

BOARD MEETING MINUTES

**Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
February 12-14, 2013**

TUESDAY, FEBRUARY 12, 2013

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

The following Board Members were present:

Ken Wells, President	Dianna Pimlott
Christine Chute, Vice President	Penny Reher
Brad Fujisaki	Roberto Linares

One Public Member position is vacant

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

Gary Schnabel, Executive Director	Karen MacLean, Administrative Director
Gary Miner, Compliance Director	Chrisy Hennigan, Office Manager
Courtney Wilson, Project Manager	Joe Ball, Chief Investigator
Gregg Hyman, Inspector	Fiona Karbowicz, Inspector
Michele Cale, Inspector	Katie Baldwin, Inspector
Annette Gearhart, Compliance Secretary	Kim Oster, Compliance Assistant

Thomas Cowan, Board Counsel

Agenda Review and Approval

MOTION

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

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

A. Items for Consideration and Discussion:

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

MOTION

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

MOTION

Motion to resume Open Session at 4:50 PM was made and unanimously carried (Motion by Chute, second by Fujisaki).

MOTION

Motion to adjourn at 4:50 PM was made and unanimously carried (Motion by Reher, second by Linares).

WEDNESDAY, FEBRUARY 13, 2013

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

The following Board Members were present:

Ken Wells, President	Dianna Pimlott
Christine Chute, Vice President	Penny Reher
Brad Fujisaki	Roberto Linares

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

Gary Schnabel, Executive Director	Karen MacLean, Administrative Director
Gary Miner, Compliance Director	Courtney Wilson, Project Manager
Joe Ball, Chief Investigator	Gregg Hyman, Inspector
Fiona Karbowicz, Inspector	Michele Cale, Inspector
Katie Baldwin, Inspector	Annette Gearhart, Compliance Secretary
Kim Oster, Compliance Assistant	

Thomas Cowan, Board Counsel

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. Executive Director Report
4. Project Manager Report
5. License/Registration Ratification (December 10, 2012 - February 8, 2013)
6. Extension Requests
7. Approval of Board Meeting Minutes (December 11-12, 2012)

MOTION

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

President Wells welcomed the former Board members and Interns that were in attendance. He asked them to introduce themselves and thanked them for attending the meeting.

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

ISSUES/ACTIVITIES

Reports:

Board Members Ken Wells and Roberto Linares had nothing to report.

Vice President Christine Chute stated that on January 16th she attended a Community Action to Reduce Substance Abuse (CARSA) Coalition meeting in Portland on behalf of the Board. The Director of the Office of National Drug Control Policy R. Gil Kerlikowske was in attendance and was also a speaker. Christine indicated that there was a lot of discussion surrounding drug take back and that CARSA is trying to involve youth to disseminate information about such programs via social media. Christine also attended a Governor's Advisory Committee Meeting on DUII. The meeting was focused exclusively on the legislature. The committee is in support of House Bill 2115 which expands the definition of intoxicants to include any drug that adversely affects a person's physical or mental faculties to a noticeable or perceptible degree.

Board Member Brad Fujisaki reported that on February 6th he and Inspector Fiona Karbowicz participated in a speaker series hosted by Pacific University. He explained that the speaker series features pharmacists with different career paths and that he and Fiona participated in a speaker series that focused on government and regulatory career paths.

Board Member Dianna Pimlott shared that at the end of January she presented at a conference for Safety Net Hospitals for Pharmaceutical Access (SNHPA) in San Francisco. Topics discussed included 340B drug discounts.

Board Member Penny Reher stated that she had recently participated in a Health Resources and Services Administration (HRSA) compliance audit.

Board Counsel Tom Cowan indicated that there have been good results on Contested Case Hearings.

Compliance Director Gary Miner reported that there are currently 19 people enrolled in the Health Professional Services Program (HPSP). One individual is a self referral. Gary was pleased to share that 100% of pharmacy inspections were completed in 2012. He also provided some highlights of different demonstrations on new technologies that have been presented for informational purposes to the compliance staff. This included InfoMax, a data recording pen for long term care that can be downloaded. Talyst, a long term care Pixys type machine that pre labels medication. Philips Medication Dispensing Service, a home system for medication delivery that has a variety of safety features. As well as an automated packaging system for long term care that is being marketed by Omnicare. Gary indicated that staff is working on trying to incorporate some of these automated functions into the long term care rules.

Gary shared that the rules the Board adopted in December are now available online. This includes the Division 041 re-organization. Gary reminded everyone that the Correctional Facility Rules were removed from Division 041 and are now located in Division 043 as part of the reorganization.

Gary also shared that he has been following legislative activities which includes monitoring the progression of bills. He advised the Board members of the charitable pharmacy bill (House Bill 2740) that establishes a waiver clause and will allow the Board to waive specific requirements in Oregon Revised Statutes (ORS) 689.772(3) if the Board determines that the waiver is in the interest of public health and safety. If House Bill 2740 goes into effect the Board will have the authority to take action on the charitable pharmacy waiver request that Multnomah County Health Department requested at the Board's December Meeting.

Gary stated that he and other staff members have had some preliminary discussions with the Veterinary Medical Examining Board about storing sedation drugs at animal shelters to be used on animals prior to euthanasia. Utilizing sedation prior to euthanasia is part of euthanasia guidelines established by the American Veterinary Medical Association (AVMA).

Administrative Director Karen MacLean reported that she is happy to be back in the office and thanked the staff for their assistance while she was out. Karen introduced Cherie Caceres who was in attendance. Cherie joined the licensing team in mid December. She is a welcomed addition and staff is excited to have a person who can speak Spanish on staff. Karen indicated that she is working with Gary Miner to establishing the recruitment for a part time inspector position. She hopes to have the recruitment opened in the next week and a half.

Karen indicated that the non prescription drug outlet renewal cycle has ended and that there were very few outlets that lapsed their registration. This renewal cycle was offered online for the first time. However, only 7% of these registrants utilized the online renewal option. We hope to see this increase in the future.

The transition to the new check processing system is continuing to go well. Karen shared that Office Manager Chrisy Hennigan is very pleased with the process and the efficiencies that have been created.

2013 Board Meeting Dates

The Board discussed changing meeting dates in October from 15,16,17 to 8,9,10. Administrative Director Karen MacLean will verify conference room availability with building management for those days. The Board decided that meeting date changes in October will only be tentative at this time.

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|------------------------|-----------|--------------------|
| • March 12 -13, 2013 | Silverton | Strategic Planning |
| • April 16 - 17, 2013 | Portland | |
| • June 11 - 12, 2013 | Portland | |
| • August 13 - 14, 2013 | Portland | |
| • October 15 -17, 2013 | Portland | |
| • December 17-18, 2013 | Portland | |

2013 Rulemaking Hearing Dates

The Board discussed the date of the next Rulemaking Hearing and elected to reschedule it from May 30, 2013 to June 27, 2013. This will allow for the possibility of more rules to be noticed and considered for rulemaking.

- May 30, 2013*
- November 21, 2013

*Rescheduled to June 27, 2013

Board Member/Staff Presentations

Board Members Ken Wells and Penny Reher indicated that they will be presenting at the Oregon State Pharmacist Association 2013 Lane County Mid-Winter CE Seminar, 2/23-24/2013, in Eugene, OR. They plan to discuss new rule changes as well as compounding issues. Inspector Gregg Hyman has been working on the power point slides in preparation for the presentation.

Board Members Ken Wells, Penny Reher and Roberto Linares attended the Oregon Pharmacist Coalition Meeting on February 12th. Executive Director Gary Schnabel attended via conference call. Issues surrounding prescriptive authority were discussed.

Board Member Brad Fujisaki indicated that the Oregon Society of Health-System Pharmacists (OSHP) made a request for a Board member to sit on a panel to discuss compounding issues on April 21st at the 2013 OSHP Annual Seminar. Board members supported Brad's participation in the panel discussion. Brad welcomed the addition of a staff member as well.

Committees/Meetings

Board President Ken Wells received an invitation from the National Association of Boards of Pharmacy (NABP) to serve on a taskforce for the Foreign Pharmacy Graduate Examination Committee (FPGEC) April 2-3 at NABP. All expenses will be covered by NABP. The Board supported Ken's participation in this taskforce.

The Board discussed the NABP 109TH Annual Meeting, May 18-21 in St. Louis, MO. Executive Director Gary Schnabel shared that the Board has been nominated for the Fred. Mahaffey Award for its efforts on the workforce survey and the drug outlet conduct rules. Board Members selected Penny Reher to be the Board's Voting Delegate for the Annual Meeting. Penny will double check her availability. NABP has offered a \$1,500 travel grant for this meeting for a voting delegate. It is available on a first come basis.

The NABP/AACP District VI, VII, VIII Meeting will be held September 8-11 in Boulder, CO. Board Members Brad Fujisaki and Roberto Linares will check with their Deans to see if their schools will share some of the travel expenses. They will report back to the Board at a later date.

Executive Director Gary Schnabel provided an update on the FDA Intergovernmental Working Meeting on Compounding that he attended on December 19th. He indicated that the meeting was well attended and that the FDA was very interested in the states thoughts on compounding. Gary indicated that the FDA is working on trying to establish an acceptable definition of

manufacturing and compounding. They discussed defining manufacturing as traditional manufacturing with NDA's and that everything else would be identified as compounding. NABP, who also participated in the meeting, would like to identify a third category of drug production that is a cross between both manufacturing and compounding. It is unknown who would regulate this third class. The FDA could be responsible for regulation or the states could. Board Counsel Tom Cowan indicated that as this third class relates to interstate commerce some states are very vigilant and invest resources into enforcement of regulations and some states are less vigilant. Therefore it can be difficult for states to regulate other states.

On February 7th Executive Director Gary Schnabel and Board Members Christine Chute and Penny Reher attended the Governor's Taskforce on Prescription Drug Abuse Meeting. They indicated that it was an informative meeting. Representatives from law enforcement and the pharmacy industry were present and participated in the work groups that were established. Each work group discussed a specific topic and provided recommendations that will be reviewed by the Governor. Topics included: increasing usage of the prescription drug monitoring program, educating the public, better drug take back options, prescribing practices, and treatment. Gary participated in the prescription drug monitoring work group. Some of their recommendations included sharing data with other states and allowing practitioners to see all of the controlled drugs that have been dispensed under their DEA Registration. Christine participated in the work-group that discussed educating the public. Some of their recommendations included educating the public to lock up controlled medications so that other people cannot access them. Other recommendations included changing practitioners prescribing habits and try to influence them to prescribe small quantities of controlled drugs to decrease the amounts that are available to the general public. Penny participated in the drug take back work- group. They discussed how they could get the DEA on board to make the take back process easier. They would like to establish a program that is safe, legal and environmentally stable. Some of their ideas included establishing post office type receptacles to be accessed by reverse distributors or that requires a two key system and restricts access to law enforcement or pharmacy staff.

Some of the statistics shared at the Governor's Taskforce on Prescription Drug Abuse Meeting include that in 2010 and 2011, Oregon was first in the nation for the use of prescription drug relievers for non-medical use. In addition, Oregon is second for the highest use of analgesics in the United States.

The Board discussed the University of Utah School on Alcoholism and Other Drug Dependencies Conference June 16-21, 2013 and the travel grant that is available. Inspector Michele Cale attended the conference last year and said that it was excellent. Board Members indicated that they would rather a Compliance Staff member attend the conference than a Board Member. Board Member Roberto Linares indicated that he will most likely attend the conference with Oregon State University. Staff will make a decision on which Compliance Staff member to send to the Utah Conference.

Research Councils - None

GENERAL ADMINISTRATION

Discussion Items

Waiver/Exception/Approval Requests

Kaiser Sunnyside Medical Center requested approval to utilize their proposed Technician Checking Validation Program (TCVP). The Board reviewed, discussed and approved their proposal.

MOTION

Motion to approve Kaiser Sunnyside Medical Center's TCVP proposal for five years was made and unanimously carried. (Motion by Reher, second by Pimlott).

T. Tucker requested an extension of his NABP Reciprocity Application. His application expired on 5/17/2012 and he requested that it be extended until 5/17/2013. The Board noted that his extension request was received on 1/5/13 long after his application expired. Staff commented that to date, his fingerprint background check packet had not been submitted to the Board office and that it is unlikely that he would be licensed by 5/17/2013. The Board denied his extension request.

MOTION

Motion to deny T. Tucker's request for a one year extension for an expired NABP application was made and unanimously carried (Motion by Fujisaki, second by Linares).

Compounding Licensure

Compliance Director Gary Miner led a discussion on compounding and licensure. Board Members liked the concept of establishing a third category for licensure. However, they were concerned about how it may impact drug shortages. They discussed allowing the third category to batch compound drugs that are in short supply for a limited time, but require quality assurance measures such as product testing. Suggested titles for this third category include Complex Compounders and Midlevel Manufacturers. The Board agreed that changes need to be made to USP 797 or quality standards need to be established. They specifically have concerns about the allowance for compounders to compound small quantities of non-patient specific medications. Although it was originally intended for physician use and not intended for larger batches being sent to other outlets, the allowance has been abused as a result of drug shortage situations in Oregon and across the country.

Compliance Director Gary Miner suggested the Board look at Division 045 and possibly re-classify things, as well as redefine the Shared Service Contract. The Shared Service Contract and other rules could be updated to include product testing, sterility testing, and/or batch testing. Quality issues could also be addressed by requiring a yearly audit from an independent organization such as PCAB. The importance of establishing clear definitions was discussed. For instance, if the rules use "small quantity" define or quantify what a small quantity is.

The Board agreed that a work-group should be developed to begin looking at these issues and draft rules. The work-group will need to keep in mind that the FDA and the United States Congress may also establish requirements that are still unknown at this time. Board Member Brad Fujisaki would like to be involved in the work-group as well as Board Counsel Tom Cowan. The Board will also include representation from hospitals, rural areas and home infusion.

Pharmacist roles in Accountable Care Organization (ACO) / Coordinated Care Organizations (CCO)

Board Member Penny Reher provided a presentation and led a discussion on the role of pharmacists in ACO or CCO organizations. A CCO is a network of all types of health care providers that agree to work together for people who receive health care coverage under a specific health plan. There are currently 15 CCO Provider Networks in Oregon. An ACO is a group of health care providers who give coordinated care and chronic disease management services to improve the quality of patient care. The organization's payment is tied to achieving health care quality goals and outcomes that result in cost savings. The Oregon Health Authority appointed pharmacists Cory Huot, Josh Bishop and Stacey Ramirez to a work-group that will explore the role of pharmacists in CCO's. The goal of the work-group is to inform CCO's about what pharmacists can bring to the CCO model. The biggest challenge will be creating a model that will successfully integrate pharmacist participation in the CCO. There are currently three CCO's in Oregon that have pharmacist involvement. They are Healthshare, Clear One Health Plan and InterCommunity Health Network which is affiliated with Samaritan Health System. As the ACO/CCO models continue to evolve, the Board can support the changing role of the pharmacist by looking at its current rules. Specifically, the Board should look at its rules regarding Collaborative Drug Therapy Management and those that relate to the practice settings of consultant pharmacists, to see if the rules need to be modified as the CCO model develops.

Delegated Authority Grid

The Board reviewed the proposed staff changes to the Delegated Authority Grid. Suggested changes relate to criteria for the failed audits of certified pharmacy technician's continuing education, as well as making limited adjustments for probation conditions. The Board discussed some of the disciplinary actions that would be allowed under Delegated Authority Grid for certified pharmacy technicians who do not satisfy the continuing education requirement or do not have a current National Certification. This includes issuing a Consent Order which requires three hours of law prior to the certified pharmacy technician's next renewal.

Compliance Director Gary Miner has been receiving a variety of requests from probationers to modify their probation terms. Board Members agreed that future Consent Orders should be amended to provide greater flexibility for probationers in limited situations. They agreed not to allow for any modifications to a probationers term within the first two years from the date of the execution of the Consent Order. In addition, any request for modification from a probationer will need to be reviewed by both the Executive Director and Compliance Director. Under the proposed changes to the Delegated Authority Grid, temporary modifications will be permissible if approved by the Executive Director and Compliance Director and will need to be ratified by the Board at the next Board Meeting. The Consent Orders that are currently in place cannot be modified.

MOTION

Motion to approve Board's Delegated Authority Grid as revised was made and unanimously carried (Motion by Chute, second by Reher).

Attorney General Opinion

On October 4th Executive Director Gary Schnabel held a meeting on practitioner dispensing. The Medical Board, Nursing Board, Dentistry Board and Veterinary Medical Examining Board

were in attendance, as well as many of their professional associations. At the meeting, the Board's statutes that provide authority to register and regulate outlets were reviewed. Many of the individuals in attendance thought that their profession was exempt from the Board's statutes. Therefore, the Board's came to a consensus to have the statutes reviewed by and have the Attorney General (AG) provide the Boards with an analysis of the Board of Pharmacy's statutory authority, as well as its Legislative intent.

Executive Director Gary Schnabel and the other Boards received the final AG opinion on February 8th. The opinion indicates that the Board of Pharmacy does in fact have the authority to regulate practitioner dispensing outlets. Gary asked the Board to advise him on how they would like him to proceed.

The Board discussed utilizing the Supervising Physician Dispensing Outlet rules in Oregon Administrative Rules, Division 043, as a template for developing similar rules and a registration process for practitioner dispensing outlets. Board Counsel Tom Cowan indicated that having an established registration process and rules to follow may be favorable to practitioners that are located in rural settings. The Board concluded that additional discussions will be necessary.

Executive Director Gary Schnabel was directed to contact the Department of Human Services Aging and People with Disabilities Office and discuss their existing requirements and registration process for nursing homes. It was noted that some nursing homes may only be administering medications and not dispensing them. Gary will also hold a second meeting with the Medical Board, Nursing Board, Dentistry Board and Veterinary Medical Examining Board. The Board will discuss next steps at its Strategic Planning Meeting.

Financial/Budget Report

Administrative Director Karen MacLean shared the November and December 2012 financials. She indicated that the Board is at 89% of its revenue based off of the projections that were forecasted three years ago.

In relation to the 2013-2015 budget request, Karen indicated that Executive Director Gary Schnabel made the decision to pull the proposed fee increase policy package for manufacturers and wholesalers as the Board's revenue/expenditures currently do not require a fee increase as previously indicated. The Board's Budget Hearing is tentatively scheduled for Wednesday February 20th.

Legislative Update

Executive Director Gary Schnabel provided an overview on some of the bills that staff are monitoring. These include House Bill 2075, House Bill 2077, House Bill 2115, House Bill 2120, House Bill 2123, House Bill 2124, House Bill 2130, House Bill 2354, House Bill 2554, House Bill 2560, House Bill 2705, House Bill 2714, House Bill 2740, Senate Bill 163, Senate Bill 171, Senate Bill 335, Senate Bill 384, Senate Bill 460 and Senate Bill 470. As the Legislative Session progresses Gary asked that the Board advise him if they would like to take a position on any bill and he will request approval from the Governor's Office.

Lisa Millet from the Oregon Health Authority's, Injury and Violence Prevention Section was present and provided the Board with an update on some of the proposed amendments that are being drafted for the Prescription Drug Monitoring Program (PDMP). Amendments include

allowing med techs and nurses to run PDMP reports for practitioners and reporting additional data to the program including sex of the patient and number of refills.

Open Forum

President Ken Wells invited members of the public to address the Board and discuss any issues of interest. There were no comments from the public.

Topics for Future Discussion

The Board prioritized and reorganized their list of topics for future discussion. It was decided that the scheduling of hydrocodone, tramadol, Canadian manufacturing of oxycodone, as well as requiring a perpetual inventory will be combined discussion items for the April Board Meeting. Establishing best practices for retail settings was identified to be discussed at a subsequent Board Meeting. The Board removed prescriptive authority for over-the-counter medications from the list of topics for future discussion, as they decided it was a more appropriate topic for the Oregon Pharmacy Coalition. There are multiple bills that are being introduced during the Legislative Session relating to Pharmacy Benefit Managers (PBM). Staff will continue to update the Board throughout the Legislative Session on any PBM bill that is related to pharmacy or directs the Board to do certain things. Staff will also continue to monitor any actions that relate to establishing a third class of OTC medications that can only be sold in pharmacies and update the Board as needed. The Board added "responsibilities of the PIC" to their list of future discussion items. The updated list is as followed:

- Hydrocodone Controlled Substance Scheduling, Tramadol, Canadian manufacturing of Oxycodone and potential perpetual inventory requirement.
 - Best Practices for Retail Settings
 - Responsibilities of the PIC – *newly added*
 - Pharmacy Benefit Managers – *continue to discuss throughout Legislative Session*
 - Prescriptive Authority for OTC's – *deleted*
 - Third class of OTC medications – *continue to watch and monitor*
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Adjourn

MOTION

Motion to adjourn at 4:10 PM was made and unanimously carried (Motion by Reher, second by Linares).

THURSDAY, FEBRUARY 14, 2013

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, Vice President

Brad Fujisaki

Dianna Pimlott

Penny Reher

Roberto Linares

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

Gary Schnabel, Executive Director

Gary Miner, Compliance Director

Joe Ball, Chief Investigator

Michele Cale, Inspector

Karen MacLean, Administrative Director

Courtney Wilson, Project Manager

Gregg Hyman, Inspector

Katie Baldwin, Inspector

Thomas Cowan, Board Counsel

Strategic Planning

The Board prioritized its list of items to be discussed at their Strategic Planning Meeting in March. The review of statutes for the purpose of clean up in ORS 475 “Controlled Substance Act” and ORS 689 “Pharmacy Practice Act” were removed from the topics to be discussed and will be reviewed at the August or October Board Meeting. Board Members reviewed the statutes last May. Staff will also review the statutes and make additional recommendations before they are presented in August or October. Board Members asked that staff look at statutes in the context of modernizing pharmacy practice. PBM’s were also removed from the list as they will be discussed at Board Meetings as the Legislative Session continues to progress. The prioritized list is as follows:

- Modernizing Pharmacist Practice *formerly* Expanding Pharmacist Practice
 - HPSP Participation / OBOP Probation/Impaired Professionals Policy Discussion/ Just Culture Presentation
 - Practitioner Dispensing and Licensure
 - Compounding
 - Other Legislative Developments or Initiatives
 - ORS 475 “Controlled Substance Act” review – *to discuss in August or October*
 - ORS 689 “Pharmacy Practice Act” review – *to discuss in August or October*
 - Pharmacy Benefit Managers – *deleted*
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Rules & Policy Discussion

Compliance Director Gary Miner asked the Board for clarification regarding the length of time in which a prescription is valid. Board Members agreed that the rule that is in place when the date the prescription is written, is the rule that should be followed. If an organization would like to shorten the length of time that a prescription is valid for, for consistency purposes they may. Gary indicated that an email will be sent to PICs via the Board’s listserve to clarify the requirement.

Pharmacy Technician Temporary Rule

Administrative Director Karen MacLean stated that the Licensing Staff has been receiving an increasing number of requests for extensions of the 1 year, non-renewable pharmacy technician licenses. Extensions have been requested as individuals decide to re-enter the pharmacy profession, complete a pharmacy trade school or prepare for the National Certification Exam. At this time the pharmacy technician license is valid for one year from the date of issuance and cannot be renewed unless the individual is under the age of 18. Karen has been working with staff to draft some proposed rules that propose to clarify the technician rules and accommodate those that are getting back into the profession. The proposed rules also update the qualifications sections for technicians and certified pharmacy technicians and delete some outdated information. Board Members had some discussion about requiring pharmacy technicians to be

18 years old and have a high school diploma or GED in order to qualify for licensure. It was pointed out that there are many high schools throughout the State that have programs to get students into the career path of pharmacy. Requiring these items would take this opportunity away unless an exception process was established. It was suggested that the Board look at defining what duties a pharmacy technician can perform and what duties a certified pharmacy technician can perform. Some Board Members thought that establishing an age requirement would help protect minors. For instance, a 12 year old would most likely do what they were told to, not knowing if it's right or wrong. Some Board Members liked establishing an age requirement of 16.

The Board did not take any action on the proposed temporary technician rule. Staff will continue to work on drafting rules for the Board's consideration. These rules will include establishing a minimum age requirement for pharmacy technicians and increasing the length of time that the registration is valid for, from one year to two years. An exception clause will also be included.

Manufacturer Temporary Rule

Compliance Director Gary Miner proposed a temporary rule that staff prepared which clarifies that any out-of-state outlet that compounds non-patient specific orders must register as a manufacturer. Registering as a manufacturer with the Board would first require the outlet to be registered with the FDA. Currently, out-of-state outlets do not qualify for a Shared Service Contract, therefore they are required to be registered as a manufacturer. The proposed temporary rule makes registration requirements more clear. The Board spent some time modifying the language to the proposed temporary rule and adopted it as revised.

MOTION

Motion to amend Manufacturer rules as revised in OAR 855-060-0004 as a temporary rule was made and carried (Motion by Reher, second by Pimlott). Wells, Reher, Fujisaki and Linares in favor of, Chute opposed.

Send Controlled Substance Rules to Rulemaking Hearing

In December, the Board sent proposed amendments in Division 080 recommended by the Oregon State Police (OSP) in relation to newer generations of synthetic drugs to rulemaking. The Oregon State Police asked that minor technical modifications be included in their proposed amendments. This includes adding a hyphen to a chemical structure as well as the word "and" to the end of a rule. The Board reviewed the minor changes as sent the proposed rules as revised to rulemaking.

MOTION

Motion to send proposed Controlled Substance rules as revised in OAR 855-080-0021 to rulemaking was made and unanimously carried (Motion by Chute, second by Reher).

Policy Decisions

Division 019 - Immunizing Pharmacists and ALERT

Compliance Director Gary Miner presented some proposed amendments suggested by the Oregon Immunization Program. The Oregon Immunization Program would like the Board to consider amending Division 019 as it relates to the ALERT system. It should be noted that the ALERT system is now referred to as ALERT2. Board Members reviewed the proposed amendments and indicated that the language should include reviewing patient history rather than performing a Drug Utilization Review (DUR) prior to the administration of any vaccination,

with the exception of the influenza vaccination. In addition, Board Members agreed that not all pharmacists have access to the ALERT2 system when performing immunizations. Therefore, language should reflect that pharmacists should access the ALERT2 system when accessible or when available. The Board asked staff to reach out to the Oregon Immunization Program and find out how hospitals would be affected by these requirements and how they collect vaccination information from hospitals. The Board also asked for clarification as to whether or not these requirements are needed for live vaccines? A member from the public stated that patients need to be educated about the importance of keeping track of their vaccination records. Board Members agreed that it may be appropriate to remind patients of this when pharmacists provide vaccination counseling. Staff will follow up with the Oregon Immunization Program.

Division 041 - Central Fill Outlets

The Board reviewed the proposed Central Fill rules that were developed by staff and a work-group. The Board agreed that the Retail Drug Outlet Registration is the appropriate registration type for both the primary and central fill pharmacy. Although the outlets will be issued a Retail Drug Outlet Registration; they will need to follow the Central Fill rules. They also agreed that the primary pharmacy should be located in Oregon. If an out-of-state pharmacy would like to use a central fill pharmacy, it needs to be located in Oregon. The central fill pharmacy in Oregon will need to follow the rules for the State where they will be shipping medications. The Board indicated that they would like the rules to reflect that a Retail Drug Outlet Registration is required. They also agreed that they would like these rules to follow the out-of-state mail order licensing model for pharmacists and technicians. This model requires the pharmacist-in-charge for Oregon to be licensed as a pharmacist with the Oregon Board of Pharmacy. The Board discussed that they would like the utilization of a central fill pharmacy to be more transparent to the customer. Therefore, the primary pharmacy who receives the request to fill a prescription must notify the patient of the possible use of a central fill pharmacy. They also stated that they would like the central fill pharmacy's name and address to appear on the label of the prescription, if a prescription is mailed directly to the patient from a central fill pharmacy. The Board hopes that this model will free up pharmacists at the primary pharmacy and will allow them to have more time to interact with the patient.

Division 041 - Central Processing Outlets

The Board reviewed the proposed Central Processing rules that were also developed by staff and a work-group. The Board stated that they liked the forward thinking in these rules and can see a lot of good use for them. For clarity purposes, the Board asked that the title of these rules be labeled "Central or Remote Processing Outlets." They also made some minor language modifications.

Division 041 - Consulting Pharmacies

The Board reviewed the proposed Consulting Pharmacies rules that were developed by staff and a work-group. They asked staff to develop a preamble for these rules to help illustrate the Board's intent and which business models they apply to. The Board would like the title of these rules to be labeled "Consulting or Drugless Pharmacies" rather than "Consulting Pharmacies". The Board had a lengthy discussion on the storage of records. They agreed that the records of a consultant pharmacist need to be protected and under the consultant's control. Generally, their requirements as they relate to the Health Insurance Portability and Accountability Act (HIPPA) are not any different than what is required by all other outlets in Division 041. The Board indicated that they would like to include in rule that the consulting pharmacist must be able to provide the Board with documentation of their pharmaceutical care activities upon request. The Board also asked staff to develop a PIC Self Inspection Report to go along with these rules once rules for consulting or drugless pharmacies are adopted.

Division 041 - Long Term Care

Inspector Gregg Hyman presented some preliminary draft concepts to update the Board's rules for long term care and community based care facilities. The draft concepts propose to incorporate new Centers for Medicare and Medicaid Services (CMS) and DEA regulations. They also establish new definitions, registration requirements and general pharmacy requirements. These rules propose to establish requirements for new technologies such as automated dispensing in long term care organizations. Gregg indicated that he will work on reconvening the Long Term Care Work-Group to get their input and help fine tune the rules. The Board thought that these concepts were a great start.

Future Rulemaking & Policy Discussion

- Div 41 Reorganization *Rulemaking 6/13*
(Includes: Drug Rooms, Retail Drug Outlets, etc.)
 - Non-Prescription Drug Outlets *Rulemaking 12/13*
 - Technician Duties *Rulemaking 1/14*
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EXECUTIVE SESSION - PUBLIC MAY NOT ATTEND, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (k).

MOTION

Motion to enter Executive Session at 1:50 PM was made and unanimously carried (Motion by Pimlott, second by Fujisaki).

MOTION

Motion to resume Open Session at 2:00 PM was made and unanimously carried (Motion by Reher, second by Linares).

Adjourn

MOTION

Motion to adjourn at 2:01 PM was made and unanimously carried (Motion by Fujisaki, second by Reher).

Accepted by:



Gary A. Schnabel, R.Ph., R.N.
Executive Director

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

Tuesday, February 12, 2013 @ 8:30 AM, Conference Room 1A
Wednesday, February 13, 2013 @ 8:30 AM, Conference Room 1A
800 NE Oregon Street in Portland, Oregon

Executive Session of the Board was held on February 12, 2013 to discuss Compliance cases, followed by motions on February 13, 2013. Working lunch held on February 12, 2013.

Board Members present for all or part of compliance session:

Kenneth Wells, R.Ph., President
Christine Chute, Vice President, Public Member
Dianna Pimlott, R.Ph.

Penny Reher, R.Ph.
Brad Fujisaki, R.Ph.
Roberto Linares, R.Ph.

Staff present for all or part of compliance session:

Gary Schnabel, R.Ph., R.N., Executive Director
Gary Miner, R.Ph., Compliance Director
Joe Ball, R.Ph., Chief Investigator
Katie Baldwin, R.Ph., Board Inspector
Michele Cale, R.Ph., Board Inspector
Gregg Hyman, R.Ph., Board Inspector
Fiona Karbowicz, R.Ph., Board Inspector

Annette Gearhart, Compliance Secretary
Kim Oster, Compliance Assistant
Karen MacLean, Administrative Director
Courtney Wilson, Project Manager
Thomas Cowan, Senior AAG

Case 2012-0036 Motion to withdraw issued Notice of Proposed Disciplinary Action.

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

Cases 2011-0641, 2012-0059 and 2012-0084 Motion to withdraw issued Notices of Proposed Disciplinary Action.

Motion by: Brad Fujisaki; Seconded by: Dianna Pimlott. *Motion unanimously carried.*

Case 2011-0670 Motion to issue Final Order denying pharmacy technician license.

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

Case 2011-0699 Motion to deny request for reconsideration.

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

Case 2011-0263 and 2011-0456 Motion to accept settlement offer.

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

Case 2011-0031 Motion to grant request to reduce UAs to 24 per year.

Motion by: Christine Chute; Seconded by: Dianna Pimlott. *Motion unanimously carried.*

Case 2011-0396 Motion to reduce report frequency to twice a year.

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

Case 2010-0487 Motion to grant removal of UA requirement, along with restrictions on working alone, number of hours and location. Deny request to lift sanctions on Pharmacist-in-Charge and preceptor restrictions.

Motion by: Penny Reher; Seconded by: Roberto Linares. *Motion carried with Dianna Pimlott opposed.*

Case 2012-0404 Motion to issue Letter of Concern to outlet.
Motion by: Brad Fujisaki; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2012-0584 Motion to close under investigation.
Motion by: Penny Reher; Seconded by: Christine Chute. Motion unanimously carried.

Case 2013-0054 Motion to revoke outlet registration and impose \$10,000 civil penalty per violation.
Motion by: Christine Chute; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2013-0057 Revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2013-0058 Revoke pharmacist license and impose \$1,000 civil penalty per violation.
Motion by: Christine Chute; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2013-0059 Revoke pharmacist license and impose \$1,000 civil penalty per violation.
Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2012-0594 Motion to issue letter of concern recommending CE in patient safety/error reduction to pharmacist and former Pharmacist-in-Charge.
Motion by: Penny Reher; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2013-0012 Motion to suspend pharmacist license and impose \$1,000 civil penalty per violation.
Motion by: Roberto Linares; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2013-0019 Motion to deny technician application and impose \$1,000 civil penalty per violation.
Motion by: Penny Reher; Seconded by: Christine Chute. Motion unanimously carried.

Case 2013-0002 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Roberto Linares; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2012-0602 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Penny Reher; Seconded by: Dianna Pimlott. Motion carried with Brad Fujisaki abstaining.

Case 2012-0542 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Penny Reher; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2012-0570 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Roberto Linares; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2012-0549 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Christine Chute; Seconded by: Penny Reher. Motion unanimously carried.

Case 2012-0603 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Christine Chute; Seconded by: Brad Fujisaki. Motion unanimously carried.

Case 2012-0600 Motion to revoke technician license and impose \$1,000 civil penalty per violation.
Motion by: Christine Chute; Seconded by: Penny Reher. Motion unanimously carried.

Case 2012-0560 Motion to impose \$1,000 civil penalty per violation against technician; issue letter of concern to PIC, cc outlet.
Motion by: Penny Reher; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2012-0556 Motion to suspend technician license and impose \$1,000 civil penalty per violation.
Motion by: Brad Fujisaki; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2012-0539 Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation and issue letter of concern regarding CII partial filling requirement to outlet.

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

Case 2012-0541 Motion to issue letter of concern to Pharmacist-in-Charge and pharmacist recommending additional 3 hours CE in medication error prevention.

Motion by: Roberto Linares; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2012-0575 Motion to impose \$1,000 civil penalty per violation against pharmacist, issue Letter of Concern recommending medication error prevention to CPT, and Letter of Concern to outlet. CC: letters to Pharmacist-in-Charge.

Motion by: Brad Fujisaki; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2012-0517 Motion to issue Letter of Concern recommending 3 hours of additional CE in medication error prevention to pharmacist and technician and CC Outlet.

Motion by: Dianna Pimlott; Seconded by: Roberto Linares. Motion unanimously carried.

Case 2012-0593 Motion to issue Letter of Concern recommending 3 hours of CE medication error prevention to Pharmacist-in-Charge, pharmacist, and technician. Issue letter of concern to outlet.

Motion by: Penny Reher; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2012-0434 Motion to issue Letter of Concern to outlet regarding tampering with or altering packaging.

Motion by: Brad Fujisaki; Seconded by: Dianna Pimlott. Motion unanimously carried.

Case 2012-0455 Motion to issue Letter of No Violation to outlet.

Motion by: Dianna Pimlott; Seconded by: Penny Reher. Motion unanimously carried.

Case 2012-0405 Motion to issue Letter of Concern recommending additional CE to Pharmacist-in-Charge and technician. CC: letters to drug outlet.

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

Motion to accept the items on the consent agenda with case 2012-0405 pulled for discussion.

Motion by: Penny Reher; Seconded by: Dianna Pimlott. Motion unanimously carried.

February 14, 2013

Motion to reopen case Case 2012-0584.

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

Case 2012-0584 Motion to revoke outlet registration and impose \$10,000 civil penalty per violation.

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