Attachment 2:

Legislative Rules Review

1. LSO receives and reviews ***proposed rules*** (I.C. section 67-5223(1)).

   (a) LSO is required to analyze proposed rules that are submitted for publication in the Administrative Bulletin. Each individual analysis is made available to the germane committee chair and vice chair and to the members of the germane joint subcommittee. A memorandum is provided with the analysis along with a copy of the proposed rule.

   (b) The memorandum addresses:
   (1) The changes the proposed rule seeks to make;
   (2) Whether these changes are substantive or housekeeping;
   (3) Any trends in agency rule writing (i.e., use of written interpretations);
   (4) Whether the agency has statutory authority to promulgate the rule.

   (c) The memo is a public record and is posted on line on the legislative web site under the link titled "*Rules Reviewed During Interim.*" An email notification is sent to the agency, the chair and vice chair of the germane committee and the members of the joint subcommittee directing them to the posted analysis. Anyone can access this analysis.

   (d) Upon notice of the intended agency action and after receipt of the proposed rule analysis for LSO, the germane joint subcommittee:
   (1) May request and hold a meeting with the agency after giving oral or written notice to LSO within 14 days of receipt of analysis. Meeting must be held within 42 days of receipt of analysis.
   (2) Issue an objection to the rule that is sent to the agency with a concise statement of the reasons for the objection.
   (3) Prepare a report for the germane committee on all rules transmitted to it outlining any objections to the proposed rules filed with the agency or stating that there were no objections to the rule.

   (e) ***Temporary rules*** are not reviewed by LSO, however, LSO receives a copy of the temporary rule at the time it is submitted for publication. (I.C. section 67-5226(5).

2. Upon commencement of the legislative session, the germane committees begin reviewing pending, pending fee, and temporary rules.

   (a) Section 67-5291, Idaho Code states...*the standing committees of the legislature **MAY** review temporary, pending and final rules which have been published in the bulletin or in the administrative code.* However, more recent changes to the APA have resulted in a more standardized, formal review process. Pending fee rules require affirmative approval by concurrent resolution to become final and effective. Similarly, a

temporary rule requires affirmative approval by concurrent resolution to remain in effect beyond the end of the session. If the pending fee rules or temporary are not reviewed, they die at the end of the session. Conversely, all non-fee pending rules would be final and effective at the end of the session.

(b) Committee chairs are free to implement procedures to expedite the rule review process, including the use of the consent calendar for non-controversial rules.

(c) Rule dockets may be approved or rejected (rejected in whole or in part).

(1) A pending rule goes into effect unless a concurrent resolution rejecting the pending rule (or any part) is adopted by both Houses. (I.C. section 67-5224(5)).
(2) A pending fee rule does not become final and effective until affirmatively approved by the legislature by concurrent resolution. (I.C. section 67-5224(5)(c)).
(3) A temporary rule (including a temporary fee rule) must be extended by concurrent resolution adopted by both Houses in order to remain in effect after the adjournment conclusion legislative session. (I.C. section 67-5226(3))
(4) A rulemaking done by proclamation is subject to review and approval. It is being reviewed as a final rule because it is already in effect but is subject to the same legislative action as a pending rule.

(d) Committees may review rules that have been previously adopted and codified as part of the Administrative Code. They need not be in the promulgation process to be subject to review. They are not, however, submitted for formal review. Only those rules undergoing change are submitted for review and approval. Review of final rules would require of the approval leadership to bring the rule before the committees.

3. Once the germane committee has completed review of the rules dockets that have been submitted to it, a rules report is prepared by the committee and sent to leadership.

(a) Rule review reports are due in writing to the Pro Tem and the Speaker. This is usually by the first week of February.

(b) Letter reports should detail:
(1) Whether the germane committee has rejected, in whole or in part, any rule docket;
(2) The type of rule rejected (pending, fee, or temporary);
(3) If a rule docket has been rejected in whole, the docket number of rejected docket; and
(4) If a rule docket has been rejected in part, the docket number and the IDAPA number of each rule subdivision that is being rejected.

4. Based upon the germane committee report, LSO will prepare the appropriate concurrent resolution.

(a) A separate concurrent resolution will be prepared for each pending rule docket which is rejected in whole or in part. The concurrent resolution for a rejected pending rule docket may be first introduced in either the Senate or the House.

(b) An omnibus concurrent resolution adopting all non-rejected pending fee rules and listing the individual rejected pending fee rules by IDAPA and docket number will be prepared. Traditionally, the omnibus concurrent resolution approving and rejecting pending fee rules is introduced in the Senate.

(c) An omnibus concurrent resolution adopting all non-rejected temporary rules and listing the individual rejected temporary rules by IDAPA and docket number will be prepared. Traditionally, the omnibus concurrent resolution approving and rejecting temporary rules is introduced in the Senate.

5. All rules expire on July 1st unless approved and extended by statute. (I.C. section 67-5292.)

LEGISLATIVE RULES REVIEW

Three Groups of Rules to Be Reviewed During the 2015 Legislative Session and the Actions Taken by the Legislature

Type of Rule	Status	Action That Can Be Taken
Group 1 - Pending Rules (Yellow) Pending rules adopted by agencies during calendar year 2014 and submitted for legislative review in 2015.	Not in Effect	Can be rejected in whole or in part. If the Legislature takes no action, rule goes into effect after the adjournment of the 2012 session. Must be rejected by concurrent resolution.
Group 2 – Pending Fee Rules (Green) Pending rules adopted during calendar year 2014 that impose a fee or a charge or that increase an existing fee or charge.	Not in Effect	Must be affirmatively approved by concurrent resolution. If the Legislature takes no action, rules never become final and effective. (Approved by an omnibus concurrent resolution approving all fee rules. Excepts out rejected rules.)
Group 3 – Temporary Rules (Salmon) Temporary (emergency) rules approved by the Governor that went into effect prior to session (most during calendar year 2014) without legislative review or public input. These can include fee increases also.	Temporarily in Effect	Expire upon the conclusion of the 2015 session unless the Legislature extends by concurrent resolution. (Approved by an omnibus concurrent resolution approving all temporary rules. Excepts out rejected rules.)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1404

NOTICE OF RULEMAKING - ADOPTION OF PENDING RULE

EFFECTIVE DATE: This rule has been adopted by the agency and is now pending review by the 2015 Idaho State Legislature for final approval. The pending rule becomes final and effective at the conclusion of the legislative session, unless the rule is approved or rejected in part by concurrent resolution in accordance with Sections 67-5224 and 67-5291, Idaho Code. If the pending rule is approved or rejected in part by concurrent resolution, the rule becomes final and of full force and effect upon adoption of the concurrent resolution.

AUTHORITY: In compliance with Section 67-5224, Idaho Code, notice is hereby given that this agency has adopted a pending rule. The action is authorized pursuant to Section 54-1717, Idaho Code.

DESCRIPTIVE SUMMARY: The following is a concise explanatory statement of the reasons for adopting the pending rule and a statement of any change between the text of the proposed rule and the text of the pending rule with an explanation of the reasons for the change:

This pending rule is necessary to harmonize labeling requirements with 2014 statutory changes. Changes from proposed to pending language create an exception for veterinarians.

The text of the pending rule has been amended in accordance with Section 67-5227, Idaho Code. Only those sections that have changes that differ from the proposed text are printed in this bulletin. The complete text of the proposed rule was published in the October 1, 2014 Idaho Administrative Bulletin, **Vol. 14-10, pages 347 through 360.**

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year: NA

ASSISTANCE ON TECHNICAL QUESTIONS: For assistance on technical questions concerning this pending rule, contact Mark Johnston, Executive Director, (208) 334-2356.

DATED this 28th Day of November, 2014.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
P. O. Box 83720
Boise, ID 83720-0067
Tel: (208) 334-2356
Fax: (208) 334-3536

THE FOLLOWING NOTICE WAS PUBLISHED WITH THE PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: A public hearing concerning this rulemaking will be held as follows:

Wednesday, October 22, 2014, 1:00 p.m.

Idaho Capitol Building
700 W. Jefferson St., Room WW53
Boise, Idaho 83702

The hearing site will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

This docket of rules provides various forms of clarification, and harmony with 2014 statute changes. This docket also addresses the situation whereby a patient cannot use their dispensed drugs when being admitted to an institutional facility because the drugs are not unit dosed packaged. This docket of rules clarifies that a pharmacist foreign graduate is required to obtain 1,500 student pharmacist hours; clarifies that a technician-in-training may only renew two times; harmonizes the standard drug labeling rule with 2014 statutory changes; creates a new limited pharmacy repackaging rule; clarifies when a controlled substance inventory is to be taken; allows pharmacist immunizers to utilize all forms of injectible epinephrine; clarifies that statutory requirements of nonresident registered pharmacists also pertain to nonresident licensed pharmacists; clarifies pharmacy security requirements; combines various pharmacy authorized entry rules into one rule; and updates remote dispensing site security and training requirements, also requiring a continuous quality improvement program.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: None.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking: NA

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1401 in the July 2, 2014 Idaho Administrative Bulletin, **Vol. 14-7, page 125**, and in the August 6, 2014 Idaho Administrative Bulletin, **Vol. 14-8, page 84**.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: NA

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 22, 2014.

DATED this 29th Day of August, 2014.

LSO RULES ANALYSIS MEMO

THE FOLLOWING IS THE TEXT OF DOCKET NO. 27-0101-1404

031. PHARMACIST LICENSURE BY EXAMINATION: FOREIGN PHARMACY GRADUATES.

01. Licensure Submission Requirements. To be considered for licensure, a graduate of a school or college of pharmacy located outside of the United States must submit an application for licensure by examination, ~~certification by the FPGEC, and~~ certification of completion of a minimum of fifteen hundred (1500) experiential hours~~.~~, and: ~~(4-4-13)~~( )

a. Certification by the FPGEC; or ( )

b. Certification of graduation from a doctorate of pharmacy program from an accredited school or college of pharmacy within the United States. ( )

02. Affidavit. An Idaho State Board of Pharmacy Employer's Affidavit certifying the experiential hours of a foreign pharmacy graduate must be signed by a pharmacist licensed and practicing in the United States and submitted to the Board. The Board may also request verifiable business records to document the hours. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

041. TECHNICIAN-IN-TRAINING REGISTRATION.
A person who has not obtained or maintained technician certification may apply for registration as a technician-in-training if the person satisfies all other requirements for registration as a technician and obtains and maintains employment as a technician-in-training. (4-4-13)

01. Duties. Upon registration, a technician-in-training may perform any of the duties allowed by statute or rule to be delegated to a registered technician under the supervision of a pharmacist. (3-21-12)

02. Renewal. The registration of a technician-in-training must be renewed by June 30 annually, ~~but is~~ however a technician-in-training may only renew~~able two (2) times~~ a technician-in-training registration twice. ~~(4-4-13)~~( )

03. Registration Expiration. Upon the final expiration of a technician-in-training registration, a person must satisfy the technician certification and registration requirements of these rules to be lawfully employed as, or otherwise perform the duties of, a technician. (3-21-12)

04. Cancellation of Registration. Failure to maintain employment will result in the cancellation of the registration. (4-4-13)

(BREAK IN CONTINUITY OF SECTIONS)

140. STANDARD PRESCRIPTION DRUG LABELING.
Unless otherwise directed by these rules, a prescription drug must be dispensed in an appropriate container that bears the following information: (3-21-12)

01. Dispenser Information. The name, address, and telephone number of the dispenser (person or business). (3-21-12)

02. Serial Number. The serial number. (4-4-13)

03. Date. The date the prescription is filled. (3-21-12)

04. Prescriber. The name of the prescriber. (3-21-12)

05. ~~Patient~~ Name. ~~The name of the patient, and if the patient is an animal, the species;~~ ~~(3-21-12)~~( )

a. If a person, the name of the patient; ( )

b. If an animal, the name and species of the patient; or ( )

c. If a school for epinephrine auto-injectors pursuant to Section 33-520A, Idaho Code, the name of the school. ( )

06. **Drug Name and Strength**. Unless otherwise directed by the prescriber, the name and strength of the drug (the generic name and its manufacturer's name or the brand name). (3-21-12)

07. **Quantity**. The quantity of item dispensed. (3-21-12)

08. **Directions**. The directions for use. (3-21-12)

09. **Cautionary Information**. Cautionary information as required or deemed appropriate for proper use and patient safety. (3-21-12)

10. **Expiration**. An expiration date that is the lesser of: (3-21-12)

a. One (1) year from the date of dispensing; (3-21-12)

b. The manufacturer's original expiration date; (3-21-12)

c. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (3-21-12)

d. A shorter period if warranted. (3-21-12)

11. **Refills**. The number of refills remaining, if any, or the last date through which the prescription is refillable~~;~~. ~~and~~ ~~(3-21-12)~~( )

12. **Warning**. The warning: "Caution: State or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed~~.~~," *except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be utilized.* ~~(3-21-12)~~( )

13. ~~Pharmacist~~ **Identification**. The initials or other unique identifier of the dispensing pharmacist or dispensing prescriber. ~~(1-1-13)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

146. REPACKAGING.
A pharmacy may repackage a drug previously dispensed to a patient, pursuant to the patient or the patient's agent's request, if: ( )

01. Unit Dose. The drugs are repackaged into unit dose packaging. ( )

02. Pharmacist Verification. The repackaging pharmacist verifies: ( )

a. The identity of the previously dispensed drugs as matching the label on the container that the drugs were initially dispensed within; and ( )

b. The validity and accuracy of the original prescription drug order. ( )