

**MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
May 28, 2015**

**Coeur d'Alene Resort
Coeur d'Alene, Idaho**

This meeting of the Board was held to conduct regular Board business.

Chairman Holly Henggeler, PharmD, called the meeting to order at 8:06 a.m. In attendance were Board members Nicki Chopski, PharmD; Rich de Blaquiére, PharmD; Kris Jonas, PharmD; and Ed Sperry, Public Member, as well as Mark Johnson, RPh, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Andy Snook, DAG; Lisa Culley, CPhT, Jaime Sommer and Wendy Shiell, Compliance Officers; Fred Collings, Chief Controlled Substance Investigator; Travis Richins, ISU PharmD Candidate, Ellen Mitchell and guests.

Dr. Jonas motioned to approve the minutes of the January 20, 2015 meeting with minor corrections; Dr. Chopski seconded, and the motion carried unanimously.

Agenda item BOP 15-066 was vacated.

The Board took up the matter of Lisa M. Peterson, PharmD. Dr. Peterson inadvertently filled a prescription for Torsemide 10mg with Torsemide 20mg. Dr. Peterson signed a Stipulation and Consent Order agreeing to complete Oregon State University's online continuing education program 'Patient Safety and Medication Error Prevention for Pharmacy' within 90 days. Dr. Chopski motioned to accept the stipulation as written; Dr. de Blaquiére seconded, and the motion carried unanimously.

Mr. Johnston introduced Travis Richins, ISU PharmD Candidate, who is currently serving a rotation at the Board office. Mr. Richins researched the CutisPharma compounding kits as requested by the Board at their last meeting. Mr. Richins explained that the inclusion of a firm or its products in the NDC directory does not denote approval by the FDA of the firm or any of its marketed products. The Board was surprised by this finding.

The Board took up the matter of Christine Ludwig, DVM, Controlled Substance Registration applicant. Dr. Ludwig attended the hearing without legal counsel. Board staff denied Dr. Ludwig's application based on past drug-related criminal history. Dr. Henggeler swore Dr. Ludwig in and asked for her testimony. The Idaho Board of Veterinary Medicine (IBVM) issued her a conditional license on 10/28/2014. Dr. Ludwig attended a 60 day inpatient treatment facility and reports being in step 6 of her 12 Step program. For the last 18 months, Dr. Ludwig has participated in and been compliant with a recovery program.

Upon completion of the hearing, Dr. Chopski motioned to grant delegated authority to Board staff to process the application pursuant to the completion of the following:

- A review by Southworth Associations and compliance with any recommendations, including potential PRN enrollment and a 72 hour in-patient evaluation.
- Coinciding approval of DEA registration, as DR. Ludwig's DEA registration has lapsed.

Dr. Jonas seconded. During further discussion Mr. Johnston reminded the Board of the falsification of the application submitted by Dr. Ludwig. Dr. Jonas offered a substitute motion to include the original motion and to fine Dr. Ludwig \$500 for falsifying the application. Dr. Chopski seconded, and motion carried unanimously.

The Board took up the matter of Christopher Erb, RPh. Mr. Erb attended the hearing with legal counsel Ned Milenvovich and John Southworth of Southworth Associates, who administers the Board's PRN program. The Board's staff denied Mr. Erb's application based on past drug related criminal history. Following Dr. Henggeler's swearing in of Mr. Erb, Mr. Milenkovich and Mr. Southworth, Mr. Erb presented his testimony. Mr. Erb pled guilty to multiple felony charges in Florida from 2001 – 2010. His Florida pharmacist license was revoked in 2002. He moved to Idaho in 2013 and entered the Board's PRN program, as Florida passed a law that prohibited Mr. Erb from reapplying for pharmacist licensure. Mr. Southworth supports Mr. Erb in obtaining his license to practice pharmacy, as he has been PRN compliant for nearly two years.

Upon completion of the hearing, Dr. Jonas motioned to issue Mr. Erb's pharmacist license and controlled substance registration based on the following:

- Successful completion of the NAPLEX exam.
- Successful completion of the Idaho based MPJE exam.
- 520 internship hours (40 hours per year, 13 years away from practice).
- Restriction of being a PIC for 5 years.
- Enrollment and compliance with PRN as long as he is licensed in Idaho.

Mr. Sperry seconded. During discussion, Mr. Sperry requested Mr. Erb submit an annual report on his progress while in PRN, but Dr. Chopski disagreed. Following further discussion, Dr. Jonas amended her motion to add:

- An annual appearance before the Board at the Board's discretion

Mr. Sperry seconded the amended motion. Drs. Jonas and de Blaquiere and Mr. Sperry were in favor of the motion, and Dr. Chopski was opposed. The motion carried.

The Board took up the matter of Lonnie Huntsinger, PharmD. Dr. Huntsinger attended the hearing without legal counsel. Dr. Huntsinger's pharmacist license and controlled substance registration were surrendered and subsequently revoked based on diversion of controlled substances in 2013. Dr. Henggeler swore Dr. Huntsinger in and he presented his testimony. Since his last appearance before the Board he has obtained an endorsement from his probation officer and has completed his community service. He is compliant with his PRN contract and has the support of PRN. At the conclusion of the hearing Dr. de Blaquiere motioned to approve the application with the condition that Dr. Huntsinger may not be PIC for the remainder of his original PRN contract and that he must maintain continued compliance with his current PRN contract until its expiration. Dr. Jonas seconded. Drs. Jonas, Chopski and de Blaquiere voted for the motion, and Mr. Sperry voted against it; the motion carried. Dr. Henggeler then asked Mr. Johnston to research continuing education on drug abuse in pharmacy.

Mr. Johnston presented the Board's financial report. The Board is currently underspent by 12.5% due in large part to monies not expended on the licensing system. Staff is currently working with attorneys from the Division of Purchasing and GLS, the vendor, to determine the contract end date. While temporary raises and a few small bonuses were issued, the Board will

remain underspent in personnel too, due to monies saved from the open inspector position earlier in the fiscal year. The Board has purchased a high resolution scanner for fingerprint cards, which will be installed in the next few weeks.

Mr. Johnston presented the Board travel calendar. A conference call is scheduled for July 27, 2015 at 8:00 a.m. in the Board office, with two additional meetings scheduled: August 12-13, 2015 and October 28-29, 2015 in Boise. Drs. Chopski and Jonas along with Mr. Sperry will attend the NABP District meeting in Lake Tahoe on September 14-17, 2015.

Mr. Richins presented the CPE review, which was requested during the last Board meeting, including a complete review and statistical analysis of actual Board approved CPE over the past two years, ACPE recommendations, a study of other state CPE requirements, readily available CPE including on-line live CPE, and draft language changes to rule 050 and 051 as per the Board's passed motion at the last Board meeting. Dr. Henggeler asked the Board if they wanted to change each of the current CPE requirements: sterile compounding, immunization, law, live, and Board approved CPE. For each category the Board gave unanimous consent to keep the requirement, unchanged. At the conclusion of Mr. Richins' presentation, Dr. de Blaquiére commented that although the Board did not vote to change rule 50 or 51, he is satisfied that a thorough review was conducted, which is what was requested of the Board at the last meeting.

The Board took up the matter of Jessica Wood, pharmacy technician applicant. Ms. Wood attended the hearing without legal counsel. The Board's staff denied Ms. Wood's application based on her self-disclosure of drug abuse. Dr. Henggeler swore Ms. Wood in, and she presented her testimony. Ms. Wood has completed an intensive outpatient substance abuse program in Moscow as well as the Latah County Drug Court Program (LCDCP). She has a recommendation from her supervisor at Walgreens who wants to promote her to an Assistant Store Manager in Training, for which Walgreens requires a pharmacy technician registration. Ms. Wood also has a recommendation from the LCDCP coordinator. At the conclusion of the hearing, Dr. Chopski motioned to process the application once there is a technician-PRN contract in place. Dr. Jonas seconded, and motion carried unanimously.

The Board took up the matter of Damian Dugger, a pharmacy technician applicant. Mr. Dugger attended the hearing telephonically without legal counsel. The Board's staff denied Mr. Dugger's application based on his self-disclosure of drug abuse. Dr. Henggeler swore Mr. Dugger in and he presented his testimony. Mr. Dugger has participated in counseling through Integrated Family & Community Services and is currently working at Walgreens with hopes to move into a management position. At the conclusion of the hearing Dr. Jonas motioned to approve the application, and Mr. Sperry seconded. After further discussion Dr. Jonas withdrew her motion. Dr. Chopski motioned to deny the application, and Mr. Sperry seconded. Mr. Sperry and Dr. Chopski voted for the motion, and Drs. de Blaquiére and Jonas voted opposed. Dr. Henggeler broke the tie with a vote for denial, and the motion carried, denying the application. The Board instructed Mr. Dugger to return at a future meeting with letters of support from his employer and a more recent evaluation. They believe more time needs to pass before they can approve an application from him.

The Board took up the matter of Karleen Lynes, PharmD. Dr. Lynes attended the hearing without legal counsel. Dr. Henggeler recused herself based on a professional relationship with Dr. Lynes. Dr. Lynes' pharmacist license and controlled substance registration were surrendered and subsequently revoked based on diversion of controlled substances in 2014. Dr. de Blaquiére assumed the Chair, swore Dr. Lynes in, and she presented her testimony. Dr. Lynes completed a 90 day inpatient treatment program and is currently enrolled and compliant

with PRN. At the conclusion of the hearing Dr. Chopski motioned to approve the reinstatement application on the condition that the PRN contract stays in place. Mr. Sperry seconded. Following discussion Dr. Chopski amended her original motion to include that Dr. Lynes may not act as PIC for the duration of the PRN contract. Dr. Jonas seconded the amended motion, and the motion carried unanimously.

Rex Force, PharmD, presented the Board with the following requests related to the ISU Bengal Pharmacy Telepharmacy project:

1. Expand the number of remote dispensing sites that may be supervised by a PIC
2. Raise the ratio of pharmacists to student pharmacists and technicians at the remote dispensing site to reflect that at other retail pharmacy sites
3. Eliminate the *requirement* that the telepharmacy be located within a medical facility
4. Consider drafting a rule that would allow remote dispensing sites to serve as supervising pharmacies (and vice versa)

Following discussion of the above requests, Dr. Chopski motioned to allow one PIC to supervise the dispensing sites plus 2 remotes sites, and Dr. Jonas seconded; the motion carried unanimously. Dr. Chopski then motioned to raise the ratio to 6:1 to match retail requirements, and Dr. Jones seconded; the motion carried with Dr. de Blaquiére opposed. Due to time, Dr. Chopski motioned to table Items 3 and 4 until the July conference call, and Dr. de Blaquiére seconded; the motion carried unanimously. Therefore, the Board acted upon changes to the amended waiver or variance, but still intends to consider the requests for rule change in time to promulgate for the 2016 legislature.

Whitney Hahn from Nephron Pharmaceuticals presented information regarding common canisters inhalers that are being used at St. Luke's Hospital facilities in Idaho. Patients that are treated at St. Luke's may use doses from a multi-dose inhaler, then the same inhaler is cleaned and fitted with a new mouth piece for the next patient. Ms. Hahn believes this practice causes a multitude of infection control issues. The Board was concerned with contamination and the possible spread of disease. Mr. Fraser indicated that the Board has received two complaints about this practice. Dr. Chopski suggested Ms. Hahn consult with others in their industry and see if they supported Nephron's take on the matter. And to talk with other regulating bodies or accreditation agencies such as Health and Welfare Bureau of Facility Standards and the Joint Commission to take up the cause as she isn't sure it is a Board of Pharmacy issue. Mr. Johnston will ask ISHP/St Luke representatives to rebut at the next Board meeting. There is also a question about how the canisters are labeled, and if they are returned in compliance with Board rule, if handled by the patient themselves.

Brady Dowding, PharmD from Department of Health & Welfare Behavioral Health, presented to discuss the Department's compliance with the Board's Prescriber Drug Outlet (PDO) rules and issues concerning Patient Assistant Prescriptions (PAP). Board rules do not allow the PDO (or a pharmacy) to provide unused medications (those prescriptions not picked up by the patient) to be dispensed to another patient. Mr. Johnston indicated that this is a complicated issue that might be best addressed by H&W themselves, within the Legend Drug Donation Act, at the 2016 legislature. The Board was concerned with the H&W estimate of \$1.4 million, if the Board enforced its rules. After discussion, Mr. Sperry motioned to exercise enforcement discretion with the state facilities only until July 1, 2016, when a potential change to Idaho Code would go into effect. Dr. de Blaquiére seconded, and the motion carried with Dr. Jonas opposed.

Dr. Chopski motioned for Dr. Jonas to become the Vice Chairman of the Board when Dr. de Blaquiére takes the Chair at the end of this meeting. Dr. de Blaquiére seconded, and the motion carried with Dr. Jonas abstaining.

During Legislation & Rule Review, Mr. Johnston presented the 2016 draft rules, the draft changes to the Controlled Substance Act, and draft 2016 statute changes with highlighted changes from the last meeting. Mr. Johnston indicated that there is still work to be performed upon the CS statute definitions and Dr. Jonas' request to mandate prescriber phone numbers upon prescription drug order blanks. Mr. Johnston briefly commented upon a sample form letter that he had mailed to various veterinarians in response to Board received, form letter, complaints and requests for promulgation. The Board was entertained by Mr. Johnston's response letter and declined to promulgate. Mr. Johnston discussed a request from the Department of Health & Welfare, Division of Public Health, Bureau of Emergency Medical Services and Preparedness for the Board to promulgate a rule that would allow pharmacists to dispense pursuant to a state issued protocol during a declared emergency. The Board directed Mr. Johnston to draft such a rule.

Mr. Johnston recapped the Board's rule promulgation process for biosimilars in fiscal year 2015 and a meeting that he had with Lilly. By 2020 drugs that are approved via the 505 and 351 pathways by the FDA will both be listed in the Purple Book, as per the federal law. Most drugs approved through the 505 pathway are insulins. The Board was not very excited about additional biosimilar rule promulgation, and was glad that a few years could pass before doing so. Additionally, subsequent to the Board's 2015 biosimilar rule promulgation, a bill was introduced to require "communication" when interchanging a biosimilar. The bill did not receive a hearing, but it is expected to in 2016. The bill was result of industry compromise, and Ricard Palombo, R.Ph from Express Scripts, stood to explain how his company came to support such compromise language. Following Mr. Palombo's comments, the Board had an appreciation for why various pharmacies and other groups would compromise, but the Board felt as though the need to compromise in Idaho was negated by said 2015 promulgation. Mr. Johnston asked the Board to consider how the Board's staff should represent the Board in response to the likely reintroduction of said bill in 2016.

Dr. Jonas motioned to move into executive session as authorized by Idaho Code 67-2345(1)(b) to consider the evaluation, dismissal or disciplining of, or to hear complaints or charges brought against, a public officer, employee, staff member or individual agent, or public school student, Dr. Chopski seconded, and Dr. Henggeler took roll call, which was unanimous to enter executive session at 5:00 p.m. Dr. Jonas motioned to leave executive session at 5:10pm. Dr. Chopski seconded, and the motion passed unanimously.

Hearing no further business, Dr. Chopski motioned to adjourn. Dr. Jonas seconded, and the motion carried unanimously. The meeting adjourned at 5:10 p.m.