



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

July 7, 2016
Meeting Minutes
Comfort Inn
Evergreen Room
1620 74th Ave. SW.
Tumwater, WA 98501

CONVENE

Chair Tim Lynch called the meeting to order July 7, 2016.

Commission Members:

Olgy Diaz, Public Member
Tim Lynch, PharmD, Chair
Elizabeth Jensen, PharmD
Steve Anderson, RPh
Cheryl Adams, PharmD
Kenneth Kenyon, PharmD, BCPS
Jerrie Allard, Public Member
Christopher Barry, RPh
Matthew Ronayne, RPh
Sepi Soleimanpour, RPh, MBA-HA
Teri Ferreira, RPh
Nancy Hecox, PharmD, Vice Chair
Maureen Sparks, CPhT
Judy Guenther, Public Member

Guest / Presenters:

Absent Commission Member:

Arun Sambataro, Public Member

Staff Members:

Joyce Roper, AAG
Steven Saxe, Executive Director
Doreen Beebe, Program Manager
Rich Cieslinski, Rules Coordinator
Gordon MacDonald, RPh, Chief Investigator
Leann George, Secretary Senior

Absent Staff Member:

Irina Tiginyanu, Pharmacy Technician Analyst

Call to Order

- 1.1 Approval of Business Meeting Agenda
- 1.2 Approval of May 26 & 27, 2016 Meeting Minutes

MOTION: Elizabeth Jensen moved that the Commission approve the Amended Business Meeting Agenda. Steve Anderson seconded. **MOTION CARRIED: 14-0.**

MOTION: Steve Anderson moved that the Commission approve the May 26 & 27, 2016 Meeting Minutes with suggested corrections. Judy Guenther seconded. **MOTION CARRIED: 14-0.**

Rules Hearing

Bill Kellington, DOH Staff Attorney, Andy Fernando, HSQA Rules and Legislation Manager along with Brett Lorentson, HSQA Rules Coordinator were able to provide the Commission some clarification to the language regarding the proposed amendments to WAC 246-860-100 to establish clearer standards of conduct for pharmacy health care providers.

MOTION: Cheryl Adams moved that the Commission approve the proposed language to WAC 246-860-100 with some suggested minor changes. Steve Anderson seconded. **MOTION CARRIED: 14-0.**

Consent Agenda

- 2.1 NPLeX Monthly Report Acceptance
 - May and June 2016
- 2.2 Pharmacies and Other Firm Application Approval
 - New and Closed Pharmaceutical Firms Report
- 2.3 Pharmacy Technician Training Program Approval
 - a) Cascade Specialty Pharmacy
 - b) Elma Pharmacy
 - c) Rosauers Supermarket
- 2.4 Ancillary Utilization Plan Approval/Technician Specialized Functions
 - a) Geneva Woods
 - b) Group Health
 - c) PacMed - Specialized Functions IV Admixtures
 - d) Virginia Mason – Specialized Function IV Admixtures
 - e) Yokes Pharmacy
- 2.5 Automated Drug Distribution Device Approval
 - a) Cascade Valley Hospital – Arlington Surgery Center
 - b) PeaceHealth United General – Medical Center

c) Swedish Health Services - First Hill Surgery Center

MOTION: Elizabeth Jensen moved to approve Consent Agenda Items 2.1, 2.2, 2.3(a, b, c), and 2.4(a, b, c, d, e). Sepi Soleimanpour seconded. **MOTION CARRIED: 14-0.**

MOTION: Elizabeth Jensen moved to approve Item 2.5(a, b, c) Sepi Soleimanpour seconded. Nancy Hecox recused herself. **MOTION CARRIED: 13-0.**

Old Business

Communication and Resolution Program (CRP)

Dr. Thomas Gallagher (MD) presented an update to the Communication and Resolution Program (CRP) to the Commission. He provided an update of the progress that has been done since 2010. CRP is a process to address patient adverse/unanticipated outcomes to the Commission. After further discussion and questions from the Commission members they feel this would be good fit for PQAC.

MOTION: Ken Kenyon moved that the Commission form a subcommittee to explore expanding the CRP implementation program to the Pharmacy Commission. The subcommittee will come back to the Commission with “next steps”. Cheryl Adams seconded. **MOTION CARRIED: 14-0.**

The committee assigned to work with Dr. Gallagher and MQAC are Ken Kenyon, Olgy Diaz, Steve Saxe and an AAG.

NABP District 7 Meeting

Steve Saxe was asked in May to look at the estimated cost for the Commission and staff to attend the NABP District 7 Meeting held September 11 – 14, 2016, in Portland, Oregon for an opportunity to have a team building experience. This is not within reason according to the Pharmacy Commission budget. The budget will allow for the Executive Director and two Commission members to attend. This led into other discussions such as possibly designating one member to attend all of these meetings, the policy regarding members who attend these meetings that are paid for by their employer, and other discussions regarding allowing members to take turns for the experience and educations as others who have attended. Due to the long discussion some members felt it would be a good idea to table this until later to process what has been discussed.

MOTION: Christopher Barry moved that the Commission table this until after lunch. Ken Kenyon seconded. **MOTION CARRIED: 14-0.**

After lunch the Commission made a decision.

MOTION: Judy Guenther moved that Steven Saxe, Olgy Diaz and Tim Lynch will attend the NABP District 7 Meeting on September 11 – 14, 2016, in Portland, Oregon. Maureen Sparks seconded. **MOTION CARRIED: 14-0.**

Accreditation Council on Pharmacy Education Accreditation's (ACPE)

At the May meeting the Commission asked to review the ACPE's 2016 Accreditation Standards and Guidelines for recognition of its accreditation of colleges and schools of pharmacy and discuss any issues if they felt there were some concerns.

The Commission acknowledged their review and acceptance of the standards and there was no further discussion.

New Business

HIV/AIDS Training for Licensure Requirements

Doreen Beebe led the discussion with the Commission. Staff was asked to look further into this requirement and if there was a way to minimize/eliminate this requirement for licensure. The Commission was asked to consider if a student or graduate from an ACPE accredited school or college of pharmacy be deemed to have meet the HIV/AIDS training as part of their professional degree program. If determined appropriate this would authorize an applicant for Intern registration and/or pharmacist license to sign the attestation of completing the required hours, four for interns and seven for pharmacists.

MOTION: Elizabeth Jensen moved that the PQAC staff create a policy around the HIV/AIDS education qualifications for licensure and bring to the Commission for approval. Steve Anderson seconded. **MOTION CARRIED: 14-0.**

National Association of State Controlled Substances Authorities

Mr. Saxe led the discussion with the Commission to discuss sending the Executive Director to the National Association of State Controlled Substances Authorities (NASCSA) conference in New Orleans LA on October 18 – 21, 2016. The Commission asked what he would bring back from this conference and they did feel if DOH was sending someone this person could bring back a report to the Commission.

MOTION: Judy Guenther moved to approve Steven Saxe, Executive Director to NASCSA. Sepi Soleimanpour seconded. Nancy Hecox, Elizabeth Jensen and Steve Anderson opposed. **MOTION CARRIED: 11-3.**

Ancillary Utilization Plan for Location Change

Steven Saxe and Gordon MacDonald led the discussion and answered the questions from the Commission regarding the process for Ancillary Utilization Plan approvals for a change in pharmacy location applications. The current policy requires all AUP's to be reviewed by the Commission which is done during business meetings. This can cause a pharmacy relocating hardship because they must wait for approval before the inspection and receiving a new pharmacy license. After staff had discussed this with licensees and investigators often time these AUPs are operating exactly the same and although a different location the set-up is the same.

MOTION: Christopher Barry moved that staff work with pharmacy and pharmacy investigator to verify or attest to the following: now change to ownership just location, no change to type of personnel utilized at the pharmacy, AUP remains the same as original pharmacy location and the pre-location inspection had a satisfactory finding to transfer the pharmacy inspection score from routine inspection performed prior to the relocation. Then staff will notify the pharmacy that because this is a relocation of an existing pharmacy this is only an update of existing AUP with NO changes the pharmacy passed the initial inspection and the AUP is considered approved solely for the purpose of processing the change of location paperwork. Nancy Hecox seconded. **MOTION CARRIED: 14-0.**

Legislative Decision Package and Budget Update

Steve Saxe shared with the Commission the proposal Decision Package for Commission input and guidance. Pharmacy went from a seven-member Board to a 15-member Commission with no staff added and a larger workload. There are three projected fee rules in development over the next six years. These are needed to keep fund balanced at 15 percent. Steve will take the input from this discussion and do more work. This will be sent to the Commission before the Decision Package gets submitted. The Commission is asking to look at a detailed analysis of the budget to make sense of its current status of standing in the red.

Open Forum

Grant Chester provided his view on the background of HB1800. He also spoke about difference between OII and Construction review and the requirements for USP 797. Tim Lynch shared that he can see that there is a difference but they are all working together and there is some improvement.

Julie Akers thanked the Commission for the work with Dr. Gallagher she suggested a Commission member with community pharmacy background also work with the committee because that work will affect the practice settings of these pharmacies as well. She is seeing graduates from out of state that are offered a job in Washington aren't able to get a WA intern licensure while they prepare for licensure because they are no longer advancing towards graduation but a foreign pharmacist can, she asked that the Commission and staff look into this.

Regarding HIV training if the Commission could look at the RCW's around this that would be great because this education that is already provided.

Craig Pederson shared how much he appreciates the work the Commission does. He spoke in support of making Commission meeting materials available to the public and asked if he could get a status update.

Doreen Beebe has been participating in a group around standardizing an agenda and providing materials on the web. We did develop the request form for a disclaimer that hasn't been consistently distributed with request for presenting at a business meeting; changes are being made to our website. At this point we are just not there. There is a lot of work to get this up and running. Doreen hopes to be able to post some things by September if not there will be an updated during that meeting.

Steve and Doreen will look at the intern policy and out of state pharmacists and them receiving an intern license while waiting for Washington licensure to discuss at a future meeting.

The Commission adjourned for Executive Session at 12:18 p.m.

The Commission reconvened from Executive Session at 1:00 p.m.

Committee Reports and Rule Project Updates

Inspection Committee

Tracy West shared that inspection subcommittee a planning meeting last Friday open for stakeholders to call in to but no comments were taken this was focused on what work to do next and the next steps in our process. We were asked to draft language and guidance to work on self-inspection forms inspectors will begin the work on forms first. All forms/tools and language will be moved forward without the full Commissions review and input.

ADDD's Rule

The rule has been approved by the Secretary however there was a glitch in the rules system and this wasn't able to be filed to meet the Code Reviser Deadline. This is problematic because we planned to hold a public hearing on August 18, 2016. We will have to hold the public hearing during the September meeting or we can hold a special meeting any time after August 23, 2016.

Sterile Compounding

Rich Cieslinski provided an update from USP 797 and 800. The Compounding Expert Committee is currently reviewing all of the public comments received. At this point there isn't an anticipated date for publication for the chapter due to such high volume of public comments. The chapter is being revised based on the input that was received. Based on the nature of the significance of the comments received the committee will determine whether the chapter will be republished in the Pharmacopeial Forum for another round of public comments. Chapter 800 is now published in the First Supplement to USP 39-NF on February 1, 2016 but has a delayed official implementation date of July 1, 2018. Steve Saxe suggested that the Compounding Committee get together and talk about what the next moves are.

Continuity of Care

The rule was approved by the Secretary however the filing date was missed due to a glitch in the system. We would like to hold a special meeting for to keep it moving forward.

Electronic Transmission

Doreen Beebe shared that the first stakeholder meeting was June 14, 2016. It was a good meeting although there wasn't a huge turnout. The next stakeholder meeting will be held at the end of the month. The committee will be looking at what other states do and what draft language should include and the vendors will be invited. Also, it was decided that definitions should be the first step for clarification.

Donated Prescriptions

Starting the CR 101 process for submission and doing the memo to start the rules process. There are two WACs that will need to have amended language. This is still in the planning stages of that. At this point we are looking at a guidance document since the legislation that was passed doesn't mention rule writing around it. We will be looking into whether a guidance document will be better suit this situation.

Hospital Pharmacy

Rich Cieslinski reported that the official language has been filed for the emergency rule and staff received a copy back. This language will be brought to the Commission July 29, 2016 for review. The CR-101 for the permanent rule is in review and once reviewed it will be filed. There is another piece of this rule regarding fees there has never been an emergency fee rule. This is being worked on with the Secretary there will be a hearing on August 28 regarding this piece.

Long Term Care

This rule was approved by the Commission to move forward the CR-101 is in the beginning stages.

Pharmacy Assistants Registration Fee

The Secretary's office does most of the work on fee rules and this one is moving forward. The language in the statute matches the rule this will allow for this rule to begin at the CR-102 state.

Suicide Prevention and Awareness

The CR-101 is in the works. This rule is tied to the Safe Homes Task Force led by the UW School of Social Work. A sub-committee related to the pharmacy component is being led by WSPA and School of Social Work and their first sub-committee meeting was held July 6, 2016.

Chapter 246-887 WAC

Doreen Beebe asked the Commission to consider approving proposed changes to Chapter 246-887 WAC. The rule amendments include technical corrections, adding tramadol to schedule IV, and remove hydrocodone combination products from schedule III to be consistent with Title 21, Code of Federal Regulations.

MOTION: Elizabeth Jensen moved that the Commission approve proposed changes to Chapter 246-887 WAC. Teri Ferreira seconded. **MOTION CARRIED: 14-0.**

Outpatient Emergency Medications

Brett Lorentson led the Commission through the amended language and asked the Commission to consider approving proposed changes to WAC 246-873-060 Outpatient Emergency Medications, to implement ESSB 5460 (section 1).

MOTION: Steve Anderson moved that the Commission accept the draft language WAC 246-873-060 Outpatient Emergency Medications with some suggested amendments. Christopher Barry seconded. **MOTION CARRIED: 14-0.**

Overview of Formal Five-year Legislative Review

Andy Fernando provided the Commission an overview of legislative mandate for formal five-year review process of all rules affecting Department of Health programs. There was some follow-up discussion on what staff needs from the Commission to help move rules work forward. Doreen Beebe and Tracy West will present a work plan to the Commission once it is complete.

Correspondence

The Commission discussed the correspondence received or distributed on its behalf.

- Containment Technologies Group, Inc.
- NABP e-Mailbag
 - a) 2016 MPJE Item Pool Review and New Item Selection
 - b) Multistate Pharmacy Inspection Blueprint Implementation Update
 - c) NABP Action Taken Across Examination Programs in Response to the CDC's Recommendation Involving Non-Injectable Flu Vaccine
 - d) Live Student and Healthcare Professional Continuing Education Webinar Hosted by FDA's Division of Drug Information

Commission Members' Open Discussion and Reports

Open Discussion

Cheryl Adams brought up the fact that Gordon MacDonald continues to ask for guidance for his investigators. She would like to have a standing item/space on the agenda for him to share his concerns for Commission guidance. Possible have a group that focuses only on communication. There was discussion about social media Steve Saxe committed to look further into this option. Cheryl also asked how the backlog of submissions for approval being dealt with.

Christopher Barry suggested the Bylaws should be updated and offered to do this and bring forward some suggested changes for Commission review at the next meeting. He feels we need to get buy in on some of these rules as they are being updated even though we are only regulating the pharmacy profession. Some of our rules are not just about Pharmacy.

Maureen Sparks asked for confirmation that the Friday meetings are on as discussed as she hasn't seen an updated Meeting schedule.

Commission Member Reports

Cheryl Adams reported:

- She attended the Northwest Washington Pharmacy Convention (NWPC) held by WSPA.
- Cheryl participated on the inspection committee.

Jerrie Allard reported:

- Attended the NWPC, she attended a number of sessions. Jerrie shared some of her highlighted moments while she was there.

Matthew Ronayne reported:

- He attended the NWPC.

Nancy Hecox reported:

- She assisted staff in ADDD reviews and with reviewing some Collaborative Drug Therapy Agreements.
- She worked on the MOU this has been written and reviewed and now working on the next step which is to get an appointment for negotiations.

Steve Anderson reported:

- He attended the University of Washington School of Pharmacy graduation ceremony on June 10, 2016.
- He participated at the June 14th electronic transmission stakeholder meeting in Kent.
- Steve wrote an article for the PQAC newsletter that will be published “Electronic Prescription for Controlled Substances and the Signature Requirement.”

Chris Barry reported:

- He participated at the inspection committee meetings.
- Chris also assisted with the MOU writing.
- Mr. Barry is preparing for retirement on July 22, 2016.

Maureen Sparks reported:

- She has recently accepted a promotion she will be spending half of her time as an Instructor in the pharmacy Technician program and half time as Department Chair in the Science Division.

Teri Ferreira reported:

- She attended the NWPC. She and Steve Saxe participated in the Long Term Care Academy.
- She attended the Leaving Age of Washington which was a not for profit meeting.
- Teri attended the for profit Washington Association Care meeting

Sepi Soleimanpour reported:

- She also attended the NWPC.
- Sepi attended a few other Board of Pharmacy meetings and the WSPA Board meeting.
- She attended the UW Curricula Activity.
- Sepi worked and participated on the inspection committee and ADDD

Tim Lynch reported:

- He also participated in the work on the MOU.
- Participated on the emergency prescription rule work, and the inspections committee.
- Mr. Lynch received fellow ships status for ASHP.

Commission Action Plan

Steve Saxe provided an update on the action plan besides the rules portion that has already been reported on.

- There is still discussion and work being done regarding a dashboard for PQAC.
- We are looking at communications, stakeholders, webinars, newsletter and meeting management website. We want to focus on these topics not just rules.

- Steve would like to revise the action plan and would like to draft a dashboard to help stay focused on the plan, how we are doing, attendance to these meetings and ways to streamline our meetings.
- Steve would like to make a dashboard of the staff work that the Commission needs to approve he would like to find a way to streamline this work as well.
- There was discussion to work on these things at the next Friday meeting.

Staff Reports

Executive Director

Steve Saxe reported:

- He asked for two Commission members to be part of the interview panel. Nancy Hecox, Cheryl Adams and Judy Guenther offered to participate.
- Lisa Roberts is still out we should be updated on her status sometime within the next week.
- Steve attended the NWPC and he did try to attend all the academies.
- He attended the Idaho law session.
- Mr. Saxe also attended the UW curriculum planning session they are looking at revamping their curriculum.
- Steve attended the medical program directors for the emergency medical system. Trying to finalize the work done on HB1625.

Attorney General

Joyce Roper reported:

- The Stormans case has been decided it is now over after almost 10 years. The 9th circuit decision stands. The expense of attorney fees goes by the waist side. There will be some sectors that will be watching how this pharmacy applies the rule.

Pharmacist Consultant

Rich Cieslinski reported:

- He is busy splitting his time between being a rules coordinator, a pharmacist consultant and working on the five year review.

Chief Pharmacist Investigator

Gordon MacDonald reported:

- In state pharmacy, 1500, non-resident 903
- Pharmacy License are declining because we don't have good rules and hold pharmacies at very high standards
- He updated the Commission on the OII workload prioritization that was implemented in February. January to June 2016 completed 740 inspections, 283 routine, 220 new license inspections 28 drug researches and 51 change of ownership remainder were closure inspections.
- Gordon has about 35 issues the investigators are looking for guidance he hopes to bring to the next meeting.
- One issue that seems to be a huge concern is patient counseling an increased number of complaints around this. Again, the investigators are looking for guidance on this as well. This even happens during an inspection.

Open Forum

Jeff Rochon, WSPA invited the Commission to attend a workshop for medical billing for SB 5557 August 10, 2016 and the WSPA Annual meeting in October. He thanked the

Commission for their work and support. We are working on the Suicide Prevention and Awareness with Steve Saxe.

Julie Akers commented on the work regarding the inspection committee, the stakeholders are excited about inspections going to the notice of correction the concern was that this system will be reviewed under the OII.

Grant Chester commented on the topic of investigators asking for guidance and he feels this should be provided to the public.

Lisa Hodgson clarified that the delays for posting documents to public has nothing to do with PQAC staff Doreen Beebe has been working hard on this.

Christopher Barry mentioned that Doreen Beebe needs some Commission members to volunteer for hearings. Commission members were asked to look at the hearing schedule and their personal/work schedules and volunteer.

There being no further business, the board adjourned at 4:15 p. m.

Respectfully Submitted by:

Leann George, Program Support

Approved August 19, 2016

Tim Lynch, Chair

*Washington State Pharmacy Quality
Assurance Commission*