



State of Idaho
Division of Occupational and Professional Licenses
Board of Pharmacy

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Minutes of 09/12/2024

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|-----------------|-----------------------------|-----------------|--|
| Board | Kris Jonas, PharmD, Chair | Division | Nicki Chopski, PharmD, Executive Officer |
| Members | Kevin Ellis, PharmD | Staff: | Russ Spencer, General Counsel |
| Present: | Justin Messenger, PharmD | | Berk Fraser, RPh, Chief Investigator |
| | Anna Hoenke, PharmD | | Mike Celeste, Investigations Supervisor |
| | | | Susan Villanueva, Board Support Specialist |

Others

Present: Eric Nelson, Prosecutorial Counsel

The meeting was called to order at 8:32 AM by Justin Messenger, PharmD.

Approval of Minutes

A motion was made and seconded to approve the 06/13/2024 minutes. The motion carried.

DIVISION BUSINESS

Financial Update: Dr. Chopski gave the preliminary 2024 fiscal year-end financial update. The Board will receive the finalized report at the next meeting. Dr. Chopski informed the Board that they continue to have a large cash balance. She noted that later in the meeting, staff will review options to assist the Board in effectively reducing its cash balance to align with the legislature's expectations.

Licensing System Update: Dr. Chopski informed the Board of the current progress of the new licensing system, which went live on July 1, 2024. Dr. Chopski answered questions from the board regarding pharmacy employee rosters.

Health Professionals Recovery Program (HPRP) Update: Katie Stuart provided an update on the HPRP program to the Board. Ms. Stuart stated that six (6) licensees are currently enrolled in the program. She informed the Board that they have seen a decrease in participants since COVID across all professions due to workforce shortages. She said she expects the numbers to increase over the next few years. Ms. Stuart spoke to the Board about setting up booths at various events for program outreach. Ms. Stuart stated that in June, she visited all the support groups through HPRP and provided information about Connection is the Cure and the scholarship program they are working on for HPRP.

Board Training – Public Member: Mr. Spencer presented training on the importance and duties of public members.

BOARD BUSINESS

Zero-Based Regulation (ZBR):

The Board reviewed public comments regarding the new proposed rules received during the open public comment period. They are as follows:

Concern:

The Alliance for Pharmacy Compounding asked the Board of Pharmacy to clarify its interpretation of Rule 406.05 (Proposed Rule 200.14(e)) and adopt a position in accordance with the FDA's draft guidance document. The comments recommended no proposed language changes.

Response:

The Idaho Board of Pharmacy appreciates the comment. Currently, Idaho follows federal law. The document referenced by the Alliance for Pharmacy Compounding is in draft form and is unenforceable. If the document is finalized and implemented by the FDA, then the Board of Pharmacy may enter into rulemaking to remedy any discrepancies between federal and state law. The Board does not wish to change the rules based on a draft document.

Concern:

Eli Lilly expressed concern that compounded products do not receive the same level of scrutiny as products produced by a drug manufacturer, increasing the likelihood of deviances in the purity and sterility of the final product. Eli Lilly expressed its support of Rule 406.05 and recommended that the Board of Pharmacy continue forward with the draft language.

Response:

The Idaho Board of Pharmacy appreciates the comment and is committed to ensuring proper regulatory oversight of the pharmacy profession, ensuring public health and safety are not compromised when rule changes are made.

Concern:

The Board of Pharmacy received comments about changes to the definition of "Pharmaceutical Care" in IDAPA 24.36.01.010. The Idaho Medical Association (IMA) expressed concern about the inclusion of "imaging" in subpart (d). IMA acknowledged that under previous rules, pharmacists had the authority to order and interpret laboratory tests; however, the new inclusion of "ordering and interpreting ... imaging" was concerning, given that pharmacists lacked the requisite education, training, and experience to do so and should not replace the role of a radiologist. The IMA recommended striking "and imaging" from the rule definition.

Response:

The Idaho Board of Pharmacy appreciates the comment of the IMA and agrees that pharmacists should not act as radiologists. Rather, they should use the results of radiologists' reports to guide decision-making in accordance with Idaho Code § 54-1733. Inclusion of "and imaging" in the previous definition was not meant as a change or deviation from current practice standards. The Board staff receives inquiries from pharmacists about whether ordering imaging for patients is permitted by statute and rule. The inclusion of the phrase "and imaging" was designed to clarify practice standards, given there are no rules or statutes prohibiting pharmacists from performing this function.

The board acknowledged that most pharmacists do not currently practice in a setting that routinely requires them to order imaging. However, hospital and primary (ambulatory) care setting pharmacists have been performing this role for many years, beginning with the adoption of collaborative practice agreements.

Concern:

The IMA also expressed concern that the removal of “coordinating and integrating pharmaceutical care services within the broader health care management services” from the definition of Pharmaceutical Care Services may lead to fragmented care, preventing pharmacists from practicing collaboratively with other healthcare professionals.

Response:

The updated definition elevated working in collaboration with other healthcare professionals from the subparts into the main part of the definition; it did not remove that requirement. Rather, Idaho statutes and rules require pharmacists to practice within the limits of their education, training, and experience. Since 2018, the Board of Pharmacy has included notification provisions in its rules, above and beyond what other professions, including medicine, provide to primary care providers. The board expects pharmacists to act collaboratively, and this rule change will not deter cross-professional collaboration and referral when deemed necessary.

Concern:

The IMA further expressed concern about inclusion of “diagnosing” in subpart (a) of the definition of Pharmaceutical Care Services. The IMA believes that the previous definition, which included "performing or obtaining necessary assessments of the patient’s health status, including the performance of health screening activities or tests," was sufficient to describe the scope of practice for pharmacists. They assert there are nuanced differences between the original language and the new language of "diagnosing” and recommended the Board of Pharmacy revert to the previous language.

Response:

During discussion, the Board clarified that this rule change was not substantive in nature and did not change pharmacists' current scope of practice. The board discussed that the revision was necessary to align the terminology used by the rule with the statute, specifically Idaho Code § 54-1733.

Since 2011, the Idaho Legislature has continually reauthorized and thoughtfully revised pharmacist scope of practice to meet public health needs. Under Idaho law, pharmacists are allowed to independently prescribe, consistent with their education, training, and experience. I.C. §§ 54-1704, 54-1705. To write a valid prescription, all providers, including pharmacists, must first make a diagnosis. I.C. § 54-1733.

The board reiterated that pharmacists properly engaged in diagnosing and prescribing does not replace the role of a physician. Under the rules of the Board, any condition beyond the scope of a pharmacist's education, training, and experience must be referred to the appropriate healthcare provider.

Public Comment:

Dr. Tim Frost, a pharmacist, Idaho resident, and owner of the healthcare consulting company 50 Elixir, provided a timeline of key legislative events that impacted pharmacist scope of practice starting with House Bill 191 (2017), House Bill 182 (2019), and Senate Bill 1245 (2022). The latter, which passed unanimously, consolidated well-established definitions within the Pharmacy Practice Act and provided the Idaho Board of Pharmacy statutory authority to further define these definitions in the rule. These three bills highlight Idaho’s shift to a standard of care regulatory model codified most recently in 2024 by House Bill 527.

He questioned the premise for removing or striking portions of the definition of Pharmaceutical Care Services, stating that “it is a term that has been well-used and refined since before the Board of Pharmacy rule rewrite in 2011. Initially, pharmaceutical care services focused on Medication Therapy Management (MTM); today, it includes interpreting lab tests, conducting

patient assessments, also known as diagnosing, and other broad clinical responsibilities”. Dr. Frost stated that the definition of Pharmaceutical Care Services is nuanced in nature, with some clear and broadly understood aspects, while other portions benefit from additional enumeration by rule. “Will unintended consequences arise by removing this definition, impacting women's healthcare access, preventative care, treatment for minor ailments, and clinical services provided by pharmacists both in and out of the hospital setting? It is important for pharmacists to know they already have clear statutory authority to continue performing these services if the rule is removed.”

Dr. Frost agreed with IMA that pharmacists should not replace radiologists. However, he contended that since 1998, under collaborative practice agreements, pharmacists, particularly hospital pharmacists, have been ordering laboratory tests and imaging in clinical settings in collaboration with cardiologists and infectious disease doctors. This practice has allowed pharmacists to fill healthcare gaps and aid doctors in invaluable ways.

To conclude, Dr. Frost reminded the Board of Pharmacy that since the passage of HB 611 in 2006, a valid prescription order requires a diagnosis be made arising from a valid patient-prescriber relationship, except under limited exceptions such as for prescribing epinephrine or naloxone. If the Board of Pharmacy chooses to remove the definition of Pharmaceutical Care Services, this change will have no impact on the legal authority surrounding clinical services that pharmacists may render throughout the state. Pharmacists will revert to the statutory guidance of standard of care, which allows pharmacists to diagnose, prescribe, order, and interpret laboratory tests and imaging if it falls within their education, training, and experience.

Dr. Jennifer Adams, PharmD, EdD, FAPHA, FNAP, Associate Dean for Academic Affairs at Idaho State University College of Pharmacy – Dr. Adams shared that the Accreditation Council for Pharmacy Education (ACPE) requires all colleges of pharmacy, including Idaho State University, to incorporate the Pharmacist Patient Care Process (PPCP) into their curriculum ensuring all pharmacists are trained to provide clinical services. PPCP teaches student pharmacists to diagnose ailments, prescribe, order, and interpret laboratory tests and imaging, implement patient-specific care plans, monitor outcomes, and refer to other healthcare professionals when appropriate. Student pharmacists know the importance of monitoring patient progress through appropriate imaging and testing, such as using a chest X-ray to track response to treatment for tuberculosis.

The proposed language within the definition of Pharmaceutical Care reflects the rigorous clinical training all pharmacists undergo and mirrors essential components of the PPCP taught to student pharmacists. This definition is instrumental in supporting consistent, standardized training of pharmacists and aligns with the legal and educational frameworks necessary for pharmacists' full-scope practice.

Josh Scholer, Deputy General Counsel for the Division of Financial Management & Office of Governor Brad Little, provided guidance to the board. He stated that Pharmaceutical Care Services' current form is an incomplete list and lacks enforceability. His recommendation was to strike rule 010.19 Pharmaceutical Care in its entirety. He relayed that recently; the Idaho Tax Commission encountered a similar situation where one of their rules contained a non-exhaustive list to provide situational clarity. Ultimately, they were advised to remove the incomplete list and chose to do so. In recent years, executive branch agencies have been advised to remove incomplete lists from their rules and provide guidance documents as a supplement instead.

Mr. Scholer advised if Pharmaceutical Care Services is struck from the rule, regulatory

enforcement will default to the clear statutory authority that provides for the standard of care model adopted by the Board and approved by the legislature. Clinical services currently rendered as pharmaceutical care by pharmacists will still be allowed, including but not limited to diagnosing, prescribing, ordering, and interpreting laboratory tests and imaging if they fall within their education, training, and experience.

To mitigate the confusion of licensees about pharmacists' scope of practice, Mr. Scholer recommended that the board work with Idaho State University and other local associations as the board develops a guidance document.

Board's Options

Following board discussion and public comment, the Board of Pharmacy was advised they had three potential options:

1. Accept the rules as in their current format
2. Strike (d) "and imaging" from the definition of Pharmaceutical Care
3. Strike the non-exhaustive list from the definition of Pharmaceutical Care Services, and then incorporate the remainder of that definition into rule 200.01, Scope of Practice.

The Board's Decision:

Proposed Rule 002.09. A motion was made and seconded to strike the non-exhaustive list from the definition of Pharmaceutical Care Services, and then incorporate the remainder of that definition into rule 200.01, Scope of Practice, as proposed during public comment. The motion carried.

Proposed Rule 100.03(d). A motion was made and seconded to move this subsection to rule 100.07 Practitioner Controlled Substance Registration. The motion carried.

Proposed Rule 200.14(e). Although this topic was discussed at length, no draft language was provided, and the Board decided to make no changes to this section, understanding that it would be able to reenter rulemaking in the future should there be a change in federal law.

The Board Chair called for and received public comment at the end of each section. The Idaho Board of Pharmacy appreciated all comments received from the public.

A motion was made and seconded to adopt the proposed rules as pending, with changes as discussed. The motion carried.

The Board directed staff to work with Idaho State University and others to produce a guidance document that will be posted on the BOP website.

MOUD Grant Update: Dr. Chopski reviewed information regarding the Medications for Opioid Use Disorder Grant (MOUD). She stated that the grant was \$350,000.00, and at this time, five (5) applications have been submitted, with two (2) granted and the others being reviewed. Of those who applied, all were pharmacists. To qualify for the grant, the applicant must not be a new graduate and must have been out of school for a minimum of two (2) years. The hope is that many more applicants will apply for the grant before it expires on June 30, 2025.

Delegated Authority: The Board reviewed all authorities presently delegated to staff. After discussion, a motion was made and seconded to allow Board staff to continue utilizing delegated authority as presented. The motion carried.

Draft Statute Review: The Board reviewed the updated uniform-controlled substance list, which has new scheduling for Schedule I, 37-2705; Schedule III, 37-2709; and Schedule IV, 37-2711. After discussion, the Board independently determined through a motion to approve the draft language to schedule substances as written. Following a second, the motion carried.

Conference Attendance Requests & Reports: The Board reviewed submitted travel reports and discussed and supported attendance for upcoming conferences.

EXECUTIVE SESSION

A motion was made and seconded to enter Executive Session pursuant to Idaho Code § 74-206(1)(d) to consider records related to an applicant's ability to obtain, or a licensee's ability to retain, a license, which is exempt from public disclosure. The vote was: Dr. Ellis, aye; Dr. Messenger, aye; Dr. Jonas, aye; Dr. Hoenke, aye. The motion carried.

A motion was made and seconded to exit the Executive Session. The motion carried.

Applications:

A motion was made and seconded to keep the terms of the Stipulation and Consent Order as before with no changes for application number 1, as discussed in the executive session. The motion carried.

A motion was made and seconded to grant the modification of the Stipulation and Consent Order for application number 2, as discussed in executive session. The motion carried.

Discipline:

A motion was made and seconded to enter into a Stipulation and Consent Order with the terms discussed in the executive session for cases 1, 2, and 3. The motion carried.

A motion was made and seconded to authorize the Board Prosecutor to file an administrative complaint should any negotiations expire or be rejected. The motion carried.

Adjourn

There being no further business, the meeting was adjourned at 3:53 PM.

The next meeting is on 12/19/2024.

