

MINUTES
SENATE HEALTH & WELFARE COMMITTEE

DATE: Tuesday, January 29, 2013

TIME: 3:00 P.M.

PLACE: Room WW54

MEMBERS PRESENT: Chairman Heider, Vice Chairman Nuxoll, Senators Lodge, Hagedorn, Guthrie, Martin, Lakey, Bock and Schmidt

ABSENT/ EXCUSED:

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** convened the meeting at 3:02 p.m.

MINUTES: **Chairman Heider** asked for the approval of the January 14, 2013 Senate Health and Welfare Committee minutes.

MOTION: **Senator Martin** moved to approve the January 14, 2013 minutes as written. The motion was seconded by **Senator Bock**. The motion carried by **voice vote**.

GUBERNATORIAL APPOINTMENT HEARING: **Chairman Heider** asked for the committee's consideration of the Gubernatorial Appointment of Sue A. Payne to the Idaho Commission for the Blind and Visually Impaired. **Senator Martin** asked if political party affiliation had anything to do with appointments. (See Attachment 3 for Senator Schmidt's research on Senator Martin's question.)

MOTION: **Vice Chairman Nuxoll** moved to send the Gubernatorial Appointment of Ms. Payne to the Idaho Commission for the Blind and Visually Impaired to the floor with recommendation that it be confirmed by the Senate. **Senator Bock** seconded the motion. The motion carried by **voice vote**. **Senator Bock** said he will carry the appointment to the floor since Ms. Payne is in his district.

PASSED THE GAVEL: Chairman Heider passed the gavel to Vice Chairman Nuxoll.

DOCKET NO. 23-0101-1201 **Sandra Evans**, Executive Director of the Idaho Board of Nursing, said **Docket No. 23-0101-1201** constitutes administrative rules necessary to support statutory changes enacted by the 2012 Idaho Legislature. (See Attachment 4 for presentation speech.)

Vice Chairman Nuxoll asked Ms. Evans to explain the restrictions for nurses on prescribing/dispensing medication. **Ms. Evans** said before advanced practice nurses can prescribe and dispense they must have a provider-patient relationship established. The change in the statute last year allowed an exemption for those providers who, for instance, might be prescribing and/or dispensing in cases of an emergency or an epidemic where the prescribing and dispensing is for the better good of the public and they couldn't have had established that relationship. The statute has gone into effect but the administrative rules were inconsistent with that exemption so it allows for that now to happen with advanced practice nurses as well. **Vice Chairman Nuxoll** asked if the nurses can prescribe/dispense even if it isn't an emergency. **Ms. Evans** said there are clear provisions in the statute that define situations when it would be appropriate for that to happen.

Chairman Heider asked for Ms. Evans to define what a matriculated student is. **Ms. Evans** said a matriculated student is a student who is acquiring credits that lead toward a degree that will be conferred – as opposed to a non-matriculated student who is going to college and picking up arbitrary courses not necessarily leading to a degree that would be conferred.

Senator Lakey asked if a certified nurse midwife can perform surgical type of procedures. **Ms. Evans** said they could perform relatively minor procedures directly related to the scope of practice in the prepartum, postpartum and antepartum care of women. An example would be an episiotomy. **Senator Lakey** asked if a certified registered nurse anesthetist had full use of anesthetics. **Ms. Evans** said their scope is quite broad.

MOTION: **Senator Martin** moved to approve **Docket No. 23-0101-1201**. **Senator Bock** seconded the motion. The motion carried by **voice vote**.

DOCKET NO. 23-0101-1202 **Ms. Evans** went over the changes reflected in **Docket No. 23-0101-1202** and what those changes accomplish. (See Attachment 5 for presentation speech.)

MOTION: **Chairman Heider** moved to approve **Docket No. 23-0101-1202**. **Senator Lakey** seconded the motion. The motion carried by **voice vote**.

Vice Chairman Nuxoll introduced Mark Johnston, Executive Director of the Idaho Board of Pharmacy. **Mr. Johnston** first noted that he teaches pharmacy law at Idaho State University and recognized a group of students in the audience who were present to get extra credit. **Mr. Johnston** then gave an overview of the Board of Pharmacy. (See Attachment 6.)

Mr. Johnston said he was requesting adoption of four dockets of rules. Two of them contain changes to the same rule which is a definition section. **Mr. Johnston** said the board promulgated 72 pages of new rules last year, made a few mistakes and aim to fix those today. The board's licensees and registrants demand a certain level of performance and the board engaged in much negotiated rulemaking, fulfilling the public's various requests. The board held two negotiated public rulemaking sessions and, in total, received 18 pieces of public comment during the official 21-day public comment period in October alone.

DOCKET NO. 27-0101-1201 **Mr. Johnston** said **Docket 27-0101-1201** contains non-substantive changes; housekeeping. He said there was no real public comment believed to be controversial. (See Attachment 7.)

MOTION: **Senator Martin** moved to approve **Docket No. 27-0101-1201**. **Senator Schmidt** seconded the motion. The motion carried by **voice vote**.

**DOCKET NO.
27-0101-1202**

Mr. Johnston said **Docket No. 27-0101-1202** is quite lengthy and consists mostly of corrections such as eliminating a page and a half of print that was word for word out of a Food and Drug Administration (FDA) publication called the "Orange Book" which lists generics that are able to be substituted for a brand-name product. Now, the Orange Book is just incorporated by reference. **Mr. Johnston** said the board also added the "Green Book," which lists veterinarian products that are able to be generically substituted, to the selection criteria. (See Attachment 8 for presentation on docket corrections.)

Senator Lodge mentioned the Epilepsy Bill (HB 534) that passed through legislature approximately a year ago and asked Mr. Johnston to refresh her memory in regard to drug substituting. **Mr. Johnston** said there are two different terminologies: generically selecting and generically substituting. In some states they mean one in the same. Generic substitution is not really a term that's legal in Idaho. Pharmacists generically select a product that is bioequivalent, therapeutically equivalent, listed in the Orange Book and, according to the FDA, they're interchangeable – that's what the Epilepsy Bill referred to. When a pharmacist generically selects, there were certain notifications that had to happen after the fact. **Mr. Johnston** said generic substitution is a whole different category where, in a hospital or nursing home, there's a formulary committee that says that you're able to substitute one drug for another drug that isn't a generic but it's in the same drug class.

Vice Chairman Nuxoll asked if a pharmacist can substitute a generic drug for a brand name drug and if the patient is informed. **Mr. Johnston** said many states, including Nevada, have moved to a model where pharmacists have to dispense the generic if there's one available – they have to generically select it in the name of increased costs and the cost of healthcare. **Mr. Johnston** said Idaho hasn't gone that far and leaves the professional judgment up to the pharmacist if they want to generically select a product, which has to be A-rated in the Orange Book. There's no notification that has to be given except in the case of epilepsy drugs and certain circumstances which are in statute. Generic substitution is a whole different category and only happens in a nursing home and a hospital. An example of a generic selection would be that a doctor prescribed Motrin and the pharmacist dispensed ibuprofen. Generic substitution is the doctor prescribed Motrin, and Aleve – another anti-inflammatory, but not the same drug altogether – was dispensed. **Mr. Johnston** said since substitution only happens in a nursing home or a hospital where there are in-patients who may be incapacitated; there's certainly no patient notification or approval process. As a physician, when you sign on to have prescriptive rights in the hospital, you have the understanding that there's a formulary and the drug that you prescribe might be switched to another drug in that class. It's just one of your conditions of employment and it has existed for decades. **Vice Chairman Nuxoll** asked, yes or no, can a pharmacist not substitute a generic drug for a brand-name drug, in a regular pharmacy, without notifying the patient. **Mr. Johnston** said that really isn't a yes or no question. Can you select a generic drug without notification? Yes. Can you substitute? That really doesn't exist. **Mr. Johnston** said you don't 'substitute' a generic drug for a brand name drug, you 'select' a generic drug for a brand name drug. And, in a retail pharmacy, if a generic drug is selected for the brand-name drug, there's no notification requirement except on the label – the pharmacy is required to list the drug that was generically selected as well as the brand-name medication prescribed. No other notification is required unless it's the first time ever and you're required to be counseled, unless you refuse to accept the counseling.

Senator Guthrie asked, in regard to dispensing of medications to jails, if there's a hiccup, the drug is dispensed wrongly and there's a problem – where would the liability rest. **Mr. Johnston** said the pharmacist is always responsible for a misfilled prescription. Even if there were students or technicians that helped, it clearly goes to the pharmacist who did the final check. If the pharmacist did their job and adequately labeled the prescription and it was someone else who administered the medication incorrectly, then it would be the person responsible for the incorrect administering. **Mr. Johnston** said if a drug is incorrectly prescribed, there is a shared responsibility between the prescriber and the pharmacist – the pharmacist is the safety veil and is supposed to catch errors that a prescriber might make.

Senator Lakey asked if a doctor specifically prescribes a brand name only, then a pharmacist can't do generic selection. **Mr. Johnston** said that was correct. **Senator Lakey** asked what the requirements were for a mail order, out-of-state pharmacy to be able to provide medication to people in Idaho. **Mr. Johnston** said there is a registration process for the parent facility that specifically says they can only select or substitute according to Idaho law. There are very few other responsibilities. **Mr. Johnston** said there is a docket of rules that he hopes the committee hears later this session after a bill passes on the exact same subject. The bill, which has been sent to print and has already had its RS hearing, further addresses the out-of-state mail service pharmacy act. It will wrap it into the Idaho Pharmacy Act and strike the entire out-of-state mail service pharmacy act. The current regulation is lacking and the board aims to fix that later this session. **Senator Lakey** asked if there are some requirements mail order pharmacies have to follow. **Mr. Johnston** said, the way it reads currently, is if the Idaho board notices an issue, it can ask the home state board of pharmacy to address the issue. If the home state board of pharmacy initiates an investigation within 45 days, Idaho has to accept their ruling and can't do anything else. If the home state board doesn't initiate an investigation within 45 days, and there's serious psychological or serious physical damage done to an Idaho resident – not just a misfill that wasn't ingested – then the Idaho board can initiate its own investigation.

MOTION:

Senator Bock moved to approve **Docket No. 27-0101-1202**. **Senator Martin** seconded the motion. The motion carried by **voice vote**.

**DOCKET NO.
27-0101-1203**

Mr. Johnston said **Docket No. 27-0101-1203** was created for two reasons. One, with a complete rules rewrite last year, the board regulated, for the first time, Automated Dispensing and Storage systems (ADS) – Pysix-type machines in hospitals, Parata-type in retail pharmacies and InstaMed-type machines in doctors' offices and pharmacies. ADS systems are machines that categorically store drugs for use by prescribers, nurses or pharmacists. There are various parameters as to who can have access, what the security is, what drugs can be included, etc. It was really an unregulated practice before this. But, there are some enhancements and the Idaho Society of Health-System Pharmacists, among others, came forward and asked for the changes. During a lengthy negotiation, everyone agreed on the changes. (See Attachment 9 for changes.)

Senator Schmidt asked about a section of the rule book that referred to vending machines. **Mr. Johnston** said the section Senator Schmidt was looking at pertained to the types of vending machines that can be found in places such as hotels and contain medicine such as Advil. The ADS section in the rule book, while it looks like a new rule, was derived from another rule.

Senator Lakey asked what the phrase "a system must be substantially constructed" meant. **Mr. Johnston** said it's a term borrowed from the Drug Enforcement Administration (DEA) which is used when referring to the enclosure that controlled substances in a prescriber's office have to be locked within. A pharmacy is able to intersperse controlled substances within their inventory, which can be better instead of just opening a drawer and giving a robber everything that's in the drawer. A prescriber has to lock their controlled substances up because they have limited amounts of controlled substances and more people that are wandering around that aren't registrants or licensees in a doctor's office. **Mr. Johnston** gave an example of an InstaMed machine going into a hospital that was deemed substantially constructed because it weighed 2,000 pounds and was bolted to the floor. **Senator Lakey** asked about a portion of the rule that required a dispensing machine only dispense drugs or devices that have been previously dispensed to the patient and if that meant nothing new can come out of the machine for a particular individual. **Mr. Johnston** said the board was hesitant in allowing drugs that required consultation and initial fills to be stocked in a machine like that in a retail pharmacy. So, in a pharmacy system – not a prescriber system or an Emergency Room system – they did restrict it to refills only. However, if it's the same drug someone has had for 17 years – and maybe not a refill, but it has been previously dispensed to the person – the pharmacy would be able to put that into the machine.

Vice Chairman Nuxoll asked if there were any complaints to this rule. **Mr. Johnston** said the board did hold two public hearings that were printed in the Idaho Administrative Bulletin. Nothing but support came out of the public comment as well as a comment that was helpful to make the board's rule better. The board didn't see any negative comment.

MOTION:

Senator Guthrie moved to approve **Docket No. 27-0101-1203**. **Senator Hagedorn** seconded the motion. The motion carried by **voice vote**.

**DOCKET NO.
27-0101-1204**

Mr. Johnston said that last year, when the board rewrote all the rules regarding **Docket 27-0101-1204**, the practice of pharmacy was affected through the definition of pharmaceutical care. The Board of Medicine had a concern that perhaps the Board of Pharmacy had gone a little bit too far and had dabbled into the practice of medicine as opposed to the practice of pharmacy. **Mr. Johnston** said the Board of Medicine agreed not to testify against the Board of Pharmacy's entire docket of rules for this perception last year as long as the Board of Pharmacy came back and had corrective language this year. (See Attachment 10 for corrective language.)

Senator Hagedorn asked, with the drug shortage component, if any feedback is required to the doctor after a pharmacist does a generic substitution to let the doctor know a change was made in case there is an issue. **Mr. Johnston** said the board entertained that thought, went back to the physicians and the physicians didn't want it. **Mr. Johnston** said physicians are fed up with useless communication and, really, in the delay of therapy of their patients.

Vice Chairman Nuxoll asked if a clinical pharmacist gives out prescriptions. **Mr. Johnston** said the term clinical pharmacist is not a term that's recognized in law but it is a term that some other states hand out certifications for and a term that is being taught in the universities. Really, a pharmacist that works in a retail pharmacy is a clinician also. They counsel, they catch drug interactions and some would argue that they have the most patient contact and thus are the biggest clinicians. **Vice Chairman Nuxoll** asked if any pharmacists are allowed to write up prescriptions. **Mr. Johnston** said pharmacists do have two very limited forms of prescriptive authority: one, they can prescribe immunizations and for dietary fluoride supplements, such as chewable tablets or drops; Secondly, the main function of a pharmacist is to dispense drugs pursuant to the prescriptions of prescribers. But, a pharmacy has really evolved into a cognitive services position, too. **Mr. Johnston** said there are many pharmacists who work full time and never see an actual drug. All they are doing is reviewing charts and making more clinical types of decisions.

MOTION: **Senator Hagedorn** moved to approve **Docket No. 27-0101-1204**. **Senator Guthrie** seconded the motion. The motion carried by **voice vote**.

PASSED THE GAVEL: **Vice Chairman Nuxoll** thanked Mr. Johnston for his time and turned the gavel back over to Chairman Heider.

Chairman Heider thanked Vice Chairman Nuxoll for doing a very nice job on the rules this session. **Chairman Heider** recognized Mr. Johnston's students in the audience and said they not only should get extra credit for coming, but should get A's for sitting through the legislative process. **Chairman Heider** said having done so will bring them more up to speed on what's expected once they become pharmacists.

ADJOURNED: There being no other business, **Chairman Heider** adjourned the meeting at 4:24 p.m.

Senator Heider
Chairman

Linda Hamlet
Secretary