

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 8 WHOLESALE PRESCRIPTION DRUG DISTRIBUTION

16.19.8.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy.
[16.19.8.1 NMAC - Rp, 16.19.8.1 NMAC, 12-02-09]

16.19.8.2 SCOPE: All individuals and entities engaged in the wholesale distribution of prescription drugs, including manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, manufacturer's warehouses, distributor's warehouses, chain drug warehouses, wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distribution.
[16.19.8.2 NMAC - Rp, 16.19.8.2 NMAC, 12-02-09]

16.19.8.3 STATUTORY AUTHORITY: Section 61-11-6(A)6 NMSA 1978 directs the board of pharmacy to provide for the licensing of drug manufacturers, repackagers and wholesale drug distributors and for the inspection of their facilities and activities. Section 61-11-6(A)7 NMSA 1978 authorizes the board to enforce the provisions of all state laws pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs, cosmetics or poisons, including the New Mexico Drug, Device and Cosmetic Act, Chapter 26, Article I NMSA 1978. Pursuant to Section 26-1-18 of the Drug, Device and Cosmetic Act, the board is authorized to promulgate regulations for the efficient enforcement of the act.
[16.19.8.3 NMAC - Rp, 16.19.8.3 NMAC, 12-02-09]

16.19.8.4 DURATION: Permanent
[16.19.8.4 NMAC - Rp, 16.19.8.4 NMAC, 12-02-09]

16.19.8.5 EFFECTIVE DATE: December 2, 2009, unless a different date is cited at the end of a section.
[16.19.8.5 NMAC - Rp, 16.19.8.5 NMAC, 12-02-09]

16.19.8.6 OBJECTIVE: The objective of Part 8 of Chapter 19 is to implement the Federal Prescription Drug Marketing Act of 1987 (Pub. L. 100-293, amending the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 321 et seq.), by providing minimum standards, terms and conditions for the licensing by the board of persons who engage in wholesale distribution of prescription drugs.
[16.19.8.6 NMAC - Rp, 16.19.8.6 NMAC, 12-02-09]

16.19.8.7 DEFINITIONS:

- A. "Adulterated"** a drug or device shall be deemed to be adulterated if it:
- (1) consists in whole or part of any filthy, putrid, or decomposed substance;
 - (2) has been produced, prepared, packed or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;
 - (3) is a drug and the methods used in or the facilities of controls used for its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of the New Mexico Drug, Device and Cosmetic Act (this article) as to safety and has the identity and strength and meets the quality and purity characteristics which purports or is represented to possess;
 - (4) is a drug and its container is composed in whole or part of any poisonous or deleterious substance which may render the contents injurious to health;
 - (5) is a drug and it bears or contains for purposes of coloring only a color additive which is unsafe within the meaning of the federal act or it is a color additive the intended use of which in drugs is for the purpose of coloring only and is unsafe within the meaning of the federal act;
 - (6) purports to be or is represented as a drug the name of which is recognized in an official compendium and its strength differs from or its quality or purity falls below the standard set forth in such compendium; such determination as to strength, quality and purity shall be made in accordance with the tests or methods of assay set forth in such compendium or in the absence of or inadequacy of such tests or methods of assay, those prescribed under the authority of the federal act; no drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality or purity therefore set forth if such standard is plainly stated on its label; whenever a drug is recognized both in the United States

pharmacopoeia and the homeopathic pharmacopoeia of the United States it shall be subject to the requirements of the United States pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States and not those of the United States pharmacopoeia;

(7) is not subject to the provisions of Subsection B of 16.19.8.7 NMAC and its strength differs from or its purity or quality falls below that which it purports or is represented to possess;

(8) is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength or substituted wholly or in part therefore.

B. "Authenticate" means to affirmatively verify before any wholesale distribution of a prescription drug acquired outside of the normal distribution channel occurs, that each transaction listed on the pedigree has occurred in accordance with the rules of the board.

C. "Authorized distributor of record" means a wholesale distributor with whom a manufacturer, manufacturer's co-licensed partner or the affiliated group of either the manufacturer or co-licensed partner 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:

(1) the wholesale distributor has a written agreement currently in effect with the manufacturer, manufacturer's co-licensed partner or the affiliated group of either the manufacturer or co-licensed partner evidencing such ongoing relationship; and

(2) the wholesale distributor is listed on the current list of authorized distributors of record issued by the manufacturer, manufacturer's co-licensed partner or the affiliated group of either the manufacturer or co-licensed partner. This list must be updated on no less than a monthly basis.

D. "Blood" means the whole blood collected from a single donor and processed either for transfusion or further manufacturing.

E. "Blood component" means that part of blood separated by physical or mechanical means.

F. "Co-licensed partner or product" means an instance where two or more parties have the right to engage in the manufacturing or marketing of a prescription drug, consistent with FDA's implementation of the Prescription Drug Marketing Act.

G. "Common carrier" means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including prescription drugs for compensation.

H. "Counterfeiting" means engaging in activities that create a counterfeit drug.

I. "Counterfeit drug" means a drug that is deliberately and fraudulently mislabeled with respect to its identity, ingredients or sources. Types of such pharmaceutical counterfeits may include:

(1) identical copies: which are counterfeits made with the same ingredients, formulas and packaging as the originals but not made by the original manufacturer;

(2) look-alikes: which feature high-quality packaging and convincing appearances but contain little or no active ingredients and may contain harmful substances;

(3) rejects: which are drugs that have been rejected by the manufacturer for not meeting quality standards;

(4) re-labels: which have passed their expiration dates or have been distributed by unauthorized foreign sources and may include placebos created for late-phase clinical trials.

J. "Counterfeit prescription drug" means a dangerous drug which, or the container or labeling of which, without authorization:

(1) bears the trademark, trade name, or other identifying mark, print, device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packaged, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by such other drug manufacturer, processor, packer, or distributor;

(2) from the original manufacturer is an imitation of another dangerous drug or has been deliberately mislabeled (for example, as to its strength or expiration date) but it shall not include a dangerous drug or placebo intended for use in a clinical trial that is intentionally labeled or marked to maintain proper blinding of the study.

K. "Dangerous drug" also known as a "prescription drug" means a drug other than a controlled substance enumerated in schedule I of the Controlled Substance Act, that because of potentiality for harmful effect or the method of its use or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug and hence for which adequate directions for use (directions under which the layman can use a drug or device safely and for the purposes for which intended) cannot

be prepared. A drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe the drug if it:

- (1) is a habit-forming drug and contains any quantity of a narcotic or hypnotic substance or a chemical derivative of such substance that has been found under the federal act and the board to be habit-forming;
- (2) because of its toxicity or other potential for harmful effect or the method of its use or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioner licensed by law to administer or prescribe the drug;
- (3) is limited by an approved application by Section 505 of the federal act to the use under the professional supervision of a practitioner licensed by law to administer or prescribe the drug;
- (4) bears the legend "Caution: federal prohibits dispensing without prescription";
- (5) bears the legend "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian";
- (6) bears the legend "RX only"; or
- (7) has been declared a dangerous drug by the board of pharmacy.

L. "Designated representative" means an individual designated by the wholesale distributor who will serve as the responsible individual of the wholesale distributor with the board who is actively involved in and aware of the actual daily operation of the wholesale distributor.

M. "Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug or by that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, that manufacturer's exclusive distributor, by an authorized distributor of record or by the affiliated group of any of these entities that purchased the product directly from the manufacturer or from one of these entities whereby:

- (1) the wholesale distributor takes title to but not physical possession of such prescription drug;
- (2) the wholesale distributor invoices the pharmacy, pharmacy warehouse or other person authorized by law to dispense or administer such drug;
- (3) the pharmacy, pharmacy warehouse or other person authorized by law to dispense or administer such drug receives delivery of the prescription drug directly from the manufacturer or from the manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, that manufacturer's exclusive distributor or by the affiliated group of any of these entities from an authorized distributor of record, that purchased the product directly from the manufacturer or from one of these entities.

N. "Drug" means articles:

- (1) recognized as drugs in any official compendium or supplement thereto, designated from time to time by the board for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals;
- (2) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals;
- (3) other than food, intended to affect the structure or any function of the body of humans or other animals;
- (4) intended for use as a component of any articles specified in Paragraphs (1), (2), (3) or (4) of Subsection N of 16.19.8.7 NMAC.

O. "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug as defined by the Prescription Drug Marketing Act of 1987.

P. "Emergency medical reasons" include, but are not limited to:

- (1) the transfer of a prescription drug between a wholesale distributor or pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruption of regular distribution schedules;
- (2) the sales to nearby emergency medical services, i.e. ambulance companies and firefighting organizations in the same state or same marketing or service area or nearby licensed practitioners of prescription drugs for use in the treatment of acutely ill or injured persons;
- (3) the provision of minimal emergency supplies of prescription drugs to nearby nursing homes for use in emergencies or during hours of the day when necessary prescription drugs cannot be obtained;
- (4) the transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

Q. "Exclusive distributor" means an entity that:

- (1) contracts with a manufacturer, manufacturer's co-licensed partner or affiliated group of either to provide or coordinate warehousing, wholesale distribution or other services on behalf of the entity they have

contracted with who takes title to that manufacturer's or manufacturer's co-licensed partner's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug;

(2) is licensed as a wholesale distributor under this chapter;

(3) to be considered part of the "normal distribution channel" must also be an authorized distributor of record.

R. "Facility" means facility of a wholesale distributor where prescription drugs are stored, handled, repackaged or offered for sale.

S. "FDA" means food and drug administration, a federal agency within the United States department of health and human services, established to set safety and quality standards for drugs, food, cosmetics and other consumer products.

T. "Federal act" means the Federal Food, Drug and Cosmetic Act.

U. "Immediate container" means a container and does not include package liners.

V. "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs or devices, consistent with the FDA definition of "manufacturer" under the agency's regulations and interpretive guidance's implementing the Prescription Drug Marketing Act.

W. "Manufacturing" means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis; and includes packaging or repackaging, labeling or relabeling and the promotion and marketing of such drugs or devices; also included is the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, licensed practitioners or other persons.

X. "Misbranded" means a label to an article that is misleading. In determining whether the label is misleading there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device or any combination of the foregoing, but also the extent to which the label fails to reveal facts material in the light of such representations or material with respect to consequences that may result from the use of the article to which the label relates under the conditions of use prescribed in the label or under such conditions of use as are customary or usual.

Y. "Normal distribution channel" means a chain of custody, including intracompany sales, transactions or transfers, for a prescription drug that goes directly or by drop shipment from the manufacturer, its affiliated group as defined in Section 1504 of the Internal Revenue Code, manufacturer's co-licensed partner or its affiliated group or from any of these entities to their third party logistics provider or exclusive distributor without respect to whether title is transferred to:

(1) either a pharmacy or to other designated persons authorized by law to dispense or administer such drug to a patient; or

(2) an authorized distributor of record and then to either a pharmacy or to other designated persons authorized by law to dispense or administer such drug to a patient; or

(3) an authorized distributor of record to one other authorized distributor of record to an office-based healthcare practitioner or pharmacy or to other designated persons authorized by law to dispense or administer such drug to a patient; or

(4) a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy to either a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or

(5) an authorized distributor of record to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy to either a patient or other designated persons authorized by law to dispense or administer such drug to a patient.

Z. "Official compendium" means the official United States pharmacopoeia-national formulary or the official homeopathic pharmacopoeia of the United States or any supplement to either of them.

AA. "Pedigree" means the recorded history of the drug.

BB. "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of pharmacies under common ownership and control.

CC. "Prescription drug" means any human drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act.

DD. "Repackage" means repackaging or otherwise changing the container, wrapper or labeling to further the distribution of a prescription drug excluding that completed by the pharmacists responsible for dispensing product to the patient.

EE. "Repackager" means a person who repackages.

FF. “Selling of drugs, devices or cosmetics” shall be considered to include the manufacturer, production, processing, packing, exposure, offer, possession and holding of any such article for sale and the sale and the sale and the supplying or applying of any such article in the conduct of a drug or cosmetic establishment.

GG. “Significant loss” means any loss of a prescription drug that exceeds a reasonable level established by like persons which requires that loss to be reported to the board or as required by the DEA or other state or federal agencies for prescription drugs and controlled substances.

HH. “Third party logistics provider” means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug’s sale or disposition; such third party logistics provider must be licensed as a wholesale distributor under this Act and to be considered part of the **“normal distribution channel”** must also be an **“authorized distributor of record”**.

II. “USP standards” means standards published in the current official United States pharmacopoeia-national formulary.

JJ. “Wholesale drug distribution” means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control;

(2) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(C)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) 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;

(7) the sale, purchase or trade of blood and blood components intended for transfusion;

(8) any entity exempted by this regulation must keep specific records of purchase, sale, or any manner of distribution of any prescription drug in accordance with Subsection H of 16.19.13 NMAC;

(9) the distribution of prescription drug samples by representatives of the manufacturer, manufacturer’s co-licensed partner, affiliated group of either or authorized distributor of record;

(10) drug returns, when conducted by a hospital, health care entity or charitable institution in accordance with 21 CFR 203.23;

(11) the sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use;

(12) the sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets;

(13) the sale, purchase, distribution, trade or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer, manufacturer’s co-licensed partner or any affiliated group of either has stated in writing to the receiving authorized distributor of record that they are unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(14) the delivery of or offer to deliver a prescription drug by a common carrier solely in the common carrier’s usual course of business of transporting prescription drugs and such common carrier does not store, warehouse or take legal ownership of the prescription drug;

(15) the sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned or recalled prescription drugs to the original manufacturer, manufacturer’s co-licensed partner or any affiliated group of either, original wholesale distributor or to a third party returns processor or reverse distributor.

KK. "Wholesale drug distributor" means anyone engaged in the wholesale distribution of prescription drugs, including but not limited to, manufacturer's, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers and distributors warehouses, manufacturer's exclusive distributors, drug wholesalers or distributors, independent wholesale drug traders, third party logistics providers, retail pharmacies that conduct wholesale distribution and pharmacy warehouses that conduct wholesale distribution.

[16.19.8.7 NMAC - Rp, 16.19.8.7 NMAC, 12-02-09]

16.19.8.8 WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS:

A. Every wholesale drug distributor, wherever located, who engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and regulations of this state before engaging in wholesale distribution of prescription drugs. Wholesale distributors cannot operate from a place of residence. Where wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the board of pharmacy.

B. Common or contract carriers or warehousemen, or an employee thereof, whose involvement in the wholesale distribution of prescription drugs occurs in the usual course of his business or employment shall not be required to obtain a wholesale drug distributor license from the board.

[16.19.8.8 NMAC - Rp, 16.19.8.8 NMAC, 12-02-09]

16.19.8.9 MINIMUM REQUIRED INFORMATION FOR WHOLESALE DRUG DISTRIBUTION LICENSURE:

A. Every wholesale distributor who engages in the wholesale distribution 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 deed for the property on which the wholesale distributor's establishment is located, if the property is owned by the wholesale distributor or a copy of the wholesale distributor's lease for the property on which the establishment is located that has an original term of not less than one (1) calendar year, if the establishment is not owned by the wholesale distributor;
 - (8) information regarding general and product liability insurance, including copies of relevant policies;
 - (9) a description of the wholesale distributor's drug import and export activities;
 - (10) a copy of the wholesale distributor's written policies and procedures as required in Subsection G of 16.19.8.13 NMAC;
 - (11) the information collected pursuant to Paragraphs (6) and (10) of this subsection shall be made available only to the board, the third party working on behalf of the board and to state and federal law enforcement officials; the board shall make provisions for protecting the confidentiality of the information collected under this section.
- B.** Every wholesale drug distributor who engages in wholesale distribution shall submit a reasonable fee to be determined by the board.
- C.** Each facility that engages in wholesale drug distribution must undergo an inspection by the board or a third party working on behalf of the board for the purpose of inspecting the wholesale drug distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the board but not less than once every three (3) years. Manufacturing facilities located outside of this state are exempt from inspection by the board if the manufacturing facilities are currently registered with the food and drug administration in accordance with Section 510 of the federal act.
- D.** All wholesale distributors must publicly 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 board within thirty (30) days of such change unless otherwise noted.
- F.** Information submitted by the wholesale drug distributor to the board or the third party working on behalf of the board that is considered trade secret or proprietary information as defined under this states privacy and trade secret/proprietary statutes shall be maintained by the board or the third party working on behalf of the board as private or trade secret proprietary information and be exempt from public disclosure.
- G.** The board shall have the authority to recognize a third party to accredit and inspect wholesale distributors.
- H.** The board may license by reciprocity, a wholesale distributor that is licensed under the laws of another state if:
- (1) the requirements of that state are deemed by the board to be substantially equivalent, or;
 - (2) the applicant is accredited by a third party recognized by the board.
- I.** Any applicant that is denied accreditation described under Subsection H 16.19.8.9 NMAC shall have the right of review of the accreditation body's decision, by:
- (1) the board; and
 - (2) the accreditation body.
- J.** The board approved accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.
- K.** The board may waive a requirement of this chapter for wholesale distributors that have obtained and maintain a board approved accreditation.
- [16.19.8.9 NMAC - Rp, 16.19.8.9 NMAC, 12-02-09]

16.19.8.10 MINIMUM QUALIFICATIONS:

- A.** The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution 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 manufacture or 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 consider the results of a criminal and financial background check of the applicant, including but not limited to all key personnel involved in the operations of the wholesaled distributor, including the designated representative responsible for facility operations, purchasing, inventory control and the person or persons they report to, all company officers, key management, principals, and owners with ten percent (10%) or greater ownership interest in the company (applying to non-publicly held companies only) to determine if an applicant or others associated with the ownership, management or operations of the wholesale distributor have committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state and federal laws, at the applicant's expense and will be sufficient to include all states residence since the person has been an adult. Manufacturers and packagers, licensed by the Federal Food and Drug Administration shall be exempt from criminal and financial background checks.

C. The applicant shall provide and attest to a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

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 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.

E. Request for an alternative reduced wholesale license fee: The board shall collect the full license fee as set by the board unless the board determines that collection of the license fee would be inconsistent with the public interest. The applicant/petitioner shall provide the board with any information necessary to make that determination including:

- (1) business/organization profit status under federal and state code;
- (2) impact on the health and safety of New Mexico citizens;
- (3) volume of distribution in New Mexico;
- (4) sole source of dangerous drugs; and
- (5) financial hardship for applicant/registrant.

[16.19.8.10 NMAC - Rp, 16.19.8.10 NMAC, 12-02-09]

16.19.8.11 PERSONNEL: As a condition of receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained by law. Each person that is issued an initial or renewal license as a wholesale distributor whether in state or out of state must designate in writing on a form required by the board a person for each facility to serve as the designated representatives of the wholesale distributor.

A. To be certified as a designated representative a person must:

- (1) submit an application on a form furnished by the board and provide information that includes but is not limited to:
 - (a) information required to complete the criminal and financial background checks required under Subsection B of 16.19.8.10 NMAC;
 - (b) date and place of birth;
 - (c) occupations, positions of employment and offices held during the past seven (7) years;
 - (d) principal business and address of any business corporation or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;

(e) whether the person during the past seven (7) years has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating and state or federal laws regulating the possession, control or wholesale distribution of prescription drugs or devices, together with details of such events;

(f) whether the person has been during the past seven (7) years, the subject of any proceeding for the revocation of any professional or business license or any criminal violation and if so, the nature of the proceeding and the disposition of the proceeding;

(g) description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven (7) years, which manufactured, administered, prescribed, wholesale distributed or stored prescription drugs and devices in which such businesses were names as a party in a lawsuit;

(h) description of any criminal offense (not including minor traffic violations) of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere; if the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within fifteen (15) days after the disposition of the appeal, submit to the board a copy of the final written order of disposition;

(i) photograph of the person taken within the previous year under procedures as specified by the board;

(j) name, address, occupation, date and place of birth for each member of the person's immediate family, unless the person is employed by a wholesale distributor that is a publicly held company; as used in this subparagraph, the term "member of the immediate family" includes the person's spouse(s), children, parents, siblings, the spouses of the person's children and the spouses of the person's siblings; and

(k) any other information the board deems relevant;

(2) have a minimum of two years of verifiable full-time managerial or supervisory experience in a pharmacy or wholesale distributor licensed in this state or another state, where the person's responsibilities included but were not limited to recordkeeping, storage and shipment of prescription drugs;

(3) may serve as the designated representative for only one wholesale distributor at any one time, except where more than one licensed wholesale distributor is co-located in the same facility and such wholesale distributors are members of an affiliated group as defined in Section 1504 of the Internal Revenue Code;

(4) be actively involved in and aware of the actual daily operations of the wholesale distributor;

(a) employed full-time in a managerial position by the wholesale distributor;

(b) physically present at the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation or other authorized absence;

(c) aware of and knowledgeable about all policies and procedures pertaining to the operations of the wholesale distributor.

B. The criminal and financial information collected pursuant to this section shall be made available only to the board, a third party recognized by the board and to state and federal law enforcement officials. The board and a third party recognized by the board shall make provisions for protecting the confidentiality of the information collected under this section.

C. Each licensed wholesale distributor located outside of this state that wholesale distributes prescription drugs in this state shall designate a registered agent in this state for service of process. Any licensed wholesale distributor that does not so designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed wholesale distributor growing out of or arising from such wholesale distribution. A copy of any such service or process shall be mailed to such wholesale distributor by the board by certified mail, return receipt requested, postage prepaid, at the address such licensed wholesale distributor has designated on its application for licensure in this state. If any such wholesale distributor is not licensed in this state, service on the Secretary of State only shall be sufficient service.

D. A designated representative must complete training programs that address applicable state and federal laws and are provided by qualified in-house specialists, outside counsel or counseling specialists with capabilities to help ensure compliance.

[16.19.8.11 NMAC - Rp, 16.19.8.11 NMAC, 12-02-09]

16.19.8.12 VIOLATIONS AND PENALTIES: The board shall have the authority to suspend or revoke any licenses granted under this part on the grounds established by law or regulations; and may impose fines or civil penalties if allowed by law.

[16.19.8.12 NMAC - Rp, 16.19.8.12 NMAC, 12-02-09]

16.19.8.13 MINIMUM REQUIREMENTS FOR THE STORAGE AND HANDLING OF PRESCRIPTION DRUGS AND FOR THE ESTABLISHMENT AND MAINTENANCE OF PRESCRIPTION DRUG DISTRIBUTION RECORDS BY WHOLESALE DRUG DISTRIBUTORS AND THEIR OFFICERS, AGENTS, REPRESENTATIVES, AND EMPLOYEES:

A. Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed 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 prescription drugs that are outdated, damaged, deteriorated, misbranded, counterfeit or suspected of being counterfeit or adulterated, otherwise unfit for distribution or wholesale distribution or that are in immediate or sealed, secondary containers that have been opened;
- (4) be maintained in a clean and orderly condition; and
- (5) be free from infestation by insects, rodents, birds, or vermin of any kind; and
- (6) be a commercial location and not a personal dwelling or residence; and
- (7) provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information; and
- (8) provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting or diversion of prescription drugs or devices; and
- (9) controlled substances must be isolated from non-controlled substance drugs and stored in a secure area in accordance with DEA security requirements and standards.

B. Security and anti-counterfeiting. All facilities used for wholesale drug distribution 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 prescription drugs are held shall be limited to authorized personnel.
- (4) All facilities shall be equipped with an alarm system to detect entry after hours.
- (5) 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.
- (6) 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.
- (7) Authentication of pedigrees:
 - (a) wholesale distributors that acquire prescription drugs from other wholesale distributors outside the normal distributors channel shall authenticate the pedigree of all such prescription drugs back to the authorized distributor of record, unless an electronic pedigree and track and trace system, which documents each transaction is in place;
 - (b) authorized distributors of record from whom other wholesale distributors have acquired prescription drugs outside of the normal distribution channel, shall cooperated with pedigree authentication efforts and verify the provided information in a timely manner;
 - (c) each authorized distributor of record that has distributed a prescription drug for which an acquiring wholesale distributor is conducting a pedigree authentication, shall verify for the acquiring wholesale distributor, upon request, detailed information regarding its acquisition of the prescription drug, including:
 - (i) date of acquisition;
 - (ii) lot number or control number;
 - (iii) acquisition invoice number; and
 - (iv) name, address, telephone number and email address (if available) of the manufacturer or wholesale distributor from which the prescription drug was acquired.
 - (d) if the authorized distributor of record is unable to authenticate the pedigree of the prescription drug, that wholesale distributor shall contact the manufacturer in an attempt to authenticate the pedigree, in so doing:
 - (i) the authorized distributor of record must provide the manufacturer with all relevant information it possesses; and
 - (ii) the manufacturer must confirm or deny the information provided in a timely manner;

(e) if the wholesale distributor attempting to authenticate the pedigree of the prescription drug is unable to authenticate the pedigree, the wholesale distributor shall quarantine the prescription drug and file a report with the board and FDA within three (3) business days after completing the attempted authentication; and

(f) if the wholesale distributor attempting to authenticate the pedigree of the prescription drug is able to authenticate the pedigree, the wholesale distributor shall maintain records of the authentication for three (3) years and shall produce them to the board upon request.

C. 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 the United States Pharmacopeia-National Formulary (USP/NF).

(1) If no storage 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.

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

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

D. Examination of Materials.

(1) 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.

(2) 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.

(3) Upon receipt, a wholesale distributor must review records for the acquisition of prescription drugs or devices for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

(4) The record keeping requirements in Subsection F of 16.19.8.13 NMAC shall be followed for all incoming and outgoing prescription drugs.

E. Returned, damaged, and outdated prescription drugs.

(1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or other persons authorized to administer or dispense drugs or for a pharmacy's intracompany warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy. Returns of expired, damaged, recalled or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesale distributor only either to the original manufacturer, manufacturer's co-licensed partner, or any affiliated group of either or a third party returns processor. The returns or exchanges of prescription drugs (saleable or otherwise) including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of this chapter, so long as they are exempt from the pedigree requirement of the FDA's currently applicable Prescription Drug Marketing Act guidance.

(2) Prescription drugs that are outdated, damaged, deteriorated, misbranded, counterfeit, suspected counterfeit or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed, surrendered to the appropriate authority or returned to their supplier.

(3) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(4) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality 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 wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(5) When prescription drugs are adulterated, counterfeited, contraband, misbranded or suspected of being adulterated, counterfeit, contraband or misbranded, notice of the adulteration, counterfeiting, contrabandage,

misbranding or suspected adulteration, counterfeiting, contrabandage or misbranding shall be provided within three (3) business days of that determination to the board, FDA, manufacturer, manufacturer's co-licensed partner, any affiliated group of either or wholesale distributor from which they were acquired. Any prescription drug returned to a manufacturer or wholesale distributor shall be kept under proper conditions for storage, handling, transport, shipment and documentation showing that proper conditions were maintained and shall be provided to the manufacturer or wholesale distributor to which the prescription drugs are returned.

(6) Any prescription drug whose immediate or sealed outer or secondary containers or product labeling are adulterated, misbranded, counterfeited, contraband or suspect of being counterfeit or contraband shall be quarantined and physically separated from other prescription drugs until it is destroyed or returned to the manufacturer, manufacturer's co-licensed partner, any affiliated group of either or wholesale distributor from which it was acquired. When the immediate or sealed outer or secondary containers or product labeling of any prescription drugs are adulterated, misbranded, counterfeited, contraband or suspect of being counterfeit, or contraband, notice of the adulteration, misbranding, counterfeiting, contrabandage or suspected counterfeiting or contrabandage shall be provided within three (3) business days of that determination to the board, FDA, manufacturer or wholesale distributor from which it was acquired.

(7) The record keeping requirements in Subsection F of 16.19.8.13 NMAC shall be followed for all outdated, damaged, deteriorated, misbranded, counterfeit, suspected counterfeit or adulterated prescription drugs.

(8) Contraband, counterfeit or suspected to be contraband or counterfeit drugs, other evidence of criminal activity and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the board and FDA.

(9) The shipping, immediate or sealed outer or secondary container or product labeling and accompanying documentation, suspected of or determined to be counterfeit, contraband or otherwise fraudulent shall not be destroyed until its disposition is authorized by the board and FDA.

F. Record keeping.

(1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

- (a) the identity and quantity of the drugs received and distributed or disposed of; and
- (b) the dates of receipt and distribution or other disposition of the drugs;
- (c) 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;
- (d) manufacturer's representatives must maintain receipt and disposition records for all dangerous drugs in compliance with the requirements of the Federal Prescription Drug Marketing Act of 1987.

(2) 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.

(3) 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.

(4) Pedigrees shall be provided to another wholesale distributor or pharmacy for prescription drugs that leave the normal distribution channel before wholesale distribution to such other wholesale distributor, pharmacy or other person authorized by law to prescribe and dispense prescription drugs. The pedigree shall minimally include the following information for each transaction:

- (a) the source of the prescription drug(s), including the name and principal address of the seller;
- (b) the proprietary and established name of the prescription drug, the amount of the prescription drug, its dosage form and dosage strength, the date of the purchase, the sales invoice number, container size, number of containers, expiration date(s), and lot number(s) or control number(s) of the prescription drug;
- (c) the business name and address of each owner of the prescription drug and its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the prescription drug;
- (d) information that states that the wholesale distributor has conducted due diligence of the wholesale distributor(s) from which the wholesale distributor purchased; and

(e) a certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate under penalty of perjury;

(f) if electronic pedigree or electronic files are maintained they shall be maintained consistent with 21 CFR 203.60, including any amendments thereto.

(5) Wholesale distributors 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.

G. Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories; wholesale drug distributors 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 wholesale distributors 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 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 cannot 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 applicable federal and state requirements;

(7) a procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband or suspect of being contraband, in the inventory and reporting of such discrepancies within ten (10) business days to the board and appropriate federal or state agency upon discovery of such discrepancies;

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

(9) a procedure for conducting, authentication of pedigrees in accordance with Subsection B of 16.19.8.13 NMAC (Security and anti-counterfeiting) and standards adopted by the board;

(10) a procedure that ensures all common carriers contracted with or utilized by the wholesale distributor conduct a criminal background check and drug screen of the employees whose responsibilities include the known handling of prescription drugs;

(11) a procedure for conducting periodic assessments of the security provisions of common carriers contracted with or utilized by the wholesale distributor that at a minimum must specify that vehicles must be secured by locks on all doors and windows when the driver is not present, there shall be no unapproved stops during the delivery route and that the vehicle must not be left running in the absence of the driver;

(12) a procedure or set procedures designated to address high-risk deliveries that may require the common carriers contracted with or utilized by the wholesale distributor to make deliveries only to highly-visible, well-lit locations during certain prescribed time periods agreed upon with the customer and the use of varied routing.

H. Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

I. Compliance with federal, state, and local law: wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Wholesale drug distributors shall permit board authorized personnel 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, 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.

(2) Wholesale drug distributors that deal in controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local and DEA regulations.

(3) A licensed wholesale drug distributor may distribute only to persons who are licensed to possess dangerous drugs.

(4) 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.

J. Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing including Subsection G of 16.19.8.13 NMAC.

[16.19.8.13 NMAC - Rp, 16.19.8.13 NMAC, 12-02-09]