

## IDAPA 27 - BOARD OF PHARMACY

### 27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1504

#### 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, 2015.

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:

This rulemaking docket adds missing or incomplete language allowing for statewide protocols. In the event of a federal or state declared emergency, new language would allow a pharmacist to perform drug therapy management as well as other patient care services according to statewide protocol in conjunction with the Board of Pharmacy and the Idaho Department of Health and Welfare. In addition, changes would allow for the suspension of requirements for those engaged in the scope of practice for which they are licensed in another state. New language would also allow for temporary pharmacies as well as mobile pharmacies and requirements therefor. Changes also provide that a pharmacist be allowed to refill prescriptions essential to the patients' health or continuation of therapy.

**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(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1501 in the July 1, 2015 Idaho Administrative Bulletin, [Vol. 15-7, page 71](#) and in the August 5, 2015 Idaho Administrative Bulletin, [Vol. 15-8, page 106](#).

**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: NA

**ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS:** For assistance on technical questions concerning the proposed rule, contact Alex Adams, 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 28, 2015.

DATED this 4th Day of September 2015.

Alex Adams  
Executive Director  
Board of Pharmacy  
1199 W. Shoreline Ln., Ste. 303  
P. O. Box 83720  
Boise, ID 83720-0067  
Phone: 334-2356  
Fax: (208) 334-3536

**THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1504**  
**(Only Those Sections With Amendments Are Shown.)**

**016. BOARD OF PHARMACY LICENSURE AND REGISTRATION.**

The Board is responsible for the control and regulation of the practice of pharmacy in or into the state of Idaho, which includes the licensure or registration of professional, supportive, and ancillary personnel who engage in or support the practice. The Board is also responsible for the control, regulation, and registration of persons or drug outlets that manufacture, distribute, or dispense controlled substances within or into the state. Licenses or registrations required by state or federal law, or both, must be obtained prior to engaging in these practices or their supportive functions, except that the Board may suspend such requirements for the duration of a national, state or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, for individuals engaged in the scope of practice for which they are licensed in another state. (3-21-12)( )

**01. Pharmacy Practice Act Licenses and Registrations.** The Board will issue or renew a license or a certificate of registration upon application and determination that the applicant has satisfied the requirements of the Idaho Pharmacy Act and any additional criteria specified by these rules for the license or registration classification. Licenses and certificates of registration issued pursuant to Title 54, Chapter 17, Idaho Code, expire annually on June 30 unless an alternate expiration term or date is specifically stated in these rules. (3-21-12)

**02. Idaho Controlled Substances Act Registrations.** The Board will issue or renew controlled substance registrations upon application and determination that the applicant has satisfied the requirements of the Idaho Controlled Substances Act and any additional criteria specified by state or federal law applicable to applicants that manufacture, distribute, or dispense, or conduct research with, controlled substances. Registrations issued pursuant to Title 37, Chapter 27, Idaho Code, must be renewed annually by June 30 for pharmacists and by December 31 for all other registrants. (4-4-13)

**a.** Unless a wholesaler, an applicant for an Idaho controlled substance registration must hold a valid, unrestricted Idaho license to prescribe, dispense, or administer controlled substances and, unless a pharmacist or certified euthanasia technician, a valid federal DEA registration. If a required license or registration is cancelled or otherwise invalidated by the issuing agency, the Idaho controlled substance registration will be correspondingly cancelled. (3-21-12)

**b.** A registrant engaging in more than one (1) group of independent activities, as defined by federal law, must obtain a separate Idaho controlled substance registration for each group of activities if not exempted from separate DEA registration by federal law. (3-21-12)

**(BREAK IN CONTINUITY OF SECTIONS)**

**060. DRUG OUTLET LICENSURE AND REGISTRATION.**

A license or a certificate of registration, as applicable, is required for drug outlets doing business in or into Idaho. A license or certificate of registration will be issued by the Board to drug outlets pursuant to, and in the general classifications defined by, Section 54-1729, Idaho Code. (3-21-12)

**01. New Drug Outlet Inspections.** Prior to approving the issuance of a new license or registration, each drug outlet may be inspected to confirm that the facility is appropriately equipped and has implemented proper procedures and minimum standards necessary for compliance with applicable law. Prescription drugs may not be delivered to a new drug outlet location and the drug outlet may not open for business prior to satisfactory completion of the opening inspection, if required. (3-21-12)

**02. Licenses and Registrations ~~Nontransferable~~ Transferability.** ( )

**a.** Licenses and Registrations Nontransferable. Drug outlet licenses and registrations are location specific and are nontransferable as to person or place, except in the event of a national, state, or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency. If the ownership or location of an outlet changes, any registration or license issued to it by the Board is void. (3-21-12)( )

**b.** Temporary Pharmacy Facilities and Mobile Pharmacies. The Board may approve or disapprove temporary pharmacy facilities and mobile pharmacies and shall make arrangements for appropriate monitoring and inspection of such facilities on a case-by-case basis. To provide pharmacy services during a national, state, or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, pharmacies may arrange to temporarily locate or relocate to a temporary pharmacy facility or mobile pharmacy if the temporary pharmacy facility or mobile pharmacy: ( )

**i.** Is under the control and management of the pharmacist-in-charge or designated supervising pharmacist; ( )

**ii.** Is located within the declared disaster area or affected areas; ( )

**iii.** Notifies the Board of its proposed location; ( )

**iv.** Is properly secured to prevent theft and diversion of drugs; ( )

**v.** Maintains records in accordance with laws and rules of the state; and ( )

**vi.** Ceases the provision of services with the termination of the declared emergency, or as otherwise authorized by the Board. ( )

**03. Nonresident Drug Outlet.** The Board may license or register a drug outlet licensed or registered under the laws of another state if the other state's standards are comparable to those in Idaho and acceptable to the Board, evidenced by an inspection report. (7-1-13)

**(BREAK IN CONTINUITY OF SECTIONS)**

**116. PRESCRIPTION DRUG ORDER: REFILLS.**

**01. Refill Authorization.** A prescription drug order may be refilled when permitted by state and federal laws and only as specifically authorized by the prescriber. (3-21-12)

**a.** A pharmacist, utilizing his best professional judgment, may dispense a prescription drug that is not a controlled substance up to the total amount authorized by the prescriber including refills. (3-21-12)

**b.** Refills exceeding those authorized by the prescriber on the original prescription drug order may only be authorized through issuance of a new and separate prescription drug order. (3-21-12)

**02. Emergency Prescription Refills.** A pharmacist may refill a prescription for a patient when: ( )

**a.** ¶The prescriber is not available for authorization if, in the professional judgment of the pharmacist, a situation exists that threatens the health or safety of the patient should the prescription not be refilled. Only sufficient medication may be provided, consistent with the dosage instructions, to maintain the prescribed treatment until, at the earliest possible opportunity, the issuing or an alternative prescriber is contacted for further renewal instructions. (3-21-12)( )

**b.** Upon the declaration of a national, state, or local emergency by the President of the United States,

the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, and subject to the provisions of Subsection 310.02 of these rules, a pharmacist may dispense a refill of a prescription drug, not to exceed a thirty (30)-day supply if, in the pharmacist's professional judgment, the prescription drug is essential to the patient's health or continuation of therapy. ( )

**(BREAK IN CONTINUITY OF SECTIONS)**

**310. PHARMACIST: COLLABORATIVE PHARMACY PRACTICE AND STATEWIDE PROTOCOL AGREEMENTS.**

**01. Collaborative Agreement.** Pharmacists and prescribers may enter into collaborative pharmacy practice through a written collaborative pharmacy practice agreement that defines the nature and scope of authorized DTM or other patient care services to be provided by a pharmacist. (3-21-12)( )

~~01~~**a.** Agreement Elements. The collaborative pharmacy practice agreement must include: (3-21-12)

~~01~~**i.** Identification of the parties to the agreement; (3-21-12)

~~01~~**ii.** The establishment of each pharmacist's scope of practice authorized by the agreement, including a description of the types of permitted activities and decisions; (3-21-12)

~~01~~**iii-** The drug name, class, or category and protocol, formulary, or clinical guidelines that describe or limit a pharmacist's authority to perform DTM; (3-21-12)

~~01~~**iv.** A described method for a prescriber to monitor compliance with the agreement and clinical outcomes of patients and to intercede where necessary; (3-21-12)

~~01~~**v.** A provision documenting a prescriber's right to override a collaborative practice decision made by a pharmacist whenever deemed necessary or appropriate; (3-21-12)

~~01~~**vi.** A provision allowing any party to cancel the agreement by written notification; (3-21-12)

~~01~~**vii.** An effective date; and (3-21-12)

~~01~~**viii.** Signatures of the parties to the agreement and dates of signing. (3-21-12)

~~01~~**ix.** Amendments to a collaborative pharmacy practice agreement must be documented, signed, and dated. (3-21-12)

~~01~~**b.** Board Review. The original collaborative pharmacy practice agreement and any subsequent revisions must be made available to the Board upon request. (3-21-12)

~~01~~**c.** Agreement Review. The collaborative pharmacy practice agreement must be reviewed and renewed annually and revised when necessary or appropriate. (3-21-12)

~~01~~**d.** Documentation of Pharmacist Activities. The patient care provided pursuant to the agreement must be documented in the patient's permanent record in a manner that allows it to be readily available to other healthcare professionals providing care to the patient. (3-21-12)

**02. Statewide Protocol Agreement.** A pharmacist may perform DTM or other patient care services according to a statewide protocol agreement issued by the director of the Idaho Department of Health and Welfare, in conjunction with the Board, for the purpose of improving public health. The protocol agreement must include: ( )

**a.** An effective date; ( )

- b.** The geographical portion of the state where the protocol agreement is to be effective; and ( )
- c.** The drug name, class, or category and protocol, formulary or clinical guidelines that describe or limit a pharmacist's authority to perform DTM or other patient care services. ( )