

BOARD MEETING MINUTES
OREGON BOARD OF PHARMACY
Oregon State Library
250 Winter Street NE, Room 103
Salem, OR 97301-3950

Thursday, November 1, 2007 at 8:00 AM, Room 103

Thursday, November 1, 2007

8:00 AM OPEN SESSION, Ann Zweber, RPh. Presiding

Roll Call

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

Ann Zweber, President
Cathy Lew, Vice President
Marc Watt
Linda Howrey
Lee Howard

Board Member Dianna Pimlott arrived late; and Board Member Bernie Foster was absent.

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

Gary Schnabel, Executive Director
Gary Miner, Compliance Director
Karen MacLean, Administrative Director
Joe Ball, Chief Inspector
Gregg Hyman, Inspector
Michele Cale, Inspector
Meg Aulerich, Inspector
Annette Gearhart, Compliance Secretary
Jennifer Hess, Management Secretary

Tom Cowan, Board Counsel

Pharmacist Consultant Paige Clark arrived late.

Agenda Review and Approval

MOTION

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

Board Meeting Dates 2007

- December 4 – 5, 2007 Portland

Board Meeting Dates 2008

- January 29 – 30, 2008 Corvallis
- April 15 – 16, 2008 Portland / Hillsboro
- June 10 – 11, 2008 Portland

- August 12 – 13, 2008 Portland
- October 14 – 15, 2008 Eugene
- December 9 – 10, 2008 Portland
- January 20-21, 2009 Corvallis

Strategic Planning Meeting

- March 18 - 19, 2008 Welches

RULEMAKING HEARING

Public hearing for proposed changes to the following divisions in OAR Chapter 855:

- A. **Division 06:** The proposed amendment adds the definition of Consultant Pharmacist that was formerly in Division 41 as this term is now used in several Divisions; amends the definition of “Unprofessional Conduct”.

There were no public comments on Division 06.

- B. **Division 10:** This proposal adds a rule, as required by statute, to implement the statutory authority to conduct state and nationwide background checks and to require fingerprints of subject individuals under designated circumstances. Rule is modeled on similar rules adopted by Department of Administrative Services, Board of Dentistry and Board of Chiropractors.

There were no public comments on Division 10.

- C. **Division 19:** These proposed changes implement the Boards desire to have all rules pertaining to pharmacists in one division. Many of these rules were formerly in Division 41. New issues included will put into rule policy determinations that the Board has expressed in the past few years.

Representatives were present from Medco to comment on Division 19 proposed changes. Primary issues surround out of state pharmacist licensure requirements and how to deal with the conflict between the home state laws and rules vs. Oregon’s laws and rules. They were seeking clarification of the rule intent.

There was some discussion and clarification on the new requirements for PIC training.

- D. **Division 35:** This proposal adds a new class of non-prescription drug outlet to permit the Oregon Food Bank, and its subsidiary not-for-profit food distribution centers, to distribute donated non-prescription drugs to needy individuals.

There were no public comments on Division 35.

- E. **Division 41:** These proposed changes reorganize, delete and renumber rules in this division since rules pertaining to pharmacists have been moved to Division 19.

Representatives from Medco also commented on proposed revisions to Division 41. It is their opinion that the rules are burdensome to out of state pharmacies and these proposed rules may present conflicts with other states rules.

- F. **Division 42:** This proposal moves the rule on licensing of nuclear pharmacists to Division 19 with all other licensing rules for pharmacists.

There were no public comments on Division 42.

- G. **Division 45:** This is a new division of rules regarding compounding of drugs. It includes many standards directly from USP 797, but allows for variances to meet local needs. Staff will be proposing that the rule requiring specialty construction and equipment should not be effective until January 2009.

Pharmacist Tom Eilers from Northwest Compounders appeared to offer a suggestion to 855-045-0270 (2) to modify the documentation requirement. Tom also offered that while the changes to these rules are significant, he supports the new rules and believes it will help continue to provide quality service to patients. Finally, he asked for time to put these rules into effect prior to enforcement.

Pharmacist Eric Litner from Consones Pharmacy appeared to comment and ask a number of technical questions about this rule.

- H. **Division 55:** This division is repealed as the Board no longer has statutory authority to regulate DMSO.

There were no public comments on Division 55.

Staff will prepare a summary of the oral and written comments and provide them to the Board for review prior to the December Board meeting.

GENERAL ADMINISTRATION

Designated Representatives

Compliance Director Gary Miner discussed a proposed revision to the Wholesale compliance guidelines. At the August meeting, the Board provided direction in regard to how staff should handle a variety of issues. Two new issues were discussed. When a company does not appoint a Designated Representative within 30 days of request, the Compliance staff will send a letter via registered mail to respond within 15 days. If no response, Compliance will open a case and issue a notice of Failure to Cooperate and a civil penalty. Second, when there are two corporations located in the same facility, is there a need for more than one Designated Representative? The Board asked to have the Applicant submit a detailed description of the managerial process and include the hours that he/she will be physically present at the facility. Compliance staff will review the information on a case by case basis.

PDMP Proposed Legislation

Executive Director Gary Schnabel reviewed the latest version of the PDMP language. Gary reviewed the many changes made since the October Board Meeting where the newest language was first handed out. With the help of Board staff and Kathy Hahn from the Oregon Pain Management Commission, the final language is one that all parties working on the edits are happy with. The Board Members discussed the changes, and motioned to support the revised language.

MOTION

Motion to support the revised Prescription Drug Monitoring Program Language as written was made and unanimously carried. (Motion by Watt, second by Pimlott

National Alliance Conference, Washington DC – December 6 – 7, 2007

Executive Director Gary Schnabel asked the Board for permission to send Pharmacist Consultant Paige Clark along with Kathy Hahn from the Oregon Pain Management Commission to Washington DC to attend the National Alliance Conference. Gary shared that this meeting would be a great opportunity for them to learn more about Prescription Drug Monitoring Programs across the country and to network with other individuals who can help in the process of implementing a program in Oregon. The Board discussed and approved Paige and Kathy's travel, and asked that they provide a report on the meeting at the January Board Meeting in Corvallis. Travel expenses will be covered through the Federal Grant.

MOTION

Motion to approve Paige Clark and Kathy Hahn's travel to Washington DC for the National Alliance Conference was made and unanimously carried. (Motion by Watt, second by Howard)

EXECUTIVE SESSION

PUBLIC MAY NOT ATTEND, pursuant to ORS 676.175, ORS 192.660(1)(k).

MOTION

Motion to enter into Executive Session at 10:30 was made and unanimously carried. (Motion by Howard, second by Lew)

MOTION

Motion to exit out of Executive Session and into Open Session at 3:45 was made and unanimously carried. (Motion by Howrey, second by Howard)

Motions for Disciplinary Action – See Compliance Minutes

Open Forum

No Public Comment

MOTION

Motion to adjourn at 3:55 was made and unanimously carried. (Motion by Howard, second by Howrey)

Minutes Accepted By:



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

BOARD COMPLIANCE MINUTES
Oregon State Board of Pharmacy
800 NE Oregon Street #150
Portland, OR 97232

November 1, 2007 @ 10:00 a.m.
Oregon State Library, Conference Room 103
Ann Zweber, R.Ph. Presiding

An Executive Session of the Board to discuss Compliance was held on November 1, 2007 at the Oregon State Library Conference Room 103 located at 250 Winter Street NE in Salem.

Board Members present for all or part of compliance session:

Ann Zweber, R.Ph., President
Cathryn Lew, R.Ph., Vice President
Lee Howard, Public Member
Linda Howrey, R.Ph.
Dianna Pimlott, R.Ph.
Marc Watt, R.Ph.

Board Member absent:

Bernie Foster, Public Member

Staff present for all or part of compliance session:

Gary Schnabel, Executive Director

Gary Miner, Compliance Director
Meg Aulerich, Board Investigator
Joe Ball, Board Investigator
Michele Cale, Board Investigator
Gregg Hyman, Board Investigator
Jennifer Zanon, Board Investigator
Annette Gearhart, Compliance Secretary

Karen MacLean, Administrative Director
Paige Clark, Consultant Pharmacist
Jennifer Hess, Management Secretary
Thomas Cowan, Senior AAG
Ed Schneider, PRN Program Director
Pam Aldersebaes, PRN Assistant

Staff absent:

Katie Baldwin, Board Investigator
Tony Burtt, Project Manager

Working lunch held.

BOARD APPEARANCES:

Case 2007-0181

Motion to reinstate pharmacist license and place on 10 year probation, with 5 year PRN contract, was unanimously accepted. Motion by: Marc Watt; Seconded by: Lee Howard.

ADMINISTRATIVE DISCUSSION:

Case 2006-0458

Motion to accept Administrative Law Judge's proposed order denying a hearing on the merits of the proposed disciplinary action, and issue Default Order revoking license and issuance of Certified Pharmacy Technician license was unanimously accepted. Motion by: Linda Howrey; Seconded by: Lee Howard.

Case 2006-0644

Motion to accept Administrative Law Judge's proposed order and issue Final Order denying Technician License was unanimously accepted. Motion by: Dianna Pimlott; Seconded by: Marc Watt.

Case 2007-0331

Motion to grant outlet's request and add scenario to Board's authority to staff regarding wholesaler's grid was unanimously accepted. Motion by: Linda Howrey; Seconded by: Dianna Pimlott.

Case 2007-0152

Motion to impose \$1,000 civil penalty per violation, with minimum of \$500,000 civil penalty, was unanimously accepted. Motion by: Marc Watt; Seconded by: Dianna Pimlott.

Case 2007-0278

Motion to issue Letter of Concern to pharmacy was unanimously accepted. Motion by: Marc Watt; Seconded by: Lee Howard.

Case 2007-0036

Motion to deny reconsideration was unanimously passed. Motion by: Lee Howard; Seconded by: Marc Watt.

Case 2007-0360

Motion to grant retired status (close under investigation) was unanimously accepted. Motion by: Lee Howard; Seconded by: Dianna Pimlott.

Motion to delegate to the Compliance Director authority to return application as incomplete without CE completion was unanimously accepted. Motion by: Dianna Pimlott; Seconded by: Marc Watt.

CASE REVIEW:

Case 2007-0224

Motion to revoke technician license and impose \$1,000 civil penalty per violation was unanimously accepted with Marc Watt abstaining due to conflict of interest. Motion by: Lee Howard; Seconded by: Dianna Pimlott.

Case 2007-0289

Motion to revoke license and impose \$1,000 civil penalty against technician; and issue letters of notification to PIC and pharmacy was unanimously accepted. Motion by: Marc Watt; Seconded by: Linda Howrey.

Case 2007-0217

Motion to request intern's appearance before the Board was unanimously accepted with Marc Watt abstaining due to conflict of interest. Motion by: Linda Howrey; Seconded by: Lee Howard.

Case 2007-0319

Motion to revoke technician license and impose \$1,000 civil penalty was unanimously accepted. Motion by: Marc Watt; Seconded by: Linda Howrey.

Case 2007-0197

Motion to revoke pharmacist license and impose \$1,000 civil penalty per violation was unanimously accepted with Linda Howrey abstaining due to conflict of interest. Motion by: Dianna Pimlott; Seconded by: Marc Watt.

Case 2007-0304

Motion to deny pharmacist application was unanimously accepted. Motion by: Marc Watt; Seconded by: Dianna Pimlott.

Cases 2007-0201 and 2007-0172

Motion to impose \$1,000 Civil Penalty against pharmacy, or in lieu of, submit QA plan on special counseling requirements; and issue Letter of Concern to R.Ph, technician and PIC, refer case 2007-0172 to the nursing board, was unanimously accepted with Linda Howrey abstaining due to conflict of interest. Motion by: Dianna Pimlott; Seconded by: Cathryn Lew.

Case 2007-0249

Motion to deny pharmacist reciprocal application was unanimously accepted. Motion by: Linda Howrey; Seconded by: Cathryn Lew.

Case 2007-0094

Motion to impose \$1,000 Civil Penalty against pharmacist; or earn 3 hours of CE in medication error prevention and report error to ISMP within 60 days in lieu of civil penalty (CE is not eligible for CE requirements for renewal purposes) was unanimously accepted. Motion by: Linda Howrey; Seconded by: Marc Watt.

Case 2007-0254

Motion to impose \$1,000 Civil Penalty against pharmacist; or earn 3 hours of CE in medication error prevention and report error to ISMP within 60 days in lieu of civil penalty. CE is not eligible for CE requirements for renewal purposes. Letter of Concern to pharmacy was unanimously accepted with Marc Watt abstaining due to conflict of interest. Motion by: Dianna Pimlott; Seconded by: Lee Howard.

Case 2007-0298

Motion to impose \$1,000 Civil Penalty against pharmacist; or earn 3 hours of CE in medication error prevention in lieu of civil penalty. CE is not eligible for CE requirements for renewal purposes. Letter of Concern to pharmacy **and in**

Case 2007-0332

Motion to impose \$500 Civil Penalty against technician; or earn one hour of CE in medication error prevention in lieu of civil penalty. CE is not eligible for CE requirements for renewal purposes. Letter of Concern to pharmacy was unanimously accepted. Motion by: Linda Howrey; Seconded by: Marc Watt.

Case 2007-0266

Motion to issue Letter of Concern to the pharmacy was unanimously accepted. Motion by: Marc Watt; Seconded by: Linda Howrey.

COMPLIANCE CONSENT AGENDA:

**Cases listed under the compliance 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 case will be removed from the compliance consent agenda and placed on the regular compliance agenda.*

**Motion to accept the items on the consent agenda was unanimously accepted. Motion by: Marc Watt;
Seconded by: Lee Howard.**

LETTERS OF CONCERN CASES:

Case 2007-0218

Motion to issue Letter of Concern to pharmacist; CC: PIC and pharmacy

WARNING NOTICES:

Cases: 2007-0169, 2007-0211, 2007-0214, 2007-0221, 2007-0225, 2007-0228, 2007-0229, 2007-0230, 2007-0233, 2007-0241, 2007-0248, 2007-0250, 2007-0251, 2007-0252, 2007-0259, 2007-0260, 2007-0261, 2007-0262, 2007-0263, 2007-0264, 2007-0270, 2007-0273, 2007-0274, 2007-0278, 2007-0280, 2007-0281, 2007-0282, 2007-0284, 2007-0286, 2007-0287, 2007-0292, 2007-0293, 2007-0316, 2007-0317, 2007-0322, 2007-0340, 2007-0343, 2007-0345, 2007-0348, 2007-0350 and 2007-0352.

UNABLE TO SUBSTANTIATE:

Cases: 2007-0120, 2007-0246, 2007-0258, 2007-0295, 2007-0300 and 2007-0307.

NO VIOLATION:

Cases: 2007-0137, 2007-0206, 2007-0220, 2007-0255, 2007-0290, 2007-0294 and 2007-0302.

C.E. AUDIT CASES:

Authority delegated to the Compliance Director by the Board Members on August 8, 2006, [grant staff authority to issue LOC if CE completed in June or to take and pass MPJE (in lieu of discipline) within 120 days if CE not completed by end of June]. Authorize staff (2/7/2007) to issue NPDA to suspend pharmacist license if MPJE not taken and passed within 120 days.

Cases: 2007-0357, 2007-0358 and 2007-0359.

UNREGISTERED OUTLET CASES:

By authority delegated to Oregon Board of Pharmacy Staff by the Board Members on 2/7/2007 and amended on 4/17/2007, notices to impose \$1,000 civil penalty notices have been issued to:

Cases: 2007-0121, 2007-0124, 2007-0127, 2007-0132 and 2007-0257.

UNSWORN FALSIFICATION (INTENT UNKNOWN)-CE LETTERS:

By authority delegated to Oregon Board of Pharmacy Staff by the Board Members on 8/8/2006 and confirmed on 2/7/2007, the following applicants and licensees have been issued CE in lieu of discipline letters:

Cases: 2007-0288, 2007-0313, 2007-0327, 2007-0328, 2007-0336, 2007-0337, 2007-0338, 2007-0354 and 2007-0374.

DENIAL OF TECHNICIAN APPLICATION ORDERS:

By authority delegated to Oregon Board of Pharmacy Staff by the Board Members on December 1, 2004 and amended on 4/17/2007, the following \$1,000 civil penalty and denial of technician licenses notices have been issued:

Cases: 2007-0236 and 2007-0315.

TECHNICIAN LICENSES GRANTED WITH PROBATION:

By authority delegated to Oregon Board of Pharmacy Staff by the Board Members on October 11, 2005 and confirmed on 2/7/2007, the following technician licenses have been granted with probation:

Cases: 2007-0226 and 2007-0268.

UNREGISTERED PRECEPTOR:

By authority delegated to Oregon Board of Pharmacy Staff by the Board Members on 2/7/2007, letters of concern have been issued to:

Case: 2007-0239

DEFAULT ORDERS:

By authority delegated to Oregon Board of Pharmacy Staff by the Board Members on August 12, 2004 and confirmed on 2/7/2007, the following default orders have been issued:

Cases: 2007-0070 and 2007-0076, 2007-0077, 2007-0088, 2007-0144, 2007-0150, 2007-0162 and 2007-0212.

UPDATES / For Your Information:

- Open cases under investigation.
- Cases that have been opened and then "Closed Under Investigation" to preserve incoming complaint information should future action be necessary.
- Cases that currently have hearings requested.