

BOARD MEETING MINUTES

**Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
August 12-14, 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, AUGUST 12, 2014

Ken Wells, R.Ph. Board President, called the meeting to order at 9:00AM.

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	Chrysi 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	Kim Oster, Compliance Assistant
Cherie Caceres, Licensing Representative	Kate Hill, Compliance Assistant

Thomas Cowan Sr. AAG Board Counsel

Installation & Introduction of New Board Member Kate James

The Board welcomed pharmacist Kate James to the Board. Kate was appointed by the Governor and confirmed by the Legislative Senate Rules Committee. Her appointment began July 1, 2014 and runs until June 30, 2018. Kate received her pharmacy degree from Oregon State University, College of Pharmacy and is a compounding pharmacist and owner/president of Broadway Apothecary in Eugene, Oregon. In 2008, her pharmacy was one of the first in the nation to achieve the Pharmacy Compounding Accreditation Board (PCAB) accreditation. Kate is active in a number of professional organizations such as the: Oregon Pain Society, Oregon State Pharmacy Association, American Pharmaceutical Association, and the International Academy of Compounding Pharmacists. Among other honors and awards, in 2012, she received the designation of fellow from the International Academy of Compounding Pharmacy. In addition to her pharmacy contributions, she's also a Board Member for the Science Factory Children's Museum and the Pain Society of Oregon. Kate's knowledge and experiences are a welcome addition to the Board. Kate stated that she is excited to be a member of the Board and believes that she has something to contribute.

Agenda Review and Approval

MOTION

Motion to approve the agenda was made and unanimously carried (Motion by Reher, 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

B. Executive Director Performance Update & Review pursuant to ORS 192.660(2) (i).

MOTION

Motion to enter Executive Session at 9:08 AM was made and unanimously carried (Motion by Reher, second by Anderson).

MOTION

Motion to resume Open Session at 3:48 PM was made and unanimously carried (Motion by Anderson, second by Linares).

MOTION

Motion to enter Executive Session for the purpose of the Executive Directors performance review per ORS 192.660 at 3:50 PM was made and unanimously carried (Motion by Linares, second by Anderson).

MOTION

Motion to resume Open Session at 5:20 PM was made and unanimously carried (Motion by Anderson, second by Linares).

Adjourn

MOTION

Motion to adjourn at 5:21 PM was made and unanimously carried (Motion by Anderson, second by Linares).

WEDNESDAY, AUGUST 13, 2014

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

The following Board Members were present:

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

Kate Hill, Compliance Assistant

Gary Miner, Compliance Director

Chrisy Hennigan, Office Manager

Joe Ball, Chief Investigator

Gregg Hyman, Inspector

Katie Baldwin, Inspector

Brianne Cooper, Inspector

Kim Oster, Compliance Assistant

Thomas Cowan Sr. AAG Board Counsel

Introduction of New Board Member Kate James

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

9:15AM V. GENERAL ADMINISTRATION

Discussion Items

Waiver/Exception Requests

Compliance Director Gary Miner and Administrative Director Karen Maclean presented two waiver requests to the Board for their consideration.

Central City Concern requested that the Board add a waiver clause to OAR 855-044-0070 to exempt the requirement of tracking lot numbers. However, this waiver is not needed until December. Therefore, it will be discussed with future rulemaking items on Thursday. Central City Concern also requested a waiver from OAR 855-044-0050 to accept donated drugs with an expiration date of less than nine months. Sandy Anderson the pharmacist-in-charge of this pharmacy appeared to describe their situation, request and to answer questions. She indicated that they would like to use a company that is going to help them obtain medications from long term care pharmacies. However, when they receive the medication it is already repackaged and the expiration date is lost. If there were to be a recall, everything that contains that lot number would be recalled. The expiration date is what is used on blister packs. Some medications will be directly administered to the patient. The pharmacy will be utilizing a company that will match donors with recipients' i.e. charitable pharmacies. This company is already doing this in California. Sandy indicates that their pharmacy dispenses 600-900 prescriptions per week and

they are very hopeful that this new process will help them to better serve their patients and help with better medication adherence. At some point they hope to have a partnership with Outside In, a small local non-profit that they can donate medications to, however this will require another rule change for the Board to consider.

Board Member Penny Reher shared that she had recently heard of a company called Dispensary of Hope. This company partners with drug manufacturers. Drug manufacturers often produce excess drugs and then have to destroy the medications with 11 months of dating remaining. Dispensary of Hope gets the drug manufacturers in contact with charitable organizations where they can donate the drugs for free. Then the drug manufacturer gets a tax credit for their donation. Sandy thanked Penny for the information and will look into this company and their services.

The Board asked Sandy to provide the Board with a status update within six months of implementation and approved Central City Concern's waiver request.

MOTION

Motion to approve Central City Concern's waiver request in OAR 855-044-0050 for five years and to provide an update to the Board within six months of implementation was made and unanimously carried. (Motion by Reher, second by Linares).

T. Flinkman is requesting an extension of her Score Transfer that expired 7/6/14. Her extension request was denied by staff because she was provided the deadline in writing on two separate occasions and didn't send a request until after the deadline had passed. The Board also denied her request to extend her Score Transfer.

MOTION

Motion to deny T. Flinkman's request to extend Score Transfer was made and unanimously carried (Motion by Chute, second by Reher).

Medication Reconciliation

Executive Director Marc Watt and Compliance Director Gary Miner stated that it has become apparent that medication reconciliation is an issue that has evolved. They shared that an inspector had received a phone call about a process where the technicians were taking medication history and inputting it into patient's records. Board Staff thought that pharmacists should be doing this. Staff also received a phone call where someone was inquiring if a technician could take history and input unsupervised after hours if the information was remotely checked and then verified by a pharmacist. The Board asked if these activities are occurring strictly in emergency room settings. Staff stated that it is occurring in multiple types of practice settings. The Board emphasized that it is important that there is a good record. This requires an accurate Drug Utilization Review (DUR). Unfortunately, what is often happening now is that there is no initial DUR. In turn that can create duplications or doses that have been missed. The treatment that is going to happen depends on accurate medication information.

A Board Member commented that the hospital side of medication reconciliation has been studied and records are most accurate when someone from the pharmacy is gathering the information rather than a registered nurse or medication assistant. If the Board requires that only a pharmacist can do medication reconciliation, health systems may take this away from the pharmacy department. The Board stated that there is a huge opportunity to create a safer system and that staff should ask health systems how they are currently handling medication reconciliation to help

better define what the pharmacist should be doing and what the technician should be doing. Technicians may be able to take the lead with this if supervised by a pharmacist. However, training and education needs to be done. Pharmacist Sally Logan stated that what medication reconciliation means in the ER is what that patient is taking today. However, medication reconciliation upon discharge is probably the most important thing. This ensures that a pharmacist can review medication and do a DUR.

Executive Director Marc Watt stated that staff will reach out to some of the health systems to find out their best practices. Maybe in the future rules will be developed for technicians to reinforce what the Board's expectations are. Jennifer Grove, Director of Pharmacy at Providence invited that Board to come out to one of their hospitals to continue the dialogue about this topic. A Board Member commented that it may be helpful to review at a location that can provide an EPIC demonstration. This could help the Board to feel more comfortable and understand what is and is not happening.

Technician Checking Validation Program (TCVP) Request

Compliance Director Gary Miner presented a TCVP request from Sky Lakes 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.

The Board inquired about their hazardous drug list. Pharmacist Mychal Amos, Pharmacist-in-Charge of Sky Lakes Medical Center Pharmacy stated that most of their hazardous drug list is comprised of IVs. Mychal indicated that they do not have a lot of cart fill and are looking at implementing an automatic dispensing program. The Board also inquired about the technician testing system and exam. Mychal stated that they worked closely with Asante Rogue Regional Medical System to develop their TCVP program and that their exam is very similar to Asante's. He also indicated that if the technician fails the exam, they have to find the answers and retest and that at least one practical training session is required prior to testing. The Board reviewed the training material and noted that Oregon Revised Statutes were referenced rather than Oregon Administrative Rules.

The Board approved Sky Lakes Medical Center Pharmacy's TCVP request for five years with condition to provide status update in one year from the date of implementation and to make corrections to OAR references and provide a list of their high risk medications.

MOTION

Motion to approve Sky Lakes Medical Center Pharmacy's TCVP proposal with corrections made to OAR references and after providing a list of high risk medications to the Board for five years was made and unanimously carried. (Motion by Anderson, second by Fujisaki).

Remote Processing Application

Compliance Director Gary Miner presented a Remote Processing Application for CVS/Pharmacy Central Pharmacy Services that is requesting approval for licensure. It was noted that all application requirements and application checklist items have been satisfied. The Board briefly discussed what would happen if an error occurs in the dispensing process. They indicated that if an error occurs the Board will work with the other state Boards of Pharmacy depending on where it occurred in the dispensing process, i.e. filling error.

The Board approved their application with the condition to provide status update in one year from the date of implementation.

MOTION

Motion to approve CVS/Pharmacy Central Pharmacy Services Remote Processing Application was made and unanimously carried. (Motion by Anderson, second by Fujisaki).

Marijuana Dispensary Businesses

Compliance Director Gary Miner and Pharmacist Consultant Fiona Karbowicz stated that there are many marijuana dispensary businesses throughout the state that are now using the words “Apothecary or Pharmacy” in their business name. Historically, the Board has had concerns with businesses using these names when they are not actual pharmacies. The Board asked if staff could contact the Oregon Health Authority (OHA) and ask them to put a restriction in their rules to not allow them to use words such as “Apothecary, Pharmacy, or Farmacy” in their business name. Staff indicated that they had asked OHA before to do this and they indicated that they were too busy. However, their rules are currently open for public comment so we can ask them again now. The Board would like staff to provide testimony as they think that name differentiation could be helpful for the patient and that alternative names and the spelling of pharmacy can confuse people whose English is a second language.

Internship Hours/Clinical Experience Verification and Certification

Administrative Director Karen MacLean indicated that notification from the New York Board of Pharmacy was received that they are no longer verifying internship hours for other Boards. Karen inquired as to whether or not the Oregon Board should continue to verify internship hours for other Boards of Pharmacy. The Board indicated that they would like staff to continue to provide verification of hours.

Appearance

William Cover, R.Ph., Corporate Manager, Michael J. Simko R.Ph., Senior Counsel, for Walgreens provided a detailed presentation on the Walgreens Well Experience Pharmacy floor plan and workflow model. The Board inquired about the counseling process. Walgreens indicated that technicians would still do their same functions and if there is counseling, the pharmacist will perform that responsibility. The Board also inquired about what staffing levels will be required in the new workflow proposal. Walgreens indicated that staffing will be done based on volume and hours and that typical staffing would be one technician and one pharmacist, it just depends on volume. However, their new workflow proposal isn't about how to minimize pharmacist in staffing, it is to make the pharmacist most relevant to patient care. They indicated that staffing will be done appropriately. A Board Member suggested that if there is only a single pharmacist on staff that they should not have them sit at a desk, but rather to minimize distractions and so that they won't be interrupted when they could be performing something like a final verification. The Board asked if there were any concerns nationwide regarding HIPPA and inadvertent release of information with the new open layout. Walgreens stated that the proposal had been reviewed by the Office of Civil Rights to address this concern.

Walgreens stated that they currently have pharmacies in 49 states, with North Dakota being the exception and at this time there are 10 or fewer states that don't have the new floor plan/workflow

in implementation. The pharmacists that have worked in the new model indicate that they are able to have more quality interactions with patients. It was asked where the Drug Utilization Review (DUR) first enters into the new process. Walgreens indicated that when the pharmacist reviews data entry a DUR is conducted and that the new technology utilized is a significant improvement because of the quality steps involved. The Board asked how return to stock is handled. Walgreens stated that return to stock is done manually. It was also asked if there was a procedure in place for mixing lot numbers. Walgreens stated that the lot number process is incorporated in their policies and procedures as well as their training program and all bottles are imaged and handled one at a time. The Board thanked Walgreens for their appearance.

Resume Remaining Discussion Items

Compliance Director Gary Miner and Pharmacist Consultant Fiona Karbowicz provided an update on the Compounding Workgroup. They indicated that the workgroup last met on July 30th and discussed a crosswalk of Division 045 rules and USP 795/797. The workgroup also discussed the restructuring of Division 045. The next meeting will take place this Fall and at that time restructuring recommendations will be drafted and reviewed.

Cultural Competency Policy Statement Review

Executive Director Marc Watt, Administrative Director Karen MacLean, and Pharmacist Consultant Fiona Karbowicz shared that the Oregon Health Authority is in the process of finalizing the draft for its cultural competency continuing education (CE) rules pursuant to 2013 House Bill 2611. They propose to have draft rules in place after September 3rd and a Rulemaking Hearing in November. They are hoping to adopt final rules in January. This legislation allows health care professional boards to adopt rules which may require a person authorized to practice the profession to receive cultural competency CE approved by the Oregon Health Authority. A number of Board's have implemented policy statements to allow cultural competency CE as part of their CE. Staff asked the Board if they wanted to consider adopt of a draft policy statement in support of cultural competency education. The Board reviewed a proposed policy statement drafted by staff and unanimously motioned to accept it. It will be added to the Board's website under Position Statements.

MOTION

Motion to approve Cultural Competency Continuing Education Policy Statement was made and unanimously carried. (Motion by Anderson, second by James).

Healthcare Provider Status

Executive Director Marc Watt and Compliance Director Gary Miner discussed pharmacist healthcare provider status. They indicate that advanced practice for pharmacists has been discussed at the Pharmacy Coalition and they believe that as proposed, it would be too much for the Board to evaluate and quantify if a pharmacist is qualified for this designation.

The group who is preparing a proposed concept for legislative consideration has taken California's language from California Senate Bill 493 and attempting to put it into Oregon's Statutes. Staff has real concerns with this concept and believes there will be unintended consequences if this concept is passed as is. Currently there is no mention of collaborative therapy agreements and it says that the Medical Board can have some oversight. This could potentially mean dual licensure with both Boards.

Board Counsel Tom Cowan doesn't think there is a consensus about what advanced practice for pharmacists' means, and believes that it is very risky to put this language in front of a legislator who may accept it as is.

Staff indicated that they would like to see provider status for pharmacists to go forward now as it is needed for reimbursement and then come back and take an educated approach towards advanced practice. Board Counsel Tom Cowan stated that if advanced practice is achieved as proposed, there would be segregation at the cost of excluding many pharmacists who could take advantage of this practice. Tom believes there can be many unintended consequences with what is being proposed to move forward and that there needs to be consensus.

Biennial/Alternate License Expiration Schedule

Executive Director Marc Watt and Administrative Director Karen MacLean proposed a concept to make Certified Oregon Pharmacy Technician and Pharmacist licenses expire every two years rather than every year. Marc stated that biennial licensure would help reduce applications by 25%. If biennial licensure was implemented, the proposal would be to issue the first two year license for a one year fee. In addition, the expiration dates for certified Oregon pharmacy technicians and pharmacists would be on alternating years ending in June 30th. It was noted that LED's background checks would still be conducted annually. They believe that biennial licensure would allow staff to provide better service to its licensees and more efficient workflow overall. However, it will require a significant amount of outreach. The proposal would include making the transition for pharmacists in 2015.

The Board supported this concept and directed staff to bring a proposal back to the next Board Meeting.

Board Meeting Schedule

Executive Director Marc Watt stated that he has observed a trend with the current Tuesday and Wednesday Board meeting schedule. He stated that staff is often stressed the Friday before the Board Meeting and the Monday directly before the Board Meeting is very busy. Marc believes that staff could provide the Board with a better product if the days of the Board Meeting were switched to Wednesday and Thursday. This could be started next year based on room availability.

The Board supported the scheduled change and suggested that staff look at other venues to implement more quickly if possible.

ISSUES/ACTIVITIES

Reports:

Board President Ken Wells reported that he had attended incoming Board Member Kate James orientation. He stated that the orientation was beneficial to him as a Board Member and that it was a great experience to be able to sit in on case reviews.

Board Member Kate James reported that her orientation was fantastic and that the Board office is a well oiled machine. She shared that it was amazing to watch staff's work in progress.

Board Member Penny Reher reported that she had attended a 340B Conference in July on behalf of her employer. She stated that the meeting was very regulatory in nature. She had the opportunity to walk Capitol Hill and lobbied two days with Oregon Congressional Representatives. Penny indicated that the conference was very interesting and eye opening from a regulatory point of view.

Board Member Brad Fujisaki reported that he had attending the Compounding Work-Group Meeting.

Board Vice President Roberto Linares and Board Members Christine Chute and Heather Anderson had nothing to report.

Executive Director Marc Watt reported that he and Pharmacist Consultant Fiona Karbowicz had talked to CNN about medication issues related to Death with Dignity. He has also been spending a lot of time working on budget preparation. Marc and Fiona also had a positive meeting with the Oregon Patient Safety Commission. They would like to do an appearance at the Board's December meeting to discuss ways to collaborate.

Board Counsel Tom Cowan had nothing to report.

Compliance Director Gary Miner reported that 59% of pharmacy inspections have been completed. He also indicated that there are currently 14 individuals enrolled in the Health Professional Services Program (HPSP) and that they are all Board referrals.

Gary had a few field questions to ask the Board. The first question was concentrated on the use of tamper evident prescription paper. It was asked who required the use of tamper evident prescription paper as the paper is available for purchase from the general public. It was determined that tamper evident prescription paper is only required for Medicare and Medicaid patients under the Patriot Act. The second question had to do with the transfer of a prescription. Recently one pharmacy told another pharmacy that only a pharmacist could request a faxed copy of a prescription that a patient wants transferred to another pharmacy. The pharmacy had stated that it was a new Board requirement that only a pharmacist can initiate the call and ask for the fax copy. The Board confirmed that there had not been a recent rule change or decision to require this. Pharmacist Sally Logan stated that the pharmacy may have confused this with Washington's requirement as Washington limits transferring to only a pharmacist. The third question was regarding authentications and electronic prescribing of controlled substances. Someone had inquired if the Board will be considering adopting any rules around the configuration of two factor authentication for the electronic prescribing of Schedule II Controlled Substances. Gary stated that 31% of pharmacies in Oregon are accepting electronic submission of Schedule II Controlled Substances. The Board stated that they will not be adopting any rules at this time as the double authentication is a DEA requirement.

Pharmacist Consultant Fiona Karbowicz reported that she has been attending many meetings and that her other recent activities were summarized in her Pharmacist Consultant report that the Board had previously received.

Administrative Director Karen MacLean reminded the Board not to "reply all" when replying to an email that all Board Members are copied on to avoid generating a public meeting. She reported that the electronic fingerprinting contract has been signed and that there will be more to follow at the next meeting. She also stated that the scanning project contract has been signed. Therefore staff will begin working with the vendor to implement the system to scan licensing files and move

towards a paperless office. Karen reported that the Licensing Department is in its Certified Pharmacy Technician, Manufacturer, Wholesaler, and Drug Distribution Agent renewal cycle. Karen shared that on most days, the electronic Certified Pharmacy Technician renewals are being processed and updated expiration dates are being reflected on the Board's website the same day that the banking information is received. LEDs background checks are also current. Facilities are taking a bit longer as Wholesaler Class I Outlets have documents that are required for submission.

Board Member/Staff Presentations

Pharmacist Consultant Fiona Karbowicz attended the July 8th Pharmacy Coalition Meeting. She stated that provider status and advanced practices were discussed. Also discussed was a Pharmacy Benefit Manager (PBM) auditing tool kit. This provides information and resources for pharmacies. It also provides suggestions on how to present information to the Insurance Commission if pharmacies are in dispute with a PBM. Fiona also provided the Coalition with an update on non-pharmacy dispensing.

Executive Director Marc Watt and Compliance Director Gary Miner attended the June 12th Professional Practice Roundtable Meeting. They discussed potential changes to requirements for technicians.

Committees/Meetings

Pharmacist Brianne Cooper attended the 2014 University of Utah School on Alcoholism and Other Drug Depend Conference in July. She provided the Board with a PowerPoint presentation on some of the information she learned. She commented that this may be the last year that the conference is offered due as they've lost use for the location.

Pharmacist Laura Elvers will be attending Sterile Compounding Inspection Training in Chicago, Illinois from September 17-18th. This program is sponsored by NABP and the travel expenses are also covered by NABP.

Board Vice President Roberto Linares, Board Member Penny Reher and Inspector Gregg Hyman will be attending the NABP District VI-VIII Meeting from 9/21-24/2014 in Whitefish, Montana.

Staff asked the Board how many people they would typically like to send to the NABP Annual and District meetings each year? Some Board Members preferred to limit the number of people that are sent. Others commented that these meetings serve as great learning opportunities and to find out what challenges other Boards are facing. It was determined that the Voting Delegate and Executive Director or the Executive Director's designee should attend the Annual Meeting and that two Board Members and the Executive Director or the Executive Director's designee attend the District Meeting.

Compliance Director Gary Miner will be attending Pacific University's ACPE On-site evaluation October 21-23rd.

Executive Director Marc Watt will be attending the National Association of State Controlled Substances Authorities Annual Meeting October 21-24th. Marc received a scholarship to defray the cost of attending this meeting.

Board Members Penny Reher and Heather Anderson and Pharmacist Consultant Fiona Karbowicz will be attending the OSPA Annual Meeting November 7-9th. They will be providing a Board of Pharmacy law CE opportunity for pharmacists.

Board Meeting Dates

- October 7 - 8, 2014 Portland
- December 2-3, 2014 Portland
- February 10-12, 2015 Portland
- April 7-8, 2015 Portland
- June 9-10, 2015 Portland
- August 11-13, 2015 Portland
- September 15-16, 2015 TBA
- October 6-7, 2015 Portland
- December 15-16, 2015 Portland

There is a scheduling conflict for the Board's September 2015 Strategic Planning Meeting. Staff will work with the Board to reschedule this meeting.

Rulemaking Hearing Dates

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

Financial/Budget Report

Executive Director Marc Watt and Administrative Director Karen MacLean provided the Board with the May 2014 financial report as well as biennial comparisons from 2009-2011, 2011-2013, and 2013-2015. Karen indicated that the 2015-2017 budget is being coded differently and as a result some of the comparisons may look a little strange in the future. Some of the items highlighted on the 2015-2017 agency requested budget include the PERs increase, a revamp in the supply and services setting, and a DOJ rate increase. Karen also explained some of the policy packages which include fixing the Executive Director's salary compression, adding the services of DAS Enterprise Human Resources, and adding a proposal to add two new positions; a Licensing Manager and Public Service Representative III for Licensing. Other policy packages include upgrading the agency database, an increase in IT professional rates, costs associated with paperless records retention, medical lab testing for compound testing, and merchant fees for credit card fees.

Legislative Update - None

Topics for Future Discussion

Board President Ken Wells and Executive Director Marc Watt will be working together to get these items added on to future agendas.

- Auto Refills
- Responsibilities of the PIC

- PIC Requirements for site attendance
 - Counseling on all Controlled Substance dispensing
 - Workgroup for Working Conditions
 - CCO's / Medical Home
 - Temporary Pharmacies
 - Long Term Care
 - How Final Orders are published on the BOP website
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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 – none
2. MPJE Scores - none
3. Pharmacist Consultant
4. Project Manager Report
5. License/Registration Ratification (June 7, 2014 – August 8, 2014)
6. Extension Requests
7. Approval of Board Meeting Minutes (4/8-9/14 and 6/10-11/14)

MOTION

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

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

Pharmacist Jackson Leong stated that he was pleased to see the Technician Survey come out. He shared that trying to keep track of over 120 national certifications has been exhausting and hopes to see future changes made to the national certification requirement. Jackson also commented on the amount of people the Board should send to a meeting. Jackson believes that two people is relevant, as one person can't attend all meetings in the track. Also there is networking which is valuable. Jackson stated that he hasn't seen the Board waste tax payer money or licensing fees.

Adjourn

MOTION

Motion to adjourn at 4:16 PM was made and unanimously carried (Motion by James, second by Anderson).

THURSDAY, AUGUST 14, 2014

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

The following Board Members were present:

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

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Gary Miner, Compliance Director

Chrisy Hennigan, Office Manager

Joe Ball, Chief Investigator

Gregg Hyman, Inspector

Laura Elvers, Inspector

Thomas Cowan Sr. AAG Board Counsel

General Administration continued.

Rules & Policy Discussion

The Board added the following topic to the agenda.

Family Planning and County Health Work-Group Update

Pharmacist Consultant Fiona Karbowicz provided an update on the Family Planning and County Health Work-Group. The work-group has had one meeting at which creating new rules to establish a larger formulary, eliminate duplicate licensure, and personnel were discussed. Staff will continue working with the work-group and draft rules which will be presented to the Board in 2015.

Review Rulemaking Hearing Report – None

Consider Adoption of Temporary Rules – None

Send Rules to Rulemaking

Division 019 Pharmacists

The Board's temporary rule to allow pharmacy residents who have been accepted into a program the ability to reciprocate sooner in order to satisfy residency requirements expires October 22, 2014 and is applicable to nonresident pharmacists who have obtained licensure in another state, but have less than one full year of pharmacist licensure to reciprocate. Approximately 10 individuals took advantage of the temporary rule in order to begin a residency in 2014.

The Board sent this rule to rulemaking. Note: there will be no rulemaking hearing for this rule unless it is requested.

MOTION

Motion to send Licensing by Reciprocity rules in OAR Chapter 855, Division 019 to rulemaking was made and unanimously carried (Motion by Anderson, second by Linares).

Consider Adoption of Rules – None

Rules Policy Issues for Discussion:

Tramadol Federal Update

Staff provided the Board with an update on Tramadol. Effective August 18, 2014, the Federal Government is making this drug a Schedule IV Controlled Substance. A second email notifying licensees of the change will be sent via the Board's list-serve.

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

Compliance Director Gary Miner, Pharmacist Consultant Fiona Karbowicz, and Project Manager Courtney Wilson presented a timeline of Federal and Oregon Board of Pharmacy potential actionable items as they relates to the Drug Supply Chain Security Act (DSCSA). Over the last several months staff has been working on drafting amendments to its wholesaler, drug distribution agent, and manufacturer rules as a result of DSCSA. These rules were sent to stakeholders for comment. The staff reviewed the stakeholders' comments and some of the changes were incorporated into the draft rules. The Board reviewed the initial draft rule amendments and concepts. The draft rules either adopt concepts of the Federal law or exceed Federal requirements. Board Counsel Tom Cowan commented that when staff creates its FAQs relating to changes and the DSCSA the differentiations between DSCSA and the Board will needed to be noted with an explanation of why the Board has a different requirement. He also suggested that an intent paper be developed with a Rulemaking Notice once the Board sends the rules to rulemaking.

Dan Bellingham from the Healthcare Distribution Management Association (HDMA) was in attendance. He stated that California, Idaho, and Oklahoma are also working on rule changes. He indicated that the FDA has to propose certain licensure by January 2015. However, the industry doesn't expect to see draft rules before then due to the lack of funding.

Pharmacy Security

A summary of other states security rules regarding the pharmacy or prescription areas was reviewed. The majority of the other states include the following components in their rules: locks, electronic barriers, entry detection, physical barriers, alarm systems, combination lock control, passwords, positive identification of an individual, electronic and alarm systems with supervised transmittal lines, standby power back up and security cameras. Staff will utilize some of these models when they begin drafting amendments to the Board's security rules.

Procedural Rules

The Board reviewed the draft amendments to its model rules of procedure. If adopted, these rules will need to be updated if the Board adopts subsequent versions of the Attorney General's Uniform and Model Rules of Procedure under the Administrative Procedures Act at its Annual Business Meeting.

Controlled Substances

The Board reviewed a proposed rule amendment to include delta-9-tetrahydrocannabinol (THC) in Schedule II of the controlled substance rules. There was a brief discussion whether Marinol is included in the definition of Delta 9 THC and staff will provide a response at the next meeting.

Technician Licensure Requirements

Pharmacist Consultant Fiona Karbowicz provided an overview of the survey results relating to technician licensure requirements. She reported that 80% of survey respondents indicated that there should be a minimum age for technicians. The most referenced age was 18. Most respondents reported that they could obtain their high school transcript or GED certificate if it was requested. 60% of respondents thought that individuals should be given more than one year but less than two years to obtain national certification while 40% were not in favor. 65% of certified pharmacy technicians were in support of dropping the requirement to recertify while only 48% of pharmacists supporting dropping the requirement. If the requirement to recertify was dropped pharmacists preferred replacing it with traditional continuing education while certified pharmacy technicians preferred replacing it with onsite training. 75% of pharmacists were in support of requiring 10 hours of continuing education per year. 85-90% of all respondents were in favor of keeping the current law and patient Oregon specific continuing education requirements.

The Board reviewed the draft rule amendments to the technician rules. The draft rules incorporate the majority of the survey feedback. It was recommended that the draft rules incorporate what type of continuing education is required of the proposed 10 hours. It was discussed if national certification should be required again if a certified pharmacy technician has had a lapsed registration with the Board. The Board determined that if the certified pharmacy technician has had a lapsed registration greater than five years and would like to reinstate, national certification exam would need to be re-taken and passed.

A Board Member stated that the Accreditation Council for Pharmacy Education (ACPE) has created a new term for continuing education. It is called continuous professional development. The Board may want to consider using this language in its rules.

Charitable Pharmacy

The Board reviewed an exemption clause requested to be added to the records section of the charitable pharmacy rules by Central City Concern.

IX. OPEN FORUM At the completion of regular Board Business, any Board licensee or member of the public is invited to meet with the Board to discuss issues of interest (typically the last item of the meeting) There were no public comments.

Adjourn

MOTION

Motion to adjourn at 11:51 AM was made and unanimously carried (Motion by Reher, second by James).

Accepted by:

A handwritten signature in black ink, appearing to read "Watt", written over a horizontal line.

Marcus Watt, R.Ph.
Executive Director

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

Tuesday, August 12, 2014 @ 9:00 AM, Conference Room 1A Wednesday, August 13, 2014 @ 8:30 AM, Conference Room 1A Thursday, August 14, 2014 @ 8:30 AM, Conference Room 1E (note: different room) 800 NE Oregon Street in Portland, Oregon
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Executive Session of the Board was held on August 12, 2014 to discuss Compliance cases, followed by motions on August 13, 2014.

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	Fiona Karbowicz, R.Ph., Pharmacist Consultant
Michele Cale, R.Ph., Board Inspector	Annette Gearhart, Compliance Secretary
Gregg Hyman, R.Ph., Board Inspector	Kim Oster, Compliance Assistant
Laura Elvers, R.Ph., Board Inspector	Kate Hill, Temporary Compliance Assistant
Brianne Cooper, R.Ph., Board Inspector	Thomas Cowan, Senior AAG

Case 2013-0501 Motion to accept signed consent order.

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

Case 2013-0542 Motion to deny request.

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

Case 2013-0364 Motion to accept ALJ Barber's June 2014 Ruling on Motion for Summary Determination and Proposed Order.

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

Case 2012-0322 Motion to reduce probationer's UAs to 20 per year.

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

Case 2008-0391 Motion to grant pharmacist request.

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

Case 2013-0508 Motion to issue Letter of Concern to outlet.

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

Case 2014-0010 Motion to issue Letter of Concern outlet and upper management.

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

Case 2014-0260 Motion to revoke outlet license, impose \$10,000 civil penalty per violation; deny location change application.

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

Case 2014-0136 **Motion to impose \$10,000 civil penalty per violation against outlet; and in**
Case 2014-0285 **Motion to suspend pharmacist license and impose \$1,000 civil penalty per violation**
against Pharmacist-in-Charge.
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0248 **Motion to impose \$5,000 civil penalty per violation against outlet; letter of concern to**
Pharmacist-in-Charge; and in
Case 2014-0279 **Motion to impose \$2,000 civil penalty stayed in Case 2009-0028 and impose \$1,000**
civil penalty per violation against pharmacist.
Motion by: Penny Reher; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0263 **Motion to revoke outlet license and impose \$10,000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0244 **Motion to revoke outlet and impose \$10,000 civil penalty per violation.**
Motion by: Brad Fujisaki; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0075 **Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion carried with Brad Fujisaki recused.

Case 2014-0205 **Motion to suspend intern license.**
Motion by: Penny Reher; Seconded by: Christine Chute. Motion carried with Brad Fujisaki recused.

Case 2014-0241 **Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0240 **Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation.**
Motion by: Penny Reher; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0246 **Motion to issue Letter of Concern to pharmacist.**
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0162 **Motion to revoke pharmacist license and impose \$1,000 Civil Penalty per violation.**
Motion by: Brad Fujisaki; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0069 **Motion to close under investigation.**
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0147 **Motion to revoke technician license and impose \$1,000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0187 **Motion to impose \$5,000 civil penalty per violation against outlets;**
Case 2014-0188 **Motion to issue letter of concern Pharmacist-in-Charge;**
Case 2014-0256 **Motion to issue letter of concern Pharmacist-in-Charge; and**
Case 2014-0249 **Motion to impose \$1,000 civil penalty per violation against technician.**
Motion by: Heather Anderson; Seconded by: Christine Chute. Motion unanimously carried.

Case 2014-0276 **Motion to impose \$1,000 civil penalty per violation against technician; and in**
Case 2014-0298 **Motion to impose \$10,000 civil penalty per violation against outlet; issue letter of**
concern to all Pharmacist-in-Charge involved.
Motion by: Penny Reher; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0239 **Motion to revoke manufacturer and wholesaler registrations and impose \$10,000 civil**
penalty per violation.
Motion by: Kate James; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0071 **Motion to revoke technician license and impose \$1,000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0290 **Motion to grant technician license.**
Motion by: Roberto Linares; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0242 **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 2014-0270 **Motion to deny intern license and impose \$1,000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion carried with Roberto Linares recused.

Case 2014-0295 **Motion to grant intern license.**
Motion by: Penny Reher; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0237 **Motion to deny intern license.**
Motion by: Penny Reher; Seconded by: Brad Fujisaki. Motion carried with Roberto Linares recused.

Case 2014-0206 **Motion to grant pharmacist license.**
Motion by: Christine Chute; Seconded by: Kate James. Motion unanimously carried.

Case 2014-0220 **Motion to grant technician license.**
Motion by: Brad Fujisaki; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0200 **Motion to grant technician license.**
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0294 **Motion to grant technician license.**
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0170 **Motion to deny technician license and impose \$1,000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0201 **Motion to deny technician license and impose \$1,000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0059 Motion to issue letter of concern.
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0154 Motion to issue Letter of Concern to outlet, PIC and pharmacist.
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0114 Motion to issue no violation letters to pharmacy and pharmacist.
Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0047 Motion to suspend technician license and issue letter of concern to pharmacy and pharmacist, CC: letter of concern to Pharmacist-in-Charge.
Motion by: Heather Anderson; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0107 Motion to issue Letter of Concern to outlets; and issue Letter of Concern to pharmacists with recommendation of 3 hours CE in patient safety/medication error prevention; and cc Letter of Concern to Pharmacist-in-Charge.
Motion by: Brad Fujisaki; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0119 Motion to issue letter of concern to pharmacist; CC letter of concern to Pharmacist-in-Charge and outlet.
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2014-0202 Motion to deny technician license.
Motion by: Heather Anderson; Seconded by: Christine Chute. Motion unanimously carried.

Case 2014-0098 Motion to issue letter of concern to outlet; and in
Case 2014-0132 Motion to issue letter of concern to outlet and CC: Pharmacist-in-Charge.
Motion by: Roberto Linares; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0082 Motion issue letter of concern to pharmacist and CC: pharmacy.
Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2014-0193 Motion to issue letter of concern to pharmacist; CC: outlet.
Motion by: Roberto Linares; Seconded by: Christine Chute. Motion unanimously carried.

Motion to accept the items on the consent agenda with Case Nos. 2014-0202; 2014-0098/2014-0132; 2014-0082 and 2014-0193 pulled for discussion.
Motion by: Christine Chute; Seconded by: Penny Reher. Motion unanimously carried.

LETTERS OF CONCERN CASES:

Case: 2014-0194 Pharmacist: letter of concern

Cases: 2014-0226 Outlet: CC Letters of concern
2014-0286 PIC: Letter of concern recommending 3 hours CE in patient safety/error prevention, not counseling or documenting counseling of patient on new medication.
2014-0287 R.Ph.: Letter of concern recommending 3 hours CE in patient safety/error prevention.
2014-0288 CPT: Letter of concern recommending 3 hours CE in patient safety/error prevention.

Case: 2014-0148 P.I.C.: letter of concern

Case: 2014-0135 P.I.C.: letter of concern
Pharmacy: no action - PIC is the owner

Case: 2014-0150 Outlet: Letter of concern to request new procedure for license verification.

Case: 2014-0225

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.

DEFICIENCY NOTICES:

Cases: 2014-0060, 2014-0078, 2014-0090, 2014-0094, 2014-0142, 2014-0181, 2014-0182, 2014-0184, 2014-0186, 2014-0190, 2014-0191, 2014-0192, 2014-0219, 2014-0221, 2014-0222, 2014-0223, 2014-0224, 2014-0235, 2014-0245, 2014-0247, and 2014-0284.

UNABLE TO SUBSTANTIATE:

Cases: 2014-0149, 2014-0197, 2014-0198, 2014-0227, 2014-0230, and 2014-0232.

NO VIOLATION:

Cases: 2014-0030, 2014-0048, 2014-0134, 2014-0153, 2014-0207, 2014-0243 and 2014-0257.

NO JURISDICTION:

Case: 2014-0199

C.E. AUDIT CASES:

Authority delegated to the Compliance Director by the Board [grant staff authority to issue LOC if CE completed in June or to take and pass MPJE (in lieu of discipline) within 120 days if CE not completed by end of June]. Staff authorized to issue NPDA to suspend pharmacist license if MPJE not taken and passed within 120 days.

Case: 2013-0456

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.]

Cases: 2014-0103, 2014-0208, 2014-0209, 2014-0210, 2014-0211, 2014-0212, 2014-0213, 2014-0214, 2014-0215, 2014-0217, 2014-0218, 2014-0228, 2014-0250, 2014-0251, 2014-0252, 2014-0254 and 2014-0265.

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)

Cases: 2014-0131, 2014-0171 and 2014-0173.

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: 2014-0203, 2014-0236, 2014-0253 and 2014-0264.

DENIAL OF TECHNICIAN APPLICATION ORDERS:

By authority delegated to Oregon Board of Pharmacy Staff by the Board denial of technician licenses notices have been issued in:

Case: 2014-0238.

SURRENDERED LICENSE:

Case: 2014-0122