



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

**Pharmacy Quality Assurance Commission
Pharmacy Business Practice Committee Meeting**

[DOH – Public Health Laboratories](#)

1610 NE 150th Street
Shoreline, WA 98155-9701

September 2, 2015

9:00 a.m. – 11:00 a.m. (in person and by Webinar)

You must register to receive dial-in information.

Register at <https://attendee.gotowebinar.com/register/7245072810797787393>

Once registered, you will receive an email confirming your registration, and information you will need to join the webinar.

*Note: Public discussion at this meeting is welcome. Written comments is always welcome before and after the meeting. Please submit written comments to wspgac@doh.wa.gov, email subject line: **Pharmacy Business Practice Committee.***

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| 1. Introduction, Agenda and Process | All |
| 2. Discuss <i>Draft PIC and Shared Accountability Rules - this is the first time that this potential business practices rule language will be discussed.</i> | |
| a. Review written comments. | Committee members |
| b. Open discussion | All |
| c. Discuss next steps. | All |
| 3. Plans for future meetings. | Committee members |

Potential Business Practices Rule Language Discussion Draft Including Staff Comments

First Review September 2, 2015

AMENDATORY SECTION

WAC 246-863-060 Licensed pharmacists—Employed as responsible pharmacist managers—Duty to notify ~~board~~commission.

(1) Licensed pharmacists employed as responsible pharmacist managers, also known as pharmacist-in-charge or PIC, for a pharmacy shall ~~at once~~ immediately notify the state ~~board of pharmacy~~ pharmacy quality assurance commission (commission) in writing of such employment and shall comply with ~~such~~ all instructions as ~~may be received~~ provided by the commission.

(2) A pharmacist shall ~~also at once~~ immediately notify the ~~state board of pharmacy~~ commission in writing of termination of employment as a ~~responsible manager~~ pharmacist-in-charge of any pharmacy location. ~~Please refer to WAC 246-869-070 for additional information~~

(3) A Pharmacist shall not be designated as the PIC for more than one pharmacy location without prior written approval by the commission, unless one or more of the other locations are licensed as a health care entity under RCW 18.64.450.

(4) A pharmacist approved by the commission to serve at multiple locations as the PIC at multiple locations shall:

Comment [DEB1]: A pharmacy's license becomes inactive without a PIC. Should there be a grace period or wait to see how stakeholders address this issue? Frequently asked question.

Comment [JAR2]: This language is problematic. What are we talking about here? What "instructions"? I know this is in the current rules, but let's fix this.

Comment [SA3]: Need to specify here that the PIC of a *single* pharmacy that is not a HCE is practicing onsite for a minimum of 30 hours per week or 50% of the operational hours of the pharmacy, whichever is less.

Comment [JAR4]: Or operate under a hospital pharmacy license under ESSB 5460?

Comment [JAR5]: Clarifies that it is the multiple locations, not the fact of being the PIC, which is subject to commission approval.

Comments submitted by (in the order they appear in the document):

DEB – Doreen Beebe, Program Manager

JAR – Joyce Roper, AAG

SA – Steve Anderson, RPh, Commission Member

(a) Practice pharmacy at each location for a minimum of 20 hours or fifty percent of the pharmacy's operational hours per week, whichever is less; and

(b) Conduct quarterly self-inspections of each site.

Copies of the self-inspections must be retained in the pharmacy for two years and made available for review inspection by the commission or its designee upon request.

(5) The PIC shall develop a written plan of correction within 30 days from the date a deficiency is found or documented in an inspection or self inspection of the pharmacy site.

(a) A copy of the plan of correction shall be retained in the pharmacy accompanied by the initiating inspection report and a quarterly written follow-up report.

(b) The follow-up report must document any significant progress towards the resolution of the deficiencies each quarter until the deficiencies have been resolved.

(c) These reports must be kept on file in the pharmacy for two years and made available for review inspection by the commission or its designee upon request.

AMENDATORY SECTION

WAC 246-869-060 Employers to require evidence of pharmacist's qualifications.

(1) It shall be the duty of every employer to require suitable evidence of qualifications to practice pharmacy before they permit anyone to be in charge, compound or dispense drugs on their premises.

NEW SECTION

WAC 246-869-058 Qualification to Become a Pharmacist in Charge

Comment [JAR6]: Is remote (audio-visual) practice permitted to count towards those hours?

Comment [JAR7]: Is there a description about what should be included in a "self-inspection"?

Comment [JAR8]: Why quantify? Wouldn't it be sufficient to document any progress towards resolution of the deficiencies?

Comment [SA9]: Follow-up report(s) should be substituted for report as it may take more than one quarter to resolve the deficiency(s).

Comment [JAR10]: Suggest amending the current WAC instead of writing a new one. This helps point out that there already is a requirement for the employer-license holder to vet the qualifications of employee-pharmacists, techs, etc.

(±2) A pharmacist must meet the following qualification to be designated the pharmacist-in-charge:

(a) Experience ~~Complete~~ as a licensed practicing pharmacist for at least one year ~~of pharmacy practice as a licensed pharmacist;~~ and

Comment [JAR11]: Suggest experience rather than "completion".

(b) Successful ~~Completion~~ of a commission approved pharmacist-in-charge training program either before appointment or within 30 days after the ~~appointment~~.

Comment [DEB12]: May need to consider providing an outline of training requirements/topics or stipulate that the training is offered/provided by the Commission.

(2) ~~The commission may authorize an exemption to the one year of pharmacy practice requirement if the pharmacist can demonstrate they are capable of carrying out the responsibilities of the pharmacist-in-charge position.~~

Comment [SA13]: Do we need or want to specify that the pharmacist appear before the PQAC at a business meeting or allow some other means of demonstrating capability?

Comment [JAR14]: Suggest deleting this, unless the Commission is prepared to identify the standards which must be met to satisfy the Commission to grant an exemption. Otherwise, there could be a claim of arbitrary granting/denying of exemptions.

NEW SECTION

WAC 246-869-062 Responsibilities of the Pharmacist-in-Charge

(1) Oversight and responsibility for ancillary staff and other employed pharmacists ~~Utilizing personnel to assist the pharmacist.~~ The pharmacist-in-charge (PIC) shall determine the extent to which personnel may be used to assist the employee or contracted pharmacist and shall assure that the pharmacist is fulfilling his or her supervisory and professional responsibilities. This does not preclude delegation to an intern or extern or delegation to ancillary staff consistent with WAC 246-863-095. The pharmacist-in-charge (PIC) ~~and the pharmacy employing the pharmacy personnel~~ shall retain all ~~professional and personal~~ responsibility for any assisted tasks performed by pharmacy personnel. ~~under his or her responsibility,~~ as shall ~~the pharmacy employing such personnel.~~ The PIC shall determine

Comment [JAR15]: Suggest put it here instead of as an "afterthought" in the last clause of the sentence.

Comment [JAR16]: I'm not sure what is meant by "personal" responsibility. If the phrase "professional and personal" means all responsibility, then rather than parse professional and personal, stating all responsibility should suffice.

Comment [JAR17]: There are too many "responsibilities" here.

~~the extent to which personnel may be utilized to assist the pharmacist and shall assure that the pharmacist is fulfilling his or her supervisory and professional responsibilities. This does not preclude delegation to an intern or extern.~~

Comment [JAR18]: Changing the order of these sentences brought more clarity to this subsection.

~~(2)The PIC shall verify that all personnel working in the pharmacy hold an active and appropriate license, registration or certification.~~

~~(3)The PIC shall ensure all pharmacy staff have adequate training to perform duties appropriate to the practice site.~~

~~(4)The PIC shall implement and maintain a quality assurance program for the pharmacy.~~

~~(5)The PIC shall ensure that all pharmacy personnel comply with all state and federal laws, rules, and regulations governing the practice of pharmacy.~~

~~(6) Upon appointment as the pharmacist-in-charge (PIC), the PIC shall review copies of reports of any inspections of the pharmacy within the previous two years.~~

Comment [SA19]: Include inspections and last self-inspection. Also include if no inspection has been completed within the last two years, the PIC shall review the last formal inspection by the PQAC.

~~(7)The PIC pharmacist-in-charge is responsible for:~~

~~(a) Maintaining the security of the pharmacy, and the security and accountability of all drugs stored in the pharmacy.~~

~~(b)Implementing policies and procedures regarding quality pharmacy services, including but not limited to:~~

~~(i) drug control,~~

~~(ii) drug distribution,~~

~~(iii) patient compliance accountability,~~

~~(iv) inspections, and~~

~~(v) recordkeeping.~~

~~(c)Subversion of the authority of the pharmacist in charge, by any person, by impeding the management of the prescription department in the compliance of federal and state pharmacy laws, rules, and regulations is a violation of the pharmacy license.~~

(8d) The PIC shall notify the pharmacy license holder of any violations or potential violations of any law, rule or court order existing within the pharmacy. If ~~within reasonable amount of time,~~ a plan of correction is not implemented within thirty (30) days or less, if patients are immediately endangered, ~~appropriate action has not been taken to address the issues in subsection (7) (d),~~ within a reasonable amount of time, the PIC shall submit a written ~~account~~ report to the pharmacy license holder with ~~and send a copy~~ simultaneously sent to the pharmacy quality assurance commission.

Comment [DEB20]: Does reasonable need to be defined?

Comment [JAR21]: Yes, see the re-write

(e9) Retaliatory action by the pharmacy license holder or any person associated with the license holder against the PIC for submitting a report under subsection (8) above or in fulfilling his or her responsibilities in assuring compliance with the laws of this state or of the United States relating to drugs shall be grounds for action against the pharmacy license under RCW 18.64.165. ~~Subversion of the authority of the pharmacist-in-charge, by any person, by impeding the management of the prescription department in the compliance of federal and state pharmacy laws, rules, and regulations is a violation of the pharmacy license.~~

Comment [DEB22]: Would this fit better under the license holder?

Comment [JAR23]: Yes, however, it would be worthwhile to address retaliation for submitting the reports to the commission or for requiring adherence to the drugs laws here. See suggested language

AMENDATORY SECTION

WAC 246-869-070 ~~Responsible manager~~ Pharmacist-in-Charge

Appointment - Pharmacy License Holder - Duty to notify commission.

- (1) Every ~~nonlicensed proprietor~~ pharmacy license ~~of holder~~ of one or more pharmacy ~~ies~~ locations shall place in charge of each pharmacy a licensed pharmacist who shall be known as the "responsible pharmacist manager," ~~or pharmacist-in-charge (PIC).~~

~~The pharmacy license holder shall be responsible for employing a professional, competent, and legally qualified pharmacist-in-charge.~~

Comment [JAR24]: This subsection seems redundant (see WAC 246-869-060 above).

(2) ~~The nonlicensed proprietor~~pharmacy license holder shall immediately report to the state ~~board of pharmacy~~pharmacy quality assurance commission (commission), in writing, the name of the ~~"responsible manager~~pharmacist-in-charge," who shall ensure that the pharmacy complies with all the laws, rules, and regulations pertaining to the practice of pharmacy. Every portion of the establishment coming under the jurisdiction of ~~the~~pharmacy laws and rules shall be under the full and complete control of ~~the designated pharmacist-in-charge~~such responsible manager.

Comment [JAR25]: This and the amendments to WAC 246-863-060 seem duplicative – reporting from both the PIC and the pharmacy license holder? Seems as though reporting from one should satisfy the requirement for notification.

~~(34) A now-licensed proprietor~~The pharmacy license holder shall ~~at once~~immediately notify the ~~board of pharmacy~~commission in writing of the termination of employment of a ~~pharmacist-in-charge~~responsible manager and the pharmacy license holder shall appoint a pharmacist acting as the PIC or a permanent PIC within 5 days of the departure of a PIC.

Comment [JAR26]: This seems duplicative of WAC 246-869-062(1). Perhaps the last sentence "Every portion . . ." should be moved into WAC 246-869-062(1).

Comment [JAR27]: Again, this duplicate notification does not seem necessary. WAC 246-863-060 puts this responsibility in the PIC. It should be one or the other, rather than both having to submit the same report.

(a) If the pharmacy license holder fails to employ a licensed pharmacist as the pharmacist-in-charge, due to extended illness, death, resignation, or for any other reason, the pharmacy license holder shall notify the commission in writing.

Comment [SA28]: The 5 days is in conflict to the 30 days below. Comments from stakeholders indicated they are having difficulty hiring PIC's. The language pulled from the Arkansas rule helps alleviate that.

(eb) The commission, at its discretion, may grant up to 30 days for the pharmacy license holder to employ a pharmacist-in-charge. Operating a pharmacy beyond the time limit set by the commission is a violation of rule and each day so operated will be a separate offense.

Comment [DEB29]: Draft states: the pharmacy license holder shall notify the PQAC in writing immediately, and appoint a new PIC, either temporary or permanent, within 30 days. If a new PIC is not employed at the pharmacy within 30 days, the pharmacy license holder must notify the PQAC and employ within the next 60 days, or such additional time at the discretion of the PQAC, a new PIC, or cease to operate as a pharmacy in the State of Washington.

Note: the pharmacy license becomes inoperable without a PIC. Suggest the language that Steve pulled from the Arkansas' rules.

(4). Please refer to WAC ~~246-863-060~~58 for additional information.

Comment [JAR30]: Agree with the above comment. Perhaps there could be some language re: petitioning for an extension due to extraordinary circumstances, such as but not limited to death, hospitalization, or other similar unforeseeable life events.

Comment [JAR31]: There is an -863-060 (see the first amendatory section above), but no -863-058.

NEW SECTION

WAC 246-869-072 Responsibilities of the Pharmacy License Holder

(1) The pharmacy license holder of each pharmacy, the pharmacist-in-charge, and all staff pharmacist shall share the responsibility of the legal operation of the pharmacy to ensure patient safety and compliance with all federal and state laws, rules, and regulations governing the practice of pharmacy.

(2) An immediate supervisor of a PIC of a pharmacy in the state of Washington shall be currently licensed in Washington as a pharmacist, pharmacy technician, or pharmacy assistant. A PIC working for a non-pharmacist pharmacy license holder may only be supervised by the non-pharmacist pharmacy license holder with respect to workplace policies which do not require the specialized knowledge of a pharmacist, such as, but not limited to, tardiness, absenteeism, respectful treatment of co-workers and customers. If the PIC is supervised in his or her professional capacity, the immediate supervisor of the PIC shall be currently licensed in Washington as a pharmacist. Such supervisor, as the agent of the pharmacy license holder, shall share the pharmacy license holder's responsibility to ensure patient safety and the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

(3) The pharmacist-in-charge and the pharmacist on duty shall control all aspects of the pharmacy practice. The pharmacy license holder shall not override the control of the PIC or pharmacist on duty decisions as it pertains to pharmacy practice.

Comment [DEB32]: 1. Removed "including all inspection" since the requirement for inspections is in rule. Suggested language stated: The pharmacy license holder of each pharmacy shall share responsibility with the Pharmacist-in-Charge (PIC) and with all staff pharmacists to ensure patient safety and the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy. The pharmacy license holder shall be responsible for employing a professionally competent, legally qualified Pharmacist-in-Charge.

Comment [JAR33]: This language is in conflict with WAC 246-869-062 where the pharmacy license holder and the PIC share responsibility for everything, including staff pharmacists, and here we put staff pharmacists on equal footing with the pharmacy license holder and the PIC. We cannot have the PIC and pharmacy license holder as the primary and also put the staff pharmacy on equal footing.

Comment [JAR34]: A pharmacy technician or assistant cannot be professionally supervising a pharmacist.

Comment [JAR35]: A pharmacy technician or assistant cannot be professionally supervising a pharmacist.

Comment [DEB36]: I believe this issue was voted down at the last meeting. Please verify if this section needs to be removed.

Comment [SA37]: I thought we were voting down the proposal for all pharmacy personnel involved in any aspect of pharmacy operations to be licensed. My experience through casework shows a definite need for the immediate supervisor to the PIC's to be licensed and accountable also.

Comment [JAR38]: I think we need something to introduce this "pharmacist on duty" because now we are shifting (delegating?) the PICs responsibility to any staff pharmacist who happens to be on duty. This is the type of blurring which made the PIC's responsibilities less clear and we should explore whether that is absolutely necessary. Instead, we could say that if multiple licensees are responsible for the breach of pharmacy laws or unprofessional conduct

~~(4) Any reprisal by the pharmacy license holder against the PIC or the pharmacist on duty for reporting to the commission policies, actions or inactions that compromise patient safety or violate state or federal laws, rules or regulations may be grounds for disciplinary action against the pharmacy license.~~

Subversion of the authority of the PIC by any person in impeding the management of the pharmacy in compliance with federal and state drug laws, rules and regulations shall be grounds for action against the pharmacy license under RCW 18.64.165.

Comment [BD(39)]: DEB: This was changed from shall to may since the decision to discipline is discretionary decision by the commission. If the violation is below threshold the commission may decide not to discipline but to issue a notice of correction or other action.

Comment [JAR40]: This is redundant of WAC 246-869-062(9). On the other hand, this would be an appropriate place for the previously deleted language which was more general than the submission of the report, so I added it here.

WAC 246-869-075 Pharmacy Compliance Officer

(1)The business or organization that licenses multiple pharmacies in Washington state shall designate a person as the pharmacy compliance officer, who ~~and they~~ must be a licensed pharmacist under chapter 18.64 RCW.

(2)If the compliance officer resides in another state, he or she must also be duly licensed as a pharmacist in that state.

(3) The business or organization shall immediately notify the ~~pharmacy quality assurance commission (commission)~~ in writing of the appointment of ~~at~~ the compliance officer.

(3)The compliance officer may be the PIC~~pharmacist-in-charge~~ or hold any other position within the business or organization.

(4)Upon appointment, the compliance office shall immediately review all ~~state and federal~~ inspection reports of the business' or organization's pharmacies that operate within the state of Washington.

(e5)The compliance officer and pharmacy license holder~~s~~ shall share the responsibility to ensure patient safety and legal operations of all the pharmacies licensed by the business or

Comment [DEB41]: Was there thoughts that this person could be someone other than a pharmacist?

Comment [SA42]: The following section needs to be inserted to address the above comment:

The Compliance Officer may also be a PIC, Director of Pharmacy, or hold any other position within the business or organization.

This addresses the stakeholders' complaint that they would have to hire a separate pharmacist to be the compliance officer, yet it still holds one person responsible for the safe and legal operation of their pharmacies in Washington.

Comment [DEB43]: The language provided by Steve states that the compliance officer "shall be licensed in WA as well as maintain pharmacist licensure in his/her state of original licensure."

Do you want them to maintain their original licensure as well as be licensed in the state in which they reside?

organization; including but not limited to, compliance with all federal and state laws, rules, and regulations governing the practice of pharmacy.

(36) The compliance officer shall be accountable to the ~~pharmacy quality assurance~~ ~~commission~~ for systemic violations of rules, laws, and chronic compromises of patient safety on behalf of the business or organization of the pharmacy license holder.

(7) ~~and~~ When directed by the commission, the compliance officer shall be responsible for submitting a plan of corrective action and ensure its implementation.

(83) If the compliance officer becomes disabled or leaves the employment of the business or organization, the business or organization shall immediately notify the commission in writing and appoint a new compliance officer, either acting or permanent within 30 days.

(a) If a new compliance officer is not designated by the business or organization within 30 days, the business shall notify the commission in writing and request an extension.

(b) Upon receipt of the request, the commission shall granted a 60 day extension. Additional time may be granted at the discretion of the commission.

(c) If ~~Failure to appoint~~ a new compliance officer has not been appointed within the time frame specified above, including any extension granted by the Commission, then ~~once the extension has lapse~~ the business or organization must cease to operate its pharmacies in the state of Washington.

Comment [JAR44]: Caution, pharmacies replacing PICs are only given 5 days. Why 30 days here?

Comment [JAR45]: This language should be consistent with the standard for granting extensions for pharmacies replacing PICs in WAC 246-869-070(4) – see my notes for that subsection.



Washington State Department of Health
 WA Pharmacy Quality Assurance Commission - Business Practices Committee

Issue Assessment – Accountability

Draft 2 – For Public Comment – May 15, 2015

<p>Concerns</p>	<ul style="list-style-type: none"> • The origin of most pharmacy statutes and rules occurred during a period when pharmacies typically were small businesses owned by pharmacists who operated them. Over the years, the reality has shifted to a preponderance of pharmacies with institutional or large corporate ownership (permit holders). • Lack of personal accountability of the permit holder, its officers, and the Pharmacist in Charge (PIC) prevents resolution of patient safety concerns and rule violations involving pharmacy operations. • This may lead to a "revolving door syndrome" of repetitively replacing lower level management, such as the PIC and/or staff, while core problem(s) or violation(s), which are rooted in policy, remain unresolved. Such policies may not be changed even in the face of serious adverse public safety events without rules clearly delineating accountability, penalty assessment, and plan of corrective action requirements for the permit holder, policy makers, policy enforcers, and facility management. • Experience on confidential disciplinary panels has led some Commission members to wonder whether there was an adequate legal framework to assign shared accountability between permit holders and professionals, and then act against the permit holders when necessary. Issues of shared accountability also can occur between multiple licensed pharmacy businesses that may have roles in the process from receipt of prescription through dispensing and counseling. • Accountability has limited meaning without the possibility of effective regulatory action. Washington law permits suspension or revocation of a pharmacy license, but there is no explicit statutory mention of intermediate penalties such as fines or enforceable action plans.
<p>Evidence</p>	<ul style="list-style-type: none"> • Many comments have come to the Commission, including through the open field item in the 2014 Washington Pharmacy Survey, showing concern that contemporary conditions often make it difficult for PICs and line pharmacists to exercise the degree of professional discretion to maintain practices that avoid error. • See “Concerns” regarding Commission members’ experience regarding shared accountabilities in the course of confidential disciplinary deliberations.
<p>Current Law (Summary and References)</p>	<ul style="list-style-type: none"> • Every operator of a pharmacy must place a pharmacist in charge (PIC). (RCW 18.64.020) Each non-licensed proprietor of a pharmacy must appoint a responsible pharmacist manager (RPM) “Every portion of the establishment coming under the jurisdiction of the pharmacy laws shall be under the full and complete control of such responsible manager” (WAC 246-869-070). There is no requirement for the PIC of a non-resident pharmacy to have a WA pharmacist license. • Washington law allows for suspension or revocation of a pharmacy license for violations of pharmacy law. There is no provision for fines for domestic (in-state) pharmacies, but fines of up to \$1,000 can be assessed on non-resident pharmacies (RCW 18.64.390). In contrast, there is authority under the Uniform Disciplinary Act (RCW 18.130) for assessing fines on licensed pharmacists, technicians or assistants, as well as other disciplinary actions short of license revocation or suspension such as

	<p>limitations on practice or additional training (continuing education).</p> <ul style="list-style-type: none"> • A January 25, 2015 memo from Assistant Attorney General Joyce Roper to the Commission, titled “Overview of Regulatory Authority For Licensed Business Entities” – for which the Commission waived attorney-client privilege on January 29 – confirmed existing legal authority for the Commission to proceed to enforcement if a licensed pharmacy related business shares responsibility for violation (“violated or permitted any employee to violate” a pharmacy law). Disciplinary sanctions could include negotiated settlements (not including fines), such as compliance with a plan of correction, that are lesser than suspension or revocation of the license.
<p>Other States (Summary)</p>	<ul style="list-style-type: none"> • States such as Alabama, Texas, Virginia, and West Virginia specifically address accountability. • Alabama and West Virginia shift accountability from the PIC to the permit holder if the permit holder is contributing to or causing a violation--West Virginia requires the PIC to address the permit holder in writing first. • Texas and West Virginia clarify PIC accountability versus permit holder accountability and assign accountability accordingly. The PIC is responsible for the practice of pharmacy and the permit holder is responsible for administrative and operational functions. Texas requires the permit holder to consult with the PIC for advice pertaining to these functions. • Virginia specifies disciplinary action against the permit holder for overriding the PIC. • Nebraska specifies disciplinary action against the permit holder for retaliation against an employee or patient who files a complaint with the DHHS. • Oregon is considering a new rule related to non-resident PICs but it would be better to hold consideration until action occurs on the proposal (expected May 28). Oregon now has an <i>optional</i> PIC training program. Idaho offers non-resident PICs a choice between licensure and registration (the latter to assure a point of contact). Arizona required non-resident PICs to have an AZ license for a number of years but temporarily rescinded this requirement • Arizona and New Hampshire reportedly also have provisions related to shared accountability (beyond AZ provisions on non-resident PICs). Further research may be needed on this; the Committee welcomes information on applicable provisions.
<p>Action Options (Rule Making or Other)</p> <p><i>These options are not mutually exclusive</i></p>	<p>At its meeting on April 30, 2015 the Business Practices Committee considered a wide range of options to improve the incentives for accountabilities by pharmacies (license holders) and pharmacy personnel. The Committee request public comments on the pros and cons the following possible options/“trial balloon.” The Committee will review all feedback prior to deciding on what ideas to move forward to in-person discussion and potential rule development.</p> <ol style="list-style-type: none"> 1. <i>All Committee members agreed that “shared accountability” should be addressed more completely, without change in WAC, through more careful attention to the role of firms (license holders) in the course of investigations, Commission disciplinary panel decisions on opening cases and determining charges, and approaches to settlements. This would build on the recent (January 2015) legal clarifications addressed under “Current Law” above.</i>

2. Public comment is requested on possible new requirements for the Pharmacist in Charge (PIC) to assure experience, focus and accountability:
 - Consider requiring pharmacists to have at least three years of post-licensure practice experience before becoming a pharmacist in charge unless given specific approval from the PQAC. This would prevent businesses from placing unsuspecting newly licensed pharmacists in the responsibility of the PIC position without having the experience. (Discussion noted that this could have impacts the difficulty of finding PICs and on the availability of jobs for recent pharmacy graduates.)
 - Consider requiring specific training for PICs, and/or support non-regulatory actions to increase the availability of such training.
 - Consider limiting the PIC position to one pharmacy and require that the PIC work in that facility at least 30 hours per week or 50% of the operational hours, whichever is less.
 - Consider requiring a newly appointed PIC be given a copy of and allowed to review the last two pharmacy inspection reports before assuming control and responsibility of the pharmacy.
 - Consider requiring all PIC's of non-resident pharmacies that regularly fill and ship prescriptions to patients in Washington State to be licensed as pharmacists in the state of Washington, so that they will learn WA requirements and be accountable to observe them. (Other options such as registration may or may not achieve the same goals.)

3. Public comment is requested on possible new requirements related to relationship between license holder and the PIC or other pharmacists:
 - Consider forbidding businesses from coercing or forcing pharmacists to violate their professional judgment.
 - Consider forbidding businesses from requiring the PIC to implement business practices that compromise patient safety, overriding the PIC's decisions with regard to patient safety or compliance with state or federal rules and regulations, or enacting policies that undermine or interfere with the PIC's abilities to maintain such safety and compliance.
 - Consider prohibiting employer reprisal for refusing to compromise patient safety.
 - Consider shifting accountability from the PIC to the permit holder if the PIC notifies the permit holder in writing of policies or violations adversely affecting public safety or compliance with state or federal rules and regulations. (Some Committee members expressed concern that this might work contrary to the principle of shared accountability apportioned based on specifics of an event.)
 - Consider requiring all supervisors of Washington PIC's to be licensed pharmacists in the State of Washington.
 - Public comment is requested on possible other means, including changes in WAC, that would further clarify the basis for assigning shared accountability between the PIC and permit holder.

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| | <ol style="list-style-type: none">4. Public comment is requested on possible new requirements for license holders intended to increase accountability:<ul style="list-style-type: none">• Consider requiring businesses to have a pharmacy regulations compliance officer who is responsible for all operations of the company to the Commission and who is licensed as a pharmacist in Washington State.• Consider requiring all managers or corporate officers involved in any aspect of pharmacy operations who reside in or maintain a permanent office in Washington State and who make, apply, enforce, or are responsible for policies that affect the safety of patients or compliance with federal or state pharmacy laws and regulations in pharmacies operating in the state of Washington, to be licensed in Washington State as pharmacists or pharmacy assistants.
5. The Committee noted two areas of action related to this topic of accountability, which already are under development.<ul style="list-style-type: none">• As authorized by the Commission on March 12, a work group will be established to consider changes in the methods of pharmacy license inspections. This could include a Statement of Charges/Plan of Correction approach, with appropriate oversight of implementation of planned corrections including potential for disciplinary actions. The CR-101 published October 30, 2014 allows for consideration of rule changes that might be necessary to implement changes in inspection processes.• The Commission already supports legislation to establish authority to levy fines on licensed pharmacies, in order to added options for enforcement. This was the subject of Department of Health request legislation in 2015, with PQAC support. This is not rulemaking topic due to lack of statutory authority. |
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The Committee requests public comment on the actions, options, and “trial balloon” above. Comments received by **June 5, 2015**, will be considered by the Committee for further action on these issues at the Committee or Commission. Submit comments to WSPQAC@doh.wa.gov.