

MINUTES
SENATE HEALTH & WELFARE COMMITTEE

DATE: Thursday, January 26, 2012

TIME: 3:00 P.M.

PLACE: Room WW54

MEMBERS PRESENT: Chairman Lodge, Vice Chairman Broadsword, Senators Darrington, Smyser, Heider, Vick, Nuxoll, 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.

MINUTES: **Chairman Lodge** called the meeting to order at 3:12 p.m.

RS 21038 **Senate Concurrent Resolution endorsing the Idaho Alzheimer's Planning Group's efforts to create a statewide plan. Vice Chairman Broadsword** stated that a review of a similar RS that the Committee approved for printing last week revealed errors in some federal information. Those errors have been corrected and she is requesting that the Committee send to print **RS 21038** containing the corrected information, and asked that **Chairman Lodge** request on the floor that it be brought back to the Committee for a full hearing.

MOTION: **Senator Darrington** moved, seconded by **Senator Smyser**, that **RS 21038** be sent to print. The motion carried by **voice vote**.

GAVEL CHANGE: **Chairman Lodge** passed the gavel to **Vice Chairman Broadsword** to conduct rules review.

DOCKET NO. 27-0101-1102 AND DOCKET NO. 27-0101-1101 **Relating to Rules of the Idaho State Board of Pharmacy (Pending Fee) - Chapter rewrite and (Pending) - Chapter repeal. Mark Johnston**, Executive Director, Idaho Board of Pharmacy, advised that he will be presented two dockets, the first Docket is an entire rewrite of the Rules of the Idaho Board of Pharmacy (Board) and the second Docket is a repeal of the current rules. He stated that in 2009 JFAC appropriated funds to hire outside legal counsel for this three-year project to promulgate new and reorganized rules to provide Board licensees and registrants, subject to regulation under the Idaho Pharmacy Act, the Uniform Controlled Substances Act, the Out-of-State Mail Service Pharmacy Act, and the Wholesale Drug Distribution Act, an updated and more comprehensive set of rules governing the practice of pharmacy in Idaho. This proposed rewrite reorganizes the Board's rules, provides a more comprehensive list of definitions and fee schedules, and provides new rules affecting the practice of pharmacy and controlled substance registrants not previously addressed. These rules have been addressed at 20 public Board meetings, Notice of Intent to Promulgate has been published, and negotiated rulemaking sessions have been held around the state.

Mr. Johnston stated the rules eliminate some fees and add some new fees, but there is an overall decrease in dedicated fund fees generated by an estimated \$4,000 per year. The rules will also result in more efficient use of staff and better inspection criteria and procedures. He reviewed for the Committee the fees being eliminated and detailed new or additional fees.

Vice Chairman Broadsword noted that the Board now has a dedicated fund balance in excess of \$1.5 Million and is working to make all fees fair for the licensees and registrants.

Mr. Johnston advised that some requirements were eliminated because of overlap with federal law and Idaho Code or simply because they were outdated. He indicated the Board would no longer be responsible for tracking Extern hours as that is done by Idaho State University. He listed reductions, including pharmacy minimum standards related to space and fixtures. He advised the new rules standardize records retention at three years and definitions are now in one place rather than scattered throughout the rules. A Waivers and Variances section will allow the Board flexibility.

Fees had also been scattered throughout the rules and the reorganization has added a comprehensive Fee Schedule so they are all in one place. Electronic secure record keeping systems are required, with grandfathering for those pharmacies not having computers. Patient counseling documentation is required and labeling must be standard. Automatic dispensing and storage systems are regulated. The Student Pharmacist regulations have been expanded and unprofessional conduct standards revised to deal with drug and alcohol abuse while at work. Pharmacy operating rules are set forth and provisions added for dealing with permanent closing of pharmacies. Retail Telepharmacy is no longer a pilot program and regulations have been expanded. The Institutional Rules Review Committee has defined hospital responsibilities and director responsibilities as well as allowed procedures in the event of a pharmacist's absence. Rules regulating prescriber drug outlets such as doctor offices are included.

Mr. Johnston stated the Board had worked with the Board of Veterinary Medicine to revamp the orders for Veterinary Drug Outlets, basically pharmacies for Vet drugs without pharmacists, requiring additional security and the use of certain forms. Although Idaho has no manufacturers at this time a section was added covering inspection and requirement to follow federal guidelines.

Mr. Johnston advised that these rules are supported by the Idaho State Pharmacy Association, the Idaho Society of Health-Systems Pharmacists, and Idaho Retail Association. He stated the only opposition to the rule comes from the Veterinary Medicine group. That group has expressed opposition to Pending Rule #204, requiring that specified data on controlled substances must be reported weekly. He stated that some of the rural vets who dispense small amounts of controlled substances are inconvenienced by the rule and do not see a benefit to it. After meeting with some of the vets and reviewing the data collected by the Board during the past nine months, although time has not allowed a formal policy to be established by the Board, he is suggesting a tentative policy that would provide a reporting exemption for those vets prescribing controlled substances not more than ten times per week.

Supporting documents related to this testimony have been archived and can be accessed in the office of the Committee Secretary (see Attachment #1).

Vice Chairman Broadsword asked **Mr. Johnston** to confirm that through policy the Board of Pharmacy will be making a change so that vets do not have to report unless they have filled at least ten prescriptions for a controlled substance that week. **Mr. Johnston** responded that is correct.

In response to questions from **Senator Schmidt**, **Mr. Johnston** advised that the Idaho Hospital Association has been a part of negotiations and is supporting the rule. It is also his understanding that the Idaho Health Systems Pharmacists have discussed the rule with the Idaho Hospital Association but he has not personally participated in those discussions. He stated that a prescription by definition must be filled by a pharmacy, and that when a prescriber dispenses a drug in a labeled vial, this would properly be referred to as a dispensing and, if there are several pills in a bottle, that is one dispensing. **Chairman Lodge** asked how this would apply if she were to pick up several syringes of medication for new born calves. **Mr. Johnston** responded that would be one dispensing; however, it would be unlikely that those syringes would contain a controlled substance.

TESTIMONY:

Dr. Les Stone, President, Idaho Veterinary Medical Association, from Idaho Falls, spoke **in opposition** to **Docket No. 27-0101-1102, Section 204**. He related that he has a small veterinary practice providing a spay and neuter program for pets of financially challenged people in his area. He indicated he often does more than 12 cases in a week and the requirement for electronic reporting is a hardship on his practice. He requested an exemption from the Board and received a response that this would be addressed at the next Board meeting. In the meantime he was instructed to continue the use of the paper reporting form, which he stated is not designed for veterinarians and he feels the data requested is generally useless. He further stated that the amount of controlled substance drugs dispensed by veterinarians is small and that is not where the abuse problem lies.

Supporting documents related to this testimony have been archived and can be accessed in the office of the Committee Secretary (see Attachment #2).

Vice Chairman Broadsword commented that a veterinarian recently dispensed for her dog 30 units of the same drug she had been given for pain by her dentist, so there is potential for abuse; however, she would agree that pain medication prescribed for a cat is not likely to be abused. What the Board is trying to get at is those drugs that can be sold on the street. At her request **Dr. Stone** listed some controlled substance drugs used by veterinarians.

In response to a question from **Senator Schmidt** related to the abuse of Fentanyl patches, **Dr. Stone** advised that Fentanyl patches are most generally used after orthopedic surgery and one patch is generally placed on the animal. **Vice Chairman Broadsword** asked if veterinarians are required to keep track of controlled substance dispensing for their DEA license. **Dr. Stone** responded that there is no separate report beyond the usual tracking.

TESTIMONY:

Dr. Gary Lewis, owner of a veterinary clinic in Twin Falls and Chairman of the Board of the Idaho Veterinary Medical Association, spoke **in opposition** to **Docket No. 27-0101-1102, Subsection 204**. He commented that this is an unnecessary cost as there is a lack of evidence that drug diversion is a problem in veterinary medicine. He further stated that a vet-client-patient relationship (VCPR) must exist before prescribing a controlled substance and if a VCPR is honored, it greatly reduces the possibility of diversion of a controlled substance.

Vice Chairman Broadsword pointed out that the rule does not apply just to veterinary medicine and if the Committee rejects the rule, the old rules would remain in place. So, the solution would be to work with the Board to try and fix the problem through policy.

Senator Darrington commented that this Docket is a marvelous work that has been undertaken over a long period of time and the only part of the rule there seems to be any question about is the requirement that veterinarians report controlled substance dispensings.

The committee discussed at length the effect of these rules on veterinarians, and in particular, small rural practices. They discussed the burden of reporting placed upon small practices; the fact that the reporting form is not relevant to veterinary practice; the ratio of controlled substances dispensed by veterinarians versus physicians; and the options available for exempting the small practices, including writing a rule to exempt veterinarians, and establishing a Board policy to exempt small veterinary clinics dispensing controlled substances not more than ten times in a week.

Mr. Johnston advised that the majority of states now share prescription drug abuse information through a federal reporting system. He stated that prescription drug abuse is now a bigger issue than methamphetamine, cocaine, and heroine combined. He did agree that veterinarians dispense only a small portion of controlled substance drugs compared to prescriptions issued for humans. He stated that pending rules have been in effect for nine months and during that time the Board has listened to the concerns of the people and made adjustments through policy. He noted that the reporting requirement is not a burden on the people the Board wants to get information from at this point, and is proposing by policy to exempt out all veterinarians who dispense controlled substances not more than ten times in a week. The rules provide for an exemption by the Board and if a veterinarian dispenses a controlled substance more than ten times a week, but those dispensings are small doses, they can request an exemption.

Vice Chairman Broadsword asked if a statute that exempted the veterinarians of the state from having to report to the Board would be something the Board would welcome or object to. **Mr. Johnston** indicated he would have to discuss that with the Board; his feeling is they would not oppose it, but would not support it either.

TESTIMONY:

Dr. Rena Carlson, Pocatello, an Idaho delegate to the American Veterinary Association, spoke **in opposition to Docket 27-0101-1102**. She agreed with the previous testimony and indicated veterinarians play a miniscule role in controlled substance dispensings and the information they are being asked to report is not relevant. She stated that 13 states now exempt Veterinarians from reporting controlled substance dispensings.

Vice Chairman Broadsword asked if her association would be willing to sit down with **Mr. Johnston** and try to come up with a solution that meets the needs of all and addresses public safety. **Dr. Carlson** responded that is something they want to do. When asked specifically by **Senator Darrington** if she would be comfortable with the policy proposed by **Mr. Johnston** to exempt those veterinarians dispensing controlled substances not more than ten times in a week, **Dr. Carlson** stated that her organization would probably disagree, as they do not feel the veterinarian population as a whole adds value to the intent of Subsection 204, and they would prefer an exemption of all veterinarians. **Senator Broadsword** pointed out that if Subsection 204 is rejected it would affect all pharmacies, not just veterinarians.

Mr. Johnston advised that if the entire docket is rejected it will not help the veterinarians with this issue as the current rule contains the same language. He further stated that there are two reasons why we have this rule. One is to assist prescribers and pharmacists in prescribing and filling prescriptions, and the other is to address any illegal activity. It isn't just diversion on the part of the animal owner that might be of concern, the Board has diciplined 28 practitioners—not just pharmacists—in the last 12 months who were guilty of diversion. The Board can tell by the new rules when an abnormal quantity of product is ordered into a small veterinary clinic; they don't have to know what the dispensings are to know that is something they should take a look at. When a large quantity is ordered into a veterinary hospital which is also dispensing a large quantity, the Board really needs to know what the dispensing information is to see if not just the veterinarian but any of the lay personnel are involved in diversion. He agrees the information from the small veterinarians is not so important and if the Board collects from the big

dispensers, that is all they need to take a look at. If data is collected for a year and it turns out there is not really a problem, the Board has the flexibility to make a change through policy. Striking the rule does not solve the problem. Having it in statute might solve the problem; but if we can all do it collectively, and he feels the parties have shown that they can, it works.

Senator Schmidt noted that diversion in his opinion is the most important issue and diversion is truly a function of numbers, so we need to know the numbers. It appears that prescriptions for humans is much greater than for animals. If the threshold is large dispensing hospitals who are already computerized and the process for them to report is simple, then we can come to a simple solution.

MOTION: **Senator Bock** moved, seconded by **Chairman Lodge**, that the Committee approve **Docket No. 27-0101-1102**, chapter rewrite, and **Docket No. 27-0101-1101**, chapter repeal.

Chairman Lodge commented that she is confident **Mr. Johnston** will work with the veterinarians to make sure Board policy is implemented to help the small veterinarians. She thanked **Mr. Johnston** and others involved for the hard work in rewriting these rules. **Senator Bock** also expressed confidence that **Mr. Johnston** will provide a solution through Board Policy. **Senator Darrington** spoke in support of the motion stating that veterinarians should be careful to comply with the reporting requirements until they are formally advised of a policy change by the Board. **Vice Chairman Broadsword** noted that it is good that the changes that need to be made can be made through policy.

Chairman Lodge requested that the Board of Pharmacy inform the Committee when the policy has been formally changed.

Senator Heider commented that the way the rule is written does not work for those in veterinary medicine and without the Committee saying no to this rule change, the Board of Pharmacy is under no official obligation to make changes. He therefore will be voting against the motion. **Senator Nuxoll** stated she agrees with **Senator Heider's** comments.

Vice Chairman Broadsword stated that she has every confidence that when a rule leaves here and the agency has agreed to work on it and that is set forth in the minutes, they will comply with the direction given by the Committee.

VOTE: The motion to approve **Docket No. 27-0101-1102** and **Docket No. 27-0101-1101** passed by voice vote, with **Senators Heider** and **Nuxoll** voting "Nay."

GAVEL CHANGE: **Vice Chairman Broadsword** acknowledged Idaho State University pharmacy students in attendance and welcomed them. She returned the gavel to **Chairman Lodge**.

ADJOURN: **Chairman Lodge** thanked **Vice Chairman Broadsword** for a good job of guiding the Committee through rule changes. She announced that Thursday, February 2, the Committee will be touring the Idaho State Dental facility in Meridian and bus transportation will be provided. The meeting was adjourned at 5:07 p.m.

Senator Lodge
Chairman

Lois Bencken
Secretary