Dear Senators LODGE, Broadsword & Werk, and
Representatives BLOCK, Nielsen & Henbest:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Idaho Board of Pharmacy:

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0810).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 10-27-08. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 11-24-08.

_____The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-2475, or send a written request to the address or FAX number indicated on the memorandum enclosed.

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Research & Legislation Staff - Paige Alan Parker

DATE: October 8, 2008

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0810 (Proposed))

The Board of Pharmacy submits Docket No. 27-0101-0810 (hereinafter "proposed rule"), amending the Board's rules found at IDAPA 27.01.01. According to the Board, the proposed rule is authorized pursuant to section 54-1717, Idaho Code.

Sections 54-1701 to 54-1726, 54-1728 to 54-1739, 9-1701 and 9-1702, Idaho Code, are the components of the Idaho Pharmacy Act. Section 54-1717, Idaho Code, provides general rulemaking authority for the Board of Pharmacy under that Act.

According to the Board, the proposed rule requires that the pharmacist-in-charge work a substantial part of his or her working time at the pharmacy of which such person is the pharmacist-in-charge. The Board states that the proposed rule imposes a certain work week and/or work month requirement.

According to the Board, no fee or charge is imposed by the temporary and proposed rule. The Board states that there is no anticipated impact to the general fund greater than $10,000 during the fiscal year as a result of the temporary and proposed rule. According to the Board, negotiated rulemaking was not conducted because of the simple nature of the rulemaking. The Board states that public hearing(s) will be scheduled if requested in writing by 25 persons, a political subdivision, or an agency, not later than October 15, 2008. All written comments must be delivered to the Board on or before October 22, 2008.

ANALYSIS

Generally, the proposed rule substitutes the term "pharmacist-in-charge" for "pharmacist manager" and the term "licensed employee-pharmacist" for "registered employee-pharmacist." IDAPA chapter 27.01.01, the Rules of the Idaho Board of Pharmacy, does not have a definition for "pharmacist-in-charge," although that term is used extensively throughout the rule. Section 268.01 of the existing rule, dealing with remote pharmacies, states that the "pharmacist-in-charge is responsible "for all aspects of the operation of the Pilot Remote Pharmacy including safety, accuracy, security, and patient confidentiality."

Under the proposed rule, the pharmacist-in-charge must annually notify the Board of the identity of the pharmacy's pharmacist-in-charge and each licensed employee-pharmacist and requires any change in pharmacy technician (along with change in pharmacist or extern/intern employment) be reported by the pharmacist-in-charge to the Board within 10 days (up from 5 days under the existing rule). Section 156.02.

Deleted by the proposed rule is the requirement that a non-registered proprietor of a pharmacy place an Idaho licensed, responsible pharmacist manager in charge of the pharmacy and immediately report any change in such person to the Board. Instead, the proposed rule requires the pharmacist-in-charge to immediately report any change in the pharmacist-in-charge of the pharmacy to the Board. Section 156.03.

Section 156.04 of the proposed rule states the responsibilities of the pharmacist-in-charge. The pharmacist-in-charge is responsible for every part of the "drug outlet" (the term under the existing rule is "stores") and its operations coming under regulation of the pharmacy laws. The proposed rule requires that no pharmacist shall be designated and function as the pharmacist-in-charge of a pharmacy unless such person spends a substantial part of his working time each month working in the pharmacy. The proposed rule does not specify what a "substantial part of his working time each month" means.

SUMMARY

The proposed rule is vague as to what "substantial part of [the pharmacist's] working time each month" must be spent working in the pharmacy. The Department's proposed rule change appears to be authorized under section 54-1717, Idaho Code.

cc: Idaho State Board of Pharmacy
Mark D. Johnston

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO BOARD OF PHARMACY

DOCKET NO. 27-0101-0810

NOTICE OF RULEMAKING - 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: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 15, 2008.

The hearing site(s) 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:

Existing rules require that each pharmacy designate a pharmacist-in-charge who is responsible for the management of that pharmacy. The Board believes that it is in the interests of public health, safety, and welfare to require that a pharmacist-in-charge of a pharmacy work a substantial part of his or her working time at the pharmacy of which they are the pharmacist-in-charge, so it proposes amending its rule accordingly. The proposed rulemaking amends rule to require that a pharmacy's pharmacist-in-charge work at that pharmacy a certain amount of time during a work week and/or work month.

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: None.

NEGOTIATED RULEMAKING: Pursuant to 67-5220(1), Idaho Code, negotiated rulemaking was not conducted because of the simple nature of the rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., 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, 2008.

DATED this 13th day of August, 2008.

Mark D. Johnston, R.Ph.
Executive Director
Idaho Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720
Boise, ID 83720-0067
Phone: (208) 334-2356
Fax: (208) 334-3536

THE FOLLOWING IS THE TEXT OF DOCKET NO. 27-0101-0810

156. PHARMACIES.

01. Change of Ownership or Location. In case of change of ownership or location of a pharmacy, the original registration becomes void and must be returned with a new pharmacy application. (7-1-93)

02. Annual Employee Report ~~of Pharmacy Employer~~. Annually, on the date of renewal of registration, the ~~*pharmacy employer*~~ pharmacist-in-charge must notify the Board of the ~~*registered pharmacist-manager*~~ pharmacist-in-charge of the pharmacy, ~~*and*~~ each ~~*registered*~~ licensed employee-pharmacist, and each extern/intern training in the pharmacy, on the place provided on the application. However, ~~A~~any change in pharmacist, pharmacy technician, or extern/intern employment ~~*must*~~ shall be reported by the pharmacist-in-charge to the Board within ~~*five*~~ ten (~~5~~10) days. ~~*(7-1-93)*~~( )

03. ~~*Responsible*~~ Reporting Change in Pharmacist-in-Charge ~~*Manager*~~. ~~*A non-registered proprietor of a pharmacy shall place in charge of such pharmacy a pharmacist licensed in the state of Idaho who shall be known as "responsible pharmacist manager" and the non-registered proprietor*~~ The pharmacist-in-charge shall ~~*immediately*~~ report any change in the pharmacist-in-charge of the pharmacy to the ~~*state*~~ Board ~~*the name of the pharmacist manager*~~ immediately. ~~*(7-1-93)*~~( )

04. Qualifications and Responsibility of the Pharmacist-In-Charge ~~*Manager*~~. ~~*Responsible*~~ The pharmacist-in-charge ~~*managers of pharmacies owned by non-registered proprietors are*~~ shall be responsible for the management of, ~~*such stores so far as they are affected by the pharmacy laws. Every part of the establishment coming under the regulation of the pharmacy laws*~~ and shall be under the full and complete control of, ~~*such responsible pharmacist manager*~~ every part of the drug outlet and its operations coming under the regulation of the pharmacy laws. No pharmacist shall be designated as the pharmacist-in-charge of a pharmacy and no pharmacist shall function as the pharmacist-in-charge of a pharmacy unless the person so designated and so functioning spends a substantial part of his working time each month working in the pharmacy of which he has been designated the pharmacist-in-charge. ~~*(7-1-93)*~~( )

05. Return of Drugs or Other Items. In the interest of public health, drugs, medicines, sickroom supplies, devices and items of personal hygiene shall not be accepted for return by any pharmacist or pharmacy after such drugs, medicines, sickroom supplies, devices and items of personal hygiene have been taken from the premises where sold, distributed or dispensed, except that medications for in-patients of residential or assisted living facilities, licensed skilled nursing care facilities, and hospitals may be returned to the dispensing pharmacy for credit provided the medications are liquid medications that have been supplied in manufacturer sealed containers and remain unopened, or the medications are in unopened "Unit Dose" packaging. In addition, the conditions set forth in Paragraph 156.05.b. of these rules must be satisfied: (3-20-04)

a. Unit Dose is defined as medications packaged in individually sealed doses with tamper-evident packaging (for example, single unit of use, blister packaging, unused injectable vials and ampules). (3-20-04)

b. The following conditions must be satisfied: (3-20-04)

i. The medications must be returned with tamper-evident packaging intact and with no evidence of tampering. (3-20-04)

ii. In the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity. (4-5-00)

iii. Policies and procedures are followed for the appropriate storage and handling of medications at the facility and for the transfer, receipt, and security of medications returned to the dispensing pharmacy. (4-5-00)

iv. A system is in place to track restocking and reuse to allow medications to be recalled if required. (4-5-00)

v. No controlled substance may be returned except those delivered by Unit Dose on a daily delivery system. (4-5-00)

vi. If the drug is repackaged by the pharmacy, each repackage container must be labeled in accordance

with the following (for purpose of this rule, any change from the original manufacturer's packaging prior to delivery of the medication to the hospital or the facility shall be considered repackaging): (3-20-04)

(1) Name and strength of the medication; (3-20-04)

(2) A suitable expiration date which shall not be later than the expiration date on the original manufacturer's container, or one (1) year from the date the drug is repackaged (If a medication that was repackaged and delivered to the hospital or facility is thereafter returned to the pharmacy and subsequently repackaged again, the expiration date hereunder shall not be later than the expiration date used when the medication was initially repackaged.); (3-20-04)

(3) The date the medication was repackaged; (3-20-04)

(4) The manufacturer's lot number, expiration date, and identity; and (3-20-04)

(5) The identity of the pharmacist responsible for the repackaging. (3-20-04)

c. If the information required under Subparagraphs 156.05.b.vi.(4) and 156.05.b.vi.(5) of these rules is maintained in the internal records of the pharmacy, those requirements may be omitted from the labeling. The labeling requirements of Subparagraph 156.05.b.vi. of these rules shall apply in addition to the labeling requirements under Section 159 of these rules. (3-20-04)

d. Medications that have been outside the custody and control of the hospital or facility for any reason, are not eligible for return. In order to be considered as having been in the custody and control of the hospital or facility, the medications must have been delivered by the dispensing pharmacy directly to the hospital or facility or to an agent thereof who is authorized and qualified to accept delivery, and the medications must then be held by the hospital or facility in an area suitable for storing medications and not accessible to any patients. Once a medication has passed from the hospital or facility storage area to the patient or to the patient's designee for any reason, the medication is no longer eligible for return. (3-20-04)

e. Medications otherwise eligible for return under this rule by virtue of their packaging but that have become ineligible for return for any reason must be marked as follows: (3-20-04)

i. Such medications that are released for self-administration by the patient, or for administration outside the hospital or facility premises or that are otherwise released to be taken outside the custody and control of the hospital or facility, shall first be clearly marked and identified "Not Eligible For Return" provided however, the foregoing requirement for marking shall not apply to the daily dose of medication released to a patient on the day such dose is to be administered provided the hospital or facility does not allow any such medication to be returned to the same medication storage area as medications eligible for return. (3-20-04)

ii. Such medications that are received by the hospital or facility from the patient or the patient's representative, and not directly from the dispensing pharmacy, and that are to be stored in the same storage area as medications which are eligible for return, shall first be clearly marked and identified "Not Eligible For Return." (3-20-04)

iii. In the event medications otherwise eligible for return under this rule by virtue of their packaging are discovered to be ineligible for return because they have been outside the custody and control of the hospital or facility, or for any other reason, such medications shall be clearly marked and identified "Not Eligible For Return" immediately upon discovery if they are to remain stored in the same storage area as medications that are eligible for return. (3-20-04)

f. Each pharmacy and the pharmacist-in-charge shall be responsible for consulting with each hospital or facility from which the pharmacy will accept returns under Section 156 of these rules to ensure that the hospital or facility has an employee who is trained and knowledgeable in the proper storage, use, and administration of medications at the hospital or facility, and to ensure that the hospital or facility has in place and enforces written protocols that will ensure compliance with the conditions necessary to allow returns. The pharmacist-in-charge must review and approve the protocols. The pharmacy must keep a copy of the protocols, as well as the written approval

thereof, on file in the pharmacy and produce the same for Board inspectors upon request. (3-20-04)

g. Each pharmacy and the pharmacist-in-charge that will be accepting returns under Section 156 of these rules shall establish written protocols for the pharmacy that will ensure compliance with Section 156 of these rules for all returns. The pharmacist-in-charge must review and approve the protocols. The pharmacy must keep a copy of the protocols, as well as the written approval thereof, on file in the pharmacy and produce the same for Board inspectors upon request. (3-20-04)

06. Damaged Drugs. To sell, offer for sale, barter or give away any drugs damaged by fire or water or by any other means that might affect the potency of the drug is prohibited without first obtaining the written approval of the Board. (7-1-93)

07. Dangerous Drugs. Legend, controlled substances, or other limited sale items must be stored in accordance with United States Pharmacopoeia/National Formulary requirements in the prescription area (where prescriptions are compounded, dispensed or filled) and in a manner as to limit access to licensed pharmacists or authorized personnel of that area only. Failure to comply with this requirement shall be prima facia evidence of unprofessional conduct. (7-1-93)