

BOARD MEETING MINUTES
Oregon State Board of Pharmacy
800 NE Oregon St.
Portland, OR 97232
December 5-6, 2006

Tuesday, December 5, 2006 @ 9:00, Conference Room 140 Wednesday, December 6, 2006 @ 8:30 am, Conference Room 140

Tuesday, December 5, 2006

9:00 OPEN SESSION, Ann Zweber, R.Ph. Presiding

Meeting was called to order at 9:00 by Ann Zweber

Roll Call

The following Board members were present:

Ann Zweber, Vice President

Cathy Lew

Linda Howrey

Dianna Pimlott

Marc Watt, Lee Howard, and Bernie Foster were absent

The following staff members were present:

Gary Schnabel, Executive Director

Karen S. MacLean, Administrative Director

Gary Miner, Compliance Director

Joe Ball, Chief Investigator

Tony Burt, Project Manager

Paige Clark, Pharmacist Consultant

Michele Cale, Inspector

Judy VanUden, Inspector

Mike Beck, Inspector

Annette Gearhart, Compliance Secretary

Jennifer Hess, Management Secretary

Tom Cowan, Board Counsel

Consent Agenda Approval*

MOTION

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

Agenda Review and Approval

MOTION

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

Executive Session – Combined meeting of the full Board and compliance staff

Items for Consideration and Discussion – **EXECUTIVE SESSION – PUBLIC MAY NOT ATTEND, pursuant to ORS 676.175, ORS 192.660(1)(k).**

MOTION

**Motion to enter into Executive Session at 9:08 was made and unanimously carried.
(Motion by Lew, second by Pimlott)**

MOTION

**Motion to exit out of Executive Session at 4:40 was made and unanimously carried.
(Motion by Lew, second by Howrey)**

MOTION

Motion to adjourn at 4:41 was made and unanimously carried. (Motion by Lew, second by Howrey)

Wednesday December 6, 2006

8:30 OPEN SESSION, Ann Zweber, R.Ph. Presiding

Meeting was called to order at 8:51am by Ann Zweber

A. Roll Call

The following Board members were present:

Ann Zweber
Cathy Lew
Linda Howrey
Dianna Pimlott

Marc Watt, Lee Howard and Bernie Foster were absent

The following staff was present:

Gary Schnabel arrived after an awards ceremony in Wilsonville.
Karen S. MacLean Administrative Director
Gary Miner, Compliance Director
Tony Burt, Project Manager
Paige Clark, Pharmacist Consultant
Joe Ball, Chief Investigator
Judy VanUden, Inspector
Michele Cale, Inspector
Mike Beck, Inspector
Annette Gearhart, Compliance Secretary
Courtney Frank, Licensing Representative
Jennifer Hess, Management Secretary

Tom Cowan, Board Counsel

MOTION

**Motion to enter into Executive Session at 8:52 was made and unanimously carried.
(Motion by Lew, second by Howrey)**

MOTION

Motion to close Executive Session and enter into Open Session at 9:15 was made and unanimously carried. (Motion by Howrey, second by Lew)

Agenda was revised at Board member Cathy Lew's request. Cathy requested discussion regarding the location of 2007 Board Meeting dates.

MOTION

Motion to approve revised agenda was made and unanimously carried. (Motion by Lew, second by Pimlott)

Motions for Disciplinary Action

Compliance Director Gary Miner read compliance cases for Motions.

Please refer to Compliance Minutes for Motions.

ISSUES/ACTIVITIES

Reports

Board President/Members

Cathy Lew – Attended two meetings and met with Dr. Le Clair from the Board of Medical Examiners, and Dr. Gary Young the President Elect of the Lane County Medical Society, as well as representatives from the Pain Society regarding the Prescription Drug Monitoring Program (PDMP). Board Member Lew also met with the USP 797 Advisory Council.

Linda Howrey– Attended the Immunization Practices Advisory Team (IPAT) meeting at which the major topic was the two new vaccines. The meeting next week will discuss legislation to further reduce age on immunizations.

She also attended a meeting between Pacific University and the School of Dental Health where it was discussed that there were some problems associated with dental hygienists and their prescribing rights. They are able to prescribe only fluoride products, but pharmacies aren't accepting prescriptions from them. Dental hygienists are limited in the drugs they can prescribe, but ultimately it is the pharmacists' responsibility to keep up with who can prescribe what, and to fill prescriptions accordingly. Gary Schnabel commented that he wanted to make it clear that the Board isn't denying the prescriptions, but the pharmacies and insurance companies.

Linda also attended the annual Oregon State Pharmacy Association meeting. She noted that it was a good meeting, and was well attended. They have raised 22,000 in scholarships for both Oregon State and Pacific Universities.

Board Counsel - No News

Executive Director Gary Schnabel reported that on November 30, the Board of Pharmacy received an award at ceremonies for National Meth Awareness Day. The award consists of a certificate signed by "Drug Czar" John Walters the Director of the National Office of National Drug Control Policy (ONDCP). The Board also received the Presidents declaration of National Meth Awareness Day signed by George W. Bush. John Horton presented the award on behalf of the ONDCP. Board President Marc Watt

accepted the award, Vice President Ann Zweber, and Executive Director Gary Schnabel, and Administrative Director Karen MacLean were also in attendance. The award was for the Board of Pharmacy's participation in controlling methamphetamine precursors. ONDCP picked the Board of Pharmacy and two other organizations in Oregon to receive this award for their outstanding contributions. In addition, the Board also received the "Presidents Award" from the Oregon Narcotics Enforcement Association. The award was presented by Captain Ed Mouery of the Oregon State Police during the ONEA's annual educational conference in Wilsonville.

Gary also spoke about planning a reception for past and present Board Members at the National Association of Boards of Pharmacy (NABP) annual meeting in May, which is being held in Portland. He has talked to NABP to see if the reception can be held in conjunction with the welcome reception on first night. Karen is working with NABP staff to see about having board staff help in exchange for reduced registration fees.

Compliance Director Gary Miner noted that the 2007 Pharmacist in Charge (PIC) self inspection forms are now available online, and that post card reminders will go out by Friday. The law test for continuing education will be available within the next week. It was also noted that 87% of pharmacies have been inspected for 2006.

Administrative Director Karen MacLean reminded the Board that the Board Meeting in Corvallis will be extended to include a short evening meeting on February 5, beginning at 7pm.

Non prescription drug outlet renewals have gone out, and are due by end of this month, there are about 40% renewed. The agency is still looking to fill the vacant pharmacy inspector position.

Karen and other members of the Board staff met with the Board of Nursing regarding future IT support. The Board of Nursing has given us notice that they are moving from the building and the Board will need to make other IT support arrangements. The Board of Nursing IT staff provided information on services what we will need from an IT support agreement, what start up costs may average, and what it may cost each month. Board staff will make up a transition plan when it gets closer to the move and provide updates to the Board.

Finally Karen received an email from Ken Shafermeyer, from the Institute for the Certification of Pharmacy Technicians (ICPT). Ken provided information that in Oregon 43 candidates have taken EXCPT Exam and that there has been a high pass rate. Ken will provide a report periodically to keep the Board updated.

PRN Director - No Report

Project Director Tony Burt gave an update on the Drug Disposal Meeting. Their objective is to reach a consensus on the best drug take back program in Oregon. Most members of the group favor locally organized programs, and agreed that local utility or solid waste programs were the most logical place for drug disposal. The group will watch current programs to see how they are working, and meet again in January.

In helping to plan the NABP District Meeting, Tony has received some offers of sponsorship, and is in the process of contacting other industry partners for further

assistance and sponsorship. Tony's meeting with staff to discuss business continuity planning. They have identified high level issues we may have in-case of an emergency, and have reported them to Department of Administrative Services as required. The planning focuses on internal leadership succession and communication issues in order to keep the agency running.

Pharmacist Consultant Paige Clark attended a number of meetings regarding the Prescription Drug Monitoring Program including the Professional Society of Pharmacists, and the Southern Oregon Pharmacists Association. Jennifer Bolen was a guest speaker at a PDMP meeting. Paige continued work with the Governor's Meth Taskforce, and along with Executive Director Gary Schnabel is communicating information about the Prescription Drug Monitoring Program and early addiction intervention projects. She continues to attend the State Agency Public Information Officers meetings in Salem.

Along with Gary Miner, Paige will be giving a law update to the Lane County Pharmacists Association in February. Paige also gave an update on the Oregon State Pharmacy Association's continuing education program and coordination of continuing education on Plan B topics throughout the state.

2006 - 2007 Board Dates:

The Board reviewed the 2007 Board Meeting Dates and discussed specifics for the April meeting.

- February 5 – 7, 2007 Corvallis
- April 17-19, 2007 Portland/Hillsboro
- June 5 -6, 2007 Portland
- August 7 – 8, 2007 Portland
- October 16-17, 2007 Portland
- December 4 – 5, 2007 Portland

Other Dates of Interest:

- May 19 - 22, 2007 Portland NABP Annual Meeting
- October 3 - 6, 2007 Ashland NABP/AACP District VII/VIII Meeting

Cathy Lew questioned Board members and staff as to if we could move the August meeting to Eugene. No decision was made, will discuss further at the February meeting.

Committees/Meetings

Emergency Preparedness Immunizations, October 19, 2006

Linda Howrey discussed a meeting she had with Mary Debro from the Immunization Department at the Department of Human Services, and the group discussed general Immunization practices.

Rural Health Coordinating Council

Mike Patrick offered a written and verbal update on the Rural Health Coordinating Council (RHCC). He thanked the Board for re-appointing him. Mike provided both a written and oral presentation on the history and purpose of the RHCC. The Council meets quarterly, and members give reports on what is happening in their field, and how it affects rural health. In past years, the

committee has had money to give as grants, and has generously given to EMS, and at the last meeting in July discussed Bioterrorism Preparedness Needs.

Cathy Lew had questions regarding pharmacy technician certification and if it is an issue to get certified living in a rural area, Mike responded that being in a rural area hasn't really affected anything, but having testing locally is helping.

Ann Zweber had a question about pharmacists in rural areas wanting to expand their position in health care, Mike responded that he hasn't heard much about expanding roles.

OSU/Pacific Meeting, November 20, 2006

Linda Howrey reported on the latest meeting between Oregon State and Pacific Universities Schools of Pharmacy. The main topic was preceptor training; the group reviewed Accreditation Council for Pharmacy Education (ACPE) guidelines for intern ratios, and the need for a policy on criteria for preceptors to meet. The idea was brought up about offering continuing education credit for preceptors. The Board would like to look at joint guidelines for preceptors that would apply to both schools. We could possibly offer assessment forms, and training for preceptors online. The group is planning on meeting again in the future.

2006 NABP/AACP District 7 & 8 Meeting, October 4-6, 2006

Cathy Lew thanked the California Board of Pharmacy for gathering a good representation of the districts, and appreciated appearances from the California colleges, and speakers. Gary Schnabel was nominated for Treasurer from NABP District 7. The Board will support Cathy Lew's nomination of continuing in Gary's Executive Committee seat. Cathy needs support from a couple more states to run. Administrative Director Karen MacLean attended to glean information on how the meeting is run in preparation for the 2007 Oregon meeting. Karen came out of the meeting with a lot of ideas on what we want to do for our meeting next year.

Gary Delander from Oregon State University will chair the planning committee. The Committee is very open to ideas, and suggestions for potential agenda items, and speakers. Project Manager Tony Burt will act as staff liaison.

NABP Fall Education Conference, November 2-4, 2006

Executive Director Gary Schnabel and Board Counsel Tom Cowan attended. Both Gary and Tom commented that content of the meeting was really good, had very good quality speakers, and was presented well. This was Tom's first NABP meeting. Gary is trying to get a DVD that was shown regarding controlled substances, showing a pharmacist and his fall into drug addiction.

Research Councils:

USP 797

Cathy Lew reported that they have decided to form a sub-committee. The committee has reviewed the NABP model administrative rules for the Board, but the NABP rules have not been released to the public yet. Cathy Lew also shared issues that will require further research by the committee, such as nuclear facilities, and ophthalmic compounding. They can still use an Advisory Committee for fiscal impact.

Electronic Transmission/Signatures

Project Manager Tony Burt reported that the Research Council has not had a meeting since September. The Council is hopeful that the DEA will address the electronic transmission of prescriptions for controlled drugs, and they will look at Oregon's position on the issue when that occurs. Members of the Council are currently looking into issues regarding hospitals and long-term care facilities. The next meeting will be after the new year.

Medication Therapy Management Service

No Report

Position Papers

Ann Zweber obtained research from other states regarding patient safety. A brief statement regarding patient safety, and/or posting information on our Board's website with links to resources may be helpful.

Process for Implementation of Research Councils

The Board reviewed the current policy on research councils, and elected not to form any new research councils at this time. See 'Research Councils' on page 6.

GENERAL ADMINISTRATION

The Board reviewed the report from the November 1, 2006 Rule Making Hearing. The Board motioned as follows:

1. Prophylactics and Contraceptives
No testimony.

MOTION

Motion to amend OAR 855-070-0005 was made and unanimously carried. (Motion by Lew, second by Howrey)

2. Controlled Substance Exceptions
One written testimony - in full support

MOTION

Motion to amend OAR 855-080-0028 was made and unanimously carried. (Motion by Howrey, second by Lew)

3. Continuing Education regarding Pain Management
Testimony, majority of comments were regarding if this was a yearly requirement, or just one time. Rule was amended to show this was a one time legislative requirement.

MOTION

Motion to adopt OAR 855-021-0016 as amended was made and unanimously carried. (Motion by Lew, second by Howrey)

4. Certified Pharmacy Technician Fees
No public testimony

MOTION

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

5. Wholesaler Rules

Project Manager Tony Burt walked the Board through the rule revisions and outstanding issues relating to the Wholesaler Rules. Overall there is consensus with the stakeholders for these rule revisions.

MOTION

Motion to amend OAR 855-006-005 was made and unanimously carried. (Motion by Lew, second by Howrey)

MOTION

Motion to adopt OAR 855-060-0001 with revisions was made and unanimously carried. (Motion by Lew, second by Howrey)

MOTION

Motion to amend OAR 855-065-0001 as amended was made and unanimously carried. (Motion by Lew, second by Pimlott)

MOTION

Motion to amend OAR 855-065-0005 with amendments as written was made and unanimously carried. (Motion by Howrey, second by Lew)

MOTION

Motion to adopt OAR 855-065-0006 with amendments and deletion was made and unanimously carried. (Motion by Lew, second by Pimlott)

MOTION

Motion to amend OAR 855-065-0007 as amended was made and unanimously carried. (Motion by Lew, second by Howrey)

MOTION

Motion to amend OAR 855-065-0009 as amended was made and unanimously carried. (Motion by Lew, second by Howrey)

MOTION

Motion to amend OAR 855-065-0010 as amended was made and unanimously carried. (Motion by Lew, second by Pimlott)

MOTION

Motion to adopt OAR 855-065-0012 was made and unanimously carried. (Motion by Lew, second by Howrey)

MOTION

Motion to adopt OAR 855-065-0013 was made and unanimously carried. (Motion by Lew, second by Howrey)

Appearances:

Rick Sahli – Providence

Waiver Request

Rick Sahli, Regional Pharmacy Director for Providence Health Services; Paul Mattson, Providence Milwaukee; and Gary Edmondson, Providence St. Vincent appeared to make a waiver request on behalf of Providence Health Services. Mr. Sahli appeared to request an exception to OAR 855-041-0205(4) for Providence Milwaukee Hospital. The request is to not require a pharmacist check and verify a drug selected by a pharmacy technician before it is sent to a nursing station when a bar code system is being utilized. In the bar code system a medication is scanned at bedside by a nurse before administration to verify that it is the correct drug, time and dosage. The thought is that this is equivalent to having a pharmacist check the drugs and the request is for relief from that requirement for pharmacist verification.

In 1991, the Board approved a request by Providence Medical Center in Portland where the verification of technician filled unit dose carts by the use of bar codes satisfies the requirement of OAR 855-041-0205(4). However, OAR 855-041-0205(4) no longer exists and the current rule OAR 855-025-0040(2)(g) specifically requires the pharmacist verify the accuracy of unit dose cart fills. The logic behind the rule is that before a drug is brought to a patient it needs to be checked by the pharmacist to verify that it is correct to what the prescriber ordered. Orders are being reviewed for interactions and correct information at the point of order entry, the system produces a pick list, a technician pulls the drug, and the drug is scanned by nurse at bedside for further verification.

The Board asked about where the facility received unit dose packages/bar code packages, who checks that the bar codes are correct, how errors are tracked, what the weaknesses are to the system and about the potential for breakdown, if there is any time a non-bar coded product goes to a patient, and where in the system there is the human element for error.

Drugs are produced with bar code on bottle; manufacturers are sending drugs out with bar codes. In 1991, they were one of first to use bar code system. If the drug bottle doesn't come with bar code the pharmacy will put it on the bottle.

The pharmacist verifies the accuracy of the bar code on the medication. A technician will validate bottle to bar code strips.

A log is kept of who entered information, and who packaged drug.

Primarily it is at the packaging and verification point. For example, aspirin could be bar coded as being Tylenol. Sometimes bar codes fall off, making sure that correct generic is linked to brand name, time spent by nurse to fix bar codes mistakes. Studies show that med errors are greatly decreased when using a bar code system.

Not totally relying on bar code but rely on unit dose package. The bar code ensures that correct drug and dose are being used. Since more hospitals have gone into bar code scanning system Providence has worked with outside

packager to package unit doses and bar code drugs for them and over the years the need to repackage and bar code packages has decreased.

It happens, but the nurse sends the product back to the pharmacy. The medication has to have a bar code since the bar code also tracks that a drug was given to a patient. In the operating room drugs are not bar coded and they have their own supply of drugs. If something gets to the floor without a barcode a nurse calls and the drug is sent back

Compliance Director Gary Miner stated that there is no exception clause in the section that is being discussed in Division 025 and in Division 041 rule 0210(2)(a) under duties of pharmacist a drug must be verified by pharmacist. In Division 06 verification is defined as the pharmacist confirming the correctness, exactness, accuracy... of functions performed by a pharmacy technician.

Board Counsel Thomas Cowan stated that legally, not exempting would be saying that "A" = "B" in this case in policy perspective how we respond should be consistent.

There was discussion among the Board that under the current law there is not an exemption clause and that exemptions need to have time limits as well as the need for the full Board to be present for this discussion in determining the best policy for practice.

Board Counsel Thomas Cowan suggested staying away from using waver language. The board will have to evaluate the 1991 decision and decide on how to move forward with this facility and still follow technician rule and pharmacist rule.

The Board stated that for now Providence Portland could continue their same practice but Providence Milwaukee is not granted their request. The Board talked about possible rule changes and the need to look at this again at the February Board meeting.

Providence offered to host a field trip to tour the facility and to be involved in rule writing or in any way the Board asked.

Susanne Hiland – Wal-Mart Presentation Regarding Kiosks

Susanne Hiland, Pharm.D a representative from Wal-Mart gave a presentation about the Automated Will-Call Bin's the company wants to install in Oregon Wal-Mart Pharmacies. Also appearing before the Board was Bob Hansen from Asteros, and Bill Holmes from APM, representatives from the companies who have manufactured the Will-Call Bins that are already in Wal-Mart Pharmacies. Together they explained how the Will-Call Bin works, along with security features, and prescription delivery features. Susanne and her guests shared how well the Will-Call Bins have worked out in other states across the country. The Board had many questions for Susanne, mainly regarding the Board's rule that a licensed pharmacist must consult with the customer at the time of prescription pick-up. With an automated machine no consult would be available if the customer picked up the prescription after hours. Susanne shared that the Board

and pharmacies could program the Will-Call Bin to only be available during the hours that the pharmacy is open, and security features could be added or changed to comply with Oregon statutes.

Lee Harman

Presentation and Questions for the Board

Pharmacist Lee Harman and his wife, a technician in his former store appeared to request the Board's consideration to support him regarding OMAP's case against him. The Board deferred to Board Counsels recommendation that since this issue is before the Court of Appeals for consideration, it would be inappropriate for the Board to get involved.

Staff Policy Questions

a) Compliance Director Gary Miner asked the Board about a pharmacy technician who is working at two different sites, they are owned by the same corporation; the first site is a pharmacy where the technician is supervised by a licensed pharmacist, the second a Doctors office where the supervising Doctor is not licensed through the Board of Pharmacy, is this ok. Board determined that this is ok.

b) Gary Miner provided an example of when IV drugs may not have numbered prescription labels, and if the barcode on the bag would qualify as the prescription number. The barcodes are unique to each bag, and is able to determine who made the bag, when the bag was made, and how much of the actual drug is in the solution. The Board determined that this was acceptable, as long as the barcode was unique to the prescription and bag.

c) Gary Miner presented a recommendation for a format change of rules regarding moving parts of Division 41 which directly speaks to pharmacists, not pharmacies to Division 19. Ideas for changes may be ready for discussion at the February Board meeting. The Board was leaning in the direction of the move, but wanted further discussion on the issue.

Emergency Preparedness

Discussion moved to February Board Meeting.

Home State Licensure

Discussion moved to April Board Meeting.

FPGEE Waiver Request

Compliance Director Gary Miner presented a waiver request from a Canadian pharmacist is licensed and in good standing in Washington. Requests waiver from taking Foreign Pharmacy Graduate Equivalency Exam (FPGEE).

MOTION

Motion to grant FPGEC waiver request was made and unanimously carried. (Motion by Lew, second by Howrey)

OSU Third Year Clerkship Site Approval

Administrative Director Karen MacLean presented the Oregon State University 3rd year clerkship sites Deanna Moretz provided for Board approval. List has

been reviewed by staff, and syllabus has been submitted. This list has been accepted by staff.

MOTION

Motion to approve OSU third year clerkship sites was made and unanimously carried. (Motion by Lew, second by Howrey)

Pharmacy Practice Issues

Executive Director Gary Schnabel provided an update on current activities relating to the Board's position statement on Considering Moral and Ethical Objections. NARAL has submitted a request for updating the language. Due to time constraints further discussion was moved to the February Board meeting.

Portland Police Request for Temporary Rulemaking

Gary Miner submitted a request from the Portland Mayor, Multnomah County District Attorney's office, and Portland Police regarding a request for temporary rule making. There is a growing issue regarding the illegal sales of prescription drugs that are not controlled drugs, for example Clonidine. Individuals are re-selling this drug on the street to enhance the effect of other street drugs. The request asks for clarification of who has lawful possession of prescription drugs. If approved, rule will be effective January 1, 2007.

MOTION

Motion to approve temporary rulemaking and permanent rulemaking was made and unanimously carried. (Motion by Lew, second by Howrey)

Oregon Board of Pharmacy Website

Discussion moved to February Board Meeting.

Budget Report

Accounting & Budget Update

Discussion moved to February Board Meeting.

Legislation

Prescription Drug Monitoring Program (PDMP)/Grant & Legislation

Executive Director Gary Schnabel reported that LC-1161 was approved by the Senate Interim Public Health Committee and will be 2007 SB-34. A speaker is coming out for the Lane County meeting to educate Pharmacists about PDMP. The Board is seeing a lot more momentum and support from people and organizations regarding the Prescription Drug Monitoring Program.

Legislative Concepts (LC-366; LC-638)

Administrative Director Karen MacLean reported on the agencies Legislative Concepts. LC366 has been withdrawn, while LC638 has been approved and will move forward.

Strategic Planning Rules 2007

Project Manager Tony Burt presented a time table that staff has been working on for rule development in 2007. Tony recommends that an Advisory Committee for Division 41 is needed, Ann Zweber supports forming the committee

Open Forum

No Public Comments

MOTION

Motion to adjourn meeting at 4:25 was made and unanimously carried. (Motion by Lew, second by Pimlott)

Minutes Accepted By:

Gary A. Schnabel, Executive Director

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