

Oklahoma State Board of Pharmacy
Emergency Manufacturer Rules

Effective 5/12/2008

CHAPTER 20. MANUFACTURERS, PACKAGERS AND WHOLESALERS
SUBCHAPTER 3. MANUFACTURERS

535:20-3-1. Manufacturer permit; Purpose

(a) The rules in this Subchapter set the minimum standards and requirement for persons who must license as a manufacturer as defined in 59 O.S. 353.1 before engaging in manufacturing as required in 59 O.S. Section 353.18 (B) and (C).

(b) The rules of this Subchapter are to implement the requirement in the Pharmacy Practice Act and may include requirements for the Utilization of Used Prescription Medication Act.

~~(a) A manufacturer permit entitles the permit holder to manufacture and wholesale Rx Only drugs (prescription drugs) from the licensed location.~~

~~(b) A manufacturer permit is only valid for the name, ownership and location listed on the permit.~~

~~(c) A new permit is required within 10 days if name, ownership or location changes.~~

~~(d) Each manufacturing location must be licensed.~~

~~(e) Each manufacturer whose product is sold in Oklahoma is required to obtain and maintain an Oklahoma manufacturer permit.~~

[Agency note: (a)-(e) of this section are moved to 535:20-3-2 (b)-(f)]

535:20-3-1.1. Definitions [Reserved]

535:20-3-2. Registration; manufacturer licensing or permit requirement

(a) All manufacturers of Rx Only (dangerous) drugs conducting interstate and/or intrastate transactions in Oklahoma shall register annually with the Board of Pharmacy.

(1) Permits shall be issued only to those manufacturers which satisfy the provisions of Title 59, O.S., Section 353.18 (B)(1)(2) et seq., and all rules of this Title, et seq.

(2) Each manufacturer must comply with the Federal Food, Drug and Cosmetic Act Good Manufacturing Practices Act (GMPA, 21 U.S.C., Sec. 331 et seq.), the Prescription Drug Marketing Act of 1987 (PDMA, 21 U.S.C., Sec. 331 et seq.) and/or any other applicable federal, state, or local laws and regulations.

(b) A manufacturer permit entitles the permit holder to manufacture and wholesale Rx Only drugs (prescription drugs) from the licensed location.

(c) A manufacturer permit is only valid for the name, ownership and location listed on the permit.

(d) A new permit is required within 10 days if name, ownership or location changes.

(e) Each manufacturing location must be licensed.

(f) Each manufacturer whose product is sold in Oklahoma is required to obtain and maintain an Oklahoma manufacturer permit.

[Agency note: (b)-(f) of this section were formerly 535:20-3-1 (a)-(e)]

535:20-3-3. Minimum required information for licensure

~~The minimum required information for manufacturer licensure shall be as set forth in 535:20-7-4 regarding wholesalers and in 535:25 and this Title.~~

(a) Applicants shall be registered with the federal Food and Drug Administration (FDA) as a manufacturer.

(b) All manufacturer applicants must meet the requirements under the Oklahoma Pharmacy Act, this Title and the rules in 535:25 for applicants.

(c) Manufacturer applicants must submit a satisfactorily completed application together with the

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required fee annually. This application shall include, at least, the following:

- (1) The name, full business address, and telephone number;
- (2) All trade or business names used by the manufacturer applicant;
- (3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;
- (4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);
- (5) The name(s) of the owner and/or operator of the manufacturer applicant; and
- (6) Any other information the Board deems necessary to protect the public health.

535:20-3-4. Minimum qualifications

(a) All manufacturers must conform to the federal Good Manufacturing Practices GMPA, and/or any other applicable federal, state or local laws and regulations.

(b) The minimum qualifications for manufacturers shall be the same as those set forth in ~~535:20-7-5~~ regarding wholesalers and in 535:25 and this Chapter.

(c) The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in manufacturer of drugs or devices:

- (1) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, manufacturer, wholesale or retail drug distribution, or distribution of controlled substances;
- (2) Any felony convictions of the applicant under federal, state, or local laws;
- (3) The applicant's past experience in the manufacture or distribution of drugs, including controlled substances;
- (4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;
- (5) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;
- (6) Compliance with licensing requirements under previously granted licenses, if any;
- (7) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,
- (8) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(d) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

535:20-3-5. Personnel

—(a) Personnel employed in manufacturing shall have sufficient education, training and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

~~(b) The Board shall as required in 353.18(B), at a minimum, consider those qualifications listed in 535:20-3-5 535:20-7-5 for personnel employed in wholesale distribution.~~

535:20-3-6. Minimum requirements for Rx Only drug storage, handling, maintenance and records

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The minimum requirements for RX Only (dangerous) drug storage, handling, maintenance and records for manufacturers shall be the same as those set forth in 535:20-7-7 through 535:20-7-7.10 regarding wholesalers. The following decimal sections shall describe the minimum requirements for the storage and handing of drugs, and for the establishment and maintenance of drug records by manufacturers and their officers, agents, representatives, and employees.

535:20-3-6.1. Facility requirements

(a) All manufacturers of drugs shall conform to U. S. Food and Drug Administration (FDA) Current Good Manufacturing Practice Regulations (CGMP).

(b) All manufacturers shall conform to the Oklahoma Pharmacy Act and the rules of this Title.

(c) Each facility at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be licensed by the Board;

(2) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(3) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

(4) 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;

(5) Be maintained in a clean and orderly condition; and,

(6) Be free from infestation by insects, rodents, birds, or vermin of any kind.

535:20-3-6.2. Multiple Licensing

(a) A manufacturing facility shall not be in a facility where a retail pharmacy is located.

(b) The manufacturing facility shall be located apart and separate from any retail pharmacy, licensed by the Board of Pharmacy, as set forth in this Title and 535:25-3-5.

535:20-3-6.3. Security

(a) Each facilities used for manufacturing shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well-controlled.

(2) The outside perimeter of the premises shall be well-lighted.

(3) Entry into areas where drugs are held shall be limited to authorized personnel.

(b) All facilities shall be equipped with an alarm system to detect entry after hours.

(c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

535:20-3-6.4. Storage

All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(1) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

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(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs.

(3) The recordkeeping requirement in this Title for manufacturers shall be followed for all stored drugs.

535:20-3-6.5. Examination of materials

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(c) The recordkeeping requirement in this Title for manufacturers shall be followed for all incoming and outgoing drugs.

535:20-3-6.6. Returned, damaged, and outdated drugs

(a) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.

(b) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the manufacturer shall consider, among other things:

(1) The conditions under which the drug has been held, stored or shipped before or during its return; and,

(2) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(c) The recordkeeping requirements for manufacturers in this Title shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

535:20-3-6.7. Recordkeeping

(a) Manufacturers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(b) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(d) Each manufacturer should maintain an ongoing list of persons with whom they do business.

535:20-3-6.8. Written policies and procedures

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(a) Manufacturers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(b) Manufacturers shall include in their written policies and procedures the following:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

(A) Action initiated at the request of the Food and Drug Administration (FDA) or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

(B) Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(C) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(2) A procedure to ensure that manufacturers prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(A) This procedure shall provide for written documentation of the disposition of outdated drugs.

(B) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

535:20-3-6.9. Responsible persons

Manufacturers shall establish and maintain lists of officers, directors, managers and other persons in charge of drug manufacturer, distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

535:20-3-6.10. Compliance with federal, state and local laws

(a) Manufacturers shall operate in compliance with applicable federal, state, and local laws and regulations.

(b) Manufacturers shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(c) Manufacturers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulations.

535:20-3-6.11. Salvaging and reprocessing

Manufacturers shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

535:20-3-9. Prohibited Conduct

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(a) The following shall be considered prohibited conduct and be a violation of these rules:

(1) Engaging in the manufacturing of drugs

(A) with intent to defraud or deceive, failing to maintain or provide a complete and accurate record, when required;

(B) destroying, altering, concealing, or failing to maintain complete and accurate records for any drug manufactured, when required;

(C) knowingly purchasing or receiving drugs from a person, not authorized to distribute drugs, or,

(D) selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs, under the jurisdiction in which the person receives the drug(s).

(2) Forging, counterfeiting, or falsely creating any label for a drug(s) or who falsely represents any factual matter contained in any label of a drug(s).

(3) Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a drug or the commission of any other act with respect to a drug that results in the drug being misbranded.

(4) Manufacturing, purchasing, selling, delivering or bringing into the state contraband drug(s), or any one who illegally possesses any amount of contraband drug(s); or,

(b) Any violation of the rules of registrant conduct in 535:25:9 is prohibited conduct.