

## IDAPA 27 – BOARD OF PHARMACY

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

DOCKET NO. 27-0101-1405

#### NOTICE OF RULEMAKING - ADOPTION OF PENDING RULE

**EFFECTIVE DATE:** This rule has been adopted by the agency and is now pending review by the 2015 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 or rejected in part by concurrent resolution in accordance with Section 67-5224 and 67-5291, Idaho Code. If the pending rule is approved or rejected in part 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.

This pending rule is necessary to consistently regulate the distribution of drugs by wholesalers, manufacturers, outsourcing facilities and pharmacies. Changes from proposed to pending language include the striking of existing rule 270 in full, which only addressed dispensers, and the drafting of new rule 615, which incorporates much of proposed rule 270. This pending language also includes proposed rule #242, which was moved from another docket. Additional changes from proposed to pending language include completing the list of statutorily allowed pharmacy distribution, including certain federal Drug Quality and Security Act requirements, adding an exemption, and adding prohibited acts.

The text of the pending rule has been amended in accordance with Section 67-5227, Idaho Code. Only those sections that have changes that differ from the proposed text are printed in this bulletin. The complete text of the proposed rule was published in the October 1, 2014 Idaho Administrative Bulletin, Vol. 14-10, pages 361 through 363.

**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:

This rulemaking is expected to increase the number of Board registrants slightly, at one hundred thirty dollars (\$130) per.

**ASSISTANCE ON TECHNICAL QUESTIONS:** For assistance on technical questions concerning this pending rule, contact Mark Johnston, Executive Director, (208) 334-2356.

DATED this 28<sup>th</sup> day of November, 2014.

Mark Johnston, R.Ph.  
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

266. -- ~~26970~~. (RESERVED)

**270. Emergency Drug Distribution By A Dispenser.**

*For an emergency medical reason, pursuant to Section 54-1752(16), Idaho Code, The distribution of a drug by a dispenser may distribute (without obtaining a wholesale distribution registration) a drug to another dispenser, is permitted only as follows:* (3-21-12)(    )

~~**01. Authorized Recipients.** *A dispenser may distribute prescription drugs only to a person licensed or registered by the appropriate state licensing agency to dispense or prescribe such prescription drugs. A dispenser may distribute controlled substances only to a person who holds a valid federal and Idaho state controlled substance registration, unless exempted by federal or state law.*~~ (    )

~~**02. Authorized Dispensing.**~~ (    )

~~**01a. Emergency Medical Reasons.** *For purposes of this rule, an emergency medical reason is a situation where a quantity of a prescription drug is needed by a dispenser without an may be distributed by a dispenser to an authorized recipient if a legitimate alternative source for the drug is not reasonably available and the drug is unavailable through a normal distribution channel in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining the drug.*~~ (3-21-12)

~~**02. Allowable Amount.** *The amount of the drug distributed must in an emergency may not reasonably exceed the amount required for immediate dispensing use.*~~ (3-21-12)(    )

~~**b. Office Use.** *Minimal quantities of prescription drugs may be distributed by a pharmacy to a prescriber for in office administration (and not for subsequent dispensing or distribution).*~~ (    )

~~**03. Delivery Requirements.** *Prescription drugs distributed by a dispenser may be delivered only to the premises listed on the authorized recipient's license or registration.*~~ (    )

~~**04. Suspicious Order Monitoring.** *A dispenser must have adequate processes in place for monitoring purchase activity of authorized recipients and must identify suspicious ordering patterns that identify potential diversion or criminal activity related to controlled substances, such as orders of unusual size, orders deviating substantially from a normal pattern, orders for drugs outside of the prescriber's scope of practice, and orders of unusual frequency.*~~ (    )

~~**035. Controlled Substance Distribution Invoice.** *Distributions must be pursuant to an invoice and not a prescription drug order. For controlled substances, each dispenser must retain a signed receipt of the distribution that includes at least:*~~ (3-21-12)(    )

~~**a.** *The date of the transaction;*~~ (3-21-12)

~~**b.** *The name, address, and DEA registration number of the distributing dispenser;*~~ (3-21-12)

~~**c.** *The name, address, and DEA registration number of the receiving dispenser;*~~ (3-21-12)

~~**d.** *The drug name, strength, and quantity for each product distributed; and*~~ (3-21-12)

~~**e.** *The signature of the person receiving the drugs.*~~ (3-21-12)

~~**06. Reporting.** *Specified data on controlled substances distributed by dispensers must be reported at least monthly to the Board in a form and manner prescribed by the Board.*~~ (    )

(BREAK IN CONTINUITY OF SECTION)

**611. -- 6194. (RESERVED)**

**615. DRUG DISTRIBUTION.**

**01. Authorized Distributors.** The following drug outlets may distribute legend drugs in or into Idaho, in compliance with these rules, pursuant to the following restrictions: ( )

**a.** A licensed or registered wholesale distributor and a registered manufacturer in compliance with the Idaho Wholesale Distribution Act and the Idaho Pharmacy Act; ( )

**b.** An FDA and Idaho registered outsourcing facility in compliance with 21 U.S.C. Section 353b of the Food, Drug and Cosmetic Act; ( )

**c.** A dispenser without being licensed or registered as a wholesale distributor according to the following restrictions: ( )

**i.** A dispenser may distribute to authorized recipients for an emergency medical purpose in which an alternative source for a drug is not reasonably available in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining a drug. The amount of the drug distributed in an emergency must not reasonably exceed the amount required for immediate use; ( )

**ii.** A dispenser may distribute intracompany to any division, subsidiary, parent, affiliated or related company under common ownership and control of a corporate entity; ( )

**iii.** A pharmacy may distribute to another pharmacy pursuant to a sale, transfer, merger or consolidation of all or a part of a pharmacy, whether accomplished as a sale of stock or business assets; ( )

**iv.** A pharmacy may distribute compound positron emission tomography drugs or radiopharmaceuticals, if in compliance with applicable federal law; and ( )

**v.** A pharmacy may distribute minimal quantities of prescription drugs to a prescriber for in-office administration, including the distribution of compounded drug product in the absence of a patient specific prescription drug order if: ( )

(1) The compounded drug product is not sterile and not intended to be sterile; ( )

(2) The compounded drug product is not further dispensed or distributed by the practitioner; and ( )

(3) The quantity of compounded drug product distributed is limited to five percent (5%) of the total number of compounded drug products dispensed and distributed on an annual basis by the pharmacy, which may include a drug compounded for the purpose of, or incident to, research, teaching or chemical analysis. ( )

**02. Distribution.** An authorized distributor must furnish: ( )

**a.** Drug product only to a person licensed by the appropriate state licensing agency to dispense, conduct research with or independently administer such drugs; ( )

**b.** Scheduled controlled substances only to a person who has been issued a valid controlled substance registration by the DEA and the Board, unless exempt by state or federal law; ( )

**c.** Federally required transaction documentation, including transaction information, transaction history, and transaction statements with each distribution; and

d. Drug product only to the premises listed on the authorized receiving person's license or registration. Delivery to a hospital pharmacy receiving area satisfies this requirement, provided that authorized receiving personnel sign for receipt at the time of delivery. ( )

**03. Controlled Substance Distribution Invoice.** Distributions must be pursuant to an invoice and not a prescription drug order. For controlled substances, each dispenser must retain a signed receipt of the distribution that includes at least: ( )

**a.** The date of the transaction; ( )

**b.** The name, address, and DEA registration number of the distributing dispenser; ( )

**c.** The name, address, and DEA registration number of the receiving dispenser; ( )

**d.** The drug name, strength, and quantity for each product distributed; and ( )

**e.** The signature of the person receiving the drugs. ( )

**04. Monitoring Purchase Activity.** An authorized distributor must have adequate processes in place for monitoring purchase activity of customers and identifying suspicious ordering patterns that identify potential diversion or criminal activity related to controlled substances such as orders of unusual size, orders deviating substantially from a normal pattern, orders for drugs that are outside of the prescriber's scope of practice, and orders of unusual frequency. ( )

**05. Reporting.** An authorized distributor must report specified data on controlled substances distributed at least monthly to the Board in a form and manner prescribed by the Board, except when distributing intracompany. ( )

**06. Prohibited Acts.** The following acts are prohibited: ( )

**a.** Distribution of any drug product that is adulterated, misbranded, counterfeit, expired, damaged, recalled, stolen, or obtained by fraud or deceit; and ( )

**b.** Failing to obtain a license or registration when one is required to distribute in or into Idaho. ( )

**616. – 619. (RESERVED)**

**~~809. Prescription Drug Pedigrees.~~**

~~Each person, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, engaged in wholesale distribution of prescription drugs that leave or have left the normal distribution channel must tender a pedigree to the person receiving the drug upon delivery. A retail pharmacy or chain pharmacy warehouse must comply with these pedigree requirements only if engaging in wholesale distribution. (3-21-12)~~

~~**01- Pedigree Contents.** A pedigree for each prescription drug must contain the following information: (3-21-12)~~

~~**a-** The proprietary and established name of the drug; (3-21-12)~~

~~**b-** The container size; (3-21-12)~~

~~**c-** The number of containers; (3-21-12)~~

~~**d-** The dosage form; (3-21-12)~~

