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.