



State of Washington
Department of Health

December 11, 2015
Business Meeting Minutes
Highline Community College
2400 s 240th St
Des Moines, WA 98198

CONVENE

Chair Al Linggi called the meeting to order December 11, 2015.

Commission Members:

Al Linggi, RPh, MBA
Arun Sambataro, Public Member
Steve Anderson, RPh
Dan Rubin MPP, Public Member, Vice Chair
Christopher Barry, RPh, Chair
Tim Lynch, PharmD
Nancy Hecox, PharmD
Matthew Ronayne, RPh
Olgy Diaz, Public Member
Judy Guenther, Public Member
Cheryl Adams, PharmD
Gary Harris, RPh
Sepi Soleimanpour, RPh, MBA-HA

Guest / Presenters:

Paula Meyer, Executive Director for NCQAC
Leslie Emerick, Consultant for East Asian
Medicine Association
Andrew McIntyre, President of East Asian
Medicine Association
Zachery Fulton, East Asian Practitioner
Traci Mitchell, PharmD, MHA Manager of
Pharmacy Svcs & Infection Control for
Evergreen Health Monroe Hospital
Gerald Steele, Attorney at Law
Chris Baumgartner, Drug Systems Director
Leo Raudys, Liaison for Call2recycle

Absent Commission Member:

Maureen Sparks, CPhT
Elizabeth Jensen, PharmD

Staff Members:

Joyce Roper, AAG
Lisa Hodgson, Director of HPF
Lisa Roberts, RPh. Pharmacy Consultant
Cathy Williams, RPh, Pharmacist Consultant
Irina Tiginyanu, Pharmacy Technician Analyst
Doreen Beebe, Program Manager
Gordon MacDonald, RPh, Chief Investigator

Absent Staff Members:

Leann George, Secretary Senior

Call to Order

- 1.1** Approval of Business Meeting Agenda.
- 1.2** Approval of October 29, 2015 Regular Business Meeting Agenda
- 1.3** Approval of October 30, 2015 Special Meeting Minutes.

MOTION: Dan Rubin moved that the commission approve 1.1. Steve Anderson second.
MOTION CARRIED: 13-0.

MOTION: Dan Rubin moved that the commission approve 1.2 with the amendment. Judy Guenther second. **MOTION CARRIED: 13-0.**

MOTION: Judy Guenther moved that the commission approve 1.3 with amendment. Dan Rubin second. **MOTION CARRIED: 13-0.**

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
 - October 2015
- 2.2 Pharmacies and Other Firm Application Approval
 - New and Closed Pharmaceutical Firms Report
- 2.4 Pharmacy Technician – Specialized Functions Approval
 - a. Seattle Children’s Hospital Tech check Tech
 - b. MultiCare Medical Center (Tacoma General) Tech check Tech
 - c. Providence Holy Family – Medication Reconciliation
 - d. Providence Sacred Heart
 - i. Tech check Tech
 - ii. Medication Reconciliation
- Automated Drug Distribution Device Approval
 - St. John Medical Center – St. John Medical Broadway
- 2.5 Dialysis
- Electronic Prescription Transmission System Approval –*no items*
- Follow-up Report on Routine Remote Medication Order Processing
- 2.9
 - Forks Hospital

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

MOTION: Dan Rubin moved that the commission approve items 2.1, 2.2, & 2.5 on the consent agenda and to remove 2.4 (a, b, c &d) and 2.9 for further discussion. Judy Guenther second. **MOTION CARRIED: 13-0.**

Legislation

Nursing Care Quality Assurance Commission

Paula Meyer, Executive Director for Nursing Care Quality Assurance Commission (NCQAC) handed a packet to the commission with the updated *HB2080*. Paula Meyers then discussed *HB2080* and asked the commission for a letter of support or signing in support at the hearing for this bill for the 2016 legislation. This bill is regarding notification of changes in an applicant or licensees’ criminal history.

MOTION: Dan Rubin moved that commission staff send a letter of support of *HB2080* for NCQAC legislation and that PQAC consider similar type of legislation in the future. Judy Guenther second. Olgy Diaz and Arun Sambataro opposed. **MOTION CARRIED: 11-2.**

East Asian Medicine Association

Lisa Hodgson introduced Leslie Emerick, Governmental Consultant for the WA East Asian Medicine Association. Leslie introduced Andrew McIntyre, President East Asian Medicine Association and Zackery Fulton, East Asian Practitioner. They each participated in discussing their proposal and discussing the commission's concerns and questions. A big concern was about the drugs not being FDA approved. It is not the commission's authority to regulate another profession. The commission was asked to provide feedback on legislation proposed by the East Asian Medicine Practitioner Association to amend RCW 69.41.030 to grant authority to purchase, possesses, and administers sterile water, herbs, minerals, vitamins in liquid form, and nutritional supplements. AAG, Joyce Roper provided some possible direction on how they can change their language in this statute to allow the East Asian Medicine Association can continue to regulate their profession not PQAC.

Requests/Proposals

Evergreen Health

Cathy Williams led the discussion from Evergreen Health Monroe Pharmacy asking the commission for approval to provide remote medication order processing services for the detox unit at Evergreen Health Recovery Center, a licensed health care entity in Monroe. Traci Mitchell, Manager of Evergreen Health Recovery Center presented the proposal to the commission.

MOTION: Dan Rubin moved that the commission approve proposal by Evergreen Health Monroe Pharmacy to provide remote medication order processing services for the detox unit at Evergreen Health Recovery Center, a licensed health care entity in Monroe with a report back in one year. Staff will work with Traci Mitchell on the standard information to provide in the report back. Christopher Barry second. **MOTION CARRIED: 13-0.**

Rulemaking and Committee Reports

Petition to Amend WAC 246-883-020

Gerald Steel, Attorney at Law representing King County Citizens against Fluoridation and Washington Action for Safe Water asked the commission to consider amending WAC 246-883-020 clarifying the designation of legend drugs.

Mr. Steel has petitioned the board now the commission in regarding the fluoridation of water several times. The last petition was denied in March 2013. After Mr. Steel provided his presentation to the commission AAG, Joyce Roper followed up with some background on the petitions in the past and why they were denied. She also provided some definition clarification regarding the petition to amend WAC 246-883-020 to the commission.

MOTION Tim Lynch moved that the commission acknowledge Mr. Steels concern regarding the language in WAC 246-883-020 and that the commission engages in the rule making process to address the language so that it is reflective of current practice and references FDA requirement for legend drugs and to approve the petition for CR101 to clean up this language. Judy Guenther second. Christopher Barry, Gary Harris, Nancy Hecox and Steve Anderson opposed. **MOTION CARRIED: 9-4.**

Note: The commission and Mr. Steele agreed that this will be added to the commissions rule docket subject to its rule prioritization.

King County Citizens against Fluoridation and Washington Action for Safe Water

Gerald Steel, Attorney at Law asked the commission to consider a request for rulemaking by adopting a new rule to clarify that fluoridation chemical additives and fluoridated drinking waters are drugs pursuant to RCW 18.64.011(12), 69.04.009, and 69.41.010(9) when the intended use is to aid in the prevention, mitigation and/or prophylactic treatment of dental caries disease. Mr. Steel again presented his petition and the details to this potential new rule. During this presentation he shared the reasons his past petitions were denied.

AAG, Joyce Roper made some clarifications on the petition presented by Mr. Steel. The biggest issue is the Court of Appeals looked back at their decision made many years ago this decision stated, that fluoridating substances in drinking water are NOT drugs. The commission is not in the position to override decisions made by the Court of Appeals or the Supreme Court. The only way for this to be changes is for legislation to change the law.

MOTION: Gary Harris moved that the commission deny the petition for rulemaking to adopt a new rule to clarify that fluoridation chemical additives and fluoridated drinking waters are drugs pursuant to RCW 18.64.011(12), 69.04.009, and 69.41.010(9) when the intended use is to aid in the prevention, mitigation and/or prophylactic treatment of dental caries disease. This decision is based on the Court of Appeals decision. Steve Anderson second. Arun Sambarato opposed. **MOTION CARRIED: 12-1.**

The commission adjourned for Executive Session and Case Presentations at 12:00 p.m.

The commission reconvened from Executive Session and Case Presentations at 1:00 p.m.

Legislation Cont'd

Second Substitute Senate Bill 5052

Chris Baumgartner, Drug Systems Program Director briefed the commission on stakeholder work to develop a recommendation regarding the rescheduling or de-scheduling of medical marijuana, and other options.

During the 2015 legislative session, Second Substitute Senate Bill 5052 (SB 5052) was passed by the legislature. It was signed by Governor Inslee on April 24, 2015. The Governor vetoed Sections 42 and 43, which would remove from Schedule I of Washington State's Controlled Substances Act any medical marijuana product that the Department of Health identifies in rule as "appropriate for sale to qualifying patients and designated providers in a retail outlet that holds a medical marijuana endorsement.

November 20, 2015 during stakeholder meeting three options developed by the department was presented than department collected input from stakeholders. The attendees represented patients, growers and dispensaries/retail stores. No attendees identified themselves as health care practitioners or members of law enforcement. The majority stakeholders responded that none of the options would work. Overwhelmingly, the group was in favor of completely de-scheduling and de-regulating marijuana and treating it like any other plant (removing it completely from the Controlled Substances Act).

Chris Baumgartner asked the commission to weigh in on the three options that were presented to the stakeholders. AAG, Joyce Roper provided clarification and helped answer questions the commission had. WSPA was asked to explain their position statement. This statement from May of 2013 ago and has not been updated or reviewed but they believe marijuana does need to be rescheduled. There was a great discussion within the commission and sharing their differences of opinions the main concern is keeping patients safe.

MOTION: Christopher Barry moved that the commission support **Option 3: Amend the Washington State Controlled Substances Act (CSA) to be consistent with I-502 and SB 5052 and Chapter 69.51A RCW. All other use would still be illegal.** Steve Anderson second.
MOTION FAILED: 2-11

After this motion was initially made the discussion continued and there were other purposed options. This motion didn't pass.

MOTION: Tim Lynch moved that the commission support amending **Option 2 into an Option 5: Do nothing to impact recreational marijuana but classify medicinal marijuana as a legend drug that is a schedule that we can work on in our process. It's a legend drug at a minimum and a potential scheduled drug depending on work with stakeholders and others. We do regulate the management and use of medical marijuana as a medication.** Nancy Hecox second. Dan Rubin, Christopher Barry and Steve Anderson opposed. **MOTION CARRIED: 9-3**

Meet Me Calls

The commission was asked to designate a representative and alternate member to participate on the weekly Department of Health "Meet Me Call" to discuss legislative bills with potential impact to multiple programs/professions.

MOTION: Judy Guenther moved to designate Tim Lynch, Arun Sambataro and Dan Rubin to represent PQAC on the Meet Me Calls. Gary Harris second. **MOTION CARRIED: 13-0.**

Requests/Proposals cont'd

King County Call2recycle Pharmaceutical Waste Takeback Program

Lisa Roberts introduced Leo Raudys with Call2recycle. Mr. Raudys presented the commission some background on Call2recycle, a status update on what Call2recycle has been up to in King County then some operational details on how they plan to provide this service in King County. This gave the commission an opportunity to ask questions and share concerns and suggestions.

Call2recycle worked with staff and Gordon MacDonald and was thankful for the helpful feedback provided. The program must be up and running by April 2016. By the end of each delivery the training will be given to the pharmacists in these pharmacies. The commission was then asked to consider the policies and procedures of the King County Call2recycle Pharmaceutical Waste takeback program for potential collection sites in pharmacies.

MOTION: Cheryl Adams moved that the commission not get involved in Take Back Programs and leave it to the DEA to regulate as long as the program has been approved by a governmental agency but the vendors must be approved by PQAC in direct accord of federal standards (DEA). Judy Guenther second. **MOTION CARRIED: 13-0.**

MOTION: Tim Lynch moved that the commission approve Return Meds as an authorized vendor for Take Back Programs. Gary Harris second. **MOTION CARRIED: 13-0.**

New Business

Consent Agenda Items for Discussion

2.4 Pharmacy Technician – Specialized Functions Approval

- a. Seattle Children’s Hospital Tech check Tech
- b. MultiCare Medical Center (Tacoma General) Tech check Tech
- c. Providence Holy Family – Medication Reconciliation
- d. Providence Sacred Heart
 - i. Tech check Tech
 - ii. Medication Reconciliation

MOTION: Cheryl Adams moved that the commission approve items 2.4 (a, b, c &d) and help staff figure out the specialized IV portion of the AUP and instruct the inspectors not to take action until PQAC and staff come up with a plan/process. Sepi Soleimanpour second. **MOTION CARRIED: 13-0.**

2.9 Follow-up Report on Routine Remote Medication Order Processing

- a. Forks Hospital

MOTION: Dan Rubin moved to approve the Remote Medication Order Processing for another year and they must follow-up but they must clarify in writing to the commission if the pharmacy technicians are operating without a pharmacist. Tim Lynch second. **MOTION CARRIED: 13-0.**

Correspondence

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

- Characteristics of Complaints- report by Dr. Hecox shared that she wrote a paper and it has been accepted for publication and has been given to the WSPA to give to pharmacies in our state for a teaching tool.
- Lisa Hodgson had some correspondence with WISHA regarding 5460. There won’t be work done on this project right now. We are focusing our efforts on our action plan.

Committee Reports

Technology rules

Al Linggi shared the committee met four times and had limited stakeholder involvement twice. The committee outlined and had excellent response from some experts there are still a few issues. DOH rules experts are now engaged are currently working on this. The next meeting was schedule for December 18, 2015 but now has been moved to the beginning of January. There needs to be a new Chair for this committee. Tim Lynch nominated Sepi Soleimanpour to chair this committee.

MOTION: Tim Lynch moved that the commission nominate Sepi Soleimanpour as the new technology committee chair. Nancy Hecox second. **MOTION CARRIED: 15-0.**

Pharmacy Business Practice Rules Committee

The committee is now on hold. Nothing has been done since last reported.

Inspection Process Rules Committee

Tim Lynch updated the commission. The committee has been working with staff on setting up first scoping meeting. On December 18, 2015 a meeting will be held to work thru stakeholder meeting scheduling and setting up framework for our work as a committee,

Pharmacy Compounding Rules Committee

Al shared that this committee has been put on hold until USP comes out with the updated USP. Lisa Hodgson shared that the Inspection committee will be working on an interim check list so pharmacies can be provided guidance until USP is updated. Invitations were sent out to the Stakeholders. Tim Lynch worked with Gordon MacDonald on interim check list.

Commission Members' Open Discussion and Reports

Tim Lynch reported:

- Attended ASHP this week and in October
- Early October presented at ASHP Leadership meeting
- Working with Gordon MacDonald and other staff on interim compounding checklist and Inspection process

Matthew Ronayne reported:

- Attended the WRAPP Training
- Went through five different pharmacy schools
- Toured a compounding pharmacy in Spokane

Sepi Soleimanpour reported:

- Been educating herself on Oregon Birth Control
- Spent a week in Idaho learn about their rules and regulations
- Spent past couple weeks on specialty central fill works

Steve Anderson reported:

- He attended the last business practice committee meeting

Nancy Hecox reported:

- Attended business practice meeting, technology meeting, and medical marijuana meeting via webcast she is the liaison.
- She managed to get her paper published.

Cheryl Adams reported:

- Went to the WSPA Annual Meeting and did presentation for Chris Humberson and ended

up with great dialogue with the WSPA and asked for input from stakeholders.

Judy Guenther reported:

- Went on a long term care pharmacy and facility tour in Bellevue

Gary Harris reported:

- Attended pharmacy business practice meeting

Dan Rubin reported:

- Attended the CAC meeting on November 12-13 in Washington DC. The conference theme was, “Demonstrating Current Competence: Where Are We? Where Are We Headed?” Mr. Rubin provided a more detailed written report to fellow commission members
- Did a lot of work on consumer outreach area
- Worked with Lisa Hodgson and Lisa Roberts and some other Executive Directors on internal DOH coordination he is set up to attend Washington Senior Lobby. There are three areas that would be good for DOH.

Al Linggi reported:

- Attended the strategy meeting UW School of Pharmacy. Overall applications for pharmacy schools are down by about 10%
- Spent six hours to come up with the RSA packet that was received.
- This was Al Linggi last commission meeting.

Elizabeth Jensen reported:

- Moving pharmacy into a new clinic
- Passed board certification for ambulatory care specialty
- Clinic opened up a Coumadin pharmacy

Election of Officers

Each member that was nominated or interested in these positions briefed their fellow commission members as to why they want to be in these positions.

Tim Lynch was elected as the 2016 Chair for the Pharmacy Commission.

Nancy Hecox was elected as the 2016 Vice Chair for the Pharmacy Commission.

University of Washington’s School of Pharmacy Curriculum Committee

The commission was asked to designate a member to represent the commission on University of Washington’s School of Pharmacy Curriculum Committee. Sepi Soleimanpour and Tim Lynch were appointed to represent PQAC on this committee.

Special Meeting

The commission was asked to discuss a day and time for a special meeting before 2016. A senator asked for some information to update a statute during legislation. Chris Humberson developed a spreadsheet that has been sent to senator staff but the commission hasn’t seen it. This special meeting is for the commission to discuss the spreadsheet. The commission agreed to December 29, 2015.

Staff reports

Lisa Hodgson reported:

- There was some discussion on rulemaking activities about a month behind we have been without a rules coordinator. Rich Cieslinski has been hired who will start December 16, 2015 as the new rules coordinator.
- Gordon MacDonald continues to review the inspection reports to identify any inconsistent application of rules or law. He is also working to update the Inspection Customer Satisfaction survey.
- IIO is working on a plan to provide pharmacies with advance notice of inspection using a time frame of six months and will include tips on a successful inspection.
- Ronald Rupke provided tactical communication training to the investigators
- Staff working with communication consultant to improve our communication to the stakeholders and the public.
- Working with Gordon MacDonald to develop a webinar on the inspection process hope to deliver that webinar in January.
- New member orientation will be held on December 18, 2015.
- Template developed for presentations to the commission. We are enforcing timelines for packet submissions so they will be received 2 weeks in advance.
- Doreen Beebe has been working with vendors to purchase a sound system that can be used at our meeting locations with no system.
- Long term care report was submitted to legislator on time.
- Staff developed a rulemaking document to extend emergency rules to allow pharmacies to provide medications in a declared emergency.
- Developed a notice of rulemaking to give notice that the commission plans to amend the sexual misconduct rules.

Joyce Roper reported:

- There is a new due date for the Stormans petition from the plaintiffs is January 4, 2016.

Lisa Roberts reported:

- She attended technology committee meeting and has been actively working on the rules
- Still working on lengthy e-prescribing project.
- Attended two different DOH rules writing courses
- Multiple mandatory training classes.

Open Forum

Doreen Beebe presented Al Linggi a special thank you in the interim until his plaque comes thanking him for his service with some words of appreciation.

Jeff Rochon from WSPA shared a report about the WSPA Annual Meeting. He invited the commission to attend their board meetings and or annual meetings. A great deal of work has been done regarding provider status for pharmacist. Three documents came out of all this work that will be sent out. Four workgroups developed on the billing portion of *Bill5557*.

Membership survey was done to better highlight the differences between our members. So WSPA can better serve its members. Thanked Al Linggi for all of his work on the commission.

BUSINESS MEETING ADJOURNED

There being no further business, the board adjourned at 5:08 pm

Respectfully Submitted by:

Leann George, Program Support

Approved January 21, 2015

A handwritten signature in black ink, appearing to read "Tim Lynch", written in a cursive style.

*Tim Lynch, Pharm.D., MSChair
Pharmacy Quality Assurance Commission*

