MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
Conference Call – Board office
1199 Shoreline Lane Ste 303, Boise, Idaho
April 2, 2014

This meeting of the Board was commenced, pursuant to the Board's 3/13/14 approval of Bengal Pharmacy's petition for variance, to establish conditions of such approval.

In attendance at the Board's office were Ed Sperry, Public Member and Mark Johnston, RPh, Executive Director. In attendance telephonically were Chairman Nicole Chopski, PharmD, Vice Chairman Holly Henggeler, PharmD, Board members Rich de Blaquiere, PharmD and Kristina Jonas, PharmD, as well as Kerry Casperson, PhD, Rex Force, PharmD, BCPS, FCCP, Associate Dean for Research, Dean Paul Cady, RPh, PhD, and Kim Lynn, PharmD, who represent Bengal Pharmacy.

All parties had previously received a draft waiver approval document detailing several potential conditions, as drafted by Mr. Johnston and the Board's Deputy Attorney General, Nicole McKay, pursuant to the 3/14/14 Board meeting deliberations and a subsequent conversation between Bengal Pharmacy and Mr. Johnston. Chairman Chopski called the meeting to order at 7:02pm and asked Mr. Johnston to detail the topic's occurrences to date. The Board then proceeded to deliberate upon each draft condition with pointed verbal input from Bengal Pharmacy's representatives where appropriate.

> ***Draft condition a: All controlled substances in the remote dispensing site must be stored: [options include in an ADS, in cassettes, in a locked area or dispersed throughout the stock of non-controlled substances].***

After much debate, Dr. de Blaquiere motioned to allow the dispersal of controlled substances throughout the stock of legend drugs. Mr. Sperry seconded. After further discussion, Dr. de Blaquiere amended his motion: controlled substances must be stored in a locked area. Dr. de Blaquiere consciously did not provide further description of said locked area, as he wanted Bengal Pharmacy to have the flexibility to determine if a cabinet, room, or other locked structure was an appropriate safeguard. Chairman Chopski called for the vote, the motion passed 3-1 with Dr. Henggeler opposed.

> ***Draft condition b: The remote dispensing site must be secured at all entrances after hours and access permitted only through two factor credentialing as provided in IDAPA 27.0101.604.3.3.i. through iii. (Consider a requirement whereby a pharmacist from Bengal Pharmacy allows remote entry to a technician possessing a key at the remote dispensing site.)***

After discussion, Dr. Chopski asked for unanimous consent to approve condition b as written, without the consideration included in parentheses. Dr. Chopski polled the Board and unanimous consent was granted.

Draft condition c: The remote dispensing site must be equipped with a security system capable of date, time and user stamping and 120 day data retention.

After discussion, Dr. Chopski asked for unanimous consent to approve the condition as written, but to change the record retention period to 90 days. Dr. Chopski polled the Board and unanimous consent was granted.

Draft condition d: The remote dispensing site must be equipped with a security system capable of providing an adequate number of simultaneous views of the remote dispensing site and storing data for a minimum of 120 days.

After discussion, Dr. Henggeler motioned to add “entire” before the second use of “remote”, change the record retention period to 90 days, change “security” to “surveillance”, and to strike “simultaneous” or replace it with a word such as “full”. Dr. Jonas seconded, and the motion passed unanimously.

Draft condition e: The remote dispensing site must be constructed with walls that extend to the roof and solid core or metal doors, and all doors and other access points must be equipped with locking devices and be constructed in a manner so that hinge hardware is accessible only from inside the remote dispensing site.

After minimal discussion, Dr. Chopski asked for unanimous consent to approve condition e as written. Dr. Chopski polled the Board and unanimous consent was granted.

Draft condition f: Access to the remote dispensing site must be limited to the pharmacist and technicians unless otherwise authorized by the pharmacist.

After discussion, Dr. Chopski asked for unanimous consent to approve condition f, with the understanding that the final word smithed language would support rule 710.09 (and not allow access that conflicts with it) and would incorporate similar language as in the definition of “secured pharmacy”, in order to allow customers access to OTC sales, the counseling area, etc. Dr. Chopski polled the Board and unanimous consent was granted.

Draft condition g: All controlled substances must be double counted by the technician at the remote dispensing site.

After much discussion, Dr. de Blaquiere motioned to strike condition g in full. Dr. Jonas seconded. The motion passed 3-1 with Dr. Henggeler opposed.

Draft condition h: Perpetual inventory must be kept for all schedule II controlled substances. Upon dispensing a schedule II controlled substance, the remote dispensing site technicians must count the remainder and log each prescription in written or electronic form.

Draft condition i: The pharmacist's monthly inspection of the remote dispensing site must include an audit of all controlled substance inventories.

Dr. de Blaquiere believed that condition h and condition i should be considered together. The Board's lengthy discussion included the differentiation of an inventory from an audit. Mr. Johnston explained that an inventory is a quantity count of certain inventory that is within a drug outlet at any particular point in time, utilized as a starting point for an audit. An audit is a reconciliation of a starting inventory, plus received inventory, minus dispersed inventory (usually in the form of dispensing, but could include other distributions, such as expired product to a reverse distributor). The results of such an audit calculation are expected to match the quantity remaining within the drug outlet. After much discussion, Dr. de Blaquiere motioned to accept condition h as written, and within condition i for "audit" to be changed to "inventory" and for condition i to only pertain to three controlled substances per month. Mr. Sperry seconded. Dr. Jonas and Dr. Henggeler voted nay. Dr. de Blaquiere and Mr. Sperry voted aye. Chairman Chopski broke the tie and voted nay. The motion failed. Dr. Henggeler motioned to approve condition h as written. Dr. Jonas seconded. The motion passed unanimously. Dr. Henggeler motioned to quantify condition i to pertain to three controlled substances only, audited every other month. Dr. de Blaquiere and Mr. Sperry voted nay. Dr. Henggeler and Dr. Jonas voted aye. Chairman Chopski broke the tie with an aye vote, and the motion passed.

Draft condition j: Bengal Pharmacy must develop and implement a continuous quality improvement program to review and evaluate the remote dispensing site operation.

After little discussion, Chairman Chopski asked for roll call unanimous consent, which was granted.

Draft condition k: The remote dispensing site must institute a random drug screening of technicians with a minimum of ___ tests per year.

Dr. Henggeler motioned to approve condition k as written with six tests per year. The motion died for a lack of a second. After much discussion, Dr. de Blaquiere motioned to strike condition k in full. Mr. Sperry seconded. Dr. de Blaquiere and Mr. Sperry voted aye. Dr. Henggeler and Dr. Jonas voted nay. Chairman Chopski broke the tie by voting nay. The motion failed. Dr. Jonas motioned to approve condition k as written, with "with a minimum of __ tests per year" struck. Mr. Sperry seconded. After more discussion, Dr. Jonas amended her motion to accept condition k with "a minimum of one test per year". Dr. Jonas and Dr. Henggeler voted aye. Dr. de Blaquiere and Mr. Sperry voted nay. Chairman Chopski broke the tie by voting aye. The motion passed.

Draft condition l: The remote dispensing site certified technicians must have 2,000 hours of experience as a technician in Idaho.

After discussion, Chairman Chopski asked for roll call unanimous consent to approve condition l as written. Unanimous consent was granted.

Draft condition m: The remote dispensing site must report diversion and error rates to the Board quarterly during the waiver period.

After much discussion, which included the various potential definitions of an error, Dr. Henggeler motioned to strike condition m in full and to add “and quarterly submit to the Board the results of the CQI” to the end of condition j. The motion passed with three in favor and Dr. de Blaquiere abstaining.

Draft condition n: In the absence of pharmacist at Bengal Pharmacy viewing through video communication the stocking of an ADS machine, the pharmacist must view the opening of the secured tote that prescription drugs are delivered within.

After discussion, Chairman Chopski asked for roll call unanimous consent to change draft condition n to read “The pharmacist must view the opening of the secured tote that prescription drugs are delivered within and the stocking of controlled substances into the locked area.” Unanimous consent was granted.

Dr. de Blaquiere motioned to adjourn at 9:53pm. Mr. Sperry seconded. The motion passed unanimously.