MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
April 4, 2013
Earl R Pond Student Union Building
Idaho State University Campus – Pocatello, Idaho

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

Chairman Berk Fraser, RPh. called the meeting to order at 8:15 a.m. In attendance were Nicole Chopski, PharmD.; Holly Henggeler, PharmD, Rich de Blaquiere, PharmD, Ed Sperry, Public Member, Mark Johnston, RPh., Executive Director, Nicole McKay, DAG, Colleen Zahn, DAG, Compliance Officers Lisa Culley and Gina Knittel, Ellen Mitchell and guests.

Dr. Chopski motioned to approve the minutes of the January 17, 2013 meeting with minor corrections. Dr. de Blaquiere seconded, motion carried unanimously. Dr. Chopski motioned to approve the minutes of the February 21, 2013 Emergency Conference Call as written, Dr. Henggeler seconded, motion carried unanimously.

Chairman Fraser commenced the Negotiated Rulemaking session pursuant to the Notice of Intent to Promulgate Rules that was published in the March Idaho Administrative Bulletin and posted to the Board's website. Mr. Johnston explained that the Board's compounding committee, which is comprised of pharmacists from around the State, was also distributed the draft. Mr. Johnston then read written public comment from Taylor Neilson of West Valley Hospital, Les Gieselman, RPh of St Luke's RMC Pharmacy, Travis Walthall, RPh of Custom Rx Pharmacy, Vic Allen, RPh of Vic's Family Pharmacy, and Jason Reading, PharmD of R&R Pharmacy. The Board proceeded to deliberate the draft rules in detailed fashion, including the different aspects of each piece of public comment when the particular sub rule was addressed. For example, pursuant to Vic Allen's comments, the Board directed Mr. Johnston to expand the labeling section to address the distribution of compounded product in the absence of a patient specific prescription drug order and to clarify the definition of the 5% allowance for distribution of non-patient specific compounded product. Dr. Henggeler thought the draft would include a more detailed definition of compounding, subsequent to the brief statutory definition in House Bill 239. Mr. Johnston noted that the FDA now has a definition of compounding on their web site.

At various points throughout the deliberations, verbal public comment was provided. Gary Pullen, RPh of Prescription Center Home Care spoke in detail about the practice of sterile repackaging. The Board directed Mr. Johnston to incorporate sterile prepackaging into the compounding draft, as an allowable but regulated practice. Lori Gebo-Shaver, PharmD of Shaver's Pharmacy commented that USP 797 does not require nasal sprays to be sterile, just nasal inhalants, and the Board accepted her requested change. Comment was also received from John Sullivan, PharmD of St. Luke's RMC Pharmacy. Melissa Sutton, CPhT of Shaver's Pharmacy commented that she was in possession of an FDA letter which explained that compounding with Domperidone was allowable. Considerable discussion ensued concerning documentation of compounded products. Elaine Ladd, PharmD of Ladd's Family Pharmacy spoke to the common practice of maintaining a production record, detailing the compounding of each product, Dr. de Blaquiere concurred with Dr. Ladd's comments. Dr. Chopski would like to see compounds for immediate use and compounds that are already documented in the electronic record keeping system to be exempt from such additional documentation.

Dr. Chopski believes that most of the draft sterile compounding, policy and procedure components should be moved to the general compounding section, as the components pertain to non-sterile compounding also. Dr. Henggeler wants to ensure that these rules cover those who compound and dispense or distribute compounded product into Idaho. Mr. Johnston noted that this draft does not address potential, additional sterile compounder licensure or registration. Mr. Johnston explained that in addition to the Board's direction during this session, he was going to work on the structure of the rules, as well as revising, striking, and/or harmonizing awkward, extraneous, or inconsistent language.

Chairman Fraser commenced the negotiated Rule Making session on Delivery pursuant to the Notice of Intent to Promulgate Rules that was published in the March Idaho Administrative Bulletin and posted to the Board's website. Mr. Johnston read written public comment received by David Moore, RPh of PharMerica, which requested changes to the draft to allow the return of certain drugs by authorized common carrier to the proposed, secured delivery area and from Vicki Pickett Baer, RPh

who is in support of an ante room where drugs could be stored until the courier arrives. There was also verbal public comment on the topic. After a short debate, Dr. de Blaquiere motioned to direct Mr. Johnston to draft such changes. Dr. Chopski seconded. The motion passed with Dr. Henggeler opposed.

Chairman Fraser asked Mr. Johnston to lead the agenda item entitled Legislation and Rule Review. Mr. Johnston reported that all of the Board's dockets of rules passed, with the first four dockets already in effect and the fifth docket to become effective on 7/1/13, when changes to Idaho Code also become effective. Board initiated, House Bill 16, 17 and 239 all of which passed, as did ISHP's Board diversification bill, the Office of Drug Policy's "Spice" bill, and IVMA's dispensing bill. Other bills such as biosimilar substitution, Epi-Pens in schools, and pharmacist name badges did not pass or did not even receive a hearing.

Mr. Johnston listed potential 2014 rule or statute changes. In addition to compounding and delivery, the list included biosimilar substitution, Soma being spelled incorrectly in statute, clarification that a pharmacy cannot also be a wholesaler, a statutory change that would require pharmacies to correct certain PMP data, harmonizing the definition of acute care hospital in Idaho law, and including remote office location as rule 029.02.a.iii. Mr. Johnston asked the Board if they had other items to add to the list. Dr. Henggeler would like to see pharmacist prescriptive authority extended to smoking cessation products. Mr. Johnston said that he would talk to ISPA about running such a bill. Dr. de Blaquiere would like the Board to address the promotion of a benefit that is tied to a purchase. Ms. McKay volunteered to research the subject, including current federal law.

Mr. Johnston reported that an Idaho registered pharmacy has applied to also be a wholesaler distributor out of the same facility. Mr. Johnston believes that the pharmacy desires use its pharmacy registration to purchase prescription items in high demand, due to shortages, and distribute them to wholesalers using the wholesaler license that has been applied for, thus skirting the Idaho Wholesale Drug Distribution Act. In researching, Mr. Johnston learned that other states prohibit such dual registration/licensure through a rule that mandates that wholesale distributors quarantine open packages of Rx items. Mr. Johnston read Board rule 805.01: "Wholesaler Quarantine: Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined." The Board agreed that a pharmacy cannot also be a wholesaler.

Chairman Fraser called case BOP 10-006 regarding Keri Woodall, RPh to order. Ms. Woodall was not present. Per a Board Order, Ms. Woodall was to enroll in the Southworth PRN program and comply with all terms and conditions of that program. Ms. Woodall is accused of failing to comply with said Order. Colleen Zahn, DAG presented the Board's evidence and solicited telephonic testimony from Ashley Gochnour, Senior Compliance Monitor with Southworth Associates. At the conclusion of Ms. Zahn's case presentation, Mr. Sperry motioned to revoke Ms. Woodall's pharmacist license and controlled substance registration. Dr. Henggeler seconded, motion carried unanimously.

Ms. Zahn presented the Stipulation and Consent Order signed by Amy J Mgonja, PharmD to settle a case involving a dispensing error. The stipulation includes a $500 administrative fine and completion of six additional hours of continuing pharmacy education pertaining to prescription or medication errors within 90 days of the execution of the Order. Dr. Henggeler motioned to accept the stipulation, Dr. Chopski seconded, motion carried unanimously.

Ms. Zahn presented the Stipulation and Consent Order signed by Evan Hathaway, DDS to settle a case involving …*acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception of subterfuge; failure to maintain records of controlled substance inventory and ….prescribing, administering, dispensing or delivering a controlled substance to oneself….* The stipulation includes compliance with the stipulation for two years; maintaining a perpetual controlled substance inventory; submitting inventory logs, controlled substance invoices and DEA 222 forms to Board staff every three months; and limited authority to prescribe, administer or dispense controlled substance drugs. Dr. Henggeler motioned to accept the stipulation, Mr. Sperry seconded, motion carried unanimously.

Ms. Zahn presented the Stipulation and Consent Order signed by James Alexander, RPh to settle a case involving a violation of Board Rule 503 Prescription Delivery Restrictions. The stipulation includes a $2,000 administrative fine. Dr. de Blaquiere motioned to accept the stipulation, Mr. Sperry seconded, motion carried unanimously. The Board also directed the inspectors to verify delivery records and procedures of Mr. Alexander's pharmacy.

Ms. Zahn presented the Stipulation and Consent Order signed by Terry Spohr, PA. Mr. Spohr is ordered to comply with his current PRN contract for five years, after which he will submit a letter of compliance from PRN to the Board. Dr. Henggeler motioned to accept the stipulation, Dr. de Blaquiere seconded, motion carried unanimously.

Ms. Zahn presented the Stipulation and Consent Order signed by Jeffrey Nielsen, PharmD to settle a case involving a dispensing error. The stipulation includes a $500 administrative fine and completion of six additional hours of continuing pharmacy education pertaining to prescription or medication errors within 90 days of the execution of the Order. Dr. Henggeler motioned to accept the stipulation, Mr. Sperry seconded, motion carried unanimously.

Ms. Zahn presented the Stipulation and Consent Order signed by K Leanne Givens, RPh to settle a case involving a dispensing error. The stipulation includes a $500 administrative fine and completion of six additional hours of continuing pharmacy education pertaining to prescription or medication errors within 90 days of the execution of the Order. Dr. Henggeler motioned to accept the stipulation, Dr. de Blaquiere seconded, motion carried unanimously.

Ms. Zahn presented the Stipulation and Consent Order signed by Jason Ebrahimpour, PharmD. to settle the case involving a dispensing error; during the investigation Dr. Ebrahimpour was unable to provide evidence of counseling being offered or provided. It was the consensus of the Board that this error could have been avoided with proper counseling of the patient. The stipulation includes a $1,000 administrative fine and completion of six additional hours of continuing pharmacy education pertaining to prescription or medication errors within 90 days of the execution of the Order. Dr. Chopski motioned to accept the stipulation, Dr. Henggeler seconded, motion carried unanimously.

Ms. Zahn presented the Stipulation and Consent Order signed by H Aaron Blaser, DDS to settle a case involving diversion of controlled substances. The stipulation requires compliance with the stipulation for three years from the date of execution; Dr. Blaser must hand write or order through electronic prescribing all controlled substances (a restriction on verbal order issuance); he may not order, handle, posses, prescribe or dispense any Schedule II drugs including samples, he must abstain from personal use of controlled substances except as prescribed to him by another prescriber; he may not store any controlled substances in his home, office or car and must comply with his Board of Dentistry stipulation. Mr. Sperry motioned to accept the stipulation, Dr. Chopski seconded, motion carried unanimously.

Ms. Zahn presented the Stipulation and Consent Order signed by Denice Moffat, DVM to settle a case involving violation of Board Rule 203 which prohibits prescribing for self. The stipulation includes requires Dr. Moffat to maintain a perpetual inventory of controlled substances ordered, dispensed and kept on hand; she agrees to have a lock box installed and attached to her residence to store all controlled substances and to notify drug wholesalers that she purchases from not to leave controlled substances at her residence without obtaining a signature of acceptance of delivery. Dr. Henggeler motioned to accept the stipulation, Dr. de Blaquiere seconded, motion carried unanimously.

Eddie Reyes addressed the Board to appeal the staff denial of his Pharmacy Technician in Training application; staff denial was based on information submitted with his application and obtained from the Idaho Supreme Court Data Repository. After lengthy discussion, Dr. Henggeler motioned to uphold the staff denial of the application, Dr. Chopski seconded. After discussion with Mr. Reyes a roll call vote on the motion found three in favor of denial with Mr. Sperry opposed. Motion carried.

Lynda Carr, owner and manager of Troy Drugs attended the meeting telephonically to appeal staff denial of her out of state mail service pharmacy application; staff denial was based on evidence the pharmacy is an ‘on-line’ pharmacy with contract doctors that don’t have a valid doctor/patient relationship. Dr. Henggeler motioned to uphold staff denial of the application based on the lack of a valid doctor/patient relationship, Dr. Chopski seconded. After discussion with Ms. Carr a roll call vote on the motion found all in favor of denial of the application. Motion carried.

Mr. Johnston began the discussion of pre-printed prescription blanks for certain compounded prescriptions. Due to time, Mr. Sperry motioned to table this discussion, as well as the discussion concerning an institutional pharmacy distributing prepackaged drugs to hospital prescribers for further dispensing. Dr. Chopski seconded. Motion carried unanimously.

Dr. de Blaquiere exited the meeting.

Mr. Johnston presented the financial report showing the board is considerably under spent. Mr. Johnston presented the travel calendar, which includes the upcoming continuing education that Mr. Johnston will be presenting around the state and the NABP annual meeting.

Dr. Henggeler motioned to go into executive session as allowed by Idaho Code 67-2345(1)(a) to discuss items exempt from public record. Dr. Chopski seconded, roll call resulted all in favor. Motion carried. The Board entered executive session at 5:10 pm. Mr. Sperry motioned to leave executive session at 5:25 pm, Dr. Chopski seconded, motion carried unanimously.

Dr. Chopski motioned to adjourn the meeting, Mr. Sperry seconded. Motion carried unanimously. Meeting adjourned at 5:28 pm. The next meeting of the Board is scheduled for June 3, 2013 in Boise, Idaho.