MINUTES

SENATE HEALTH & WELFARE COMMITTEE

DATE:	Wednesday, March 09, 2016
TIME:	3:00 P.M.
PLACE:	Room WW54
MEMBERS PRESENT:	Chairman Heider, Vice Chairman Nuxoll, Senators Hagedorn, Martin, Lee, Harris, Schmidt and Jordan
ABSENT/ EXCUSED:	Senator Lodge
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 Senate Health and Welfare Committee (Committee) to order at 3:01 p.m.

GUBERNATORIAL APPOINTMENT: **Consideration of Gubernatorial Appointment of Jay F. Kunze to the Hazardous Waste Facility Siting License Application Review Panel (Panel)**. **Chairman Heider** introduced Mr. Kunze, informed the Committee that Mr. Kunze was participating via teleconference from Pocatello, Idaho. He asked Mr. Kunze to tell the Committee about himself and why he would like to be reappointed to the Panel.

Mr. Kunze stated this will be his fourth appointment to the Panel. The Panel has only been involved in the review of the hazardous burial site near Grand View, Idaho, prior to opening the site and again when the site was expanded. **Mr. Kunze** stated that he is willing to serve again. **Mr. Kunze** stated that, until ten years ago, he served as the Dean of Engineering at Idaho State University and he currently still teaches engineering classes. **Mr. Kunze** discussed his professional experience prior to working at Idaho State University, including working for the Idaho National Laboratory (INL) for more than 20 years.

Chairman Heider asked the Committee members if they had any questions.

Senator Martin asked about Mr. Kunze's background. **Mr. Kunze** replied he was born and raised in Pittsburgh, Pennsylvania, and came to Idaho when was about 26 to work on the aircraft nuclear propulsion project. In addition to the work experience mentioned above, Mr. Kunze also headed the nuclear engineering program at the University of Missouri for 12 years.

Noting that the Panel has not met for three years, **Senator Schmidt** he asked if the Panel has ever considered making recommendations regarding continued existence. **Mr. Kunze** responded he has also questioned this issue.

Chairman Heider said that most of the Committee members have toured the Grand View site and have been very impressed with the safety record and with the vigilance with which they manage that site. **Mr. Kunze** noted that he also was impressed with the safety record at the site. **Mr. Kunze** added that he thinks Idaho is doing its fair share of the work to keep the nation safe and environmentally clean.

MOTION: There being no more questions, **Senator Martin** moved to send the Gubernatorial appointment of Jay F. Kunze to the Hazardous Waste Facility Siting License Application Review Panel to the floor with recommendation that he be confirmed by the Senate. **Senator Lee** seconded the motion. The motion carried by **voice vote**. Senator Guthrie will carry the appointment on the floor of the Senate.

S 1382 **Relating to the Definition of the Practice of Nursing**. **Sandra Evans**, Executive Director for the Idaho Board of Nursing, presented this bill.

Ms. Evans stated that this bill amends Idaho Code to update the definition of "practice of nursing." The current definition is outdated and no longer descriptive of today's nursing practice. The updated definition clearly articulates the diversity of settings in which nurses practice and the variety of roles in which they engage. Additionally, the updated definition affirms that the practice of nursing takes place where the recipient of care is located. There is no fiscal impact for this bill.

MOTION: There being no questions, **Senator Harris** moved to send **S 1382** to the floor with a **do pass** recommendation. **Vice Chairman Nuxoll** seconded the motion. The motion carried by **voice vote**. Senator Martin will carry the bill on the floor of the Senate.

H 483 **Relating to Pharmacist Who Dispense Biological Products**. **Ken McClure**, Attorney representing the Idaho Medical Association and Amgen, a maker of biologic medicines, presented this bill.

Mr. McClure stated that last year the Board of Pharmacy implemented a rule that allowed for the substitution of one biologic medicine for another at the discretion of the health plan and the dispensing pharmacist. **Mr. McClure** discussed the differences between chemical medicines and biologic medicines (see attachment 1). He stated that because biologic medicines usually come from a single cell line, they are not easily replicable. The FDA allows other manufacturers to fast track the approval of biologic medicines that are similar to the originally approved biologic medicine. These medicines are called biosimilars and it is important to note that they are not identical to the original biomedicine because they come from a different cell strain. **Mr. McClure** noted that the availability of multiple biologics to treat the same condition is a good thing because it allows choice and price competition, and because one specific biosimilar may be more effective in treating a particular patient than any other biosimilar. This bill requires a pharmacist to notify the patient's physician when the pharmacist substitutes one biosimilar for another. **Mr. McClure** reviewed the exceptions to the reporting requirements. This bill informs the physician of the biologic medicine dispensed, so that if the patient experiences any problems, the physician can respond appropriately.

Chairman Heider asked the Committee members if they had any questions.

Senator Hagedorn asked for clarification regarding under what circumstances no reporting would be allowed for a biological product with no approved interchangeable products. **Mr. McClure** clarified the language by stating that said that if a pharmacist dispenses any biological product they are required to report to the physician, unless there is no substitute which could be made. In other words, the drug was dispensed as prescribed because no appropriate substitution exists. **Mr. McClure** acknowledged that the language is confusing, but it was necessary to balance the concerns of all interested parties.

Vice Chairman Nuxoll asked why this communication is necessary if pharmacists enter dispensing information into an electronic database. And she asked why patients are not responsible enough to know what specific biologic medicine they are receiving. Regarding Vice Chairman Nuxoll's first question, **Mr. McClure** responded that if a pharmacist enters the dispensing information into an appropriate electronic database, they will be considered in compliance with the reporting requirement. However, if the biologic is dispensed by a pharmacist that does not use an electronic system, they would be required to fax such information to the physician. Regarding Vice Chairman Nuxoll's second question, **Mr. McClure** stated that although a patient may be aware of the substitution, they may forget to tell their physician about the substitution. Patients may have adverse reactions several months after taking the medication. **Vice Chairman Nuxoll** asked what pharmaceutical products are required to be entered into the shared electronic systems. **Mr. McClure** stated that there are two primary public shared systems: (i) the Prescription Monitoring Program (PMP) for controlled substances and (ii) the Immunization Reminder Information System (IRIS) for immunizations. Biologics are not included in those systems, but rather in a database system that exists in the private sector.

Senator Martin asked whether this legislation primarily addresses notifications regarding refills. **Mr. McClure** explained that the reporting requirements may also be applicable to the initial prescription. **Senator Martin** asked Mr. McClure to confirm that the patient would not be telling the physician that there was a substitute; the person that fills the prescription would notify the physician of the substitution. **Mr. McClure** confirmed that the pharmacy filling the prescription would enter the dispensing information into the electronic health record, in the PMP or would fax the information to the physician.

TESTIMONY: **Chairman Heider** invited testimony.

Dr. Troy Rohn, pharmacology professor at Boise State University holding a PhD in pharmacology, testified in support of the bill. **Dr. Rohn** discussed his work and experience with biologic medications to demonstrate the difference between biologics and biosimilars. He stated that this bill is a good piece of legislation that is not too onerous for pharmacies. **Vice Chairman Nuxoll** asked why reporting of a substitution biologic is required instead of optional. **Dr. Rohn** responded that he thinks reporting is required because the physician is in the best position to make determinations about a patient's course of treatment. **Vice Chairman Nuxoll** asked if, instead of making notification a requirement, couldn't the patient tell their physician. **Dr. Rohn** said many of the diseases treated by biologics are chronic diseases in which adverse reactions could occur months after taking a particular medication. This legislation ensures that the physician is kept in the loop regarding which medications are dispensed to the patient.

Dr. Patrick Knibbe, rheumatologist, testified in support of the bill. **Dr. Knibbe** said he thinks the checks and balances provided for in this bill ensure that all parties involved in a patient's treatment are aware of what product has been dispensed to the patient. **Dr. Knibbe** discussed his rationale as physician for wanting pharmacists to report this type of information. **Senator Lee** asked whether it is more appropriate for a physician, who is concerned about biosimilars, to write the prescription to "dispense as written," instead of relying on pharmacist reporting. She also asked what actions Dr. Knibbe would take, if he was notified that a biosimilar had been dispensed. **Dr. Knibbe** said that an insurance company or pharmacies may "veto" his "dispense as written" instruction. He reiterated the importance of transparency for physicians to make decisions in the best interest of their patients.

Stephanie Benjamin testified that her daughter has been battling juvenile arthritis for eight years. She said it has been a journey to find which biologic medication will control her daughter's inflammation and reduce the pain. An effective biologic was found and has been working for about two years now, giving her an improved quality of life. **Ms. Benjamin** expressed how grateful she was to have research and development of biosimilar medications. However, although these medications are similar, they're not identical and may not bring relief to all patients. She noted her concern regarding a pharmacist's ability to substitute a patient's biologic medication without the authorization of the patient's physician. **Ms. Benjamin** asked the Committee not to allow biologic substitutions unless the patient's doctor has been notified and is allowed time to review if the substitution is in the patient's best interest. **Vice Chairman Nuxoll** asked if Ms. Benjamin had stated, in her testimony, that pharmacists can substitute biologic prescriptions without letting patients know. **Ms. Benjamin** said it was her understanding that those decisions could be made without necessarily consulting the physician and that the pharmacist may choose a different medication.

Luke Cavener, Statewide Director for the American Cancer Society (ACS) Cancer Action Network (CAN), which is a non-partisan public policy advocacy arm of the ACS, testified in support of this bill. **Mr. Cavener** stated that this bill will ease the burdens of cancer patients in Idaho.

CLOSING REMARKS: Referencing an earlier question by Senator Lee, **Mr. McClure** commented that a physician retains the right to "dispense as written." This is not an adequate solution because, if the FDA does its job properly, the biosimilar may be just as good and it is almost certain to be cheaper and as a result covered by a health plan. "Dispense as written" may result in patients being unable to afford prescribed medications. Referencing Vice Chairman Nuxoll's earlier question, **Mr. McClure** stated that the substitution is made after the physician writes the prescription; this bill seeks to ensure that the medical record is updated accordingly. **Mr. McClure** added that the bill does have a sunset clause and noted that he expects that electronic health records, at some point, will make this record-keeping process completely unnecessary.

Chairman Heider asked the Committee members if they had any questions.

Senator Martin asked if other states are enacting similar laws, or whether Idaho is one of the first to address this issue. **Mr. McClure** responded that most states either have enacted similar laws or are considering such laws at this time.

MOTION: There being no more questions, **Senator Hagedorn** moved to send **H 483** to the floor with a **do pass** recommendation. **Senator Harris** seconded the motion. The motion carried by **voice vote**. Senator Hagedorn will carry the bill on the floor of the Senate.

ADJOURNED: There being no further business, **Chairman Heider** adjourned the meeting at 3:55 p.m.

_____

Senator Heider
Chair

_____

Karen R. Westbrook
Secretary

_____

Kara Machado
Assistant