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.

MONDAY, JANUARY 9, 2017

Kate James, R.Ph, Board President called the meeting to order at 10:09am.

Roll Call
The following Board Members were present in person or via telephone:
Kate James, President     Penny Reher, Vice President
Christine Chute     Roberto Linares
Rachael DeBarmore     Ken Wells
Cyndi Vipperman     Heather Anderson
Dianne Armstrong

The following staff members will be present for all or part of this session:
Marc Watt, Executive Director   Gary Miner, Outgoing Compliance Director
Karen MacLean, Administrative Director  Brianne Efremoff, Incoming Compliance Director
Mo Klein, Project Manager  Chrisy Hennigan, Licensing Department Supervisor
Fiona Karbowicz, Pharmacist Consultant  Joe Ball, Chief Investigator
Cheryl Fox, Inspector  Victoria Wallace, Inspector
Katie Baldwin, Inspector  Laura Elvers, Inspector
Rachel Melvin, Executive Support Specialist

Agenda Review and Approval

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

GENERAL ADMINISTRATION

Rules
Review Rulemaking Hearing Report & Comments - Administrative Director Karen MacLean commented that the report was given at the December 7, 2016 meeting; however, because we carried over the remainder of the rules for consideration today, she gave the
mailing to the Board as a reminder for the rest of the rules.

Consider Adoption of Temporary Rules – None

Consider Rules and send Rulemaking Hearing – None

Consider Adoption of Rules

**Division 007 & 041 - Drug Room**
Pharmacist Consultant, Fiona Karbowicz reviewed the rule language and each definition for the Division 007 & 041 Drug Room rules. Compliance Director, Gary Miner spoke about why Drug Rooms are registered, and provided some examples, such as a fire station, which stores some drugs, but does not have a pharmacist on site. He mentioned that the world has changed and we need to have options for flexibility within this category. Board Member, Christine Chute asked for clarification about the different Drug Rooms. Fiona said this rule encompasses everything we currently consider acceptable for a Drug Room, this includes rooms are where drugs are, but there may not be a pharmacist present. Today, we have other types of drug supplies that need to be licensed and in compliance in order to maintain proper drug storage.

**MOTION**
Motion to permanently amend and adopt rules in OAR Chapter 855 Division 007 as noticed was made and unanimously carried (Motion by Wells, seconded by Reher).

**MOTION**
Motion to permanently amend and adopt Drug Room rules in OAR Chapter 855 Division 041 Sections 1001, 1036 and 5005 as noticed was made and unanimously carried (Motion by Wells, seconded by Armstrong).

**Division 019 - Volunteer Limited Liability**
Pharmacist Consultant, Fiona Karbowicz defined the proposed rule amendment language for Division 019 pertaining to laws related to limited liability for pharmacist volunteers. The rule states that pharmacists may claim the state liability limitation upon registration with Oregon Board of Pharmacy. She also mentioned that the new form will be available on Board’s website.

**MOTION**
Motion to permanently adopt Liability Limitations for Volunteers rules in OAR Chapter 855 Division 019 Section 0123 as noticed was made and unanimously carried (Motion by Anderson, seconded by Wells).
Division 041 – Outlet Notification Requirement
Pharmacist Consultant, Fiona Karbowicz presented the outlet revisions. Administrative Director, Karen MacLean mentioned that there were two comments received, one from NACDS (National Association of Chain Drug Stores) and CVS asked for clarification of this rule and NACDS provided recommended language in their written comments. Board members discussed this rule, the merits of it, benefits for the Board, staff, employers, consistency of reporting this information etc. There was some thought that the language needed more definition, others thought it was asking for too much. This is required statutorily for technicians and staff thinks this will be helpful going forward for consistency, case development and the existing health care professional reporting requirements. Roberto Linares is concerned that this will generate more workload for the Board staff and employers, but Marc and Gary reiterated that this happens currently for technicians and we receive some notices about pharmacists, but not all, and this would make it consistent. Heather Anderson said this is good for both employer and for the Board, it’s freeing the employer up from the value judgement of what to report or not. Board Counsel, Tom Cowan stated that employers are trying to separate themselves in certain cases and that there is a tremendous amount of under reporting that occurs today.

MOTION
Motion to permanently amend Outlet Personnel Requirement rules in OAR Chapter 855 Division 041 Section 1010 as noticed was made and carried (Motion by DeBarmore, seconded by Anderson). Linares opposed.

Division 041 & 080 - Drug Take Back
Pharmacist Consultant, Fiona Karbowicz reviewed the DEA’s rule for Drug Take Back and explained that we get a fair number of calls regarding the Board’s expectations and or recommendations on this topic, because we have been silent in our rules. We hope that these rules will address the inquiries related to drug take back processes and perhaps empower pharmacy outlets to provide take back services.

MOTION
Motion to permanently amend Drug Take Back rules in OAR Chapter 855 Division 041 Section 1045 and 1046 as noticed was made and unanimously carried (Motion by Anderson, seconded by Wells).

MOTION
Motion to permanently amend Drug Take Back rules in OAR Chapter 855 Division 080 Section 0105 as noticed was made and unanimously carried (Motion by Wells, seconded by Anderson).

Division 041 - Remote Dispensing Machines
Pharmacist Consultant, Fiona Karbowicz reminded the Board that staff receives occasional requests for alternative technology that is outside the original intent of this rule. These changes will allow for new technology in long term care facilities and appropriate dispensing by a Registered Nurse when a pharmacist is not onsite.
MOTION
Motion to permanently amend Remote Dispensing Machine rules in OAR Chapter 855 Division 041 Section 4100 and 4120 as noticed was made and unanimously carried (Motion by DeBarmore, seconded by Armstrong).

Division 043 and Division 110 – Dispensing Practitioner Drug Outlets
Pharmacist Consultant, Fiona Karbowicz stated that we received multiple public comments regarding Dispensing Practitioner Drug Outlets (DPDO) and the fee rule was omitted during the original rulemaking review and notice. It is included in this draft. Staff will make the request to DAS for approval of this additional fee. The current draft incorporates some of the considerations submitted by the public to make the rules clearer including removing the requirement for the product identification label, references to traditional vs non traditional dispensing, etc. The Product Identification Label is a requirement for pharmacies, but this is not something that is required within the scope of practice for a practitioner who dispenses, nor would they have software that contains this information to produce a label. Ultimately, the goal is to register the larger scale dispensers.

Board Member, Christine Chute wanted to know why “homeopathic” language was included with natural thyroid in the same sentence. Fiona edited the language and added a separate line for it. Compliance Director, Gary Miner reminded the Board that the language used to develop this rule, comes from a hospital rule, with the understanding that the idea is for short-term dispensing. Board Counsel, Tom Cowan stated that most practitioners would structure their practice around the idea that these are just for circumstances to get the patient started and then have the prescription filled at a pharmacy for the remainder of the medication. Board Member, Ken Wells stated that he is concerned about not having a unique identifier on the label for patient safety purposes.

The Board discussed the timing of the next rulemaking hearing on this topic and decided to send to rulemaking sooner than later. Administrative Director, Karen MacLean will identify a hearing date for public input prior to the April Board meeting and get the Notice filed.

There was some additional discussion about how this is affecting patients without their knowledge and the merits of why these rules are needed to allow for inspections where larger scale dispensing occurs. It was pointed out that there are increased dispensing options being marketed to practitioners with the focus on convenience and onsite prescription dispensing; these are without appropriate regulatory oversight and consideration of the complete patient medication record and drug utilization review that a pharmacist regularly conducts for new prescriptions. Heather Anderson stated that it is our job to manage the risk; is it being stored properly, how it’s acquired, is it expired, etc. Board Counsel, Tom Cowan stated that the world of dispensing has changed radically in the last 5 yrs. It’s a sophisticated process on how it’s supplied and the access to drugs. Cyndi Vipperman stated, “What would the public think if they knew drugs came from places that weren’t approved and in order to keep people safe, they need to be stored properly and dispensed correctly. Christine asked if we are confident that this is such a problem that we need these rules. Marc gave an example of how expired vaccines were administered and had to be re-administered once the error was found, this was a serious patient safety issue.

MOTION
Motion to send Dispensing Practitioner Drug Outlet rules in OAR Chapter 855-043-0505, 0515, 0520, 0525, 0530, 0535, 0540, 0545, 0550, 0555, 0560 to rulemaking hearing as revised was made and unanimously carried (Motion by Wells, seconded by Anderson).
MOTION
Motion to send Dispensing Practitioner Drug Outlet fee rules in OAR Chapter 855-110-0007 to rulemaking hearing was made and unanimously carried (Motion by Anderson, seconded by Armstrong).

Division 044 - Charitable Pharmacy Donations/Distribution
Fiona Karbowicz, gave an update on 2016 SB1514 and answered the question “why no REMS? She stated that charitable pharmacies are not required to have a pharmacist on staff at all times. Marc Watt stated that even if they do have a pharmacist, they might not be trained on REMS drugs. He mentioned that we need this to be an Oregon program for Oregon licensed pharmacies. We aren’t sure how to manage which drugs are coming from and where and if they are or aren’t licensed in Oregon. It matters if it has been distributed from another state to be repackaged.

MOTION
Motion to permanently amend Charitable Pharmacy rules in OAR Chapter 855 Division 044 Sections 0001 and 0030 as noticed was made and unanimously carried (Motion by Wells, seconded by Armstrong).

Policy Issues for Discussion
Compliance Director, Gary Miner defined Depot as a storage and transfer location. He gave an example of how rural cities in Eastern Oregon use it because of how remote their locations are and they regularly do not have common drugs readily available. The original intent for this rule was for emergencies when someone just cannot make it to the pharmacy in very rural areas of the state and to allow for a transfer. Gary encouraged the Board to look at policy decisions, for example, in California, kiosks are allowed. ORS 689.527 prohibits the use of automatic vending machines except as approved by rule adopted by the Board. Ken Wells stated that the purpose was not to open the doors wide open. Gary recommends better definition of use as there is a growing concern that the intent of the depot rules are being interpreted too broadly. Penny Reher asked for recommendations regarding new technology driven solutions.

Discussion Items
Waiver Requests
Lane County Health Department Waiver Request
Fiona Karbowicz explained Lane County Health Dept. is requesting a waiver of the security section to allow unlicensed personnel to handle the full storage and distribution functions of vaccines inventory management. Staff thinks that this request is outside the scope of delegation and reached out to the Board of Nursing to see if they have “best practices” established. Fiona mentioned that they are in the process of doing their due diligence on their end and will circle back with Board and will bring back to Board when they get an answer.
Oregon State Hospital

Compliance Director, Gary Miner and Pharmacist Consultant Fiona Karbowicz, provided an overview of the TCVP 1 year report submitted by Oregon State Hospital (OSH). OSH received Board approval to implement TCVP in June 2015 and provided their report for the Board to review in the fall of 2016. There was no additional discussion.

MOTION
Motion to accept Oregon State Hospitals TCVP 1 year report, report back in five years was made and unanimously carried. (Motion by Wells, seconded by Chute).

Workplace Survey update

Executive Director Marc Watt and Compliance Director Gary Miner gave a PowerPoint presentation on the workplace survey results. Top issues continue to be staffing matrix, technicians pushing pharmacists, the public pushing for speed, pharmacists’ pressure to do a good job and the need for someone to be able to make changes to staffing. Marc stated that things were better prior to this survey, but have since turned negative. Board Member Ken Wells stated that he thought it was interesting that the District Managers (DM’s) who responded, reported super positively compared to the other categories. Administrative Director, Karen MacLean suggested we post results to OBOP website. Marc asked if all Board Members had read the article from the Chicago Tribune that he had forwarded; he had spoken with the author of the article, who stated that work overload for the pharmacist was a contributing factor to the failure rate for errors. Given the ongoing similar issues in Oregon, he proposed establishing a required position in each pharmacy called a Pharmacy Safety Officer (PSO). The PSO can be a PIC, RPM, DM, etc. to have someone we could go to if needed.

Gary Miner then expanded on this concept as a spin-off from what the Board did with hospitals, which fits more of an operations approach by requiring a Chief Pharmacy Officer that requires an OR licensed Pharmacist. This is important, because we have seen some issues with non-pharmacist DM’s in the retail setting. The CPPA (Center for Pharmacy Practice Accreditation) standards were mandatory in hospital. Gary sees this going in the same direction for retail pharmacies. Some type of accreditation review will help verify that pharmacies are complying with an approved set of standards such as practice management, patient care services and quality improvement to demonstrate positive outcomes. For example, should pharmacies incorporate intentional breaks, i.e. require a 30-minute anti-fatigue / lunch break. Poison is in all drugs, and the Board’s focus should be, was the drug being given safely; was there deliberate care to ensure that what’s being dispensed to a patient, is accurate and correct for that individual patient, that a complete drug utilization review has been completed, that the patient has received thorough counseling on that new prescription etc. The pharmacy focus is on documenting that counseling is done, rather than proving the pharmacist did the counseling. Gary suggested the Board might want to look at reverse ratios to mandate staffing levels, i.e. at least two people at all times, one of those a pharmacist. Ultimately, you have to get to someone who can make change in the organization.

The Board had an extensive discussion about this proposal. Comments and questions included, we have PIC’s, could we add this as a requirement instead of creating a new role. Most PIC’s have no power to effect change. PIC’s have all of the responsibility, but no ability to adopt change. Why a person not an outlet? What about interjecting language into the outlet license, with something like “they have to outline the changes in the workplace environment”? Managers are only given so much FTE
regardless if it is a chain or not. Other states have pharmacist to pharmacist technician ratio requirements, look at their models. Retail corporate job performance is different from hospitals', not off DUR checks, counseling, etc.; retail wants x number of immunizations, but pharmacists do not have the time to do the shots. A PSO would ensure the staffing ratio works for patient safety. Putting a PSO is a conflict with PIC. The PIC is too busy and overworked to take on this additional responsibility. It should be a decision maker and that's not always the PIC. What if there aren’t people who want to take those jobs? Pharmacists get pressure from corporate, technicians and the public; this would give the PSO the ability to relieve some of this pressure.

Board Counsel Tom Cowan asked if the issue is simply a reduction in errors or is it that the working environment day to day is prone to errors or good practice. He advises we need to identify and carefully frame what we are trying to accomplish. Is it the environment or is it something else; we need to clarify what this question is.

President Kate James polled the Board for what they would like to do next. They decided to focus on the Pharmacy Safety Officer (PSO) evaluation and staff will work to gather information and develop a solution for the Board to consider.

**Auto-refill update**

Pharmacist Consultant Fiona Karbowicz spoke about the edits and clarified the rule revisions from meeting on 1/3/17. Board Member Christine Chute said this will not impact mail order. Board Member Ken Wells wanted clarification on the strength, same medication, and dose. Board Member Heather Anderson thinks we should add language that states if it’s a continuation of therapy, if it is revised in dosing or strength it needs to be added in as a new auto-refill script. President, Kate James stated that she did not like the “controlled substances” on auto refill, nor does Board Member Cyndi Vipperman. The Board asked to remove controlled substances language and will send it out for comment and circle back to it later. Staff will edit draft rules for further consideration at the February Board meeting.

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**Credentialing Issues**

Executive Director Marc Watt spoke about the increased amount of requests we are receiving regarding “credentialing” and disciplinary records availability, especially for prescribing pharmacists. Ideally, pharmacists should be able to bill and be paid for services, this is a changing landscape. Fiona will be reaching out to the people coordinating credentialing at OHA. We do not understand this entirely and are continuing to learn.

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**Compounding Update**

Fiona Karbowicz gave highlights of how other states have increased CE requirements. Working with the FSMB (Federation of State Medical Boards) to address physician compounding (ambulatory surgery centers, chiropractic, cancer, cosmetic surgery, orthopedic, pain, radiology, rheumatology and urology) NABP is talking about this as well. Gary Miner said we need to look at shared service contracts, batch sizes possibly built into the rules, defining what is manufacturing vs compounding.
Multnomah County Health Department prescription pain pill campaign survey request

Executive Director Marc Watt presented a request from Multnomah County Health Department to utilize OBOP’s list serve to send out a pain pill campaign survey request. The Board denied this request.

Marc asked if the Board would delegate approval to Board President/Vice President related to list serve use to avoid delays in communication in between Board Meetings. Board members agreed this was acceptable as long as it’s related to public safety and requested to receive a report of use at the next meeting.

MOTION
Motion to authorize Board President and Vice President to review and approve requests for use of agency list serve to avoid delays was made and unanimously carried. (Motion by Wells, seconded by Reher).

ISSUES/ACTIVITIES

Reports:
Board President/Members – Christine gave an update on the Governor’s DUII meeting she attends for the Board. There will be another bill this session on impairing substances. Oregon had seen a decline in the past ten years, however that was lost in the last two years and there has been an increase in fatalities. Dianne attended a conference presented by OHSP for Pharmacy Technicians. Kate attended the Board Member Forum meeting at NABP in December, the takeaways were pretty much everything we are working on such as the Technician job description.

Executive Director Marc Watt stated that he attended an Opiate Summit in Coos Bay where the topics included the opiate epidemic and how Southern Oregon is dealing with this issue. Marc spoke about the meningococcal situation in November at OSU and how we worked closely with other agencies during the outbreak. The Pacific University Fellowship program is moving forward and staff will be meeting with candidates soon and he mentioned that this is the first program like it in the country. Inspector interviews to fill Brianne Efremoff’s vacancy are under way and that he hopes to have that position filled soon.

Board Counsel –

Gary Miner, Outgoing Compliance Director congratulated new Compliance Director Brianne Efremoff on her promotion and thanked all staff and Board, as well as Federal and State agencies that assisted to help us adopt all of the rules that were introduced during his tenure. He presented a timeline of his career with OBOP and the areas of improvement when he took the helm such as improving relationships and communications with licensees and categorizing rules to make them easier for licensees to understand. He presented his accomplishments in the areas of compliance through education and teaching and outreach. He pointed out the new rules that were introduced during his time and his final thoughts about solutions we might consider in the future.

Pharmacist Consultant Fiona Karbowicz stated that the Birth Control Consultative Committee are reviewing the updated forms. Fiona reported she’ll be traveling to Roseburg to do outreach about Naloxone.

Administrative Director Karen MacLean provided some information regarding the new format for the
Annual Performance Progress Report we complete for the legislature. We are required to submit this annually and they have changed the reporting program and some of the data capture information. The newest report is on the website. Karen’s also been focused on preparing materials for the Board’s budget presentation.

Licensing Program Supervisor Chrisy Hennigan reported Licensing has completed part 1 of the Certified Pharmacy Technician audit where 517 people were part of the audit selection. There was a response rate of 97%, and of that, 88% or 440 people completed CE within the correct timeframe. Sixty licensees either did not complete all 10 hours, or completed it outside of the 9/1/15 – 8/31/16 timeframe, 14 licensees failed to respond to the audit notice. Chrisy and Executive Support Specialist Rachel Melvin attended the System Automation Annual Users Conference in Baltimore. It was a good introduction to the new license interface upgrade. Licensing Representative updates: Devin Emerson’s last day with OBOP was December 30th, Jennifer Hummel has taken over the Technician licensing and Rene’ Sanders has taken over the Non-Prescription Drug Outlets. We have interviews scheduled for January 25 and 26 and have five candidates for our vacant position. The pharmacy renewal notices will be going out this week. We have updated the forms this year and a big change for the required Supplemental Information forms is that we are no longer requiring the PIC’s to sign the form. We are also putting the Retail & Institutional renewals online; all others will continue to be paper renewals. Licensing hopes that these changes will really streamline the renewal process. Effective 11/1/16, the NAPLEX exam questions increased from 185 to 250 questions. The testing time allowed also changed from 4 hours to 6 hours. We are in discussions with NABP regarding a change in how we certify eligibility to take the NAPLEX and the MPJE exams. Currently, our staff certifies eligibility to NABP. Colorado and Utah have already changed their model and tasked the process of certifying eligibility to NABP. We believe that if we also change to this model, it will definitely streamline the process for both the Board staff and applicants for Pharmacist licensure. We are hoping to have the new process in place for the 2017 graduates.

Project Manager - None

### Board Member/Staff Presentations

- Pharmacy Coalition – 10/18/16, 12/13/16, 2/7/17 (no January meeting)
- Professional Practice Roundtable – 11/10/16, 1/17/17
- Health System Outreach Meeting – none

### Committees/Meetings

OSPA Annual Mtg. 10/21-23, 2016, Clackamas, OR – Fiona talked about the Coalition legislation that may affect Pharmacy and she and Bri did a panel discussion on birth control.

OSHP Mtg. 11/5/2016, Portland, OR – Victoria Wallace attended this meeting.

OBOP/OSU, 1/17/17 – video conference program re: PIC Self-Inspection Form, Fiona and Bri to present.

OSPA Lane Co. Mid-Winter Mtg. 2/18-19/2017, Eugene, OR – Fiona and Ken Wells to present.

NABP Annual Mtg. 5/20-23/2017, Orlando, FL – The Board discussed who and how many people
should attend this year’s annual meeting; we need a voting delegate and back up, it needs to be the Executive Director or a Board Member. NABP has a Travel Grant available for the voting delegate, Karen will apply as soon as possible to meet deadline.

**MOTION**
Motion to send incoming President Penny Reher as the Oregon voting delegate to the 2017 NABP Annual Meeting or Executive Director Marc Watt as alternate voting delegate was made and unanimously carried. (Motion by DeBarmore, seconded by Wells).

**Board Meeting Dates**
- February 8-9, 2017  Portland
- April 5-6, 2017  Portland
- June 7-8, 2017  Portland
- August 9-11, 2017*  Portland  (*3-day meeting)
- October 11-12, 2017  Portland
- November 8-9, 2017  TBA  (Strategic Planning)
- December 13-14, 2017  Portland
- February 7-9, 2018
- April 4-5, 2018
- June 6-7, 2018
- August 8-10, 2018
- October 3-4, 2018
- November 7-8, 2018
- December 12-13, 2018

**Rulemaking Hearing Dates**
- May 25, 2017
- November 28, 2017
- May 23, 2018
- November 27, 2018

**Financial/Budget Report**
Administrative Director Karen MacLean stated that the Board of Pharmacy is in a good position; agency spending continues to be under on expenses; likely to exceed revenue expectations due to unanticipated and an indeterminate number of new licenses. Our budget appeal was approved and we are moving toward the Governor’s Recommended Budget for session. There is not a current plan for fund sweeps, but that could change.

**Legislative Update**
Executive Director Marc Watt stated, there are two bills that may affect the agency. A drug take-back program where OBOP would have to work with DEQ and with manufacturers, but we will not have to manage the take back program on our own. Second, the Pharmacy coalition has a formulary bill they are submitting. We will have more information after Session starts in February.

**Strategic Planning**
Update given by Administrative Director Karen MacLean where she mentioned that not all parties have the opportunity to review the facilitator’s report yet, hope to have an update in February.
Approve Consent Agenda*

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

1. NAPLEX Scores – May 1 – Aug 31, 2016
2. MPJE Scores – May 1 – Aug 31, 2016
3. License/Registration Ratification – October 5, 2016 – December 6, 2016
4. Extension Requests – none
5. Approval of Board Meeting Minutes – August 10-12, 2016
6. Approval of Board Meeting Minutes – October 5-6, 2016
7. Approval of Board Meeting Minutes – December 7, 2016

MOTION
Motion to accept Consent Agenda was made and unanimously carried. (Motion by Reher, seconded by Chute).

OPEN FORUM - At the completion of regular Board Business, any Board licensee or member of the public is invited to meet with the Board to discuss issues of interest (typically the last item of the meeting)

Jacob Thompson, Regulatory Pharmacy Director for Providence has a vision to simplify health for everyone. He submitted formal requests to OBOP for Drug Depot and explained that their patients have sent complaints and concerns.

Paige Clark from OSU stated that they have 200 plus pharmacists credentialed for birth control.

Adjourn

MOTION
Motion to adjourn at 4:15PM was made and unanimously carried. (Motion by Wells, seconded by Reher).

Accepted by:

[Signature]

Marcus Watt, R.Ph.
Executive Director