



State of Washington
Department of Health

**Amended Meeting Minutes
July 30, 2015**

Blackriver Training and Conference Center
Cedar/Duwamish Rooms
800 Oakesdale Ave. S.W.
Renton, WA 98057

CONVENE

Vice Chair Dan Rubin called the meeting to order at 9:10 a.m.

Commission Members:

Dan Rubin MPP, Public Member, Vice Chair
Christopher Barry, RPh
Steve Anderson, RPh
Elizabeth Jensen, PharmD
Tim Lynch, PharmD
Maureen Sparks, CPhT
Nancy Hecox, PharmD
Matthew Ronayne, RPh
Olgy Diaz, Public Member
Judy Guenther, Public Member
Cheryl Adams, PharmD
Gary Harris, RPh,
Arun Sambataro, Public Member

Guest / Presenters:

Paul Thompson, Pharmacy Director
for Navos Hospital
James Hall, PharmD for ReliantRx
Patrick O'Connor, Pharmacy Director
for TCH
Ponce Bautista, Director of Pharmacy
for Premier Long Term Care

Absent Commission Members:

Al Linggi, RPh, MBA, Chair
Sepi Soleimanpour

Staff Members:

Joyce Roper, AAG
Christopher Humberson RPh, Executive Director
Greg Lang, Pharmacy Investigator
Lisa Roberts, RPh. Pharmacy Consultant
Cathy Williams, RPh, Pharmacist Consultant
Doreen Beebe, Program Manager
Irina Tiginyanu, Pharmacy Technician Analyst
Leann George, Secretary Senior
Gordon MacDonald, RPh, Chief Investigator

CALL TO ORDER

- 1.1 Approval of Business Meeting Agenda.
- 1.2 Approval of June 11, 2015 Meeting Minutes.

MOTION: Gary Harris moved that the commission approve 1.1; Nancy Hecox second.
MOTION CARRIED: 13-0.

MOTION: Steve Anderson moved that the commission approve 1.2; Matthew Ronayne 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**
 - June 2015
- 2.2 Pharmacies and Other Firm Application Approval**
 - New and Closed Pharmaceutical Firms Report
- 2.3 Pharmacy Tech Training Program Approval**
 - a. 1st Ave Pharmacy
 - b. Fairway
 - c. Native Project Pharmacy
 - d. Skagit Valley College
 - e. Yakima Valley Farm Workers Clinic
- 2.4 Pharmacy Technician – Specialized Functions Approval**
 - a. Holy Family Hospital – Tech check Tech; IV admixture preparation; and Taking Medication List
 - b. Providence Centralia Hospital – Medication Lists
 - c. Skagit Valley Hospital – Tech check Tech
 - d. Yakima Valley Memorial Hospital – Tech check Tech
- 2.5 Automated Drug Distribution Device Approval**
 - Snoqualmie Valley Hospital
- 2.6 Electronic Prescription Transmission System Approval**
 - Epic Willow Ambulatory

Items 2.7 and 2.8 were deleted from the consent agenda.

The commission requested that Items 2.3 (a, b, c, d & e), 2.4 (a & b), 2.5 & 2.6 be pulled from the Consent Agenda for further discussion.

MOTION: Chris Barry moved that the commission approve items 2.1, 2.2, & 2.4 (c & d) on the consent agenda. Steve Anderson second. **MOTION CARRIED: 13-0.**

REPORTS

Commission Members

Gary Harris reported:

- Spent the month of June in Africa
- He has participated in business practice meetings via teleconference calls.
- Mr. Harris attended a meeting of the University of Washington Pharmacy Alumni Association as its current president.

- He gave a lecture last week to a pharmacy technician training program at a North Seattle Community College.
- Gary attended a Dean's Club Event the last week of July 2015.

Nancy Hecox reported:

- She has participated in all 3 rules committees; Business practices, Sterile Compounding and Pharmacy Technology.
- Nancy went out with Tyler Varnum and Eleanor Carbett last week on a hospital inspection, which was an "eye opener".

Tim Lynch reported:

- Participated in Pharmacy Technology committee
- Working with ASHP on their leadership conference and a mid-year conference in December 2015.
- Participating on a work group regarding the pharmacy inspection process

Olgy Diaz reported:

- Completed the new commission member orientation.
- she will be going along on a pharmacy inspection on July 30th.

Cheryl Adams reported:

- Participated in phone conference with Tim Lynch's work group regarding pharmacy inspections.
- Since the last meeting Cheryl has been reading past meeting minutes and newsletters to catch up on hot topics. Also, she has reached out to representatives of stakeholders in our pharmacy world, WSHA, WSPA, and Senator Linda Parlette.

Dan Rubin reported:

- July 20 he participated in a leadership meeting of members of boards and commission with some of the DOH management.
 - ✓ A system called Citrix is being rolled out to commission members and a specific email will be provided to members instead of using personal emails along with providing access to certain documents.
 - ✓ A process improvement manager will be provided at the division level. There also will be more focus on analytics and metrics to explore sources of health care errors from available data, which might be valuable to the Commission
 - ✓ Models are being developed for voluntary engagement between people who have been injured and those who assume responsibility (practitioners). This initially focused on medical doctors and will expand over time, initially focusing on a single profession at a time.
 - ✓ There was an update on interstate licensing compacts with Nursing as a prime example. This is relevant to our work related to both pharmacists and pharmacies.
 - ✓ Many Critical Access Hospitals are struggling and at the DOH level there is an effort to try to find other ways to look at regulatory status.
 - ✓ There was a brief discussion of new procedures for FBI fingerprint checks, which allows for updates if the individual has subsequent criminal justice "hits" after the initial request so long as there is an ongoing purpose for the information such as licensing.

- Last Friday Al and Dan met with a consultant hired by DOH to examine stakeholder perceptions of many areas of our communications. The report was only available to them late last week and will be shared with the Commission at a later meeting.

Elizabeth Jensen reported:

- Monday and Tuesday also went with Tyler Varnum and Eleanor Carbett for inspections. Elizabeth recommended that all commission members participate in these if given the opportunity.
- She participated in two Business Practice meetings since the last commission meeting.
- Elizabeth attended the Planning Session in Tacoma July 29, 2015.

Arun Sambataro reported:

- As a new member, Arun has been reading newsletters so she can get up to speed and be an effective commission member.

Steve Anderson reported:

- He attended the Business Practice in Kent on June 30, 2015.
- Steve had knee surgery July 10, 2015.
- He participated in the Business Practice meeting via teleconference July 16, 2015.
- He passed the Oklahoma MPJE July 22, 2015
- He also attended the Business Practice meeting in Tacoma July 28, 2015.
- Along with commission members and staff attended the Planning Session July 29, 2015.

Maureen Sparks reported:

- On July 8, 2015 she attended the Pharmacy Technician Educators Council Meeting in New Orleans.
 - ✓ While there heard a report from someone from the USP 797 expert panel.
 - ✓ Talk from Pharmacy Technician Certification Board regarding the 2020 initiative where all technicians that sit for the national certification test must graduate from an ASHP accredited program.
 - ✓ She participated in a discussion with ASHP publication manager who is looking to publish a new book on sterile compounding for technicians.

Judy Guenther reported:

- She participated in conference call with other members on inspection processes.
- Judy went on an inspection with Brad Dykstra to a long term facility. This was a great experience.

Executive Director

Chris Humberson reported:

- Chris attended several sessions to organize the planning session
- He received and shared the report on recommendations for improving communications
 - ✓ Some are within the control of the commission/ others are with DOH
 - ✓ (e.g. PQAC web site improvements / Listserve and functionality)
- On July 16, 2015 Chris held a Spokane Long Term Care Stakeholder meeting

- He attended a Seattle Meeting with stakeholders and legislators as follow up to Opioid overdose legislation from 2015.
- Chris attended a UPWG quarterly meeting: They are considering updating their charter and pursuing recent legislation on Naloxone deployment.
- Chris is lead on HPF Office Morale Improvement Program for:
 - ✓ Telecommuting
 - ✓ Flex schedules

Assistant Attorney General

Joyce Roper reported:

- On July 23, 2015 the Ninth Circuit issued its ruling in the Stormans case and reversed the ruling of Judge Leighton and said the Pharmacy Commission's rules were neutral and generally applicable. The Ninth Circuit said the rules did not target the religious beliefs of the Storman's Corporation and the two individual pharmacists who filed the lawsuit. These rules did not violate the First Amendment of the Constitution. The two million dollar judgment for Plaintiffs' attorneys' fees and costs is no longer pending against the Pharmacy Commission. However, the Plaintiffs' attorneys have notified the State's attorneys that they will seek review of this decision.

Consultant Pharmacists

Lisa Roberts reported:

- Lisa accompanied Brad Dykstra on two inspections. Being on the other side of the inspection was a very different perspective.
- Aside from routine duties, she has coordinated two pharmacy technology rules meetings on June 25 and July 24, 2015. There are approximately 40 people split into six working groups.

Supervising Pharmacist Investigator/Field Investigator

Gordon MacDonald reported:

- Last month we started inviting the commission members to attend inspections with the PharmacyInspectors. It would be very valuable for commissioners to see how inspections are done currently.
- Inspection team is continuing to work on a CE program regarding sterile compounding for licensees.
- Gordon attended all subcommittee meeting in pharmacy technology and business practice meetings.
- He has been working with DOH EMS program helping them with some implementation questions regarding hospital supplying drugs to to EMS and Ambulance services as well as residential treatment facilities who obtain Health Care Entity licenses.

LEGISLATION, RULEMAKING, AND POLICY DEVELOPMENT

Final Legislation Update

Passed Bills with Legislative Implementation Plans:

SHB 1625 Ambulances & aid, drugs

HB 1637 Tribes/ Prescription Monitoring

ESHB 1671 Opioid overdose medications
SSB 5027 Prescription Drug Monitoring
SSB 5268 Eye drop prescription refills
ESSB 5460 Prepackaged emergency medications in ER
ESSB 5557 Services provided by pharmacists
ESB 5577 Pharmaceutical waste
ESB 5935 Biological products
ESSB 6052 Sect. 219(II) Operating budget – PQAC developing proposed statutory language regarding long-term care pharmacies for the legislature by Nov 15, 2015.

Planning Session Debrief

Dan Rubin updated the public on some of the discussion at the planning session on July 29, 2015. The commission and staff met in an open meeting discussed priorities in our sizable rule making list and a number of areas of our own operational process in developing rules and other matters. Briefly discussed whether or not we had the best frequency and duration of meetings. Rule priorities:

- a) Sterile compounding
- b) Pharmacy technology
- c) Business practices, except rest and lunch breaks for pharmacists
- d) Inspection process
- e) A petition we accepted to do emergency rulemaking regarding the drug Vyvanse for binge eating.

We looked at the nature of our agenda process and streamlined the presentations. We will minimize live presentations during a meeting since the commission has already read the material. This will allow the commission to focus more on their questions/concerns during discussion.

Committee Updates

a) Pharmacy Business Practice

Dan Rubin provided a brief update on the Business Practice work done. The Business Practice Committee met June 30 and July 28, 2015. They completed the review through the content areas related to share accountability between PIC and business entities. At this point, the committee is beginning process of drafting rule ideas. That will be discussed with interested parties before any language is sent out.

b) Technology

Lisa updated the commission on the Technology rules. The workgroup has 35-40 members. They decided to divide the workgroup into 6 categories. They have met twice June 25 and July 24, 2015. After the July meeting, each group from all 6 categories came up with some preliminary material together. We are hoping to put that up on our website for public to see. The workgroup has a week to provide input on where/when they would like the next meeting.

c) Long-Term Care Workgroup/Rules

Chris Humberson provided an update on the Long Term Care. The 2015 legislature requested that the commission provide stakeholder-focused recommendations for any needed statutory changes in a report by November 15th, 2105. This report will be based upon the completed stakeholder work already conducted and additional stakeholder work

scheduled in August of 2015 with focus specifically on any statutory recommendations by the commission's work with stakeholders.

Three stakeholder meetings were held in Kent, Washington, Vancouver, Washington and Spokane, Washington from March 2015 to July 2015. The meetings were two hours in length in the evenings and were facilitated as a conversation regarding issues of concern to scope the problems and opportunities currently present in Long Term Care pharmacy operations. An average of forty people attended each of the sessions. In the final meeting in Spokane, the NABP Long Term Care pharmacy model rules were discussed as part of a discussion on options for rule development, as well as the legislative action requesting stakeholder input on any recommended statutory changes in LTC pharmacy that the commission would suggest. With two additional stakeholder meetings planned, we expect to have active participation to reach consensus.

d) Inspection process committee

Tim Lynch provided an update on inspection process committee. The committee met earlier in July just to discuss the inspection process. Discussion was based around the process of these inspections. There will be another meeting held in a couple weeks about the investigators to discuss how to provide investigators interpretive guidance. With the outdated rules puts investigators in a difficult situation with the way things are being done now. We will be focused on patient safety issues as a priority.

Approved Rulemaking Activities Updates

a) Electronic Prescription Communication Rules

Doreen Beebe updated the commission on Electronic transmission prescription. When the commission first proceeded with the process to incorporate the changes required from legislation law into the WAC's, it was recognized that this would not be easy to meet the criteria for abbreviated rulemaking. So now the CR101 is being prepared for filing and could be in the review stages within DOH rules process.

b) Pharmaceutical Compounding Rules (Sterile)

Chris Humberson gave an update to the commission on the Sterile Compounding rules. The second draft is done it is being vetted with the members of the committee should be out in a week for a comment period between 6-8 weeks.. It has been dialed back with regard to taking out USP 800 streamline and making sure elements we have specifically address gray areas in 797. We are hoping to bring this to the commission in the fall after the comment period.

c) Inspection Process Rules Update

Chris Humberson gave a quick update on the purpose of the Inspection Committee. This process is to try and determine how and if we should move from the point system to another type of system with a plan of correction. Brittany Mahung scheduled a meeting in Kent August 4, 2015 to get a base line and scope this out as to where the commission needs to go. We haven't talked about agenda yet.

Petition for Emergency Rulemaking

Chris Humberson gave a brief background to the commission regarding Shire US Inc., is asking the commission to consider emergency rule making to amend WAC 246-887-040 Designation of nonnarcotic stimulant drugs for purposes of RCW 69.50.402 (1)(c) and

WAC 246-887-045 Prescribing, dispensing, or administering of Schedule II nonnarcotic stimulants.

Background:

The commission first heard a non-emergency request for this action at the April 2015 Commission meeting in Bellingham Washington. At that time, the commission's decision was to deny the petition and defer to future rule work in the general area, given the quantity of rulemaking processes now under way.

In June 2015, the commission was asked to reconsider their request, given a raised level of awareness of this issue legislatively. The commission decided to open the section of rulemaking in this area in the regular rulemaking process, which is in process.

A bill was introduced late in the 2015 session to change the RCW to include binge eating disorder within the existing language. A legislative request for official AGO review of the current RCW governing this class of medications has also been made.

The regular rulemaking process is proceeding. Since there is only the addition of the condition of binge eating disorder to the WAC, a more timely process appears to be possible than the standard 12-18 months.

MOTION: Chris Barry moved the commission deny the request for emergency rule making to amend WAC 246-887-040 Designation of nonnarcotic stimulant drugs for purposes of RCW 69.50.402 (1)(c) and WAC 246-887-045 Prescribing, dispensing, or administering of Schedule II nonnarcotic stimulants because the request does not meet statutory requirements for emergency rule making. Gary Harris second. **MOTION CARRIED: 13-0.**

Emergency Disaster Rules

Chris Humberson led this discussion asking the commission to consider rulemaking to adopt standards to address patients' access to medications during governor declared emergencies.

Last year when Carlton Complex fire erupted, the commission and staff were challenged how to provide medication to those that are displaced in these situations. Gordon, Lisa, Doreen and Joyce Roper were able to quickly put together draft guidance in consult with the DEA on what would be required to provide people with a certain amount of medication. When we looked at this draft this year, it was really imperative that we need to address it in an emergency rule instead of just a letter of guidance.

The commission and staff looked at the language provided and went through it to add suggested amendment to the language. This is tabled until later in the meeting after suggested language is added for action.

CONSENT AGENDA

2.3 Pharmacy Tech Training Program Approval

- a) 1st Ave pharmacy
- b) Fairway
- c) Native Project Pharmacy

d) Skagit Valley College

Cheryl Adams had questions about the forms and procedural questions for the reviewer. There were no other concerns. This will be improved per the request of the commission member.

MOTION: Nancy Hecox moved to approve **2.3 (a, b, c, d)**. The commission would like a report back on **2.3(b)**. Steve Anderson second. **MOTION CARRIED: 13-0.**

e) Yakima Valley Farm Workers Clinic

Same procedural concern here. Elizabeth Jensen recused herself.

MOTION: Steve Anderson moved to approve **2.3 (e)**. Nancy Hecox second. Elizabeth Jensen recused herself. **MOTION CARRIED: 13-0.**

2.4 Pharmacy Technician – Specialized Functions Approval

- a) Holy Family Hospital – Tech check Tech; IV admixture preparation; and Taking Medication List

Cheryl Adams had more concerns about the form and the reviewing process. Chris Humberson suggested Cheryl work with Irina and Maureen to update the form.

- b) Providence Centralia Hospital – Medication Lists

MOTION: Elizabeth Jensen moved to approve **2.4 (a & b)**. Gary Harris second. Cheryl Adams abstained. **MOTION CARRIED: 12-0.**

2.5 Automated Drug Distribution Device Approval

- Snoqualmie Valley Hospital

Gary Harris had concerns about the override list and a nurse's ability to control or access the ADDD. This hospital has an older device. This is an all or nothing regarding the overrides. It is a constraint within the device. Lisa spoke to him directly and nurses know that they must wait for order to be populated on a screen on overrides unless it is an emergency and there is a daily and monthly review of these actions.

MOTION: Nancy Hecox moved to approve **2.5**. Steve Anderson second. **MOTION CARRIED: 13-0.**

2.6 Electronic Prescription Transmission System Approval

- Epic Willow Ambulatory

Chris Barry we have 118 electronic transmission systems that are not approved he would like to recommend this be denied and ask them to come to the commission and tell us why they have waited to come to the commission for approval. Elizabeth Jensen suggested that Joyce Roper draft a letter to these outstanding systems. Joyce said this was discussed at the Planning session on how to move forward on reviewing these outstanding ADDD's request for approval. Receive a list of these vendors send out a communication to them on the requirements and let them come forward for approval.

MOTION: Steve Anderson moved to approve **2.6**. Gary Harris second. **MOTION CARRIED: 13-0.**

OPEN FORUM

Lauri St. Ours, for Director of government relations for the Washington Health Care Association. They represent 80% of the skilled nursing centers and 70% of assisted living facilities. I am here to affirm our commitment to the work on Long Term Care Pharmacy regulations. We believe our pharmacist and our Long Term Care Pharmacies are one of the keys to quality in long term care services. I have been working closely with Chris over the past few months. Had the opportunity to tour with him in a LTC to show him how things work. Laurie invited any of the commission members to visit a LTC.

Dennis McAllister for Express Scripts he wanted to follow up on Maureen Sparks comment regarding the changes on ACPE, ASHP and PTCB on pharmacy technician education. Very few states have level of oversight Washington does regarding pharmacy technician education. These rules are written to catch the bad guys. This was something that was to protect students with no over sight so they are attending schools that are legit and provide them the education they need to move forward in their career. This is a bigger deal for other states not so much Washington because of the over sight provided in this state.

Mike for ReliantRx. He spoke on behalf of his independent LTC pharmacy. His concern is there doesn't seem to be much representation of true LTC on the commission. He urged the commission to visit a LTC facility. He invited the commission to his LTC pharmacy anytime.

The board adjourned for Executive Session and Case Presentations at 12:05 p. m.

The board reconvened from Executive Session and Case Presentations at 1:05 p.m.

DISCUSSION

List and Label Request

Doreen Beebe led the discussion to the panel that was asked to consider granting recognition to Postgraduate Healthcare Education, LLC as an approved educational organization allowing it to received lists of pharmacist, technicians, and pharmacy interns.

MOTION: Chris Barry moved to grant recognition to Postgraduate Healthcare Education, LLC as an approved educational organization. Tim Lynch second. **MOTION CARRIED: 4-0.**

Notice of Required Evaluation

Marlee O'Neal supervising staff attorney and Diana Staley led the discussion about the process for requiring applicants, under certain circumstances, to obtain a substance use evaluation prior to licensure. There seems to be gaps in our process and we really need a new more efficient way of doing this. We started this new program Notice of Required Evaluation (NRE) as a pilot that has been going on for one year and still has a few things to

work out. There are about 48 applicants, however there continues to be more applicants entering this program. Some have refused to enter this program and not get their credential, some needed monitoring and some didn't. It has been a very successful pilot program up to date. This pilot program is an option not mandatory and works closely with WRAPP.

The commission asked to table this until the next meeting asking for more formalized information.

Santo Daime Church's

Chris Humberson and the commission received a letter from Gary Schnabel, who is now working as a consultant after his retirement from the Oregon Board of Pharmacy, regarding the Santo Daime Church's use of a Schedule 1 drug, DMT, in the Church's sacramental tea. This church has parishes in Oregon and recently opened a parish in Washington. The Church is asking the commission to authorize its use of DMT in its sacramental tea and declare that this use is not a violation of the controlled substance act. The Oregon Board apparently issued such a letter authorizing the Church's use of DMT in its sacramental tea. This church also filed a lawsuit against the federal government to allow the use of DMT under the federal controlled substances act, and the federal courts ruled in the Church's favor because the federal government is subject to the Restoration of Religious Freedom Act, a federal law. Joyce is asking the Commission to authorize her to include Deputy Solicitor General Alan Copsey to assist in this request.

MOTION: Maureen Sparks moved to approve Alan Copsey and Joyce to research and advise the Commission on the Santo Daime Church's request. Judy Guenther second.

MOTION CARRIED: 13-0.

Emergency Disaster Rules (continued)

Chris Humberson continued leading this discussion from the amendments that were suggested in the morning when this was initially discussed. The commission had a chance to go through and add the suggested amendments. They made a few more changes to update WAC 246-869-105.

MOTION: Steve Anderson moved that the commission adopt the amendments to the Emergency Disaster Rule WAC 246-869-105 as an emergency rule under CR-103E. Nancy Hecox second. **MOTION CARRIED: 13-0.**

MOTION: Maureen Sparks moved to file a CR-101 for the regular rulemaking for the same language this will be put up for comment. Matthew Ronayne second. **MOTION CARRIED: 13-0.**

Business Meeting Calendar

Doreen Beebe led the discussion with the commission asking them to approve the 2016 business meetings calendar. There was a discussion regarding different meeting schedules.

MOTION: Chris Barry moved that the commission meetings stay on a six week schedule and that the planning session be tentatively planned May 25, 2015. Matthew Ronayne second. **MOTION CARRIED: 13-0.**

Delegation of Authority

Doreen Beebe asked the commission to consider renewing its delegation of signature authority and decision –making delegation regarding specific adjudicative proceedings. In addition, the commission was asked to consider delegating authority to approve requests for lists and label request made by entities accredited as a continuing education provider by the Accreditation Council for Pharmacy Education (ACPE).

MOTION: Steve Anderson moved that the commission renew its delegation of signature authority and decision making -delegation to the health law judge regarding specific adjudicative proceedings. Matthew Ronayne second. **MOTION CARRIED: 13-0.**

MOTION: Steve Anderson moved that the commission delegate decision making authority to the default order. Elizabeth Jensen. Elizabeth Jensen second. **MOTION CARRIED: 13-0.**

MOTION: Steve Anderson moved that the commission delegate the authority to approve requests for lists and label request made by entities accredited as a continuing education provider by the Accreditation Council for Pharmacy Education (ACPE) only. Chris Barry second. Elizabeth Jensen abstained. **MOTION CARRIED: 12-0.**

Correspondence

The commission discussed correspondence received or distributed on its behalf.

- Thank you letter from Greg Hovander

PRESENTATIONS

Navos Hospital

Cathy Williams introduced Paul Thompson, Pharmacy Director from Navos Hospital asking them to consider a request for *retrospective* approval of its policies and procedures allowing home based pharmacists to perform remote medication order processing services after hours.

Overview

- Navos Hospital is licensed as a 70-bed acute care psychiatric hospital that provides inpatient mental health services to children and adults.
- The hospital is located in West Seattle and is open 24/7.
- Daily staffing of physicians is from 9am to 3p and of pharmacists from 7:30am to 3:30pm.
- Nurses are staffed 24/7.
- During a pharmacy inspection in May of 2013, the pharmacy inspectors noted that a significant volume of medication orders occurred when pharmacy services were not available ‘after hours’ and these orders were administered to patients prior to being reviewed by a pharmacist.
- This was raised as a significant safety concern that could “...could be resolved with off-site, remote order entry and remote verification by the pharmacist.
- Concerns by hospital and pharmacy administration and the medical staffed lead to the implementation of a RMOP process for handling these ‘after hours’ medication orders.
- This was not submitted until April of 2015 that the proposal was submitted for review.

- The RMOP service is provided by staff pharmacists from their homes in accordance with security requirements that specify password-protected and encrypted access to the hospital's server and protection of all HIPAA information in the home setting. This occurs via an encrypted (authenticated) gateway, or VPN.
- Remote processing is 'scheduled' to occur every 3-4 hours prior to the scheduled medication passes during the time when medication orders are more likely to be created. RMOP is initiated and concluded during a specified time frame, meaning that each complete log-in and log-off is cyclical. Override medications are used for emergency situations.

The commission members share a concern that these and other proposals are not coming for approval before being used. There was a discussion on reporting back, what to report back who to report back in person or via a letter providing required information.

Mr. Thompson was able to answer any questions from the commission regarding security, where these pharmacists will be working from and Navos quality assurance.

MOTION: Nancy Hecox moved the commission approve Navos Hospital policies and procedures allowing home based pharmacists to perform remote medication order processing services after hours. Navos Hospital must provide a written report in one year with specific information. Steve Anderson second. Chris Barry abstained. **MOTION CARRIED: 12-0.**

ReliantRx

Cathy Williams led this presentation and introduced The Commission will consider for approval policies and procedures submitted by ReliantRx to provide remote order processing and workload balancing services.

Overview

- Long term care pharmacy serving over 6,000 patients in multiple states
- Other services:
 - ✓ Compounding
 - ✓ Medical supplies
 - ✓ Mobile immunizations and antipsychotic injections

Why

- Timely access to medication is of utmost importance to ReliantRx
- Medication errors related to non-specialty packaged medications
- In the patients best interest to have a single pharmacy dispensing to critically analyze drug interactions, contraindications, and appropriateness of all medications

Currently operating 2 separate pharmacies under common ownership

- ✓ Spokane
- ✓ 70 employees
- ✓ 24 hours

Richland

- ✓ 3 employees
- ✓ M-F 8-5

Remote order processing (RMOP): Ability for each pharmacy to remotely

- Receiving, interpreting, and clarifying medication orders
- Data entry and transferring of medication order information
- Performing drug regimen review

- Performing therapeutic interventions
- Providing drug information concerning medication orders or drugs

Supplemental workload balancing

- DOES NOT count in pharmacist/technician ratio at remote location
- Both pharmacies operate within legal 3:1 ratio
- DOES NOT allow dispensing without a licensed pharmacist present
- DOES NOT include final prescription verification
- DOES NOT include supervision of technicians at remote location

Logistics and information security

- Each pharmacy location shares a centralized computer server
- All information is sent over an encrypted virtual private network (VPN)
- Pharmacy software (Framework) can run multiple pharmacies
- Retains ability to audit all activity
- Prescriptions records will be held at each location if RMOP is utilized in dispensing.
- All staff trained in HIPPA

Patient Safety and Quality Assurance

- All staff performing RMOP will be fully trained and follow policy and procedures
- Medication errors and near misses will be tracked objectively
- Responsible managers implement action plans monthly in response to any errors
- All staff participating in supplemental workload balancing and RMOP will review all errors
- Volume and timeliness of orders will also be evaluated
- Policies and procedures will be reviewed annually

Conclusion

- LTC patients will benefit from timely access to medications
- LTC patients will benefit from accurate Drug Utilization Review (DUR) that accounts for all chronic conditions and potentially interacting medications
- LTC patients will benefit from reduced medication administration errors

MOTION: Steve Anderson moved that the commission approve the policies and procedures submitted by ReliantRx to provide remote order processing and workload balancing services.

Elizabeth Jensen second. **MOTION CARRIED: 13-0.**

Toppenish Community Hospital

Lisa Roberts led the presentation and introduced Patrick O'Connor from Toppenish Community Hospital. Mr. O'Connor asked the commission to consider their policies and procedures to receive remote medication order processing services for approval.

Overview:

Toppenish Community Hospital

- Rural for-profit hospital
- Toppenish, Washington, Yakima County
- Owned by Community Health Systems
- Licensed 62 bed, average census 15
- MAP – Electronic Health Record
- Pharmacy hours: M-Sat 7:30 am to 4:00 pm, closed Sunday
- 1 FTE pharmacist
- 2 FTE technicians

- 4 per diem pharmacists (average 24 hrs/wk)
- 2 per diem technicians
- Located on the Yakama Indian Reservation in Yakima County, Central Washington
- 20 miles from Yakima

Yakima Regional Medical and Cardiac Center

- Urban for-profit hospital
- Yakima, Washington, Yakima County
- Owned by Community Health Systems
- Licensed 214 bed, average census 60
- MAP – Electronic Health Record
- Pharmacy hours: 24/7/365
- 7 FTE pharmacists
- 7 FTE technicians
- 4 Per diem pharmacists
- 3 Per diem technicians

Relationship

- Common ownership by CHS
- Share the same Mission and Vision
- Both use HMM pharmacy management system and MAP electronic medical record
- Common lab, eMAR, CPOE, etc
- Several pharmacists and technicians have or currently work at both facilities

Summary

- Shared EHR, pharmacy management system, CPOE, lab, radiology, eMAR and Outlook account allows for seamless order entry and ensures secure access.
- YRMCC pharmacists have access to and are trained on all the policies and procedures of TCH pharmacy.
- YRMCC pharmacists are made aware of changes to the policies and procedures via email communication by the TCH Director of Pharmacy.
- TCH Designated House Supervisor (RN) on-site 24/7
- TCH pharmacist on-call 24/7 for urgent on-site needs not fulfilled by RMOE.
- Quality issues will be investigated and dealt with by the Directors of Pharmacy of TCH and YRMCC.
- There will be no remote supervision of technicians.
- The Process
- TCH pharmacist will notify YRMCC pharmacy when they are transferring services.
- YRMCC pharmacist will access TCH orders via a secured VPN connection.
- YRMCC pharmacist will process written and CPOE medication orders as per the policies and procedures and pharmacy manual provided by TCH.
- The YRMCC pharmacist will access the TCH EHR to gather information to complete order entry when needed.
- The YRMCC pharmacist will be available for consultation with TCH staff should they call.
- The YRMCC pharmacist will call TCH staff to clarify any questions that arise during their coverage.
- Upon arriving to work, the TCH pharmacist will review the hand-off communications and resolve any issues.
- Orders entered remotely by YRMCC pharmacists are saved in a queue and are available for review by the TCH pharmacist if needed.

- In the case that power or network connection is lost at YRMCC, the pharmacist will notify TCH nursing supervisor and the hospitals will follow their respective down-time procedures. Acudoses will go on override.
- In the case that power or network connection is lost at TCH, the nurse supervisor will notify YRMCC pharmacy and the hospitals will follow their respective down-time procedures. Acudoses will go on override.

Request

- Yakima Regional Medical & Cardiac Center (YRMCC) seeks approval to provide Remote Medication Order Entry services to Toppenish Community Hospital (TCH) between the hours of 16:00 to 07:30 M-Sat and all day on Sunday.
- TCH seeks approval to receive Remote Medication Order Entry services from YRMCC during the above mentioned hours.
- Period of 1 year with automatic renewal, may be terminated by either party without cause with appropriate notice.

During the presentation the commission discussed the security about “faxing” prescriptions via Outlook. Concerns related to encryption of prescriptions in PDF format in e-mails in their closed system. This is not acceptable for the commission at all. Mr. O’Connor is asked to go back and find alternatives to fix this problem.

MOTION: Tim Lynch moved to delay this request for approval for 4- 6 weeks to allow time for Patrick O’Connor to research and provide information on security of this way of faxing prescriptions or to find an alternative. Steve Anderson second. Nancy Hecox and Elizabeth Jensen recused themselves. **MOTION CARRIED: 11-0.**

Yakima Regional Medical and Cardiac Center

The commission was asked to consider for approval policies and procedures submitted by Yakima Regional Medical and Cardiac Center to provide remote medication order processing to Toppenish Community Hospital.

This is the second portion to the Toppenish Community Hospital request.

MOTION: Matthew Ronayne moved that this be tabled for 4-6 weeks as well. Gary Harris second. Nancy Hecox and Elizabeth Jensen recused themselves. **MOTION CARRIED: 11-0.**

Premier LTC Pharmacy

Lisa Roberts provided some brief background of Premier LTC Pharmacy. The commission was asked to consider approving the policies and procedures submitted by Premier LTC Pharmacy for use of MedDispense an automated drug distribution devise at Park West Skilled Care Facility.

Background

- Premier LTC Pharmacy recently acquired Park West Skilled Care Facility in Seattle, Washington, from Mercury Pharmacy.
- This automated device had previously been placed in the skilled nursing facility without approval by the prior pharmacy.
- The Pharmacy Director at Premier was informed by his pharmacy inspector that he needed to obtain Pharmacy Commission approval to be operating an ADDDs at this long-term-care facility. The Pharmacy Director has included pictures demonstrating

he has currently taped off the device with signs posted that the device cannot be used until proper commission approval is received.

- Premier LTC Pharmacy currently services four long-term-care facilities; however, Park West Skilled Care Facility is the only facility utilizing an automated drug distribution device.
- The Pharmacy Director has stated that he has purchased an interface between their pharmacy software (QS1) and the automated device (MedDispense).
- The interface is scheduled to arrive by the end of July 2015.
- Current policy states that with the interface, patient names will populate into the device, and the pharmacists will be prospectively reviewing orders during pharmacy hours of operation.
- Pharmacy hours are as follows: Monday – Friday 0930 to 1800 and Weekends 0900-1700.
- There is a pharmacist on call when the pharmacy is closed.
- The pharmacy currently employs 2-3 pharmacists and 6-9 pharmacy technicians daily.

MOTION: Tim Lynch moved to approve the policies and procedures submitted by Premier LTC Pharmacy for use of MedDispense, an automated drug distribution device at Park West Skilled Care Facility. Steve Anderson second. Dan Rubin and Gary Harris recused themselves. **MOTION CARRIED: 11-0.**

STATUS REPORTS

Cathy Williams introduced Cheryl Pell, Director of Operations for Medication Review who provided a power point presentation to the commission for an update on the use of remote medication order entry services/telepharmacy services provided by Medication Review at the pharmacies listed below. These were approved in May 2014.

- a. Columbia Basin
- b. Coulee Medical Center
- c. East Adams Rural
- d. Klickitat Valley
- e. North Valley
- f. Odessa Memorial Healthcare Center
- g. Prosser Memorial
- h. Quincy Valley

The power point presentation showed graphs of how many prescriptions were processed using the services along with any deficiencies, reasons why there were deficiencies and how these were handled. She answered all the questions the commission had specifically are the pharmacy technicians being monitored. Yes, there are cameras in every pharmacy and all data is archived. Yes, the pharmacy technicians are being monitored. There were some questions regarding the duties of these technicians. There was zero misfills from the system.

MOTION: Tim Lynch moved that the commission extend the remote supervision of pharmacy technician demonstration project for the another year with a report back with specific data. Steve Anderson second. Nancy Hecox abstained, Elizabeth Jensen opposed. **MOTION CARRIED: 11-0.**

OPEN FORUM

Jeff Rochon from WSPA had a couple questions that came to him. There was a segment in the last newsletter regarding ancillary pharmacy staff and specialized functions he would like some clarification. If there is no communication from DOH staff after submitting an AUP what does that mean? There has also been questions regarding the commission and the direction with rules work? Is there a formal process to gain a clarification of a WAC? Jeff asked if there are updates please let him know so he can share with members who are asking clarification.

BUSINESS MEETING ADJOURNED

There being no further business, the board adjourned at 5:05 pm

Respectfully Submitted by:

Leann George, Program Support

Approved September 17, 2015

Dan Rubin, Vice-Chair

Washington State Board of Pharmacy

