MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
May 29, 2014
Coeur d'Alene resort, Coue d'Alene, Idaho

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

Chairman Nicole Chopski, PharmD, called the meeting to order at 8:08 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; Berk Fraser, RPh, Deputy Executive Director; Nicole McKay and Colleen Zahn, DAGs; Fred Collings, Chief Controlled Substance Investigator; Lisa Culley, Tanya Conner 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 3/13/14, 4/2/14, and 4/21/14 Board meetings with minor corrections. Dr. Jonas seconded, and the motion carried unanimously.

Ms. Zahn presented a stipulation and order for David Mackowiak, PharmD, who was not in attendance and was not represented by legal counsel. Dr. Mackowiak stipulated to a $500 fine for mis-filling a prescription drug order, a $500 fine for failure to counsel, and six additional continuing pharmacy education (CPE) hours pertaining to prescription or medication error and/or patient counseling. Dr. de Blaquiere motioned to approve the stipulation as written, and Dr. Henggeler seconded. During discussion, Dr. de Blaquiere noted a poster presentation at the recent NABP annual meeting by the Oregon State Board Pharmacy explaining a robust CPE program addressing dispensing safety. Dr. Chopski was concerned that a large chain had no organized system of documenting counseling. Elizabeth Keller, PharmD stated that she works in a Walgreens pharmacy and that there was an electronic means to document counseling. Mr. Fraser stated that there did not seem to be a universal system of counseling documentation within Walgreens pharmacies, as many stores keep a paper log. Mr. Johnston stated that he has spoken to Walgreens corporate representatives who indicate that pharmacists who are not documenting counseling are not following company policy. Dr. Chopski asked for the vote, and the motion passed unanimously.

Ms. Zahn presented a stipulation and order for Eldon Riggle, RPh, who was not in attendance and was not represented by legal counsel. Mr. Riggle stipulated to a $500 fine and six additional CPE hours pertaining to prescription or medication error for mis-filling a prescription drug order. Dr. Henggeler motion to accept the stipulation as written, and Dr. Jonas seconded. After minimal discussion, Dr. Chopski asked for the vote, and the motion passed unanimously.

Ms. Zahn presented a stipulation and order for Charles Davis, RPh, who was not in attendance and was not represented by legal counsel. Mr. Davis stipulated to a $500 fine and 6 additional CPE hours related to labeling, failure to utilize warning labels, and failure to distribute a required FDA MedGuide. Dr. Henggeler motioned to accept the stipulated order as written, and Dr. Jonas seconded. During discussion, it was noted that MedGuides are required for each dispensing of a refilled prescription. The Board also discussed electronic record keeping systems that record counseling documentation that might not have actually occurred. Dr. Chopski asked for the vote, and the motion passed unanimously.

Ms. Zahn presented a stipulation and order for Justin Sanders, PharmD, who was not in attendance and was not represented by legal counsel. Dr. Sanders stipulated to a $500 fine for mis-filling a prescription, a $500 fine for not offering counseling, and six additional hours of CPE pertaining to medication error and/or patient counseling. Dr. Jonas motioned to accept the order as written. Dr. Henggeler seconded. During discussion, the Board expressed concern over continued counseling violations. Dr. Chopski asked for the vote, and the motion passed unanimously.

Ms. Zahn presented a stipulation and order for Paul Allen, RPh, who was not in attendance and not represented by legal counsel. Mr. Allen stipulated to a $500 fine for mis-filling a prescription, a $500 fine for failing to offer counseling, and 6 additional CPE hours pertaining to medication error and/or patient counseling. Dr. de Blaquiere motioned to accept the order with a minor correction, and Dr. Jonas seconded. Dr. de Blaquiere inquired as to when a technician is also disciplined for mis-filled prescriptions. Mr. Johnston responded that technicians are typically only disciplined if their involvement goes beyond duties allowed by law. The Board discussed increased penalties for harm, such as with this case and Mr. Davis' case, but ultimately the Board decided that harm was too difficult to qualify. Potentially, a case with harm could go to hearing and not be stipulated. The Board directed Mr. Johnston to reiterate counseling and counseling documentation requirements in the next Board Newsletter. Dr. Chopski asked for the vote, and the motion passed unanimously.

Ms. Zahn presented a stipulation and order for Butler Schein Animal Health Supply, who stipulated to a $2,000 fine and a written plan for compliance for four distributions of controlled substances to a

veterinarian who did not hold a valid Idaho Controlled Substance Registration. Butler Schein was represented telephonically by attorney, Jason Reich, who presented the written plan and explained that the veterinarian was properly licensed by the Idaho Board of Veterinarian Medicine and registered with the DEA. Dr. Henggeler motioned to accept the stipulation and order as written. Dr. Jonas seconded. During discussion, the Board asked if the stipulated fine was consistent with prior, similar Board orders in which a fine was levied for each shipment. Mr. Johnston indicated that negotiations started at an $8,000 fine, but ultimately were negotiated down to $2,000, and he explained that changes to Idaho Code that become effective on 7/1/14 will make such violations abundantly clear. Dr. Chopski called for the vote and the motion passed unanimously.

Ms. Zahn presented the stipulation and orders for Gloria Hansen, RPh, Lori Hockenberry, PharmD and PIC, and Walgreens Pharmacy 05185. None of the respondents were present or represented by legal counsel. Ms Hansen failed to renew her controlled substance registration by 6/30/14 and continued to work, even after receiving written notification from the Board's staff. The pharmacy, PIC and Ms. Hansen stipulated to penalties pursuant to the Board's hypothetical direction from the 1/21/14 Board meeting, which was reaffirmed at the 3/13/14 Board meeting. Ms Hansen stipulated to a $2,000 fine. Dr. Hockenberry stipulated to a $1,000 fine. Walgreen stipulated to a $1,000 fine. Dr. de Blaquiere motioned to accept the stipulated orders. Dr. Henggeler seconded. Dr. de Blaquiere clarified that his motion pertained to all three orders. Dr. Chopski asked for the vote, and the motion passed unanimously.

Joshua Deiss, PharmD, appeared without legal counsel to request reinstatement of his pharmacist license and controlled substance registration. Dr. Henggeler recused herself due to a previous professional relationship with Dr. Deiss. Dr. Deiss delivered proof of compliance with the Board's Pharmacy Recover Network (PRN) and a complete reinstatement application. Dr. Deiss was questioned concerning dates, employment status and the circumstances surrounding his drug use, diversion, and rehabilitation compared to the documents provided. Dr. de Blaquiere motioned to reinstate Dr. Deiss' license and registration, with the conditions that Dr. Deiss cannot hold the position of Pharmacist-in-Charge (PIC), cannot be a preceptor of student pharmacists, and must remain compliant with his PRN contract. Dr. Jonas seconded. Dr. de Blaquiere clarified his motion: the PIC and preceptor restrictions are to terminate with successful completion of Dr. Deiss' PRN contract. Dr. Chopski asked for the vote, and the motion passed unanimously.

Benjamin Hurley, PharmD, appeared with legal counsel, Richard Hall, in support of his application for licensure via reciprocity from the state of Oregon. Dr. Hurley is currently subject to an order of the Oregon Board of Pharmacy. Dr. Chopski recognized Dr. Hurley's presented materials including his application, said board order, and letters of recommendation. Ms. McKay read from Section 54-1723, Idaho Code, which requires a reciprocity applicant to not have restrictions upon their license in any other state and counseled the Board on this statutory restriction to approving Dr. Hurley's application. Mr. Hall referred the Board to rule #033, which states that a reciprocity applicant must be "in good standing in another state at the time of the application". Mr. Hall believes that Dr. Hurley's license is in good standing in Oregon, albeit subject to an order. The ensuing discussion included statute superseding rule and Dr. Hurley's explanation of the events in Oregon. Dr. Jonas motioned to deny Dr. Hurley's application until his licenses in all other states are unrestricted. Dr. Henggeler seconded. Dr. Chopski asked for the vote, and the motion passed unanimously. Via unanimous consent, the Board instructed the Board's staff to approve Dr. Hurley's application once his licenses are no longer restricted in all other states.

The Board took up the matter of Kellie Ann Smith, PharmD, Benewah Medical Center, Ann Gumaer Oehlert, RPh and PIC, and Jacob T. VanVleck, PharmD and PIC.

Dr. Smith appeared with legal counsel, Pat Fannin. Dr. Smith is accused of working without an Idaho pharmacist license at Benewah Medical Center on 16 dates from July 2013 to March 2014. Ms. Zahn represented the Board and had brief opening remarks. Mr. Fannin's opening remarks were extensive, including admitting 6 exhibits. Mr. Fannin explained that Dr. Smith renewed her CS registration timely, but was confused by new procedures to renew her license. Mr. Fannin provided great detail in describing the factors that lead to such confusion. Ms. Zahn called Berkeley Fraser to testify, entering 4 additional exhibits during the questioning. Mr. Fraser was cross examined by Mr. Fannin and questioned by the Board. Mr. Fannin called Dr. Smith to testify, who was cross examined by Ms. Zahn. Ms. Zahn and Mr. Fannin presented closing statements, in which Mr. Fannin urged the Board to not impose discipline, due to the mitigating circumstances, the potential results of reporting such discipline to other entities, and the fact that 0.3% of the Board's licensed pharmacists also did not renew correctly. Dr. Henggeler motioned to enter executive session as allowed by Idaho Code 67-2345(f). Dr. Jonas seconded, and Dr. Chopski called for a roll call vote, which was unanimous. Upon returning from executive session, Dr. Henggeler motioned to fine Dr. Smith $200. Dr. Jonas seconded. Dr. Chopski called for the vote, and the motion passed unanimously. Ms. McKay asked the Board to clarify which alleged violation(s) the Board was imposing a fine. As there was disagreement among the Board members, Dr. de Blaquiere motioned to reconsider. Dr. Jonas

seconded. Dr. Chopski asked for the vote, and the motion passed with Dr. Henggeler opposed. The Board broke for lunch. Upon returning from lunch, the Board continued their deliberations, and then Dr. de Blaquiere motioned to charge $200 for attorney costs and fees, not for a particular violation. Dr. Jonas seconded. After discussion, Dr. Chopski called for the vote, and all were opposed. The motion failed. Dr. de Blaquiere motioned to charge costs of $200, but the motion failed for lack of a second. Dr. Henggeler motioned to fine $200 for violations of Board rule 17.03 and 17.04. Dr. Jonas seconded. The motion passed with Dr. de Blaquiere opposed.

Ms Oehlert presented with legal counsel Chris Kerley. Ms. Oehlert is accused of not fulfilling her corresponding responsibility for compliance with the law by allowing an unlicensed pharmacist to practice within the pharmacy for which she was PIC. All agreed to admit the exhibits and testimony of the prior hearing and to proceed directly to closing statements. Ms. Zahn and Mr. Curley presented brief closing statements. The Board had no questions. Dr. Jonas motioned to fine $100. Dr. Henggeler seconded. Dr. Chopski asked for the vote, and the motion passed unanimously.

Dr. VanVleck presented with legal counsel, Mr. Kerley. Dr. VanVleck is accused of not fulfilling his corresponding responsibility for compliance with the law by allowing an unlicensed pharmacist to practice within the pharmacy for which he was PIC. All agreed to admit the exhibits and testimony of the prior hearings and to proceed directly to closing statements. Ms. Zahn and Mr. Curley presented brief closing statements, and the Board asked a few questions. Dr. Henggeler motioned to fine $100, and Dr. Jonas seconded. Dr. Chopski asked for the vote, and the motion passed unanimously.

Benewah Medical Center was represented by legal counsel, Helo Hancock. Benewah Medical Center is accused of not fulfilling its corresponding responsibility for compliance with the law by allowing an unlicensed pharmacist to practice within its pharmacy. All agreed to admit the exhibits and testimony of the prior hearings and to proceed directly to closing statements. Ms. Zahn and Mr. Hancock presented brief closing statements, and the Board questioned Mr. Hancock. Dr. de Blaquiere motioned to dismiss the charges without discipline. Dr. Jonas seconded. Dr. Chopski asked for the vote, and the motion passed unanimously.

Mr. Johnston asked for delegated authority to stipulate to the penalties and violations that the Board imposed in the Smith, Oehlert, and VanVleck hearings. Dr. de Blaquiere motioned to grant such delegated authority to the Board's staff as long as the pharmacist did not work after being notified of such lack of licensure. Dr. Jonas seconded. Dr. Chopski called for the vote, and the motion passed unanimously.

Duane Hughes, RPh, appeared without legal counsel to request reinstatement of his pharmacist license and controlled substance registration. Mr. Hughes presented proof of PRN compliance and a complete reinstatement application. The Board questioned Mr. Hughes about his recovery. Dr. de Blaquiere motioned to reinstate with the restrictions of not holding the position of PIC, not being a preceptor of student pharmacists, and continued compliance with his PRN contract. The PIC and preceptor restrictions will terminate at the successful conclusion of Mr. Hughes' PRN contract. Dr. Jonas seconded. Dr. Chopski called for the vote, and the motion passed unanimously.

Dr. Chopski called for open public comment and there was none.

Rule 330.02.b requires immunizing pharmacists "to hold a current certification in basic life support for healthcare providers offered by the American Heart Association or a comparable Board-recognized certification program". Mr. Johnston reported that the Board has two companies that have recently requested Board recognition and asked if the Board preferred to hear presentations from these companies at a future Board meeting or if the Board would grant the Board's staff delegated authority to review and potentially grant such recognition. The Board was concerned about recent debates concerning such comparable designations. Mr. Johnston indicated that Mr. Fraser would be conducting the comparable study. Dr. Henggeler motioned to grant delegated authority. Dr. de Blaquiere seconded. Dr. Chopski asked for the vote, and the motion passed unanimously.

The Board took up the matter of Community Health Association of Spokane (CHAS). Nathan Halvorson appeared with Keri Sullivan-Walker, PharmD and Cheryl Cervantes. During the 3/13/14 open meeting of the Board, the Board rejected a CHAS waiver request involving a pharmacy lavatory. CHAS presented essentially the same request with different circumstances. The costs of constructing a lavatory within the proposed pharmacy drastically increased, as city code required all lavatories to be upgraded to ADA compliance, if an additional lavatory is installed in the proposed pharmacy. Additionally, CHAS was requesting registration as a limited service pharmacy due to their customer base being entirely 340b eligible. The Board determined that CHAS' proposed pharmacy was indeed a retail pharmacy and not a limited service pharmacy. CHAS' waiver request also included an alternative plan: opening a prescriber drug outlet, for which a lavatory is not required. Dr. Henggeler motioned to approve the 3/13/14 waiver request with the understanding that $30,000+ to construct a

lavatory is an undue hardship. Dr. Jonas seconded. Dr. Chopski called for the vote, and the motion passed unanimously.

Section 54-1713, Idaho Code, requires the Board to elect a chairman annually and a chairman cannot serve consecutive terms. Dr. Chopski's term as chairman is expiring on 7/1/14, when Dr. Henggeler will assume the duties of the chair. Dr. Jonas motioned to elect Dr. de Blaquiere vice chairman. Dr. Henggeler seconded. Dr. Chopski called for the vote, and the motion passed unanimously.

Mr. Johnston presented the Board's travel calendar. Dr. Chopski, Dr. de Blaquiere, and Dr. Jonas will be attending the 2014 NABP district meeting with Mr. Johnston. Dr. Jonas will be attending NABP's Board Member Interactive Forum in December of 2014 with Mr. Johnston. Dr. Chopski will serve as an alternate for that meeting. The Board discussed moving the previously scheduled August meeting up a week and subsequently rescheduling the July meeting conference call meeting. Both meetings will be scheduled via e-mail the following week.

Mr. Johnston presented the Board's financial report. With 89% of the fiscal year passed, the Board has expended 85% of its appropriation. The Board was able to pay its employees substantial bonuses for the second year in a row, as approved by the Division of Financial Management, due to the salary savings of not having a northern Idaho inspector for most of the fiscal year. The Board is yet to pay over $40,000 in IT costs, so at the conclusion of the fiscal year, the Board will expend nearly all of its annual appropriation.

Dr Chopski again called for open public comment. Reece Christensen explained that his pharmacy had been approached by a manufacture who wanted the limited service pharmacy to administer injections pursuant to valid prescription drug orders. Mr. Johnston clarified that pharmacists can administer any drug pursuant to a valid prescription drug order, not just immunizations. Mr. Christensen sought clarification about what patient population his limited service pharmacy could serve. The Board agreed that he could service his current customers. Mr. Christensen was asked to detail the program in writing for Mr. Johnston to evaluate the appropriateness of a limited service pharmacy participating in such a program.

Dr. Chopski addressed the inspectors and asked if they had any topics for the agenda item: Inspector Q & A. Mr. Fraser recapped the stipulations from earlier in the day that addressed counseling and counseling documentation violations. Both Mr. Fraser and Mr. Johnston are concerned about a lack of counseling, a lack of counseling documentation, misunderstanding of counseling and counseling documentation law, electronic record keeping systems that assist in falsifying counseling documentation, and a variety of other counseling issues. The Board was also very concerned, but due to time, terminated the discussion and instructed Mr. Johnston to create an agenda item at the August Board meeting whereby the discussion may continue. The Board encouraged pharmacies to participate.

Dr. Chopski asked Mr. Johnston to present the agenda item entitled Legislation and Rule Review. Mr. Johnston presented initial draft language on potential 2015 statute and rule changes, mainly collated from the Board's direction at meetings over the past year. He explained that federal Track and Trace law passed as the second half of the Compounding Quality Act, the changes were complicated, and some of the changes go into effect on 1/1/15. As many of the changes require State changes Mr. Johnston will have a more complete draft of wholesale distribution changes at the next meeting. Mr. Johnston then detailed draft changes to:

37-2709: a recent DEA change that the Board is mandated to place into Idaho law.

37-2718: obtain ability to restrict a controlled substance registration, enforce a Board order, and discipline an expired controlled substance registrant (54-1728 too), plus housekeeping.

37-2726: clarifying that subpoenas requesting PMP data for civil cases will not be fulfilled.

54-1718: changes to fingerprint requirements.

54-1729, 54-1732, 54-1732, 54-1752, and 54-1753: mainly wholesale drug distribution changes pursuant to federal changes and housekeeping.

Rule definitions & Rule 130: biosimilar substitution.

Rule 21, 74, and 740: recognizes new federal category of outsourcing facility.

Rule 41: clarifies technician-in-training renewal.

Rule 140: labeling changes pursuant to passed 2014 legislation.

Rule 144: pharmacy repackaging of another pharmacy's dispensed prescription.

Rule 206: clarifying annual inventory dates.

Rule 239: The Board's draft compounding rule revised pursuant to federal changes. Draft changes to rule 240 addressing sterile compounding were not discussed due to time and a lack of clarity from the FDA.

Rule 330: Allow an immunizer's emergency kit to contain bulk epinephrine, not just epinephrine auto injectors.

605: Clarifying pharmacy security requirements.

710: Telepharmacy changes pursuant to prior deliberation of Bengal Pharmacy's approved waiver.

Due to time, the Board's comments were limited to:

- To the next Board meeting, the Board wanted Mr. Johnston to bring examples that necessitate the proposed restriction of pharmacies wholesale distributing controlled substances.
- Clarify that the initials of the prescriber on standard drug labels are actually the initials of the dispensing prescriber in a prescriber drug outlet.
- Separate two proposed requirements of repackaging into two different line items and distribute to Ed Snell, RPh, for comment, as Mr. Snell was the initiator of the topic.
- Request that the requesting ISU student pharmacist, Mark Vance, appear at a future Board meeting to present upon the draft changes to allow epinephrine bulk in an immunizer's emergency kit.
- Word smith two factor credentialing language.
- Allow non-sterile, non-patient specific, pharmacy distribution of compounded drug product, pursuant to certain restrictions.

The Board will consider this, updated, and additional draft language at a July conference call meeting.

Dr. Henggeler motioned to adjourn. Dr. de Blaquiere seconded. Dr. Chopski asked for the vote, and the motion passed unanimously. The meeting adjourned at 6:01pm PST.