HEALTH & WELFARE COMMITTEE

ADMINISTRATIVE RULES REVIEW

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2010 Legislative Session

Supplemental Review Book

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0904

NOTICE OF RULEMAKING - ADOPTION OF PENDING RULE

EFFECTIVE DATE: This rule has been adopted by the agency and is now pending review by the 2010 Idaho State Legislature for final approval. The pending rule becomes final and effective at the conclusion of the legislative session, unless the rule is approved, rejected, amended, or modified by concurrent resolution in accordance with Section 67-5224 and 67-5291, Idaho Code. If the pending rule is approved, amended, or modified by concurrent resolution, the rule becomes final and effective upon adoption of the concurrent resolution or upon the date specified in the concurrent resolution.

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

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

In response to the public comment that was received, the Board has determined to adopt the pending rule which includes a change in text from the proposed rule. The change in text is necessary to clarify requirements regarding the receipt, verification, and storage of donated drugs and who may receive and dispense donated drugs.

The text of the pending rule has been amended in accordance with Section 67-5227, Idaho Code. All sections that published as proposed in the October Bulletin are being republished in this Bulletin to show the changes made to the pending rule. The complete text of the proposed rule was published in Book 2 of the October 7, 2009 Idaho Administrative Bulletin, Vol. 09-10, pages 247 through 250.

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

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

DATED this 21st day of January 2010.

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Board of Pharmacy
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THE FOLLOWING NOTICE WAS PUBLISHED WITH THE PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: 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.

THE FOLLOWING IS THE TEXT OF THE PENDING RULE

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 in the original *unit dose* packaging; *or* *( )*

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

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. *( )*

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. *A* licensed pharmacist, physician, *physician assistant, or an advanced practice professional nurse with prescriptive authority* at the *qualifying* charitable clinic or center will be responsible for defining a specified set of drugs that will be included in their formulary. *( )*

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

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

i. Certifies that the *donated* 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 *nursing home* has only donated drugs on the *qualifying* charitable clinic or center's formulary; *( )*

iv. Certifies that the donating *nursing home* 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 *nursing home*; *( )*

vi. Lists the name of the donating *nursing home* and the name of the receiving *qualifying* 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 *qualifying* charitable clinic or center with the donated drugs. *( )*

03. Receipt of Donated Drugs. *Donated drugs may be received at a qualifying*

charitable clinic or center by a pharmacist, physician, physician assistant, advanced practice professional nurse with prescriptive authority, dentist, optometrist, or authorized clinic personnel. *( )*

***04. Verification of Received Drugs**.* *( )*

a. *R*eceipt of each donated drug *must be verified against* each manifest *by a pharmacist, physician, physician assistant, advanced practice professional nurse with prescriptive authority, dentist, optometrist, or authorized clinic personnel*. *( )*

b. In the event that the identifying patient information is not removed by the donating entity, the *information must be removed or redacted* at the charitable clinic or center. *( )*

c. *Before donated drugs are placed with a qualified charitable clinic or center's regular stock, a licensed pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority must:* *( )*

i. Verify utilizing a current drug identification book, a computer program, or an online service for the same that the donated drugs meet the criteria in Subsection 380.01 of these rules; *( )*

ii. Verify that the name and strength noted on the label of each unit of the donated drug is correct; and *( )*

iii. Determine that the donated drugs are not adulterated or misbranded and that they are safe to dispense. *( )*

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

05. 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 *qualifying* 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 *nursing home*. *( )*

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

d. The space in which drugs are stored must be *secured* at all times *and accessible only to* pharmacists, physicians, *physician assistants, dentists, optometrists, advanced practice professional nurses with prescriptive authority, and authorized clinic personnel.* *( )*

0*6*. 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 *licensed* pharmacist, physician, *physician assistant*, *dentist*, *optometrist*, *or an advanced practice professional nurse with prescriptive authority* working at a *qualifying* 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. *Licensed p*harmacists, physicians, *physician assistants*, *dentists*, *optometrists, and advanced practice professional nurses with prescriptive authority* dispensing donated drugs are required to provide patient counseling. *( )*

0*7*. Miscellaneous. ( )

a. *Authorized clinic personnel means an individual who is:* *( )*

i. Under the general supervision of a licensed pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority; and *( )*

ii. Named in writing by the qualifying charitable clinic or center's medical director or consultant pharmacist. *( )*

b. *The qualifying charitable clinic or center must maintain a list of the names of authorized clinic personnel, their individual duties, and a summary of their qualifications.* *( )*

c. *Physician assistant has the same definition as in Section 54-1803, Idaho Code.* *( )*

d. *Qualifying charitable clinics or centers receiving donated drugs must develop policies and procedures to assure that authorized clinic personnel will comply with applicable federal, state, and local laws.* *( )*

e. *D*rugs donated under these rules must not be sold, resold, offered for sale, traded, or transferred to another charitable clinic or center. *( )*

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

0*8*. Record Keeping Requirements. ( )

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

b. *Qualifying c*haritable 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).