OREGON BOARD OF PHARMACY
BOARD MEETING MINUTES

Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
August 9-10, 2017

The mission of the Oregon State Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale and distribution of drugs.

WEDNESDAY, AUGUST 9, 2017

Penny Reher, R.Ph, Board President, called the meeting to order at 8:44AM

Roll Call
Penny Reher, President    Rachael DeBarmore, Vice President
Roberto Linares     Kate James
Shannon Larson     Cyndi Vipperman
Dianne Armstrong     Christine Chute
Second Public Member position - vacant

The following staff members will be present for all or part of this session:
Marc Watt, Executive Director   Brianne Efremoff, Compliance Director
Karen MacLean, Administrative Director   Chrisy Hennigan, Licensing Supervisor
Fiona Karbowicz, Pharmacist Consultant   Joe Ball, Chief Investigator
Cheryl Fox, Inspector     Jane Gin, Inspector
Katie Baldwin, Inspector     Laura Elvers, Inspector
Brian Murch, Inspector     Annette Gearhart, Compliance Secretary
Kim Oster, Compliance Assistant   Rachel Melvin, Executive Support Specialist

Tom Cowan, Sr. AAG Board Counsel
Tim Frost, Board Fellow
Mary Beth Baptista, Executive Director Naturopathic Examiners Board, Guest

Board President, Penny Reher introduced new Board Member, Shannon Larson, R.Ph. and read her the installation speech. Shannon is a 2008 Pharm D. Graduate of Oregon State University School of Pharmacy. She currently works as a staff pharmacist at Safeway Pharmacy in Newberg. Shannon’s work experience since licensure in 2008 has primarily been in the community-based retail setting that includes a few years in a compounding pharmacy. Shannon is excited to be on the Board.

Agenda Review and Approval

MOTION
Motion to approve the agenda was made and unanimously carried (Motion by Chute, seconded by James).
Board Member / Staff Responsibility Roles
Board Counsel Tom Cowan discussed the roles of Board and staff from the perspective of ORS 689, which includes a very long list of duties charged to the board. However, staff function out of the purview of the board and have specific duties to accomplish. While staff accomplishes many responsibilities, some are non-delegable. These non-discretionary acts that need to be taken in a board meeting such as disciplinary actions that can only be taken by the board. Board meetings happen to allow for only those things the board can take action on. The Executive Director’s role is to delegate direction to staff and to stay in contact with the Board President regularly to accomplish the board’s directives.

Contested Case Deliberation pursuant to ORS 192.690(1) - Not Open to the Public

EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (k).

A. Items for Consideration and Discussion:
   1. Deliberation on Disciplinary Cases and Investigations
   2. Personal Appearances
   3. Warning Notices
   4. Case Review

MOTION
Motion to enter Executive Session at 9:06AM was made and unanimously carried (Motion by James, seconded by Larson).

MOTION
Motion to resume Open Session at 2:21PM was made and unanimously carried (Motion by Chute, seconded by Armstrong).

OPEN SESSION - PUBLIC MAY ATTEND - At the conclusion of Executive Session, the Board will convene Open Session and continue the following listed agenda items

Approve Consent Agenda*

*Items listed under the consent agenda are considered to be 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. NAPLEX Scores – 9/1/16 – 4/30/2017
   2. MPJE Scores – 9/1/16 – 4/30/2017
   4. Board Minutes – June 7-8, 2017

MOTION
Motion to approve the consent agenda was made and unanimously carried (Motion by James, seconded by Vipperman).
ISSUES/ACTIVITIES

Reports:
Board Member, Christine Chute attended the Governor’s DUII meeting and reported that states with legalized marijuana have seen an increase of 3.5% in car accidents while here in Oregon this has increased 4.5%. Law enforcement is reporting they are seeing more people under the influence of marijuana when stopping people for suspected DUII and that binge drinking has increased significantly among young drinkers. Board Member, Roberto Linares stated that he had also seen similar reports from OSU. Executive Director, Marc Watt stated he read a report from Colorado that stated they weren’t able to tie marijuana to increased accident rates and are in support of relaxing marijuana laws. Roberto reported that he attended a Latino event at the Governor’s mansion. He also attended AACP meeting where a focus was the possibility of making student volunteer events a required co-curricular activity that would need to be tracked.

Marc reported that we’ve been receiving calls from OHA regarding the availability of Naloxone in pharmacies around the state and they haven’t been successful in getting help from pharmacists. Marc suggested that we increase our outreach to pharmacists. Marc also reported that the DEA plans to reduce opioids by an additional 20% in 2018 and they are seeing trends in downward prescribing as a result of the reduction implemented for 2017 so far. Board President, Penny Reher stated that she is concerned and that it’s problematic why end users haven’t been informed how they are going to implement the annual limit. She stated that she would like to see some communication regarding how they are going to allocate it instead of waiting until the last quarter, which happened before. Penny thanked Board Member, Kate James, Board Vice President, Rachael DeBarmore and Board Counsel, Tom Cowan for their help with new board member orientation and Kate thanked staff for their help. Marc reported that we completed the conversion for HPSP and estimated it will save the agency about $70,000. He also mentioned that DAS will be billing us for their work on the transition, which was a surprise to us. Lastly, Marc reported that Josh Free is our new representative for 2017 HB 3262.

Board Counsel, Tom Cowan agreed that orientation was great and thanked everyone for their help.

Compliance Director, Brianne Efremoff reported they held their quarterly staff meeting and that inspections are at 44% and expects to complete on time and that caseload is currently around the same amount quoted at previous board meeting. We now have 20 people in HPSP.

Pharmacist Consultant, Fiona Karbowicz stated that she has been busy streamlining our internal processes for CE approval and shared service contracts. She facilitated the Consultative Contraceptive Committee meeting in July where the Committee discussed the new legislation adding the depo shot and ring. They reviewed updated forms and training program. She will have more to report later in the meeting. She also stated that the Oregon Pain Management Commission is updating their CE program.

Administrative Director, Karen MacLean reported that we completed the following items, transition for HPSP, the grant for our Fellowship, extended our IT consultants contract, secured Donna Silverberg for our upcoming strategic planning meeting. She stated that she also updated and prepared orientation materials for the new board member orientation meeting and documents as well as coordinated the annual update for the NABP Survey of Pharmacy Laws with staff’s help.
Licensing Program Supervisor, Chrisy Hennigan reported that Licensing has been receiving applications from 2017 graduates as well as a large amount of reciprocity applications. We have been tracking the new pharmacist licensing procedure and it took 47 – 72 days for applicants to be licensed since graduating. Five 2017 graduates from Pacific and one 2017 from OSU are now licensed; it only took 68 days from graduation to licensure for our first Idaho State graduate and we will continue to evaluate so we will be able to give future classes a better idea of what to expect. She stated that from the date of the first exam to licensure is averaging 35 days and it takes approximately 16 business days from the date we receive an application to issuing the license, which includes the time it takes for an applicant to receive the fingerprint instructions, schedule and complete the fingerprint appointment and OSP/FBI processing time. The team feels good about our turn-around time, especially since we implemented the new RPH licensing process and the new 6/30 expiration date for technicians. Licensing Representative, Michael Hunt managed to process and issue new pharmacist licenses while also renewing existing pharmacist licenses when typically Licensing Representatives, Jennifer Hummel and Rene’ Sanders would assist but Rene’ was assisting in Compliance while Kim Oster was on leave, and Jennifer worked feverishly to process Certified Pharmacy Technician licenses before June 30th.

Chrisy reported that they had 24 license extension requests, issued 119 Certified Pharmacy Technician licenses in April and May combined and 146 Pharmacy Technician licenses, totaling 265 Technician licenses. In June we issued 186 CPT licenses and 81 Pharmacy Technician licenses for a total of 267. Chrisy stated that it is truly a team effort and thanked all staff who assist with opening the mail, processing the payments and fingerprints, scanning the applications, the licensing review, supervisory review and finally the printing and stuffing of envelopes. She reported that audit notices will be sent out via email at the end of August to approximately 1500 pharmacists who renewed their license and she mentioned that there will be an additional question added the audit this year regarding OHA’s cultural competency. Approximately 1400 pharmacists reported that they completed CE related to cultural competency and we are now required to ask if the cultural competence CE completed was on the OHA approved list.

We are in the midst of Wholesaler/Manufacturer/Drug Distribution license renewal and have two staff working on this complicated renewal cycle. 73% of the renewals we have received so far via mail have issues and require follow up and it seems that the majority of facilities struggle submitting a properly completed renewal application. Lastly, Chrisy stated that we are exploring adding other payment options on our website such as possibly accepting American Express & Discover.

Project Manager, Mo Klein – None

**Board Member/Staff Presentations**

Pharmacy Coalition – 7/11/2017 Executive Director, Marc Watt stated that it was a review of the various bills and outcomes summarized for the year and that it was a successful legislative session.

Professional Practice Roundtable – 9/20/2017 Marc indicated it was primarily a review of the legislative session.

Acute Care Health System Roundtable meeting – 6/20/2017 Pharmacist Consultant, Fiona Karbowicz reported that at this quarterly meeting, the chair requested OBOP provide an overview of ow the board does business, waiver requests and a description of the process for review.
They asked for information regarding the practice of administrative law, policy and rule making and how long those processes take. The meeting was well attended and it helped us streamline some of our own processes. Executive Director, Marc Watt stated that some members voiced their opinions on how quickly we move on some decisions.

Northern OR CCO’s Naloxone & Drug Take Back Outreach Seaside – 6/26/2017 Pharmacist Consultant, Fiona Karbowicz presented to 30 people in Seaside and mentioned that HB 3440 has since passed.

**Committees/Meetings**

2017 FDA Intergovernmental Working Meeting on Pharmacy Compounding, 9/26-27/2017, Silver Spring, MD – Pharmacist Consultant, Fiona Karbowicz and Compliance Director, Brianne Efremoff will attend the 6th annual meeting and FDA will be covering their travel expenses.

NABP Executive Officer Meeting, 10/2-4/2017 – Chicago, IL – Executive Director, Marc Watt will attend, he’s found this to be a valuable meeting in the past.

NABP Districts 6-8 Meeting, 10/8-11/2017, San Antonio, TX - Executive Director, Marc Watt stated that he will attend this meeting and mentioned that 2017 HB 5006 reduced our budget by 3.5% at the end of session, which also reduced our in and out of state travel budget by 20% total. Marc reported that board meeting travel is the majority of our travel budget and asked the board if they wanted to discuss changing our meetings and travel so we can adjust our budget projections. Board President, Penny Reher thanked staff for condensing the August meeting from 3 days down to 2 days to help reduce costs. Penny stated that the seat for the NABP District 7 Executive Committee is opening in the spring and wants representatives from Oregon to attend this meeting and to participate. At the last board meeting, the board decided to send two people, the Executive Director and a board member. Penny then recommended that Board Vice President, Rachael DeBarmore attend with Marc. Board member, Christine Chute inquired about the formulary committee and how this trip will impact our travel budget and in is not in favor or travel. Rachael will attend with Marc.

OSPA Annual Convention - 10/21-22/2017 Pharmacist Consultant, Fiona Karbowicz stated that we will have a booth this year and will be attending with Board Member, Cyndi Vipperman and Compliance Director, Brianne Efremoff and Executive Director, Marc Watt.

OSHP Fall Seminar – 11/18/17, Portland - Pharmacist Consultant, Fiona Karbowicz stated we will have a booth and that she will be speaking about unique careers in pharmacy.

OSPA Lane County – 2/17-18/2018 Board Member, Kate James will attend, but stated she needs volunteers to speak.

**Board Meeting Dates**

- October 11-12, 2017 Portland
- November 8-9, 2017 Silverton
- December 13-14, 2017 Portland
- February 7-9, 2018 Portland (Strategic Planning)
- April 4-5, 2018 Portland
- June 6-7, 2018 Portland

(*3 day meeting)
• August 8-10, 2018* Portland (*3 day meeting)
• October 3-4, 2018 Portland
• November 7-8, 2018 Portland
• December 12-13, 2018 Portland

Rulemaking Hearing Dates
(The following dates are reserved for potential rulemaking hearings and identified only for planning purposes and approved by the Board. Actual Rulemaking Activities will be noticed as required by law and may deviate from this schedule as needed.)

• November 29, 2017
• May 23, 2018
• November 27, 2018

Financial/Budget Report – Executive Director, Marc Watt reported he is concerned because HB 5006 reduced our budget by $261,147 during the end of session with reductions in travel, AG, DAS and personnel. He stated that he is anticipating that the costs associated with the database upgrade project will increase because of the amount of time that has passed since the original proposal. He also reported that the DOJ flat rate and hearings costs for 2015-17 were larger than projected and will impact the 2017-19 biennium with an increase of 8.08% which will possibly put us in the position of having to go to the E-Board for additional funding. Marc reported that our data showed an increased amount of hearings and stated that most of our state health related boards use the flat rate model, except Board of Nursing who are paying as needed. Board President, Penny Reher asked that staff keep the board posted. Marc reported that travel reductions came in at 20% total, 10% in-state and 10% out-of-state and a hiring slowdown adjustment of $169,448.

Legislative Update – Executive Director, Marc Watt stated that more and more pharmacists are being requested to be on various committees.

Strategic Planning – Administrative Director, Karen MacLean gave a high-level overview of the outcomes from last year’s meeting.

2017 Facilitator Update – Karen stated that Donna Silverberg is going to be our facilitator again for continuity purposes. Board President, Penny Reher stated that because of the ongoing opioid crisis, where should BOP be in this discussion and could this be a potential topic for the agenda. Executive Director, Marc Watt asked the board if they would consider a one-day session or even skip alternate years to reduce costs. He also asked the board to consider narrowing down the agenda and prioritizing the topics that need to be addressed in a timely manner.

OPEN FORUM – None

Adjourn

MOTION
Motion to adjourn at 3:50PM was made and unanimously carried (Motion by Vipperman, seconded by James).
THURSDAY, AUGUST 10, 2017

Penny Reher, R.Ph, Board President, called the meeting to order @ 8:32AM

Roll Call
Penny Reher, President Rachael DeBarmore, Vice President
Roberto Linares Kate James
Shannon Larson Cyndi Vipperman
Dianne Armstrong Christine Chute
Second Public Member – vacant

The following staff members will be present for all or part of this session:
Marc Watt, Executive Director Brianne Efremoff, Compliance Director
Karen MacLean, Administrative Director Chrisy Hennigan, Licensing Supervisor
Fiona Karbowicz, Pharmacist Consultant Joe Ball, Chief Investigator
Cheryl Fox, Inspector Jane Gin, Inspector
Katie Baldwin, Inspector Laura Elvers, Inspector
Brian Murch, Inspector Annette Gearhart, Compliance Secretary
Kim Oster, Compliance Assistant Rachel Melvin, Executive Support Specialist

Tom Cowan, Sr. AAG Board Counsel
Tim Frost, Board Fellow

Board President, Penny Reher introduced new Board Member, Shannon Larson and Fellow, Tim Frost.

Motions for Contested Cases & Disciplinary Action

GENERAL ADMINISTRATION

Discussion Items

Waiver Requests - Multnomah County

Pharmacist Consultant, Fiona Karbowicz reported that Multnomah County has requested an extension on their previous waiver request. This renewal request would continue to allow each of Multnomah County's seven charitable pharmacies to dispense donated refrigerated medications. This furthers public health and safety by giving uninsured patient's access to medications that would otherwise be unattainable.

MOTION
Motion to approve Multnomah County Health Department Charitable Pharmacies request to continue waiver of OAR 855-044-0050(1)(j) for five years was made and unanimously carried. (Motion by James, seconded by Armstrong).
Update re: Board Authorities, Policies and Compliance (ABC) Guidelines

Compliance Director, Brianne Efremoff presented and defined the current ABC’s. With today’s policy discussion, she asked direction specific to the Board’s concepts with the goal of bringing something back in October for adoption.

Bri asked Inspector, Cheryl Fox to present information/research specific to our current DUII/BAC guidelines with the suggestion to revise them based on information from subject matter experts (SME) and DOJ guidelines. Following discussions with the Compliance Department, three areas were identified for the board to consider:

1) Should we lower the BAC threshold for Board presented cases from .20% to .15%,
2) Should we change the required case presentation in the case of two DUI’s (regardless of BAC levels) within 10 years, to within 15 years, and
3) How should we treat DUI’s where the licensee/applicant has refused a breathalyzer?

All SME’s agreed that a BAC > .20% is severely intoxicated and that we consider a BAC > .15% as it is nearly twice the legal limit and this would reflect the threshold that DOJ uses when implementing fines and requiring treatment.

Diversion Eligibility is defined in statute and states that the defendant is eligible for diversion if they have not been convicted of a DUI within the period beginning 15 years before the date of the commission of the present offense. The statute states a defendant is not eligible for diversion if they have participated in a diversion or rehabilitation program within the 15 years prior to the current offense.

Applicants/licensees that have refused the breathalyzer. It was suggested by all SMEs that Board investigators obtain the drug and alcohol evaluation that was required by DOJ as a result of the DUI AND request a new evaluation if their last drug and alcohol was greater than 12 months ago. While evaluations dated over 12 months ago provide information and insight, a DSM V diagnosis is only relevant to 11 questions/qualifiers that refer to substance use within the last 12 months, which doesn’t provide a clear picture of where the person is today. By requesting a current evaluation, it will also require the applicant/licensee to sign a release of information to the Inspector, which would allow us the ability to discuss the case with the evaluator, which would also help the evaluator make a well-informed evaluation.

Brianne recommended that we use the RBH list of approved evaluators and that we do have thresholds that have to be met and stated that rural areas are difficult, but we’ve been flexible. The quality of the evaluator is important and the evaluations are expensive and currently applies to technicians and pharmacists.

Brianne then spoke about our current applications regarding the information we capture and asked if we need to revise the current application or simply scrutinize the information more in the future. She asked the board what is it that we want from our applicants in order to screen them properly and gave a timeframe that shows how staff deals with arrests and unsworn falsification. Board Counsel, Tom Cowan stated that he believes the application is working as we intended. Brianne stated that staff felt they would rather have the information vs. not having the information from LEDS.

Board Members had a lengthy discussion and decided that it boils down to the applicant creating an honest relationship with the Board; honesty is a core value in our practice. Some board
members believe applicants are misinterpreting the language on our current application and use their own definition of “arrest or “conviction”. Executive Director, Marc Watt stated that it’s better to have applicants report everything, because most of our Technician applicants have issues deciphering what to report and when.

Brianne reported that we are seeing high levels of domestic violence on background checks and Marc stated if there is any evidence at the scene in Oregon, most people go to jail regardless, which turns into domestic violence arrests, but results in less convictions, not including the felony version based on his experience working in law enforcement.

---

**Providence Request** – Board President, Penny Reher announced that this request was postponed until a future board meeting.

---

**Asante Rogue Valley TCVP 5-year Renewal Request** –

Compliance Director, Brianne Efremoff mentioned that this is the first TCVP 5-year renewal received and reminded the board of the 2017 ABC’s discussion that added TCVP to “B-Board Policies” in June.

Policy directs a renewal of a TCVP approval every 5 years, ongoing, or if major changes in the Policies & Procedures occur. Asante now includes three approved locations, TCVP is site specific.

**MOTION**
Motion to approve Asante Rogue Valley’s request to continue TCVP for 5-years and report back in August 2022 for 5-year renewal was made and unanimously carried. (Motion by James, seconded by Armstrong).

---

**Asante Three Rivers Medical Center 1-year report** –

Having no questions, the Board approved the 1-year TCVP report. As noted previously, report at year five in 2021 or before if major changes in the Policies and Procedures occur.

**MOTION**
Motion to accept Asante Three Rivers Medical Center’s one year TCVP report. Report back in February 2021 for 5-year renewal per agency policy was made and unanimously carried. (Motion by Vipperman, seconded by Chute).

---

**Board Per Diem Policy Discussion**

Administrative Director, Karen MacLean spoke about the Board’s decision to move forward with increasing the per diem. She provided a draft policy and asked the board if they would clarify what criteria should be considered for activities other than scheduled Board Meetings. It was suggested that any other activities needed to last at least two hours or more. She asked if rulemaking hearings, board prep and post-board meetings qualify.
Board members had a brief discussion about other state board’s policies and what is considered per diem related time and what it would look like if we kept it at $30. They also inquired about how the new formulary committee might impact us financially since we will be covering the costs. The board proposed a 2 hour minimum and $100 per diem moving forward, not to include board meeting prep, but to include other meetings they speak at as well as travel time for those. Staff will revise the rule and policy and will bring it back to October’s board meeting.

2017 HB 2397 – Initial Planning

Executive Director, Marc Watt stated that the Governor’s office will be sending out an email in their efforts to recruit members to join the Public Health and Pharmacy Formulary Advisory Committee. Marc stated that each of the three boards is requested to submit three recommendations for each professional position by October for consideration. The Governor is seeking a diverse group. Our board has three positions to fill and will need to select nine pharmacists. A number of nurse practitioners have already applied and the first meeting will be towards the end of January 2018. The Committee will be tasked with reviewing requests and deciding what barriers to put around supported proposals for recommendation to the board. Staff intends to begin with lower level prescriptions that are a nuisance to practitioners. The logistics are still being worked on, such as what type of documentation, how to record it in patient’s charts, etc.

Board President, Penny Reher stated she was curious how this program will impact staff. Board Member, Christine Chute stated that we should look into video-based meetings to save money and Board Vice President, Rachael DeBarmore asked when would the board be able to review the applications. The board decided it was best to have general guidelines in place to make the process simpler for nominations. Marc stated that it’s in the early stages and we just aren’t sure yet how this will impact our staff or budget and Administrative Director, Karen MacLean will coordinate sending the applicants information to the board prior to October’s board meeting for review.

Pharmacy Technician Extension Requests

Licensing Program Supervisor, Chrisy Hennigan explained this was the first list of extensions since we shifted to a two-year Pharmacy Technician license. The Board will only be seeing these requests once a year.

MOTION
Motion to approve Pharmacy Technician Extension requests as revised was made and unanimously carried (Motion by Vipperman, seconded by Larson). Armstrong abstained

Drug Expiration Dates

Board President, Penny Reher spoke about concerns regarding drug expiration dates as well as the drug shortages for injectable types of drugs, in hospitals. A possible solution was to submit a resolution to NABP District 7 at the upcoming meeting for NABP to work with the FDA to extend expiration dates especially on drugs that are necessary to save a patient’s life in a code situation. Specifically asking the FDA to re-evaluate their drug expiration date processes while safely extending expiration dates.
Executive Director, Marc Watt stated that this is more of a national level issue and thought it would be best to propose this opportunity at the upcoming NABP meeting to a larger audience. There are too many risk management issues if states decided to dispense outdated drugs, it should fall on the FDA. Penny reported that Pfizer and the FDA did come to an agreement to extend dates on some drugs. Board Member, Roberto Linares stated that data exists from manufacturers that backs up the potency of certain expired drugs but wanted to know how this might impact inspections having expired medications and the label issue not matching the manufacturers.

Fred Meyer/PPS Request –

Pharmacist Consultant, Fiona Karbowicz reviewed Fred Meyer’s request to utilize an alternative pharmacist verification process, which she stated is currently being used in other states, but stating she couldn’t find any rules associated with it within those states. Board President, Penny Reher asked the board members if they have enough information today to make a decision, but the board felt that this request was a bit overwhelming and had concerns about which party is responsible if errors are made by this kind of technology. Fiona informed the board that this is the same machine currently used for mail-order and central fill. Board Member, Kate James stated she has concerns about how pharmacists will still interact with the patient and their ability to understand the patient’s needs, and that this proposal is asking the board to circumvent the final check rule. Board Member, Christine Chute stated that 14 other states are accepting this procedure. Penny asked board members what they need in order to make a motion? Board Member, Roberto Linares would like to see what happens to the personnel where they’ve replaced people with these machines and what are the future implications using automation outside of drug distribution. Executive Director, Marc Watt stated that in the right environment, this technology works, but in a different setting that perhaps isn’t so contained, it might not work such as a retail environment. Fiona will do more research and will reach out to Fred Meyer for additional data, especially errors made by a person vs. machine and perhaps ask them to provide additional information.

Rulemaking Hearing Report & Comments –

Project Manager, Mo Klein recapped the Rulemaking Hearing report regarding proposed rules for Dispensing Practitioner Drug Outlets and associated licensing fees and gave a brief summary that included, who attended and who testified, comments received both written and oral, individuals who voiced their support and those who opposed.

MOTION
Motion to accept Rulemaking Hearing Report was made and unanimously carried. (Motion by Chute, seconded by Armstrong).

Consider Adoption of Rules -

Division 043 – Dispensing Practitioner Drug Outlets & Division 110 – Fees

Pharmacist Consultant, Fiona Karbowicz reviewed revisions and the board approved. The fee will be waived until January 1, 2019 and will be noted on our application renewal form.
MOTION
Motion to adopt Dispensing Practitioner Drug Outlet rules in OAR Chapter 855-043-0505, 0515, 0520, 0525, 0530, 0535, 0540, 0545, 0550, 0555, 0560 was made and unanimously carried (Motion by James, seconded by Vipperman).

MOTION
Motion to adopt Dispensing Practitioner Drug Outlet fee rules in OAR Chapter 855-110-0007 as revised was made and unanimously carried (Motion by Armstrong, seconded by Larson).

Consider Adoption of Temporary Rules – None

Policy Issues for Discussion

Administrative Director, Karen MacLean spoke about the Division 010 draft rule revision regarding criminal background checks. This revised draft rule refers us back to legislatively mandated DAS rules and criteria and that all agencies were required to adopt uniform rules for criminal background checks.

Division 019 – Contraceptive Update

Pharmacist Consultant, Fiona Karbowicz spoke about 2017 HB 2527 regarding the addition of the vaginal ring and injectable contraceptives to the items a trained pharmacist can prescribe, dispense, and administer. The training module has been created and we will updating the outline for board review along with the updated forms. She mentioned that rules were revised to meet the statutory language with the potential to submit these to rulemaking in November, adopt in December and effective by January 1, 2018 per the legislation.

Paige Clark from OSU stated that they have had some interaction with physicians and reported that other states are already using the new training module and that the training is ready to be rolled out as soon as the board approves it. She mentioned that this program is auditable and able to provide data of who has taken and completed the training. She reported that pharmacists can take the training now, but not administer until Jan 1st, 2018 and that inspectors will see a 2nd certificate after pharmacists complete this module and that they are currently working on creating the additional certificate.

OSU will also send out a mass mailer notifying end users prior to administrating or prescribing to current certified pharmacists. Board staff will send out an email, perhaps a postcard if needed to communicate the 2nd training module. Fiona stated that she receives a monthly report from OSU that provides data of who has taken the training. Board Counsel, Tom Cowan stated that we could require or add some language to the rule that states “current” certification if needed.

MOTION
Motion to approve the Board approved updated ACPE accredited educational training program be released immediately. (Motion by Larson, seconded by Vipperman).
After some discussion regarding the concern that board members have not seen an outline of the training. The Board asked to have a special meeting to review and approve the training prior to the next scheduled board meeting. Board President, Penny Reher then called for a motion to withdraw the previous motion.

**MOTION**

Motion to withdraw previous motion to approve updated ACPE training program was made and unanimously carried. Motion by Larson, seconded by Vipperman).

---

**Division 019 & 041 – Naloxone Update**

Pharmacist Consultant, Fiona Karbowicz reviewed the revised draft rule language and stated that 2017 HB 3440 removed many facets of the OHA Naloxone training requirements, so now it’s more aligned with other states. Board Vice President, Rachael DeBarmore asked about a scenario such as care-givers picking it up, but the prescription as well as the insurance being used is for the end user. Executive Director, Marc Watt stated that the barriers have been removed by striking out all of this language and that the goal is to get Naloxone out to the public.

---

**Division 019 & 041 – Community Pharmacy Personnel / PIC**

Pharmacist Consultant, Fiona Karbowicz reviewed the draft revisions, which adds a new requirement that a “District Manager (DM)” must be an Oregon licensed pharmacist. She also stated that the PIC ‘empowerment’ language as well as ‘housekeeping’ updates were added to the PIC rule, but not meant to replace the PIC. Board Member, Christine Chute stated she would like simpler language that simply states “must be an Oregon licensed pharmacist” and nothing more because she is concerned we are dictating more responsibilities. Board Counsel, Tom Cowan stated that the goal is about empowering PIC’s and their position and we need to make it clear in the pharmacy world, which is difficult because not all organizations are structured the same way.

Board Vice President, Rachael DeBarmore stated that there is a gap in the position, because DMs can come from other states. Board President, Penny Reher commented that for health systems that cross state lines, she assumes the rules are silent and isn’t sure how large the gap might be and that the rule does not state a maximum number of PICs that can be supervised. Tom stated that we might want to come back with some examples staff have experienced out in the field for our October board meeting.

Fiona stated that the underlying issue is patient safety and we are trying to create a PIC that the board wants. A PIC that is evaluating is doing what we’ve asked them to do. If they follow these guidelines, it should increase the accountability of the outlet and we’ve tried to build this up to the reality of how the PIC functions day to day, knowing they aren’t able to authorize some of the things dictated by the outlet. Board Member, Shannon Larson stated that she liked the revisions and believes this will empower the PIC, while not putting extra tasks on the daily duties and believes it will help the PIC if they need to come to the board if the outlet isn’t acknowledging the issues. Rachael stated that we need to define the intent and it is necessary to educate; she is concerned about the unintended consequences. Tom stated that we tried to craft this around professional judgement and personal discretion.
Division 041 – Remote Distribution Facility

Pharmacist Consultant, Fiona Karbowicz reviewed the draft rule and discussed why we relocated this rule to attempt to provide clarity that RDFs are specific to institutional pharmacies only. Staff is receiving inquiries to allow remote supervision of technicians for unintended situations. The ‘preamble’ (lines 53-57) provides the intent, which had previously been ‘silent’.

Division 041 – Pharmacy Drug Delivery

Pharmacist Consultant, Fiona Karbowicz stated that staff constantly receive calls and emails about this rule. The draft revisions clarify the intent for depoting, the name is edited to reflect intent and allows a pharmacy to deliver to an alternative location designated by a single patient’s individual request. A patient may request delivery to their care provider’s office, etc. for the purpose of the drug to be administered. Waivers will be considered for specific scenarios only, such as for rural/frontier access. The issue is the larger scale of depoting, how far does the pharmacy extend. This draft rule also relates to the technology rules. The board had a lengthy discussion on where the drugs would be delivered and if the rule is too restrictive.

Policy Issues for Discussion

Interactive Dispensing Machines / Pharmacy Technology Rules

Pharmacist Consultant, Fiona Karbowicz reported that staff has been working on creating these complex rules in such a way as to best retain traditional pharmacy services, such as DUR, interactive/real-time audio-visual “face-to-face” counseling. “Interactive Dispensing Machine” or IDM is an Automated Pharmacy System affiliated with a resident primary pharmacy that holds completed prescriptions for patient pick-up or where a pharmacist uses remote technology to fill, label and dispense a completed prescription for patient pick-up.

Fiona asked if the board wants to limit or specifically address approval criteria for proximity to the primary pharmacy. Executive Director, Marc Watt suggested that they should be located within 10 miles of a pharmacy. Fiona also asked the board if they want to allow clinics to utilize IDM’s, which would give the pharmacy the flexibility to manage it. Fiona asked the board if it would be considered a conflict of interest for the pharmacy who owns the device, knowing that they could possibly want to only prescribe what drugs are in the device. Fiona stated that she sees these intersecting with the non-technology methods, one size doesn’t fit all like with the depot rule. We are looking to have solutions available that will work best for each scenario and we currently have a rule in effect for emergency room’s. The board members asked several questions and Fiona stated she will do more research and bring it back more data to the October board meeting.

Compounding Rules Policy Discussion

Pharmacist Consultant, Fiona Karbowicz spoke about compounding rules and the various approaches that are being considered, but due to the complexities, staff is doing additional research. Fiona stated that USP 800 continues to create a great deal of concern to the profession and asked the board if they would like staff to pursue additional language to address USP 800 or move it towards the jurisdiction of OSHA. Board Member, Kate James stated she believes that the FDA and OSHA should manage this. Board President, Penny Reher stated that
her health system has put together a team in advance knowing that this will be go into effect July 2018 and mentioned that she has also been asked if the board is going to give guidance on this in the future and what the expectations will be. Fiona mentioned that we are still waiting for the NABP/Utah BOP survey results and mentioned that she and Compliance Director, Brianne Efremoff will be attending the 6th Annual FDA 50-State meeting in September and will continue to gain insight.

Fiona then asked the Board if they want to consider requiring additional initial and/or ongoing CE for compounding and possibly just for sterile compounding for Pharmacists and Certified Technicians or would it be better to allow that to be handled via policies and procedures / training for compounding staff to remain current. Some states have built CE into their rules about this. Kate stated that there is all kinds of CE available and you have to have it all documented if you are following 797. Fiona then asked the board if they want to require all APIs (active pharmaceutical ingredients) to be listed as the drug name on the label. Kate and Penny stated that it’s so important that they know what’s in those products and it’s a disadvantage when they have to use an outside compounder. Fiona asked the board if they want to continue to allow Same Day Use, which extends the amount of time longer than what the FDA allows, which we have in place for rural use. She then asked the board if they want to require compounding errors to be reported to MedWatch and/or to the board. We’ve seen this language in other state’s rules and it is getting to be the standard especially if we move to accredited credentialing. Fiona will have more information in October.

OPEN FORUM –

Michael Mone’ with Cardinal Health and current Ohio Board of Pharmacy member spoke about 797 chapter 71 a USP standard and elements that are tied to nuclear pharmacy that extends BUD. Michael also commented that Cardinal Health bought MTM Outcomes. He suggested that our board may want to defines telepharmacy, which is included in the NABP Model Rules, which might help us determine some of the other aspects of the technology discussion held today.

Mark Currie from Asteris, commented that they are currently in 38 states and can provide us with language re: automation. Stated that they have their product placed all over the country. He suggested the board might invite companies to come in and have an automation presentation. Mentioned that they are now operating in Washington state.

Kyle Mulder with TSS who provides technical guidance around USP800 is in effect now.

Adjourn

MOTION
Motion to adjourn at 4:02PM was made and unanimously carried (Motion by James seconded by Armstrong).

Accepted by:

Marcus Watt,
Executive Director
Executive Session of the Board was held on Wednesday, Aug. 9, 2017 to discuss Compliance cases, followed by motions on Thursday, Aug. 10, 2017. Working lunch held.

Board Members present for all or part of compliance session:
- Penny Reher, RPH, President
- Rachael DeBarmore, RPH, Vice President
- Kate James, RPH
- Roberto Linares, RPH
- Shannon Larson, RPH
- Dianne Armstrong, CPT
- Cyndi Vipperman, CPT
- Christine Chute, Public Member
- Vacant position, Public Member

Staff present for all or part of compliance session:
- Brianne Efremoff, RPH, Compliance Director
- Joe Ball, RPH, Chief Investigator
- Katie Baldwin, RPH, Board Inspector
- Laura Elvers, RPH, Board Inspector
- Cheryl Fox, RPH, Board Inspector
- Jane Gin, RPH, Board Inspector
- Brian Murch, RPH, Board Inspector
- Marcus Watt, R.Ph., Executive Director
- Karen MacLean, Administrative Director
- Fiona Karbowicz, R.Ph., Pharmacist Consultant
- Chrissy Hennigan, Licensing Program Supervisor
- Annette Gearhart, Compliance Secretary
- Kim Oster, Compliance Assistant
- Thomas Cowan, Senior AAG

Board guests present for all of the compliance session:
- Mary Beth Baptista, Executive Director
- Tim Frost, Board Fellow
- Naturopathic Examiners Board

**Motion to grant T. Haywood technician license extension until 6/27/2018.**
Motion by: Kate James; Seconded by: Cyndi Vipperman. Motion carried with Dianne Armstrong opposed.

**Cases 2017-0146; 2017-0162  Motion to ratify signed Consent Orders.**
Motion by: Christine Chute; Seconded by: Shannon Larson. Motion unanimously carried.

**Case 2015-0542  Motion to grant request to reduce UAs to 12 annually.**
Motion by: Cyndi Vipperman; Seconded by: Dianne Armstrong. Motion unanimously carried.

**Case 2014-0202  Motion to grant request to discontinue testing.**
Motion by: Dianne Armstrong; Seconded by: Cyndi Vipperman. Motion unanimously carried.

**Case 2017-0259  Motion to grant pharmacist license.**
Motion by: Kate James; Seconded by: Christine Chute. Motion unanimously carried.
Cases 2016-0288 and 2016-0348  Motion to accept proposed Consent Orders.
Motion by: Dianne Armstrong; Seconded by: Christine Chute. Motion carried with Shannon Larson recused.

Case 2017-0255  Motion to issue Stipulated Consent Order with 5-year probation.
Motion by: Cyndi Vipperman; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2017-0238  Motion to ratify Stipulated Consent Order.
Motion by: Kate James; Seconded by: Dianne Armstrong. Motion carried with Roberto Linares recused.

Case 2017-0172  Motion to revoke technician license and impose $1,000 civil penalty per violation.
Motion by: Dianne Armstrong; Seconded by: Cyndi Vipperman. Motion unanimously carried.

Case 2017-0237  Motion to grant Intern license with Board direction.
Motion by: Christine Chute; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2017-0121  Motion to deny technician license and impose $1,000 civil penalty.
Motion by: Cyndi Vipperman; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2017-0184  Motion to grant intern license.
Motion by: Shannon Larson; Seconded by: Kate James. Motion unanimously carried.

Case 2017-0244  Motion to grant intern license with Board direction.
Motion by: Kate James; Seconded by: Christine Chute. Motion unanimously carried.

Case 2017-0143  Motion to close with Board direction.
Motion by: Dianne Armstrong; Seconded by: Cyndi Vipperman. Motion unanimously carried.

Case 2017-0197  Motion to impose $10,000 civil penalty against outlet.
Motion by: Christine Chute; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2017-0192  Motion to issue reprimand and impose $1,000 civil penalty per violation against pharmacist.
Motion by: Christine Chute; Seconded by: Shannon Larson. Motion unanimously carried.

Case 2017-0147  Motion to suspend technician license for 14 days and impose $1,000 civil penalty.
Motion by: Dianne Armstrong; Seconded by: Christine Chute. Motion carried with Cyndi Vipperman recused.

Case 2017-0234  Motion to impose $1,000 civil penalty per violation against pharmacist.
Motion by: Kate James; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2017-0142  Motion to close case with Board direction.
Motion by: Christine Chute; Seconded by: Cyndi Vipperman. Motion unanimously carried.
Case 2017-0144  Motion to close with Board direction.
Motion by: Cyndi Vipperman; Seconded by: Christine Chute. Motion unanimously carried.

Case 2017-0187  Motion to issue reprimand and impose $1,000 civil penalty per violation against pharmacist.
Motion by: Dianne Armstrong; Seconded by: Kate James. Motion unanimously carried.

Case 2017-0145  Motion to close with Board direction.
Motion by: Dianne Armstrong; Seconded by: Kate James. Motion unanimously carried.

Case 2017-0173  Motion to close with Board direction.
Motion by: Cyndi Vipperman; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2017-0206  Motion to close with Board direction.
Motion by: Christine Chute; Seconded by: Kate James. Motion unanimously carried.

Case 2017-0178  Motion to close case with Board direction.
Motion by: Dianne Armstrong; Seconded by: Kate James. Motion unanimously carried.

Case 2017-0179  Motion to close with Board direction.
Motion by: Kate James; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2017-0219  Motion to close with Board direction.
Motion by: Cyndi Vipperman; Seconded by: Christine Chute. Motion unanimously carried.

Case 2017-0174  Motion to close with Board direction.
Motion by: Dianne Armstrong; Seconded by: Shannon Larson. Motion unanimously carried.

Case 2017-0204  Motion to impose $1000 civil penalty per violation against Pharmacist; and close case with Board direction.
Motion by: Christine Chute; Seconded by: Cyndi Vipperman. Motion unanimously carried.

Case 2017-0182  Motion to close with Board direction.
Motion by: Kate James; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2017-0210  Motion to grant pharmacist license.
Motion by: Christine Chute; Seconded by: Shannon Larson. Motion unanimously carried.

Case 2017-0169; 2017-0212; 2017-0215  Motion to deny pharmacist license and impose $1,000 civil penalty per violation.
Case 2017-0096; 2017-0105; 2017-0170; 2017-0208; 2017-0211, 2017-0243  Motion to deny technician license and impose $1,000 civil penalty per violation.
Motion by: Kate James; Seconded by: Dianne Armstrong. Motion unanimously carried.
Cases 2017-0207, 2017-0222, 2017-0225 and 2017-0231  Motion to close with Board direction.
Motion by: Cyndi Vipperman; Seconded by: Christine Chute. Motion unanimously carried.

Motion to accept the items on the consent agenda with cases 2017-0207, 2017-0222, 2017-0225 and 2017-0231 pulled for discussion.
Motion by: Christine Chute; Seconded by: Dianne Armstrong. Motion unanimously carried.

Cases Closed with Board Direction: