MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
June 7-8, 2017

Board Office/Oxford Suites
Boise, Idaho

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

Chairman Kristina Jonas, PharmD, called the meeting to order at 1:00 p.m. In attendance were Board members Rich de Blaquiere, PharmD; and Holly Henggeler, PharmD. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Fred Collings, Chief Investigator; Lisa Culley, CPhT, Jaime Thompson, and Wendy Shiell, Compliance Officers; Andy Snook, Deputy Attorney General; Erik Sevillano, IT Systems Integration Analyst; Misty Lawrence, Management Assistant; Ellen Mitchell, Program Information Coordinator, and several members of the public.

Dr. de Blaquiere motioned to approve the April 13-14, 2017 minutes with discussed corrections. Dr. Henggeler seconded, and the motion carried unanimously.

Dr. Henggeler motioned to grant delegated authority to allow the executive director to add a $2,000 fine to facilities and a $500 fine to individuals as a penalty for failure to pay an administrative fine within a required timeframe, and that non-payment of fines to be paid within 30 days. Dr. de Blaquiere seconded, and the motion carried unanimously.

The Board took up the matter of the Consent Agenda, which contained the following matters:

- Board Performance Dashboard
- Travel Calendar
- Exercises of Delegated Authority
- Director's Expenses

Dr. de Blaquiere motioned to remove the Dashboard and the Travel Calendar for further discussion. Dr. Henggeler seconded, and the motion carried unanimously. Dr. de Blaquiere motioned to approve Exercises of Delegated Authority and Director's Expenses. Dr. Henggeler seconded, and the motion carried unanimously.

Dr. Adams congratulated the compliance team for completing its 18 month inspection cycle and exceeding the state's goal for both pharmacies and prescriber drug outlets. Given the difficulty of navigating the state with the unusually difficult winter, meeting and exceeding the goal was a major success for the agency. Dr. Adams also noted a significant increase in Prescription Monitoring Program (PMP) use (which has nearly doubled with the introduction of Gateway®), and pharmacist PMP registrations, now at 99.7%. The increase is a result of House Bill 5, which requires pharmacist PMP registration with an effective date of July 1, 2017. Mr. Fraser explained the copious efforts to have all pharmacists with a Controlled Substance Registration registered with the PMP prior to renewal of their pharmacist license.

Dr. de Blaquiere requested Teresa Anderson provide an update on PMP trends across the nation, as she has attended several PMP related meetings recently. Ms. Anderson indicated there are many conversations in the community about a national PMP system, though a vendor has not been named. She also mentioned Wisconsin and a few other state PMPs are collecting data on opioid overdoses, overdose deaths, and controlled substance related arrests. The states that are collecting this data are 'home grown' systems, built by each individual state. The Board thanked Ms. Anderson the update. Following a brief discussion, Dr. de Blaquiere motioned to accept the Dashboard and Travel Calendar. Dr. Henggeler seconded, and the motion carried unanimously.

Misty Lawrence presented the Board's financial report:

- As of May 31, 2017, 92% of the fiscal year has elapsed and 67% of the budget has been expended.
- No Capital Outlay (CO) expenses have been expended as of yet. The agency received $10,050 from the sale of 2 vehicles and that is earmarked for installation of visual equipment in the meeting room.
- $250,000 is slated for a new licensing system. The Board received a carryover appropriation to use the money in the FY18.
- Personnel Costs (PC) are 87% expended, and the agency is anticipating reverting $1,200.
- Operating Expenditures (OE) are 58% expended. Several contracts will be finalized in the next few weeks. The building lease for the remainder of FY17 and FY18 is $86,000; Appriss (PMP) contract is $62,000; the first month of credit card fees for the new fiscal year is $15,200; GLS (current licensing system) annual licensing fees are $70,000. These amounts plus the regular monthly expenses will bring the budget close to 100% expended.
- FY17 started with a cash balance of $2,411,780. The current cash balance exceeds this by $162,500 due to the increase in revenue flow in May.
- Currently trending at 19% increase in revenue over last year at this time, we are expecting to end the year with a 7-9% increase. Last year we were up 7% over the previous year.

Dr. Chopski arrived at 1:25 p.m. Mr. Sperry arrived at 1:40 p.m.

The Board took up the matter of Appeals and Reinstatements.

Samuel C. Flegal, PharmD attended the meeting without legal counsel. He is requesting reconsideration of his reciprocity application from Oklahoma. Board staff was unable to approve his application based on disciplinary action in his home state. Dr. Flegal indicated he has been out of the practice of pharmacy for three years, though he has kept current on his continuing pharmacy education (CPE). Following discussion Dr. de Blaquiere motioned to allow the application to move forward pursuant to the condition of a five year PRN contract. Dr. Chopski seconded. Following discussion, Dr. de Blaquiere amended his motion to allow the application to move forward contingent upon a five year Pharmacist Recovery Network (PRN) contract with Southworth Associates, a letter of support from the Oklahoma PRN program, verification of CPE hours (one year lookback to meet Idaho requirements),

continued compliance with PRN, not act as the Pharmacist-in-Charge (PIC) for the duration of PRN contract, comply with all state and federal laws, notify the Board of intent to work outside of Idaho, not work at more than two locations, and not work more than 40 hours per week. Dr. Chopski seconded, and the motion carried unanimously.

Chad Jungert, RPh, owner of Irwin Drug in Grangeville, attended the meeting without legal counsel to request reinstatement of his PIC privileges and clarification of the technician ratio as it relates to his compounding lab. Following discussion the Board concluded Dr. Jungert's compounding lab and compounding technician can be supervised by the existing video cameras. The rules do not specify 'direct supervision' and his compounding technician is included in the pharmacist to technician ratio.

Dr. Jungert's license was reinstated in February 2016, though he indicated that he did not return to work until July 2016. He has been compliant with his PRN contract as evidenced by a letter from Southworth Associates. He indicates it is a burden on his business for him to not be able to be the PIC. Following discussion Dr. Henggeler motioned to approve Dr. Jungert being PIC of his pharmacy. Dr. Chopski seconded, and the motion carried unanimously.

Damian Dugger, Pharmacy Technician-in-Training applicant, attended the meeting without legal counsel. Mr. Dugger originally appeared before the Board in 2015 as Board staff was unable to approve his application due to previous criminal history. The Board issued an order following his appearance at the 2015 meeting denying his application. Following discussion Mr. Sperry motioned to approve the application. Dr. de Blaquiere seconded. Following further discussion, Chairman Jonas called for the vote. Motion carried with Dr. Henggeler opposed.

Jason Dalling, PharmD attended the meeting without legal counsel to request release from his Board Order. Dr. Dalling entered into a five year contract with Southworth Associates and has successfully completed all the requirements included in the contract as well as his Board Order. Following discussion Dr. de Blaquiere motioned to release Dr. Dalling from the conditions of his Order. Dr. Henggeler seconded. Following a brief discussion, Chairman Jonas called for the vote, motion carried unanimously.

Brad Stoick, RPh attend the meeting without legal counsel. Dr. Henggeler recused herself. Mr. Stoick updated the Board on his progress, indicating he has been working steadily and continuing to heal from his skiing accident. Following a brief discussion the Board granted unanimous consent for Mr. Stoick to apply for renewal of his pharmacist license and controlled substance registration.

Chairman Jonas requested Erik Sevillano research the possibility of the Board creating a mobile application for the agency's law book. Mr. Sevillano presented his research, which indicated the cost of an application capable of providing the Board's law book in digital format ranged from $25,000 to $35,000 with an annual maintenance cost of 20% of the upfront cost. Alternatively, the cost of redesigning the Board's website to make it 'mobile friendly' would range from $10,000 to $15,000 without a perceived increase to maintenance costs. During the month of research, 20% of visitors accessed the website and law book using mobile devices, the law book was downloaded 210 times. Considering these factors, staff's opinion is the current cost of acquiring an application is too high for the potential

number of downloads, though modifying the website to be more user friendly would potentially increase downloads in the future.

Having finished its anticipated caseload early, the Board briefly discussed Chapter 4 of its proposed rules, regarding Pharmacist Prescriptive Authority. The Board reviewed general considerations that would apply to all drugs or devices the Board considers, specifically primary care provider notification, the need for a legitimate patient-prescriber relationship, etc. Dr. Krystalyn Weaver noted that the Board's articulated general requirements follow the Patient Care Process adopted by the Joint Commission of Pharmacy Practitioners.

Mr. Sperry motioned to amend the agenda to include an executive session as an agenda item. Mr. Sperry based his motion on recently obtained information he believed served as basis for amending the agenda to add an executive session. The purpose of the proposed executive session would be to evaluate a current employee and consider the hiring of a new employee, pursuant to Idaho Code Sections 74-206(1)(a) and (b), respectively. Dr. Chopski seconded, and the motion carried unanimously.

Mr. Sperry motioned to enter executive session as allowed by Idaho Code 74-206(1) (a) and (b) as they relate to the evaluation of current employee and the consideration of hiring a new employee. Dr. Chopski seconded, and the motion carried unanimously following a rollcall vote. The Board entered executive session at 4:30 p.m. Dr. de Blaquiere motioned to leave executive session. Mr. Sperry seconded, and the motion carried unanimously. Executive session ended at 4:57 p.m. The Board made no decisions during executive session and no motions were brought following the executive session.

Dr. Henggeler nominated by motion, Dr. Chopski to serve as Chairman effective July 1, 2017. Dr. de Blaquiere seconded, and the motion carried unanimously.

Dr. Chopski nominated by motion, Dr. Jonas to serve as Vice Chairman effective July 1, 2017. Mr. Sperry seconded. Following discussion, Dr. Chopski amended her motion to nominate by motion Dr. Henggeler. Mr. Sperry seconded, and the motion carried unanimously.

Mr. Sperry motioned to adjourn, Dr. de Blaquiere seconded, and the motion carried unanimously. Meeting adjourned at 5:04 p.m.

June 8, 2017 – Oxford Suites, Boise, Idaho

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

Chairman Kristina Jonas, PharmD, called the meeting to order at 9:00 a.m. In attendance were Vice Chairman, Nicki Chopski, PharmD; Board members Rich de Blaquiere, PharmD; and Holly Henggeler, PharmD. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Lisa Culley, CPhT, Jaime Thomas, and Wendy Shiell, Compliance Officers; Andy Snook, Deputy Attorney General; Misty Lawrence, Management Assistant; Ellen Mitchell, Program Information Coordinator, and several members of the public.

Chairman Jonas asked Dr. Adams to discuss House Bill 212 which provides prescriptive authority to certain psychologists. Section 54-2320 specifically requires the Board of Pharmacy to recommend a pharmacist for the advisory panel. Dr. Adams suggested Stephen Carlson, PharmD for the nomination. Dr. Carlson works at Intermountain Hospital and has extensive knowledge in the area of mental health. Following a brief discussion Dr. Henggeler motioned to nominate Dr. Carlson. Dr. de Blaquiere seconded, and the motion carried unanimously.

Dr. Adams provided a brief overview of the rule book arrangement. It had originally been proposed as five chapters, though as the project has progressed a few chapters have been added. The new proposed chapters are as follows:

1. Rules Governing Procedure
2. Rules Governing Licensure and Registration
3. Rules Governing Pharmacy Practice
4. Rules Governing Pharmacist Prescriptive Authority
5. Rules Governing Compounding
6. Rules Governing DME, Manufacture and Wholesale
7. Rules Governing Veterinary Drug Outlets

The Board has dedicated extensive time this year to reviewing proposed rule language, and has been through all of the revised chapters at least in a high level capacity. Dr. Adams noted that today's meeting will focus primarily on Chapters 1 and 3. Drafts of both of these chapters had been made available to members of the public through the Public Meeting Materials posted in advance of the meeting, and hard copies were provided to interested members of the public who were in attendance. Redlined versions were also reviewed. The Board welcomed public participation throughout the day, and incorporated many suggestions that were provided by members of the public.

Dr. Adams noted that an official notice of intent to promulgate rules was published in the June 7, 2017 edition of the Idaho Administrative Bulletin. The Board published this notice earlier than usual to give sufficient notice to the public of the upcoming session. The Board also provided more detail than usual of the proposed changes in the notice, given the scope of this year's rulemaking. Dr. Adams further noted that he's scheduled meeting individually with relevant stakeholder groups to provide them with an in-depth overview of the proposed rulemakings so that they are prepared for the officially noticed negotiated rulemaking session in August.

Dr. Adams noted that today's discussion is an outgrowth of its March meeting related to "permissionless innovation." At that meeting, the Board provided direction to re-focus the relevant rules on the "practice of pharmacy" not the "business of pharmacy" and to remove business model and technology specifics, instead focusing on "what" must occur.

The Board reviewed the following proposed additions to Chapter 1, 024. Unprofessional Conduct:

- "Standard of Care" - Dr. Adams explained the language for Standard of Care is based on Board of Medicine (BOM) and Board of Nursing (BON) language and will be the basis for disciplinary action when patient care doesn't meet the care that

would be provided by others in the profession. The Board granted unanimous consent to include this definition as written.

- "Unnecessary Services or Products" – This is also based on language from BOM and BON and is carved out to address the possible ethical dilemma where a pharmacist may prescribe and then dispense a product that may be unnecessary. The Board granted unanimous consent to include this definition as written.
- "Identification of Support Personnel" – following a brief discussion this section may be moved to another section or struck.

During a review of Chapter 3 - Rules Governing Pharmacy Practice, the following changes were approved by the Board:

- 100.03 – change 'pharmacist' to 'person,' which reflects that the PIC at a prescriber drug outlet may be a prescriber.
- 101.01.b – limited the requirement for an alarm only to non-institutional drug outlets that stock controlled substances.
- 101.03 – removed 'in accordance with USP-NF requirements' from the language about drug storage and replaced it with language that notes drugs must be stored 'appropriately to safeguard product integrity'.
- 101.06 – added language to note that this controlled substances disposal rule applies to controlled substances 'that are owned by the drug outlet' and does not relate to drug takeback programs that collect for destruction unused or unwanted drugs from individual patients. The latter is covered by proposed rule 216(02).
- 102.04 – changed to 'verification of dispensing accuracy must be performed to compare the drug stock selected to the drug prescribed. If verification of dispensing accuracy is not performed by a pharmacist or prescriber an electronic verification system must be used that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label.' This edit reflects that the electronic verification can occur at any step in the dispensing process and does not need to be used in conjunction with the 'final' check.
- Added 103.c 'Any function that requires the use of a pharmacist's or prescriber's professional judgment must be checked by a pharmacist or prescriber.'
- 104 – added 'When the services being performed are related to prescription fulfillment or processing, the drug outlet must comply with the following' to note that the requirements listed for offsite pharmacy services are not intended to apply to offsite vaccination clinics or similar clinical services.
- 104.02 – removed 'common' from the title and removed 'Audit Trail Documentation' requirements as this duplicates a requirement that is proposed in the Electronic Recordkeeping System rule.
- 105.05 – changed to 'Stocking and replenishing drugs in an alternative designated area may be performed by:
    i. A pharmacist or prescriber; or
    ii. Appropriate support personnel using either an electronic verification system or a two person checking system.'
- 106.01.a – added 'with an adequate number of views' to the requirements for video surveillance at a drug outlet without at onsite pharmacist (such as a remote dispensing site).

- 106.05-6 – removed ‘designated’ which implied that only a pharmacist who had been named in advance could respond to an emergency at a drug outlet without at onsite pharmacist.
- 201.03 – Noted that the tampering is ‘at the time of presentation’ and that this rule is not intended to prevent a pharmacist from marking a controlled substance prescription, such as adding a missing element in consultation with a prescriber.
- 201.07 – modified to read ‘An institutional drug order may exempt the patient’s address, the dosage form, quantity, prescriber’s address, and prescriber’s DEA registration number,’ which carries on all the current exemptions from institutional drug orders in the current rulebook.
- 204.03.b – removed language regarding emergency refills for controlled substances; this would allow only the emergency refill of a non-controlled substance.
- 205.02 – removed ‘and does not increase the cost of the drug’.
- 205.03 – replaced ‘historical’ with ‘sufficient’ and added ‘the change’.
- 207.01 - amended the transfer rules to coincide with federal law changes; a member of the public noted that DEA is currently revisiting federal rules so the Board felt it would be least disruptive to coordinate with federal law.
- 213.03 – added that the government identification necessary to satisfy the positive identification requirement for the dispensing of a controlled substance must be ‘valid’.
- 215.01 – added ‘as long as appropriate measures are taken to ensure product integrity’ to reflect that some new methods of delivery (e.g., drones) may not be suitable for certain environmental conditions and products.
- 301.03 – added ‘Drug outlets that utilize offsite pharmacy services for product fulfillment or processing must track the identity and location of each individual involved.’
- 400.01- removed obsolete language related to user accounts.

Chairman Jonas thanked the members of the public for their extensive and beneficial feedback, and called for any final public comment. Ryan Fuchs, Idaho State University pharmacy student, expressed his excitement and appreciation of the direction the Board is taking with the rules. He believes the practice of pharmacy will become more innovative with this approach. The Board thanked him for attending the meeting and participating in the discussion.

The Board will reconvene in July to review all updated rule drafts in an open, public meeting prior to the officially noticed negotiated rulemaking session.

Hearing no further discussion Dr. Henggeler motioned to adjourn. Mr. Sperry seconded, and the motion carried unanimously. Meeting adjourned at 4:18 p.m.