

MINUTES
SENATE HEALTH & WELFARE COMMITTEE

DATE: Tuesday, February 17, 2015

TIME: 3:00 P.M.

PLACE: Room WW54

MEMBERS PRESENT: Chairman Heider, Vice Chairman Martin, Senators Nuxoll, Hagedorn, Tippetts, Lee, Johnson (Lodge), Schmidt and Lacey

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 Senate Health and Welfare Committee (Committee) to order at 3:02 p.m.

H 0004 **Mark Johnston**, Executive Director, Board of Pharmacy (BOP), Department of Health and Welfare, explained Idaho Code required every person who manufactures, distributes, dispenses, or conducts research with controlled substances (CS) to annually obtain a registration issued by the BOP. If a registrant is found negligent, Idaho Code allows the BOP to suspend or revoke their registration. He said the BOP believes some violations that deserve a penalty did not rise to the level of suspension or revocation.

Mr. Johnston said **H 0004** would grant the BOP the authority to restrict CS registrations and enforce stipulated agreements that restrict CS registrations. Additionally, **H 0004** would allow the BOP to impose a fine of up to \$2,000, which is the current fine ceiling in the Idaho Pharmacy Act. Over the past two years, the BOP has fined an average of \$525 per order. Fines are a lesser penalty to utilize in certain cases to deter recidivism, where suspension and revocation are sometimes too harsh as penalties. He reported **H 0004** contains many changes that were initiated by an increasing need to restrict CS registrations for those prescribers who divert CS, and he urged the Committee to send **H 0004** to the floor with a do pass recommendation.

Vice Chairman Martin asked how the BOP would decide how much to fine an individual.**Mr. Johnston** replied each case was unique, but the BOP liked to act consistently as a deterrent to potential future abuse. He said fining the maximum was not the BOP's philosophy.

Senator Schmidt asked if licensed midwives were considered prescribers. **Mr. Johnston** said there were two kinds of midwives in Idaho. Midwives who are advanced practice nurses, certified nurse anesthetists, and nurse practitioners have prescriptive authority. Midwives who do not have the qualifications do not have prescriptive authority. **Senator Schmidt** said he remembered giving midwives authority to dispense drugs during labor. **Mr. Johnston** said he was correct. What they obtained was the ability to obtain and administer prescription drugs, but they did not get the ability to prescribe drugs.

Senator Tippets asked if, with passage of this legislation, the BOP would be able to impose a fine and, in addition, collect the costs of prosecution, attorney fees, administrative costs, and costs of hearing transcripts. **Mr. Johnston** said that was partially correct. The BOP has the ability to recoup their costs when they go to a proceeding such as a hearing. When they restrict pursuant to a stipulation, they do not have the ability to recoup their costs. **Senator Tippets** asked him to explain. **Mr. Johnston** said they did not have the ability to restrict registrations. They have had the ability to suspend and revoke registrations, so the initial focus of this bill is to obtain the ability to restrict registrations. They would actually have to bring somebody into a BOP hearing or a proceeding to be able to recoup costs. **Senator Tippets** asked if other boards had the authority, in addition to levying fines, to also recoup the costs that were enumerated. **Mr. Johnston** could not speak for any other board. **Senator Tippets** asked Mr. Johnston to explain the meaning of stipulation. **Mr. Johnston** explained instead of bringing every person who potentially could be disciplined before the BOP in a hearing or hiring a hearing officer to create findings of fact and conclusions of law to present to the BOP, the law allows for the administrative agency and the registrant to come to a stipulated agreement where both agree to the violation and the stipulated penalty. It is quicker and cheaper for all. He said they do not have this ability for CS registrants. They do in the Idaho Pharmacy Act and almost every other agency probably has the ability to stipulate, so it is odd that they do not have it in the Uniform Controlled Substances Act.

Senator Hagedorn said the language "or conduct research with" was in one place but not mentioned in other places in **H 0004**. He asked Mr. Johnston to clarify. **Mr. Johnston** said originally it was left out of the statute then added at the end as an afterthought. This change strikes the language at the end of the bill and includes it in the main part of the bill. **Senator Hagedorn** suggested the BOP should have Legislative Services (LSO) look at the rest of the statute for consistency and add the language "or conduct research with" everywhere it should be included so there was no question.

Senator Nuxoll asked what new groups were being added. **Mr. Johnston** replied they were not adding new groups. **Senator Nuxoll** asked a follow-up to Senator Schmidt's question on whether midwives were already included in this and if they had to register. **Mr. Johnston** said the nurse-midwives who were advanced practical nurses with prescriptive authority were subject to it. Other midwives who had the ability to obtain and administer a small amount of prescription items pursuant to a formulary would not have to register because that formulary did not include CS.

Senator Tippets asked why the BOP needed the ability to not only recover the costs but impose an additional \$2,000 on top of that. **Mr. Johnston** replied because they could not currently fine when they stipulated and because they believed a fine penalty decreased the amount of recidivism by the people who received the fine and by people who read about the fine in the BOP order and newsletters.

Vice Chairman Martin asked what actions by prescribers would be cause for a fine. **Mr. Johnston** responded there was a wide variety and gave a number of examples. Being able to impose a fine would give the BOP an alternative to suspension or revocation, depending upon the severity of the offense.

MOTION:

Senator Schmidt moved to send **H 0004** to the floor with a **do pass** recommendation. **Vice Chairman Martin** seconded the motion. The motion carried by **voice vote**. **Senator Nuxoll** requested that she be recorded as voting nay. Senator Schmidt will carry the bill on the floor.

QUESTION: **Senator Johnson (Lodge)** asked how many members are on the BOP. **Mr. Johnston** explained the BOP has five members. Four members have to be active pharmacists, one of whom has to have substantial experience in hospital pharmacy, one has to have substantial experience in retail pharmacy and the other two can be mixed. The fifth is a member of the public who needs no ties to pharmacy.

H 0005 **Mr. Johnston** said Idaho Code requires the BOP to fingerprint applicants in order to check the Idaho Central Criminal History and Federal Bureau of Investigation (FBI) databases. The process often takes up to six weeks unlike other states. While the BOP believes fingerprinting is a useful tool for licensure and registration, a six-week delay is often a considerable public safety issue as pharmacies work shorthanded. **H 0005** would waive the fingerprint requirement for applicants seeking reinstatement whose license or registration has lapsed by less than a year. He urged the Committee to send **H 0005** to the floor with a do pass recommendation.

Senator Hagedorn asked who the BOP was removing from the list. Previously it said all applicants and now there were only three different groups. Who are they now leaving out of that and why? **Mr. Johnston** said it was a small group of people who are the designated representatives of a wholesale distributor who is not a licensee or a registrant. That would become more apparent in the discussion of **H 0008**.

Senator Tippetts asked why someone would have to be fingerprinted again if they had been fingerprinted before. **Mr. Johnston** said the FBI certifies their fingerprint background check for six months. When statute said they have to reprint someone who was being reinstated and it had been longer than six months since their last fingerprinted background check, they had to do the fingerprint-based background check again.

MOTION: **Vice Chairman Martin** moved to send **H 0005** to the floor with a **do pass** recommendation. **Senator Tippetts** seconded the motion. The motion carried by **voice vote**. Vice Chairman Martin will carry the bill on the floor.

H 0006 **Mr. Johnston** explained currently a prescription drug order may be communicated by telephone, fax, or hand-delivered by a prescriber or their agent to a pharmacy. He said the Drug Enforcement Agency (DEA) allowed electronic prescribing of controlled substances pursuant to considerable federal regulation and an expensive approval process. He said the BOP had championed a public request to legalize the electronic transmission of prescription drug orders by licensed practical or professional nurses in an institutional facility for a patient of that facility to a pharmacy via a secure interoperable information technology system. While the DEA will not allow this for CS, the BOP believes the benefit to public safety outweighs the potential for privacy violations. This system already exists in hospitals, whereby a physician at the patient's bedside can have their nurse enter an order into a computer system in which the pharmacy retrieves the data and dispenses the prescription. **H 0006** would allow such transmissions from nursing homes, just like in the hospital. The BOP championed a request from the public to run this bill, and one of the requesters, Bill Silvias, was present for the Committee to ask any technical questions. **Executive Director Johnston** said this change to Idaho Code was necessary to keep up with the advancement of technology.

Senator Tippetts asked where the word "may" was changed from "shall" in **H 0006**. **Chairman Heider** observed the only place was at the top of page 2, line 6.

Senator Schmidt asked how a midwife with only dispensing authority fit in this, since dispensing midwives do not have prescribing authority. **Mr. Johnston** said they did not fit because they were not prescribers and only had the ability to administer to the patient in front of them. They could not send take-home doses home. **Senator Schmidt** asked how a midwife obtains drugs. **Mr. Johnston** said in the Idaho Wholesale Drug Distribution Act, pharmacies are allowed to distribute, in the absence of a patient-specific prescription drug order, manufactured products to a prescriber for office use. Since midwives don't operate out of an office they cannot go to a pharmacy in Idaho and buy the product. Midwives have to go through a wholesale distributor which is a struggle for them because they do not have wholesale volume, so wholesale dealers do not want to sell to them.

TESTIMONY: **Bill Silvias**, a Treasure Valley pharmacist who works in long-term care, spoke in favor of **H 0006**. He said he would be affected directly by this legislation. He was one of the pharmacists who presented it to the BOP for consideration of the statute change.

Senator Hagedorn asked Mr. Silvias if this was a duplication of current institutional policy to hospice. **Mr. Silvias** said no, this is separate.

Senator Schmidt asked Mr. Johnston how this compares with the work of the Telehealth Task Force regarding rules and statutes. **Mr. Johnston** said it is independent from the Task Force. **H 0006** adds an additional form of communication for taking a verbal order and entering it into the data system to send it to the pharmacy.

MOTION: **Vice Chairman Martin** moved to send **H 0006** to the floor with a **do pass** recommendation. **Senator Lee** seconded the motion. The motion carried by **voice vote**. Senator Hagedorn will carry the bill on the floor.

H 0007 **Mr. Johnston** explained the BOP was statutorily mandated to maintain Idaho's Prescription Monitoring Program (PMP), whereby certain data of dispensed CS is collected, collated into patient and prescriber profiles, and made available to authorized users. The two statutory purposes for creating the PMP were assisting in identifying illegal activity related to the dispensing of CS and transmission of prescription drug orders, and assisting the BOP in providing information to patients, practitioners and pharmacists to help avoid inappropriate use of CS. **Mr. Johnston** said there was no statutory allowance to release PMP data pursuant to subpoenas for civil law suits, such as divorce and child custody cases. In Idaho, attorneys have subpoena power and often the BOP receives phishing subpoenas from one spouse's attorney wanting the other spouse's private health information (PHI). The BOP continually uses its resources to have contract attorneys at the Attorney General's office pen denials for such requests. The BOP realizes there may be valid reasons why PMP data might be pertinent to a civil case. **H 0007** would require that a presiding judge issue a subpoena for PMP data and would clearly codify that a subpoena from an attorney was not a valid method to obtain PMP data. He said the BOP checked with the administrative director of the courts who responded that the courts had no issue with the bill. **Mr. Johnston** urged the Committee to send **H 0007** to the floor with a do pass recommendation.

MOTION: **Senator Hagedorn** moved to send **H 0007** to the floor with a **do pass** recommendation. **Senator Nuxoll** seconded the motion. The motion carried by **voice vote**. Senator Hagedorn will carry the bill on the floor.

H 0008

Mr. Johnston explained Congress passed the Drug Quality and Security Act in November 2013. Provisions of this act become effective at various dates over the next decade, so he expects to present future bills on this topic. The first provision became effective on January 1, 2015, and preempted states from tracking the distribution of prescription drugs. Due to this preemption, **H 0008** strikes several definitions and lines of the Idaho Pharmacy Act (IPA) and the Idaho Wholesale Drug Distribution Act (IWDDA) that require and regulate pedigrees, which are transaction information statements that accompany certain drug distributions. This project grew past its initial focus as the BOP also wanted to address the issue of grey wholesaling as addressed in a congressional report and a National Association of Boards of Pharmacy (NABP) task force white paper. Additionally, Congress passed the Ryan Haight Act, which placed certain duties upon wholesale distributors of CS, which the BOP also desires to enforce for public safety.

Mr. Johnston reported the IWDDA was very needed, considering the immense amount of counterfeit, dangerous drugs that exist in other countries. He said Idaho was progressive in passing the IWDDA in 2007, but perhaps premature in terms of language development as it had been altered in some fashion by the Idaho Legislature nearly every year since its inception. **H 0008** addresses many outstanding issues that still remain within the IWDDA. **Mr. Johnston** reported the BOP worked with the Healthcare Distribution Management Association (HDMA), the national association for wholesalers, who applauded the BOP for addressing many outstanding issues before other states had. He was not aware of any opposition to the bill, which was prompted by federal preemptions. He urged the Committee to send **H 0008** to the floor with a do pass recommendation.

Senator Schmidt asked about Idaho Code § 54-1734, possession of legend drugs, and how midwives fit into it as legally possessing drugs. **Mr. Johnston** said midwives were not included, and they should have been listed in § 54-1734. **Senator Schmidt** commented that Mr. Johnston would probably be back to do that next year.

Senator Nuxoll stated she was having difficulty going along with **H 0008** because of the amount of federal government preemption of law.

MOTION:

Senator Schmidt moved to send **H 0008** to the floor with a **do pass** recommendation. **Senator Lacey** seconded the motion. The motion carried by **voice vote**. **Senator Nuxoll** requested that she be recorded as voting nay. Senator Schmidt will carry the bill on the floor.

FURTHER DISCUSSION:

Senator Hagedorn asked Senator Schmidt if **H 0008** should be sent to the 14th Order for amendment to include the midwives this year rather than wait for a new bill next year. **Senator Schmidt** said it should be a project for next year due to its complexity.

H 0009

Mr. Johnston explained Idaho Code § 37-2702(d) says that if any substance was designated, rescheduled, or deleted as a CS under federal law and notice was given to the BOP, the BOP should similarly control the substance under the act after the expiration of 30 days. He said § 37-2714 mandated that the BOP update Idaho's schedules of CS annually. The proposal accomplished the BOP's statutory requirement to update, as the DEA had during the past year. He also said the substances were already controlled in Idaho; this bill would put into print what was already law. **Mr. Johnston** urged the Committee to send **H 0009** to the floor with a do pass recommendation.

Senator Johnson (Lodge) asked if the BOP had to accept federal regulations or if they were just a guideline. **Mr. Johnston** said the federal government took a lot into account to change a drug's schedule. In most cases, the BOP wanted a drug to be controlled in Idaho if the federal studies said it should be controlled. He was not aware of a product scheduled federally and not scheduled in Idaho. Ninety-nine percent of the thousands of CS drugs written into Idaho Code are exactly the same as the federal schedule, but Idaho has scheduled approximately 1 percent more. Some examples are illicit drugs like bath salts, spice and what's commonly known as the date rape drug. He said the BOP takes its independent authority to schedule seriously.

Senator Nuxoll asked if the BOP had ever rejected something the federal government had deemed necessary to follow. **Mr. Johnston** said, during his years as Executive Director, the BOP had not rejected anything on the federal schedule, but the BOP had scheduled more stringently than the federal government.

MOTION: **Vice Chairman Martin** moved to send **H 0009** to the floor with a **do pass** recommendation. **Senator Hagedorn** seconded the motion. The motion carried by **voice vote**. Vice Chairman Martin will carry the bill on the floor.

ADJOURNED: There being no further business, **Chairman Heider** adjourned the meeting at 4:12 p.m.

Senator Heider
Chairman

Erin Denker
Secretary

Paula Tonkin
Assistant Secretary