

BOARD MEETING MINUTES

Oregon State Board of Pharmacy

800 NE Oregon #150 & 120C

Portland, OR 97232

April 4 – 5, 2006

Tuesday, April 4, 2006

OPEN SESSION, Linda Howrey, RPh. Presiding

Roll Call

The following members were present:

Linda Howrey, President
Ann Zweber, Vice President
Cathryn Lew, Vice President
Bernie Foster
Lee Howard
Blake Rice
Marcus Watt

Introduced our new Pharmacist Consultant, Paige Clark

The following staff were present for this session:

Gary Schnabel, Executive Director
Karen MacLean, Administrative Director
Thomas Cowan, Assistant Attorney General
Gary Miner, Compliance Director
Joe Ball, Chief Inspector
Mike Beck, Inspector
Michele Cale, Inspector
Judy Van Uden, Inspector
Tony Burt, Project Manager
Annette Gearhart, Compliance Secretary
Paige Clark, Pharmacist Consultant

MOTION

Motion to accept the items on the revised consent agenda was made and unanimously carried. (Motion by Lew, second by Watt.)

Motions for Disciplinary Action

See Board Compliance Minutes for case numbers and detailed information.

Wednesday, April 5, 2006

RULEMAKING SESSION, Linda Howrey, RPh. Presiding

Roll Call

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

Linda Howrey, President
Ann Zweber, Vice President
Cathryn Lew, Vice President
Bernie Foster
Lee Howard
Blake Rice
Marcus Watt

The following staff was present for all or part of this meeting:

Gary Schnabel, Executive Director
Karen MacLean, Administrative Director
Thomas Cowan, Assistant Attorney General
Gary Miner, Compliance Director
Joe Ball, Chief Inspector
Mike Beck, Inspector
Michele Cale, Inspector
Judy Van Uden, Inspector
Tony Burt, Project Manager
Annette Gearhart, Compliance Secretary
Paige Clark, Pharmacist Consultant

New staff member, Paige Clark, Pharmacist Consultant was introduced. Paige joins us with an extensive background in pharmacy consulting and project management.

Rulemaking Discussion – *Howrey/Schnabel*

Immunization Rules

The Board reviewed the rule to make sure that consistent language and references to the Department of Human Services had been incorporated.

MOTION:

Motion to amend OAR 855-041-0500, 855-041-0510 and 855-041-0520 was made and unanimously carried. (Motion by Howard, second by Rice)

Returned Drugs Rules

The Board discussed the merits of keeping a log of returned drugs and decided this was not necessary.

MOTION:

Motion to amend OAR 855-041-0080 was made and unanimously carried. (Motion by Watt, second by Rice)

Technician Related Rules

The Board discussed at length the proposed rules and comments made at the rulemaking hearing. There seems to be a lot of fear among pharmacy technicians about having to take an exam. Many are concerned that the exams are not balanced in their focus towards retail on one hand or hospitals on the other. The Board feels that both exams are entry-level and not specialized. The Board also discussed the merits of having a defined list of duties included. Board Members Watt and Howard urged we go with an exception list. A letter of exception could be kept in company policies as documentation. Finally, there was a discussion about "grandfathering" in for technicians. The Board believes it is important for all pharmacy technicians to be nationally certified and that "grandfathering" will not be applicable to certification of pharmacy technicians.

MOTION:

Motion to repeal 855-006-0005 was made and unanimously carried. (Motion by Howard, second by Rice)

MOTION:

Motion to amend OAR 855-006-0010 as revised was made and unanimously carried. (Motion by Lew, second by Howard)

MOTION:

Motion to amend OAR 855-025-0001 as revised was made and unanimously carried. (Motion by Lew, second by Rice)

MOTION:

Motion to amend OAR 855-025-0005 was made and unanimously carried. (Motion by Howard, second by Lew)

MOTION:

Motion to adopt OAR 855-025-0010 as revised was made and unanimously carried. (Motion by Howard, second by Zweber)

MOTION:

Motion to adopt OAR 855-025-0015 was made and unanimously carried. (Motion by Rice, second by Zweber)

MOTION:

Motion to adopt OAR 855-025-0020 was made and unanimously carried. (Motion by Lew, second by Howard)

MOTION:

Motion to adopt OAR 855-025-0025 as revised was made and unanimously carried. (Motion by Howard, second by Rice)

MOTION:

Motion to adopt OAR 855-025-0030 as revised was made and unanimously carried. (Motion by Howard, second by Lew)

MOTION:

Motion to adopt OAR 855-025-0035 as revised was made and unanimously carried. (Motion by Lew, second by Howard)

MOTION:

Motion to adopt OAR 855-025-0040 as revised was made and unanimously carried. (Motion by Rice, second by Foster)

MOTION:

Motion to retain and amend original rule with minor revision OAR 855-025-0050 was made and unanimously carried. (Motion by Howard, second by Rice)

MOTION:

Motion to adopt OAR 855-025-0060 as revised was made and unanimously carried. (Motion by Lew, second by Rice)

MOTION:

Motion to repeal OAR 855-041-0020, 855-041-0203, 855-041-0205 and 855-041-0120 was made and unanimously carried. (Motion by Howard, second by Lew)

MOTION:

Motion to amend OAR 855-110-0005 as revised was made and unanimously carried. (Motion by Zweber, second by Lew)

Pseudoephedrine Rules

The Board discussed issues around the 3.6 and 9 gram limits as revised by the Ffederal Combat Meth Act. The DEA has given Board staff some direction; however we are waiting for something in writing to confirm how this may or may not apply to the Oregon Law. Staff and Board Counsel will follow up. It was noted that OSU Intern, Sarah Brown has prepared a poster for the Annual NABP meeting on the progression the new pseudoephedrine rules in Oregon. Rob Bovett made a presentation showing a 41% reduction in meth labs and provided an update on the issue. They expect a 74% reduction after it's scheduled on July 1st. The Board thanked Rob for his continued support and thorough information.

MOTION:

Motion to repeal OAR 855-050-0037, 855-050-0038, 855-050-0039, 855-050-0041, 855-050-0042, 855-050-0043 was made and unanimously carried. (Motion by Rice, second by Howard)

MOTION:

Motion to amend OAR 855-050-0070, 855-080-0022, 855-080-0023, 855-080-0028, 855-080-0031, 855-080-0065, 855-080-0070, 855-080-0075, 855-080-0095, 855-080-0105 was made and unanimously carried. (Motion by Rice, second by Foster)

ISSUES/ACTIVITIES

Board President/Members

Board President Howrey reported on the PSOP meeting. Ann Zweber presented on the technician rules and gave an update regarding pseudoephedrine at two OSPA meetings. Marc Watt joined her for one of those sessions. Cathy Lew and Paige Clark will attend the upcoming Annual Pain Society meeting on April 15th in Eugene. Cathy will also present at the upcoming DEA Drug Disposal and OSHP meetings.

Board Council

No report.

Compliance Director

Inspector Beck is doing a great job and is ahead of last year at this point on inspections. 180 have been completed so far, including a good cross-section of facilities. Inspections were made between January and April 1.

They are trying to schedule law CE's around the state. In the May newsletter, there will be a note for people to contact the Board if they are interested. They are in discussion with the DEA on the topic of licensing for campus settings.

A "Pharmacy Technician & Certified Pharmacy Technician Training Supplement" that was prepared by staff was reviewed by the Board. It was approved and will be added to the website.

Administrative Director

Administrative Director Karen MacLean provided administrative and licensing coverage for the Executive Director while he was on vacation. Compliance Director, Gary Miner also provided coverage as needed for pharmacy practice and compliance issues.

Paige Clark is now on board. The inspector position is still open due to the salary. Management Secretary, Tessra Bradshaw is leaving the agency. Her last day is Friday. Karen thanked Tessra for her work with the Board and wished her well. Board members and other staff present also thanked her with a round of applause and well wishes. The recruitment notice will be out by the end of the week.

The online renewals upgrade on current credit card and treasury interface is facing complications.

Meeting preparations for the June Board meeting at the Riverhouse in Bend are set up. Local pharmacists will be contacted for a *Meet and Greet* with the Board. Former Board Member, Mike Patrick may be able to assist.

PRN Director

No report.

Research Councils

Remote Dispensing – Rice

No report.

USP 797 – Lew/Miner

Board Member Lew is keeping up with Sue Stein on this topic. They have six people on the Council signed up and will set up a meeting. The timeline for everyone to be on board is January 1, 2008.

Electronic Transmission Signatures – Watt

They have a group identified and will begin meeting. They are still trying to get one key person. Medicare Part D requirements must be available by 1/1/07. There is a new sense of urgency. Inspector Van Uden is helping with this.

Central Fill – Dulwick

Former Board Member Allan Dulwick is heading this committee. Executive Director Schnabel commented that Allan was under the impression he was done. The Board says there is more work to do. Notify Allan.

Medication Therapy Management Service – Howrey

Board Member Howrey has agreement from some key people to be involved with this Council. They are still assembling others and are not ready to move forward yet.

Practice Models: Correctional Facilities

Compliance Director Miner received approval to get together a “work group” to talk about correctional facilities.

Practice Models: Long-Term Care

Board Member Zweber is working on a new committee dealing with long-term care.

Foreign Importation

A Nevada legislator directed their board to write rules for importing drugs from Canada to start in May. Our Governor has heard and is questioning if we can do that. Executive Director Schnabel reported that the Governor’s office is still silent on the denial of the HHS waiver request.

Board Meeting Dates

The Board discussed possible dates for the 2007 NABP District VII/VIII meeting. The best options are:

- October 3-6 District Meeting, Ashland
- October 16-17 Board Meeting, Portland

Committees / Meetings

HB 2485 Judiciary Committee Hearing Update, March 7, Salem – Rice/Schnabel

The purpose of this appearance was to provide the committee an update on the Board’s progress to implement HB 2485. Board Member Rice reported on a possible additional report to give Shearing and Wyeth an update. This was the second appearance. Board Member Rice did the presentation. PSE alternative products reformulated with phenylephrine are coming on the market. The Legislature was pleased.

Wholesale Model Rules Organizational Meeting, March 16, Portland – Rice/Cale

Board Member Rice made a good presentation on Wholesale Model Rules. A handout with a timetable was provided. There was a good cross representation present and they were concerned the Board would do something out of the norm. There was also concern that each state will have different rules. The group will be working from the NABP Model rules. A tracking device, like a radio frequency identification (RFID) chip, might be an option. Board Member Rice, Project Manager, Tony Burt and Inspector Cale will meet with the group again on May 4.

NABP Annual Meeting, April 8 – 11, San Francisco – Schnabel

Executive Director Schnabel will be attending the NABP Annual Meeting late this week and early next week. It is the first time presenting a poster at the NABP meeting. The poster on Pseudoephedrine laws in Oregon was created by OSU PharmD candidates Sarah Brown and Lindsay Brown. Resolutions will require a vote. Board Member Howrey is the voting delegate. Blake Rice will also attend the first two days before leaving for Washington DC. Executive Director Schnabel will be presenting, “Come to Portland” for the 2007 Annual Meeting.

Prescription Drug Monitoring Program Conference, April 12 – 13, Washington DC
Board Member Rice and Janet Preller, Corvallis Clinic Risk Manager, will attend. Funding for the Harold Rogers Prescription Drug Monitoring Grant Program has been guaranteed for two more years. Board Member Rice has met with state senators and representatives from his area, and Board Executive Director Schnabel has been in touch with legislators.

Appearances

Kate Farthing and Larry Carter of Wellpartner re: Consumer Outreach
Request for Board to participate in a public education *Oregonian* supplement in October 2006, highlighting National Pharmacist month. A number of associations have joined together to sponsor this consumer outreach. The supplement will come out on the first Sunday in October. A sample of the proposed supplement was distributed. It will be finalized by June or July. The goal is to educate the public about the practice of pharmacy and how their pharmacist may help them in the future. They are working to secure funding. The Board approved participation.

MOTION

Motion to participate in “October is Pharmacists” month was made and unanimously carried. (Motion by Lew, second by Zweber)

Sarah Ainsworth from NW Women’s Law Center and Kathryn Wilcox from Planned Parenthood re: Emergency Contraception

Ms. Ainsworth and Ms. Wilcox are aware of our policy statement in the newsletter regarding moral and ethical objections. They think it doesn’t go far enough and say we should have a rule or policy statement that is stronger in supporting patient access. They believe no moral objections should be communicated to the patient. Sarah outlined a sample policy for seamless access. (see page 10 – “Emergency Contraception” for Board discussion and response)

Jennifer Zannon from Walgreens appearance re: Remote from Home Concept

Jennifer Zannon presented Walgreen’s “Remote from Home” PowerPoint presentation on requesting mail service only. The Board requested a more detailed request, follow-up of the Arizona model and requested Compliance to do an inspection. There may be licensing issues.

Buck Stevens, RX.com and Dan Ramirez appearance: Prescription by Mail

This system is not just central fill. The system allows for multiple chains to use a common mail order system. They call it “store-based mail order.” Rx.com store-based mail order/ Rx.com fulfillment:

- Retains ownership of the prescription at the store
- Receives “backend” rebates for 90-day store-based mail programs
- Participates in mandatory mail programs in your area
- Provides access

There are two distinct operations of PBM (prescription by mail) mail facilities. One is front end operations; the other is done at the local store. The second is the done through automation. This is the piece they do.

A thorough presentation was made on the state of mail order and Rx.com opportunities. Strategy benefits are:

- Provides access to 90-day mail order benefit plans.
- Maintains patient choice.
- Authorizes retailer to retain ownership of prescription and refills.
- Facilitates retailer's ability to profitably fill prescription. 90-day benefit.
- Retailer retains store identity.
- Faster turnaround time.
- "Class of trade" pricing for 90-day benefit.

Questions/Responses:

Executive Director Schnabel asked questions. (How do they make money? What is the safety mechanism against a dispensing error?) Buck Stevens explained how filling is safety performed. Pharmacists are licensed per various state requirements.

APHA statement: "Who is paying pharmacists now? Now a manufacturer is willing to pay. They do fill controlled substances.

The Board thanked them for their appearance.

GENERAL ADMINISTRATION

Discussion

Staff Policy Questions- Miner

Compliance Director Miner presented a question regarding pseudoephedrine 9 gram limit. The Board is waiting for Board Counsel to research this issue.

NABP Proposed Resolutions – Schnabel

Board Executive Director Schnabel explained the resolutions that will be presented.

Public Information (Discipline) - Lew/Zweber

Board Member Lew asked the Board members if they looked at other Board Web sites regarding public disclosure. The Board discussed the Board of Nursing's recent challenges on this topic. Administrative Director MacLean commented that she had received an e-mail request for all disciplinary action. She provided the agency license verification link. The Board of Dentistry provides limited information. The Board of Medical Examiners lists names. Most of the sites are similar to ours. Compliance Director Miner asked the question "What about letters in lieu of discipline?" It's probably reportable. The Board discussed issues relating to public documents and notices.

Patient Safety Commission

Invite Dave Widen from the Patient Safety Commission to our next meeting to provide an update.

Pain Management Position Statement

Board Member Lew and Pharmacy Consultant Clark reported on their findings of how other states handle policy statements on this topic. They reviewed samples from Iowa, Texas, Wisconsin, Board of Medical Examiners, and the Board of Nursing. They have talked with Kathy Hahn, Chair of the Oregon Pain Commission. She would like to provide input to the policy statement. They will draft something for the Board to review for the next meeting.

MOTION

Motion to approve FPGE waiver request was denied unanimously. (Motion by Rice, second by Zweber)

MOTION

Motion to approve OSU waiver request was approved for one school year unanimously. (Motion by Zweber, second by Watt)

MOTION

Motion to approve Walgreens waiver request for returned drugs including controlled substances was approved with an effective date of the rule filing unanimously. (Motion by Zweber, second by Blake)

Automated Dispensing & Waiver Request – Miner

Portland Adventist hospital pharmacy asked if they can put some kind of automated dispensing machine in a clinic. Compliance Director Miner's suggestion is to make them meet the BME labeling requirements. Karen Nishi of Cardinal Health was asked to appear and gave a demonstration and explanation of Pyxis automated dispensing machines. Board Staff have received a number of requests and felt it would be useful for the Board to hear how this technology works in order to respond. Long-term care facilities are using Pyxis machines. They come with various levels of security. Sacred Heart Medical Center is asking for a waiver. Technicians get a list of medicines and get the medications. Then the technician has them checked and then fills Pyxis machine. Cottage Grove hospital has no pharmacy. They use Pyxis only. It is located in a room registered as a drug room. The Technician is unsupervised. A sealed cube can be delivered by a clerk or technician. An unsupervised technician can not fill the cube.

Hospital Take Home Pack - Miner

Gary Miner presented a request to allow hospital take home packs. Under current rule OAR 855-041-0120(4), a hospital cannot give out a take home pack. Dosage is limited to 24-hour supply. The Board discussed this issue and if there is a 24-hour pharmacy within fifteen miles of the hospital that solves the problem. Staff will research federal law and bring information to the next meeting.

Licensing of Nonprescription Drug Outlets – Schnabel

Pat Allen from the Office of Regulatory Streamlining was present to ask the Board if there are ways to combine the licensing of non-prescription drug outlets in with other agencies licensing functions. One-third of the outlets who should have a license may not be licensed. Enforcement is incoming-call driven. Are there other ways besides licensing to achieve compliance? He believes the Administrative Procedures Act may provide an avenue simply through the small business requirement waiver. The Board may not need a legislative statement of change to no longer license these outlets. There are a lot of questions that Staff presented on this topic. Fundamentally, our statute says we must register all non-prescription drug outlets. We're not sure how this would work. Fiscal would need to do research. The Board directed staff to work with Pat on this issue and report back to the Board as time allows.

Emergency Contraception

The Board discussed the presentation from earlier today. The Board believes the current policy is sufficient and until there is evidence that pharmacists are creating barriers for consumers, they plan to leave the policy as is. The Board just has not received more than 1-2 complaints to justify changing the policy as Ms. Ainsworth suggests is necessary. Board Member Rice thinks the position statement covers the issues. If we get some cases, maybe it is a consumer safety issue. Discuss with the pharmacy association (OSPA) to ensure alignment. We can't regulate what a pharmacy carries. Counsel prefers having a case before the Board considers this. Nothing has happened to cause us to change our current position. There is a possibility of working on legislation that relates to collaborative therapy. The Board thinks we need to support and go there if the stakeholders are interested. Staff will follow up with Ms. Ainsworth.

Rule Review Update

Administrative Director MacLean provided an update on the status of several rules that have been in progress. The current rules have consumed a majority of the time and staff is working on the outstanding issues.

Budget Report

Accounting & Budget Update – MacLean

Budget kick-off is starting up, more details to follow in June.

Legislation

Executive Director Schnabel reported on the status of preparation the 2007 Legislative Concepts

Prescription Drug Monitoring Program

Senators Gordly and Kruse would like to discuss carrying the Bill next session. They would like to have the Pain Commission provide a letter of support. They've asked the Board to appear at the Senate Interim Committee on Public Health May 11. We should seek someone on the House's side, such as Representatives Morgan or Barnhart. We need to show how this problem exists in Oregon and why this program would make a difference. Executive Director Schnabel shared a recent letter from someone seeking help.

Agency Transition

Administrative Director MacLean provided details about the concept that would remove the agency from its current structure within the Health Related Licensing Board to it's own agency within the state system. At this point, the Governor's office and DAS Budget and Management have approved the transition.

Update Civil Penalties and Recover Administrative Costs

A concept has been submitted to increase the limit on civil penalties and recover administrative costs. Added to this concept was a component that added penalties for wholesaler violations. This concept is a placeholder until more information can be finalized with Board Counsel.

OPEN FORUM

No one was present for open forum.

MOTION

Motion to enter into Executive Session for review of executive performance evaluation was made and unanimously carried. (Motion by Rice, second by Watt)

MOTION

Motion to adjourn the meeting at 4:15 p.m. was made and unanimously carried. (Motion by Rice, second by Watt)

Minutes accepted by:

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