

Oregon State Board of Pharmacy
800 N.E. Oregon Street, Suite 425
Portland, Oregon

April 14, 1999

MINUTES

I. ROLL CALL-AGENDA APPROVAL-ANNOUNCEMENTS

President Patrick called the Board meeting to order at 8:30am, Wednesday, April 14, 1999.

The following members were present:

Michael Patrick, President
Allan Dulwick, Vice President
Blake Rice
Joseph Schnabel
Lynn Talton
Marie Williams

Helen Noonan-Harnsberger was absent due to an employment commitment.

The following staff and counsel were present for all or portions of the meeting:

Gary Schnabel, Acting Executive Director, Compliance Director
Carolyn Gibson, Administrative Programs Manager
Grace Cheung, Inspector
Lawrence Martin, Inspector
Paul Mattson, Inspector
Steve Schulte, Inspector, Acting Compliance Director
Frank Mussell, Board Counsel

The agenda for the April 14, 1999 meeting was approved by consensus of the Board.

II. BOARD MEETING DATES

May 12-13, 1999 Tentative
June 9-10, 1999
July 21-22, 1999
August 20-22, 1999 Bandon
September 22-23, 1999
November 17-18, 1999

In order to save travel time and expense, the Board directed Gibson to try to obtain lodging and meeting facilities at Silver Falls State Park, Salem, for the Board's August, 1999 strategic planning meeting.

Relative to the May meeting, members suggested continuing with regular Investigative

Oregon Board of Pharmacy Minutes - April 14, 1999

Page 2

Compliance meetings but holding just a one day meeting or a telephone conference call to cover regular Board business, if necessary. President Patrick said depending upon the time frame for the Search Committee interviews, he will decide later whether to keep the May Board meeting date or move the meeting into early June.

Acting Executive Director Schnabel stated the Oregon Revised Statutes dictate that the Board meet at least every three months.

III. REVIEW OF MINUTES

MOTION **Motion was made and unanimously carried to approve the minutes of the January 20-21, 1999 and March 5, 1999 Special meeting as written, and the March 10-11, 1999 meeting as corrected.**
(Motion by Dulwick, second by Williams)

IV. STRATEGIC PLANNING

1999-20 meeting - no detailed discussion was held.

V. ISSUES/ACTIVITIES

A. Reports

1. Board President/Members - No report
2. Executive Director

Acting Director Schnabel reported that the action items from the January and March meetings have, for the most part, not been completed.

Schnabel also reported that he and Board member Schnabel staffed the Board of Pharmacy table at a Y2K fair held in Salem. Schnabel stated this may be an issue the Board needs to discuss at some point. Schnabel said he was amazed at some of the questions asked such as concerns about diabetics, epileptics, and people on various heart medications and what might happen to their drug supplies relative to the Y2K situation. Schnabel said many people asked what the Board of Pharmacy was doing to insure drug supplies are available. Schnabel said the only reason there might be a shortage of drug supplies is if people universally begin hoarding or stockpiling prescription drugs or there is a nationwide transportation shutdown. He said stock piling was a more likely to be a problem than a transportation shutdown.

Acting Director Schnabel wondered whether the Board felt staff should do any research by contacting manufacturers and wholesalers to find out what they are doing to insure adequate supplies of drugs are available and what transportation alternatives are being considered. A member of the

Oregon Board of Pharmacy Minutes - April 14, 1999
Page 3

Board meeting audience spoke out and stated Pharma has put together some information and he would be willing to obtain a copy of their report and submit it to the board if Board members would be interested. Schnabel responded that he would like to have the report and will distribute it to the Board.

3. Compliance Director - No report
4. Board Counsel - No report

B. Laws/Rules

1. Legislation - 1999
 - a. SB 184 - Pharmacy Technicians

President Patrick stated the Board's technician bill is essentially dead at this time. Passage of this bill would have give the Board authority to discipline technicians. An agreement with the Oregon Hospital Association relative to this bill did not occur.

- b. SB 185 - Veterinary drug outlets

Patrick stated this bill is also looking like it will go nowhere. Patrick said he spoke to Noonan-Harnsberger before the Board meeting and she indicated that the cattlemen she has spoken to have no problem with the bill other than the \$25 registration fee.

Acting Director Schnabel stated he had a meeting with the Veterinary Board yesterday and they were quite supportive of the rule and were disappointed to hear that it may be dead. The Veterinary Board is also concerned with prescription drugs being out where they should not be and used inappropriately. Schnabel said the vet board was not concerned that cattlemen were using the drugs inappropriately but they share the same concern as the Board of Pharmacy which is unintended exposure and diversion of the drugs.

- c. SB 769 - Accuracy labels

Acting Director Schnabel stated he, President Patrick, and Tom Holt, Executive Director, Oregon State Pharmacists Association, had a meeting yesterday that included some NACDS members as well as representatives from Fred Meyer, Albertsons, and Kaiser. The Legislative Committee Administrator was also present. Schnabel said the group had a very good two hour discussion in which they talked about what kinds of compromises could be reached.

Schnabel said the result of the meeting was a proposal he and Patrick will share with the Board and that the other members present will share with their people. The proposal contained the following three main points:

Oregon Board of Pharmacy Minutes - April 14, 1999
Page 4

- Go back to Committee Chairman Fischer and tell him this bill is not necessary and can be taken off the table;
- The July 1, 2000 implementation date for the Board's rule will remain in effect and there will be a period of two years after this date that rather than taking disciplinary action for discovery of non-compliance, the Board would issue a warning notice or letter of concern or some other sort of communication which would have to be responded to explaining why they were not compliant yet and what stage they were in with regard to implementation of accuracy labels. Acting Director Schnabel said the Board would need to adopt rules explaining what action would be taken by the Board during this interim period of time for non-compliance;
- Final compliance deadline of June 30, 2002. Effective with this date, discipline would be taken on outlets not complying with the accuracy label rule.

If approved this legislation will get the Board through the next legislative session and creates a two year period for implementation to take place.

Board member Schnabel reminded the Board that it was their original intent when they adopted their accuracy label rule to take effect at a specified future date, that no disciplinary action would be taken by the Board for a period of time after the rule took affect. Schnabel stated in his opinion, this new proposal merely puts in writing what was the Board's original thinking at the time their rule was initially filed.

Board member Williams asked if the Board was aware of any large outlets ready to implement the accuracy label by July, 2000. She stated she believed this would become the standard of practice the minute any large company initiates the practice. Williams believes this will be an excellent marketing tool for those pharmacies ready to activate accuracy labels. Dulwick stated he believed Kaiser Permanente will be ready by the original deadline of January, 2000.

Rice stated that if the majority of outlets have complied and accuracy labels become the standard of practice, then if there is a case that goes to court and the pharmacy involved does not yet have accuracy labels, it will not speak well for that pharmacy. He feels this has been a long process which began in 1996, but he feels it shows the legislature that the Board is willing to take the additional time they are requesting. This is a consumer safety issue and it is the consumer who benefits first and that's who the Board is here to protect.

A member of the audience stated AARP has accuracy labels on their work list and they intend to comply. AARP has some Y2K and internal computer upgrade issues that are also on the list.

Oregon Board of Pharmacy Minutes - April 14, 1999
Page 5

Inspector Schulte added that the Compliance staff is not wanting to run out and cite people, however, if the Board receives a dispensing error complaint today, letters of concern may be sent, however, a year from now that same dispensing error may cause the dispensing pharmacist or outlet to receive a more severe type of disciplinary action if the outlet involved has not made any move to institute the accuracy label practice.

MOTION Motion was made and unanimously carried to approve the accuracy label proposal outlined and immediately begin the process of getting started on the rule change and establishment of a work group to deal with the language.
(Motion by Williams, second by Talton)

President Patrick would like to see a rough draft of the new accuracy label language at the next Board meeting with a rules hearing held in September, October, or November 1999. Staff will respond back to Senator Fischer regarding the Board's approval of the proposal and the establishment of a work group to develop rule language.

d. SB 491 - Death With Dignity

Acting Director Schnabel stated there were a couple new amendments in the bill which would not involve pharmacy. One of the revisions resolves the health care provider issue by including in the definition of 'health care provider' anyone who dispenses medication.

e. SB 823 - Exec. Dir. Appointment by Governor

Board member Schnabel stated he tried to speak with Mark Gibson of the Governor's office about this bill but he was apparently not in the office. Schnabel said he spoke with another representative of the Governor's office who stated she would pass the information along to Gibson.

At this point the Board does not know where the Governor's office stands on this bill.

f. SB 1005 - Unlawful to Contact Patients Re Drug Therapy

Tom Holt, OSPA, Executive Director, stated Senator Bryant wants a working group assigned to this bill but so far none has been appointed. He said there was a lot of opposition to this bill at the legislature.

g. HB 2010 - Pharmacist's Refusal to Fill Prescription

Acting Director Schnabel stated this bill had a hearing but he does not know where it is currently.

Oregon Board of Pharmacy Minutes - April 14, 1999

Page 6

- h. SB 2690 - Phy. Coalition Bill for R.Ph. Medication Admin

Holt, OSPA, stated this bill is due for hearing the end of April.

- i. HB 3030 - Eliminates Limited Naturopathic Formulary

Action Director Schnabel stated this bill is actually a housekeeping bill that will not result in changing the formulary. The early language has been amended so that it clearly is now a housekeeping bill.

- j. HB 2465 - Super board

This bill would create a health regulatory oversight board. The Board reviewed various requirements of the bill. This regulatory oversight board would be funded by a \$2 fee from every registrant or licensee of every health related licensing board. The bill contained many inconsistencies noted by the Board. Board members agreed this would create bigger government.

**MOTION Motion was made and unanimously carried to oppose HB 2465 and to provide oral or written testimony against this bill.
(Motion by Schnabel, second by Rice)**

- k. Other legislation

Acting Director Schnabel mentioned SB 1079 which would authorize the Board of Pharmacy to issue a civil penalty to a drug outlet not to exceed \$10,000 per violation. Schnabel does not know who sponsored this bill. Holt, OSPA, stated there is a general trend this session to increase fines by licensing boards.

Schnabel mentioned three additional bills, HB 2702 establishes an interim task force to study health related licensing boards; HB 2788 eliminates the Governor's office and all state agency's authority to file legislative measures; and SJR 18 would authorize the legislature to disapprove any agency's administrative rules by ballot vote.

2. Rules

- a. Rite Aid request to change PIC rule

The Board reviewed some draft language submitted by Rite Aid. President Patrick stated this issue was taken to POP chats for discussion. POP Chats thought the issue merited review and was willing to put together a work group. Patrick stated this is the only company who has notified the Board of the need for such a rule change, but he said it is definitely worth forming a study group to look at the rule.

Oregon Board of Pharmacy Minutes - April 14, 1999
Page 7

Board member Schnabel stated he found it somewhat ironic and a little difficult to believe that reducing oversight in pharmacies improves orderliness and accuracy and compliance in pharmacies. Schnabel said he felt just because some other state in the country has a more permissive rule in their state did not mean that that should be the standard of practice in all states.

Holt, OSPA, said he discussed the issue with Krahulec, Rite Aid, and the possibility of a work group in August sometime outside the legislative system. Holt stated Krahulec indicated he would be willing to support such a group on that basis. He stated part of the discussion was that there was the possibility of a legislative proposal by Rite Aid relative to this issue.

A Rite Aid representative at the meeting stated Krahulec was tentatively agreeable to supporting and participating on such a work group. He said it was Rite Aid's desire to make the rule easier for independent and chain pharmacists to understand and adhere to.

MOTION Motion was made and unanimously carried to appoint a work group to review the PIC rules.
(Motion by Dulwick, second by Rice)

Holt said he would assist the Board in determining membership on the work group. The Board will try for a July or August work group meeting. Dulwick said the Board needed to make sure the rule is written in such a way that the current level of accountability and control is maintained over the pharmacy.

Mark Whitlow, Rite Aid attorney, was present in the audience stated it was somewhat of an oddity that the PIC requirements are indicated in the Administrative Rules rather than in the Statutes. It was Rite Aid's thinking that the definition and some of the other elements of the PIC requirement would more appropriately be located in the statute. In the short term, Rite Aid will continue to have difficulties in complying with the PIC elements, particularly in the area of replacement, therefore, he said the timing of this was very important to them. Something to assist Rite Aid in the interim would be appreciated especially in the area of allowing one PIC for more than one outlet at a time and a greater length of time to replace a PIC.

Inspector Schulte made reference to a previous weekly Rite Aid/Board of Pharmacy meeting in which this question came up. Schulte stated that as long as any pharmacy has another pharmacist who is willing to open the pharmacy that day, they have a person who could sign on as PIC that day. He said the company may not want that particular person to sign on but someone is usually available. Schulte stated for this reason he can see no time when a gap without a PIC would occur under normal circumstances. Schulte stated, in other words, if you have a pharmacist to work on any given day, you have a person capable of being a PIC on any given day.

Board member Schnabel stated it's a serious matter to the Board when there is a new PIC pharmacist in the store every day. The PIC represents orderliness, stability, and continuity in a store

Oregon Board of Pharmacy Minutes - April 14, 1999

Page 8

and this facilitates accurate and proper dispensing of prescriptions, and ability to get to know the prescribers and the patients.

Dulwick stated in his history on the Board he has never seen evidence that the Board takes action on lack of PIC's for very short periods of time such as when a PIC is terminated, where a PIC leaves the pharmacy without notice and does not return, or dies. The only incidences of disciplinary action taken that he could remember were cases where an outlet was without a PIC for days, weeks or months. Dulwick emphasized that the Board's responsibility is toward the public and he cannot see how changing the rule would benefit the public. President Patrick agreed. Dulwick said he would be very hesitant to grant any kind of waiver at this point without a lot of thought or behind it.

Acting Director Schnabel stated it appears the Board and staff are in agreement that at the present time Rite Aid has a staffing problem and the Board is concerned about changing a rule or granting a temporary waiver to any pharmacy to accommodate a staffing problem. The other question is the PIC rule itself and it may be time to review the rule and the Board is willing to do that. Schnabel stated in addition, that under the current action plan with Rite Aid, they have agreed, under that plan, to have a PIC in each store.

b. Scheduling of Ultram

Acting Director Schnabel stated that at a previous meeting, the Board had received a request from a physician for the Board to schedule Ultram. This particular physician noted abuse in some of his patients and he requested the Board look at the problem and schedule it. At that time the Board decided to gather information from other states through the NABP mailbag. From the mailings the Board has received from other states, it appears other states have not seen sufficient problem to move them to schedule Ultram.

Bill Struyk, Johnson & Johnson, who was present in the audience, stated he contacted the FDA when he saw this item on the agenda. Struyk said the FDA has no meeting scheduled now or in the foreseeable future to reconsider this issue. He said there is no other state that has any rule making or any scheduling activity ongoing with Ultram nor is any scheduled.

The Board will take no action on Ultram at this time but will continue to monitor this issue and bring it back for discussion if the need arises.

c. BME Collaborative Therapy rule

Board member Schnabel stated the Board of Medical Examiners is having their first reading of their version of the collaborative drug therapy rule this week. This is a parallel rule to that of the Board of Pharmacy. Board member Schnabel stated he would write a letter to the BME thanking them for the action taken on their rule.

Oregon Board of Pharmacy Minutes - April 14, 1999

Page 9

d. Technician/clerk duties

Board member Rice stated the Board staff has been receiving a lot of calls about what technicians and clerks can legally do in the pharmacy and where the line between them is drawn. Actual prescription/patient information can only be handled by the technician. Issues concerning prescriptions and patients contain confidential information which must be protected. Entering the profile information is a technician duty which cannot be delegated to a clerk.

A lengthy discussion ensued about what specific duties are considered technician only duties and what other duties are clerical duties that are not the practice of pharmacy. Williams stated her primary concern are the large number of cases that come before the Board where a clerk has handed out a prescription that has not been authorized by the pharmacist to be handed out to the patient.

President Patrick suggested sending this issue to the next POP Chats for discussion. If POP Chats finds too much gray area that needs definition, the Board can go from there.

C. General Administration/Discussion

1. Ratification of new licenses

**MOTION Motion was made and unanimously carried to ratify the licenses issued from March 9, 1999 through April 9, 1999 as presented to the Board.
(Motion by , second by)**

2. Approval of NAPLEX scores - no scores received

3. Approval of MPJE scores - no scores received

4. Budget

Gibson and Schnabel reported on the state of the Board's budget as of April 12th. Gibson stated the Board currently has a budget limitation balance of \$153,000 to last through June 30th. Once the Governor signs the Board's supplemental limitation bill, \$109,563 will be added to the limitation, however, portions of the supplemental money can only be expended on specific budget items (\$10,000 for the Executive Director search, approximately \$63,069 toward the hearings officer and Attorney General relative to the progression of the Rite Aid Pharmacy Corporation settlement, and approximately \$36,494 available for general services and supplies).

Gibson estimated the Board would need approximately \$245,000 (\$80,000 to \$85,000 per month) to cover Board operations through June 30th. With the supplemental money, the Board may be able to make it through the biennium but it will be very tight.

Oregon Board of Pharmacy Minutes - April 14, 1999
Page 10

Board member Schnabel stated his concern about having another Board meeting when funds are so limited. He suggested the Board continue the monthly Investigative Compliance meetings with two or three Board members and put other Board business that can wait, on hold until July. President Patrick stated it had been his plan to bring in candidates for interview for the Executive Director position on a scheduled Board meeting date so that both could be done without Board members having to make a second trip to Portland.

5. Peace Health request for oral counseling waiver

The Board reviewed a letter of request from Peace Health. Inspector Schulte stated they do not need the waiver since they are a retail pharmacy delivering outside the immediate pharmacy. This practice is considered mail order and they are already covered. Schulte stated he has already talked with Peace Health and explained this issue and they are satisfied. No further action is necessary.

6. Board appointments

No action is necessary at this time. The Board appointments will be considered by the Governor's office at the conclusion of the legislative session.

7. Lloyd Center Pharmacy Service Plan

Gibson referred the Board to the January minutes under the appearance of Don West, Lloyd Center Pharmacy. Board members Rice and Noonan-Harnsberger had volunteered to come up with some basic guidelines and questions for Board staff to take with them when they go to see the work flow at Lloyd Center Pharmacy. The issues of quality assurance, training and/or certification, and counseling are what the Board is primarily concerned with at this or any other pharmacy requesting an increase in technicians.

Rice and Dulwick will re-review the Lloyd Center request packet and report back to the Board at the next meeting. This issue was delayed due to the appearance by Don West prior to the Board being able to review the related materials. The Board asked that staff contact West to explain this point and indicate that the Board will be discussing the issue again at the next Board meeting.

8. OSPA magazine articles

The Board discussed the need to prepare articles for upcoming issues. The following were some suggested articles and the names of Board members volunteering to write them.

- Rice: Accuracy label update, when the time comes for an update.
- Noonan-Harnsberger: What and where was the opposition and what was the purpose of the veterinary drug outlet legislation.
- Patrick: Proposed rules, committees/work groups to be formed by Board, what are

the issues and who can pharmacists contact for more information about the issues.

D. Compliance - Wednesday 8:30am

1. Investigative Committee report

MOTION Motion was made and unanimously carried to accept staff recommendations for warning notices in cases 99-0049, 99-0077, 99-0078, 99-0079, 99-0090, 99-0095, 99-0096, and 99-0099.
(Motion by Talton, second by Schnabel)

MOTION Motion was made and unanimously carried to fine the PIC \$500 and send a letter of concern to the outlet in Case 99-0097 for failure to verify that a technician is currently registered prior to being utilized. The technician's registration had expired 9-30-98.
(Motion by Talton, second by Rice)

Case 99-0117 has been held pending further investigation.

MOTION Motion was made and unanimously carried to fine the pharmacy outlet \$1,000 for failure to have a PIC.
(Motion by Talton, second by Schnabel)

MOTION Motion was made and unanimously carried to send letters of concern to the pharmacist, the PIC, and the pharmacy outlet in Case 98-0219 for failure to have an expiration date on the prescription label.
(Motion by Talton, second by Schnabel)

MOTION Motion was made and unanimously carried to issue orders of reprimand to the dispensing pharmacists and the PIC, and a letter of concern to the pharmacy outlet in Case 98-0234 for dispensing a prescription not in accordance with the prescriber's authorization.
(Motion by Talton, second by Schnabel)

Case 99-0021 will be held for further investigation.

MOTION Motion was made and unanimously carried to send letters of concern to the pharmacist and the PIC and a \$1,000 fine to the pharmacy outlet in Case 99-0028 for failure to initiate and provide counseling.
(Motion by Talton, second by Rice)

MOTION Motion was made and unanimously carried to send letters of concern to the pharmacist, the PIC, and the pharmacy outlet in Case 99-0056 involving a technician where a prescription was dispensed not in accordance with the prescriber's authorization.
(Motion by Talton, second by Schnabel)

Oregon Board of Pharmacy Minutes - April 14, 1999
Page 12

The Board reminded staff of their previous directive to track and log all cases involving technicians for use at the next legislative session.

MOTION **Motion was made and unanimously carried to issue orders of reprimand to both pharmacists and the pharmacy outlet and fine the PIC \$500 in Case 99-0086 for allowing a non-registered person to act as a technician, for not clearly identifying technicians for the public, for having no written procedures on file which describe a technicians duties and the training received.**
(Motion by Talton, second by Schnabel)

MOTION **Motion was made and unanimously carried to issue an order of reprimand to the pharmacy outlet and fine the PIC \$300 in Case 99-0092 for allowing a person other than a registered pharmacist or pharmacist intern to counsel a patient or patient's agent.**
(Motion by Talton, second by Schnabel)

ADMINISTRATIVE DISCUSSION - COMPLIANCE

F. Staff Cases

MOTION **Motion was made and carried to accept staff recommendations in Cases 99-0043, 99-0010, 99-0011, 99-0030, 99-0052, 99-0053, 99-0067, 99-0069, 99-0085, 99-0106, 99-0029, 99-0046, 99-0047, 99-0048, 99-0051, 99-0060, 99-0061, 99-0062, and 99-0064.**
(Motion by Talton, second by Schnabel; Patrick abstained)

Staff Case 99-0072 was held for further investigation.

G. Next Investigative Staff meeting: May 11, 1999

H. Discussion

1. The Board held a discussion about changing letters of concern to orders of reprimand and applied on a case by case basis. The decision was made to begin issuing orders of reprimand.

2. Case 98-0094-B

MOTION **Motion was made and unanimously carried to issue an order of dismissal in Case 98-0094-B.**
(Motion by Talton, second by Schnabel)

Oregon Board of Pharmacy Minutes - April 14, 1999

Page 13

3. Case 99-0036 - The Board reviewed the consent order in this case from last month in which condition #3 was added.

4. Case 99-0127

MOTION Motion was made and carried to initiate disciplinary action in Case 99-0127. (Motion by Talton, second by Schnabel; Patrick abstained)

E. Committees/Meetings

1. Consumer Information

Williams stated the public education brochure is ready to be printed but is on hold pending confirmation of funding. The funding is to be donated by Fred Meyer and Roche Labs.

2. POP Chats

Acting Director Schnabel referred the Board to the list of topics discussed at the last meeting. The next meeting is scheduled for July 16, 1999 at 1:30pm in the Board office.

3. Executive Director search

The Board reviewed a profile/demographic summary of the eleven candidates currently under consideration, put together by John Block, past board member and Chair of the Search Committee. The committee hopes to narrow the list to three or four for actual face to face interviews.

4. Pain & Symptom Management Task Force

Acting Director Schnabel referred the Board to a copy of the final report of the Pain and Symptom Management Task Force to the Seventieth Oregon Legislative Assembly and Governor John Kitzhaber. He also reviewed with the Board various legislative bills and resolutions proposed as a result of the Pain and Symptom Task Force recommendations.

MOTION Motion was made and unanimously carried to support the Pain and Symptom Task Force resolutions. (Motion by Rice, second by Schnabel)

5. NABP Annual meeting

Although there is no Board funding, President Patrick will attend the NABP Annual meeting at his own expense. Patrick will be the Board's only delegate.

Oregon Board of Pharmacy Minutes - April 14, 1999
Page 14

F. Open Forum **Wednesday - 3:30pm**

There were no requests to speak during the open forum section of the meeting. Several members of the Board meeting audience spoke at various times throughout the meeting.

The Board meeting was adjourned at 4:30pm on Wednesday, April 14, 1999.

Minutes Accepted By:

Gary Schnabel, R.N., R.Ph.
Acting Executive Director
Oregon Board of Pharmacy

Carolyn
April 99.wpd