



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504
WASHINGTON STATE BOARD OF PHARMACY
Meeting Minutes
April 11, 2013
Department of Health
Point Plaza East Conference Room 152/153
310 Israel Rd SE
Tumwater WA 98501

CONVENE

Chair Christopher Barry called the meeting to order at 9:07 a.m., April 11, 2013

Board Members:

Christopher Barry, RPh, Chair
Emma Zavala-Suarez, Public Member
Elizabeth Jensen, PharmD
Donna Feild, RPh, MBA, Vice Chair
Dan Rubin, Public Member
Sepi Soleimanpour, RPh, MBA-HA

Guest / Presenters:

Rudy Leighton, Providence Infusion
Hospital Services
Cindy Chan, Providence Infusion
Hospital Services
Gail Bunker, Pharmacy Manager for
MultiCare Medical Center
Doug Thompson, Director of Clinical Services
for Columbia Basin Health Association
Linda Higginson, Director of Pharmacy
for Providence Centralia
Karen Bright, Director of Pharmacy for
Olympic Medical Center

Guest / Presenters continued:

Dr. Thomas Hazlet, University of Washington
UW PharmD Students
Bridgette Lorenzen
Mikalla Cheney
Thomas Gorlin
Elize Knutzen

Staff Members:

Joyce Roper, AAG
Christopher Humberson, Executive Director
Grant Chester, Chief Investigator
Greg Lang, Pharmacy Investigator
Tyler Varnum, Pharmacy Investigator
Tim Fuller, Pharmacist Consultant
Cathy Williams, Pharmacist Consultant
Doreen Beebe, Program Manager
Leann George, Secretary Senior

- 1.1 Approval of Business Meeting Agenda
- 1.2 Approval of the February 21, 2013 Business Meeting Minutes
- 1.3 Approval of Consent Agenda

MOTION: Donna Feild moves that the board approves 1.1, 1.2, and 1.3. Elizabeth Jensen second.

MOTION CARRIED: 4-0.

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.

- 1) NPLEx Monthly Report Acceptance
- 2) Pharmacies and Other Firm Application Approval
- 3) Pharmacy Tech Training Program Approval
 - a. Kelley-Ross Pharmacy
- 4) Ancillary Utilization Plan Approval
- 5) Pharmacy Technician – Specialized Functions Approval
 - a. Providence St Mary Medical – Technician’s Taking Med Lists
 - b. Central Washington Hospital Inpatient Pharmacy – Technicians’ taking Med Lists
- 6) Automated Drug Dispensing Device Approval
 - a. GHC Olympia
 - b. GHC Tacoma Medical Center
- 7) Electronic Prescription Transmission System Approval
 - a. Rx 30 – Transaction Data Systems
 - b. Rx3000 – Pharmacy Computer Services Inc
- 8) Sample Drug Distribution Approval
 - a. HealthPoint Pharmacies
- 9) Household Pharmaceutical Waste Take Back Program Approval
- 10) Tamper Resistant Prescription Paper/Pads Approval

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 4, 9, and 10** were **deleted** from the agenda.

MOTION: Donna Feild moved that the board approve items 1, 2, 3,5,6,7 (a), and 8. Item 7 (b) was pulled from the consent agenda. Elizabeth Jensen second.

MOTION CARRIED: 4-0.

REPORTS

Board Member

Elizabeth Jensen reported:

- Elizabeth went to the senate for her confirmation hearing. She found it to be very interesting.
- She felt the planning session held April 10, 2013 was productive and appreciated the format.

Emma Zavala-Suarez reported:

- She also went to the senate for her confirmation. She felt the questions being asked were interesting and all in all it was an exciting experience.

Donna Field reported:

- Donna announced she has taking a new position in North Carolina and will be leaving the board. She shared that she has enjoyed being on the board and finds it to be a privilege.

Executive Director

Christopher Humberson reported:

- Addressed WSPA Pharmacy Legislative day with Tim Fuller with Students from UW on Feb 25th.
- Attended several hearings and helped prepare testimony for DOH representatives for WA. House and Senate Health Care Committees (more in Leg report)
- Attended the Veterinary Board of Governors meeting on March 4th in Kent to discuss pharmacist responsibility in filling/counseling prescriptions for pets.
- Spent morning of March 12th at Oregon Pharmacy Board planning session to gain perspective on their work on compounding rules, technology rules, strategic planning and business practice rules recently.
- Submitted articles for Veterinary Newsletter on Pharmacist-Veterinarian relationships and finding common ground and on pharmacist prescription responsibility.
- Attended second WSPA WSU student Legislative day in Olympia on March 25th to speak to students.
- Attended National Drug Abuse Summit in Orlando for DOH for week of April 1st to learn about efforts to reduce opioid abuse and listen to national speakers and programs on the issues.
- Working with WSPA to include a CE on Veterinary medicine in Idaho Meeting in June 2013.
- Speaking on October 4th to Veterinary Association on Prescription Medication issues.

Assistant Attorney General

Joyce Roper reported:

- A decision came out of the District Court in New York to make Plan B available over the counter for all ages the Federal Government has thirty days to appeal. We have been looking at it from the perspective of the Stormans Case on behalf of the board and what implications there are. Keep in mind the Stormans Case involves Plan B and Ella not just Plan B. We will keep track of what is going on and see what the Federal Government does with any appeal.

Consultant Pharmacists

Tim Fuller reported:

- Hosting UW Extern Svetlana Nozdrina and WSU Extern Robin Seagrove. These students contributed a great deal while they were at the board. In addition to their field experiences with the Pharmacist investigators, they spent time in the board office developing and completing projects and reduced my very large backlog of collaborative drug therapy agreements. They used their knowledge, communication skills, and confidence to revise agreements with requestors. I have never had externs do this before.
- Presented with Chris Humberson to the UW students on Pharmacy legislative day.
- Participated in federal review of the DOH Receipt, Stage, and Store operation with a particular focus on medication repackaging.
- Attended Hazard Drug Advisory Committee meeting: see Handling of Hazardous Drugs Exposure Risk Algorithm (attached). Algorithm needs to be supported training, transport, administration, policies and procedures, amount and frequency.
- Participated in Local Health Jurisdiction-Pharmacy Template MOU Operation Plan Work Group meeting.
- Attended FDA Cascadia Conference to share current activities among 5 states and 2 provinces.

Chief Investigator/Field Investigator

Grant Chester reported:

- The pharmacist investigators are finding that there are many pharmacies which are involved in take back programs not approved by the board and are not disposing of the drugs they collect appropriately. The investigators have found bags of unsecured legend drugs, some with controlled substances, in pharmacies. The investigators are educating the pharmacists on the proper handling of returned drugs.
- Bill Kristin participated at the WSU Pharmacy Class March 28, 2013.
- Tina Lacey and Grace Cheung participated in the NABP/ MPJE exam writing March 21-22, 2013.

Greg Lang reported:

- Pharmacists in the field are continuing to have problems with their workload.
- The investigators enjoyed working with the externs and felt they were able to provide the externs with a great overall experience.

PRESENTATIONS

Providence Report to the Board - Preparing Non-Patient Specific Products

Rudy Leighton and Cindy Chan from Providence Infusion and Pharmacy Services provided the board a six-month status report on its practice of preparing non-patient specific products within a hospital system.

Compounding Resumed November 2012, Non-Patient Specific

- Servicing Providence Hospitals in Washington
- Sterile-to-sterile compounding
- Currently preparing four products
- Three additional products in testing

Highest Quality Sterile Environment

- PIPS has achieved and continues to maintain a state of environmental control that meets or exceeds USP 797 Standards
- Internal monthly environmental testing
 - ✓ Air sampling
 - ✓ Surface sampling
 - ✓ Continuous temperature and humidity monitoring
- Semi-annual environmental testing by Technical Safety Services which provides independent USP 797 compliant testing
 - ✓ Air sampling
 - ✓ Surface sampling
 - ✓ Temperature, humidity and room differential pressure monitoring

Quality Assurance

- ✓ Simplifi 797 software application
- ✓ Tracks all tasks, processes, and competencies required for USP 797 compliance:
 - Daily inspection, cleaning, sanitizing of IV hoods, pumps, scales to maintain sterility.
 - Monthly cleaning of ISO environments
 - Monthly drug outdate checks
 - Temperature, humidity, and pressure monitoring
 - Sterility testing
 - Annual training for pharmacists and technicians
- QCU - Dedicated Quality Control Unit
- End-Product Sterility Testing

Pharmacy Technician Training Program

- Media Fills, Gloved Fingertip Sampling
- Observed Competencies, Written Exams
- Critical Point® online competencies
- Competencies specific for batching technicians
- Total average initial training time per pharmacy technician:
(without batching): 677 HOURS. Total average initial training time per pharmacy technician: (with batching): 904 HOURS. Annual Training per Pharmacy Technician: 55 HOURS.

Pharmacist Training Program

- Media Fills

- Observed Competencies
- Hands-on clean room training
- Critical Point® online competencies
- Total training time initially and annually per pharmacist: +40 hours

Rudy Leighton invited anyone from the board to come visit his facility. There was not much discussion regarding this update presentation.

MultiCare Report to the Board- Telepharmacy

Tim Fuller introduced Gail Bunker, Pharmacy Manager for MultiCare Medical Center. Gail provided the board a six-month status report on its use of telepharmacy technology:

- 1) To provide after hours services to Covington ED Nursing staff sterile medication preparation for administered medications in the Emergency Department; and
- 2) To verify patients' own medications at five MultiCare Sleep Centers.

Tele-Pharmacy: Covington ED Nurse Preparation of High Risk Medications

- Covington ED does not have 24 hour Pharmacy Services, trained RNs prepare IV admixtures when the pharmacy is closed. Tacoma General pharmacists observe nurse preparation of high risk IV admixtures via tele-pharmacy conferencing. Pharmacists document double check of admixture prepared in EPIC ED Notes.

Tele-Pharmacy Calls of High Risk Admixture Preparation

- Pharmacists staff the Covington ED from 12:00 noon to 7:00 pm daily.
- After hours order verification is supported by TG pharmacists due to their pediatric training.
- Select High Risk IV admixtures prepared after hours require pharmacist tele-pharmacy observation
- An average of 6/month High Risk IV admixtures are prepared after hours

Tele-Pharmacy: Verification of Patient Own Medications in Sleep Centers

- MultiCare has six Sleep Centers located at Auburn, Covington, Gig Harbor, Good Samaritan, South Hill and Tacoma General.
- Joint Commission requires pharmacy oversight of medication administration.
- Pharmacy remotely verifies patient's own medications via high resolution camera.

Tele-Pharmacy: Verification of Patient Own Medications in Sleep Centers

- In August 2012 there was a one month pilot of pharmacist verification of patient own medications from the Tacoma General Sleep Center.
- 104 medications of 41 patients were verified by tele-pharmacy
- There was an average of 2.5 medications per patient
- Pharmacists spent an average of 30 minutes per day verifying sleep center patient own medications at Tacoma General Sleep Center
- It was projected that verification of patient own medications at all MultiCare Sleep Centers would take approximately 3 hours of pharmacist time per day
- Staffs working at the Sleep Centers are non-licensed staff that is not authorized to administer medication. Tele-conferencing was also being used by nursing staff to observe medication administration.
- The sleep center project is currently on hold until resources can be allocated for pharmacy and nursing staff.

MultiCare Health Systems (MHS) – Centralized Pharmacy Practice

Gale Bunker from MultiCare presented a proposal for four centralized pharmacy services to support multiple MHS facilities, services to include:

- 1) Centralized Repackaging of Oral Solids
- 2) Centralized Repackaging of Non-Sterile Compounded Oral Liquids and Topicals
- 3) Centralized Batching of Compounded Sterile Products
- 4) Pyxis Central Fill

Overview:

MultiCare Pharmacy Services supports five hospitals, seven surgical centers, one free standing Emergency Department, five outpatient oncology clinics, ten retail pharmacies and over one hundred physician offices.

Centralized Services: Four Proposals across MultiCare Facilities

- MHS has grown to include several medical campuses with unique populations and varied workloads. The BOP request is to provide specific centralizing functions through a Manufacturing License.
- Goals:
 1. Ensure all medications within MultiCare have a readable barcode.
 2. Improve efficiency and optimize care at all MultiCare facilities.
- Specific programs requested include:
 1. Proposal 1: Centralized Repackaging of Oral Solids
 2. Proposal 2: Centralized Repackaging of Non-Sterile Compounded Oral Liquids and Topicals
 3. Proposal 3: Centralized Batching of Compounded Sterile Products
 4. Proposal 4: Pyxis Central Fill
- Applicable laws:
 1. RCW 18.64.045 Manufacturer’s License
 2. WAC 246-895-010 Pharmacy – Good Manufacturing Practice
 3. WAC 246-871 Pharmaceutical – Parenteral Products

Proposal 1: Manufacturing License for Oral Solid Centralized Packaging

- MultiCare Pharmacy Services will continue to purchase unit dose packaging whenever possible.
- Controlled substances will not be provided by centralized packaging.
- Tacoma General and Good Samaritan Hospital Pharmacies to provide oral solid bulk repackaging for other MultiCare facilities.
- Centralized packaging of oral solids will occur when:
 - Unit dose form is unavailable
 - The manufacturer unit dose form has an unreadable barcode

Autopak

- Oral solid non-narcotic bulk repackaging to be performed on AutoPak machine.
- AutoPak places a viable barcode on each package.
- AutoPak expiration date is one year from packaging unless expires sooner
- Biohazard and highly allergenic medications will not be packaged in the AutoPak machine due to contact contamination. These items may still be packaged for central distribution using the

Euclid or bubble pack packaging methods; these packages will also require a viable barcode for centralized distribution.

Distribution

- Packaging requests will be sent to Tacoma General or Good Samaritan Hospitals for processing.

Proposal 2: Manufacturing License for Non-Sterile Compounded of Oral Liquid and Topicals

- No Controlled Substances will be compounded for central distribution.
- MultiCare sites may request a compounded medication in bulk or unit-dose. Unit-dosed products will be packaged with viable barcode.
- Distribution
 - Compounding requests will be sent to Tacoma General for processing.
 - Completed unit-dose compounds to be couriered to requesting MultiCare.

There was some confusion on the language with this proposal with respect to clarification of compounding and manufacturing. A couple questions from the board about bar-coding.

Proposal 3: Manufacturing License for Compounded Sterile Products

- Tacoma General and Good Samaritan Hospital Pharmacies to provide compounded sterile product batch preparation for other MHS facilities.
- The majority of admixtures will be prepared on site, compounded sterile product batching will be used for:
 - Non-controlled substances only
 - High volume items such as cefazolin 2g piggybacks
 - Standard premixed drips unavailable due to drug shortages such as heparin infusions

Distribution

- Compounded sterile product requests will be sent to Tacoma General or Good Samaritan Hospitals for processing
- Cold Chain Transportation will be using during transport
 - Products requiring refrigeration will be placed in an insulated container with frozen cold packs to maintain temperature between 2-8°C (35-46°F)
 - Products requiring freezer transportation will be transported in Vaxisafe or another approved freezer storage unit to maintain temperatures at -15°C (+5°F) or colder

Concerns from the board were regarding MHS following 797 rules and pharmacist competency. There were some questions on the future of this particular type of compounding.

Proposal 4: Central Pyxis Fill

- Tacoma General and Good Samaritan Hospital Pharmacies to provide central Pyxis fill for the other MHS campuses.
- Advantages of Central Pyxis Fill
 - Centralized decision making
 - Process standardization
 - Re-deployment of resources on more patient centric activities
 - Improved inventory management
 - Ideal for multi-location acute care facilities
- Refill quantities determined by Pyxis report specific to each campus
- Non Controlled Substances only

- Courier transports to receiving campus, chain of custody documented

Staff Training and Competency

Oral Solid Centralized Packaging:

- Technician must complete Talyst and AutoPak competencies to be certified on equipment to package oral solids.

Non-Sterile Compounded Products:

- Technician must complete a non-sterile compounding competency to compound non-sterile compounds.

Compounded Sterile Products:

- Technician must complete initial and annual IV certification.

Central Pyxis fill:

- Technicians must complete an initial and annual Pyxis competency and be certified on Talyst and AutoPak to perform central fill.
- Technicians must be certified in the specialized Tech-Check-Tech Board of Pharmacy approved program to check Pyxis fill.

Quality Assurance Program

Oral Solid Centralized Packaging:

- Only a pharmacist can enter a new medication into the AutoPak system.
- Pharmacist check of all oral solid packages.
- Pharmacist to verify, medication name, strength, manufacturer, expiration date, lot and barcode.

Non-Sterile Compounded Products:

- All recipes pre-approved through Compound Assist.
- Two step pharmacist check on all non-sterile compounded products including verification of weight on pharmaceutical scale.

Compounded Sterile Products:

- Pharmacist check of all compounded sterile products.
- Direct inoculation sterile tests are performed on all batched compounded sterile products with extended dating.

Central Pyxis fill:

- Triple check process: double check occurs during central fill, third check occurs by filling technician.
- Quarterly Pyxis fill audits performed.

MOTION: Donna Feild moved to approve MultiCare Health Systems proposal for a Manufacturing License for Oral Solid Centralized Packaging with the understanding that the policy and procedures are reviewed by Tim Fuller. If there are concerns, this is no longer approved. Sepi Soleimanpour second. Chris Barry recused himself. **MOTION CARRIED: 5-0.**

MOTION: Donna Feild moved to deny MultiCare Health Systems proposal for a Manufacturing License for Non-Sterile Compounded of Oral Liquid and Topicals. The board would like to have changes in the language differentiating between compounding and manufacturing and for the board to review the policy and procedures. Sepi Soleimanpour. Chris Barry recused himself. **MOTION CARRIED: 5-0.**

MOTION Donna Feild moved to deny MultiCare Health Systems proposal for Manufacturing License for Compounded Sterile Products. The board would like some additions to the policy and procedures.

- 1) How 797 standards rules will be followed
- 2) Pharmacist competency was described as overseeing the compounding by pharmacy technicians. Multicare needs a training program for their pharmacists.

The board would like to review the policy and procedures. Sepi Soleimanpour second. Chris Barry recused himself. **MOTION CARRIED: 5-0.**

MOTION: Donna Field moved to approve MultiCare Health Systems proposal for Tacoma General and Good Samaritan Hospital Pharmacies to provide central Pyxis fill for the other MHS campuses with the understanding the policy and procedures are reviewed by Tim Fuller. If there are concerns this is no longer approved and must return to the board. Sepi Soleimanpour second. Chris Barry recused himself. **MOTION CARRIED: 5-0.**

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. This item was pulled because Elizabeth Jensen had to recuse herself. The board needed to wait until there was a quorum to vote on this item.

- 7) Electronic Prescription Transmission System Approval
b.Rx3000 – Pharmacy Computer Services Inc

MOTION: Donna Feild moved that the board approve items 7 (b) that was pulled from the consent agenda. Emma Zavala-Suarez second. Elizabeth Jensen recused herself. **MOTION CARRIED: 5-0.**

Columbia Basin Health Association (CBHA) Othello Family Clinic Pharmacy – Role Based Pharmacy Technician Ratio Proposal

Cathy Williams introduced Doug Thompson, Director of Clinical Services for CBHA who presented the proposal to utilize pharmacy technicians and technicians-in-training based on assigned work role to maintain the standard ratio of three technicians to one pharmacist (3:1) when there are fluctuations in pharmacist staffing levels.

Columbia Basin Health Association

- Serving the medical needs of Othello and the surrounding area for 40 years.
- 27,000 patients, 150,000 visits in 2012.
 - ✓ 90% of patients below 200% of poverty
 - ✓ +50% Spanish translation
- JCHO certified Community Health Center.
- Safetynet provider: medical and dental services without regard to ability to pay.
- Provides low cost 340B medication.

Health Home

- Provide a single source for all of a patient's primary care needs.

- All services are provided in English and Spanish.
- Single Electronic Dental Record (EDR) linked to Electronic Medical Record (EMR).
- Single medical chart shared by all providers.
- Single patient history for all CBHA pharmacies.

CBHA Locations

Othello

- 14th Avenue Medical Center (Medical, Social Services)
- Othello Family Clinic (Medical, Dental, Optometry, Social Services)

Mattawa

- Wahluke Family Health Center (Medical, Dental, Optometry, Social Services)

Connell

- Connell Family Clinic (Medical, Dental, Optometry, Social Services)
 - ✓ Telepharmacy (Othello Family Clinic Pharmacy) (2012)

Othello Family Clinic Pharmacy (OFCP)

- Staffing
 - ✓ Pharmacy Director (RPhD): 1
 - ✓ Pharmacists: 3
 - ✓ Pharmacy technicians: 5.5 (+1 at telepharmacy)
 - ✓ Pharmacy assistants: 6.5
- Volume: 696 Rx/day YTD 2013
- Scriptpro SP200 robotic filling (45% of prescriptions)
- Barcode controlled workflow (Etreby)

Technology

- SureScripts ePrescriptions
- Pharmacy Management System (Etreby by Cerner)
 - ✓ Patient profile, billing, inventory, etc.
 - ✓ Workflow controlled by barcodes and login IDs
 - ✓ Point of Sale system
- Robotics (ScriptPro SP200 fill 45% of Rxs)
- Pill counter (Eyecon optical counter)
- Electronic Medical Record
 - ✓ Accessible to pharmacists and technicians

Why OFCP?

- Covers pharmacist absence at WFCP.
- Covers technician absence at WFCP and Connell telepharmacy.
- Safetynet: literacy, language, transportation
- High volume (690 Rx/day)
- Established color coded uniform policy.
- Established Role based software security.
- No 'front end' retail cashiers.
- Extreme difficulty recruiting bilingual technicians.

Services Provided

- OFCP functions

- ✓ Collaborative practice agreements
- ✓ Medication dispensing
- ✓ Patient consultation
- ✓ Provider consultation
- ✓ MTM reviews
- ✓ Limited compounding (<0.1% of Rx)

How it will work

- When fully staffed
 - ✓ All technicians will wear black uniforms and have ‘RxTechnician’ security level.
- When short pharmacists
 - ✓ Select techs will change to red uniforms and have security level changed to ‘RxAssistant’.
 - ✓ Red ‘techs’ will be assigned to assistant roles; insurance calls, refill calls, cashier, etc.

Governance

- Visibility
 - ✓ Red vested staff currently not allowed to perform certain duties, this would not change.
 - ✓ Pharmacists and managers responsible for enforcement.
- Technology
 - ✓ Security is set in Etreby by role, not by individual.
 - ✓ Staff member’s role can be changed quickly.
 - ✓ Reporting available to investigate suspected violations.

Benefits

- Open Every Day
 - ✓ With more techs on staff OFCP can cover sick days at all 3 locations.
- Recruiting/Retention
 - ✓ Ability to offer advancement to top performers.
- Patient Safety
 - ✓ Technicians performing all filling operations.
- Patient Service
 - ✓ Never having to send home support staff.

Summary

- Limited to OFCP.
- No increase of the 3:1 ration.
- Technician count by role rather than licensure.
- Roles identified by colored uniforms.
- Roles restricted by software security levels.
- Managers and staff pharmacists to insure compliance.

This is a topic that the board and investigators have a lot of concerns about. There was plenty of discussion and questions. Main concerns were pharmacist workload, technicians doing technician work when they are working as an assistant. How is that prevented and are there sufficient documentation showing who is working as what role and when? Once a prescription is processed, who fills it? Having pharmacist checking so many prescriptions per day is an unsafe practice. The pharmacist workload

seems to be an issue. Some of the board members feel this seems to be an issue of needing another pharmacist.

MOTION: Donna Feild moved that the board table this proposal until July and allow Tyler Varnum visit the site to observe this practice. The board would like Tyler to provide feedback. They would like him to look at the log audit feature and how it is track able, receive some input from the staff pharmacists on the workload issue. Also this would give CBHA an opportunity to look into resources to find a pharmacist that could fix this issue all together. Elizabeth Jensen second. **MOTION CARRIED: 6-0.**

Providence Centralia - Remote Medication Order Processing

Cathy Williams led this presentation by introducing Karen Bright, Pharmacy Director for Olympic Medical Memorial Hospital and Linda Higginson, Pharmacy Director for Centralia. They presented the proposal for Providence Centralia to provide remote medication order processing services to Olympic Memorial Hospital.

Providence Centralia Hospital (PCH)

- Rural not for profit Catholic Health Care
- Licensed 128 bed
- Centralia, Washington
- Pharmacy Hours 24/7/365
- EPIC – Electronic Health Record

Olympic Medical Hospital (OMH)

- Rural Public Hospital-Sole community
- Licensed 80 beds
- Port Angeles, Washington
- Pharmacy Hours 0530-2400 daily
- May 2013 EPIC - EHR

PCH – OMH Relationship

- OMH is affiliated with Swedish HealthServices
- Sublicense of the Providence EPIC Electronic
- Health Record is a component of our Providence – Swedish affiliation
- OMH and PCH utilized the same ElectronicHealth Record build

Contract Agreement Summary

- PCH to provide Remote Order Processing to OMH 23:30 to 05:30
- Agreement renewed annually, may terminate by either party without cause 60 days notice
- Common EPIC build will provide seamless order verification process
- PCH available phone consultation to OMH staff for clinical questions
- OMH to provide onsite orientation

Policy and Procedure – Overview

- Computerized Physician Order Entry
- OMH staff clarify unclear orders
- PCH pharmacists trained OMC CPA's
- OMH standardize formulary, IV concentrations with PCH to reduce variation

- PCH Pharmacist
 - 1) Verify Orders
 - 2) Perform Drug Regimen reviews – Manages Alerts
 - 3) Interprets clinical data
 - 4) Performs Therapeutic Interventions
 - 5) Provides drug information
- OMH On-Call Pharmacist available for urgent referrals
 - 1) Drug unavailable outside of normal channels
 - 2) Drug storage – drug requiring special mixing procedures
 - 3) Unique clinical situations
 - 4) Procedures related to another service line
- OMH Designated Nurse Supervisor
 - 1) Coordinate and direct medication access
 - 2) Access to After Hours automated dispensing cabinet
 - 3) Coordinate communication with PCH pharmacist
 - 4) Coordinate communication with OMH on-call pharmacist
- Automated Dispensing Cabinets
 - 1) Profiled
 - 2) Override list approved by OMH medical, nursing and pharmacy staff
 - 3) Overrides available only in urgent/emergent situations where delay may cause patient harm

Quality Assurance

- Conducted routinely by OMH and PCH management
 1. Adverse Drug Events tracked & investigated by OMH Director and reported to PCH Director for follow up
 2. Compliance with CPA's and Policy/Procedures reviewed monthly by OMH Director
 3. Monthly parameters monitored to include, variances in timeliness of order and any variations outside of policy
 4. Volumes and timeliness of order verification
 5. Availability of PCH Pharmacists for routine clinical questions
 6. Performance feedback from OHM staff
 7. Daily retrospective review by OMH all medications removed on override

MOTION: Donna Feild moved that the board approve the proposal for Providence Centralia to provide remote medication order processing services to Olympic Memorial Hospital as presented and to report back after six months after started. With this report the board would like them to include quality data and the opinions from the hospital staff being served. Second. **MOTION CARRIED: 6-0.**

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

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

DISCUSSIONS

2013 Legislative Session

SHB 1155 modifies RCW 69.41 and RCW 69.50 to allow electronic transfer of schedule II controlled substances and standardizes language. Substitute bill standardizes language in RCW 69.41 and RCW 69.50. Companion bill SB 5416

Crossed over to senate, executive action taken on 03/21/13 by Health Care committee, passed to rules committee for 2nd reading.

SHB 1182 adds pharmacists to RCW 69.41.030 as a practitioner with CDTA; we are already in RCW 69.50. Crossed over to senate, executive action taken on 03/21/13 by Health Care committee, passed to rules committee for 2nd reading.

SHB 1382 allows drug manufacturers, drug wholesalers, hospitals, pharmacies, nursing homes, boarding homes, adult family homes and medical clinics, to donate (return) drugs in an original sealed and tamper evident package, or open package, if it contains a single unit doses that remain intact (excluding controlled substances and with at least 6 month remaining on the expiration date). These donations may be made to a pharmacy for redistribution without compensation or the expectation of compensation. The pharmacy may redistribute the drugs to another pharmacy, pharmacist, prescribing practitioner for use to treat uninsured and low income individuals. Companion bill to SSB 5148.

Crossed over to senate, in Health Care committee, scheduled for public hearing on 03/14/13.

HB 1609 renames the Board of Pharmacy to Pharmacy Quality Assurance Commission, increasing membership from 7 to 15 members (10 pharmacists, 4 public, 1 technician).

Crossed over to senate, executive action taken on 03/21/13 by Health Care committee, passed to rules committee for 2nd reading.

HB 1800 allows the compounding of medications for physician offices, ambulatory surgical centers, or ambulatory surgical facilities to be used by a physician for ophthalmic purposes for non-specific patients. Crossed over to senate, first reading, referred to Health Care committee, scheduled for public hearing on 03/27/13 at 5:30 PM.

HB 1808 addresses the situation where a legal amount of marijuana is found at a retail store that holds a pharmacy license. The store manager or employee must promptly notify the local law enforcement agency, after notification to law enforcement the store manager or employee must properly dispose of the marijuana.

Crossed over to senate, first reading, referred to Health Care committee, scheduled for public hearing on 03/27/13 at 5:30 PM.

ESB 5104 places epinephrine auto-injectors in schools, companion bill to HB 1578.

Crossed over to house, executive action taken on 03/26/13 by House Committee on Education should pass to rules committee on 03/27/13.

SSB 5148 allows drug manufacturers, drug wholesalers, hospitals, pharmacies, nursing homes, boarding homes, adult family homes and medical clinics, to donate (return) drugs in an original sealed and tamper evident package, or open package, if it contains a single unit doses that remain intact (excluding controlled substances and with at least 6 month remaining on the expiration date). These donations may be made to a pharmacy for redistribution without compensation or the expectation of

compensation. The pharmacy may redistribute the drugs to another pharmacy, pharmacist, prescribing practitioner for use to treat uninsured and low income individuals. Companion bill to HB 1382. Crossed over to house, in Health Care and Wellness committee scheduled for executive session on 03/28-29/13.

SB 5149 Concerning crimes against pharmacies, creates a one year sentencing enhancement for a person convicted of a robbery offense committed against a pharmacy.

Crossed over to house, in House Committee on Public Safety, scheduled for public hearing on 03/20/13.

SSB 5213 requires managed care plans contracting with Medicaid to require that any patient with five or more prescriptions be placed in an automatic review process with a primary care provider to ensure appropriateness and screen for drug interactions at least annually.

Crossed over to house, in Health Care and Wellness committee scheduled for executive session on 03/28-29/13.

SSB 5416 modifies RCW 69.41 and RCW 69.50 to allow electronic transfer of schedule II controlled substances and standardizes language. Substitute bill standardizes language in RCW 69.41 and RCW 69.50. Companion bill HB 1155

Crossed over to house, executive action taken by Health Care and Wellness committee on 03/26/13 should pass to rules committee on 03/27/13.

SSB 5459 under certain circumstances, a pharmacist is allowed to dispense up to a 90 day supply if the valid prescription specified an initial quantity of less than a 90-day supply followed by refills. The pharmacist must notify the prescriber if dispensing an increase in dose units. See HB 1583.

Crossed over to house, executive action taken by Health Care and Wellness committee on 03/26/13 should pass to rules committee on 03/27/13.

SB 5524 authorizes Washington pharmacies to fill prescriptions written by physician assistants in other states. Companion bill to HB 1596.

Crossed over to house, executive action taken by Health Care and Wellness committee on 03/26/13 should pass to rules committee on 03/27/13.

Rules and Planning Session

Christopher Humberson, Executive Director and Doreen Beebe led the update on the rules and the planning session.

April 10, 2013 the Board of Pharmacy had a planning session. The majority of the time was spent talking about what was done at the January board meeting. At that meeting the board had decided to open rules on four particular areas. Which were *Compounding, Pharmacy Technology, Pharmacy Business Practices, and Pharmacist Interns and Preceptor's*. Being in Legislation Session and looking to hire someone in Kitty Slatter's rules position. Doreen has been working on the CR101 on Compounding. The CR101 draft has been entered into the DOH Rules Management System. We are hoping to start holding stake holder meetings at the end May if the CR101 gets filed.

2013 NABP Meeting

The board was asked to review and provide input on meeting resolutions for consideration at the 109th NABP Annual Meeting in St. Louis MO on May 18- 21.

District 1

RESOLUTION – Pharmacy Compounding Sterile Products

Whereas the demand for compounded medication has increased and the need for pharmacies to provide the best quality to their patients by producing a high quality compound is required; and

Whereas, supply shortages of critical, lifesaving prescription medication may increase the demand for compounded medications; and

Whereas, pharmacies engaging in sterile compounding must meet or exceed United States Pharmacopeia high quality standards; and

Whereas, pharmacies engaging in high risk sterile compounding imposes a greater risk to patient's safety; and

Whereas, patient safety is the primary mission of the state boards of pharmacy and the National Association of Boards of Pharmacy (NABP);

Therefore, be it resolved that NABP encourage Boards of Pharmacy who license compounding pharmacies that engage in sterile compounding to require accreditation through a nationally recognized accreditation body, such as Pharmacy Compounding Accreditation Board (PCAB) or similar accreditation body approved by the board.

Be it further resolved that NABP review and, if necessary, propose amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* to address appropriate regulation requiring accreditation of pharmacies engaging in sterile compounding.

District 2

RESOLUTION #1

Whereas despite great strides in securing our drug distribution system from adulterated, misbranded and counterfeit drugs, problems remain, and

Whereas contemporary systems allow for receiving medications in a timely and efficient fashion, and

Whereas federal and state provisions allow for intra-company transfers of medications, and

Whereas properly constructed laws and regulations can allow boards of pharmacy to provide waivers to cover emergency disruptions in our drug delivery systems,

Therefore, be it resolved that the National Associations of Boards of Pharmacy (NABP) urge its member boards of pharmacy to prohibit pharmacies from utilizing the 5% wholesaler transfer allowance to introduce drugs for resale, with the exception of emergency situations declared by the board and except the legitimate return of drugs to the manufacturer or wholesaler from whom the drugs had been purchased.

MOTION: Dan Rubin moved that the board support District 2 resolution #1. Donna Feild second.
MOTION CARRIED: 6-0.

RESOLUTION #2 – Pharmacy Compounding Sterile Products

District 2 was approached by District 1 to support and co-sponsor their resolution titled: “Pharmacy Compounding Sterile Products”.

The seven states of District 2 present at the business session fully endorsed the concept of the D1 resolution, but with the one minor grammatical correction (line 4: impose vs. imposes) and the striking of the wording “...such as the Pharmacy Compounding Accreditation Board (PCAB) or similar accreditation body.....”

It was suggested that as D1 had already approved the resolution as written, that the proper course of action would be for D2 to submit the same resolution with the above listed change/correction, as the two documents would be harmonized via the NABP Resolutions Committee process.

It was therefore agreed (vote of 6-1) to submit the amended wording of the D1 resolution noted above as a separate D2 resolution.

MOTION: Dan Rubin moved that the board support District 2 resolution as improvement of District 1 resolution and support District 2 compounding sterile products resolution and District 7 task force on compounding reconstitution of drug infusion in medical clinics resolutions. We support all as stated. Donna Feild second. **MOTION CARRIED: 6-0.**

District 3

RESOLUTION - Concerning PBM Model for States

Whereas, the member boards of NABP adopted resolution #108-6-12 at the 108th annual meeting of the association acknowledging the need for state regulations of PBMs and utilization of the NABP model state pharmacy act and model rules as a starting point for states to develop and implement regulations for the PBMs; and

Whereas, State Boards of Pharmacy are charged with the responsibility of protecting the patients or applicable citizenry as it relates to patient safety, patient health and patient services through Pharmacy; and

Whereas, the practices, decisions or rules of PBMs directly affect patient safety, patient health and patient services; and

Whereas, the regulations of PBMs extend beyond individual state borders, and requires cooperation and communication among the state boards of pharmacy; and

Whereas, there is a need to determine the status of PBM regulations in the states in order to revise the NABP model act, model to provide a cohesive strategy for revising and reviewing these model regulations.

Therefore to be resolved that NABP convene a task force to review the status of PBM regulations in all of the states, further cooperation and collaboration among the states regarding the regulations of PBMs

and reviewing and revising the PBM model act to provide a cohesive and current guideline for states to utilize in developing regulations.

MOTION: Dan Rubin moved that the board support District 3 resolution with the suggestion that they involve state insurance regulatory entities as well as a pharmacy regulatory entity. Donna Feild second.
MOTION CARRIED: 6-0.

District 4 -Co-supports two district resolutions proposed

1. Co-supports District 2 *Pharmacy Compounding Sterile Products*
2. Co-supports District 8 *Proposal for the alternate delivery of mandatory Patient Package Information (PPI) in the interest of environmental concerns and protection of patient privacy.*

District 5 -No Substantive Resolutions Proposed

District 6 – No Resolutions Proposed

District 7

RESOLUTION #1 - Definition of Pharmacy Compounding

Whereas pharmacy compounding has been a traditional part of pharmacy practice and continues to be practiced by many pharmacists; and,

Whereas pharmacy compounding is regulated by the state boards of pharmacy; and,

Whereas pharmaceutical manufacturing is primarily regulated by the United States Food and Drug Administration (FDA); and,

Whereas a lack of clarity in the definitions of and the distinctions between pharmacy compounding and pharmaceutical manufacturing has allowed manufacturing to occur under the guise of pharmacy compounding with tragic consequences,

Therefore be it resolved that NABP work with the FDA, the state boards of Pharmacy and other interested parties to establish mutually agreeable definitions for pharmacy compounding and pharmaceutical manufacturing; and,

Be it further resolved that NABP update its Model Act and Rules to reflect the new definitions.

RESOLUTION # 2 - Compounding and Reconstitution of Drugs for Infusion

Whereas recent tragic events involving products compounded and reconstituted for infusion which were contaminated, adulterated or misbranded have demonstrated the significant risks that exist when drugs are compounded and reconstituted for infusion; and,

Whereas a variety of medical practices, including but not limited to, oncology, rheumatology and gastroenterology employ nurses and pharmacy technicians, registered or unregistered, to compound

and reconstitute sterile products for infusion in their clinics, which often involve complicated calculation; and,

Whereas the final product of compounding and reconstitution of sterile products within a prescriber's office may not be checked by the prescriber prior to administering or dispensing; and,

Whereas United States Pharmacopeia (USP) guidelines for the preparation of sterile products for Infusion may not be followed in these medical clinics, potentially leading to unsafe conditions and unnecessary risk to patients,

Therefore be it resolved that NABP establish a multidisciplinary taskforce or other appropriate vehicle including the Federation of State Medical Boards and the National Council of State Boards of Nursing to address the compounding and reconstitution of sterile products for infusion in medical clinics or other establishments without pharmacist oversight; and,

Be it further resolved that NABP work through the taskforce or other appropriate vehicle to establish consensus that the compounding and reconstitution of sterile products for infusion in medical clinics is considered to be pharmacy compounding which must be performed only by or in consultation with a licensed pharmacist and must comply with the USP Chapter 797 guidelines for the preparation of sterile products.

RESOLUTION # 3 - Performance Metrics and Quotas in the practice of Pharmacy

Whereas when the Institute for Safe Medicine Practice (ISMP) surveyed 673 pharmacists, 83% believed that distractions due to performance metrics or measured wait times contributed to dispensing errors and 49% felt specific time measurements was a significant contributing factor; and,

Whereas Performance metrics, defined as the measurement of speed and efficiency of prescription work flow by measuring parameters, including but not limited to, prescription wait times, percentage of prescriptions filled within a specific time period, number of prescriptions verified per pharmacist and the number of immunizations given per pharmacist shift, may distract pharmacists and impede professional judgment; and,

Whereas the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that decrease the pharmacist's ability to perform Drug Utilization Review, decrease interaction with patients, decrease attention to detail and lead to unsafe conditions in the pharmacy; and,

Whereas the ISMP is advocating for change or elimination in the use of performance metrics and quotas in pharmacies,

Therefore be it resolved that NABP assist the state boards of pharmacy to regulate, restrict or prohibit the use of performance metrics or quotas in pharmacies and,

Be it further resolved that NABP review and propose amendments to the Model Act and Rules to address the regulation or prohibition of the application of performance metrics and quotas to

pharmacists in the practice of pharmacy in order to protect the health and safety of pharmacy customers and pharmacy employees.

MOTION: Donna Feild moved that the board support District 7 resolution #3. Dan Rubin second. Sepi Soleimanpour recused herself. **MOTION CARRIED: 5-0.**

District 8

Resolution - Proposal for the alternate delivery of mandatory Patient Package Information (PPI) in the interest of environmental concerns and protection of patient privacy

Whereas there are many tons of unread and discarded PPI deposited in virtually every pharmacy trash receptacle and,

Whereas the electronic world offers acceptable alternative ways for the patient to access PPI and,

Whereas patients often request and may prefer receiving PPI via electronic means:

Therefore be it resolved that NABP explore discussing with the FDA and state Boards of Pharmacy regarding the feasibility of allowing patients the choice of accessing mandatory PPI through electronic means.

MOTION: Donna Feild moved that the board support District 8 resolution Dan Rubin second. **MOTION CARRIED: 6-0.**

CriticalPoint's Sterile Compounding Boot Camp

Chris Humberson, Executive Director asked the board to consider approving funds for a pharmacist investigator to participate in a program on current sterile compounding best practices. The intention would be to send one or two investigators. These investigators will then train the others and then use videos and other means of education (train the trainer). The one or two who attended the boot camp will be the main resource for others. Also after returning they will be asked to present to the board.

MOTION: Donna Feild moved that the board approve funds for a pharmacist investigator to participate in a program on current sterile compounding best practices. Elizabeth Jensen second. **MOTION CARRIED: 6-0.**

New Board of Pharmacy Vice-Chair

MOTION: Donna Feild moved that Elizabeth Jensen take the position of Vice Chair for the Board of Pharmacy. Sepi Soleimanpour second. . **MOTION CARRIED: 6-0.**

Continuing Education (CE) Approval

Cathy Williams asked the board to consider approving CE recognized by another state board of pharmacy in lieu of an independent review and approval. WAC 246-861-040(5) states, "The board of

pharmacy may accept comparable continuing education units which have been approved by other boards of pharmacy.”

MOTION: Donna Feild moved that the board approve CE recognized by another state board of pharmacy in lieu of an independent review and approval. **MOTION CARRIED: 6-0.**

Accreditation of Schools/Colleges of Pharmacy

The board was asked to consider reaffirming its recognition of the American Council on Pharmacy Education (ACPE) accredited professional programs of colleges and schools of pharmacy as the official list of approved pharmacy programs.

MOTION: Donna Feild moved that the board recognize the American Council on Pharmacy Education (ACPE) accredited professional programs of colleges and schools of pharmacy as the official list of approved pharmacy programs. **MOTION CARRIED: 6-0.**

Correspondence

The board may discuss any correspondence received or distributed.

- Citizens' Petition to BOP 3-27-13 - Attachment 1
- Citizens' Petition to BOP 3-27-13 - Attachment 2
- Citizens' Petition to BOP 3-27-13 - Attachment 3
- Citizens' Petition to BOP 3-27-13 - Attachment 4
- Citizens' Petition to BOP 3-27-13 - without Attachments
- Reponse to Fluoride Petition

University of Washington – Pharmacy Students’ Law Presentation

Dr. Thomas Hazlet, University of Washington Pharmacy Students introduced the PharmD students. Each group of student presented their pharmacy law projects to the board on these topics.

Increasing Accessibility of Hormonal Birth Control

Mikalla Cheney, Thomas A. Gorlin, Elise B. Knutzen

Safe Pharmacy Work Environment: Amendment to Ensure Safe Pharmacy Practice

Bridgette Lorenzen, Christine Chan, Ivan Huang, Sumin Lee, Michelle Lin, Kris Martinson, Brian Muller, Sheeva Panahinia, Hana Sperling, Mary Slate Williams
Presented by: Bridgette Lorenzen

OPEN FORUM

Jenny Arnold from the Washington State Pharmacy Association shared that WSPA will be hosting a webinar May 16, 2013 from 9:30 a.m.-10:30 a.m. There will be an email sent out as a reminder.

There being no further business, the board adjourned at 4:37 pm

PRESENTATION OF AGREED ORDERS

CLOSED SESSION

Next scheduled business meetings: May 30, 2013 – 9:00 a.m.

Department of Health
Point Plaza East Conference Room 152/153
310 Israel Rd SE
Tumwater WA 98501

Respectfully Submitted by:

*Leann George, Program Support
Approved on May 30, 2013*

*Christopher Barry, Chair
Washington State Board of Pharmacy*