BOARD MEETING MINUTES

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
December 11-12, 2019

The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

WEDNESDAY, DECEMBER 11, 2019

President, Cyndi Vipperman called the meeting to order at 8:34AM.

Roll Call
Cyndi Vipperman, President
Roberto Linares
Rachael DeBarmore
Wassim Ayoub
Public Member, Vacant

Shannon Beaman, Vice President
Dianne Armstrong
Tim Logan
Michelle Murray

The following staff members will be present for all or part of this session:
Joe Schnabel, Executive Director - excused
Briannne Efremoff, Compliance Director
Fiona Karbowicz, Pharmacist Consultant
Joe Ball, Chief Investigator
Laura Elvers, Inspector
Jane Gin, Inspector
Kim Oster, Compliance Coordinator
Tom Cowan, Sr. AAG, Board Counsel

Karen MacLean, Administrative Director
Chrsy Hennigan, Licensing Manager
Rachel Melvin, Operations Policy Analyst
Katie Baldwin, Inspector
Cheryl Fox, Inspector
Brian Murch, Inspector
Loretta Glenn, Management Secretary
Joanna Tucker Davis, Sr. AAG, Board Counsel

Agenda Review and Approval

MOTION
Motion to approve the agenda was made and unanimously carried (Motion by Ayoub, seconded by Beaman).

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

MOTION

Motion to enter Executive Session at 8:37AM was made and unanimously carried (Motion by Beaman, seconded by Ayoub).

Deliberation on Disciplinary Cases and Investigations
Contested Case Deliberation pursuant to ORS 192.690(1) – Not open to the public

MOTION
Motion to resume Open Session at 3:17PM was made and unanimously carried (Motion by Beaman, seconded by Armstrong).

The Board proceeded with some of the agenda items from Thursday’s agenda.

Approve Consent Agenda

• NAPLEX Scores – May 1, 2019 – August 31, 2019
• MPJE Scores – May 1, 2015 – August 31, 2019
• License/Registration Ratification September 25, 2019 – December 4, 2019
• Pharmacy Technician Extensions – none
• Board Minutes – October 2-3, 2019

MOTION
Motion to approve Consent Agenda was made and unanimously carried (Motion by Linares, seconded by Beaman).

Board Meeting Dates

• February 5-7, 2020* Portland (*3 day meeting)
• April 15-16, 2020 Portland
• June 17-18, 2020 Portland
• August 12-14, 2020* Portland (*3 day meeting)
• October 14-15, 2020 Portland
• November 18-19, 2020 TBA (Strategic Planning)
• December 16-17, 2020 Portland
• February 10-12, 2021* Portland (*3 day meeting)
• April 7-8, 2021 Portland
• June 9-10, 2021 Portland
• August 11-13, 2021* Portland (*3 day meeting)
• October 13-14, 2021 Portland
• November 3-4, 2021 TBA (Strategic Planning)
• December 8-9, 2021 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.)

• May 27, 2020
• November 24, 2020
• May 26, 2021
• November 23, 2021
Financial/Budget Report

Administrative Director Karen MacLean reported that documents provided include the final month expenses of the 2017-19 biennium that ends 12/31/19. Overall, we had more revenue than anticipated due to more new and renewed licenses than projected over 3 years ago; interest income, which is driven by the federal rates that went up and more miscellaneous revenue from laws and rules, paid verifications and list request production. Additionally, expenditures were approximately 7% ($498,515) under the Legislatively Adopted Budget. This resulted in a higher than anticipated ending balance of approximately 11.57 months. These numbers will be finalized by the end of the year. The September and October Financial Reports bring us current for the 2019-21 biennium, we are on track for expenditures as anticipated, with the largest non-payroll expenses in IT Professional services for the MLO upgrade as anticipated.

Oregon Opioid Tapering Guidelines

Executive Director Joe Schnabel advised that the Oregon Opioid Tapering Guidelines were developed by an OHA Task Force with the goal to reduce harms to patients associated with opioid use and promote patient-centered care.

- The goal of the Oregon Opioid Tapering Guidelines is to reduce harms to patients associated with opioid use and promote patient-centered care. The guidelines lay out general principles and best practices for opioid tapering, potential indications for and approaches to tapering, reasons for referral, and long-term support strategies.

- Emphasis that tapering may not be required in all patients, requires collaboration between patient and provider, and should be individualized when undertaken.

- Emphasizes:
  - using multidisciplinary approach, when possible
  - keeping up to date on advances in care
  - specific tapering plans should be individualized and collaborative

- Public testimony was considered and received at every meeting. The main concerns were that providers would interpret these guidelines as required and that patients would be tapered inappropriately. Many revisions were made to the document as a result of public input.

- Note: Endorsement will not be acknowledged on the document.

MOTION
Motion to endorse the Oregon Opioid Tapering Guideline was made and unanimously carried (Motion by Murray, seconded by Ayoub).

Adjourn

MOTION
Motion to adjourn at 3:36PM was made and unanimously carried (Motion by Beaman, seconded by Armstrong).
THURSDAY, DECEMBER 12, 2019

President, Cyndi Vipperman called the meeting to order at 8:30AM

Roll Call
Cyndi Vipperman, President                      Shannon Beaman, Vice President
Roberto Linares                                      Dianne Armstrong
Rachael DeBarmore                                    Tim Logan - excused
Wassim Ayoub                                          Michelle Murray
Public Member, Vacant

The following staff members will be present for all or part of this session:
Joe Schnabel, Executive Director                     Karen MacLean, Administrative Director
Brianne Efremoff, Compliance Director                Chrisy Hennigan, Licensing Manager
Fiona Karbowicz, Pharmacist Consultant               Rachel Melvin, Operations Policy Analyst
Joe Ball, Chief Investigator                        Katie Baldwin, Inspector
Laura Elvers, Inspector                              Cheryl Fox, Inspector
Jane Gin, Inspector                                   Brian Murch, Inspector
Kim Oster, Compliance Coordinator                    Loretta Glenn, Management Secretary
Tom Cowan, Sr. AAG – Board Counsel

Motions related to Disciplinary Action - see the end of this document

Safety Message from the Board

Board President Cyndi Vipperman stated that proper storage of drugs is a critical public safety issue. Due to consistent findings of noncompliance with drug storage rules, the Board articulated expectations:

- Licensees and registrants are aware that any drug stored outside of the manufacturer’s labeled storage is considered an excursion.
- Pharmacists must take appropriate action when an excursion occurs, including documentation of action taken.
- Pharmacists, PICs, and outlets must know their corresponding responsibilities when an excursion occurs and to know that all lines of accountability will be reviewed as part of case assessments.
- Outlets must have an appropriate alarm system in place to notify pharmacy staff when an excursion occurs or to prevent an excursion from occurring.
- Outlets must have temperature monitoring records available at the time of inspection, which means viewable when requested and PICs should anticipate review of these records on all inspections.

Acknowledge Tom Cowan Sr. Assistant Attorney General
Joe Schnabel acknowledged Tom Cowan, who has served as the Board’s Counsel for the past 15 years, with a plaque. He has consistently guided the Board on a path that has helped us protect the public while keeping us on a solid legal foundation. We would like thank Tom for his many years of dedicated and skillful service and wish him a happy and healthy retirement!
GENERAL ADMINISTRATION

Policy Discussion re: SB 9 Emergency Insulin Refill Prescribing

Pharmacist Consultant Fiona Karbowicz presented an overview of the laws/rules related to policy items in regards to SB 9 related to emergency refills of insulin and supplies. She summarized when the pharmacist may prescribe, including a list of provisions. She covered what constitutes “evidence” and asked the Board to provide additional direction for the training program and referrals, to help with outreach and the Board’s expectations. She provided several examples of “physical evidence” and scenarios to the Board, including situations that may “lack physical evidence”. She stated that the documentation by the pharmacist will be critical. The Board asked a few questions related to multiple refills and how it’s tracked and what if a patient isn’t present? The assessment visit needs to be documented and must be face to face, regardless if the patient is there.

Fiona stated that a pharmacist may use any method for documentation, including paper or electronic. Pharmacists must understand their legal prescribing authorities and documentation shall be enough to satisfy requirements of the regulations, and be available for the inspection or any complaint, and for a referral. If the patient isn’t in the pharmacy database, the pharmacist is expected to create a new patient record. Fiona reiterated that offering this service is voluntary. Fiona hopes that all pharmacists and pharmacies understand that the training, the rules and training program is now an option for prescribing in emergency situations. This isn’t meant to replace the patient’s healthcare processes, it’s an adjunct service for emergencies only and the pharmacist should counsel the patient with that understanding. Shannon Beaman stated that the pharmacist should understand that it doesn’t end with just filling and dispensing the prescription, they will need to go further and follow up with the patient and the physician; there is a level of pharmacist professionalism expected <by pharmacists participating in assessment and prescribing services>. Based on Board conversation, it is anticipated that insurers can utilize 3rd payer messaging to alert pharmacies/pharmacists when patients are receiving emergency refills of insulin at multiple pharmacies. Fiona stated that the information in the slides will be provided to be a part of the outreach/awareness, FAQs, and be included in the training program.

Rules

Review Rulemaking Hearing Report & Comments

Rachel Melvin, Rules Coordinator and Hearings Officer provided an overview of the Hearing Report.

- No public testimony at the hearing and minimal written comments received
- NABP and CVS provided comments on the Compounding rules
- NABP provided comments on the FPGECE and Military Spouse/Domestic Partner rules
- No written comments received on the remaining proposed rules

MOTION

Motion to accept the 11/26/19 Rulemaking Hearing Report was made and unanimously carried (Motion by Armstrong, seconded by Ayoub).

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Consider Adoption of Rules

**Division 006 & 045 – Drug Compounding and Definitions**

Pharmacist Consultant Fiona Karbowicz reviewed the proposed language revisions and the Board discussed the rules effective date and determined this rule’s effective date is upon filing.

Fiona reported that there are certain items, such as veterinary office use, definition of compounding, bulk/API, and any other items once new drafts of USP 795/797 are published, that have been bookmarked for future discussions. Additionally, she informed the Board that the December 2019 newsletter provides guidance to licensees about shared services.

The Board discussed USP 800 compliance expectations. Fiona asked the Board for insight related to USP 800 expectations regarding hazardous drugs related to storing, preparing, transporting and administering as well as identifying a “designated person who is qualified and trained to be responsible for policies and procedures, staff training, documented assessment of risk if performed related to hazardous drugs. The Board discussed issuance of a statement, encouraging compliance with USP 800 for public health and safety, and they expect to see people complying and working toward compliance.

**MOTION**

Motion to amend Definition rules in OAR 855-006-0005 and Compounding rules in OAR 855-045-0200, 0210, 0220, 0240 and 0270 and repeal rules in OAR 855-045-0230, 0250 and 0260 effective upon filing was made and unanimously carried (Motion by Linares, seconded by DeBarmore).

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**Division 010 – Military Spouse/Domestic Partner Temp. Auth.  SB 688/HB 3030**

Licensing Manager Chrisy Henrigan clarified that the rule effective date is 1/1/2020 and all of the requirements of reciprocity per ORS 689.265 are still required and the use of the NABP eLTP does not change. The authorization is being treated as a “designator” on a pharmacist license and does not circumvent the reciprocity process and all requirements for licensure.

**MOTION**

Motion to adopt Military Spouse/Domestic Partner Temporary Authorization rules in OAR 855-010-0130 effective January 1, 2020 was made and unanimously carried (Motion by Ayoub, seconded by Linares).

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**Division 019 & 031 – FPGE – SB 855**

Licensing Manager Chrisy Henrigan stated that the effective date of this rule is 1/1/2020 and that the NABP e-Profile Connect portal will be used to verify the certification as a primary source verification. It is current practice of the Board to verify the original certifications, for the highest assurance of authenticity.

**MOTION**

Motion to amend Foreign Pharmacy Graduate Examination Committee (FPGE) rules in OAR 855-019-0150 and OAR 855-031-0010 effective January 1, 2020 was made and unanimously carried (Motion by Beaman, seconded by Linares).
**Division 019 & 041 – Naloxone revisions – SB 910**

Pharmacist Consultant Fiona Karbowicz reviewed the proposed language revisions regarding Naloxone and stated that we would recommend making this rule effective date upon filing. She spoke about an OHA program poster that is available and was sent out via 1st-serve. She stated that staff identified the outdated 2006 position statement entitled Treatment and Management of Pain (mailing A8) that is no longer relevant and asked that the Board consider removing it.

**MOTION**

Motion to amend Naloxone rules in OAR 855-019-0460 and OAR 855-041-2340 and repeal OAR 855-019-0450, 0455 and 855-041-2300 effective upon filing was made and unanimously carried (Motion by DeBarmore, seconded by Linares).

**MOTION**

Motion to remove the outdated 2006 OBOP Position Statement was made and unanimously carried (Motion by DeBarmore, seconded by Ayoub).

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**Division 019 - Contraception Prescribing (age 18 law sunset) ORS 689.689**

Pharmacist Consultant Fiona Karbowicz reviewed the proposed language regarding the “sunset” of the age 18 requirement currently in law for contraceptive prescribing. Effective 1/1/2020, the age restriction in the contraceptive prescribing law is removed. This means that when a pharmacist is assessing a patient < 18, the pharmacist does not explicitly need evidence of a previous prescription from another practitioner. Pharmacists must use professional judgment.

**MOTION**

Motion to repeal Contraceptive Prescribing rule in OAR 855-019-0420 effective January 1, 2020 was made and unanimously carried (Motion by Beaman, seconded by Linares).

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**Division 080 – Controlled Substances – Animal Euthanasia - SB 71**

Pharmacist Consultant Fiona Karbowicz reviewed the proposed language revisions regarding animal euthanasia drug outlet requirements, which add sedatives and analgesic medications, and expectations, which go into effect on January 1, 2020. Michelle Murray asked if Inspectors will be inspecting these outlets and Brianne Efremoff confirmed that they will be inspecting in 2020 and have dual oversight with OVMEB, as well as with DEA. Staff resources will be utilized for outreach and for identifying concerns. It will be very important to collaborate with OVMEB and DEA when compliance issues are identified during inspections, as there are items from October meeting discussions, which are still pending: OVMEB plans to create a formulary of about 3 sedative/analgescic drugs that will be permitted – staff to keep OBOP in the loop about their rules & policies. Staff has asked for clarity from OVMEB about CET certification – staff to keep OBOP informed as more is understood. Further, there is concern of the limited disciplinary options in both OBOP and OVMEB regulations (per statute) – essentially, the authority provides only for the ability to suspend or revoke the outlet, which is not ideal if the people (CET, vet, manager, etc.) are responsible for compliance or diversion issues at the outlet.

**MOTION**

Motion to amend Animal Euthanasia Drug Outlet rules in OAR 855-080-0100 effective January 1, 2020 was made and unanimously carried (Motion by Murray, seconded by Ayoub).
Consider Adoption of Temporary Rules

Division 041 Prescription readers HB 2935

Pharmacist Consultant Fiona Karbowicz reviewed the proposed temporary rule language related to new legislation (HB 2935), which requires notification to all patients that accessibility services for visually impaired patients are available in the form of a prescription reader, a device to audibly convey labeling information; the law is operational on 1/1/2020. She described the context related to SB 698 with a different operative date of 1/1/2021. The rules are intended for all prescription drugs dispensed directly to patients and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies. Fiona stated that the law is on the books now and will be effective January 1st; the justification for the Board to issue a temporary rule is that the law directs the Board to write a rule, and it is a way to inspire licensee awareness of the new requirement. A temporary rule is effective for 180 days, which gives the Board opportunity to gather financial data from pharmacies to inform the law/rules fiscal impact.

At the Board's direction at the October meeting, a RAC invitation was sent out an invitation to stakeholders via listserve which will build the fiscal impact and collect insight from members of the group which will inform the rule. Interest letters are due by 12/20/19 with an anticipated meeting to be held on 1/22/20 with potential of a second meeting on 2/19/20 if warranted. Board President, Cyndi Vipperman asked the Board for a volunteer to join the RAC and Board Vice President, Shannon Beaman volunteered.

Both laws direct pharmacies to provide accessible labels to patients, focused on medication safety for vulnerable populations, such as visually impaired and limited English proficiency.

MOTION
Motion to adopt temporary rule in OAR 855-041-1131 effective January 1, 2020 was made and unanimously carried (Motion by Beaman, seconded by Armstrong).

Consider sending rules to Rulemaking Hearing – none

Public Health and Pharmacy Formulary Advisory Committee Update

Pharmacist Consultant Fiona Karbowicz gave a brief update on the last committee meeting held on 10/25/19 as well as reviewed their recommendations. She stated that the group worked and voted on Protocol 'packages' which include algorithms, that are being prepared by staff for first look at rules potentially in February 2020 for Tobacco Cessation, Travel medicines and PEP. The next meeting will be held on March 6, 2020.

Discussion Items
Policy Items for Discussion: Cultural Competency Continuing Education

Pharmacist Consultant Fiona Karbowicz provided a presentation about Cultural Competency CE (2019 HB 2011) and OBOP CE requirements. The Law is operative on July 1, 2021. The Board agreed that requirements to complete CE in the topic of cultural competency shall apply to pharmacists and pharmacy technicians, similar to other CE requirements, with completion attestation on license renewals. Staff to bring next steps for policy/rule development to February 2020 meeting, to continue the discussion. It is noted that these changes will prompt revisions to (or removal of) OBOP’s 2014 CCCE Position Statement OBOP CE.
OSU Emergency Insulin Refill Training Program Review

Pharmacist Consultant Fiona Karbowicz invited guests from OSU to the table, Paige Clark, Christine Heimrich and Sharon Rask and Lorinda Anderson (phone) to discuss the revised OSU Emergency Insulin Refill Training program. The 1-hour online program is aligned and oriented to the law’s specific directives, and includes a diabetes refresher. Staff is able to provide additional direction to the program, particularly related to the Board’s discussion earlier (see pg. 5) about evidence, professional judgment and use of the optional patient questionnaire/RPH algorithm.

Michelle Murray wanted to know if diabetes review module was ACPE approved. Paige stated that it currently is not ACPE approved, but it is robust and very informational for pharmacists. Roberto Linares had questions regarding the billing piece and how pharmacists receive payment. Paige stated that a pharmacist must follow certain processes to qualify for payment, of which the billing codes are being created and activated.

MOTION
Motion to approve the OSU Emergency Insulin Refill Training Program was made and unanimously carried (Motion by Beaman, seconded by Ayoub).

Waiver Requests

Request to schedule Clonazolam

Executive Director Joe Schnabel gave the Board some information regarding Clonazolam, which is a benzodiazepine sold as a designer drug online as "liquid benzos" and in counterfeit Xanax bars. According to the Oregon State Police (OSP) it has been seen in Possession of Controlled Substance cases 11 times, it has been in 2 deaths, and 3 DUII urines in Oregon in 2019 (first half). Rob Bovett (Association of Oregon Counties) and OSP have requested that non-FDA approved benzodiazepines be scheduled as C-i in Oregon. Virginia and Louisiana are the only states that currently have scheduled Clonazolam as a Schedule I. The lack of regulation allows for the product to be openly sold on the internet and easy to obtain in its various forms to include liquid, pellets/pills, blotters and powder.

The Board directed staff to draft rules for consideration.

Strategic Planning update

Administrative Director Karen MacLean provided information regarding the survey results in regards to the Board’s proposed “Values” and supporting values discussed during the Strategic Planning meeting. The list of values considered includes: Integrity, Quality, Safety, Accountability, Excellence and Professionalism. The Board discussed their survey results, the values list and supporting values that were identified to further the planning efforts. They decided to remove the value of “excellence” as it is duplicated in the supporting value of “quality”. There was additional discussion about the supporting values and staff will provide this to Pivotal to incorporate into the craft plan for the Board’s review.

<table>
<thead>
<tr>
<th>VALUES</th>
<th>SUPPORTING VALUES</th>
</tr>
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<tbody>
<tr>
<td>Integrity</td>
<td>Honesty, Ethics and Respect</td>
</tr>
<tr>
<td>Quality</td>
<td>Excellence, Value and Worth</td>
</tr>
<tr>
<td>Safety</td>
<td>Protection, Security and Care</td>
</tr>
<tr>
<td>Accountability</td>
<td>Trust, Responsibility and Transparency</td>
</tr>
<tr>
<td>Professionalism</td>
<td>Expertise, Commitment and Competence</td>
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MOTION
Motion to adopt the following values and supporting values for the Oregon Board of Pharmacy: Integrity, Quality, Safety, Accountability, Professionalism was made and unanimously carried (Motion by DeBarmore and seconded by Ayoub.)

Executive Director Joe Schnabel reported that staff and Pivotal have been working to prepare documents reflecting the Strategic Planning outcomes and next steps. Pivotal is working to articulate the five major priority areas that were identified during the planning meeting. Staff is beginning to discuss tactics to achieve outcomes in each goal area, which includes prioritizing, implementing, measuring, and reporting outcomes to the Board. Pivotal will provide a draft plan by early January for review, staff will present the strategic planning meeting minutes and the drafted plan at the Board's February meeting.

Staff are working to outline the Strategic Goal Areas:
- Drug Outlet Licensing
- Scope of Practice/Safe Practice/Roles and Responsibilities of Pharmacists & Technicians, and Technology Use in the Practice
- Rules Development/Review Philosophy and Strategy
- Global Approach to Communications and Engagement

There was discussion about the fifth goal area related to technology that was incorporated into the more global scope of practice goal area, along with technicians, as both assist a pharmacist in the practice of pharmacy. Staff will have specific tactics for each goal area and proposed timelines for Board review and comment.

CBD Update

Compliance Director Brianne Efremoff provided an informational update on cannabidiol (CBD) products and pending regulatory changes regarding their sale in Oregon. She stated that other states are also struggling with how to regulate the sale of CBD products especially in pharmacies. Inspectors have reported finding non FDA approved CBD products in pharmacies intended for dispensing and labeled by the manufacture as treating ailments or as a dietary supplement, this clearly is not permitted and these incidents have been reported to the FDA. Brianne stated that there is a lot of misinformation out there, including but not limited to who will regulate CBD and if marketing for human consumption is legal. Staff will continue to inform the Board and update our FAQs as more information is provided by other regulators, including the FDA, Oregon Department of Agriculture and the Oregon Department of Justice.

Drug Outlet Inspections

Compliance Director Brianne Efremoff briefly discussed drug outlet inspections and the importance of proactive regulation as a vital function the Board must take to fulfill its mission and purpose to protect the health safety and welfare of the public.

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ISSUES/ACTIVITIES

Reports

Board President Cyndi Vipperman thanked everyone who attended Strategic Planning meeting and reported that it was important that we achieve our goals. Shannon Beaman attended the NABP meeting in Boise, had interesting topics.

Executive Director Joe Schnabel reported that he is teaching OSU/OHSU Pharmacy Law course in 2020 for the last time this winter term.

Board Counsel, Tom Cowan reported that we have one additional case that may or may not be resolved before his retirement. He thanked the Board for the opportunity to practice the law in an area that really matters. He stated that staff really represent all of the “Values” discussed during the meeting.

Compliance Director, Brianne Efremoff reported on three main topics, important information from the 2019 NABP Compliance Officer and Counsel Meeting (Compliance Officer meeting), updates on the 2020 Self-Inspection Form, and priorities for the upcoming 2020 Inspection cycle. The Compliance Officer meeting highlighted that many states are struggling with the same issues we are including but not limited to drug theft, utilization of technology and technicians, unsafe workplace conditions, and regulatory oversight of pharmacist services including prescribing. The meeting discussions were insightful and she believes many topics should be further addressed in future Board Meeting policy discussions. For example, understanding standard of care, which can be a legal term of art, and the need to clearly articulate exceptions via rule to a pharmacist practicing. Also, how to incorporate a pharmacist’s expanded scope of practice into the inspection process to ensure that we are fulfilling the Board’s legal requirements to regulate both people and places. Updated 2020 Self-Inspection Forms will be available by the first week of January. This year the compounding questions are located on one separate Compounding Self-Inspection form. All pharmacies performing compounding will need to complete this inspection form in addition to their retail or hospital inspection form. As a reminder this is an open book test, please remember to pay extra attention to the areas that are bolded or underlined, these are areas we continually see noncompliance. Also, if a section includes the term “Note”, this section is referencing areas where we have seen cases and discipline. For the 2020 inspection cycle the compliance team will be focusing on full compliance with drug storage rules and controlled drug security and reconciliations. Please ensure that all processes are documented and maintained on site readily retrievable at the time of inspection. Staff will also focus on compounding and an mal euthanasia clinics this year.

Pharmacist Consultant, Fiona Karbowicz reported that she and other staff had the privilege to attend the Oregon Department of Justice Law Conference. Takeaways included ideas that staff can implement to improve internal agency processes, like P&Ps for responsibilities, and fresh ideas that can be incorporated into new staff/new Board member onboarding and ongoing training. She also provided an update from the most recent Immunization Policy Advisory Team (IPAT) meeting: we may see an increased focus and more public service announcements related to HepA vaccination; and the CDC’s Advisory Committee on Immunization Practices (ACIP) is updating recommendations and we expect changes to patient inclusion criteria for certain vaccinations, and more patients will need prescriptions from care providers for those vaccines requiring “shared clinical decision-making”. We expect more to come from the Oregon Immunization Program.

Administrative Director, Karen MacLean reported that she also attended the DOJ Public Law Conference and focused on sessions related to public meetings and public records as well as contracting. She reported that the Box project is not moving forward as the contract terms could not be met. Rachel worked hard on getting this set up and Karen had jumped in on a contracting issue that had to be addressed last year. We couldn’t come to an acceptable agreement that met the state’s needs, so we’ve parted ways on this project. We’re now moving to research other options.
The MLO upgrade project continues to move along. We have a number of outstanding issues that we continue to work through with System Automation. Overall, staff are successfully working in the new system. Some of the online processes are still in need of work. Chrisy will have more specifics to report. Again, thank you to Chrisy Hennigan and Kim Oster for all of their efforts on this project. We couldn’t have gotten it done without them.

The Office Manager recruitment has been completed. We anticipate a start date in early January 2020 for our new employee. Karen continues to work on Strategic Planning with Pivotal and the Leadership Team and is gearing up for the 2021-23 budget development that starts early next year.

Licensing Manager, Chrisy Hennigan reported that on 10/28/19 we went live with the new MyLicense Office or “MLO” upgrade and there have been some challenges but overall it has gone well. To date, we have successfully launched 8 online renewals and several license update processes. It was the hope to have implemented the new applications and license update capabilities, but conflicting priorities have slowed down the process. Chrisy and Kim Oster attended the System Automation annual user’s conference in November and were presented with the MyLicense Innovation award.

The Oregon Board of Pharmacy was recognized for the following accomplishments:

- Only agency to migrate from the outdated L2k system to the newly released version of the MyLicense Office 4.12 platform, which includes System Automation hosting our database in the cloud environment.
- Migrated the back office system to MLO and also configured and launched newest online processes and eVerification system all in the same rollout.
- Migration completed in 172 days from contract signing to implementation.

Nonprescription drug outlet renewals were mailed out mid-November. 19% of the renewals were completed at the time of this meeting. The charge in process has been difficult for some. We are using the lessons learned through this initial facility renewal to revise some of our language and create user guides to make it easier for future renewals. There are individuals who have expressed frustration with the new system for facilities. Online renewal has been optional in the past and all that was required was the renewal fee if they renewed by paper. The new system requires an individual to create an account and log in to verify annually that all information contained in the record is complete and accurate and attest to compliance with the Oregon Board of Pharmacy laws and rules for each facility renewal. With the new eGov system, the renewal fee is only one of the required elements for renewal and additional action is required.

An issue in the eVerification system was identified. In the conversion, disciplinary records that were imported into the MLO system attached to all parties related to a case, rather than just the party that received discipline. The vendor has been asked for a list to identify records that need attention. They are currently being addressed as identified and a staff member will be assigned to the task once the list is received. The 2017-2019 continuing education audit resulted in 556 pharmacists that were successfully audited through the use of the CPE monitor without any action required by those individuals. To date, 649 of the 713 or 91% of the pharmacists have passed the CE audit.

As of January 1, PTCB is implementing changes to their exam and eligibility requirements. The exam will be organized into 4 knowledge areas rather than the current nine and will focus on essential knowledge that applies across practice settings. The new requirements to take the exam, include either completing a PTCB-recognized education/training program or have completed at least 500 work hours and attest to fulfilling specified knowledge requirements. It will take a technician just over 3 months at 40 hours a week or just over 6 months at 20 hours. Since a technician license is issued for a period of at least one, but not to exceed two years, our tech license allows enough time to meet the 500 hour requirement. This is in contrast to NHA who requires completion of a training program (can be employer-based or offered by a national pharmacy association) or have completed at least 1200 hours of

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supervised pharmacy related work experience in the health field within any 1 year in the last 3 years. It will take a technician 7.5 months at 40 hours a week or 15 months at 20 hours a week to meet the hours requirement.

Operations Policy Analyst, Rachel Melvin reported that she has been working diligently with the leadership team on revising and organizing website content on the new website, due to the implementation of MLO and streamlining of processes. Anticipates a future launch date coming soon. She stated that she's been working on draft rules, logistics and creation for new RAC for HB 2935/SB 698, attended the DOJ public law conference with very informative breakouts related to rulemaking. She also stated that she is working on Continuity of Operations Plan, which has converted from a simple paper plan to a robust, software-based program called Boldplanning designed for state level emergency preparedness, which includes master plans for the agency with items such as delegation of authority, etc. She also reported that she is still performing as both the Office Manager and Operations Analyst and is looking forward to developing the new Office Manager who potentially starts in January.

Conferences/Meetings

PAST MEETINGS

NABP District VI-VIII Mtg. Boise, ID, 10/6-9/2019 - Executive Director, Joe Schnabel reported that the NABP/AACP District VI-VIII meeting was held at the Idaho State Capitol. The theme of the meeting was “Permissionless Innovation” and the keynote speaker was an author and Mercatus Center “scholar” whose thesis was that the “precautionary principal” stifles innovation and is unjustified. A few state boards of pharmacy appear to be adopting permissionless innovation (particularly in our District, VIII), while most do not appear to believe that model is in the public interest. Most presentations had a theme of expanding the pharmacists’ scope of practice and enhancing license mobility outside of the current NABP Electronic Licensure Transfer Program.

FDA 50 State Meeting – DC, 10/10-11/2019 – Compliance Director, Brianne Efremoff and Inspector, Cheryl Fox attended and will bring back some information in February.

OSHP Fall Seminar 11/16/19 – Portland (booth) – Executive Director, Joe Schnabel reported that Board of Pharmacy had an exhibitor’s table. Many pharmacists and students stopped to ask questions, but location appeared to reduce traffic on their side of the room.

NABP Compliance Officer/Legal Counsel Forum -12/4-5/2019 – Brianne Efremoff attended and shared information regarding this meeting in her Board report.

FUTURE MEETINGS
OSPA Lane Co. Mid-Winter CE Seminar – 2/15-16/2020 – Eugene – Schnabel/Karbowicz/Baldwin
NABP Board Member Forum – Jan 28-29, 2020, Chicago, IL – Vipperman

OPEN FORUM –
Adjourn

MOTION
Motion to adjourn at 2:48PM was made and unanimously carried (Motion by Beaman, seconded by Linares).

Minutes – December 11-12, 2019
Accepted by:

[Signature]
Joseph Schnabel, Pharm D., R.Ph
Executive Director
Executive Session of the Board will be held on Wednesday, December 11, 2019 to discuss Compliance cases, followed by motions on Thursday, December 12, 2019. Working lunch scheduled.

Board Members present for all or part of compliance session:
- Cyndi Vipperman, CPT, President
- Shannon Beaman, RPH, Vice President
- Dianne Armstrong, CPT
- Wassim Ayoub, RPH
- Rachael DeBarrmore, RPH
- Roberto Linares, RPH
- Tim Logan, Public Member
- Michelle Murray, RPH
- VACANT, Public Member

Board Members absent on December 12, 2019:
- Tim Logan, 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
- Kim Oster, Compliance Coordinator
- Joseph Schnabel, RPH, Executive Director
- Karen MacLean, Administrative Director
- Fiona Karbowicz, R.Ph., Pharmacist Consultant
- Chisby Hennigan, Licensing Manager
- Rachel Melvin, Operations Policy Analyst
- Thomas Cowan, Senior AAG
- Joanna Tucker Davis, Senior AAG

Cases 2018-0358, 2018-0667 & 2019-0397  Motion to accept Stipulated Consent Order, and in; Cases 2017-0361 & 2019-0164  Motion to accept Stipulated Consent Order.
Motion by: Wassim Ayoub; Seconded by: Shannon Beaman. Motion carried with Roberto Linares recused.

Case 2018-0367  Motion to grant request for modification of probation.
Motion by: Wassim Ayoub; Seconded by: Michelle Murray. Motion unanimously carried.

Case 2018-0426  Motion to grant request for modification of probation.
Motion by: Rachael DeBarrmore; Seconded by: Dianne Armstrong. Motion unanimously carried.

Cases 2018-0750 and 2018-0028  Motion to grant reconsideration of Final Order by Default.

Cases 2018-0750, 2019-0028, and 2019-0560  Motion to accept Stipulated Consent Order.
Motion by: Michelle Murray; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2018-0297  Motion to accept Stipulated Consent Order.
Motion by: Michelle Murray; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2018-0305  Motion to accept Consent Order.
Motion by: Rachael DeBarrmore; Seconded by: Shannon Beaman. Motion unanimously carried.
Case 2019-0376  Motion to impose $10,000 civil penalty per violation against outlet;
Case 2019-0570  Motion to revoke pharmacist license and impose a $1,000 civil penalty per violation;
Case 2019-0571  Motion to close with Board direction.
Motion by: Dianne Armstrong; Seconded by: Michelle Murray. Motion unanimously carried.

Case 2019-0549  Motion to impose $10,000 civil penalty per violation against outlet;
Case 2019-0724  Motion impose $1,000 civil penalty per violation against pharmacist; and close with Board direction.
Motion by: Rachael DeBarmore; Seconded by: Michelle Murray. Motion unanimously carried.

Case 2019-0287  Motion to impose $10,000 civil penalty per violation against outlet; and in
Case 2019-0673  Motion to impose $1,000 civil penalty per violation against PIC.
Motion by: Shannon Beaman; Seconded by: Michelle Murray. Motion unanimously carried.

Case 2019-0400  Motion to impose $10,000 civil penalty per violation against outlet; and in
Case 2019-0685  Motion to impose $1,000 civil penalty per violation against Pharmacist-in-Charge.
Motion by: Dianne Armstrong; Seconded by: Michelle Murray. Motion unanimously carried.

Case 2019-0276  Motion to impose $10,000 civil penalty per violation against outlet; and in
Case 2019-0678  Motion to impose $1,000 civil penalty per violation against PIC; and in
Case 2019-0679  Motion to impose $1,000 civil penalty per violation against pharmacist H.; and in
Case 2019-0680  Motion to impose $1,000 civil penalty per violation against pharmacist T.
Motion by: Shannon Beaman; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2019-0278  Motion to impose $10,000 civil penalty per violation against outlet; and in
Case 2019-0681  Motion to impose $1,000 civil penalty per violation against PIC; and in
Case 2019-0682  Motion to impose $1,000 civil penalty per violation against pharmacist.
Motion by: Dianne Armstrong; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2019-0557  Motion to impose $10,000 civil penalty per violation against outlet; and in
Case 2019-0686  Motion to impose $1,000 civil penalty per violation against Pharmacist-in-Charge.
Motion by: Michelle Murray; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2019-0587  Motion to revoke pharmacist license and impose $1,000 civil penalty per violation.
Motion by: Wassim Ayoub; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2019-0584  Motion to revoke technician license and impose $1,000 civil penalty per violation.
Motion by: Wassim Ayoub; Seconded by: Shannon Beaman. Motion unanimously carried.

Case 2018-0731  Motion to revoke technician license and impose $1,000 civil penalty per violation.
Motion by: Rachael DeBarmore; Seconded by: Michelle Murray. Motion unanimously carried.

Case 2019-0567  Motion to deny technician license and impose $1,000 civil penalty per violation.
Motion by: Dianne Armstrong; Seconded by: Shannon Beaman. Motion unanimously carried.

Case 2019-0627  Motion to deny intern license and impose $1,000 civil penalty per violation.
Motion by: Rachael DeBarmore; Seconded by: Michelle Murray. Motion unanimously carried.

Case 2019-0715  Motion to close with Board direction.
Motion by: Dianne Armstrong; Seconded by: Rachael DeBarmore. Motion carried with Roberto Linares and Wassim Ayoub recused.
Case 2019-0625  
Motion to deny technician license and impose a $1,000 civil penalty per violation.  
Motion by: Michelle Murray; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2019-0599  
Motion to close with Board direction.  
Motion by: Rachael DeBarmore; Seconded by: Michelle Murray. Motion unanimously carried.

Case 2019-0663  
Motion to grant technician license.  
Motion by: Rachael DeBarmore; Seconded by: Wassim Ayoub. Motion unanimously carried.

Case 2019-0630  
Motion to close with Board direction.  
Motion by: Wassim Ayoub; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2019-0628  
Motion to deny technician license and impose $1,000 civil penalty per violation.  
Motion by: Michelle Murray; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2019-0624  
Motion to close with Board direction.  
Motion by: Rachael DeBarmore; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2019-0389  
Motion to impose $1,000 civil penalty per violation against pharmacist; and in  
Case 2019-0721  
Motion to impose $1,000 civil penalty per violation against pharmacist.  
Motion by: Michelle Murray; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2019-0409  
Motion to impose $1,000 civil penalty per violation against pharmacist and close case  
with Board direction.  
Motion by: Michelle Murray; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2019-0572  
Motion to close with Board direction.  
Motion by: Rachael DeBarmore; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2019-0408  
Motion to revoke outlet registration and impose $10,000 civil penalty per violation.  
Motion by: Michelle Murray; Seconded by: Dianne Armstrong. Motion unanimously carried.

Case 2019-0427  
Motion to close with Board direction.  
Motion by: Shannon Beaman; Seconded by: Michelle Murray. Motion carried with Cyndi Vipperman recused.

Case 2019-0043  
Motion to close with Board direction.  
Motion by: Rachael DeBarmore; Seconded by: Shannon Beaman. Motion unanimously carried.

Case 2019-0640  
Motion to close with Board direction.  
Motion by: Michelle Murray; Seconded by: Wassim Ayoub. Motion unanimously carried.

Case 2019-0668  
Motion to close with Board direction.  
Motion by: Dianne Armstrong; Seconded by: Rachael DeBarmore. Motion unanimously carried.

Case 2019-0240  
Motion to close with Board direction.  
Motion by: Wassim Ayoub; Seconded by: Michelle Murray. Motion unanimously carried.

Case 2019-0550  
Motion to close with Board direction.  
Motion by: Shannon Beaman; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2019-0626  
Motion to grant pharmacist license and close with Board direction.  
Motion by: Michelle Murray; Seconded by: Shannon Beaman. Motion unanimously carried.
Case 2019-0410  Motion to impose $10,000 civil penalty per violation against outlet.
Motion by: Dianne Armstrong; Seconded by: Michelle Murray. Motion unanimously carried.

Cases 2019-0586, 2019-0597 and 2019-0598  Motion to deny technician license and impose $1,000 civil penalty per violation.
Case 2019-0603  Motion to close with Board direction.
Case 2019-0671  Motion to deny pharmacist license and impose $1,000 civil penalty per violation.
Motion by: Dianne Armstrong; Seconded by: Roberto Linares. Motion carried with Shannon Beaman recuse on Case 2019-0671.

Motion to accept the items on the consent agenda with Case 2019-0550 pulled for discussion.
Motion by: Rachael DeBarmore; Seconded by: Roberto Linares. Motion unanimously carried.

Cases Closed with Board Direction: