



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

PHARMACY QUALITY ASSURANCE COMMISSION

Regular Scheduled

Business Meeting Minutes *Amended*

December 5, 2013

Highline Community College

Mt. Constance

2400 South St.

Des Moines, WA 98198

CONVENE

Chair Christopher Barry called the meeting to order December 5, 2013

Commission Members:

Christopher Barry, RPh, Chair
Gary Harris, RPh,
Elizabeth Jensen, PharmD, Vice-Chair
Dan Rubin, MMP, Public Member
Sepi Soleimanpour, RPh, MBA-HA
Steve Anderson, RPh
Nancy Hecox, PharmD
AL Linggi, RPh, MBA
Tim Lynch, PharmD
Maureen Sparks, CPhT
Emma Zavala-Suarez, J. D., Public Member
Kristina Logsdon, Public Member

Absent Commission Members:

Maura Little, Public Member

Guest / Presenters:

Will Rhodes, Program Director for WRAPP
Micki Kedzierski, Volunteer with WRAPP
Chris Baumgartner, PMP Program Manager
Thomas Schilling, Pharmacy Clinical Director
for Yakima Valley Farm Workers Clinic
Douglas Crafton, RPh, President & CEO
of Medication Review
Christopher Terriff, RPh, VP Clinical Operations
of Medication Review
Andrew J Burton PharmD for Summit Pacific Med Ctr
Lisa Roberts, R.Ph, Pharmacy Director for
Willipa Harbor Hospital
Robert Brower, Director of Operations
at RxRemote Solutions
Beata Przebinda, Regional VP for Comprehensive
Pharmacy Services

Staff Members:

Joyce Roper, AAG
Christopher Humberson, Executive Director
Gordon MacDonald, Chief Investigator
Tyler Varnum, Pharmacy Investigator
Tim Fuller, Pharmacist Consultant
Cathy Williams, Pharmacist Consultant
Peggy Crain, Rules Coordinator
Leann George, Secretary Senior

Absent Staff Members:

Doreen Beebe, Program Manager

1.2 Approval of Business Meeting Agenda.

1.3 Approval of July 18, 2013 Meeting Minutes.

MOTION: Elizabeth Jensen moved that the commission approves 1.2 and 1.3. Al Linggi second.

MOTION CARRIED: 11-0.

New Member Introduction

Kristina Logsdon is a second generation Japanese American. Since moving to Seattle in 2001, she has worked for and served on the board of a number of nonprofits engaging in issues such as environmental health, sustainable agriculture, and civic engagement of underrepresented communities. Her most recent adventure has taken her outside of the nonprofit world to local government. She currently serves as Senior Legislative Aide to King County Council member Rod Dembowski

Maura Little is the Life Science Sector Lead for the Washington State Department of Commerce. As the state lead, she supports the development and expansion of the Life Sciences industry, with a goal to recruit, retain and expand the industry. Previous to her current role, she was the Washington State Director of Government Relations for the American Cancer Society Cancer Action Network. After graduating from the University of Washington, Maura spent 5 years supporting then Congressman Jay Inslee's legislative agenda as a Legislative Assistant and Community Liaison.

Maura is a life-long resident of Washington State. She currently resides in Seattle with her husband and son.

Steve Anderson is a 1980 graduate of the University of Wyoming School of Pharmacy. He has been a licensed pharmacist in the state of Washington since 1980, and was employed as a pharmacy manager with the Bartell Drug Company for 30 years. Steve has been a Clinical/Affiliate Faculty member of the University of Washington School of Pharmacy and preceptor since 1989, and is an APhA Immunization Instructor, and an AHA CPR/First Aid Instructor. He is currently the Assistant Pharmacy Manager at Costco Wholesale's RX E-Commerce division in Everett, Washington.

Dr. Nancy Hecox is the Clinical supervisor for Tieton Village Drugs in Yakima Washington. She received her BSPharm in 1978 from Massachusetts College of Pharmacy, returning to school in 1994 to obtain her PharmD from Idaho State University. She has worked in retail pharmacy, independent and chain drugstores and has taught pharmacology at Pacific Northwest University College of Medicine. She also helped start the WRAPP program and worked as the chemical dependency counselor for that organization for 6 years.

Dr. Hecox has published articles in various journals and has presented topics concerning pharmacists participation public health services at several conferences. In addition, Dr Hecox may be found running ½ marathons, hunting, fishing and hiking all over the world. She lives in Selah, WA with her husband Ray and two Weimeraners, Gus and Cooper.

Al Linggi is a Consultant/Contractor for McKesson Corporation. Prior to June 2013 he served as Vice President, Corporate Business development for McKesson Corporation located in San Francisco, CA. His responsibilities for the Corporation included business development, strategic planning, investment alliances and acquisitions. Al actively participated or managed over 17 investment/acquisitions for McKesson Corporation. Throughout his tenure with McKesson, Mr. Linggi has held numerous positions: 1) President, Medication Management, 2) President and General Manager McKesson Specialty Services, 3) Vice President Product Development, Mr. Linggi has 40 years of experience in the pharmaceutical industry. A registered pharmacist, Al spent twenty-three years with the Franciscan Health System serving St. Joseph Hospital and Health Care Center in Tacoma, Washington prior to joining McKesson.

Mr. Linggi is well published and served on numerous boards of directors for national and regional organizations as well as advisory boards for Creighton University, University of Tennessee and University of Washington Schools of Pharmacy. Mr. Linggi served as an active member of the Washington State Board of Pharmacy from 2008 to 2012. Al graduated from the University of Washington School of Pharmacy and has an Exec. He has a MBA from Fuqua School of Business at Duke University. Al is happily married to Sheila (42 years), lives in Tacoma, Washington and has five children (two of which are pharmacists) and 8 grandchildren.

Tim Lynch is the Associate Vice President, Pharmacy Services for Franciscan Health System of Tacoma Washington. Franciscan Health System is comprised of 7 hospitals, over 100 physician clinics and a community hospice program that includes an inpatient hospice facility. Tim has responsibility for all hospital pharmacy departments, 7 retail pharmacy locations, 5 pharmacy managed pharmacotherapy clinics, a durable medical equipment program and a pharmacy managed research center. In addition, Tim is the residency program director for an ASHP accredited PGY1 residency program with 6 residents. Tim received both his BS in pharmacy and his Doctor of Pharmacy degree from the University of Washington. Tim also received a Masters in Healthcare Management from Troy University, completed a fellowship from the Advisory Board Company, completed a PGY1 residency at St. Joseph Medical Center in Tacoma Washington and is an affiliate assistant professor at the University of Washington. Tim is the past president of the Washington State Pharmacy Association as well as the Chair of ASHP Pharmacy Business Management Section Advisory Group. Tim also supports ASHP as a guest surveyor for residency program accreditation. Tim is a recipient of the Washington State Pharmacist of the Year and the Washington State Health System Pharmacist of the Year awards. Tim continues to organize a state-

wide health system pharmacy leadership meeting twice a year to share best practices across Washington State.

Maureen Sparks graduated from the program I now teach over 20 years ago. In 1995 a part time position came open at Clover Park Technical College for a clinical pharmacy technician instructor. Maureen found teaching to be a blast, and has been at CPTC ever since.

It is an ASHP accredited program, and believes that pharmacy technicians need education to perform the increasingly responsible tasks technicians are now taking on. She has been a member of the Pharmacy Technicians Educators Council, and served on the board as Secretary for four years 2007 – 2011. This organization has been instrumental in changes to the Pharmacy Technician Certification, and promotion of a standard education for pharmacy technicians.

During Maureen’s career at Clover Park Technical College she served on many committees, including Curriculum, Tenure, College Assembly and Labor/Management. She is currently the Faculty Union President. Since 1999 she has been a per-diem technician for St. Clare Hospital, part of the Franciscan Health System. Every day she feels she learns new things about the practice of pharmacy.

Maureen and her husband enjoy traveling in their motor home, 4 wheeling in the mountains, and drag race at Bremerton raceway. Maureen like to garden and she likes to build race cars. She has 4 children and 6 grandchildren and enjoys spending time with her families.

CONSENT AGENDA

Items listed under the consent agenda are considered routine agency matters and will be approved by a single motion of the Board 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

- July - October

2.2 Pharmacies and Other Firm Application Approval

- July - October

2.5 Pharmacy Technician – Specialized Functions Approval

- a) Providence Tech check Tech- Renewal
- b) Peacehealth St. Joseph Medical Center
- c) Legacy Salmon Creek

2.6 Automated Drug Distribution Device Approval

- a) Pharmerica

2.7 Electronic Prescription Transmission System Approval

- a) Weno Exchange LLC – New
 - b) Prodigy Data Systems, Inc./PROscript 2000- Renewal
 - c) Surescripts – Renewal
 - d) Toptec Software_ MD ToolBox Rx – New
 - e) SuiteRx LLC – IPS (Intelligent Pharmacy Software – New
 - f) Health Business Systems Inc – RxAxis – Renewal
 - g) PDX, Inc – EPS (Enterprise Pharmacy System) - Renewal
- 2.10** Tamper Resistant Prescription Paper/Pads Approval
- a) Kaye-Smith Enterprises, Inc.

Items listed under the consent agenda are considered routine agency matters and will be approved by a single motion of the board without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. **Items 2.3, 2.4, 2.8 and 2.9** were **deleted** from the agenda.

MOTION: Gary Harris moved that the Commission approve items 2.1, 2.2, 2.7 and 2.10. Items 2.5 (a) and (b) and 2.6 were pulled for further discussion. Elizabeth Jensen second. **MOTION CARRIED: 11-0.**

REPORTS

Commission Members

Gary Harris reported:

- Attended retirement party for Keith Campbell
- Gary has been invited to continue to give his lecture on pharmacy law and Ethics to the Washington State University students of Pharmacy. Now that Keith Campbell is no longer there and the school has moved to Spokane Gary will give this lecture for one more year and would like to pass that opportunity on to a commission member in that area.

Dan Rubin reported:

- Dan was on a recreational trip with his family at paint a plate place he made a ceramic PQAC plate to represent the Pharmacy Quality Assurance Commission.
- At the end of October he attended a national nonprofit organizations conference called the Citizen Advocacy Center. Department of Health has played an active role in supporting that organization. There were a number of members from various boards and commissions at this meeting.

Elizabeth Jensen reported:

She attended the ACPE re-accreditation of University of Washington College of Pharmacy. It was a great conference and felt it was well put together. They provided the attendees with such great packets and information.

Christopher Barry reported:

- Sacred heart went thru a computer change over been 3 months of learning and a lot left to be learned.

Al Linggi reported:

- He also attended the NABP District 6, 7, 8 Meeting in Boulder, Colorado.
- Monday listened in to FDA conference on drug quality security act Obama passed. Very interesting.
- Tuesday attended the University of Washington School of Pharmacy practice board. Dean Bailey is leaving he is taking a year sabbatical and will return as a faculty member at University of Washington.
- Al was appointed to UW School of Pharmacy curriculum committee. We help design curriculum that is commensurate to current pharmacy practices today.

Steve Anderson reported:

- He was recently at University of Washington on a preceptor committee we help ACPE committee recertify members of Washington's preceptor program. There were some tough questions but really turned out well for the University of Washington.
- He also listened in on FDA conference on drug quality security act Obama passed.

Nancy Hecox reported:

- Other than providing thousands of vaccinations she also has Collaborative Drug Therapy Agreement with the providers of Merk.
- Nancy has free vaccine from them. If someone doesn't have the vaccine or doesn't know how to do it she would be glad to assist. So there is no reason not to get your Pertussis vaccine.

Tym Lynch reported:

- September Tym conducted hospital leadership meeting for Washington State there were many great presentations.
- He gave a presentation to his organization regarding transition care in pharmacy practice what the pharmacy profession can do to improve that.
- He is coordinating a medication reconciliation effort to come up with best practices for transitioning care between long term care and acute care and other environments in the community and how we do hand offs to improve that

Executive Director

Christopher Humberson reported:

- In September he attended the NABP District 6, 7, 8 meeting in Boulder, Colorado. Covered Prescription Drug Abuse Issues, Inter-professional Precepting of Professionals, Issues related to Marijuana and pharmacology, patient considerations, DEA proposed rule for disposal of Controlled Substances, and an update on Federal Compounding legislation. Mark Johnson discussed proposed by-laws for the District 7, by executive committee member Mark Johnson, ED of Idaho Board of Pharmacy. During business meeting sessions, the district introduced a

resolution regarding pharmacy and veterinary colleges work together on cross educational opportunities for both professions by facilitating rotations and elective coursework at the respective colleges. This was met with unanimous approval to send to the executive committee for consideration.

- At the end of September Chris attended the Executive Director Meeting in Chicago
 - ✓ Topics of discussion were:
 - ✓ Compounding Blueprints and plans by states of Virginia, New Jersey, Nevada, and Minnesota.
 - ✓ Expanding Uniformity and Simplifying License Transfer between states.
 - ✓ Synchronization of Medication Scheduling
 - ✓ Update on PMP Interconnect and Integrations
 - ✓ Training Compliance Officers; other states solutions on training.(Texas, AR,
 - ✓ Practitioner Dispensing (Oregon presentation based upon ATTNY General Opinion) and regulation of Drug Outlets.
 - ✓ Discipline and Fines (S.C.)
- In October Chris spoke to Washington Veterinary Association Annual Meeting about Pharmacist-veterinarian collaboration and the Pharmacy Commission efforts to promote proper counseling and accurate prescription services from Washington State pharmacists.
- November he met with Exec Director and Chief Compliance Officer at Oregon board to continue facilitation of cooperation. This was an opportunity to introduce Gordon MacDonald to them both.
- Also in November he was able to attend the Thursday Board meeting of Washington State Pharmacy Association with Don Painter for an open forum and to answer questions from WSPA board members. He did attend WSPA awards luncheon to recognize those Washington State pharmacists who have been licensed to practice for 50 years.
- He visited the University of Washington Rx School and attended the UWSOP Law class to discuss and review their projects.
- Chris and Chris Barry attended Department of Health Board and Commission Leadership meeting comprised of various boards and commission leadership and DOH Leadership.
- He received National Association of Boards of Pharmacy appointment to Committee on Law Enforcement/Legislation to represent WAPC and NABP District 6, 7, 8. Meeting scheduled for January 21-22 in Chicago, IL.

Assistant Attorney General

Joyce Roper reported:

- Introduced Jack Bucknell, who recently joined the attorney general's office. He is now an assistant attorney general instead of staff attorney and Joyce asked him to assist by serving as back up legal advisor for the Pharmacy Commission. This seemed a natural fit, since he also worked with the Commission as a staff attorney and is familiar with the Commission's laws.

- The Commission previously heard a petition for rulemaking submitted by an attorney representing organizations opposed to fluoridation. The Commission declined to open rulemaking to amend its rules on legend drugs. The attorney representing the organization filed an appeal of the Commission’s decision to not open rulemaking as requested by the petition. On behalf of the Commission, a motion to dismiss the appeal was filed. The Thurston County Superior Court granted the Commission’s motion to dismiss. We are now waiting to see if an appeal to the Court of Appeals is filed in the next 30 days. If no appeal is filed, then the case is resolved.
- The Stormans case was scheduled to be argued in 9th Circuit Court of Appeals in October. The day before arguments were to be presented, one of the 3 judges recused himself. The argument was then rescheduled to be heard on Monday December 1, 2013 in San Francisco. A week before the December 1 date, the 9th Circuit issued an order on its own motion delaying arguments until the US Supreme Court decides a case that is now pending, *Conestoga Woods vs. Sibelius*, which challenges the Affordable Care Act’s requirement for employers to include contraceptive coverage in health insurance for their employees. The question of whether a for-profit corporation has the First Amendment protections for the free exercise of religion is a central question in that case.

Consultant Pharmacists

Cathy Williams reported:

- Cathy introduced herself to the new commission members and provided a brief bio of her background.

Tim Fuller reported:

- Tim also shared a brief bio of himself to the new commission members.

Pharmacy Supervisor Investigator/Field Investigator

Gordon MacDonald reported:

- The Investigators hold the distinct dual role of conducting both investigations and inspections. The State is divided into ten regions with each Investigator assigned to a region. Those regions and assigned Investigators can be found at the end of this memorandum. All nine current Investigators (our E. Washington region is currently vacant due to a recent retirement) come from varied practice backgrounds and collectively hold more than thirty-two years of experience with the Commission. On average, each investigator has been a licensed pharmacist for more than 20 years. Consider them your “eyes and ears” in those regions. They are a resource to contact when you are reviewing investigation reports and they welcome your contact and feedback. I encourage you to contact them directly with questions when considering novel requests by licensees. Undoubtedly they’ve been to the facility and may provide you some additional perspective.

- Currently the Pharmacist Investigator acts as a resource for and provides pharmacy expertise to other law enforcement agencies in conducting drug related criminal investigations. The Pharmacist Investigators conduct investigations of alleged drug law and pharmacy practice violations using their current education, training and experience. All Investigators have been trained in interviewing technique and have completed Departmental and State required investigative training.
- Investigators have also completed up to thirty hours of online training regarding sterile product preparation due to the importance placed on compounding by the Commission. One Investigator has recently received in-depth training at the Critical Point Sterile Compounding “Boot Camp” and another will receive the same training in the spring of 2014 to serve as resources for the other Investigators. As inspectors, the Pharmacist Investigators conduct routine and complex inspections of firms licensed by the Department. Those firms include; Pharmacies (retail, hospital, long-term-care, parenteral, nuclear, mail-order, internet etc.), drug manufacturers, drug wholesalers, K9 drug dog handlers, humane societies, researchers, state institutions, shopkeeper outlets, jails/correctional facilities, health care entities and all other sites where legend drugs, controlled substances, precursor substances, and over-the-counter drugs are sold, stored, dispensed or administered. These firms total over 2,100 in number and include 1,425 pharmacies for an average of over 200 firms per Investigator.
- In addition to firm inspections, Investigators conduct investigations authorized by the Commission on any of the 6939 Pharmacists, 895 Pharmacy Interns, 9146 Pharmacy Technicians and 9473 Pharmacy Assistants licensed in Washington in addition to the 2100 firms previously mentioned.
- In the period from November 1, 2012 to October 31, 2013 Investigators performed 1,513 inspections and completed 181 investigations.
- Investigations and inspections consume approximately 80% of the Investigators duties. The remainder of their time is spent providing technical assistance to both internal and external stakeholders regarding pharmacy practice, providing consultation regarding drug law and coordinating with other State and Federal agencies. As a participating member of the NABP (National Association of Boards of Pharmacy) and having opted to use the MPJE (Multi-state Pharmacy Jurisprudence Exam) as the licensure examination, the Commission is obligated to maintain the pool of questions in that exam. The Investigators have been assigned to fulfill this duty on behalf of the Commission because of their position as a pharmacy law expert. One of our Investigators is a member of the MPJE Review Committee (MRC) which works to ensure that questions submitted by all states across the country are reviewed and meet the current standards. They also assist state question writers in drafting defensible questions.

- Investigator William “Bill” Kristin (E. Washington) retired November 30th after serving the State Board of Pharmacy and Pharmacy Quality Assurance Commission for over thirty years. His dedication, depth of experience, knowledge and leadership will be missed.

Tyler Varnum reported:

- In 2012 it was identified that there was a need for more robust compounding rules and a need for the investigators to be trained more in depth.
- Tyler completed training 30 plus hours of online training all relating to 797 compliance provided by Critical Point.
- In September he received another 19 hours of live training at the Critical Point Compounding “Boot Camp” in Denver, CO.
- Eric Kastango (elected member of USP Expert Committee for Sterile Compounding, cGMP manager, Baxter, Coram, extensively published). Kate Douglass (a USP <797> Study Co-Director, extensively published, Coram, Solumet). James T Wagner (USP Expert Committee member, lead Controlled Environmental Testing Association (CETA) efforts for USP guidance documents, USP Hazardous drug compounding expert committee, steering committee member for NSF/ANSI)
- There were attendees from all corners of the country; NY, IL, LA, NC and CO. He was the only inspector from WA but there were others, 2 from LA and 2 from NC.
- Most of the attendees were pharmacy managers, pharmacists and technicians from hospitals, large industry like Cardinal, Pharmacy One Source and even some independent retail pharmacy practices.
- Objectives of the training ranged from the broad scope and objectives of 797 all the way to the practical experience in environmental testing, end product testing, facility design and the performance of aseptic manipulations.
- Tyler felt that Critical Point provided exceptional training for anyone involved in either the regulation of or the practice at a compounding pharmacy.
- The main points of the Critical Point training and elements in 797 were:
 - ✓ “Maintaining a clean state of control” in your environment.
 - ✓ Operator competencies/training.
 - ✓ CSP checks and tests.
- Most facilities that produce CSP’s need assistance in one or more of these areas.
- “Safe harbor” helping to maintain the sovereignty of pharmacy compounding by demonstrating reproducible quality.

CONSENT AGENDA Item 2.5(a)

Providence Tech check Tech- Renewal was pulled from the Consent Agenda for further discussion.

MOTION: Dan Rubin moved that the commission conditionally approve Providence Pharmacy Technician Specialized Functions renewal subject to their follow up by the January meeting in the specific areas of change that was recommended by staff. Also, the commission would like the wording in their APUP be changed from “a Level A pharmacy assistant” (which is inconsistent) to “pharmacy technician.” Sepi Soleimanpour second. **MOTION CARRIED: 11-0.**

CONSENT AGENDA Item 2.5(b)

PeaceHealth St. Joseph Medical Center Pharmacy Technician Specialized Functions was pulled from the Consent Agenda for further discussion.

MOTION: Dan Rubin moved that the commission conditionally approve PeaceHealth St. Joseph Medical Center Pharmacy Technician Specialized Functions subject to their follow up by the January meeting in the specific areas of change that was recommended by staff. Sepi Soleimanpour second. **MOTION CARRIED: 11-0.**

CONSENT AGENDA Item 2.6

Pharmerica’s Automated Drug Distribution Device was pulled from the Consent Agenda for further discussion.

MOTION: Dan Rubin moved that the commission conditionally approve Pharmerica’s Automated Drug Distribution Device now subject to they will not go live until the commission has approved an initial list. Emma Zavala-Suarez second. **MOTION CARRIED: 11-0.**

PRESENTATIONS

Washington Recover Assistance Program for Pharmacy

The commission heard a brief overview of Washington Recover Assistance Program for Pharmacy (WRAPP). – Will Rhodes, Program Director, and Micki Kedzierski also provided an update and clarification on contract/statement of work and audit findings.

Micki discussed the recent audit of the programs and how they have been addressing the issues identified in the report. WRAPP asked the commission to consider guidance on making some changes to the Contract and Statement of Work Modifications related to the audit.

1. Re-designation of categories of participation from three categories: "Voluntary", "Voluntary-in-Lieu (Case-in Progress)" and "Board-Ordered" to two categories: "Voluntary" and "Mandatory".

MOTION: Nancy Hecox moved that the commission make motion to support the request to Re-designate categories of participation from three categories: "Voluntary", "Voluntary-in-Lie" and "Board-Ordered" to two categories: "Voluntary" and "Mandatory". Gary Harris second. **MOTION CARRIED: 11-0.**

2. Designation of phases to "Intake/Assessment", "Treatment", and "Monitoring". WRAPP considers these phase designations to more accurately define phases in the WRAPP monitoring program than the UAs/month phases used by other practitioner groups.

MOTION: Gary moved that the commission accepts the language changes for the phases of treatment as purposed by WRAPP. Sepi Soleimanpour second. **MOTION CARRIED: 11-0.**

3. Provision of WRAPP services to unlicensed and/or non-practicing clients

MOTION: Nancy Hecox moved that the commission support changing provisions of WRAPP services to unlicensed and/or non-practicing clients. Gary Harris second. **MOTION CARRIED: 11-0.**

Prescription Monitoring Program Overview and Update

Program Director Chris Baumgartner provided an overview and update of the prescriptions monitoring program to the commission.

Overview/History

- A PMP is a program designed to improve patient safety and protect public health with the goal of reducing overdose deaths, hospitalizations, and other related prescription drug abuse issues.
- Records for dispensing of controlled substances are submitted to a central database by pharmacies and other dispensers.
- Health providers and other authorized users are able to register for access, and once approved, can view information through a secure web portal.
- PMP information can help providers avoid duplicative prescribing and dangerous drug interactions; and help identify substance abuse or pain management issues.
- Legislation was passed in 2007 (RCW 70.225)
- Federal funding was obtained in October 2010 to start implementing the program
- Rules were adopted in July 2011 (WAC 246-470)
- DOH contracted with an application service provider for data collection and reporting in July 2011
- An additional federal award was obtained in October 2011 to finalize implementation
- **2011**
 - Begin Data Collection – October 1
 - Begin Mandatory Reporting – October 7
 - Begin DOH/PMP Staff/Licensing Board Access – October 26
 - Begin Oversight Agencies Access – November 15

- Begin *Pilot* Data Requestor Access – December 1
- **2012**
 - Begin Data Requestor Access – January 4
 - Begin Law Enforcement/Prosecutorial Agencies Access – February
 - Begin Medical Examiners/Coroners Access – May
 - Operations, Maintenance, Enhancements – ongoing

PMP Operational Funding

- HB 1565 provides ongoing funding through the Medicaid
 - Signed by Governor on 4/23
- The signed operating budget (6/30) includes funding for the PMP from this account and from HCA.
- The operating budget also includes a proviso requiring the PMP to integrate with EDIE.

Goals for Washington's PMP

- To give practitioners an added tool in patient care
- To allow practitioners to have more information at their disposal for making decisions
- To get those who are addicted into proper treatment
- To help stop prescription overdoses
- To educate the population on the dangers of misusing prescription drugs
- To make sure that those who do need scheduled prescription drugs receive them
- To curb the illicit use of prescription drugs

Data Submission Compliance

- At the end of October 2013 we had:
 - 1,444 licensed resident pharmacies
 - 600 licensed non-resident pharmacies
- We average 98% compliance each month
- Pharmacies who do not dispense controlled substances file a no dispensing of CS form with the program
- 2 complaints filed to date for non-compliance

Who isn't required to submit data

- Practitioners who directly administer a drug
- A licensed wholesale distributor or manufacturer
- Prescriptions provided to patients receiving inpatient care at hospitals
- Pharmacies operated by the Department of Corrections (unless an offender is released with a dispensing)
- Veterans Affairs, Department of Defense or other federally operated pharmacies (Indian Health Services is now reporting voluntarily & Veterans Affairs should be soon)

Who Has Access

- Prescribers & dispensers - in regards to their patients
- Licensing boards – in regards to investigations
- Individuals – in regards to any prescription dispensed to them

- DOH/Vendor – in regards to program operation
- Law Enforcement/Prosecutor – for bona fide specific investigations
- Medical Examiner/Coroner – cause of death determination
- HCA (Medicaid), L&I (Worker’s Comp), DOC (Offenders)
- De-identified information may be provided for research and education

Future enhancements / Version 4.2

- As part of our grant enhancements we are required to upgrade our data collection format to the most recent version
- A new implementation guide was sent out in April so dispensers could begin work
- Data submission in the new format began in October 2013

Interstate Data Sharing

- The technical components are now in place
- The next step will be putting into place data sharing agreements with state PMPs
- Once in place WA providers will be able to select additional states to request data from when using our system

Health Information Exchange

- We have built the connection to our state HIE (OneHealthPort) this summer.
- In phase II starting this fall:
 - Connection through the HIE to UW Medicine
 - Connection through the HIE to EDIE
- If you know of other organizations who would be interested in connecting this way please have them contact DOH

Yakima Valley Farm Workers Clinic

Cathy Williams gave a brief overview before introducing Dr. Thomas Schilling, Pharmacy Clinical Director for Yakima Valley Farm Workers Clinic (YVFWC). Dr. Thomas Schilling asked the commission to consider approving services to clinics using workload balancing via remote order processing and use of collaborative drug therapy agreements. He would like to expand the functions of the YVFWC Call Center.

Overview:

2012 YVFWC Served 119,614 patients

- 66.5%....Hispanic
- 27.7%....White, Non-Hispanic
- 28.4%....Best served in a language other than English
- 34.6%....Migrant/seasonal farm workers or their dependents
- 76.6%.....Income below 100% FPL
- 43.9%.....Medicaid
- 8.5%.....Medicare

2012 Patient Encounters Totaled 540,735

Medical....406,661

Dental.....72, 989
Mental Health....32, 181
Other Professionals (RD)....10, 160
Enabling Services....17, 081

Six YVFWC Pharmacies located in our Washington Clinics. All participate in the **Federal 340b** drug program and provide care to all eligible YVFWC clinic patients:

- **Yakima**
- **Toppenish**
- **Grandview**
- **Walla Walla**
- **Spokane (2)**

Definition of Workload Balancing: Assisting our local pharmacies with their prescription workload using the shared Pharmacy Software, EnterpriseRx®.

The remote pharmacist will be authorized to perform the following functions:

- ✓ Process Prescription Reception and Inbound Communications
- ✓ Prescription Data Entry
- ✓ Process Adjudication Exceptions
- ✓ Prescription Renewal Requests

Authorized functions would NOT include:

- ✓ Product Dispensing
- ✓ Verification
- ✓ Patient Counseling

Processing prescriptions through the pharmacy Enterprise Rx system:

- The *Pharmacist* or the *Pharmacy Technician* under the direct Supervision of a Pharmacist may process prescriptions in the Enterprise Rx system.

Renewal of prescriptions requested by the patient:

- Only a *Pharmacist* approved by the Pharmacy Commission under our CDTA protocol may process prescription renewal requests.

Workflow Steps for Processing a Medication Order

1. Receipt of the prescription order (New Rx or Refill Rx) in Reception or Inbound Communications Queues
2. Data Entry
3. Adjudication resolution*
4. Product Dispensing
5. Verification/DUR resolution
6. Patient Counseling

**Only steps 1 – 3 will be done by a remotely as workload balancing*

Where are the Remote Functions Going to be Performed

Remote processing of existing prescription orders will be done at another pharmacy or from the call center, or a remote location.

Remote processing of prescription renewals using the CDTA will be performed *only* by a pharmacist at another pharmacy, from the call center, or a remote location.

Responsible Pharmacist

- The individual who takes responsibility for the final medication dispensed to the patient.

- In our remote process, the **local pharmacist*** is the “Responsible Pharmacist”
*She/he needs to have performed or directly supervised all of the workflow steps for product handling, dispensing, prescription verification, and patient counseling during the preparation of the prescription order for the patient.

Pharmacy Call Center

Location:

- YVFWC Yakima Clinic where our Yakima Pharmacy is located.

Oversight:

- Currently by the Yakima Pharmacy Manager

Call Center Agents:

- Are Registered Pharmacy Assistants.

Function:

- Receive prescription refill and renewal requests from patients and enter them into the Pharmacy Software System

Call Center Procedures

1. The patient tells the call center agent the prescription number they would like to refill.
2. The call center agent locates the prescription number in the patient’s medication profile
3. If the exact prescription number is not found in the profile, the call is transferred to the pharmacist in the local pharmacy.

Prescription Renewal Process

1. Patient requests prescription renewal by contacting the Pharmacy Call Center.
2. Call center agent saves this request in the reception queue of the local pharmacy.
3. If there are no refills remaining, when the local pharmacy staff opens the prescription in the reception, EnterpriseRx will allow them to initiate a renewal request that goes to the pharmacist’s work list in the Electronic Medical Record system, (IC-Chart).
4. Pharmacist approves the prescription renewal if allowed by the CDTA or forwards it to the provider for approval.
5. Approved prescriptions sent to the pharmacy by the pharmacist or the provider.

Benefits for Our Pharmacy

Workload

Workload balancing spreads the workload over the entire pharmacy system helping local pharmacy to:

- Reduce Patient Wait time
- Improve overall efficiency
- Allow the pharmacist more time with the patient

Quality Improvement

More time spent on workflow steps our data shows result in the highest percentage of medication errors

Improved Safety

Reducing medication errors to improve patient safety

Benefits for Pharmacy Call Center

Current Yakima Pharmacy Responsible Manager may devote all of her time to the Yakima Pharmacy instead of both the pharmacy and call center

More efficient for the local pharmacy: Fewer calls forwarded to local pharmacy and are handled by the Call Center Pharmacist

MOTION: Tym Lynch moved that the commission approve Yakima Valley Farm Workers Clinic workload balancing proposal as presented. Al Linggi and Elizabeth Jensen recused themselves, and Gary Harris opposed. Sepi Soleimanpour second. **MOTION CARRIED: 8-1.**

MOTION: Nancy Hecox moved that the commission approve Yakima Valley Farm Workers Clinic’s proposal to add a pharmacist in the call center as “Responsible Manager” to expand call center with the requirement that it **MUST** be licensed as a pharmacy. Elizabeth Jensen recused herself, Tym Lynch abstained. Dan Rubin second. **MOTION CARRIED: 9-0.**

The board adjourned for Executive Session and Case Presentations at 12:30 p. m.

The board reconvened from Executive Session and Case Presentations at 1:30 p.m.

Medication Review

Chris Terriff, VP Clinical Operations and Doug Crafton, President and CEO provided an updated overview of Medication Review and the remote medication order processing services it provides.

Company Background

- 2005 – Pharmacy management services – rural hospitals
- 2009 began remote order entry services
- Today – remotely enter/verify in excess of 9,000 Rx’s per week
- Licensed in 10 states
- Two regional offices – Spokane, WA & Minden, NV
- Serve 18 of 39 critical access hospitals in WA
- Pharmacy management services

Our Culture

- Clinically trained RPh’s – hospital experience
- Incentivize our pharmacists for BCPS, CDE, etc.
- Centralized order processing
- Strict hiring guidelines
- Faculty & Adjunct Faculty at WSU College of Pharmacy
- Rotation site for WSU College of Pharmacy
- WSU preceptor of the year awards

All of these provide a clinical setting that encourages learning, competency, high practice standards, and forward thinking.

Policy & Procedure Overview

- Medication Review P & P when providing order entry
- Ancillary Personnel Utilization Plan at Med Review
- Secure transmission of medication order/notice

- Electronic Health Record (EHR) at remote site
- Automated Drug Dispensing Device required
- Order transmission/disaster recovery downtime
- On-site Pharmacist-In-Charge
- Ancillary Personnel Utilization Plan Remote Facility
- CQI & Reporting

Electronic Supervision of Technicians

- Remotely supervise the daily activities of the Pharmacy Technician by digital interactive video, audio, data transmission and/or still image capture.
- Medication Review Pharmacists are responsible for verifying accuracy of filled orders prior to release of medications (ADDD fills, direct to staff, repackaging bulk to unit dose)
- Technician to Pharmacist Ratio 3:1
- Permanent digital records archived and readily retrievable for minimum 2 years

Continuous Quality Improvement

Measure current and improve future work!

- Productivity
- Clinical Consultations/Interventions
- Order Variance/Error – incorrect entry & harm vs. no harm
- Adverse Drug Events
- State/Federal Regulations Update
- Implementation/Strategies for improvement

Hospital Pharmacy CQI Reporting

- Order volumes per facility
- Order deficiencies – aka Pharmacist Interventions
- QI data back to the facility
- Track medication errors

Summit Pacific Medical Center

Tim Fuller introduced Dr. Andrew Burton, PharmD. Dr. Burton provided an overview of Summit Pacific Medical Center's (SP-MC) use of Medication Review for remote medication order processing services. The commission was asked to consider for approval SP-MC's policies and procedures.

Background

- Opened February, 2013
- 10-bed Medical Unit + Emergency Department
- Critical Access Hospital
- Located in Elma, WA: Population 3,052
- Nearest hospital is 24 miles away
- Pharmacy Department open approximately 20 hours/week

- Uses Pyxis Automated Drug Distribution Device for medication distribution control

Remote Order Entry

- Provided by Medication Review
- 1206 orders entered for SPMC in November
- Provides 24-hour pharmacy services in accordance with WAC 246-873-050 including
 - ✓ Order entry
 - ✓ DUR checks
 - ✓ Drug information
 - ✓ Dosage calculation

Procedure Overview

- Nursing staff reviews and scans written medication order and indicates if order is urgent (STAT)
- Remote order entry pharmacist receives order and checks order against patient profile for accuracy, completeness, and contraindications
- Pharmacist enters order into Pyxis system
- Nurse can then access medication from the Pyxis Medstation for administration

Advantages

- Every order is reviewed by a pharmacist for accuracy, allergies, interactions, etc prior to administration by nursing staff
- Orders are entered promptly, 24/7
- Nursing staff has immediate access pharmacist via phone and instant messaging

Security

- Accessed via private VPN tunnel
- SHA1 AES 256 Bit Encryption
- Allows only specific computers within the Medication Review network access to Pyxis Console

24-hour Hospital Pharmacy

- 10-Bed Medical Facility
- Only 40 med orders processed per day
- Not reasonable or cost effective

On-Call Hospital Pharmacist

- Excessive delay in medication delivery
- Nurse overrides in Pyxis system to access medications omits pharmacist order verification
- Safety concern

SPMC Requirements of 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 Summit Pacific Medical Center's policies and procedures regarding medication order processing

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

MOTION: Dan Rubin moved that the commission approve Summit Pacific Medical Center’s remote order entry as proposed. Elizabeth Jensen second. **MOTION CARRIED: 11-0.**

Willapa Harbor Hospital Pharmacy

Lisa Roberts, Director of Pharmacy will provide an overview of Willapa Harbor Hospital Pharmacy’s use of Medication Review or another Washington State Board of Pharmacy approved Remote Order Processing Company for remote medication order processing services.

Policy:

Provide medical and nursing staff with twenty-four hour pharmacist services for electronic medication order verification and clinical pharmacist consultation.

Procedure:

The hospital will provide continued pharmacist services after hours when the hospital inpatient pharmacy is closed.

Willapa Harbor Hospital inpatient pharmacy is staffed with a full-time pharmacist covering at least forty hours of pharmacy services weekly. Hours may be subject to change depending on the needs of the facility.

In order to provide continued pharmacist services after hours and on weekends, the hospital will enter into a written contract or agreement Medication Review Washington State Board of Pharmacy approved Remote Order Processing Company. The written contract will be reviewed annually and may terminate by either party without cause. Medication Review or Washington State Board of Pharmacy approved Remote Order Processing Company must provide Washington State licensed pharmacists for remote electronic medication order verification and clinical consultation. The remote pharmacists must provide their current pharmacist license for Willapa Harbor Hospital Pharmacy Department to maintain on file. All remote pharmacists must comply with federal and state laws and regulations. Any out-of-state pharmacy providing remote order processing services must be licensed as a non-resident pharmacy.

Medication Review Washington State Board of Pharmacy approved Remote Order Processing Company will not be responsible for the dispensing of a prescription drug; however, they will be responsible for the following:

1. Receiving, interpreting, clarifying and remote processing of medication orders
2. Data entry and transferring of medication order information
3. Interpreting clinical data
4. Performing therapeutic interventions
5. Performing drug regimen review

6. Providing drug information/clinical consultation to nursing or medical staff

Willapa Harbor Hospital and the Medication Review or Washington State Board of Pharmacy approved Remote Order Processing Company must share common electronic files or have appropriate technology to allow secure access to the pharmacy's information system and likewise, to provide the Medication Review with access to the information necessary or required to process a medication order. Willapa Harbor Hospital utilizes Computerized Physician Order Entry (CPOE).

Willapa Harbor Hospital is responsible for maintaining records of all orders entered into their information system including orders entered from a remote location. Medication Review or Washington State Board of Pharmacy approved Remote Order Processing Company must provide Willapa Harbor Hospital with the ability to audit the activities of the individuals remotely processing medication orders.

The Remote Processing Order Entry facility must conform to Willapa Harbor Hospital's drug formulary, therapeutic interchange program, IV concentrations, standard administration times, and collaborative dosing agreements. Willapa Harbor Hospital will provide the Remote Order Entry facility with this information.

Medication Review or Washington State Board of Pharmacy approved Remote Order Processing Company must follow Willapa Harbor Hospital's policy and procedure manual relating to the pharmacy's operations. This manual shall include the following:

1. Outline the responsibilities of the pharmacy and Medication Review
2. A list of the name, address, telephone numbers, and all license/registration numbers of the pharmacy/pharmacists involved in remote order processing.
3. Maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activities of each pharmacist who performed any processing
4. Compliance with federal and state laws and regulations
5. A continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Such Quality Assurance will be conducted routine and will include:
 - i. Adverse Drug Event tracking
 - ii. Volumes and timeliness of order verification
 - iii. Performance feedback from Willapa Harbor Hospital nursing and medical staff

This policy and procedure manual will be reviewed annually and documented upon completion of review.

MOTION: Tym Lynch moved the commission approve Willipa Harbor Hospital's proposal to provide services with Medication Review or another Washington State Board of Pharmacy approved Remote Order Processing Company and the use of Automated Drug Dispensing Device (ADDD). Steven Anderson second. **MOTION CARRIED: 11-0.**

CAPSA Solutions

Tim Fuller led the discussion for CAPSA since Andrew Sherrill, VP Long Term Care, Capsa Solutions Inc. did not attend. Tim began to provide information on CAPSA's new product Electronic Emergency Kits for nursing homes.

The commission tabled this presentation for the January meeting so someone from CAPSA can answer the commission's question and concerns.

RxRemote Solutions

Tim Fuller introduced Beata Przebinda, Regional VP for Comprehensive Pharmacy Services asked the commission to approve RxRemote Solution's remote order processing service. The commission asked a few questions regarding some concerns.

- All pharmacists that will be practicing for this facility are Washington State licensed.
- The entire system is encrypted.
- Each hospital and nursing station is given is assigned specific fax line.
- This does not affect the pharmacist to pharmacy technician ratio because there are no pharmacy technicians practicing

MOTION: Gary Harris moved that the commission accept RxRemote Solutions Remote Medication Order Processing Services to provide services for FairFax. Elizabeth Jensen second. **MOTION CARRIED: 11-0.**

FairFax Hospital Everett and Kirkland

Beata Przebinda, Regional VP for Comprehensive Pharmacy Services requested approval for FairFax Hospital Everett and Kirkland to use RxRemote Solutions Services.

Overview

- Fairfax Hospital is a psychiatric hospital located in Kirkland, WA.
- 157 licensed beds.
- We offer:
 1. Inpatient Hospitalization
 2. Partial Hospitalization

3. Treatment for co-occurring Disorders and Medical Detoxification.

- On 10/22/13, Fairfax Hospital received a Certificate of Need to operate a 30 bed acute psychiatric hospital.
- Fairfax Behavioral Health Everett (Fairfax Everett) will be located on the 7th floor in the South Building at the Pacific Campus of Providence Regional Medical Center.
- Fairfax will be leasing 21,000 square feet for the unit.

Pharmacy

- Clean, secure, separate room.
- Medications will be stored on shelves; controlled substances will be locked in a separate, locked cabinet.
- The pharmacy will contain a sink, work space, an area to prepare medications, refrigerator, and climate controls.

Day to Day Operations

- Fairfax Hospital’s Medication Management Policies and Procedures will serve as the template for operations at Fairfax Everett Pharmacy.
- A Pharmacist in Charge will work 4-5 hours a day Monday through Friday and will report to the Director of Pharmacy.
- Pharmacy staff members at Fairfax Hospital will be cross trained to work at both facilities.
- AmerisourceBergen (ABC) will supply medications Monday through Friday.
- A pharmacist will be present to accept all deliveries from ABC.
- Control substances movement will be tracked and documented.
- Medication orders sent up to 5pm, will be processed by the Fairfax Pharmacy, Kirkland location.
- After hour medication orders will be processed by Remote Order Entry Fairfax Everett Pharmacy will utilize the same formulary as Fairfax Hospital, Kirkland.

Pyxis Automated Drug Distribution Devices

- Profile Driven Pyxis ADDD’s (2) will be located in the medication room.
- These ADDD’s will interface with the pharmacy patient profiles.
- The pharmacist will be responsible for filling the ADDD’s daily as required and for maintaining them.
- See Medication Management P&P’s for further information.

After some discussion the board felt there needs to be a clarification in the P&P regarding “verbal orders.” This was the biggest concern the commission had regarding this proposal. The P&P needs to be amended.

MOTION: Elizabeth Jensen moved that the commission table this proposal until January requesting that Policy & Procedures for FairFax Hospital Everett and Kirkland be updated. Kristina Logsdon second. **MOTION CARRIED: 11-0.**

OTHER

White Bagging

Chris Humberson led this discussion. The practice of having patient-specific medications or supplies delivered directly to the practice setting (hospital outpatient infusion center or physician office) or a secondary in-state pharmacy that then supplies product(s) sent by specialty pharmacies for use by a specific patient.

Background

- Specialty drugs are a subgroup of medications that are often biotech/gene based products that are usually high cost and require complex care and monitoring. They are most often injectable drugs with many being infusion based. White bagging is the practice of having patient specific medications dispensed directly to the practice setting (outpatient infusion center, physician office or hospital). Usually this distribution is done by a 3rd party specialty drug pharmacy per mandate of the insurance company.
- Specialty drug expense is increasing at an alarming rate and as purely a cost reduction effort, the insurers have mandated specialty drugs to come from dedicated facilities at locations across the US. The drug is dispensed as a prescription from one of these facilities based on an order generated by the patients managing healthcare provider. Because the drug is billed at the time it is filled by the specialty pharmacy, the institution delivering the care is not allowed to bill for any pharmacy related services (drug ordering, acquisition, order maintenance, storage preparation and mixing, patient monitoring, care coordination and documentation). In this regard, the delivery system is doing the work, assuming the liability for infusion but without reimbursement.

Assessment

- There is an increasing trend to carve out specialty drug distribution using specialty pharmacies that are not part of the delivery system. Often this prescription dispensing is being done contrary to state regulations but enforcement with either the distributor (specialty pharmacy) or the receiving organization (Care Delivery Organization) has been variable. The mostly out of state specialty pharmacies have often taken a passive “not my problem approach” that they are just filling the prescription, billing the insurer and shipping the drug and it’s up to the organization to figure out how to comply with regulations.

The commission would like staff to do more research and discussion to determine what the needs are for the safety of patients in Washington State.

Collaborative Drug Therapy Agreements

The commission discussed the communication that was distributed in August 2013 regarding the standards for acceptance of CDTAs.

Background

- Relevant to this discussion is how the path, once decided at that time, the process was not followed as decided by the board at that time. There have been no subsequent decisions by the board to divert from this original 2003 decision referenced in any subsequent meetings of the Board of Pharmacy to date.
- The WSPA at the time supported the board decision as noted in the minutes by Rod Shafer, Executive Director of the WSPA.
- This information should be considered given the board discussion of CDTA's at the May 30, 2013 meeting and the subsequent August communication of a return to the board approved process from 2003, recognizing CDTA's as agreements between pharmacists and prescribers and not as agreements between prescribers and business entities in which a pharmacist may be employed.

Communication

- When it is time to renew your Collaborative Drug Therapy Agreement (CDTA), please ensure that your agreement clearly establishes a relationship between the medical prescriber and the pharmacist. Under RCW 18.64.011(25), CDTA's cannot establish a delegation of prescriptive authority between a business entity and a medical provider. Please see [WAC 246-863-100](#) for more information.
- The Pharmacy Quality Assurance Commission (Commission) plans to provide more detailed information regarding CDTAs in October. The practice of submitting a cover memo listing all pharmacists as party to a single CDTA does not meet the legislative intent of the Practice of Pharmacy, [RCW 18.64.011\(25\)](#), and will no longer be accepted nor considered as a valid or active CDTA submission. Additionally, all pharmacists engaging in CDTA's, and care documentation will be required to maintain a copy of their agreements at their practice site for inspection upon request.
- Any pharmacists employed through a pharmacy relief service must operate under the pharmacist's own CDTA. No other accommodation is acceptable.
- Furthermore, a pharmacy intern can perform under an approved CDTA if an intern's preceptor has an agreement is in active status by the Commission.

The commission allowed the public to speak on this matter regarding their concerns. Each concern was heard and addressed by the commission and Joyce Roper, AGG.

OPEN FORUM

There being no further business, the board adjourned at 5:45 pm

PRESENTATION OF AGREED ORDERS

CLOSED SESSION

Next scheduled business meetings: Business Meeting Agenda

Date: December 6, 2013
Time: 9:00 a.m.
Location: Highline Community College
Mt. Constance
2400 South 240 St.
Des Moines, WA 98198

Respectfully Submitted by:

*Leann George, Program Support
Approved on January 23, 2014*

*Christopher Barry, Chair
Washington State Board of Pharmacy*