

Meeting Minutes	<p align="center"><b>Rules Advisory Committee Meeting</b>  <b>PIC / Community Pharmacy Personnel and Compliance Requirements</b>  <b>June 29, 2018, 1:15-3:15pm</b>  <b>Portland State Office Building, 800 NE Oregon St., Portland OR 97232</b>  <b>Conference Room ID</b></p>
<p><b><u>Committee Members</u></b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Laura Abrahamson, RPh – Industry Representative</li> <li><input type="checkbox"/> Jason Boeshans, RPh – Pharmacist-In-Charge Representative</li> <li><input type="checkbox"/> Laura Churns, RPh – Industry Representative</li> <li><input type="checkbox"/> Anna Emoto, RPh – Staff Pharmacist Representative</li> <li><input type="checkbox"/> Dan Kennedy, RPh – Hospital Representative</li> <li><input type="checkbox"/> Yolanda Marcotte, CPhT – Technician Representative</li> <li><input type="checkbox"/> Jill McClellan, RPh – Pharmacist-In-Charge Representative</li> <li><input type="checkbox"/> Blake Rice, RPh – Former Board of Pharmacy Member Representative</li> <li><input type="checkbox"/> Elizabeth Scheer, RPh – Pharmacist-In-Charge Representative</li> <li><input type="checkbox"/> Carrie Senn, RPh – Staff Pharmacist Representative</li> <li><input type="checkbox"/> Lorri Walmsley, RPh – Industry Representative</li> </ul> <p><b><u>OBOP Staff to Committee</u></b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Marcus Watt, Executive Director</li> <li><input type="checkbox"/> Karen MacLean, Administrative Director</li> <li><input type="checkbox"/> Fiona Karbowicz, Pharmacist Consultant</li> </ul>	
<b>Agenda Item</b>	<b>Desired Outcome</b>
Welcome	Roll call Introductions
Committee Business	<ul style="list-style-type: none"> <li>❖ Committee Overview and Purpose               <p>The PIC / Community Pharmacy Personnel and Compliance Rules Advisory Committee (RAC) was selected to discuss the language and impacts of the Board’s draft rules. The Board was seeking input related to the policy directives the rule clarifies, as well as the potential fiscal impact. This RAC provides the structure for stakeholder and industry insights.</p> <p>Pharmacist Consultant Fiona Karbowicz presented an informational set of slides, defining a rule, providing a background of agency promulgation of rules, and outlining the purpose of a RAC. The presentation described the objectives of these Personnel/Compliance rules as well as the context and considerations for the RAC. (see pg. 4-21 of this document)</p> </li> <li>❖ Committee Dialogue               <p>Committee members shared concerns, opinions and personal experiences related to this topic. They discussed why the rules <i>are</i> and <i>are not</i> necessary. As a way to invoke as much dialogue as possible, members took additional turns to speak, as often the sharing by one member inspired another’s thoughts.</p> <p>Points shared are provided:</p> <ul style="list-style-type: none"> <li>▪ Staffing concerns and the need to allow a PIC to “run the pharmacy”</li> <li>▪ Looking at this from a national perspective, there are no other states where rules such as this exist; there is a hope that these concerns can be addressed</li> </ul> </li> </ul>

	<p>in other ways and there is not a need for this in other states – rule is not necessary</p> <ul style="list-style-type: none"> <li>▪ Concerned about the negative impact on patients, if PICs are allowed to make decisions on the services provided</li> <li>▪ Pharmacists feel that they are being put in unsafe working conditions, as they are stuck in the push/pull of business needs vs. patient needs</li> <li>▪ There is a shared accountability when decisions are made externally by non-licensed persons; one member suggested this could be looked at from the hospital perspective - hospital administrators are not typically mandated to be a physician</li> <li>▪ A new PIC will have lots of questions and needs support from corporate; if the person is a non-pharmacist, he/she is not often qualified to provide the appropriate answer, legally or clinically, etc.</li> <li>▪ Per the challenges shared by the Board, related to non-licensed supervisory personnel directing pharmacists, such as inappropriate clinical directives (give an immunization or medication, when it is not clinically warranted) or non-licensed corporate liaison not providing investigatory information requested by Board inspectors, it was suggested that the Board can rely upon current processes for obtaining information and investigations of specific wrong-doing rather than put this rule in place</li> <li>▪ Challenges reported that it may be even more difficult to hire PICs and supervisors if these rules are adopted. By requiring Oregon pharmacist licensure, it limits potentially great employees from supervisory positions; a company wants to always hire the most qualified person, and a Supervisor's skill set is different than a PIC's; another member shared that her company deems the "best qualified person" to be a licensed pharmacist in all states where they work – maybe the rules can allow a grace period for pharmacist licensure, such as 90 days</li> <li>▪ In light of the PIC shortage we currently have, concerns that this language will make this situation worse; another member shared the PIC shortage may be due to the fact that currently PICs have limited autonomy</li> <li>▪ A member had been asked to do something illegal by a non-licensed supervisor and there is a general tone that the company doesn't care about this wrong-doing, they will just pay the fine and move on; there are hotlines that an employee can use for specific circumstances, such as these; another member shared that she worked for a non-pharmacist DM who did not understand how a pharmacy runs – they lost a lot of good employees due to this person and her lack of knowledge</li> <li>▪ Concern that the current language is too broad for PIC responsibilities; The PIC responsibilities, as currently written are concerning, particularly from a liability standpoint; other members shared concerns with the PIC language and do not see the direct tie to increased patient safety; Do these rules add more to a PIC's plate? They are already so busy</li> <li>▪ We work in a broken healthcare system – cannot see how the PIC rules will improve patient outcomes</li> <li>▪ One member's spouse got a license in another state because of the professional expectations</li> <li>▪ Committee members shared thoughts on the challenges of being a PIC and of being a PIC at 2 locations simultaneously</li> </ul>
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	<ul style="list-style-type: none"> <li>❖ Review of Draft Proposal &amp; Fiscal</li> </ul> <p>With approximately 30 minutes remaining for the meeting, Committee members went around the room providing suggestions for edits and enhancements to the rules, in the event that the Board considers moving forward with proposed rules. The draft with comments and suggested edits is provided. (see pg. 22-25 of this document)</p>
Good of the Order	<ul style="list-style-type: none"> <li>❖ Wrap up and next steps – It was determined that the Committee’s work is not complete. We will attempt to schedule a second meeting prior to the Board’s upcoming August meeting, if that is possible. Administrative Director Karen MacLean will work with member’s availability via Doodle Poll.</li> <li>❖ Next meeting - TBD</li> </ul>

# **PIC & COMMUNITY PHARMACY PERSONNEL/ COMPLIANCE RULES**

**OREGON BOARD OF PHARMACY RULES ADVISORY COMMITTEE (RAC) MEETING – JUNE 29, 2018**

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# WHAT IS A RULE?

1. Any Agency directive, standard, regulation or statement
2. Of general applicability
3. That implements, interprets or prescribes law or policy, or
4. That describes the procedure or practice requirements of any agency

# WHERE ARE RULES FOUND?

- **Oregon Administrative Rules (OAR)**-official compilation of rules & regulations having the force of law in Oregon
    - [http://sos.oregon.gov/archives/Pages/oregon\\_administrative\\_rules.aspx](http://sos.oregon.gov/archives/Pages/oregon_administrative_rules.aspx)
  - Compiled & issued annually by the **Secretary of State's Archives Division**
  - Monthly updates, including notice of *intended* rule action, in ***Oregon Bulletin***
    - <http://arcweb.sos.state.or.us/pages/rules/bulletin/past.html>
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# WHEN IS A RULE REQUIRED?

- When required / written in statute
  - To interpret broad statutory authority
  - To amend, suspend, or repeal existing rule
  - **Tip:** Statute mandates *what*, and the rule mandates *how* (implementation)
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# WHEN IS A RULE NOT REQUIRED?

- When the rules for the sections of the legislation are clear enough to administer without rulemaking.
  - When the agency merely interprets an existing rule (*unless the interpretation changes – this can occur pursuant to contested cases, for example*)
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May be established and used for rules in which there are issues that may substantially impact the interests of persons or entities ("stakeholders"), who will likely be affected by the proposed rulemaking.

## **RULES ADVISORY COMMITTEE (RAC)**

# RULES ADVISORY COMMITTEE - PURPOSE

- Involve the public in the development of public policy
- Estimate financial impact on interested persons/entities, including small businesses, as well as the fiscal impact on the public
- Members must represent interests of persons likely to be affected by the rule

\*A RAC's role is **advisory** only.\*

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# PERMANENT RULEMAKING PROCESS

- Agency notifies rules coordinator of rulemaking content and timeline
  - Agency provides notices to legislators, “interested parties,” & public, seeking input to rules; May utilize a RAC
  - Agency describes fiscal impact on entities, including small businesses
  - Agency conducts public hearing and provides opportunity for oral testimony and written comments on proposed rules (rulemaking record)
  - Agency considers all input and finalizes rules
  - Agency submits final rules to Secretary of State
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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.

# **OBOP MISSION STATEMENT**



# PROPOSED RULES - OBJECTIVES

- Current edits proposed to Division 019 (Pharmacists) and 041 (Drug Outlets) address Retail/Community Pharmacy Drug Outlet personnel and compliance requirements:
    - Explain that a person who directs the professional activities of PICs must obtain licensure as an Oregon Pharmacist (RPH)
    - Clarify the roles and responsibilities of an Oregon Pharmacist-in-Charge (PIC)
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# RELATED STATUTES

- **ORS 689.005(30)(k)** The practice of pharmacy means the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy
- **ORS 689.205** The State Board of Pharmacy shall make, adopt, amend and repeal such rules as may be deemed necessary by the board, from time to time, for the proper administration and enforcement of this chapter. Such rules shall be adopted in accordance with the procedures specified in ORS chapter 183.

# CONTEXT / CONSIDERATIONS

- Changes in the practice and industry trends
    - Independent vs. Chain pharmacies
  - Increase in the number of “District Area Managers” who are non-pharmacists or non-Oregon licensed pharmacists
  - PICs increasingly powerless to practice according to their own professional judgment
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# **COMMITTEE MEMBER SHARING & DIALOGUE**

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# RULE DRAFT – “DM” LANGUAGE

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

*Alternative:*

(2) Each resident community pharmacy that employs a person who directs the professional activities of PICs shall ensure that:

(a) The person is an Oregon licensed pharmacist; and

(b) When a vacancy occurs, the pharmacy will notify the Board within ten business days

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# RULE DRAFT – PIC LANGUAGE

- (1) Each community pharmacy drug outlet (RP) must have an Oregon licensed pharmacist designated as Pharmacist-in-Charge (PIC) who is responsible for the daily operations of the pharmacy. The PIC is responsible for exercising professional judgment and discretion to ensure a pharmacy environment that is safe and effective, and fulfils the responsibilities listed in Division 019.
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# RULE DRAFT – PIC LANGUAGE (*CON'T*)

- (4) The PIC is responsible for exercising professional judgment and discretion to ensure a pharmacy environment that is safe and effective, to include:
- (a) Assessing pharmacy demand, and workload;
  - (b) Evaluating pharmacy staffing, inventory, resources, and capacity;
  - (c) Prioritizing pharmacy tasks, responsibilities, and assignments; and
  - (d) Modifying pharmacy workflow and services provided.
-

# **COMMITTEE MEMBER DISCUSSION: FISCAL IMPACT**

- ❖ **Identify state agencies, units of local government, and members of the public likely to be economically affected by the rules**
  - ❖ **Effects on small businesses**
-



**\*THANK YOU\*  
VERY MUCH**

We appreciate your participation  
in this important work!



1 **General Community Pharmacy**

2 **855-041-2105 Personnel**

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

8 *Possibly a hybrid of the follow proposed wording for sub (2)?*

9 **(2) Each resident community pharmacy that employs a person who directly / immediately**  
 10 **supervises and directs the professional activities of a PIC shall ensure that the person is an**  
 11 **Oregon licensed pharmacist.**

12 *Alternative*

13 **(2) Each resident community pharmacy that employs a person who directly oversees the**  
 14 **professional activities of PICs shall ensure that:**

15 **(a) The person is an Oregon licensed pharmacist; and**

16 **(b) When a vacancy occurs, the pharmacy will notify the Board within ten business days.**

17 *Is a vacancy allowed – is there a need to define timeframe? Is the person working to obtain*  
 18 *active licensure? Challenge for niche-pharmacies...*

19 *Alternative*

20 **(2) Each resident community pharmacy that employs a person who directly / immediately**  
 21 **supervises and directs the day-to-day professional activities of multiple PICs shall ensure**  
 22 **that the person is an Oregon licensed pharmacist or is an individual licensed with the**  
 23 **Board and who completes a Board approved training program..**

24 *Does it have to be an RPH? Or can it be any licensee (for the Board's regulatory "tie"?)*

25 *Require that the DM (non-licensed and/or OR-licensed) take a PIC Training-type program*  
 26 *(would need to be a different class), instead of this licensure requirement. It was noted this may*  
 27 *be a staff burden to create a new class.*

28 *-lets people know what the Board's expectations are... terminology/practice of pharmacy*  
 29 *elements would need to be identified when teaching non-licensed/non-RPH individual*

30 *-class plus the DM's commitment to the position creates the tie to the Board*

31 *-a 3 hour class vs. real-life experience (skepticism was noted)*

32  
 33 *General question: Is there a ratio/max of number of PICs a DM shall directly supervise?*



## Pharmacist-in-Charge

855-019-0300

### Duties of a Pharmacist-in-Charge

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

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

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

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

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

~~(4) The PIC is responsible for~~ must perform the following the duties and responsibilities: exercising professional judgment and discretion to ensure a pharmacy environment that is safe and effective. to include:

~~(a) Assessing pharmacy demand, and workload;~~

~~(b) Evaluating pharmacy staffing, inventory, resources, and capacity;~~

~~(c) Prioritizing pharmacy tasks, responsibilities, and assignments; and~~

~~(d) Modifying pharmacy workflow and services provided.~~

#### *Alternative*

~~(4) The PIC shall~~ must perform the following the duties and responsibilities: exercise professional judgment and discretion to ensure a pharmacy environment that is safe and effective, which may include / such as:

(a) Assessing pharmacy demand, and workload;

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

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

(d) Modifying pharmacy workflow and services provided.

66 *Mandate notification to upper management and/or Board when issues arise?*

67 *Concerns that PICs will not want to take on this position, thinking that these are new*  
 68 *requirements.*

69 *If removed, can a-d be articulated by the Board in policy vs. in rule?*

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

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

73 (b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within  
 74 15 days of becoming PIC;

75 (c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the  
 76 pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may  
 77 be granted as specified in OAR 855-041-0120-**6310**;

78 (d) In a hospital only, the PIC is responsible for providing education and training to the nurse  
 79 supervisor who has been designated to have access to the pharmacy department in the absence of  
 80 a pharmacist;

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

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

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

89 ~~(5) (6)~~ The PIC is responsible for ensuring that the following activities are correctly completed:

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

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

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

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

- 100 (e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs;
- 101 (f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such
- 102 training should include an annual review of the PIC Self-Inspection Report;
- 103 (g) ~~Implementing a~~ **Maintaining the continuous** quality assurance plan **program** for the
- 104 pharmacy;
- 105 (h) The records and forms required by this section must be filed in the pharmacy, made available
- 106 to the Board for inspection upon request, and must be retained for three years.
- 107 ~~(6)~~ (7) The PIC, **along with other pharmacy and supervisory personnel** licensed pharmacy
- 108 personnel, must ensure that the pharmacy is in compliance with all state and federal laws and
- 109 rules governing the practice of pharmacy ~~and that all controlled substance records and~~
- 110 ~~inventories are maintained in accordance with all state and federal laws and rules.~~
- 111 *Strengthens the outlet's shared responsibility, and the "ownership" by the supervisory personnel*
- 112 Stat. Auth.: ORS 689.205
- 113 Stats. Implemented: ORS 689.151, 689.155
- 114