MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
JANUARY 17, 2013
HOLIDAY INN – BOISE, IDAHO

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

Chairman Berk Fraser, RPh. called the meeting to order at 8:00 a.m. In attendance were Board members Rich de Blaquiere, Pharm D.; Nicole Chopski, Pharm D.; Holly Henggeler, Pharm D.; Ed Sperry, and Mark Johnston, RPh., Executive Director; Nicole McKay, DAG; Colleen Zahn, DAG; Compliance Officer Lisa Culley, and Ellen Mitchell.

Dr. Chopski motioned to approve the minutes of the November 2, 2012 meeting as written. Dr. Henggeler seconded. Motion carried unanimously.

Chairman Fraser requested Mr. Johnston present an overview to begin the negotiated rulemaking hearing on compounding. Mr. Johnston spoke to the history of law surrounding compounding Vs manufacturing, the New England Compounding Center tragedy, congressional inquiries of the Board, FDA hearings, proposed congressional bills, the National Association of Boards of Pharmacy's four part plan, and Idaho compounding law.

Mr. Johnston then read written public comment submitted pursuant to the notice posted in the Idaho Administrative Bulletin:

- Dawn Berheim, Pharm D, Director of Pharmacy St. Luke's Boise/Meridian, suggested adding language to state rules to establish references other than manufacturer directions for appropriate compounding, such as peer reviewed journal articles or other professional resources (USP, international journal of compounding, Trissels, etc) to establish appropriate admixing procedures. Regarding mandatory compliance with USP 797 and/or 795, Dr. Berheim requested that the Board consider approaching this as a performance improvement project at the drug outlet level, with the expectation that sites will be working toward full compliance in the interest of patient safety, but recognizing that there are real barriers to achieving full compliance.

- Cathy Cashmore, Pharm D, Associate Dean, ISU College of Pharmacy, is concerned with the inability to provide "office use" products and its impact on patient safety. Specifically, the ability to provide bulk technetium-99m to hospitals is one of her concerns. This product is used for stat add-on diagnostic procedures to determine the presence of pulmonary embolisms, GI bleeds, etc. If these products were required to be provided as patient specific and were needed after hours, it could take a pharmacist up to 5 hours to provide the drug. Dr. Cashmore felt strongly that requiring USP 797 compliance would be an unnecessary burden, especially for facilities compounding products that are "very short lived and inherently bacteriostatic/cidal".

- Brent Cornell, RPh, indicated in his written comment that he is concerned about potential federal agency additional oversight of compounding, specifically compounding sterile injectable products. He recommends looking at the actual number of injuries versus the number of patients that need urgent treatment.

- Kent Alexander, RPh wrote that there must be a compromise to USP 797 for traditional compounding, indicating that USP 797 compliance is out of reason for most pharmacies.

- Mike Nield, DVM was recently informed that he is now unable to obtain compounded medications for office use in Idaho and wanted to know if he could compound the products himself for office use and dispense to patients.

- Barry Feely, RPh addressed the Board in person as well as providing written comment, as compounding is a large part of his business in northern Idaho. He is a member of IACP, supports their views, is concerned that traditional compounding will be jeopardized by federal action, and wants to help the Board promulgate workable rules. He'd like to start with identifying levels of compounding from simple compounding to compounding hazardous medications. He believes worker and environmental safety needs should be addressed, in addition to patient safety. He would also like to see mandatory training for pharmacy staff. Mr. Feely would like "office use" compounding to remain as an option for pharmacies and practitioners.

- Lorri Gebo Shaver, RPh owner Shaver Pharmacy & Compounding Center in Pocatello, which is PCAB accredited, submitted written comment to the Board and appeared to reiterate her comments. She has been involved in compounding for the last 18 years and has taught Compounding at ISU College of Pharmacy for 5 years. Ms Shaver believes the Board should:

    1. Require pharmacies to obtain and maintain separate Non-sterile and Sterile Product Preparation licenses if their practice involves those respective activities.

    2. Require all Non-sterile Product Preparation licenses holders to sign an annual attestation that their compounding facilities and activities are in full compliance with USP 795 and;
        a. submit the following information as a requirement for their annual license renewal:
            i. An analysis from an approved, independent outside laboratory for a nonsterile compounded product from each quarter of the prior year. The nonsterile analysis must include potency testing. This would remove the time burden for on-site inspections from the inspectors while ensuring compliance.

    3. Require all Sterile Product Preparation license holders to sign an annual attestation that their compounding facilities and activities are in full compliance with USP 797 and;
        a. submit the following information as a requirement for their annual license renewal:
            i. The last two Certificates of Hood Inspections by an approved, independent testing service. USP 797 requires hood inspections twice yearly. This would ensure that pharmacies preparing sterile products are at least operating in a sterile environment per ISO standards. This would also remove the time burden for on-site inspections from the inspectors while ensuring compliance.
            ii. An analysis from an approved, independent outside laboratory for a sterile compounded product from each quarter of the prior year. The sterile analysis must include both potency and sterility testing. This, again, would remove the

time burden for on-site inspections from the inspectors while ensuring compliance.

4. Require "for office use only" labeling requirements. Practitioners, both for humans and animals, must have access to products for in office use that are not available on the market.

- Tori Shaver, owner of Shaver Pharmacy & Compounding Center, addressed the Board, as he believes there is sterile compounding taking place in non-sterile environments. He is also concerned the FDA may be given oversight of compounding pharmacies and encourages more licensing and certification of compounding pharmacies. He believes that enforcement of current rules may help address the issue of poorly compounded medications as well.

- Matthew Murray, Pharm D representing Customedica pharmacy in Eagle supports distribution of “for office use” compounded products that are used in clinical trials, when medications are temporarily unavailable, and for pediatric medications use in NICU, for example. He supports USP 797 in a lighter form and mandatory training for all personnel, including technicians. He agrees that some pharmacies are following USP 797 and 795, and some that just think they are. He is not as concerned with low to medium risk sterile compounds as compared to high risk compounds. He reports that the expiration date requirements in USP 797 are burdensome for small pharmacies. Customedica currently sends products for sterility testing and all employees that enter their clean room are trained.

- Pam Eaton, Executive Director of Idaho State Pharmacy Association and Idaho Retailers Association addressed the Board indicating she had sent the information regarding compounding rules to both groups and comments were strong on both sides of the issue.

- Mark Phillips, Pharm D, Director of Pharmacy St Alphonsus Regional Medical Center (SARMC) believes patient safety trumps convenience. He reported that many hospitals don’t compound high risk drugs, as they have out of state pharmacies compound these products for them. Dr. Chopski asked Phillips what SARMC’s plan is if they are no longer able to obtain product from out of state pharmacies. Dr. Phillips indicated they would need to look in state or possibly upgrade their own sterile compounding site. He reports that TJC doesn’t inspect well for compounding, normally the inspector is a doctor or a nurse and aren’t aware of what to look for. He supports USP 797 in a lighter form and compounding for office use.

Mr. Johnston stated that the time has passed for agencies to introduce their own legislation, though Rep. John Rusche indicated he would run legislation on the Board’s behalf. Following discussion, the Board directed Mr. Johnston to:

- Pursue training for inspectors
- Add compounding information to CE presentations
- Prepare draft legislation that creates statutory authorization to address “office use” compounding in rule, including a definition of compounding.
- Investigate licensure versus registration of non-sterile and sterile compounders

- Modify application and inspection forms to include questions to identify sterile compounders
- Enforce current rules for those that are currently engaging in illegal sterile compounding
- Draft rules that allow limited “office use” compounding, mandate a lighter form of 797, establish non-sterile compounding parameters, require sterile compounding CE, and address compounder safety, such as mandatory “powder hoods”.

Chairman Fraser asked Mr. Johnston to initiate the negotiated rulemaking hearing concerning delivery. Mr. Johnston reviewed the delivery proceedings from a prior meeting in which the Board heard a request to promulgate rules that would allow pharmacy delivery to an ante room for subsequent delivery driver pick up. Mr. Johnston provided the Board with a survey of states concerning the use of such ante rooms. None specifically allowed this practice in law, but South Dakota had extensive, liberal, delivery law and Indiana detailed this exact practice, as allowed via their Board policy, reporting they had no issues concerning the practice.

Dave Moore, RPh from Pharmerica submitted a proposed, draft rule for Board consideration. Mr. Johnston commented that terminology within the proposal would have to be harmonized with Idaho law, at a minimum.

Chairman Fraser asked for public comment.

- Greg Nelson, Pharm D addressed the Board regarding the proposed rule. He works for Ivesco and primarily deals with cattle. Their products are delivered in pallets of five gallon buckets. Orders are filled for the dairies and delivered by the salesmen. Ivesco supports having an ante room to store the drugs, allowing the salesmen to have access to transfer the product to the common delivery carrier. Ivesco’s regular hours are limited to one day a week.

- Jackoline Livingston, ISU pharmacy student, addressed the Board representing Mr. Moore, as he was unable to attend. She reported that it is inconvenient for the pharmacist to wait for the courier to arrive to pick up the product. The product has already been checked by the pharmacist, is secured in locked totes and is stored in a locked room. Medications are delivered to long term care facilities, not individuals. To her knowledge they have never had a damaged tote or a shortage; ties are tamper evident and she believes there are policies and procedures in place in the event of tampering or damage.

Dr. Chopski motioned to direct Mr. Johnston to proceed with drafting rules for ante room storage for subsequent delivery. Mr. Sperry seconded. Motion carried with Dr. Henggeler opposed.

Mr. Johnston presented the matter of “as directed” prescriptions. Idaho law requires directions on the label of a prescription. Veterinarian prescriptions are being dispensed with “as directed” directions, as lengthy herd directions do not fit on the label, and the ranch is left to calculate the dosage pursuant to the manufacturer’s directions, if available. Mrs. Culley indicated if the ranch hand called the pharmacy they would actually be talking to the pharmacists, so she sees the real issue with veterinarian drug outlet (VDO) dispensing. When the ranch hand calls the VDO they are only talking to a veterinary drug technician (VDT). The Board determines that “as directed” directions do satisfy Idaho prescription drug order and labeling minimum requirements.

Mr. Johnston presented the Board financials. 53.15% of the fiscal year has elapsed and the Board has spent 40.77% of the appropriated budget. 5.41% of the federal grant has been spent. Mr. Johnston detailed progress on Board projects. The Board staff worked with four other agencies in securing a contract for a new licensing system built by GL Solutions. Installation is slated for late summer of 2013. NABP has been developing a prescription monitoring program, and Idaho has been selected as one of the five to receive the program for no cost for the first five years. Installation is slated for fall 2013.

Mr. Johnston presented the FY2014 budget request and the Governor's recommendation. He will keep the Board informed as the FY2014 request moves through the legislative process. Mr. Johnston explained the request for funding to hire for the open technical records specialist position and the change of the Senior Compliance Officer position to Deputy Executive Director. The Board's staff has completed the zero based budgeting project.

Mr. Johnston presented the Board's final bill language and current status of promulgation of the Board's rules.

Mr. Johnston presented the Board's travel calendar, including his scheduled spring CE programs. He included the Prescription Drug Abuse Working Group Meeting, as it is a significant meeting of all the medical boards and law enforcement involved; they are gaining traction. The NABP annual meeting is scheduled for St Louis on May 18-21, 2013; Mr. Fraser and Dr. Henggeler are interested in attending. Mr. Johnston will arrive one day early for the Executive Committee meeting.

The Idaho Veterinary Medical Association (IVMA) requested a Board appearance to present 2013 proposed legislation. Les Stone, DVM, Brett Bingham, DVM and Rena Carlson, DVM appeared. Dr. Stone questioned whether a veterinarian is required to be present when a prescription is dispensed. Mr. Johnston recapped the Board's written response to this question, from six months ago. Ms. McKay scrutinized the Board of Veterinary Medicine's Practice Act and discovered there was no statutory authorization for veterinarians to dispense in Idaho. IVMA has partnered with Representative Tom Loertscher, who is in attendance today, to address this issue during this legislative session. Dr. Stone then sought clarification on the rules veterinarians must follow when dispensing. Following discussion, Ms Chopski accessed the Board's web site and read the letter that was distributed to all veterinarians via US mail 17 months ago and read the application for a Prescriber Drug Outlet that lists the rules that apply to veterinarian dispensing. Dr. Stone had said letter in his immediate possession. Representative Loertscher thanked the Board for their assistance in this matter.

Jason Kreizenback and Skip Smyser of Lobby Idaho appeared before the Board representing Genentech. They presented draft legislation regarding biosimilar products. Mr. Johnston has suggested many edits to their draft language, some of which have already been incorporated into the draft the Board was considering. Dr. Henggeler motioned to approve the legislation. Dr. Chopski seconded. After further discussion Dr. Henggeler amended her motion to support the legislation only if several detailed changes were incorporated into the draft. Dr. Chopski seconded. The motion carried unanimously.

Mr. Johnston introduced the Board's new Prosecuting Deputy Attorney General, Colleen Zahn. Ms. Zahn announced that Case BOP-13-012 was vacated and presented the stipulation and order for John Mark Jensen, DMD. Fred Collings, Chief Investigator for the Board discovered discrepancies will reviewing wholesaler sales reports. Mr. Collings visited Dr. Jensen's office to review his dispensing logs. It was discovered the required annual inventory had not been

completed. During the interview Dr. Jensen admitted using zolpidem for his own use. Dr. Chopski motioned to accept the stipulation as written. Dr. de Blaquiere seconded. Motion carried unanimously.

Mr. Johnston presented a question from Dwayne Sheffler, RPh regarding the possibility of the hospital dispensing pharmacy pre-packaged drugs from their clinics, which are located within the hospital, similar to Registered Nurse dispensing that is allowed from their emergency room. After a lengthy discussion, the Board tabled the discussion due to time.

Mr. Johnston discussed his meeting with the Idaho Prosecutor's Association. They may be opposed to the Board's Controlled Substance legislation that proposes to incorporate by reference DEA schedules.

Dr. Henggeler motioned to enter into executive session as authorized by Idaho Code 67-2345(1)(a) to consider hiring a public officer, employee, staff member or individual agent, wherein the respective qualities of individuals are to be evaluated in order to fill a particular vacancy or need. Dr. de Blaquiere seconded the motion. Motion carried unanimously. Mr. Sperry motioned to leave executive session. Dr. de Blaquiere seconded. Motion carried unanimously. Executive session ended at 5:03pm.

As there was no further business to address, Dr. de Blaquiere motioned to adjourn the meeting. Mr. Sperry seconded. Motion carried unanimously. Meeting adjourned 5:04 p.m.