

BOARD MEETING MINUTES

Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
September 23, 2009

Wednesday, September 23, 2009 @ 9:00 AM, OBOP Conference Room

WEDNESDAY, SEPTEMBER 23, 2009

OPEN SESSION, Linda Howrey, R.Ph. Presiding

Linda Howrey, Board President, called the meeting to order at 9:01 AM.

Roll Call

The following Board members were present or attended by telephone:

Linda Howrey, President	Bernie Foster
Dianna Pimlott, Vice President	Larry Cartier
Ken Wells	

Board members excused:

Lee Howard
Ann Zweber

The following Staff were present for the meeting:

Gary Miner, Compliance Director	Joe Ball, Chief Investigator
Karen MacLean, Administrative Director	Chrisy Hennigan, Office Manager
Meg Aulerich, Pharmacy Inspector	Tony Burt, Project Manager
Paige Clark, Pharmacist Consultant	Loretta Glenn, Management Secretary
Michele Cale, Pharmacy Inspector	

Agenda Review and Approval

MOTION

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

Prior to approval of the Consent Agenda, the Board had a brief discussion about the purpose of the surety bond. Compliance Director, Gary Miner advised the Board the surety bond is for the purpose of collecting civil penalties specifically from out-of-state wholesalers. The waivers included in the Consent Agenda are for outlets that distribute medical devices. These outlets are not able to obtain VAWD accreditation and the Board has waived the inspection and surety bond requirement for device outlets a number of times this past year.

Approve Consent Agenda*

1. Wholesale Medical Device Waiver Requests
(waiver of Surety Bond and/or VAWD)

- Smiths Medical *Registrations: W1-0003087, W1-0003071 & W1-0003070, W1-0003246 & W1-0003247 and a new facility.*
 - Tri-anim Health Services, Inc. *Registration: W1-0003093*
2. Department of Human Services Waiver Request *Registration: W1-0001383*
 3. OSU Intern/Preceptor Ratio 2:1 exceptions and site list
 - Sandy Anderson 2:1 ratio request
 - Cathy Zerhung 2:1 ratio request
 - OSU Updated Out-of-State Site List approval request

MOTION

Motion to approve Consent Agenda waiver requests and exceptions was made and unanimously carried. (Motion by Cartier, second by Wells).

President Howrey asked the Board Members if they have any conflicts with the following meeting schedule. None were mentioned.

ISSUES/ACTIVITIES

A. Board Meeting Dates 2009

- October 13 -14, 2009 Portland
- December 14 - 15, 2009 Portland

2009 Rulemaking Hearing Date

- November 23, 2009 Portland

Board Meeting Dates 2010

- January 26 - 27, 2010 Portland
- March 9 - 10, 2010 Strategic Planning
- April 6 - 7, 2010 Portland
- June 15 - 16, 2010 Portland
- August 3 - 4, 2010 Portland
- October 12 - 13, 2010 Portland
- December 14-15, 2010 Portland

GENERAL ADMINISTRATION

Wholesale waiver requests:

Multnomah County Materiel Management

Registrations: W1-0001039

Compliance Director, Gary Miner presented this request. The outlet serves as the central procurement source of family planning products, including pharmaceuticals, for partners of the State Family Planning program. These benefits are provided to 36 counties.

They are requesting a waiver from surety bond. The county is a home rule political subdivision of the State of Oregon, self-insured and traditionally covers insurance obligation under a letter of explanation or a certificate of self insurance. Last year the Board approved waiving the surety bond requirement.

Additionally, the outlet requested a waiver from Designated Representative requirement. They indicate that the need for a Designated Representative in a commercial setting is understood, but the County is not structured like a business. They state that the DR responsibilities are shared among several management staff. Board Staff met with the licensee. There is no need for a waiver of the Designated Representative requirement. Licensee submitted an outline of their business model which best reflects how the Designated Representative's duties are managed in Multnomah County. As a government organization, these duties are not the responsibility of one individual.

MOTION

Motion to waive surety bond requirement was made and unanimously carried. (Motion by Cartier, Second by Foster).

VetSource #F

Registration W1-0003046

Compliance Director, Gary Miner presented this request. VetSource is a wholesaler requesting an extension on the existing surety bond waiver which was approved in December of 2008. The waiver allowed the outlet to provide a surety bond in the amount of \$10,000. The outlet indicates that it is unable to secure a \$100,000 bond without fully collateralizing it.

Licensee appeared before the Board at the December 2008 Board Meeting stating that VetSource holds surety bonds in many other states.

MOTION

Motion to deny reduced surety bond request was made and unanimously carried. (Motion by Foster, Second by Pimlott), Cartier abstained. Member Zweber, while not present, also indicated support for denial of this request.

Testing Accommodation request

Administrative Director, Karen MacLean presented this request. Pharmacy Technician requests more time and a quiet room free from distractions to take a national technician certification exam. This request is supported by doctor. The Board has allowed testing accommodations if additional documentation supported the request.

MOTION

Motion to approve testing accommodation was made and unanimously carried. (Motion by Cartier, Second by Wells).

Accepting Intern Out-of-State Hours

Administrative Director, Karen MacLean presented this request. Under rules in Division 19 and Division 31, intern hours earned outside Oregon must be certified either by the board of pharmacy of the state where they are earned, or by an *authorized certifying representative or authority*. As several state boards (such as Iowa, Colorado and New York) do not track and will not certify intern hours, we need to clarify who the Board recognizes as an *authorized certifying representative or authority* so that students can get appropriate credit.

MOTION

Motion: The Oregon Board of Pharmacy recognizes an ACPE accredited school or college of pharmacy as an *authorized certifying authority or representative*, as those terms are used in

Divisions 019 and 031 for the purpose of certifying intern hours performed outside Oregon in a state where the board of pharmacy will not certify the hours. (Motion by Cartier, Second by Wells).

St. Luke's waiver request

Compliance Director, Gary Miner presented this request. St. Luke's is a Boise, Idaho outpatient facility that is licensed in Oregon because *Oregon Medicaid* requires it for reimbursement. Oregon residents travel to Idaho for treatment because it's closer than coming to Portland. The outlet is requesting a waiver of the PIC requirement.

OAR 855-019-0100 requires all out-of-state pharmacies to have a pharmacist-in-charge. It also allows for a waiver in the event the Board believes it will further public health or safety. The Board had a lengthy discussion about this request around patient care, patient safety, public health and not wanting to be road block to accessibility. There was also discussion about why they needed to be licensed in Oregon if the services and dispensing occur in Idaho. The Board asked Staff to contact Oregon Medicaid to determine if there are other out of state providers being reimbursed. Staff will report back as soon as possible.

MOTION

Motion to approve PIC waiver request was made and unanimously carried. (Motion by Cartier, Second by Pimlott).

NABP Fall Symposium 12/3-4/09

Administrative Director, Karen MacLean presented this topic. The NABP Fall Symposium will be held in Tucson in December. The topics this year are Legalization of Drugs: Is the Time Right for Medical Marijuana, and Public-Private Partnerships: Stimulus Packages for Dwindling State Resources.

The Board discussed this briefly at the August meeting and decided at this meeting to send member, Ann Zweber to the Symposium as she is currently the Board's representative following possible Oregon legislation in the next session. Ann will provide a report to the Board at the January meeting.

Fluoride request for information

President Howrey presented a new request regarding fluoride that was received since the last meeting. This request included new questions about the manufacturing of fluoride products. At the June 2009 meeting, the Board received information from Board Counsel regarding the Board's authority over this topic. At that time, the Board decided that fluoride use is already regulated by other state and federal agencies and they are satisfied with that regulatory oversight. The Board decided not to re-visit this topic any further.

MOTION

Motion to re-affirm the Board's position as decided in June 2009 based on Board Counsel's research was made: "The Board concluded they were satisfied with the current EPA oversight" and no further action will be contemplated. This motion was unanimously carried. (Motion by Wells, Second by Cartier).

Division 019 (Immunization) Temporary Rule update

Administrative Director, Karen MacLean provided the Board with an update on the Temporary Rules for Division 019 that were adopted in August relating to immunizations administered by pharmacists to individuals 11 years old and older. Because the enacting legislation does not go into effect until 2011, it was not necessary to implement a temporary rule. Staff were able to withdraw the temporary rule and prepared a written notice for the website to clarify the timing of the new legislation for stakeholders. New rules will be promulgated during 2010 through the regular rulemaking process.

McKesson H1N1 waiver update

Administrative Director, Karen MacLean provided the Board with an update on a request from McKesson for licensure waivers associated with the new H1N1 distribution facilities.

McKesson received the exclusive contract to distribute the H1N1 vaccine. In order to meet a September 1st licensing requirement, they asked the Governor to facilitate the waiver of licensure requirements. The Governor authorized a *public health action* under the emergency statutes. The DHS, Director of Public Health requested assistance under the public health action statute and Executive Director, Gary Schnabel utilized his authority to facilitate waiver of certain licensing requirements for four McKesson temporary wholesale drug outlets under the Board's new Public Health Emergency Rules in Division 007.

Pacific Univ. Intern/Preceptor Ratio 2:1 exceptions

Compliance Director, Gary Miner presented two 2:1 Intern/Preceptor ratio request for Pacific University. The first establishes a 2:1 ratio not involving direct patient care for Preceptor Kristine Marcus R.Ph. Rotation is on teaching methods, curricular development, research and service to the university, college or school. The Board has not contemplated this type of 2:1 ratio in the past.

MOTION

Motion to approve Pacific University's 2:1 intern/preceptor ratio request for Kristine Marcus was made and unanimously carried. (Motion by Cartier, Second by Pimlott).

The second request posed to the Board is whether or not they would approve more than a 1:1 ratio for students to assist with the H1N1 immunizations during this flu season? This request came through a request to the school from Washington County Public Health, as they plan how to distribute and administer the immunization quickly this fall. They need help. The Board had a lengthy discussion about safe management, experience, the need for the students to be in a current clerkship, trained on technique, certified immunizers etc.

The Board concluded that allowing a certified immunizing pharmacist along with two certified immunizing students would be acceptable, but did not feel that a higher ratio was permissible. Further, the Board recognizes that the need will be state-wide and this exception is extended to OSU and Pacific University. It will be the College/School of Pharmacy's responsibility to make sure the clerkship is defined and students are trained and immunization certified.

The Board also was clear that this is not meant to be extended to general flu immunization.

MOTION

Motion to approve a 2:1 pharmacist to intern ratio, for the purpose of H1N1 immunizations. All pharmacists and interns must be “immunization certified”. Intern must be in a currently approved clerkship. This action is intended to facilitate immunizations throughout the state during this pandemic as defined by the Department of Human Services, Public Health Division. (Motion by Foster, Second by Cartier.)

Strategic Planning – moved to October.

Topics for future discussion

President Howrey asked Administrative Director, Karen MacLean to go over new topics identified for future discussion. They include: a Family Planning Clinic Request, Technician Training Programs, Research Councils and Continuing Education. As requested, Research Councils will be on the agenda for October.

MOTION

Motion to adjourn at 10:10 AM was made and unanimously carried (Motion by Cartier, Second by Pimlott).

Minutes accepted by:



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