

MINUTES
SENATE HEALTH & WELFARE COMMITTEE

DATE: Wednesday, January 10, 2018

TIME: 3:00 P.M.

PLACE: Room WW54

MEMBERS PRESENT: Chairman Heider, Vice Chairman Souza, Senators Martin, Lee, Harris, Agenbroad, Foreman, Potts, and Jordan

ABSENT/ EXCUSED: None

NOTE: The sign-in sheet, testimonies and other related materials will be retained with the minutes in the committee's office until the end of the session and will then be located on file with the minutes in the Legislative Services Library.

CONVENED: **Chairman Heider** called the meeting of the Health and Welfare Committee (Committee) to order at 3:00 p.m.

PAGE INTRODUCTION: **Chairman Heider** welcomed Heidi Kofoed from Eagle as the Committee Page for the first half of the 2018 Legislative Session. **Chairman Heider** asked Ms. Kofoed to tell the Committee about herself.

DOCKET NO. 27-0101-1701 **Rules of the Idaho State Board of Pharmacy. Alex Adams**, Executive Director of the Idaho State Board of Pharmacy (BOP), presented this docket. **Dr. Adams** introduced himself and BOP members Nicole Chopski, Edmund Sperry, and Holly Henggeler, who were also in attendance. **Dr. Adams** explained that the BOP repealed its existing rule book and replaced it with six new rule chapters that are better organized around specific topics. **Dr. Adams** noted that Docket 27-0101-1701 is the chapter repeal. He mentioned that the repeal and replacement chapters reduce the overall word count in the BOP rules by 55 percent, reduces restrictions by 62 percent, and eliminates six categories of licensure and registration. **Dr. Adams** assured the Committee that the BOP preserved or strengthened rules relating to compounding and controlled substances such as opioids.

MOTION: There being no more testimony or questions, **Senator Harris** moved to approve **Docket No. 27-0101-1701**. **Senator Jordan** seconded the motion. The motion carried by **voice vote**.

DOCKET NO. 27-0101-1702 **Rules of the Idaho State Board of Pharmacy Relating to General Provisions. Dr. Adams** noted that this docket is the BOP's chapter of General Provisions. It establishes definitions and abbreviations, establishes parameters for BOP inspections and investigations, and specifies grounds for unprofessional conduct and professional discipline. **Dr. Adams** stated that only a few changes were made to the existing rules. Some definitions were added (e.g., CLIA-waived test, clinical guidelines), and two items were added to the unprofessional conduct rule to increase pharmacist accountability. **Dr. Adams** reported that the docket was presented at 15 public meetings. He did not recall any public concerns or comments regarding this docket.

MOTION: There being no more testimony or questions, **Senator Foreman** moved to approve **Docket No. 27-0101-1702**. **Senator Harris** seconded the motion. The motion carried by **voice vote**.

**DOCKET NO.
27-0102-1701**

Rules of the Idaho State Board of Pharmacy Governing Licensure and Registration. **Dr. Adams** explained that this docket is the BOP's chapter on Licensure and Registration. **Dr. Adams** noted three primary changes to the relevant rules. First, the rules eliminate six categories of licensure that the BOP found to be redundant or which exist only in a minority of states. As an example, he reported that the BOP's category of non-pharmacy retail outlets appears to be licensed in just two states. The BOP does not have a history of receiving complaints against such entities, nor have periodic inspections yielded concerns. Second, the rules change the BOP's license renewal deadline from June 30th for most individual licenses to a birth month renewal deadline. **Dr. Adams** explained that the birth month renewal model requires individuals to renew their licenses by the end of their birth month. He asserted that this is designed to stabilize staff workload and revenue collection throughout the year, guarding against the need to increase staffing. Third, this docket adjusts several fees. **Dr. Adams** pointed out that some of the fees appear to increase, but separate fees were eliminated, ultimately yielding overall dollar savings to licensees. He stated that 97 percent of Idaho pharmacists would realize a savings of \$20 per year due to elimination of redundant fees. He also noted that Idaho's pharmacy licensing fees generally fall below national averages. Across 15 public hearings, the BOP heard no complaints or comments regarding the proposed fee adjustment. **Dr. Adams** announced that the Idaho Veterinary Medical Association submitted a letter in support of the docket (see attachment #1).

TESTIMONY:

Chairman Heider invited testimony.

Mark Johnston introduced himself as the former Executive Director of the Idaho State Board of Pharmacy and the current Senior Director of Pharmacy Regulatory Affairs for CVS Health. He announced his support of all seven BOP rule dockets before the Committee. **Mr. Johnston** commended the BOP for the open, transparent, and collaborative nature of their rulemaking process.

Senator Jordan inquired whether the elimination of the inactive pharmacist license category would cause individuals in that category to lose benefits they may be receiving from professional associations. **Dr. Adams** reported that there are currently only four individuals in the inactive pharmacist category. The BOP will grandfather those individuals into the category, so that they may retain their inactive pharmacist status and any associated benefits.

MOTION:

There being no more testimony or questions, **Senator Martin** moved to approve **Docket No. 27-0102-1701**. **Vice Chairman Souza** seconded the motion. The motion carried by **voice vote**.

**DOCKET NO.
27-0103-1701**

Rules of the Idaho State Board of Pharmacy Governing Pharmacy Practice. **Dr. Adams** stated that this docket is the BOP's chapter on Pharmacy Practice. This docket establishes professional practice standards, rules for filling and dispensing prescriptions, and recordkeeping and reporting requirements. **Dr. Adams** noted substantive updates in this chapter related to removing restrictions on telepharmacy, physician dispensing, return of unused medications that remain in the custody of the pharmacy, and one-time emergency refills. He stated that the BOP removed restrictions on the types of doors, windows, and bathrooms that pharmacies must have for pharmacists. In addition, the pending rule would: allow electronic recordkeeping in place of paper recordkeeping; remove restrictions on out-patient and emergency room dispensing; and eliminate the requirement for health systems to discard unused medication, as long as product integrity was maintained and the medication did not leave the custody of the health system.

Chairman Heider asked how long it takes to obtain a prescription from a telepharmacy and how prescriptions are delivered. **Dr. Adams** explained that telepharmacies involve a remote dispensing site which looks like a brick-and-mortar

pharmacy, but which has no pharmacist on-site. Instead, there is a pharmacy technician on-site, along with all necessary drug products. A pharmacist in a remote location oversees all operations via secure video feed. **Dr. Adams** stated that the wait time at a telepharmacy is similar to the wait time at a traditional pharmacy.

Chairman Heider asked Dr. Adams to clarify whether a telepharmacy has pharmaceuticals on hand. **Dr. Adams** confirmed that telepharmacies do possess a stock of pharmaceuticals. He remarked that telepharmacies are subject to stricter requirements than traditional pharmacies because there is no pharmacist on-site.

Senator Martin requested additional information regarding the limitations of telehealth. **Dr. Adams** reported that other states have implemented mile restrictions on telepharmacies; Idaho has not done so. **Dr. Adams** commented that the BOP did not want to limit the competitiveness or scope of telepharmacies by imposing a mile restriction.

Senator Lee commended Dr. Adams for his work on the docket. She also commended Idaho pharmacists for their willingness to expand the prescriptive authority of physicians. **Senator Lee** then asked how the number of physicians with dispensing authority compares to the number of pharmacists in Idaho. **Dr. Adams** responded that there are more dispensing physicians in the state than retail pharmacies. He cited that there are around 293 physician dispensing outlets and 287 retail pharmacies in Idaho.

MOTION: There being no more testimony or questions, **Senator Harris** moved to approve **Docket No. 27-0103-1701**. **Senator Lee** seconded the motion. The motion carried by **voice vote**.

**DOCKET NO.
27-0104-1701**

Rules of the Idaho State Board of Pharmacy Governing Pharmacist Prescriptive Authority. **Dr. Adams** explained that the statutory authority for this docket stems from H 191, which was passed during the 2017 Legislative Session. However, pharmacists in Idaho have been able to prescribe certain medications since the 1990s. While working on **Docket No. 27-0104-1701**, the BOP held negotiated rulemaking sessions with stakeholders, 15 public hearings, and several meetings with the Food and Drug Administration and the Federal Trade Commission. As a result of these meetings, the BOP developed a four-part litmus test to determine which drugs pharmacists can prescribe to patients. Pharmacists may only prescribe drugs that meet all four criteria, which are: 1.) The drug must fit within the statutory intent of H 191; 2.) Pharmacists elsewhere must already be prescribing the drug; 3.) There must be published studies regarding the results of pharmacist prescription of the drug; and 4.) BOPs in other states must confirm the findings of published studies.

Dr. Adams addressed the concern that the wording of the docket created ambiguity regarding pharmacist prescription of statins. The BOP's intent was for pharmacists to prescribe statins only to individuals with an existing diagnosis of diabetes. **Dr. Adams** declared that the BOP plans to promulgate a temporary rule to eliminate the ambiguity in the docket.

Dr. Adams described the safeguards that the BOP built into the rules, including the requirement that pharmacists use a protocol based upon clinical guidelines or evidence-based research. The goal of the protocol is to filter out high-risk and medium-risk patients so that they may seek a more appropriate venue for care. The protocol establishes guidelines for when a pharmacist must refer a patient to another health care professional, and it must be submitted to the BOP annually for review. BOP inspectors will also proactively inspect the protocols while in the field. For the drugs of highest concern, such as those for cold sores, the BOP developed

template protocols.

Senator Harris requested that Dr. Adams repeat and clarify the fourth point of the litmus test used to determine which drugs are eligible for pharmacist prescription. **Dr. Adams** stated that the fourth point of the litmus test is Board of Pharmacy attestation. The Idaho BOP spoke with its counterparts in other states that allow pharmacist prescribing in order to learn from their experience.

Senator Jordan stated that she received many emails citing statutory concerns about this docket, but none of the emails cited a specific conflicting statute. She asked Dr. Adams to explain the statutory concerns people had about the docket. **Dr. Adams** stated that H 191 establishes four categories of drugs which can be prescribed by pharmacists. Drugs only need to fit in one of the categories to be eligible for pharmacist prescription. **Dr. Adams** explained that there is some confusion about whether a drug has to be in all four categories or just one. The BOP heard many questions about this and about the categorization of drugs in **Docket No. 27-0104-1701**. In the docket, the BOP categorizes drugs by condition, in accordance with the World Health Organization's categorization of drugs. **Dr. Adams** noted that he received many questions about whether statins and urinary tract infection (UTI) medications fall within legislative intent. The BOP believes UTIs fit within legislative intent because they are minor and generally self-limiting, which is one of the eligible drug categories listed in H 191. The BOP also believes statins fit within legislative intent because they do not require a new diagnosis, another H 191 category of eligible drugs. Pharmacists can only prescribe statins to individuals who have a diagnosis of diabetes.

Senator Jordan asked if the BOP had seen an increase in complaints as a result of the increase in pharmacist prescribing authority. **Dr. Adams** stated that the BOP has not seen an increase in complaints. He told the Committee that the BOP has heard many reports of pharmacist prescriptions helping patients. There is also no known increase to potential pharmacist liability .

Senator Martin asked how the docket would affect consumer cost and safety. **Dr. Adams** responded that the prices depend upon market forces, but pharmacist prescribing in other states has caused prices to decrease. He stated that there is a safe track record for pharmacist prescribing due to accountability mechanisms such as the four-part litmus test.

Vice Chairman Souza thanked Dr. Adams for the many discussions they have had about statins. She stated that she appreciates the new wording of the rules regarding the prescription of statins.

TESTIMONY: **Chairman Heider** invited testimony.

Ken McClure introduced himself on behalf of the Idaho Medical Association (IMA). He noted that many doctors emailed the Committee in opposition to the rule docket. The BOP spoke with other jurisdictions that allow pharmacists to prescribe drugs, but **Mr. McClure** asserted that none of these jurisdictions were in the United States. He stated that Idaho is the first state to grant pharmacists such broad prescribing authority. The IMA participated in the BOP's negotiated rulemaking session and submitted comments expressing concern. **Mr. McClure** explained that health care professionals are making efforts to coordinate and manage care as to prevent unnecessary duplication. He stated that H 191 and this docket run counter to this effort. He referenced the four categories of drugs eligible for pharmacist prescription as listed in H 191. **Mr. McClure** explained that symptoms of a UTI can also be symptoms of a more severe condition. The IMA asked the BOP to require patients to take a test to confirm that they have a UTI before allowing a pharmacist

to prescribe UTI medication. The BOP did not include this requirement in the rule docket because doctors often do not perform such tests. **Mr. McClure** stated that doctors may not administer a test because they know the patient's medical history, whereas a pharmacist may not. **Mr. McClure** mentioned that the IMA is also concerned about the overutilization of antibiotics, which may be leading to the development of antibiotic-resistant superbugs.

Mr. McClure expressed concern about pharmacists prescribing statins. He stated that physicians determine whether a diabetic patient should be on a statin by observing their liver function and other factors. **Mr. McClure** noted that a pharmacist would not have this information and might prescribe a statin to a patient who is not a good candidate for a statin. He requested that the BOP limit the scope of the rule docket and require a UTI test prior to writing a prescription.

Senator Lee recognized Mr. McClure's role in helping increase physician access in Idaho. She asked Mr. McClure if he was concerned about the rule docket falling outside the legislative intent of H 191. She also asked if Mr. McClure would like the Senate to try to clarify the legislative intent of H 191 during the 2018 Legislative Session. **Mr. McClure** responded that he does not want the Senate to open H 191 and make it more broad.

Senator Lee restated Mr. McClure's assertion that physicians know more about a patient's medical history than a pharmacist. She inquired whether he thought this was true in rural areas where access to care is more limited. She then pointed out that someone who has had a UTI before will likely be able to recognize the condition and could save money by going straight to a pharmacy, not to a physician. **Senator Lee** also asked Mr. McClure if physicians and pharmacists could work together on other issues related to access. She invited Mr. McClure to suggest issues on which the two groups could coordinate to improve Idaho's health care system. **Mr. McClure** clarified that the IMA does not mind allowing pharmacists to prescribe UTI medication, as long as the patient has first taken a test to confirm the condition. He stated that the BOP had dismissed the IMA's concerns and that it would be difficult for the two groups to work together in the future.

Senator Martin asked how this rule docket would affect consumer cost and safety. **Mr. McClure** responded that the rule would not likely lead to any deaths, but it could compromise some patients' health. He stated that the rule degrades quality of care.

Vice Chairman Souza pointed out that Idaho has the second lowest number of physicians per capita in the United States. She stated that many people cannot afford health care and that urgent care facilities can be expensive. **Vice Chairman Souza** shared that she knows a doctor who does not administer a test to confirm if someone has a UTI. Instead, he waits to see if the first round of antibiotics solves the problem. She asked what the difference is between someone going to a pharmacist for a prescription versus seeing a physician at urgent care who does not know their medical history. **Mr. McClure** stated that the IMA does not mind allowing pharmacists to prescribe UTI medicine, as long as the patient first takes a test to avoid misdiagnosis. He expressed that he does not see this as an impediment to access. **Mr. McClure** repeated the concern that the rule docket will cause pharmacists to prescribe statins to diabetics who are not good candidates for statins.

Andy Snook introduced himself as a Deputy Attorney General of the State of Idaho and spoke as general counsel for the BOP. **Chairman Heider** stated that the BOP maintains that there are no legal issues with this docket, but that Mr. McClure seemed to disagree. **Chairman Heider** asked Mr. Snook how he would reconcile

those opposing views. **Mr. Snook** noted that he observed the BOP reviewing evidence-based research in order to support its position that UTI medication should be eligible for pharmacist prescription. He found that the BOP's classification of UTIs as minor and generally self-limiting was appropriate, given the evidence. **Mr. Snook** also counseled that pharmacist prescription of statins fits within legislative intent as long as no new diagnosis is required.

Senator Lee asked Dr. Adams how many individuals in Idaho are already prescribed statins. **Dr. Adams** stated that 38 percent of diabetics within the appropriate age range are not on statins. Within that percentage, only a small portion have appropriate exclusion criteria. In Idaho, the gap between the number of patients who should take statins and the number who actually do is higher than the national average.

Senator Lee emphasized that the Committee does not think that Idaho's doctors are incompetent. She inquired whether it would be possible for pharmacists to simply send a letter to Idaho doctors informing them that a specific patient could benefit from statins. **Dr. Adams** stated that this is an option for pharmacists, although it may not be effective. He then cited a study which showed that it required 13 phone calls for a patient to obtain a prescription for a statin.

Senator Potts commended Dr. Adams for increasing patient access to medications that are used regularly. He asked why the BOP chose not to require a UTI test before prescribing UTI medication. **Dr. Adams** noted that the BOP followed clinical guidelines. The American Congress of Obstetricians and Gynecologists does not require a urine analysis before prescribing UTI medication.

MOTION: There being no more testimony or questions, **Senator Foreman** moved to approve **Docket No. 27-0104-1701**. **Senator Lee** seconded the motion. The motion carried by **voice vote**.

DOCKET NO. 27-0105-1701 **Rules of the Idaho State Board of Pharmacy Governing Drug Compounding.** **Dr. Adams** presented this docket and reported that no substantive edits were made to these rules aside from minor typographical changes.

MOTION: There being no more testimony or questions, **Senator Martin** moved to approve **Docket No. 27-0105-1701**. **Senator Harris** seconded the motion. The motion carried by **voice vote**.

DOCKET NO. 27-0106-1701 **Rules of the Idaho State Board of Pharmacy Governing DME, Manufacturing, and Distribution.** **Dr. Adams** presented this docket and stated that the BOP made no substantive edits to these rules, aside from a conforming edit to account for the elimination of a license category in a previous chapter.

MOTION: There being no more testimony or questions, **Senator Martin** moved to approve **Docket No. 27-0106-1701**. **Senator Jordan** seconded the motion. The motion carried by **voice vote**.

WELCOME: **Chairman Heider** welcomed Senator Potts and the committee secretary to the Committee.

ADJOURNED: There being no further business at this time, **Chairman Heider** adjourned the meeting at 4:39 p.m.

Senator Heider
Chair

Rachel Goodman
Secretary