STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
May 13, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order May 13, 2022, 9:01 a.m.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Helen H. Jung, PharmD, MBA
Ken Kenyon, PharmD, BCPS
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Matthew Ray, PharmD

Commission Members Absent:
Bonnie Bush, Public Member
Patrick Gallaher, BS, BPharm, MBA, MPH
Ann Wolken, PharmD, RPh

Staff:
Marlee O'Neill, Interim Executive Director, Pharmacy Commission
Lindsay Trant, Interim Deputy Director, Pharmacy Commission
Christopher Gerard, AAG
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

1. Call to Order Teri Ferreira, Chair

1.1 Meeting Agenda Approval – May 13, 2022.

MOTION: Craig Ritchie moved to approve the meeting agenda for May 12, 2022. Ken Kenyon, second. Motion carries, 11:0.

2. New Business

2.1 Compounding Animal Drugs from Bulk Drug Substances – Taifa "Nomi" Peaks informed the commission that staff members recommend the commission affirm that while it is aware of the FDA's GFI# 256, Washington law only permits a pharmacist in a state-licensed pharmacy to compound animal drugs from BDS for office stock for nonfood-producing animals if one of the exceptions in RCW 18.64.011(21) applies, or the pharmacy has also obtained a manufacturer license. Exceptions:

- The activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, personally prepares, compounds, packages, or labels such substance or device.
- The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;

- The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;
- The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or
- The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

MOTION: Craig Ritchie moved to direct staff to create an FAQ to address the exceptions discussed and clearly identify what is and is not allowed. Jerrie Allard, second. Motion carries, 11:0.

Stakeholder input:

- **Dawn Ipsen, chair, WSPA** Compounding Special Interest Group (SIG) and **Michelle Moser** (owner, Makers Compounding Pharmacy in Mount Vernon, compounding pharmacist) asked/discussed the following:
  1. If a compounded medication is needed on Saturday, and the pharmacies do not open until Monday, do these exceptions apply?
  2. Does FDA's GFI #256 allow veterinarians to have office stock to resell? Nomi Peaks – the FDA's GFI# 256 at page 16; section 4, may help address question about resale.
  3. When will the compounding subcommittee meet?

- **Aja Senestraro, Veterinarian, Veterinary Board member** – an FAQ would be very helpful. Dawn described a very common scenario. The whole office use and dispensing from that office use is not well understood.

2.2 Plan for Return to In-person Meetings

MOTION: Ken Kenyon moved to hold the July 2022 meeting virtually as it is not reasonably safe to hold the meeting in person and to have staff explore venues to reserve for future in-person meetings once it is reasonably safe to do so. Craig Ritchie, second. Motion carries, 11:0.

3. Rules and Legislative Updates.

3.1 Overview of Rules Process Presentation – Joshua Munroe delivered a presentation on rules and the rulemaking process.

3.2 Update on Uniform Facilities Enforcement Framework – Lindsay Trant updated the commission on the UFEF: The draft is almost finished – it includes adding fining authority, placing conditions on a license, and a statement of deficiencies/plan of correction process for facility enforcement in addition to the process we have for inspections. The division will send the full request to the agency to consider presenting it the legislature in 2023.

3.3 Implementation for SHB 1675: Dialysate/dialysis device manufacturer and wholesalers – Joshua Munroe updated the commission on the implementation of SHB 1675, specifically for the commission to consider amending WACs 246-945-090 through –093 to include manufacturers and wholesalers.

MOTION: Jerrie Allard moved to direct staff to draft a policy document to review at the next meeting as well as staff continue to monitor the priority list of our rulemaking projects. Craig Ritchie, second. Motion carries, 11:0.

Stakeholder input:

- **Gail McGaffick,** lobbyist, Fresenius Medical Care North America urged the commission to prioritize this issue. Also, if a guidance document is issued, can stakeholders legally rely on the guidance document in lieu of rules?

  Chris Gerard – informed the commission the question cannot be answered until the guidance document is complete.

- **Jessica Fortescue,** lobbyist, Baxter Healthcare – agree with Gail to speed up and prioritize the rulemaking if possible.

- **Jenny Arnold,** WSPA – this law change was reflecting what is currently existing in practice and ensure the law is up to date and accurate. I do not think it is urgent, but important.

3.4 Initial Discussion for Rulemaking on Accessible Labeling – Joshua Munroe reviewed the status of CR-101 related to accessible labeling. A survey distributed to licensees was proposed for the purpose of collecting data on whether and how accessibility services are currently provided by licensees. Lindsay Trant informed the commission the status of PQAC staff resources and how we are moving forward to complete this rulemaking.

Craig Ritchie would also like to have information from software vendors. Matthew Ray expressed concern to specifically connect to the more rural stakeholders.

MOTION: Craig Ritchie moved to authorize staff to develop a survey to licensee(s) to determine what is available and what impact is anticipated. Hawkins DeFrance, second. Motion carries, 11:0.

Stakeholder input:

- **Sharla Glass, Envision America** – suggests obtaining guidance into the standards from USP the committees that drafted Chapter 17 and 1265. As well as Wisconsin Health Literacy group has a lot of information.

- **Jenny Arnold, WSPA** – Nevada also has rules that could be used as a model. Encourage the commission to consider a rule making workshop.

- **David Streeter, Washington State Hospital Association** – An important rule making and would like to offer to help develop and distribute the survey. Technological capabilities required of pharmacies to implement both vision/language translation services. Also, the cost element has varied greatly. I have other recommendations that we would be happy to provide to the commission offline.

- **Don Downing, University of Washington School of Pharmacy** – the definition of label should be considered broader than the traditional prescription container label and that cloud-

based information should be considered part of a label, even if it's a QR code or something to ensure patients and non-resident pharmacies and providers can access the information needed for safety. I have not heard any discussion about the effectiveness and safety of these various solutions. Finally, small business economic impact study would need to be addressed.

- **Marci Carpenter, President National Federation of the Blind in Washington and member of the Federation's national Board** – we also would like to partner with the commission with the goal that everyone have safe, timely, and independent access to prescription label information.

  Domeg Moore, Health Equity Circle Language Access Team – a team of health science students, ready to collaborate on this issue. What is the typical time frame for data collection process? Also, could a policy statement be applied during the rulemaking process for this issue?

  Lindsay Trant responded once the survey goes out, it would be out for a few weeks and then determine the results. The commission would need to determine if a policy statement is needed. A policy statement is not as feasible as it would require a similar amount of stakeholder work as rulemaking to determine what is included in the policy statement.

3.5 Emergency rule refiling – COVID CII Prescribing WSR 22-07-063

MOTION: Craig Ritchie moved that the commission find that the emergency still exist and that emergency rule WSR 22-07-063 should be refiled. Hawkins DeFrance, second. Motion carries, 11:0.

MOTION: Craig Ritchie moved that the commission allow staff to insert correct rule number pertaining to dispensing emergency oral CII prescription drugs. Hawkins DeFrance, second. Motion carries, 11:0.

3.6 Emergency rule refiling – Medication Assistance WSR 22-07-063

MOTION: Craig Ritchie move that the commission find that the emergency still exist and that emergency rule WSR 22-07-063 should be refiled. Hawkins DeFrance, second. Motion carries, 11:0.

4. Open Forum.

- **Jenny Arnold, WSPA**
  - **Medication errors being criminally liable** – Tennessee Nurses case where nurse was found criminally liable for having a medication error in her practice setting. I ask the commission be mindful and potentially bring up on a future meeting the discussion of criminalizing medication errors vs. keeping with a just culture and looking at systems of errors and ensure we are committed to transparency, open discussion of medication errors, and not criminalizing any one individual that might be caught in that process. Many of us reviewing the TN Nurses case saw opportunities where better processes should have been put in place to minimize. I think that individual was left holding the bag. ISMP write up also addresses criminalizing medication errors.

- **White bagging** – there is an absolute urgency for the commission to address this issue. The compounding committee is working on this, but urgently need to have a meeting of the compounding committee to regulate the process of white bagging. Our pharmacies are being put in very compromising positions having to manage and dispense medication that have not been their possession. There is concern it is only a matter of time before patient harm occurs because of white bagging.

- **Pharmacist screening/evaluating** – the ability of a pharmacist to offer a screening or some evaluation such as blood pressure was tied directly to medications and having a medication or diagnosis code on file. I think that compromises the ability of pharmacists to offer blood pressure screening or other services that have been consistent with the practice of pharmacy for the last (at least) 20 years. I think we need to look at the potential of opening up rules. There are other emergency proclamations needing to be evaluated and potentially discontinuing.

- **Marci Carpenter, National Federation of the Blind** – thanks the commission for being willing to move to using Zoom. Apple's screen reader does not work well with GoToWebinar.

- **Erika Anderson** re: non-resident pharmacies. Is there an update regarding the system for stakeholders to validate the non-resident pharmacies who do not follow the minimum requirements and require a third-party inspection – outside of sending a public records request? Secondly, regarding approved third-party inspections, it is not clear if California Board of Pharmacy report and there was no other third-party … is that acceptable as a third-party even though it is not listed in the policy statement and inspection from another state who is following minimum requirements.

  Lindsay Trant mentioned the option now is the public records request, but this has been submitted as a request for the new licensing platform (HELMS) which is quite a way off, but they are aware.

  Commissioner Tim Lynch responded that the out-of-state licensees go through an exception process with a quorum of the commission. If they are not able to provide the documentation for licensure, a quorum of the commission reviews each application and determines if the submitted materials are acceptable or may ask for additional information. If they are an approved licensed pharmacy in Washington, they either met all the requirements or have gone through the exception process.

  Chris Gerard: The way that the directive is written, the non-resident pharmacy can submit an inspection report from any approved inspection program, not restricted to their home state or the one third-party inspection program that is approved.

5. Commission Member Reports. *Information/Action.*

5.1 Commissioner Reports

- **Chair**
  - **NABP Annual Meeting** – Jerrie Allard and Teri Ferreira will be attending the annual NABP meeting next week. Teri will be the voting delegate and Jerrie is the alternate for PQAC.
  - **Northwest Pharmacy Convention** – Nomi Peaks and Teri Ferreira will be presenting at the end of May.
- **Pharmacy Practice Subcommittee** – met in November and tasked staff with a few action items. Since that time staff have revised the sample AUP with the subcommittee's feedback as well as revisited the misfill investigation guidelines. Both of these documents will return to the subcommittee prior to presenting to the full commission. The subcommittee will also take up the

pharmacy assistant scope of practice questions raised in the last business meeting. Next meeting June 14, 2022.

- **Compounding Subcommittee** – date of next meeting has not been set.
- **Legislative Subcommittee** – meeting Friday, June 3. Will meet regularly on the first Friday of each month thereafter.

5.2 Open discussion related to items or issues relevant to commission business/pharmacy practice – None.

6. Staff Reports *Information/Action.*

6.1 Interim Executive Director – Marlee O'Neill

- **Scheduling meetings** – Please respond if staff reaches out to schedule meetings.
- **Staff Kudos** – Attorney General Ferguson announced a resolution in a case against opioid distributors. Last week an AAG contacted Marlee and wanted to thank DOH staff for their assistance. I wanted to publicly acknowledge OILS, PQAC, OCS, etc. staff spent hundreds of hours explaining our processes and procedures, going over laws and rules, ILRS reports, gathering files, documenting, being deposed and signing declarations… all under significant time restraints during their/our regular duties.
- **Staffing update** – hired a permanent Deputy Director for the commission: Lindsay Trant!

6.2 Deputy Director – Lindsay Trant

- Thank you all.
- **Staffing update** –
  - **Rules and Legislative Coordinator** – Joshua Munroe has been permanently hired for this position.
  - **Open Positions**
    - **Permanent Pharmacy Inspector** – interviews have completed and moving through the recruitment process.
    - **Project Pharmacy Inspector** – of the three positions, one has been filled, a second one soon, and one remaining.
    - **Nonpermanent HSC4** – reposted.
    - **Pharmacy Inspector Supervisor** – reposted.
    - **Executive Director** – reposted to reflect the pharmacist qualification is a preferred requirement.

6.3 Assistant Attorney General – Christopher Gerard

- **Accessible Labeling Item** – to provide further feedback, I would highly recommend the commission not consider a policy/guidance document related to this issue. The amount of work it will take to put this together would be the same amount of work put into rulemaking.
- **Staff Kudos** – Thank you, Marlee, for recognizing the work and effort on the opioid distributor case. The pharmacy commission was heavily emphasized in the litigation which involved significant amount of time for DOH/PQAC staff.

7. **Summary of Meeting Action Items –** Commissioner and staff will revisit action items identified during today's business meeting.

- **2.1 Compounding Animal Drugs from Bulk Drug Substances.** Staff will craft an FAQ to address the exceptions and definitions of manufacturers in the questions raised today.
- **2.2 Plan for Return to In-person Meetings.** July meeting will be remote. Staff will explore sites for future meetings.
- **3.3 Implementation for SHB 1675: Dialysate/dialysis device manufacturer and wholesalers.** Policy statement and guidance document will be developed.
- **3.5 Implementation for SHB 1675: Dialysate/dialysis device manufacturer and wholesalers.** Staff will craft a survey for stakeholders to assist in moving forward with the rulemaking process.
- **3.5 Emergency rule refiling – COVID CII Prescribing WSR 22-07-063.**
- **3.6 Emergency rule refiling – Medication Assistance WSR 22-07-063.**

Business Meeting Adjourned – 11:47 am