



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION
Meeting Minutes
December 20, 2019
Highline Community College
Building 8 Mt. Constance Room
2400 S 240th St
Des Moines WA

CONVENE

Chair, Tim Lynch called the meeting to order at 8:00 a.m.

Commission Members:

Kenneth Kenyon, PharmD, BCPS
Uyen Thorstensen, Pharmacy Technician
Teri Ferreira, RPh, Vice-Chair
Steve Anderson, RPh
Craig Ritchie
Jerrie Allard, Public Member
Patrick Gallaher, RPh
Tim Lynch, PharmD, Chair
Sepi Soleimanpour, RPh, MBA-HA
Olgy Diaz, Public Member
Kat Wolf-Khachatourian, PharmD

Staff:

Lauren Lyles-Stolz, Executive Director
Pharmacy
Tracy West, Deputy Director
Chris Gerard, AAG
Doreen Beebe, Program Manager
Bonita Campo, Office Manager
Marlee O'Neill, Director of Office
Inspection and Legal Services

Absent Commission Members:

Bonnie Bush, Public Member - excused
Judy Guenther, Public Member - excused
Matt Ronayne - excused
Michael Sieg - excused

CLOSED SESSION - CASE PRESENTATION

The Commission entered into a closed session to discuss proceedings concerned with discipline of license holders pursuant to RCW 42.20.140(1).

The Commission entered into a closed session for case presentations at 8:05 a.m.

The Commission reconvened from the closed session at 8:57 a.m.

Chair, Tim Lynch called the business meeting to order at 9:10 a.m.

1. Call to Order

December 20, 2019 Meeting Agenda Approval

MOTION: Craig Ritchie moved to approve the December 20, 2019 meeting agenda. Teri Ferreira seconded. **MOTION CARRIED: 12-0**

October 23, 2019 Meeting Minute Approval

MOTION: Craig Ritchie moved to approve the October 23, 2019 meeting minutes. Steve Anderson seconded. **MOTION CARRIED: 12-0**

October 24, 2019 Meeting Minute Approval

MOTION: Craig Ritchie moved to approve the October 24, 2019 meeting minutes. Teri Ferreira seconded. **MOTION CARRIED: 12-0**

October 25, 2019 Meeting Minute Approval

MOTION: Craig Ritchie moved to approve the October 25, 2019 meeting minutes. Teri Ferreira seconded. **MOTION CARRIED: 12-0**

2a. Consent Agenda – Routine Approvals

2.1 National Precursor Log Exchange Monthly report –November 2019

2.2 Pharmaceutical Firms Application Report Approval

a. Closed - October 18, 2019 thru December 10, 2019

b. New/Open – October 18, 2019 thru December 10, 2019

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)

a. Kaiser – Specialized Functions\

b. Optum Pharmacy

c. Suncrest Pharmacy

d. Washington Pharmacy

e. Alto Pharmacy

2.4 Pharmacy Technician Training Programs

a. Hilltop Pharmacy LLC

b. Kadlec Regional Medical Center

c. Moses Lake Community Health Center

d. Ray’s Pharmacy

e. Sy Pharmacy and Wellness

f. Tim’s Pharmacy and Gift Shop

g. Value Drug

Jerrie Allard asked to pull item 2.3c from the consent agenda and recused herself from voting on that item.

MOTION: Steve Anderson moved that the Commission approve agenda item 2.3c. Craig Ritchie seconded.

Kat Wolf-Khachatourian asked to pull item 2.3b from the consent agenda and recused herself from voting on that item.

AMENDED MOTION: Steve Anderson moved that the Commission remove agenda items 2.3b and 2.3c and approve remaining agenda items. Craig Ritchie seconded. **MOTION CARRIED: 11-0**

MOTION: Steve Anderson moved that the Commission approve agenda item 2.3b. Craig Ritchie seconded. **MOTION CARRIED: 11-0**

2b. Regular Agenda/Items Pulled from 2a. No discussion.

3. Old Business

Update on Communication and Resolution program (CRP) – memorandum of understanding (MOU). Chris Gerard led the discussion on the work of the subcommittee. He explained that the template used for the MOU is the same as the Osteopathic board, requiring mostly terminology changes from Osteopathic to PQAC.

Update on CBD in pharmacies. Chris Gerard updated the Commission on his research into CBD in pharmacies. Chris was unable to give any clear options at this time without additional work with the AAG's that work specifically with liquor and cannabis. The Commission agreed to wait for further analysis from Chris.

4. New Business

Consider a request by Walgreens for a specialized function for pharmacy technicians to deliver filled prescription to secure lockers for patients opting into the service provided for an employer group.

Sepi Soleimanpour recused herself from this discussion and any subsequent vote.

Lorri Walmsley, RPh, Director Pharmacy Affairs -Walgreens addressed the Commission to report on their efforts to provide secure drug delivery to employees on the Microsoft campus. She detailed the pharmacy's plans to deliver employee prescriptions to secure lockers. Employees would be required to scan a QR code to open the locker and retrieve their drugs. They are currently waiting for PQAC approval before building out the workflow to allow security to open the locker in a failsafe situation.

The Commission had a robust discussion. Some of the concerns included:

- security of lockers;
- documentation of pharmacist counseling;
- methods use to confirmation of delivery and pick up
- whether technicians have legal authority to possess and store the drugs
- issues around license of location; pharmacy scope of practice;
- definition and requirements of a common carrier
- legal pathway for licensing options for extensions of a pharmacy; and t
- delivery outside of a pharmacy is not provided in chapters 69.41 and 18.64 RCW

Chris Gerard, AAG shared that the current analysis written by Tracy West is consistent with PQAC's previous position on the storage of drugs outside a licensed pharmacy. Drugs must be stored and placed in a location where somebody has legal authority to do so. The key piece in chapters 69.41 RCW is the definition of practitioner and if pharmacies have the authority to dispense drugs in the manner requested.

No action taken. The Commission directed staff to come back with further analysis to include the regulation of a common carrier, and if there is a legal pathway to allow a pharmacy to store patient drugs outside the pharmacy for patient pick-up.

The Commission adjourned for a break at 10:20 a.m.

The Commission reconvened at 10:37 a.m.

Discuss the scope of practice for pharmacy technicians as it relates to administration of immunizations. Review proposals from Bartell Drugs and Albertsons and provide direction.

Patrick Gallaher and Steve Anderson recused themselves from discussing and voting on this item.

DISCUSSION: Tracy West reviewed the two AUP's requesting approval for pharmacy techs to administer vaccinations under the supervision and practice of a pharmacist who has an appropriately executed collaborative drug therapy agreement (CDTA) to immunize. Her discussion focused on whether the request should be considered permissible as a general practice and as well as in relation to this specific request. She shared that 18.64A gives the Commission broad authority to set the scope of practice for pharmacy technicians. Tracy explained that her analysis lays out the pharmacist scope of practice. She shared that allowing technicians to administer vaccines could be an option, but there are things the commission should consider when allowing this practice. The pharmacist should make all the decisions, complete the intake and assessment work, and prepare the immunizations. The technicians should only be administering the vaccination. Determining who can or cannot receive an immunization is discretionary. She feels the Commission must ensure there is a workflow or procedure in place affirms the technician is only administering the immunization. There are options outlined in her recommendations. Tracy feels that under current rules, there is a pathway for this and there will definitely be one with the proposed rules.

Initial concerns included CDTAs and how they are written. If administering vaccines should be included under specialized function for pharmacy technicians, if so this would require additional approval. How do we ensure pharmacists is completing the assessment, is creating checkboxes for professionals appropriate rather than relying on the complaint process? What is the appropriate training? Should training include compounding and reconstituting, administration techniques, selection criteria of technicians chosen for training, and how to evaluate their competency? What consistent standards/components of training must be included in a guidance document?

Rob Geddes, Director of Pharmacy, Regulatory Affairs for Albertsons, addressed the Commission. He explained that they did not place training into the AUP so it was not a blanket delegation, but only specific to the technicians selected for training. The Chair stated that he would like to see that in the AUP as well as their selection criteria and how techs are evaluated for competency.

Mr. Geddes explained that they operate out of Idaho and with the recent changes to that state's rule rewrite they were approved to conduct a pilot project. In October 2016, they were granted a waiver to run a pilot within the state in conjunction with WSU. Training was vetted through that process. Adjustments were made after the pilot to make sure the training was adequate. The training was conducted in December of 2016, and the pilot ran through May of 2-17. Twenty-five pharmacy techs took WSU training and within 6 months, there had been 953 immunizations given with zero adverse events. Idaho now has over 500-trained techs that have taken WSU's course and are providing immunizations. The Idaho Board of Pharmacy reports that there have

been no adverse events in three years.

Mr. Geddes shared that the Washington State Technician Immunization training is voluntary and consists of 10 hours of instruction both at home and live. Techs must pass an assessment, a knowledge test and live demonstration. They are trained in single use, pre-filled syringes as well as reconstitution and multiple use vials. The first patient(s) administration is observed by a pharmacist. Idaho has policies and procedures that this operates under which he will add to their AUP to retain its integrity. Idaho's immunization rate increased by 39% for flu and 37% for others during the 2018-19 flu season.

Julie Akers, WSU College of Pharmacy and Pharmaceutical Sciences addressed the Commission to respond to Tracy's question if the training had to be approved by the Idaho Board of Pharmacy. Ms. Acres explained that there was no specific training mentioned, just that training had to be developed. WSU developed a training that covers technician duties as they relate to the administration of immunizations. It is the exact same training pharmacists take, just has less clinical decision making and pieces that the tech will not be involved in. WSU has signed a contract and is rebranding to be a nationally available pharmacy technician training program.

Also discussed was if the Commission is required to approve the training since they have to approve other technician training programs. Teri Ferreira asked if the training requirements and selection criteria could be identified in a guidance document without calling out specific programs. Tracy confirmed stating that the purpose is to both help the Commission and staff who process the AUP's ensure that all the standards and requirements have been met and that the document can be based off of the WSU training program but does not have to specify that program.

MOTION: Teri Ferreira motioned to approve with a guidance document.

FIRST AMENDED MOTION: Teri Ferreira amended her motioned to approve the two AUP's subject to outlining a training program, which is modeled after the WSU training program, and to identify the selection criteria for who is eligible to do this work. Approval is pending the delivery of those products. Craig Ritchie seconded. ***There was no vote on this motion***

DISCUSSION: Tracy noted that the Bartels AUP does include language stating the tech must complete a certification of immunization administration program. Mr. Lynch commented that Bartels could use WSU's training criteria to satisfy their AUP requirements.

Mr. Geddes asked if they needed to wait for another meeting for additional approval. The Chair stated they would need to amend their AUP to reflect the training and selection criteria to satisfy the requirements.

Julie Akers commented that they did not specifically add language regarding selection criteria to the AUP's that she has helped with because current statute states that a pharmacist can decide whom to delegate to. Mr. Lynch stated that the exact language is more appropriate as it is a discretionary function of a pharmacist to delegate.

Both AUP's state that the pharmacist will retain all of the discretionary function and will only delegate to techs who have gone through a certificate program. Ms. Acres agreed to provide Bartels' language with learning objectives.

Ken Kenyon asked for clarification about adding specific selection criteria to the AUP, which is a business function, defining what is in the training program, and defining a specialized function. Chris Gerard, AAG explained that requiring an ACPE accredited immunization training program in the guidance document means creating a standard and a specialized function that would have to go in a rule. If that will be the guidance, it needs to make its way into a rule to be an enforceable standard. He explained that it would be a deficiency if a tech did not meet the training requirement hours, and would have to be enforced. Mr. Lynch contended that techs could argue it is within scope because it is a delegated function, and technically, there is no legal basis for the Commission to deny an AUP. Chris Gerard stated that he needs to double check the new rules and suggested in the interim to adopt an interpretive statement. After a vigorous conversation, it was agreed that a specific training program not be called out in the guidance document, but rather to make clear pharmacists are responsible for all decisions made leading up to the administration of the immunization and that the AUP states that delegated techs must have proper training. Tracy West stated that the department could put out a newsletter article as an educational tool for licensees.

SECOND AMENDED MOTION: Teri Ferreira amended her amended motion to approve the two AUP's as written, one including specificity of training, and the other simply stating that the techs will be trained. The Commission will develop a guidance document that would give pharmacists and pharmacies the specific training expectations and the pharmacist's responsibilities. Sepi Soleimanpour seconded.

DISCUSSION: The Chair requested that the motion provide a way to validate that the techs providing immunizations are doing it appropriately. He is in support of pharmacy technicians administering immunizations with assurances that until this becomes standard practice that they must follow some type of training framework. A guidance document needs to include the framework for a training program that has been validated. Tracy West said she would write the guidance document to include didactic, and experiential components. The Chair suggested that the training should be included in the utilization plans for technicians. He agreed that approving the proposed AUPs conditionally so long as the training components are added. Chris Gerard assured the commission that they could proceed with the conditional approval of the AUP upon presentation of a training program that meets the specific criteria.

THIRD AMENDED MOTION: Teri Ferreira amended her amended motion to approve the two AUP's as submitted with the condition that training protocols will be submitted to staff that outline the specialized function. Staff will create a guidance document that details what specific training AUP's must be included in the future. Craig Ritchie seconded.

VOTE ON SECOND AMENDED MOTION. MOTION CARRIED: 10-0

VOTE ON THIRD AMENDED MOTION. MOTION CARRIED: 10-0

The Commission adjourned for lunch at 11:54 a.m.

The Commission reconvened from lunch at 12:10 p.m.

Teri Ferreira, Vice Chair presided over this portion of the meeting in Tim Lynch's temporary absence.

Identify Commission representatives for Weekly Legislative Update Calls.

The Office of Health Professions conducts weekly Meet Me calls during leg session and requests

a member of PQAC participate. The calls will be held weekly on Wednesday mornings from 8:30 – 9:00 a.m. beginning January 13 through the end of the session. Patrick Gallaher and Tim Lynch will participate. Staff agreed to check with Judy Guenther to see if she is interested as well. Kat Wolf-Khachatourian will be the alternate.

Presentation by Darrin Grondel, Director of Washington Traffic Safety Commission regarding work related to impaired driving was cancelled.

Discuss the increase in pharmacy robberies and break-ins and possible guidance to the pharmacy community. Lauren Lyles-Stolz, Executive Director Pharmacy shared that there have been eight pharmacy robberies and burglaries since late October in Olympia, Aberdeen, Renton and Tenino. The department has encouraged inspectors to work with local law enforcement to share prevention tips. A GovDelivery (listserv) notice went out to licensees in late November describing an actual robbery and pointed to prevention tips, and a Governor's Alert was sent yesterday to the to the Governor's office for situational awareness. We have provided a DEA brochure and an article outlining pharmacy prevention tips. An email from a pharmacist who has been robbed asked the Commission to think about education surrounding PTSD post robbery. EAP programs and crisis counseling were suggested as a resource for affected staff. Lauren will follow up with pharmacy inspectors and suggest they provide this option to affected businesses. Law enforcement will come out and give suggestions about how to prevent these events. Local law enforcement does situational awareness training. It would be good to develop a better understanding of best practices for prevention.

Tracy West shared that inspectors try to contact pharmacies after a robbery or burglary the same day we learn of the incident to review the situation and provide technical assistance. Patrick Gallaher asked if it is possible to provide general details regarding patterns and/or trends to others for prevention purposes. Tracy shared that inspectors have been doing this and invited an attending investigator to comment. Adam Wood, DOH Supervising Investigator stated that law enforcement does a good job communicating patterns and trends. He suggested that pharmacies reach out to their local law enforcement agencies asking for prevention tips.

Correspondence - Lauren Lyles-Stolz shared that the previous Executive Director, Steve Sachs used to provide an NAPB update and asked if this would still be helpful. Kat felt that it is helpful in respect to opportunities to participate in NABP sub-committee applicants. The updates made the Commission aware of grant opportunities, training, travel assistance and educational opportunities. She felt it was helpful to have a reference to what other boards and committees were doing. It was agreed. Lauren will continue to provide updates. In addition, Teri Ferreira asked to include inspection updates. Tracy will include in the Deputy's report.

5. Rules, Legislation, Program and Department Updates

The Commission considered a change to chapter 246-945 WAC Pharmacy Quality Assurance Commission rules specific to the inventory frequency for chemical capture programs administered by the Department of Fish and Wildlife.

Lauren Lyles-Stolz explained that WDFW reached out to the Department stating that because of the rule rewrite they have gone from an annual inventory to a daily inventory at beginning and end of shift. WDFW would like to be in compliance, but this is not practical to the way they conduct their business. They have asked for reconsideration to conduct a monthly or weekly inventory

MOTION: Ken Kenyon motioned to approve monthly drug inventories. Patrick Gallaher seconded.
MOTION CARRIED: 12-0

Tim Lynch rejoined the meeting at 12:40 p.m.

The Commission discussed potential edits to approved rules, chapter 246-945 WAC, regarding adopting specific USP chapters through the rule re-write. Staff provided an update on potential changes to the definition of compounding in RCW 18.64.011.

Tracy proposed moving forward in 2021 or if asked provide assistance if House Bill 1352 is introduced this legislative session to isolate the definition of compounding. In practice, reconstitution is not compounding and we want to make that distinction. Chris Gerard offered that adopting the USP definitions from the revised chapters would require additional changes to RCW 18.64.270. He suggested leaving the definition of compounding as is and call out non-sterile preparations that are considered reconstitution. Tracy feels this is the best option for defining the commission's intent. She expressed that this does not mean that the bill will go before the legislature. It is a short session in 2020 but it is best to be prepared.

After considerable discussion, it was decided that Tracy will meet with Kelly Cooper to try to schedule commissioner meetings with legislators and commissioners will attend meetings with legislators if asked. She will also continue to work on the strategic plan. Tracy will bring the draft rule language regarding non-sterile preparation back to the next meeting.

MOTION: Ken Kenyon motioned to approve the draft rule language adopting four USP compounding standard chapters by incorporating the language in the final proposed rule language to be filed with CR102. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 12-0**

The Commission adjourned for a break at 1:40 p.m.

The Commission reconvened at 1:45 p.m.

Rulemaking activities – There was no discussion

The Commission discussed finalizing a strategic plan for developing 2021 request legislation. Lauren Lyles-Stolz reviewed some of the 2019 legislative priorities and asked the commissioners to start thinking about the top priorities for the upcoming session. She suggested considering a partnership forum with other commissions. Some issues suggested were the Pharmacy Practice Act, kiosks, facility enforcement, licensure and fining authority. Lauren will follow up with the partnership forums.

Open Forum

Billy Chow, from Bartels Drugs, commented that the clarification on USP 800 and compounding was helpful, and was in support of the earlier presentation of the locker program. He asked if the Commission's position has changed on demonstration projects. Tracy informed him it had not. The proposal today would include any situation using a lock box.

Sub-Committee and Commission Member Reports - None

Commissioner Reports - None

Commissioners' open discussion related to items or issues relevant to Commission business/pharmacy practice. -None

Staff Reports Information/Action.

Executive Director – Lauren Lyles

Lauren gave a staffing update. She has identified a candidate for the Pharmacy Supervisor position and had the green light from HR to move to the reference and background checks. Reference requests have gone out. A candidate is identified for the Spokane pharmacy investigator position and is moving thorough the employment offer steps and will backfill the pharmacy investigator position that will be left vacant. She expects to be 95% staffed by the beginning of the year.

Deputy Director – Tracy West

Tracy shared that she has developed a transition plan for Caitlin Gates' position. Michael Sieg has resigned from PQAC and she is working with the Governor's office to replace both Matthew Ronayne and Michael.

Assistant Attorney General – Christopher Gerard

Mr. Gerard attended the NABP legal counsel interactive forum - it was a really good experience and would like to attend in the future.

Requests for Review by Commission Panel

Panel members were, Tim Lynch, Craig Ritchie, Patrick Gallaher, Kat Wolf-Khachatourian and Steve Anderson. There were no questions from the panelists nor the applicants. Steve Anderson recommended approving re-testing. The panel approved requests 9.2 and 9.3. Because the panel was unable to confirm attendance by applicant 9.1, his study plan approval is deferred to a future meeting.

Summary of Meeting Action Items – The Commission did not revisit action items identified during today's business meeting.

Business Meeting Adjourned.

Due to inclement weather and travel advisories, the Commission adjourned at 1:59 p.m.

*Respectfully Submitted by:
Bonita Campo, Office Manager
Approval January 31, 2020*



*Tim Lynch, Chair
Washington State Pharmacy Quality
Assurance Commission*