



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.