MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
January 12-13, 2017

Holiday Inn – Boise Airport
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; Holly Henggeler, PharmD; and Ed Sperry, Public Member. 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 Sommer and Wendy Shiell, Compliance Officers; Misty Lawrence, Management Assistant; Andy Snook, Deputy Attorney General; Ellen Mitchell, Program Information Coordinator, and several members of the public.

Dr. Chopski motioned to accept the minutes of the October 26-27, 2016 meeting as written. Dr. Henggeler seconded, and the motion carried unanimously.

Chairman Jonas exercised her discretion in re-ordering the agenda and asked Dr. Adams to provide an update on the status of current Board legislation and rules. Dr. Adams indicated the Board rules were heard by the House Health & Welfare committee on Wednesday and all five of the rule dockets were approved in full. There were a few questions regarding telepharmacy and whether they are required to report to the PMP. The Board's rules will be reviewed by the Senate today at 3:00 p.m. Mr. Fraser will sit in for Dr. Adams during the Board meeting if it is not finished by the start of the Senate hearing.

There was a question regarding Docket 27-0101-1603, specifically Board Rule 330.03 and the level of supervision required during technician immunization. Dr. Adams provided the following draft interpretation of supervision for the Board's review:

> For the purposes of pending rule 330.03 in rule docket 27-0101-1603, supervision requires the supervisor to be physically present and immediately accessible."

Following a brief discussion Dr. Chopski motioned to adopt the interpretation as written. Dr. de Blaquiere seconded, and the motion carried unanimously. Dr. Chopski mentioned it may be a good time for the Board to review 'supervision' and how it is used in the entirety of the law book.

Dr. Adams noted that all of the Board's proposed agency bills will be introduced to the House Health & Welfare committee tomorrow morning at 9:00 a.m. RS24894 is amending 54-1704 to add tobacco cessation products to the list of products that

pharmacists may prescribe. Dr. Adams shared comments from the Idaho Board of Medicine. Following a brief discussion the Board decided to move ahead with the existing language. The Board noted that it reviewed the evidence on the safety and effectiveness of the products, as well as the outcomes achieved in other jurisdictions that allow pharmacists to prescribe these products. In consideration of this evidence, the Board believes its existing bill is well-tailored to achieve public health outcomes for Idahoans. The Board directed Dr. Adams to follow-up with the Board of Medicine, and to thank them for their feedback, as well as for their continued partnership around areas of mutual interest.

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. Adams highlighted the pharmacists' use of PMP through the Board's online platform is 8%, with the use of PMP Gateway® cumulative use is now at 27%. Currently Gateway® is only being used by Fred Meyer/Smiths stores in Idaho.

Dr. de Blaquiere motioned to approve the Board Performance Dashboard, the Travel Calendar, and the Director's Expenses, and removing the Exercises of Delegated Authority for discussion. Dr. Chopski seconded, and the motion carried unanimously.

Dr. de Blaquiere indicated he had asked Board staff to add the Delegated Authority code to the spreadsheet to make clear what authority had been used. Following a brief discussion, Dr. de Blaquiere motioned to approve the Exercises of Delegated Authority, Mr. Sperry seconded, and the motion carried unanimously.

A review of the upcoming meetings on the Travel Calendar resulted in the following:

- Dr. Henggeler will attend the NABP Annual meeting in Orlando and is interested in the National Drug Abuse conference
- Mr. Sperry will attend both the NABP Annual meeting and the Northwest Convention in Coeur d'Alene
- Dr. Jonas will attend the NABP Annual meeting
- Dr. de Blaquiere will attend the Northwest Convention
- Dr. Chopski will attend the NABP Annual meeting, possibly the Northwest Convention and is interested in the APhA meeting

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

- First Pharmacy Associates LLD dba Riverpoint Pharmacy – Failed to renew their mail order pharmacy license in a timely manner and shipped 138 prescriptions to Idaho patients during the time they were unlicensed. The facility also operated without an Idaho licensed/registered pharmacist-in-charge. By signing the Stipulation and Consent Order Riverpoint Pharmacy agrees to pay $20,000 in administrative fines.

- Walgreens #10314 – Closed four hours earlier than their posted hours. By signing the Stipulation and Consent Order Walgreen Pharmacy agrees to pay $2,000 in administrative fines.

- Walgreens #12503 – Employed a pharmacist without a Controlled Substance Registration as their pharmacist-in-charge. By signing the Stipulation and Consent Order Walgreen Pharmacy agrees to pay $2,000 in administrative fines.

- Ciara Minor, PharmD – Worked as a pharmacist/pharmacist-in-charge for Walgreen 12503 without a Controlled Substance Registration. By signing the Stipulation and Consent Order she agrees to pay $200 in administrative fines.

- Samuel D. Gardner, DO – Received a 1,000 count bottle of phentermine and a 500 count bottle of zolpidem at his registered address. Dr. Gardner failed to obtain a Prescriber Drug Outlet registration, failed to maintain proper dispensing records, failed to report dispensations to the PMP, and removed the medication from his registered location to his home address. By signing the Stipulation and Consent Order Dr. Gardner agrees to not store, maintain, or dispense any controlled substances, including samples, in his office, home, automobile, or any other area. He also agrees to abstain from the personal use or possession of controlled substances, except those prescribed, administered, or dispensed to him by another so authorized by law who has full knowledge of his history.

- Timothy G. Biediger, PharmD – Filled a prescription for clorothiazide 250 mg with chlorthalidone. He adjusted the dosage of the chlorthalidone to match the dosage of clorothiazide 250 mg as ordered by the prescriber. Dr. Biediger did not counsel the patient's parent who picked up the medication. The patient became seriously ill and was transported to the local emergency room. By signing the Stipulation and Consent Order he agrees to pay $2,000 in administrative fines, costs incurred by the Board for a hearing officer, and $433.18 for the Board's prosecuting attorney's expenses, and a seven day suspension of his license and registration.

Dr. Henggeler motioned to remove the Stipulation and Consent Orders for Walgreens 10314 and Dr. Biediger; and accept the Stipulation and Consent Orders for First Pharmacy Associates, Walgreens 12503, Ciara Minor, and Samuel Gardner. Dr. Chopski seconded, and the motion carried unanimously.

Following a brief break the Board took up the matter of Walgreens 10314.This is the second time a Walgreens Pharmacy has closed due to a lack of staff. Following discussion Dr. Chopski motioned to accept the Stipulation and Consent Order. Dr. Henggeler seconded, and the motion carried unanimously.

The Board took up the matter of Timothy G. Biediger. Following a brief discussion Dr. de Blaquiere motioned to amend the Stipulation and Consent Order and reduce the fine to $1,650, add completion of 'Patient Safety and Medication Error Prevention for Pharmacy' program provided by Oregon State University at a cost of $350, the Board prosecutor's out of pocket expense of $433.18, and a seven consecutive day suspension of his license and registration. Dr. de Blaquiere amended his motion to add the suspension is to be served within thirty days of the Order being fully executed. Dr. Henggeler seconded. Following a brief discussion, Chairman Jonas called for the vote, and the motion carried unanimously.

The Board took up the matter of the Administrative Complaint Hearing regarding Tony D. Wright, PharmD. Dr. Wright attended the hearing telephonically without legal counsel. Carl Withroe, DAG attended to represent the Board. It is alleged Dr. Wright refilled a controlled substance prescription four days after the initial fill, which should have lasted for ten days. Early filling of controlled substance prescriptions violates IDAPA 27.01.01.116.01.a. which reads "A pharmacist, utilizing his best professional judgment, may dispense a prescription drug that is not a controlled substance up to the total amount authorized by the prescriber including refills." Dr. Wright is also accused of unprofessional conduct as defined by IDAPA 27.01.05.500.06 which reads in part, "failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents or labeling."

Chairman Jonas swore Fred Collings, Chief Investigator, and Dr. Wright in and asked for opening statements. Mr. Withroe indicated the early refill was identified by Mr. Collings during a review of Unsolicited Reports (UR) run by Board staff. He indicated the computer system used in the pharmacy by Dr. Wright didn't alert him to the early refill. Dr. Wright doesn't believe he is in violation of the above mentioned rules as there is no definition of 'early refills' and he did follow the directions of the prescriber. Following testimony by Fred Collings, Chief Investigator, and Dr. Wright the Board began deliberations. Following deliberations Dr. de Blaquiere motioned to find Dr. Wright not to be in violation of the rules as stated in the complaint. Motion died for lack of a second. Following further deliberations Dr. de Blaquiere motioned to find Dr. Wright is not in violation of the rules as stated in the complaint and there be no penalty assessed. Dr. Henggeler seconded. The vote resulted in Drs. Henggeler and de Blaquiere in favor of the motion, with Dr. Chopski and Mr. Sperry opposed. Chairman Jonas broke the tie voting in favor of the motion, finding no violation of the rules as stated in the complaint.

The Board took up the matter of Theodore Kalkreuth, PharmD. Dr. Kalkreuth attended the meeting with his legal counsel, Steve Lamberson. Dr. Kalkreuth is requesting the Board approve his reciprocity application as staff was unable to approve it based on prior criminal history. Mr. Lamberson explained Dr. Kalkreuth does not have a felony conviction, it is instead a deferred judgement. Judgement has been deferred for 24 months, upon completion of the 24 month period with no criminal activity the charges will be dismissed. Following questioning by the Board, Dr. Henggeler motioned to accept the application once letters of good standing have been received from Washington and Colorado boards of pharmacy. The motion died for lack of a second. Following a brief discussion, Dr. de Blaquiere motioned to proceed with the application, Mr. Sperry seconded, and the motion carried unanimously.

Following a brief break the Board took up the matter of Margarita Baird. Ms. Baird attended the meeting telephonically without legal counsel. Ms. Baird is requesting the Board approve her Pharmacy Technician in Training application as staff was unable to approve based on prior criminal history. Ms. Baird was forthcoming with information for the Board and answered several questions. Mr. Sperry motioned to accept the application, Dr. de Blaquiere seconded, and the motion carried with Dr. Henggeler opposed.

The reinstatement hearing for Elizabeth Cameron, NP was vacated due to a lack of appearance by the respondent.

The Board took up the reinstatement hearing for Shelly Wray, NP. Ms. Wray attended the meeting telephonically without legal counsel. She is asking the Board to remove the restrictions placed on her Controlled Substance Registration on October 23, 2014. Following questions from the Board, Dr. Chopski motioned to remove the conditions and restrictions on Ms. Wray's registration and return it to an unconditioned status. Dr. de Blaquiere seconded, and the motion carried unanimously.

Mr. Fraser presented the Board with three draft policies, Conflict of Interest Policy, Email Records Retention Policy, and Meeting Travel Summary Policy. The Conflict of Interest Policy formalizes what Board members have done in the past when they have recused themselves from hearing specific topics or cases. When a Board member recuses themselves they are to remove themselves from the dais. The Email Records Retention Policy is designed to ensure records are kept by Board staff consistent with other state policies. The Meeting Travel Summary is a brief document to be completed by Board members and/or staff when traveling to meetings, trainings, or conferences. This brief recap will assist in determining the benefits of attending such functions. Following a brief discussion Dr. de Blaquiere motioned to approve all three policies as written, Dr. Henggeler seconded, and the motion carried unanimously.

Misty Lawrence, Management Assistant presented the Board's financial packet.

- As of December 31, 2016, 50% percent of the fiscal year has elapsed and 41% of the budget has been expended. There hasn't been any Capital Outlay (CO) expenses as of yet. The sale of 2 vehicles resulted in $10,050 that will be used to set up the conference/board room the remaining $250,000 in CO is for a new licensing system. Staff has been meeting with Division of Purchasing on a weekly basis to complete the RFP for the licensing system. There is one more next week to finalize a few items and then it will be posted.

- Personnel Costs are 49% expended with approximately $30,000 in one-time salary savings due to vacancies and delays in filling the IT position. The CEC distribution instructions generally arrive in March and staff will determine if salary savings is usable.

- Operating Expenses are 41% expended. Budget to expenses are in line for the current period. Of note, the Board will experience about $10,000 in savings from delaying the move into the new space until February 17. These funds will likely go toward the final set up of the space. The space is complete, the final city inspection took place yesterday with the final occupancy permit to arrive shortly. The audio/ visual solutions are slated to be in place prior to the March meeting.

- The current Cash Fund balance is $2,290,100. Disbursements are still exceeding revenue though the gap is much smaller.

- Reports are showing a 6% increase in revenue over this same period last year.

- Controlled Substance Registration renewal period resulted in 96.6% of registrants renewed on time.

- The Governor's recommendation to JFAC differs in employee benefit costs as estimates are used to create the budget and the actual costs are realized after the budget submission. The other variance is in the CEC line item because we use a 1% multiplier in the budget request but the Governor's recommendation is 3%.

- There are 2 additional line items in the budget revision that was submitted November 22, 2016. Item 4.30 is a supplemental request for $60,000, for FY17 (current year) appropriation and Item 12.03 is $180,000 for FY18. Both are line items are for required spending authority to contract with Health and Welfare to facilitate uptake in PMP Gateway® use by prescribers and pharmacists.

Dr. Henggeler shared the Pharmacy Technician Immunization training is going well. The technicians are excited about the opportunity. Dr. Adams was able to stop by during a training and noted the excitement of the technicians in being part of a historic change in their practice.

Dr. Adams returned to the meeting and provided the Board an update on today's legislative hearing before the Senate Health & Welfare committee. All five rule dockets were approved by the Senate. With both House and Senate approval, the Board's rules are poised to take effect upon adjournment of the legislature, which is anticipated to be March 24, 2017.

Dr. Henggeler motioned to adjourn, Mr. Sperry seconded, and the motion carried unanimously. Meeting adjourned at 4:08.

January 13, 2017 – Holiday Inn Boise Airport

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

Chairman Kristina Jonas, PharmD, called the meeting to order at 10:00 a.m. In attendance were Vice Chairman, Nicki Chopski, PharmD; Board members Rich de Blaquiere, PharmD; Holly Henggeler, PharmD; and Ed Sperry, Public Member. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Lisa Culley, CPhT, Jaime Sommer and Wendy Shiell, Compliance Officers; Misty Lawrence, Management Assistant; Andy Snook, Deputy Attorney General; Sharon Treese, Wendy Muir, and Sarah Kosty, Licensing Specialists; Ellen Mitchell, Program Information Coordinator, and several members of the public.

Dr. Adams presented information relating to a new licensing system and a review of current licensing deadlines.

In 2016, Board staff began working on a Request for Proposals (RFP) to identify a licensing system that best meets the agency's needs now and in the future. With an anticipated build-out of a new system for FY18, staff believes this as an opportune time to discuss potential changes to existing licensure process.

Dr. Adams presented a memo detailing research and considerations with respect to licensure renewal deadlines, with a goal of better balancing internal workload and revenue collection throughout the fiscal year. He noted that the Board may conclude that the current model is the best model for Idaho, though staff believes it is beneficial to have the conversation. The memo was a collaborative staff effort, with significant input and assistance from the licensing and compliance teams.

In considering the experiences of other state Boards of Pharmacy, as well as the other health regulatory boards in Idaho, Board staff identified twelve (12) potential licensing models for consideration. Board staff performed simulations on each of the twelve (12) models to project the monthly case load for renewals and the resulting monthly revenue. Data for each of the models was presented for the Board's consideration. Board staff recommends Birth Month Model 3, which they believe maximizes the benefits to the agency's workload and revenue while minimizing the downsides. Under this model:

- All individual licenses would be due for renewal by the end of the individual's birth month;
- All facility licenses would be due for renewal by December 31st.
- Both facilities and individuals would have a 60 days period to renew their license/registration (this would be modified from the current 10 week period)
- The late renewal period would remain as is -- up to 30 days from expiration date.
- Any license/registration lapsed by more than 30 days would require a full reinstatement application (including new fingerprints) and a new license/registration would be issued.

Following a discussion of the various models, the Board granted permission to move forward with drafting statute and rule changes to implement Birth Model 3 renewal process.

Dr. Adams next presented three (3) additional opportunities to streamline workload by reforming three license types for the Board's consideration:

1. **Technician-in-Training Renewals:**
   Technician-in-Training registrations may currently be renewed twice. Thus, depending on the initial date of registration, the total duration a technician may remain in training status is variable. One option for consideration is creating a one-time technician-in-training registration with a two-year duration from the date of issue. This would standardize the length an individual may be a technician-in-training. In addition, all technicians-in-training need an association to an employer and Board staff has to routinely cancel registrations when such an association is terminated. Under the proposed model, technicians-in-training would be held to the same requirements as any other licensee (e.g., notifying Board staff of an employment change within 10 days).

Following discussion the Board granted permission to move forward with drafting rules to modify the Pharmacy Technician-in-Training to be a two-year, non-renewable registration with the notification requirements of other licensees. Dr. Adams will work with staff to make this change budget neutral.

2. **Non-Pharmacy Retail Outlets:**
   The Board has 1,186 licensed non-pharmacy retail outlets. These include gas stations and other retailers that sell over-the-counter products to the public. Only Idaho and Arizona are known to require this type of registration. Dr. Adams noted that Board compliance officers have historically struggled to ensure all entities are licensed and inspected regularly.

Mr. Snook offered clarification on unlicensed activity indicating the statute must specifically say the Attorney General's Office has jurisdiction and if it doesn't the process starts with the local authority either county or city officials. If Board staff doesn't

have inspection authority over a facility it would prohibit the requirement for the facility to provide records, but would not prohibit staff from visiting the facility to see if they had expired medications on the shelves.

Following an extensive discussion that included questions about public safety and the limited inspection staff, the Board asked Dr. Adams to conduct additional research and provide the information at the April meeting.

3. **Pharmacist Controlled Substance Registration:**
   Through our conversations with NABP, DEA, NAMSDL, and others, we have identified that Idaho is among a minority of states that require a controlled substance registration – in addition to pharmacist licensure -- in order to dispense controlled substances.

Following a brief discussion the Board granted permission to draft language to strike the Pharmacist Controlled Substance Registration.

Board staff also puts forth for consideration five (5) concepts to enhance clarification in license types. While these are not specifically geared towards staff workload and revenue collection, these would help address confusion amongst both staff and licensees.

1. **Interns vs. Externs:**
   A common source of confusion in licensing is the difference between an "extern" and "intern" license defined below). Following a brief discussion the Board granted permission to draft language to strike the extern registration and condense it with interns.

2. **Inactive Status**:
   While inactive pharmacists are exempt from continuing education requirements, the licensee must go through the traditional reinstatement process in order to return to an active license. Thus, there is no real advantage of an inactive license relative to having no license.

Following a brief discussion the Board granted permission to draft language to strike the inactive pharmacist status, while grandfathering in the current inactive pharmacists.

3. **Create a Student Pharmacy Technician Registration Category:** Board Rule 40 requires technicians to be at least eighteen (18) years of age and be a graduate of a high school or the recipient of a high school equivalency diploma. The rules of the Board currently permit age and education waivers to be granted by the Board's executive director. A student pharmacy technician registration would allow individuals who are enrolled in a high school or technician training program to register without the need for an education waiver.

Following discussions the Board granted permission to move forward with drafting language to create a student technician category, and to also lower the minimum age for certified technicians and technicians-in-training to sixteen (16).

4. **Registered Pharmacists:**
   Another common area of confusion is when out-of-state pharmacists must be licensed or registered to practice into the state. These instances are reviewed in Rule 29. Dr. Adams noted that as the business and technology environments change, it is becoming increasingly nuanced and difficult to determine if an individual must be licensed or if they may be registered to practice into Idaho. As an example, an out-of-state pharmacist performing centralized pharmacy services at a long-term care facility that is not registered as a pharmacy must be licensed; however if that facility ships a single product into the state, the pharmacist may be registered as opposed to licensed.

   Dr. Adams noted that Board staff's recommendation is that if a nonresident individual is working for a non-resident facility registered with the Board, only the PIC must be licensed or registered. If a nonresident individual is working independently across state lines, the individual must be licensed by the Board.

Following an in-depth discussion the Board granted permission to draft language to clarify when a pharmacist must be licensed versus registered to practice into Idaho, in accordance with the staff recommendation.

5. **Prescriber Drug Outlet (PDO):**
   Currently, prescriber drug outlets (PDOs) do not have to designate a PIC or director under Idaho law. Board staff has observed several recent disciplinary cases involving PDOs and feels that designating a point person who is responsible for compliance is a beneficial step toward improving patient safety. It may also be beneficial to further clarify that PDOs are expected to adhere to all pharmacy requirements, including dispensing only when the prescriber is present.

During discussion Ms. Sommer suggested these facilities be inspected prior to being issued a registration. The Board agreed that going forward the facilities would have an on-site inspection prior to a registration being issued and granted permission to move forward with drafting language to require a director for PDO facilities. The director must be an Idaho licensed prescriber with valid DEA and Idaho Controlled Substance registrations as appropriate.

Next, Dr. Adams noted that if the Board moves to a birth month model of renewal for individual pharmacist licensees, some changes may be necessary to the current continuing education requirements in order to enable staff to audit appropriately and efficiently. Staff believes that the carryover of unused credits would be extremely difficult to enforce in a birth month renewal model, as the carryover month would vary per individual.

In reviewing NABP's Survey of Pharmacy Law, Board staff identified several other areas of the current continuing education requirements in Idaho laws that are among the minority of states. These include the educator exemption, law requirement, sterile compounding requirement, live training requirement, and CME acceptance.

In addition, Dr. Adams drew a distinction between Board-led and Board-approved continuing education:

1. Board-led CPE – such as a law program led by the Executive Director, or a home study program developed by the Board and available on the Board's website; and
2. Board-approved CPE for private organizations such as pharmaceutical manufacturers, in which Board staff is asked to review a program for appropriateness and lend its stamp of approval.

Following an extensive discussion the Board was in favor of streamlining the continuing education to fifteen (15) hours of ACPE-approved credit, with no other delineated requirements. The Board also requested additional research on this topic to include the cost of ACPE accreditation for what we currently distinguish as Board-led programs.

Dr. Adams reviewed two additional miscellaneous topics. Currently, a facility must complete a Drug Outlet Registration form to register an Automated Dispensing System (ADS). There is no fee required with this registration, and all ADS's are covered by this rule. By contrast, federal law requires an ADS to be registered with the DEA *only* at an off-site location, such as a long term care facility, and *only* if the ADS is used for routine dispensing. In addition, the Board currently has a registration for nursing homes with a fee of $35. We do not currently inspect nursing homes, and it is most common for nursing homes to be serviced by an off-site pharmacy and/or an ADS. Following discussion the Board granted permission to draft language striking the nursing home registration and harmonizing the ADS registration with federal law.

Current Idaho law requires mail service pharmacies to meet certain hour and day restrictions under rule 730. This matter has been raised by several mail service and specialty pharmacies as difficult to achieve under current business operations. Idaho shares this law with several states. Following a brief discussion the Board requested additional research on this topic for presentation at the April meeting.

Dr. Adams thanked Board staff and the licensing team for their input on these topics and their continued dedication.

The Board took up the agenda item Counseling Documentation. Of note was the article published by the Chicago Tribune on December 15, 2016. The article was an account of how Midwest pharmacies responded when a patient presented with prescriptions that, when taken together, could cause the patient significant harm. Mr. Fraser indicated he and the compliance officers had discussed the article and counseling at great length. He would like to create a secret shopper program to obtain hard data for Idaho. Dr. de Blaquiere believes a newsletter dedicated to the topic of patient counseling is in order.

During the discussion the Board directed compliance staff to collect two random prescriptions including documentation of counseling during each inspection. The data may be used for surveying compliance and possible discipline.

At the conclusion of the discussion the Board directed staff to approach the topic of counseling from an educational standpoint and they will revisit the topic at a future meeting. The compliance team will conduct a spot audit of prescription records to obtain a baseline on counseling.

Hearing no further business Mr. Sperry motioned to adjourn, Dr. de Blaquiere seconded, and the motion carried unanimously. Meeting adjourned at 4:47 p.m.

MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
March 9, 2017

Holiday Inn – Boise Airport
Boise, Idaho

This meeting of the Board was held to discuss the Board's strategic plan for fiscal year 2018.

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; Holly Henggeler, PharmD; and Ed Sperry, Public Member. 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; Misty Lawrence, Management Assistant; Andy Snook, Deputy Attorney General; Ellen Mitchell, Program Information Coordinator, and several members of the public.

Dr. Adams presented a proposed work plan for 2017 that started with the licensing strategic discussion that was conducted during the January meeting, and continues with today's strategic discussion on "permissionless innovation." The first draft of the new licensing rules resulting from these discussions will be reviewed in April and again in July. Draft rules resulting from today's meeting will be part of the statewide listening sessions and continuing education programs, and will be reviewed by the Board in June and July. Both work streams will culminate in negotiated rulemaking in August, and proposed rulemaking in October. The Board was supportive of Dr. Adams' proposed timeline.

In preparation for the today's discussion Board members read the book *Permissionless Innovation: The Continuing Case for Comprehensive Technological Freedom* by Adam Thierer. The Board discussed permissionless innovation in the context of regulating the profession of pharmacy. The Board noted that technology, education, and training continue to evolve and have spurred some new models of care that have increased safety and improved public health substantially. Rules hindering such innovations can thus hurt public health. Dr. Adams noted that it is important to understand that permissionless innovation does not imply there should be no regulation, but instead focuses on *optimal* regulation by also acknowledging that technology and services are subject to control by market mechanisms including, but not limited to:

- Consumer acceptance and demand
- Payer credentialing and policies (e.g., prior authorizations)
- Private accreditation and credentialing
- Facility policies
- Liability insurance and the threat of civil suit
- Provider comfort level and self-restraint

Market mechanisms work in tandem with regulations and jointly help protect the public while enabling practice up to a provider's clinical ability.

In discussing one innovative model, Don Klepser, PhD, MBA an associate professor at University of Nebraska Medical Center College of Pharmacy, presented information related to a study he was involved in where flu and strep throat tests were offered by pharmacists, who were then empowered to prescribe based on the results of the test and the patient's clinical presentation. The study showed that 35% percent of the patients who sought care in the pharmacy didn't have a primary care doctor; about 40% were seen at night and on weekends (outside of normal physician office hours); and 96% were satisfied after being seen by pharmacists for strep and flu. Dr. Klepser indicated the pharmacists only treated low risk patients. Patients with high or low blood pressure, respiratory distress, and pregnant women were referred to physicians. Some of the challenges of testing at the pharmacy include finding a collaborating prescriber. Dr. Klepser noted that states are starting to look at moving this more to an autonomous model of care given the strong results that have been achieved. Dr. Klepser further mentioned that one common concern regarding the model was the theoretical impact on antimicrobial resistance; Dr. Klepser noted that the model actually led to more judicious use of antimicrobials, as pharmacists do a great job of following

protocols. One study estimated a 40% to 60% decrease in overall antimicrobial use under the pharmacy model relative to traditional medical care.

The Board also discussed several concepts related to adapting a prescription, including:

1. Extending a prescription for continuity of care;
2. Changing dosage forms/dose/quantity; and
3. Formulary compliance.

During discussion Dr. de Blaquiere noted the pharmacist has become the communication tool between the physician's office and the patient. The pharmacy faxes refill requests to the office and passes on messages from them to the patient. The Board directed Dr. Adams to draft language so it defers to the professional judgement of the pharmacist in these situations.

Dr. Adams broached the topic of regulatory enforcement for pharmacist prescribing. Instead of preparing drug-specific continuing education, he offered Idaho Board of Nursing's language, which states that the practitioner must only prescribe for drugs for which he or she is "educationally prepared and for which competence has been achieved and maintained" as a starting point. Mr. Sperry believes the market will create training for various medications. Dr. Paul Cady, dean of the ISU College of Pharmacy, indicated each professional is responsible to maintain their professional competence. Dr. Henggeler supports the concept as it would increase access, she wants to be certain public safety is addressed.

Moving forward the Board may consider adding verbiage to rule 500: Unprofessional Conduct. Idaho Board of Nursing has language that allows enforceability in instances in which there is a "substantial departure from established and customary standards of care which, under similar circumstances, would have been exercised by a licensed peer". The Board supported adding similar language to rule 500.

Dr. Adams introduced the topic of optimizing the Board rulebook. There are a handful of opportunities to strategically trim the rulebook to enable innovation, while preserving the Board's top priority--protecting the public:

- Streamline areas in which market mechanisms provide sufficient checks and balances;
- Minimize duplication from federal law while preserving enforceability;
- Cluster and consolidate similar rules;
- Focus on "practice of pharmacy" issues, not "business of pharmacy" issues; and
- Create a cohesive framework for centralization of services.

Dr. Adams suggested the organization of the rulebook in chapters as follows:

1. Rules of Procedure of Board of Pharmacy (modest change)
2. Rules for Licensure and Registration (update in progress)
3. Rules Related to the Practice of Pharmacy (truncate)
4. Rules Related to Pharmacist Prescribing (new)
5. Rules Related to Compounding, Manufacturing, and Distribution (no change)

Following discussion the Board was supportive of the reorganization of the rulebook as presented by Dr. Adams, with the exception of moving compounding from Chapter 5 to Chapter 3.

Anne Lawler, executive director of the Board of Medicine (BOM) presented information on how BOM regulates based on a "standard of care" in disciplinary cases and the benefits and challenges that such a model presents, along with information regarding corrective action plans. Ms. Lawler indicated Idaho Code 54-1814(7) is used frequently by her Board in disciplinary cases. It states, "the provision of health care which fails to meet the standard of health care provided by other qualified physicians in the same community or similar communities, taking into account his training, experience and the degree of expertise to which he holds himself out to the public". Basing action on a standard of care requires BOM staff to identify professionals in the community that can speak to how a patient was treated and if that treatment is in line with the way other professionals of similar training and experience would have treated the patient. These professionals are called on to consult as the Board investigates a case and, if needed, to act as expert witnesses. Standard of care

may be one way in an urban area and very different in a rural area, and thus it is important to choose these expert witnesses carefully. Ms. Lawler shared a complaint showing the Board how a complaint would be written. She provided examples of how the standard of care can change over time, and noted the benefit of such a regulatory model is avoiding constant updates to rules to keep pace with such changes. Ms. Lawler indicated BOM uses hearing officers for Administrative Hearings and the Board creates the disciplinary documents. BOM hearings and disciplinary actions are done in executive session and are not public. They also have their own in-house attorney to prosecute their cases. BOM has recently started using a Corrective Action Plan (CAP) in some cases. The CAP is signed by the executive director versus the board chair and allows for requiring licensees to attend educational classes without having official disciplinary action. As it isn't official or formal action, it is not required to be reported to the National Practitioner Data Bank (NPDB). If the respondent doesn't agree to the CAP, staff still has the option to pursue a Stipulation and Order.

The Board thanked Ms. Lawler for her information and was appreciative of her presentation.

Dr. Adams addressed the topic of delegated authority versus a CAP. Staff would need clear direction as to which of the delegated authority may be addressed as CAP in the future. Dr. Adams and Mr. Snook will research the issue and bring information to the April meeting.

Dr. Adams introduced the concept of creating a cohesive framework for centralization. As the technology environment unfolds, new businesses models will emerge that are unknown today but will yield significant improvements in patient care. Historically, states have brought such business models or technology vendors before the Board, and if permission is granted, regulations are written for that specific business model or technology that soon becomes outdated. Some examples include:

- 290: ADS Systems: Minimum Standards
- 291: ADS Systems: Self-Service Systems
- 292: ADS Systems: Institutional Facilities
- 320: Pharmacist: Independent Practice
- 321: Technician: Remote Data Entry Sites
- 610: Centralized Pharmacy Services
- 640: Institutional Facility: Offsite Pharmacy Practice Standards
- 641: Institutional Facility: Offsite Services – First Dose Pharmacy
- 650: Institutional Facility: Centralized Pharmacy Services
- 710: Retail Telepharmacy With Remote Dispensing Sites

An alternative approach would be creating a framework of "what" needs to occur (e.g., receipt of prescription order, drug use review, product verification, counseling, audit trail documentation, inventory), regardless of "where" or "how" it occurs. Enhancements could be added for certain variables, such as controlled substance storage vs. no controlled substance storage, on-site vs. offsite supervision, etc. This could create a permissive environment that does not require the Board to approve each and every innovative business model or technology as long as it adheres to the framework of "what" needs to occur.

The Board was generally supportive of the approach, and asked Dr. Adams to draft rules to that effect. The Board discussed starting aggressively with the framework and giving the public ample time to comment and suggest things to add back in versus the Board's usual approach of chipping away slowly at a topic.

Dr. Chopski motioned to adjourn the meeting, Dr. de Blaquiere seconded. The motion carried unanimously, meeting adjourned at 3:06 p.m.

MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
April 13-14, 2017

Capitol Building
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; Holly Henggeler, PharmD; and Ed Sperry, Public Member. 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; Carl Withroe, Deputy Attorney General; Ellen Mitchell, Program Information Coordinator, and several members of the public.

Dr. Henggeler motioned to approve the January 12-13, 2017 minutes with minor corrections. Mr. Sperry seconded, and the motion carried unanimously.

Dr. Chopski motioned to approve the March 9, 2017 minutes as written. Dr. Henggeler 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. Henggeler motioned to approve the Consent Agenda minus the Exercises of Delegated Authority document. Dr. de Blaquiere seconded, and the motion carried unanimously. Following discussion, Dr. Henggeler motioned to accept the Exercises of Delegated Authority document, Dr. de Blaquiere seconded, and the motion carried unanimously.

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

- Lucas Snell, PharmD – During the annual inspections of Luke's Family Pharmacy in 2015 and 2016 the inspector noted outdated drug products in the pharmacy's stock of anticipatory compounded products. The Board has the authority to impose an administrative fine of $2,000 per occurrence. However, by signing the Stipulation and Consent Order, Dr. Snell agreed to pay a $1,000 administrative fine.

- David W. Tomey, PA – Entered into a Stipulation and Order with the Board of Medicine agreeing to take record keeping and pain management classes as well as other conditions outlined in the Order. By signing the Board of Pharmacy Stipulation and Consent Order, Mr. Tomey agreed to perform a PMP check on each patient prior to providing any opioid prescriptions and documenting such search.

- Walgreens 04942 – Failed to pay a previously imposed administrative fine. By signing the Stipulation and Consent Order they have agreed to pay an additional $500 administrative fine in addition to the previously assessed fine of $1,000 within 30 days of the date the Order is signed.

- Walgreens 05565 – Failed to pay a previously imposed administrative fine. By signing the Stipulation and Consent Order they have agreed to pay an additional $500 administrative fine in addition to the previously assessed fine of $2,000 within 30 days of the date the Order is signed.

Mr. Sperry motioned to approve the Consent Agenda with the exception of both Walgreens cases and Lucas Snell. Dr. de Blaquiere seconded, and the motion carried unanimously. Dr.

Adams provided the Board with an email from Dr. Snell requesting his fine be lowered. Following a brief discussion, Dr. Henggeler motioned to accept the Stipulation as written, Dr. Chopski seconded, and the motion carried unanimously.

In the matter of Walgreens 04942, Mr. Sperry motioned to reject the Stipulation and replace the $500 fine with a 24 hour suspension of pharmacy operations. Dr. Chopski seconded. During discussion Dr. de Blaquiere expressed his surprise that the fine was so low. Following discussion, Mr. Sperry withdrew his motion. Dr. de Blaquiere motioned to reject both Walgreens 04942 and Walgreens 05565 Stipulation and Consent Orders, Dr. Chopski seconded, and the motion carried unanimously.

Dr. Adams sought direction from the Board for future stipulations of this nature. The Board suggested that in future cases of failure to pay an administrative fine within the required timeframe, the Board would assess a $2,000 fine for facilities, or a $500 fine for individuals.

The Board took up the matter of Alan Maxwell, RPh. Mr. Maxwell attended the meeting without legal counseling. He is requesting the Board remove the restrictions on his pharmacist license, returning it to a non-conditioned status. Following discussion Dr. Henggeler motioned to grant Mr. Maxwell's request, Dr. Chopski seconded, and the motion carried with Mr. Sperry abstaining.

The Board took up the matter of Richard Pines, DO. Dr. Pines attended the meeting with legal counsel Dan Skinner. Dr. Pines' Controlled Substance Registration was revoked on July 17, 2013, he is requesting the Board allow reinstatement of his registration. Following a brief presentation by Mr. Skinner, Dr. Henggeler motioned to mirror the Board of Medicine (BOM) Order, Dr. de Blaquiere seconded. During discussion Mr. Snook commented the Board may consider mirroring only the relevant BOM prescribing conditions, if any. Following further discussion Dr. Henggeler amended her motion to grant reinstatement of Dr. Pines' Controlled Substance Registration without conditions upon a completed application and that there are not extraneous issues, Dr. de Blaquiere seconded, and the motion carried unanimously.

The Board took up the matter of Kenneth Blackner, MD. Dr. Blackner attended the meeting with legal counsel J.D. Oborn. Dr. Blackner's Controlled Substance Registration was restricted January 20, 2015 for controlled substance record keeping violations. Dr. Blackner is requesting his Controlled Substance Registration be returned to a non-conditioned status. Following a brief presentation by Mr. Oborn, Dr. Chopski motioned to remove the restrictions on Dr. Blackner's registration, Dr. Henggeler seconded, and the motion carried unanimously.

Dr. Adams presented the Board's financial report.

- As of March 31, 2017, 75% of the year had elapsed and 56% of the budget had been expended. There have been no Capital Outlay (CO) expenses, though there is $10,050 from the sale of two vehicles that will be used to set up the conference/board room; the remaining $250,000 will go toward a new licensing system. The Board received carryover appropriation to use the $250,000 in the next fiscal year.

- Personnel Costs (PC) are 72% expended with $28,000 in one-time salary savings due to vacancies and delays in filling the IT position. Change in Employee Compensation (CEC) has been distributed according to a matrix that used each employee's evaluation and comp-ratio to determine increases. Due to salary savings increases were effective March 26.

- Operating Expenditures (OE) are 51% expended. The building contract, Appriss contract, and the licensing system renewal contract are all outstanding. Once these contracts are in place, the expenditures will be in line with the timing of the year.

- The fiscal year began with a cash fund balance of $2,411,780. Disbursements are still exceeding revenue, though this should even out after renewals begin later this month.

- The budget is currently in line this time of year. Currently trending an 8.2% increase in revenue over last year at this time and a 14.9% increase in expenditures

Chairman Jonas asked Dr. Adams to frame the discussion of Corrective Action Plans (CAP). Anne Lawler, executive director of the Board of Medicine (BOM) presented information to the Board at their March 2017 meeting, indicating BOM had begun using CAP this past December as a way to regulate registrants and licensees without formal discipline. Dr. Adams indicated CAP would be a subset to the Delegated Authority (DA) that has already been granted by the Board. Exercises of DA have traditionally been reported to HPDB as disciplinary action, whereas CAP would be an informal agreement between Board staff and the registrant/licensee and wouldn't carry a monetary penalty of more than $250. In a case where CAP was not successful, the Board still has the authority to pursue a Stipulation and Consent Order or go to hearing.

Following the lunch break the Board took up the matter of Andrew Welch Reinstatement Hearing. Mr. Withroe informed the Board that Mr. Welch's attorney, Mr. Pendlebury had emailed him indicating Mr. Welch was withdrawing his application for reinstatement. Neither Mr. Welch nor Mr. Pendlebury will be appearing today. Dr. Chopski motioned to vacate the agenda item, Dr. Henggeler seconded, and the motioned carried unanimously. Mr. Sperry commented that Mr. Welch had withdrawn a previous application, Mr. Snook will review current policies to determine when Mr. Welch will be able to request reinstatement again.

During the March 2017 meeting of the Board, the Board asked Mr. Snook to research the Board's authority relating to unlicensed practice of pharmacy in Idaho. Currently, the Board's authority to impose discipline is limited to those persons or entities with, or applying for the issuance or reinstatement of, a license or registration issued by the Board. If a licensee or registrant were to engage in the unlawful practice of pharmacy, the Board has the authority to discipline the license or registrations. However, if a person or entity who is not licensed or registered with the Board engages in unlawful practice of pharmacy, the Board wouldn't have any authority to discipline that person or entity. These types of cases would fall under the jurisdiction of local law enforcement or the US Food and Drug Administration or the US Drug Enforcement Agency. If the Board desires to expand its authority to encompass any persons or entities practicing pharmacy in, or into, Idaho, regardless of licensure or registration, statutory amendments would be needed. Such amendments could be similar to the Idaho Board of Veterinarian Medicine or the Idaho Public Contractors License Board where, generally, administrative authority extends beyond licenses to the actual individual or entity that holds, or should hold, the license. The Board decided no action would be pursued regarding this in the upcoming year.

The Board held a brief discussion on House Bill 191, which passed the legislature near unanimously (69-0; 33-1), which grants the Board rulemaking authority to designate which drugs, drug classes, or devices pharmacists may prescribe, as long as they fall within the statutorily authorized parameters. The Board discussed drafting some general requirements related to education, patient-prescriber relationships, notification, etc.

Dr. Henggeler motioned to adjourn, Dr. Chopski seconded, and the motion carried unanimously. Meeting adjourned at 3:08 p.m.

April 14, 2017 – State Capitol – Senate Majority Caucus Room

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; Holly Henggeler, PharmD; and Ed Sperry, Public Member. 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; Ellen Mitchell, Program Information Coordinator; Erik Sevillano, IT Systems Integration Analyst, and several members of the public.

Chairman Jonas asked Dr. Adams to frame the discussion regarding License Statutes and Rules. A full discussion on the Board's direction was held in January and detailed in the January minutes. Board staff worked diligently to update rule language pursuant to the Board's direction, and copies of the drafts were made available to members of the public online in advance of the meeting.

The Board requested the addition of the following definitions to Chapter 1:

- Accreditation Council for Continuing Medical Education (ACCME)
- Continuing Medical Education (CME)
- Flavoring agent

The Board requested the following changes to Chapter 2:

- 021.07 Reinstatement of License or Registration: Add ‘consideration of a request for reinstatement’ and ‘as applicable’ after fingerprint card

- 023. Fee Schedule
  - License and Registrations—Professionals: Include ‘Student Technician’ in the fee for technicians at $35
  - License or registration reinstatement fee changed to ‘one-half of the amount of the annual renewal’
  - Add Administrative Services fees for experiential hours certification and duplicate pharmacist certificate of license

- Add 035.02 to describe CME credits that may be acceptable, and cap the amount of CME at three (3) hours

- 038.02.a add ‘Following graduation, if a pharmacist license application has been submitted, the pharmacist intern license will be extended at no cost for up to six (6) additional months from the date of application as a pharmacist, after which time the individual will need to submit a new application to continue to be a pharmacist intern.’

- 038.02.b add ‘be obtained’

- 041.02 & 043.03 add ‘The Board’s executive director may grant a brief extension for the purposes of employment continuity to a technician-in-training who is awaiting the completion of the education requirement necessary to become a certified pharmacy technician.’

- Add 050.03.a Temporary Pharmacy License Issued Prior to Operation. Upon request on a Board form, the Board may issue a temporary pharmacy license prior to the pharmacy being open for business provided that the applicant owns another registered pharmacy in Idaho and has designated a PIC. Prescription drugs may not be delivered to the pharmacy until successful completion of a new drug outlet inspection.

- 050.05 add ‘record’ of controlled substances

Idaho State University student pharmacists James Hunt and Mervan Newbold presented a rule concept to the Board regarding the addition of a diagnosis code to each prescription. After discussion, the Board tasked staff with additional research.

Hearing no further discussion Mr. Sperry motioned to adjourn, Dr. Chopski seconded, and the motion carried unanimously. Meeting adjourned at 3:57 p.m.

MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
July 12, 2017

Conference Call
Idaho State Board of Pharmacy Office
Boise, Idaho

This meeting of the Board was held to discuss the Board's draft rule dockets in advance of the August negotiated rulemaking session as well as potential agency legislation for the 2018 Legislative session.

Chairman Nicole Chopski, PharmD called the meeting to order at 7:00 a.m. Roll call of those attending telephonically included Board member Rich de Blaquiere, PharmD, and several members of the public.

In attendance at the Board office were Chairman Chopski, PharmD, Holly Henggeler, PharmD, Kris Jonas, PharmD, Alex J. Adams, PharmD, MPH, Executive Director, Andy Snook, Deputy Attorney General, Misty Lawrence, Management Assistant, and Ellen Mitchell, Program Information Coordinator. Ed Sperry, Public Member arrived during the rules discussion.

Dr. Henggeler motioned to accept the minutes of June 7-8, 2017 as written. Dr. Jonas seconded, and the motion carried unanimously.

Chairman Chopski asked Dr. Adams to frame today's discussion.

Dr. Adams noted that the goal of today's call is to finalize the *drafts* of each rule chapter that will be discussed at the Board's upcoming negotiated rulemaking session, which is scheduled for August 1, 2017. As a reminder, Dr. Adams noted that the official notice of intent to promulgate rules was published in the June 7, 2017 edition of the Idaho Administrative Bulletin, detailing the scope of the rulemaking session. In addition to the requisite Bulletin notice, Board staff has personally informed various stakeholder groups of the meeting, and included an article in its quarterly print newsletter to licensees and registrants. In addition, the Board is hosting sessions in Coeur d'Alene, Boise, and Idaho Falls in late July so that interested persons who are unable to attend the formal session, and who are unwilling to submit written comments, have a venue to provide feedback on the draft rules.

Dr. Adams noted that the Board has spent considerable time discussing the relevant rule changes at each of its open, public meetings this year. Having reviewed the proposed redline edits of the existing rulebook at these previous meetings, the Board will begin working exclusively off of the clean, edited versions that will eventually be published as the proposed rule dockets. Dr. Adams noted that copies of these clean versions were available to any interested person on the Board's website prior to the call. Dr. Adams also noted that the Board is now proposing six chapters instead of seven, and that under this proposal, veterinary drug outlets would have the legal ability to continue operations without needing a registration from the Board, as long as they follow the statutory definition (which excludes certain drug categories). If an outlet did carry any of these excluded drug categories, they would need to register as a prescriber drug outlet in order to maintain compliance with law.

The Board made the following changes to these publicly available drafts:

Legislative Proposal

- Removed 54-1723(3) and removed the word 'initial' from 54-1723(f). This proposal is consistent with a policy adopted by the National Association of Boards of Pharmacy (NABP) in 1995.

Following a brief discussion Dr. Jonas motioned to strike removed 54-1723(e) as the practice hour requirement is still covered in by Rule 32.03. Dr. Henggeler seconded, and the motion carried unanimously. The Board also invited a presentation at the August meeting regarding emerging methods of routing a prescription to a pharmacy.

Chapter 1 – Rules Governing Procedure

- 022.10 – Modified to add "expired" products, as had previously been covered in Rule 261.
- 022.15 – Added 'knowingly using' for clarity.

Chapter 2 - Rules Governing Licensure and Registration

- 023.01 – Modified nomenclature for clarity. Specifically, the word "original" was removed from "pharmacist license" as this category will now cover pharmacists who are being licensed by initial examination and by reciprocity. The word "nonresident" was added in front of "pharmacist registration" to further differentiate it from pharmacist licensure.
- 030.02 – Changed title to 'Nonresident Pharmacists'.
- 042.02 – Clarified that the fingerprint-based background check exemption for student technicians is for individuals 'under the age of eighteen'.
- 050.03 – Changed 'drug outlet' to 'pharmacy' for clarity and removed the requirement that the individual must already own another registered drug outlet.

Mr. Sperry arrived at 8:35 a.m.

Chapter 3 - Rules Governing Pharmacy Practice

- 202. – Added reference to Subchapter D for valid prescription drug orders and labeling.
- 204.02 – Modified for clarity, removing the screen size and definition requirements.
- 304.03.b –Changed the limitation on emergency refills to once in a six month period, with a thirty day supply as the new maximum quantity.
- 314. – Modified for clarity related to delivery to a prescriber.
- 315. – Modified to ensure all existing allowances related to delivery are upheld in the new rules. The emphasis on "institutional facilities" was remove, and it now applies to "institutional facility patients" and broadened to include drugs with tamper-evident features.

Chapter 4 - Rules Governing Pharmacist Prescriptive Authority

- Added nebulizers, insulin pen needles, and syringes for patients with diabetes.

Chapter 5 - Rules Governing Compounding

- No substantive changes

Chapter 6 - Rules Governing DME, Manufacture and Wholesale

- No substantive changes

Chairman Chopski called for public comment, none was offered.

Hearing no further discussion Dr. Jonas motioned to adjourn. Mr. Sperry seconded, and the motion carried unanimously. Meeting adjourned at 9:54 a.m.

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.

MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
August 1-2, 2017

Idaho State Capital
Boise, Idaho

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

Chairman Nicki Chopski, PharmD, called the meeting to order at 8:00 a.m. In attendance were Board members Kris Jonas, PharmD, Ed Sperry, Public Member, and Holly Henggeler, PharmD. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director, Lisa Culley, CPhT, and Jaime Thompson, Compliance Officers, Andy Snook, Deputy Attorney General, Misty Lawrence, Management Assistant, Ellen Mitchell, Program Information Coordinator, Meredith Oliver, the Board's intern from the University of Mississippi, and several members of the public.

Dr. Jonas indicated that the draft minutes of the July 12th meeting referenced the listening sessions conducted in various parts of the state, but did not mention the two sessions held in Boise. Dr. Jonas motioned to approve the July 12, 2017 minutes with the discussed corrections. Dr. Henggeler 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. Jonas motioned to approve the Consent Agenda. Mr. Sperry seconded, and the motion carried unanimously.

Dr. Chopski introduced the Negotiated Rulemaking Session. She commended all those who submitted written comments and those in attendance. Dr. Chopski believes all participants have the same goal of improving the health and welfare of all Idahoans, though she noted there may be some differences of opinion in how to achieve that goal. Dr. Chopski noted that each comment will receive proper consideration. The Board has been working on the drafts since January 2017, and has taken an evidence-based approach and has looked to the literature as well as other jurisdictions as a starting point. Dr. Chopski asked Dr. Adams to give an overview of the rulemaking process for those that have not attended any of the public sessions that have led up to today's public comment period.

Dr. Adams shared that the Board's approach to this rulemaking has been to organize the rule book into chapters by subject, and to focus specifically on the practice of pharmacy versus the business of pharmacy, and to create room for new models of care and new technology as it becomes available. There have been no substantive changes proposed to the rules regarding compounding, DME, distribution, or manufacturing. Similarly, the Board has preserved the intent of all rules related to controlled substances.

The Board conducted two public strategic planning meetings, with the first one in January 2017 focused on Licensing and Registration reform and the second held in March 2017 focused on Permissionless Innovation. During the April, June, and July 2017 Board meetings, the Board reviewed early drafts of the rules along with evidence and data to support the suggested changes. The Board incorporated public feedback at each of the open meetings. Dr. Adams also conducted five public listening sessions around the state during the month of July, presented at various conferences, and engaged in personal meetings with multiple stakeholder groups.

This meeting begins the first of two negotiated rulemaking sessions, with an additional negotiated rulemaking conference call scheduled for August 30, 2017, as published in the

August edition of the Idaho Administrative Bulletin. The August 30th conference call will be an opportunity for the public to comment on changes made during this initial negotiated rulemaking meeting. The Board's intent in hosting the meeting via conference call is to allow stakeholders across the state an opportunity to participate. Following the August 30 meeting, the Board intends to publish its Proposed Rules in the Administrative Bulletin on October 4, 2017, followed by a Proposed Rulemaking Hearing on October 25, 2017. Lastly, the Board intends to publish its Pending Rules in the December edition of the Administrative Bulletin.

Dr. de Blaquiere arrived at 8:30 a.m.

Dr. Chopski opened the public comment period with Chapter 4, Rules Governing Pharmacist Prescriptive Authority. The meeting minutes will briefly summarize core elements raised by those commenting; written comments that were submitted will be archived in full as part of the rulemaking docket.

Dr. Adams indicated that he saw two primary questions regarding legislative intent. First, several written comments noted that some of the drugs listed by the Board are for conditions that require a diagnosis, such as lice or cold sores, and the commenters felt that House Bill 191 specifically excluded drugs that require a diagnosis. Dr. Adams shared a note from the Legislative Services Office (LSO) regarding the use of the word "or" in I.C. § 54-1704(5)(e)(iii), as enacted by House Bill (HB) 191 (2017):

> "Or" is a disjunctive particle used to express an alternative or to give a choice of one among two <u>or more</u> things. *Frasier v. Frasier*, 87 Idaho 510, 514, 394 P.2d 294, 296-297 (1964). It's therefore unnecessary to list "or" after each item in the list; the use of the word once indicates that the list presents alternatives. This is discussed on page 30 of LSO's Concise Drafting Manual. If (i), (ii), and (iii) were intended to be read as requirements instead of alternatives, the word "and" would have been included following (ii).

The Legislative Services Office indicated that the initial draft of HB 191 included "or" after each item in (e)(i) through (iv) and that they advised that this was unnecessary.

Dr. Adams noted that HB 191 thus gave the Board discretion when a diagnosis is needed if the condition is minor, or if the condition requires a CLIA-waived test in order to diagnose, or if the drug is to be used in an emergency.

Dr. Adams noted that he had received comments regarding the rules not listing actual drugs or drug classes, instead focusing on conditions. Dr. Adams noted the language from HB 191: "Drugs, **<u>drug categories</u>** or devices." (emphasis added) Dr. Adams noted that the term 'drug category' was added to enable the Board to draft rules that are broader than individual drugs. Drugs are categorized in many ways, according to both national and international health organizations. For example, drugs can be categorized according to their chemical structure, their mechanism of action, or by the diseases/conditions they are intended to treat. Dr. Adams noted precedent in legislation both in Idaho and elsewhere to organize by condition, as this may be more transparent and understandable (e.g., "FDA-approved drugs **indicated** for lice" as opposed to "scabicides.")

No follow-up comments regarding legislative intent were offered by commenters at the meeting.

The Idaho Medical Association (IMA) submitted written comments prior to the meeting. Ken McClure and Molly Steckel attended at the meeting. Ms. Steckel highlighted a few of the specific concerns of the IMA, reiterating her board is not strictly opposing the draft language, but would like to work with the Board of Pharmacy to create alternative verbiage. The IMA's main concerns as highlighted by Ms. Steckel include:

- <u>Nausea</u> – Although a common ailment it can be the sign of a more serious disease state.
- <u>Uncomplicated UTI</u> – This will require a new diagnosis, meaning in most cases a pharmacist may not prescribe for this condition. The pharmacist should be required to perform a CLIA waived test.

- Influenza (specifically in pediatric patients) – Children can be more susceptible to neuropsychiatric effects that have been seen when prescribing antivirals for children.
- Group A Strep - Roughly 15% of children are carriers and test positive but don't need treatment.
- Diabetes – There isn't necessarily a gap in care if a patient is not prescribed statins by their primary care provider.
- Short Acting Beta Agonists – Rescue inhalers can be used too often and part of asthma management from a primary care standpoint is knowing how often a patient is filling their albuterol.
- Travel Drugs – Have the potential to contribute or compound mental health issues. Blanket authority shouldn't be granted.

Dr. Adams noted the IMA's concern over fragmented care as it is also a concern of the Board's. The Board's desire is for patient treatment to be patient centered, team based, and coordinated among all health care providers, and has added the notification requirement to facilitate communication between a prescribing pharmacist and primary care provider. Dr. Adams asked Mr. McClure if his association had any recommendations or suggestions aside from the required notification included in the draft rules, and asked specifically what retail clinics are doing to address this concern. Mr. McClure didn't have any specific suggestions and indicated the concern is based on the notification coming after the patient has received the prescription, believing the communication between the pharmacist and physician should come prior to the patient ingesting the medication. He believes the breakdown is in the retail setting, though the process would work well in an institutional setting.

Jenny Arnold, PharmD, Washington State Pharmacy Association (WSPA) attended the meeting to express her organization's support of the Board's draft rules. Dr. Arnold coordinated the development of the curriculum for the Clinical Community Pharmacist Tools, which is a collection of Accreditation Council for Pharmacy Education (ACPE) approved continuing education modules that are currently in use in Washington State. Washington pharmacists are currently prescribing for many of the conditions that are proposed in the Board's rules. The program starts with the fundamentals of pharmacist care including patient assessment. She indicated that pharmacists are using protocols to identify whether a patient's symptoms fit within clinical guidelines, or if alarm symptoms are present that may trigger a referral. As an example, if a patient's symptoms are consistent with the uncomplicated urinary tract infection (UTI) protocol, the pharmacist must determine whether they can treat the patient for the illness or if referral symptoms are present. The Clinical Community Pharmacist Tools provides 13 modules covering different disease states. Dr. Arnold stated pharmacists are treating patients with minor illnesses every day as patients seek over-the-counter (OTC) pain medications, nausea medication, and a multitude of other OTC medications. These rules give patients that can't access primary care due to work barriers or other barriers a safety net and an option other than the emergency room or urgent care clinics for access to medical care.

Dr. Adams inquired if Dr. Arnold had suggestions for the draft language regarding education. Dr. Arnold noted she was pleased to see that there isn't an hour limit on education as it allows pharmacy schools to integrate the training into their curriculums. She feels an hour requirement can exclude some high quality programs. Dr. Arnold noted that approximately 5% of Washington pharmacies are Clinical Community Pharmacies. These pharmacies triage, assess, and prescribe for patients with minor ailments, while referring patients with certain symptoms. Most of these pharmacies are currently treating uncomplicated UTIs, and a sample treatment protocol had been submitted and reviewed by the Board.

Tim Frost, PharmD, attended the meeting to commend the Board for taking an evidence-based approach to pharmacist prescribing. Dr. Frost submitted a study regarding pharmacist prescribing of statin medications that was conducted in community pharmacies. He stated that the study showed that pharmacists can identify care gaps, provide patient assessment, and monitoring of the progress of these patients. Dr. Frost asked that the rule be extended to all patients and not just those with diabetes. Dr. Frost indicated that another study noted that patients were 3.3 times more likely to achieve their cholesterol goals when a pharmacist prescribed their medication over other prescribers.

Lorri Walmsley, Senior Manager, Pharmacy Affairs, Walgreen's expressed her support for the Board's conservative approach to pharmacist prescribing. She appreciates the education requirement is broad, allowing corporations to adopt appropriate risk mitigation strategies;

she noted that Walgreen's ensured all their pharmacists were trained prior to allowing prescribing of Naloxone even though there was no requirement in Idaho law to do so.

Pam Eaton, Executive Director, Idaho State Pharmacy Association, and Idaho Retail Pharmacy Council, submitted prior written comment. Her comment was related to desire for pharmacist prescribing of prophylactic flu treatment for those living in the immediate household to a patient that has tested positive using a CLIA waived test. She reiterated that as a community, pharmacists are conservative and often slow to adapt. She provided examples of slow uptake, which she indicated meant that these prescribing rules are unlikely to open the floodgates to inappropriate prescribing. She noted that pharmacists are generally conservative as it related to expanded duties and will ensure they are well trained prior to taking on prescribing to patients.

Mark Johnston, RPh, CVS Regulatory Affairs and NABP Executive Committee, shared a Centers for Medicare & Medicaid Services (CMS) informational bulletin dated January 17, 2017 that states in part:

> "CMCS recognizes that states continue to look for innovative tools to address pressing public health issues, such as the opioid epidemic or preventing influenza infections. State flexibilities in expanding the ability of pharmacists to prescribe, modify, or monitor drug therapy for certain medications may be effective at helping to address such issues by improving access to care. CMCS encourages states to consider using these methods to promote access particularly to those drugs that can help address priority public health issues."

Mr. Johnston reiterated the federal government recognizes the gap in health care and is asking states to do exactly what Idaho is doing with pharmacist prescribing. He also asked that all OTC medications be recognized in patient prescribing as diabetic test strips are included. He noted that it is a long standing practice for pharmacists to prescribe OTCs, though many payers do not pay for them as payment is at the discretion of the payer. He also asked the Board not to over-regulate the education requirement to provide these services. He believes excessive education requirements may defeat the legislature's goal of increasing access to safe and effective care by expanding pharmacist prescribing. He also asked the Board to consider adding a rule that pharmacists may prescribe certain drugs and devices to supplement an infusion prescription. He provided examples where this may be of use, and specifically suggested saline, heparin, infusion pumps, and some acute infusion reaction medications.

Dr. Adams inquired as to the maximum heparin dose of 100 units per milliliter proposed by Mr. Johnston. It was explained that this is the common dose for a heparin flush; heparin for other therapeutic uses has a dose range much higher than the maximum proposed.

Dennis McAllister, RPh, indicated the ACPE standards for colleges have been in place for 20 years. He agrees most pharmacists will work where they are comfortable and where they have knowledge and jurisdiction. Mr. McAllister commended the Board for formalizing what has been happening in rural pharmacies for many years.

Paul Cady, Dean, Idaho State University College of Pharmacy (ISU) commended the Board on the draft rules. ISU has been preparing students for services such as those outlined in the Board's draft rules for many years and he has been waiting for the time to come for pharmacists to be allowed to do what they have been trained to do. ACPE requirements include patient assessment and the College has prepared their students to care for complicated patients, and he believes the training is more than adequate. All professions must adapt to changes in their fields as things change. He supports the concept of reporting prescriptions to the primary care provider as it is what should be done in a team-based approach. He shared an experience where he had been to an urgent care and received new medication, but when he had returned to his primary care provider they were unaware that he had received them. There is no requirement for urgent care clinics to notify primary care providers of treatment or prescriptions even though the clinic collects the information. He looks forward to other categories of medications being added to pharmacist's prescriptive authority in the future.

Linda Garrelts MacLean, RPh, Vice Dean, Washington State University expressed her support of the Board's draft rules. She worked on a research project in Washington related to pharmacist prescribing for roughly 25 illnesses, many of which overlap with the conditions included in the Board's draft rules. Ms. Garrelts MacLean's indicated her project was quite successful. Pharmacists at several companies, including Fred Meyer, Bartell Drug, Costco,

etc. participated in the research. She noted strong, positive patient feedback and noted that results are going to be published soon. She noted that there have been zero reported adverse events due to therapy.

Laura Churns, PharmD, Albertsons, Director of Legislative & Regulatory Affairs, expressed her company's support of Chapter 4 and the increased access to patient care. She asked the Board to consider expanding the authority of this chapter to include hormonal contraceptives, prenatal vitamins, yeast infection medications, and propecia.

Following a brief break, Dr. Chopski asked Dr. Adams to share the remaining written public comment submitted to the Board.

The Idaho Academy of Family Physicians submitted written comment prior to the meeting, their comments included:

- Education – Education standards regarding the list of medical conditions are not defined by the rule. Standards should be set to achieve, monitor, and maintain competency on listed conditions along with a regular review of the standards.
- Patient-Prescriber Relationship – Concerns related to a pharmacist achieving a patient prescriber relationship.
- Collaboration – No clear restrictions on which patients are appropriate for consultation or referral. Due to the lack of restrictions the patient-centered medical home model of care would be fractured.
- Follow-Up Care Plan – A clear course of action should be developed for follow-up with all patients.
- Notification – The term 'if applicable' is obscure and should be replaced with a clear process.
- Documentation – The term 'upon request' leaves notification of the patient and their provider on the patient, this should be changed to mandatory and be the responsibility of the pharmacist.

The Idaho Primary Care Association submitted written comment prior to the meeting as summarized below:

- 020.01 Education – Concerns regarding how competence is determined, achieved, and maintained.
- 020.03 Patient Assessment – Concerns regarding lack of access to patient's health records.
- 020.06 Documentation – Questioned how the data will be transmitted.
- 021.05 UTI – Concerns regarding determination of 'uncomplicated' and process of diagnosis.
- 022.01-05 Question regarding provision of devices and if they would only be supplied to patients with an existing asthma diagnosis.
- 024.01-02 Clinical Gaps – Concerns regarding the primary care provider should be managing gaps as they have access to current lab results and a comprehensive medical history of their patients.

Michael E. Klepser, PharmD, Professor, Ferris State University College of Pharmacy encouraged the Board to expand clinical access for prophylactic agents for family members and close contacts as warranted for influenza.

Allison Dering-Anderson, PharmD, Clinical Associate Professor, University of Nebraska College of Pharmacy shared lessons learned in recent studies:

- Exacting thresholds are not helpful, thresholds for referral are much easier to work with and actually result in better care;
- Prophylaxis therapy for household members of an influenza positive patient should be written into protocols with guidance on who should be offered prophylaxis and who should be referred;
- Vaccination recommendations should be a part of collaborative agreements (when used) and protocols to assure that they are not missed.

Deanna Tran, PharmD, BCACP, Assistant Professor, Co-Director, Pharmacy Practice Laboratories, University of Maryland School of Pharmacy, submitted research she had conducted on pharmacist-prescribed travel drugs.

Hannah Renner, PharmD, Community Pharmacy Research Fellow, University of Pittsburgh School of Pharmacy, submitted research indicating only 63% of U.S. adults with diabetes aged 40 and over take a prescription cholesterol-lowering medication, though the American College of Cardiology/American Heart Association guideline indicates patients with diabetes aged 40-75 should be treated with moderate to high intensity statin medications. She noted her research on pharmacist intervention to increase statin prescribing rates in this guideline-recommended population.

Heather Hammerstedt, MD, and Chuck Washington, MD, emergency room physicians submitted separate but nearly identical comments highlighting the following:

- Sect 020.01 Education: there are no specific recommendations for education to be achieved before prescribing for the conditions outlined.
- Sect 020.03 Patient Assessment: how will the pharmacist diagnose the conditions in 021-025?
- Symptoms of nonemergency and emergency illness overlap 90% of the time. It is easy without the appropriate training to miss a more serious condition.
- Sect 021.04 Nausea: how will pharmacists diagnose a condition based on nausea?
- Sect 021.05 Uncomplicated UTI: How will pharmacists determine?
- There is no provision in the proposed rules to put any limits on the age of the patient that a pharmacist can prescribe for
- There is no provision in the proposed rules to prohibit a pharmacist prescribing for certain high risk patients/conditions: pregnancy, etc.

No comments were received regarding the Collaborative Pharmacy Practice and Statewide Protocol rule, which has been organized into this section from the existing rules.

Mr. Sperry stated he believes the Board has taken great care in drafting these rules and appreciates the public comments from various stakeholders. Mr. Sperry asked Mr. McClure and Ms. Steckel about efforts to educate physicians regarding the prescribing of opioids. Ms. Steckel indicated the information obtained from the American Medical Association has indicated there is no correlation between education and prescribing habits. Some providers are more educated than others in regards to this type of prescribing based on their specialties. They are also talking with the Office of Drug Policy on this topic.

Dr. Chopski asked Dr. Adams to open public comment on Chapter 1. The Board is adding draft language regarding Standard of Care based on the March 2017 presentation by Anne Lawler, Executive Director of the Idaho Board of Medicine. Dr. Adams summarized public comment submitted by Pam Eaton on behalf of her organizations, related to Unprofessional Conduct which included:

- Excessive provision of controlled substances – There is no definition of ‘clearly excessive.’
- Prescriber incentives – Concerned about how this impacts company goals regarding flu shots administered, etc.
- Standard of Care – Concerned the definition is too broad and vague.

Dr. Adams summarized the public comment received regarding Chapter 2:

- From a listening session – feedback that the Board should consider a two-year license vs. an annual renewal.
- Dr. Adams also noted there are two instances in which the word “nonresident” may be added to clarify the registration requirement.
- No comments were received regarding any of the fee modifications.

Dr. Adams summarized the public comment received regarding Chapter 3:

- From a listening session – One pharmacist asked if professional judgement could be overridden by corporate policy.
- Bill Silvius – the current language prevents the change in package size for controlled substances, and he provided an example of where this would be useful and in the best interest of patient care for a controlled substance.

Pam Eaton submitted the following comments on behalf of the Retail Pharmacy Council:

- Prescription Drug Order Validity: Tampering – Requests clarifying language that would constitute tampering.

- Prescription Drug Order Validity – Requests language to clarify earliest fill dates for patients receiving multiple prescriptions.
- Recordkeeping Inventory after Theft – Suggests changing from 48 hours to 72 hours as 48 hours is insufficient time to complete an inventory.
- Reporting Requirements: Employment Changes – Recommends striking the rule as the PIC may not be aware of the new place of employment and the burden should be on the licensee.

No comments were received regarding Chapters 5 or 6, either in writing or verbally at the meeting.

John Sullivan, PharmD, Idaho State Hospital Association, expressed the support of his organization for the Board's draft rules.

Dr. Chopski called for miscellaneous comments, not related to any existing rulemaking.

Dr. Adams shared public comment submitted by Kelly Krawtz, PharmD, BCPS on behalf of St. Luke's internal medicine physicians requesting guaifenesin with codeine be a schedule 4 medication so it is reported to the PMP.

Dr. Adams shared a written comment from Charles Clark, RPh, from Salmon, expressing his concerns related to the Board's direction and to telepharmacy.

Ms. Garrelts MacLean shared an update on the Pharmacy Technician Immunization Program waiver, for which WSU created a technician immunization training program. They are about to publish the results and the article will be shared with the Board. She indicated the program was a great success in building confidence in the technicians that participated. WSU has continued to improve their training program, and have increased from a 2 hour program to a 4 hour program based on feedback from pharmacists and technicians. They will launch a 'train the trainer' program in the future.

Dr. Cady expressed his position to have the OTC Schedule 5 medications be prescribed by pharmacists so they are reported to the PMP, which he believes will create a better picture of all controlled substances received by patients.

Cassandra Carper, PharmD, from Walmart expressed concern that some pharmacists may not be comfortable telling their employers they are uncomfortable with the ratio.

Dr. Chopski thanked all for participating in the negotiated rulemaking session. The Board members will deliberate on all the feedback received, and take up the rules the following day to consider changes based on the feedback.

The Board next took up the matter of Consent Agenda: Stipulations, which contained one item related to Marley Drug. Marley Drug representatives did not attend the meeting, nor did their legal counsel. Marley Drug is located in Winston-Salem, North Carolina. During a review of their dispensing records by the North Carolina Board of Pharmacy, it was discovered that Marley Drug was shipping prescription medication to Idaho residents without proper licensure between May 2015 and December 2016. By signing the Stipulation and Order Marley Drug agrees to pay fine in the amount of $7,600. Dr. Henggeler motioned to approve the stipulation, Dr. Jonas seconded, and the motion carried unanimously.

Dr. Chopski asked Dr. Adams to frame the conversation regarding Corrective Action Plans (CAP). Dr. Adams referenced the presentation by Anne Lawler, Executive Director of the Board of Medicine in March 2017. Staff has reviewed the current Delegated Authority (DA) list and identified those that are minor and could be resolved using CAP and not reported as discipline to HPDB. If a registrant or licensee chooses not to accept the conditions of CAP, or if the individual does not complete the CAP in the stated time, the Board retains the option of pursuing an Administrative Complaint or a Stipulation and Consent Order. Following a brief discussion, Dr. Jonas motioned to accept the CAP policy as written. Mr. Sperry seconded, and the motion carried unanimously.

Misty Lawrence presented the Board's financial report:

- At fiscal year close expenditures were up 18.3% over last year and receipts were up 11%. For comparison, in FY 16 Expenditures were down -4.5% and Receipts up 6%
- Highlights of changes in Revenue.

    - Fines increased by 75% - or $31,800 over last year. FY15-$20,700; FY16-$42,300 104% increase and FY17 $74,100.
    - Miscellaneous Revenue Increased by 15% or $1,600 over last year. This is revenue from overpayments, refund processing fees, and return check fees. We refunded $7,400 of the $12,100 collected.
    - Other licensing fees decreased by 14%, or $13,200. This includes significant decreases in late fees. Reinstatement, and prior year fees as well as an increase in background checks, $3,200 or 100 BGC's.
    - Registration fees were up 10%, or $135,100, and licensing fees were up 8%, or $26,800.
- Fiscal year 2017 ended with 96.7% of the budget expended.
    - Personnel Cost was 99.4% expended –$73.46 was reverted. After early distribution of Change in Employee Compensation and allowable bonuses we were able to move the remaining amount to Capital Outlay (CO).
    - Operating Expenditure (OE) was 91.2% expended. A total of $60,872.47 was reverted.
    - Original OE appropriation was 99.9% expended with only $872.47 reverted
    - $60,000 was as a supplemental to cover the Health & Welfare contract. Unfortunately, none of these funds were expended before the end of the fiscal year.
- CO - $250,000 originally appropriated for the licensing system has been carried over to FY18. CO was 100% expended. Staff was able to secure the visual portion of the new board room setup and purchase adjustable legs to modify the remaining desks in the office.
- Beginning of the fiscal year cash balance was $2,411,780. Ending cash balance was $2,610,200. Showing an increase of $198,420 over last year.

Renewal Period Update:

12,550 renewal notices sent out.

- Of those 11,426 or 91.04% renewed, 98.87 renewed on-time; 1.13% renewed late
- 35 or .28% - have not provided all required information
- 559 or 4.45% - are currently not renewed
- 530 or 4.22% - notified staff they are not renewing

Pharmacists that currently hold CS registrations were required to register with the PMP, all but 9 are accounted for.

Year End Licensing Info:

New applications - Approved: 3387, increase of 102 or 3% over LY

Total license/registration issued in FY17 22048, increase of 888 or 4%

Current Active Licenses: 20,739

- In-State Pharmacies: 383
    - Retail: 289
    - Hospital: 58
    - Limited: 36
- Prescriber Drug Outlets: 285
- Mail Service: 626
- Nonresident Central Drug Outlet: 41
- Outsourcing Facility: 33
- Nursing Home: 58
- DME: 420
- Veterinary Drug Outlet: 9
- Manufacture: 457
- Wholesaler: 505
- Distributor: 310
- OTC Wholesaler: 213
- Narcotic Treatment Center: 3
- Non-Pharmacy Retail Outlet: 1227
- Pharmacists total: 3253
    - Licensed 2666
    - Registered, nonresident 587
    - Controlled Substance Registrations: 1779
- Student Pharmacist: 393
    - In-school: 366
    - Graduates: 27
- Pharmacy Technicians: 2545
    - Certified: 1686
    - Training: 565
    - Grandfathered: 294
- Veterinary Drug Technician: 25
- Practitioner Controlled Substance: 8156

The Board took up the waiver request from Archway Apothecary. Matthew Hardey, Secretary/Treasurer, attended the meeting telephonically. Mr. Hardy is requesting a waiver from the 'sixth day' of operation requirement of rule 730. His pharmacy only provides nicotinamide adenine dinucleotide (NAD), which is a sterile solution only available to physicians as a nutritional supplement for the treatment of drug addiction. Following discussion Mr. Sperry motioned to approve the waiver request contingent of the pharmacy providing only NAD to physicians, and the waiver expires on July 1, 2018. Dr. Jonas seconded, and the motion carried with Dr. Henggeler opposed.

Nicole Fitzgerald, interim Director of the Office of Drug Policy (ODP), provided an update on the Millennium Fund Grant Prescription Drug Take Back program. The request was to purchase prescription drop boxes and to provide funds for marketing to grantees. The goal is to increase the ability of patients to dispose of unused and unwanted medications through convenient disposal locations. In May, ODP selected 11 pharmacy organizations, serving 21 locations. Some pharmacies have used marketing funds for television and radio ads to bring awareness to the program. ODP will be funding additional drop boxes. Funding is available until June 2018, and interested pharmacies were encouraged to contact either ODP or the Board for additional information.

Dr. Jonas motioned to amend today's agenda and address the brief summary of agency legislation and the executive session today instead of tomorrow, as the Board's business has completed early. Dr. Henggeler seconded, and the motion carried unanimously.

Dr. Chopski asked Dr. Adams to lead the discussion of 2018 agency legislation. Dr. Adams distributed the draft language for 54-1733 Transmission of a Written Drug Order. He indicated if this legislation passed in 2018, the Board would need to promulgate rules surrounding the change, and it would only become operational if the Board adopted rules.

Mark Johnston, presented information regarding PhotoRx, which has been approved in Arizona as a pilot program. The mobile application is still in development, and isn't available yet. Following the presentation the Board granted unanimous consent to move forward with draft language for future legislation.

Dr. Adams shared there is some non-substantive cleanup of the Controlled Substance Act (CSA) that is being proposed for the annual CSA bill. This was work left behind by the Board's previous executive director, and the time seemed right for the Board to move forward with it. Dr. Adams will share the language with external stakeholders and the Board can take it back up at the October meeting.

Dr. Henggeler motioned to enter executive session as allowed by Idaho Code 74-206. (1)(a) - (b) as they relate to items related to employees. Mr. Sperry seconded, roll call vote resulted with all in favor. The Board entered executive session at 2:11 p.m. Dr. Henggeler motioned to leave executive session. Dr. de Blaquiere seconded, and the motion carried unanimously. Executive session ended at 2:51 p.m.

Mr. Sperry motioned to adjourn, Dr. de Blaquiere seconded, and the motion carried unanimously. Meeting adjourned at 2:55 p.m.

August 2, 2017

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

Chairman Nicki Chopski, PharmD, called the meeting to order at 8:00 a.m. In attendance were Board members Rich de Blaquiere, PharmD, Kris Jonas, PharmD, Ed Sperry, Public Member, and Holly Henggeler, PharmD. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director; Lisa Culley, CPhT, and Jaime Thompson, Compliance Officers, Andy Snook, Deputy Attorney General, Misty Lawrence, Management Assistant, Ellen Mitchell, Program Information Coordinator, Meredith Oliver, the Board's intern from the University of Mississippi, and several members of the public.

Dr. Chopski gave an overview of the day and shared that there were a few items moved to yesterday's agenda given extra time available. She assured those in attendance if they were there for one of the moved items, she would give them an opportunity to speak to the item. She asked Dr. Adams to remind the Board of public comments as they discussed any

changes to the final drafts. Dr. Adams reviewed the public comments that had been submitted both in writing and verbally. The Board deliberated on each comment, and a summary of the Board's action is noted below.

Chapter 1 – **Rules of Procedure.**

Discussion of Chapter 1 resulted in the following:

- Change the title of Chapter 1 from "Rules of Procedure" to "General Provisions" to better capture that Chapter 1 establishes general provisions and serves as a parent chapter for the five following chapters.
- 22.08 Excessive Provision of Controlled Substances – no change.
- 22.11 Prescriber Incentives – no change.
- 22.16 Standard of Care – no change.
- 22.17 Unnecessary Service or Procedure – no change.

Chapter 2 – Rules Governing Licensing and Registration.

- 007 Official Board Journal – strike 'and copies may be obtained from the Board office' as all newsletters are online. This change will be made for all chapters.
- 030 Added 'Nonresident' for clarity; the Board is trying to highlight the distinction between pharmacist licensure vs. registration. Registration is a pathway that only certain nonresident pharmacists may pursue.
- 035 Added 'Nonresident' for clarity.
- Regarding comments to provide a two year license, the Board made no change.

Chapter 3 – **Rules Governing Pharmacy Practice.**

Dr. Adams reminded the Board they had received one comment regarding the pharmacist to support personnel ratio. Following a brief discussion the Board determined they did not want to re-address the ratio at this time. Following discussion the Board made the following determinations related to Chapter 3:

- 100.02 Prescriber Delegation – add 'or pharmacist intern.'
- 300.03 Tampering – no change.
- 300.06 Expiration – no change.
- 400 Inventory After Loss – no change at this time, though staff will connect with the DEA to better understand how the Board's current rule differs from the federal Controlled Substances Act. Board staff will address this on the August 30th conference call.
- 402.02 Employment Changes – strike the duplicative reporting requirements in terms of change of employment, which currently requires both the PIC and the individual to report in 10 days. The Board felt reporting by the PIC is still important in the instance an individual was terminated for controlled substances related causes. To address termination for adulteration, rule 402.05 was amended to require reporting of adulteration or misappropriation of a controlled substance in accordance with Section 37-117A of Idaho Code.
- 402.04 Individual Information Changes – add 'in employment or changes' for clarity to the individual reporting requirements.

Chapter 4 – **Rules Governing Pharmacist Prescriptive Authority**

- 020 – Added 'all nonprescription drugs and devices' to coincide with existing practices; the Board wanted to avoid having to otherwise list OTC drugs individually.
- 020.01 Education – There were general comments about the education requirements related to medications pharmacists may be prescribing. The verbiage regarding prescribing was adapted from the Nurse Practitioner Act. The Board discussed previous Idaho legislation, and examples from other jurisdictions. Dr. Jonas noted that there are differences between new graduates and seasoned practitioners, and that there is a professional responsibility for all health professionals to keep up to date in accordance with their practice. Following considerable discussion Dr. Jonas motioned to leave the verbiage of 020.01 as written. Dr. de Blaquiere seconded, and the motion carried with Dr. Henggeler opposed.

- 020.02 Patient-Prescriber Relationship – no change; the confusion from the comments seemed to stem from a misreading of the statute, which Dr. Adams clarified by reading a statement from the Legislative Services Office (LSO). The Board heard no further comments or concerns related to legislative intent after the LSO analysis was read.
- 020.03 Patient Assessment – added:

> 'At a minimum, the pharmacist must maintain a patient assessment protocol based on current clinical guidelines that specifies the following:
>
> a. Patient inclusion and exclusion criteria; and
> b. Explicit medical referral criteria.
>
> The pharmacist must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines. The pharmacists' patient assessment protocol, and any related forms, must be made available to the Board upon request.'

The Board noted that this added language is intended to address the concerns raised by medical groups. By requiring pharmacists to maintain a treatment protocol linked to a clinical guideline that sets guideposts for the Board's expected standard of care. The Board noted that several comments asked about setting age limits or carving out high-risk populations in the rules; the Board noted that there are *de facto* age limits and limitations on high-risk populations because of the link to clinical guidelines. As an example, Dr. Adams noted that the national guidelines related to statin use in patients with diabetes is targeted to patients between the ages of 40 and 75. If, however, the Board limited in rule the statin use in patients with diabetes to patients in this age range, the Board would have to update the rule every time the clinical guidelines changed. It would be a constant process and even with temporary rules, there would be lags between when clinical guidelines change and when a temporary rule becomes effective. Thus the Board deferred to prevailing clinical guidelines, as other health professions have, and requires updating when necessary. By requiring a protocol linked to clinical guidelines, the Board is setting the bar higher than other health professions currently require. Making the protocols available to the Board upon request creates an accountability mechanism as the compliance officers may request the protocol for audit at any point in time.

- 020.05 Follow-up Care Plan – no change, as this language is adapted from House Bill 4, which the legislature approved unanimously.
- 020.06 Notification – changed "if applicable" to "if identified by the patient," which clarifies that the pharmacist is expected to notify the patient's primary care provider, however some patients may not have a primary care provider, and thus if none is listed, no notification is able to be given. Dr. Adams noted that in his testimony to the Senate, he indicated a one-size-fits-all approach may not be possible, and asked if the Board wanted to consider requiring notification for only a subset of the drugs or drug categories in which notification made the most clinical sense. He noted it may not be important for certain conditions (e.g., lice or cold sores). Dr. Chopski commented she believes the notification after prescribing requirement is critical and wants notification for all pharmacist prescriptions. The Board discussed notification as an additional accountability mechanism built into the rules. If a pharmacist deviates from clinical guidelines, the provider who receives the notification can file a complaint with the Board. This accountability mechanism goes above and beyond other health professions currently.
- 020.07 Documentation – add 'any notification provided' which requires pharmacists to document the notification provided under 020.06. This reflects the importance the Board ascribes to the notification requirement.
- 021.04 Nausea – Dr. Adams will conduct additional research for the August 30 meeting pursuant to concerns raised. The Board wants to learn more from the jurisdictions on how they have addressed the stated concerns, and if the concerns have materialized.
- 021.05 Uncomplicated UTI – Dr. Adams will conduct additional research for the August 30th meeting. In particular, the Board will learn more about current practices regarding the management of UTIs via phone call.
- 023 Pharmacist Prescribing Based on CLIA Waived Test – Dr. Adams will conduct more research for the August 30th meeting based on comments regarding neuropsychiatric effects in pediatric patients; add 'When a person has tested positive for influenza, a pharmacist may additionally prescribe an antiviral medication to an

individual who has been exposed to the infectious person and for whom clinical guidelines recommend chemoprophylaxis.'

- Streptococcus - Dr. Adams will conduct more research for the August 30th meeting based on the comments submitted regarding strep carriers.
- 024 Clinical Gaps (statins) - Dr. Adams will conduct more research for the August 30th meeting to try to gauge the extent to which the national gap, reported to be near 40%, could be attributable to legitimate exclusions, such as pregnancy in diabetic patients aged 40 to 75.
- 025 Travel Drugs – add 'non-controlled drugs' to coincide with the language in House Bill 191. Dr. Henggeler expressed her desire to have an education requirement around travel drugs. Following a brief discussion, the Board directed Dr. Adams to conduct additional research for the August 30th meeting to assess the extent to which this is included in the pharmacy curriculum.
- Add section 026 Supplements to an Infusion Order, with a limitation on the heparin dose to 100 units per milliliter.
- Add section 027 Emergency Situations, which limits the prescribing of these drugs to an emergency, limits the quantity to 'the minimum quantity necessary', and requires the pharmacist to contact emergency medical services as soon as possible. This adapts language that was used in the opioid antagonist and epinephrine auto-injector prescribing that has been previously approved by the legislature.

Mr. Sperry reminded the audience of his experience serving on the Utah Medical Board. He reiterated the Board has taken an evidence-based approach to drafting the rules and are within the scope of the legislative intent. Mr. Sperry took issue with the comments regarding education as he believes physicians haven't taken the initiative to educate around the opioid issue. He stated he has always had exceptional care from pharmacists. When his physician was unable to gain success in lowering his blood pressure his physician referred him to the pharmacist, who was able to get his blood pressure down.

Dr. Chopski thanked all participants, and welcomed any organizations to meet with Board staff in the time-period between rulemaking sessions to provide more feedback or assist with research on the outstanding topics.

Dr. Adams provided a recap of the items that were moved from today's agenda to yesterday. There were no public comments for these items.

Christopher Erb attended the meeting to update the Board on his progress toward obtaining an Idaho Pharmacist License. Mr. Erb has been working at MedSync Pharmacy with Josh Gerke, PharmD. He stated he has enjoyed the practice setting and is happy to be back in the pharmacy. He is 50 months into his PRN contract and has been successful in the program. Mr. Erb shared that he had received a charge of disturbing the peace for a recent interaction; the case is working its way through the court system. He is about three months from sitting for the NAPLEX. Dr. Adams cited the possible change in the rules that could affect Mr. Erb's time frame. The Board thanked him for his update and thanked him for attending the meeting.

Dr. Chopski called for further public comment. Hearing none, Dr. Henggeler motioned to adjourn, Dr. de Blaquiere seconded, and the motion carried unanimously. Meeting adjourned at 11:40 a.m.

MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
August 30, 2017

Conference Call
Board Office - Boise, Idaho

This meeting of the Board was held to conduct negotiated rulemaking.

Chairman Nicki Chopski, PharmD, attended the meeting telephonically and called the meeting to order at 9:00 a.m. Also attending telephonically were Board member Rich de Blaquiere, PharmD, and several members of the public. In the Board office were Ed Sperry, Public Member, Holly Henggeler, PharmD, Kris Jonas, PharmD, Alex J. Adams, PharmD, MPH, Executive Director, Andy Snook, Deputy Attorney General, Meredith Oliver, the Board's intern from the University of Mississippi, Dalila Del Real, the Board's Intern from Idaho State University, and Ellen Mitchell, Program Information Coordinator.

Public members who identified themselves on the conference call include:

- Susie Pouliot and Molly Steckel, Idaho Medical Association (IMA)
- Lee Flinn, Idaho Primary Care Association (IPCA)
- Laura Churns, Albertsons
- Tim Frost, Pacific University
- Michael Klepser, Ferris State University
- Krystalyn Weaver, National Alliance of State Pharmacy Associations
- Heidi Hart, Andrew Baron, Jeff Larson, Michael Triolo, Terry Reilly Health Services
- Ed Rickerts, Quarles & Brady
- Mark Johnston, CVS

The Board took up the matter of the August 1-2, 2017 minutes. Dr. Jonas noted some minor corrections. Dr. Henggeler motioned to approve the minutes with the discussed corrections. Mr. Sperry seconded, and the motion carried unanimously.

The Board took up the matter of negotiated rulemaking. Dr. Chopski indicated since the bulk of the comments received were related to Chapter 4 Rules Governing Pharmacist Prescriptive Authority, those comments would be addressed first. She indicated we would address Chapters 1-3 and Chapter 5 if there was time today and if not they would be addressed at the October meeting. No comments were received regarding Chapter 6. Dr. Chopski called for Board and public comment regarding Chapter 6. Hearing none the Board directed Dr. Adams to publish Chapter 6 in the Administrative Bulletin in October as drafted.

Chapter 4 – Rules Governing Pharmacist Prescriptive Authority

Dr. Chopski asked Dr. Adams to present the comments received regarding Chapter 4; the Board had tasked Board staff with researching several comments raised by medical groups at the August 1-2, 2017, negotiated rulemaking meeting, and Board staff conducted research and prepared summaries. Dr. Adams noted that he had sent 753 pages of research, clinical guidelines, and trade articles for the Board to review for this call.

The following is a summary of the feedback and comments received and the Board's actions.

Dr. Chopski asked Dr. Adams to review comments received on 020.06 Notification. Dr. Adams noted the prior concern from the IMA:

> "Nothing in this rule outlines how a pharmacist will identify the patient's primary care provider. If it is a question on a patient questionnaire, will pharmacists be required to inquire further if the patient leaves that question blank?"

Dr. Adams suggested the following amendment to rule 020.06 to address the IMA's concern:

> "The pharmacist must inquire about the identity of the patient's primary care provider and, if one is identified by the patient, provide notification within five (5) business days following the prescribing of a drug.

Following a brief discussion the Board granted unanimous consent to move forward with Dr. Adams' suggested language.

Dr. Adams noted a second part of IMA's concern:

> "Should the pharmacist be required to review previous prescriptions for the patient to assess whether there appears to be a consistent physician of record? Presumably a pharmacist would not prescribe medications to a diabetic patient without knowing if that patient is under the active care of a physician?"

Dr. Adams noted that there are some items on the list where it may be more important to notify the prescriber of record rather than the patient's primary care provider. For example, if the prescriber of a valid infusion order is not the patient's primary care provider, it may make more sense to notify the individual who ordered the infusion order itself. To address this issue raised by IMA, Dr. Adams suggested the following amendment to rule 020.06:

> "In the instance in which the pharmacist is prescribing to close a gap in care or to supplement a valid prescription drug order, the pharmacist must alternatively notify the provider of record."

Following a brief discussion the Board granted unanimous consent to move forward with Dr. Adams' suggested language.

Dr. Adams noted that the IPCA expressed concern related to the notification provision that there may be unintended consequences in that patients may seek treatment from pharmacists instead of establishing themselves with a primary care provider. IPCA indicated that they do not have any studies validating this concern. Mr. Sperry was confident as more people seek treatment, pharmacists will refer as appropriate. Dr. Adams indicated it would be a great opportunity for primary care providers to partner with pharmacies and provide a list of providers in the area that were accepting new patients. The Board believes that this concern is best addressed between providers in the community, rather than addressing it in law.

Dr. Adams next moved to rule 020.07 Documentation. He listed IPCA's concern:

> "The proposed rules for documentation would apply to a pharmacist prescribing drugs for various conditions ranging from motion sickness to a statin drug. This is a contrast to requirements applied to physicians. The Idaho Board of Medicine requires a physician to maintain adequate patient records, or legible records that contain at a minimum, subjective information, an evaluation and report of objective findings, assessment, or diagnosis, and the plan of care."

Dr. Adams indicated he reviewed the Board of Medicine rules. He suggested the following amendment to rule 020.07 to address the IPCA concern:

> "The pharmacist must maintain documentation adequate to justify the care provided, including, but not limited to the information collected as part of the patient assessment, the prescription record, any notification provided as required under this section, and the follow-up care plan."

Following a brief discussion the Board granted unanimous consent to move forward with Dr. Adams' suggested language.

Dr. Adams next addressed IMA's comment on rule 020.07:

> "Requiring documentation be made available to the patient or the patient's provider only "upon request," splinters the medical home model of care. Documentation will be kept in silos where the patient's other providers will not have knowledge of, or access to, records regarding a patient's treatment or medication history. Patients don't always know what is important clinical information to convey to their primary care physicians who then cannot provide optimal care to their patients if only an incomplete medical record is accessible."

The Board indicated that the "upon request" language had been carried over from House Bill 4, but that all information retained by the pharmacy can be requested by the patient or their providers, as allowable under HIPAA. The Board noted there may be confusion between the mandatory notification requirement, which will automatically go to the provider, and the requirement to maintain documentation, which can be requested at any subsequent time. Following a detailed discussion regarding some confusion created by the requirement to provide documentation 'upon request' the Board granted unanimous consent to strike that portion of the rule and move forward, while reaffirming that any record should be provided to the patient or provider as allowable under HIPAA.

The IPCA asked the Board to encourage voluntary participation in the Idaho Health Data Exchange (IHDE). Dr. Adams reminded the Board that IHDE had presented to them a few years ago and the Board was very supportive of their program. Dr. Adams has a call scheduled with IHDE later in the week to determine what the other medical boards are doing. Dr. Chopski asked Dr. Adams to determine if there are fees associated with participation. The Board re-affirmed their support of voluntary participation among pharmacies and pharmacists. Dr. Adams indicated that neither the Board of Medicine, nor the Board of Nursing require participation in the IHDE, and that the comment did not request this either. He indicated he will assess how these other boards have encouraged voluntarily participation so that the Board of Pharmacy could match or exceed their efforts. Dr. Adams noted that he understands from IHDE's senior marketing coordinator that IHDE has presented to the Board of Nursing, but not the Board of Medicine.

Dr. Adams indicated there were no comments received regarding rule 022 Pharmacist Prescribing of Devices.

Dr. Adams next presented comments for rule 023 Pharmacist Prescribing Based on CLIA-Waived Test. The Idaho Society of Health-System Pharmacists noted that the CLIA Waived tests occasionally have false negatives, and asked the Board to consider removing the requirement of the tests and allow diagnosis on symptoms alone. The Board noted that all of the research for flu and strep is anchored around CLIA-waived tests and all tests have false negatives. Following a brief discussion the Board chose to maintain the CLIA-waived test requirement as currently drafted. The Board noted that studies have shown this to improve antimicrobial stewardship, a key part of mitigating widespread antibiotic resistance.

Dr. Adams noted the Board had asked staff to research the concern previously raised by IMA with respect to rule 23.01 Influenza:

> "Prescribing antivirals to pediatric patients can be difficult because children are more susceptible to the neuropsychiatric effects that have been seen in antivirals for influenza, i.e., psychosis. Primary care physicians and pediatricians use clinical judgment based on the medical history and overall health of the child when deciding whether to administer antivirals. Pharmacists would not have access to the medical history of the child and would be less able to use appropriate clinical judgment."

Dr. Adams provided multiple studies for the Board to review. In brief, he indicated the pediatric age for Tamiflu appeared to be lowered from 1 year to 2 weeks in 2012. The reports of neuropsychiatric events were mostly from Japan and a decade old. The package insert reiterates no connection has been established between these events and Tamiflu. Further, the package insert indicated: "Estimates of neuropsychiatric event frequency cannot be made but they appear to be uncommon based on usage data." While the package insert does not provide an estimate, Dr. Adams shared one estimate he found:

- 8 events per million prescriptions in adults in the U.S.
- 19 events per million prescriptions in children in the U.S.

Dr. Adams also contacted an infectious disease professor to assess the Board's findings. The professor indicated the incidents are rare and that that experts agree the benefits of treatment far outweigh the risk. Given the totality of evidence, Dr. Adams asked the Board if it should remove flu from the list or limit treatment to adults based on the data. After lengthy discussion, the Board is in support of leaving it on the list given the clear benefits relative to the risks. Dr. Adams asked the audience to submit additional information and/or studies that the Board should review prior to the October meeting.

Dr. Adams next took up IMA's comment on rule 023.02 Group A Streptococcus:

> "Regarding pediatric patients, fifteen percent of children are colonized (strep carriers) and will test positive even when strep is not the cause of their illness or even when they are not sick. Clinical decision making around this issue is frequently not straightforward and would be difficult to do at the pharmacy level."

The Board had tasked staff with researching this concern, and Dr. Adams had provided research for the Board to review in advance of the call. In brief, he indicated IDSA guidelines suggest no treatment for asymptomatic patients; the Board rule specifically indicates treatment for "symptomatic" patients. If a symptomatic carrier presents, it is prudent to treat them according to feedback Dr. Adams had received from two infectious disease professors. Dr. Adams again called on the audience for additional information and/or studies that the

Board hasn't seen. He reiterated the draft rules are based on a preponderance of the evidence gathered and encouraged stakeholders to come forward if they have additional information. The Board directed Dr. Adams to leave medications indicated for Group A Streptococcus on the list and will review any additional information submitted by external stakeholders at the October meeting.

Dr. Adams indicated that the IDSA guidelines specifically refer to the condition as "Group A Streptococcal Pharyngitis" and he recommended amending the rule to mirror this language. Following further discussion the Board granted unanimous consent to update the title to Group A Streptococcal Pharyngitis.

Dr. Adams next took up IMA's comment relative to rule 024.01 Pharmacist Prescribing for Clinical Gaps in Care. One part of their comment noted:

> "There are many reasons it is clinically inappropriate for a pharmacist to prescribe a statin for a diabetic patient. Assuming there is a gap in care could be an inappropriate or even dangerous assumption. Diabetic patients are complicated patients who are usually on multiple medications."

Dr. Adams noted that this measure stems from the ACC/AHA guidelines, and that the Medicare program had adopted this measure as a national goal for improvement. To assess the extent of the gap, and if there were legitimate reasons for exclusion, as had been indicated by IMA, the Board solicited input from the statin use in patients with diabetes (SUPD) measure developer, the Pharmacy Quality Alliance (PQA). Per PQA:

- "The SUPD measure is endorsed by the National Quality Forum (NQF #2717) and evaluates the percentage of patients ages 40-75 years who were dispensed a medication for diabetes that received a statin medication (a higher rate is better)."
- "The American College of Cardiology/American Heart Association (ACC/AHA) guidelines recommend the use moderate- to high-intensity statin therapy for primary prevention for persons aged 40 to 75 years with diabetes (class 1 recommendation). The American Diabetes Association also recommends the use of statin therapy for patients with diabetes between the ages of 40-75."
- "Atherosclerotic cardiovascular disease (ASCVD) is the leading cause of morbidity and mortality for patients with diabetes in addition to being the largest contributor to costs of diabetes care. Patients with diabetes aged 40 to 75 years are at a markedly increased lifetime risk for the development of ASCVD, experience greater morbidity, and are at a decreased likelihood of survival following the onset of ASCVD.[1] Data from meta-analyses including over 18,000 patients with diabetes from 14 randomized trials of statin therapy, showed a 9% proportional reduction in all-cause mortality and 13% reduction in vascular mortality for each mmol/L (39 mg/dL) reduction in LDL cholesterol."
- "This SUPD measure is endorsed by NQF (#2712). It is currently on the Medicare Part D display page for 2018 (using 2016 data), and the Centers for Medicare and Medicaid (CMS) plans to add it to the Part D 2019 Star Ratings (using 2017 data)."
- "Patients with diabetes frequently do not receive interventions or meet target goals to reduce cardiovascular risk. Approximately 33% to 49% of patients with diabetes do not meet their target goals for A1C, blood pressure, and LDL cholesterol levels. In an analysis of US national registry data from 204 cardiology practices from May 2008 through October 2013, 38% of patients ages 40 to 75 years with diabetes and no cardiovascular disease had not been prescribed statins. The analysis also showed wide variation in statin use across cardiology practices included in the study."
- "The 2017 Medicare Part D Display Measures (using 2015 data) are publicly available: Among 528 Part D contracts, the reported rate for the Statin Use in Persons with Diabetes measure (DMD17) ranged from 59% to 89% (mean, 75%; standard deviation, 4.1%)."

Dr. Adams noted he was unable to find comments from medical groups expressing concerns over legitimate gaps when CMS solicited public comments on inclusion of the measure as part of the Star Ratings program. The Board reviewed the studies showing the gap, and compared the rate of legitimate exclusions (e.g., pregnancy) and found that these legitimate reasons account for a tiny fraction of the reported gap. During discussion, Dr. Henggeler noted the overwhelming evidence shown in the studies and the notification of the provider within five days, she is comfortable with leaving this rule as written. She noted that

medication carries benefits and risks. Following extensive discussion the Board directed Dr. Adams to leave the rule as written.

Dr. Adams noted that there were other elements to IMA's concerns with rule 024.01:

> "A patient may not be on statins because of elevated liver function tests. The pharmacist would not know this."
>
> "The standard of care is that when a new statin is started, the patient should have appropriate labs checked no later than 3 months after starting the statin. A pharmacist is not in a position to perform, obtain, or interpret these labs."

Dr. Adams noted that these concerns may stem from confusion over current pharmacy law. Dr. Adams noted that nearly every state allows pharmacists to order and interpret lab tests. Nearly 10,800 pharmacies held CLIA certificates of waiver (COW) in a 2015 study. Idaho has allowed pharmacies to obtain a COW for years, and Idaho was reported as having one of the highest rates nationally of pharmacies performing CLIA-waived testing.

In addition, IMA commented:

> "Patients are prescribed diabetic medications (metformin likely being the most common) for a variety of non-diabetes-related conditions. The pharmacist is not in a position to differentiate between patients who are or who are not diabetics in these situations or to assess the need for statins."

Dr. Adams stated that pharmacists differentiate between diagnoses every day as part of the counseling requirement. The Board indicated requiring prescribers to note the diagnosis as part of the prescription drug order would be alleviate this concern if it is one. The Board has discussed this several times, most recently at its April 2017 meeting, and invited all parties to work with the Board toward having the diagnosis added as a requirement on valid prescription drug order as it would have many benefits to public health. Ohio recently required it for controlled substances to provide pharmacists one more tool to combat opioid overprescribing. The Board granted unanimous consent to leave statins for diabetes patients on the list and again asked stakeholders to submit additional evidence related to the studies the Board has reviewed for the October meeting.

The Board next took up comments related to rule 024.02 Short-Acting Beta Agonists (SABA). IMA commented:

> "Managing asthma, a potentially lethal condition, can be difficult. Part of asthma management from a primary care physician standpoint is knowing how frequently a patient is refilling albuterol, getting them back into the office if refills are happening too frequently, and explaining that additional refills will not be authorized until the patient is seen. It is critical to know why the patient is using more asthma medication than prescribed. Having refills at the pharmacy level could interfere with patients returning to their physician for crucial follow-up care and improvement of controlled medication management."

Dr. de Blaquiere noted that he believes the notification requirement satisfies this concern. The pharmacist is required to notify the patient's provider of record within five (5) days, and thus the provider will remain abreast of frequency, while ensuring the patient continues to receive the medication that is needed. Following discussion the Board granted unanimous consent to amend the rule to narrow the prescribing authority to only patients with asthma, and only to patients who had a previous prescription for a SABA. Thus, the pharmacist could not start a SABA for a patient who had never been on one, but could continue one if the patient ran out. The Board amended the language as follows:

> "Short-Acting Beta Agonists. Short-acting beta agonists (SABA) for patients with asthma who have had a prior prescription for a SABA, and who have a current prescription for a long-term asthma control medication."

The Board next took up rule 025 Pharmacist Prescribing of Travel Drugs. The Board had tasked Board staff with researching the extent to which this is covered in the current pharmacy curriculum. The Board had discussed in length comments submitted by medical groups regarding the pharmacist education requirements, and the Board felt this may be one area to specify a requirement. Dr. Adams indicated the Accreditation Council for Pharmacy

Education (ACPE) specifically listed travel immunizations in its standards and guideline documents, but did not speak specifically to “travel medicine.” Dr. Chopski asked if Dr. Adams reviewed the curricular standards for nursing and medicine. Dr. Adams indicated he did not, but noted that one of the studies he sent the Board suggests that travel medicine is not core to their curriculum either. Following extensive discussion the Board granted unanimous consent to amend the rule to add a pharmacist education requirement. The Board did not want to establish a specific number of hours for the program, and did not want to limit it to ACPE programs as some national and international groups on travel medicine also offer programming that may be useful. The amendment follows:

> “A pharmacist who successfully completes an accredited CPE or CME course on travel medicine may prescribe any non-controlled drug recommended for individuals traveling outside the United States that are specifically listed in the federal CDC Health Information for International Travel (e.g., Yellow Book). The pharmacist may only prescribe drugs that are indicated for the patient’s intended destination for travel.”

The Board next took up rule 026 Pharmacist Prescribing to Supplement an Infusion Order. The comment that had been previously submitted to the Board had an “etc.” at the end of each bulleted list. Dr. Adams cut this from the draft rule as he believes it is at odds with House Bill 191, which requires the listing of drugs, drug categories, or devices. Dr. Adams received feedback from a participant at the Twin Falls listening session that this list may be missing Emla cream. Rather than listing a specific brand product, Dr. Adams suggested that if the Board wanted to act on this requirement that they should consider broadening it to “local anesthetics for IV port access.” Following discussion, the Board granted unanimous consent to add it to the rule.

In addition, the Board had received a comment from John Sullivan on rule 026 that noted the heparin units as currently drafted use an unapproved abbreviation. The Board granted unanimous consent to spell out “units per milliliter” in connection with the heparin flush prescribing.

The Board discussed comments received regarding rule 027 with respect to a pharmacist prescribing a SABA in an emergency. He indicated he believes the concern was rooted in confusion that a pharmacist would simply give a SABA to a patient in respiratory distress without consideration to the underlying cause, and that the patient would not seek further care. Dr Adams noted the rule, as drafted, would only be exercised in an emergency situation while an ambulance is on its way. To assess if there could be any harms from a patient using a dose of SABA while an ambulance is on its way, Dr. Adams contacted a professor in the pulmonary field. The professor indicated that even if the patient had congestive heart failure, pneumonia, or a heart attack, a low dose beta agonist albuterol “would not worsen anything.” Dr. Adams also referenced an article to that effect, which he had shared with the Board from the Journal of Emergency Medicine. Based on the evidence and discussion, the Board chose to leave the rule as drafted. The Board invited additional evidence or feedback from stakeholders prior to the October meeting.

The Board had received several comments requesting additional products be added to the rules for pharmacists to prescribe. The Board indicated it did not want to consider new products at this late juncture, with the exception of medications of Lyme disease prophylaxis, since this had been submitted in advance, research was shared with the Board in advance of the call, and IMA had also been provided a good faith heads up in advance of the call. Following a discussion of Lyme disease prophylaxis the Board granted unanimous consent to add rule 028 as follows:

> “Pharmacist Prescribing for Lyme Disease Prophylaxis After a Recognized Tick Bite: A pharmacist may prescribe antimicrobial prophylaxis for the prevention of Lyme disease in accordance with clinical guidelines.”

The Board invited specific feedback on this addition for the October meeting.

Dr. Adams presented a comment received from IPCA on rule 200:

> “Who sets the statewide pharmacy prescribing protocols? What happens if an individual collaborative agreement does not comply or is significantly different from the statewide protocol? A physician assistant or registered nurse is required to enter into an agreement with a physician for supervision. These agreements should have similar supervising requirements.”

Dr. Adams noted that this language is not new, and that it is existing law that has been moved into this chapter as part of the reorganization of the law book into different chapters. Dr. Adams detailed the history of the rule, having first been included in a docket related to emergency preparedness for catastrophic events. Since it was existing law, the Board granted unanimous consent to keep it as is, but invited additional feedback from stakeholders for the October meeting.

The Board circled back to rule 020.01 Education. The Board discussed the education provision at length at the first negotiated rulemaking session based on comments received from the public. Dr. Adams noted that no additional specific concerns were submitted in writing for the follow-up meeting, though he had heard one verbal comment from the Board of Medicine meeting. Specifically it was noted that some of the studies the Board is using stem from other countries, and it was suggested that pharmacy education in the countries may be "more clinical." He contacted ACPE as they accredit all U.S. Doctor of Pharmacy (PharmD) programs and consult internationally. ACPE indicated the United States requires the entry-level doctorate degree versus a bachelor's or master's degree in the reference countries. ACPE further shared that the U.S. PharmD programs have more experiential and inter-professional requirements than international programs.

The Board took up rule 20.03 related to patient assessments. ISHP submitted a comment noting that clinical guidelines are not always available for each condition on the list. Dr. Adams noted that he has used the guidelines on the website provided by the Agency for Healthcare Research and Quality to identify relevant guidelines, and confirmed that that is indeed the case for several conditions (e.g., lice and cold sores). The Board granted unanimous consent to amend this section to emphasize clinical guidelines, when available, and the use of evidence-based research as a fallback when clinical guidelines are not available. The amendment follows:

> "03. Patient Assessment. The pharmacist must obtain adequate information about the patient's health status to make appropriate decisions based on clinical guidelines or evidence-based research findings and mitigate potential contraindications and interactions, among other potential adverse health outcomes.
>
> a. At a minimum, for each drug or drug category the pharmacist intends to prescribe, the pharmacist must maintain a patient assessment protocol based on current clinical guidelines, when available, or evidence-based research findings that specifies the following:
>
> i. Patient inclusion and exclusion criteria; and
> ii. Explicit medical referral criteria.
>
> b. The pharmacist must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings. The pharmacist's patient assessment protocol, and any related forms, must be made available to the Board upon request."

Dr. Adams inquired about the Board's desire to list specific clinical guidelines, rather than just defining "clinical guidelines" in Chapter 1. Dr. Chopski is hesitant to list guidelines by organization or association. She indicated there are sometimes two different sets of guidelines for some conditions, diabetes as an example. Dr. Chopski asked Dr. Adams if the Board of Medicine or Board of Nursing lists specific guidelines, and he indicated he is not aware of them doing so based on his review of their laws. The Board chose not to list specific sets of clinical guidelines in the rules at this time but invited additional feedback based on the experience of other health professions.

Dr. Adams noted that medical organizations have submitted comments to the Board about listing specific medical referral criteria in rules. The Board reiterated these are best addressed in the protocol as it would otherwise necessitate constant rule updates. Washington State presented to the Board on their protocols at a previous meeting for conditions such as urinary tract infections (UTIs). The Board encouraged any stakeholders with concerns over referral criteria to submit protocols based on clinical guidelines, and noted that this would be a great opportunity for collaboration. Dr. Adams shared an anecdote he heard from Canada in which the physician who had expressed the most concerns ended up drafting a protocol that the Board shared as guidance, and that the same physician now

speaks favorably on the topic and has received grant funding to evaluate the patient care gains that have been achieved from pharmacist prescribing.

The Board concluded Chapter 4 by reviewing rule 021. Dr. Adams noted that no concerns were submitted for lice, cold sores, or motion sickness, and Dr. Henggeler indicated the medical groups even expressed support for their inclusion. Groups have, however, submitted concerns for both nausea and UTIs. The Board tasked staff with researching these concerns, and multiple studies and clinical guidelines were circulated in advance of the meeting.

Dr. Adams reviewed IMA's concerns over UTIs. For one, IMA noted:

> "Prescribing for an uncomplicated urinary tract infection almost always will require a new diagnosis. This means that in almost all cases a pharmacist may not prescribe for a UTI without performing a CLIA waived test. At the very minimum, this rule ought to require a pharmacist to perform that test."

Dr. Adams noted that similar concerns were raised by a member of the Board of Medicine, who suggested a urine culture is part of the standard treatment guidelines. Dr. Adams shared his research on the most up-to-date ACOG guidelines revealed the following:

> **"**When is a urine culture necessary?
>
> "The initial treatment of a symptomatic lower UTI with pyuria or bacteriuria does ***not*** require a urine culture." (emphasis added)

Dr. Adams reiterated the Board's previous discussion about the diagnosis and treatment of UTIs via phone call, which do not involve a urine culture. The Board had been provided five (5) studies on diagnosis and management via phone call, and several lay articles on this as well. The Board decided not to require a urine culture as a result of the clinical guidelines and the common practice of treating via phone call, but invited additional evidence on this for the October meeting.

The IMA additionally submitted comments relative to UTIs as follows:

> "It can be very dangerous for a pharmacist to assume a diagnosis of "Uncomplicated Urinary Tract Infection" simply because a patient has had one or more UTIs in the past. Clinical examples presenting as pain with urination and/or frequency of urination include (but are in no way limited to):
> - STI's – herpes, chlamydia, gonorrhea, syphilis, etc.
> - Rheumatologic issues: Reiter's syndrome
> - Yeast infections (which may be the presenting symptom of new diagnosis of diabetes)
> - Uncontrolled diabetes
> - Bladder cancer
> - Pyelonephritis
> - Kidney stones
> - Constipation
> - Endometrial/Uterine cancer
> - Endometriosis"

The Board reiterated its position that the differential diagnosis via phone call has proven successful, and that the required protocol requires inclusion, exclusion, and referral criteria that would distinguish between these. Stakeholders who have concerns are encouraged to collaborate on a protocol or send additional research for consideration at the October meeting.

The Board also reviewed the research Dr. Adams sent around related to nausea. The Board found that nausea prescribing is common in Canada, and that only two provinces narrowed this authority, and did so to pregnancy-related nausea. The Board is not aware of any issues that have arisen in Canada. Dr. Adams asked the Board if it wished to narrow the nausea prescribing to continuing previous nausea medications that the patient has been prescribed. After discussion, the Board granted unanimous consent to keep the rule as drafted, but invited additional evidence to be submitted for the October meeting.

Dr. Chopski called for additional comment regarding Chapter 4, Dr. Baron from Terry Reilly expressed his concern regarding nausea, though he expressed support for pharmacist prescribing generally. Dr. Chopski asked Dr. Baron to meet with Board staff prior to the October meeting and consider drafting a protocol to address his concerns.

No other verbal comments were provided on the call.

Chapter 1 – General Provisions

Dr. Adams shared that no comments were received for Chapter 1, but that staff had one suggestion of adding "reverse distributor" to the list of outlets that are licensed as limited service outlets. Dr. Adams explained that this is not a change in policy, because the Board currently licenses reverse distributors as such, and it is merely attempting to make the list complete. Following a brief discussion the Board granted unanimous consent to add reverse distributor as a limited service outlet.

Chapter 2 – Rules Governing Licensure and Registration

Dr. Adams noted he has heard of a draft policy that a pharmacist intends to bring to the National Association of Boards of Pharmacy that would standardize the CPE timeline to coincide with the calendar year. Dr. Adams noted that Board compliance staff is supportive of this change. Following discussion the Board granted unanimous consent to amend rule 33 as follows:

> "Pharmacist License Renewal: CPE Requirements:
> Each pharmacist applicant for license renewal must complete fifteen (15) CPE hours each calendar year between January 1 and December 31."

Dr. Chopski noted that she would like to look at this provision again at the October meeting.

The Idaho Veterinary Medical Association (IVMA) submitted the following written comments prior to the meeting:

- Expressed support of the elimination of Veterinary Drug Technician and Veterinary Drug Outlet registrations.
- Suggested moving current Board of Pharmacy regulatory authority for veterinarians to the Board of Veterinary Medicine.
- Suggested separating human and veterinary prescriber drug outlets

Dr. Adams believes separation will make it easier to coordinate with the Board of Veterinary Medicine in regulation of these facilities. Following discussion the Board granted consent to separate the two. Dr. de Blaquiere expressed concerns over getting rid of oversight of veterinary offices that dispense for outpatient use, and Dr. Adams will invite IVMA to the October meeting for further discussion.

Chapter 3 – Rules Governing Pharmacy Practice

Dr. Adams shared the following additional comments submitted prior to the meeting:

- Rule 201.04, regarding an unsafe work environment due to understaffing and who is ultimately responsible? The Board chose not to address this comment at this time.
- Rule 302, request to add a phone number as a requirement of the prescription order. The Board attempted to address this matter in prior years and will not take it up again at this time.
- Rule 303, which allows a pharmacist to fill a prescription one time in 12 months. Dan Houdeshell who lost his son due to a lack of a refill is very supportive of this rule and shared information on other states that have recently adopted "Kevin's Law."

Jeffrey K. Larsen, Director of Business Management at Terry Reilly Health Services submitted the following written comment prior to the meeting:

- 314.02 Destruction or Return of Drugs or Devices: Restrictions Institutional Facility
  - Suggested adding 'federally qualified heath centers' and defining the same.

Following a brief discussion the Board approved the change as follows:

> "Did Not Reach Patient. Non-controlled drugs that have been maintained in the custody and control of the institutional facility or dispensing pharmacy may be returned if product integrity can be assured. Controlled substances may only be returned from a hospital daily delivery system under which a pharmacy dispenses no

more than a twenty-four (24) hour supply for a drug order, or up to a seventy-two (72) hour supply for a drug order if warranted for good patient care."

Dr. Adams presented rule 400.02 that was tabled from the last meeting. He and Fred Collings agreed to strike the rule as long as staff still received the DEA Form 106. Rule 400.02 was found to be above and beyond federal requirements. The Board granted unanimous consent to strike the requirement in 400(02) related to inventory after discovery of theft or loss.

Edward D. Rickert, Attorney for MedAvail Technologies, which is a manufacturer of automated dispensing systems (ADS), submitted the following written comments prior to the meeting:

- 204.07 Drug Outlets That Dispense Drugs to Patients Without an Onsite Pharmacist or Prescriber
  - Suggested adding an additional exemption clarifying the ADS is an extension of the drug outlet that operates it and doesn't require separate licensing
- Suggested adding a rule to address record storage for self-service ADS
- Suggested revising the definition of 'reconstitution' to allow drug products that need to be reconstituted to be dispensed from ADS with premeasured water so patients may reconstitute the product at home.

Following a brief discussion Mr. Rickert and Dr. Adams will work together to draft language to present to the Board at the next meeting. The Board further expressed its belief that the reconstitution rule as drafted already covers the scenarios Mr. Rickert raised, and that no change was needed at this time as it is already permitted.

Chairman Chopski called for further public comment. Hearing none, Dr. Henggeler motioned to adjourn, Mr. Sperry seconded, and the motion carried unanimously. Meeting adjourned at 11:10 a.m.

MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
October 25-26, 2017

Idaho State Capital Building
Boise, Idaho

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

Chairman Nicole Chopski, PharmD, called the meeting to order at 9:00 a.m. In attendance were Vice Chairman, Holly Henggeler, PharmD; Board members Rich de Blaquiere, PharmD; Kristina Jonas, PharmD; and Ed Sperry, Public Member. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Lisa Culley, CPhT, Jaime Thompson, and Wendy Shiell, Compliance Officers; Misty Lawrence, Management Assistant; Andy Snook, Deputy Attorney General; Ellen Mitchell, Program Information Coordinator, Colter Shirley, the Board's intern from Idaho State University (ISU), and several members of the public.

Dr. Jonas motioned to accept the minutes of the August 30, 2017 meeting with minor corrections. Mr. Sperry seconded, and the motion carried unanimously.

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

a. Board Performance Dashboard
b. Travel Calendar
c. Exercises of Delegated Authority
d. Director's Expenses

Dr. de Blaquiere motioned to approve consent agenda items a, b, and d. Dr. Henggeler seconded, and the motion carried unanimously. In response to a question on the high number of canceled controlled substance registrations, Mr. Fraser noted this stems from the notification provided by other medical boards to the licensing staff of non-renewal of professional licenses, which triggers the cancellation. The Board granted staff delegated authority to cancel registrations in this situation. Mr. Fraser explained the pharmacy extern registration that was canceled was due to notification from ISU College of Pharmacy that the student was no longer enrolled in the pharmacy program. He also indicated Board staff had issued three Corrective Action Plans (CAP) after the deadline for inclusion in materials for this meeting. Dr. Jonas motioned to approve the Exercises of Delegated Authority. Dr. Henggeler seconded, and the motion carried unanimously.

Dr. Chopski introduced the Proposed Rulemaking Session. She noted that in accordance with the Idaho Administrative Procedures Act, today marks the official close of the 21-day public comment period for the proposed rules the Board of Pharmacy published in the October 4, 2017 Idaho Administrative Bulletin. Board staff received some written comments in advance of the meeting and several individuals signed in to provide verbal testimony.

Dr. Chopski extended her thanks to the Board members for their hard work throughout the process and for adhering to their articulated primary goals to:

1) Ensure an open and transparent process; and

2) Ensure decisions are based on the best available information.

This is the seventh public meeting to discuss the rules, and the third officially noticed public hearing on the rules. Board staff also hosted 8 town hall meetings across the state, and met individually with Idaho stakeholder groups and federal agencies.

Dr. Chopski also extended thanks to the many members of the public who have actively engaged in the process. She noted the Board has tried to keep evidence front and center in their decision-making and many in attendance have helped strengthen its proposed rules.

Dr. Chopski indicated it was unlikely that all stakeholders agree with all of the decisions made by the Board to date, but believes everyone has the same goal: to ensure that the health, safety, and welfare of the public is preserved and protected, and that the active engagement of all parties has created a better end-product. Dr. Chopski indicated the Rule Dockets would be

addressed in the order in which they were published in the Administrative Bulletin. She also indicated any changes to the draft language would be published on the Board's website by tomorrow morning so stakeholders would have an opportunity to review them and provide feedback prior to the finalization of the pending rules.

Docket No. 27-0101-1701- Repeal

- No verbal comments were provided at the meeting, and Dr. Adams indicated that no written comments were received in advance of the meeting.

Docket No. 27-0101-1702 – Chapter 1 - General Provisions

- No verbal comments were provided at the meeting.
- Dr. Adams reviewed the written comments received in advance of the meeting:
    - Rule 023. Unprofessional conduct was proposed to be changed to read 'any licensee or registrant', based on staff comment. The Board directed Dr. Adams to include this in the written update to be posted before the final session.
    - Pam Eaton, Director of the Idaho Retailers Association and Idaho State Pharmacy Association submitted written comment asking for clarification on Rules 023.16 and 023.17. The Board felt these had both been adequately addressed at previous meetings and suggested no changes be made.

Docket No. 27-0102-1701 – Chapter 2 – Licensure & Registration

- No verbal comments were provided at the meeting.
- Dr. Adams reviewed the following written comment in advance of the meeting:
    - Jessie Modlin, PharmD submitted a comment requesting Idaho synchronize the continuing education (CE) requirement period with Washington making CE due at the time of birth month renewal instead of calendar year. Dr. Adams reminded the Board that a resolution was forthcoming at the National Association of Boards of Pharmacy (NABP) to standardize all CE due dates to coincide with the calendar year. Dr. Jonas stated it will lessen the burden of CE audits as all CE will be due at the same time. Dr. Adams noted staff will require Continuing Medical Education (CME) certificates to be submitted to the office between December 1 and December 31 each year. NABP is currently developing a mobile app to allow upload of CME certificates to the Continuing Pharmacy Education (CPE) Monitor, making it easier for licensees to submit and for staff to retrieve the certificates. Given that, the Board decided to not suggest any changes.

Docket No. 27-0103-1701 – Chapter 3 – Rules Governing Pharmacy Practice

- No verbal comments were provided at the meeting.
- Dr. Adams reviewed the following written comment received in advance of the meeting:
    - Quarles & Brady submitted a comment on Rule 400.05, requesting that records from an Automated Dispensing System be allowed to be kept at the central pharmacy. Dr. Adams suggested modifying the language to read 'Records may be retained at a central location in compliance with federal law.' Dr. Adams noted that this would allow any record – controlled or non-controlled – to be kept centrally in compliance with federal law, and the Board would not have to update the rule each time federal law changes. The Board directed Dr. Adams to include this in the written update to be posted before the final session.

Docket No. 27-0104-1701 – Chapter 4 – Prescriptive Authority

Dr. Chopski requested that Dr. Adams provide a brief overview of House Bill (HB) 191 that authorized the Board to promulgate this rule chapter. Dr. Adams noted that the bill did not create prescriptive authority for pharmacists, but changed the process in which prescriptive authority decisions were made. Idaho Pharmacists began prescribing in 1998, with drugs that pharmacists could prescribe independently being added frequently since 2011. HB191 allows

the Board to promulgate rules related to pharmacist prescribing of drugs, drug categories, and devices provided they meet one of the four statutorily authorized conditions. Controlled substances, compounded medications, and biological drugs are specifically excluded by the statute.

Dr. Chopski indicated there were several comments regarding this rule docket, and she noted that the remaining concerns rest with a minority of the drug categories and devices. There were no concerns expressed with two-thirds of the rules and she believes that is a great starting point.

She also noted a few written comments seemed to conflate the rules with the protocols that are required under the rules. Rule 020 requires that each pharmacist use a protocol that specifies the inclusion, exclusion, and referral criteria for each drug they intend to prescribe. She noted that protocols are powerful, evidence-based accountability tools.

Dr. Chopski further noted that the Board has previously stated it will post template protocols on their website for use, and they have extended an invitation to everyone wanting to participate in the process. The Board has been fortunate to have many physicians and pharmacists work together on template protocols, a sample of which was included in the public meeting materials posted on the Board's website prior to the meeting.

Dr. Chopski reiterated all interested parties are welcome to attend the protocol workshops. Information is available on the Board website, with workshops scheduled for November 16th and December 7th. The goal of the workshops is to collaboratively finalize the template protocols and ensure the appropriate safeguards are put in place while balancing patient access, choice, and competition. Dr. Chopski noted that while she encourages in-person participation, she realizes it can be difficult for those outside of Boise. The Board has provided a conference line to ensure maximum participation from any willing party.

Dr. Chopski believed many of the written comments suggested exclusion or referral criteria that would be better addressed in protocols instead of the rules. She reminded the Board members that when evaluating comments, they need to determine if recommendations are best addressed in rules or in template protocols. Rules take 9 to 12 months to update, and changes to clinical guidelines or the applicable standard of care, could necessitate constant temporary rules if the rules get too granular.

Dr. Chopski indicated comments would be organized by drug class, then general comments, and miscellaneous comments would be heard last.

Rule 021.01 Lice

- No verbal comments were provided at the meeting, and Dr. Adams indicated that no written comments were received in advance of the meeting.

Rule 021.02 Cold Sores

- Dr. Adams indicated that no written comments were received in advance of the meeting.
- Shasta Kilminster-Hadley, staff attorney for the Board of Medicine (BOM), offered verbal testimony indicating BOM believes cold sores require a diagnosis and are not appropriate for autonomous pharmacist prescribing. She indicated though cold sores fall within the legislative authority of HB191 a diagnosis is required to ensure a cold sore is not gonorrhea or genital herpes and thus it makes this drug category inappropriate for autonomous pharmacist prescribing.
- Dr. Adams briefly summarized that this drug category has been commonly prescribed by pharmacists with no known safety issues.

Rule 021.03 Motion Sickness

- Before taking public comment Dr. Chopski proposed amending this rule to narrow it to 'motion sickness prevention'. She noted that this category was initially added because Rule 25 for travel medicine is specific to the CDC Yellow Book, which is for international travel. She indicated it was arbitrary to allow a pharmacist to provide motion sickness patches for an Idahoan embarking on a Mediterranean cruise but not an Alaskan cruise. Many people have been worried about differential diagnosis for actual motion sickness,

though the intent has always been prevention, and making that clear in the rule would be an appropriate amendment according to Dr. Chopski. The Board members were all in support of this amendment.

- Ms. Kilminster-Hadley commented that narrowing the rule to motion sickness prevention would address BOM concerns.

- Mark Johnston, RPh, CVS Health commended the Board for the many opportunities provided for public comment during the rules re-write process. Mr. Johnston shared in 1991, Florida received statutory authority for pharmacist prescriptive authority for 20-30 individual drugs, many of which have since gone over the counter. One drug that has remained on the list is scopolamine patches. Mr. Johnston spoke with the Florida Board of Pharmacy to see if there had ever been complaints related to pharmacist prescribing for motion sickness. The representative from the Florida Board indicated they had not received a single complaint. Mr. Johnston again commended the Board on the work they had done on the topic.

- The Board directed Dr. Adams to narrow “motion sickness” to “motion sickness prevention” in the written update to be posted before the final session.

Rule 021.04 Nausea

- Dr. Adams reviewed the history of the addition of this category and believed it varied from the Board’s original intent. Nausea was originally added during conversations surrounding travel drugs and the 10-15 year history of pharmacists safely and appropriately prescribing nausea medications without incident. Pharmacist prescribing is limited to the CDC Yellow Book, which is specifically for international travel, not domestic travel. He believes it is appropriate to remove nausea from the list as the only other category potentially relevant in the CDC Yellow Book was altitude illness prevention, though he understands that making a change that late is not advisable.

- Kathleen Sutherland, MD, Chairman of the Board of Medicine, believes further discussion is in order regarding altitude illness prevention as it has to be determined if a patient has an underlying lung disease, which complicates the decision to prescribe medications for altitude illness prevention. She is not in favor off adding it to the rule.

- Mark Johnston, RPh, CVS, indicated he saw many Canadians with altitude illness when he filled prescriptions in the Lake Tahoe, Nevada area. He indicated they would ask for Gravol, as it was an over the counter medication in Canada. He acknowledged many of the evidence-based decisions that the Board has made have been based on decades of prescriptive authority in Canada. He suggested there isn't evidence of prescribing for nausea in Canada because Gravol is still an over-the-counter product. Moving motion sickness to preventative and then considering striking nausea, he believes the Board is missing a category that pharmacists are amply able to prescribe for according to protocols. He hopes if the Board chooses to remove it in full today, that they would consider it for next year. He is in support of not removing nausea, and is in favor of at least adding in altitude sickness prevention.

- Molly Steckel, Policy Director, Idaho Medical Association, asked for clarification on protocols. Dr. Adams responded that the rules mandate pharmacists to use protocols and that the Board will have templates available on its website. A pharmacist could deviate from the template only if they have good justification for doing so, as the protocol must be linked to clinical guidelines and evidence-based research. Part of the reason the Board didn't want to mandate protocols, is there are protocols that are widely available for all the conditions listed. A representative from the Washington State Pharmacy Association testified before the Board on August 1 indicating they had protocols in use in dozens of pharmacies throughout Washington for flu, strep, and UTIs, among other conditions. The Board did not want to create a monopoly for any private organization, but also did not want to prevent use of their validated protocols by imposing a government mandate on a bureaucratically developed protocol. Ms. Steckel indicated she is not aware of any other health profession that requires the use of protocols.

- Ms. Kilminster-Hadley – BOM has a number of concerns about including nausea and recommends removing it entirely. She expressed BOM's willingness to work with BOP over the next year to look at the prevention of altitude illness. She reiterated nausea should not be on the list as it is a symptom of so many diseases.

Following an extensive discussion the Board chose to pull nausea from the list for this year and directed Dr. Adams to strike it in the written update to be posted before the final session. Dr. Adams will place it on his work list for next year. Ms. Kilminster-Hadley reiterated BOM is committed to working with BOP throughout the year to see what categories can be called out that would not require a diagnosis.

Rule 021.05 Uncomplicated Urinary Tract Infections (UTI)

- Joseph Williams, MD, Idaho Urologic Institute expressed his concern regarding pharmacist prescribing for this category. He mentioned the guidelines indicate it is acceptable to treat for an appropriate UTI if it is demonstrated though microscopy and he doesn't believe it fits with a CLIA-waived test as microscopy requires a designation above and beyond a CLIA-waived laboratory testing, which requires physician oversight of the laboratory that is established.

- Sky Blue, MD, infectious disease specialist that has been practicing in Idaho for 20 years stated he has seen the resistance start to overtake antibiotic development. He believes having UTIs on the list crosses the line into diagnosing. He indicated that evidence based guidelines can vary from one expert to another and it comes down to the interpretation of a CLIA waived test without the use of other tests or a questionnaire in the clinical setting. He questions whether there is such a thing as an uncomplicated UTI.

- Ms. Kilminster-Hadley expressed BOM concern over UTIs being a condition that requires treatment with antibiotics. Antibiotics without proper stewardship can be dangerous. She stated that doctors in Idaho are graded based on their antibiotic stewardship as there is a growing problem with antibiotic and antimicrobial resistance that is developing super bugs that can't be treated.

- Andrea Winterswyk, PharmD stated she agrees there needs to be a detailed medical history, she also believes that history can be provided by the patient. Patient assessment is crucial, yet prescriptions are often issued to patients calling in to the prescriber's office that haven't seen the provider yet, and the prescription is issued based on symptomology. She indicated the rates of Ciprofloxacin resistance to E.coli, which is the most commonly isolated pathogen, has increased significantly. They are finding that pharmacists would have the ability to employ and refer to a stewardship for which they would be evaluated on their own independent licensure as well as the protocol. Access is important, and can be seen as a triage tool as it is face to face and not a phone call. Women are able to self-diagnose with 90% positive correct in value in studies based on symptomology.

- Paul Cady, PhD, Dean, ISU College of Pharmacy addressed the concepts of antibiotic stewardship assuring the Board this has been part of training of pharmacists for many years. Along with antibiotic stewardship, an important rule of pharmacists has been antibiotic de-escalation. In the late seventies, early eighties, his responsibility in the public health service was focused around antibiotic de-escalation with the treatment of UTIs and otitis media where the incidents and rate of resistance to the common antibiotic treatment or for anti-infective treatment, we were losing the ability to use common treatments because they had been misused by traditional prescribers.

Following public comment Dr. Adams provided a recap of the research that had been reviewed extensively at previous public meetings.

- Dr. Adams noted that the Board's intern also participated in a webinar by ACOG on September 20, 2017. Prior to the first statistic being presented, there was a poll of the attendees, asking the question: Before treating an uncomplicated UTI, which is recommended? The majority of the attendees answered: Treat based on symptoms

with a positive urine dipstick for leukocyte, esterase, or nitrate. That answer was incorrect. They cited a study that said there are two typical symptoms of uncomplicated UTI. If a patient has two or more symptoms, the likelihood of uncomplicated cystitis is greater than 90%. The other item from that webinar was UTIs are self-diagnosed more than 85 to 95% of the time by women.

- Dr. Adams noted that one option for the Board to consider is narrowing UTIs to 'recurrent' UTIs. Dr. Jonas expressed her concern over 'recurrent'. Dr. Adams suggested there is a difference between 'recurrent' and 'relapse' and this is where protocols would come in. The Board decided that this topic was best addressed in the protocol workshops. Dr. de Blaquiere reminded the Board there is a notification of the primary care provider attached to these rules as well.

- Dr. Sutherland applauded the Board for the notification of the primary care provider, though the problem is that a large percentage of the public doesn't have one. She indicated 25% of the patients seeking treatment from Saint Alphonsus' Telehealth group don't have a primary care provider. Dr. Adams agreed this would be a great area for collaboration, and referenced previous meetings in which this topic has been discussed.

Rule 022.01 Inhalation Spacers

- Laura Churns, PharmD, Director of Pharmacy Legislative and Regulatory Affairs at Albertsons expressed her support of pharmacist prescribing inhalation spacer as well as the devices that follow. They are common sense items that are easy to prescribe as they are indicated by the presence of another prescription.

- Dr. Adams indicated that no written comments were received in advance of the meeting.

Rule 022.02 Nebulizer

- Ms. Kilminster-Hadley – indicated BOM has no issues with nebulizers and indicated the other items in this category are excellent.

Rule 022.03 Diabetes Blood Sugar Testing Supplies

- No verbal comments were provided at the meeting, and Dr. Adams indicated that no written comments were received in advance of the meeting.

Rule 022.04 Insulin Pen Needles

- Dr. Adams received one comment requesting 'insulin' be stricken from the rule leaving 'pen needles'. The examples given were Byetta, Victoza and some of the new specialty drugs that use pen needles that are not insulin products.

The Board directed Dr. Adams to strike "insulin" in the written update posted before the final session.

Rule 022.05 Syringes

- Dr. Adams indicated that no written comments were received in advance of the meeting.

- Mr. Sperry requested 'patients with diabetes' be struck, leaving 'syringes'.

- The Board directed Mr. Snook to research this topic more prior to the final meeting.

Rule 023.01 Influenza

- Dr. Blue noted that treatment for influenza is only effective when instituted very early in the illness and that overuse of antivirals can cause resistance in influenza and other illnesses.

Rule 023.02 Group A Streptococcal Pharyngitis

- Dr. Malek noted that using the simple strep test doesn't rule out other potential complications of strep infection. Only an examination can rule out peritonsillar abscess,

or if the patient is only a carrier of strep.

- Dr. Blue indicated institution of the CLIA-waived test is dependent on pretest probability and has to be interpreted in context with symptoms.

- Dr. Adams noted that written comments have focused on antimicrobial resistance, though the studies suggest the opposite. There are suggestions that this would reduce antibiotic use 40-60%. No alternative studies were presented.

- Dr. John Holmes, Research Professor at ISU noted that ISU has implemented a new training on CLIA-waived tests for all students which include the strep test.

Rule 024.02. Short-Acting Beta Agonist (SABA)

- Dr. Sutherland expressed concerns about pharmacist prescribing of these medications as they don't have access to the patient's full medical history. She indicated that asthma is misdiagnosed by physicians on a daily basis. Just because a patient has a prior prescription for an inhaled steroid and a short-acting beta agonist doesn't mean they should get one at the pharmacy given the potential for the patient having been misdiagnosed. Their physician will know when they have received their last beta agonist and they don't prescribe these over the phone.

- Ms. Kilminster-Hadley believes one of the issues with how the rule is written is that it is written toward patients with a diagnosis of asthma and who have prior prescription for a SABA and who have a current prescription for a long-term asthma control medication. This could indicate the patient wasn't able to manage their therapy with a SABA or that they were overusing it in a way that became dangerous for their health and that their primary care provider is no longer willing to provide them with a prescription and instead has them on a different therapy. She indicated BOM believes pharmacists should be involved in medication management in this area, but more from the aspect of calling the primary care provider to see why the patient doesn't have a SABA and see if the provider will prescribe one.

- Jennifer Adams, PharmD, Associate Dean, ISU College of Pharmacy, provided comments as an asthma patient that has a primary care provider. She shared that she has had instances where her prescription for SABA had expired and needed a new one. It would have been very convenient for her if she could have gone to the pharmacy to have it refilled quickly. Dr. Adams provided additional comments as a licensed pharmacist in Idaho who has provided education to patients about the difference between their long-acting medications and their short-acting medications. Pharmacists are very capable of educating patients about medication adherence and using motivational interviewing. She believes it is a pharmacist's responsibility to ensure the patient understands which medication they're supposed to use on a daily basis and which one is for rescue.

- Dr. Winterswyk noted that her current position in a residential unit enables her to see a patient two-three times during their admission. She has the patient demonstrate using the inhaler so she can determine if they need a spacer and if they are rinsing their mouth. She believes pharmacists can have a great impact on patients in this area.

Rule 021.024. Statins

Dr. Chopski opened the discussion by asking for feedback on "clinically appropriate" situations in which a diabetic should not be on a statin beyond the well-known contraindications since that seemed to be the sticking point in written comments. No such comments were provided at the meeting.

- Dr. Holmes indicated there are many studies available on the use of statins in diabetic patients but that 40% to 50% of patients with diabetes are not prescribed statins despite the well-known guidelines. He noted a study found that 57% of this is attributable to practice-level variation. He noted a Lancet study on the benefits vs. risks of statins that found nearly all side effects attributed to statins are not actually caused by statins, and that the benefits far outweigh the risk. He believes any of the issues can be addressed in protocols.

- Dr. Malek noted that he would like to see baseline labs and adequate follow-up with the patient be included in the rule.

- Ms. Kilminster-Hadley indicated BOM agreed that statins are currently under-prescribed, and suggested a different way to approach this issue is to collaborate on an outreach campaign in the state to try to increase the use of statins for patients that need it.

- Dr. Adams presented written comments from Dr. Deeb Eid regarding expanding statin prescribing to all patients instead of just diabetic patients. Dr. Eid indicated these drugs are available over-the-counter in some countries, and studies have found this to be safe.

- Dr. Holmes mentioned a study indicating 80% of the time pharmacists call a provider when there wasn't a prescription for statins, so there is a gap in care. There is no reason except the one patient that had elevated liver function tests. Baseline labs can be done with CLIA waived tests. He reiterated there is a fear of statin side effects that has been caused by the news media and healthcare providers have bought into that fear. That fear is getting in the way of patient care. The evidence is very clear that the benefits outweigh the risks.

- Marcus Hurst, PharmD, District Manager, Broulims noted that one of Centers for Medicare and Medicaid Services (CMS) strategic goals is to improve the quality of care and general health for Medicare beneficiaries. Toward this goal CMS assigns star ratings to healthcare entities for services linked to patient outcomes. Dr. Hurst has been working toward having all eight of his pharmacies obtain a 5 star rating with CMS. In January 2017, with the help of a 3rd party, he identified 903 diabetic patients in his system that did not have a statin prescription. Several patients were removed from the list following review leaving 675 patients. Letters were sent to the providers of all 675 patients requesting collaboration to start the patients on statins. Dr. Hurst received 109 responses, and 13 new prescriptions for statins. There were some responses indicating the patient didn't need statins as their cholesterol numbers were within a healthy range, showing a lack of awareness of current clinical guidelines. Dr. Hurst supports the rule as written.

- Lorri Walmsley, RPh, Senior Manager, Pharmacy Affairs, Walgreens, expressed her support of the proposed rule. CMS has defined measures to improve quality of care. One of the ways pharmacists can address this measure is by using EQUIPP, which is a platform that evaluates Medicare Part D and identifies outlier patients. A review of the EQUIPP data for Idaho specifically, Idaho falls below the national average for this particular measure, as well as far below the five-star rating of 80.6%, Idaho is 72.5%. Based on this data, it's evidenced that there are true gaps in care for Idaho and actually beyond what there are at the national level. In a project that was conducted in one state for Walgreens, pharmacists contacted 226 patients for interventions. Of those patients, 29 patients had statins added. Pharmacists identified 48 patients that statins were inappropriate for care at that time. They concluded the biggest gap in care was the failure of physicians to respond. Of the 226 patients' physicians contacted, 48.7% did not respond after multiple attempts. She urged the Board to maintain the rules as proposed for this state as the evidence shows that the pharmacist may improve outcomes for these patients.

- Ms. Steckel, IMA, noted their board consists of 19 physicians of different specialties from around the state. Most of them have received notification from pharmacists for their patients. Anecdotally they have never changed their care based on being notified by a pharmacist as they had already done the evaluation and determined not to put their patient on the medication. They didn't like the idea of the pharmacist prescribing the drug for their patient.

- Katie Erickson, PharmD indicated that she prescribes statins and believes the fact that pharmacists have been prescribing statins for over 30 years just isn't being acknowledged. She understands the theoretical concerns over safety, but the data doesn't suggest that it has been a harmful practice.

- Dr. Churns echoed the support previously expressed and believes implementation of this rule will improve outcomes and ultimately reduce overall healthcare costs in Idaho. Roughly 10% of the adult population in Idaho has diabetes and not all of them are eligible to take statins. As the most accessible healthcare provider, pharmacists are well positioned to serve as critical access points to fill the medication gap. She reiterated that pharmacists aren't interested in replacing the role of the patient's primary care provider, but to work collaboratively with them. Prescribing isn't new for pharmacists and the communication is present whether the pharmacist prescribes to the patient or refers them back to their primary care provider.

- Dr. Adams suggested one way to narrow the rule is to say that it is only for patients who have a 'current' prescription for a drug for diabetes. Dr. Holmes asked why the Board would narrow it, when others have asked for the rule to be broadened. The Board instructed Dr. Adams to narrow it as proposed in the draft that will be posted prior to the final session.

Rule 021.025. Travel Drugs

Dr. Chopski noted that the Board added specific training requirements to this rule based on previous public comments. Pharmacists must complete a CPE or CME course on travel medications. ISU has several faculty members that have taught on this topic in the past and have volunteered to attend 'train the trainer' programs to ensure future pharmacists are proficient in this area. Dr. Cady confirmed this is the case.

- Ms. Walmsley noted that California promulgated rules last year that went into effect similar to the rules presented here.

- Ms. Kilminster-Hadley noted that the BOM has no opposition to travel drugs being included.

- Ms. Eaton expressed her support for the Board's proposed rules and commended them for their hard work.

Rule 021.026. Supplement an Infusion Order

- No verbal comments were provided at the meeting, and Dr. Adams indicated that no written comments were received in advance of the meeting.

Rule 021.027. Emergency Situations

- Dr. Malek noted that he believes that if there is a delay in EMS it is appropriate for a pharmacist to prescribe these medications. When EMS is readily available, he believes it should be EMS initiating therapy.
- Ms. Kilminster-Hadley suggested adding 'threatens the health and safety of the patient, and the pharmacist does not believe that emergency medical services can respond in time'. Ms. Kilminster-Hadley offered to provide draft language later in the meeting.

Rule 021.028. Lyme Disease Prophylaxis

- Dr. Malek expressed concern as the majority of tick bites do no result in Lyme disease and Idaho isn't an epidemic area for it.

- Dr. Adams noted that the link to clinical guidelines limits treatment to patients who traveled from such an area.

- Ms. Kilminster-Hadley suggested adding 'pursuant to CDC guidelines'. The Board instructed Dr. Adams to narrow it as proposed in the draft that will be posted prior to the final session

Following the lunch break Dr. Adams reviewed the proposed changes to the Controlled Substances Act. There were several changes in federal law, requiring changes to Idaho's law. Aside from the changes required by federal law Dr. Adams took up the mostly stylistic changes left by his predecessor, Mark Johnston. One item is a substantive change, 37-2727 that addresses controlled substances and opioid narcotic treatment programs. There is some

language that is not in the Controlled Substances Act, that requires take-home doses prepared pursuant to a valid order of the prescriber, be checked by a pharmacist. This requirement goes above and beyond the requirements in the federal Controlled Substances Act. Dr. Adams introduced Jason Austin, executive director, Raise the Bottom who spoke on how striking this requirement would affect practice.

Mr. Austin explained patients must meet certain criteria and milestones in their treatment in order to obtain 'take home' medications. Since a pharmacist is only at the facility once a week, patients that have emergencies are often denied medication. Mr. Austin is asking the Board to allow a nurse to dispense the medication and remove the requirement for a pharmacist to verify the order. Following discussion Mr. Sperry motioned to strike 'pharmacist' from the requirement. Dr. Jonas seconded, and the motion carried unanimously.

Dr. Chopski returned to Rule Docket 27-0104-1701 and called for public comment on Rule 020, Pharmacist Prescribing: General Requirements.

Rule 020.01. Education

- Ms. Kilminster-Hadley noted the BOM does not believe this rule sets any standards for competency.

- Dr. Cady stated the education process of pharmacists is extensive and involves diagnostic criteria. All colleges of pharmacy in the country are accredited, and pharmacists are trained healthcare providers. Healthcare professionals have a responsibility to achieve the training required to complete new functions within their field. If a healthcare provider fails to obtain the proper training they should be required to appear before their licensing board. He supports relying on the professionalism of pharmacists to obtain the training they need.

- Ms. Steckel noted the IMA feels schools and accreditation bodies bear the responsibility to evolve and teach what is required, not the role of the Board.

- Dr. Jennifer Adams noted that when students graduate from any health profession program they are educated based on what practice is like today and the future. As they work in their profession they will be exposed to new things, the practices evolve. ISU reviewed their curriculum in light of these rules and found that they've been training pharmacists for these practices for many years. ISU curriculum is competency based education and you'll find the same competency based education all over the country. She wants to see professionals practicing at the top of their education and training. She commended the Board for adding this section of education, recognizing it isn't required of any other healthcare provider in Idaho, and it adds one more layer of safety for Idaho patients. She is confident that ISU graduates are prepared for the additional responsibility.

- Dr. Malek expressed how much he values the PharmDs that he has worked with. He has benefited from their antibiotic stewardship, their suggestions in medication changes, and their many contributions to healthcare. He is still concerned about pharmacists making diagnosis and treating UTIs and other aspects of the rules.

- Ms. Walmsley expressed support for the way the education piece is outlined. She believes the pharmacy employers and the pharmacists that are exercising their prescriptive authority have all been properly trained without the regulatory burden. She indicated Walgreens provided training to their pharmacists to prescribe Naloxone though it was not required by the rules.

- Ms. Kilminster-Hadley recapped that the BOM has concerns with only 5 of the 22 drug and device categories that remain in the rules: cold sores, UTIs, strep throat, SABAs, and statins.

- Dr. Cady encouraged the Board to always put the patient first. You protect the public by allowing qualified individuals to provide necessary care.

Docket No. 27-0105-1701 – Chapter 5 - Compounding

- Dr. Adams noted he had received a comment from Shaver Pharmacy & Compounding Center supporting the strengthening of the compounding laws.

Docket No. 27-0106-1701 – Chapter 6 – DME, Manufacturing, & Distribution

- No verbal comments were provided at the meeting, and a lone written comment identified a typo that the Board has corrected.

The Board took up the matter of Precision Medical Pharmacy. Board staff was unable to process their renewal based on past disciplinary action, and current probation status in Utah. Kerry Brown, PIC attended the meeting without legal counsel. Mr. Brown shared a gap analysis he created to address the violations on the Utah inspection report. Following a detailed discussion, Mr. Sperry motioned to approve the application with a stipulation mirroring Utah's probation, reporting of any notices and/or action from Utah to the Board, Dr. de Blaquiere seconded. Following a brief discussion, the motion carried with Dr. Henggeler opposed.

Dr. Adams presented proposed the Board's Agency Legislation:

- 54-1705(4) definition of Counseling – strike 'shall'
- 54-1733 add (i) If a prescriber makes a diagnosis of an infectious disease in a patient, the prescriber may prescribe or dispense antimicrobials to an individual who has been exposed to the infectious person in accordance with clinical guidelines for chemoprophylaxis.
- 54-1733A(a) – add 'or a digital image thereof in accordance with rules adopted by the board'

Following a brief discussion the Board granted unanimous consent to move forward with the agency legislation as proposed.

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

- Wells Pharmacy Network – The Board's investigator reviewed the Board's PMP and Wells Pharmacy dispensing records and determined Wells Pharmacy was filling invalid controlled substance prescriptions for Idaho patients. By signing the Stipulation and Consent Order the Respondent agreed to pay the Board a $10,000 administrative fine.

- Stephanie Terrell, NP - Failed to notify the Board or DEA of a change in office location within 10 days; dispensed controlled substances to herself; failed to maintain proper dispensing records for controlled substances; and failed to obtain a Prescriber Drug Outlet registration as required. By signing the Stipulation and Consent Order, Ms. Terrell agreed to pay a $2,000 administrative fine.

- Larry Weiner, MD – Failed to register for the Prescription Monitoring Program, and failed to renew his controlled substance registration. By signing the Stipulation and Consent Order, Dr. Weiner agreed to pay a $2,000 administrative fine.

- Michael Barbo, PA – Following an Alford plea to a felony conviction in June 2016, Mr. Barbo entered into a Stipulation and Order with the Idaho Board of Medicine. By signing the Stipulation and Consent Order Mr. Barbo agreed to abide by the terms of his court ordered probation, the terms of the Board of Medicine Order, and the Board of Pharmacy Order.

Dr. Jonas motioned to remove Wells Pharmacy from the Consent Agenda and approve the remaining three items, Mr. Sperry seconded, and the motion carried unanimously.

Following a brief discussion, Dr. Henggeler motioned to approve the Wells Pharmacy Network stipulation as written. Dr. Jonas seconded, and the motion carried unanimously.

Dr. Chopski exercised her discretion as Chair and moved Item G: Financial Report to tomorrow's agenda.

Dr. de Blaquiere motioned to go into Executive Session citing 74-206(1)(f) To communicate with legal counsel for the public agency to discuss the legal ramifications of and legal options for pending litigation, or controversies not yet being litigated but imminently likely to be litigated. Dr. Henggeler seconded and the motion carried unanimously following a roll call vote; entered executive session 4:45 pm.

After communicating with the Board's legal counsel pursuant to Idaho Code 74-206(1)(f), Dr. Jonas motioned to leave executive session. Dr. de Blaquiere seconded, and the motion carried unanimously; executive session concluded at 5:18 p.m.

Hearing no further business, Dr. Jonas motioned to adjourn the meeting. Mr. Sperry seconded, and the motion carried unanimously. Meeting adjourned at 5:19 p.m.

October 26, 2017

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

Chairman Nicole Chopski, PharmD, called the meeting to order at 9:00 a.m. In attendance were Vice Chairman, Holly Henggeler, PharmD; Board members Rich de Blaquiere, PharmD; Kristina Jonas, PharmD; and Ed Sperry, Public Member. Also in attendance were Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Lisa Culley, CPhT, Jaime Thompson, and Wendy Shiell, Compliance Officers; Misty Lawrence, Management Assistant; Andy Snook, Deputy Attorney General; Ellen Mitchell, Program Information Coordinator, Colter Shirley, the Board's intern from Idaho State University (ISU), and several members of the public.

Misty Lawrence presented the Board's financial report. Mrs. Lawrence highlighted the following points:

Fiscal year 2018 budget with 25% per cent of the year elapsed and 22.4% of the budget expended.

- Personnel Cost (PC) is 23.13% expended – Currently trending approximately $4,000 in salary savings.
- Operating Expense (OE) is 28.02% expended.
- Capital Outlay (CO) $250,000 was originally appropriated for the licensing system in FY17, that amount has been carried over to FY18. Staff is working on the purchase of the Board laptops and the contract for the licensing system is in the final stages. The first payment to the software vendor is anticipated to be in December or January. Payment to the new vendor will be incremental as items are completed.

<u>Current Cash Balance</u>

- Cash Fund balance as of September 30, 2017. This fiscal year started with a cash balance of $2,610,200. Disbursements are currently exceeding receipts by $265,195 or 106%. This trend will not reverse until Nov/Dec when the revenue from Controlled Substance renewals starts to come in. First quarter revenue is also down.

<u>4 Year budget Trend Comparison Fiscal 1st QTR FY15-FY18</u>

- Expenditures are right on target for the first quarter and in line with appropriation at 22.4% expended
- Revenues are trending down 28%, $58,700 in this 1st Qtr.
  - This includes a decrease in:
    - Renewal Fees: ($34,495)
    - New application Fees: ($13,922)
    - Late/Reinstate: ($7,188)
    - Misc./Fine/Inspect: ($3,025)
- The renewal fee decrease is not actually a decrease but a matter of when the monies were collected. Late fees also decreased. At the August meeting staff reported a successful spring renewal and an increase in Licensing & Registration fees of $161,900 for the entire fiscal year. When comparing the last quarter of Fiscal years 16 and 17, there was an increase in renewal fees of $125,547. This is due to a higher percentage of registrants that renewed on-time, decreasing the number of registrants paying late fees.
    - When comparing the complete renewal periods Spring 16 to Spring 17 without regard to fiscal year, Apr-July, we realized an increase of $88,440 in Spring 17, although this increase came in Apr-Jun so we aren't seeing that in July (FY18).

- The decrease in application fees (New Applications & Background Checks) is seen across most application types although many of them have a variance of less than 10 applications and are not noteworthy this early in the year. No application type has seen an increase of 10 or more applications. We have received 143 less applications in the 1st qtr. compared to the 1st qtr. of FY17.

FY17 Monthly Cash Flow - Receipts and expenditures by month for the fiscal year.

August jumps out with a significant increase in expenditures. SWCAP (Governmental Overhead) annual payment of $62,900 and an Appriss payment in the amount of $97,240 for the Gateway and NarxCare licenses issued through the Health and Welfare contract. The Appriss payment was reimbursed by Health & Welfare but that revenue was not received until September.

- September revenue when removing the reimbursement was $32,460.

FY18 Budget/Appropriation changes

- Appropriation approved for FY18 2,049,200
- Re-appropriation $250,000, for the licensing system build. This re-appropriation was approved in the last legislative session along with our budget request.
- There is a request for a supplemental of $37,300 in order to have enough appropriation this fiscal year to fully expend the available funds through the Health and Welfare contract. There was $60,000 in appropriation in FY17 that we were unable to expend due to timing issues with contracts. Current FY18 appropriation is $180,000
    - The federal fiscal year runs Oct 1 – Sept 30 so monies available in a federal fiscal year cross over 2 state fiscal years. We were able to spend the $97,240 out of the money that was available in the first Federal Fiscal year, but not before the end of our FY17 so that full amount was expended in FY18. We have $217,300 available to be reimbursed in FY18 this includes the $97,240 already expended and the $120,000 we have available for reimbursement through September 2018. The supplemental of $37,300 will bring our appropriation for this project to the $217,300.
- If the supplemental is approved final appropriation for FY18 will be $2,336,500

FY19 Budget request – Maintenance items

- All one-time monies were removed from the FY18 budget ($475,700), this includes one-time appropriation for the DHW contract, licensing system build, and the replacement of board computers.
- Without these the FY19 ongoing base is $1,860,800
- No request for agency specific maintenance items for FY19, all items shown are required by DFM.
- 10.11 is a decrease of $28,700, the state anticipates a decrease of about $1,900 per employee for health insurance.
- 10.12 is a variable benefit increase of $6,100, as the workman's comp calculation increased from .0085 to .0087 and the state is projecting the retirement rate to increase from .1132 to .1194.
- The next two line items are SWCAP items. SWCAP items include: Treasure, Statewide Accounting and Payroll, Attorney General, and Risk management fees. The appropriation for these is the actual costs for each item in FY17 that will be paid in FY19. Agencies are automatically given appropriation for these expenses and there is only a line item request when the cost of these items changes by more than $50 in a given year.
- 10.41 Attorney General Fees. Increase of $18,000. In FY16 AG expenses were $37,200, FY17 they were $55,200.
- 10.45 Risk management fees – Decrease of $200. There was a decrease in Liability (100), and in Auto (100)
- 10.61 1% salary multiplier. This represents 1% of full time employee's salary. This is the place holder for CEC increases and will change depending on the increase approved,

we have seen a 3% increase the last couple of years. No word on what we might see this year.

Line item requests – Both ongoing requests

- 12.01 - $20,000 Annual Maintenance for Prescriber Report cards. Currently working with Appriss and DHW to roll out the Prescriber Report Cards this year. DHW will pay the implantation fee of $75,000 and the first year maintenance fee of $20,000. The Board will be responsible for the annual maintenance after the 1st year.
- 12.02 - $120,000, is for the Prescription Drug Overdose Prevention grant and DHW contract that tasks the Board with facilitating uptake of Gateway and NarxCare. Requesting as an ongoing appropriation as DHW anticipates this money could be available for several years. This will alleviate the burden of requesting this amount every year. When the money is no longer available the appropriation will be removed from the base.
- FY19 budget request with SWCAP is $2,003,900

Budget comparison

- The revenue on this report represents actual revenue for FY15-FY17, and estimated revenue numbers for FY18 & FY19, assumption to any increase or decrease in revenues estimated can be found on the B-11 page 7 of the budget request. In summary we are calculating a 5% increase in licensing revenue and the annual $120,000 for the DHW contract.
- Expenditure numbers are based on actual expenditures for FY15-17 and on either approved or requested appropriation for FY18 and FY19. For this comparison I did add in the supplemental request for FY18 and the SWCAP numbers for FY19.
- Overall our FY19 Budget request is a 14.3 % decrease, but all of the requests in our FY19 budget are ongoing and will increase our base budget by $143,000 or a 7.7% increase. Of this $120,000 is coming from the reimbursement contract. So the net increase to the base budget that will affect our cash flow is $23,000 or 1.3%
- What's missing?
    - Licensing system fee increase. The implementation fee will cover the build and the first year after GO LIVE. Go LIVE is slated to be June of 2018 so the licensing system fee is covered for FY19. We will be requesting an increase in the ongoing maintenance in FY20. I will be able to provide more detail on this at the next meeting.
- RFP update
    - Purchasing has indicated they hope to award a contract before November. If they are able to award the contract quickly staff will be able to start the project as soon as November 15.
    - The timeline is very aggressive and will take a large portion of staff time in order to meet the deadlines. Estimation at this point is 2.5 staff members for a full 12 weeks. Most of this staff time will come from Erik, Berk, and Misty, but will also include time from licensing staff.
- Staff update: Sharon Treese has officially put in her retirement application, her official retirement date will be December 31, 2017 though her last day in the office is November 24, beyond that she will be on vacation.

The Board thanked Mrs. Lawrence for her comprehensive update.

Dr. Chopski asked Dr. Adams to begin the finalization of the rule dockets. Proposed updates based on the prior day's discussion were posted online last evening so that stakeholders could review them in advance.

Docket 27-0101-1701 - Chapter Repeal

- No changes were made.

- Dr. de Blaquiere motioned to finalize Docket 27.0101.1701 as written. Dr. Jonas seconded, and the motion carried unanimously.

Docket 27-0101-1702 - General Provisions

- Rule 023. – replace ‘pharmacist, pharmacist intern, or technician’ with ‘any licensee or registrant’
- Dr. Jonas motioned to approve moving forward with Docket 27.0101.1702 with the change noted change to rule 023. Dr. Henggeler seconded, and the motion carried unanimously.

Docket 27-0102-1701 – Rules Governing Licensure and Registration

- Dr. de Blaquiere motioned to approve 27.0102.1701 as written. Dr. Jonas seconded, and the motion carried unanimously.

Docket 27-0103-1701 – Rules Governing Pharmacy Practice

- Rule 400 – modify to read ‘Records may be retained at a central location in compliance with federal law’

Dr. Henggeler motioned to approve 27.0103.1701 Dr. Jonas seconded, and the motion carried unanimously.

Docket 27-0104-1701 – Rules Governing Pharmacist Prescriptive Authority

- Rule 20.03 – Modified to read ‘The pharmacist must obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care’

- Added rule 020.03.e. - Any patient assessment protocol for a drug or drug category that is made available by the Board satisfies subsections (a) through (c) of this rule.

- Rule 021.03 – added ‘prevention’

- Rule 021.04 – Strike

- Rule 022.04 – Strike ‘insulin’

- Rule 024.01 – Modified to read ‘Statins, for patients who have a current prescription for a drug for diabetes.

- Rule 028. – Replace ‘clinical’ with ‘current CDC guidelines’
- Dr. Jonas motioned to approve the changes to 27.0104.1701 with the posted changes and the changes discussed today along with the addition of the protocols covering A, B, and C. Dr. Henggeler seconded and the motion carried unanimously.

Dr. de Blaquiere motioned to put in formal policy a commitment to develop protocols for the 5 remaining drug categories of concern to the BOM: cold sores, UTIs, Strep A, statins, and SABAs. In addition, even though there were no expressed concerns over influenza, the Board committed to a protocol for that condition as well. The Board further committed to working collaboratively with other stakeholders to develop these template protocols through upcoming protocol workshops. In addition the Board will update its proactive inspection forms for enforcement. Mr. Sperry seconded, and the motion carried unanimously.

Dr. Adams reiterated to BOM and IMA that he strongly encourages and hopes for participation and engagement during the upcoming protocol workshops. He stated Board staff is happy to co-host the workshops and/or engage in meetings between the workshops. Dr. Henggeler asked that some workshops be held in the evening to accommodate those that are unable to attend during the day, as in physicians and others. Dr. Adams is happy to accommodate as he has done in the past with town hall meetings. Often he conducts a 7:00 a.m. meeting and a 7:00 p.m. meeting to catch as many participants as possible.

Dr. Chopski expressed her appreciation for the physicians that attended the meeting yesterday and participated in the rules discussion. She believes the rules are much stronger with the active participation of the stakeholders yesterday.

The Board took up the matter of Twilla Wilkinson. Mrs. Wilkinson attended the meeting with her husband without legal counsel, to appeal to the Board for her pharmacy Technician-in-Training registration. Board staff was unable to approve her application based on a previous felony conviction. Following a brief discussion, Mr. Sperry motioned to approve the application. Dr. de Blaquiere seconded and the motion carried unanimously.

The Board took up the matter of Kim Warren. Ms. Warren attended the meeting telephonically and without legal counsel, to appeal to the Board for her pharmacy Technician-in-Training registration. Board staff was unable to approve her application based on her lack of a high school diploma. Following a brief discussion, Dr. Henggeler motioned to approve the application, with the understanding that she work toward and obtain her high school diploma or equivalency, and maintain employment at Shopko. Dr. Jonas seconded and the motion carried unanimously.

The Board took up the matter of Richard M. Sutton, RPh. Mr. Sutton attended the meeting without legal counsel. Mr. Sutton requested the Board release him from the requirement of maintaining his contract with Southworth Associates. Following Mr. Sutton's testimony and a brief discussion, Dr. Henggeler motioned to deny the request and require Mr. Sutton to maintain his current program. Dr. Jonas seconded and the motion carried with Mr. Sperry abstaining. Mr. Sperry acknowledged Mr. Sutton's progress and encouraged him to continue his program and engage with the groups on his area.

Mr. Fraser presented the Board an update on remote dispensing pharmacies (RDP). The Board currently has eight registered RDPs. Teton Pharmacy operates two locations, one in Ammon and one in St. Anthony. They currently rotate their supervising pharmacy. Teton Pharmacy in Idaho Falls maintains a pharmacist on duty at all times. The Mylar family will be opening a new clinic and RDP in Victor. K-Mart had a news release indicating they had converted one of their pharmacies in Illinois to an RDP and may convert the Idaho Falls store. Dr. Adams indicated he would add an RDP update to the Consent Agenda for future meetings.

Dr. Chopski questioned if there was an indication of how often the RDP video and/or audio systems go down. Mr. Fraser indicated there isn't a way to tell unless someone complains. One of the facilities was shutting the system down due to the noise from the host pharmacy. They were instructed not to turn off the system, as they are required to remain on during hours of operation. Mr. Fraser suggested RDP facilities may need to be inspected more frequently than the current 18-month rotation.

Mr. Fraser also presented the Board with the results of the CPE audit. He selected pharmacists that had less than 12 CPE credits. He also issued a secondary request letter, which he hasn't done in the past. He will accept responses until November 1. The advent of NABP's CPE Monitor increases the efficiency with which Board staff can conduct the annual CPE audit. Using data obtained from NABP's CPE Monitor on September 7, 2017, there were 100 pharmacists licensed in Idaho who had completed fewer than 12 ACPE-approved credits over the 2016 to 2017 license year (15 hours required). After a complete audit in which individuals were invited to submit statements of credit, Board staff determined 36 individuals did not pass this year's audit.

Number of Valid Credits	# of Pharmacists
Completed 0 or did not respond	13
Completed 1 to 6	4
Completed 7 to 10 hours	4
Completed 11 to 14 hours	6
Completed 15 hours but did not complete live or/and law	9
Total	**36**

Mr. Fraser recommended the use of delegated authority to resolve cases with the following penalties proposed:

- Pharmacists with 9 or fewer hours, $1000 per year the pharmacist falsely reported on license renewal that they were compliant with their CPE.

- $200 per missed CPE hour and the pharmacist must complete twice as many CPE hours for each hour missing within 60 days.
- For each pharmacist that completed the full amount of CPE hours but did not complete live and/or law $100 per missed CPE hour and the pharmacist must complete twice as many CPE hours for each hour missing within 60 days.

Following further discussion, Dr. Jonas motioned to accept the recommendations as presented. Mr. Sperry seconded. The vote resulted in Dr. Jonas and Mr. Sperry in favor of the recommendation, Drs. Henggeler and de Blaquiere opposed. Chairman Chopski voted in favor and the motion carried.

First Lady Lori Otter and Debbie Field, Truth208 Board Treasurer, attended the meeting to share information about Truth 208, which is the product of the Millennial Fund in response to medication abuse. Medication abuse accounts for over 60% of the overdose deaths in Idaho. Idaho currently ranks 4th in the nation per capita in overdose deaths. Mrs. Otter asked the Board to take over Truth 208 as she believes it would be a good fit. The program comes with existing grant money to pay for outreach and a contract employee. Mrs. Otter indicated the program has been successful and could be rebranded and sold to other states in the future. The Board agreed that it would be a good fit and believes the end of the fiscal year would be a good time for transition. Mrs. Otter and Dr. Adams will arrange planning meetings in the future.

Dr. Chopski called the hearing of Chad Jungert, RPh to order. Dr. Jungert attended the hearing with his attorney Grant Burgoyne. Steve Olsen, DAG represented the Board. Mr. Jungert is accused of violating the terms of his Stipulation and Consent Order dated June 2, 2016. Specifically, he is accused of failure to comply with his Pharmacists Recovery Network agreement. Each party presented evidence and testimony for the Board's consideration. Following extended testimony, Dr. Chopski called for a brief break.

Following the break, Dr. Chopski suggested continuing the hearing until a later date. She also moved the agenda item 2018 Meeting Dates to coincide with the hearing date.

Dr. de Blaquiere left the meeting at 6:30 p.m. for his return flight.

Dr. Henggeler motioned to adjourn, Dr. Jonas seconded, and the motion carried unanimously. Meeting adjourned at 6:49 p.m.

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Nicole Chopski, Chairman Holly Henggeler, Vice-Chairman

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Member Member

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Member Alex J. Adams, Executive Director