MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
June 3, 2013
Holiday Inn, Boise, Idaho

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

Chairman Nicole Chopski, PharmD, called the meeting to order at 8:05 a.m. In attendance were Holly Henggeler, PharmD, Rich de Blaquiere, PharmD, Ed Sperry, Public Member, Mark Johnston, RPh., Executive Director, Nicole McKay, DAG, Colleen Zahn, DAG, Fred Collings, Chief Investigator, Lisa Culley, Compliance Officer, Ellen Mitchell and guests.

Dr. Henggeler motioned to approve the minutes of the April 4, 2013 meeting as written. Dr. de Blaquiere seconded, motion carried unanimously.

Chairman Chopski commenced the negotiated rulemaking session regarding compounding, pursuant to the Notice of Intent to Promulgate Rules that was published in the April Idaho Administrative Bulletin and posted to the Board's website. Mr. Johnston presented draft language and written comments from Matt Murray of Customedica, Taylor Neilson of West Valley Medical Center, Rudy DeLeon of Dick's Pharmacy, Mark Rotman of Cardinal Health, Chad Jungert of Irwin Drug, and Devin Trone of Medicap Pharmacy. Mr. Neilson and Mr. Trone, as well as Kip Ladd of Ladd's Family Pharmacy provided verbal comments. After much discussion, the Board directed Mr. Johnston to make the following changes:

- Non-substantive changes, such as spelling, grammatical errors and confusing language.
- Define high risk sterile product preparation.
- Define reconstitution and revamp its usage.
- Incorporate, from the Compliance Policy Guidance for FDA Staff and Industry, the restriction on compounding drugs that are prohibited for compounding or withdrawn or removed from the market for safety reasons.
- Delete "or captured by the filter" from the hazardous drug sub-rule.
- Add "strength of significance" to the list of allowable reasons why a commercially available drug may be compounded.
- Strike "evaluation of added substances and differences in rate and extent of bio-availability of active ingredients" as a required element of the policy and procedures manual.
- Clarify that "if any" drug potency analysis is conducted records must be maintained in a readily retrievable manner.
- Add "or distributing" after existing key uses of "dispensing" to include "for office use" compounding.
- Revamp "accuracy" sub-rule to include USP-NF published potency ranges.
- Add "as appropriate" to "equipment" sub-rule.
- Strike "vented" from sterile "hazardous drugs" rule, as vented is already differentiated in Compounding Drug Products' "hazardous drugs" sub-rule.
- Strike draft language, "when necessary", from "sterile product preparation equipment…protective apparel" sub-rule.
- Require hood certification every 6 months, as opposed to every 12 months.
- Change "sterile" to "sterilization" in "products requiring sterilization" sub-rule.
- Allow "opened or partially used packages of ingredients" to be utilized according to "manufacturer's guidelines or another reliable source", in addition to the draft language.

Crystal Spencer, Robert Shannon and Michael Altree, representing AmericanPharma, presented information regarding their PharmaWatch software system and proper drug storage conditions, especially for vaccines. AmericanPharma requested rule making to require advanced temperature monitoring systems that assist with maintaining USP storage requirements. Mr. Johnston requested language from other states, Idaho Health and Welfare, and CMS that support the presentation. After much discussion, Dr. de Blaquiere motioned to have the Board's staff research the issue and find a workable solution for pharmacies in our state. Dr. Henggeler seconded, the motion carried unanimously.

Chairman Chopski commenced the negotiated rulemaking session regarding delivery and ante rooms, pursuant to the Notice of Intent to Promulgate Rules that was published in the April Idaho Administrative Bulletin and posted to the Board's website. Mr. Johnston presented updated draft language and suggested that the placement change from rule 503 to rule 604. After discussion, in addition to small non-substantive changes, the Board directed Mr. Johnston to add a provision requiring that the secured delivery area be attached to or located adjacent to the pharmacy that filled the prescriptions.

Ashley Gouchner, representing Southworth Associates, requested that the Board allow peer assistance entities access to the Prescription Monitoring Program (PMP), specifically to use as a tool to monitor professionals in their programs. Ms Gouchner presented written comment in support of the request from Penelope Ziegler, MD, Medical Director of the Virginia Health Practitioner's Monitoring Program, indicating they have access to Virginia's PMP and use it regularly to identify relapses, confirm prescriptions and detect self prescribing. Ms. Gouchner contacted the Federation of Physician State Health Programs and discovered there are currently 11 states that allow PRN programs access to their PMP data. Ms. Gouchner also presented compelling information regarding a recent case where having access to PMP data could have helped one of their participants. After discussion Mr. Sperry motioned to run a bill that would allow such access. Dr. Henggeler seconded. Dr. de Blaquiere wants to maintain control of who is accessing the information. Mr. Johnston clarified the access would be by fax only, not online access. Chairman Chopski called for the vote, all in favor, motion carried unanimously.

During Inspector Q & A, Mr. Johnston presented several pre-printed prescription blanks provided by various pharmacies. The blanks are pharmacy specific and bear the individual pharmacy's ingredients for compounded drug products, allowing the prescriber to 'check the box' of the drug or formula to be prescribed. The Board expressed concern with the pharmacy name, address, and map on the blanks, as it could be construed as requiring the patient to present at that specific pharmacy. The Board addressed a similar issue in November 2006 by recommending that pharmacy specific information be removed from the blank over concerns related to unfair advertising. The Board agreed that the pre-printed prescription blanks can be beneficial for accuracy. The Board cited IDAPA 27.01.01.504: Unlawful Advertising and directed Mr. Johnston to pen an article for the newsletter indicating that prescription blanks for controlled substances must be on non-copyable paper, cautioning that the DEA may have issue with the pharmacy acting as an unauthorized prescriber's agent, and mandating that no pharmacy specific information is allowed on the blanks. Mr. Johnston will notify the out of state mail service pharmacies that are known to be using these forms by letter.

Mr. Johnston presented the questions from former Board member, Dwayne Sheffler, R.Ph that were tabled at previous Board meetings. Mr. Sheffler would like prescribers, who are located within a hospital, to dispense drugs pre-packaged by the pharmacy, similar to hospital emergency room (ER) dispensing. The Board approved of such operation if the hospital is also registered as a prescriber drug outlet. Mr. Sheffler would like the hospital ER to dispense drugs to inmates, when no other pharmacy in the community is open for business. The Board disapproved of the request, as Board rule requires patients to be seen in the ER in order for drugs to be dispensed by an ER registered nurse.

Mr. Johnston presented rule 202.02: Controlled Substances Non-Prescription Dispensing. When rewriting all rules in 2012, the quantity restriction was erroneously struck. Mr. Johnston requests rule promulgation that would return the quantity limitation to 120 ml. Dr. Henggeler motioned as such. Mr. Sperry seconded, and the motion carried unanimously.

David Miller, RPh owner and manager of Millers of Wyckoff, attended the meeting telephonically to appeal the staff denial of his out of state mail service pharmacy application. The denial was based on past disciplinary action by the New Jersey Board of Pharmacy. Mr. Miller explained the past action and the corrective measures he has taken to prevent future issues. Mr. Miller clarified that all compounded drugs dispensed into Idaho would be patient specific. Dr. de Blaquiere motioned to approve the application; the motion died due to lack of a second. After discussion, Dr. de Blaquiere motioned to approve the application as they are in good standing with their resident state board and adequately answered the Board's questions. Mr. Sperry seconded, and the motion carried unanimously.

Mr. Johnston requested direction from the Board regarding non-ACPE or CME continuing pharmacy education (CPE) programs that the Board's staff approves. Mr. Johnston has assumed the duty of approving such CPE over the past few months and has discovered many prior Board approved CPE

programs that he feels are not in harmony with the definition of CPE. Mr. Johnston provided several examples. Mr. Johnston also reported on the national movement to eliminate Board approved CPE, as the United States Department of Education recognizes ACPE as the sole provider of pharmacy CPE, and Board CPE approval is reported as undermining the national standard. Additionally, Mr. Johnston reports that 17% of the pharmacists audited for CPE were in violation of Board rule, and if the Board required ACPE or CME CPE exclusively, the Board could audit every pharmacist annually, as opposed to the current laborious audit process. Dr. Henggeler motioned to eliminate Board approved CPE. Mr. Sperry seconded. After much discussion that included Dr. Chopski's hesitation, Dr. Henggeler amended her motion to eliminate Board approved CPE by rule, by directing the Board's staff to be more stringent when approving CPE until such rules are promulgated and by posting notice of such proposed changes in the Board's Newsletter. Dr. de Blaquiere seconded, the motion carried unanimously.

Colleen Zahn, DAG, presented the Stipulation and Consent Order signed by Lisa Worthington, RPh, to settle a case involving improperly accepting returns of controlled substances from long term care facilities. Ms. Worthington appeared in person. The stipulation included a $5,000 administrative fine payable within 180 days of the execution of the Order and completion of three additional hours of continuing pharmacy education pertaining to disposal of legend drugs and/or controlled substances within 90 days of the execution of the Order. Dr. Henggeler motioned to accept the stipulation, Dr. de Blaquiere seconded, the motion carried unanimously.

Ms. Zahn presented a hypothetical situation in which a licensee had been disciplined for an action and then was subsequently convicted of a felony for the same action. Ms. Zahn sought guidance on whether the Board would want to set the matter for hearing, at which the Board may impose further discipline, or if the Board would be satisfied with their original Board order. In the hypothetical situation, the Board preferred to set the matter for hearing, but Ms. McKay expressed concern over the possibility of 'double jeopardy'. The Board directed Ms. McKay to research the issue further and report back and directed Ms. Zahn to add a clause to stipulations that would allow the Board to revisit stipulations in the case of a subsequent felony conviction. The Board also directed Mr. Johnston to pen a Newsletter article explaining that it is a felony to use a computer to commit fraud, such as altering the on hand quantities in an attempt to disguise diversion.

Board rule 710 requires a retail telepharmacy with remote dispensing sites to demonstrate that there is limited access to pharmacy services in the community in which the remote site is proposed. William Edwards, PharmD, submitted a written request for the Board to determine if Troy, Idaho is an appropriate site for a telepharmacy to be operated by Gritman Medical Center Pharmacy in Moscow, Idaho. The Board had several questions for Mr. Edwards, who was not in attendance. Due to time constraints, Mr. Sperry motioned to table the discussion until the August meeting and invite Dr. Edwards to attend. Dr. de Blaquiere seconded, the motion carried unanimously.

Mr. Johnston presented Idaho Code 54-1755: Pedigree, which mandates implementation of track and trace pedigree technology. Since this technology is not universally available across the entire prescription pharmaceutical supply chain, the Board may extend the requirement by one year. Dr. Henggeler motioned to extend the implementation date by one year. Dr. de Blaquiere seconded, motion carried unanimously.

Mr. Johnston presented a situation where an applicant wants to run one pharmacy with two registrations. The "embedded pharmacies" would be in separate (though adjoining) facilities, have separate inventories and equipment, but share a pharmacist-in-charge (PIC). Dr. Henggeler motioned to deny the situation per rule 300: PIC Qualifications, which doesn't allow a person to be PIC at more than one location. If the potential applicant submits an application, the Board's staff is to refer the matter to the Board in an open, public meeting. Mr. Sperry seconded, motion carried unanimously.

Mr. Johnston presented the Board travel calendar.

Mr. Johnston presented the Board's financials.

As this was the final meeting of fiscal year 2013 Dr. Henggeler motioned for Dr. Chopski to serve as Chairman for fiscal year 2014. Mr. Sperry seconded, motion carried unanimously. Mr. Sperry motioned for Dr. Henggeler to serve as Vice Chairman for fiscal year 2014. Dr. de Blaquiere seconded, the motion carried with Dr. Henggeler opposed.

Mr. Sperry motioned to adjourn the meeting. Dr. de Blaquiere seconded, the motion carried unanimously. The meeting adjourned at 5:50 pm. The next meeting of the Board will be by conference call to discuss legislation and rules and is scheduled for July 29, 2013 in Boise, Idaho.