STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
June 3, 2021 - Minutes

Convene: Chair, Tim Lynch called the meeting to order June 3, 2021, 9:00 a.m.

Commission Members:
Tim Lynch, PharmD, Chair
Teri Ferreira, RPh, Vice Chair
Jerrie Allard, Public Member
Bonnie Bush, Public Member
Hawkins DeFrance, Nuclear Pharmacist
Patrick Gallaher, BS, BPharm, MBA, MPH
Ken Kenyon, PharmD, BCPS
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Judy Guenther, Commissioner
William Hayes, PharmD, CCHP

Staff Members:
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy Commission
Christopher Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Lindsay Trant, Rules and Legislative Coordinator
Joanne Miller, Program Manager, Pharmacy Commission
Amy L Robertson, Pharmacy Admin.

1. Call to Order Tim Lynch, Chair

1.1. Meeting Agenda Approval – June 3, 2021

MOTION: Craig Ritchie moves to accept meeting agenda; Hawkins DeFrance, second. Motion carries, 11:0.

2. FDA MOU Update

Lauren Lyles-Stolz updated the commission FDA's responses to questions the commission posed in a letter sent to the FDA on January 8, 2021. Lauren also informed the commission that the National Association of Boards of Pharmacy (NABP) have requested the FDA extend the delay in enforcement of § 503A(b)(3)(B)(ii) of the Federal Food, Drug and Cosmetic Act (FD&C Act). This section of the FD&C Act limits out-of-state distribution of compounded drug products by pharmacists, pharmacies, and physicians, to no more than 5 percent of the total prescription orders dispensed or distributed in States that have not entered into the FDA's memorandum of understanding (MOU). NABP has explained to FDA that the continued delay in enforcement will allow states to engage in relevant rulemaking and legislative activity to approve and implement the MOU.

Lauren explained that based on the FDA's response and NABP's request, commissioners could consider the following action as it relates to the FDA's MOU: (1) approve the MOU, (2) reject the MOU, or (3) direct staff to contact FDA to request delayed enforcement without limitation until more states establish a plan to move forward. PQAC would need to decide whether to sign or not sign the FDA MOU.

MOTION: Craig Ritchie moves the commission direct staff to write to the FDA requesting a two-year delayed enforcement of § 503A(b)(3)(B)(ii) of the FD&C Act, until more states are able to establish a pragmatic plan to move forward with rulemaking and any necessary legislative action/statute changes (option #3). Teri Ferreira, second. Motion carries, 11:0.

3. Old Business- The Commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. Information/Action

3.1. Guidelines for investigating misfill cases

Lauren Lyles-Stolz updated the commission on the procedure for investigating misfill cases. There are other possible questions the commission might consider in updating these guidelines to understand the environments (trends, patterns vs. isolated events) that may be impacting patient safety.

There is jurisdiction overlap on the rulemaking process with L&I and workplace conditions. The commission has worked with L&I in the past on this overlap. Lauren reached out the L&I prior to this meeting and let them know we were working on this item. They did not have any concerns on this issue at this time.

Taifa Peaks (stakeholder) asked if L&I was considering rulemaking changes regarding professional work hours for pharmacists (and persons with degrees). To the best of our knowledge, no. However, the data PQAC is gathering may open conversations in the future.

MOTION: Craig Ritchie moves we take the following action as discussed:

1. Create a subgroup to formulate questions related to gathering additional data for misfills.
2. Request Dr. Lyles-Stolz to work with American Pharmacists Association (APhA) to better understand when results from their survey will be completed and how we can encourage participation in that survey.
3. Use the data gathered from the additional questions to better understand what issues/factors are impacting patient safety.
4. Consider external guidance for licensees about what questions the commissioners would consider for misfill cases.

Patrick Gallaher, second. Motion carries, 11:0.

3.2. Zero Report and Suspicious Orders

Christie Strouse, Deputy Director, reported PQAC staff has encountered operational challenges related to WAC 246-945-585 specifically as it relates to compliance tracking. We request the commission to consider modification to the rule to mitigate these operational challenges. In addition, consider other potential technical fixes.

MOTION: Teri Ferreira motions to accept Option 1: Zero Report Technical Language Rule Revisions creation language to file CR101 to amend rule and the extend enforcement discretion for zero reports for 12-months from July 3, 2020. Jerrie Allard, second. Motion carries, 11:0.

5. Summary of Meeting Action Items

1. **Suspicious Order Reports** – staff follow thru on action from option 1and develop communication to licensees regarding enforcement discretion.
2. **Guidelines for investigating misfill cases** – commission members were asked to email Lauren Lyles-Stolz (cc: Joanne Miller) if interested in joining the subcommittee.
3. **FDA MOU Update** – Follow up letter to FDA requesting delayed enforcement action on §503a.

Business Meeting Adjourned, 10:37 a.m.

Next scheduled business meeting: **June 4, 2021**
Business Meetings
9:00 a.m.
Virtual – by Webinar