MINUTES

SENATE HEALTH & WELFARE COMMITTEE

DATE:	Tuesday, March 05, 2019
TIME:	3:00 P.M.
PLACE:	Room WW54
MEMBERS PRESENT:	Chairman Martin, Vice Chairman Souza, Senators Heider, Lee, Harris, Burtenshaw, Bayer, Jordan, and Nelson
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 Martin** called the meeting of the Senate Health and Welfare Committee (Committee) to order at 3:00 p.m.
H 182	**Representative Zollinger** presented **H 182**, amending existing law to revise provisions regarding prescription medications. He stated that this bill represents a minor change, but with implications to Idaho code. It has garnered widespread support, with most members of the House Health and Welfare Committee listed as cosponsors along with six members of this Committee. The bill allows for expanded dispensing and prescribing authority if certain requirements are met. Approved medications are limited to conditions that do not require a new diagnosis. The Board of Pharmacy (Board) will not adopt rules authorizing pharmacists to prescribe controlled substances and psychoactive drugs. **Representative Zollinger** cited a body of evidence that pharmacist-delivered care enhances care, lowers overall healthcare costs, and improves patient outcomes.
DISCUSSION:	**Senator Jordan** inquired if there have been any concerns or complaints raised regarding this change. **Representative Zollinger** replied that he is not aware of any complaints. His neighbor is a professor at the University of Idaho in the pharmacy department and the input from him has been very favorable. He noted that members from the Board were in attendance who might also respond to that question. **Berk Fraser**, Interim Director of the Board, reported that there have been no complaints, only praise for this initiative. Patients who would have had to travel a great distance for medication to treat chronic conditions were instead able to obtain medications from their local pharmacy. **Chairman Martin** invited Alex Adams, PharmD, former Executive Director of the Board of Pharmacy to testify. **Dr. Adams** stated that he has drafted many of the prescribing rules as well as pharmacy statute, so is well-positioned to respond to any comments or concerns. He reported robust debate about technicalities on the House side. Based on conversations with the Attorney General's Office, **Dr. Adams** expressed confidence that any legal arguments presented today will have merit.

Chairman Martin asked for clarification regarding language. **Dr. Adams** explained that the bill used language in existing law. He gave examples of authority that this Committee has already approved. "Minor" and "self-limiting" are common medical terms; a self-limiting condition will resolve on its own. A cold sore is a good example of a minor condition that is not likely to resolve on its own, but there can be embarrassment associated with having a cold sore. The sooner one can start antiviral medication, the more likely that the cold sore will resolve quickly. That condition, along with lice and other conditions, are already approved under the current rules. **Dr. Adams** cited Canada as an excellent example of leadership in managing minor ailments, allowing pharmacists to treat 30 to 40 different minor ailments. An example of a condition treated by pharmacists in Canada that is not on our current list, is pinkeye. Part of what Representative Zollinger is trying to resolve with this bill is to avoid the political fire storm that results every time the Board adds a medication to the list. A perfect example this year was when the Board added mild acne to the list. The testimony in opposition stated that only a board-certified dermatologist is uniquely qualified to diagnose and treat mild acne. Studies show that teenaged girls are able to self-diagnose mild acne with a high degree of diagnostic accuracy. The current rules have already approved a list of conditions that do not require a diagnosis. Prevention is another perfect example. Folks going on church mission trips to certain parts of Asia receive a recommendation from the Centers for Disease Control to bring malarial prophylaxis. No diagnosis is needed. Also already approved under the current rules are add-on therapies to address a gap in care. All diabetics between the ages of 40 and 75 are supposed to be on a statin medication to manage cardiovascular risk. Somehow, 40 percent of physicians forget to prescribe that statin. Last year, the Legislature approved the ability of a pharmacist to close that gap in care. The pharmacist is not diagnosing diabetes, they are addressing a known gap in patient care. Last year, the Legislature heard testimony from a physician who testified that statins are so safe and effective that they should be dispensed as over-the-counter medication.

TESTIMONY:

Kimberly Hecht, Manager of Specialty Business Development, Albertsons Companies, testified in support of the bill. Albertsons has a long history of providing safe and effective patient care services that help improve the health of their patients and communities. Albertsons looks forward to the flexibility this bill will provide to improve access to patient care services in a deliberate, safe, and responsible manner that will better meet the needs of their patients.

Jennifer Adams, PharmD, Associate Dean for Academic Affairs, Idaho State University College of Pharmacy, spoke in support of the bill. **Professor Adams** assured the Committee that pharmacists are well-trained and prepared to provide these services. The actions taken by the drafters of this legislation and by the Board will allow Idaho pharmacists to more effectively serve patients in rural areas. Idaho State University has attracted new faculty to the College of Pharmacy, and students from out of state, who specifically sought out Idaho State University because they want to practice at the top of their education and not be limited in scope.

Mike Reynoldson, Vice President of Public Affairs, Blue Cross of Idaho, spoke in support of the bill. His organization has membership in all markets throughout 44 counties, from the individual market to the large business market. The priority for Blue Cross of Idaho is quality care at an affordable price and this bill provides that and proper safeguards for their members.

Pam Eaton, on behalf of the Idaho Retailers Association, Retail Pharmacy Council, and the Idaho State Pharmacy Association, stood in support of the bill. She also extended support on behalf of Melinda Merrill, Northwest Grocers Association, who could not be in attendance. **Ms. Eaton** reported that the American Association for Retired Persons supports this bill, stating that every opportunity to reduce unnecessary costs for the senior population should be examined. The bill increases competition and choice for all consumers, and that leads to better care at lower costs. **Ms. Eaton** shared a story about a rural pharmacy that fully utilizes the prescribing authorities already granted; many of their patients are uninsured or under-insured. Pharmacists understand the complex interactions between medications and disease and this bill gives them the ability to contribute to care at the top of their education. The National Quality Forum reports that pharmacists in the United Kingdom are permitted to prescribe almost all medications, with few exceptions. It reports that pharmacies in the United States are even better prepared to add prescribing authority to their scope of practice than their counterparts in other countries, given the extensive training and education required for pharmacy licensure.

Ken McClure testified on behalf of the Idaho Medical Association (IMA), in opposition to the bill. **Mr. McClure** stated the IMA recognizes that the policy initiatives in place prefer patient convenience and access to pharmaceuticals, over the extra layer of care that can come with controlling pharmaceuticals through physician prescriptions. He stated that he is not here to tell the Committee that the IMA disagrees with this policy, because the Committee already knows that they do. Instead, he asked for consideration of a problem with the legislation, not regarding what it is trying to do, rather, how it does it. Legislation has been passed in prior years stating that pharmacists can prescribe according to the rules of the Board, but has now added rules that indicate what a pharmacist must do when prescribing. The IMA is less concerned about the list of drugs that can be prescribed, or the fact that pharmacists are going to prescribe these, but rather with the rules that govern patient safety and prescribing practices and this legislation is inconsistent with those rules. If the Committee passes this bill as it is, striking reference to rules and language regarding Food and Drug Administration (FDA) labeling requirements, it allows for too-broad prescription authority to pharmacists. **Mr. McClure** asked the Committee to consider amendments that the House sponsor and Dr. Adams have not agreed to accept. He reiterated that the IMA's concern is not with a pharmacist's ability to prescribe more medications, rather that there is no apparent limit to that authority in rules or statute if this bill passes. Under this legislation, a pharmacist would be allowed to prescribe any drug, for any condition with a prior diagnosis. Those are not always minor or self-limiting conditions. They include cancer, schizophrenia, heart disease, and a whole host of serious conditions for which patients should be seeing physicians, not pharmacists. The IMA does not want to take away the right of pharmacists, under this bill or under current law, to prescribe for minor and self-limiting conditions or for travel medications. It only asks the Committee to reflect on the implications of authorizing a pharmacist to prescribe anything allowed under an FDA label to a patient who has a prior diagnosis.

DISCUSSION: A lengthy discussion ensued regarding interpretation of the language within the proposed bill. **Vice Chairman Souza** requested clarification. **Chairman Martin** invited Dr. Alex Adams to take the podium.

Dr. Adams commented that this bill has been significantly scrutinized and subjected to repeated legal allegations that began when the Board started rulemaking in 2017. He reported that the definition of the word "or" became an issue and he learned the legal definition of "or" from Elizabeth Bowen, Principal Drafting Attorney with the Legislative Services Office. This Committee has already approved things that do not require a new diagnosis, but are not minor: malarial prophylaxis is a great example. Malaria is not considered to be a minor or self-limiting condition, but malarial prophylaxis does not require a new diagnosis. If the real question is whether this authority would be abused, it is the experience of the Board that pharmacists are rather conservative in their management. He used as an example practice authority in Alberta, Canada. Alberta affords broad, independent prescriptive authority with none of the limitations found in this bill. Alberta pharmacists can prescribe controlled substances and compounds, are not limited by FDA labeling, or to minor ailments or new diagnoses— they can prescribe for anything. Five years after their bill passed, less than 10 percent of pharmacists have prescribed, because they're building their comfort level. Most of what they prescribe for new diagnoses are one-time refills as bridge therapy to get patients back to their physicians. As an example, a patient traveling north to Yellowstone National Park from Salt Lake City might realize they forgot their insulin at home. A pharmacist could then write a one-month prescription for their insulin to get them through that trip.

Dr. Adams referenced Mr. McClure's testimony expressing concern that general prescribing requirements will go away. **Dr. Adams** shared a conversation he had with the Attorney General's Office, in which their opinion was that the rules do not go away. The Board requires pharmacists to have a protocol. It is the only profession in Idaho that requires the professional to use a protocol in order to prescribe. The Board requires notification back to the primary care provider. What this bill strikes is the requirement to list drugs, drug categories, or devices individually. It does not strike the requirement for notification. Put simply, there is no conflict between the statute and rule. Representative Rubel, a Harvard-trained lawyer who cosponsored the bill, asked during House discussions if this rulemaking authority were to go away, would the Board have rulemaking authority elsewhere. The answer to that is yes: The Board shall make, adopt, amend, and repeal, such rules and regulations as may be deemed necessary by the Board. The Board has general rulemaking authority that can make rules for general prescribing requirements with or without that language, which does not apply to drugs, drug categories, and devices. The next question is whether the rules stand. Those rules are for the proper administration and enforcement of this act. The Board has enforcement authority over everything within this act, including the rules, and that is reiterated in three other sections of code. There is enforcement authority layered throughout. The pharmacy statutes have been amended 126 times. Earlier in this legislative session, the Legislature passed **H 10** unanimously, which made significant changes to 16 sections of code. At no point during that bill—or during discussion around any of the other 126 amendments—has the question of rule enforceability been an issue. The Legislature would have to pass a concurrent resolution for elimination of those rules. No such concurrent resolution has been brought forth or is forthcoming. One of the last bills passed every year is a bill to statutorily re-enact all the rules. One of the last bills this Legislature will pass this session will be to reauthorize statutorily, the very rules that will not be going away.

Dr. Adams stated that the most important thing the Board accomplished over the last two and a half years is the addition of language regarding unprofessional conduct, stating that a deviation from the standard of care is grounds for professional discipline where the Board can revoke, restrict, or rescind a license. Standard of care is defined as what a reasonable, prudent pharmacist would do in the same or similar situation. If, for example, a pharmacist tried to prescribe for diabetes, considering it to be a minor ailment, and that notification went back to the patient's primary care professional who then filed a complaint, the Board could investigate the complaint as a standard of care violation. It is the same standard of care used in nursing, medicine, and other health professions. On average, the Board disciplines 62 licensees aper year. Compare that to dentistry at 4.4 cases, medicine at 17 cases, nursing at 15.8 cases, and veterinary medicine at 2.2 cases. This Board has provided more proactive oversight and has pursued more discipline. Pharmacy is the only health profession that sends inspectors to every site annually. Inspectors review protocols and the records of what pharmacists have prescribed. **H 182** creates a framework to allow some flexibility, so that every year the Legislature does not have to hear how grievous harm can result if a pharmacist prescribes for mild acne.

Mr. McClure reiterated that the statute is inconsistent with the rules. Rules must be supported in statute. He is concerned that there could be a case in which a court will determine inconsistency and therefore the rule is not enforceable. He further stated that if he were a pharmacist disciplined for failing to meet the standard of care for having prescribed according to an FDA label, rather than according to what other pharmacists do, he would point directly to the statute. He asserted that if the Committee passes this bill, it would remove the ability of the Board to ensure the public is protected from improper prescribing, and the authority to discipline someone who improperly prescribes. Those issues can be addressed by an amendment that does no harm to the purpose of the legislation.

Chairman Martin inquired what Mr. McClure's intent would be if the bill is sent to the amending order. **Mr. McClure** assured the Committee, Dr. Adams, Representative Zollinger, and Ms. Eaton that he would make every effort to ensure that an agreed-upon amendment supported the bill and that a hostile amendment would not be brought.

Senator Lee commented that this Committee has had a lot of experience hearing negative feedback about this bill, but she is very pleased to report that in her local community, access really has improved and people have been served well. She stated that adding an amendment could create conflict in the rulemaking process.

Chairman Martin invited Representative Zollinger to make closing comments. **Representative Zollinger** stated that they had the same discussions in the House before it passed unanimously. The House took it to their legal experts who concurred. Some of the rules in place right now include sections regarding prescribing authority, education requirements, collaboration with primary physicians, and record keeping. The profession has very complicated rules regarding what they may prescribe. The rules do not go away. The only part that this bill strikes is the list of specific drugs. The bill complies with all the prescribing rules already in place, so there is no need for an amendment. **Representative Zollinger** asked the Committee to send **H 182** to the floor with a do pass recommendation.

Vice Chairman Souza shared that she considered the Telehealth bill and this Pharmacy bill to be two noteworthy accomplishments during her tenure in the Senate. The bill provides better care, lowers the cost of the care, and makes care more readily available.

Senator Jordan commented that this bill offers a cautionary tale, stating the Legislature tends to look at a bill as a separate section of code. She felt that the most telling part of the conversation today was looking at Chapter 54 in its entirety, where it describes and assigns the rulemaking and the enforcement authority. In that context, it appears to be appropriately regulated and controlled.

MOTION: **Vice Chairman Souza** moved to send **H 182** to the floor with a **do pass** recommendation. **Senator Jordan** seconded the motion. The motion carried by **voice vote**.

ADJOURNED: There being no further business at this time, **Chairman Martin** adjourned the meeting at 3:58 p.m.

Senator Martin
Chair

Margaret Major
Secretary