MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
October 22-23, 2014

Idaho State Capitol Building, Boise, Idaho

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

Chairman Holly Henggeler, PharmD, called the meeting to order at 9:33 a.m. In attendance were Board members Nicki Chopski, PharmD; Rich de Blaquiere, PharmD; Kristina Jonas, PharmD; and Ed Sperry, Public Member, as well as Mark Johnston, RPh, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Nicole McKay, DAG; Lisa Culley, CPhT and Jaime Sommer, Compliance Officers; Ellen Mitchell and guests.

Dr. Jonas motioned to approve the minutes of the August 6-7, 2014 meeting with minor corrections; Mr. Sperry seconded, and the motion carried unanimously.

Scott Carrell, Executive Director of the Idaho Health Data Exchange (IHDE) presented an informative Power Point presentation of the history of IHDE and how it is currently being used. IHDE is a repository connected through hospital, medical provider and laboratory electronic medical records (EMR) that collects pertinent data regarding patient's healthcare. Information is shared real time allowing providers to make better decisions regarding patient care, reduce healthcare costs and facilitate access and retrieval of clinical data. IHDE charges enrollees $390 per year which allows for four logins and passwords; one licensed provider may have three people enrolled under them. IHDE is accessed with a secure username and password; passwords are required to be changed every 90 days, and security is continually monitored. Access is currently limited to providers, hospitals and laboratories though patient access will be available in the future.

Three years ago IHDE had 300 users, there are now over 2500 users. Mr. Carrell is asking the Board to share information from the prescription monitoring program (PMP) for incorporation into IHDE. Following Mr. Carrell's demonstration of IHDE, Dr. Chopski asked if there were penalties, specifically felony charges, for mis-use of the program such as the Board's PMP rules carry. Mr. Carrell explained IHDE operates under the Office of Civil Rights at the federal level and there are multiple audit trails built into the system allowing IHDE to block any offending user and provide information to the Office of Civil Rights to assist in any follow-up investigations. They have had to block a few users. Mr. Johnston asked Mr. Carrell about federal grant money that has been available to connect IHDE and PMPs and if he has seen any of these types of projects utilized, but Mr. Carrell indicated he had not. Mr. Johnston inquired about prescription information contained within the IHDE, and Mr. Carrell responded that Surescripts had provided data on roughly 90% of dispensed prescriptions; data for dispensed prescriptions that were not paid in full or in part by a third party payer composed the missing 10%. Once conversion to a new vendor is complete, Surescripts data is expected to be available within the IHDE once again. Dr. de Blaquiere wanted to know if pharmacists had access the system, and Mr. Carrell indicated pharmacists are allowed to access, though few are currently enrolled.

Neal Watson, Member Liaison, NABP presented the Verified Pharmacy Program (VPP) which was created in response to the NECC tragedy and member boards' requests for regulatory uniformity among states and an information sharing network to share critical licensure and inspection information among states, similar to the Electronic Licensure Transfer Program (ELTP) for pharmacists. VPP creates an electronic profile for each pharmacy and links the

pharmacy with key personnel electronic profiles including the PIC. Steering committees are being created to draft a uniform inspection report to be completed by state inspectors and uploaded to the NABP database. It is assumed the uniform report would be used in conjunction with each state's own supplemental report containing that state's specific requirements. Boards have the option of recognizing VPP inspections and requiring applications to be made through VPP. If pharmacies are required to apply through VPP, NABP will verify all the information submitted in the application and ensure there is a 'qualified' inspection report included or on file with VPP. A qualified inspection is one completed in the past 24 months or the last 12 months if the facility is providing compounding services. Application fees for VPP range from $1995 to $3000, in addition to any state licensure/registration fees. Following Mr. Watson's presentation Dr. Jonas motioned to provide NABP with the Board's current inspection reports, have Mr. Fraser attend the steering committee meeting, and to contract with NABP to provide sterile compounding inspection training for our inspectors at their first few inspections after the Board's compounding docket of rules is promulgated. Dr. de Blaquiere seconded. Drs. Jonas and de Blaquiere and Mr. Sperry were in favor, and Dr. Chopski was opposed; the motion carried.

Daniel Bellingham, Senior Director State Government Affairs, Healthcare Distribution Management Association (HDMA) presented public comment regarding proposed wholesale legislation. His discussion focused on the 2013 federal law: Drug Supply Chain Security Act, which is the second part of the Drug Quality and Security Act. Mr. Bellingham presented a time line, explaining that the Board will have to make changes to law periodically over the next decade, and he commended the Board for being one of the few proactive states who are currently revising state law pursuant to the new federal preemption. Although Mr. Bellingham had no suggested changes for the Board's draft language, Mr. Johnston alerted the Board to suggested changes in their agenda packet that were submitted by Idaho's Legislative Services Office (LSO).

The Board granted unanimous consent for the following changes suggested by LSO:

- 54-1734(c) – change 'not for resale' to 'but not for further distribution'
- 54-1734(g) – strike the "; and " and replace with a period.
- 54-1734(f) – unstrike the word "and"

Dr. Henggeler requested that the Board's staff review all uses of the term "not for resale", such as within proposed rule #144.

Upon returning from lunch, Chairman Henggeler call the meeting back to order at 1:04 p.m. Chairman Henggeler called for public comment regarding proposed legislation and clarified the Board would hear comment today, but not deliberate until tomorrow. The following people gave verbal testimony.

Mark Romer, ISU Pharmacy Student presented a compilation report of 40 pieces of public comment that were received pursuant to the official open, public comment period. Mr. Romer added his own public comment that included:

- Add outsourcing facility to rule 600.02
- Require outsourcing facilities to submit copies of all adverse event reports submitted to the Secretary of Health and Human Services
- Add language to the 2015 proposed rule 074 to inform the public that the distribution of compounded drugs applies for 'only human use'
- Add language referencing the 'purple book'

Troy Rohn, PhD, Professor Boise State University, holds a PhD in pharmacology, has researched Alzheimer's disease for the last twenty years, and has written a biotech white paper. Dr. Rohn said that biologic compounds can't be replicated as they are too large, too complex and produced in living cells, and he fears that biosimilars that are not exact could cause patient safety concerns, such as unwanted side effects. Dr. Rohn believes that the prescriber must be notified of a substitution. He reports that eight states have passed similar legislation with seven of those states requiring the pharmacist to contact the prescriber in the event of a substitution, Florida being the exception.

Dr. Patrick Knibbe, MD, a rheumatologist and President of the Idaho Chapter of the American College of Rheumatoid Arthritis, expressed concern over the complexity of biologics. Dr. Knibbe graciously answered numerous Board questions. He is in favor of notification edits to the proposed rules and noted that this is mainly a mail service pharmacy issue, as traditional retail pharmacies rarely dispense biologics. Dr. Knibbe states that substitution is often mandated by insurance companies who may take weeks to approve prior authorization request, so he is in favor of transition therapy. He believes this to be a cost and not a patient safety issue, and he therefore believes that the use of Dispense as Written to not be a valid alternative.

Matthew Murray, PharmD, rose in support of much of the Board's proposed compounding rules and presented numerous requests for change, including the use of the term "active pharmaceutical ingredient", the striking of COA's required by a US company, consideration of foreign country compendiums, certain record keeping changes, allowances for dispensing while sterility tests are performed, and use of certain hoods.

Elizabeth Criner, representing the American Cancer Society reiterated her August testimony, however they have not finalized recommendations. They support patient disclosure.

William Yoon, representing Sandoz Biopharm indicated that biologics are used in 50 countries. He distributed compromise language that was drafted by a number of brand name and biosimilar producing drug companies. Such language includes a notification/communication parameter. When questioned by Dr. Chopski about biosimiliars use in Europe, he was unable to comment.

Stephen Marmaras, Global Health Living Foundation (GHLF) appeared with patient, Stacy. They support active and direct communication between doctors and pharmacists. Dr. Henggeler asked if fax communication would suffice and Mr. Marmaras thought it would.

Bruce Lott, Vice President, Mylan, stood in support of his August testimony and the Board's proposed rules as written. He spoke of the difference between biosimilar and interchangeable FDA designations and that the FDA requires no change in bioavailability, efficacy or safety when approving biosimilars and imposes even more requirements for interchangeable products, such as after market study. He reported that 8 states recently rejected proposed changes that would mandate notification/communication, most recently PA. Of the 8 states that passed biosimilar language, 3 require notification, 3 sunset a notification parameter, and 2 have no real notification requirements.

Rich Palombo, RPh, Express Scripts, asked the Board to trust the FDA's science and future Purple Book listings. He believes the prescriber has ultimate control via the use of "dispense as written". He believes that patients have a right to choose their own therapy.

Woody Richards, Americas Health Insurance Plan (AHIP) supported the Board's draft and does not believe that this is a public health crisis as others would want the Board to believe.

Gino Grampp, representing Amgen, reported that there are safety issues with biosimiliars in Europe. As the FDA requires reporting of adverse events after market, he believes that notification/communication is very important, otherwise adverse events from one product might be reported under a different product's name. He spoke of the potential difficulty in sleuthing what product was dispensed, especially if dispensed via a mail service pharmacy. He explained that MA language is the result of a mandatory interoperable system by the year 2017, and he supports SureScript database sharing as a potential resolution to the notification/communication debate.

Ken McClure, JD representing the IMA and Amgen, submitted written testimony, mainly from local physicians who support notification/communication.

Kim Wynn, PharmD stood in support of her previously submitted written public comment regarding telepharmacy supervising pharmacist's practice location.

Misty Lawrence, Management Assistant, presented the Board's financial report. Ms. Lawrence indicated 31% of the current fiscal year has elapsed with approximately 29% of the appropriation having been expended. She presented the most recent audit report covering fiscal years 2009, 2010, 2011 and 2012 which showed no findings or recommendations; the two findings from the previous audit were satisfactorily resolved. Ms. Lawrence offered a review of the fiscal year 2016 budget request of $1.6 million. Of note is the request to replace the vehicle for the northern Idaho inspector and replace two office vehicles with one hybrid vehicle.

Rex Force, PharmD, and Paul Cady, Dean, RPh, MS, PhD, from Idaho State University College of Pharmacy (ISU) presented a request for waiver and extensions of variance regarding Bengal Pharmacy. In April 2014 the Board granted Bengal Pharmacy a variance from certain requirements of rules 710.10.d and 711 subject to conditions specified in the approval. Drs. Force and Cady are requesting the same considerations for the following:

- Provision of telepharmacy services into a remote dispensing site in Challis, ID as the owners of Village Square Pharmacy want to close, leaving more than 4300 residents without local pharmacy services.
- Provision of telepharmacy services into a remote dispensing site at Lost Rivers Medical Center clinic in Mackay, ID.
- Provision of telepharmacy services into a remote dispensing site at Adams County Health Clinic in Council, ID as their service was discontinued September 1 as the new owners of the supervising pharmacy declined to continue the service.

After extensive discussion and clarification, Dr. de Blaquiere motioned to approve the request with the following conditions:

- The PIC may not be designated for more than one remote dispensing site in addition to Bengal Pharmacy or two dispensing sites if not acting as the PIC of Bengal Pharmacy.
- Bengal Pharmacy must have available a pharmacist who is able to be on site at any of the remote dispensing sites the same day as needed.
- The ratio of pharmacists to student pharmacists and technicians may not exceed one pharmacist for every 5 student pharmacists and technicians in total in the operation of remote dispensing sites.

Dr. Chopski seconded the motion. Chairman Henggeler clarified all conditions placed on Arco apply to the additional locations. Chairman Henggeler called for the vote; all were in favor. The motion carried unanimously.

Mr. Johnston presented the Board staff travel calendar including Ms. Culley and Ms. Sommer attending STARS training in Denver and Teresa Anderson, PMP Program Information Coordinator, attending the Harold Rogers PMP meeting in Washington, DC in September and the Alliance/NASCA meeting in Atlanta in October. Mr. Johnston has taught several continuing pharmacy education programs, including in Sun Valley for ISHP's fall meeting. Mr. Johnston attended the NABP District meeting in Whitefish, MT with Drs. Chopski, de Blaquiere and Jonas and Mr. Sperry. He also attended the DEA Conference on Diversion in Kansas City, MO and the NABP Executive Director Interactive Forum in Chicago, IL. Mr. Johnston's future travel includes the ASPL meeting in Indian Wells, CA with Ms. McKay, the NABP Board Member Interactive Forum in Chicago, IL with Dr. Jonas, and the NABP Executive Committee meeting in December.

Mr. Johnston presented a request from Kevin Reddish, PharmD, to publish the names of registrants disciplined by the Board instead of just their initials. After discussion, Dr. Jonas motioned to publish the whole name of all discipline cases in the newsletter, and Mr. Sperry seconded. During discussion the Board directed Mr. Johnston to pen an article for publication in the other medical board's newsletters conveying the Board's concern with prescriber diversion, as evidenced by recent Board orders. Mr. Johnston indicated he also had a Power Point presentation regarding recordkeeping available if the other Boards' would like him to present to their registrants/licensees, as he has for dentists and veterinarians. Dr. Henggeler called for the vote: Mr. Sperry and Dr. Jonas for, and Drs. Chopski and de Blaquiere against. Dr. Henggeler broke the tie with a vote against, and the motion failed. Initials only will continue to be utilized.

Mr. Johnston presented a request from Andrea Lynch, PharmD, to modify the Board's policy on what can be changed on a schedule II prescription drug order to include adding the alpha quantity, if missing. After discussion the Board approved of the request and directed Mr. Johnston to republish the December 2012 Newsletter article, updated.

Dr. Jonas motioned to adjourn the meeting until 8:00 a.m. October 23, 2014, Dr. Chopski seconded, motion carried unanimously. The meeting adjourned at 5:41 p.m.

October 23, 2014

Chairman Holly Henggeler, PharmD, called the meeting to order at 8:05 a.m. In attendance were Board members Nicki Chopski, PharmD; Rich de Blaquiere, PharmD; Kristina Jonas, PharmD; and Ed Sperry, Public Member, as well as Mark Johnston, RPh, Executive Director; Nicole McKay, DAG; Fred Collings, Chief Controlled Substance Investigator; Lisa Culley, CPhT and Jaime Sommer, Compliance Officers; Ellen Mitchell and guests.

Staff provided the Board with public comment that was received since their supplemental Board packet was finalized 2 days prior through the end of the official 21 day comment period, 5pm the night before. The meeting paused, as the Board took some time to review this material.

Mr. Johnston presented draft language that incorporated the FDA's Purple Book into proposed Docket 27.0101.4201, pursuant to Mr. Romer's public comment. Mr. Johnston then discussed three potential options that would address the immense amount of public comment concerning pharmacist notification/communication back to the prescriber after the substitution of an FDA approved, interchangeable biosimiliar.

- The Board could approve of current proposed language that does not include notification/communication.
- The Board could add notification/communication language
- The Board could add compromise language submitted by Sandoz, language utilized by Massachusetts, or similar language that would impose some sort of notification with qualifiers.

Dr. de Blaquiere did not think that a notification/communication parameter was needed, as pharmacists and prescribers already work together, and he expressed confidence in the FDA's drug approval procedures. Mr. Sperry noted that it may be years before an FDA approved interchangeable biosimilar is approved and voiced that a notification/communication sunset provision is an option, as other states have done. Dr. Jonas also trusted the FDA and lists prescriber utilization of "Dispense as Written" as a viable option. Dr. Chopski believed that this issue is not one of a pharmacist choosing to dispense an interchangeable product but rather an insurance company mandating the dispensing of an interchangeable product; therefore she believed that the issue of notification/communication is best resolved by such third party payers and not the Board. Dr. Chopski noted that the Board does not often legislate to the fear of a potential issue, as in the case of notification/communication. Dr. de Blaquiere noted that this issue could be revisited if a need was proven and that the FDA requires biosimilars to be proven safe and effective, not just bioavailable as in the case of generic approval. Dr. Henggeler voiced support of language that excludes notification/communication and asked for a motion. Dr. Jonas motioned to approve language that includes the Purple Book and makes no other changes to the proposed language. Dr. de Blaquiere seconded. During discussion Dr. Chopski expressed that she was impressed and offended by the exaggerated campaign that produced a public belief that this is a public safety issue. Chairman Henggeler called for the vote, and all were in favor; the motion carried unanimously.

The Board debated the public comment of Matthew Murray, PharmD. After much discussion, which included foreign country compendiums and dispensing medications pending an ongoing sterility test, the Board directed Mr. Johnston to make the following changes to Docket 27.0101.1403:

- 239.02: Change all applicable uses of the term "bulk drug substances" to "active pharmaceutical ingredient".
- 239.02.b: Strike the requirement for a COA to be "issued by a firm located in the United States" and add "expired, returned, or disposed of" after "emptied".
- 239.05.b: Pursuant to a motion by Dr. de Blaquiere, a second by Mr. Sperry and a unanimous Board vote, strike "If any drug product analysis is conducted, records must be maintained in a readily retrievable manner".
- 241.01.c: add a provision that allows for a hood that re-circulates air back into the room, if the PIC or Director can provide written documentation attesting to the safety of such ventilation.

The Board asked William Silvius, PharmD, to come forward to discuss changes to Section 54-1733, Idaho Code, that were drafted in response to Dr. Silvius' August request. Mr. Silvius stood in favor of the Board's draft, and he stood for questions. Mr. Johnston explained that the project started as a request to approve nurse communication of a valid prescription drug order from a nursing home to a pharmacy electronically, as current law only allows such communication via fax or verbally. Subsequently, the project morphed into a complete revision of 54-1733, as many bills run by other entities have changed the statute over the years, and it no longer read concisely. Most changes are not substantive, but rather organizational, involve

terminology, etc. Additional substantive changes include allowing hospice nurses similar rights of communication. The Board approved of the draft with the following edits:

- Review all uses of the word “practitioner” for potential change to “prescriber”
- Rewrite the awkward and proposed 54-1733(5)(b)

The Board took up the matter of Richard M. Sutton, RPh, who was not in attendance and not represented by counsel. Colleen Zahn, DAG presented an Order Adopting Stipulation to Continue Hearing until the January 2015 meeting of the Board. Dr. Chopski motioned to accept the stipulation, and Dr. de Blaquiere seconded, and the motion carried unanimously.

The Board took up the matter of Brent Dion, PharmD, who was not in attendance and not represented by counsel. Ms. Zahn presented the Stipulation and Consent Order. Dr. Dion inadvertently provided a prescription to the wrong patient in January 2014. Dr. Dion also failed to counsel the patient’s mother even though it was a newly prescribed medication. Dr. Dion stipulated to a $500 fine and six additional CPE hours pertaining to prescription or medication error and/or patient counseling for the prescription error and a $500 fine for failing to counsel. Dr. Chopski motioned to accept the stipulation, Dr. de Blaquiere seconded, and the motion carried unanimously.

The Board took up the matter of Shelley Wray, NP, who was not in attendance and not represented by counsel. Ms. Zahn presented the Stipulation and Consent Order. Ms. Wray applied for a controlled substance registration in August 2014. She self-reported opioid dependence to the Board of Nursing in 2013 and was referred to Southworth Associates. Southworth submitted a letter to the Board office indicating Ms. Wray is compliant with her PRN program. Dr. de Blaquiere motioned to accept the stipulation, Dr. Jonas seconded, and the motion carried unanimously.

The Board took up the matter of Brett Zundel, PA who was not in attendance and not represented by counsel. Ms. Zahn presented the Stipulation and Consent Order. Mr. Zundel voluntarily surrendered his ability to handle schedule II controlled substances in January 2014. Mr. Zundel contacted Board staff in August 2014 to request reinstatement of his schedule II privileges for hydrocodone combination products only, when he learned that DEA was rescheduling such products from schedule III to schedule II. Dr. Chopski motioned to accept the stipulation, Mr. Sperry seconded, and the motion carried unanimously.

The Board took up the matter of Sarah Tarantino, PharmD, who was not in attendance and not represented by counsel. Scott Zanzig, DAG, presented the Stipulation and Consent Order. Dr. Tarantino received a prescription for DES (diethylstibesterol) 1 mg and substituted Estradiol 1 mg instead of. Dr. Tarantino stipulated to a $500 fine and six additional CPE hours pertaining to prescription or medication error. Dr. de Blaquiere motioned to accept the stipulation, Dr. Chopski seconded, and the motion carried unanimously.

The Board took up the matter of Melissa Tollinger, PharmD, who was not in attendance and not represented by counsel. Dr. Jonas recused herself due to a professional relationship with Dr. Tollinger. Scott Zanzig presented the Stipulation and Consent Order. Dr. Tollinger inadvertently filled a prescription with lisinopril and hydrochlorothiazide instead of benazepril and hydrochlorothiazide. Dr. Tollinger stipulated to a $500 fine and six additional CPE hours pertaining to prescription or medication error. Dr. de Blaquiere motioned to accept the stipulation, Mr. Sperry seconded, and the motion carried unanimously.

The Board took up the matter of Deborah Hollingsworth, NP, who was not in attendance and not represented by counsel. Scott Zanzig presented the Stipulation and Consent Order. Ms. Hollingsworth failed to maintain required controlled substance inventories at her clinic in

Emmett, dispensed medications to patients without obtaining a Prescriber Drug Outlet registration, did not maintain records of medications dispensed to patients, dispensed medication to herself and family, and stored controlled substances in an unregistered location. Ms. Hollingsworth stipulated to not order, handle, administer or dispense any controlled substances, including samples for office use, and she shall not store or maintain controlled substances in her home, office or car and shall abstain from personal use or possession of controlled substances except under the authority of another practitioner. Dr. de Blaquiere motioned to accept the stipulation, Dr. Chopski seconded, and the motion carried unanimously.

The Board took up the matter of H Keith Couch, DDS, who was not in attendance and not represented by counsel. Scott Zanzig presented the Stipulation and Consent Order. Dr. Couch failed to maintain required controlled substance inventories at his office in Idaho Falls, dispensed medications to patients without obtaining a Prescriber Drug Outlet registration, dispensed controlled substances to his family, and transferred controlled substances to an unregistered location. Dr. Couch stipulated to not order, handle, administer or dispense any controlled substances, including samples for office use, and he shall not store or maintain controlled substances in his home, office or car and shall abstain from personal use or possession of controlled substances except under the authority of another practitioner. Mr. Sperry motioned to accept the stipulation, Dr. Jonas seconded, and the motion carried unanimously.

The Board took up the matter of Evan Hathaway, DDS, who was not in attendance and not represented by counsel. Dr. Jonas recused herself due to a professional relationship with Dr. Hathaway. Scott Zanzig presented the Stipulated Amendment to Stipulation and Consent Order. Dr. Hathaway requested reinstatement of his schedule II prescriptive authority due to the DEA's rescheduling of hydrocodone combination products from schedule III to schedule II. Dr. Hathaway stipulated that he shall be permitted to prescribe, but not administer or dispense schedule II drugs. Dr. Chopski motioned to accept the stipulation, Dr. de Blaquiere seconded, and the motion carried unanimously.

Case #15-015 was vacated.

The Board took up the matter of Joshua Deiss, PharmD. Dr. Deiss attended the meeting without counsel. Chairman Henggeler disclosed a professional relationship with Dr. Deiss and announced that she will not vote in the event of a tie or comment during the proceedings, though she will still preside. Dr. Henggeler swore Dr. Deiss in prior to his testimony. Dr. Deiss requested Board approval for an inactive pharmacist license and thus discontinuation of his current Board order. He explained that retail pharmacy was currently detrimental to his successful completion of his recovery, so he quit his job. He recently accepted a teaching position at CWI, and he feels his current salary cannot cover the cost of the PRN program. He requested to have an inactive license in lieu of failing to fulfill his PRN requirements and having his license revoked. The Board deliberated and generally felt that inactive status was not appropriate for this situation, that Dr. Deiss would benefit from continued PRN enrollment, and that the costs were not prohibitive. Dr. Henggeler called for a motion. Dr. Chopski motioned to deny the application, and Mr. Sperry seconded. After discussion, Mr. Sperry offered a substitute motion to delay a decision for six months, and Dr. Jonas seconded the substitute motion. After more discussion, Chairman Henggeler called for the vote, and all were opposed; the motion failed. Dr. Chopski restated her original motion to deny the application, and Dr. de Blaquiere seconded and clarified Dr. Deiss can reapply at regular intervals. Chairman Henggeler called for the vote, and the motion carried unanimously. Dr. Deiss indicated he wanted to voluntarily surrender his license and left the meeting.

The Board considered public comment from Kim Wynn, PharmD, requesting a rule change that would allow a pharmacist to supervise a remote dispensing site from another remote dispensing site, not just from within the supervising pharmacy. The Board delayed action on her request for one year, so that ISU could first open the multiple sites for which they were granted waivers and then determine if such operation was feasible and in the best interests of public safety.

The Board considered written public comment from Lyman Holyoak, PharmD, who requested that the performance of a prospective drug review be added to proposed rule #146: repackaging. After much discussion, the Board declined to make such a change.

The Board considered part of the written and verbal comment submitted by Mr. Romer concerning outsourcing facilities and readily agreed to add “outsourcing facility” to rule 600.01 and 600.02.

The Board took up the matter of Mark Wright, DDS. Dr. Wright attended the meeting telephonically without counsel. Chairman Henggeler swore Dr. Wright in prior to his testimony. Dr. Wright requested his controlled substance (CS) registration be returned to unconditioned status as he has complied with the Board’s Order from 2012. Dr. Chopski motioned to approve his request and restore his CS registration to unconditioned status, and Dr. Jonas seconded; the motion carried with Mr. Sperry opposed.

The Board considered additional public comment from Mr. Romer concerning outsourcing facilities and readily agreed to clarify that proposed rule 074 pertains to drug products for human use only. After discussion, the Board also directed Mr. Johnston to draft a provision in proposed rule 740 mandating that outsourcing facilities report to the Board all adverse event reports submitted to the Secretary of Health and Human Services.

The Board took up the matter of Alesia Caranto. Ms. Caranto, Certified Technician applicant, attended the meeting without counsel. Board staff denied Ms. Caranto’s application for a certified technician based on notification of a drug related crime within the application. She appealed to the Board for approval. After hearing that Ms. Caranto was remorseful, the crime involved illicit drugs only, and she had completed the criminal probation period, Dr. Jonas motioned to approve the application. Mr. Sperry seconded, and the motion carried unanimously.

The Board took up the matter of P Allen Frisk, RPh. Mr. Frisk attended the meeting without counsel. Mr. Frisk recounted circumstances that led to his voluntary surrender of his license and asked the Board to reinstate. Mr. Johnston clarified Mr. Frisk had submitted a complete application with the required amount of CPE. After hearing from Mr. Frisk, Mr. Sperry motioned to reinstate Mr. Frisk’s license upon successful completion of a 72 hour evaluation, PRN enrollment and compliance with any recommendations from PRN. Dr. Jonas seconded, and after more discussion Chairman Henggeler called for the vote; the motion carried unanimously.

Chairman Henggeler asked Mr. Johnston to resume the agenda item entitled inspector Q & A. Mr. Johnston explained that the 2014 Idaho Legislature, via resolution, directed the Idaho Department of Health and Welfare to create a telemedicine council, in response to the Idaho Board of Medicine’s recent discipline of a physician involved in such a practice. The council has been meeting regularly and has requested Mr. Johnston’s appearance and explanation of Section 54-1733(1), Idaho Code, which was penned by the Board a decade ago to combat illegal internet prescription dispensing. Mr. Johnston is concerned that the Board will be looked upon negatively by the council, as the Idaho Board of Medicine has used the statute to back their disciplinary decision. The Board agreed that the statute itself is not the issue, but rather the Board of Medicine’s interpretation of the statute. The Board directed Mr. Johnston to support the legalization of telemedicine in Idaho, if implemented in a step wise approach with

warning of unintended consequences that might arise from the changing of 54-1733, which has worked for a decade to combat egregious, illegal activity.

Mr. Johnston discussed a recent development in the Board's licensing department. It was discovered that a certified technician had allowed her PTCB national certification to expire, but she continued to work and maintain registration as a certified technician. This prompted Mr. Johnston to request PTCB to supply the names of all Idaho technicians with expired national certification. The list that PTCB delivered was quite long. Mr. Johnston asked the Board for guidance and potential delegated authority to discipline. After much discussion, the Board was more concerned with application renewal falsification than a lapse in certification during the fiscal year. Dr. de Blaquiere was concerned with consistency, relating this issue to a pharmacist falsifying a renewal application when continued pharmacy education requirements were not met, and he believed that it was the Board's responsibility to track such lapses, not the PIC. Dr. Chopski made a motion to:

- Have the Board identify all currently registered technicians with lapsed certifications for all Board recognized national certification entities, not just PTCB.
- Send all lapsed certified pharmacy technicians, their PIC, and their employer a letter indicating that the technician has 30 days to become re-certified.
- Promulgate a rule in 2016 that grants the Board authority to cancel a certified pharmacy technician registration if it has lapsed.
- If a certified technician works past the 30 day warning period, the Board delegates the Board's staff to stipulate to a $100 fine and notice for hearing if the technician is unwilling to stipulate.
- If a certified technician has falsified an application due to the lapsing of national certification, the Board delegates the Board's staff to stipulate to a $250 fine and to notice for hearing if the tech is unwilling to stipulate.
- Investigate if the Board's licensing software can be adapted to upload certification certificates upon renewal.

Mr. Sperry seconded. After more discussion, Dr. Henggeler called for the vote. Dr. Chopski and Mr. Sperry were in favor of the motion, and Dr. de Blaquiere and Dr. Jonas voted against the motion. Dr. Henggeler broke the tie with a vote in favor of the motion, which carried.

The inspectors had no further items of discussion.

Mr. Sperry left the meeting at 4:00 p.m.

The Board considered the public comment from Silver Valley Veterinary Clinic, requesting an alternative warning addition to rule 140.12, as rule 140.12 pertains to prescription labels for human use. The Board readily agreed and directed Mr. Johnston to pen such changes.

The Board considered public comment from Dawn Berheim, PharmD, requesting an exemption for intra-company sales from many of the proposed requirements of distributing pharmacies in rule 270. The Board agreed to exempt intra-company sales from the proposed controlled substance reporting parameter only: 270.06. Mr. Johnston proceeded to explain some inconsistencies between the Board's proposed wholesale distribution changes to Idaho code, requirements of an outsourcing facility, and distributing pharmacies. The Board directed Mr. Johnston to make necessary changes to proposed rule and statute to ensure consistency in the regulation of drug distribution, regardless of the type of drug outlet.

Dr. Chopski detailed potential issues that she wanted Mr. Johnston to review for potential change, including the definition of agent, the use of "manufacture" vs "manufacturing", the title "discipline of registration", and the use of "prescriber" vs "practitioner".

Mr. Johnston noted that proposed statute changes that involve fingerprinting, the prescription monitoring program, and controlled substance scheduling, as well as certain rules within Docket 27.0101.1404, were not discussed at this two day meeting, so the language would move forward to the 2015 Idaho Legislature without change.

Dr. Jonas motioned to adjourn, Dr. Chopski seconded, motion carried unanimously. Meeting adjourned at 4:49 p.m.