STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION
Meeting Minutes
September 7, 2018
Highline Community College
Mt. Constance Room
2400 S. 240 St.
Des Moines, WA

CONVENE

Chair, Tim Lynch called the meeting to order September 7, 2018 at 9:07 am.

Commission Members:
Elizabeth Jensen, PharmD
Tim Lynch, PharmD, Chair
Cheryl Adams, PharmD, Vice-Chair
Teri Ferreira, RPh
Judy Guenther, Public Member
Steve Anderson, RPh
Uyen Thorstensen, Pharmacy Technician
Kenneth Kenyon, PharmD, BCPS
Jerrie Allard, Public Member
Michael Sieg, PharmD
Kat Wolf-Khachatourian, PharmD
Matthew Ronayne, RPh

Absent Commission Member:
Arun Sambataro, Public Member
Olgy Diaz, Public Member
Sepi Soleimanpour, RPh, MBA-HA

Staff:
Christopher Gerard, AAG
Steven Saxe, Executive Director
Tracy West, Deputy Director
Irina Tiginyanu, Pharmacy Technician Analyst
Leann George, Secretary Senior
1. Call to Order

1.1 Business Meeting Agenda

MOTION: Steve Anderson moved to approve the September 7, 2018 Meeting Agenda. Judy Guenther seconded. MOTION CARRIED: 12-0.

1.2 Meeting Minutes – June 29, 2018, 2018

MOTION: Steve Anderson moved to approve the June 29, 2018 Special Meeting Minutes. Judy Guenther seconded. MOTION CARRIED: 12-0.

1.3 Meeting Minutes – July 23, 2018

MOTION: Steve Anderson moved to approve the July 23, 2018 Meeting Minutes. Judy Guenther seconded. MOTION CARRIED: 12-0.

1.4 Meeting Minutes – July 26, 2018

MOTION: Steve Anderson moved to approve the July 26, 2018 Meeting Minutes. Judy Guenther seconded. MOTION CARRIED: 12-0

2. Consent Agenda

2.1 National Precursor Log Exchange Monthly report – August 2018

2.2 New and Closed Pharmaceutical Firms Application Report Approval
   a) Closed July 9th through August 16, 2018
   b) New – July 9th, 2019 through August 16, 2018

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)
   a) Creekside Pharmacy
   b) Healthpoint Pharmacies
   c) Jefferson Healthcare Pharmacy
   d) Premier Long Term Care Pharmacy
   e) Quincy Community Health Center Pharmacy
   f) Samaritan Hospital Pharmacy – Specialized Functions
   g) Trios Pharmacies

2.4 Pharmacy Technician Training Programs Approval
   a) Astria Sunnyside Hospital
   b) Yakima Valley College

2.5 Pharmacy Technician Ratio Exemption Approval
   a) Everett ProPac Payless

2.6 Electronic Prescription Transmission System Approval
   a) Epic Willow Ambulatory
   b) G-Med, Inc. – gCardio
   c) G-Med, Inc. – gGastro
   d) G-Med, Inc. – gGastro Cloud
   e) G-Med, Inc. – gMed Connect
   f) G-Med, Inc. – gUro
MOTION: Steve Anderson moved that the Commission approve consent agenda items 2.1, 2.2 (a-b), 2.3 (a-g), 2.4 (b), and 2.6 (a-f) and pull Items 2.4 (a) and 2.5 (a) for further discussion. Matthew Ronayne seconded. **MOTION CARRIED: 12-0.**

3a. Tamper Resistant Paper Rx Paper
The Commission was asked to consider a proposal for approval as approved tamper-resistant prescription paper by Plus Technologies, LLC a plain paper printing solution.

MOTION: Steve Anderson moved to approve the request from Plus Technologies, LLC’s plain paper printing solution. Matthew Ronayne seconded. **MOTION CARRIED: 12-0.**

Old Business

3.1 Action Item Update
Executive Director, Steve Saxe updated the Commission on the status of tasks assigned during the past Commission meetings.

**Completed:**

- Letter to Healthcare Committee chairs – This letter offered to share information about pharmacy issues, specifically examples of compounding related statutes. Representative Cody’s office has responded and we are working with the DOH policy office on follow-up and setting up a meeting.

  **MOTION:** Cheryl Adams moved that Commissioners, Ken Kenyon, Tim Lynch, Elizabeth Jensen and Judy Guenther represent the Pharmacy Commission in a meeting with Representative Cody to discuss the issues of concern discussed in the letter to the Healthcare Committees. Steve Anderson seconded. **MOTION CARRIED: 12-0.**

- Medical Commissions request for Attorney General Office formal opinion on Collaborative Drug Therapy Agreements - The Commission approved and submitted the public comment. The Commission is also receiving copies of comments being submitted by some stakeholders.

- Collaborative Drug Therapy Agreement (CDTA) – Separate from the AGO opinion the commission asked to collect public input for the continuation of the CDTA signature discussion. The majority of questions seem to focus on refill centers. The commission will continue this discussion with the new input.

- Letter to Midwifery Committee – Staff submitted a letter of support of Midwifery program rules project.

- USP 795 Draft Comment – Staff finalized the drafting and submitting comments reflecting the Commission’s concerns related to the revised USP 795 Chapter.

**In Process:**

- Opioid Dispensing Best Practice article – Staff will work with Commissioners on an opioid red flags / best practices article. Staff suggest this outreach be
incorporated into the work of the opioid response plan workgroup and the education efforts tied to the HB 1427 Opioid Prescribing rules.

- Review of misfill grid and NCQAC chart – The subcommittee has identified some additional work they want to complete. They will continue working on this process following other priority work.
- Examine the use of Administrative Law Judges for entity enforcement cases.

3.2 Guidance Document and CDTA v. Protocols in refill authorization centers
At the July business meeting staff was asked to publish a guidance document regarding signing prescriptions under a CDTA for stakeholder comment. Staff received 31 comments, which were provided to the Commission for review. Staff sought direction from the Commission on next steps in terms of how to move forward with the guidance document and the standards around signed prescriptions. Deputy Director, Tracy West, AAG, Christopher Gerard and Executive Director, Steve Saxe put together a Protocol vs CDTA flow chart to differentiate what happens under each and who needs to sign the prescription in each scenario.

The Commission agrees with the DEA regulations that controlled substances under a protocol or standing order must be authenticated by a prescriber. AAG, Christopher Gerard will work with Commissioners on the guidance document using the feedback from the comments and the discussion during this meeting. The Commission asked to reiterate that Pharmacists are also prescribers.

4. Legislation, Program, and Department Updates

4.1 2019 Legislative Update
Executive Director, Steve Saxe provided a brief update regarding the 2019 Legislative requests.

a) Pharmacy Commission Request Legislation

Both requests are still moving forward through the Department of Health and Office of Financial Management.

There was a non-substantial change to the electronic prescription transmission request.

- The language around the requirement regarding policy and procedures addressing patient confidentiality was left in.

b) DOH Prevention and Community Health Division – Modernization of STD laws

Executive Director, Steve Saxe asked the Commission if they would support the request from the Prevention and Community Health Division to modernize STD laws including the repeal of statutes related to AIDS education and training for health professions, health care facility employees, public school employees, and state and local government employees.
MOTION: Elizabeth Jensen moved that the Commission provide a letter of support for support the Prevention and Community Health Division who is requesting to repeal statutes related to AIDS education and training for health professions, health care facility employees, public school employees, and state and local government employees. Steve Anderson seconded. MOTION CARRIED: 12-0.

4.2 Commission Budget Report
Executive Director, Steve Saxe discussed the plans to do some adjustment to the revenue to make up for overcharges to the PQAC budget that were discovered. This will be made up during the next two fiscal years.

Commissioner, Ken Kenyon provided an update to the Commission about the work of the sub-committee. They met in August to discuss next steps now that the fee increases have been implemented. The goal will be to develop a budget that is more realistic with the expenses of the Commission. The sub-committee believes there really needs to be a budget impact statement on every rule or process that is changed.

4.3 Complaint Intake Process Overview
Deputy Director for the Office of Investigations and Legal Office Services (OILS), Marlee O’Neill and Complaint Intake Manager, Brian York led the complaint intake overview with the Commission. The Commission received a power point of the process used to take complaints. They were able to answer questions from the Commissioners.

After, the discussion the Commission asked that staff develop a more formalized process for taking complaints. All staff supporting the Pharmacy Commission is required to use the Health System Quality Assurance (HSAQ) complaint intake form and send directly to complaint intake.

5. Rules, Sub-Committee and Commissioner Reports

5.1 The Commission will consider withdrawing the CR-101 filings where the subject matter will be incorporated in the rule re-write.


MOTION: Elizabeth Jensen moved that the Commission authorized the withdrawal of WSR 16-19-077, WSR 16-12-016, WSR 13-11-096, and WSR 16-21-041. This will ensure that resources are focused on the Commissions priority and these rule projects will be incorporated in the rules re-write project. Ken Kenyon seconded. MOTION CARRIED: 12-0.

5.2 Commission Reports
Ken Kenyon reported:
• He enjoyed hosting Deputy Director of OILS, Marlee O’Neill who brought her team to tour his pharmacy for a better understanding of that type of facility and how it operates.

5.3 Commissioners’ Open Discussion
Commissioner Kat Wolf Khachatourian shared an experience that confirmed those in medical professions may not fully understand the advanced level of the pharmacy profession and that a National PharmD degree attainment takes a pharmacist beyond just being a traditional “druggist”. Jeff Rochon, from the WSPA spoke on this and shared he has engaged in some discussions with colleagues in the Medical profession regarding these issues and at the end of the day they were in alignment with the issues and have promised to work with WSPA to ensure there is support from the Medical profession going forward.

6. New Business

6.1 Review draft interpretative statement to clarify “emergency medical reasons” in WAC 246-879-010(10(e)
During the June rule re-write discussion the Commission directed staff to draft an interpretive statement regarding the definition differences of “emergency medical reason” between the FDA and WA State. The FDA definition of “emergency medical reasons” limits transfers to alleviate temporary drug shortages between entities. The Commission’s definition includes the transfer to a practitioner.

After reviewing the draft interpretive statement there was agreement that the conclusion statement needs to be clearer for the licensees. Staff was asked to work on the clarity of the standard in this statement as well and bring back to the October meeting for review.

6.2 Discuss tracking of Chronic Conditions and Allergies required under chapter 246-875 WAC
Executive Director, Steve Saxe led the discussion asking the Commission for guidance around the practice of entering and tracking of allergies, chronic conditions, medication history and other clinical information. With the new inspection process questions have come up and this has been identified as a deficiency on some inspection reports. In evaluating the plan of correction there has been discussion of what would be an appropriate goal.
The importance of a pharmacist obtaining chronic conditions, allergies, medication history and other pertinent health information is an ongoing challenge for pharmacists. Entering and tracking of allergies, chronic conditions, medication history and other clinical information is paramount for a pharmacist to complete an adequate drug utilization review. The Commission agrees a pharmacy should have a process to capture and maintain this information. However, there was concern regarding accuracy of this information depending on the source or if a pharmacist is making assumptions from medications only.

The Commission tasked staff to go back and summarize what was discussed and bring it back to the Commission in October for review.

**MOTION:** Ken Kenyon moved that the Commission provide guidance to the investigators that during an inspection they should *note* whether or not there is a process for chronic conditions and allergies and that the facility is adhering to their defined process. Steve Anderson seconded. **MOTION CARRIED: 12-0.**

### 6.3 Discuss and update existing Commission policies and procedures:

a) Updates to Secure and Responsible Drug Disposal Programs - Guidance Document.

This was updated to reflect the DEA’s recent changes to their list of acceptable and non-acceptable disposable products to be placed into registered collection receptacles.

**MOTION:** Ken Kenyon moved to accept changes as written to stay consistent with the DEA’s regulations. Steve Anderson seconded. **MOTION CARRIED: 12-0.**

b) Updates Policy #56 – Labeling of Outpatient Medications for Administration

Executive Director, Steve Saxe and Deputy Director, Tracy West will work with Commissioners to make sure the intent is captured in the language of the amended policy and bring it back for review and approval.

c) Rescind Policy #46 Use of ADDDs in Residential Treatment Facilities

This is no longer necessary under the new ADDD rules in chapter 246-874 WAC. In the new rules the Commission made it clear who the rules were applicable to eliminating confusing language in the old rules.

**MOTION:** Elizabeth Jensen moved to rescind Policy #46 use of ADDDs in residential treatment facilities. Judy Guenther seconded. **MOTION CARRIED: 12-0.**

d) Reaffirm Policy # 3 Accreditation of Colleges of Pharmacy

**MOTION:** Ken Kenyon moved that the Commission reaffirm Policy #3 Accreditation of College Pharmacy. Steve Anderson seconded. **MOTION CARRIED: 12-0.**
6.4 Practicing Pharmacy Outside of a Pharmacy
Deputy Director, Tracy West led the discussion with the Commission asking for guidance to inquiries that staff has been receiving on whether a pharmacist or technicians can perform certain functions that fall under the definition of the “practice of pharmacy” outside a licensed pharmacy such as, compounding. Tracy shared answers that have been used for these inquiries and asked for Commission approval and or input to provide stakeholders consistent messages that represent what the Commission wants.

**MOTION:** Kat Wolf-Khachatourian moved that the Commission approve the answers used to respond to inquiries around pharmacy functions being performed outside of a pharmacy with changes to repackaging as discussed. Teri Ferreira seconded. **MOTION CARRIED:** 12-0.

6.5 The Commission will consider renewing its delegation:
   a) Signature authority to designated staff (ED, Credentialing Manager, etc.) to sign on behalf of the Commission on specific routine tasks/approvals.

**MOTION:** Ken Kenyon moved to approve the signature authority with the addition of Deputy Director on the list. Steve Anderson seconded. **MOTION CARRIED:** 12-0.

   b) Decision-making as it relates to select adjudicative services

**MOTION:** Elizabeth Jensen moved to approve the decision making as it relates to adjudicative services and delegate to the Executive Director to appoint Brief Adjudicative Procedure (BAP) Officers. Judy Guenther seconded. **MOTION CARRIED:** 12-0.

6.6 The use of DEA Registration Numbers in Hospital Settings.
Deputy Director, Tracy West wanted to follow up with the Commission for guidance on additional publication or educational opportunities to stakeholders. There have been several questions around the proper use of DEA registration numbers in hospital settings.

It was agreed that there will be work done with Washington State Pharmacy Association (WSPA) and Washington State Hospital Association (WSHA) to continue to educate and reemphasized the process to use a hospital’s DEA registration number with an additional suffix for a pharmacist or other providers. However, if the pharmacist leaves the hospital, the pharmacists would need their own DEA registration.

6.7 Correspondence
The Commission reviewed and discussed correspondence received or distributed on its behalf.
   a) Constituent Correspondence
      ✓ Prescription Transfer Policy
      ✓ Authorization for non-Child Resistant Packaging (non-CRP)
   b) General Correspondence
6.8 NABP/AACP District 6, 7 & 8 Meeting
The Commission agreed that Commissioner, Steve Anderson will attend the NABP/AACP District 6, 7, & 8 Meeting with Executive Director, Steve Saxe representing the Washington State Pharmacy Quality Assurance Commission.

6.9 Pulled Consent Agenda Items

2.4 (a) Astria Sunnyside Hospital Technician Training Program
This was pulled by Commissioner, Cheryl Adams with the concern that the DVD being used as an educating tool for sterile compounding is outdated.

MOTION: Cheryl Adams moved that the Commission approve the Astria Sunnyside Hospital Pharmacy Technician Training program with the requirement that they use an updated sterile compounding education tool. Elizabeth Jensen recused herself. Steve Anderson seconded. MOTION CARRIED: 11-0.

2.5 (a) Everett ProPac Payless Ratio Exemption Request
This was pulled by Elizabeth Jensen to share her concerns about removing the pharmacist to technician ratio.


** Elizabeth Jensen was dismissed

7. Requests
Panel A that includes Commissioners, Steve Anderson, Judy Guenther, Michael Sieg and Teri Ferreira Panel A was asked to hear requests from applicants.

7.1 Consider for approval a study plan submitted by applicant to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE) and North American Pharmacist Licensure Examination (NAPLEX)

The Commission panel discussed the applicants study plans, declined her request to retake the NAPLEX until she has completed the Kaplan course, and provided her results for the panel’s review. The panel authorize the applicant to retake the NAPLEX.

7.2 Consider for approval a study plan to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE) 60778456

The panel denied the applicant’s request to retake the MPJE. They requested that the applicant purchase the NABP Law Survey to create a personal outline with all other details
of the study plan, including times devoted to study. The applicant was asked to return with the revised study plan at a future meeting.

8. Staff Reports

8.1 Executive Director’s Report

*Steve Saxe reported:*

Mr. Saxe provided a report for the Commission.

- The position of Deputy Director for Pharmacy that Tracy West was appointed to in March 2018 is now permanent.
- Recruitment for the Rules Coordinator has begun.
- Angelica Pauley took another job outside of state service effective August 3, and we are evaluating the staffing needs given the work to be done moving forward.
- Lisa Roberts is now a Pharmacy Investigator.

8.2 Assistant Attorney General

Christopher Gerard reported:

- He has been doing a lot of work with Deputy Director, Tracy West and Executive Director, Steve Saxe on the Rules Re-Write project.
- Christopher has also been doing work regarding animal drug compounding.

*There being no further business, the board adjourned at 3:33 p.m.*

Respectfully Submitted by:

Leann George, Program Support for Approval October 18, 2018

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*Ken Kenyon, Acting Chair*  
*Washington State Pharmacy Quality Assurance Commission*