MINUTES

HOUSE HEALTH & WELFARE COMMITTEE

DATE:	Wednesday, January 14, 2015
TIME:	9:00 A.M.
PLACE:	Room EW20
MEMBERS:	Chairman Wood, Vice Chairman Packer, Representatives Hixon, Perry, Romrell, Vander Woude, Beyeler, Redman, Troy, Rusche, Chew
ABSENT/ EXCUSED:	Representative Vander Woude
GUESTS:	Greg Metsker and Bruce Christopherson, ICBVI; Dennis Stevenson, Rules Coordinator; Elli Braun, Veritas Advisors; Mark Johnston, BOP; DiAnn Butterfield, ISU Student Pharmacist; Stacey Satterlee, ACS CAN; Wood Richards, AHIP.

Chairman Wood called the meeting to order at 9:01 a.m.

DOCKET NO. 15-0202-1401:

Greg Metsker, ICBVI Assessment and Training Program Manager, presented **Docket No. 15-0202-1401**, requesting the Committee reject the Rule changes. The Workforce Opportunity and Innovation Act (WOIA) has changed all regulations. They are awaiting further information on the changes needed to align with the WOIA.

Responding to a question, **Mr. Metsker** said only the changes would be rejected. The existing Rule would remain in effect.

MOTION:

Rep. Rusche made a motion to reject **Docket No. 15-0202-1401.**

For the record, no one indicated their desire to testify.

VOTE ON MOTION:

Chairman Wood called for a vote on the motion to reject **Docket No. 15-0202-1401. Motion carried by voice vote.**

DOCKET NO. 27-0101-1403:

Mark Johnston, Executive Director, Board of Pharmacy, presented **Docket No. 27-0101-1403**. The New England Compounding Center (NECC) tragedy and resulting Compounding Quality Act (CQA) have led to Rule changes to address Idaho's lack of compounding regulation and align with the CQA.

Dr. Johnston said the changes include labeling requirements for compounded drug product distributed or compounded in anticipation of valid prescription drug orders. Limited exceptions are established to regulate non-sterile compounding. New general compounding standards include active pharmaceutical ingredients, equipment, disposal, and reiteration of federal law. Policy and procedure changes address pertinent pharmacy practice settings, accuracy parameters, and record keeping requirements.

The existing sterile product preparation Rule is enhanced to further define dosage forms, compounder responsibilities, regulation of environmental control devices, and documentation.

The hazardous drug preparations Rule combines and expands existing sections of non-sterile compounding, ventilation, labeling, equipment, supplies, contamination prevention, hazardous waste, policy, procedures, and training.

Responding to a question, **Dr. Johnston** explained that compounding is performed by someone legally able to possess drugs, such as a pharmacist. When a formula is not available from a manufacturer, drugs are mixed to create a specialized product, pursuant to a drug order, to meet a patient's needs.

MOTION: **Rep. Hixon** made a motion to approve **Docket No. 27-0101-1403.**

For the record, no one indicated their desire to testify.

VOTE ON MOTION: **Chairman Wood** called for a vote on the motion to approve **Docket No. 27-0101-1403. Motion carried by voice vote.**

DOCKET NO. 27-0101-1404: **Mark Johnston**, Executive Director, Board of Pharmacy, presented **Docket No. 27-0101-1404**, which contains various unrelated subjects.

Changes require Canadian pharmacy school graduates, who earn their Doctorate of Pharmacy in the U.S., complete the same experiential hours as other pharmacists.

The two renewals for a technician-in-training registrant are now tied to the individual, instead of the registration, establishing a lifetime limit.

Prescription drug orders for epinephrine auto injectors are now allowed in the school's name, instead of patient's name, with the same labeling for dispensing prescribers as pharmacies, and an exception for dispensing veterinarians.

A new Rule was created to allow a second pharmacy to repackage medication previously dispensed by another pharmacy, letting nursing and assisted living facility patients use unit dose packaged medication with adequate safety.

Annual inventories for controlled substance registrants can be conducted within seven days of the prior year's inventory and their inventory clock reset can occur any time within the year and seven day window.

Pharmacists administering immunizations are required to carry an emergency kit for use in acute allergic reactions. A Rule change allows utilization of vials or ampules of epinephrine, instead of auto injectors, which are expensive and often have short expiration dates.

Regulation of licensed pharmacists practicing into Idaho is changed to match regulation of those practicing in Idaho.

The requirement that pharmacy door hinges be located on the inside have conflicted with state law and are modified to allow tamper proof hinges.

Changes to telepharmacy requirements include training, technology, and security.

MOTION: **Vice Chairman Packer** made a motion to approve **Docket No. 27-0101-1404.**

Responding to a question, **Dr. Johnston** said the pharmacy door Rule change offers a grandfathering clause for long-established buildings.

For the record, no one indicated their desire to testify.

VOTE ON MOTION: **Chairman Wood** called for a vote on the motion to approve **Docket No. 27-0101-1404. Motion carried by voice vote.**

DOCKET NO. 27-0101-1405: **Mark Johnston**, Executive Director, Board of Pharmacy, presented **Docket No. 27-0101-1405**. As of January 1, 2015, the Federal Drug Quality and Safety Act (DSCSA) preempted state tracking of prescription drug product. This strikes Rule 809, Prescription Drug Pedigrees, in full.

A new Rule was promulgated to collate statutory and Rule requirements between wholesalers, outsourcing facilities, and pharmacies, regardless of the practice setting. It opens service to an area that has been unserved since the CQA was passed.

For the record, no one indicated their desire to testify.

MOTION: **Rep. Romrell** made a motion to approve **Docket No. 27-0101-1405. Motion carried by voice vote.**

DOCKET NO. 27-0101-1402: **Mark Johnston**, Executive Director, Board of Pharmacy, presented **Docket No. 27-0101-1402**. Responding to the NECC tragedy, the CQA resulted in the creation of a new drug outlet type: the outsourcing facility, which compounds and distributes product for practitioner in-office administration. These larger facilities distribute larger product requirements instead of patient-specific product. About one hundred outsourcing facilities are federally registered, none of which are located in Idaho, although they distribute here.

Fees were established at the statutory maximum of $500 for initial registration and $250 for renewal. Registration application requirements include federal registration, the identity of an Idaho registered or licensed pharmacist-in-charge, and a qualified inspection report. As most outsourcing facilities were already registered in Idaho as Mail Service Pharmacies, they may also continue dispensing patient-specific prescription into Idaho, as long as they follow federal and state dispensing and distribution law.

Answering a question, **Dr. Johnston** said operation within Idaho requires a qualified inspection, which may take ninety days. During that time they cannot operate within the state. There are alternative ways to get an inspection, including a request of the Board of Pharmacy.

For the record, no one indicated their desire to testify.

MOTION: **Rep. Chew** made a motion to approve **Docket No. 27-0101-1402. Motion carried by voice vote.**

ADJOURN: There being no further business to come before the committee, the meeting was adjourned at 9:34 a.m.

_____

Representative Wood
Chair

_____

Irene Moore
Secretary