

**Rules Advisory Committee Meeting**

**PIC / Community Pharmacy Personnel and Compliance Requirements**

**August 23, 2018, 9:15-11:15am**

**Portland State Office Building, 800 NE Oregon St., Portland OR 97232**

**Conference Room 1B**

**Minutes**

**Committee Members**

- |  |   |
|--|---|
| <input type="checkbox"/> Laura Abrahamson, RPh | <input type="checkbox"/> Jason Boeshans, RPh    |
| <input type="checkbox"/> Laura Churns, RPh     | <input type="checkbox"/> Anna Emoto, RPh        |
| <input type="checkbox"/> Dan Kennedy, RPh      | <input type="checkbox"/> Yolanda Marcotte, CPhT |
| <input type="checkbox"/> Jill McClellan, RPh   | <input type="checkbox"/> Blake Rice, RPh        |
| <input type="checkbox"/> Elizabeth Scheer, RPh | <input type="checkbox"/> Carrie Senn, RPh       |
| <input type="checkbox"/> Lorri Walmsley, RPh   |   |

**OBOP Staff to Committee**

- |   |   |
|---|---|
| <input type="checkbox"/> Marcus Watt, Executive Director        | <input type="checkbox"/> Fiona Karbowicz, Pharmacist Consultant |
| <input type="checkbox"/> Karen MacLean, Administrative Director |   |

Agenda Item	Desired Outcome
Welcome	Roll call – All members present; Laura Abrahamson via phone.  Introductions
Committee Business	<ul style="list-style-type: none"> <li>❖ Review - Committee Overview and Purpose           <ul style="list-style-type: none"> <li>○ Pharmacist Consultant Fiona Karbowicz provided the Committee with a review of the RAC’s background and purpose via slides (attached).               <ul style="list-style-type: none"> <li>▪ Current edits proposed to Division 019 (Pharmacists) and 041 (Drug Outlets) address Retail/Community Pharmacy Drug Outlet personnel and compliance requirements:                   <ul style="list-style-type: none"> <li>• Explain that a person who directs the professional activities of PICs must obtain licensure as an Oregon Pharmacist (RPh), noting that the language of the proposed “DM rule” does not mandate the use of this position, however if there is a position such as this in the organizational structure, and that person immediately supervises and directs the professional activities of PICs, then the proposed rules would require the person to be an Oregon licensed pharmacist.</li> <li>• Clarify the roles and responsibilities of an Oregon Pharmacist-in-Charge (PIC), noting that a PIC is the Board’s liaison and all pharmacists are currently expected to comply with law/rule in order to maintain a work environment that is safe for the public. Proposed edits to 855-019-0300 are meant to articulate those expectations.</li> </ul> </li> </ul> </li> <li>○ She shared a brief summary of where the group left off at the June 29, 2018 meeting, per the meeting minutes emailed to the Committee on 7/10/2018.</li> </ul> </li> <li>❖ Continue Committee Dialogue           <ul style="list-style-type: none"> <li>○ The Committee members continued their dialogue related to the policy directives of these rules. Members began by sharing new ideas and thoughts based on the first meeting. Additionally, some members had the opportunity to share with</li> </ul> </li> </ul>

other pharmacists and technicians – Committee members shared the insights provided to them by these other stakeholders. Comments included:

- Some PICs are worried about civil liability with their duties being more clearly defined, versus generally articulated; whereas another suggested that civil recourse is always present and these rules would not increase liability
  - Are the rules even needed? If so, it may be better to keep the language general, to decrease PIC anxiety. A member stated “If I was not as closely in ‘the loop’ of Board processes, I would think that these rules would require me to do more, such as create additional policies and procedures and other updates.”
  - Someone has to focus on safety – that is the role of the PIC. But if the PIC can’t impact safety, why have one?
  - Hope that health and safety of a patient is always a pharmacist’s top priority – are rules needed to express this?
  - It is concerning when a company’s expectations come before patient safety; problem when a PIC can’t “stand up to corporate”
  - A Committee member shared a circumstance when their pharmacy was constantly in need of additional staffing and she reported to a non-licensed supervisor. Initially this person responded with “Can’t you just tell this other pharmacist to work faster?” but the member was able to explain the safety implications and then the supervisor was “okay with it”. Member sees staffing/labor as a guideline, but not a steadfast rule and is willing to “go over” with staffing and inventory, when needed
  - A “one size fits all” approach for this type of requirement is not realistic. There are some jobs that require the supervisor to cover facilities in multiple states and this would be a large burden in those circumstances
  - There is a general trend for rules to be less prescriptive and this language may be “bucking that trend” – Committee member is a “big fan” of pharmacists developing and exercising professional judgment
  - PICs and pharmacists may be interested in the [ISMP’s Self-Assessment](#) tool to help identify safety at their pharmacy. It’s a great tool and a useful “eye-opener”
  - The proposed rules are too prescriptive; better to rely on ‘Standard of Care’ regulation as the gold-standard; [NABP 2018 resolution](#) forming a task force to explore this
  - These rules may not be needed; there are many examples of great leaders who are non-licensed or non-pharmacist supervisors
  - We have HR and other ethics departments available to address the concerns; laws are not needed for “what-ifs”
- Members took an informal poll of being in support or opposition of each policy prerogative:
- Regarding PIC, generally: 1 in support as written; 8 fully or partially opposed, particularly unless language is re-written, 2 neutral – Comments:
    - We need something in rule; okay with broader language
    - I support more vague language

	<ul style="list-style-type: none"> <li>• I oppose lists in rule language</li> <li>• Leave it broader; the more you define, the harder it becomes to measure</li> <li>• I already know these are my duties; not needed in rule language</li> <li>• Not getting more with extra verbiage</li> <li>• Cannot see direct link or specific improvement to patient safety</li> <li>• Broader rules are more “future proof”</li> <li>• Language is intimidating; increased worry about civil liability; one may consider stepping down as PIC. If others also step down, this could be very challenging especially in rural areas</li> <li>• “Wavering” – What’s needed most is PIC professional judgment and discretion</li> <li>• “Mixed”</li> </ul> <ul style="list-style-type: none"> <li>▪ Regarding DM requirement, generally: 6 in support, 4 in opposition, 1 neutral – Comments: <ul style="list-style-type: none"> <li>• I want my supervisor to be a pharmacist, however this does not always guarantee they have a good grasp of the law</li> <li>• I support this; it is the right thing to do for patient safety and provides an avenue for a pharmacist’s professional development</li> <li>• This is healthcare, not “widgets”; this position must be a licensed pharmacist</li> <li>• A DM needs to be a pharmacist; consider including a waiver clause for anomalies</li> <li>• The DM must be a pharmacist; there is a direct tie to patient safety and licensure gives the OBOP the enforcement needed</li> <li>• Pharmacists understand how to do this job; numbers are the focus for corporate</li> <li>• This will not force a person’s ability to do their supervisory job better; OBOP already has disciplinary abilities</li> <li>• Due to various practice settings, OR-licensed pharmacist DM will pose challenge for licensure for outlet’s doing business in many states</li> <li>• OBOP has the ability to hold the outlet responsible for “bad actors”</li> <li>• Not necessary - May cause a DM shortage and is a cost burden</li> <li>• It’s a “toss-up”; cannot address all variables such as personality, personal initiative or training via rule – not sure if a rule can fix this; a non-pharmacist should not be directing my professional activities or my professional judgment</li> </ul> </li> <li>○ Two Committee members asked the Board to more clearly articulate the problems these rules are attempting to address, to include specific examples of issues.</li> </ul>
--	--

	<ul style="list-style-type: none"> <li>▪ Executive Director Marc Watt stated that staff had, in fact, investigated cases of non-licensed supervisors direction of PIC's or pharmacist's professional judgement</li> <li>❖ Continue Review of Draft Proposal &amp; Fiscal <ul style="list-style-type: none"> <li>○ Based on the discussion, a few additional comments were added to the draft language.</li> <li>○ Regarding fiscal impact, the Committee understood its role to identify the costs of compliance. These include: state agencies, units of local government, and members of the public likely to be economically affected by the rule(s) as well as the effect on small businesses. Comments included: <ul style="list-style-type: none"> <li>▪ Hard to determine fiscal without a final rule available</li> <li>▪ At a minimum, there would be the licensing fees involved</li> <li>▪ If a PIC were to be more in control over staffing, the fiscal impact to the pharmacy outlet could be millions for a large chain</li> <li>▪ Concerned of the financial impact this would have on the current non-licensed DMs who would lose their jobs</li> <li>▪ May be rural area vacancies for both PIC and DM, which increase costs to find 'floater' who get hotel and driving expenses paid by company</li> <li>▪ Do the new '<a href="#">predictive scheduling laws</a>' intersect with these policies?</li> <li>▪ Often the costs a business incurs are passed along to consumers and/or addressed in employee salaries</li> <li>▪ Will pharmacy chains stop doing business in Oregon and go to neighboring states instead? May impact access to care in Oregon; Skepticism was noted in response to this statement</li> <li>▪ Will there be additional OBOP agency costs, for example increased money for inspector's time? Concern regarding "nebulous investigations"</li> </ul> </li> </ul> </li> </ul>
Good of the Order	<ul style="list-style-type: none"> <li>❖ Wrap up and next steps <ul style="list-style-type: none"> <li>○ Pharmacist Consultant Karbowicz stated that the Board's next meeting is Thursday, October 4, 2018 and this topic is an agenda item. The minutes and related documents will be provided for Committee review and will be sent to the Board as a mailing.</li> </ul> </li> </ul>