MINUTES OF THE
IDAHO STATE BOARD OF PHARMACY
August 30, 2018

Conference Call
Idaho State Board of Pharmacy Office
Boise, Idaho

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

Chairman Nicole Chopski, PharmD, called the meeting to order at 8:00 a.m. In addition to Dr. Chopski, those attending telephonically included Vice Chairman, Holly Henggeler, PharmD; Rich de Blaquiere, PharmD; Andy Snook, Deputy Attorney General; Wendy Shiell, Compliance Officer; and several members of the public.

Attending from the Board office were Kristina Jonas, PharmD; Alex J. Adams, PharmD, MPH, Executive Director; Berk Fraser, RPh, Deputy Executive Director; Amy Hickerson, CPhT; Misty Lawrence, Management Assistant; Ellen Mitchell, Program Information Coordinator, and rotation students Hnin Khin and Ademola Are.

Dr. Jonas motioned to approve the minutes from the August 2, 2018 meeting with minor corrections to the Travel Calendar. Dr. Henggeler seconded, and the motion carried with Dr. Chopski voting in favor of the motion. Dr. de Blaquiere abstained as he was not in attendance at August 2, 2018 meeting.

Dr. Chopski framed the discussion for negotiated rulemaking.

She indicated this is the second of two scheduled negotiated rulemaking sessions and the seventh public meeting since February in which draft regulations have been discussed. The Board may make changes to the proposed rules and agency bills during this meeting. Any changes made will be incorporated into the proposed rule drafts which will be published in the October 3, 2018 Administrative Bulletin, triggering the official 21-day public comment period.

Following a review of each chapter, Dr. Chopski called for public comment. The Board also reviewed written comments submitted in advance of the meeting.

Rule Docket No. 27-0101-1801 – Chapter 1, General Provisions

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

No changes were made to the docket.

Rule Docket No. 27-0102-1802 – Chapter 2, Rules Governing Licensure and Registration

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

No changes were made to the docket.

Rule Docket No. 27-0103-1802 – Chapter 3, Rules Governing Pharmacy Practice

The Board reviewed four written comments received in advance of the meeting.

Hannah Wesolowski, Director of Advocacy for NAMI, submitted a letter co-signed by Michael Sandvig, NAMI Idaho requesting the Board amend Rule 305.05 regarding prescriber-authorized substitution by requiring clearer documentation of intent by adding the following:

> "(i) Written prescriptions: department therapeutic substitution, the words "therapeutic substitution allowed" must be handwritten by the prescriber on the prescription and may not be pre-printed, rubber stamped, or otherwise be produced on the prescription form. Check boxes, or other notations on an original prescription drug order that indicates "substitution instructions" are not valid methods to clearly indicate therapeutic substitution is permitted for written prescriptions."

> "(ii) Electronic prescription drug orders: to permit therapeutic substitution, the practitioner or practitioner's agent must clearly indicate by entering the free text "therapeutic substitution allowed" in the substitution instructions and the electronic prescription drug order. If the practitioner or practitioner's agent does not indicate "therapeutic substitution" on an electronic prescription drug order, the prescriber does not authorize therapeutic drug substitution."

NAMI indicated its belief that the addition would "avoid any unintended consequences from inadvertent miscommunications regarding the prescriber-authorized therapeutic substitution."

Similarly, Melisa McEwen, Associate Director of State Government Affairs and Advocacy at Otsuka America Pharmaceutical, Inc. requested the following via written comment:

> "Otsuka respectfully requests that the proposed draft rule be amended to clarify the specific steps required by the prescriber to authorize therapeutic substitution in a manner consistent with the referenced Kentucky and Arkansas Rules for prescriber-authorized therapeutic substitution by requiring a prescriber to hand write "therapeutic substitution allowed" on the prescription or similarly, for an electronic prescription, free text "therapeutic substitution allowed.""

Molly Steckel, Policy Director, for the Idaho Medical Association (IMA) noted that their organization supports the rule as drafted and felt that physicians have a good understanding of therapeutic substitution and does not feel there is a need to limit how the designation is made.

Mark Johnston, Senior Director, Pharmacy Regulator Affairs, CVS Health, pointed out that the statute is in effect and that all of the proposed suggestions would limit or narrow the existing law.

Dr. Adams noted several potential issues with the proposed additions. For example, the suggestions address the scenarios regarding written and electronic prescriptions, but they do not cover: 1) verbal prescriptions; 2) facsimile prescriptions; or 3) digital image prescriptions. Further the suggestion would disallow several scenarios that are allowed in Arkansas and Kentucky and would be at odds with notations in Idaho law. Dr. Adams noted that, despite requests, the commenters were unable to identify any patient safety issues that have emerged in either of the states that have allowed this for a collective fifteen years.

The Board noted that the primary concern seems to be rooted in the fear that physicians may accidentally "clearly indicate" therapeutic substitution is allowed. To the extent organizations have concerns that physicians, pharmacists, and patients are not appropriately educated on this topic, Dr. Adams volunteered to assist with any educational efforts that may emerge from the commenters.

Linda Rosenberg, President, and CEO of the National Council for Behavioral Health, expressed support for the physician and patient opt in provisions. She expressed concern that it is unclear how the patient's consent is to be indicated and where that will take place.

Nathaniel Z. Counts, Senior Policy Director of Mental Health America submitted a written comment asking the Board to ensure the rules do not negatively impact individuals with mental health conditions.

Dr. Adams briefly reviewed the history of the proposed addition to Rule 305.05. It stemmed from House Bill 339, which passed the Idaho legislature in 2018 by wide margins. The bill does not compel any rulemaking action by the Board and went into effect on July 1, 2018.

Dr. Adams noted that the rule, by design, merely repeats the statute and does not add anything to the existing law. The only reason the Board intends to add it to rule is to make Rule 305 become a one-stop resource for all forms of substitution as the rule addresses substitution in hospitals, skilled nursing facilities, during shortages, and for biological products; thus pharmacists will not have to comb through multiple statute and rule sections to find all the provisions governing substitution in different scenarios.

Dr. Adams suggested carving out psychotropic drugs from the rule. The Board felt that the rule will not include psychotropic drugs generally but noted instances in which a physician and patient may voluntarily opt in. The Board left the rule as written but invited additional feedback for the October meeting.

Rule Docket No. 27-0104-1802 – Chapter 4, Rules Governing Pharmacist Prescriptive Authority

Marcus Hurst, Supervisor of Broulim's Pharmacy, submitted a public comment noting that Broulim's pharmacists have advertised the availability of clinical services at their stores, and as a result, he noted the following allegations:

- "[S]ome medical doctors have informed their colleagues that they will no longer send prescriptions to Broulim's pharmacy;" and
- "[W]e have been informed that a group of healthcare professionals in the Idaho Falls area are considering dropping any of their patients who accept a prescription from a pharmacist."

Dr. Hurst asked the Board to strike the notification requirement in Rule 020 so that care is not fragmented.

Dr. Chopski noted that the Board originally intended for the rule to reduce fragmentation of care and that no other health profession had a similar requirement.

Ms. Steckel believed the comment was from an outlier and not widespread. She noted IMA supports the notification requirement as written.

Dr. Adams noted that he agreed completely with IMA. He also noted that the Board's intention behind the notification is to ensure not just coordinated care, but also to have an accountability mechanism in place for pharmacist prescribing.

Pam Eaton, Executive Director of the Idaho State Pharmacy Association, indicated that she supports keeping the notification requirement as written.

Dr. Chopski called for additional comment on the docket and no comments were provided. No changes were made to the docket.

The Board further reiterated its call for additional evidence to be submitted on any of the proposed rules at the October meeting.

Rule Docket No. 27-0105-1801 – Chapter 5, Rules Governing Drug Compounding

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

No changes were made to the docket.

Rule Docket No. 27-0106-1801 – Chapter 6, Rules Governing DME, Manufacturing, and Distribution

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

No changes were made to the docket.

Next, Dr. Chopski called on Dr. Adams to present the proposed agency bills for the 2019 legislation, drafts of which have been on the Board's website for review.

Pharmacy Practice Act – Legislative Proposal

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

No changes were made to the draft bill.

Controlled Substances Act – Legislative Proposal

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

No changes were made to the draft bill.

Dr. Chopski called for any remaining public comments on any agenda item, and no comments were offered.

Dr. Jonas motioned to adjourn, Dr. de Blaquiere seconded, and the motion carried unanimously. Meeting adjourned at 8:45 a.m.