Table of Contents

27.01.06 – Rules Governing DME, Manufacturing, and Distribution

IDAPA 27
TITLE 01
CHAPTER 06

27.01.06 – RULES GOVERNING DME, MANUFACTURING, AND DISTRIBUTION

000. LEGAL AUTHORITY.
This chapter is adopted under the legal authority of the Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code; the Idaho Pharmacy Act, the Idaho Wholesale Drug Distribution Act, and the Idaho Legend Drug Donation Act, Title 54, Chapter 17, Idaho Code; and specifically pursuant to Sections 37-2702, 37-2715, 54-1717, 54-1753, 54-1755, and 54-1763, Idaho Code. (7-1-18)

001. TITLE AND SCOPE.
In addition to the General Provisions set forth in IDAPA 27.01.01, "General Provisions," the following title and scope shall apply to these rules: (7-1-18)

01. Title. The title of this chapter is "Rules Governing DME, Manufacturing, and Distribution," IDAPA 27, Title 01, Chapter 06. (7-1-18)

02. Scope. The scope of this chapter includes, but is not limited to, provision for, and clarification of, the Board's assigned responsibility to regulate and control drug manufacturing and distribution. (7-1-18)

002. WRITTEN INTERPRETATIONS.
In accordance with Title 67, Chapter 52, Idaho Code, this agency may have written statements that pertain to the interpretation of, or to compliance with the rules of this chapter. Any such documents are available for public inspection and copying at cost at the Idaho Board of Pharmacy office. (7-1-18)

003. ADMINISTRATIVE PROCEEDINGS AND APPEALS.
Administrative proceedings and appeals are administered by the Board in accordance with the "Idaho Rules of Administrative Procedure of the Attorney General," IDAPA 04.11.01, Subchapter B -- Contested Cases, Rules 100 through 800. (7-1-18)

01. Place and Time for Filing. Documents in rulemakings or contested cases must be filed with the executive director of the Board at the Board office between the hours of 8 a.m. and 5 p.m., Mountain Time, Monday through Friday, excluding state holidays. (7-1-18)

02. Manner of Filing. One (1) original of each document is sufficient for filing; however, the person or officer presiding over a particular rulemaking or contested case proceeding may require the filing of additional copies. A document may be filed with the Board by e-mail or fax if legible, complete, and received during the Board's office hours. The filing party is responsible for verifying with Board staff that an e-mail or fax was successfully and legibly received. (7-1-18)

004. INCORPORATION BY REFERENCE.
No documents have been incorporated by reference into these rules. (7-1-18)

005. BOARD OFFICE INFORMATION.

01. Street Address. The office is located at 1199 Shoreline Lane, Suite 303, Boise, Idaho. (7-1-18)

02. Mailing Address. The mailing address is P.O. Box 83720, Boise, Idaho 83720-0067. (7-1-18)

03. Telephone Number. The telephone number is (208) 334-2356. (7-1-18)

04. Fax Number. The fax number is (208) 334-3536. (7-1-18)

05. Electronic Address. The website address is https://bop.idaho.gov. (7-1-18)

06. Office Hours. The office hours are 8 a.m. to 5 p.m., Mountain Time, Monday through Friday,

excluding state holidays. (7-1-18)

006. PUBLIC RECORDS ACT COMPLIANCE.
Board of Pharmacy records and filings are subject to compliance with the Idaho Public Records Act, Title 74, Chapter 1, Idaho Code. (7-1-18)

007. OFFICIAL BOARD JOURNAL.
The official journal of the Board is the electronic Idaho State Board of Pharmacy Newsletter. A link to recent versions of the newsletter is posted on the Board's website. Board licensees and registrants are presumed to have knowledge of the contents of the newsletter on the date of publication. The newsletter may be used in administrative hearings as proof of notification. (7-1-18)

008. – 009. (RESERVED)

010. DEFINITIONS AND ABBREVIATIONS.
The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the definitions and abbreviations found at IDAPA 27.01.01.010 through 012 are applicable to these rules. (7-1-18)

011. – 019. (RESERVED)

020. DME OUTLET STANDARDS.

01. Policies and Procedures. A DME outlet must adopt policies and procedures that establish: (7-1-18)

a. Operational procedures for the appropriate provision and delivery of equipment; (7-1-18)

b. Operational procedures for maintenance and repair of equipment; and (7-1-18)

c. Recordkeeping requirements for documenting the acquisition and provision of products. (7-1-18)

02. Sale of Specified Prescription Drugs. Registered DME outlets may hold for sale at retail the following prescription drugs: (7-1-18)

a. Pure oxygen for human application; (7-1-18)

b. Nitrous oxide; (7-1-18)

c. Sterile sodium chloride; and (7-1-18)

d. Sterile water for injection. (7-1-18)

03. Prescriber's Order Required. Prescription drugs and devices may only be sold or delivered by a DME outlet upon the lawful order of a prescriber. (7-1-18)

021. -- 029. (RESERVED)

030. 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: (7-1-18)

a. A licensed or registered wholesale distributor and a registered manufacturer in compliance with the Idaho Wholesale Distribution Act and the Idaho Pharmacy Act; (7-1-18)

b. An FDA and Idaho registered outsourcing facility in compliance with 21 U.S.C. Section 353b of the Food, Drug and Cosmetic Act; (7-1-18)

c. A dispenser without being licensed or registered as a wholesale distributor according to the following restrictions: (7-1-18)

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 necessary for immediate use; (7-1-18)

ii. A dispenser may distribute intracompany to any division, subsidiary, parent, affiliated or related company under common ownership and control of a corporate entity; (7-1-18)

iii. A dispenser may distribute to another dispenser pursuant to a sale, transfer, merger or consolidation of all or a part of a dispenser, whether accomplished as a sale of stock or business assets; (7-1-18)

iv. A dispenser may distribute compound positron emission tomography drugs or radiopharmaceutics, if in compliance with applicable federal law; and (7-1-18)

v. A dispenser 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: (7-1-18)

(1) The compounded drug product is not sterile and not intended to be sterile; (7-1-18)

(2) The compounded drug product is not further dispensed or distributed by the practitioner; and (7-1-18)

(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 dispenser, which may include a drug compounded for the purpose of, or incident to, research, teaching or chemical analysis. (7-1-18)

02. Distribution. Unless statutorily exempted, an authorized distributor must furnish: (7-1-18)

a. Drug product only to a person licensed by the appropriate state licensing agency to dispense, conduct research with or independently administer such drugs; (7-1-18)

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; (7-1-18)

c. Federally required transaction documentation, including transaction information, transaction history, and transaction statements with each distribution; and (7-1-18)

d. Drug product only to the registered address of the authorized receiving person. Delivery to a hospital pharmacy receiving area satisfies this requirement, provided that authorized receiving personnel sign for receipt at the time of delivery. (7-1-18)

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: (7-1-18)

a. The date of the transaction; (7-1-18)

b. The name, address, and DEA registration number of the distributing dispenser; (7-1-18)

c. The name, address, and DEA registration number of the receiving dispenser; (7-1-18)

d. The drug name, strength, and quantity for each product distributed; and (7-1-18)

e. The signature of the person receiving the drugs. (7-1-18)

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. (7-1-18)

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. (7-1-18)

06. Prohibited Acts. The following acts are prohibited: (7-1-18)

a. Distribution of any drug product that is adulterated, misbranded, counterfeit, expired, damaged, recalled, stolen, or obtained by fraud or deceit; and (7-1-18)

b. Failing to obtain a license or registration when one is required to distribute in or into Idaho. (7-1-18)

031. -- 039. (RESERVED)

040. WHOLESALER: STANDARDS.
These wholesaler rules establish the minimum standards for the storage and handling of drugs by wholesalers and their officers, designated representative, agents, and employees and for the establishment and maintenance of records required for persons engaged in wholesale drug distribution. (7-1-18)

041. WHOLESALER: FACILITY REQUIREMENTS.
Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must: (7-1-18)

01. Minimum Physical Standards. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations; (7-1-18)

02. Minimum Environmental Standards. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions; (7-1-18)

03. Quarantine Area. Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened; (7-1-18)

04. Maintenance Requirements. Be maintained in a clean and orderly condition; and (7-1-18)

05. Pest Controls. Be free from infestation by insects, rodents, birds, or vermin of any kind. (7-1-18)

042. WHOLESALER: FACILITY SECURITY.
Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows: (7-1-18)

01. Access from Outside. Access from outside the premises must be kept to a minimum and well controlled; (7-1-18)

02. Perimeter Lighting. The outside perimeter of the premises must be well lighted; (7-1-18)

03. Authorized Entry. Entry into areas where drugs are held must be limited to authorized personnel; (7-1-18)

04. Alarm Systems. Facilities must be equipped with an alarm system to detect entry after hours; and (7-1-18)

05. Security Systems. Facilities must be equipped with security systems sufficient to protect against theft, diversion, and record tampering. (7-1-18)

043. WHOLESALER: DRUG STORAGE REQUIREMENTS.

Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by current requirements of the USP-NF, to preserve product identity, strength, quality, and purity. Temperature and humidity recording equipment, devices, or logs must document proper storage of drugs. (7-1-18)

044. WHOLESALER DRUG SHIPMENT INSPECTION REQUIREMENTS.

01. Examination on Receipt. Each shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution. (7-1-18)

02. Outgoing Shipment Inspections. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents. (7-1-18)

045. WHOLESALER: QUARANTINE.

Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor. (7-1-18)

01. Container Adulteration. Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined. (7-1-18)

02. Other Conditions Requiring Quarantine. Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards. (7-1-18)

046. WHOLESALER: RECORDKEEPING REQUIREMENTS.

Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs. (7-1-18)

01. Record Contents. The records must include at least: (7-1-18)

a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (7-1-18)

b. The identity and quantity of the drugs received and distributed or disposed of; and (7-1-18)

c. The dates of receipt and distribution or other disposition of the drugs. (7-1-18)

02. Records Maintenance. Records may be maintained in an immediately retrievable manner at the inspection site or in a readily retrievable manner at a central location. (7-1-18)

047. WHOLESALER: PERSONNEL.

01. Responsible Person Designees. A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications. (7-1-18)

02. Adequate Personnel. A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities. (7-1-18)

03. Designated Representative Continuing Education. A wholesaler's designated representative must complete training and continuing education on state and federal laws pertaining to wholesale distribution of prescription drugs provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance. (7-1-18)

048. WHOLESALER: POLICIES AND PROCEDURES.
Wholesalers must adopt policies and procedures for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting errors and inaccuracies in inventories, and as necessary to ensure compliance with the following: (7-1-18)

01. Distribution of Oldest Approved Stock First. The oldest approved stock of a drug product must be distributed first except if extraordinary circumstances require a temporary deviation. (7-1-18)

02. Recalls and Withdrawals. Drugs must be recalled or withdrawn upon: (7-1-18)

a. A request by the FDA or other local, state, or federal law enforcement or other government agency, including the Board; (7-1-18)

b. A voluntary action by a manufacturer to remove defective or potentially defective drugs from the market; or (7-1-18)

c. An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design. (7-1-18)

03. Crisis Preparation. Wholesalers must prepare for, protect against, and competently handle a crisis affecting the security or operation of a facility, including a fire, flood, or other natural disaster, a strike, or other situations of local, state, or national emergency. (7-1-18)

049. (RESERVED)

050. DRUG MANUFACTURERS.
These rules are applicable to drug manufacturers located within the state of Idaho. Non-resident manufacturers engaged in wholesale drug distribution in or into Idaho must comply with the Idaho Wholesale Drug Distribution Act and rules, as applicable. (7-1-18)

01. Standards. A manufacturer must ensure compliance with the federal "Current Good Manufacturing Practice" requirements. (7-1-18)

02. Records. A manufacturer must adopt policies and procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law. (7-1-18)

051. -- 999. (RESERVED)

Subject Index