MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
January 21, 2014
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 8:02 am. In attendance were Board members Holly Henggeler, PharmD; Rich de Blaquiere, PharmD; and Kristina Jonas, PharmD, as well as Mark Johnston, RPh., Executive Director; Nicole McKay, DAG; Fred Collings, Controlled Substance Investigator, Lisa Culley and Jaime Sommer, Compliance Officers; Ellen Mitchell and guests. Ed Sperry, Public Member, was unable to attend.

Dr. Henggeler motioned to accept the minutes of the October 22-23, 2013 meeting with minor corrections. Dr. Jonas seconded, and the motion carried unanimously.

Mark Strahl, representing Specialty Homecare Lifeline joined the meeting telephonically to request that the Board determine if a pharmacy's dispensing in their company's unique "pizza box" system meets Idaho labeling and packaging requirements. Such dispensing will be loaded at a patient's residence into a Phillips Lifeline Medication Dispenser. Mr. Strahl answered many Board questions, but ultimately the decision centered around only the pharmacy dispensing and not what was subsequently done with the dispensing. The Board focused its consideration upon rule 145: Prescription Drug Packaging, after confirming with Mr. Strahl that Rule 140: Standard Prescription Drug Labeling would also be met by the dispensing pharmacy. After much discussion, Dr. de Blaquiere moved compliance with Idaho packaging and labeling requirements. Dr. Jonas seconded, and the motion carried unanimously.

Kerry Casperson, PhD, manager of Bengal Pharmacy at Idaho State University (ISU), appeared in person to request approval of a "twist" on traditional dispensing. ISU wants to operate a kiosk in the parking lot of the student union building, where the Bengal Pharmacy is located, using pneumatic tubes and computer monitors to facilitate communication between patients visiting the kiosk and the actual pharmacy. The "twist" is a technician manning the kiosk. The kiosk would never house any drugs except the ones being immediately dispensed, and there would be operational cameras on at all times the kiosk is open. The discussion included options, such as a pharmacist in the kiosk overseeing technicians and/or student pharmacists in the pharmacy, pharmacists in the pharmacy overseeing technicians and/or student pharmacists in the kiosk, and pharmacists in both the pharmacy and the kiosk at the same time. The Board ultimately determined that a pharmacist had to be within the pharmacy, the kiosk was acceptable, and the kiosk could be staffed by either a second pharmacist, a student pharmacist, or a technician.

As Dr. Casperson was in appearance, Mr. Johnston had asked him to present on the proposed telepharmacy operation between Bengal Pharmacy and an Arco location, which is rumored to replace Lost River Drug. Dr. Casperson provided preliminary information on the project, which stimulated much discussion concerning topics such as telepharmacy, security, Automated Dispensing and Storage Systems, registration, dispensing, delivery and operations. Dr. Henggeler expressed concern over the security of controlled substances. Dr. de Blaquiere reported that he recently reviewed other state's law and expressed concern that Idaho's telepharmacy law might be too restrictive and out dated. Dr. Casperson was encouraged to submit a complete application and to review the Board's telephamacy rules (710-712), along with the rule 013: Waivers and Variances.

Mr. Johnston reported that the Troy Clinic decided to withdraw their telepharmacy request, which was presented at the last meeting, and that he, Mr. Sperry, and Dr. Jonas recently visited Park-Vu Pharmacy in Fruitland and its remote dispensing site in Council.

Starla Higdon, RPh, Executive Director of Treasure Valley Food Allergy Network presented a draft bill that would allow epinephrine auto injectors to be dispensed to schools in Idaho. Ms. Higdon presented on the severity of food allergies, the lack of access to the potentially life-saving drug, a program whereby schools could receive four free auto-injectors annually, the provision defining that only trained individuals could administer the drug, and that the program was voluntary for schools. Mr. Johnston reported that he identified three statutory conflicts that the bill would create and that the bill's sponsors were addressing each issue within the bill. Draft changes to the Idaho Pharmacy Act include labeling in the name of a school, an exemption to the patient-prescriber relationship requirement, and a provision for legal possession by school agents. Dr. de Blaquiere noted the dispensing pharmacist is not included in the exemption from civil liability and was concerned about the disposal of outdated pens. After discussion the Board granted unanimous consent for Mr. Johnston to support this bill.

Chairman Chopski asked Mr. Johnston to frame the next agenda item regarding repackaging. Mr. Johnston reported that the Board had traditionally believed that a pharmacy that repackaged drugs that were previously dispensed by another pharmacy was required to be registered as a repackaging manufacturer by the FDA. However, Mr. Johnston found an FDA Guidance Document issued in 1991, which is still effective today, that explains that such repackaging is acceptable, if conducted within the practice of pharmacy. Mr. Johnston presented collated rule language from other states that allow such a practice. Ed Snell, RPh, appeared to request rule promulgation that would allow and regulate such repackaging. Mr. Snell explained the need for repackaging when retirees of the railroad receive mail order prescriptions in vials and the retirees are subsequently institutionalized. The Idaho Department of Health and Welfare requires drugs within an institutional facility to be unit dose packaged, thus the issue at hand. The Board directed Mr. Johnston and Ms. McKay to proceed with penning rules regarding repackaging in pharmacies.

During Legislation and Rule Review Mr. Johnston explained that the Board's staff has received oral reports of chiropractors receiving compounded drugs from mail order pharmacies. Chiropractors don't have prescriptive authority in Idaho and mail service pharmacies should not be dispensing or distributing to them. Mr. Johnston reported that a bill may be introduced to grant chiropractors limited prescriptive authority. If a chiropractor bill is introduced, Mr. Johnston was directed to explain the current issues, but take no position.

Chairman Chopski asked for public comment. Elaine Ladd, PharmD owner of Ladd's Family Pharmacy, explained she is losing business to mail service pharmacies because she won't provide 'office use' compounds, since the enactment of the Compounding Quality Act. The Board directed Mr. Johnston to begin enforcing patient specific compounding on a priority basis, starting with high risk, out of state compounders, while the Board awaits further FDA clarification of the Compounding Quality Act. The Board directed Mr. Johnston to report such pharmacies to the FDA and to send a letter to cease and desist. Dr. de Blaquiere requested that Mr. Johnston pen an article for the Board newsletter reminding pharmacists that distribution of compounded drug product in the absence of a patient specific prescription drug order is not legal in Idaho and that enforcement is coming.

Mr. Johnston reiterated the Board's decision from the 1/9/14 Board meeting to withdraw the Board's pending compounding rules. Mr. Johnston explained changes to the Board's bill that would allow Southworth associates access to PMP data that related to enrollees in the PRN program. The language now allows an individual to designate another to receive the individual's data, which accomplishes the Board's directive with less controversy. There are no other changes to the Board's pending rules or draft bills.

Scott Zanzig, DAG, presented the Stipulation and Consent Order signed by Ronald Todd Gatesh, PharmD. Dr. Gatesh mis-filled a new prescription and assigned the wrong prescriber. Additionally, there was no record of patient counseling. The stipulation calls for a $1,000 fine and six hours of continuing education related to filling errors. Dr. Henggeler motioned to accept the stipulation as written, and Dr. Jonas seconded. Dr. Henggeler clarified that the motion includes a $500 fine and continuing education for the mis-fill and a $500 fine for failure to counsel. The motion carried unanimously.

Mr. Zanzig presented the Stipulation and Consent Order signed by Craig Holman DPM. In June 2013 Fred Collings discovered Dr. Holman had purchased a 500 count bottle of hydrocodone and two 100 count bottles of zolpidem from Moore Medical. Mr. Collings verified Dr. Holman did not have a Prescriber Drug Outlet (PDO) registration for his facility and that he was not reporting dispensed controlled substances to the PMP. Dr. Holman admitted to personal use of the medications. Dr. Holman stipulated to having no controlled substances in his office or personal property that were not prescribed to him and would only issue written controlled substances prescription drug orders for patients. Dr. de Blaquiere motioned to accept the stipulation as written, and Dr. Jonas seconded. The motion carried unanimously.

Mr. Zanzig presented the Stipulation and Consent Order signed by Richard Arrossa, PharmD. Dr. Arrossa filled a forged prescription for Roxicodone, which was in violation of numerous statutory and rule requirements. The stipulation calls for a $500 fine and six hours of continuing education related to filling errors. Dr. de Blaquiere motioned to accept the stipulation as written, and Dr. Jonas seconded. Dr. Chopski questioned how staff became aware of this issue. Mr. Collings indicated it was found during unsolicited reporting within the PMP. After discussion, the motion carried unanimously.

The agenda item for Entirely Pets Pharmacy's application was vacated.

Dr. Chopski asked for an update on Idaho State Police (ISP) fingerprinting process and time frames. The Board's staff was receiving results within two weeks, but the current wait is three to four weeks. Time frames continue to fluctuate. The Governor's recommendation does include appropriation for a fingerprint scanner, which will reduce the processing time to just a few days.

The Board reviewed the delegated authority that it had granted to the Board's staff. No changes were made.

Mr. Johnston presented a hypothetical situation related to renewal of controlled substance registrations. After much discussion, the following motions were made, pursuant to the presented hypothetical situations:

1) *Should pharmacists who hypothetically work without a CS registration, but who do not work once notified (while waiting for reinstatement), be offered a stipulation of a $200 fine for working without a CS registration, be sent to hearing in front of the Board, or not be disciplined?*

   Dr. Henggeler motioned to fine the pharmacist $200 and the PIC $100. Dr. de Blaquiere seconded and clarified the violation occurs on the first day working without a registration. The motion carried unanimously.

2) *Should a pharmacist who hypothetically works before and after receiving notification of non-renewal (worked while waiting for reinstatement) be offered a stipulation of a $200 fine for working without a CS registration, be sent to hearing in front of the Board, or not be disciplined?*

   Dr. de Blaquiere motioned to fine the pharmacist $750, the PIC $500, and the pharmacy registrant $500. Dr. Henggeler seconded. Dr. Jonas voted in favor. Dr. Henggeler voted opposed. Dr. de Blaquiere abstained, and Dr. Chopski voted in favor. The motioned carried.

3) *Should a pharmacist who hypothetically waited weeks to apply for reinstatement after multiple notifications of non-renewal, including verbal notification, and who hypothetically works both before and after such notifications (while waiting for reinstatement) be offered a stipulation of a $200 fine for working without a CS registration, be sent to hearing in front of the Board, or not be disciplined?*

   Dr. Henggeler motioned to fine the pharmacist $1,500 and the PIC $750. (If the pharmacist and PIC are the same person the fine would be $1,500). The motion failed for lack of a second. Dr. Jonas motioned to fine the pharmacist $1,000, fine the PIC $1,000 and fine the pharmacy $10 per controlled substance prescription filled for the time of practicing without a registration. Dr. de Blaquiere seconded. After discussion Dr. Jonas amended her motion to fine the pharmacist $1,000, fine the PIC $1,000, and fine the pharmacy $10 per controlled substance prescription filled from the time of first notification by the Board, plus the cost of the investigation fees to be paid by the pharmacist. The motion failed for lack of a second.

Ms. McKay drafted a fine schedule to address the above issues with consistency. The Board altered the schedule as follows:

Hypo	Pharmacist	Pharmacy	PIC
1	$200	$0	$100
2	$1,000	$500	$500
3	$2,000	$1,000	$1,000

Dr. de Blaquiere motioned to accept the schedule, with no exception if the pharmacist, PIC and the pharmacy registrant are the same person, and replacing the previous motions on the hypothetical situations. Dr. Jonas seconded, and Dr. Henggeler was opposed. The motion carried. The Board directed the staff to reinstitute the old policy of notifying the inspectors of those pharmacists who didn't renew by July first annually.

4) *Should the Board promulgate a change to rule 017, extending or eliminating the need for reinstatement for those who do not renew timely? Alternatively, should the Board run a bill that clarifies that the fingerprinting requirement in 54-1718 only pertains to applicants who lost their licenses due to discipline?*

Dr. de Blaquiere motioned to run a bill that changes the fingerprint requirement to only new applicants, those reinstating after being out of the profession one year or longer, and those reinstating after

expiration of a suspended or revoked license or registration. Dr. Henggeler seconded, the motioned carried unanimously.

Mr. Johnston presented a draft policy for Temporary Technician in Training registration. After discussion the Board granted unanimous consent to adopt the policy as written.

Mr. Fraser shared the following information with the Board:

- The new prescription monitoring program AWARxE is progressing. A will be sent letter sent to all pharmacies introducing the new system with instructions on how to register to report to the new system. Pharmacies can begin registering on January 24th. The go live date is February 19th. The old system will be in place until February 24th.

- The search for an inspector for north Idaho: the first announcement did not result in a hire and the position has been reposted. Lisa Culley went to north Idaho to conduct inspections in October and November. Both inspectors are currently taking calls for north Idaho.

- Ongoing difficulties encountered with the conversion to the new licensing system still exist. While the legislature considers the Board's request for appropriation to fund its vacant full time employee position, Mr. Fraser has assumed many licensing duties.

- All pharmacies in Idaho will be inspected in a two year period.

Mr. Fraser presented a hypothetical situation whereby a pharmacy employee is diverting a large amount of medications. There is a corresponding responsibility for the pharmacy and PIC to appropriately secure controlled substances. When should the pharmacy and/or the PIC be disciplined for not fulfilling their corresponding liability? The Board directed the Board's staff to initiate disciplinary proceedings against the PIC when 5,000 dosage units or more are diverted.

Mr. Johnston presented the financial review. The Board is currently under spent by 10% in total, mainly due to the open inspector position. Mr. Johnston will be presenting the budget to JFAC for the first time this year, due to work load at LSO. The Governor did not recommend the Board's request for $10,000 to purchase a sound system to record the Board meetings, as other agencies had the same request at a lower dollar amount. All other line items did appear in the Governor's recommendation.

Mr. Johnston reviewed the travel calendar. Most of his continuing education programs are listed, though a few more will be scheduled. The following attendees were confirmed:

- May 17-20 – NABP Annual Meeting Phoenix, Arizona: Mr. Johnston, Drs. Chopski, Henggeler, & de Blaquiere. Dr. Jonas will arrive one day late.
- 5/30-6/1 NW Pharmacy Convention in Coeur d'Alene: Mr. Johnston, Drs. Chopski, Jonas, & de Blaquiere.

Board meeting dates were set:

- July 28, 2014 Conference Call, if needed.
- August 13-14, 2014 – State Capital. August 13 is expected to start at 1pm, if needed.
- October 22-23, 2014 – Boise. October 22nd is expected to start at 1pm.

With no further business Dr. Henggeler motioned to adjourn the meeting, and Dr. Jonas seconded. The motion passed unanimously, and the meeting adjourned 5:04 pm.