TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 35 DRUG WAREHOUSE

16.19.35.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.
[16.19.35.1 NMAC - N, 11-15-10]

16.19.35.2 SCOPE: This section applies to all licensed clinics, hospitals and pharmacies.
[16.19.35.2 NMAC - N, 11-15-10]

16.19.35.3 STATUTORY AUTHORITY: Section 61-11-6(A)(6) NMSA 1978 authorizes the board of pharmacy to provide for the licensing of all places where dangerous drugs are stored or administered and for the inspection of their facilities and activities. Section 61-11-14(B)(10) NMSA 1978 authorizes the board to issue limited drug permits for home care services.
[16.19.35.3 NMAC - N, 11-15-10]

16.19.35.4 DURATION: Permanent.
[16.19.35.4 NMAC - N, 11-15-10]

16.19.35.5 EFFECTIVE DATE: November 15, 2010, unless a different date is cited at the end of a section.
[16.19.35.5 NMAC - N, 11-15-10]

16.19.35.6 OBJECTIVE: The objective of Part 35 of Chapter 19 is to establish standards for the safe and competent storage of pharmaceutical products in facilities located off-site from the licensed clinic, hospital or pharmacy.
[16.19.35.6 NMAC - N, 11-15-10]

16.19.35.7 DEFINITIONS: "Drug warehouse" means an off-site physical storage location of a clinic, hospital or pharmacy currently licensed by the New Mexico board of pharmacy. Dangerous drugs may be stored for the use of the licensed clinic, hospital or pharmacy.
[16.19.35.7 NMAC - N, 11-15-10]

16.19.35.8 FACILITIES:

A. All facilities at which prescription drugs are stored shall:

(1) be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

(2) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security;

(3) have a quarantine area for storage of prescriptions that are outdated, damaged, deteriorated, misbranded, counterfeit or suspected of being counterfeit or adulterated, otherwise unfit for use;

(4) be maintained in a clean and orderly condition;

(5) be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) be a commercial location and not a personal dwelling or residence;

(7) provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting or diversion of prescription drugs or devices.

B. Controlled substances must be isolated from non-controlled substance drugs and stored in a secure area in accordance with DEA security requirements and standards.
[16.19.35.8 NMAC - N, 11-15-10]

16.19.35.9 STORAGE: All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or in compliance with standards in the current edition of an official compendium, such as United States pharmacopeia-national formulary (USP/NF).

A. If no requirements are established for a prescription 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.

B. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices or logs shall be utilized to document proper storage of prescription drugs.

C. The record keeping requirements in Subsection F of 16.19.8.13 NMAC shall be followed for all stored prescription drugs.

[16.19.35.9 NMAC - N, 11-15-10]

16.19.35.10 SECURITY:

A. All facilities used for drug warehouses shall be secure from unauthorized entry and;

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

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

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

B. All facilities shall be equipped with a security system that will provide suitable protection against, detect and document any instances of theft, diversion or counterfeiting and;

(1) all facilities shall be equipped with an alarm system to detect entry after hours;

(2) all facilities shall be equipped with a security system that will provide suitable protection against theft and diversion;

(3) the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

[16.19.35.10 NMAC - N, 11-15-10]

16.19.35.11 EXAMINATION OF MATERIALS:

A. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, contraband, suspected of being counterfeit or contraband, or other damage to the contents.

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

C. Upon receipt, a drug warehouse must review records for the acquisition of prescription drugs or devices for accuracy and completeness.

[16.19.35.11 NMAC - N, 11-15-10]

16.19.35.12 RECORD KEEPING:

A. Drug warehouses shall establish and maintain inventories and records of all transactions regarding receipt and distribution of other disposition of prescription drugs. These records shall be maintained at the clinic, hospital or pharmacy and must include the following information:

(1) the identity and quantity of the drugs received and distributed or disposed of; and

(2) the dates of receipt and distribution or other disposition of the drugs;

(3) the name, location and license number of the business, health care practitioner or other entity appropriately licensed to possess, dispense, distribute, administer or destroy prescription drugs.

B. Inventories and records shall be made available for inspection and photocopying by authorized inspectors employed by the board and authorized federal, state or local law enforcement agency officials for a retention period of three (3) years following disposition of the drugs.

C. Registrants must petition the board for a waiver in order to store the required records at an alternate location. The registrant must provide the board in writing, of the address (mailing and street), telephone number, and the name and title of the person designated by the registrant as the custodian of the records. Any changes of custodian or location of records must be reported in writing to the board within fifteen (15) actual days. Any records approved by waiver to be stored at an alternate location must be available within two (2) working days of a request by authorized board personnel or officials of a federal, state or local law enforcement agency.

D. Drug warehouses shall report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and FDA and where applicable to the DEA.

[16.19.35.12 NMAC - N, 11-15-10]

16.19.35.13 WRITTEN POLICIES AND PROCEDURES:

A. Drug warehouses shall establish, maintain and adhere to written policies and procedures which shall be followed:

(1) for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures;

(2) for identifying, recording and reporting losses or thefts; and

(3) for correcting all errors and inaccuracies in inventories.

B. Drug warehouses shall include in their written policies and procedures the following:

(1) a procedure whereby the oldest approved stock of a prescription drug product is distributed first; the procedure may permit deviation from this requirement if such deviation is temporary and appropriate;

(2) a procedure to be followed for handling recalls and withdrawals of prescription drugs; such procedure shall be adequate to deal with recalls and withdrawals due to;

(a) any action initiated at the request of the food and drug administration or other federal, state or local law enforcement or other government agency, including the state licensing agency;

(b) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(c) any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design;

(3) a procedure to ensure that drug warehouses prepare for, protect against, and handle any 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;

(4) a procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed; this procedure shall provide for written documentation of the disposition of outdated prescription drugs; this documentation shall be maintained for three (3) years after disposition of the outdated drugs;

(5) a procedure for the destruction of outdated prescription drugs in accordance with state and federal laws, including all necessary documentation, maintained for a minimum of three (3) years and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements;

(6) a procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels and packaging can not be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of three (3) years and the appropriate witnessing of the destruction of any labels, packaging, immediate containers or containers in accordance with all federal and state requirements;

(7) a procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drugs to the board, FDA as required by the agency and if applicable, DEA, within three (3) business days.

[16.19.35.13 NMAC - N, 11-15-10]

16.19.35.14 RESPONSIBLE PERSONS: Drug warehouses shall establish and maintain lists of officers, directors, managers and other persons in charge of drug warehouse storage and handling, including a description of their duties and a summary of their qualifications.

[16.19.35.14 NMAC - N, 11-15-10]

16.19.35.15 COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAW: Drug warehouses shall operate in compliance with applicable federal, state and local laws and regulations.

A. Drug warehouses shall permit board authorized personnel and authorized federal, state and local law enforcement officials to enter and inspect their premises, delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

B. Drug warehouses that deal in controlled substances shall register with the board and the DEA and shall comply with all applicable state, local and DEA regulations.

C. A licensed drug warehouse may distribute only to persons who are licensed to possess dangerous drugs.

D. Controlled substances may only be distributed or delivered to persons in this state who are registered by the board and the DEA to possess controlled substances.

[16.19.35.15 NMAC - N, 11-15-10]

16.19.35.16 MINIMUM REQUIRED INFORMATION FOR DRUG WAREHOUSE LICENSURE:

A. Every clinic, hospital or pharmacy requiring off-site storage of drugs shall license with the board by application and provide information required by the board on an application approved by the board, including but not limited to:

(1) all trade or business names used by the licensee (includes "is doing business as" and "formerly known as") which cannot be identical to the name used by another unrelated wholesale distributor licensed to purchase drugs or devices in the state;

(2) name(s) of the owner and operator of the licensee (if not the same person) including;

(a) if a person: the name, business address and date of birth;

(b) if a partnership: the name, business address, date of birth of each partner and the name of the partnership and federal employer identification number;

(c) if a corporation: the name, business address, date of birth, title of each corporate officer and director, the corporate names, the name of the state of incorporation, federal employer identification number, the name of the parent company, if any; the name and business address of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, including over-the-counter (OTC) stock, unless the stock is traded on a major stock exchange and not OTC, publicly held corporations may request a waiver to the requirements of this Paragraph pursuant to 16.19.32 NMAC;

(d) if sole proprietorship: the full name, business address, date of birth of the sole proprietor and the name and federal employer identification number of the business entity;

(e) if a limited liability company: the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, the name of the state in which the limited liability company was originated;

(f) any other relevant information that the board requires;

(3) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the wholesale distributor that engages in the distribution of drugs and additional information as required in Subsection F of 16.19.8.13 NMAC;

(4) a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the wholesale drug distributor by any other state and federal authority that authorizes the wholesale distributor to purchase, possess and distribute drugs;

(5) a list of all disciplinary actions by state and federal agencies against the wholesale distributor as well as any such actions against principals, owners, directors or officers;

(6) a full description of each facility and warehouse, including all locations utilized for drug storage or distribution; the description must include the following:

(a) square footage;

(b) security and alarm system descriptions;

(c) terms of lease or ownership;

(d) address and;

(e) temperature and humidity controls;

(7) a copy of the drug warehouse written policies and procedures.

B. Every clinic, hospital or pharmacy who operates a drug warehouse shall submit a reasonable fee to be determined by the board.

C. Each drug warehouse must undergo an inspection by the board or a third party working on behalf of the board for the purpose of inspecting the warehouse operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the board.

D. All drug warehouses must display or have readily available all licenses and the most recent inspection report administered by the board.

E. Changes in any information in this section shall be submitted to the board or to the third party working on behalf of the boar within thirty (30) days of such change unless otherwise noted.

[16.19.35.16 NMAC - N, 11-15-10]

16.19.35.17 MINIMUM QUALIFICATIONS:

A. The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in warehousing of prescription drugs within the state:

(1) any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) any felony convictions of the applicant under federal, state or local law;

(3) the applicant's past experience in the distribution of prescription drugs, including controlled substances;

(4) the furnishing by the applicant of false or fraudulent material in any application made in connection with prescription drug manufacturing or prescription drug distribution;

(5) suspension 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;

(6) compliance with licensing requirements under previously granted licenses, if any;

(7) compliance with requirements to maintain or make available to the board or to federal, state, or local law enforcement officials those records required under this section; and

(8) any findings by the board that the applicant has violated or been disciplined by a regulatory agency in any state for violating and federal, state, or local laws relating to drug or device wholesale distribution;

(9) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

B. 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 in the public interest. Public interest considerations shall be based upon factors and qualifications that are directly related to the protection of the public health and safety.

[16.19.35.17 NMAC - N, 11-15-10]

HISTORY OF 16.19.35 NMAC: [RESERVED]