MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
Conference Call – Board office
1199 Shoreline Lane Ste 303, Boise, Idaho
April 21, 2014

This meeting of the Board was commenced to hear a Motion for Reconsideration of the Board's 3/27/14 order issued to Richard Sutton, R.Ph.

In attendance at the Board's office were Board members Ed Sperry, Public Member; Kristina Jonas, PharmD; Mark Johnston, RPh, Executive Director; and Colleen Zahn, DAG. In attendance telephonically were Chairman Nicole Chopski, PharmD; Vice Chairman Holly Henggeler, PharmD; Rich de Blaquiere, PharmD; as well as Mr. Sutton and his legal counsel, Donald Chisholm.

Chairman Chopski called the meeting to order at 7:08 pm and initiated Mr. Sutton's agenda item. Ms Zahn had no opening comments, preferring previously submitted documents stand on their own. Mr. Chisholm had brief opening remarks that included urging the Board to approve the motion, instead of having the decision reviewed judiciously without such Board reconsideration. Dr. Chopski led a discussion with the Board that included the Administrative Procedures Act and the signed Stipulation To Defer Action On Motion To Stay Suspension Of Licenses. Dr. Henggeler motioned to grant the Motion for Reconsideration and to hear the matter at the Board's regularly scheduled meeting on May 29, 2014 in Coeur d'Alene, Idaho. Dr. Jonas seconded the motion. During discussion, Dr. Henggeler asked for an updated spread sheet of prior Board orders by category of violation, including felony convictions. Chairman Chopski called for a roll call vote; all were in favor of the motion.

Since the Board had commenced an open, public meeting to hear the Sutton matter, Mr. Johnston posted an agenda with a second item: Legislation and Rule Review. Chairman Chopski asked Mr. Johnston to initiate such discussion. Mr. Johnston referred the Board to previously distributed documents.

The first legislative topic discussed was "office use" compounding or more specifically, the distribution of compounded drug product in the absence of a patient specific prescription drug order. Such distribution appears to be illegal both federally and in Idaho. The Board is currently enforcing such state law on a priority basis, starting with non-resident, sterile compounding. Much discussion ensued, including discussion concerning the federal Compounding Quality Act, various association positions, the 50 state FDA meeting on compounding that Mr. Johnston recently attended in Maryland, State law, and current, resulting, business practices recently reported to the Board. The Board decided to initiate enforcement of State law that prohibits the distribution of all sterile "office use compounding", starting with notification to registrants and licensees by publication of such information in the Board's June Newsletter. There are currently 41 outsourcing facilities registered with the FDA. The Board will continue to utilize enforcement discretion on the distribution of non-sterile compounded drug product for

“office use” until the FDA clarifies many points within section 503A of the federal Food, Drug and Cosmetic Act. The Board will reconsider the former pending docket of compounding rules at a future meeting.

The second legislative topic discussed concerned how to register Outsourcing Facilities. The Board ultimately decided to promulgate a rule in 2015 for such a category. In the mean time, the Board’s staff shall register such facilities as mail service pharmacies if they also dispense filled prescriptions and limited service drug outlets if they do not.

The third legislative topic discussed concerned technician-in-training renewal. The Board decided that the two renewal limit in rule 041.02 referred to renewals in a life time, not per individual registration, and instructed Mr. Johnston to clarify via rule promulgation in 2015. The Board did condone the issuance of a technician-in-training registration for a hypothetical certified technician who failed to maintain certification, while such a technician obtains re-certification, even if the technician had previously renewed a technician-in-training registration two times. Such additional registration shall not be renewable.

The forth legislative topic discussed concerned technicians receiving verbal “refill authorization”. Pursuant to rule 116, such authorization shall result in the production of a new prescription drug order; refills are not to be added to an existing prescription. This could be perceived to be in conflict with rule 400.03, which prohibits technicians from receiving verbal prescription drug orders. Dr. Henggeler read from a 2008 Board Newsletter, which addressed this very topic, authorizing such technician action. The Board directed Mr. Johnston to re-publish the article in an upcoming Board Newsletter, updating the article to refer to the new rule numbers. The Board did not believe that clarification via rule promulgation was needed.

The fifth legislative topic discussed concerned the Board’s recent approval of Bengal Pharmacy’s waiver. The Board debated if each condition should be promulgated into Board rule. After much discussion, the Board directed Mr. Johnston to table the requirement of a random drug screening program until the next meeting. The Board wants to wait for Bengal Pharmacy’s quarterly reports before evaluating the removal of the ADS requirement from telepharmacy rule and potentially adding the requirements of a locked area to store controlled substances, a perpetual CII inventory, controlled substance audits, and pharmacist audio/visual supervision of the opening and stocking of controlled substances. The Board directed Mr. Johnston to promulgate in 2015 the same security requirements that regulate a pharmacy, pharmacist approval and video supervision of access to the secured area of the remote dispensing site by authorized visitors, a 2,000 hour requirement of a certified technician working in a remote dispensing site, two factor credentialing for access to the remote dispensing site, security capable of date, time, and user stamping, ninety day record retention of the surveillance system and said entry data, and a CQI requirement.

The sixth and final legislative topic discussed concerned pharmacists compounding and potentially dispensing from a prescriber’s office. Mr. Johnston is presenting upon the

topic at the 2014 annual NABP meeting, and he distributed his Power Point to the Board earlier in the day. The Board wanted to allow such practice, but was concerned with the lack of regulation that pertains to it, when compared to the same practice within a pharmacy. After much discussion, the Board believed that a pharmacist could practice in a physician's office pursuant to a collaborative practice agreement.

Dr. Jonas motioned to adjourn. Mr. Sperry seconded. All were in favor. The meeting adjourned at 8:58pm.