

MINUTES
SENATE HEALTH & WELFARE COMMITTEE

DATE: Thursday, January 14, 2016

TIME: 3:00 P.M.

PLACE: Room WW54

MEMBERS PRESENT: Chairman Heider, Vice Chairman Nuxoll, Senators Lodge, Hagedorn, Martin, Lee, Harris, Schmidt and Jordan

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 meeting to order at 3:01 p.m. and welcomed everyone to the first meeting of the Senate Health and Welfare Committee (Committee). **Chairman Heider** stated that the members of the Committee were excited to begin the session and voiced appreciation for the public's participation.

INTRODUCTIONS: **Chairman Heider** introduced the new committee secretary, Karen Westbrook, and thanked her for her capable and efficient assistance. Next, Chairman Heider introduced the new page, Jared Kelly, and asked him to tell the Committee about himself. **Jared Kelly** informed the Committee that he lives just outside of Blackfoot, Idaho, attends Snake River High School and enjoys both playing and watching many different sports. After high school, Jared plans to serve a Latter-day Saints mission, attend college and study law. **Chairman Heider** thanked Jared for assisting the Committee.

PASSED THE GAVEL: **Chairman Heider** announced that the Committee would review rules from the Board of Pharmacy and passed the gavel to Vice Chairman Nuxoll to conduct the rules review.

Vice Chairman Nuxoll requested that Alex Adams introduce himself and present the rules of the Board of Pharmacy.

DOCKET NO. 27-0101-1502 **Rules of the Idaho State Board of Pharmacy Related to Institutional Pharmacy Dispensing.** **Alex Adams**, Executive Director of the Idaho State Board of Pharmacy (Board), introduced himself and stated that he would be presenting four pending rule dockets and one pending fee rule docket for the Committee's approval.

Mr. Adams stated that for each docket, the Board held (i) an open conference call on July 27, 2015; (ii) an open negotiated rulemaking session on August 12-13, 2015; and (iii) open proposed rulemaking session on October 28-29, 2015. **Mr. Adams** then informed the Committee that more than 25 diverse stakeholders participated in those sessions.

Senator Martin requested that Mr. Adams provide the Committee with a summary of his professional background. **Mr. Adams** stated that he has lived in Idaho and has served as Executive Director of the Board for approximately four months. Prior to accepting his current position, **Mr. Adams** explained that he lived in Washington, D.C., where he served as the Vice President of the National Association of Chain Drug Stores.

Returning to **Docket No. 27-0101-1502**, **Mr. Adams** explained that the basis for this change comes from the 1976 Supreme Court case *Abbott Laboratories v. Portland Retail Druggists Association, Inc.* In this case, the retail druggists argued that medications were being sold to nonprofit hospitals at a favorable rate unavailable to retail pharmacies, which resulted in unfair competition by the nonprofit hospitals. In its decision for the retail pharmacists, the Supreme Court detailed what is and is not permissible dispensing by a hospital pharmacy. To alleviate confusion among pharmacists in Idaho, this proposed change would make Idaho rules consistent with the Supreme Court's *Abbott Laboratories* decision. This rule, which defines permissible and impermissible hospital dispensing, would prevent hospitals from unfairly competing with retail pharmacists in Idaho.

Vice Chairman Nuxoll called for questions.

Senator Hagedorn inquired what comments and opposition, if any, the Board received during negotiated rulemaking. **Mr. Adams** reported that the Board received no comments in opposition of this proposed rule. Further, **Mr. Adams** reported that the Board received strong support from the Idaho Society of Health-System Pharmacists.

Senator Schmidt noted that there was significant latitude in the rule that would allow certain hospital pharmacies to dispense medication when retail pharmacies are open or when retail pharmacies are not open. In response, **Mr. Adams** stated that another rule addressed emergency room dispensing when community pharmacies are open. The rule before the Committee would not change that additional rule. **Senator Schmidt** asked whether the additional emergency room rule would be in conflict with the "in limited quantities and reasonable time duration" language in the rule currently before the Committee. **Mr. Adams** acknowledged Senator Schmidt's concern and indicated that the Board should address the issue in 2017 rulemaking.

MOTION: There being no more questions, **Senator Martin** moved to approve **Docket No. 27-0101-1502**. **Chairman Heider** seconded the motion. The motion carried by **voice vote**.

DOCKET NO. 27-0101-1503 **Rules of the Idaho State Board of Pharmacy Clarifying the Practice of Compounding.** **Mr. Adams** informed the Committee that this rule clarifies a previously adopted rule that was based on the federal Drug Quality and Security Act. The rule currently before the Committee proposes definitions for terms that were used, but undefined, in the previously adopted rule. Specifically, this rule defines (i) "hazardous drugs" to align with recommendations from the National Institute for Occupational Safety and Health; (ii) "USP 795" and "USP 797" to relate back to the United States Pharmacopeia; and (iii) "compounding" to carve out certain low-risk product and procedures such as reconstitution. **Mr. Adams** then reviewed certain provisions that were ultimately omitted from the current rule due to comments received during the public comment period.

Vice Chairman Nuxoll called for questions.

MOTION: There being no questions, **Senator Hagedorn** moved to approve **Docket No. 27-0101-1503**. **Senator Harris** seconded the motion. The motion carried by **voice vote**.

**DOCKET NO.
27-0101-1504**

Rules of the Idaho State Board of Pharmacy Related to Emergency Preparedness. **Mr. Adams** informed the Committee that this rule incorporates National Association of Boards of Pharmacy model language that recognizes the important role of pharmacy in mitigating public health emergencies. First, this rule would allow license reciprocity for pharmacists during an emergency declared by the President of the United States or the Governor of Idaho. Second, this rule would allow the transfer of a pharmacy license to a mobile or temporary pharmacy during an emergency. Third, this rule would allow pharmacists to refill certain medications for patients during an emergency when a primary care provider is not available. Finally, this rule would authorize protocol agreements among state agencies.

Vice Chairman Nuxoll called for questions.

Senator Jordan noted that rule related to mobile or temporary pharmacies requires that the provision of these services must cease "with the termination of the declared emergency; or as otherwise authorized by the Board." **Senator Jordan** asked if there were specific criteria for the Board to follow when authorizing continuing services. **Mr. Adams** responded that emergency declarations typically cover a short period of time, and this language gives the Board flexibility to continue services if, in the Board's judgment, the community still needs the services. **Senator Jordan** asked if the Board has established policies that dictate the criteria under which a continuation of services could be authorized by the Board. **Mr. Adams** responded that policies were not yet in place due to the newness of the emergency preparedness rules but indicated that he expects the Board to adopt more detailed emergency preparedness policies in the future.

MOTION:

There being no more questions, **Senator Lee** moved to approve **Docket No. 27-0101-1504**. **Senator Lodge** seconded the motion. The motion carried by **voice vote**.

**DOCKET NO.
27-0101-1505**

Rules of the Idaho State Board of Pharmacy Updating Certain Definitions. **Mr. Adams** informed the Committee that this rule modifies the definition of "pharmaceutical care services" to include ordering and interpreting laboratory tests. **Mr. Adams** noted that pharmacies are now the fourth leading provider of laboratory tests. He added that 37 percent of all pharmacies in Idaho are now providing basic laboratory tests, and the Idaho Bureau of Labs currently provides certificates of registration to pharmacies that provide laboratory tests. **Mr. Adams** stated that the Board has updated the regulation to be consistent with the practice of pharmacy as it continues to grow. In addition, this rule provides a general definition of "reconstitution" as the process of adding water to a powered medication. **Mr. Adams** reminded the Board that the practice of reconstitution was carved out of the definition of compounding in a previous rule.

Vice Chairman Nuxoll called for questions.

Senator Jordan stated that Idaho Code § 54-1704 does not articulate the "ordering and interpreting of laboratory tests" as an acceptable practice of pharmacy. On behalf of Senator Schmidt, **Senator Jordan** then asked Mr. Adams to speak to that apparent conflict. Noting that Senator Schmidt submitted this question to the Board prior to this meeting, **Mr. Adams** stated that he requested the Attorney General identify the statutory authority for this rule when it was originally promulgated. **Mr. Adams** then informed the Committee that Idaho Code § 54-1705(29) provides a broad definition of "pharmaceutical care" that may be further defined by the rules of the Board. Therefore, as authorized by Idaho Code § 54-1705(29), the Board has, from time to time, updated the definition of "pharmaceutical care services" as the practice of pharmacy continues to evolve. Citing an example of the evolving practice of pharmacy, **Mr. Adams** noted all schools of pharmacy in the U.S. are accredited by the Accreditation Council for

Pharmacy Education, which has set a national standard requiring all graduating pharmacy students to be able to order and interpret laboratory tests.

MOTION:

There being no more questions, **Senator Harris** moved to approve **Docket No. 27-0101-1505**. **Senator Hagedorn** seconded the motion. The motion carried by **voice vote**.

**DOCKET NO.
27-0101-1501**

Rules of the Idaho State Board of Pharmacy Related to Retail Non-pharmacy Outlet Registration. **Mr. Adams** reported that Idaho currently has two different classes of registrations for non-pharmacy outlets that stock over-the-counter medications based upon the number of medications the non-pharmacy retail outlet stocks: (i) Class A non-pharmacy retail outlets, which stock more than 50 medications, and (ii) Class B non-pharmacy retail outlets, which stock 50 or fewer medications. Currently Idaho has registered 299 Class A outlets, each paying a \$60 registration fee, and 814 Class B outlets, each paying a \$25 registration fee. Registration fees cover administrative costs including inspections to confirm products are not expired, adulterated or misbranded. To improve administrative efficiency, **Mr. Adams** stated that the Board has proposed to combine these two classes of registrations into one class, regardless of the number of medications stocked, with all non-pharmacy retail outlets paying a \$35 registration fee. **Mr. Adams** noted that the budget impact of this modification will be de minimis. Additionally, **Mr. Adams** reviewed other "housekeeping" changes with the Committee, drawing particular attention to (i) an increase in experiential hours required for foreign-trained pharmacists to be consistent with requirements for pharmacists trained in the U.S. to obtain a license and (ii) updated requirements for controlled substances storage to be consistent with federal law.

Vice Chairman Nuxoll called for questions.

Senator Hagedorn asked Mr. Adams to clarify the delta change in the fees to be received. **Mr. Adams** responded that Idaho currently receives \$38,290 in fees under this rule, and that under the proposed rule Idaho would receive \$38,955 in fees.

Chairman Heider noted that controlled substances must be stored in "substantially constructed cabinets" and asked whether that term was particularly defined. **Mr. Adams** responded that the term comes from the federal Controlled Substances Act and the term is not specifically defined in that Act. However, **Mr. Adams** noted that Board inspectors have asked for clarity regarding that term, and the Board is working to post pictures of both appropriate and inappropriate storage cabinets. **Chairman Heider** requested that the Board work to revise the rules in the future to include a definition of "substantially constructed cabinet."

Vice Chairman Nuxoll inquired whether there was negotiated rulemaking for this rule and asked what comments were received. **Mr. Adams** confirmed that an open public comment session was held and that negotiated rulemaking was conducted for this rule. **Mr. Adams** confirmed that the Board received zero comments on this rule, but he noted that anecdotally the Board had received positive feedback. **Vice Chairman Nuxoll** also asked for clarification regarding the rulemaking process, and **Mr. Adams** responded that the Board follows the process of the Office of the Administrative Rules Coordinator and provided details of that process. Following up, **Vice Chairman Nuxoll** asked if public comment was held collectively for all dockets or individually for each docket. **Mr. Adams** responded that public comment sessions were held collectively, but noted that the sessions could be conducted individually in the future. **Vice Chairman Nuxoll** then asked why the controlled substances storage requirements were not previously in the Idaho rules. **Mr. Adams** noted that all pharmacies that stock controlled substances must be registered with the federal Drug Enforcement Administration and must comply with the federal Controlled Substances Act,

including the storage of medications. Therefore, Idaho pharmacies have previously been held to this requirement, and now Idaho law is consistent with the federal requirement.

MOTION: There being no more questions, **Chairman Heider** moved to approve **Docket No. 27-0101-1501**. **Senator Lodge** seconded the motion. The motion carried by **voice vote**.

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

ADJOURNED: **Chairman Heider** thanked Mr. Adams for is presentation. There being no further business, **Chairman Heider** adjourned the meeting at 3:40 p.m.

Senator Heider
Chair

Karen Westbrook
Secretary