

## BOARD MEETING MINUTES

### Oregon State Board of Pharmacy 2013 Strategic Planning Meeting

Oregon Garden Resort  
895 West Main St., Trillium Room  
Silverton, OR  
March 11-12, 2014

*The mission of the Oregon State Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale and distribution of drugs.*

### TUESDAY, MARCH 11, 2014

#### **OPEN SESSION**

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

The following members were present for all or part of the meeting:

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

Excused Absence: Dianna Pimlott, Vice President

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

Marc Watt, Executive Director	Karen MacLean, Administrative Director
Gary Miner, Compliance Director	Chrisy Hennigan, Office Manager
Courtney Wilson, Project Manager	Joe Ball, Chief Investigator
Fiona Karbowicz, Pharmacist Consultant	

Thomas Cowan, Board Counsel

#### **MOTION**

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

Penny turned the meeting over to the Facilitator Sue Dicile of Sue Dicile Group.

Sue provided the framework for this meeting and provided a provided a summary of themes from pre-session interviews.

Executive Director Marcus Watt provided some opening remarks. He's been here for six weeks and learning the intricacies of state government and meeting with each staff member; they are a special group of people and motivated to do their jobs well. Some of his highlighted activities or priorities include: establishing a staff recognition program, revamping the weekly report for staff to include the Board Members, non-practitioner dispensing and a goal to improve communications, reaching out to association stakeholders (OSPA/OSHP) and plans to attend these meetings, meeting with the Governor's Office Appointments Coordinator, establishing metrics for our operations, improving efficiencies and providing the best service we can.

Administrative Director Karen MacLean provided an overview of the 2013 Strategic Planning objectives. Several of the items were completed such as: 2013 Legislative Developments that the Board was tracking, with the exception of Practitioner dispensing that moved to a work group, all issues were resolved. The Board will continue to address policy considerations such as Medication Errors, Pharmacists & Marijuana Use, Auto Refills, Fraud Work, Probationer's Policy, Modernizing Pharmacist Practice, Multicultural Issues, Work Force Survey, Compounding, Succession Planning and Budget Development & on-going operations on an as needed basis.

Two topics that will continue into the new plan and to be discussed further at this meeting included: Technician's Duties and Non-pharmacy dispensing.

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Sue facilitated discussions on the following:

## THE EMERGING FUTURE

*Board members considered the issues, trends, opportunities and challenges in the Board of Pharmacy's strategic environment.*

### **The changing pharmacy business and practice model**

- Ubiquitous sales and dispensing of drugs: "an Amazon-type model."
- Pharmacy is increasingly about cognitive skills and drug therapy, and less about dispensing, which will be automated.
- Dramatic increase in the cost of specialty drugs, which will be 40% of the market, because it's "where the money is," and because the ACA has given life and market to "orphan" drugs.
  - The shift to specialty drugs has many unknowns. The shift is being driven by 3<sup>rd</sup> party players with little definition about why specialty drugs have been pulled out of general practice.
- The above practices in the name of efficiency are deconstructing the role of the community pharmacist, and have implications for patient safety.
- The transitions noted above mandate that billing must be tied to patient "chair time."
- Transitions are being driven by the profit motive. This represents a change for both the pharmacist and the consumer who still need a network in the community setting.
- CCOs now pay for dispensing only and the future reimbursement path is undefined, as there is a billing code, but no funding for cognitive services. (Note – reimbursement models do exist, e.g. Kaiser and the V.A.)
- The transition: from "volume of meds dispensed" to "patient consulting on meds (what is needed and not needed) may drive new malpractice issues, concerns and accountabilities.
- Medical reconciliation: If a pharmacist sees a mistake are they / should they be empowered to revise the prescription? Will we / should we get to the point where the physician diagnoses and the pharmacist selects the best drug? If a need is identified can/should the pharmacist fill the need without a loop back to the physician? (Note: models for these exist now, e.g. at Kaiser and V.A.)

### **Systems and Technology**

- Technology is squeezing out more profit and changing the business model. Technology has the potential to produce more efficiency and safety, but will require the Board to be highly nimble.
- Medication reconciliation re-design is driving questions about "What do we need a pharmacist to do?" and "What can a technician do?"
- The practice is becoming system-dependent. The Board may need to regulate decision-support I.T systems for pharmacy, or at least establish a policy or standards about introduction of risk and assurance of patient safety.

- The board needs to embrace systems as a means to help people do their jobs AND establish system management policy, plans and standards.
- Regulation is a burden at discharge: “the check-boxes supersede patient safety.”
- System complexity inhibits use by doctors.
- System dependency raises the question about the role in patient information – what is the role and whose role is it?

### **Telemedicine**

- Telemedicine is emerging now through a bill that could create conflict between the boards of Pharmacy and Medicine. Questions being raised include:
  - How to get lab results with telemedicine?
  - Is an open door created to pill mills?
  - What is the impact of the loss of “touch” to the patient?
  - What is the role of the Board of Pharmacy?

### **Convergence**

- As the lines between practices blur greater collaboration among boards may be necessitated.

The Board reviewed the mission statement and agreed that the current statement encompasses all that it needs to include. The Board is focused on patient safety.

The Board prioritized how specific trends and issues rank strategically based on timing and mission-criticality. See plan at the end of this document.

### **PREDICTIONS ABOUT THE PRACTICE – 2019**

*Based on the previous discussion, Board members made the following predictions about the industry/practice of pharmacy over the course of the upcoming two year planning cycle.*

- There will be incremental change from volume dispensing to a greater consultative role.
  - The rate of change in the practice = the rate of change of the business model.
  - A key barrier: pharmacist advice has traditionally been free.
- Fiscal change will be quantifiable. Patient outcomes due to change are unlikely to be quantifiable.
- CCOs may accelerate the change in the business model.

### **APPROACH TO EMERGING ISSUES AND CHANGE: PROACTIVE OR REACTIVE?**

*This topic was raised in pre-session interviews with board members.*

- Key questions:
  - Do we move the profession forward or do we respond to movement in the profession?
  - How responsive should the Board be to the actions of other regulatory bodies?
- (Upon discussion it was agreed that)
  - In general the Board of Pharmacy is responsive – responds to requests and supports the evolution of the practice.
  - The Board is proactive when there is a clear danger to public safety, and by doing outreach in the industry to keep up to date and in touch on emerging issues.
  - As a responsive/reactive body the Board needs to be nimble.

## STRATEGIC OBJECTIVES / OUTCOMES

*Board members identified critical strategic objectives for the long term and for the upcoming planning cycle.*

Long Term	2014 -2016 Planning Cycle
Licensees operating at the top of their license.	➤ <b>Technician licensing streamlined and workable.</b>
The workplace environment will not have an adverse impact on patient safety.	➤ <b>A valid framework from which to take workplace safety actions.</b>
An adequate and safe drug supply for the State of Oregon is assured.	➤ <b>A strategy is in place to address drug shortages.</b> ➤ <b>Dispensing issues have been resolved in a way that supports patient safety.</b>

## EXPLORATION OF KEY ISSUES

*The Board established intentions and guidance to staff on the following key issues:*

### Non-Pharmacy Dispensing

*Several variables were identified, including quantity, patient safety with regard to access, and degree of departure from the Board's traditional sphere of influence. At the conclusion of the discussion the Board established the following approach:*

In light of the evolving business practices in the industry:

- The Board is clarifying its existing approach.
- The clarification addresses quantity. (Note: quantity thresholds will be lower for controlled substances.)
- Complaints resulting from non-pharmacy dispensing sources that are below quantity thresholds will be tracked and reported to the appropriate regulatory body.
- Veterinarian dispensing needs to be included.
- Access, particularly in rural parts of the state, will be factored in to the Board's approach.
- The Board will establish voluntary/informational standards.
- Patient Safety

### Technician Registration

*At the conclusion of the discussion the Board established the following approach:*

- A Pharmacy Technician has a year from entry plus the remainder of the second year until 9/30 to become certified. (2<sup>nd</sup> license renewal)
- The current thinking is that a CE is required; however...
- ...The Board would like to get feedback on the CE via a survey or information hearing to determine the value placed on the CE. If an informational hearing is held it should include a method for getting input from throughout the state.
- The minimum age for a Pharmacy Technician is 16.
- The Board wants to evaluate the option of requiring the PIC/employer to provide 2 hours of training for PTs per year. Training can be confirmed by the PIC on other annual filings which will eliminate the need for a separate audit process.

## **Work Environment Expectations**

*At the conclusion of the discussion the Board established the following approach:*

- The Board is aware of the difficulties, but wants to explore the potential of establishing rules to prohibit retaliation against a PIC exercising his/her professional judgment.
- Protection from retaliation is a key component in empowering PICs to use professional judgment in the interest of creating a safe work environment.

## **Technician Duties**

*The staff asked for guidance as to whether the Board supports a prescriptive rules-oriented approach or a more general advice approach toward establishment of technician duties. The board discussed several hypothetical applications of both approaches. At the conclusion of the discussion the Board established the following approach:*

- The approach is situational.
  1. In areas posing a significant degree of risk there should be a more prescriptive approach.
  2. For areas that are clearly within the purview and capabilities of a technician a prescriptive approach is not needed.
  3. In the gray area between 1 and 2 the approach should be considered situationally. Some situations should be addressed via a "PIC empowerment," general guidance framework. Other situations may call for being addressed more prescriptively.
  4. Statutory restrictions need to be considered.
  5. Rules are non-specific for RPh duties in non-dispensing roles.

## **Public Information and Outreach**

*Board members noted that the primary information source provided by the Board is a public website. The following other potential services were brainstormed:*

- Content, vetted for validity, posted at the website (non-original OBP content, e.g. the newsfeed from NABP).
- Press releases when medicines-related issues are about to hit the news.
- Volunteers at public events, who can interface with the public and provide information.
- Creation of a more statewide presence. Could be through holding meetings throughout the state, or some other method.
- Filling the need as a source of pharmacist-critical information such as fraud alerts. The OBP could provide PICs with a clear and focused source. Could take the form of email blasts to PICs.
- Partnering with other state agencies with public health roles, e.g. the State Dept. of Health.

*The board outlined some of the constraints and complicating factors around the public information and outreach role.*

- Constraints around what the board does not do.
- Constraints of cost and resources.
- Lack of / need for clarity about the audience for the website.
- Risk of introducing new distractions into pharmacists' workflow.
- Licensees are unclear about the role of the OBP except for its disciplinary role, and don't think of it as a source of information.

*Board members noted the following about the purpose of an OBP outreach function:*

- The purpose of public outreach and information is for people to have a source of valid information so that, as consumers, they are educated about the medicines they take.
- There should be easily available information about the Board and its mission; however the primary purpose is to insure a source of valid information.

At the close of the discussion the following three-point role definition was agreed upon. Board members noted that the scope of the role would be circumscribed by resources:

1. Crucial public health information to the public.
2. Licensee notification.
3. Availability of information about the OBP and its mission.

## **MOTION**

**Motion to adjourn at 4:48\_PM was made and unanimously carried (Motion by Anderson, second by Fujisaki).**

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## **WEDNESDAY, MARCH 12, 2014**

### **II. 8:30 AM OPEN SESSION, Penny Reher, R.Ph. Presiding**

#### Roll Call

Penny Reher, President

Christine Chute

Roberto Linares

Ken Wells

Brad Fujisaki

Heather Anderson

Excused Absence: Dianna Pimlott

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

Marc Watt, Executive Director

Gary Miner, Compliance Director

Courtney Wilson, Project Manager

Fiona Karbowicz, Pharmacist Consultant

Karen MacLean, Administrative Director

Chrisy Hennigan, Office Manager

Joe Ball, Chief Investigator

Brianne Cooper, Inspector

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### **BOARD DEVELOPMENT**

*In pre-session interviews board members noted they wanted to set time aside at the strategic planning session to have an exchange about communication styles and preferences with their new Executive Director.*

*During the discussion, ED Marc Watt noted that:*

- *He would characterize his style of working with his board as informal. He values open communication and prefers an “open door / open phone” policy.*
- *He is comfortable with a “cc” if board members wish to contact staff member directly with inquiries.*
- *He sees his role as 1) carrying out the policy established by the board, and 2) running the agency.*

*Board members noted their preferences for working with their ED:*

- *Use periodic newsletters.*
- *Keep us up-to-speed, but don’t bombard us with information.*
- *Let us know what is happening in the agency. We don’t need all the details, but we do need a “heads-up.”*
- *Our over-arching expectation is “No surprises.”*

*The Board reviewed it's 2014 – 2016 PRIORITIES, STRATEGIES, TACTICS AND MILESTONES (See the strategic plan outline at the end of this document)*

Two topics that the Board did not get to were moved to the April Board meeting agenda they are: Non-resident pharmacies inspection reports and Non-resident PIC requirements.

*After lunch, the Board continued under staff facilitation to complete the following work:*

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

Items for Consideration and Discussion

**MOTION**

**Motion to enter Executive Session at 1:02 PM was made and unanimously carried (Motion by Wells, second by Anderson).**

**MOTION**

**Motion to resume Open Session at 1:20 PM was made and unanimously carried (Motion by Chute, second by Anderson).**

**OPEN SESSION**

Motions for Disciplinary Actions

**MOTION**

**Motion to withdraw the notice of proposed disciplinary action for Case 2014-0003 was made and unanimously carried (Motion by Fujisaki second by Anderson).**

**MOTION**

**In Case 20013-0203, Motion to amend and include failure to cooperate was made and unanimously carried (Motion by Chute second by Wells).**

**The Art of an Investigation**

Compliance Director Gary Miner presented the development of an investigation, what happens when a complaint is received, interviewing the parties, gathering information, when we ask a licensee to come in for an interview and why; what happens when it's a diversion case, preparing a report for the Board, and staff review. He then explained that the Compliance staff also meets with Board Counsel prior to each Board meeting for a case review. They look at the past history of similar cases and adjust recommendations as needed; they are adding additional reports for specific cases as the Board requested. There was some discussion and the Board asked some clarifying questions about process, future reports and training for inspectors.

**Expunged Records**

Board Counsel Tom Cowan reported how there is a utility for Board's to assess information on applications and renewals within the information in the criminal arena. This often appears as an expunged record. However, what's officially expunged and what is thought to be expunged are two different things. Also from one state to another, the term expunge is defined differently etc.

For a record to be truly expunged, it has to be recorded with the court. There is documentation

of some kind; it's not just a conversation with an attorney that an action or activity is expunged. Getting something expunged doesn't allow you to re-write history. We want and need our applicants and licensees to be honest with the Board.

When applicants and licensees are forth coming and provide information that is most helpful. There are times when there is confusion about what is really expunged. For example, the applicants answer "no" to all the questions and the Board learns later through the criminal background check process, that a conviction exists; The Board can investigate. The Board can decide what's relevant and should instruct staff what they do and do not want to see. After some discussion, the Board supported the idea of adding a statement on the applications regarding any response on an application. The applicant is responsible to make sure it's accurate and they have the supporting documentation to verify it. FAQ's will be developed for the website to provide more information.

### **Legislative Update**

Pharmacist Consultant Fiona Karbowicz reported that staff had reviewed ORS Chapter 689 in detail to identify housekeeping issues to be recommended for a future session. She provided an update on the 2014 session; the electronic prescriptions for controlled substance II and prescription synchronization bills passed and several bills directed to work groups during the interim including telemedicine and practitioner dispensing.

### **2015-17 Budget Development**

Administrative Director Karen MacLean advised that the 2015-17 budget development process will begin in the next week. Revenue estimates will be due by month end and policy packages will be developed. She explained that policy packages are for adding new or additional dollars to the agencies operational budget. Some of the things that we're evaluating to possibly add include: a new Licensing Manager position, additional resources for the move to a paperless office, an increase for expenses associated with banking merchant fees etc. More to be discussed as instructions are provided. The statewide Budget Kick-off session will be held March 13<sup>th</sup>.

Board President Penny Reher announced that former Executive Director Gary Schnabel had been selected as one of the recipients for this year's Oregon State University Icons of Pharmacy.

Board members thanked Sue and the staff for their preparation for this meeting.

### **OPEN FORUM**

Shannon Cervantes who attended the Open Session portions of the meeting from Wal-Mart shared with the Board that she attended the meeting to take notes and provide information back to their staff on this year's meeting.

### **MOTION**

**Motion to adjourn at 3:00 PM was made and unanimously carried (Motion by Anderson, second by Fujisaki).**

Accepted by:



Marcus Watt  
Executive Director

# OREGON BOARD OF PHARMACY STRATEGIC PLAN

## THE MISSION OF THE OREGON STATE BOARD OF PHARMACY

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.

<b>STRATEGIC OBJECTIVES</b>			
<b>Licensees' operating excellence: "At the top of their license."</b>	<b>No adverse impact on patient safety due to the workplace environment</b>	<b>An adequate and safe drug supply for the State of Oregon.</b>	
<b>Objectives 2014 – 2016 / Priority Outcomes</b>			
<b>Technician licensing that is streamlined and workable, resulting in fewer administrative errors by technicians</b>	<b>A valid framework from which to take workplace safety actions that meet the intent of patient safety</b>	<b>A strategy is in place to insure critical drug shortages are avoided</b>	<b>Non-pharmacy dispensing issues are resolved in support of patient safety.</b>
<b>Strategies &amp; Tactics</b>			
<ul style="list-style-type: none"> <li>• Hold an informational hearing on the technician licensing process. If "go":</li> <li>• Draft and adopt administrative rules.</li> <li>• Create a graphic representation to clearly illustrate how technician licensing works.</li> </ul>	<ul style="list-style-type: none"> <li>• Conduct proactive outreach to licensees outlining concerns and issues, and providing prevention advice and education on conditions that could trigger an action / mitigation.</li> <li>• Create a graphic representation of the paths to workplace action.</li> <li>• Draft and adopt administrative rules.</li> </ul>	<ul style="list-style-type: none"> <li>• Staff work with FDA to insure Oregon has/retains the ability to use compounders for shortage drugs.</li> <li>• Obtain a root-cause analysis of drug shortage causes as they relate to Oregon.</li> <li>• Open Division 45.</li> <li>• Establish and implement the strategy.</li> </ul>	<ul style="list-style-type: none"> <li>• Conduct outreach and debrief feedback with stakeholders. Compile and document stakeholders' interests and concerns.</li> <li>• Refine and share our plan and timeline.</li> <li>• Obtain support from legislators, boards and associations.</li> <li>•</li> </ul>

# Oregon Board of Pharmacy 2014 – 2016 Strategic Plan: MILESTONE CHART

	2014			2015				2016				2017
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
<b>Technician Licensing</b>												
Hearing on the technician licensing process.		◆										
Draft and adopt administrative rules			◆ □									
Graphic representation to illustrate how technician licensing works,				◆								
Data shows fewer administrative errors by technicians												◆
<b>Workplace Environment</b>												
Graphic representation of the paths to workplace action.			◆									
Proactive outreach to licensees with advice and education re action triggers							◆					
Administrative rules drafted and adopted.								◆				
<b>Drug Shortage Strategy</b>												
Work with FDA to insure ability to use compounders for shortage drugs.	◆											
Obtain a root-cause analysis of drug shortage causes			◆									
Open Division 45.			◆									
Establish and implement the strategy.				◆	→	→	→	→	→	→	→	→
<b>Dispensing</b>												
Outreach to collect and compile stakeholder feedback		◆										
Refine and share plan and timeline		◆										
Solicit support of legislators, boards and associations			◆									

K EY: ◆=milestone/task achievement. →=ongoing ◆=goal achievement