



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
*Olympia, Washington 98504*  
**PHARMACY QUALITY ASSURANCE COMMISSION**

*April 30, 2015*  
*Amended Meeting Minutes*  
Best Western Plus  
Lakeway Inn & Conference Center  
Mt. Baker Room  
714 Lakeway Drive  
Bellingham, WA 98229

**CONVENE**

Chair Al Linggi called the meeting to order March 12, 2015.

*Commission Members:*

Al Linggi, RPh, MBA  
Christopher Barry, RPh, Chair  
Gary Harris, RPh,  
Steve Anderson, RPh  
Dan Rubin MPP, Public Member, Vice Chair  
Elizabeth Jensen, PharmD  
Tim Lynch, PharmD  
Sepi Soleimanpour, RPh, MBA-HA  
Maureen Sparks, CPhT

*Absent Commission Member*

Nancy Hecox, PharmD

*Staff Members:*

Lilia Lopez, AAG  
Christopher Humberson R.Ph, Executive Director  
Brad Dykstra, Pharmacy Investigator  
Lisa Roberts, R.Ph. Pharmacy Consultant  
Cathy Williams, R.Ph, Pharmacist Consultant  
Doreen Beebe, Program Manager  
Irina Tiginyanu, Pharmacy Technician Analyst  
Leann George, Secretary Senior  
Gordon MacDonald, R.Ph, Chief Investigator

*Absent Staff*

Joyce Roper, AAG

*Guest / Presenters:*

Dr. Andy Kim, Senior Medical Science  
Liaison at Shire US Inc.  
Mark Lenker, Director, US Government  
Relations & Public Policy at Shire US  
Jeffrey Gombosky, Public Affairs  
Consultant for Shire US Inc.  
Glen Adam, Pharmacy Director  
for Confluence Health  
DR. Peter Rutherford, CEO of Confluence  
Dr. Julie Smith, Oncology Infusion  
Manager for Confluence Health  
Mary Gunkel, Director of Oncology  
for Confluence Health  
Craig Pedersen, Pharmacy Manager  
Carol Sue Janes, Attorney for Confluence

*Guest / Presenters(continued)*

Lannay Turay, Pharmacy Director for  
Jefferson Hospital  
Cliff Richards, PharmD Othello  
Community Hospital

## **CALL TO ORDER**

- 1.1 Approval of Business Meeting Agenda.
- 1.2 Approval of March 12, 2015 Meeting Minutes.

**MOTION:** Chris Barry moved that the commission approve 1.1. Gary Harris second.  
**MOTION CARRIED: 9-0.**

**MOTION:** Chris Barry moved that the commission approve 1.2 with suggested amendment. Steve Anderson second. **MOTION CARRIED: 9-0.**

**CONSENT AGENDA** - Items listed under the consent agenda are considered routine commission matters and will be approved by a single motion of the Commission without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.

- 2.1 NPLEx Monthly Report Acceptance
  - March 2015
- 2.2 Pharmacies and Other Firm Application Approval
  - New and Closed Pharmaceutical Firms Report
- 2.3 Pharmacy Tech Training Program Approval
  - a. Bob Johnson Pharmacy
  - b. International Academy of Merchandising and Design – dba Sanford-Brown College
  - c. Rite Aid – renewal
  - d. Walgreens – renewal
  - e. Wasems, Inc.
  - f. Island Drug
- 2.4 Pharmacy Technician – Specialized Functions Approval
- 2.5 Automated Drug Distribution Device Approval
  - a. Cascade Medical
  - b. FairFax Behavioral Health
  - c. Jefferson Healthcare – Surgical Associates Health Care Entity
  - d. Propac Pharmacy – Fort Vancouver Convalescent Center
  - e. Kelley Ross Pharmacy – skilled nursing facilities
- 2.6 Electronic Prescription Transmission System Approval
  - PharmacyRx e-prescribing system
- 2.7 Sample Drug Distribution Approval
- 2.8 Tamper Resistant Prescription Paper/Pads Approval
- 2.9 Pharmaceutical Take-back Program
  - San Juan County – Friday Harbor Drug, Lopez Pharmacy, and Ray’s Pharmacy

Items 2.4, 2.7, and 2.8 were deleted from the consent agenda.

Sepi Soleimanpour recused herself from Item 2.3 (d).

**MOTION:** Elizabeth Jensen moved that the commission pull items 2.3 (b, c, d & f) for further discussion. Dan Rubin second. **MOTION CARRIED: 9-0.**

**MOTION:** Chris Barry moved that the commission approve items 2.1, 2.2, 2.3 (a & e), 2.5, 2.6 & 2.9 on the consent agenda. Steve Anderson second. **MOTION CARRIED: 9-0.**

## **REPORTS**

Commission Members

*Tim Lynch reported:*

- Met with Al to talk about some issues related to interpretations of WAC's concerning non hospitalized patients it was a great discussion. Tim wanted to bring this forward to the commission for further discussion and consideration. How the current WAC's are being interpreted and applied to some patients underneath the hospital licensure but being viewed as non-hospitalized patients. This has the potential to impact the quality and safety of care provided to our patients. The goal would be to get the commission to understand the ramifications of these interpretations.
- He will be one of the facilitators at the Leadership session for ASHP in October.
- Tim participated in the creation of WSPA Hospital Pharmacy Leadership Meeting next month.
- He attended the ASPHP Pharmacy Business Manager Advisory Group.

*Steve Anderson reported:*

- He attended a Business Practice Committee Webinar March 30 and April 15.
- On April 2 Steve attended the UW Strategic Planning Committee Meeting
- Steve flew to Alabama for a license interview. Steve delivered a message from the Alabama Board of Pharmacy to our commission saying, "Hello."
- Steve took and passed the Michigan MPJE and is now licensed in Alabama.

*Sepi Soleimanpour reported:*

- Sepi participated in the Business Practice Committee Webinars.

*Elizabeth Jensen reported:*

- She also participated in the Business Practice Committee Webinars.

*Dan Rubin reported:*

- He has been spending a significant amount of time on the Business Practice Committee.
- Dan shared he has spent a considerable amount of time with a friend who is dying. He expressed his appreciation for the team work in Palliative Care that occurs in many hospitals. His friend was so grateful to have honest discussion about how his life was going to end.

*Al Linggi reported:*

- He attended the UW P-3 Policy & Strategy Meeting for the UW School of Pharmacy.
- He also attended the UW School of Pharmacy Facility and Curricula Meeting.
- He receives a considerable amount of dialogue and phone calls regarding some of the issues the commission is working on, specifically with the business of process. For the most part the concern is based upon prioritization, regulation of some of the particular issues.

- For the July Planning Session Al suggested the commission work on a complete prioritization with input on all the rules and regulations. Prioritization of the work that needs to be done with milestones and timing. The commission needs to take a look at our existing staff and help make recommendations to the Executive Director on prioritization and utilization of current staff so we can meet timelines we outline for prioritized issues that we need to work on.

*Gary Harris reported:*

- He attended the UW Strategic Planning Committee Meeting.
- Gary also participated in the Business Practice Committee Webinar.
- He participated in the UW School of Pharmacy Alumni Association board meeting to pick the two pharmacist of the year the awards that will be given out at the Katterman's Lecture. For the first time this year they will be giving a lifetime achievement award.
- Gary is Co-Chair for the UW School of Pharmacy campaign takes place through the summer until next year.

Executive Director

*Chris Humberson reported:*

- Attended a 50 state FDA meeting in Maryland for Washington State to discuss sterile compounding issues and related inspection formats for states to utilize.
- Attended National Drug Abuse Summit meeting in Atlanta representing Washington State and DOH.
- Participated in business practice committee meetings
- Participated in quarterly UPWG
- Met twice with WSHA representatives on SB 5460 and other related issues
- Met with Long Term Care stakeholders in Kent
- Met with Senators Becker and Parlette and DOH staff re: pharmacy commission activity.
- Lisa Roberts and I met with Senator Parlette, Reps Harris, Cody, Schmick and their staffs to provide technical assistance regarding issues concerning bio-similar legislation.
- Over the course of the legislative session, Lisa Roberts, Doreen Beebe, and I work on 35-bill analysis for the department. You should be proud of the quality of their work.
- Working with Cathy, Irina and LeAnn, we were able to implement and completely resolve the CDTA backlog that existed at the office as of six weeks ago. Leann?
- We posted the rules coordinator position and have not found a suitable candidate to date to succeed Peggy Crain.

USP 797/ Sterile Compounding Training Review

Gordon MacDonald, Chief Pharmacist Investigator and Brad Dykstra and Julie Faun Pharmacist Investigators shared a presentation to the commission regarding the Compounding Boot Camp.

Background

Regulatory Change

- January 1, 2004 USP 797 first published
- 2004 NIOSH Alert published
- 2008 USP 797 revised
- 2013 the Drug Quality and Security Act becomes law

- June 2013, USP 797 adopted as minimum standard in Washington
- Current Law RCW 18.64.270(2)
- “Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products.”
  - RCW 18.64.270 (2)
  - Failure to meet minimum standards for sterile compounding may result in criminal liability RCW 18.64.270 (3)

#### Historical Negative Events

- 1998 California - 11 children become ill with bloodstream infections associated with contaminated prefilled saline syringes.
- 2001 Missouri - 4 children contract *Enterobacter cloacae* infection from IV ranitidine compounded in hospital pharmacy.
- 2002 North Carolina - 5 patients develop *Exophiala* infection from contaminated methylprednisolone, 1 died
- 2004 Several states - 36 patients develop *Pseudomonas* from contaminated heparin syringes.
- 2007 Washington, Oregon - 3 patients die after receiving IV colchicine compounded at high concentration.
- 2011 California, Florida, Tennessee - 16 patients develop severe eye infection after contaminated Avastin.
- 2011 Alabama - 19 patients develop *Serratia marcescens* infections after receiving contaminated TPNs. 9 died.

#### Landmark Event

- 2012 - New England Compounding Center (NECC) Pharmacy
  - ✓ 751 people had documented infections
  - ✓ 64 deaths
  - ✓ NECC was licensed in Washington
  - ✓ USP 797 was adopted by Mass prior to NECC fall out
    - NECC was doing surface sampling, air sampling, glove tip sampling, media fill test, maintained cleaning logs (They just ignored results)

#### Subsequent Negative Events

- 2013 New Jersey Compounding pharmacy closed and all drugs recalled after mold found in bags of mag sulfate.
- March 25, 2015 North Carolina All sterile and non-sterile drugs from compounding pharmacy recalled nationwide.

#### FDA Action

- Section 503A Traditional compounding pursuant to a prescription
- Section 503B Outsourcing facilities (not pursuant to patient specific prescriptions) must follow stricter standards (cGMPs). 51 registrants to date.
  - Form 483: An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgement may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. Higher level of scrutiny

#### Compounding Boot Camp Review

USP 797 has been a minimum standard since 2004

Learning a “State of Control”

- The hands-on training is critical to understanding the entire concept of USP 797 and sterility.
- You can't pick and choose parts of compliance because they're all inter related..

#### Specific Focus Lessons of Class

- Review of USP 797
  - ✓ Low risk, medium risk, high risk
- Primary engineering controls
  - ✓ Secondary engineering controls

#### Training Take Aways

- Engineering control and certificate analysis
  - ✓ Jim Wagner (president Controlled Environment Consulting, on USP expert committee) reviewed a certification that is common to Washington pharmacies and found it deficient
- Interactive exercises
  - ✓ Performed glove tip sampling
  - ✓ Smoke studies
  - ✓ Particle Counts
- Developing a cleaning program
- Environmental sampling
  - ✓ Allows for early detection
  - ✓ Monitors State of Control
- Beyond use dates
  - ✓ Recognizes the possibility of contamination
- Developing policies and procedures
  - ✓ Critical part of USP 797 compliance
  - ✓ Must involve all employees in the system
  - ✓ Without them, employees cannot be expected to understand what to do
  - ✓ Establish acceptable ranges

After the presentation the commission was able to ask Brad Dykstra and Julie Faun about their opinions and what they felt about the program.

A couple suggestions from the commissions were that there should be some communication out to the stakeholders making them aware of what they are engaging in and what the standards are in compounding. Elizabeth suggested that the investigators start doing some sort of CE that educates the stakeholders on what they have learned in this Boot Camp.

#### Challenges faced by stakeholders:

- Financial
- The selection of the hoods, no guidance to address the iso-hoods / glove box and how they relate to 797 and what environment they need to be in.
  - The commission asked the investigators to provide this information to the stakeholders/commission members.
- Engage with certifiers and have commission communicate with certifiers letting them know of any different expectations.
- Guidance from investigators and what they are going to look for.

Note: All of these guidelines and recommendations and any other information are published in the USP 797. Investigators ask as part of the process that pharmacist in charge

or whoever should be well read on 797 it is a 38 page document that is what the investigators are looking for.

## **LEGISLATION, RULEMAKING, AND POLICY DEVELOPMENT**

### **Rulemaking Petition**

Cathy Williams introduced the team from Shire US Inc. to allow them to provide some background to the commission about the petition to amend WAC 246-887-040 Designation of non-narcotic stimulant drugs for purposes of RCW 69.50.402, and WAC-246-887-045 Prescribing, dispensing, or administering of Schedule II nonnarcotic stimulants.

Shire US Inc, aka Shire Pharmaceuticals or 'Shire', is a pharmaceutical company and the patent holder for a newer nonnarcotic stimulant, name Vyvanse (Lisdexamfetamine Dimesylate). Vyvanse is indicated for both the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients six years and older, and as of January 30, 2015, Binge Eating Disorder in adults. Vyvanse was approved by the FDA for the treatment of ADHD, effective February 26, 2007.

The active ingredient in Vyvanse, Lisdexamfetamine Dimesylate, is listed as a Schedule II stimulant in RCW 69.50.206(d)(5). Lisdexamefetamine was added to the list of Schedule II stimulants in 2010. Under RCW 69.50.402(1)(c), it is unlawful (a Class C felony) for a practitioner to prescribe, order, dispense, administer, supply, or give to any person.

The legislature has granted the commission the authority to add medical conditions for which Schedule II nonnarcotic controlled substances may be prescribed by rule adoption, in consultation with the Medical Commission and the Osteopathic Board. The issuance of a letter or a newsletter article would have no effect on the language in RCW 69.50.402. To the extent that prescribers are unwilling to prescribe Vyvanse due to concern that doing so is a violation of RCW 69.50.402, which could subject them to criminal enforcement, a letter or an article in the newsletter would not have any force or effect on the application of that statute.

**MOTION:** Dan Rubin moved the commission reject the petition to amend WAC 246-887-040 Designation of non-narcotic stimulant drugs for purposes of RCW 69.50.402, and WAC-246-887-045 Prescribing, dispensing, or administering of Schedule II nonnarcotic stimulants. The reason for the rejection is the statute about petitions sets such extraordinary timelines and it is not felt it is consistent with the commissions overall priorities.

Dan also moved that the commission work on a possible broader approach to this issue based on indications not names of drugs at the planning session. Gary Harris second.

**MOTION CARRIED: 9-0.**

## **PRESENTATIONS**

### **Confluence Follow-up**

Chris Humberson led the discussion of the follow-up on Confluence's request for a demonstration project approval for remote infusion services at Moses Lake and Omak. Glenn Adams introduced his team from Confluence Health. Mr. Humberson provided a brief background on the ongoing request and to reach a conclusion to the matter of their request for a pilot program approval at their Omak Clinic and the continuation of the pilot program at their Moses Lake Clinic facility, where in both cases they wish to utilize a pharmacy technician for sterile compounding that will be remotely supervised by a pharmacist located off site in Wenatchee.

## Background

- Confluence came to the Pharmacy board in November 2012 to request a pilot program at their Moses Lake clinic to utilize remote pharmacist supervision of a technician in preparing parenteral solutions, including chemotherapy medications. At the time they stated in a memo provided to the board that they were following USP 797 as a matter of hospital policy. The basis of this approval was the concern of patients access to medications being provided by the nursing staff at the clinic. The board approved this pilot program without being provided information on WACs 246-878 or 246-871 regarding the requirement of a pharmacist to be on site in this case.
- In September 2014, the commission was approached about extending this pilot program to their Omak clinic. The commission provided tentative approval which they rescinded in October 2014 after learning that a pharmacist was on site in the Omak facility and that access was not a central issue.
- In November 2014, Tyler Varnum and Commissioner Hecox visited both Moses Lake and Omak facilities and found several operational concerns. This information was provided to the commission and Confluence in December 2014.
- January 29<sup>th</sup>, 2015, the commission voted to provide Confluence with technical assistance to assess both their facilities in Moses Lake and Omak for compliance with Washington State statutes regarding minimum requirements for pharmacy sterile compounding by April 30, 2015. Inspectors again made visits to both facilities to provide technical assistance and assist with improving their operational capabilities.

The last site visit was on April 13<sup>th</sup> provided in the report to the commission which outlines the ongoing issues. Safety still remains a concern for the patients at these facilities.

There is legislation that the Department of Health and WSHA worked on that needs some clarification on the interpretation of it and will it pass or not. The underlying question is do these two facilities need to be licensed to practice pharmacy. This is still an issue that needs to be addressed.

Mary Gunkel from Confluence Health, Oncology nurse feels that the safety of our patients and the safety of compounding would be compromised if nurses go back to compounding. A nurses training is not dedicated to compounding. Dr. Peter Rutherford, CEO of Confluence feels that the initial focus has been lost in the discussion regarding all the other issues. He is committed to providing safe high quality care to patients. At this point Confluence doesn't have a funding issue "they are not going to go cheap on this but they do need to keep the lights on". He assured that Confluence will not attempt to do anything that is not safe that is not appropriate, this is his community. The commission members took turns asking the Confluence team questions and sharing their concerns with the team.

**MOTION:** Dan Rubin moved the commission take no action on the Moses Lake pilot as is and Omak pilot with pharmacist as is. Steve Anderson second. Elizabeth Jensen opposed.  
**MOTION CARRIED: 8-1.**

This continues to be a hot topic with over an hour of detailed discussion. If you would like more details, staff can provide further information.

## **OPEN FORUM**

*Jeff West* shared some issues he has concerns he has as a Quality Improvement Consultant working specifically on reducing adverse drug events to his knowledge there is not reliable accurate adverse drug event incident prevalence data at the community level. He is looking for an accurate report to reduce adverse drug events. Along with the lack of reports for medication reconciliation that directly affects adverse events.

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

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

## **LEGISLATION, RULEMAKING, AND POLICY DEVELOPMENT**

2015 Legislative Session Update

Legislation Report

### **Passed:**

**SHB 1625** providing drugs to ambulances

Delivered to Governor for signature

**ESHB 1671** opioid overdose medications

Delivered to Governor for signature

**SSB 5268** eye drop refills

Governor signed. Chapter 85, Laws of 2015, effective 07-24-15

**ESSB 5441** patient med coordination

Delivered to Governor for signature

**ESSB 5460** prepackaged ER meds

(Title is now “pharmacy services in hospital emergency rooms and hospital clinics”)

Delivered to Governor for signature

**ESB 5577** pharmaceutical waste

Delivered to Governor for signature

(PQAC was support only)

**SB 5935** biologics III

Delivered to Governor for signature

### **Appear to be DEAD:**

**SB 5557** services provided by pharmacists

**SHB 1369** student volunteers

**HB 1675** biologics I

**HB 1679** biologics II

**HB 1719** pharmacy asst. registration/discipline (agency request bill)

**HB 1732** meal/rest breaks & mandatory OT for certain healthcare workers

**HB 1765** marijuana authorized only in Rx pill form

**ESHB 1845** pharmaceutical waste

**SB 5291** epi auto-injectors for authorized entities

**SB 5434** synthetic cannabimimetics

**SB 5493** cannabis health & beauty aids

(companion bill HB 1753 introduced Jan 28)

**SB 5549** pharmacy asst. registration/discipline (agency request bill)

**SB 5695** insurance coverage for opioid reversal drugs

**SB 5815** naturopath Rx authority

**SB 5821** updating pharmacy provisions I

**SB 5822** updating pharmacy provisions II

**SB 5857** pharmacy benefit managers

(Note: Small independent pharmacies testified they would be out of business by year's end lacking the provisions in the amendment; issue is PBM failure to reimburse pharmacies for their cost for drugs)

#### Compounding Rules Update

Chris Humberson updated the commission on the Compounding rule. The second working draft is proceeding more slowly without a Rules Coordinator to facilitate the redraft. I personally have read all 129 pages of comments and anticipate the second working draft to be released for comment period on June 15<sup>th</sup>.

#### Technology Committee Update

AL Linggi gave the commission an update on the Technology Committee. There was a request sent out on listserv asking stakeholders to volunteer to be on a sub-committee to review and give input to the committee. We have about 12 volunteers to date. There has been data pulled on some technology arenas. Once we get someone to coordinate some dates and times we are ready to move forward.

#### Pharmacy Business Practice Committee Update

Dan Rubin updated the commission on the work the Business Practice Committee has done.

- March 19, 2015 the committee mapped a plan for arriving at the point of identifying high-level action options in key areas (“trial balloons”) by the planned April 30 meeting (1) staffing and workload, (2) performance metrics and quotas; and (3) breaks.
- March 30, 2015 Steve Anderson presented an overview of other states’ regulations related to the environment/space for clinical services. Gordon MacDonald also presented on the most frequent issues that arise in inspections, and the committee had a preliminary discussion of some issues related to the commission’s planned exploration of whether to move toward a Notice of Deficiency/Plan of Correction approach to inspections. Dan Rubin provided an overview of the stronger published research literature brought to the committee’s attention in relation to its scope, with focus on a couple of literature reviews and those sources using endpoints related to quality and safety. There is meaningful evidence that high workload, interruptions, distractions and inadequate lighting increase occurrence of dispensing errors.
- April 15, 2015 Joseph Clifton and Sarah Butterbaugh presented a slightly updated version of the presentation on prescription transfer incentives that a group of UW PharmD students originally presented to the commission.
- Chris Humberson distributed a compendium of the most relevant current Washington rule (WAC) sections, and these will be cited and attached as relevant to

each “issue assessment.”

- Steve Anderson also very briefly summarized the range of other states’ rules related to Quality Improvement, Assurance and Control.

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

Cathy Williams updated the commission on the Nursing Taskforce. There were 8 out of 50 Pharmacy Boards shared that they did not prevent access to nursing students. We are looking for more input from the stakeholders. The next Taskforce meeting is May 13 and the nursing commission will summarize the information they gathered from the four questions they sent out.

#### Long-Term Care Pharmacy Workgroup Update

Chris Humberson led the update to the commission.

- Electronic storage of orders -The discussion revolved around how prescription information sent from the nursing facility to the long term care pharmacy was stored at the pharmacy location.
- Electronic signatures of orders/verification issues-The concern regarding how these orders are signed and verified by the pharmacist and the process or such. Most physicians do not visit a facility but every thirty days per CMS and thus may be signing orders/prescriptions at that time.
- Nurses/agents faxing prescription orders/prescriptions -Discussion of the standard of practice of sending orders with multiple medications via a fax machine rather than sending as a prescription that meets all the elements of a prescription.
- Prescriptions verses orders in closed door setting -Discussion of how settings are different and that long term care pharmacy operations are more like a hospital than a retail pharmacy operation since they accept no walk in clientele.
- NABP Model rules on LTC pharmacy operations -Discussion around the adoption of the NABP model rules and the determinations that they reached about LTC practice of pharmacy.
- Faxing of orders and prescriptions -A major concern of stakeholders, who believe that in a LTC setting that processing orders is no different than a hospital setting and that to compare to a retail pharmacy operation is not accurate.
- E-RX verses CPOE - “prescriptions” not in patient’s hands.

#### Proposed Resolutions

Christopher Humberson led the discussion with the commission on their position regarding resolutions for consideration at the 111<sup>th</sup> Annual NABP Meeting on May 16-19.

##### **Submitted by District 1**

##### **Resolution #1 – Draft Resolution for Technicians (Co-supported by District 2)**

**WHEREAS**, the pharmacist’s scope of responsibility is expanding and should be expanded further to ensure the provision of current and additional patient care services surrounding medication therapy and

**WHEREAS**, technicians assist in the practice of pharmacy and, under the supervision of a pharmacist, can perform prescription entry and validation tasks that would further assist the pharmacist and

**WHEREAS**, the current education of technicians in relation to this expanded role has not been determined

**THEREFORE BE IT RESOLVED** that NABP work with PTCB and other stakeholders to study the current status of technician education and what future educational processes and requirements that may be needed to support the expanded role and regulation of technicians assisting in the practice of pharmacy.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Resolution #2 – Pharmacist Use of the Prescription Drug Monitoring Program (MA)  
(Co-supported by Districts 2 & 4)**

**WHEREAS** prescription drug abuse is the fastest growing drug problem in the United States,

**WHEREAS** the unintentional drug overdose death rates in recent years has been driven by increased use of opioid analgesics,

**WHEREAS** the pharmacist is often the last line of defense in preventing prescription drug abuse,

**THEREFORE BE IT RESOLVED** that National Association of Boards of Pharmacy (NABP) encourage state boards of pharmacy to educate pharmacists on the use of the prescription drug monitoring program (PMP) and to develop best practices to guide pharmacists when to access the PMP to include when a pharmacist becomes aware of a person currently, including but not limited to the following;

- (1) Receiving controlled substances from multiple prescribers;*
- (2) Receiving controlled substances for more than twelve consecutive weeks;*
- (3) Abusing or misusing controlled substances (i.e. over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a controlled substance, or an unfamiliar patient requesting a controlled substance by specific name, street name, color, or identifying marks);*
- (4) Requesting the dispensing of controlled substances from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area); or*
- (5) Presenting a prescription or controlled substances when the patient resides outside the usual pharmacy geographic patient population.*

**THEREFORE IT BE FURTHER RESOLVED** that NABP collaborate with the appropriate stakeholders to facilitate pharmacist access to PMP data and seamlessly integrate PMP data in pharmacy workflow.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Resolution #3 – Prescriber Use of the Prescription Monitoring Program (MA)  
(Co-Supported by Districts 2 & 4)**

**WHEREAS** prescription drug abuse is the fastest growing drug problem in the United States,

**WHEREAS** the unintentional drug overdose death rates in recent years has been driven by increased use of opioid analgesics,  
**WHEREAS** the prescriber is often the first line of defense in preventing prescription drug abuse,  
**THEREFORE BE IT RESOLVED** that National Association of Boards of Pharmacy (NABP) work with The Federation of State Medical Boards (FSMB) and prescriber stakeholders groups to educate prescribers about Prescription Drug Monitoring Programs (PMP) and encourage the adoption of legislation/regulations requiring the prescriber to access the PMP prior to the issuance and authorization of a controlled substance prescriptions to a patient for the first time.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Submitted by District 2**

**Resolution #1 (NJ) (Co-supported by District 1)**

**WHEREAS**, by 2030 there will be 75 million people over the age of 65 which is a 40% increase over current population; and  
**WHEREAS**, there is a critical shortage of primary care practitioners in our country; and  
**WHEREAS**, pharmacists are the most accessible health care professionals and providers in the community;  
**THEREFORE BE IT RESOLVED** that NABP convenes a taskforce with other key healthcare stakeholders to explore the feasibility and practicality of granting pharmacists limited prescriptive authority to meet patient needs.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Resolution #2- (NJ) (Co-supported by District 1)**

**WHEREAS**, by 2030 there will be 75 million people over the age of 65 which is a 40% increase over current population; and  
**WHEREAS**, there is a critical shortage of primary care practitioners in our country; and  
**WHEREAS**, pharmacists are the most accessible health care professionals and providers in the community;  
**THEREFORE BE IT RESOLVED** that NABP collaborate with interested stakeholders to develop an informational program to educate the public and other health care professionals about the role of pharmacists in the health care continuum, including information on pharmacist care services such as medication therapy management, counseling on prescription drug usage, and providing immunizations.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Submitted by District 4**

**Resolution #1 – Draft Resolution for Technicians**

**WHEREAS**, the pharmacist's scope of responsibility is expanding and should be expanded further to ensure the provision of current and additional patient care services surrounding medication therapy and  
**WHEREAS**, technicians assist in the practice of pharmacy and, under the supervision of a pharmacist, can perform prescription entry and validation tasks that would further assist the pharmacist and

**WHEREAS**, the current education of technicians in relation to this expanded role has not been determined

**THEREFORE BE IT RESOLVED** that NABP work with PTAC and other stakeholders to study the current status of technician education and what future educational processes and requirements that may be needed to support the expanded role and regulation of technicians assisting in the practice of pharmacy.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

### **Resolution #2**

**WHEREAS** Congress has enacted the Drug Quality and Security Act;

**WHEREAS** certain portions of the Compounding Quality Act remain unclear;

**THEREFORE, BE IT RESOLVED** that NABP update model law accordingly and collaborate with the FDA to clarify conflicting and/or ambiguous language.

**MOTION:** Chris Barry moved that the commission does not support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

### **Resolution #3**

**WHEREAS** Congress has enacted the Drug Quality and Security Act;

**WHEREAS** Drug Supply Chain Security Act substantially changes wholesale distribution law, including certain preemption of state law and changes in licensure;

**WHEREAS** the Act becomes effective periodically over the next decade;

**WHEREAS** the Act requires regulation promulgation periodically over the next decade;

**THEREFORE, BE IT RESOLVED** that NABP update model law until all provisions of the

Act and its regulations have become effective.

**THEREFORE, BE IT FURTHER RESOLVED** that NABP provide public comment during regulation promulgation as necessary.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

### **Submitted by District 5**

#### **PENDING - Resolution #1 – Ensure Public Confidence in NABP and its Member Pharmacy Boards (MN)**

**WHEREAS**, NABP is an independent, impartial professional organization that supports and assists its member state boards of pharmacy in protecting the public health;

**WHEREAS**, a primary mission of NABP's member pharmacy boards is to protect the public by licensing, regulating, and when necessary, disciplining individuals and entities licensed and regulated by member pharmacy boards; and

**WHEREAS**, to ensure public confidence that NABP and its member pharmacy boards are free from an appearance of conflict of interest or bias in the execution of their duties that may be created by sponsorships, grants and other financial support at NABP annual meetings by individuals and entities who are licensed and regulated by member pharmacy boards;

**THEREFORE BE IT RESOLVED**, that NABP will not accept sponsorships, grants or other financial support for any event or activities at NABP's annual meetings from individuals and entities who are licensed or regulated by member pharmacy boards.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Submitted by District 6**

**Resolution #1 (Co-supported by District 7 & 8)**

**WHEREAS** there is a national and state movement to obtain provider status for pharmacists; **WHEREAS** provider status is important to the advancement of the pharmacy profession;

**THEREFORE BE IT RESOLVED** that NABP follow/adopt APhA provider status model **THEREFORE BE IT RESOLVED** that NABP work collaboratively with APhA and other pharmacy organizations to have a cohesive message to driver provider status recognition nationally; Therefore be it further resolved that NABP develop a task force to create model act language to assist boards in oversight and regulation of independent providers in pharmacy practice.

**MOTION:** Chris Barry moved that the commission does not support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Resolution #2 (Co-supported by District 7)**

**WHEREAS** there is diversity among states regarding pre-licensure experience requirements;

**WHEREAS** this diversity in pre-licensure experience requirements may negatively impact new graduates seeking licensure in states other than where they graduated from;

**THEREFORE BE IT RESOLVED** that NABP encourages states to accept ACPE accredited pre-licensure experience as satisfying preliminary licensure requirements;

**THEREFORE BE IT ALSO RESOLVED** that NABP encourages states to adopt the use of a centralized NABP database to confirm graduation of new graduates.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Submitted by District 7**

**Resolution #1 (ID) (Co-supported by Districts 6 & 8)**

**WHEREAS** Congress has enacted the Drug Quality and Security Act; **WHEREAS** certain portions of the Compounding Quality Act remain unclear; **THEREFORE, BE IT RESOLVED** that NABP convene a task force to update model law accordingly and to collaborate with the FDA to clarify conflicting and/or ambiguous language.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Resolution #2 (ID) (Co-supported by Districts 6 & 8)**

**WHEREAS** Congress has enacted the Drug Quality and Security Act;

**WHEREAS** Drug Supply Chain Security Act substantially changes wholesale distribution law, including certain preemption of state law and changes in licensure;

**WHEREAS** the Act becomes effective periodically over the next decade;

**WHEREAS** the Act requires regulation promulgation periodically over the next decade;

**THEREFORE, BE IT RESOLVED** that NABP convene an ongoing task force to update model law until all provisions of the Act and its regulations have become effective.

**THEREFORE, BE IT FURTHER RESOLVED** that the task force provide public comment during regulation promulgation as necessary.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**Submitted by Minnesota**

**PENDING** – **Ensure Public Confidence in NABP and its Member Pharmacy Boards**

**WHEREAS**, NABP is an independent, impartial professional organization supporting and assisting its member state boards of pharmacy in protecting the public health; and **WHEREAS**, a primary purpose of NABP's member pharmacy boards is to protect the public by licensing, regulating, and when necessary, disciplining individuals and entities licensed and regulated by member pharmacy boards; and

**WHEREAS**, NABP and its member pharmacy boards are vigilant of the obligation to be free from conflicts and the appearance of conflicts of interest or bias in the execution of their assistance and duties, respectively; and

**WHEREAS**, sponsorships, grants and other financial support at NABP annual meetings by individuals and entities who are licensed and regulated by member pharmacy boards could be interpreted as a conflict or the perception of a conflict of interest despite the fact that the support is in the form of unrestricted grants and appropriately overseen both by internal controls and the approval of NABP as a provider of continuing pharmacy education by the Accreditation Council of Pharmacy Education (ACPE);

**THEREFORE BE IT RESOLVED**, that NABP commission a task force to review the present practice and policies for accepting sponsorships and grants for the Annual Meeting and provide recommendations to the NABP Executive Committee to replace such sponsorships and grants with other means of support in order to continue to maintain the high quality of the Annual Meeting as well as NABP's objectivity and unbiased presentations and activities at the Annual Meeting.

**MOTION:** Chris Barry moved that the commission support this resolution. Tim Lynch second. **MOTION CARRIED: 9-0.**

**PRESENTATIONS**

Jefferson Hospital

Lisa Roberts introduced Lanny Turay the Pharmacy Director for Jefferson Hospital. He is here to provide a presentation to the commission asking for approval for Jefferson Hospitals remote medication order processing.

Background:

- Jefferson Hospital (Jefferson Healthcare) is a critical access hospital located in Port Townsend, Washington.
- 25 critical access bed hospital they see about 15 patients a day.
- 2.4 pharmacists a week.
- Jefferson Hospital Pharmacy is open Monday through Friday 0630 to 1800 and 0730 to 1630 weekends and holidays.
- They currently utilize CPOE with EPIC software.
- They are currently using Medication Review as their outside pharmacy vendor and have been doing so for approximately two years.

- The pharmacy's policies and procedures are in accordance with the WA State Pharmacy Quality Assurance Commission's current guidelines.
- During a recent hospital pharmacy inspection, it was discovered that this pharmacy was utilizing remote order processing but did not have Pharmacy Commission approval for Remote Processing of Medication Orders.

**MOTION:** Chris Barry moved that the commission approve Jefferson Hospitals remote medication order processing services, Medication Review. Elizabeth Jensen second.

**MOTION CARRIED: 9-0.**

## DISCUSSION

Pass Assured

Irina Tiginyanu introduced David Dubose, President and CEO of Pass Assured On-line technician training program asked the commission for approval of his program.

PassAssured Program Structure

- 300 Hours of course content
- Self-paced instruction for high school seniors or adults
- Teacher facilitates
  - Tutor when necessary
  - Encourages completion
- Delivery formats
  - Class within a class
  - Self-contained
  - Independent study
  - Distance learning

PassAssured Program Capabilities

- Online course content:
- Videos and Learn Files (text) Course content caters to the visual and audio type learners
- Organized:
- There are six sections with forty-four subsections (Medical Review Section is organized by classifications of drugs.)
- Addendums:
- Study Aids, Interview, Effective Communication, HIPAA Regulations, Virtual Rx Electronic flash cards (Study Aids)
- Contains: Pronunciations of Brand/Generic Drug Names, Drug Images/PA's Top 200 Drugs/Classifications/Drug Use
- *Testing System:*
  - 1,000+ questions
  - Random Test Generation
- 5 Levels:
  - Subsection Quiz
  - Section Test
  - Tutored Exam
  - Final Exam

- Exit Exam
- Separate 1,000 question test bank
  - Educator must give student access
  - 125 Questions
  - 3 Hour Time Limit
- Once accessed, must complete Automated grade book / Student progress monitored by Facilitator
- All Tests Retrievable for review via ECP

PassAssured's PTP

- All Future Technicians must also complete
  - WA State Pharmacy law
  - Aids / HIV

**MOTION:** Dan Rubin moved to reject as a stand-alone program but approves this as a potential didactic training. Chris Barry second.

Dan Rubin rescinded his motion.

**MOTION:** Dan Rubin moved that the commission reject as an all-encompassing pharmacy technician training program but may be used in conjunction with an approved pharmacy technician program that includes pharmacist oversight. Elizabeth Jensen second. Maureen Sparks recused herself. Chris Barry abstained. Steve Anderson and Sepi Soleimanpour opposed. **MOTION CARRIED: 5-2.**

## **CONSENT AGENDA**

### 2.3 Pharmacy Tech Training Program Approval

#### b) International Academy of Merchandising and Design – dba Sanford-Brown College

Elizabeth Jensen asked if this can be approved with no pharmacy manager. They are opening up a new school that is why there is no pharmacy manager.

**MOTION:** Elizabeth Jensen moved that the commission deny this Pharmacy Tech Program they can come back when they have a pharmacy manager. Chris Barry second..

**MOTION CARRIED: 9-0.**

#### c) Rite Aid – renewal

Elizabeth Jensen was concerned about a question and answer on a form about licensure.

**MOTION:** Elizabeth Jensen moved that the commission approve the Rite Aid Pharmacy Tech Program. Maureen Sparks second. **MOTION CARRIED: 9-0.**

#### d) Walgreens – renewal

The training portion was missing in the documents submitted by the pharmacy consultant to the commission. The documents were retrieved so the commission executive director could review could review and provide further information to the commission.

**MOTION:** Steve Anderson moved that the commission approve the Walgreen Tech Program. Tim Lynch second. Sepi Soleimanpour recused herself. **MOTION CARRIED: 8-0.**

f) Island Drug

There was not an initial effective date given to Island Drug and the commission was asked to back date the effective date by the pharmacist consultant.

**MOTION:** Chris Barry moved that the commission approve Island Drug Pharmacy Tech Training Program effective as of today. Steve Anderson second. **MOTION CARRIED: 9-0.**

Route of Licensure for Foreign Trained Pharmacist completing – Non-traditional PharmD program. This was tabled until the June 2015 meeting.

Correspondence

The commission discussed correspondence received or distributed

- a. Prescription Pricing – Letter from Consumer
- b. Need for Broader Access to Pharmacy Services – Letter from Consumer/Practitioner
- c. DEA News Release – Fentanyl Alert
- d. CNEWS – Council on Nursing Education in Washington State = Nursing Students' Access to Automated Drug Dispensing Devices (ADDDs)/
- e. Swedish Medical Center – support student nurses' access to ADDDs
- f. Long-term Care Workshop – Stakeholder comment
- g. CTG, Inc. – Compliance to Pharmacy Compounding Regulations and Standards
- h. NABP Mailbag April 2015

**STATUS REPORTS**

PeaceHealth Southwest Medical Center

Cathy Williams shared some background the written document provided by Victoria Tamis who was unable to attend the meeting. PeaceHealth was asked to provide a letter with the data the commission asked for after they were given approval for their specialized function: Technicians checking the work of other technicians in stocking emergency medication boxes/trays and automated dispensing cabinets.

**Assessment/Data and Outcomes:**

- We had 16 technicians that started the process for ADC checking. All completed the didactic training between April 24th and July 3rd, 2014. All passed the initial written examination with a score of 93% or greater. One technician failed the first attempt at finding the 3 errors hidden in the fill. The technician subsequently passed the following attempts successfully.
- The program had to be discontinued for a timeframe when the pharmacy resident had departed the organization and pharmacy management was transitioning. Pharmacists resumed checking the ADC and box fills during that time frame until the monthly checks were completed. When the program was resumed, all subsequent monthly and quarterly check resulted in 100% accuracy.
- We had three technicians that completed the code tray and box checking process. They each received an additional 8 hours of didactic learning. All passed the written exam with a result of 90.5% or greater. They then had to check 10 trays or

boxes to find 3 errors in the trays or boxes. The three technicians then had trays checked by a pharmacist for accuracy. The monthly fill had an expected accuracy of greater than 99%. Three initial monthly tray and box 'fills" were required. After this, the trays and boxes are checked quarterly. All fills, trays and boxes that were checked by the pharmacist were completed at a 100% accuracy rate.

**Hours the project freed up pharmacists to perform other patient care:**

- There are 13 ADC fills per day that require approximately 15 minutes per fill to check; hourly stock outs require approximately 5 minutes to check. Checking of these fills require approximately 315 minutes or 5 hours and 15 minutes to complete daily.
- There are approximate 15 anesthesia trays that are checked daily utilizing the tech check tech program; time to complete the checks is approximately two minutes per tray. There are approximately three Rapid Sequence Intubation (RSI) boxes that require checking daily; time to complete is approximately four minutes per box. Time spent per day is about 42 minutes to check trays and boxes.
- It is estimated that the pharmacy department is saving nearly six hours per day in pharmacist time having the technicians check each other. This adds up to over one full time pharmacist over the past year (2190 hours). We have reallocated pharmacist staff in the department over the past several months to provide an additional transitional care pharmacist service to address medication education issues and access to mediations on discharge. This service has been very well accepted by hospital administration and providers. Central distribution pharmacists are spending more time managing medication protocols that do not require a decentralized presence to manage.

**Lessons learned from staff and supervision:**

- We have learned that technicians that complete these tasks on a daily basis can be more efficient than pharmacists that rotate through distributive functions and are subject to multiple interruptions for drug information needs. Drug shortages and inventory issues for the products in the ADCs, trays and boxes are addressed more completely. The technicians work directly with the pharmacy purchasing team to manage inventory; pharmacists are only interrupted for unresolvable concerns related to utilizing alternate medications. Technicians are having more of an impact on patient care and the feel more empowered as a caregiver.

**Report Back for Othello Hospital**

Cathy Williams introduced Cliff Richards, responsible pharmacy manager for Othello Hospital. He presented via teleconference to report back the use of remote medication order processing services by Medication Review to the commission.

Cliff shared data on the medication refill/restock requests for first six months of use.

- 1305 medications were reviewed
- Technicians were remotely monitored on 48 different days, the other days pharmacist was working.
- No errors filling the machine
- 14 items were marked as deficient

- Average time for Medication Review pharmacist to review the ADDD refill contents is 18.8
- This has been a great and has enhanced the ability to get patients medication in a timely manner
- Scanning Function is required
- Input from technician and Medication Review is going well and is still being fine-tuned.

**MOTION:** Tim Lynch moved that the commission approve the continuation of the demonstration project. Elizabeth Jensen second. Chris Barry recused himself. **MOTION CARRIED: 8-0.**

## **OPEN FORUM**

### **BUSINESS MEETING ADJOURNED**

*There being no further business, the board adjourned at 4:00 pm*

*Respectfully Submitted by:*

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*Leann George, Program Support  
Approved June 11, 2015*

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*Al Linggi, Chair  
Washington State Board of Pharmacy*