugs sold in Oregon longer than 36 months.  
Requires department to order manufacturer to refund excessive price increases to purchasers of prescription drugs.  
Declares emergency, effective on passage.
### OBOP Priority Bills

Report Date: March 16, 2017

**Oregon Board of Pharmacy**

<table>
<thead>
<tr>
<th>Bill Name</th>
<th>Priority</th>
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<tbody>
<tr>
<td>SB 818</td>
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<tr>
<td><strong>INTRO</strong></td>
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<tr>
<td>Relating to opioid analgesic drug products.</td>
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<tr>
<td>Requires health benefit plan that covers opioid analgesic drug products to cover abuse-deterrent opioid analgesic drug products, at no greater cost to insured than other preferred drugs under plan, and specifies other requirements regarding coverage.</td>
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<tr>
<td>SB 869</td>
<td>1</td>
<td>1:00PM 03/28/2017</td>
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<tr>
<td><strong>INTRO</strong></td>
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<td>Senate Committee</td>
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<td>Health Care</td>
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<td>Public Hearing</td>
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<tr>
<td></td>
<td></td>
<td>HR B</td>
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<tr>
<td>Relating to informed consent for vaccinations.</td>
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<tr>
<td>Requires health care practitioner, before administering vaccination to child, to obtain informed consent from parent of child or, if child is emancipated or has reached age of majority, from child. Establishes requirements for obtaining informed consent.</td>
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<tr>
<td>SB 893</td>
<td>3</td>
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<tr>
<td><strong>INTRO</strong></td>
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<tr>
<td>Relating to treatments for patients with terminal diseases.</td>
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<tr>
<td>Permits expressly identified agent, pursuant to lawfully executed advance directive and in accordance with Oregon Death with Dignity Act, to collect and administer prescribed medication for purpose of ending patient's life in humane and dignified manner if patient ceases to be capable after having received prescription for life-ending medication.</td>
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<tr>
<td>SB 951</td>
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<tr>
<td><strong>INTRO</strong></td>
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<tr>
<td>Relating to opioids.</td>
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<tr>
<td>Requires insurers offering health benefit plans to provide coverage for abuse-deterrent opioid analgesic drug products. Defines terms.</td>
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Acknowledgments

Prepared by

Oregon Pain Management Commission
500 Summer St., NE E-65
Salem, OR 97301
PMC.Info@state.or.us

This report respectfully submitted by the OPMC on January 27, 2017.

An electronic version is available at the OPMC website,
http://www.oregon.gov/oha/OHPR/PMC/Pages/Reports.aspx

A hard copy may be obtained by contacting the OPMC staff at 503-373-1605.
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- Executive summary ................................................................. 4
- OMPC purpose ........................................................................... 6
- Oregon educational institution pain management curricula reviewed ......................................................... 7
- OPMC online pain module and provider education .................................................................................. 8
- Proposed legislation .................................................................. 10
- Patient advocacy .......................................................................... 11
- Projects .......................................................................................... 13
- Summary .......................................................................................... 15
  - Key concerns .................................................................................. 15
  - Recommendations: ....................................................................... 15
The Oregon Pain Management Commission (OPMC) submits this report on health care educational institutions’ curricula on pain and pain management, per the legislative requirement in Oregon Revised Statute 413.572. This report also shares information on statewide efforts to address the opioid epidemic and the overlapping issues of the treatment of pain in Oregon.

The OPMC’s primary work is to improve provider education on pain and pain management. The OPMC endorses the recommended curricula published by the International Association for the Study of Pain as a standard from which to review Oregon’s health care educational institutions’ curriculum. The OPMC will work with these institutions to identify gaps in the curriculum and make recommended changes. The OPMC has a statutory requirement to review pain management curricula of educational institutions, but participation in the review process by the educational institution is voluntary. In 2015–2016, three schools participated in the review process. The OPMC is awaiting response from six schools for reviews in 2017–2018. The OPMC does not have any recommendations for legislative action related to curriculum reviews at this time.

The OPMC, as directed in ORS 413.590, requires certain licensed health care professionals to complete an Oregon-specific pain management training module. The online module’s survey shows it is viewed more than four hundred times per month or 5,559 times in 2015 and 5,538 times in 2016. The module is completed by those health care professionals required by statute to complete as well as others. The current survey does not provide the feedback to identify the professional classes of those others.

In this past year the OPMC published an updated version of their online educational module “Advancing Pain Management in Oregon” to include Oregon-specific information, current research and recommended models of care for the treatment of pain. The module introduces a new understanding of pain and a proposed new pathway of treatment. Improved format changes to the online module are planned for next year.

The OPMC has proposed legislation SB 50, for the 2017 Legislature to expand the pain education requirement to an additional nine health care professionals who treat patients with pain. Pain is complex and results from a combination of biological, psychological and social factors. Just as the cause of an individual’s pain may include many factors, the treatment and
management of their pain may require a combination of physical, psychological, pharmacological treatment modalities and social supports to address the whole person with an interdisciplinary approach. Information is essential to successful pain management. Providers should have updated research and treatment recommendations to support improved decision-making with their patients. The SB 50 also amends the frequency of the educational requirement from one time to once every four years.

The OPMC receives phone calls, hears public testimony and engages in dialogue with people who have chronic pain. Their messages clearly demonstrate a climate of fear, frustration, anger and misunderstanding. Treatment of pain is complicated by limited access to integrated physical and mental health care, concerns about medication safety and prescribing guidelines, and lack of reimbursement for alternative and comprehensive treatment options. The statewide efforts to address prescription drug overdose, misuse and dependency have intended benefits for the population as a whole. However, the individual patients with pain are experiencing significant distress. Individuals with chronic pain are forced to make medication changes and the message they hear is that the medication changes are based on law. The clear language and intent of the CDC Prescribing Guidelines to treat each patient individually is not what patients are experiencing.

Inadequate pain treatment, overreliance on medications for pain management and lack of knowledge of biopsychosocial-informed care contribute to the serious public health concerns related to opioid medications. The OPMC is working with public health, behavioral health, health systems, academic institutions, policy makers and law enforcement officials on projects targeting the opioid epidemic and health care policy that affects the care of patients with chronic pain.

The OPMC identifies several key concerns and makes recommendations in this report. Most require further analysis, research and model projects during 2017–2018. The OPMC makes the following recommendations to the 2017 Legislature:

- Pass SB 50 to expand the pain educational requirement to additional health care professionals and revise frequency from one time to once every four years.
- Support measures to improve access to comprehensive services for the treatment of pain.
OMPC purpose

The Oregon Pain Management (OPMC) within the Oregon Health Authority:

- Develops a pain management educational program for required completion by health care professionals under specified licensing boards.
- Recommends curriculum to health care educational institutions.
- Represents patient concerns to the Governor and Legislature.
- Improves pain management in Oregon through research, policy analysis and model projects.

The OPMC includes representation from physical and behavioral health; an addiction specialist; pharmacy, dental, chiropractic, acupuncture and naturopathic medicine; and two public members.
Oregon Revised Statute 413.572 requires OPMC review pain management curricula of Oregon educational institutions. The OPMC makes recommendations about legislation to ensure adequate information about pain management is in the curricula of those institutions, based on the findings of the programs reviewed. The OPMC is directed to report its findings to the Legislature by January 1 of each odd-numbered year.

The following health care institutions voluntarily participated in a review of their curriculum in 2015–2016:

- National College of Natural Medicine
- Oregon Health Sciences University: School of Medicine
- University of Western States: College of Chiropractic

These reviews indicate the health care curricula of physical health providers lack content addressing the behavioral or mental health component of pain and pain management. The institutions responded to the OPMC’s recommendations with intent to improve their curriculum, which will result in better integration of physical and behavioral health for the treatment of pain.

In 2016, the OPMC defined the purpose of the review as a mechanism for quality improvement in the education of pain and pain management. The OPMC works with educational institutions to update and improve their health care curriculum related to pain. The OPMC endorses the recommended curricula published by the International Association for the Study of Pain (IASP) for each health care provider type. The health care institution will be asked to begin a self-evaluation comparing their curriculum to the IASP’s and report on gaps identified and plans to improve or make changes to the curriculum.

Participation by the health care institutions in curriculum reviews is not regulated nor required by statute. To date, the OPMC has sent written invitations to the following institutions and are awaiting their response to schedule reviews for 2017–2018:

- Pacific University: Pharmacy
- Pacific University: Psychology
- George Fox University: Psychology
- University of Oregon: Psychology
- Oregon State University: Pharmacy
- OHSU: School of Nursing
OPMC online pain module and provider education

The OPMC, as directed in ORS 413.590, requires certain licensed health care professionals to complete an Oregon-specific pain management training module. The online module’s survey shows it is viewed more than 400 times per month or 5,559 times in 2015 and 5,538 times in 2016. The module is completed by those health care professionals required by statute to complete as well as others. The current survey does not provide the feedback to identify the professional classes of those others.

The online module “Advancing Pain Management in Oregon” was revised and updated to include Oregon-specific information, current research and recommended models of care for the treatment of pain. The module is intended to provide a foundation for advancing pain management in Oregon and to increase awareness regarding evidence-based treatments for the effective management of pain. The module introduces a new understanding of pain and a proposed new pathway of treatment for a more holistic approach.

Pain treatment issues are complex and cannot be adequately addressed in the one-hour module. Information about additional expanded educational topics has been included in “Advancing Pain Management in Oregon.” Providers required to select six additional hours of continuing education curriculum on pain management may choose issues specific to their provider specialty, interests or concerns.

In addition to the recent module updates, the OPMC proposed updates to the educational format of the module and researched options for funding and development to complete. The current format does not validate learning or review for usefulness. The proposed adult learning design will provide information in a multisensory format to improve learning and retention (Figure 1).

The revised format will allow for credentialing for professional continuing education units (CEUs). Offering CEUs encourages providers to re-review the information to fulfill annual CEU licensing requirements outside of the statutory requirement in ORS 413.590.
## Figure 1. Proposed adult learning design

<table>
<thead>
<tr>
<th>Features</th>
<th>Current module</th>
<th>Proposed module</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult learning module</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visual</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Audio</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Interactive</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Testing with a requirement to pass by 85% to get certificate</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Post module survey</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provides registration information: name and license number</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Participant feedback on quality of information</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Usefulness of the information</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Impact of the information on current practices</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Course evaluation</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Certified for one hour of continuing educational units</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Data collection at the end of the module does not provide any feedback for use in evaluating or improving the module. Updates proposed to the survey include a process to evaluate the course, reports on the usefulness of the information and the impact of the information on current practices. Survey results will inform future module revisions.
Review of educational institutions’ curriculum for inclusion of pain and pain management and completion of the required OPMC’s educational program helps ensure new providers have the information they need. However, there remains a need for experienced providers to stay up-to-date on current information and continuing education as a way to better manage patient care after changes in treatment pathways and opioid prescribing guidelines.

Local and statewide efforts in Oregon involve public health, behavioral health, health systems, academic institutions, policy makers, and law enforcement officials working together to reduce the risks of abuse, addiction and unintentional overdose deaths associated with the use of opioid medications. Current information about the mechanisms of pain; evidence-based, non-pharmacologic treatment options; and strategies to reduce inappropriate opioid prescribing is necessary to address the harms associated with opioid medications.

Existing statute (ORS 413.590) identifies 10 health care professionals required to complete the continuing education on pain and pain management before initial or renewal of licensure as a one-time requirement. The OPMC has submitted SB 50 for the 2017 Legislature to expand the pain education requirement to an additional nine health care professions.

Evidence and research is rapidly evolving in pain and pain management; the OPMC updates the online module every two years. The OPMC recommends any health care professional responsible for assessing the needs of a patient with acute and/or chronic pain should have the information and confidence to treat safely and effectively. The proposed legislation also amends the educational requirement from a one-time obligation to once every four years.
Patient advocacy

The National Pain Strategy: A Comprehensive Population Health-Level Strategy for Pain 2016 states “access to safe and effective care for people suffering from pain remains a priority that needs to be balanced in parallel with efforts to curb inappropriate opioid prescribing and use practices.” The CDC Guideline for Prescribing Opioids for Chronic Pain states the recommendations are voluntary rather than prescriptive standards, and clinicians should consider the circumstance and unique needs of each patient when providing care.

The OPMC has heard testimony and talked with members of the public who are patients with chronic pain and find the clear language and intent of the CDC guidelines to treat each patient individually is not what patients are experiencing. Practitioners are telling patients the CDC guidelines are the reason for treatment plan changes such as mandatory reduction in or the complete cessation of opioid medication. The message patients are hearing is their medication changes are because of a law. The public testimony clearly demonstrates a climate of fear, frustration, anger and misunderstanding.

There are major concerns about what the public says they have experienced and heard from people in their communities regarding opioid prescriptions and other treatment. Patients who have had chronic pain for years and use opioids as a component of their pain management are now fearful they may lose this treatment.

They testified this treatment has helped them to function and they are concerned they will no longer be able to take care of themselves and become dependent on caretakers without it. Some who have tried many modalities for pain management have found opioids are an essential treatment component to maximize their quality of life. It allows them to manage the pain well enough to be able to spend time with children, grandchildren, participate in activities of daily living, move and “have what type of life they can.”

Patients are being told by their doctors they will no longer be able to get opioids. When patients have tried to locate another doctor, they are told that the doctor is not taking on people with chronic pain. Some patients are identified as drug-seeking even when they are not asking for or want opioid medication.
In addition to challenges related to their medications, patients are not able to access comprehensive treatment options. Many insurance plans do not cover or have high cost-sharing for non-pharmacologic therapies, treatment modalities and pain management programs. Patients taken off opioids are left with limited or no treatment options.

Major concerns from a patient perspective:

• Viewed with suspicion or like a criminal when seeking treatment
• Not being believed that the pain is real
• Not included in planning process/shared decision-making about medications and treatment options
• Mandated medication reductions despite a history of benefit and low risk for associated harms in their case
• Difficulty accessing practitioners
• Lack of insurance coverage for treatments other than opioids
• Disorders of addiction are treated as a moral failing rather than a disease
• Patients with chronic pain are presumed to be addicts

Living with chronic pain can be debilitating and stigmatizing. Patients want to engage in their lives at whatever level their abilities allow and need to receive treatment that is effective and respectful.
Projects

Additional projects the OPMC and members participated in during the past two years:

• Participation on the Back Line Reorganization Task Force for the Health Evidence Review Commission’s work on the Prioritized List of Health Services resulting in coverage of evidence-based, effective therapies to treat painful back conditions based on a bio-psycho-social model of care for Oregon Health Plan recipients:
  » Oregon Health Plan coverage now includes non-pharmacologic treatments for pain resulting from back and spine conditions

• OHA Opioid Initiative Task Force – [Link to Oregon Prescription Drug Overdose, Misuse and Dependency Prevention Plan]

• Participation and presentations to various groups supporting implementation of the prevention plan:
  » Oregon Coalition for the Responsible Use of Meds (OrCRM) – regional summits
    ▪ Eastern Oregon Summit in La Grande
    ▪ Central Oregon and Gorge Summit in Redmond
    ▪ Lane County Summit in Eugene
    ▪ North Coast Summit in Seaside
    ▪ SW Summit in North Bend
  » Oregon Statewide Prescribing Guidelines Task Force
  » Prescription Monitoring Program Advisory Commission
  » Tri-County Opioid Safety Coalition
  » Oregon Pain Guidance Group
  » A Thoughtful Approach to Pain Management Conference – Medford, May 2016
  » USDOJ/Law Enforcement Roundtable
• Submitted recommendations to Health Evidence Review Commission on development of Guideline Note 60: Opioid Prescribing for the Prioritized List of Health Services

• Submitted recommendations to Health Evidence Review Commission on the use of the pain scale to determine pain severity as a threshold for coverage

• Collaborative educational event planned for 2017 related to the OHP coverage changes for the integrative treatment of pain associated with back and spine conditions, coordinated by Oregon Collaborative for Integrative Medicine
Summary

Key concerns

• Need for improved provider education and training to prevent the transition of acute pain to persistent pain

• Public education on “what is pain” and “appropriate pain treatment” is lacking

• Lack of resources for individual patient advocacy

• Limited coverage for non-pharmacologic treatment of pain to reduce opioid medications

• Limited work force capacity to meet the needs of and treat patients with chronic pain conditions, manage chronic opioid therapy and/or treat identified substance use/opioid use disorders.

• No requirement of health care educational institutions to participate in curriculum reviews

Recommendations:

• Pass SB 50 expanding the requirement to take the OPMC online pain module to additional health care professionals who see patients with pain

• Provide incentives to health care educational institutions to participate in curriculum reviews

• Provide incentives to providers to expand practices rather than limiting or denying services to patients with pain

• Public service announcements and media campaign

This report is respectfully submitted by the OPMC on Jan. 27, 2017.

This report may be obtained in an electronic version at the OPMC website, http://www.oregon.gov/oha/OHPR/PMC/Pages/Reports.aspx.

A hard copy of this report may be obtained by contacting the OPMC staff at 503-373-1605.