MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
July 7th, 2014 – Conference Call
1199 Shoreline Lane #303, Boise, Idaho

This meeting of the Board was commenced to consider draft language of potential 2015 statute and rule changes.

In attendance at the Board's office were Ed Sperry, Public Board Member ; Kristina Jonas, PharmD and Board member; Mark Johnston, RPh and Executive Director; and Nicole McKay, DAG. In attendance telephonically were Chairman Holly Henggeler PharmD; Nicole Chopski, PharmD and Board member; Rich de Blaquiere, PharmD and Board member; as well as members of the public Paul Cady, Ph.D. representing Idaho State University and John Sullivan, PharmD, representing the Idaho Society of Health-System Pharmacists.

Dr. Henggeler called the meeting to order at 7:03 pm and asked for comment regarding draft minutes from the 5/29/14 Board meeting. After discussion, Dr. Jonas motioned to accept the minutes with minor changes. Dr. Chopski seconded. Dr. Henggeler called for the vote, and the motion passed unanimously.

Dr. Henggeler asked Mr. Johnston to lead the agenda item "legislation and rule review". Mr. Johnston called the Board's attention to a previously distributed copy of the Board's proposed 2015 changes to Idaho code and explained that all proposed statute changes within the Idaho Wholesale Drug Distribution Act have been removed and placed into a separate document. Mr. Johnston explained that since the draft that the Board considered at the 5/29/14 meeting, new draft of changes to the Uniform Controlled Substances Act include several housekeeping changes, such as correcting incomplete and inconsistent lists of what activities require controlled substance registration and separating "prescribe" and "administer" from the definition of "dispense". This draft includes several additional statutes not previously considered. The Board approved of these changes and other reorganization as written. Also included in this draft is the ability to fine controlled substance registrants, which all agreed could be controversial. Dr. Chopski asked Mr. Johnston and Ms. McKay to review if "compounding" should be removed from within the definition of "dispense" and separately defined. Additionally, Mr. Johnston and Ms McKay are to determine if the Board's authority to cancel a registration in rule should be memorialized in statute. Ms. McKay asked for additional time to study draft changes to 37-2729 concerning subpoenas for PMP data in civil cases. Mr. Johnston explained additional proposed housekeeping changes to 54-1734.
Mr. Johnston asked the Board to turn their attention to the previously distributed draft of the Board's proposed 2015 rule changes. In addition to the changes that the Board directed at the 5/29/14 Board meeting, the following changes have been made to the draft:

- A definition of outsourcing facility and a fee for an in-state outsourcing facility were added. References to federal law were corrected. Language concerning an outsourcing facility's coincidental activity was updated.
- New proposed rule changes were added, clarifying that a foreign graduate who obtains a PharmD in the United States still has to complete 1,500 intern hours.
- Several non-substantive changes to rule 239 (compounding) were completed.
- Pursuant to USP's proposed Chapter 800, a new rule 241 for hazardous drug compounding was drafted, including moving portions of rule 239 and 240 into 241.

- A new rule 340 that duplicates statutory requirements of registered pharmacists and drug outlets into rule was created, in order to also regulate non-resident licensed pharmacists in the same manner.
- Substantial non-substantive changes to rule 605 were drafted in an effort to clarify intent and organize, which lead to the creation of a new rule, 611-pharmacy authorized entry, which combines portions of three existing rules.
- The allotted time for a repackaging pharmacy to complete such activity was increased from one day to three days.

After much discussion, which included Dr. Cady's input on foreign graduates, confirmation that sterile repackaging should indeed be regulated, and a request by Dr. de Blaquiere for the Board staff to review and possibly edit the technician-in-training registration application, the Board directed Mr. Johnston and Ms. McKay to pen the following changes:

- Edit non-substantive changes to biosimilar definitions to conform with established style.
- Revise the outsourcing facility's coincidental activity sub rule to use a word other than "endorsement".
- Correct a reference to a sub rule in proposed rule 146.
- Review all compounding rules to ensure that prescribers and outsourcing facilities are regulated like pharmacists.
- Strike extraneous draft language.
- Divide the draft office use compounding sub rule into additional sub rules.
- Rewrite the differential hours sub rule within rule 605.
- Add language to ensure that the supervising pharmacist of a remote dispensing site is located within the supervising pharmacy.
-

Mr. Johnston asked the Board to turn their attention to a document containing 2014 pending changes to rule 240, sterile product preparation. The Board asked the 2014 legislature, via concurrent resolution, to not approve of these changes, while the Board awaited further clarification from FDA concerning issues within the Compounding Quality Act, including potential mandatory USP 797 compliance. In the past seven months the FDA has not provided such clarification, including responding to Mr. Johnston's written request that "FDA is unable to answer your questions at this time". After much discussion, the Board decided to re-run the 2014 pending changes to rule 240, without edit. Additional factors that influenced the Board's decision included: inspector training, resources, not being able to enforce federal law even if federal law was clear, and the fact that the pending changes substantially protect public safety when compared to current rule 240.

Mr. Johnston referred the Board to a document that contained language from the track and trace portion of the federal Drug Quality and Security Act, the Idaho Wholesale Drug Distribution Act, and the Board's rules concerning wholesale drug distribution. The federal law is complicated and portions go into effect at various times over the next decade. Certain changes go into effect on 1/1/15, including changes to wholesale distributor registration and pedigree requirements. As the federal Act requires states to be consistent with federal law, numerous changes are required, including some in 2015. All agreed that Mr. Johnston and Ms. McKay have substantial work to do in order to draft language for the Board to consider in time to meet 2015 statute change and rule promulgation deadlines.

Dr. Chopski motioned to adjourn. Dr. Jonas seconded. Dr. Henggeler called for a roll call vote, and the motion passed unanimously. The meeting adjourned at 9:15pm.