

BOARD MEETING MINUTES

**Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
December 2-3, 2014**

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.

TUESDAY, DECEMBER 2, 2014

Ken Wells, R.Ph. Board President, called the meeting to order at 8:30AM.

Ken Wells, President
Christine Chute
Brad Fujisaki
Kate James

Roberto Linares, Vice President
Penny Reher
Heather Anderson

The following staff members will be present for all or part of this session:

Marc Watt, Executive Director
Chrisy Hennigan, Office Manager
Fiona Karbowicz, Pharmacist Consultant
Michele Cale, Inspector
Laura Elvers, Inspector
Annette Gearhart, Compliance Secretary

Gary Miner, Compliance Director
Joe Ball, Chief Investigator
Gregg Hyman, Inspector
Katie Baldwin, Inspector
Brienne Cooper, Inspector
Devin Emerson, Compliance Assistant

Lori Lindley AAG Board Counsel

Agenda Review and Approval

MOTION

Motion to approve the agenda was made and unanimously carried (Motion by Chute, second by Fujisaki).

MOTION

Motion to enter Executive Session at 8:35 AM was made and unanimously carried (Motion by Fujisaki, second by Chute).

II. EXECUTIVE SESSION - PUBLIC MAY NOT ATTEND, 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 resume Open Session at 3:05 PM was made and unanimously carried (Motion by James, second by Linares).

III. OPEN SESSION - PUBLIC MAY ATTEND - At the conclusion of Executive Session, the Board convened Open Session to begin the scheduled agenda for December 3, 2014. The following items were covered on Tuesday afternoon.

Discussion Items

Waiver/Exception Requests

Compliance Director Gary Miner presented three waiver requests to the Board for consideration.

J. Felix requested a waiver from the FPGEC. She graduated from the University of Alberta, Canada in 2004. She also received a license to practice pharmacy in Washington in 2005. Her license in Washington is in good standing with no discipline. The Board voted to approve the waiver request.

MOTION

Motion to approve J. Felix request to waive FPGEC requirement and allow licensure through reciprocity/license transfer was made and unanimously carried (Motion by Chute, second by Reher).

Central City Concern requested a waiver from OAR 855-044-0070 to exempt them from the requirement of tracking lot numbers in the donation, distribution and dispensing records. The Board approved the waiver request.

MOTION

Motion to approve Central City Concern's waiver request from OAR 855-044-0070 for five years was made and unanimously carried. (Motion by James, second by Anderson).

Galderma Laboratories requested a waiver to allow a Designated Representative to serve in this capacity for both Galderma Laboratories and Owen Laboratories. Galderma Laboratories and Owen Laboratories will be using the same facility for their wholesale businesses. The Board approved the waiver request.

MOTION

Motion to approve Galderma Laboratories waiver request from OAR 855-065-0009 for five years was made and unanimously carried. (Motion by Reher, second by James).

Remote Processing Application Review

Compliance Director Gary Miner presented a Remote Processing Application for MedImpact Direct LLC. MedImpact Direct LLC is requesting approval for licensure as a Remote Processing

Outlet. It was noted that all application requirements and application checklist items have been satisfied. The Board approved their application.

MOTION

Motion to approve MedImpact Direct LLC Remote Processing application was made and unanimously carried. (Motion by Chute, second by Linares).

Drugless Pharmacy Applications for Review

Compliance Director Gary Miner presented two Drugless Pharmacy Applications for Kaiser Permanente Clinical Pharmacy Services. It was noted that all application requirements and checklist items have been satisfied. The Board approved both applications.

MOTION

Motion to approve Kaiser Drugless Pharmacy application was made and unanimously carried. (Motion by Reher, second by James).

Charitable Pharmacy License & Waiver Request

Compliance Director Gary Miner presented a Charitable Pharmacy Application for Volunteers in Medicine located in Springfield, Oregon. The Board reviewed their Charitable Pharmacy Application and it was approved.

Also submitted with their Charitable Pharmacy Application was a waiver request from OAR 855-044-0050. The Board reviewed their request and the circumstances for it. The waiver request was approved.

An additional request to waive OAR 855-041-1050 was submitted with their application. Volunteers in Medicine asked the Board to allow them to act as a pharmacy depot for Patient/Medication Assistance Program (PAP/MAP) medications. The Board determined that a waiver request was not required.

The Board addressed Volunteers in Medicine's request for clarification on the requirements for a Registered Nurse's (RN) involvement in dispensing at a charitable pharmacy. The Board had some discussion and concluded that under the charitable pharmacy regulations an RN can dispense after proper training by the Pharmacist-in-Charge.

MOTION

Motion to approve Volunteers in Medicine Charitable Pharmacy Application was made and unanimously carried. (Motion by Chute, second by Reher).

MOTION

Motion to approve Volunteers in Medicine waiver of OAR 855-044-0050 was made and unanimously carried. (Motion by Chute, second by Reher).

MOTION

Motion to adjourn at 3:57 PM was made and unanimously carried (Motion by James, second by Reher).

WEDNESDAY, DECEMBER 3, 2014

Ken Wells, R.Ph. Board President, called the meeting to order at 8:30AM.

Ken Wells, President
Christine Chute
Brad Fujisaki
Kate James

Roberto Linares, Vice President
Penny Reher
Heather Anderson

The following staff members will be present for all or part of this session:

Marc Watt, Executive Director

Gary Miner, Compliance Director

Karen MacLean, Administrative Director

Chrisy Hennigan, Office Manager

Joe Ball, Chief Investigator

Fiona Karbowicz, Pharmacist Consultant

Gregg Hyman, Inspector

Michele Cale, Inspector

Katie Baldwin, Inspector

Laura Elvers, Inspector

Brianne Cooper, Inspector

Annette Gearhart, Compliance Secretary

Devin Emerson, Compliance Assistant

Thomas Cowan Sr. AAG Board Counsel

President Ken Wells asked the Interns present to introduce themselves.

The Board announced that Inspector Gregg Hyman would be leaving the Board soon. They thanked him for his years of service and wished him the best of luck.

Motions for Disciplinary Action - Please see Motions for Disciplinary Cases at the end of this document.

V. GENERAL ADMINISTRATION

Rules & Policy Discussion

Review Rulemaking Hearing Report

Administrative Director Karen MacLean presented the Rulemaking Hearing Report. The Rulemaking Hearing was held on November 25, 2014. The purpose of the hearing was to receive public comment on the following proposed rules:

- Division 001 Procedural Rules
- Division 019 Licensing of Pharmacists
- Division 021 Pharmacist Continuing Education
- Division 041 Auto Refill

- Division 044 Charitable Pharmacy
- Division 080 Controlled Substances
- Division 110 Fees

25 people, other than Board staff were present for the hearing and six people provided comments. No oral testimony was received for rules in Division 001, 019, 021, 044, 080 or 110. Karen stated that the Board received oral testimony from three individuals/organizations for Division 025. The Board also received oral testimony from three individuals/organizations for Division 041. The Board did not receive any written comments on Division 001 and 044. The Board received written comments from staff on rules in Division 019, 021, 080, and 110. Some of staff's suggestions were incorporated into rules for final review. The Board received a total of seven written comments for proposed rules in Division 025. In addition, seven written comments were received for proposed rules in Division 041.

The Board reviewed and accepted the Rulemaking Hearing Report.

MOTION

Motion to accept November 25, 2014 Rulemaking Report was made and unanimously carried (Motion by Anderson, second by James).

Consider Adoption of Temporary Rules – None

Send Rules Rulemaking Hearing – None

Consider Adoption of Rules

Compliance Director Gary Miner, Pharmacist Consultant Fiona Karbowicz, and Administrative Director Karen MacLean presented the following proposed rules and the Board determined which rules to permanently adopt.

Division 001 Procedural Rules

The proposed rule amendments in Division 001 were presented. The proposed rules update the reference to the Attorney General's Uniform Model Rules of Procedures Act utilized by the Board. The Board adopted the rule amendments as proposed which will be effective January 1, 2015.

MOTION

Motion to adopt Model Rules of Procedure rule in OAR Chapter 855, Division 001 was made and unanimously carried (Motion by Chute, second by Anderson).

Division 019 Licensing of Pharmacists

The proposed rule amendments in Division 019 were presented. Amendments include changes to initiate and incorporate biennial licensure for Pharmacists during the 2015 renewal cycle. Other changes include requiring Pharmacists to provide an email address with their initial application for licensure and to notify the Board within 15 days of the change. It was proposed that the petition for reinstatement of pharmacist licenses rules be repealed and be replaced by a new section of

rules for the reinstatement of a revoked, or surrendered license. The Board made minor changes to the proposed rules which include renumbering, minor grammatical and sentence structure changes. The Board adopted rules in OAR 855-019-0100 thru 855-019-0120 as proposed. They adopted rules in OAR 855-019-0122 as revised and adopted rules in 855-019-0170 thru 855-019-0205 as revised, and adopted rules in OAR 855-019-0310 thru 855-019-0320. These rules will be effective January 1, 2015.

MOTION

Motion to adopt Licensing of Pharmacists rules in OAR 855-019-0100 thru 855-019-0120 was made and unanimously carried (Motion by James, second by Chute).

MOTION

Motion to adopt Licensing of Pharmacists rules in OAR 855-019-0122 as revised to was made and unanimously carried (Motion by Fujisaki, second by James).

MOTION

Motion to adopt Licensing of Pharmacists rules in OAR 855-019-0170 thru 855-019-0205 as revised was made and unanimously carried (Motion by Anderson, second by James).

MOTION

Motion to adopt Licensing of Pharmacists rules in OAR 855-019-0310 thru 855-019-0320 was made and unanimously carried (Motion by Anderson, second by James).

Division 021 Continuing Education

The proposed rule amendments in Division 021 were presented. Proposed amendments include a biennial structure that requires Pharmacists to complete three continuing pharmacy education units over the course of two years. In addition, rules are proposed to allow Pharmacists that reciprocate his or her license into Oregon not to be required to submit proof of continuing education during their initial renewal cycle. This has been a longstanding Board practice; it will now be clearly stated in rule. The Board made minor changes to the proposed rules and adopted them as revised. These rules will be effective July 1, 2015.

MOTION

Motion to adopt Pharmacist Continuing Education rules in OAR Chapter 855, Division 021 as revised was made and unanimously carried (Motion by Fujisaki, second by James).

Division 025 Technician Licensure Requirements

The proposed rule amendments in Division 025 were presented. Amendments include requiring a Pharmacy Technician or Certified Oregon Pharmacy Technician to be at least 18 years of age and hold either a high school diploma or GED. This does not apply to persons currently under the age of 18 licensed by the Board as a Pharmacy Technician prior to January 1, 2015.

Amendments allow for a petition to the Board to extend the Pharmacy Technician license past one year, or it may be reinstated if lapsed for more than five years. Other amendments include requiring Certified Oregon Pharmacy Technicians to complete 10 continuing pharmacy education hours from September 1 through August 31 of each license renewal cycle and effective January 1, 2015 it is proposed that national certification is no longer a requirement for renewal. It is proposed that active national certification remain a requirement for initial licensure as a Certified

Oregon Pharmacy Technician, as well as for Certified Oregon Pharmacy Technicians that have had a license that has been lapsed for more than four years and would like to have an active Oregon license. The reinstatement rules were amended to provide applicants with a more streamlined process.

Board Members expressed concern that staff may not have the time to approve continuing education. Compliance Director Gary Miner indicated that he currently reviews continuing education and that Accreditation Council for Pharmacy Education (ACPE) and Continuing Medication Education (CME) receives automatic continuing education approval. Board Members also express concern regarding onsite training for Certified Oregon Pharmacy Technicians and whether or not licensees will take it seriously. Gary commented that inspectors currently review ongoing training efforts during inspections and that will continue. There was discussion about the public comment and written testimony opposition regarding rule 0015 and eliminating the requirement for ongoing national certification however the Board determined it would have more oversight with the rules as revised. from the Pharmacy Technician Certification Board (PTCB) and the National Healthcareer Association (NHA). The Board indicated that these organizations have not provided the Board with what was it expected in terms of verification and eligibility for exam taking and continuing education review. They also indicated that the bar is being raised by adding additional continuing education requirements through the Board and they will be able to have more control over the review and audit of the requirement for increased continuing education. The Board is unsure as to what type of continuing education the PTCB and NHA accepts and whether or not they accept non ACPE continuing education. The Board made minor grammatical changes and adopted rules in OAR 855-025-0001 as noticed. Rules in OAR 855-025-0005 and 855-025-0010 were adopted as revised. Rules in OAR 855-025-0012 were adopted as noticed. In addition, rules in OAR 855-025-0015 were adopted as revised. Rules in OAR 855-025-0020 thru 855-025-0050 were adopted as noticed. Rules in 855-025-0060 were adopted as revised. All rules in Division 025 will be effective January 1, 2015.

MOTION

Motion to adopt Technician Licensure Requirements rules in OAR 855-025-0001 as noticed was made and unanimously carried (Motion by Anderson, second by Reher).

MOTION

Motion to adopt Technician Licensure Requirements rules in OAR 855-025-0005 as revised was made and unanimously carried (Motion by Chute, second by Anderson).

MOTION

Motion to adopt Technician Licensure Requirements rules in OAR 855-025-0010 as revised was made and unanimously carried (Motion by Fujisaki, second by Anderson).

MOTION

Motion to adopt Technician Licensure Requirements rules in OAR 855-025-0012 as noticed was made and unanimously carried (Motion by Anderson, second by Fujisaki).

MOTION

Motion to adopt Technician Licensure Requirements rules in OAR 855-025-0015 as revised was made and unanimously carried (Motion by Anderson, second by James).

MOTION

Motion to adopt Technician Licensure Requirements rules in OAR 855-025-0020 thru 855-025-0050 as noticed was made and unanimously carried (Motion by Anderson, second by Chute).

MOTION

Motion to adopt Technician Licensure Requirements rules in OAR 855-025-0060 as revised was made and unanimously carried (Motion by Fujisaki, second by Anderson).

Division 041 Auto Refill

The proposed rule amendments in Division 041 were presented. Amendments include establishing requirements for the use of auto-refill programs, reminders, and pick-up notifications for retail pharmacies. The proposed rules do not apply to long term care pharmacies. Executive Director Marc Watt stated that he believes that the proposed rules will save on workload as pharmacies will only fill what has been approved for refill. Compliance Director Gary Miner stated that the Board has been seeing many cases in which a Drug Utilization Review (DUR) is not being done on refills. Current DUR rules are directed to the Pharmacist. However, the Board has seen in its disciplinary cases that often times the computer system doesn't let the Pharmacist be involved in the DUR process, thus creating problems and jeopardizing patient safety. Other concerns addressed about auto refill programs include that they often times do not catch direction changes and that some systems used by pharmacies result in increased risk to patient safety. It was stated that the proposed rules help to get the Board closer to where the Pharmacist can do their professional role. Board Counsel Tom Cowan commented that the proposed rules seem to benefit patients by taking the burden off of them.

The Board agreed that the proposed rules would need a transition period so that the industry can modify their computer systems and make changes where appropriate. The Board made minor grammatical changes to the proposed rules and adopted them as revised. These rules will be effective January 1, 2016.

MOTION

Motion to adopt Auto Refill rules in OAR 855-041-1120 as revised was made and carried (Motion by Reher, second by James).

Linares, Reher, Anderson and James in favor of. Wells, Fujisaki and Chute opposed.

MOTION

Motion to make the effective date for OAR 855-041-1120 January 1, 2015 was made and unanimously carried (Motion by Anderson, second by Linares).

Division 044 Charitable Pharmacy

The proposed rule amendments in Division 044 were presented. Amendments include establishing a waiver clause to the records section of the rules. The Board adopted the proposed rules. These rules will be effective January 1, 2015.

MOTION

Motion to adopt Charitable Pharmacy rules in OAR 855-044-0070 was made and carried (Motion by Fujisaki, second by Anderson).

Division 080 Controlled Substances

The proposed rule amendments in Division 080 were presented. The proposed rules add delta-9-tetrahydrocannabinol (THC) to schedule II controlled substances for clarification. The Board adopted the proposed rules. These rules will be effective January 1, 2015.

MOTION

Motion to adopt Controlled Substances rules in OAR 855, Division 080 was made and unanimously carried (Motion by Fujisaki, second by Anderson).

Division 110 Fees

The proposed rule amendments in Division 110 were presented. The proposed amendments in Division 110 reflect the fee structure for Pharmacist biennial licensure. The proposed fee for biennial licensure is a fee that will be a continuation of the current annual fee of \$120. However, the license will be valid for two years rather than one. The electronic prescription monitoring fund fee will also be collected at a biennial rate of \$50.00, \$25 for each year of the biennium pursuant to Oregon Law, ORS 431.972. Also included is a reduction in fees for initial pharmacist applicants whose application has been received or the mailing date of the application is within 180 days of expiration. Minor changes were made to the proposed rules and they were adopted as revised. These rules will be effective April 1, 2015.

MOTION

Motion to adopt Biennial Fee rules in OAR Chapter 855, Division 110 as revised was made and unanimously carried (Motion by Reher, second by James).

Rules Policy Issues for Discussion

Hydrocodone Update/Outreach

Staff provided an update on the impacts of the Federal schedule change for Hydrocodone that became effective in October. Staff indicates that they have not received many complaints. To date there have been a total of four. Executive Director Marc Watt is responding to complaints as they are received by the Board.

PIC Requirements for Site Attendance

Compliance Director Gary Miner and Pharmacist Consultant Fiona Karbowicz provided a summary of other states requirements regarding Pharmacist-in-Charge (PIC) on site attendance.

Staff provided some suggestions for consideration by the Board for potential updates to PIC site attendance requirements. Such suggestions included requiring the PIC to be on site at one pharmacy for a minimum of 30 hours per week, or that a substantial part of the designees working time each month be in the pharmacy, or that the PIC is physically present in the pharmacy a sufficient amount of time to provide supervision and control, or that the PIC is on site a minimum of 20 hours if the pharmacy is open less than 20 hours or 50% of the time, or that the PIC is employed on a full time basis. Considerations for a pharmacist that would like to be the PIC for more than one pharmacy included requiring written approval by the Board or during emergency situations in which a minimum of 10 hours per week would be required at each pharmacy. Other considerations included only allowing a pharmacist to be the PIC at one site except when approved by the Board in which a minimum of 10 hours of physical presence in each pharmacy would be required.

The Board liked the concept of requiring a PIC to have 20 hours of onsite attendance at each pharmacy located in Oregon. They also thought it would be a good starting point to have out-of-state pharmacies continue to have an Oregon licensed pharmacist, have 10 hours of onsite attendance, and submit their PIC self inspection report to the Board. The Board directed staff to address transitional timeframes and situations such as when an out-of-state pharmacy has an Oregon licensed PIC that resigns and the pharmacy has to obtain a new Oregon licensed pharmacist. It will be discussed further if transitional timeframes will be outlined in rule. Compliance Director Gary Miner will provide drafts concepts and rules for the Board to review at its February Board Meeting.

Non Pharmacy Dispensing

Executive Director Marc Watt, Compliance Director Gary Miner, and Pharmacist Consultant Fiona Karbowicz provided an update on non pharmacy dispensing. An update from the last non pharmacy dispensing meeting with stakeholders on November 21st was provided. At the meeting November 21st meeting staff provided an updated concept to stakeholders. This concept had been approved by the Board at its October Meeting. At the meeting with stakeholders, staff provided an overview on education vs. compliance, potential registration fees were discussed, and the inspection process was explained. Board staff shared some of the stakeholder's comments as well as potential barriers they found in the concept and whether or not stakeholders supported it. Staff proposed that the Board revise the non pharmacy dispensing concept to define "drug" for non-pharmacy dispensing purposes as an FDA approved human prescription drug. In addition, it was suggested that the inspection process be revised to allow a practitioner the opportunity to invite their home licensing Board. The focus on the inspections will be on drugs intended for dispensing not administration. The registration fee may also be increased to \$100.00. The Board accepted the revisions to the concept and adopted it as proposed.

MOTION

Motion to accept Non-Pharmacy Dispensing concept was made and unanimously carried. (Motion by Anderson, second by Reher).

Appearances

Brian Hille, RPh, VP Patient and Specialty Care, Safeway Pharmacy Department, David Green, Director of Pharmacy Operations, Safeway, Jewel Hunt GVP Pharmacy Safeway, Thanh Nguyen, FNP, Providence PMG Health eXpress Program Clinical Director, Michael Young, MD, Providence Senior Medical Director-Telehealth, and Michelle Wernert, Providence Program Manager-Telehealth appeared before the Board to provide a presentation on a potential model for the utilization of pharmacy technicians in a telepresenter capacity. In partnership with Providence, Safeway Pharmacy is piloting “Health eXpress” in two locations in Oregon. These locations provide alternatives to traditional visits to a doctor’s office. The locations have a Wellness Center that provides telehealth sessions with a remote Nurse Practitioner (NP). The NPs diagnose, treat, prescribe, order labs, and make appropriate referrals as needed. Health eXpress would like to utilize Pharmacy Technicians to escort patients into the treatment room for immunizations, to provide information to patients about next steps in the care process, to connect equipment for telehealth sessions and to provide proper placement of peripheral devices for the patient under the supervision of the nurse practitioner. Health eXpress does not believe that the proposed telepresenter role that they would like Pharmacy Technicians to satisfy falls within the specific duties of a Pharmacy Technician, nor do they believe it runs contrary to what a Pharmacy Technician is not permitted to do. Additionally, they do not believe that the telepresenter duties constitute the practice of pharmacy, nursing or medicine. It was noted that Medical Assistants (MA) are currently serving in the capacity of the telepresenter at the one location in Oregon that is in operation however this is not a viable business solution long-term due to the staffing cost.

Safeway asked the Board for a waiver to allow for the use of Pharmacy Technicians as telepresenters in the wellness space outside the physical areas of the pharmacy. Providence indicated that they will provide the required education and maintain the scope and content of the education, training, and competency for the Pharmacy Technician to ensure quality and consistent standards of care. Safeway indicated that they will assure compliance with “unprofessional conduct” standards and other regulatory requirements while the Pharmacy Technician is acting in the telepresenter capacity.

The Board discussed the proposed concept and waiver request. They expressed concern as to who has authority and jurisdiction over this practice. Board Counsel Tom Cowan expressed concern over who would be accountable for the telepresenter and if it would be a Pharmacist or the Pharmacist-in-Charge. The Board would like to reach out to the Oregon Medical Board and Oregon Nursing Board to obtain their insights regarding this practice and to discuss any concerns they may have. The Board did not think they had enough information to either approve or deny Health eXpress’s waiver request. They would like to obtain more information about this practice, reach out to the Oregon Medical Board and Oregon Nursing Board, and bring this topic back for further discussion at its February Meeting.

Board Communication Outreach

Board President Ken Wells presented a proposed outreach suggestion made by Board Member Kate James. Kate proposed that after each Board Meeting, Board Members alternate highlighting the key points from the meeting and provide it to Executive Director Marc Watt within five days of the meeting. Marc would review the material and make any appropriate edits. The key points would in turn be disseminated to licensees within 14 days via the Board’s website, listserve, and other communication methods as appropriate. Board Members were in agreement that the outreach suggestion was a good idea and would like to try it beginning with the February Board

Meeting. The Board President will assign a Member to prepare outreach materials for each meeting.

Medication Reconciliation

Compliance Director Gary Miner and Pharmacist Consultant Fiona Karbowicz led a discussion on medication reconciliation. The Board discussed and emphasized the importance of an accurate patient record. Currently, there are many Pharmacy Technicians that are responsible for inputting medical data into the patient's record. However, they are doing this unsupervised and sometimes the information is never reviewed by a Pharmacist. Board Inspectors have been asked for guidelines for medication reconciliation practices. The Board determined that they would like to work on developing a definition for medication reconciliation and gain insights from pharmacies that have already have a good well established system in place. Staff will convene a workgroup and report back on this topic.

Legalization of Marijuana

Executive Director Marc Watt, Compliance Director Gary Miner, Pharmacist Consultant Fiona Karbowicz, and Board Counsel Tom Cowan discussed potential items of concern relating to the legalization of marijuana and its effect on its licensees. Staff asked the Board to begin to thinking about how it will be handling disciplinary cases related to the use of marijuana once it is legalized on July 1, 2015, as well as medical marijuana. The Board had some preliminary discussions and was in agreement that marijuana at this time is still considered a drug in Oregon. The Board will discuss this topic further in February.

ISSUES/ACTIVITIES

Reports:

Board President/Members

Board Member Christine Chute reported that she had attended a Governor's Task Force on DUII in which Mothers Against Drunk Driving (MADD), the Department of Transportation (DOT), and law enforcement were in attendance. The meeting was related to how new marijuana regulations will create new enforcement issues for law enforcement. Similarly, Executive Director Marc Watt attended a summit meeting which suggested getting individuals from the marijuana community as well as law enforcement together to come up with a good workable plan on how to enforce disciplinary matters with licensees as they relate to marijuana use.

Board Member Kate James reported that she had attended a compounding conference in Texas. She indicated that insurance companies are increasing supervision and audits of compounding. In addition USP 800 will be FDA enforceable. USP 800 will also include a substantial amount of additional facility regulations. It is unknown at this time if states will adopt and enforce USP 800.

Board Member Roberto Linares reported that he had attended a focus group in November at Pacific University. The focus group was related to exploring partnerships in pharmacies utilizing collaborative agreements.

Executive Director Marc Watt introduced new Licensing Representative Bayo Arigbon. Marc reported that he, Compliance Director Gary Miner, Pharmacist Consultant Fiona Karbowicz and Inspectors Laura Elvers and Brianne Cooper visited Walgreens Specialty Pharmacy to review

their refrigeration and alarm system. Laura and Brianne will soon be drafting new rules regarding vaccine storage requirements. Marc shared that staff continues to look into creating a Facebook page for the Board of Pharmacy. They are continuing to evaluate concerns such as inappropriate comments that are unable to be disabled. In addition, all comments may be subject to public record requirements. Marc stated that the non-pharmacy dispensing concept paper will be reviewed by the Board tomorrow and then it will be presented to stakeholders followed by Legislators in Salem. Marc stated that he appreciates the staff's hard work and commented that they have been very flexible and adaptable.

Compliance Director Gary Miner reported that there are currently 17 individuals enrolled in the Health Professionals Service Program (HPSP). They are all Board referrals and there are no self referrals at this time. Gary stated that as of November 21st 89% of pharmacies located in Oregon have been inspected. Gary shared that Inspector Brianne Cooper recently attended training on root cause analysis and assessment tools. He is happy to have a staff member with that training resource.

Pharmacist Consultant Fiona Karbowicz provided a summary of the Boards 2014 local outreach efforts. Fiona shared that the pharmacist-in-charge training program was taught to 271 licensees in 12 different presentations over the year. This included presentation to both Oregon State University and Pacific University graduating students. Fiona stated that the Board and staff gave a total of 14 presentations to licensees and members of the public this year. The presentations included law updates, programs related to patient safety and medication error prevention, the Prescription Drug Monitoring Program (PDMP), and the Pharmacist Recovery Network (PRN). Hospital as well as technician specific continuing education was also conducted throughout the state. Hospital and technician specific continuing education totals approximately 25 hours a year. Fiona shared that 12 law related education programs to first, second, and third year interns were also conducted throughout the year. This outreach totals approximately 35 hours per year associated to develop. Fiona anticipates that this number will decrease next year, as the programs are now created and will only have to be maintained moving forward. Fiona mentioned staff has done many collaborative efforts with organizations outside of Oregon. Those include the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), the National Association of Boards of Pharmacy (NABP) as well as the Washington and California Boards of Pharmacy along with countless others. Staff has also worked hard to annually update the Pharmacist-in-Charge Self Inspection Reports to be utilized as an educational tool. The Continuing Education Law Exam is also an educational tool used by licensees. These are both examples of work that is critical to helping the Board meet its mission and goals. Fiona acknowledged and thanked staff and Board members for their hard work in this year's 2014 outreach efforts.

Administrative Director Karen MacLean reported that the electronic fingerprinting contract is in place and staff is continuing to work on implementation issues; this contract does not include electronic printing for out of state candidates. Karen continues to coordinate the scanning project and will be updating the Agency's budget proposal to incorporate the Governor's Budget revisions. She also shared the results of the 2014 Certified Pharmacy Technician License Renewal Survey which was sent to Certified Pharmacy Technicians who let their license lapse during the last renewal cycle. Most respondents indicated that they did not renew because they are no longer working in Oregon.

Board Member/Staff Presentations

The next Pharmacy Coalition is scheduled for December 11, 2014.

Professional Practice Roundtable – None

Committees/Meetings

Executive Director Marc Watt attended the National Association of Boards of Pharmacy (NABP) Interactive Executive Officer Forum October 14-15th in Chicago, IL. Marc indicated that the forum was very valuable. The topic of compounding was a common topic at the forum. Marc stated that most states expressed that they would like to establish a standard for compounding inspections. NABP is establishing a work-group, Compliance Director Gary Miner and Pharmacist Consultant Fiona Karbowicz will be part of this work-group. Marc shared that he had the opportunity to meet the new Massachusetts Board of Pharmacy Executive Director. He also obtained a copy of their inspection report. The Massachusetts Executive Director indicated that it takes about six days to do a complete inspection. Marc also indicated that North Dakota now has pharmacies that have Pharmacy Technicians doing telemedicine and counseling via video. Overall, Marc thought the forum was excellent.

Executive Director Marc Watt and Compliance Director Gary Miner attended the Oregon Society of Health-System Pharmacists (OSHP) Fall Meeting on October 18th in Portland. At the meeting Marc and Gary provided a 15 minutes question and answer session.

Executive Director Marc Watt attended the National Association of State Controlled Substances Authorities Annual Meeting held on October 21-24th in Savannah, Georgia. Marc stated that there was a lot of law enforcement in attendance. There was discussion about telemedicine at the meeting. Kentucky discussed the mandatory use of the Prescription Drug Monitoring Program (PDMP). In Quincy, Massachusetts all of their law enforcement was trained on the use of Naloxone. There was also discussion of the Drug Enforcement Agency (DEA) take back programs and the fact that Hawaii, Texas, Georgia, and Delaware won't allow take back to the pharmacy.

Compliance Director Gary Miner went to Pacific University's Accreditation Council for Pharmacy Education (ACPE) on-site evaluation October 22-24th. Gary thanked the Board for sending him. The evaluation team expressed concern regarding staffing because there is no time for a break due to of the condensed program.

Board Members Penny Reher and Heather Anderson as well as Pharmacist Consultant Fiona Karbowicz provided a presentation at the Oregon State Pharmacist Association (OSPA) Annual Meeting, November 7-9th in Portland. Fiona stated that they received good feedback from attendees and that it was great to send a public member of the Board.

The Oregon State Pharmacist Association (OSPA) Lane County CE Seminar will be held February 21-25th in Eugene. Board President Ken Wells, Board Member Penny Reher, Board Member Kate James, Executive Director Marc Watt, and Pharmacist Consultant Fiona Karbowicz will be participating in the Board's presentation.

Board Meeting Dates

*Note: The Board of Pharmacy is moving its regularly scheduled meeting dates from Tuesday/Wednesday to Wednesday/Thursday beginning February 2015. *Note, the February and August Meetings have a third day and that will include a Friday. The dates below reflect the upcoming changes.*

- February 11-13, 2015* Portland (3 day meeting)
- April 8-9, 2015 TBA
- June 10-11, 2015 Portland
- August 12-14, 2015* Portland (3 day meeting)
- October 7-8, 2015 Portland
- November 4-5, 2015 Corvallis (Strategic Planning)
- December 16-17, 2015 Portland

Rulemaking Hearing Dates

- May 28, 2015
- November 24, 2015

Proposed Meeting Dates for 2016

- February 10-12, 2016* Portland (3 day meeting)
- April 6-7, 2016 Portland
- June 8-9, 2016 Portland
- August 10-12, 2016* Portland (3 day meeting)
- October 5-6, 2016 Portland
- November 2-3, 2016 TBA (Strategic Planning)
- December 7-8, 2016 Portland

Proposed Rulemaking Hearing Dates for 2016

- May 24, 2016
- November 22, 2016

MOTION

Motion to approve 2016 proposed Board and Rulemaking Hearing dates was made and unanimously carried (Motion by Reher, second by Fujisaki).

Financial/Budget Report

Administrative Director Karen MacLean presented the financial report for October as well as biennial comparisons through September 2014.

Legislative Update

Staff provided an update on the upcoming Legislative Session. The 2015 Legislative Session will begin February 2nd. Executive Director Marc Watt will work with the Board President and Vice President as needed throughout the session and will provide the Board with regular updates.

Marc noted Legislative Concept 1523 that is currently in draft form proposes to regulate pharmacy benefit manager practices with respect to mail-order pharmacies and retail pharmacies, specialty drugs and networks of pharmacies served by pharmacy benefit managers.

Lis Houchen from NACDS (National Association of Chain Drug Stores) was present and called on to comment on additional legislation that she expected to see regarding biosimilars, pharmacy benefit managers in regard to more transparent enforcement and another bill regarding provider status that is modeled after the California statute.

Topics for Future Discussion

Board President Ken Wells worked with Board Members to prioritize topics for future discussion. They are prioritized as followed:

- How Final Orders are published on the BOP website
 - Responsibilities of the PIC
 - Pharmacy Security
 - CCO's / Medical Home
 - Temporary Pharmacies
 - Long Term Care
 - Counseling on all Controlled Substance dispensing
 - Internship / Preceptors
-

Strategic Planning

Administrative Director Karen MacLean stated that the location for the Board's 2015 Strategic Planning Meeting has been secured. She also indicated that staff will provide an update on the Board's progression on strategic planning initiatives developed during its 2014 Strategic Planning Meeting at the February Board Meeting.

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
2. MPJE Scores
3. Pharmacist Consultant
4. Project Manager Report - None
5. License/Registration Ratification (October 4, 2014-November 26, 2014)
6. Extension Requests - none
7. Approval of Board Meeting Minutes (October 7-8, 2014 and
October 17, 2014)

MOTION

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

VII. OPEN FORUM – No comments.

VIII. EXECUTIVE SESSION - PUBLIC MAY NOT ATTEND, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (k).

MOTION

Motion to enter Executive Session at 4:05 PM was made and unanimously carried (Motion by Anderson, second by Reher).

IX. OPEN SESSION

MOTION

Motion to resume Open Session at 4:30 PM was made and unanimously carried (Motion by Anderson, second by Reher).

There was one additional motion for the disciplinary cases. Please see Motions for Disciplinary Cases at the end of this document.

Adjourn

MOTION

Motion to adjourn at 4:32 PM was made and unanimously carried (Motion by James, second by Fujisaki).

Accepted by:



**Marcus Watt
Executive Director**

**Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
Kenneth Wells, R.Ph. Presiding**

Tuesday, December 2, 2014 @ 8:30 AM, Conference Room 1A
Wednesday, December 3, 2014 @ 8:30 AM, Conference Room 1A
800 NE Oregon Street in Portland, Oregon

Executive Session of the Board was held on December 2, 2014 to discuss Compliance cases, followed by motions on December 3, 2014. Working lunch held.

Board Members present for all or part of compliance session:

Kenneth Wells, R.Ph., President	Brad Fujisaki, R.Ph.
Roberto Linares, R.Ph., Vice President	Kate James, R.Ph.
Heather Anderson, Public Member	Penny Reher, R.Ph.
Christine Chute, Public Member	

Staff present for all or part of compliance session:

Gary Miner, R.Ph., Compliance Director	Marcus Watt, R.Ph., Executive Director
Joe Ball, R.Ph., Chief Investigator	Fiona Karbowicz, R.Ph., Pharmacist
Katie Baldwin, R.Ph., Board Inspector	Consultant Annette Gearhart,
Michele Cale, R.Ph., Board Inspector	Compliance Secretary
Gregg Hyman, R.Ph., Board Inspector	Devin Emerson, Licensing
Laura Elvers, R.Ph., Board Inspector	Representative
Brianne Cooper, R.Ph., Board Inspector	Lori Lindley, AAG - Tuesday
	Thomas Cowan, Senior AAG -
	Wednesday

Staff absent for all of the compliance session:

Karen MacLean, Administrative Director - Tuesday
Courtney Wilson, Project Manager

Case 2014-0164 Motion to deny applicant's request.

Motion by: Penny Reher; Seconded by: Christine Chute. Motion unanimously carried.

Case 2012-0029 Motion to deny probationer's request.

Motion by: Kate James; Seconded by: Heather Anderson. Motion carried with Brad Fujisaki recused.

Case 2012-0381 Motion to deny request for early release from probation, but to drop urinalysis sanction of probation.

Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2011-0338 Motion to deny request for early release from HPSP. Grant modification allowing licensee to work up to 48 hours per week and to become Pharmacist-in-Charge after attending the Board's Pharmacist-in-Charge class.

Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0195 Motion to deny request for reconsideration.

Motion by: Christine Chute; Seconded by: Penny Reher. Motion unanimously carried.

Case 2013-0452 Motion to accept ALJ Motion for Summary Determination and proposed Order.

Motion by: Roberto Linares; Seconded by: Kate James. Motion unanimously carried.

Case 2013-0355 Motion to accept proposed order with modifications.

Motion by: Penny Reher; Seconded by: Brad Fujisaki. Motion unanimously carried. [Vote held at 4:30pm.]

Case 2014-0375 Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation and stayed civil penalty from Consent Order Case No. 2011-0456 and Case No. 2011-0263; and in

Case 2014-0427 Motion to revoke outlet registration and impose \$10,000 civil penalty per violation and stayed civil penalty in Consent Order Case No. 2011-0456 and Case No. 2011-0263; and in

Case 2014-0428 Motion to impose \$10,000 Civil Penalty per violation against outlet.

Motion by: Christine Chute; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0445 Motion to impose \$10,000 civil penalty per violation against outlet; and in

Case 2014-0339 Motion to suspend pharmacist license for one year and impose \$1,000 civil penalty per violation.

Motion by: Penny Reher; Seconded by: Heather Anderson. Motion carried with Kenneth Wells recused.

Case 2014-0229 Motion to suspend pharmacist license for 30 days.

Motion by: Penny Reher; Seconded by: Heather Anderson. Motion carried with Kenneth Wells and Kate James recused.

Case 2014-0411 Motion to impose \$1,000 civil penalty per violation against pharmacist.

Motion by: Penny Reher; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0448 Motion to deny technician license application.

Motion by: Heather Anderson; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0404 Motion to revoke technician license and impose \$1,000 civil penalty per violation.

Motion by: Penny Reher; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0440 Motion to deny technician license and impose \$1,000 civil penalty per violation.

Motion by: Brad Fujisaki; Seconded by: Christine Chute. Motion unanimously carried.

Case 2014-0397 Motion to deny technician license and impose \$1,000 civil penalty per violation.

Motion by: Heather Anderson; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0424 Motion to remove one year extension on probation and issue Letter of Concern to technician.

Motion by: Roberto Linares; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0382 Motion to revoke technician license and impose \$1,000 civil penalty per violation.

Motion by: Penny Reher; Seconded by: Kate James. Motion carried with Heather Anderson opposed.

Case 2014-0359 Motion to revoke technician license and impose \$1,000 civil penalty per violation.

Motion by: Penny Reher; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0363 Motion to suspend technician license and impose \$1,000 civil penalty per violation.

Motion by: Christine Chute; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0378 Motion to impose \$1,000 civil penalty per violation against pharmacist. Penny Reher, R.Ph. recused.

Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion carried with Penny Reher recused.

Case 2014-0418 Motion to impose \$1,000 civil penalty per violation against pharmacist.

Motion by: Penny Reher; Seconded by: Brad Fujisaki. Motion unanimously carried. [Vote held at 1:10 pm]

Case 2014-0436 Motion to grant technician license.

Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0204 Motion to deny technician license.

Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0434 Motion to grant technician license.

Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0416 Motion to grant technician license.

Motion by: Roberto Linares; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0412 Motion to Close under investigation

Case 2014-0431 Motion to Close under investigation

Motion by: Heather Anderson; Seconded by: Roberto Linares. Motion carried with Kate James recused and Christine Chute opposed.

Case 2014-0410 Motion to impose \$10,000 civil penalty per violation against outlet; and in

Case 2014-0432 Motion to impose \$1,000 civil penalty per violation against Pharmacist-in-Charge.

Motion by: Roberto Linares; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0368 Motion to impose \$10,000 civil penalty per violation against the outlet; issue Letter of Concern to Pharmacist-in-Charge and District Manager.

Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0415 Motion to impose \$1,000 civil penalty per violation against technician; and in

Case 2014-0420 Motion to impose \$5,000 civil penalty per violation against outlet; and in

Case 2014-0421 Motion to issue Letter of Concern to Pharmacist-in-Charge.

Motion by: Christine Chute; Seconded by: Roberto Linares. Motion carried with Penny Reher recused.

Case 2014-0274 Motion to impose \$10,000 civil penalty per violation against outlet.

Motion by: Penny Reher; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0351 Motion to issue Letter of Concern to pharmacist recommending 3 hours of CE in medication error prevention; issue Letter of Concern to second pharmacist and to outlet.

Motion by: Christine Chute; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0396 Motion to revoke outlet license and impose \$10,000 civil penalty per violation.

Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0385 Motion to refer case to Veterinarian Board.

Motion by: Penny Reher; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0365 Motion to issue Letter of Concern recommending 3 hours CE in medication error prevention to pharmacist and technician; CC: letters to Pharmacist-in-Charge and outlet.

Motion by: Heather Anderson; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0272 Motion to issue letter of concern to outlet, and issue Letter of Concern recommending 3 hours CE in medication error prevention to pharmacist and technician; CC: letters to Pharmacist-in-Charge.

Motion by: Kate James; Seconded by: Heather Anderson. Motion unanimously carried.

Motion to accept the items on the consent agenda with Case No. 2014-0364 pulled for discussion.

Motion by: Heather Anderson; Seconded by: Kate James. Motion unanimously carried.

LETTERS OF CONCERN CASES:

Case: 2014-0163 **Pharmacist:** letter of concern

Case: 2014-0269 **RPH:** Unable to Substantiate
RPH: Unable to substantiate
Pharmacy: Letter of Concern

Case: 2014-0392 **Outlet:** CC: letter of concern
PIC: letter of concern

2014-0333 **Drug Outlet:** Letter of Concern
PIC: Letter of Concern
RPH: Letter of Concern recommending 3 hours CE in medication error prevention

DEFICIENCY NOTICES:

Cases 2014-0293, 2014-0349, 2014-0350, 2014-0367, 2014-0369, 2014-0386, 2014-0387, 2014-0389, 2014-0402, 2014-0406, 2014-0408, 2014-0413 and 2014-0442.

UNABLE TO SUBSTANTIATE:

Cases: 2014-0316, 2014-0332, 2014-0353 and 2014-0401.

NO VIOLATION:

Cases: 2014-0380, 2014-0384 and 2014-0414

NO JURISDICTION:

Case: 2014-0429

C.E. AUDIT CASES:

Authority delegated to the Compliance Director by the Board [grant staff authority to issue LOC if CE completed in June. If CE not completed or completed outside of timeframe then 1. Take and pass MPJE and complete and submit documentation of CE licensee was short within 120 days (in lieu of discipline); or 2. Notice: \$1,500 civil penalty with Order: \$1,500 stay \$1,000 and complete and submit documentation of CE licensee was short.

Cases: 2014-0443 and 2014-0444

UNREGISTERED OUTLET CASES:

By authority delegated to Oregon Board of Pharmacy Staff by the Board notices to impose \$10,000 civil penalty notices have been issued to: (includes unregistered wholesalers, manufacturers and out-of-state pharmacies)

Case: 2014-0423

UNSWORN FALSIFICATION:

By authority delegated to Oregon Board of Pharmacy Staff by the Board, the following applicants and licensees have been issued Notice: Deny with \$1,000; proposed Consent: \$1,000 with \$850 stayed pending no further violations for 3 years and 3 hours of CE in law/ethics.

Cases: 2014-0400, 2014-0417, 2014-0425, 2014-0426 and 2014-0435

CASES CLOSED UNDER INVESTIGATION:

Cases that have been opened and then "Closed Under Investigation" to preserve incoming complaint information should future action be necessary.

Cases: 2014-0341 and 2014-0388