

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-0907

NOTICE OF RULEMAKING - ADOPTION OF PENDING RULE

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

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

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

The pending rule is being adopted as proposed. The complete text of the proposed rule was published in Book 2 of the October 7, 2009 Idaho Administrative Bulletin, Vol. 09-10, pages 258 through 261.

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:

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

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

DATED this 4th day of November, 2009.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720
Boise, ID 83720-0067
Phone: (208) 334-2356
Fax: (208) 334-3536

THE FOLLOWING NOTICE PUBLISHED WITH THE PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2009.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

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

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

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

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

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

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

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

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2009.

DATED this 28th day of August, 2009.

THE FOLLOWING IS THE TEXT OF THE PENDING RULE

321. DEFINITIONS.

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

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

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

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

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

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

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

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

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

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

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

10. Manufacturer’s Exclusive Distributor. A person who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer’s prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer’s prescription drug. Such manufacturer’s exclusive distributor must be licensed as a wholesale distributor, pursuant to Section 54-1753, Idaho Code, and must also be an authorized distributor of record to be considered part of the normal distribution channel. (4-2-08)

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

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

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

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

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

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

12. Pedigree. A document or electronic file containing information that records each

wholesale distribution of a prescription drug. (4-2-08)

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

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

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

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

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

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

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

b. The sale, purchase, distribution, trade, or transfer of a prescription drug or the offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons. (4-2-08)

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

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

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

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

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

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

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

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

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