

BOARD MEETING MINUTES

**Oregon Board of Pharmacy
Red Lion Hotel
3301 Market St. NE
Salem, OR 97301
April 8-9, 2015**

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.

WEDNESDAY, APRIL 8, 2015

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

Roll Call:

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
Fiona Karbowicz, Pharmacist Consultant
Michele Cale, Inspector
Laura Elvers, Inspector
Annette Gearhart, Compliance Secretary

Gary Miner, Compliance Director
Joe Ball, Chief Investigator
Cheryl Fox, Inspector
Katie Baldwin, Inspector
Brienne Cooper, Inspector
Kim Oster, Compliance Assistant

Tom Cowan, Sr. AAG Board Counsel

Agenda Review and Approval

MOTION

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

New Pharmacy Inspector Cheryl Fox was introduced to the Board. She expressed that she is thankful to be here.

MOTION

Motion to enter Executive Session at 9:10 AM was made and unanimously carried (Motion by Linares, second by Fujisaki).

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

Items for Consideration and Discussion:

1. Deliberation on Disciplinary Cases and Investigations
2. Personal Appearances
3. Warning Notices
4. Case Review

MOTION

Motion to resume Open Session at 3:41 PM was made and unanimously carried (Motion by James second by Fujisaki).

Financial/Budget Report

Administrative Director Karen Maclean presented the financial reports for January and February 2015. No news yet on when the Budget Work Session will be held.

Legislative Update

Executive Director Marc Watt provided an update on the Legislative Session. He indicated that Senate Bill 148 held a Work Session at the end of March. This measure proposes to add new members on to the Board of Pharmacy. The latest amendments propose adding two Pharmacy Technicians on to the Board. Marc stated that the Pharmacy Coalition wasn't in agreement on this measure, therefore they stayed neutral.

Other measures of interest include House Bill 3174. This measure would require the Board of Pharmacy to notify individuals subject to investigation for violation of proposed disciplinary action, to advise them to retain counsel and impose penalties that are appropriate to the offense.

House Bill 2683 requires the Board of Dentistry, upon request of the individual who has been disciplined by the Board, to remove from its website and other publicly accessible print and electronic publications related to disciplining individuals if individuals meet certain criteria. Executive Director Marc Watt stated that Representative Mitch Greenlick has been conducting outreach and asking other Health Professional Regulatory Boards to change the way that they post discipline as he would like more consistency amongst the Boards.

Executive Director Marc Watt stated that staff will continue to monitor these measures.

Adjourn

MOTION

Motion to adjourn at 4:01 PM was made and unanimously carried (Motion by Reher, second by James).

THURSDAY, APRIL 9, 2015

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

Roll Call:

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
Joe Ball, Chief Investigator
Cheryl Fox, Inspector
Katie Baldwin, Inspector
Brianna Cooper, Inspector

Gary Miner, Compliance Director
Courtney Wilson, Project Manager
Fiona Karbowicz, Pharmacist Consultant
Michele Cale, Inspector
Laura Elvers, Inspector
Annette Gearhart, Compliance Secretary

Tom 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

Consider Adoption of Temporary Rules

Project Manager Courtney Wilson presented proposed temporary rules in the Division 031 Internship Regulations. The proposed temporary rule would make the Preceptor Registration renewable on a biennial basis and would expire on June 30 in odd numbered years. The temporary rule is needed for the current renewal period beginning in April for Pharmacist and Preceptor licenses as they transition to biennial licensure. The Board adopted the temporary rules and also sent it to rulemaking for consideration of permanent adoption.

MOTION

Motion to adopt Preceptor Temporary rules in OAR Chapter 855, Division 031 was made and unanimously carried (Motion by Anderson, second by Reher).

MOTION

Motion to send Preceptor rules in OAR Chapter 855, Division 031 to rulemaking hearing was made and unanimously carried (Motion by Anderson, second by Chute).

Review and Send Rules to Rulemaking

Division 110 Fees

Project Manager Courtney Wilson presented proposed rule amendments in the Division 110 Fee rules. Rule amendments reflect that Pharmacy Technician licenses issued prior to January 1, 2015 to a person under 18 years of age expire June 30 in odd numbered years. Other proposed rule amendments include listing the three classifications of Manufacturers and Wholesalers to coincide with proposed amendments in the Manufacturer and Wholesaler rules. The Board sent the proposed rules to rulemaking.

MOTION

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

Division 019 and Division 041 Pharmacist-in-Charge Requirements for Site Attendance

Pharmacist Consultant Fiona Karbowicz presented proposed rule amendments in Division 019 and Division 041 relating to Pharmacist-in-Charge (PIC) requirements for site attendance. The Board reviewed the proposed drafts in Division 019. Draft I retains the allowance of a dual PIC and draft II eliminates the allowance of a dual PIC. Both drafts establish minimum onsite practicing hours at a pharmacy. The Board determined to send the proposed rule amendments in draft I of Division 019 as revised to rulemaking.

Draft rule amendments in Division 041 Personnel (Both Retail and Institutional Drug Outlets) require the pharmacy to notify the Board within five business days and identify a Pharmacist employed at the location to serve as the Board contact person. The contact person is required to be a licensed Oregon Pharmacist and is responsible for the supervision of pharmacy staff, ensuring compliance with laws and rules, and responding to Board correspondence and inquiries. There is an allowance for pharmacies to apply for a written exception from the Board if they do not have a new Pharmacist-in-Charge (PIC) designated within 60 days. The Board sent the proposed rule amendments as revised to rulemaking.

Draft rule amendments in the Division 041 Non-Resident Pharmacies rules requires non-resident pharmacies to appoint an Oregon licensed Pharmacist-in-Charge (PIC) within four months of initial licensure of the pharmacy, or within 90 days of a change in PIC. In addition, when a change of PIC occurs, the non-resident pharmacy must notify the Board within five business days and identify a contact person. The non-resident pharmacy must have an Oregon licensed PIC employed within 90 days. The contact person must be a licensed Pharmacist in the pharmacy's state of residence and is responsible for the supervision of pharmacy staff, ensuring compliance with laws and rules, and responding to Board correspondence and inquiries. A new PIC must be appointed, and communication made to the Board within 90 days or the non-resident pharmacy is required to cease drug distribution and provision of pharmacy services in Oregon. The Board sent the proposed rule amendments as revised to rulemaking.

MOTION

Motion to send Pharmacist in Charge in OAR Chapter 855, Draft 1 Division 019 and Division 041 as revised to rulemaking hearing was made and unanimously carried (Motion by Fujisaki, second by Anderson).

Division 025 Pharmacy Technician Licensure Requirements

Pharmacist Consultant Fiona Karbowicz presented proposed rule amendments in the Division 025 Licensure as a Pharmacy Technician rules. The proposed rule amendments change the expiration date of the Pharmacy Technician license to the second June 30 from the date of issuance, which is not to exceed more than two years. The Board sent the proposed rule amendments to rulemaking.

MOTION

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

Division 041 Drug Storage

Pharmacist Consultant Fiona Karbowicz presented new proposed rules for the proper storage of drugs. The new proposed rules establish requirements for the proper storage of drugs, cold storage monitoring, and vaccine drug storage. It is the Board's hope that these rules will provide Pharmacists with more guidance on proper drug storage as there are currently limited requirements in rule. The Board sent the new proposed rules as revised to rulemaking.

MOTION

Motion to send Drug Storage rules in OAR Chapter 855, Division 041 as revised to rulemaking hearing was made and unanimously carried (Motion by, Fujisaki second by Anderson).

Division 060 Manufacturers

Pharmacist Consultant Fiona Karbowicz presented proposed rule amendments in the Division 060 Pharmaceutical Manufacturer rules. Proposed rule amendments establish new definitions, incorporate outsourcing facilities as one of the Food and Drug Administration (FDA) registration types that must register with the Board as a Manufacturer, and direct third-party logistics providers to register as a Drug Distribution Agent. The Board sent the proposed rule amendments as revised to rulemaking.

MOTION

Motion to send Manufacturer rules in OAR Chapter 855, Division 060 as revised to rulemaking hearing was made and unanimously carried (Motion by Anderson, second by Fujisaki).

Division 062 Drug Distribution Agents

Pharmacist Consultant Fiona Karbowicz presented proposed rule amendments in the Division 062 Drug Distribution Agent rules. Proposed rule amendments establish new definitions and direct a third-party logistics provider to register as a Drug Distribution Agent. The Board sent the proposed rule amendments to rulemaking.

MOTION

Motion to send Drug Distribution Agent rules in OAR Chapter 855, Division 062 to rulemaking hearing was made and unanimously carried (Motion by Anderson, second by Fujisaki).

Division 065 Wholesalers

Pharmacist Consultant Fiona Karbowicz presented proposed rule amendments in the Division 065 Wholesaler rules. Proposed rule amendments update requirements for record keeping, inventory management, and prohibited practices. Proposed rule amendments also direct third-party logistics providers to register as a Drug Distribution Agent. The Board sent the proposed rule amendments as revised to rulemaking.

MOTION

Motion to send Wholesaler rules in OAR Chapter 855, Division 065 as revised to rulemaking hearing was made and unanimously carried (Motion by Fujisaki, second by Anderson).

Consider Adoption of Rules – None

Rules Policy Issues for Discussion – None

Discussion Items

Waiver/Exception/Extensions/New Application Requests

Compliance Director Gary Miner and Administrative Director Karen MacLean presented five requests to the Board for consideration.

Medicine Shoppe Pharmacy requested an extension of a waiver that was previously granted by the Board. The waiver is for the minimum equipment rule in OAR 855-041-1035 which requires a sink in the pharmacy. The pharmacy has a sink located in the restroom, does not compound, and has an alternate water supply for reconstitution of powered medicinal products. The Board approved Medicine Shoppe's waiver extension request for five years.

MOTION

Motion to approve Medicine Shoppe's request to extend their existing waiver of OAR 855-041-1035 for five years was made and unanimously carried (Motion by Fujisaki, second by Linares).

J. Graveline requested to extend her Pharmacy Technician license for three to six months. The Board approved her extension request for six months.

MOTION

Motion to approve J. Graveline's request to extend Pharmacy Technician license for six months was made and unanimously carried (Motion by Linares, second by Anderson).

J. Moore requested to extend her Pharmacy Technician license for six months. The Board approved her extension request for six months.

MOTION

Motion to approve J. Moore's request to extend Pharmacy Technician license for six months was made and unanimously carried (Motion by Reher, second by Fujisaki).

J. Iltz requested an extension of his Pharmacist reciprocity/license transfer application. The Board approved his request for 90 days from the expiration date of his reciprocity/license application.

MOTION

Motion to approve J. Iltz's request to extend Pharmacist reciprocity/license transfer application for 90 days from the date of expiration was made and carried (Motion by Chute, second by Reher). *Chute, James, Linares, Reher in favor of. Anderson, Fujisaki, Wells opposed.*

D. Howell requested an extension of her Pharmacy Technician license. The Board approved her extension request for six months.

MOTION

Motion to approve D. Howell's request to extend Pharmacy Technician license for six months was made and unanimously carried (Motion by Anderson, second by Linares).

Discussion of Future Extension Requests for Pharmacy Technician (PT) Licenses

Administrative Director Karen MacLean presented information about Pharmacy Technician extension requests being received and the timing challenges of Board meetings. Staff asked the Board if they would like to delegate the authority to grant these extensions. The Board agreed that authority should be given to staff with the following parameters: the licensee must have a clear Law Enforcement Data System (LEDS) background check, no active disciplinary action, the extension is not to exceed one year and 364 days from the original date of issuance. The Board directed staff to provide them with a list of Pharmacy Technician license extension requests approved by staff. The Board also directed staff to bring Pharmacy Technician license extension requests denied to them for review.

MOTION

Motion to authorize Executive and Administrative Director's to approve Pharmacy Technician extension requests as needed with the following parameters:

- The licensee must have a clear Law Enforcement Data System (LEDS) background check;
- No active disciplinary action; and
- The extension is not to exceed one year and 364 days from the original date of issuance.

was made and unanimously carried (Motion by Anderson, second by Reher).

Auto Refill Update

Executive Director Marc Watt, Compliance Director Gary Miner, and Pharmacist Consultant Fiona Karbowicz provided an update on the auto refill work-group. They indicated that the first auto refill work-group meeting was held on April 2nd and that it was a positive meeting. The work-group identified some problems in the Board's Prescription Refill rules that establish requirements for the use of auto-refill programs, reminders, and pick-up notifications for retail pharmacies. These rules are scheduled to become effective January 1, 2016. Staff asked the work-group to provide suggestions on how to solve potential barriers. This will be discussed at the next meeting.

Military Licensure Issues

Pharmacist Consultant Fiona Karbowicz and Administrative Director Karen MacLean discussed recent or existing statutes related to military service and licensure for Pharmacists and Pharmacy Technicians. The Board directed staff to develop a policy paper to address what the Board is doing to facilitate military personnel and their families. The policy paper will address expediting the process of licensure for qualified military personnel and their spouses as well as the ability to request a fee waiver. The Board asked that Board Counsel Tom Cowan review the policy paper and that it come back to the Board for approval.

Pharmacy Security Update

Compliance Director Gary Miner and Pharmacist Consultant Fiona Karbowicz indicated that staff is working on establishing a pharmacy security work-group. The work-group will discuss physical security, electronic security, security of records, and the overall security of the pharmacy. Board Member Penny Reher volunteered to be on the work-group.

Medication Reconciliation Update

Executive Director Marc Watt, Compliance Director Gary Miner, and Pharmacist Consultant Fiona Karbowicz indicated that they conducted their first site visit at Providence St. Vincent Medical Center. Staff will continue to visit other sites in order to be able to see and accumulate information on how different entities and health systems manage medication reconciliation. Staff has also drafted a survey to send to health systems to learn more about their practices. The Board asked staff to reach out to the Board of Nursing to see if they have a perspective on what rules nursing is a part of in the medication reconciliation process. The Board also asked staff to obtain a physician's perspective on medication reconciliation and how they see it in its most efficient process.

National Certification Technician Changes

Executive Director Marc Watt and Administrative Director Karen MacLean provided the Board with information on new requirements that the Pharmacy Technician Certification Board (PTCB) will be implementing. In 2020 PTCB will require initial candidates for certification to complete a Pharmacy Technician education program accredited by the American Society of Health Systems Pharmacists (ASHP)/ Accreditation Council for Pharmacy Education (ACPE). Board staff recently became aware of National Healthcareer Association (NHA) testing eligibility requirements which require one year of experience as a pharmacy technician or pharmacy related college coursework prior to taking the ExCPT examination. The NHA testing changes were never communicated with the Board. The Board indicated that they would like to discuss national certification and other opportunities at its strategic planning meeting.

Food and Drug Administration (FDA) Draft Memorandum of Understanding (MOU)

Compliance Director Gary Miner and Board Member Kate James provided an overview of the Food and Drug Administration (FDA) Inter-governmental Working Meeting on Drug Compounding meeting that they attended in March. They indicated that the FDA is making big strides. They have developed draft guidance on the 503B registration as well as repackaging. The FDA will be issuing guidance on animal compounding. The FDA's Memorandum of Understanding between the states was discussed. The Memorandum of Understanding (MOU) establishes an agreement between each State and the FDA regarding the inordinate amounts of compounded human drug products interstate and the appropriate investigation by each state of complaints relating to compounded human drug products distributed outside the state. The FDA has defined an inordinate amount as 30% of the number of units of compounded and non-compounded drug products distributed or dispensed both intrastate and interstate by a pharmacist, pharmacy, or physician during that month. It was indicated that the FDA is encouraging states to sign the Memorandum of Understanding. States that agree to the Memorandum of Understanding will operate with the federal government and requirements of the FDA. The Medical Board and Board of Pharmacy would need to sign the Memorandum of Understanding and follow guidelines if agreed upon. States that sign the Memorandum of Understanding can have pharmacists, pharmacies, or physicians dispense both intrastate and interstate 30% of the number of units of compounded and non-compounded drug products.

Appearance

Sarah Wickenhagen RN, NP from the Oregon Board of Nursing provided a presentation on a proposal to revise the Advanced Practice Nurse Practitioner Prescription Drug Dispensing Program. Current statutes require the training program to be jointly approved by the Board of Nursing and the Board of Pharmacy. Current prescriptive authority in Oregon Administrative Rules 851 Division 056 allows an unencumbered Registered Nurse (RN) who has an unencumbered Advanced Practiced Registered Nurses (APRN's) certification, has completed 45 hours of an APRN pharmacology course and has a DEA registration (if applicable) to prescribe, procure or authorize use of legend drugs, controlled substance, therapeutic devices, and other measures and dispensing drugs consistent with the individual's scope of specialty practice, and competency. In order to obtain dispensing authority the APRN must have Prescriptive Authority that is unencumbered. They must also submit an application that attests to the review of the APRN Prescriptive Authority in Oregon handbook, DEA Pharmacist Manual, OAR 851 Division 056, ORS Chapter 689, OAR Chapter 855, Poison Prevention Packaging: "A Guide for Healthcare Professionals", Institute for Safe Medication Practices (ISMP): "List of Error-Prone Abbreviations, Symbols, and Dose Designations (2013), and information on

electronic and hard copy drug references. A multiple choice exam must also be completed. Upon successful completion and satisfying the mentioned requirements the Oregon Board of Nursing then notifies the Board of Pharmacy that dispensing authority has been granted.

It is being proposed that all Advanced Practice Nurse Practitioners (APRNs) with prescriptive authority obtain traditional dispensing authority with the exception of Certified Registered Nurse Anesthetists. Traditional dispensing would consist of the labeling and distribution of a medication to a client which is prepackaged by a Manufacturer registered with the Board of Pharmacy or repackaged by a Pharmacist licensed with the Board of Pharmacy. It is also being proposed that Nurse Practitioners (NPs) and Clinical Nurse Specialists (CNSs) utilize automation, such as vending machines, dispensing drugs for therapies more than 72 hour supply and providing refills at the point of care. In this proposal, registration with the Board of Pharmacy would be required and practitioners registered with the Board would be subject to annual registration fees, inspections, and compliance standards. Sarah commented that there would likely be a small number of APRNs that would dispense and that it would likely be APRNs located in rural areas. In addition, dispensing would need to be limited to their scope of practice. The Board inquired about the inspection process for APRNs. It was stated that random inspections do not take place. However, if there is a complaint the Oregon Board of Nursing can inspect.

The Board agreed that they supported the Board of Nursing's proposal to revise the Advanced Practice Nurse Practitioner Prescription Drug Dispensing Program as presented. The Oregon Board of Nursing will be discussing this proposal at their April Board Meeting. They will work on updating their rules in Division 056 to incorporate proposed changes and the proposed rules will tentatively have a rulemaking hearing in September or November. The Board of Pharmacy will need to work on updating its rules in Division 043 and will need to draft rules for non-pharmacy dispensing if this is approved by the Board of Nursing.

MOTION

Motion to support in concept the Board of Nursing's proposal to revise the Advanced Practice Nurse Practitioner Prescription Drug Dispensing Program as described today (pursuant to ORS 678.390(3)/OAR 851-050-0162/OAR 855-043-0210) was made and unanimously carried (Motion by Chute, second by Anderson).

Appearance

Jane Ishmale PhD Pharmacologist, Jo Choi-Nurvitadhi 2018 Oregon State University Pharm D Candidate and Young Yoon Ham 2018 Oregon State University Pharm D Candidate provided the Board with a presentation on the results of a study that they conducted on medical marijuana dispensaries. They indicated that as of January 9, 2015, 213 medical marijuana dispensaries had been approved by the Oregon Health Authority and that there are no requirements for the education or training of personnel, or clinical and counseling services for patients. The objective of their study was to describe the knowledge and training of Oregon's medical marijuana dispensary personnel and to describe the information and advice provided in Oregon's medical marijuana dispensaries. They collected information through an online survey. Their survey asked for business and personnel information, general patient information, product information, and advice provided. 141 surveys were emailed, 47 surveys were started, and 41 surveys were completed. Their response rate was about 30%. Survey responses reflected that about 1-10 employees at the dispensary work directly with patients to help select products. The dispensaries that conduct training provide on the job training, conferences, certificate

programs, and other types of training. Other types of training include personal experience with using and growing marijuana, completing an undergraduate study of sociology of cannabis culture, and reading and watching materials on marijuana. The survey also asked where staff gets information about medical marijuana. Responses included: the internet, medical literatures, patients, colleagues, subscriptions, workshops, listservs, and other sources. On average most respondents indicated that they spend 15-30 minutes with a new patient. The average time spent with a returning patient was 1-15 minutes. The top three medical conditions for patients using medical marijuana were severe pain, post traumatic stress disorder, and cancer symptoms. A patient's condition and/or symptoms was the primary way that dispensaries determined which strain is the most appropriate for a patient. The majority of dispensaries indicated that they advise patients of precautions and regulatory requirements. Survey respondents that provide additional information to patients provide written information or product handouts depending on the patient's needs and doctor's recommendations. The most common questions patients ask include: the difference between indica and sativa, whether or not the marijuana help with a specific symptom, what the THC and CBD content is, what is CBD, price inquiries, how much to use, how to use it, and the effects. Advice provided to patients include alternative methods and delivery symptoms, marijuana types and how to consume it, healthy eating and drinking habits, edibles, quantities, effects, and that individuals respond differently. From this study the following conclusions were made: background and training for personnel in dispensaries is variable. Information provided to patients is inconsistent and that further study on dispensary practices in other states, and patient education and outcomes is warranted.

VI. ISSUES/ACTIVITIES

Reports:

Board President/Members

President Ken Wells reported that he had recently made a presentation with Vice President Roberto Linares at the Oregon State Pharmacy Association (OSPA). He had also attended a Pharmacy Coalition meeting.

Vice President Roberto Linares reported that he had attended an American Pharmacists Association (APhA) conference in San Diego, California that was law related. One of the topics discussed included how to keep your Pharmacist license in good standing.

Board Member Christine Chute reported that she had attended the Governor's Advisory Committee Meeting on DUII. She indicated that the meeting was focused primarily on legislation. The next Governor's Advisory Committee Meeting on DUII is scheduled for April 10th.

Board Member Kate James attended a Department of Defense Meeting. The meeting was focused on compounding and the escalation in prices from a payer or insurance stand point.

Board Members Brad Fujisaki and Heather Anderson had nothing to report.

Executive Director Marc Watt reported that he had recently attended a hearing on Senate Bill 520. Senate Bill 520 would allow Pharmacists to administer vaccines to individuals at least seven years of age. Marc indicated that at the hearing he was asked why more Pharmacists are not utilizing the ALERT Immunization Information System (IIS) and being more proactive to encourage immunizations. The ALERT Immunization Information System is a statewide immunization registry that collects immunization data from both public and private health care providers in an effort to create complete immunization records for individuals in Oregon. Marc

also reported that he is now on a Scientific Advisory Committee for marijuana. He will be participating in the development of rules on dosage for marijuana.

Board Counsel Tom Cowan had nothing to report.

Compliance Director Gary Miner reported that there are currently 18 individuals enrolled in the Health Professional Service Program (HPSP). They are all Board referrals. Gary indicated that at the last HPSP meeting they discussed monitoring the compliance for attendance of Alcoholic Anonymous and other recovery group meetings. At the next meeting they will be discussing how monitoring these meetings will work for individuals that the Board has enrolled in the program. Gary also reported that to date 9% of pharmacies located in Oregon have been inspected.

Pharmacist Consultant Fiona Karbowicz reported that she had worked with other State agencies to get messaging and other communications out related to the meningococcal outbreak. Fiona indicated that there was a high pharmacy presence in the response and that the pharmacy community was very engaged in the mass vaccination campaign. Fiona also reported that she has been engaged with other outreach efforts and coordinating speakers for a variety of presentations listed on the agenda.

Administrative Director Karen MacLean reported that she had been working with staff to prepare information for the Pharmacist renewal cycle and that the Pharmacist renewal notices would be mailed on April 10th after the Preceptor temporary rule has been filed. Karen stated that she has been continuing to work on the scanning project and that new scanners have been obtained and training is continuing to be coordinated with staff. There will also be a records retention schedule for the Board to review at its June meeting. Karen stated that she is working on gathering information for the Board's 2016 National Association of Boards of Pharmacy (NABP) District Meeting. She reported that she has been working with staff on developing fiscal impact statements on proposed measures this legislative session.

Board Member/Staff Presentations

Executive Director Marc Watt indicated that at the March 10th Pharmacy Coalition meeting the biosimilar legislation was discussed as well as interchangeables. Marc stated that under the laws and rules section of the Board's website, a link to the list of biosimilar products determined by the FDA to be interchangeable has been posted. The next Pharmacy Coalition meeting is scheduled for the week of April 13th.

Executive Director Marc Watt stated that at the March 12th Professional Practice Roundtable meeting adverse events for protocols with immunizations was discussed and that there will continue to be ongoing discussions on this topic. He indicated that the Oregon Patient Safety Commission was also in attendance.

Pharmacist Consultant Fiona Karbowicz and Inspector Brianne Cooper provided a presentation at the Portland Society of Pharmacists (PSOP) continuing education dinner on April 1st. They indicate that there were more participants than last year and that a lot of good questions were asked.

The Oregon State Pharmacist Association Procrastinators' Continuing Education conference will be held on April 25th. Executive Director Marc Watt and Inspector Brianne Cooper and Laura Elvers will be in attendance.

Vice President Roberto Linares and Inspector Katie Baldwin will be providing a continuing education presentation at the Linn-Benton Pharmacy Association meeting April 29th.

Committees/Meetings

The Oregon State Pharmacist Association Lane County Meeting in Eugene was held February 21st-22nd. Board Members Penny Reher and Christine Chute, as well as Pharmacist Consultant Fiona Karbowicz provided a presentation. They indicated that they received great feedback on their presentation and that people were pleased to see a public Board Member in attendance.

As previously reported Compliance Director Gary Miner and Board Member Kate James attended the 2015 Inter-governmental Working Meeting on Drug Compounding March 18th -19th in Silver Spring, Maryland.

Executive Director Marc Watt and Board Members Roberto Linares and Penny Reher will be attending the National Association of Boards of Pharmacy (NABP) Annual Meeting May 16th-19th in New Orleans, Louisiana. Vice President Roberto Linares will be the Board's voting delegate and a portion of the travel will be reimbursed by NABP. Penny will represent District VII at the NABP Resolutions Committee. Board members indicated that they will send Roberto their thoughts on the resolutions for the General Business Meeting.

Board Meeting Dates

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

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|-------------------------|-----------|----------------------|
| • 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 | |
| • February 10-12, 2016* | Portland | (3 day meeting) |
| • April 6-7, 2016 | Portland | |
| • June 8-9, 2016 | Portland | |
| • August 10-12, 2016* | Portland | (3 day meeting) |
| • October 5-6, 2016 | Portland | |
| • November 2-3, 2016 | Corvallis | (Strategic Planning) |
| • December 7-8, 2016 | Portland | |
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Rulemaking Hearing Dates

- May 28, 2015
 - November 24, 2015
 - May 24, 2016
 - November 22, 2016
-

Topics for Future Discussion

- How Final Orders are published on the BOP website
 - CCO's / Medical Home
 - Temporary Pharmacies
 - Internship / Preceptors
 - Counseling on all Controlled Substance dispensing
 - Integration of Patient Safety Commission
 - Disproportionate Licensee Disciplinary Actions
 - Reporting Requirements
-
-

Strategic Planning - None

Approve Consent Agenda*

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

1. NAPLEX Scores
2. MPJE Scores
3. Pharmacist Consultant
4. Project Manager Report
5. License/Registration Ratification (February 11, 2015-April 7, 2015)
6. Extension Requests - none
7. Approval of Board Meeting Minutes (February 11-13, 2015)

MOTION

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

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)

Board President Ken Wells invited any comments from the public.

Pharmacist Jackson Leong inquired as to the next date for the Long Term Care Rules Committee. Compliance Director Gary Miner indicated that staff needs to reach out to accrediting agencies and get their input. Jackson commented that he was appreciative that the Board is looking into the matter of medication reconciliation. He also asked the Board to consider looking into creating a requirement for a Standardized Hospital Discharge Form. He believes that this would result in better patient care.

Pharmacist Eric Littner encouraged the progression of the draft long term care rules. He indicates that they are needed to put more structure in the long term care environment.

Adjourn

MOTION

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

Accepted by:

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

**Marcus R. Watt, R.Ph.
Executive Director**

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

Wednesday, April 8, 2015 @ 9:15 AM, Mountain Rooms
Thursday, April 9, 2015 @ 9:15 AM, Mountain Rooms
Red Lion Hotel @ 3301 Market St. NE in Salem, OR 97301

Executive Session of the Board was held on 4/8/2015 to discuss Compliance cases, followed by motions on 4/9/2015. Working lunch held on Wednesday 4/8/2015.

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
Laura Elvers, R.Ph., Board Inspector	Kim Oster, Compliance Assistant
Brianne Cooper, R.Ph., Board Inspector	Thomas Cowan, Senior AAG
Cheryl Fox, R.Ph., Board Inspector	Courtney Wilson, Project Manager

Case 2014-0296 Motion to deny request for reconsideration.

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

Case 2011-0396 Motion to drop sanction 1.b. of probation and deny request to end probation.

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

Case 2013-0092 Motion to reduce UAs to 18/year.

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

Case 2013-0532 Motion to deny request.

Motion by: Kate James; Seconded by: Heather Anderson. Motion carried with Kenneth Wells opposed.

Case 2014-0480 Motion to close under investigation.

Motion by: Brad Fujisaki; Seconded by: Penny Reher. Motion unanimously carried.

Case 2015-0151 Motion to issue Letter of Concern to the pharmacy; and

Case 2014-0491 Motion to accept pharmacist's signed Stipulated Agreement; and in

Case 2015-0148 Motion to accept technician license surrendered 3/30/2015.

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

Case 2014-0526 Motion to suspend outlet license and impose \$10,000 civil penalty per violation.

Motion by: Brad Fujisaki; Seconded by: Penny Reher. Motion unanimously carried.

Case 2015-0028 Motion to issue no violation letter to outlet.
Motion by: Penny Reher; Seconded by: Christine Chute. Motion unanimously carried.

Case 2015-0085 Motion to issue letter of concern to outlet.
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0534 Motion to revoke outlet license and impose \$10,000 civil penalty per violation; and in
Case 2015-0070 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 2015-0075 Motion to impose \$10,000 civil penalty per violation outlet; and in
Case 2015-0058 Motion to issue Letter of Concern to District Manager.
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2015-0107 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 2015-0132 Motion to deny probationer's petition to reduce number of UAs or to have a cheaper test.
Motion by: Brad Fujisaki; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2015-0131 Motion to revoke technician license and impose \$1,000 civil penalty per violation; issue letter of concern to outlet.
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2015-0002 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2015-0067 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 2014-0322 Motion to accept Stipulated Consent Order surrendering pharmacist license.
Motion by: Brad Fujisaki; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0500 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Roberto Linares; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2014-0518 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0536 Motion to impose \$10,000 civil penalty per violation against outlet; and
Case 2015-0198 Motion to impose \$1,000 civil penalty per violation against Pharmacist-in-Charge;
Case 2014-0537 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Christine Chute; Seconded by: Heather Anderson. Motion carried with Roberto Linares recused.

Case 2015-0080 **Motion to revoke technician license and impose \$1,000 civil penalty per violation.**
Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2015-0060 **Motion to revoke technician license and impose \$1,000 civil penalty per violation; issue letter of concern to pharmacists and technicians that were aware of incident but did not report to Board; CC: letters of concern to outlet.**
Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2015-0078 **Motion to deny technician license and impose \$1,000 civil penalty per violation.**
Motion by: Christine Chute; Seconded by: Kate James. Motion unanimously carried.

Case 2015-0042 **Motion to revoke intern license and impose \$1,000 civil penalty per violation.**
Motion by: Penny Reher; Seconded by: Heather Anderson. Motion carried with Roberto Linares recused.

Case 2015-0077 **Motion to revoke technician license; deny certified pharmacy technician license and impose \$1,000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2015-0006 **Motion to deny pharmacist license and impose \$1,000 civil penalty per violation.**
Motion by: Kate James; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2015-0005 **Motion to impose \$1,000 civil penalty per violation against pharmacist.**
Motion by: Heather Anderson; Seconded by: Kate James. Motion carried with Kenneth Wells and Roberto Linares opposed.

Case 2015-0079 **Motion to grant pharmacist license.**
Motion by: Penny Reher; Seconded by: Heather Anderson. Motion unanimously carried.

Case 2015-0021 **Motion to deny technician license.**
Motion by: Heather Anderson; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2015-0053 **Motion to deny technician license and impose \$1000 civil penalty per violation.**
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2015-0051 **Motion to grant technician license.**
Motion by: Heather Anderson; Seconded by: Penny Reher. Motion unanimously carried.

Case 2015-0117 **Motion to grant technician license.**
Motion by: Kate James; Seconded by: Christine Chute. Motion carried with Kenneth Wells opposed.

Case 2015-0071 **Motion to impose \$10,000 civil penalty per violation against outlet; and in**
Case 2015-0118 **Motion to impose \$1,000 civil penalty per violation against pharmacist; issue letter of**
concern to technician.
Motion by: Heather Anderson; Seconded by: Roberto Linares. Motion carried with Brad Fujisaki recused.

Case 2015-0055 **Motion to suspend pharmacist license and impose \$1,000 civil penalty per violation; issue letter of concern to outlet.**

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

Case 2015-0063 **Motion to impose \$1,000 civil penalty per violation against Pharmacist-in-Charge; and**
Case 2015-0119 **Motion to impose \$1,000 civil penalty per violation against technician.**

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

Case 2015-0009 **Motion to impose \$10,000 civil penalty per violation against outlet; and in**
Case 2015-0074 **Motion to issue letter of concern to Pharmacist-in-Charge; and in**
Case 2015- 0073 **Motion to issue letter of concern to technician.**

Motion by: Penny Reher; Seconded by: Kenneth Wells. Motion unanimously carried.

Case 2015-0083 **Motion to issue Letter of Concern to technician.**

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

Case 2015-0049 **Motion to deny pharmacist license and impose \$1,000 civil penalty per violation.**

Motion by: Roberto Linares; Seconded by: Kenneth Wells. Motion unanimously carried.

Case 2014-0486 **Motion to impose \$10,000 civil penalty per violation against outlet and grant outlet license.**

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

Case 2014-0302 **Motion to suspend pharmacist license and impose \$1,000 civil penalty per violation;**
Case 2015-0178 **Motion to impose \$10,000 civil penalty per violation against outlet.**

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

Case 2014-0447 **Motion to impose \$10,000 civil penalty per violation against outlet; and in**
Case 2015-0139 **Motion to suspend Pharmacist license and impose \$1,000 civil penalty per violation.**

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

Case 2015-0015 **Motion to impose \$10,000 civil penalty per violation against outlet; and**
Case 2015-0173 **Motion impose \$1,000 civil penalty per violation against Pharmacist-in-Charge.**

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

Case 2015-0057 **Motion to impose \$1,000 civil penalty per violation pharmacist and issue letter of concern to Pharmacist-in-Charge, CC: outlet.**

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

Case 2014-0464 **Motion to issue letter of concern recommending 3 hours CE in medication error prevention to pharmacist and technician; letter of concern to outlet.**

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

Case 2014-0472 **Motion to issue letter of concern recommending 3 hours of CE in medication error prevention to pharmacist and technician; letter of concern to outlet.**

Motion by: Penny Reher; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2014-0354 Motion to issue letter of concern recommending 3 hours of CE in medication error prevention to pharmacist and technician; letter of concern to outlet.

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

Case 2015-0029 Motion to issue letter of concern recommending 3 hours of CE in medication error prevention to pharmacist and technician; CC: letters to outlet.

Motion by: Penny Reher; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2015-0054 Motion to revoke outlet registration and impose \$10,000 civil penalty per violation.

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

Case 2015-0076 Motion to issue a letter of concern recommending 3 hours CE to pharmacist; CC: outlet.

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

Case 2015-0038 Motion to issue a no violation letter to pharmacist; CC: letter to Pharmacist-in-Charge and pharmacy.

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

Case 2014-0535 Motion to issue letter of no violation to pharmacists and outlet.

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

Case 2015-0047 Motion to issue letter of no violation to Pharmacist-in-Charge and CC: outlet.

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

Motion to accept the items on the consent agenda with cases 2015-0076; 2014-0535; 2015-0038; 2015-0134 and 2015-0047 pulled for discussion.

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

LETTERS OF CONCERN CASES:

**Case: 2015-0086 PIC: CC: Letter of Concern
Pharmacy: Letter of concern**

**Case: 2014-0470 Drug Outlet: Letter of Concern (Incorrect record of prescription sale; unknown which employee was responsible)
PIC: CC Letter of Concern**

**Case: 2015-0072 Pharmacist: Letter of Concern recommending 3 hours CE in medication error prevention.
Pharmacy & PIC: CC: Letter of concern.**

**Case: 2015-0111 Drug Outlet: Letter of concern
PIC: CC Letter of concern
RPH: Letter of concern suggesting 3 hours of CE in medication error prevention**

Case: 2014-0377 Pharmacy: Letter of concern.

Case: 2015-0027 Outlet: Letter of concern to verify all registrations before providing products to customers.

**Case: 2014-0479 OUTLET: Letter of Concern
PIC: Letter of Notification**

Case: 2015-0081 **CPT:** Letter of Concern recommending 3 hours CE in medication error prevention.
Pharmacist and Outlet: CC: Letter of Concern

Case: 2015-0082 **Pharmacy:** Letter of Concern
PIC: CC: letter of concern

DEFICIENCY NOTICES:

Cases 2014-0308; 2014-0467; 2014-0481; 2014-0527; 2014-0529; 2014-0538; 2015-0022; 2015-0024; 2015-0036; 2015-0044; 2015-0045; 2015-0088 and 2015-0108.

UNABLE TO SUBSTANTIATE:

Cases: 2015-0037; 2015-0046 and 2015-0110.

NO VIOLATION:

Case: 2015-0016; 2015-0031; 2015-0040; 2015-0043 and 2015-0048.

NO JURISDICTION:

Case: 2015-0113

C.E. AUDIT CASES:

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

Case: 2014-0338

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: 2015-0127

UNREGISTERED OUTLET CASES:

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

Case: 2015-0025; 2015-0026; 2015-0030 and 2015-0068.

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: 2015-0003; 2015-0050 and 2015-0052.

“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: 2015-0062.

DENIAL OF APPLICATION ORDERS:

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

Case: 2014-0492

SURRENDERED LICENSES:

Case: 2015-0039; 2015-0041 and 2015-0115

UPDATES / For Your Information:

Case numbers from February 2015 Board meeting's Express Scripts case that have been reassigned to new cases [outlets/PICs only filled new prescriptions, no discipline proposed.]

Case #: 2015-0088; 2015-0089; 2015-0090; 2015-0093; 2015-0094; 2015-0095; 2015-0096; 2015-0101; 2015-0102; 2015-0103; and 2015-0104.

Updates:

1. Open cases under investigation.
2. Hearings Spreadsheet
3. Data from last 4 meetings
4. Historical Data