Dear Senators LODGE, Broadsword & LeFavour, and
Representatives BLOCK, Nielsen & Rusche:

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

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket Nos. 27-0101-0901 and 27-0101-0903 through 27-0101-0908).

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 11-13-09. 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 12-11-09.

_____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 26, 2009

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket Nos. 27-0101-0901 and 27-0101-0903 through 27-0101-0908) (Proposed)

The Board of Pharmacy submits Docket Nos. 27-0101-0901 and 27-0101-0903 through 27-0101-0908 (hereinafter individually and collectively "proposed rule"), amending various provisions of the Board's chapter of rules found at IDAPA 27.01.01. The purpose of the rulemaking varies with the docket number. According to the Board:

> Docket No. 27-0101-0901 requires licensees to provide the Board with notice of any changes of name, address or telephone number within ten days.
>
> Docket No. 27-0101-0903 requires pharmacies to notify the Board in writing of their hours of operation and of any change in those hours at least 30 days prior to commencing new hours of operation.
>
> Docket No. 27-0101-0904 provides standards and procedures for the transfer, acceptance, storage, inspection, distribution and dispensing of donated drugs and provisions to enforce the Idaho Legend Drug Donation Act.
>
> Docket No. 27-0101-0905 allows pharmacists to provide up to a three-month supply of legend drugs that are not controlled substances, when a prescription is written for a smaller supply but includes refills sufficient to equal the larger supply.
>
> Docket No. 27-0101-0906 allows a pharmacist to provide pharmaceutical care outside a licensed pharmacy under certain conditions.

Docket No. 27-0101-0907 adds repackagers who are authorized distributors of record for Federal Drug Administration registered manufacturers to the definition of "normal distribution channel."

Docket No. 27-0101-0908 clarifies that a pharmacy may transfer a prescription to another pharmacy without first having to fill it and clarifies the record keeping responsibility of the receiving pharmacy.

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.

Additional authority available to the Board includes sections 37-2715, 54-1753 and 54-1763, 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 54-1753(1), Idaho Code, requires every wholesale distributor who engages in wholesale distribution of prescription drugs to be licensed by the Board, with exceptions. Section 54-1763, Idaho Code, part of the Idaho Legend Drug Donation Act, requires the Board to adopt rules necessary for the implementation and enforcement of the program established under that Act and for the enforcement of Board rules promulgated thereunder.

According to the Board, no fee or charge is imposed by the 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 proposed rule. According to the Board, negotiated rulemaking was not conducted because of the simple nature of the rulemaking or, with respect to Docket No. 27-0101-0904, because negotiated rulemaking was not feasible, although Board staff did solicit information from charitable clinics to consider in developing the standards and procedures required by the Idaho Legend Drug Act.

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 21, 2009. All written comments must be delivered to the Board on or before October 28, 2009.

ANALYSIS

A. Docket No. 27-0101-0901

The proposed rule creates a new duty for every licensee and registrant to provide the Board with notice of any change to the licensee's or registrant's name, address or telephone number within ten days of the change. Section 142.03. The proposed rule also states that failure to fulfill any of the listed duties may constitute a violation of section 54-1726(a), Idaho Code, which permits the Board to refuse to issue or renew or to suspend, revoke or restrict a license for unprofessional conduct.

B. Docket No. 27-0101-0903

The proposed rule requires a pharmacy to notify the Board of the hours that it is open for business and requires notification to the Board of a desired change of hours at least 30 days prior to the change. Notification must be on a Board prescribed form. The proposed rule further requires that a pharmacy must prominently display and remain open during these hours with sufficient pharmacist staff during these hours. Section 180.08.

C. Docket No. 27-0101-0904

A new section 380 listing standards and procedures is provided by the proposed rule. In order for a drug to be eligible for donation, it must meet listed criteria dealing with identification, FDA approval and restriction, packaging, not subject to a recall and storage. Donation standards regarding responsibility, limitations on drugs eligible for donation, certification and listing requirements and copy requirements are stated. Verification, documentation and storage requirements are detailed. Limitations on what drug may be distributed to a medically indigent patient are prescribed as well as how such drugs are to be dispensed. Record keeping requirements are stated. Miscellaneous standards include the requirement that a licensed pharmacist or physician be on duty during all hours of operation of the charitable clinic or center and the prohibition on resale, trade or transfer of donated drugs. However, the proposed rule provides that an indigent may be charged a dispensing fee.

D. Docket No. 27-0101-0905

An exception to the unprofessional conduct section 184 allows a pharmacist, utilizing his best professional judgment, to provide up to a three-month supply of a legend drug that is not a controlled substance, when the practitioner has written a drug order to be filled with a smaller supply but includes refills in sufficient numbers to fill a three-month supply.

E. Docket No. 27-0101-0906

Section 165, regarding pharmaceutical care, is amended by the proposed rule to address pharmaceutical care by a licensed pharmacist outside a licensed pharmacy. Such independent practice is permitted if certain criteria regarding secure access to information and record keeping are collectively met.

F. Docket No. 27-0101-0907

This proposed rule modifies the definition of "normal distribution chain" to include within the chain of custody a prescription drug that goes from a manufacturer directly or through its co-licensed partner, third-party logistics provider or exclusive distributor to an authorized repackager whose facility is registered with the FDA and who engages in repackaging the original dosage in accordance with applicable FDA regulations and guidelines. Section 321.11.

G. Docket No. 27-0101-0908

The Board's rule regarding prescription transfer are amended by this proposed rule to describe that a receiving pharmacy that utilizes a computer prescription database that contains all of the prescription information required by law or rule must generate a hard copy to be treated as a new prescription. The proposed rule goes on to say that the pharmacy may enter the information required under the rule into its prescription database in lieu of writing the information on the hard copy of the prescription. Section 160.05. This rule appears to be contradictory.

SUMMARY

The Department's proposed rule change appears to be authorized under sections 54-1717, 37-2715, 54-1753(1) and 54-1763, Idaho Code.

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

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0901

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 21, 2009.

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:

Current licensee contact information is essential to a successful regulatory process. The current Board of Pharmacy rules do not require licensees to provide updates on a timely basis. The proposed rules will amend the standards of conduct to require licensees to provide the Board with notice of any changes to the licensee's name, address, or telephone number within ten (10) business days from the date of any such change.

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

No fees or charges are being imposed or increased through this rulemaking.

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:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, 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 28, 2009.

DATED this 28th day of August 2009.

Mark Johnston, R.Ph.
Executive Director
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 PROPOSED TEXT OF DOCKET NO. 27-0101-0901

142. ~~*STANDARDS OF CONDUCT*~~ PROFESSIONAL RESPONSIBILITIES.
A failure to fulfill any of the following duties may constitute a violation of Section 54-1726(a), Idaho Code.
( )

01. Duty to Cooperate in Investigation. It is the duty of every licensee and registrant to cooperate with a disciplinary investigation, and any failure or refusal to do so is grounds for disciplinary action. ~~*(4-6-05)*~~( )

02. Duty to Report Theft, Loss, or Adulteration. It is the duty of every pharmacist-in-charge or pharmacy director to report any theft or loss of controlled substances and any adulteration of any prescription drug to the Board, even if the theft, loss, or adulteration has been accounted for and the employee disciplined internally. The report of theft or loss, required hereunder, shall contain all of the information reported to the Drug Enforcement Administration (DEA), as required under 21 CFR 1301.74(c), and shall be reported to the Board at the same time it is reported to the DEA. (3-30-07)

03. Duty to Provide Current Contact Information. It is the duty of every licensee and registrant to provide the Board with notice of any change to the licensee's or registrant's name, address, or telephone number within ten (10) business days from the change. ( )

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0903

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 21, 2009.

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 rulemaking is necessary to alleviate any public safety issues that may be created by pharmacies not being open during their established hours of operation. The proposed rules will require pharmacies to notify the Board of Pharmacy in writing of their hours of operation and to notify the Board of any change in those hours at least thirty (30) days prior to commencing new hours of operation. The rules will require pharmacies to remain open during their stated hours of operation and to maintain sufficient staffing to ensure pharmacies are open during their stated business hours.

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

No fees or charges are being imposed or increased through this rulemaking.

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:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, 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 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
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 PROPOSED TEXT OF DOCKET NO. 27-0101-0903

180. DIFFERENTIAL HOURS.

01. Security at Pharmacy. A pharmacy must provide adequate security for its drug supplies, equipment, and records and in the absence of a pharmacist, the pharmacy must be closed. If a pharmacy is located within a larger business establishment that is open to the public for business at times when a pharmacist is not present, the pharmacy must be totally enclosed by a partition, such as a glass or metal mesh screen or a security fence, that is sufficient to provide adequate security for the pharmacy, as approved by the Board or its representatives. In the absence of a pharmacist, the pharmacy must be locked. Employees of the business establishment may not be authorized to enter the closed pharmacy during those hours that the business establishment is open to the public for business. (7-1-93)

02. Equipment, Records, Drugs, and Other Items. All equipment and records referred to in these rules and all drugs, devices, poisons, and other items or products that are restricted to sale either by or under the personal supervision of a pharmacist must be kept in the pharmacy area. (7-1-93)

03. Prescription Orders and Refill Requests. Written prescription orders and refill requests can be delivered to a pharmacy at any time. If no pharmacist is present, the prescription orders must be deposited by the patient, or his agent delivering the prescription order or refill request, into a "mail slot" or "drop box" that deposits the prescription order into the pharmacy area. The times that the pharmacy is open for business must be displayed in a manner that is prominently visible to the person depositing the prescription order. (7-1-93)

04. Storage of Prescriptions. Prescriptions shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place. (7-1-93)

05. Sale Restrictions. No drugs, devices, poisons, or other items or products that are restricted to sale either by or under the personal supervision of a pharmacist may be sold or delivered without a pharmacist being present in the pharmacy. (7-1-93)

06. Separate Telephone. Any pharmacy having hours differing from the remainder of a business shall have a separate and distinct telephone number from that of the business. The telephone shall not be answerable in the remainder of the establishment unless all telephone conversations during a pharmacist's absence are recorded and played back by the pharmacist. (7-1-93)

07. Oral Prescriptions. An oral prescription may not be accepted if the pharmacist is not present unless the prescription is taken on a recording that must inform the caller of the times the pharmacy is open. (7-1-93)

08. Hours Open for Business. A pharmacy must notify the Board, on a form prescribed by the Board, of the hours that the pharmacy is open for business. Any pharmacy desiring to change the hours that it is open for business, must notify the Board, on a form prescribed by the Board, at least thirty (30) days prior to commencing such hours. A pharmacy must prominently display in a permanent manner on or adjacent to its entrance the hours it is open for business. A pharmacy must remain open for business the hours for which the Board has received such notification and that are prominently displayed. A pharmacy must maintain sufficient staffing by pharmacists in order to ensure that the pharmacy will be open during the hours of operation for which the pharmacy provided notice to the Board. If a pharmacy is located within a larger business establishment that has hours of operation different from the pharmacy, the hours the pharmacy is open for business shall be prominently displayed, in a permanent manner, at the pharmacy area and on, or adjacent to, the entrance to the mercantile establishment. ~~(7-1-93)~~( )

09. Advertising. Any advertising by the business establishment that references the pharmacy or products sold only in the pharmacy, and that includes the hours that the business establishment is open to the public for business, must also indicate the hours that the pharmacy is open to the public for business. (7-1-93)

10. Notification to the Board of Differential Hours. Any person desiring to operate a pharmacy within an establishment having hours of business differing from the pharmacy, must notify the Board at least thirty (30) days prior to commencing such differential hours. To constitute notification, the applicant must complete and file the form provided by the Board with the required information. Board inspection and approval shall be completed prior to commencing differential hours. The inspection and approval or disapproval shall be completed within ten (10) days of receiving notification that the premises are ready for inspection. Approval or disapproval shall be predicated upon compliance with this rule and the pharmacy minimum standards set forth in Section 151 of these rules. (7-1-93)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0904

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 21, 2009.

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 Idaho Legend Drug Donation Act requires the Board of Pharmacy to promulgate rules to develop and implement the program. The proposed rules will provide standards and procedures for the transfer, acceptance, and storage of donated drugs; for inspecting donated drugs; for distribution of donated drugs; for dispensing of donated drugs; and provisions to enforce the Idaho Legend Drug Donation Act.

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

No fees or charges are being imposed or increased through this rulemaking.

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:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was not conducted to seek consensus on the content of the rule.

The Idaho Legend Drug Act, which went into effect on July 1, 2009, mandated that the Board adopt rules necessary for implementation and enforcement of the program established by the Legislature, and listed five subject areas for which the Board was to adopt rules. Negotiated rulemaking was not feasible in this context. Board staff, however, did solicit information from charitable clinics to consider in developing the standards and procedures required by the statute.

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 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
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 PROPOSED TEXT OF DOCKET NO. 27-0101-0904

366. -- ~~400~~379. (RESERVED).

380. LEGEND DRUG DONATION – STANDARDS AND PROCEDURES.

01. Drug Donation Criteria. In order to be eligible for donation, drugs must meet the following criteria: ( )

a. The drug name, strength, lot number, and expiration date must appear on the drug package or label. ( )

b. Donated drugs must be approved by the federal Food and Drug Administration and: ( )

i. Be sealed in the manufacturer's unopened original tamper-evident packaging and either: ( )

(1) Individually packaged, or ( )

(2) Packaged in unit-dose packaging; ( )

ii. Be oral or parenteral drugs in sealed single-dose containers approved by the federal Food and Drug Administration; ( )

iii. Be topical or inhalant drugs in sealed units-of-use containers approved by the federal Food and Drug Administration; or ( )

iv. Be parenteral drugs in sealed multiple-dose containers approved by the federal Food and Drug Administration from which no doses have been withdrawn. ( )

c. Donated drugs must not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug wholesaler or manufacturer. ( )

d. Donated drugs must not require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia, because of the potential for these drugs to become adulterated. ( )

e. Donated drugs must not be the subject of federal Food and Drug Administration restricted drug distribution programs, including but not limited to thalidomide and lenalidomide. ( )

02. Donation Standards. ( )

a. The licensed pharmacist or physician at the charitable clinic or center will be responsible for defining a specified set of drugs that will be included in their formulary. ( )

b. Donating entities may only donate drugs that appear on the charitable clinic or center's formulary. ( )

c. A licensed pharmacist, nurse, or physician from the donating entity must sign and date a manifest before delivery of the donated drugs to the charitable clinic or center that: ( )

i. Certifies that the drugs have been maintained in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and the United States Pharmacopoeia standards; ( )

ii. Certifies that the donated drugs have been continuously under control of a health care professional

and have never been in the custody of a patient or other individual; ( )

iii. Certifies that the donating entity has only donated drugs on the charitable clinic or center's formulary; ( )

iv. Certifies that the donating entity has complied with the provisions of these rules; ( )

v. Certifies that the patient's name, prescription number, and any other identifying marks have been removed or redacted from the package by the donating entity; ( )

vi. Lists the names of the donating entity and the name of the receiving charitable clinic or center; and ( )

vii. Lists the name, strength, expiration date, lot number, and quantity of each prescription drug to be donated. ( )

d. A copy of the manifest must be delivered to the charitable clinic or center with the donated drugs. ( )

03. Receipt of Donated Drugs. ( )

a. A licensed pharmacist must verify that donated drugs meet the criteria in Subsection 380.01 of these rules, and upon receipt must: ( )

i. Verify utilizing a current drug identification book, a computer program, or an online service for the same that the drug name and strength noted on the label of each unit of the packaged, donated drug is correct; and ( )

ii. Determine that donated drugs are not adulterated or misbranded and are safe to dispense. ( )

b. Improperly donated drugs that do not meet criteria in Subsections 380.01 or 380.03 of these rules must be destroyed, and documentation of such destruction must be maintained within a destruction record. ( )

c. A licensed pharmacist at the charitable clinic or center must document receipt of each donated drug on each manifest. ( )

d. In the event that the identifying patient information is not removed by the donating entity, the pharmacist at the charitable clinic or center must remove or redact that information. ( )

04. Storage of Donated Drugs. ( )

a. Drug storage must have proper environmental controls to assure the integrity of the drug in accordance with the drug manufacturer's recommendations and United States Pharmacopoeia standards. ( )

b. Donated drugs may be commingled with the charitable clinic or center's regular stock of drugs only if the packaging on the donated drugs has been labeled to show that the drugs were obtained through a donating entity. ( )

c. Donated drugs with packaging that has not been labeled to show that the drugs were obtained through a donating entity must be kept in an area that is separately designated from the charitable clinic or center's regular stock of drugs. ( )

d. The space in which drugs are stored must be locked at all times except during operating hours or other time when a licensed pharmacist or physician is physically present in the charitable clinic or center. ( )

05. Dispensing Donated Drugs to Medically Indigent Patients. ( )

a. Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions must not be re-dispensed to indigent patients and must be destroyed. Documentation of such destruction must be maintained within a destruction record. ( )

b. A pharmacist or physician working at a charitable clinic or center who re-dispenses donated drugs to any patient must: ( )

i. Utilize a proper and appropriate container; ( )

ii. Place a label on the container that conforms to provisions of these rules; and ( )

iii. Initial the prescription label. ( )

c. The re-dispensed drug must be assigned the same expiration date as is on the original package. ( )

d. A charitable clinic or center must maintain dispensing records for each donated drug dispensed. ( )

e. Pharmacists or physicians dispensing donated drugs are required to provide patient counseling. ( )

06. Miscellaneous. ( )

a. A licensed pharmacist or physician must be on duty during all hours of operation of the charitable clinic or center. ( )

b. Legend drugs donated under these rules must not be sold, resold, offered for sale, traded, or transferred to another charitable clinic or center. ( )

c. Nothing in these rules precludes a charitable clinic or center from charging an indigent patient a dispensing fee. ( )

07. Record Keeping Requirements. ( )

a. Donating entities must maintain all manifests in a readily retrievable fashion for at least two (2) years. ( )

b. Charitable clinics or centers must maintain destruction records, dispensing records, and manifests in a readily retrievable fashion for at least two (2) years. ( )

381. -- 400. (RESERVED).

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0905

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 21, 2009.

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 rulemaking is necessary to allow pharmacists to provide up to a three (3)-month supply of legend drugs that are not controlled substances, when a prescription is written for a smaller supply but includes refills sufficient to equal the larger supply. The proposed rulemaking amends an existing rule to clarify that a pharmacist, filling a drug order for a legend drug that is not a controlled substance, may provide up to a three (3)-month supply when the practitioner has written a prescription for a smaller supply with refills in sufficient numbers to fill the larger supply.

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

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

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, 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 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
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 PROPOSED TEXT OF DOCKET NO. 27-0101-0905

184. UNPROFESSIONAL CONDUCT.
The following acts or practices by a licensed pharmacist or a pharmacy owner declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest: (7-1-93)

01. General. Manufacturing, compounding, selling, or dispensing or permitting to be manufactured, compounded, sold, or dispensed substandard drugs or preparations. (7-1-93)

02. Secret Formulas. Using secret formulas. (7-1-93)

03. Prescriber Incentives. Allowing a commission or rebate to be paid to a person writing, making, or otherwise ordering a prescription, or providing consultant services at no charge to receive prescription business. (7-1-93)

04. Prescription Order Noncompliance. Failing to strictly follow the instructions of the person writing, making, or ordering a prescription as to refills, contents, or label, or giving a copy of a prescription to any person without marking said prescription across the face: "Copy for Information Only. Not to Be Filled," except that a pharmacist, utilizing his best professional judgment, may provide up to a three-month supply of a legend drug that is not a controlled substance when the practitioner has written a drug order to be filled with a smaller supply but which includes refills in sufficient numbers to fill a three (3) month supply. ~~(7-1-93)~~( )

05. Errors or Omissions. Failing to confer with the person writing, making or ordering a prescription, if there is an error or omission therein which should be questioned. (7-1-93)

06. False or Deceptive Advertising. Advertising in a manner that is false, misleading or deceptive, which includes making material claims of professional superiority that cannot be substantiated. (7-1-93)

07. Addiction. Being addicted or habituated to the use of alcohol or controlled substances. (7-1-93)

08. Diversion of Drug Products and Devices. Supplying or diverting drugs, biologicals, and other medicines, substances, or devices, legally sold in pharmacies, that allows unqualified persons to circumvent laws pertaining to the legal sale of such articles. (7-1-93)

09. Fraudulent Practice. Performing, or in any way being a party to, any fraudulent or deceitful practice or transaction. (7-1-93)

10. Incompetency and Negligence. Performing duties as a pharmacist or pharmacy owner in an incompetent, unskilled, or negligent manner. (7-1-93)

11. Unprofessional Conduct. Exhibiting unprofessional conduct toward customers, employees, colleagues, inspectors or others. (7-1-93)

12. Insubordination. Failure to follow an order of the Board. (2-23-94)

13. Inappropriate Conduct. Any activity by a pharmacist that is inappropriate to the conduct of the profession of pharmacy. (2-23-94)

14. Disciplinary Actions in Other States. Conduct that results in a suspension, revocation or other disciplinary proceeding or action with respect to a pharmacy or pharmacist license that the Idaho licensee holds in another state. (7-1-98)

15. Reporting Theft, Loss, or Adulteration. Failure of any pharmacist-in-charge or pharmacy director to report any theft or loss of controlled substances or any adulteration of a prescription drug to the Board, even if the theft, loss, or adulteration was accounted for and the employee was disciplined by the employer. (4-6-05)

16. Cooperating in an Investigation. Failure of any licensee to cooperate with a disciplinary investigation. (4-6-05)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0906

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 21, 2009.

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 rulemaking is necessary to allow pharmacists to provide pharmaceutical care outside of a licensed pharmacy under certain conditions. The proposed rules set forth the conditions under which a licensed pharmacist may practice outside a licensed pharmacy. These conditions address access to records and information, provide for security and documentation, and mandate the maintenance of records to provide accountability and an audit trail.

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

No fees or charges are being imposed or increased through this rulemaking.

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:

There is no negative impact to the general fund as a result of this rulemaking.

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 October 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720
Boise, ID 83720-0067
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0906

165. PHARMACEUTICAL CARE.
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 defined in these rules. (5-8-09)

01. Definitions. (7-1-99)

a. Collaborative pharmacy practice. Means 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. (5-8-09)

b. Collaborative pharmacy practice agreement. Means a written and signed agreement between one (1) or more pharmacists and one (1) or more practitioners that provides for collaborative pharmacy practice for the purpose of conducting drug therapy management services, as defined in these rules. (5-8-09)

c. Drug therapy management. Means a distinct service or group of services that optimize therapeutic outcomes for individual patients. Drug therapy 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. These services may include, but are not limited to, the following, according to the individual needs of the patient: (5-8-09)

i. Performing or obtaining necessary assessments of the patient's health status; (5-8-09)

ii. Formulating a drug treatment plan; (5-8-09)

iii. Selecting, initiating, modifying, or administering drug therapy; (5-8-09)

iv. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness; (5-8-09)

v. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (5-8-09)

vi. Documenting the care delivered and communicating essential information to the patient's other primary care providers; (5-8-09)

vii. Providing information, support services and resources designed to enhance patient adherence with his therapeutic regimens; (5-8-09)

viii. Coordinating and integrating drug therapy management services within the broader health care-management services being provided to the patient; and (5-8-09)

ix. Such other drug therapy management services as may be allowed by law. (5-8-09)

d. Health information. Means any information, whether oral or recorded in any form or medium, that: (5-8-09)

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 (5-8-09)

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 healthcare to an individual. (5-8-09)

e. HIPAA. Means the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) and any amendments thereof. (5-8-09)

f. Individually identifiable health information. Means information that is a subset of health information, including demographic information collected from an individual and that: (5-8-09)

i. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (5-8-09)

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: (5-8-09)

(1) Identifies the individual; or (5-8-09)

(2) With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (5-8-09)

g. Other pharmaceutical patient care services. Means services that may include, but are not limited to, the following: (5-8-09)

i. Collaborative pharmacy practice. (5-8-09)

ii. Such other pharmaceutical patient care services as may be allowed by law. (5-8-09)

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. (5-8-09)

i. Pharmacist's scope of practice pursuant to the collaborative practice agreement. Means those duties and limitations of duties placed upon one (1) or more pharmacists by the collaborative practitioner or practitioners, the Board, and applicable law and includes the limitations implied by the scope of practice of the collaborating practitioner or practitioners. (5-8-09)

j. Practitioner. Means, for purposes of Section 165, an individual currently licensed, registered, or otherwise authorized in Idaho to prescribe and administer drugs in the course of professional practice. (5-8-09)

k. Protected health information. Means individually identifiable health information that, except as provided in Subparagraph 165.01.k.iv. of these rules, is: (5-8-09)

i. Transmitted by electronic media; (5-8-09)

ii. Maintained in any medium described in the definition of electronic media at 45 CFR 162.103 (HIPAA privacy rules); and (5-8-09)

iii. Transmitted or maintained in any other form or medium. (5-8-09)

iv. Protected health information excludes individually identifiable health information in: (5-8-09)

(1) Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1231(g)); (5-8-09)

(2) Records described at 20 U.S.C. Section 1231 (g)(4)(B)(iv); and (5-8-09)

(3) Employment records held by a licensee in its role as an employer. (5-8-09)

02. Collaborative Pharmacy Practice. Collaborative pharmacy practice is subject to the following requirements: (5-8-09)

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. (5-8-09)

b. Contents. The collaborative pharmacy practice agreement shall include: (5-8-09)

i. Identification of the practitioner and pharmacist who are parties to the agreement; (5-8-09)

ii. The types of drug therapy management decisions that the pharmacist is allowed to make; (5-8-09)

iii. A method for the practitioner to monitor compliance with the agreement and clinical outcomes and to intercede where necessary; (5-8-09)

iv. A provision that allows the practitioner to override a collaborative practice decision made by the pharmacist whenever he deems it necessary or appropriate; (5-8-09)

v. A provision that allows either party to cancel the agreement by written notification; (5-8-09)

vi. An effective date; and (5-8-09)

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. (5-8-09)

c. Initiation of the collaborative pharmacy 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. (5-8-09)

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. (5-8-09)

e. Review. At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year. (5-8-09)

03. Independent Practice. A licensed pharmacist may provide pharmaceutical care outside of a licensed pharmacy if all of the following conditions are met: ( )

a. The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of pharmaceutical care and appropriately reviews such information before performing any such functions; ( )

b. Access to the information described in Paragraph 165.03.a. of these rules is secure from unauthorized access and use, and all access by pharmacists is documented; and ( )

c. A pharmacist providing pharmaceutical care outside of the premises of a licensed pharmacy shall

maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall: ( )

i. Provide accountability and an audit trail; ( )

ii. Be provided to the Board upon request; and ( )

iii. Be preserved for a period of at least two (2) years from the date relied upon or consulted for the purposes of performing any such function. ( )

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0907

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 21, 2009.

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 rulemaking is necessary to reflect changes made by the 2009 Idaho Legislature to the Wholesale Drug Distribution Act. The proposed rule adds repackagers who are authorized distributors of record for FDA registered manufacturers to the definition of normal distribution channel.

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

No fees or charges are being imposed or increased through this rulemaking.

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:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was not conducted because of the simple nature of the rulemaking and the need to reflect changes made in current law.

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 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0907

321. DEFINITIONS.

01. Authentication. To affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred. (4-2-08)

02. Authorized Distributor of Record. A wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following: (4-2-08)

a. The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and (4-2-08)

b. The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis. (4-2-08)

03. Chain Pharmacy Warehouse. A physical location for prescription drugs that acts as a central warehouse and performs intra-company sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership and control. (4-2-08)

04. Co-Licensed Partner or Product. An instance where two (2) or more parties have the right to engage in the manufacturing or marketing, or both, of a prescription drug consistent with the federal Food and Drug Administration's implementation of the Prescription Drug Marketing Act. (4-2-08)

05. Components. Articles intended for use as a component of any articles specified in Subsections 321.01, 321.02, or 321.03 of these rules. (4-2-08)

06. Drop Shipment. The sale of a prescription drug to a wholesale distributor or chain pharmacy warehouse by the manufacturer of the prescription drug, that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug. The wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor. (4-2-08)

07. Drug. Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendia or their supplement. (7-1-93)

08. Facility. Facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale. (4-2-08)

09. Manufacturer. A person licensed or approved by the federal Food and Drug Administration to engage in the manufacture of drugs or devices consistent with the federal Food and Drug Administration definition of "manufacturer" under its regulations and guidance implementing the Prescription Drug Marketing Act. (4-2-08)

10. Manufacturer's Exclusive Distributor. A person who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor must be licensed as a wholesale distributor, pursuant to Section 54-1753, Idaho Code, and must also be an authorized distributor of record to be

considered part of the normal distribution channel. (4-2-08)

11. Normal Distribution Channel. A chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor, or from that manufacturer directly or through its co-licensed partner, third party logistics provider or manufacturer's exclusive distributor to a repackager who is an authorized distributor of record for the manufacturer, whose facility is registered with the United States Food and Drug Administration and who engages in the practice of repackaging the original dosage form of a prescription drug in accordance with applicable regulations and guidelines of the United States Food and Drug Administration, either directly or by drop shipment to:
~~(4-2-08)~~( )

a. A pharmacy to a patient; (4-2-08)

b. A designated person authorized by law to dispense or administer such drug to a patient; (4-2-08)

c. A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; (4-2-08)

d. A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intra-company pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or (4-2-08)

e. A chain pharmacy warehouse to the chain pharmacy warehouse's intra-company pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient. (4-2-08)

12. Pedigree. A document or electronic file containing information that records each wholesale distribution of a prescription drug. (4-2-08)

13. Prescription Drug. Any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law or federal regulation to be dispensed only by prescription, including finished dosage forms and bulk substances, subject to Section 503(b) of the federal Food, Drug and Cosmetic Act. (4-2-08)

14. Repackage. Repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding any repackaging completed by the pharmacist responsible for the purpose of dispensing the drug to the patient. (4-2-08)

15. Repackager. A person who repackages. (4-2-08)

16. Sample. A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (4-2-08)

17. Third Party Logistics Provider. A person who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, but who does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third party logistics provider must be licensed as a wholesale distributor, pursuant to Section 54-1753, Idaho Code, and must also be an authorized distributor of record to be considered part of the normal distribution channel. (4-2-08)

18. Wholesale Distribution. Distribution of prescription drugs to persons other than a consumer or patient, but excluding the following: (4-2-08)

a. Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity or any transaction or transfer between co-licensees of a co-licensed product. (4-2-08)

b. The sale, purchase, distribution, trade, or transfer of a prescription drug or the offer to sell,

purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons. (4-2-08)

c. The distribution of prescription drug samples by manufacturers' representatives. (4-2-08)

d. Drug returns when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR 203.23. (4-2-08)

e. The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use. (4-2-08)

f. The sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription. (4-2-08)

g. The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets. (4-2-08)

h. The sale, purchase, distribution, trade, or transfer of a prescription drug from one (1) authorized distributor of record to one (1) additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had, to date, been exclusively in the normal distribution channel. (4-2-08)

i. The delivery of, or the offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs if the common carrier does not store, warehouse, or take legal ownership of the prescription drug. (4-2-08)

j. The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or third party returns processor, including a reverse distributor. (4-2-08)

19. Wholesale Distributor. A person engaged in wholesale distribution of drugs including, but not limited to: manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturer's and distributor's warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel, a wholesale distributor, except for a chain pharmacy warehouse not engaged in wholesale distribution, must also be an authorized distributor of record. (4-2-08)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0908

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 21, 2009.

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 rulemaking is necessary to clarify that a pharmacy may transfer a prescription to another pharmacy without first having to fill it. The proposed rule will permit a pharmacist to transfer a prescription to another pharmacy to be filled or refilled. The rule will also clarify the recordkeeping responsibility of the receiving pharmacy.

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

No fees or charges are being imposed or increased through this rulemaking.

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:

There is no negative impact to the general fund as a result of this rulemaking.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, 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 28, 2009.

DATED this 28th day of August, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-0908

160. PRESCRIPTION TRANSFER.
A pharmacist may transfer prescription order information for the purpose of filling or refilling a prescription only if the information is communicated orally directly from pharmacist to pharmacist. Such oral information can be communicated by a student pharmacist, under the direct supervision of a pharmacist, to another pharmacist as long as one (1) of the parties involved in the communication is a pharmacist. In the alternative, the transferring pharmacist may transfer the prescription order information by facsimile transmission to the receiving pharmacist. In the case of a facsimile transmission, the transmission shall be signed by the transferring pharmacist. ~~(5-8-09)~~( )

01. Transferring Prescriptions for Controlled Substances. A prescription for a controlled substance may be transferred only from the pharmacy where it was originally filled and never from the pharmacy that received the transfer. (7-1-93)

a. In addition to the information required in Subsection 160.02 the pharmacist transferring the prescription shall record on the back of the original order the DEA number and address of the pharmacy to which the transfer was made. (7-1-93)

b. The receiving pharmacist must record the DEA number and address of the pharmacy transferring the order. (7-1-93)

02. Documenting the Transfer of a Prescription. The pharmacist who transfers the prescription shall: (5-8-09)

a. Invalidate the original prescription by writing the word "void" across the face of the form; and (7-1-93)

b. On the back of the form, record the following information: his name; name of the receiving individual; name of the receiving pharmacy; date of the transfer, and the number of authorized refills available. (7-1-93)

03. Documenting the Receipt of a Transferred Prescription. The pharmacist who receives the transferred prescription shall: (5-8-09)

a. Reduce the transferred information to writing including all information required by law or rule and a notation that the prescription is a "transfer"; and (7-1-93)

b. On ~~the back of~~ the form, record the following information: his name; the name of the transferring individual; the name of the transferring pharmacy; the date of the original dispensing and transfer, the number of refills authorized, the number of valid refills remaining, the date of the last refill, and the serial number of the prescription transferred. ~~(7-1-93)~~( )

04. Documenting Prescription Transfers by Computer. Transferring pharmacies that utilize a computer prescription database that contains all of the prescription information required by law or rule may enter the information required under Section 160 of these rules into the pharmacy's prescription database (including de-activation of the transferred prescription in the database of the transferring pharmacy) in lieu of entry of the required information on the original written prescription. ~~*The receiving pharmacy must generate a hard copy to be treated as a new prescription, and the hard copy shall also contain all of the information required under Section 160 of these rules.*~~ ~~(3-30-01)~~( )

05. Documenting Receipt of Prescription Transfers by Computer. A receiving pharmacy that utilizes a computer prescription database that contains all of the prescription information required by law or rule must generate a hard copy to be treated as a new prescription; however, the receiving pharmacy may enter the information required under Section 160 of these rules into the pharmacy's prescription database in lieu of writing the information

on the hard copy of the new prescription. ( )

05~~5~~6. Transferring Prescription Refills. Prescriptions for non-controlled drugs may be transferred more than one (1) time as long as there are refills remaining and all of the provisions of these rules are followed. (7-1-93)

06~~7~~7. Transferring Prescription Between Pharmacies Using Common Electronic Prescription Files. (7-1-98)

a. For prescriptions written for drugs other than controlled substances two (2) or more pharmacies may establish and use a common electronic prescription file to maintain required dispensing information. Pharmacies using the common file are not required to transfer prescriptions or information for dispensing purposes between or among other pharmacies using in the same common electronic prescription file. (7-1-98)

b. For controlled substances pharmacies using a common electronic prescription must satisfy all documentation requirements of a manual prescription transfer. (7-1-98)

c. All common electronic prescription files must contain complete and accurate records of each prescription and refill dispensed. Hard copies must be generated and treated as new prescriptions by the receiving pharmacies. (7-1-98)