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:

27.01.01 - Rules of the Idaho State Board of Pharmacy - Statutory Changes/Wholesale Drug Distribution Act (Docket No. 27-0101-0801)

27.01.01 - Rules of the Idaho State Board of Pharmacy - Changes Re: Pharmaceutical Care Services (Docket No. 27-0101-0802)

27.01.01 - Rules of the Idaho State Board of Pharmacy - Changes Re: Grounds for Discipline/Pharmacy Techs (Docket No. 27-0101-0803)

27.01.01 - Rules of the Idaho State Board of Pharmacy - No Schedule II Order Filled 90 Days After Written (Docket No. 27-0101-0804).

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 9-17-08. 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 10-15-08.

_____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: August 26, 2008

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0801 (Proposed))

The Board of Pharmacy submits Docket No. 27-0101-0801 (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 sections 37-2715, 37-2726(1), 54-1717, 54-1725(3), 54-1734 and 54-1753, Idaho Code.

Chapter 27, title 37, Idaho Code is the Uniform Controlled Substances Act. Section 37-2715, Idaho Code, permits the Board to promulgate rules relating to the dispensing of controlled substances within Idaho. Section 37-2726(1), Idaho Code, requires the filing of all controlled substances prescriptions with the Board electronically in a format established by the Board and requires the Board to establish by rule the information to be submitted.

Chapter 17, title 54, Idaho Code, is the Idaho Pharmacy Act. Section 54-1717, Idaho Code, provides general rulemaking authority for the Board of Pharmacy. Section 54-1725(3), Idaho Code, requires the Board to adopt rules regarding continuing pharmacy education. Section 54-1734, Idaho Code, provides exceptions to the sale of prescription drugs that are not governed by chapter 17, title 54. Section 54-1753, Idaho Code, was enacted in 2007 and amended in 2008 to provide for a wholesale drug distributor licensing requirement. Subsection (9) of that section permits the Board to adopt rules to approve an accreditation body to evaluate a wholesale's operation to determine compliance with professional standards and any other applicable laws and to perform inspection of wholesale distribution operations.

The Board lists six reasons for the proposed rule change: (1) Comply with the recent wholesale drug distribution legislation; (2) provide consistency in "pharmacist in charge" usage;

(3) clarify the "pharmacist in charge" requirements and responsibilities; (4) include pharmacy technicians among pharmacy employees whose employment changes are reportable; (5) substitute "licensed" for "registered" in reference to pharmacists; and (6) reflect the change of name and designation code for an organization offering accredited continuing education programs (i.e., change "American Council for Pharmacy Education" to "Accreditation Council for Pharmacy Education" and require a "P" suffix to the universal program number). The Board also notes that because of the growing abuse of certain drugs falling within Schedule V controlled substances, it desires to amend its rules to clarify the procedure to be followed when veterinary drug outlets receive oral prescription orders.

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 September 17, 2008. All written comments must be delivered to the Board on or before September 24, 2008.

ANALYSIS

The more technical and housekeeping changes will not be discussed in this memorandum.

The proposed rule requires that the pharmacist-in-charge report any change in a pharmacy technician to the Board within five days and that the pharmacy employer report any change in the pharmacist-in-charge to the Board immediately. The pharmacist-in-charge is now responsible for every part of the "drug outlet" (rather than the "store") and its operations coming under the regulation of the pharmacy laws. IDAPA27.01.01.156.02, 03 and 04. "Drug outlet" is defined at section 54-1705(9), Idaho Code, as "all pharmacies, nursing homes, residential or assisted living facilities, convalescent homes, extended care facilities, drug abuse treatment centers, penal institutions, hospitals, family planning clinics, retail stores, wholesalers, manufacturers and mail order vendors with facilities located in this state which are engaged in dispensing, delivery or distribution of drugs and drug manufacturers and wholesalers with facilities located outside the state, but doing business within this state."

As part of information to be provided to the Board, under oath, from each wholesale drug distributor as part of the initial licensing procedure and as part of any license renewal, the proposed rule requires that the licensee provide a description of any lawsuit in which its designated representative was a named party or testified, whether in person or by deposition, during the past seven years. IDAPA 27.01.01.323.01.k.vii. This additional requirement tracks the 2008 amendment to section 54-1753(2)(h)(vii), Idaho Code.

The proposed rule deletes the licensed wholesale distributor bonding requirement. IDAPA 27.01.01.323. This deletion, and the subsidiary bond handling requirements and exceptions, track the similar 2008 amendments to sections 54-1753(6) and (7), Idaho Code.

Chapter 356 of IDAPA 27.01.01, dealing with Veterinary Drug Orders, has been amended by the proposed rule to clarify the procedure for oral prescription drug orders. The establishment is required to promptly reduce the oral order to writing on an unnumbered telephone drug order form available through the Idaho Department of Agriculture and keep the original of the completed form on file at the place of distribution. Subsequent processing is identical to the procedure for written orders. Within seventy-two hours after receiving the oral prescription order, the establishment is required to have on file at the place of distribution a written confirmation of the order, on an official numbered order form available through that Department, from the practitioner and to deliver the written confirmation to the Veterinary Drug Outlets along with the unnumbered telephone drug order form. IDAPA 27.01.01.356.04.

The proposed rule adds Schedule V controlled substances to the reporting requirement under section 469. IDAPA 27.01.01.469.

RECOMMENDATION

The Department's proposed rule change appears to be authorized under sections 37-2715, 37-2726(1), 54-1717, 54-1725(3) and 54-1753, Idaho Code.

cc: Idaho State Board of Pharmacy
Mark D. Johnston, Executive Director

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: August 26, 2008

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0802 (Proposed))

The Board of Pharmacy submits Docket No. 27-0101-0802 (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 sections 54-1705(21) and 54-1717, Idaho Code.

Chapter 17, title 54, Idaho Code, is the Idaho Pharmacy Act. Section 54-1705(21), Idaho Code, defines "pharmaceutical care" as "drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the rules of the board." Section 54-1717, Idaho Code, provides general rulemaking authority for the Board of Pharmacy.

The Board states that the proposed rule is necessary to further define pharmaceutical care in keeping with recent developments in the practice of pharmacy and allow the Board flexibility in addressing future changes in the profession regarding pharmaceutical care service. The Board states that a number of definition changes are incorporated into the proposed rule and takes elements of current rules regarding Collaborative Practice Agreement and Contents of Agreement, with modification, and combines them into a new Collaborative Pharmacy Practice rule. The Board also states that the proposed rule contains various definitions related to confidentiality of patient information.

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 September 17, 2008. All written comments must be delivered to the Board on or before September 24, 2008.

ANALYSIS

Housekeeping changes will not be discussed in this memorandum.

The proposed rule retitles section 165 of IDAPA 27.01.01 from "Pharmacotherapy" to "Pharmaceutical Care" and provides that the licensed practice of pharmacy may include pharmaceutical care, as defined. The section 165 definition subsection uses the term "collaborative pharmacy practice," in place of "collaborative practice," and defines it as "that practice of pharmacy whereby one (1) or more pharmacists have jointly agreed to work in conjunction with one (1) or more practitioners under protocol whereby the pharmacist may perform certain patient care functions authorized by the practitioner under certain specified conditions or limitations." "Collaborative pharmacy practice agreement" is similarly defined to allow that such an agreement is between "one (1) or more" pharmacists.

"Drug therapy management" has been redefined as "a distinct service or group of services that optimize therapeutic outcomes for individual patients," and such services are "independent of, but can occur in conjunction with, the provision of a drug or a device." The list of services included within "drug therapy management" has been extensively changed by the proposed rule. Among the deleted services are: "collecting and reviewing patient drug histories," "obtaining and checking vital signs," and ordering and evaluating the results of laboratory tests directly related to drug therapy." Added to the list of services are: performing or obtaining necessary assessments of the patient's health status; formulating a drug treatment plan; selecting, initiating, modifying or administering drug therapy; monitoring and evaluating the patient's response to therapy, including safety and effectiveness; performing a comprehensive drug review to identify, resolve , and prevent drug-related problems, including adverse drug events; documenting the care delivered and communicating essential information to the patient's other primary care providers; providing information, support services and resources designed to enhance patient adherence with his therapeutic regimes; coordinating and integrating drug therapy management services within the broarder health care-management services being provided to the patient; and such other drug therapy management services as may be allowed by law.

The proposed rule adds definitions for "health information," "HIPAA," "individually identifiable health information," "other pharmaceutical patient care services," "pharmaceutical care," "pharmacist's scope of practice pursuant to the collaborative practice agreement," "practitioner" and "protected health information." As advertised, "pharmaceutical care" has been defined consistently with section 54-1705(21), Idaho Code. "Other pharmaceutical patient care services" is a phrase used in the statutory (and now rule) definition of "pharmaceutical care." Pursuant to the proposed rule, that phrase includes "collaborative pharmacy practice" and "such other pharmaceutical patient care services as may be allowed by law."

"Practitioner" has been defined in the proposed rule ("an individual currently licensed, registered, or otherwise authorized in Idaho to **prescribe** and administer drugs in the course of professional practice") at variance with its statutory definition ("a physician, dentist, veterinarian, scientific investigator or other person licensed in this state and permitted by such license to **dispense, conduct research** with respect to or administer drugs in the course of professional practice or research in this state," section 54-1705(24), Idaho Code)(bold emphasis added)). A major difference is that the proposed rule includes within the definition the power to "prescribe" drugs, which is absent from the statutory definition. The statutory definitions include the power to dispense and conduct research. Although the proposed rule employs the caveat "for the purposes of Section 165," defining term in rule at variance from the statutory definition may invite litigation.

The proposed rule rewrites section 165.02 on Collaborative Pharmacy Practice. Having defined "Collaborative Pharmacy Practice" in section 165.01.a, subsection 02 provides the requirements for such practice. Foremost among the requirements is a written collaborative pharmacy practice agreement, which was previously defined in section 165.01.b, as being between one or more pharmacists and one or more practitioners that provides for collaborative pharmacy practice for the purpose of conducting drug therapy management services. The initial existence and subsequent termination of the agreement must be made available to the Board and patients or caregivers must be advised of such agreement. Documentation of allowed activities must be kept as part of the patient's permanent record and must be readily available to other authorized health care professionals providing care to the patient. Deleted from the proposed rule are specific statements regarding the types of drug therapy management decisions the pharmacist is allowed to make and a requirement for documentation of decisions made and a plan or appropriate mechanism for communication, feedback and reporting to the prescribing practitioner concerning specific decisions made.

RECOMMENDATION

The Department's proposed rule change appears to be authorized under sections 54-1705(21) and 54-1717, Idaho Code. The definition of terms in proposed rules at variance from statutory definitions should be discouraged.

cc: Idaho State Board of Pharmacy
Mark D. Johnston, Executive Director

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: August 21, 2008

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0803 (Proposed))

The Board of Pharmacy submits Docket No. 27-0101-0803 (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.

Chapter 17, title 54, Idaho Code, is the Idaho Pharmacy Act. Section 54-1717, Idaho Code, provides general rulemaking authority for the Board of Pharmacy.

The Board states that the proposed rule is necessary to clarify the grounds upon which pharmacy technicians are subject to discipline, the sanctions which may be imposed and the procedures for reinstatement.

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 September 17, 2008. All written comments must be delivered to the Board on or before September 24, 2008.

ANALYSIS

Housekeeping changes will not be discussed in this memorandum.

The proposed rule clarifies that the Board has the authority to refuse to issue or renew the pharmacy technician registration or may suspend, revoke or restrict such registration. Under the existing rule, the Board had the discretion to initiate proceedings against such a technician who prepared, compounded, distributed or dispensed medications in a negligent or improper manner or otherwise violated the rules. The proposed rule provides specific grounds for disciplinary action: (1) unprofessional conduct (as defined in the rules); (2) incapacity that prevents the technician from performing the functions with reasonable skill, competence and safety to the public; (3) being found guilty (or being convicted or receiving a withheld judgment or suspended sentence) of a felony, "any act involving moral turpitude, gross immorality, or which is in relation to the qualifications, functions, or duties of a pharmacy technician" (underlined emphasis added) or violations of the pharmacy or drug laws of Idaho, another state or the federal government; (4) fraud or intentional misrepresentation by a registrant in securing the issuance or renewal of the registration; or (5) being found by the Board of a violation of the Pharmacy Act or the Uniform Controlled Substances Act. IDAPA 27.01.01.251.05.c.

The term "any act involving moral turpitude, gross immorality, or which is in relation to the qualifications, functions, or duties of a pharmacy technician," underlined in (3) above, is poorly worded and suggests that a pharmacy technician might be disciplined for doing an act which is in relation to his qualifications, functions or duties. The Board informs that this language was adopted from section 54-1726(c)2, Idaho Code, which provides similar grounds for discipline of pharmacists. The Board will review the language in both the rule and the statute.

Under the proposed rule, upon the finding of grounds for discipline, pharmacy technician or registrant may be sanctioned as provided to section 54-1728, Idaho Code. That section includes license suspension, revocation, restriction or non-renewal, the placement on probation, and/or the imposition of an administrative fine not to exceed $2,000. Petitions for reinstatement are subject to that state as well. IDAPA 27.01.01.251.08.

RECOMMENDATION

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, Executive Director

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: August 21, 2008

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket No. 27-0101-0804) (Proposed and Temporary))

According to the Board of Pharmacy, the temporary and proposed rule is authorized pursuant to section **65-202**, Idaho Code, which provides rulemaking authority for the administrator of the division of veterans services. The general rulemaking authority for the Board of Pharmacy is actually found at section 54-1717, Idaho Code.

The Governor's justification for the temporary rule is to comply with changes in federal statutes. The Board has failed to provide a copy of the specific federal statutes upon which it relies as required by section 67-5223(1), Idaho Code. Also, "comply with changes in federal statutes" is not a listed justification for a temporary rule under section 67-5226(1), Idaho Code. The closest statutory justification is "compliance with deadlines in amendments to governing law or federal programs." Section 67-5226(1)(b), Idaho Code. The temporary rule goes into effect on September 3, 2008.

The Board states that the proposed rules are necessary to comply with changes in federal statute. The Board does not identify the federal statute with which itseeks to comply, or explain what changes in the federal statute mandate this rulemaking.

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 need for temporary 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 September 17, 2008. All written comments must be delivered to the Board on or before September 24, 2008.

ANALYSIS

The temporary and proposed rule deletes the deadline for filling a prescription for a controlled substance listed in Schedule II from the thirtieth day following the date of issue. In place of that language the temporary and proposed rule provides that no order shall be filled more than ninety days after the date the order was written. The old rule used the term "prescription for a controlled substance" while the temporary and proposed rule uses the term "order." "Order" is not a defined term under either statute or rule. "Prescription drug order" is defined at section 54-1705(29), Idaho Code. The temporary and proposed rule should be clarified by the use of defined terms.

SUMMARY

Subject to the above comments, the temporary and proposed rule appears to the authorized by section 54-1717, Idaho Code.

cc: Idaho Board of Pharmacy
Mark Johnston, Executive Director

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO BOARD OF PHARMACY

DOCKET NO. 27-0101-0801

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 Sections 37-2715, 37-2726(1), 54-1717, 54-1725(3), 54-1734, and 54-1753, 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 September 17, 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:

The proposed rule changes are necessary to:

1. Comply with recent statutory changes to the Wholesale Drug Distribution Act;
2. Provide consistency in the usage of the statutory term “pharmacist in charge”;
3. Clarify various requirements and responsibilities regarding pharmacist in charge;
4. Include pharmacy technicians among pharmacy employees whose employment changes are reportable;
5. Substitute the term “licensed” for “registered” in reference to pharmacists; and
6. Reflect the change of name and designation code for one of the organizations offering accredited continuing education programs.

Based on experience acquired in regulating veterinary drug outlets (VDO), the Board desires to amend its rule to clarify the procedures to be followed when VDOs receive oral prescription orders. Because of growing abuse of certain drugs falling within Schedule V controlled substances, the Board desires to require certain data concerning Schedule V substances be reported to the Board. Additionally, the proposed rule changes are necessary to make payment of the annual preceptor site registration fee coincide with license and registration annual renewal; limit fees due April 1 annually to student pharmacist registrations; and change the expiration date for the registration of a student pharmacist extern from July 31 following graduation to July 15 following graduation.

The proposed rules amend disclosure requirements and remove the requirement for a security bond or equivalent security and the requirement for a separate fund for security deposits. Rule changes also substitute the term “pharmacist in charge” for the terms “registered pharmacist manger” and “responsible pharmacist manager;” substitute “licensed” for “registered” when referring to a pharmacist; add pharmacy technicians to the list of employees for whom notification of employment changes must be reported to the Board; clarify which changes are reported by the pharmacy employer and which by the pharmacist in charge; extend the time for the pharmacist in charge to report changes to ten (10) days; clarify the requirement for designation of a pharmacist in charge and clarify the management responsibilities of the pharmacist in charge; and change “American Council of Pharmaceutical Education” to “Accreditation Council for Pharmacy Education (ACPE)” and require that ACPE accredited activities as of January 1, 2008 have an ACPE universal program number with the suffix “P” for pharmacist.

Rule changes require that an oral prescription order received by a VDO be promptly reduced to writing on an unnumbered telephone drug order form available through the Idaho Department of Agriculture and that the original of the completed form be kept at the place of distribution; that following reduction of the oral order to writing, subsequent processing of the order should be identical to the procedure for written orders; require that within seventy-two (72) hours after receiving an oral prescription order, a VDO shall have on file at the place of distribution written confirmation of the oral order from the veterinarian; require the VDO to attach to the written confirmation from the veterinarian the Department of Agriculture form that the VDO completed after receiving the oral order; require written confirmation from the veterinarian be signed by the veterinarian and must be copy one of a numbered three (3)-part prescription form available through the Idaho Department of Agriculture; and provide that the veterinarian may deliver written confirmation to the VDO by mail, fax, electronic transmission, or hand delivery.

Rule changes add Schedule V controlled substances to the list of controlled substances for which prescription data must be reported to the Board. Rule changes remove the preceptor site category in one rule and add the category to other rules; rename a rule category to "Student Pharmacist Registration;" renumber paragraphs; and change the expiration date for student pharmacist intern registrations from July 31 to July 15.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

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 Section 67-5220(2), 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 September 24, 2008.

DATED this 22nd day of July, 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. 27-0101-0801

134. AMOUNT OF CONTINUING EDUCATION.
The equivalent of one and one-half (1.5) continuing education units (CEU) shall be required annually of each applicant for renewal of license. One (1) continuing education unit is the equivalent of ten (10) clock hours of participation in programs approved by the Board. (7-1-93)

01. ACPE or CME. At a minimum, eight clock hours (0.8 CEU) will be all or a combination of ~~*American*~~ Accreditation Council ~~*of Pharmaceutical*~~ for Pharmacy Education (ACPE) or Continuing Medical Education (CME) approved programs. As of January 1, 2008, all ACPE accredited activities with a release date of January 1, 2008 are required to have a participant designation of P (for pharmacist) as the suffix of the ACPE universal program number. ~~*(12-7-94)*~~( )

02. Pharmacy Law. One clock hour (0.1 CEU) must be Board approved jurisprudence (pharmacy law) programs. (7-1-93)

03. Non-ACPE Approved. A maximum of six clock hours (0.6 CEU) may be non-ACPE approved programs. (12-7-94)

04. Live Attendance. Three clock hours (0.3 CEU) of the required one and one-half (1.5) continuing education units (CEU) must be obtained by attendance at live continuing education programs. (7-1-97)

05. Carryover of Certain Unused Units. Clock hours of CEU accrued during June of any given licensing period may be carried over into the next licensing period to the extent that a pharmacist's total clock hours of CEU for the given licensing period exceed the total CEUs required under these rules for the given licensing period. (5-3-03)

(BREAK IN CONTINUITY OF SECTIONS)

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 Report of Pharmacy Employer. Annually, on the date of renewal of registration, the pharmacy employer 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 (5) days of the change. ~~*(7-1-93)*~~( )

03. ~~*Responsible Pharmacist 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 shall immediately report to the state Board the name of the pharmacist manager.*~~ **Reporting Change in Pharmacist-in-Charge** The pharmacy employer shall report any change in the pharmacist-in-charge of the pharmacy to the Board immediately. ~~*(7-1-93)*~~( )

04. Responsibility of ~~*Pharmacist Manager*~~ the Pharmacist-in-Charge. ~~*Responsible pharmacist managers of pharmacies owned by non-registered proprietors are*~~ The pharmacist-in-charge 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. ~~*(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)

(BREAK IN CONTINUITY OF SECTIONS)

323. MINIMUM REQUIREMENTS FOR LICENSURE.

01. Information Under Oath. The Board requires the following information under oath from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license: (4-2-08)

a. The name, full business address, and telephone number of the licensee. (7-1-93)

b. All trade or business names used by the licensee. (7-1-93)

c. Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs. (4-2-08)

d. The type of ownership or operation (such as, partnership, corporation, or sole proprietorship). (7-1-93)

e. The name of the owner or operator, or both, of the licensee, including: (7-1-93)

i. If a person, the name of the person. (7-1-93)

ii. If a partnership, the name of each partner, and the name of the partnership. (7-1-93)

iii. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any. (7-1-93)

iv. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity. (7-1-93)

f. A list of all licenses and permits issued to the applicant/licensee by any other state that authorizes the applicant/licensee to purchase or possess prescription drugs. (4-2-08)

g. Any convictions of the applicant/licensee under any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (4-2-08)

h. Any felony convictions of the applicant/licensee under federal, state, or local law. (4-2-08)

i. Any discipline of the applicant/licensee by a regulatory agency in any state for violating any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (4-2-08)

j. The name of the licensee's designated representative for the facility, together with the personal information statement and fingerprints required for such individual pursuant to Paragraph 323.01.k. of these rules. (4-2-08)

k. For each individual identified by the licensee as a designated representative pursuant to Paragraph 323.01.g. of these rules, the licensee shall provide the following information: (4-2-08)

i. The individual's places of residence for the past seven (7) years. (4-2-08)

ii. The individual's date and place of birth. (4-2-08)

iii. The individual's occupations, positions of employment, and offices held during the past seven (7) years. (4-2-08)

iv. The principal business and address of any business, corporation, or other organization in which each such office of the individual was held or in which each such occupation or position of employments was carried on. (4-2-08)

v. Whether the individual during the past seven (7) years has been the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding. (4-2-08)

vi. Whether the individual during the past seven (7) years has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from either violating any federal or state law or regulation the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any such event. (4-2-08)

vii. A description of any involvement by the individual during the past seven (7) years with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products, and any lawsuits in which such businesses were named as a party and in which the individual was also a named party or, regardless of whether the individual was a named party, in which the individual testified in a deposition or testified as a witness at trial. ~~(4-2-08)~~( )

viii. A description of any felony criminal offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere. If the individual has a criminal conviction under appeal and a copy of the notice of appeal of that criminal offense is submitted to the Board, the licensee must submit to the Board within fifteen (15) days after disposition of the appeal a copy of the final written order of disposition. (4-2-08)

ix. A photograph of the individual taken in the previous year. (4-2-08)

02. License Required for Each Facility. If a wholesale distributor distributes prescription drugs from more than one (1) facility, the wholesale distributor shall obtain a license for each facility. (4-2-08)

03. Changes in Information Must Be Submitted to Board. Changes in, or corrections to, any information provided pursuant to Subsection 323.01 of these rules shall be submitted to the Board under oath at the time of license renewal. (4-2-08)

~~***04. Requirement for Bond or Equivalent Security**. Every wholesale distributor required to be licensed in this state shall submit to the Board a bond of not less than one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the Board and payable to the Board, such as an irrevocable letter of credit issued by a third party acceptable to the Board or a deposit in a trust account or financial institution acceptable to the Board. Chain pharmacy warehouses that are not engaged in wholesale distribution are exempt from the bond requirement. Such bond or equivalent security shall secure payment of any administrative fines or penalties imposed by the Board and any fees or costs incurred by the Board regarding that licensee when those fines, penalties, fees, or costs are authorized under the laws of this state and the licensee fails to pay thirty (30) days after the fines, penalties, fees, or costs become final. The Board may make a claim against such bond or equivalent security until one (1) year after the licensee's license cease to be valid. A single bond may suffice to cover all facilities operated by the licensee in this state. (4-2-08)~~

~~***05. Separate Fund for Deposit of Bonds**. The Board shall deposit the bonds required pursuant to Subsection 323.04 of these rules in a fund established by the Board separate from its other accounts. (4-2-08)~~

0~~6~~4. Accreditation by VAWD. The Board will recognize inspection and accreditation of wholesale distributors by the National Association of Board of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program. (4-2-08)

0~~7~~5. License by Reciprocity. The Board may license by reciprocity a wholesale distributor that is licensed under the laws of another state if: (4-2-08)

a. The wholesale distributor is accredited by the National Association of Board of Pharmacy's Verified-Accredited Wholesale Distributor's (VAWD) program; or (4-2-08)

b. The wholesale distributor is licensed under the laws of another state pursuant to standards comparable to those in Idaho and acceptable to the Board and the other state extends reciprocal treatment to distributors of this state. (4-2-08)

(BREAK IN CONTINUITY OF SECTIONS)

356. VETERINARY DRUG ORDERS.

01. Veterinary Orders for Legend Drugs. All veterinary orders for legend drugs issued to clients to be distributed by a retail veterinary drug outlet will be written on an official numbered three (3) part order form available through the Idaho Department of Agriculture. Such orders will be processed as follows: The practitioner (veterinarian) will retain the second copy in his records, original and one (1) copy will be sent to the retail veterinary drug outlet, the VDT will file the original copy in a readily retrievable manner and will attach the first copy to the order for delivery to the client. ~~(7-1-93)~~( )

02. Distribution of Veterinary Drugs. At no time will legend veterinary drugs be distributed to clients (customers) without the first copy of the practitioner order being attached in some manner. (7-1-93)

03. Retention of Drug Orders for Inspection. Original copies of drug orders will be retained by the establishment and made available for Board inspection for at least two (2) years from the date of processing. (7-1-93)

357. DRUG ORDERS.

01. Processing Veterinary Drug Orders. Veterinary drug orders are to be processed for no more than

the quantity indicated by the practitioner. (7-1-93)

a. No refilling or reprocessing is allowed. (7-1-93)

b. In the event of a split shipment, the VDT must indicate on the reverse of the original order the date, quantity and initials of the person supplying the partial order. Delivery of the remaining quantity must be made within ninety (90) days. (7-1-93)

02. Processing Orders as Written. Veterinary drug orders must be processed exactly as written by the practitioner. (7-1-93)

a. Supplying a different brand or product will be prima facie evidence of rule violation and will subject both the VDT and the establishment to disciplinary proceedings by the Board. (7-1-93)

b. Only original manufacturers' containers bearing the entire label intact may be delivered and no partial containers and no compounding is permitted by VDTs. (7-1-93)

03. Telephone Orders. To ensure proper processing and distribution of drug orders, telephone orders must be received directly by a VDT from a licensed practitioner. If the practitioner is not known to the VDT he must make a reasonable effort to determine that the oral authorization comes from a licensed practitioner, which may include a call back to the individual practitioner for verification. (7-1-93)

04. Oral Orders. ~~*Within seventy two (72) hours after receiving an*~~ All oral prescription orders ~~*the establishment will have on file at the place of distribution a written copy signed by the practitioner*~~ are subject to the following~~.~~: ~~*(7-1-93)*~~( )

a. ~~*Processing of*~~ Upon receiving an oral prescription order~~s, *will be identical to written orders in all other areas and will be*~~ the establishment shall promptly reduce~~d~~ the oral order to writing on an unnumbered telephone drug order form available through the Idaho Department of Agriculture ~~*telephone drug order blanks*~~. The establishment shall keep on file at the place of distribution the original of the completed form. ~~*(7-1-93)*~~( )

b. Following reduction of the oral order to writing, ~~S~~subsequent processing ~~*will*~~ of the order shall be identical to the procedure for written orders. ~~*(7-1-93)*~~( )

c. Within seventy-two (72) hours after receiving an oral prescription order, the establishment shall have on file at the place of distribution written confirmation of the oral order from the practitioner. Written confirmation must be copy one (1) of an official numbered three (3)-part order form available through the Idaho Department of Agriculture, signed by the practitioner. The written confirmation may be hand delivered, mailed, faxed, attached to an e-mail, or otherwise properly delivered to the Veterinary Drug Outlets (VDO). The VDO shall attach to the written confirmation the form completed by the VDO pursuant to Paragraph 357.04.a. of these rules. ( )

(BREAK IN CONTINUITY OF SECTIONS)

404. DUE JUNE 30, ANNUALLY -- TABLE.

01. Pharmacist License. (12-7-94)

a. Active: ninety dollars ($90). (3-13-02)

b. Inactive: fifty dollars ($50). (3-13-02)

02. Pharmacy. (6-1-94)

a. Pharmacy License: one hundred dollars ($100). (12-7-94)

b. Parenteral Admixture License: one hundred dollars ($100). (12-7-94)

03. Out-of-State Mail Service. (7-1-93)

a. Pharmacy, initial license: five hundred dollars ($500). (12-7-94)

b. Renewal license: two hundred fifty dollars ($250). (12-7-94)

04. Clinics and Nursing Homes. Thirty-five dollars ($35). (3-13-02)

05. Non-Pharmacy. (11-1-93)

a. "A": sixty dollars ($60). (3-13-02)

b. "B": twenty-five dollars ($25). (3-13-02)

c. "V" (Vending machines): ten dollars ($10). (3-13-02)

d. "DME": fifty dollars ($50). (7-1-98)

06. Hospitals Without Pharmacy. Thirty-five dollars ($35). (3-13-02)

07. Wholesaler (Distributor). One hundred dollars ($100). (12-7-94)

08. Controlled Substance for Wholesalers and Distributors. One hundred dollars ($100). (3-13-02)

09. Researcher, Analytical Lab. Forty dollars ($40). (3-13-02)

10. Retail Veterinary Drug Outlet - Retail or Retail/Wholesale. One hundred dollars ($100). (3-13-02)

11. Veterinary Drug Technician. Thirty-five dollars ($35). (12-7-94)

12. Pharmacy Technician. Thirty-five dollars ($35). (3-13-02)

13. Preceptor Site. Twenty-five dollars ($25). ( )

405. ~~*DUE APRIL 1 ANNUALLY*~~ STUDENT PHARMACIST REGISTRATION.

~~***01. Preceptor Site. Fee** - twenty five dollars ($25).*~~ ~~*(7-1-97)*~~

0~~2~~1. Intern. ~~*Fee - f*~~Fifty dollars ($50). ~~*(3-13-02)*~~( )

0~~3~~2. Extern. ~~*Fee - f*~~Fifty dollars ($50) at acceptance to accredited college of pharmacy, to last until July ~~*3*~~1~~5~~ following graduation. ~~*(3-13-02)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

469. PRESCRIPTION REPORTING.
All pharmacies which hold a DEA retail pharmacy registration will report by the first of every month or more often as directed by the Board, certain data, as required by the Board, on all Schedule II, III, IV, and ~~*I*~~V controlled substance prescriptions filled. The data may be reported in the form of diskette, direct computer link, magnetic tape or other method as approved by the Board. ~~*(4-2-08)*~~( )

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO BOARD OF PHARMACY

DOCKET NO. 27-0101-0802

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 Sections 54-1705(21) and 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 September 17, 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:

The proposed rule changes are necessary to further define pharmaceutical care in keeping with recent developments in the practice of pharmacy and allow the Board the flexibility to address future changes in the profession regarding pharmaceutical care services.

The proposed rule changes restructure the rule and substitute the term "pharmaceutical care" for "pharmacotherapy." The proposed rule incorporates in its definitions the statutory definition of "pharmaceutical care" and also defines both "drug therapy" and "other pharmaceutical patient care services," specifying that "collaborative pharmacy practice" is a form of "other pharmaceutical patient care services." It takes elements of current rules regarding Collaborative Practice Agreement and Contents of Agreement and combines them, with some changes, into a new rule designated Collaborative Pharmacy Practice and containing a section for "collaborative pharmacy practice agreement" and a section for "contents" of the collaborative practice agreement, along with sections for "initiation of the collaborative practice agreement" and "documentation of pharmacist activities."

The proposed rule provides definitions of "collaborative pharmacy practice," "collaborative pharmacy practice agreement," and "pharmacist's scope of practice pursuant to the collaborative practice agreement." It includes within the definition of "collaborative pharmacy practice agreement" the concept that a collaborative practice agreement is an agreement that provides for "collaborative pharmacy practice for the purpose of conducting drug therapy management services" as such services have been defined in the rules.

The proposed rule contains various definitions related to confidentiality of patient information, including: "health information," "HIPAA," "individually identifiable health information," and "protected health information."

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

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 IDAPA 04.11.01.811, 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 September 24, 2008.

DATED this 22nd day of July, 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. 27-0101-0802

165. ~~*PHARMACOTHERAPY*~~ PHARMACEUTICAL CARE.
~~*Collaborative practice between pharmacists and prescribing practitioners is allowed*~~ A licensed pharmacist's scope of pharmacy practice may include, but is not limited to, the provision of those acts or services necessary to provide pharmaceutical care as ~~*provided*~~ defined in ~~*this*~~ these rules. ~~*(7-1-99)*~~( )

01. Definitions. (7-1-99)

~~***b***~~**a.** Collaborative pharmacy practice. Means ~~*a*~~ that practice ~~*in which the prescribing practitioner makes a diagnosis, maintains ongoing supervision of patient care and refers the patient to a pharmacist, who may initiate and modify drug therapy management within the protocol established by the prescribing practitioner and the pharmacist*~~ of pharmacy whereby one (1) or more pharmacists have jointly agreed to work in conjunction with one (1) or more practitioners under protocol whereby the pharmacist may perform certain patient care functions authorized by the practitioner under certain specified conditions or limitations. ~~*(7-1-99)*~~( )

~~***a***~~**b.** Collaborative pharmacy practice ~~*A*~~agreement. Means a written and signed agreement between ~~*a pharmacist or group of*~~ one (1) or more pharmacists and ~~*a prescribing practitioner or group of prescribing*~~ one (1) or more practitioners that provides for collaborative pharmacy practice for the purpose of conducting drug therapy management ~~*of patients*~~ services, as defined in these rules. ~~*(7-1-99)*~~( )

c. Drug therapy management. Means ~~*the review of*~~ a distinct service or group of services that optimize therapeutic outcomes for individual patients. ~~*d*~~Drug therapy ~~*regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen*~~ management services are independent of, but can occur in conjunction with, the provision of a drug or a device. Drug therapy management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice. ~~*"Drug therapy management"*~~ These services may include~~s~~, but are not limited to, the following, according to the individual needs of the patient: ~~*(7-1-99)*~~( )

i. Performing or obtaining necessary assessments of the patient's health status. ( )

ii. Formulating a drug treatment plan. ( )

iii. ~~*Implementing*~~ Selecting, initiating, modifying, ~~*and managing*~~ or administering drug therapy ~~*according to the terms of the agreement;*~~. ~~*(7-1-99)*~~( )

~~*ii. Collecting and reviewing patient drug histories;* *(7-1-99)*~~

~~*iii. Obtaining and checking vital signs, including pulse, temperature, blood pressure, and respiration; and* *(7-1-99)*~~

iv. ~~*Ordering and evaluating the results of laboratory tests directly relating to drug therapy, when*~~

~~*performed in accordance with approved protocols applicable to the practice setting.*~~ Monitoring and evaluating the patient's response to therapy, including safety and effectiveness. ~~*(7-1-99)*~~( )

iv. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness. ( )

v. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events. ( )

vi. Documenting the care delivered and communicating essential information to the patient's other primary care providers. ( )

vii. Providing information, support services and resources designed to enhance patient adherence with his therapeutic regimens. ( )

viii. Coordinating and integrating drug therapy management services within the broader health care-management services being provided to the patient. ( )

ix. Such other drug therapy management services as may be allowed by law. ( )

d. Health information. Means any information, whether oral or recorded in any form or medium, that: ( )

i. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse, and ( )

ii. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual. ( )

e. HIPAA. Means the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) and any amendments thereof. ( )

f. Individually identifiable health information. Means information that is a subset of health information, including demographic information collected from an individual and: ( )

i. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and ( )

ii. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual that: ( )

(1) Identifies the individual; or ( )

(2) With respect to which there is a reasonable basis to believe the information can be used to identify the individual. ( )

g. Other pharmaceutical patient care services. Means services that may include, but are not limited to, the following: ( )

i. Collaborative pharmacy practice. ( )

ii. Such other pharmaceutical patient care services as may be allowed by law. ( )

h. Pharmaceutical care. Means the provision by a pharmacist of drug therapy management services and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in these rules. ( )

~~e~~i. Pharmacist's scope of practice pursuant to the collaborative practice agreement. Means those duties and limitations of duties placed upon ~~a~~ one (1) or more pharmacists by the collaborati~~ng~~ve practitioner or practitioner, the Board, and applicable law, and includes the limitations implied by the ~~specialty practiced by~~ scope of practice of the collaborating practitioner or practitioners. ~~(7-1-99)~~( )

~~d~~j. ~~Prescribing p~~Practitioner. Means~~, a practitioner in active practice duly~~ for purposes of Section 165, an individual currently licensed, registered, or otherwise authorized ~~and recognized by law~~ in Idaho to prescribe ~~legend~~ and administer drugs ~~and controlled substances~~ in the course of professional practice. ~~(7-1-99)~~( )

k. Protected health information. Means individually identifiable health information that, except as provided in Subparagraph 165.01.k.iv. of this rule, is: ( )

i. Transmitted by electronic media. ( )

ii. Maintained in any medium described in the definition of electronic media at 45 CFR 162.103 (HIPAA privacy rules). ( )

iii. Transmitted or maintained in any other form or medium. ( )

iv. Protected health information excludes individually identifiable health information in: ( )

(1) Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1231(g)); ( )

(2) Records described at 20 U.S.C. Section 1231 (g)(4)(B)(iv); and ( )

(3) Employment records held by a licensee in its role as an employer. ( )

02. Collaborative Pharmacy Practice ~~Agreement~~. ~~A pharmacist planning to engage in collaborative practice shall have on file at his place of practice a written agreement. The agreement may allow the pharmacist, within the pharmacist's scope of practice, to conduct a drug therapy management which must be approved by a prescribing practitioner. The collaboration that the prescribing practitioner agrees to conduct with the pharmacist must be within the scope of the prescribing practitioner's current practice.~~ Collaborative pharmacy practice is subject to the following requirements: ~~(7-1-99)~~( )

a. Collaborative pharmacy practice agreement. A pharmacist planning to engage in collaborative pharmacy practice shall have on file at his place of practice the written collaborative pharmacy practice agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the collaborative pharmacy practice agreement including the agreement itself, shall be made available to the Board for review upon request. The agreement may allow the pharmacist, within the pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement, to conduct drug therapy management services approved by the practitioner, and as defined by these rules. The collaboration that the practitioner agrees to conduct with the pharmacist must be within the scope of the practitioner's current practice. Patients or caregivers shall be advised of such agreement. ( )

b. Contents. The collaborative pharmacy practice agreement shall include: ( )

i. Identification of the practitioner and pharmacist who are parties to the agreement. ( )

ii. The types of drug therapy management decisions that the pharmacist is allowed to make. ( )

iii. A method for the practitioner to monitor compliance with the agreement and clinical outcomes and to intercede where necessary. ( )

iv. A provision that allows the practitioner to override a collaborative practice decision made by the pharmacist whenever he deems it necessary or appropriate. ( )

v. A provision that allows either party to cancel the agreement by written notification. ( )

vi. An effective date. ( )

vii. Signatures of each collaborating pharmacist and practitioner who are parties to the agreement, as well as dates of signing. Amendments to a collaborative pharmacy practice agreement must be documented, signed, and dated. ( )

c. Initiation of the collaborative practice agreement. The collaborative pharmacy practice agreement must be coupled with a medical order from the practitioner to initiate allowed activities for any particular patient. ( )

d. Documentation of pharmacist activities. Documentation of allowed activities must be kept as part of the patient's permanent record and must be readily available to other health care professionals providing care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered protected health information. ( )

~~***03. Contents of Agreement**. The agreement shall include: (7-1-99)*~~

~~***a.** A statement identifying the prescribing practitioners and the pharmacists who are a party to the agreement; (7-1-99)*~~

~~***b.** A statement of the types of drug therapy management decisions that the pharmacist is allowed to make, which may include: (7-1-99)*~~

~~*i. A detailed statement of the types of diseases, drugs, or drug categories involved, and the type of drug therapy management allowed in each case; (7-1-99)*~~

~~*ii. A detailed statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting drug therapy management; and (7-1-99)*~~

~~*iii. A statement of the activities the pharmacist is to follow in the course of conducting drug therapy management, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the prescribing practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur in the prescribing practitioners patient medical chart and may occur on the prescription record, patient profile, a separate log book, or in some other appropriate system; (7-1-99)*~~

~~***c.** A method for the prescribing practitioner to monitor compliance with the agreement and clinical outcomes where drug therapy management by the pharmacist has occurred and to intercede where necessary; (7-1-99)*~~

~~***d.** A provision that allows the prescribing practitioner to override the agreement whenever he deems it necessary or appropriate; and (7-1-99)*~~

~~***e.** The agreement must be coupled with specific orders from the prescribing practitioner to apply such agreement as drug therapy management to any particular patient. The order must constitute a valid drug order or a valid prescription and contain all information necessary to conform to such requirements. (7-1-99)*~~

~~***04.~~ e. Review~~, Renewal, and Revision of Agreement***. At a minimum, the written agreement shall be reviewed and renewed, and if necessary, revised every year. ~~*(7-1-99)*~~( )

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO BOARD OF PHARMACY

DOCKET NO. 27-0101-0803

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 September 17, 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:

The proposed changes are necessary to clarify the grounds upon which pharmacy technicians are subject to discipline, the sanctions which may be imposed, and the procedures for reinstatement. The proposed rule changes specify the grounds upon which the Board may refuse to issue or renew, or to suspend, revoke or restrict the registration of a pharmacy technician - the grounds being analogous to the grounds provided in Section 54-1726, Idaho Code, for discipline of licensed pharmacists. The proposed rule changes also specify the penalties the Board may impose upon finding the existence of grounds for discipline of any person holding a pharmacy technician registration.

FEE SUMMARY: Pursuant to Section 67-5226(2), the Governor has found that the fee or charge being imposed or increased is justified and necessary to avoid immediate danger and the fee is described herein: N/A

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 Section 67-5220(2), 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 September 24, 2008.

DATED this 22nd day of July, 2008.

Mark D. Johnston, R.Ph.
Executive Director
Idaho Board of Pharmacy
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THE FOLLOWING IS THE TEXT OF DOCKET NO. 27-0101-0803

251. PHARMACY TECHNICIANS.

01. Definition -- Pharmacy Technician. Means an individual, registered with the Board who is employed or otherwise authorized by a pharmacy registered with the Board to perform routine functions, that do not require the use of a licensed pharmacist's professional judgment, in connection with the preparing, compounding, distribution or dispensing of medications at such pharmacy, and who has been adequately trained therefor according to the written standards of such pharmacy. Such written standards shall be available to the Board and its designated personnel for inspection or approval, or both. (5-3-03)

02. Responsibility of Pharmacy and Pharmacist -- Assignment of Functions. (4-5-00)

a. The pharmacy and the pharmacist-in-charge are each responsible for all aspects of the sale at retail and the dispensing of medications, drugs, devices, and other materials at the pharmacy, including the preparing, compounding, distribution or dispensing of medications. No pharmacy or pharmacist may allow assignment to, or permit performance by, any individual, other than a registered pharmacy technician, a registered pharmacist extern/intern, or a licensed pharmacist, of any functions connected to the preparing, compounding, distribution or dispensing of medications at the pharmacy. (5-3-03)

b. The pharmacy or the pharmacist-in-charge may assign to, or allow performance by, a registered pharmacy technician only those functions connected with the preparing, compounding, distribution or dispensing of medications, which meet all of the following criteria: (5-3-03)

i. The function is routine; (4-5-00)

ii. The function is one for which the pharmacy technician is adequately trained and supervised; and (4-5-00)

iii. The function does not require the use of a licensed pharmacist's professional judgment. (4-5-00)

c. Only a registered pharmacist may do any of the following (which, without limiting the scope of the term "professional judgment," is a non-exclusive list of actions requiring a licensed pharmacist's professional judgment): (4-5-00)

i. Receive a new prescription order verbally from a prescriber or other person authorized by law. (4-5-00)

ii. Perform evaluations and interpretations of a prescription and any needed clarifications prior to filling. (4-5-00)

iii. Consult with the prescriber concerning any necessary clarification regarding a patient and his prescription. (4-5-00)

iv. Interpret any clinical data in a patient's medication record system (for example, drug usage, refill frequency, drug interactions, etc.) (7-1-93)

v. Perform professional consultation with any prescriber, nurse or other health care professional. (7-1-93)

vi. Supervise the packaging of drugs and check the completed procedure and product. (7-1-93)

vii. Issue the new prescription to the patient or his agent with consultation. (7-1-93)

viii. Supervise the activities of pharmacy technicians to insure that all such activities are performed completely, safely and without risk or harm to patients. (4-5-00)

d. A violation of the rules on pharmacy technicians by a pharmacist or a pharmacy is unprofessional conduct, and is grounds for revocation or suspension of the pharmacist's license or the pharmacy registration, or both,

issued under Sections 54-1722, 54-1723, 54-1724 or 54-1729, Idaho Code, or other appropriate disciplinary action. (4-5-00)

03. Supervision. Where a pharmacy technician performs one (1) or more functions in connection with the preparing, compounding, distribution or dispensing of medications, the pharmacy technician shall be under the supervision of a licensed pharmacist who, in addition to the pharmacy and the pharmacist-in-charge, shall be responsible for all aspects of the filled prescription including, but not limited to, the following: (4-5-00)

a. Verifying drug selection, strength, dosage form and labeling against the prescription and the contents of stock container. (7-1-93)

b. Verifying selection of the proper prescription container. (7-1-93)

04. Pharmacy Technician Ratio. The ratio of pharmacists to pharmacy technicians shall be not less than one (1) pharmacist for every three (3) pharmacy technicians in any practice setting. (4-6-05)

05. Responsibility of Pharmacy Technicians and Grounds for Discipline. ~~*(4-5-00)*~~( )

a. Pharmacy technicians shall perform all functions properly assigned to them with all necessary care. No pharmacy technician shall accept assignment of, or perform, any functions connected with the preparing, compounding, distribution or dispensing of medications unless such pharmacy technician is employed or otherwise authorized by the assigning pharmacy and such function meets all of the criteria set forth in Paragraph 251.02.b of these rules. (5-3-03)

b. The Board may initiate proceedings against pharmacy technicians who perform such tasks or functions connected with the preparing, compounding, distribution or dispensing of medications: (4-5-00)

i. That are not routine functions; (4-5-00)

ii. That the pharmacy technician is not adequately trained and supervised for; or (4-5-00)

iii. That require the use of a licensed pharmacist's professional judgment. Such persons may be charged by the appropriate authorities with practicing pharmacy without a license in violation of Section 54-1726, Idaho Code. (4-5-00)

c. The Board may ~~*initiate proceedings against pharmacy technicians who perform such tasks or functions connected with the preparing, compounding, distribution or dispensing of medications in a negligent or improper manner or otherwise violate the rules on pharmacy technicians. Such violations shall be grounds for revocation or suspension of*~~ refuse to issue or renew, or may suspend, revoke, or restrict the pharmacy technician~~'s~~ registration~~, or other appropriate disciplinary action.~~ of any person upon one (1) or more of the following grounds: ~~*(4-5-00)*~~( )

i. Unprofessional conduct as the term is defined in these rules. ( )

ii. Incapacity of a nature that prevents a pharmacy technician from performing the functions of a pharmacy technician with reasonable skill, competence, and safety to the public. ( )

iii. Being found guilty, convicted, or having received a withheld judgment or suspended sentence by a court of competent jurisdiction in this state or any other state for one (1) or more of the following: ( )

(1) Any felony. ( )

(2) Any act involving moral turpitude, gross immorality, or which is in relation to the qualifications, functions, or duties of a pharmacy technician. ( )

(3) Violations of the pharmacy or drug laws of this state, these rules, or of statutes, rules, or regulations of any other state or of the federal government. ( )

iv. Fraud or intentional misrepresentation by a registrant in securing the issuance or renewal of a pharmacy technician registration. ( )

v. Being found by the Board to be in violation of any of the provisions of Title 54, Chapter 17, Idaho Code, Title 37, Chapter 27, Idaho Code, or of these rules. ( )

06. Identification of Pharmacy Technicians. (7-1-99)

a. All pharmacy technicians working as such in community pharmacies must be identified by a name badge designating that person as a pharmacy technician. The name badge must measure no less than one (1) inch by three (3) inches and must contain the individual's printed name directly above the title of pharmacy technician. The identification badge must be clearly visible at all times. Pharmacy technicians working in an institutional setting may be exempt from the above requirement only if the institution requires a specific badge of identification to be worn by the pharmacy technician. (4-5-00)

b. All pharmacy technicians must identify themselves as a pharmacy technician on any phone calls initiated or received by them while performing pharmacy functions. (7-1-99)

07. Registration of Pharmacy Technician. (4-5-00)

a. Annual Registration. All pharmacy technicians shall register annually with the Board. The Board will develop an appropriate annual registration notice and annual registration form to be mailed to all registered pharmacy technicians prior to June 1 of each year. The notice will state the annual pharmacy technician registration renewal fee. (4-5-00)

b. Initial Registration. Before commencing duties at a pharmacy as a pharmacy technician (including previously registered pharmacy technicians who are changing pharmacies), an individual must register with the Board, pay the registration fee, and have received a certificate of registration from the Board, provided however, an individual who has not previously had his registration as a pharmacy technician revoked or suspended may commence performing duties as a pharmacy technician immediately upon the completion and mailing of the registration form and applicable fee to the Board. The initial registration period shall be from the date of initial registration to the next annual registration date. (5-3-03)

c. Contents of Registration Form. The annual registration form and the initial registration form shall be prepared by the Board, and shall require such information regarding the individual and the employing or authorizing pharmacy as the Board may reasonably require. In addition, registration shall include the statement of the pharmacy owner (or an authorized agent of the pharmacy owner), and of the pharmacist-in-charge that either: (5-3-03)

i. The individual has been adequately trained by the pharmacist-in-charge, or by the pharmacy, to perform those routine functions in connection with the preparing, compounding, distribution or dispensing of medications as are, or will be, assigned to such individual; (4-5-00)

ii. The pharmacist-in-charge or the pharmacy owner has verified that such individual possesses adequate training to perform those routine functions in connection with the preparing, compounding, distribution or dispensing of medications as are, or will be, assigned to such individual; or (4-5-00)

iii. Such individual will be adequately so trained prior to the assignment of any routine functions in connection with the preparing, compounding, distribution or dispensing of medications. (4-5-00)

08. Discipline Procedure, Penalties, and ~~*Appeal*~~ Reinstatement. Any proceedings by the Board against any pharmacy technician shall comply in all respects with the Administrative Procedure Act, Title 67, Chapter 52, Idaho Code. Upon finding of the existence of grounds for discipline of any person holding a pharmacy technician registration, or seeking a pharmacy technician registration or a renewal registration under these rules, the Board may impose one (1) or more of the penalties provided for in Section 54-1728, Idaho Code. Petitions for reinstatement shall be subject to the requirements of Section 54-1728(2), Idaho Code. ~~*(4-5-00)*~~( )

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO BOARD OF PHARMACY

DOCKET NO. 27-0101-0804

NOTICE OF RULEMAKING - TEMPORARY AND PROPOSED RULE

EFFECTIVE DATE: The effective date of the temporary rule is September 3, 2008.

AUTHORITY: In compliance with Sections 67-5221(1) and 67-5226, Idaho Code, notice is hereby given that this agency has adopted a temporary rule, and proposed rulemaking procedures have been initiated. The action is authorized pursuant to Section 65-202, 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 September 17, 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 the required finding and concise statement of its supporting reasons for adopting a temporary rule and a nontechnical explanation of the substance and purpose of the proposed rulemaking: The proposed rules are necessary to comply with changes in federal statute. The proposed rule change would strike the language of the existing rule and substitute language requiring that no Schedule II order shall be filled more than ninety (90) days after the date the order was written.

TEMPORARY RULE JUSTIFICATION: Pursuant to Section 67-5226(1)(b), Idaho Code, the Governor has found that temporary adoption of the rule is appropriate for the following reasons: The rule change is necessary to comply with changes in federal statutes.

FEE SUMMARY: Pursuant to Section 67-5226(2), the Governor has found that the fee or charge being imposed or increased is justified and necessary to avoid immediate danger and the fee is described herein: N/A

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: N/A

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, negotiated rulemaking was not conducted because of the need for temporary 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 September 24, 2008.

DATED this 22nd day of July, 2008.

Mark D. Johnston, R.Ph.
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THE FOLLOWING IS THE TEXT OF DOCKET NO. 27-0101-0804

458. TIME FOR FILLING PRESCRIPTION.

No ~~*person shall fill a prescription for a controlled substance listed in Schedule II unless the prescription is tendered to him on or before the thirtieth day following the date of issue*~~ order shall be filled more than ninety (90) days after the date the order was written. ~~*(5-3-03)*~~(9-3-08)T