



State of Washington
Department of Health

**January 21, 2016
Business Meeting Minutes
Red Lion Hotel
18220 International Blvd
Seattle, WA 98188**

CONVENE

Chair Tim Lynch called the meeting to order January 21, 2016.

Commission Members:

Maureen Sparks, CPhT
Tim Lynch, PharmD, Chair
Elizabeth Jensen, PharmD
Arun Sambataro, Public Member
Steve Anderson, RPh
Dan Rubin MPP, Public Member
Christopher Barry, RPh
Matthew Ronayne, RPh
Judy Guenther, Public Member
Cheryl Adams, PharmD
Gary Harris, RPh
Sepi Soleimanpour, RPh, MBA-HA

Guest / Presenters:

Amy Knowles, PharmD for Skyline Hospital

Absent Commission Member:

Nancy Hecox, PharmD, Vice Chair
Olgy Diaz, Public Member

Staff Members:

Joyce Roper, AAG
Lisa Hodgson, Director of HPF
Cathy Williams, RPh, Pharmacist Consultant
Irina Tiginyanu, Pharmacy Technician Analyst
Doreen Beebe, Program Manager
Rich Cieslinski, Rules Coordinator
Gordon MacDonald, RPh, Chief Investigator
Leann George, Secretary Senior

Absent Staff Members:

Lisa Roberts, RPh. Pharmacy Consultant

New Staff Introduction

The commission welcomed *Rich Cieslinski* as our rules coordinator. Rich worked for the Arizona Board of Pharmacy for over ten years before relocating to Washington State in 2013. Rich's experience as a practicing pharmacist will be an asset to the Commission as they work to update their rules.

Call to Order

- 1.1 Approval of Business Meeting Agenda
- 1.2 Approval of December 11, 2015 Regular Business Meeting Agenda
- 1.3 Approval of December 29, 2015 Special Meeting Minutes

MOTION: Dan Rubin moved that the commission approve 1.1. Sepi Soleimanpour second. **MOTION CARRIED: 12-0.**

MOTION: Gary Harris moved that the commission approve 1.2 with amendments. Judy Guenther second. **MOTION CARRIED: 12-0.**

MOTION: Judy Guenther moved that the commission approve 1.3 with amendment. Steve Anderson second. **MOTION CARRIED: 12-0.**

Consent Agenda

Items listed under the consent agenda are considered routine commission matters and will be approved by a single motion of the commission without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.

- 2.1 NPLEx Monthly Report Acceptance
 - December 2015
- 2.2 Pharmacies and Other Firm Application Approval
 - New and Closed Pharmaceutical Firms Report
- 2.4 Pharmacy Technician – Specialized Functions Approval
 - a. CHI Franciscan Health – IV Admixture
 - b. Valley Medical Center – IV Admixture
 - c. Yakima Valley Memorial Hospital- IV admixture

Items 2.3, 2.5, 2.6, 2.7, 2.8 & 2.9 were deleted from the consent agenda.

MOTION: Elizabeth Jensen moved that the commission approve items 2.1, 2.2, & 2.4 Sepi Soleimanpour second. Tim Lynch abstained. **MOTION CARRIED: 11-0.**

Old Business

Commission's Policy #36

Doreen Beebe and Erika Brown led the discussion asking the commission for clarification on the issuance/authority to issue intern registrations for participation in a postgraduate residency program. The discussion was continued from the September/October business meetings when the commission had asked for some modifications.

The main concern was for out of state applicants who are waiting to get a license to participate in a residency program. If they haven't been issued a license after 90 days they aren't able to participate. Without this policy they would be looked at as a graduate and not be eligible for a residency program at all. The credentialing team is meeting the 14 day timeline once the applicant has provided all documentation needed. Other discussion included applicants that have trouble passing the exam and the length of time some intern license are being held. Erika

Brown was asked to look into the possibility of flagging applicants that have held an intern license for 6 year or more by the next meeting for further discussion.

MOTION: Cheryl Adams moved that the commission approve Policy #36 as amended. Steve Anderson second. **MOTION CARRIED: 12-0.**

Pharmacy Ancillary Plan Review Process

Irina Tiginyanu and Maureen Sparks updated the commission on the status of updating/changing the process that ensures all pharmacy ancillary utilization plans (AUP's) are reviewed for approval by the commission.

They met with AAG, Joyce Roper via teleconference twice. There are 1,461AUP and a variety of types. There needs to be more research and work to make sure the new process is efficient. In the interim Irina Tiginyanu has put together a check list that is working well for now. The issue of programs receiving approval letters was discussed. Until credentialing is set up to send out letters approval letters will be sent out by staff and specify what the approval is for.

Maureen and Irina plan to bring a new process for reviewing AUP's to the commission for adoption at the March meeting.

New Business

Tamper Resistant Paper for Medical Marijuana

Lisa Hodgson, representing the medical marijuana program asked the commission for input on the use of paper approved by the commission under RCW 18.64.500 tamper-resistant prescription paper as the standard for medical marijuana authorizations and for staff to assist with this process.

During the discussion the commission's concerns were regarding the seal and how to recognizing the difference between pharmacy and medical marijuana paper and the workload this would add to pharmacy staff.

MOTION: Dan Rubin moved that the commission approve the tamper resistant paper that PQAC has previously approved be approved for use in medical marijuana authorization per the requirements of medical marijuana legislation that exists and the paper must have a differentiating feature between pharmacy and medical marijuana. The same approval process will be used for new tamper resistant paper for marijuana authorization that PQAC uses. Sepi Soleimanpour second. **MOTION CARRIED: 12-0.**

Correspondence

The commission discussed correspondence received or distributed on behalf of the commission.

- a. Animal Health Institute re: Animal Drug Compounding
- b. NABP MEMO– 2015 NAPLEX Third Trimester Report
- c. ASHP Release – *Accreditation Standards for Pharmacy Technician Education and Training Programs*

Maureen Sparks shared that ASHP passed a new standard for pharmacy technician training and education and the training programs that students only need one type of externship (hospital or

Retail). Maureen Sparks was asked to define exactly what the change in practice is and what the new standard is. There was some discussion that investigators are saying pharmacy assistants enrolled in a technician training program cannot make sterile products for patients. The concern is that some of the investigative team is telling facilities that until they are a licensed technician, the tech-in-training cannot compound sterile products for patient use. Commission members agreed that this has never been the case. As long as the tech-in-training (licensed as an assistant) is in a PQAC approved Technician Training program, they can compound patient specific sterile products. Then staff and Maureen were asked to draft and send out a communication to stakeholders before there is disciplinary action taken.

d. Doane's Valley Pharmacy – medication packaging

There was some discussion between the commission and AAG, Joyce Roper. Joyce is going to look more into the repackaging comment/proposal from Doane's Pharmacy and the Long Term Care legislation and report back to the commission in March.

Prescription Monitoring Update

Gary Garrety, Program Operations Manager was unavailable for the presentation Joyce Roper and Lisa Hodgson were able to discuss this item/update with the commission and provide some answers to their questions. Lisa will bring back answers to the few questions the commission had.

112th Annual NABP Meeting

MOTION: Elizabeth Jensen moved that Nancy Hecox and Maureen Sparks attend the 112th Annual NABP Meeting representing the commission. Nancy Hecox will be the voting delegate. Judy Guenther second. **MOTION CARRIED: 12-0.**

Sterile Compounding Critical Point Bootcamp

MOTION: Christopher Barry moved that the commission table this until the new guidelines come out. Chery Adams second. **MOTION CARRIED: 12-0.**

Posting Agenda Items

Joyce Roper led the discussion with the commission regarding postings agenda items to the web and RCW 42.56.270 - Public Records Act. In an effort to be transparent and post materials on our website for public we have come across some parties who are concerned about their documents being proprietary or a trade secret this wasn't anticipated. The parties and staff would like to know how to work around this. AAG, Joyce Roper provided some options to the commission on how to handle this.

MOTION: Chris moved that the commission require a court order or an injunction, in advance proving that the documents provided for presentation are proprietary or a trade secret. Steve Anderson second. Cheryl Adams, Tim Lynch, Sepi Soleimanpour, Judy Guenther, Elizabeth Jensen opposed. **MOTION CARRIED: 7-5.**

Requests/Proposals

Skyline Hospital

Cathy Williams introduced Amy Knowles, PharmD from Skyline Hospital via teleconference who was presented the report back to the commission.

MOTION: Steve Anderson moved that the commission approve Skyline Hospital's report back and their remote medication order entry services as a pilot with a report back in one year. Sepi Soleimanpour second. **MOTION CARRIED: 12-0.**

Open Forum

Grant Chester shared that he was contacted and informed that the commission is taking disciplinary action against Responsible Pharmacy Managers for the actions of their staff that the manager may or may not have known about. In the past this wasn't always done and when it was it was not consistent. Mr. Chester asked that the commission have a consensus among each other and stay consistent in how and why they discipline.

Chery Adams requested that the new members get some training regarding how to discipline, open cases and stay consistent. Doreen Beebe was asked to send out the grid that has been put together to help with consistency.

The commission discussed committing Friday mornings after the business meetings to discuss topics or do committee work Tim Lynch will ask commission members for topics or idea. Fridays are scheduled for hearings which do not always occur and the commission feels like they would like to utilize this time.

The commission adjourned for Executive Session and Case Presentations at 12:20 p. m.

The commission reconvened from Executive Session and Case Presentations at 1:22 p.m.

Legislation

Dan Rubin, Doreen Beebe and Lisa Hodgson provided an update to the commission on the legislation and the status of these bills.

SB 6203-updating statutes relating to the practice of pharmacy including long-term care settings.

HB 1528- authorizes health care providers prescribing epinephrine autoinjectors in the name of authorized entities.

HB 2458-prescription drug donation program.

HB 2431-allowing the prescription of Schedule II controlled substances to treat certain disease states and conditions.

HB 2725-authority of pharmacist to dispense prescription drugs

SB 2681-authorizing Pharmacists to prescribe and dispense contraceptives

SB 6228-an act creating the interstate medical licensure compact.

HB 2448- concerning the practice of certain East Asian medicine therapies.

HB 2475-allowing the disclosure of health care information with persons with a close relationship with a patient.

SB 6243-allows a training program for educators and parents to develop students social and emotional skills to help prevent youth suicide.

HB 2343-concerning limited licenses for medical school graduates who are not participating in a residency program.

HB 2350-defining the administration of medication by medical assistants.

HB 2294-concerning public funds being used for elective abortions.

HB 2304-concerning prescriptive authority of naturopaths.

HB 2319- concerning prescriptive drug insurance continuity of care.

SB 6149- providing reasonable accommodations in the workplace for pregnant women.

- Staff will draft a letter to support the “concept” of House Bill 2725 Authority of Pharmacists to Dispense Prescription Drugs and House Bill 2681 Authorizing pharmacists to prescribe and dispense with some changes to the language.
- The commission will comment on HB 2458 Prescription Drug Donation Program. Staff will draft a letter stating that the commission recognizes there is an access issue. They see value in this program however, they are concerned about the risk and need to see some structure to assure patient safety and that pharmacist participation is voluntary and these pharmacists can exercise their professional knowledge/judgement.

Committee Reports and Rule Making Updates

Technology Rules Committee

Sepi Soleimanpour is lead of the committee and asked Tracy West and Kyle Karinen to provide the update to the commission on the status of the Technology rules committee’s work. The commission has a “very” preliminary draft. The deadline for written comments was January 15, 2016. We received over 400 comments. We will go back to address comments, concerns and any other pieces brought to our attention. Another meeting will be held Feb 5 specific to Automated Medication System rules and some dialogue on the comments already received from stakeholders. We will then make some adjustments as needed to the draft and plan to bring the proposed rule to the commission.

Pharmacy Inspection Committee

The committee met via conference call during Christmas break. Cheryl Adams was tasked to put together a memo from the commission to the investigative team. This was sent out to all the commission members in meeting packet. AAG, Joyce Roper read the memo and had some concerns so the memo is on hold. There needs to be some additional work and in March the committee hopes to come back with either a memo or what the next steps will be. A sterile compounding check list sent out to stakeholders for discussion at the upcoming stakeholder meetings Feb. 2 and Feb. 29, 2016.

Sexual Misconduct Rule

The commission was asked to review draft rule language for approval and authorize staff to file CR102.

MOTION: Dan Rubin moved that the commission approve with a minor amendment to the proposed rule language amending WAC 246-860-100 Sexual Misconduct rule and authorize staff to file a CR-102 Proposed Rule Making and Notice of Public Hearing with the code reviser’s office. Cheryl Adams second. **MOTION CARRIED: 12-0.**

Rulemaking Champions

Rich Cieslinski asked the commission to designate commission champions for rulemaking activity.

- Outpatient ED Dispensing – Tim Lynch
- Controlled Substance Updates – Matthew Ronayne

- Electronic Transmission Information – Steve Anderson
- Donated Prescription Medications – Elizabeth Jensen
- Continuity of Care During an Emergency – Dan Rubin

Commission Members' Open Discussion and Reports

Tim Lynch reported:

- He's has been involved with the inspection committee, USP 797 guidelines, and setting up stakeholder meetings.
- He and Cheryl have been working together on the Long Term Care legislation in support of the bill.
- He's been working with ASHP on different activities.
- Tim has also been working with the hospital association regarding drug price increases.

Sepi Soleimanpour reported:

- Sepi has been participating in the inspection committee work.
- She has been doing a lot of studying regarding the technology committee. Sepi is now the chair for the technology committee.
- Sepi did some review of the Long Term Care bill.
- Attending the University of Washington Leadership and Curricula Meetings.

Chris Barry reported:

- He's been involved with the inspection committee.
- Hopes to continue to be a part of the USP 797 committee.
- Chris prepares a synopsis of the commission meetings to give to the Spokane Pharmacy Association and WSPA.

Cheryl Adams reported:

- Cheryl testified for the SB6203.
- She's been doing a lot of work on the inspection committee.

Judy Guenther reported:

- Judy has been participating on the inspection committee.

Gary Harris reported:

- Gary continues to be involved with the Pharmacy Alumni Association as President.
- He is involved with the University School of Pharmacy as Co-chair of UW Campaign.

Dan Rubin reported:

- Dan has been participating on the Meet Me Calls.
- December 21, 2015 he attended Senior Lobby meeting representing Dept. of Health and the commission.

Maureen Sparks reported:

- Maureen attended the WSPA Conference in November as a liaison for the commission and as a technician.
- She met with WSPA last week on some issues they are trying to get the technician academy up and running.

Arun Sambataro reported:

- She has been participating in Meet Me Calls.

Commission Action Plan

- Lisa Hodgson updated the remote order telepharmacy rule making haven't started not enough staff.
- We will be interviewing for temporary pharmacy consultant to assist with rulemaking and to provide back-up for the consultants.
- WSPA is interested in working with the commission to develop rules to implement Bill 5460.
- Pharmacies have received notices that they will be inspected within 6 months and the notice directs them to the website for tips on how to have a successful inspection.
- There has been a checklist developed for stakeholder meeting management and to help staff be clear when communicating with the public.
- Lisa reached out to WSPA and NACDS to establish communications.
- She previously met monthly with WSHA to discuss topics of mutual interest.
- Rich Cieslinski developed slides for a webinar on rule making. This will include just a general overview of the rulemaking process. The goal is to hold this webinar middle to end of February.
- Doreen Beebe has been working on updating the PQAC website there is more work to be done but so far she has done a great job.
- December 15, 2015 there was a New Member Orientation.
- We developed fact sheets on the commission that can be used if we get called to the legislature.

Commissioners' open discussion relevant to commission business/pharmacy practice

Elizabeth Jensen would like a list of what committees/workgroups/liaisons/champions we have going? She would also like to know who is on what? She feels like this work needs to be distributed equally. Staff was asked to provide the list of all of this work and to include the work that is on hold.

Ian Corbridge commented that he feels it would be helpful for stakeholders to have access to what the inspectors are seeing out in the field as a concerning trend and potential resolution to address those issues.

He shared that it would be helpful for individuals to have access to a document that explains what the inspection process is like, what the time frame would be like and what their rights are. We are also hearing from our members that they are having a hard time getting Pharmacist In Charge (PIC's) to fill a needed role. He asked the commission to reflect on that and see what has taken place historically that has caused this issue and see what can be done going forward to resolve this issue.

Staff reports

Lisa Hodgson reported:

- DOH is working on fee increase for Pharmacy Researchers
- Staff has been extremely busy reviewing and analyzing bills, thank you to those who have provided support and comments to assist staff.
- There has been a request to hire a temporary pharmacist consultant.
- Heard from AI and others concerns whether or not the commission is staffed appropriately. This will be looked at in the next few months.
- Continue to troubleshoot on the Citrix issue. We are very sorry for the inconvenience.

- It was requested to work on some team building within the commission there has been solicitation for a bid put out once we get some applications we will reach out to Tim Lynch and Nancy Hecox to see if this is still a direction the commission wants to take.

Joyce Roper reported:

- Preparing a response to the petition we have decided not to wait for the court to ask and given how it was written and how it was phrased we figured we really didn't want it out there without addressing it so we have asked for an extension that is now due March 7, 2016. There is a team of us that are working on preparing the commission response to the Supreme Court in the Stormans case.

Gordon MacDonald reported:

- Over the last few months he asked his field investigators to send him a list of their top five issues they see in the field. Anything with more than one hit was put on a list there were 19 items.

Open Forum

Jeff Rochon WSPA provided a quick update on some of the work with regard to SB5557 that allows pharmacist to become providers with the medical provider networks. Credentialing and privileging group will meet again within the next month. The billing coding and documentation group met last week as well as outcomes and research and the technology communications group. All these groups are looking at building the tools necessary for pharmacists to want to get into the medical provider network. As we go through this process it is important to work with you. If any of you would like to attend there is an open invitation we would love to have commission participation. We have a number of bills in this session, it's raining bills during this meeting one bill has been dropped and four committee hearings have been set. This being a short session it is fast and furious. Jeff provided some update on a few bills as well.

BUSINESS MEETING ADJOURNED

There being no further business, the commission adjourned at 4:22 pm

Respectfully Submitted by:

*Leann George, Program Support
Approved March 3, 2016*


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

