



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504
Business Meeting Minutes
Red Lion Hotel
2300 Evergreen park Dr. SW
Olympia, WA 98501

CONVENE

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

Commission Members:

Al Linggi, RPh, MBA
Christopher Barry, RPh, Chair
Steve Anderson, RPh
Dan Rubin MPP, Public Member, Vice Chair
Elizabeth Jensen, PharmD
Tim Lynch, PharmD
Sepi Soleimanpour, RPh, MBA-HA
Maureen Sparks, CPhT
Nancy Hecox, PharmD
Matthew Ronayne, RPh
Olgy Diaz, Public Member
Judy Guenther, Public Member
Cheryl Adams, PharmD

Guest / Presenters:

Jennifer Santiago, Program Manager for
Dental Commission
Dan Renfro, Project Manager for OLIC
Debbie Puryear-Tainer, Health Services
Consultant for DOH
Tommy Simpson, DOH Military Project
Jeff Corsentino, RPh Pharmacy Director
St. Joseph Medical Center
Arie Van Wingerden, RPh for SCH

Absent Commission Member:

Gary Harris, RPh,
Arun Sambataro, Public Member

Staff Members:

Joyce Roper, AAG
Christopher Humberson RPh, Executive Director
Tina Lacey, 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 March 12, 2015 Meeting Minutes.

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

MOTION: Steve Anderson moved that the commission approve 1.2 with suggested amendment. Sepi Soleimanpour 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
 - April 2015
- 2.2** Pharmacies and Other Firm Application Approval
 - New and Closed Pharmaceutical Firms Report
- 2.3** Pharmacy Tech Training Program Approval
 - a. Columbia Valley Community Health – renewal
 - b. Walla Walla General Hospital – renewal
 - c. Family Health Center Training Program – renewal
- 2.5** Automated Drug Distribution Device Approval
 - a. Harrison Medical Center - Health Care Entities
 - i. Harrison Urgent Care at Belfair
 - ii. Harrison Urgent Care at Port Orchard
 - iii. Harrison Urgent Care at Bainbridge Island
 - iv. Harrison Hematology and Oncology Infusion Center at Poulsbo
 - v. Harrison Hematology and Oncology Infusion Center at Bremerton
- 2.8** Tamper Resistant Prescription Paper/Pads Approval
 - LRP&P Graphics

Items 2.4, 2.6, and 2.7 were deleted from the consent agenda.

Dan Rubin and Chris Barry requested that Items 2.3 (a, b, c) and 2.5 (a) be pulled from the Consent Agenda for further discussion.

MOTION: Elizabeth Jensen moved that the commission approve items 2.1, 2.2, & 2.8 on the consent agenda. Nancy Hecox second. **MOTION CARRIED: 13-0.**

REPORTS

Commission Members

Cheryl Adams reported:

- She was able to attend the Tri State Convention in Idaho it was a good meeting. They covered some great topics and she used it as an opportunity to meet people who would be from the commission.

Steve Anderson reported:

- He took the Massachusetts MPJE and is now licensed there. He is now licensed in 16 states.

Maureen Sparks reported:

- She resigned her per diem position with Franciscan Health Care System after 16 years.
- She has been working with couple book companies on some USP 797 issues.

Dan Rubin reported:

- NABP in New Orleans as the commission's representative. This was his first time in that type of setting. One particular topic that struck him was the panel discussion on multi state inspections. Particularly hearing what it was like in Virginia and New Jersey and the large public impact regarding compounding issues. He felt the leaders of the regulatory bodies there were quite courageous in taking risks to pilot and participate in development of multi-state approaches to inspections. This was very meaningful to him. Second big impact for Dan was an address made by a senior DEA official at the awards banquets who spoke about his appreciation of the working relationship with state boards and commissions and how they work jointly on public interest issues. Third topic that stood out to Dan was amount of concern over the Supreme Court decision involving the North Carolina Dental board. It made Dan aware that our commission legal structure is a bit sounder in minimizing action from anti-trust legal matters since we have a strong state government role in the appointment and oversight of the commission.

Sepi Soleimanpour reported:

- She participated in two Nursing Task Force Meetings regarding access to ADDD's.
- She attended the University of Washington spending time with 3rd year students on presentation skills and speaking about the state of pharmacy profession.

Nancy Hecox reported:

- She attended the Critical Point Compounding Boot Camp with Tyler Varnum and Julie Faun.
- Nancy delivered a New Laws Presentation at the WSPA in Spokane.
- She also expanded her travel clinic to include jet lag, motion sickness and altitude sickness.

Matthew Ronayne reported:

- He attended the NW Pharmacy Convention.
- He had the opportunity to sit in on the Idaho State Pharmacy Board Meeting. Quite interesting Idaho has a lot of disciplinary. Decisions took quite a while.

Tim Lynch reported:

- He is working with ASHP on their leadership conference where he will be presenting.
- Tim participated in the ASHP Section Advisory Group on business management.
- Tim helped facilitate the WSPA Hospital Leadership Conference in Wenatchee.
- He participated on two phone calls with the two Nursing Task Force Meetings regarding nursing student's access to ADDD's.
- He attended the Western state residency conference
- Been working with Gordon, AL, Joyce, and others on labeling requirements for hospital infusion clinics for outpatients.
- Participated in webinar regarding the up and coming track and trace legislation that takes place in July 2015.

Al Linggi reported:

- He attended the WSPA Meeting in Wenatchee. He asked for help from stakeholders for assistance in rules re-write.
- Al attended a meeting at DOH regarding HCE licensing and the new legislation that passed allowing owned or operated clinics to license under hospital pharmacy license.

- Al also participated on the Nursing Task Force regarding nursing students accessing ADDD's.
- He will be attending the 2015 Pharmacy Summit.

Executive Director

Chris Humberson reported:

- He met with Joyce Roper and members of the Washington Dental Commission regarding dental office emergency kits: pharmacy providing drugs.
- He took an in depth three hour tour of Manor Care Skilled Nursing Facility in Olympia to get a better understanding of Long Term Care operations and pharmacy challenges.
- Chris met with representatives of the Washington State Veterinary Association regarding their concerns with compounding practices and rules work affecting veterinary patients.
- He attended the NABP Meeting in New Orleans with Dan Rubin. Mark Johnson the executive committee representative for our district 7 was re-elected. A week later he resigned his position as ED for the Idaho Board of Pharmacy.
- He participated in a couple of Medical Assistant workgroup meetings, trying to work through the issue of MA's retrieving drugs in clinic settings.
- Chris attended a Board of Naturopathic Medicine Meeting.
- He attended the WSPA Northwest Pharmacy Conference. Mr. Humberson also did a presentation for WSPA on Sunday on new legislation and regulation work.
- Chris attended a meeting at DOH with Al, Joyce and WSHA on HB5460.
- He held another Long Term Care stakeholder in Vancouver, WA and the next one will be held in Spokane July 15.
- He attended the UW School of Pharmacy Advisory Committee for strategic plan.
- Chris met with Peggy Odegard regarding interns and preceptor programs.
- He also continues to meet regularly with WSHA representatives on pharmacy issues in common.

Consultant Pharmacists

Lisa Roberts reported:

- Lisa met with Chris H, Doreen Beebe, Gordon MacDonald and Return Meds. They are a company working with King County on a Drug Take Back Program. Return Meds wanted to bounce ideas of staff for developing an actual kiosk that return meds would be going placed in.
- Lisa provided a brief background to the new commission members on the King County updates regarding Drug Take Back. In September 2014, the DEA put out their final rule on Drug Take Back programs that include controlled drugs. WSPQAC does not have established rules regarding Drug Take Back programs. King County developed a Take Back Program template. Return Meds was one of two companies that submitted proposals for consideration by King County which were both rejected. After making some revisions to their proposal, Return Meds stated that they will resubmit to King County for reconsideration. Return Meds would like to come to the commission for approval of their program once that is accomplished.

Supervising Pharmacist Investigator/Field Investigator

Gordon MacDonald reported:

- Today 5 field investigators are finishing their Critical Point, sterile compounding boot camp. All investigators will have had over 60 hours of sterile compound training and all have been trained in sterile compounding.
- Per Commissioner Elizabeth Jensen's request, Gordon and his investigators and PQAC staff are forming a Task Force to work on putting together a live Continuing Education course on Compounding.

LEGISLATION, RULEMAKING, AND POLICY DEVELOPMENT

2015 Legislative Session Update and Implementation

Chris Humberson provided the most recent Legislative Update to the

SHB 1625 providing drugs to ambulances: Effective July 24, 2015

What it does:

It authorizes a pharmacy that is operated by a hospital to provide drugs to ambulance or aid services for use associated with providing emergency medical services to patients; provided

1. Hospital located in same or adjacent county to the county in which the ambulance operates

- Medical program director has requested drugs from the hospital per agreed protocol
 - ✓ Drugs that are relevant to the level of service provided by ambulance and training of personnel
 - ✓ Approved as part of the prehospital protocols in the county located
 - ✓ Not contingent upon transport of patient to hospital that provided drugs.

ESHB 1671 opioid overdose medications: Effective July 24, 2015

What it does:

- Authorizes prescribing, dispensing, distributing, and delivering opioid overdose medications to a person at risk of experiencing a drug overdose, as well as to a first responder, family member, or other person in a position to assist a person at risk.
- Requires a pharmacist dispensing an opioid overdose medication to provide instructions on the proper response to an overdose.
- Permits any person or entity to possess, store, deliver, distribute, and administer opioid overdose medications with a practitioner's prescription or order.

SSB 5268 eye drop refills: Effective July 24, 2015

What it does:

- Pharmacists may refill a prescription for topical ophthalmic products at 70 percent of the predicted days of use. This applies to original prescriptions and refills. In order to refill the prescription early, the prescription must indicate the number of refill permitted and the early refill must not exceed that number. This legislation does not require the insurance carrier to pay for the early refill.

ESSB 5441 patient medication coordination: Effective July 24, 2015

What it does:

- This legislation requires health plans that provide prescription coverage to implement a medication synchronization policy for the dispensing of prescription drugs for the 2016 plan year. If an enrollee requests medication synchronization for a new prescription, the health plan must permit filling the drug for less than a one-month supply of the drug if synchronization will

require more than a fifteen-day supply of the drug, or for more than a one-month supply of the drug if synchronization will require a fifteen-day supply of the drug or less.

- The health plan must adjust the enrollee cost sharing for a prescription drug with a coinsurance that is dispensed for less than the standard refill amount for the purpose of synchronizing the medications. The health plan must adjust the cost-sharing for an enrollee for a prescription with a copay that is dispensed for less than the standard refill amount for the purpose of synchronizing by one of the following methods:
 - ✓ discounting the copayment rate by fifty percent;
 - ✓ discounting the copayment rate based on fifteen-day increments; or
 - ✓ any other method approved by the Office of Insurance Commissioner.

ESSB 5460 prepackaged ER meds

What it does:

Section One allows physicians and nurses to dispense prepackaged emergency medications to patients being discharged from a hospital ER during times when a community or hospital pharmacy are not available within 15 miles by road, or when a patient has no reasonable ability to reach the local or community pharmacy. Provided:

- The pharmacy director develops policies and procedures regarding:
 - ✓ Development of a list of medicines to be prepackaged and distributed
 - ✓ Prepackaged medications are to be prepared by a pharmacist or under supervision thereof
 - ✓ Protocols provide for proper training on types of medications available and when they can be distributed.
 - ✓ Practitioners must maintain a valid prescription for dispensed prepacks, either in writing or in EMR.
 - ✓ Limit of no more than 48 hours supply, except when services will not be available within 48 hours; Then 96 hour supply may not be exceeded. No full courses of therapy are permitted.
 - ✓ Kept in a secure location near ER to preclude the need to enter the pharmacy.
 - ✓ Medications can be dispensed only after a practitioner has counselled a patient on the medication.

Section Two: Allows a hospital pharmacy without a wholesaler license to distribute medications intercompany (common ownership or control).

Section Three: This allows a Residential Treatment Facility to obtain a Health Care entity license, as this term is redefined.

Section Four: Allows single or multi-practitioner clinics owned and operated by a hospital to list under a hospital pharmacy license for the possession of drugs. These clinics will be subject to the federal and state statutes and regulations that pertain to hospital pharmacy licenses. Should a clinic choose to license as a health care entity, only those specific statutes and regulations that pertain to health care entity licenses will apply. We are currently analyzing what hospital pharmacy regulations will pertain to any clinic listed under the hospital pharmacy license.

SB 5935 biologics products: Effective July 24, 2015

What it does:

- Every drug prescription form must contain an instruction of whether or not a generic drug or an interchangeable biological product may be substituted. If dispense as written is indicated, an interchangeable biological product may not be substituted. If substitution is permitted, the pharmacist must substitute an interchangeable biological product for the biological product prescribed if the wholesale price of the interchangeable product is less than the wholesale price of the biological product prescribed. Until August 2020, the pharmacist must notify the prescriber if an interchangeable biological product is being substituted for the drug prescribed within five days.
 - ✓ The Pharmacy Quality Assurance Commission must maintain a list of interchangeable biological products and all biological products approved as therapeutically equivalent by the federal Food and Drug Administration on its website.
 - ✓ Pharmacists and pharmacies are provided with protection from liability based on the decision to dispense the interchangeable biological product.
 - ✓ Pharmacies must post a sign that interchangeable biological products may be substituted for the drug prescribed by a patient's doctor.

ESSB 5557 Pharmacists as Providers: Effective July 24, 2015

What it does:

- Prohibits benefits from being denied, under certain circumstances, for a health care service performed by a pharmacist. Requires the insurance commissioner to designate a lead organization to establish and facilitate an advisory committee to implement the provisions of this act.
- Requires the lead organization and advisory committee to develop best practice recommendations on standards for credentialing, privileging, billing, and payment processes to ensure pharmacists are adequately included and appropriately used in participating provider networks of health plans. Requires the advisory committee to present initial best practice recommendations to the insurance commissioner and the Department of Health.

ESB 5577 pharmaceutical waste: Effective: July 24, 2015

What it does:

- By September 1, 2015, Ecology must convene a workgroup to identify problems with properly managing pharmaceutical waste, and to develop recommendations. Ecology must hire a consultant with expertise in RCRA to facilitate the workgroup. Workgroup members must include representatives of specified state agencies, state-qualified pharmaceutical waste handling facilities, statewide associations representing medical doctors, hospitals, and other health care providers, and entities with expertise in managing pharmaceutical waste. Ecology may not use information provided by pharmaceutical waste generators or handling facilities during workgroup meetings for enforcement purposes unless an activity performed or conditions at a facility pose an imminent threat of danger of death or bodily harm, or have a probability of causing environmental harm. The Legislature encourages Ecology to exercise enforcement discretion with pharmaceutical waste during the workgroup

process. By December 31, 2015, the workgroup must recommend solutions to improve pharmaceutical waste.

Electronic Transmission of Prescription

Chris Humberson and Brittany Mahugh provided some information as to why they would like to ask the commission to reconsider motion to file supplemental CR-102 regarding chapter 246-870 WAC Electronic Transmission of Prescription Information rules to implement Chapter 276, Laws of 2013.

MOTION: Steve Anderson moved that the commission withdrawal the motion to file a supplemental CR-102 regarding chapter 246-870 WAC Electronic Transmission of Prescription Information rules to implement Chapter 276, Laws of 2013 and substitute with a CR-101 to initiate significant rules process. Chris Barry second. **MOTION CARRIED: 13-0.**

Committee and Rule Updates

Pharmacy Business Practice

Dan Rubin updated the commission on where the Business Practice Committee is in process. The Committee had a meeting immediately following the April 30th business meeting. The committee reviewed written Issue Assessments in two of the areas the committee has been considering: rest and lunch breaks and appropriately shared accountability among pharmacy professionals and the licensed pharmacies where they work. The committee determined what action options would be sent out for public comment as “trial balloons” out of a larger array of options in the original Issue Assessments. One major controversy was about whether the commission should attempt to assure or regulate breaks and lunches through Commission rule making. At its April 30th meeting, the committee decided not to proceed in that direction on a presumption that the Commission does not have jurisdiction, but to continue clarifying that issue through discussion between Attorney General staff supporting PQAC and the Department of Labor and Industries. Revised versions of the two Issue Assessments were sent out for public comment and the comments received are being analyzed for a future Business Practice Committee meeting. (As a reminder, this is a trial balloon process not rule promulgation; the intent is to get further candid thoughts before moving forward with drafting any rule changes.)

Pharmacy Inspection Process

Chris Humberson briefed the new commission members on issued concerning the Pharmacy Inspection Process. There have been a number of discussions regarding the current inspection process. We are asking the commission to authorize CR-101 for rulemaking regarding the Inspection Process independent from the Pharmacy Business Practice Committee.

MOTION: Nancy Hecox moved that the commission initiate a CR-101 for inspection process rulemaking and to separate it from the Business Practice Committee with Cheryl Adams as the commission champion. Sepi Soleimanpour second. **MOTION CARRIED: 13-0.**

Technology

Lisa Roberts and Al Linggi provided an update to the commission about the Technology Rules Committee. Lisa has been doing a lot of coordination and research work. There will be a meeting June 25 at 9:00 am. There have been 25 stakeholder volunteers identified to help assist with the workgroup. Technology rules were broken up into different sections and Al assigned volunteers to each section, each with a workgroup chair.

Sterile Compounding Rules

Mr. Humberson also provided an update on the Sterile Compounding Rule. The crosswalk ad proposed second draft is close to being done. The goal of getting this out on June 15 due to work load there has been some challenges to meet the time line initially set to get these out for comment he next date Chris is hoping to get these out will be June 30, 2015. There have been some recent concerns from the Veterinarian Board and Association and compounding for animals. These concerns will be addressed with the respective stakeholders.

Nursing/Pharmacy Taskforce Update re: Students' Access to Automated Drug Distribution Devices

Joyce Roper provided the update to the commission on the work the Nursing Commission Task Force has done. After many meetings with the Nursing Commission there have been some recommendations the Task Force has come up with. The task force would like to have nursing student have access to all medication distribution devices and they would identify the best practices and the students will need to show competency and skill prior to getting access to these devices. This will be the responsibility of the nursing commission to work with the nursing education programs, along with working with the healthcare facility where the student will be working to make sure they to make sure they have the adequate training before they start accessing these devices. They want to make sure there are specific policies and procedures for the nursing education programs, health care facilities and pharmacies where the students will be accessing these devices. They will report any medication errors, near misses, and any alleged diversions to the responsible commission. There will be notification to stakeholders regarding activities going on and that there needs to be amendments or nursing rules as well as pharmacy rules. The concern is the rulemaking process takes 12-14 months and in meantime students are in schools now that feel they need to have this training for their education. What has been suggested is that there is a letter issued from each commission, or a Joint letter indicating that while rules are in process there is an understanding/ acceptance that nursing students can do this pursuant to the statute. Joyce has been working with the nursing commission in drafting a letter in hope to get this out by August.

MOTION: Dan Rubin moved that the commission support the recommendations that are coming from the joint committee and authorize our Chair and or Executive Director to sign a combined or separate letter consistent with those recommendations that would cover the interim period before there is rule making. Chris Barry second. **MOTION CARRIED: 13-0.**

Long-Term Care Pharmacy Workgroup Update

Chris Humberson led the discussion requesting authorization of a CR101 on WAC 246-865: Extended Care Facility, last updated 1/5/1994.

Background:

- In October 2014, the issues relative to practice setting standards were brought before the commission during a presentation from PointClickCare. The commission directed staff at that time to conduct informational meetings to determine the scope of the problem and issues for the commission to address in rulemaking and report back in July, 2015.
- Several legislative members have been expressing concern over the state of the outdated regulations. There is a budget proviso in the Senate budget requiring the pharmacy commission to provide a draft of possible rules to the Senate HealthCare committee by November 2015.
- The first of three meetings statewide was held on March 25th in Kent Washington with over 50 attendees. The second meeting is scheduled in Vancouver Washington on June 3rd. The final meeting is scheduled in Spokane on July 15th, 2015, with a detailed report of findings to the commission at the July 30th meeting.

MOTION: Chris Barry moved that the commission open a CR-101 filing for rulemaking on WAC 246-856 Extended Care Facilities. Elizabeth Jensen second. **MOTION CARRIED: 13-0.**

DISCUSSION

Clarification of Outpatient Infusion Standards

Tim Lynch led the discussion regarding the use of prescription and prescription labeling for medications provided to outpatient hospital-based infusion services located on the hospital campus.

Background:

- PQAC Investigators are currently inspecting hospital pharmacies with associated hospital based outpatient infusion centers using WAC 246-871 Pharmaceutical – Parenteral Products for Non-hospitalized Patients, as the basis for point deductions.
- There is confusion about the status of these hospital based outpatient infusion centers, with some of them licensed as health care entities, others licensed as pharmacies, and, after the implementation of ESSB 5460, some of them will become licensed under the hospital pharmacy license which may trigger different standards for recordkeeping and labeling under the WACs.
- The Commission’s rules focus on the dispensing of these products and not the administration of the products in these outpatient infusion centers.
- Labels for the products administered in the centers do not contain the information required for dispensed drugs.

This discussion was extensive and detailed between the commission members and staff. The commission shared some of their concerns and what needs work regarding the recordkeeping and labeling requirements for dispensing of parenteral products, which does not automatically apply when the products are being administered at hospital-owned infusion centers. The standards in WAC 246-871 address preparation, labeling and distribution in the more traditional pharmacy setting, rather than a medical setting where products are not delivered to the patients, but directly administered by a licensed health care provider, subject to the employment and oversight standards of a hospital. The

commission and investigators feel they need clarification as soon as possible to help the inspectors and those being regulated understand what is expected in this area to remain compliant.

The commission decided to form a task force not to just focus on this issue but in the context of all the other conflict that there are in Rules, RCW's and WAC's. To discuss what the commission can do to provide interpretive statements or guidelines, so if conflicts between rules and contemporary practice are identified, the commission will have a temporary remedy to apply to the situation while we continue to work on rules. The task force members are Cheryl Adams, Judy Guenther, Chris Barry, Joyce Roper, Gordon MacDonald and Tim Lynch will committee the task force.

OPEN FORUM

Richard Molitor asked that the names of the electronic transmission companies requesting approval or re approval be listed on consent agenda. So that those of us out in the community that may use these companies are aware of this and maybe have an opportunity to share with the commission that some of these companies that seem to be sending this that are deficient or not compliant.

Jeff Rochon from the WSPA thanked the commission for all their work. He offered help to the commission with anything they need.

He has a lot of confused members that want some guidance regarding WAC 246-870 and WAC 246-871 and Long Term Care and electronic prescribing. Jeff asked the commission for clarification so that he can pass on to WSPA members. Jeff invited the commission members to the upcoming meetings the WSPA will be holding.

Julie Akers wanted to add comment to the task force just created and the discussion Tim Lynch brought up. She asked that the task force be aware of the differentiation between a medication order and a prescription, so when reviewing these regulations understanding the definition these two words.

***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 Cont'd

Pharmacies Providing E-Kits for Practitioner Clinics/Dental Clinics

Chris Humberson briefed the commission on this topic. A number of practitioners that are required to stock an E-Kit in their office have been able to purchase these from a pharmacy in the past. They are now prohibited from writing prescriptions for any of these medications "for office use". However they are allowed to order via wholesaler but a wholesaler only sells in large quantities. Pharmacies that have a wholesaler license are allowed to provide smaller quantities of single use vials although they come in larger quantities under one NDC. After some internal discussion between Pharmacy Commission and Dental Commission staff, the feeling was that this is ok to allow but felt this should be brought forward to the commission.

Jennifer Santiago, program manager for Dental Commission shared that per a discussion within the Dental Commission they would like to be allowed to work with the Pharmacy Commission to come up with some type of Collaborative Agreement to provide

stakeholders, pharmacists and dentist to provide E-Kits. This would also include other practitioners.

State law has an exception in the definition in wholesaling which allows pharmacies to repackage commercially available medication in small reasonable quantities for office use by a practitioner. The drug quality security act raised question on whether repackaging could still happen or would they be considered re-packager it's not as clear because it doesn't state the word repackage they talk more about dispensing. They do allow the distribution to practitioner's offices of minimal quantities. The labeling needs to be done correctly.

After a considerable amount of discussion between the commission and Joyce the conclusion was the Pharmacy Commission is unable to assist in this situation. Chris, Doreen and Joyce will provide Jennifer a list of wholesalers and laws so she can take this back to the Dental Commission.

CONSENT AGENDA

2.3 Pharmacy Tech Training Program Approval

a) Columbia Valley Community Health

The concerns were the preceptor license is expired and the Utilization Plan mentioned that the pharmacy assistants didn't require any training but the tech section specified the aids training. The UP also described that a pharmacy assistant can obtain stock bottles for prescription filling. They need to update their UP to show there is 4 hours training required for assistants and that assistants can't obtain stock bottles.

MOTION: Cheryl Adams approve contingent on the UP plan being updated showing there is 4 hours training required for assistants and that assistants can't obtain stock bottles. Chris Barry second. **MOTION CARRIED: 13-0.**

b) Walla Walla General Hospital

The concern was some of the wording in the UP looked like they flip-flopped the word pharmacy assistant for pharmacy technician.

MOTION: Cheryl Adams moved the commission approve based upon on UP plan specialized functions. Chris Barry second. **MOTION CARRIED: 13-0.**

c) Family Health Center Training Program

They are in the middle of applying for a preceptor license and they used their UP as a job description there needs to be a clarification that this is the UP not the job description.

MOTION: Chris Barry moved that the commission approve contingent upon preceptor renewals and the UP plan updated as a UP, not a job description. Maureen Sparks second.

MOTION CARRIED: 13-0.

2.5 Automated Drug Distribution Device Approval

- b. Harrison Medical Center - Health Care Entities
 - vi. Harrison Urgent Care at Belfair
 - vii. Harrison Urgent Care at Port Orchard
 - viii. Harrison Urgent Care at Bainbridge Island
 - ix. Harrison Hematology and Oncology Infusion Center at Poulsbo
 - x. Harrison Hematology and Oncology Infusion Center at Bremerton

MOTION: Dan Rubin moved that the commission provide a provisional approval of the 5 entities using the ADDD's now through September 2015 with a requirement that the policy and procedures are updated complying with all of our WAC's, and resubmitted for approval at the September meeting. Sepi Soleimanpour second. Tim Lynch recused. Matthew Ronayne opposed. **MOTION CARRIED: 11-0.**

Routes of Licensure for Foreign-Trained Pharmacist

Doreen Beebe led the discussion with the commission asking for guidance on the routes of licensure for foreign-trained pharmacists. In the past, the non-traditional PharmD programs were seen as an advance degree program since all candidates must be licensed pharmacists. Recently an applicant has questioned this understanding which led staff to do some research.

Background:

- The Accreditation Council for Pharmacy Education adopted accreditation standards and guidelines for all professional programs in pharmacy leading to the Doctor of Pharmacy Degree adopted in 2006.
- Non-traditional PharmD programs were first introduced when the PharmD became the entry level degree and it was desired to bring licensed BS pharmacists to the PharmD level. Thus, the nontraditional degrees started, only for that purpose.
- ACPE maintains one accreditation for a program, regardless of whether they offer the traditional PharmD degree or a PharmD degree and a nontraditional – this is done to ensure quality across all pathways – if the NTPD fails to meet ACPE accreditation standard, then the entire program fails to meet that standard.

MOTION: Tim Lynch moved that the commission deny the request to review and modify our requirements for licensure for foreign graduates and that they adhere to rules that are in existence. Steve Anderson second. **MOTION CARRIED: 13-0.**

Update on Military and Military-Affiliated Applicants

Tommy Simpson III, Health Services Consultant for Military Project for DOH led this discussion updating the commission on Military and Military affiliated applicants seeking credentials in Washington State and to request the commission to allow for the initiation of rulemaking to support pharmacy technician from military trained personal and adopting rules for temporary practicing permits for spouses or domestic partners of military personnel.

Licensure for spouses and registered domestic partners of military personnel transferring to Washington

- Under state law, spouses or registered domestic partners of military personnel transferring to Washington may receive professional licenses more quickly. In order for us to do this, you must include our form and supporting documentation with your application.

Military training-experience legislation

- A law passed in 2011 affects how we evaluate certain military training and/or experience toward meeting licensing requirements. If the profession for which you're applying is listed below, please clearly state your military training in the education and training sections of the application and include supporting documentation.

Military status for spouse or registered domestic partner

- **Legislation Link:** ESSB 5969 (2011 session, RCW 18.340.020(2)(c)), Secretary regulated professions, and each Board and Commission to adopt rules granting a temporary practice permit for qualified military spouses or registered domestic partners holding an out-of-state credential of equal while the military spouse/partner completes the credentialing process.

METC & PTCB Prepare Federal Pharmacy Technicians for Success

Elevating practice across the Federal Pharmacy System through accredited training and certification

- **WASHINGTON, DC.** - Federal pharmacy technicians certified through the Pharmacy Technician Certification Board (PTCB) continue to serve their country and maximize training experiences at the Department of Defense (DoD) Military Education and Training Campus (METC) at Fort Sam Houston, TX.
- Since September 2010, the METC has operated as the largest consolidated training program in DoD history, training enlisted medical personnel in over 30 medical programs. The METC Pharmacy Technician Training Program is designed to standardize training for pharmacy technicians across federal agencies, including the Air Force, Army, Coast Guard, and Navy.
- The METC Pharmacy Technician Training Program, accredited by the American Society of Health-System Pharmacists, incorporates best practices from multiple agencies to create consistency in skills and knowledge, and promote innovative roles for federal pharmacy technicians. These roles include counseling patients, tech-check-tech, and pharmacist-independent practice in deployed settings. The curriculum is a blend of web based, classroom, laboratory, clinical, and experiential learning in the areas of calculations, pharmacotherapeutics, dispensing, sterile and non-sterile compounding, and pharmacy administration.
- Prior to graduation, students are highly encouraged to take PTCB's Pharmacy Technician Certification Exam (PTCE) to gain national recognition as a Certified Pharmacy Technician. This aligns with the METC's objective to improve the quality of pharmacy technicians as measured by a national standard and enable pharmacy technicians to perform to their highest level of education

and training.

- "At the METC, our primary goal is preparing our students to serve in the multitude of military practice settings available to pharmacy technicians, including the unique challenge of assignments independent of a pharmacist. To meet this goal, our curriculum is both fast paced and more in depth than most other pharmacy technician programs.
- The METC is on its way to becoming a national strategic resource by fostering enhanced international partnerships and contributing to educational research and innovation. "Certification and the expansion of responsibilities and skill sets have empowered pharmacy technicians to practice in ground-breaking areas within the Federal Pharmacy System," said Melissa Murer Corrigan, RPh, Executive Director and CEO of PTCB. "Of the 400,000 pharmacy technicians PTCB has certified since 1995, we are honored that many of these pharmacy technicians are part of the world's best military healthcare personnel supporting the nation."

WAC 246-12-051 - How to obtain a temporary practice permit—Military spouse.

NEW SECTION

- WAC 246-828-315 Temporary Practice Permit-Military spouse.
- "A Military spouse or state registered domestic partner of a military person may receive a temporary practice permit while completing any specific additional requirements that are not related to training or practice standards for this profession. The board (or commission), adopts the procedural rules as adopted by the department of health in WAC 246-12-051."

MOTION: Matthew Ronayne moved to approve the Pharmacy Technician Training Programs on the list provided by Tommy Simpson pending an 8 hour Washington State Law class. Elizabeth Jensen second. **MOTION CARRIED: 13-0.**

Correspondence

The commission discussed correspondence received or distributed

- a) FDA approved use of Omidria
- b) Pharmacy Alumni President, Gary Harris

Other

Old Business

Mr. Humberson led the discussion regarding some old business. At the April Meeting Shire petitioned to do rulemaking to add a Vyvance a binge eating drug to the list of nonnarcotic stimulant drugs designated under WAC 246-887-040 and – 045. The commission denied the request to do rulemaking in hopes to work on this globally. Chris was contacted by the Governor's office to reconsider the denial to the petition and approve it for rulemaking and we can go forth.

MOTION: Dan Rubin moved that the commission open a CR-101 to add Vyvance to the list of nonnarcotic stimulant drugs to WAC 246-887-040 and 246-887-045. Steve Anderson second. Elizabeth Jensen opposed. **MOTION CARRIED: 12-1.**

PRESENTATIONS

OLIC Team

Dan Renfro, Project Manager and Debbie Puryear-Tainer, Health Services Consultant provided an update on the Division of Health System's Quality Assurance's on-line credential application project.

Online Licensing and Information Collection (OLIC) Project

- Provide online portal for new license applications for health profession and facilities
- Provide streamlined, easy-to-use online applications
- Store license application data in licensing system
- Reduce the amount of time to issue licenses
- Improve patient safety and access to care
- Allow providers and facilities to provide care sooner

Online Licensing Timeline

- 3rd Quarter, 2014: Project team identified solution for online applications
- 1st Quarter, 2016: Implementation is planned to begin for online applications, phased in approach
- 4th Quarter, 2016: Implementation complete for all online applications

Information Collected

- Collect healthcare provider demographic information
- Improve healthcare workforce information
- Improve access to care and reduce healthcare disparities
- Ensure healthcare workforce is used to their best abilities in places of greatest need

Information Collected Timeline

- 3rd Quarter, 2014: Project team gathered feedback on information to be collected
- 2nd Quarter, 2015: Project team will begin identifying solution for information collection
- 4th Quarter, 2015: Implementation is planned to begin for information collection
- 2nd Quarter, 2016: Implementation complete

Remote Medication Order Processing

Cathy Williams introduced Jeff Corsentino Pharmacy Director for Peace Island Medical Center. He provided the commission a power point to the commission requesting approval of its policies and procedures to receive remote medication order processing services from St. Joseph's Medical Center.

Overview:

PeaceHealth is a not-for-profit health care system with medical centers, critical access hospitals, medical group clinics and laboratories located in AK, WA and OR.

Peace Island Medical Center

- Located on Friday Harbor in the San Juan Islands
 - 10 inpatient bed **Critical Access** Hospital
 - Onsite Pharmacist coverage 8am-4:30pm (M-F only)
 - Emergency room
 - 2 Operating rooms
 - Medical Clinic with Outpatient Oncology Center

- Average census between 0-2 patients
- Accessible by plane or boat only (it is an island after all ☺)
- Pharmacy Department FTE = 2 (1 Pharmacist & 1 Technician)
- Medication orders entered by Pharmacists=417/month (14/day)
 - Average of 7 orders/day PIMC onsite Pharmacist (50% of total)
 - Average of 7 orders/day SJMC remote order entry (50% of total)

PeaceHealth St Joseph Medical Center

- Located in Bellingham
 - Sister Hospital to PIMC (PeaceHealth owns both facilities)
 - 253 inpatient beds
 - 24/7 Pharmacist coverage
 - Pharmacy Residency Program
 - Many services including Oncology, Cardiology, Ortho, OB, etc...
 - Extremely busy ER
- Average inpatient census around 180-190 patients
- NOT on an island ☺
- Pharmacy Department FTE = 51
- Medication orders entered by RPh=60,000/month (2,000/day)

Remote Order Entry

- Pharmacist order entry of PIMC medication orders by SJMC Pharmacists in Bellingham:
 - **M-F 16:30-08:00, Sat-Sun All day & night plus Holidays**
- Handling Pharmacy clinical consultations & questions from PIMC staff during off hours.
- Physicians and Nurses have the ability to communicate with SJMC pharmacists at any point day or night during coverage.

Remote Order Entry Process

1. PIMC nurse scans med order into Pyxis connect scanner at PIMC
2. Pharmacist at SJMC logs onto Pyxis connect system using password
3. Picture of order from PIMC is available in the Pyxis connect queue
4. SJMC Pharmacist logs into PIMC Electronic Medical Record (EMR) system which is GE Centricity (same at both facilities)
5. Order entered into PIMC EMR by SJMC Pharmacist.
6. Medication now available for PIMC nurse to remove from the medication profiled Pyxis. This means that a nurse cannot remove the medication from Pyxis until the order is entered into the EMR by the pharmacist.

Why is Remote Order Entry Necessary?

- Due to the low census and low volume of order entry at PIMC, it is not reasonable to staff a pharmacist on-site 24 hours/day.
- SJMC does have 24 hour/day pharmacists on-site and due to the low volume of order entry they have the capability to enter orders for PIMC.
- SJMC pharmacists utilize the same EMR as PIMC.
- SJMC pharmacists in fact trained the PIMC RPh.

Remote order entry security

- **Current security measures in place:**
 - Transmissions are secured via DDPE and the SDE Encryption Algorithm is AES 256.
 - Microsoft VPN uses SSTP using SSL v3 over port 443, with AES encryption 128-bit.

- SSL VPN uses SSL v3 over port 443 and TLS v1 encryption 128-bit.
- Information is password protected in compliance with HIPAA and Federal Medicare regulations.
- Servers are all contained within the PeaceHealth network
- There is a dedicated Fiber Cable for Peacehealth from PIMC to SJMC

MOTION: Tim Lynch moved that the commission approve Peace Island Medical Center policies and procedures to receive remote medication order processing services from St. Joseph's Medical Center with a report back in one year with the Quality Matrix. Elizabeth Jensen second. **MOTION CARRIED: 13-0.**

Remote Order Processing

Lisa Roberts introduced Arie Van Wingerden from Sunnyside Community Hospital (SCH). Mr. Van Wingerden asked the commission for approval of SCH's policies and procedures for the use of remote medication order processing services.

Sunnyside Community Hospital

- 25 bed critical access hospital
- Located in the lower Yakima Valley with a coverage area of ~80,000 people
- Average inpatient census of 16, with an average of 53 ED visits daily
- Services include: Fulltime in house hospitalists, birthing center, general surgery, orthopedic surgery, ENT, neurosurgery, nephrology and dialysis, cardiology, urology
- In house pharmacy coverage 7 days a week, 10.5 hours M-F and 6 hours S-S
- 2 full time pharmacists and 2 full time technicians
- Pharmacist on-call during off hours
- Pyxis ADDDs utilizing profile mode in all inpatient areas and in the ED
- Meditech with eMAR and bedside medication verification
- Primarily CPOE (some physicians still using written orders – no CPOE in OB)

REMOTE ORDER PROCESSING

- Medication Review provides remote order entry when SCH pharmacist not on-site. This allows for every order to be reviewed by a pharmacist for accuracy, appropriateness, allergies, and interactions etc. prior to administration by nursing staff.
- Answers staff clinical questions
- Provide dosing calculations
- Obtain order clarification
- Provide drug information

Advantages – Patient Safety

- All orders are reviewed prospectively, 24/7
- Reduces Pyxis override removals to only true emergent situations
- Nursing and Medical staff have immediate access to a pharmacist

SCH Requirements for Medication Review

- Acquire and maintain all appropriate Washington State licenses and approval for Pharmacy and all employees
- Ensure that all pharmacists providing remote order entry have been trained on SCH policies and procedures regarding medication order processing

- All Medication Review employees with access to SCH electronic files containing patient health information must be appropriately trained in HIPPA protocol
- Continuous quality improvement program in place

Summary

- Remote order entry is not an option for Sunnyside Community Hospital, it is a necessity for safe patient care
- It is necessary to have 24/7 hour pharmacy services and order entry and verification to enable other patient safety programs –EMAR, BMV, ADDDs – to work to their full potential
- Allows for timely safe medication administration

MOTION: Chris Barry moved that the commission approve SCH’s policies and procedures for the use of remote medication order processing services with a report back in one year with the Quality Matrix. Steve Anderson second. Elizabeth Jensen recused herself. **MOTION CARRIED: 12-0.**

Remote Order Processing

Lisa Roberts introduced Lawrence Timbal from Okanogan Douglas District hospital Pharmacy (dba Three Rivers Hospital) requests approval of its policies and procedures for the use of remote medication order processing.

Background:

- Okanogan Douglas District Hospital is the official name of this facility and the name associated with their DOH license.
- Since 2011, they are now doing business as Three Rivers Hospital while retaining their official name of Okanogan Douglas District Hospital.
- This hospital is a public, not-for-profit, critical access hospital located in Brewster, Washington. The hospital averages 1.4 inpatients daily and provides general surgery and orthopedic surgery one day a week.
- The pharmacy’s hours of operation are Monday through Friday 7:00am to 3:30pm.
- The pharmacy staff consists of one full-time pharmacist in charge, one full time technician, and one part-time technician.
- This pharmacy became Commission-approved for an automated drug distribution system in January 2015. They utilize CPSI pharmacy software with the capability of CPOE (Computerized Physician Order Entry); however, it is a hybrid facility as not all prescribers are currently participating with CPOE and some are still hand writing orders.
- The pharmacy is currently planning a go-live target date of June 15, 2015 to contract with an outside vendor for remote medication order processing pending WA State Pharmacy Commission approval.
- The outside vendor will be Medication Review, Inc.
- It is typically challenging for facilities using hybrid systems with some prescriber’s hand writing orders and some utilizing CPOE.
- CPSI is a software system based out of Alabama designed for critical access hospitals. Certain settings in this system (if not set correctly) permit prescribers and nursing to enter and verify orders while completely bypassing pharmacy which allows orders to be directly available for removal from the ADDDs prior to prospective review by a pharmacist.

- Orders are flowing as they should and are prospectively reviewed by a pharmacist prior to drug removal from the automated drug distribution device

MOTION: Chris Barry moved that the commission approve Okanogan Douglas District hospital Pharmacy (dba Three Rivers Hospital) policies and procedures for the use of remote medication order processing with a report back in one year with the Quality Matrix. Steve Anderson second. **MOTION CARRIED: 13-0.**

OPEN FORUM

Chris Terriff from Medication Review shared that he enjoyed the discussion earlier defining what a prescription versus what a med order is and putting together a task force is an opportunity to look at the transition of care for patients. It's all about Medication Reconciliation in his mind and the information and education that moves with the patient.

BUSINESS MEETING ADJOURNED.

There being no further business, the board adjourned at 4:30 pm

Respectfully Submitted by:

Leann George, Program Support

Approved July 30, 2015

Dan Rubin, Vice-Chair

Washington State Board of Pharmacy

