

BOARD MEETING MINUTES

**Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
October 7-8, 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, OCTOBER 7, 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
Karen MacLean, Administrative Director
Courtney Wilson, Project Manager
Fiona Karbowicz, Pharmacist Consultant
Michele Cale, Inspector
Laura Elvers, Inspector
Annette Gearhart, Compliance Secretary

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

Thomas Cowan Sr. AAG Board Counsel

Agenda Review and Approval

MOTION

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

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 enter Executive Session at 8:33 AM was made and unanimously carried (Motion by Anderson second by James).

MOTION

Motion to resume Open Session at 2:45 PM was made and unanimously carried (Motion by Reher second by Fujisaki).

Adjourn

MOTION

Motion to adjourn at 4:15 PM was made and unanimously carried (Motion by Anderson, second by Fujisaki).

WEDNESDAY, OCTOBER 8, 2014

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

The following Board Members were present:

Ken Wells, President	Roberto Linares, Vice President
Christine Chute	Penny Reher
Brad Fujisaki	Heather Anderson
Kate James	

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
Courtney Wilson, Project 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.

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 – None

Send Rules to November 25, 2014 Rulemaking Hearing

Compliance Director Gary Miner, Pharmacist Consultant Fiona Karbowicz, and Project Manager Courtney Wilson presented the following proposed rules and the Board determined which rules to send to Rulemaking Hearing:

Division 001 Model Rules of Procedure

Project Manager Courtney Wilson presented proposed rule amendments that update the reference to the Attorney General's Uniform Model Rules of Procedures Act utilized by the Board.

MOTION

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

Division 080 Controlled Substances

Compliance Director Gary Miner presented proposed amendments in the Schedule II section of the Controlled Substance rules. The proposed rules add delta-9-tetrahydrocannabinol (THC) to schedule II controlled substances for clarification.

MOTION

Motion to send Schedule II rule in OAR Chapter 855, Division 080 to rulemaking hearing was made and unanimously carried (Motion by Fujisaki, second by Linares).

Division 019 Licensing of Pharmacists

Pharmacist Consultant Fiona Karbowicz presented amendments and proposed rules in Division 019 Licensing of Pharmacists. Amendments include changes to 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 suspended, revoked, or surrendered license as recommended by Board Counsel.

MOTION

Motion to send Licensing of Pharmacists rules in OAR Chapter 855, Division 019 as revised to rulemaking hearing was made and unanimously carried (Motion by Chute, second by Fujisaki).

Division 021 Continuing Education

Pharmacist Consultant Fiona Karbowicz presented amendments to rules in Division 021 Continuing Education. 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 to not 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 the rules.

MOTION

Motion to send Continuing Pharmacy Education rules in OAR Chapter 855, Division 021 as revised to rulemaking hearing was made and unanimously carried (Motion by Chute, second by Reher).

Division 025 Technician Licensure Requirements

Pharmacist Consultant Fiona Karbowicz presented amendments and proposed rules in Division 025. 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 also make the Pharmacy Technician license valid for only one year except by petition to the Board 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 only. It is proposed that 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.

MOTION

Motion to send Certified Oregon Pharmacy Technicians and Pharmacy Technicians rules in OAR Chapter 855, Division 025 as revised to rulemaking hearing was made and unanimously carried (Motion by Fujisaki, second by James).

Division 044 Charitable Pharmacies

Project Manager Courtney Wilson presented a waiver request to be added to the records section of the Division 044 Charitable Pharmacy rules. Central City Concern had asked the Board to consider adding a waiver clause to these rules at the Board's August Meeting.

MOTION

Motion to send Records rules in OAR Chapter 855, Division 044 to rulemaking hearing was made and unanimously carried (Motion by Reher, second by James).

Division 110 Fees

Project Manager Courtney Wilson presented proposed amendments in the Division 110 fee rules. The proposed amendments in Division 110 reflect the fee structure for Pharmacist biennial licensure. The proposed fee is a fee that will be a continuation of the current annual fee that is \$120 for a two year license for the first two year cycle. The electronic prescription monitoring fund fee will also be collected at a biennial rate. Also proposed is a reduction in fees for initial pharmacist licenses issued within 13 months of expiration.

MOTION

Motion to send Fee rules in OAR Chapter 855, Division 110 to rulemaking hearing was made and unanimously carried (Motion by Reher, second by Chute).

Division 041 Prescription Refills

Pharmacist Consultant Fiona Karbowicz presented proposed rule amendments in the Division 041 Prescription Refill rules. The proposed rules establish requirements for the use of auto-refill programs, reminders, and pick-up notifications for retail pharmacies. It is proposed that these rules not apply to long term care pharmacies.

MOTION

Motion to send Prescription Refill rules in OAR Chapter 855, Division 041 as revised to rulemaking hearing was made and unanimously carried (Motion by Chute, second by Reher).

Consider Adoption of Rules

There were no rules for the Board to consider for adoption. However, Administrative Director, Karen MacLean reminded the Board of the upcoming conference call Board Meeting at which the Board will consider adopting amendments to the Division 019 Licensure by Reciprocity rules. It was noted that the public comment period is to close Monday October 13th at 4:30 and to date no public comments have been received.

Rules Policy Issues for Discussion

Pharmacist Consultant Fiona Karbowicz provided an update on outreach to the public and pharmacies relating to the Hydrocodone schedule change. Fiona shared that two press releases were sent to the media; one in September and the other in October. The purposes of the press releases were to notify the media of the schedule change and how it may impact patients so that they in turn could notify the public. A press release was also placed on the Board's website. Two listserv notifications to pharmacists were also released. The listserv notifications highlighted future changes, potential challenges and considerations.

Division 060 Manufacturers, Division 062 Drug Distribution Agents, and Division 065 Wholesalers

The Board was sent mailers of proposed amendments to Division 060, Division 062, and Division 065 that had minor changes since the Board last reviewed the drafts in August. The Board did not have any questions on the minor revisions. Pharmacist Consultant Fiona Karbowicz stated that the rules did not need to be considered for rulemaking at this time as there are still updates and guidance documents being issued by the Food and Drug Administration (FDA) related to the Drug Quality and Security Act (DQSA). FDA guidance documents are now focusing heaving on preemptions. Board Counsel Tom Cowan stated that he would be reviewing the federal preemptions and may have a draft analysis on them at the December Board Meeting. Fiona commented that the draft rules in Division 060, Division 062, and Division 065 may be shown again to the Board in February for consideration of sending them to the May 2015 Rulemaking Hearing if necessary.

PIC Requirements for Site Attendance

Compliance Director Gary Miner and Pharmacist Consultant Fiona Karbowicz discussed the current rule requirements that indicate a PIC is required to be “employed on a regular basis” pursuant to OAR 855-019-0300(1) which states: In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis. The Board had a lengthy discussion about the importance of PIC oversight, the impact of out of state pharmacy oversight, the presence of a PIC on-sight and the expectations our Board has. There was discussion about rural pharmacies and PIC coverage. The Board asked Staff to research other states standards and report back.

Discussion Items

Waiver/Exception Requests

Compliance Director Gary Miner presented one waiver request to the Board for consideration.

PETNET Solutions requested that the Board extend their waiver which allows for the maintenance and repair of the cyclotron after hours without the presence of a licensed pharmacist. Staff recommended extending their waiver for an additional five years.

MOTION

Motion to approve PETNET Solution’s request to extend cyclotron waiver for five years was made and unanimously carried (Motion by Reher, second by Fujisaki).

Technician Checking Validation Program TCVP Request

Compliance Director Gary Miner presented a TCVP request from **Mercy Medical Center Pharmacy**. He indicated that the required application checklist items were complete and that their proposal is similar to other proposals approved by the Board. Copies of written training materials used to train technicians and technician checkers were provided. Also provided, were copies of policies and procedures and a description of how TCVP will improve patient safety. John Miller the Pharmacy Manager was available for questions.

The Board approved Mercy Medical Center Pharmacy’s TCVP request for five years with condition to provide status update in one year from the date of implementation

MOTION

Motion to approve Mercy Medical Center Pharmacy’s TCVP proposal for five years was made and unanimously carried. (Motion by Reher, second by Fujisaki).

APPEARANCE

Professor Barbara Safriet, JD, LL.M - Lewis & Clark School of Law provided a presentation to the Board on “Certain Aspects of Licensing Anti-Trust, Anti-Consumer”. Board Member Heather Anderson introduced Professor Safriet who has consulted on healthcare issues over the years. Barbara acknowledged the essential, vital and complicated importance of the Board of Pharmacy even more so than other health care boards since it regulates both people and places and has far more interaction with federal law. It is further complicated that Oregon law is in conflict with federal law in some cases. She applauded the Oregon Board of Pharmacy for what it does.

Barbara was asked to address trade and how that relates to the patient. Barbara presented a slide presentation on anti-trust and constitutional issues. She cited a North Carolina dental case

to be argued before the Supreme Court in the coming weeks regarding teeth whitening and the Sherman Act which is part of the Federal Trade Commission. This case addresses the “state action doctrine” and the 4th Circuit found that the State of NC Dental Board violated the FTC. Some of this was due to the fact that in NC the Board is made up of appointees of the Dental Association rather than appointment by the Governor and confirmation of a legislative committee like in Oregon. She highlighted that “good boards” don’t need to fret and bad cases can make bad law. In the NC case, the financial interest of the Board and its practitioners took precedence over patient care.

She talked about learning from experience, identifying needs, explaining needs, looking for consequences and identifying less restrictive ways to approach case violations. She talked about the changing scope of practice and what happens with the team based approach and more providers with prescriptive authority. A question was asked, knowing that Oregon has a disciplinary process if we were concerned about an unlicensed person and the option to utilize the Administrative Hearings process, is that ok? Professor Safreit said yes.

The Board thanked her for this interesting presentation and taking the time to prepare it for them.

Providence TCVP Follow up Report

Bradley Emslie, R.Ph., Operations Supervisor - Pharmacy Services and Randy S. Neukamm R.Ph., Operations Manager from Providence St. Vincent Medical Center appeared to provide their report on the implementation of TCVP. The Board had a few questions about the merits of TCVP at some of their other locations and it was identified that the rule testing requirements are too much for a small facility because they don’t generate the quantity necessary to meet the rule. There was a brief discussion how this could be done in a simulated way. One member asked about job satisfaction and are the pharmacists happier? The technicians appreciate increased responsibility and practicing “up” to their license type. Another member asked what the techs that didn’t pass an unannounced test learned and it was commented that they realized they just weren’t paying attention and needed to focus better. The Board accepted their report. They will need to seek re-approval five years from the time they were first approved in order to continue with the TCVP program.

Compounding Workgroup Update

Compliance Director Gary Miner and Pharmacist Consultant Fiona Karbowicz provided an update on the Compounding Workgroup. They indicated that staff had conducted an analysis on the GMP and USP regulations in comparison to our rules. They thought that this practice was a good starting point for drafting updates to existing rules. The next workgroup meeting is targeted to be held in November.

Cultural Competency Update

Administrative Director Karen MacLean provided an update on the Oregon Health Authority’s (OHA) proposed rules on cultural competence continuing education opportunities for health care professionals. She stated that the proposed rules have been noticed for rulemaking hearing and that the rulemaking hearing will be November 12, 2014. In 2013 House Bill 2611 was passed which mandated OHA to provide resources and support for improving the cultural competence of regulated health care professionals in Oregon. The statute also required that OHA report to the Oregon State Legislature about the level of participation in cultural competence continuing education among regulated health care professionals. Karen indicated that the proposed rules

require agencies to do auditing of the cultural competence continuing education and that this may be problematic for agencies.

The statement adopted by the Board at the August Board Meeting regarding cultural competency continuing education is now available on the Board's website.

Workgroup for Working Conditions

Compliance Director Gary Miner and Pharmacist Consultant Fiona Karbowicz asked the Board for direction on the workgroup for working conditions that they would like developed. Fiona and Karen reviewed the notes from Strategic Planning, some good came from the working conditions rules that were implemented. The Board discussed establishing a work group that included people from various practice settings. It was pointed out that there is tension between line pharmacists and company management and the Board might not get the open dialog it desires. There was discussion of having two groups one staff, one management. The culture of pharmacies has changed, most people are now employees and don't own their own pharmacy anymore. There was discussion that technicians need to be part of this group.

The conversation turned to the goal for this group. Is the outcome to review the existing rules, the survey data, make recommendations, and look at re-establishing a technician to pharmacist ratio? The Board needs a discussion and solutions, the expectations of a pharmacist today.

In the end, the Board agreed it would like the work group to evaluate the current rule, both positive and negative impacts; its effect on the workplace and make recommendations to make the work place safer. Fiona and Ken Wells will participate as the Board's representatives.

Board staff will work to develop a work group to take action on the above.

Healthcare Provider Status

Executive Director Marcus Watt and Compliance Director Gary Miner discussed a legislative proposal submitted by Coalition group regarding provider status and their concerns. Staff has not seen any drafts at this point, but wanted the Board to be aware of a proposal that could add a significant workload to the Board activities.

Board Communication Outreach – this topic was move to the December agenda.

DEA Drug Disposal

Pharmacist Consultant Fiona Karbowicz provided an update on the October 9th new DEA regulations that will take effect to help expand the public's options to safely and responsibly dispose of unwanted medications. New regulations include allowing certain DEA registrants such as manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registration with the DEA to become authorized collectors. Participation is voluntary. New regulations are going to require rule changes for the Board.

ISSUES/ACTIVITIES

Reports:

Board President/Members

President Ken Wells reported that he attended the Pharmacy Coalition and Roundtable meetings. Kate James also attended the Coalition and Roundtable meetings and is learning lots. She'll be attending the next compounding meeting.

Roberto Linares reported that he was invited to attend a Reception for Hispanic Heritage Month by the Governor and First Lady. He attended and it was a nice opportunity.

Christine Chute reported that she attended the Governor's DUII Committee meeting. The primary concern is how recreational marijuana will increase impaired driving. There has been an increase in CO and WA. There was also a discussion about the limits that will be acceptable in blood tests. The group supports field sobriety tests and Oregon has recently changed the ignition interlock systems adding a camera to ensure it's really you doing the blow tests. There is a concern that hospitals won't do blood draws for DUII's and that people don't understand that DUII's include marijuana use.

Executive Director Marcus Watt reported that he'd be attending the NABP Executive Officer Interactive Forum meeting in Chicago next week. This is a meeting that NABP covers the travel expenses for annually. In December, NABP will be holding an Interactive Forum for Board members. The suggestion was to send new Board Member Kate James. However, the meeting conflicts with the Board's December Board meeting and they decided not to send anyone this year.

Marc has been appointed as the NABP District 7 Chairperson for 2015 in order for us to host the 2016 District meeting in Oregon, in conjunction with the Oregon Board's 125th anniversary.

Marc presented the Board with a current draft of the Non-Pharmacy Dispensing concept as update by the polled representatives from the health care associations and Board's. The top four issues are the number of hours of supply allowed, removing the separate controlled substance registration license and fee, inspection by the Board and duplicate oversight. Pharmacist Consultant Fiona Karbowicz also discussed the disciplinary process and Compliance Director Gary Miner talked about the Board's focus on education and the goal to get outlets into compliance. Marc advised that Representative Greelick and Senator Monnes-Anderson also participated in the meeting. Rep. Greenlick challenged Marc on the license fee, was it enough? Marc will reach out to him for follow up on this topic. There was some discussion that the initial inspector might not be a pharmacist to help lower the cost and only if there are significant issues, would a pharmacist follow up. The plan would be to do annual inspections. Several of the Board's want the inspection to be based off a complaint. Our Board couldn't agree to that, but were ok with the revisions as presented.

Marc also met with a representative of Local 555 regarding the proposal to add a Pharmacy Technician to the Board. Marc suggested keeping the Board at 7 people and perhaps having one public member and one technician or a 9 member board and add one technician and one pharmacists to keep the profession well represented.

Board Counsel Thomas Cowan highlighted that there was a recent contested case that we expect a decision on in the new few weeks. He congratulated Chief Investigator Joe Ball on a great job.

Compliance Director Gary Miner reported that we're at 78% of completed inspections for the year and we're right on track to complete 100%. Marc, Joe and Gary met with Safeway and Providence regarding their Telemedicine conversation. They are hoping to do a pilot project and use Pharmacy Technicians to use cameras and other medical equipment on patients that present at Safeway that a doctor or nurse practitioner can view and consult. The Technician would take vitals. The Board had a lot of questions about staffing, protocol, training, etc. Marc encouraged them to consult with us before putting out new protocols. They will present at the December Board meeting.

Joe Ball and Inspector Gregg Hyman reviewed the MPJE exam questions. They added new questions to the exam pool and removed outdated questions.

Gary met with Christopher from the HPSP program and Ed Schneider regarding giving Board's the ability to add treatment criteria.

Pharmacist Consultant Fiona Karbowicz highlighted the number of meetings that cross over with the Oregon Health Authority (OHA). She's still working with a group at OAH to combine the Family Planning Clinic and County Health Clinic licenses together.

Administrative Director Karen MacLean reported that the MPJE and NAPLEX score results are now available on the NABP website through the individual's personal e-profile log in. This way test takers can look up their score results the same day that the Board receives them and hopefully this will reduce phone calls to the office. Karen reported on the latest update related to the fingerprinting through LiveScan. The agency contract is almost in place and we'll be moving this along as soon as possible. Office Manager Chrisy Hennigan is doing a great job helping to oversee the Licensing Team workflow and cross training during this busy season. Karen also reported that the Agency Request Budget was approved with minor revisions and she and Marc are pleased with the outcome.

Board Member/Staff Presentations

Executive Director Marcus Watt attended the Pharmacy Coalition and Professional Practice Roundtable meetings on 9/11/14. Both meetings had similar content, hydrocodone, DEA drug disposal, Coalition Legislative Concept. Kate James was also in attendance and highlighted that provider status was a big topic of conversation. Ken Wells said it was a good dialog and both meetings were well attended.

Committees/Meetings

Laura Elvers shared about the Sterile Compounding Inspection Training that was held at NABP, 9/17-18/2014. She was grateful to attend said it was a good learning opportunity. She and Michele Cale are putting together a training to share what they learned with the other Inspectors.

Inspector Gregg Hyman thanked the Board for sending him as the staff representative to the NABP District VI-VIII Meeting, 9/21-24/2014, Whitefish, MT. Gregg reported that Donna Horn did a presentation on error prevention, how to prevent errors, not blame the other person, keep asking "why". The University of Montana instructors made their own PBM and shared about that experience. There was a presentation on Pain Management and Ken Baker spoke on Pharmacy Malpractice and talked about "just cause". DQSA and the supply chain changes to pedigree and compounding 503 A/B facilities, as well as USP 797 being a minimum standard was discussed. The open forum and networking opportunities identified that states continue to have similar issues and the conversation and idea sharing was very useful.

Members Penny Reher and Roberto Linares also attended this meeting. They both appreciated the chance to go and learn from their colleagues. Penny will represent District 7 for Resolutions at the NABP Annual meeting. Roberto will continue as the representative for District 7 for the Colleges of Pharmacy. Next year's meeting will be hosted by District 8 and held in the Tahoe area. The 2016 meeting will be hosted by District 7 in Oregon.

Compliance Director Gary Miner will attend the Pacific University ACPE On-site Evaluation 10/22-24/2014.

Executive Director Marcus Watt will attend the NASCSA Annual Meeting, 10/21-24/14. Marc received a scholarship to help with travel expenses for this meeting.

Pharmacist Consultant, Fiona Karbowicz and Board Members Penny Reher and Heather Anderson will present at the OSPA Annual Meeting, 11/7-9/2014 in Portland. Fiona will also be at the Board booth and conduct a PIC class if there are enough participants that sign up.

Board Meeting Dates

- October 17, 2014 @ 9:30AM *brief conference call meeting*
- December 2-3, 2014 Portland
- 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

Administrative Director Karen MacLean asked that Board Members please review all the 2015 dates and update calendars to the new Wednesday/Thursday schedule.

Rulemaking Hearing Dates

- November 25, 2014
 - May 28, 2015
 - November 24, 2015
-

Financial/Budget Report

Administrative Director Karen MacLean gave highlights of the July and August financials. The Board continues to be underspending, but on track and has increased revenues due to the unexpected number of new applicants.

Legislative Update – None

Topics for Future Discussion – Wells

- Medication Reconciliation
- Pharmacy Security

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

Strategic Planning – MacLean

- Update to be provided.
-

Approve Consent Agenda*

Action Necessary

*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 – none
2. MPJE Scores - none
3. Pharmacist Consultant **#H**
4. Project Manager Report - **#H1**
5. License/Registration Ratification (August 9, 2014 – October 3, 2014)
6. Extension Requests - **#H2**
7. Approval of Board Meeting Minutes (August 12-14, 2014, Sept. 18, 2014)

MOTION

Motion to remove the August 12-14 Board Meeting Minutes from the consent agenda was made for revisions. The minutes were approved as revised and unanimously carried (Motion by Fujisaki, second by Chute).

MOTION

Motion to approve the consent agenda as revised was made and unanimously carried (Motion by Fujisaki, second by James).

VII. OPEN FORUM – none

Adjourn

MOTION

Motion to adjourn at 4:27 PM was made and unanimously carried (Motion by Reher, second by James).

Accepted by:

A handwritten signature in black ink, appearing to read 'Marcus Watt', written in a cursive style.

Marcus Watt, R.Ph.
Executive Director

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

Tuesday, October 7, 2014 @ 8:30 AM, Conference Room 1A
Wednesday, October 8, 2014 @ 8:30 AM, Conference Room 1A
800 NE Oregon Street in Portland, Oregon

Executive Session of the Board was held on October 7, 2014 to discuss Compliance cases, followed by motions on October 8, 2014. Working lunch held on Tuesday.

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	Karen MacLean, Administrative Director
Katie Baldwin, R.Ph., Board Inspector	Courtney Wilson, Project Manager
Michele Cale, R.Ph., Board Inspector	Fiona Karbowicz, R.Ph., Pharmacist Consultant
Gregg Hyman, R.Ph., Board Inspector	Annette Gearhart, Compliance Secretary
Laura Elvers, R.Ph., Board Inspector	Devin Emerson, Licensing Representative
Brianne Cooper, R.Ph., Board Inspector	Thomas Cowan, Senior AAG

Case 2013-0008 Motion to decrease probationer's UAs to 18 per year.

Motion by: Kate James; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0057 Deny request and continue investigation; and in

Case 2014-0058 Deny request and continue investigation.

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

Case 2014-0072 Motion to accept proposed Consent Order.

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

Case 2013-0507 Motion to accept ALJ Bignon's Ruling on Motion for Summary Determination and Proposed Order.

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

Case 2014-0208 Motion to deny petition for reconsideration of Final Order by Default.

Motion by: Penny Reher; Seconded by: Roberto Linares. Motion carried with Brad Fujisaki recused.

Case 2013-0500 Motion to accept proposed Consent Order with modifications; and in

Case 2013-0164 Motion to accept proposed Consent Order.

Motion by: Brad Fujisaki; Seconded by: Penny Reher. Motion carried with Kate James recused.

Case 2014-0292 **Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation.**
Motion by: Christine Chute; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0335 **Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation.**
Motion by: Penny Reher; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0334 **Motion to revoke technician license and impose \$1,000 civil penalty per violation;
issue Letter of Concern to outlet.**
Motion by: Brad Fujisaki; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0317 **Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation.**
Motion by: Penny Reher; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0255 **Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation.**
Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2013-0509 **Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation.**
Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0327 **Motion to revoke technician license and impose \$1,000 civil penalty per violation.**
Motion by: Penny Reher; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0323 **Motion to revoke technician license and impose \$1,000 civil penalty per violation.**
Motion by: Roberto Linares; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0304 **Motion to revoke technician license and impose \$1,000 civil penalty per violation.**
Motion by: Kate James; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0231 **Motion to revoke technician license and impose \$1,000 civil penalty; and in**
Case 2014-0372 **Motion to indefinitely suspend technician license (#2).**
Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0196 **Motion to impose \$10,000 civil penalty per violation against outlet #1; and in**
Case 2014-0324 **Motion to impose \$10,000 civil penalty per violation against outlet #2; and**
Case 2014-0326 **Motion to impose \$10,000 civil penalty per violation against outlet #3 and letter of no
violation to outlet #4.**
Motion by: Roberto Linares; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0340 **Motion to impose \$10,000 civil penalty per violation against outlet.**
Motion by: Kate James; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0318 **Motion impose \$1,000 civil penalty per violation against outlet.**
Motion by: Brad Fujisaki; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0347 **Motion to revoke technician license and impose \$1,000 civil penalty per violation.**
Motion by: Kate James; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0366 **Motion to revoke technician license and impose \$1,000 civil penalty per violation.**
Motion by: Penny Reher; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0305 **Motion to deny technician license and impose \$1,000 civil penalty per violation.**
Motion by: Brad Fujisaki; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0320 **Motion to deny technician license and impose \$1,000 civil penalty per violation.**
Motion by: Christine Chute; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0361 **Motion to grant technician license.**
Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion carried with Kenneth Wells opposed.

Case 2014-0328 **Motion to deny technician license.**
Motion by: Roberto Linares; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0140 **Motion to grant technician license.**
Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0358 **Motion to grant technician license.**
Motion by: Penny Reher; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0306 **Motion to grant technician license.**
Motion by: Kate James; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0296 **Motion to deny technician license and impose a \$1,000 civil penalty per violation.**
Motion by: Roberto Linares; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0357 **Motion to deny technician license and impose \$1,000 civil penalty per violation.**
Motion by: Penny Reher; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0168 **Motion to deny pharmacy technician license and \$1,000 Civil Penalty per violation.**
Motion by: Brad Fujisaki; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0346 **Motion to deny technician license and impose \$1,000 civil penalty per violation.**
Motion by: Kate James; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0301 **Motion to issue letter of concern to outlet, Pharmacist-in-Charge and pharmacist.**
Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0011 **Motion to set aside unable to substantiate motion from June 2014 Board Meeting, and issue letter of concern to the pharmacists and unable to substantiate to intern; CC: letters to Pharmacist-in-Charge.**
Motion by: Christine Chute; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0258 **Motion to suspend pharmacist license of District Manager, issue letter of concern to Pharmacist-in-Charge; CC: letter of concern to outlet.**

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

2014-0331 **Motion to issue letter of concern to pharmacist and drug outlet CC: letters to Pharmacist-in-Charge.**

Motion by: Brad Fujisaki; Seconded by: Kate James. Motion unanimously carried.

Motion to accept the items on the consent agenda with Case 2014-0331 pulled for discussion.

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

LETTERS OF CONCERN CASES:

Case: 2014-0273 **Drug Outlet:** CC Letters of concern.

PIC: Letter of concern recommending 3 hours CE in patient safety/error prevention.

CPT: Letter of concern recommending 3 hours CE in patient safety/error prevention.

Case: 2014-0054 **Drug Outlet:** Letter of Concern

PIC: Letter of Concern making sure the R.Ph. understands what drug the patient is requesting.

CPT: Letter of Concern for deleting a refill.

Case: 2014-0143 **PIC:** Letter of Concern suggesting 3 hours CE in error prevention; CC: outlet

RPH: Letter of No Violation

CPT: Letter of Concern suggesting 3 hours CE in error prevention; CC: outlet

Case: 2014-0303 **Drug Outlet:** CC: Letter of Concern

PIC: CC: Letter of Concern

RPH: Letter of Concern recommending 3 hours CE in Medication Error Prevention

DEFICIENCY NOTICES:

Case 2014-0185, 2014-0261, 2014-0275, 2014-0277, 2014-0278, 2014-0280, 2014-0281, 2014-0282, 2014-0289, 2014-0291, 2014-0309, 2014-0310, 2014-0311, 2014-0313, 2014-0315, 2014-0330, 2014-0343, and 2014-0360.

UNABLE TO SUBSTANTIATE:

Case: 2014-0268 and 2014-0300.

NO VIOLATION:

Case: 2014-0233, 2014-0262, 2014-0266, 2014-0321 and 2014-0336.

NO JURISDICTION:

Case: 2014-0267

C.E. AUDIT CASE:

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.

Case: 2014-0374

CPT C.E. AUDIT CASES:

Authority delegated to the Compliance Director by the Board [grant staff authority to revoke technician license to all technicians who did not respond to technician audit; and in regards all initial non-response technicians whose CE was unacceptable; and all other technicians that did not fulfill CE requirement in appropriate time period receive letters of concern.]

Case: 2014-0216 and 2014-0312.

UNREGISTERED OUTLET CASE:

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: 2014-0172

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.

Case: 2014-0329, 2014-0348 and 2014-0376.

“NO PIC” CIVIL PENALTY ORDERS and/or Letters of Concern :

By authority delegated to Oregon Board of Pharmacy Staff by the Board [Grant staff authority to issue discipline in no PIC cases: Five days or less (to allow for holiday weekends) = Letter of Concern; More than five days with no PIC = \$1,000 Civil Penalty per week starting with Day 6. (PIC gaps lasting two months - send to the Board for discipline)] the following notices with Historical orders and/or Letters of Concern have been issued:

Case: 2014-0337.

“NO PIC SELF INSPECTION” CIVIL PENALTY ORDERS:

By authority delegated to Oregon Board of Pharmacy Staff by the Board [grant staff authority to issue discipline in the form of \$1,000 Civil Penalty stay \$700 pending no further violations for three years when PIC Self Inspection Form not completed or not available as required] the following notices with Historical orders have been issued:

Case: 2014-0314, 2014-0379.

“NO CS INVENTORY” CIVIL PENALTY ORDERS:

By authority delegated to Oregon Board of Pharmacy Staff by the Board [grant staff authority to issue discipline in the form of \$1,000 Civil Penalty stay \$700 pending no further violations for three years when controlled substance inventory not completed or not available as required] the following notices with Historical orders have been issued:

Case: 2014-0344.

APPLICATIONS: PROPOSED DENY / GRANT WITH PROBATION:

By authority delegated to Oregon Board of Pharmacy Staff by the Board, the following licenses have been granted with probation, or have been issued proposed Consent Orders:

Case: 2014-0307

CASES CLOSED UNDER INVESTIGATION:

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

Case: 2014-0342

SURRENDERED LICENSE:

Case: 2014-0297