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

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

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy

(Docket Nos. 27-0101-1001 through 27-0101-1004).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the co-chairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 10-27-10. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 11-19-10.

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 334-4845, or send a written request to the address or FAX number indicated on the memorandum attached.

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

Jeff Youtz
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 PAP

DATE: October 7, 2010

SUBJECT: Board of Pharmacy - IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Docket Nos. 27-0101-1001 through 27-0101-1004) (Proposed)

The Board of Pharmacy submits Docket Nos. 27-0101-1001 through 27-0101-1004 (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. 27-0101-1001 allows the electronic prescribing of controlled substances in conjunction with the June 1 Drug Enforcement Administration (DEA) changes that allow for such electronic prescribing. The proposed rule eliminates impediments to electronic prescribing, which will be allowed in accordance with federal law, defines "emergency" and provides additional updates;
>
> Docket No. 27-0101-1002 provides for training and record keeping requirements for pharmacists administering immunizations;
>
> Docket No. 27-0101-1003 deletes a rule dealing with the wholesale distribution of legend drugs that is said to be in conflict with the Idaho Wholesale Drug Distribution Act; and
>
> Docket No. 27-0101-1004 includes information on controlled substances delivered by practitioners in the controlled substances database maintained by the Board and mandates that prescribers who deliver controlled substances to ultimate users report certain data to the Board.

According to the Board, the proposed rule is authorized pursuant to section 37-2715, Idaho Code. Chapter 27, title 37, Idaho Code, is the Uniform Controlled Substances Act. Section 37-2715, Idaho Code, provides the Board of Pharmacy the authority to promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within Idaho.

Section 37-2722(2), Idaho Code, provides additional authority for Docket No. 27-0101-1001. Section 37-2722(2) permits the Board to define by rule emergency situations in which a Schedule II drug may be dispensed upon oral prescription. Section 54-1753, Idaho Code, provides additional authority to the Board with regard to Docket No. 27-0101-1003. Sections 54-1751 through 54-1759, Idaho Code comprise the Idaho Wholesale Drug Distribution Act. Section 54-1753 grants the Board licensing authority regarding wholesale distribution of wholesale prescription drugs.

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 with respect to Docket No. 27-0101-1001, because the changes were necessitated to be in harmony with 2010 federal DEA rule changes. Informal negotiated rulemaking was conducted with the Idaho Pharmacy Leadership Counsel, whose members include the Idaho State Pharmacy Association, the Idaho Society of Health-Systems Pharmacists and the Idaho State University's School of Pharmacy with regard to Docket No. 27-0101-1002. No negotiated rulemaking was conducted with regard to Docket No. 27-0101-1003, because the Idaho Wholesale Drug Distribution Acts prohibits the acts allowed by the rule, although interested parties were notified in writing that they would need to initiate a proposed change to the Idaho Code to continue the acts contained in that docket. Informal negotiated rulemaking is said to be scheduled with the Idaho Board of Medicine and other unnamed entities before the public comment period ends with regard to Docket No. 27-0101-1004.

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 20, 2010. All written comments must be delivered to the Board's Executive Director on or before October 27, 2010.

ANALYSIS

Throughout these dockets, the term "drug order" is inserted when referring prescriptions.

A. Docket No. 27-0101-1001

This docket contains extensive modifications to the exiting rules dealing with controlled substances. Clarifications in language are made. This analysis will address the substantive changes.

Under the proposed rule, the minimum requirements for a controlled substance drug order have been expanded to include the full name and address of the patient, the dosage form of the medication prescribed, and the address and DEA registration number of the prescriber. All prescription drug orders must: comply with applicable requirements of federal law; include the name, strength and quantity; and if paper or electronic, include the prescriber's written or electronic signature. Section 159.01.

Unless otherwise directed, prescription drugs must be dispensed in a container that includes: the date the prescription is filled; the name (generic, manufacture or brand) and strength of the drug; except for compounding preparations, the physical product description (color, shape and imprint); the quantity of item dispensed; any cautionary information as may be required or desirable for proper use and patient safety; and expiration date (the lesser of one year from the date of dispensing, the manufacturer's original expiration date, the appropriate expiration date for a reconstituted suspension, beyond use date for a compounded product, or a short period when warranted pursuant to the pharmacist's professional judgement); the number of refills authorized; and the signature of the pharmacist. A mandated warning statement and a "Do Not Label" option have been deleted. Section 159.02.

The proposed rule permits a properly supervised student pharmacist to verbally communicate a drug order to a pharmacist. A document transferred by facsimile must be signed by the transferring pharmacist. Section 160.01. The pharmacist transferring prescription drug order information must void or otherwise invalidate the original prescription drug order and: the name of the receiving pharmacist; and, for a prescription drug order written for a controlled substance, the address and DEA registration number of the receiving pharmacy. Section 160.02.

A pharmacy receiving a transferred prescription drug order must document: that the prescription drug order is a "transfer;" the name of the receiving pharmacist; the name of the transferring pharmacist; the date of issuance of the original prescription drug order; the date of issuance of the original prescription drug order; the number of refills authorized by the original prescription drug order; the number of authorized refills available; and, if the transferring prescription drug order for a controlled substance, the locations of all previous refills and the address, DEA registration number, and assigned prescription number of the transferring pharmacy that originally filled the prescription. Section160.03.

The requirement that the transferred information be reduced to a writing has been deleted. Section 160.03. Other hard copy requirements for pharmacies receiving new prescriptions have been deleted. Existing rule sections 160.04.b and 05. Pharmacies electronically sharing a real-time, online database may transfer certain controlled substances up to the maximum refills permitted by law and the prescriber's authorization. Section 160.05.

The requirement for refill instructions on the face of legally refillable prescription orders has been deleted. Added is the requirement that a new prescription drug order must be maintained and a new file number issued at least every 15 months for maintenance medications. Section 162.

The proposed rule deletes the definition of "prescription" from the definitions contained at section 433.

Pursuant to the authority granted by section 37-2722(b), Idaho Code, the proposed rule revises the definition of "emergency" as one in which the prescriber determines: if immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user; that no appropriate alternative treatment is available, including administration of a drug which is not a Schedule II controlled substance; and that is not reasonably possible for the prescriber to provide a written prescription drug order to be presented to the person dispensing the substance prior to the dispensing. The pharmacist must annotate the record of an electronic prescription with the original authorization and date of the verbal order. The pharmacist must notify the Board if the presciber fails to provide a written prescription drug order within the seven-day period following the issuing of the verbal authorization for dispensing the Schedule II controlled substance. The proposed rule deletes a provision requiring the pharmacist to make a reasonable effort to determine that the oral authorization came from a registered individual practitioner if the pharmacist does not know that individual. Section 442. The remaining changes to section 442 are for clarification.

The proposed rule deletes a requirement that a notation be made of the quantity supplied on the face of the written prescription or written record of the emergency oral prescription if a Schedule II prescription cannot be fully filled. If there is any question as to whether a patient may be classified as having a terminal illness, the pharmacist must contact the prescriber prior to partially filling the prescription. Both the pharmacist and the prescriber have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient. he proposed rule deletes a 60-day limitation on Schedule II prescriptions for patients in a LTCF or with a terminal illness. Section 444. The remaining changes to section 444 are clarifying.

Specific requirements for dispensing Schedule III and IV controlled substances by a pharmacist, individual practitioner or individual practitioner are deleted by the proposed rule. Section 446. Section 450 dealing with Schedule V prescription requirements has also been deleted. Section 450. Instead, the proposed rule provides that an authorized prescriber may administer or deliver a Schedule II, III, IV or V controlled substance in the course of the prescriber's professional practice, pursuant to inventory and recordkeeping requirement of the federal law, Idaho law and the Board's rules. Section 446.

Section 496 deals with inventories. "Prescription drug orders" have been added to the records that the controlled substance registrant (formerly, "registered pharmacy") is required to maintain. Deleted are the requirements: that prescriptions for Schedule I and II substances be maintained in a separate prescription file; that prescriptions for Schedule III, IV and V controlled substances be either maintained separately or in such a form that they are readily retrievable from the pharmacy's other prescription records; that certain records are considered readily retrievable if they are properly stamped in red with the letter "C" and properly filed; that the annual inventory must be taken within seven days of the prior year's inventory; and that the annual inventory must be a written record and kept in an inventory book. Section 496.

Instead, the proposed rule provides: that drug orders, inventories and records are considered readily retrievable if they are kept in such a manner that they can be separated from all other records in a reasonable time or if they are made in some manner visually identifiable and distinguishable; that electronic prescription drug order records be maintained in compliance with applicable federal law; that the annual inventory satisfy the requirements of the federal law and regulations and the Board's rules; that an electronic record system may be used to record receipts and distributions of controlled substances and record the annual inventory; that other completed inventories may be considered to satisfy the annual inventory requirement; that a timely complete controlled substance inventory must be completed in the event of a pharmacist-in-charge change; that a complete controlled substance inventory must be conducted within 48 hours of the discovery of a theft or reportable loss of a controlled substance; and that each controlled substance registrant must maintain a current, complete and accurate record of each substance imported or exported, but that the registrant is not required to maintain a perpetual inventory. Section 496.

B. Docket No. 27-0101-1002

This docket creates new section 166 on immunization records. Two key defined terms are: "healthy patient" (an individual with no contraindications to receive immunizations); and "compromised patient" (an individual who may have an absolute or relative contraindication to receive immunity). Sections 166.01.d and c. A pharmacist may administer immunizations to healthy patients and, pursuant to a prescription drug order, to compromised patients. Section 166.02.a. The proposed rule sets forth the qualifications that the pharmacist must have to administer immunizations. Sections 166.02.b and c.

The authority to administer immunizations may not be delegated. However, a properly qualified and supervised registered student pharmacist may administered immunizations. Section 166.02.d. Written policies and procedures for disposal of contaminated supplies must be maintained. Section 166.02.e. Adverse events must be reported. Section 166.02.f. Administration of immunizations must be pursuant to specified recommendations. Section 166.03. Specified information must be provided to the patient or patient's representative. Section 166.04. Specified information must be kept in the patient's profile. Section 166.05.

An immunizing pharmacist must maintain an immediately-retrievable emergency kit sufficiently stocked to manage an acute allergic reaction and may initiate and administer auto-inject epinephrine to treat an acute allergic reaction pursuant to specified guidelines. Section 166.06.

C. Docket No. 27-0101-1003

This docket deletes a section specifying that wholesale distribution of legend drugs will be permitted only to registered veterinarians or other licensed retail veterinary drug outlets. Existing section 358. As noted above, the Board states that this section is contradicted by the Idaho Wholesale Drug Distribution Act at sections 54-1752(16) and 54-1753, Idaho Code. Section 54-1752(16) is the definition of "wholesale distribution" (the distribution of prescription drugs to

persons other than a consumer or patient, with a number of specified exceptions). Section 54-1753 is the licensing requirements for a wholesale drug distributor. The Board does not specifically identify or explain the conflict.

D. Docket No. 27-0101-1004

The proposed rule modified section 469 on prescription reporting by providing that certain data on all controlled substances (rather than Schedule, III, IV and V controlled substances) must be reported weekly (rather than monthly) or more often as required by the Board by all pharmacies holding a DEA retail pharmacy registration and that dispense controlled substances and (new) by practitioners that deliver controlled substances. However, data on such sample does not need to be reported. Deleted from the rule is the form which may be used to make the report.

SUMMARY

The Department's proposed rule appears to be authorized under section 54-1717, Idaho Code. In addition, section 37-2722(2), Idaho Code, provides additional authority for Docket No. 27-0101-1001, and section 54-1753, Idaho Code, provides additional authority with regard to Docket No. 27-0101-1003.

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. 27-0101-1001

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 37-2715, 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 20, 2010.

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 allow the electronic prescribing of controlled substances, in conjunction with June 1, 2010 Drug Enforcement Administration (DEA) changes allowing the electronic prescribing of controlled substances. The proposed rules eliminate requirements for handwritten signatures; prescriptions written in ink, indelible pencil, or typewriter; documentation allowed only on paper, hard copy prescriptions; the need for a prescription hard copy; and certain prescriptions that must be promptly reduced to writing. Electronic prescribing and electronic prescription drug order records for controlled substances will be allowed in accordance with federal law, as per this proposed rule. The term “emergency” has also been defined, as required by Section 37-2722(b), Idaho Code. Additional updates include prescription drug order and prescription labeling minimum requirements, as well as listing additional circumstances when a controlled substance inventory is to be taken.

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: N/A

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, negotiated rulemaking was not conducted because these changes were necessitated to be in harmony with 2010 federal DEA rule changes.

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

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, at (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 27, 2010.

DATED this 27th day of August, 2010.

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 FOR DOCKET NO. 27-0101-1001

159. PRESCRIPTION DRUG ORDER MINIMUM REQUIREMENTS.

01. Prescription Drug Order Requirements. ~~*All prescriptions shall at a minimum indicate*~~ A prescription drug order must comply with applicable requirements of federal law and must include at least the following: ( )

a. ~~*t*~~The name and, if for a controlled substance, the full name and address of the patient; ( )

b. ~~*t*~~The date ~~*written*~~ issued; ( )

c. The name, strength, quantity, and if for a controlled substance, the dosage form of the medication prescribed; ( )

d. ~~*t*~~The directions for use; ( )

e. ~~*t*~~The name and, ~~*strength, and amount of the medication*~~ if for a controlled substance, the address and DEA registration number of the prescriber; and ( )

f. ~~*the name of the prescriber; and, i*~~If ~~*written*~~ paper, the pre-printed, stamped, or hand-printed name of the prescriber and, if paper or electronic, the ~~*handwritten*~~ prescriber's written or electronic signature ~~*of the prescriber. No prescription is refillable unless specifically indicated by the prescriber. Further requirements for controlled substance prescriptions are contained in Subsection 433.10. of these rules*~~. ~~*(7-1-98)*~~( )

02. Prescription Labels. Unless otherwise directed by these rules, ~~*A*~~any prescription drug must be dispensed ~~*shall*~~ in a container that bears a label ~~*containing*~~ with the following information: ( )

a. ~~*t*~~The name, address, and telephone number of the dispenser (person or business)~~,~~; ( )

b. ~~*t*~~The serial number; ( )

c. ~~*and*~~ The date ~~*of*~~ the prescription ~~*or its filling,*~~ is filled; ( )

d. ~~*t*~~The name of the prescriber; ( )

e. ~~*and t*~~The name of the patient~~,~~; ( )

f. Unless otherwise directed on the order by the prescriber, the name and strength of the drug (the generic name and its manufacturer's name or the brand name); ( )

g. Excepting compounding preparations, the physical product description, such as color, shape, and imprint; ( )

h. The quantity of item dispensed; ( )

i. ~~*t*~~The directions for use~~, *name (generic or brand) of the medication (including the manufacturer's name if a generic), and*~~; ( )

j. ~~*a*~~Any cautionary ~~*statements*~~ information as may be required ~~*to protect the consumer including, when advisable*~~ or desirable for proper use and patient safety; ( )

k. An expiration date which is the lesser of: ( )

i. One (1) year from the date of dispensing; ( )

ii. ~~t~~The manufacturer's original expiration date~~, the quantity of item dispensed and~~; ( )

iii. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or ( )

iv. A shorter period when warranted, pursuant to the pharmacist's professional judgment, to protect the health or safety of the individual; ( )

l. The number of refills authorized; and ( )

m. ~~t~~The initials of the ~~person~~ dispensing ~~the prescription and the statement: "Warning: Federal or state law prohibits the transfer of this prescription to any person other than the person for whom it was prescribed." When appropriate, the prescriber may request "Do Not Label", in such cases the medication name will not appear~~ pharmacist. ~~(7-1-98)~~( )

160. PRESCRIPTION DRUG ORDER TRANSFER.

01. Communicating Prescription Drug Order Transfers. Except for prescription drug orders for Schedule II controlled substances, ~~A~~a pharmacist may transfer prescription drug order information for the purpose of filling or refilling a prescription ~~only~~ if the information is communicated ~~orally~~ verbally directly from pharmacist to pharmacist. ( )

a. ~~Such oral~~ Prescription drug order information ~~can~~ may also be communicated verbally 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. ( )

b. ~~In the alternative, the~~ When 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~~ the transfer document must be signed by the transferring pharmacist. ~~(3-29-10)~~( )

02. Documentation~~g~~ Required of the Transferring ~~of a Prescription~~ Pharmacy. The pharmacist ~~who transfers the~~ transferring prescription ~~shall:~~ drug order information must void or otherwise ~~(5-8-09)~~

~~a.~~ ~~I~~nvalidate the original prescription ~~by writing the word "void" across the face of the form;~~ drug order and ~~(7-1-93)~~

~~b.~~ ~~On the back of the form,~~ record the following information: ( )

a. ~~his~~ The name of the transferring pharmacist; ( )

b. The name of the receiving ~~individual~~ pharmacist; ( )

c. The name of the receiving pharmacy; ( )

d. The date of the transfer~~.~~; ( )

e. ~~and t~~The number of authorized refills available~~.~~; and ~~(7-1-93)~~( )

f. For a prescription drug order written for a controlled substance, the address and DEA registration number of the receiving pharmacy. ( )

03. Documentation~~g~~ Required of the ~~Receipt of a Transferred Prescription~~ Receiving Pharmacy. The pharmacist ~~who~~ receive~~s~~ing a ~~the~~ transferred prescription drug order ~~shall:~~ must ~~(5-8-09)~~

~~a.~~ ~~Reduce the transferred information to writing including all information required by law or rule and~~

~~*a notation*~~ document that the prescription drug order is a "transfer"~~:~~ and ~~*(7-1-93)*~~

~~***b.***~~ ~~*On the form,*~~ record the following information: ( )

a. ~~*his*~~ The name of the receiving pharmacist; ( )

b. ~~*t*~~The name of the transferring ~~*individual*~~ pharmacist; ( )

c. ~~*t*~~The name of the transferring pharmacy; ( )

d. ~~*t*~~The date of issuance of the original ~~*dispensing and transfer,*~~ prescription drug order; ( )

e. ~~*t*~~The number of refills authorized by the original prescription drug order~~.~~; ( )

f. ~~*t*~~The number of ~~*valid*~~ authorized refills ~~*remaining,*~~ available; and ( )

g. If transferring a prescription drug order written for a controlled substance: ( )

i. ~~*t*~~The date and locations of ~~*the last*~~ all previous refills~~.~~; and ( )

ii. ~~*t*~~The ~~*serial*~~ address, DEA registration number, and assigned prescription number of the transferring pharmacy that originally filled the prescription, ~~*transferred*~~ when different. ~~*(3-29-10)*~~( )

~~***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.* *(3-29-10)*~~

~~***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.* *(3-29-10)*~~

0~~7~~4. ~~*Transferring Prescription Between*~~ Pharmacies Using Common Electronic ~~*Prescription*~~ Files. ~~*(7-1-98)*~~( )

a. ~~*Two (2) or more p*~~Pharmacies may establish and use a common electronic ~~*prescription*~~ file to maintain required dispensing information. Pharmacies using ~~*the*~~ a common electronic file are not required to transfer prescription~~*s or*~~ drug order information for dispensing purposes between or among other pharmacies ~~*using in*~~ sharing the ~~*same*~~ common electronic ~~*prescription*~~ file. ~~*(3-29-10)*~~( )

b. ~~*All c*~~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)*~~( )

0~~1~~5. Transferring Prescription~~s~~ Drug Orders for Controlled Substances. A prescription drug order for a controlled substance listed in Schedules II, IV, or V may be transferred only from the pharmacy where it was originally filled and never from the pharmacy that received the transfer, except that pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. ~~*(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)*~~

06. Transferring Prescription Drug Order Refills. Prescription~~s~~ drug orders for non-controlled ~~*drugs*~~ substances may be transferred more than one (1) time ~~*as long as*~~ if there are refills remaining and all ~~*of the provisions of these rules*~~ other legal requirements are ~~*followed*~~ satisfied. ~~*(7-1-93)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

162. PRESCRIPTION DRUG ORDER EXPIRATION.
Prescription drug orders ~~*that are legally refillable must have the refill instructions indicated on their face. All prescription orders*~~ expire no later than fifteen (15) months after the date of issue. ~~*For long term medication orders a*~~A new prescription drug order must be obtained and a new file number issued at least every fifteen (15) months for maintenance medications. ~~*(4-6-05)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

433. DEFINITIONS -- (H - Z).

01. Hospital. The term "hospital" means an institution for the care and treatment of the sick and injured approved by the Idaho Department of Health and Welfare and entrusted with the custody of controlled substances and the professional use of controlled substances under the direction of a practitioner. (7-1-93)

02. Individual Practitioner. The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the state in which he practices to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner. (7-1-93)

03. Institutional Practitioner. The term "institutional practitioner" means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted by the United States or the jurisdiction in which it practices to dispense a controlled substance in the course of professional practice, but does not include a pharmacy. (7-1-93)

04. Laboratory. The term "laboratory" means a laboratory approved by the Board and entrusted with the custody and use of controlled substances for scientific and medical purposes and for purposes of instruction and administered by a person licensed by the state of Idaho to possess such substances. (7-1-93)

05. Name. The term "name" means the official name, common or usual name, chemical name, or brand name of a substance. (7-1-93)

06. Official Idaho Register. The term "Official Idaho Register" is defined as the official register issued by the Board that contains the required information to record the sales or disposition of Schedule V substances. The book shall be in duplicate bearing the notice to the public on the reverse side of the original sheet which is permanently bound in the book, and shall be retained for a period of two (2) years after the last dated entry. (7-1-93)

07. Owner. The term "owner" means any person having any right, title, or interest in a referenced vehicle. (7-1-93)

08. Pharmacist. The term "pharmacist" means any pharmacist licensed by a state to dispense controlled substances and includes any other person (for example, student pharmacist) authorized by a state to dispense controlled substances under the supervision of a licensed pharmacist. (7-1-93)

09. **Pharmacy**. The term "pharmacy" means every store or other place of business where prescriptions are compounded, dispensed, or sold by a pharmacist and where prescription~~s~~ drug orders for controlled substances are received or processed in accordance with federal law and the pharmacy laws and rules of this state.

~~*(7-1-93)*~~( )

~~***10.*** ***Prescription****. The term "prescription" means a prescription for a controlled substance in Schedules III, IV, or V that is an oral order given individually for the person for whom prescribed directly from the prescriber or by the prescriber's employee or agent to the pharmacist, or indirectly by means of an order written in ink, indelible pencil, typewritten, or a computer-generated hard copy signed by the prescriber, and contains the address of the prescriber, the prescriber's federal registry number, the name and address of the patient, the name and quantity of the drug prescribed, directions for use, and dated as of the date on which it is written. Written prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all respects to federal and state laws, regulations, and rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these rules.*~~ ~~*(4-11-06)*~~

1~~1~~0. **Register, Registration**. The terms "register" and "registration" refer only to registration required and permitted by Section 37-2717, Idaho Code. (7-1-93)

1~~2~~1. **Registrant**. The term "registrant" means any person who is registered. (7-1-93)

1~~3~~2. **Readily Retrievable**. The term "readily retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records, or both. (7-1-93)

1~~4~~3. **Sale**. The term "sale" as used herein includes barter, exchange, gift, or offer thereof, and each such transaction made by any person, whether as principal, proprietor, agent, servant, or employee. (7-1-93)

1~~5~~4. **Transport**. The term "transport" with reference to controlled substances, includes "conceal," "convey," and "carry." (7-1-93)

1~~6~~5. **Vehicle**. The term "vehicle" means any vehicle or equipment used for the transportation of persons or things. (7-1-93)

1~~7~~6. **Physician, Veterinarian, Dentist, Podiatrist, Osteopath, Optometrist, Pharmacist**. These titles or any similar designation, refer to persons who hold valid, unrevoked licenses to practice their respective professions in this state, issued by their respective examining boards. (12-7-94)

1~~8~~7. **Physician**. The term "physician" includes only persons licensed under Title 54, Chapter 18, Idaho Code. (7-1-93)

(BREAK IN CONTINUITY OF SECTIONS)

442. ***~~REQUIREMENT OF~~*** **EMERGENCY PRESCRIPTION DRUG ORDER - SCHEDULE II.**
-An emergency ~~*situation*~~, as ~~*defined*~~ referenced in Section 37-2722(b), Idaho Code, ~~*a pharmacist may dispense a*~~ is one in which the prescriber determines: immediate administration of the controlled substance ~~*listed in*~~ is necessary for proper treatment of the intended ultimate user; and that no appropriate alternative treatment is available, including administration of a drug which is not a Schedule II ~~*upon receiving oral authorization of a prescribing individual practitioner*~~ controlled substance; and that it is not reasonably possible for the prescriber to provide a written prescription drug order to be presented to the person dispensing the substance prior to the dispensing. ~~*(7-1-93)*~~( )

~~a~~01. **Quantity Limited**. The quantity prescribed and dispensed ~~*is*~~ must be limited to the amount

adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription drug order signed by the prescrib*ing*er *individual practitioner*). *(7-1-93)*( )

***b*02. Prescription Drug Order Reduced to Writing**. The prescription *shall* drug order must be immediately reduced to writing by the pharmacist and *shall* must contain all of the information required in Section 37-2723, Idaho Code, except for the signature of the prescrib*ing*er *individual practitioner*. *(7-1-93)*( )

c. *If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory or other good faith effort to ensure his identity, or both.* *(7-1-93)*

***d*03. Written Prescription Drug Order**. Within seven (7) days after *authorizing* issuing verbal authorization for the dispensing of an emergency *oral* prescription for a Schedule II controlled substance, the prescrib*ing*er *individual practitioner shall cause* must provide a written prescription drug order for the emergency quantity *prescribed to be delivered to the* dispens*ing*ed *pharmacist*. In addition to conforming to the requirement of Section 37-2723, Idaho Code, the prescription *shall* drug order must have written on its face "Authorization for Emergency Dispensing" and the date *of* the *oral* verbal prescription drug order was issued. *(7-1-99)*( )

***e*04. Delivery of Paper Prescription Drug Order** The *written* paper prescription drug order may be delivered *to the pharmacist in person or* by mail*; however,* if *delivered by mail, it must be* postmarked within the seven (7)-day period. *(7-1-99)*( )

***f*05. Attachment of Paper Prescription Drug Order**. *Upon receipt, the dispensing pharmacist shall attach the written* A paper prescription drug order must be attached to the *oral* verbal emergency prescription drug order that *had* was previously *been* reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the verbal order. *(7-1-93)*( )

***g*06. Notification to the Board**. The pharmacist *shall* must notify the Board if the prescrib*ing*er *individual practitioner* fails to *deliver* provide a written prescription *to him* drug order within the seven (7)-day period. *Failure of the pharmacist to so notify the Board shall void the prescribing individual practitioner's authority, conferred by this Subsection to dispense without a written prescription.* *(7-1-93)*( )

(BREAK IN CONTINUITY OF SECTIONS)

444. PARTIAL-FILL*ING* DISPENSING OF SCHEDULE II PRESCRIPTIONS.

01. Conditions for Partial-Fill Dispensing. *The partial filling of a prescription for a controlled substance listed in* A Schedule II *is permissible if* controlled substance prescription may be partially filled and dispensed when the pharmacist is unable to supply the full quantity *called for in a written or emergency oral prescription and a notation is made of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription)* ordered. *(7-1-93)*( )

01*a. *Remaining Portion of Prescription. The remaining portion of the prescription may only be filled within *the* seventy-two (72) hours *period* of the first partial filling; however, if the remaining portion is not or cannot be filled within seventy-two (72) hours, the pharmacist *shall* must so notify the prescrib*ing*er *individual practitioner*. *(7-1-93)*( )

***02*b. *Supplying Further Quantity*.** *No further quantity may* Additional quantities must not be *supplied* dispensed after *the* seventy-two (72) hours *period* from the time the initial quantity was dispensed without a new prescription drug order. *(7-1-93)*( )

03*2*. Partial-Fill *Quantities* Dispensing to LTCF and Terminal Illness Patients. A Schedule II controlled substance prescription *for a Schedule II controlled substance written* for a patient in a Long Term Care

Facility (LTCF) or for a patient with a ~~*medical diagnosis*~~ document~~*ing*~~ed ~~*a*~~ terminal illness may be filled in partial quantities ~~*to include*~~ and individual dosage units. ( )

a. If there is any question as to whether a patient may be classified as having a terminal illness, the pharmacist must contact the prescriber prior to partially filling the prescription. Both the pharmacist and the prescriber have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient. ( )

b. The pharmacist must record ~~*on*~~ that the ~~*prescription whether the*~~ patient is either "terminally ill" or an "LTCF patient." ~~*(7-1-99)*~~( )

~~*a*~~**03. Partial-Fill Documentation**. For each ~~*partial filling, the dispensing pharmacist shall record on the back of the*~~ partially filled prescription ~~*(or on another appropriate record, uniformly maintained and readily retrievable)*~~ dispensed, the following information must be recorded: ( )

a. ~~*t*~~The date ~~*of the partial filling*~~,; ( )

b. The quantity dispensed~~,~~; ( )

c. The remaining quantity authorized ~~*to be*~~ for dispens~~*ed*~~ing~~,~~; and ( )

d. ~~*t*~~The identification of the dispensing pharmacist. ~~*(7-1-99)*~~( )

~~***b.*** *Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date, unless sooner terminated by the discontinuance of medication.* *(7-1-99)*~~

(BREAK IN CONTINUITY OF SECTIONS)

446. ~~*REQUIREMENT OF PRESCRIPTION - SCHEDULE III OR IV*~~ PRESCRIBER ADMINISTRATION AND DELIVERY OF CONTROLLED SUBSTANCES.
An authorized prescriber may administer or deliver a controlled substance listed in Schedules II, III, IV, or V in the course of the prescriber's professional practice, pursuant to the inventory and recordkeeping requirements of federal law; Section 37-2720, Idaho Code; and these rules. ( )

~~***01. Dispensing a Controlled Substance -- Pharmacist.*** *A pharmacist may dispense a controlled substance listed in Schedule III or IV, that is a prescription drug as determined under the federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Section 37-2722(c), Idaho Code, except for the signature of the prescribing individual practitioner.* *(7-1-93)*~~

~~***02. Dispensing a Controlled Substance -- Individual Practitioner.*** *An individual practitioner may administer or dispense a controlled substance listed in Schedule III or IV in the course of his professional practice without a prescription, subject to Section 37-2720, Idaho Code.* *(7-1-93)*~~

~~***03. Dispensing a Controlled Substance -- Institutional Practitioner.*** *An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III or IV pursuant to a written prescription signed by a prescribing individual practitioner, pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all of the information required in Section 37-2723, Idaho Code, except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user subject to Section 37-2720, Idaho Code.* *(7-1-93)*~~

(BREAK IN CONTINUITY OF SECTIONS)

450. ~~*REQUIREMENT OF PRESCRIPTION - SCHEDULE V*~~ RESERVED.

~~***01. Dispensing Schedule V Controlled Substances**. A pharmacist may dispense a controlled substance listed in Schedule V pursuant to a prescription as required for controlled substances listed in Schedule III and IV in Section 451 of these rules. (7-1-93)***~~

~~***02. Refilling Schedule V Controlled Substances Requires Authorization**. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription. If no such authorization is given, the prescription may not be refilled. (7-1-93)***~~

~~***03. Labeling Schedule V Controlled Substances for Dispensing**. A pharmacist dispensing a Schedule V substance pursuant to a prescription shall label the substance in accordance with Section 448 of these rules and file the prescription in accordance with Section 449 of these rules. (7-1-93)***~~

~~***04. Dispensing Schedule V Controlled Substances by Individual Practitioner**. An individual practitioner may administer or dispense a controlled substance listed in Schedule V in the course of his professional practice without a prescription, subject to Section 37-2720, Idaho Code. (7-1-93)***~~

~~***05. Dispensing Schedule V Controlled Substances by Institutional Practitioner**. An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule V only pursuant to a written prescription signed by the prescribing individual practitioner, pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 37-2723, Idaho Code, except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user subject to Section 37-2720, Idaho Code. (7-1-93)***~~

(BREAK IN CONTINUITY OF SECTIONS)

496. CONTROLLED SUBSTANCE INVENTOR~~Y~~IES, PRESCRIPTION DRUG ORDERS, AND RECORDS.
Each ~~*registered pharmacy shall*~~ controlled substance registrant must maintain the prescription drug orders, inventories, and records of controlled substances as follows: ~~*(7-1-93)*~~( )

01. Inventories and Records for Schedules I and II. Prescription drug orders, ~~*I*~~inventories, and records of ~~*all*~~ controlled substances listed in Schedules I and II ~~*shall*~~ must be maintained separately from ~~*all*~~ other prescription drug orders and records of the pharmacy~~*, and prescriptions for Schedule I and II substances shall be maintained in a separate prescription file*~~. ~~*(7-1-93)*~~( )

02. Inventories and Records for Schedules III, IV, and V. Prescription drug orders, ~~*I*~~inventories, and records of controlled substances listed in Schedules III, IV, and V ~~*shall*~~ must be maintained ~~*either*~~ separately from ~~*all*~~ other prescription drug orders and records ~~*of the pharmacy*~~ or in such ~~*form*~~ manner that the information required is readily retrievable ~~*from ordinary business records of the pharmacy. Prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy*~~. ~~*(7-1-93)*~~( )

03. Readily Retrievable Paper Prescription Drug Orders. Controlled substance ~~*P*~~prescription~~*s will be deemed*~~ drug orders, inventories, and records are considered readily retrievable if~~*, at the time*~~ they are ~~*initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one (1) inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances, except that for pharmacies employing*~~

stored in an electronic recordkeeping or an alternative system ~~*for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy prescription with a red "C" is waived*~~ in such a manner that they can be separated from all other records in a reasonable time or if they are made in some manner visually identifiable and distinguished from other records or from other items appearing on the records. Electronic prescription drug order records must be maintained in compliance with applicable federal law. ~~*(7-1-99)*~~( )

04. Annual Inventory of Stocks of Controlled Substances. Each ~~*registered pharmacy shall annually, within seven (7) days of the prior year's inventory, take*~~ controlled substance registrant must conduct an inventory of all stocks of controlled substances ~~*on hand, following*~~ at least annually in a form and manner that satisfies the ~~*general*~~ inventory requirements ~~*for inventories*~~ of federal law, regulations, and these rules. ~~*(5-8-09)*~~( )

a. ~~*The annual inventory, required in these rules, shall be a written record resulting*~~ Inventories of controlled substances required by these rules must result from a physical (or actual) count of stock on hand or in the control of the ~~*pharmacist-in-charge of a particular pharmacy*~~ registrant. ~~*(7-1-93)*~~( )

b. ~~*Automated data processing equipment*~~ An electronic recordkeeping system may be used to ~~*provide lists of items (products) and to*~~ record receipts and ~~*issues*~~ distributions of ~~*various items, but not*~~ controlled substances and to ~~*produce*~~ record the annual inventory if the inventory is also maintained in a written, typewritten, or printed form at the registered location. ~~*(7-1-93)*~~( )

~~***c.*** *The record of inventory shall be kept in the inventory book provided by the Board or in another bound book (not loose leaf) suitable to meet the needs of inventory reports.* *(7-1-93)*~~

~~***d*****c.**~~ Upon completion, the inventory ~~*will*~~ must be dated as of the day ~~*taken*~~ conducted, ~~*indicating*~~ noted as to whether it was ~~*taken*~~ conducted at the opening or closing of business, and signed by the party that ~~*took*~~ completed the inventory. ~~*(7-1-93)*~~( )

d. Complete inventories conducted as otherwise required by these rules may also be considered in complying with the annual inventory requirement. ( )

05. Separate Inventories for Each Location. A separate inventory ~~*shall*~~ must be ~~*made by a registrant for*~~ conducted and maintained at each registered location ~~*and shall be kept at the registered location*~~. ~~*(7-1-93)*~~( )

06. Inventory ~~*Must Be In Written Form*~~ on Change of Pharmacist-in-Charge (PIC). A~~*n*~~ complete controlled substance inventory must be ~~*maintained in a written, typewritten or printed form. If taken by use of an oral recording device it must be promptly transcribed*~~ conducted in the event of a PIC change. The inventory must be conducted following the close of business on the last day of employment of the outgoing PIC and prior to opening for business on the first day of employment of the incoming PIC. However, a single inventory is sufficient if there is no lapse of employment between the outgoing and the incoming PICs. ~~*(7-1-93)*~~( )

~~***07.*** ***Maintaining Written Inventory****. Such inventory must be maintained on the premises for a minimum of three (3) years.* *(7-1-93)*~~

07. Inventory on Discovery of Theft or Loss of Controlled Substances. A complete controlled substance inventory must be conducted within forty-eight (48) hours of the discovery of a theft or reportable loss of a controlled substance. ( )

08. Inventory on Addition~~*s*~~ to Schedule~~*s*~~ of Controlled Substances. On the effective date of ~~*a rule adding*~~ an addition of a substance to a~~*ny*~~ schedule of controlled substances, ~~*which substance was, immediately prior to that date, not listed on a schedule,*~~ every registrant ~~*required to keep records*~~ who possesses that substance ~~*shall take*~~ must conduct an inventory of all stocks of the substance on hand, and thereafter, ~~*such substance shall be*~~ include~~*d*~~ the substance in each inventory ~~*made*~~ conducted by the registrant ~~*pursuant to Subsection 496.04 of these rules*~~. ~~*(7-1-93)*~~( )

09. Maintaining ~~*Current List*~~ Record of Each Substance. Each ~~*registered pharmacy shall*~~ controlled substance registrant must maintain a current, complete, and ~~*current list*~~ accurate record of each substance

manufactured, imported, received, ordered, sold, delivered, exported, or otherwise disposed of by the ~~*pharmacy; order forms; and other required records*~~ registrant in ~~*such*~~ a ~~*manner as to be*~~ readily retrievable manner, except that a registrant is not required by this rule to maintain a perpetual inventory. ~~*(7-1-93)*~~( )

10. Maintaining Inventories. Inventories must be maintained on the registered premises for a minimum of three (3) years. ( )

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1002

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 37-2715, 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 20, 2010.

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:

Training and recordkeeping requirements for pharmacists administering immunizations are needed to protect the health and welfare of the citizens of Idaho. The proposed rule would establish qualifications for pharmacists to immunize and establish recordkeeping requirements.

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: N/A

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, informal negotiated rulemaking was held with the Idaho Pharmacy Leadership Counsel, whose members include the Idaho State Pharmacy Association, the Idaho Society of Health-Systems Pharmacists, and Idaho State University's School of Pharmacy.

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

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, at (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 27, 2010.

DATED this 27th day of August, 2010.

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 FOR DOCKET NO. 27-0101-1002

166. IMMUNIZATION RECORD.

01. Definitions. ( )

a. ACPE means the Accreditation Council for Pharmacy Education. ( )

b. CDC means the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. ( )

c. "Compromised Patient" means an individual who may have an absolute or relative contraindication to receive immunizations. ( )

d. "Healthy Patient" means an individual with no contraindications to receive immunizations. ( )

02. Qualifications. ( )

a. A pharmacist may administer immunizations to healthy patients, and pursuant to prescription drug order to compromised patients. ( )

b. To qualify to administer immunizations, a pharmacist must first; ( )

i. Successfully complete an ACPE accredited or comparable course that meets the standards for pediatric, adolescent, and adult immunization practices recommended and approved by the United States Public Health Service Advisory Committee on Immunization Practices and includes at least; ( )

(1) Basic immunology, vaccine and immunization protection; ( )

(2) Diseases that are preventable through vaccination and immunization; ( )

(3) Recommended immunization schedules; ( )

(4) Vaccine and immunization storage and management; ( )

(5) Informed consent; ( )

(6) Physiology and techniques for administration of immunizations; ( )

(7) Pre-immunization and post-immunization assessment and counseling; ( )

(8) Immunization reporting and records management; and ( )

(9) Identification, response, documentation, and reporting of adverse events. ( )

ii. Hold a current certification in basic cardiopulmonary resuscitation (CPR) offered by the American Heart Association or the American Red Cross; ( )

c. Pharmacists qualified to administer immunizations must also annually complete a minimum of one (1) hour of ACPE approved continuing education related to vaccines, immunizations, or their administration within the continuing education required by Section 134 of these rules. ( )

d. The authority to administer immunizations may not be delegated; however, a registered student pharmacist that has satisfied the immunizing pharmacist qualifications may administer immunizations under the direct supervision of a qualified immunizing pharmacist. ( )

e. An immunizing pharmacist must maintain written policies and procedures for disposal of used or contaminated supplies. ( )

f. An immunizing pharmacist must report any adverse events to the health care provider identified by the patient, if any, and to the CDC. ( )

03. Immunization Administration. Immunizations must be administered pursuant to the latest recommendations issued by the CDC. A pharmacist must have a current copy of, or on-site access to, the CDC's "Epidemiology and Prevention of Vaccine-Preventable Diseases." ( )

04. Vaccine Information Statement. A current CDC-issued Vaccine Information Statement corresponding to the vaccine administered must be provided to the patient or the patient's representative for each immunization administered. ( )

05. Recordkeeping. For each immunization administered, the following information must be maintained in the patient profile: ( )

a. The name, address, allergies, and date of birth of the patient; ( )

b. The date of administration; ( )

c. The name, manufacturer, dose, lot number, and expiration date of the vaccine; ( )

d. Documentation identifying the Vaccine Information Statement provided; ( )

e. The site and route of administration; ( )

f. The name and address of the patient's health care provider, if any; ( )

g. The name of the immunizing pharmacist and, if any, the student pharmacist; ( )

h. Any adverse events encountered; and ( )

i. The date on which an adverse event was reported to the patient's health care provider, if any. ( )

06. Emergencies. ( )

a. An immunizing pharmacist must maintain a immediately-retrievable emergency kit sufficiently stocked to manage an acute allergic reaction to an immunization. ( )

b. An immunizing pharmacist may initiate and administer auto-inject epinephrine to treat an acute allergic reaction to an immunization pursuant to guidelines issued by the American Pharmacy Association (APhA). ( )

16~~6~~7. -- 175. (RESERVED).

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1003

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 37-2715, 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 20, 2010.

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:

Rule 358 (IDAPA 27.01.01.358) needs to be stricken because it is in conflict with the Idaho Wholesale Drug Distribution Act, Sections 54-1752(16) and 54-1753, Idaho Code. The proposed change strikes Rule 358 in its entirety because it is in conflict with the Idaho Wholesale Drug Distribution Act.

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: N/A

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, negotiated rulemaking was not conducted because the Idaho Wholesale Drug Distribution Act prohibits the acts allowed by this rule. Interested parties were notified in writing that they would need to initiate a proposed change to Idaho Code in order to continue the acts detailed in this rule.

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

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, at (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 27, 2010.

DATED this 27th day of August, 2010.

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 FOR DOCKET NO. 27-0101-1003

358. ~~*DISTRIBUTION*~~ RESERVED.
~~*Wholesale distribution of legend drugs will be permitted only to registered veterinarians or other licensed retail veterinary drug outlets.*~~ ~~*(7-1-93)*~~

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1004

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 37-2715, 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 20, 2010.

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 is necessary to include information on controlled substances delivered by practitioners in the controlled substances prescriptions database maintained by the Board pursuant to Sections 37-2726 and 37-2730(A), Idaho Code. This information is not currently captured in the database and should be included in order to protect the health and welfare of the citizens of Idaho. The proposed rule would mandate that prescribers who deliver controlled substances to ultimate users would have to report certain data to the Board, just as dispensing pharmacies are required to do currently.

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: N/A

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, negotiated rulemaking was not conducted as the need for this rule was not apparent until such time that negotiated rulemaking was infeasible; however, informal negotiated rulemaking is scheduled with entities, including the Idaho Board of Medicine, before the public comment period ends, allowing for potential changes before the rule becomes pending.

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

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director, at (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 27, 2010.

DATED this 27th day of August, 2010.

Mark Johnston, R.Ph., Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
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Phone: (208) 334-2356
Fax: (208) 334-3536

THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 27-0101-1004

469. PRESCRIPTION DRUG ORDER REPORTING.

Certain data on all controlled substances must be reported weekly or more often as required by the Board by ~~A~~all pharmacies ~~*that*~~ holding a DEA retail pharmacy registration ~~*will report certain data on all Schedule II, III, IV, and V*~~ that dispense controlled substances~~*, prescriptions filled, as required by the Board, by the first of every month or more often, as directed by the Board*~~ and by practitioners that deliver controlled substances. ~~*The data may be reported in the form of diskette, direct computer link, magnetic tape or other method approved by the Board.*~~ Data on controlled substance prescription drug samples does not need to be reported. ~~*(5-8-09)*~~( )