

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 8 WHOLESALE DISTRIBUTORS; THIRD PARTY LOGISTICS PROVIDERS;
REPACKAGERS; DRUG SUPPLY CHAIN SECURITY ~~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; third party logistics providers; manufacturers, and repackagers.
[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 (board) 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 Food, Drug and Cosmetic Act, 21 United States Code (U.S.C.) 351 et seq., as amended by the Drug Supply Chain Security Act of 2013 (Pub. L. 113-54) 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 wholesale distributors, third party logistics providers and repackagers; and by replicating the federal requirements relating to product tracing, identification and verification 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 ~~(A)(6) 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. "Affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly:

(1) one business entity controls, or has the power to control, the other business entity; or

(2) a third party controls, or has the power to control, both of the business entities.

~~**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" means:

(1) in the case of a manufacturer or repackager, having a valid registration as a drug establishment with the FDA under section 510 of the federal act.

(2) a licensed wholesale distributor, who is compliant with the licensure reporting requirements under section 503(e) of the federal act;

(3) a licensed third-party logistics provider, who is compliant with the licensure reporting requirements under section 584(b) of the federal act;

(4) in the case of a dispenser, having a valid license under NM State law.

~~**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 DSCSA 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 law 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, third party logistics provider, or repackager who will serve as the responsible individual of the wholesale distributor, third party logistics provider, or repackager with the board who is actively involved in and aware of the actual daily operation of the wholesale distributor, third party logistics provider, or repackager. The designated representative is responsible for all aspects of the facility operation.

M. “Dispenser” means:

(1) a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

(2) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5) of the federal act.

N. “Disposition” with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

O. “Distribute or distribution” means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a drug pursuant to a prescription.

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.~~

PN. "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 **PN** of 16.19.8.7 NMAC.

QQ. "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.

R. "DSCSA" means the Drug Supply Chain Security Act.

SP. "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;~~

(12) the transfer or sales by a pharmacy 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, consistent with the DSCSA and successor FDA regulations;

~~(23) the provision of minimal emergency supplies of prescription drugs by a pharmacy to nearby nursing homes for use in emergencies or during hours of the day when necessary prescription drugs cannot be obtained;~~

(3) the transfer or sale of naloxone by a dispenser for rescue use in accordance with § 24-23-1 NMSA 1978;

(4) the transfer or sale of a drug pursuant to a specific patient need

~~(4) the transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.~~

IQ. "Exclusive distributor" means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser. 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.~~

UR. "Facility" means facility of a wholesale distributor, repackager, or third party logistics provider where prescription drugs are stored, handled, repackaged or offered for sale.

VS. "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.

WF. “Federal act” means the Federal Food, Drug and Cosmetic Act.

X. “Homogeneous case” means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

Y. “Illegitimate product” means a product for which credible evidence shows that the product:

(1) is counterfeit, diverted, or stolen;

(2) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(3) is the subject of a fraudulent transaction; or

(4) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

ZU. “Immediate container” means a container and does not include package liners.

AA. “Licensed” means:

(1) in the case of a wholesale distributor:

(a) having valid licensure with the board; and

(b) for facilities located outside of NM:

(i) having valid licensure by the state from which the drug is distributed;

or

(ii) if the state from which the drug is distributed has not established a licensure requirement, is licensed by the FDA (beginning at such time as federal regulations are promulgated to implement section 583 of the federal act).

(2) in the case of a third-party logistics provider:

(a) for facilities located outside of NM:

(i) having valid licensure by the state from which the drug is distributed

when required by that state; and

(ii) having a valid registration with the FDA (beginning at such time as federal regulations are promulgated to implement section 584 of the federal act, unless the FDA has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof); or

(iii) having valid licensure with the board.

(b) for facilities located in NM: having valid licensure with the board.

BBV. “Manufacturer” means (1) A person that holds an application approved under section 505 of the federal act or a license issued under section 351 of the federal public health service act for such drug, or if such drug is not the subject of an approved application or license, the person who manufactured the drug; (2) a co-licensed partner of the person described in paragraph (1) that obtains the drug directly from a person described in paragraph (1) or (3); or (3) an affiliate of a person described in paragraph (1) or (2) that receives the product directly from a person described in paragraph (1) or (2). 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.

CCW. “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.

DDX. “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; or~~

~~_____ (6) _____ sale of drugs from pharmacies to wholesaler for resale is prohibited.~~

EEZ. **“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.

FF. **“Package”** means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product. An individual saleable unit is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

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.

GGCC. **“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.

HH. **“Product”** means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but does not include:

- (1) blood or blood components intended for transfusion,
- (2) radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by the State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021),
- (3) imaging drugs,
- (4) an intravenous product described in clause (14), (15), or (16) of definition WW. (“transaction”),
- (5) any medical gas as defined in section 575 of the federal act,
- (6) homeopathic drugs marketed in accordance with applicable guidance under the federal act, or
- (7) a drug compounded in compliance with section 503A or 503B of the federal act.

II. **“Product identifier”** means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product, meeting the requirements of the DSCSA.

JJ. **“Product tracing information”** means, for each transaction: the recorded transaction history, transaction information, and transaction statement meeting the requirements of the DSCSA.

KK. **“Quarantine”** means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

LLDD. **“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.

MMEE. **“Repackager”** means a person who owns or operates a facility that repackages and relabels a product or package for:-

- (1) further sale; or
- (2) distribution without a further transaction.

NN. **“Return”** means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

OO. **“Returns processor or reverse logistics provider”** means a person who owns or

operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

PPFF. “Selling of drugs, devices or cosmetics” shall be considered to include the manufacture, 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.

QQGG. “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.

RR. “Specific patient need” means the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

SS. “Standardized numerical identifier” means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

TT. “Suspect product” means a product for which there is reason to believe:

- (1) is potentially counterfeit, diverted, or stolen;
- (2) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- (3) is potentially the subject of a fraudulent transaction; or
- (4) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

UU. “Third-party logistics provider” means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

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”.

VV. “Trading partner” means:

- (1) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or
- (2) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

WW. “Transaction” means the transfer of product between persons in which a change of ownership occurs, but does not include:

- (1) intracompany distribution of any product between members of an affiliate or within a manufacturer;
- (2) the distribution of a product among hospitals or other health care entities that are under common control; for the 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;
- (3) the distribution of a product for emergency medical reasons including a federal or state declared public health emergency, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
- (4) the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) of the federal act;
- (5) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 503(d) of the federal act;
- (6) the distribution of blood or blood components intended for transfusion;

(7) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

(8) 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 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(9) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

(10) the dispensing of an approved animal drug product approved under section 512(c);

(11) products transferred to or from any location that is licensed by the Nuclear Regulatory Commission or by the State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

(12) a combination product that is not subject to approval under section 505 or licensure under section 351 of the Public Health Service Act, and that is:

(a) a product comprised of a device and one or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(b) two or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

(c) two or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a `medical convenience kit' as described in clause (13) of this definition;

(13) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a `medical convenience kit') if:

(a) the medical convenience kit is assembled in an establishment that is registered with the FDA as a device manufacturer in accordance with section 510(b)(2) of the federal act;

(b) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

(c) in the case of a medical convenience kit that includes a product, the person that manufactures the kit:

(i) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(ii) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(d) in the case of a medical convenience kit that includes a product, the product is:

(i) an intravenous solution intended for the replenishment of fluids and electrolytes;

(ii) a product intended to maintain the equilibrium of water and minerals in the body;

(iii) a product intended for irrigation or reconstitution;

(iv) an anesthetic;

(v) an anticoagulant;

(vi) a vasopressor; or

(vii) a sympathomimetic;

(14) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(15) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(16) the distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) the distribution of a medical gas (as defined in section 575 of the federal act); or

(18) the distribution or sale of any licensed product under section 351 of the Public Health Service Act that meets the definition of a medical device under section 201(h) of the federal act.

XX. “Transaction history” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

YY. “Transaction information” means:

- (1) the proprietary or established name or names of the product;
- (2) the strength and dosage form of the product;
- (3) the National Drug Code number of the product;
- (4) the container size;
- (5) the number of containers;
- (6) the lot number of the product;
- (7) the date of the transaction;
- (8) the date of the shipment, if more than 24 hours after the date of the transaction;
- (9) the business name and address of the person from whom ownership is being transferred;

and

- (10) the business name and address of the person to whom ownership is being transferred.

ZZ. “Transaction statement” means a statement, in paper or electronic form, that the entity transferring ownership in a transaction:

- (1) is authorized as required under the DSCSA;
- (2) received the product from a person that is authorized as required under the DSCSA;
- (3) received transaction information and a transaction statement from the prior owner of the product, as required under section 582 of the federal act;
- (4) did not knowingly ship a suspect or illegitimate product;
- (5) had systems and processes in place to comply with verification requirements under section 582 of the federal act;
- (6) did not knowingly provide false transaction information; and
- (7) did not knowingly alter the transaction history.

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

BBB. “Verification or verify” means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582 of the act.

CCC. “Wholesale drug distribution” means the distribution of a prescription drug to a person other than a consumer or patient, or receipt of a prescription drug by a person other than the consumer or patient, but does not include:

- (1) intracompany distribution of any drug between members of an affiliate or within a manufacturer;
- (2) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;
- (3) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a federal or state declared public health emergency, except that, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
- (4) the dispensing of a drug pursuant to a prescription;
- (5) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;
- (6) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (7) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;
- (8) the distribution of a drug by the manufacturer of such drug;
- (9) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;
- (10) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;
- (11) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e) of the federal act;
- (12) saleable drug returns when conducted by a dispenser;

(13) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to as a "medical convenience kit") if:

(a) the medical convenience kit is assembled in an establishment that is registered with the FDA as a device manufacturer in accordance with section 501(b)(2) of the federal act;

(b) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 801 et seq.];

(c) in the case of a medical convenience kit that includes a product, the person that manufactures the kit:

(i) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(ii) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(d) in the case of a medical convenience kit that includes a product, the product is:

(i) an intravenous solution intended for the replenishment of fluids and electrolytes;

(ii) a product intended to maintain the equilibrium of water and minerals in the body;

(iii) a product intended for irrigation or reconstitution;

(iv) an anesthetic;

(v) an anticoagulant;

(vi) a vasopressor; or

(vii) a sympathomimetic;

(14) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(15) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(16) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) the distribution of medical gas, as defined in section 575 of the federal act;

(18) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(19) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 of the federal act for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

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.~~

~~**DDD. "Wholesale distributor"** means a person or entity (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale drug distribution.~~

~~**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; A, 06-08-16]~~

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.** Wholesale distributors cannot operate from a place of residence.~~

~~**C.** Where wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the board of pharmacy.~~

~~**D.** A wholesale distributor located in NM shall be located apart and separate from any pharmacy.~~

~~**EB.** 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 be licensed with the board by submitting an application and providing information required by the board on an application approved by the board, including but not limited to:

(1) applicant's full name; 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, third party logistics provider, or repackager licensed by the board to purchase drugs or devices in the state; full business address and telephone number;

(2) type of ownership, e.g. individual, partnership, limited liability company or corporation;

(3) name(s) of the owner(s) of the applicant, including:
(a) if a person, the name, address, Social Security number or FEIN, and date of birth;
(b) if other than a person, the name, address, Social Security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(c) if a corporation, the State of incorporation; and
(d) if a publicly traded corporation, the information in (A)(3)(b) is not required for corporate officers and corporate directors;

(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;

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

(43) 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;

(5) evidence of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;

(64) 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;

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

(86) a full description of each facility and warehouse located in New Mexico, 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 IG of 16.19.8.13 NMAC (written policies and procedures);

(11) a facility located outside of NM shall submit a copy of a current satisfactory inspection report issued by the FDA, or State licensing authority, or by a third-party inspection service approved by the FDA or the State authority licensing such wholesale distributor, or by the board;

~~(12)~~ the information collected pursuant to Paragraphs ~~(5), (8), (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 located in New Mexico 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 facility and 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 applicant submits documentation of a current satisfactory inspection conducted by the FDA, or State licensing authority, or by a third-party inspection service approved by the FDA or the State authority licensing such wholesale distributor, or the board; and

~~(2) 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.~~

I. Every wholesale distributor must furnish a bond or other equivalent means of security, as follows:

(1) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of \$100,000 or other equivalent means of security acceptable to the board.

(2) For purposes of clause (1) above, the board may accept a surety bond in the amount of \$25,000 if the annual gross receipts of the previous tax year for the wholesaler is \$10,000,000 or less.

(3) If a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in NM shall be waived.

[16.19.8.9 NMAC - Rp, 16.19.8.9 NMAC, 12-02-09]

16.19.8.10 MINIMUM QUALIFICATIONS:

A. The board shall prohibit a person from receiving or maintaining licensure for wholesale distribution if the person:

(1) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of subsection (i) or (k) of section 301, or any felony violation of section 1365 of title 18, United States Code, relating to product tampering; or

(2) has engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

BA. 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 or any other sanction 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 regulatory and 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 part section; and
- (8) any findings by the board that the applicant has violated or been disciplined, or the subject of administrative action or other sanction, by a regulatory or licensing 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.

CB. The board shall consider the results of a criminal and financial background check and fingerprinting of the applicant, ~~including but not limited to all key personnel involved in the operations of the wholesaler distributor, including the~~ and 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 wholesaler 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 FDA Federal Food and Drug Administration shall be exempt from criminal and financial background checks.~~

DC. 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.

ED. 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.

FE. 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 wholesaler 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) evidence of criminal background check and fingerprinting, the background check shall be sufficient to include all states residence since the person has been an adult 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 and Social Security number;

(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;~~

(de) 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;

(ef) 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;

(fg) 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;

(gh) 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~~

~~(hk) 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;~~

(23) 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;

(34) be actively involved in and aware of the actual daily operations, purchasing and inventory control 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, suspect or illegitimate, 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.

(G) Board Inspection 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 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.

F. (5) Theft or loss. A wholesale distributor shall have and follow diversion detection and prevention plan that includes prescription drugs. 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. Product tracing, product identifier, and verification: Wholesale distributors licensed by the board shall comply with the requirements for tracing products through the distribution system as defined in sections 353 and 360eee, et seq., of the DSCSA, 21 U.S.C. 301, et seq., and successor FDA regulations, with respect to the role of such wholesale distributor including any requirements with respect to: transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

H. Authorized trading partners: The trading partners of a wholesale distributor may be only authorized trading partners.

IG. 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;~~

~~(910) 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;~~

~~(101) 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;~~

~~(112) 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.~~

JH. 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.

KI. Compliance with federal, state, and local law: ~~W~~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, and to confiscate prescription drugs and records to the extent authorized by law or rules. 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 wholesale distributor may distribute only to authorized trading partners. Product shall be delivered only to the licensed address of the authorized trading partner. 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.

L.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 ~~I~~G of 16.19.8.13 NMAC (written policies and procedures).
[16.19.8.13 NMAC - Rp, 16.19.8.13 NMAC, 12-02-09]

16.19.8.14 THIRD PARTY LOGISTICS PROVIDER LICENSING REQUIREMENTS

A. Every third party logistics provider, wherever located, who engages in providing third party logistics 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 as a third party logistics provider of prescription drugs.

B. Third party logistics providers cannot operate from a place of residence.

C. Where third party logistics operations are conducted at more than one location, each such location shall be licensed by the board.

D. A third party logistics provider located in NM shall be located apart and separate from any pharmacy.

[16.19.8.14 NMAC - N, XX-XX-17]

16.19.8.15 MINIMUM REQUIRED INFORMATION FOR THIRD PARTY LOGISTICS PROVIDER LICENSURE:

A. Every third party logistics provider, located in NM or located in another state and not licensed as a third party logistics provider by the FDA, who engages in third party logistics activities involving product shall be licensed with the board, by submitting an application and providing information required by the board on an application approved by the board, including but not limited to:

(1) applicant's full name; 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, third party logistics provider, or repackager licensed by the board; full business address and telephone number;

(2) type of ownership, e.g. individual, partnership, limited liability company or corporation;

(3) name(s) of the owner(s) of the applicant, including:

(a) if a person, the name, address, Social Security number or FEIN, and date of birth;

(b) if other than a person, the name, address, Social Security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(c) if a corporation, the State of incorporation; and

(d) if a publicly traded corporation, the information in (A)(3)(b) is not required for corporate officers and corporate directors.

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

(4) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the third party logistics provider that engages in the distribution of drugs;

(5) evidence of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;

(6) a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the third party logistics provider by any other state and federal authority that authorizes the third party logistics provider to possess and distribute drugs;

(7) a list of all disciplinary actions or any other sanction by state and federal agencies against the third party logistics provider as well as any such actions against principals, owners, directors or officers;

(8) a full description of each facility and warehouse located in NM, 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;

(9) a description of the third party logistics provider's drug import and export activities;

(10) a copy of the third party logistics provider's written policies and procedures as required in Subsection D of 16.19.8.18 NMAC;

(11) a facility located outside of NM shall submit a copy of a current satisfactory inspection report issued by the FDA, or State licensing authority, or by a third-party inspection service approved by the FDA or the State authority licensing such third party logistics provider, or by the board.

(12) the information collected pursuant to Paragraphs (5), (8) and (10) of this subsection shall be made available only to 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 third party logistics provider who engages in third party logistics activities involving prescription drugs and required to be licensed by the board shall submit a reasonable fee to be determined by the board.

C. Each facility located in New Mexico that engages in third party logistics must undergo an inspection by the board for the purpose of inspecting the third party logistics facility and operations prior to initial licensure.

D. All third party logistics providers 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 subparagraph A of this section shall be submitted to the board within thirty (30) days of such change unless otherwise noted.

F. Information submitted by the third party logistics provider 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 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 inspect third party logistics providers.

H. The board may license by reciprocity, a third party logistics provider that is licensed under the laws of another state if:

(1) the applicant submits documentation of a current satisfactory inspection conducted by the FDA, or State licensing authority or by a third-party inspection service approved by the FDA or the State authority licensing such third party logistics provider, or by the board; and

(2) the requirements of that state are deemed by the board to be substantially equivalent.

[16.19.8.15 NMAC - N, XX-XX-17]

16.19.8.16 MINIMUM QUALIFICATIONS:

A. The board will not license a third-party logistics provider when the FDA has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and published notice thereof.

B. The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in providing third party logistics 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;

(5) suspension, revocation or any other sanction 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 regulatory and 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 part; and

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

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

C. The board shall consider the results of a criminal and financial background check and fingerprinting of the applicant and designated representative responsible for facility operations, to determine if an applicant or others associated with the ownership, management or operations of the third party logistics provider have committed criminal acts that would constitute grounds for denial of licensure.

D. 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.

E. 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.

[16.19.8.16 NMAC - N, XX-XX-17]

16.19.8.17 PERSONNEL: As a condition of receiving and retaining a third party logistics provider license, the licensee shall require each person employed in any prescription drug third party logistics 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 third party logistics provider 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 third party logistics provider.

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) evidence of criminal background check and fingerprinting, the background check shall be sufficient to include all states residence since the person has been an adult;

(b) date of birth and Social Security number;

(c) occupations, positions of employment and offices held during the past seven (7) years;

(d) 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;

(e) 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;

(f) 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, distributed or stored prescription drugs and devices in which such businesses were names as a party in a lawsuit;

(g) 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;

(h) any other information the board deems relevant;

(2) may serve as the designated representative for only one third party logistics provider at any one time, except where more than one licensed third party logistics provider is co-located in the same facility and

such third party logistics providers are members of an affiliated group as defined in Section 1504 of the Internal Revenue Code;

(3) be actively involved in and aware of the actual daily operations and inventory control of the third party logistics provider;

(a) employed full-time in a managerial position by the third party logistics provider;

(b) physically present at the third party logistics provider 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 third party logistics provider.

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. No third party logistics provider shall have as an owner or designated representative anyone convicted of any felony violation of subsection (i) or (k) of section 301 or any violation of section 1365 of title 18, United States Code relating to product tampering;

D. Each licensed third party logistics provider located outside of this state that distributes prescription drugs into this state shall designate a registered agent in this state for service of process. Any licensed third party logistics provider 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 third party logistics provider growing out of or arising from such drug distribution. A copy of any such service or process shall be mailed to such third party logistics provider by the board by certified mail, return receipt requested, postage prepaid, at the address such licensed third party logistics provider has designated on its application for licensure in this state. If any such third party logistics provider is not licensed in this state, service on the Secretary of State only shall be sufficient service.

E. 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.

[16.19.8.17 NMAC - N, XX-XX-17]

16.19.8.18 MINIMUM STANDARDS FOR THIRD PARTY LOGISTICS PROVIDERS:

A. Reporting: Each facility of a third-party logistics provider shall comply with the FDA annual reporting requirements.

B. Storage practices, facilities: All third party logistics provider facilities at which prescription drugs are stored, warehoused, handled, held, 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, suspect or illegitimate, otherwise unfit for 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.

C. Security and anti-counterfeiting: All facilities used for third party logistics drug storage or 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.

D. Policies and procedures: Each third party logistics provider must have written policies and procedures to:

(1) address receipt, security, storage, inventory, shipment, and distribution of a product;

(2) identify, record, and report confirmed significant losses, or thefts in the United States;

(3) correct errors and inaccuracies in inventories;

(4) provide support for manufacturer recalls;

(5) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

(6) ensure that any expired product is segregated from other products and returned to the manufacturer, repackager, or their agent, or destroyed;

(7) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

(8) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

E. 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.

F. Inspection: Each third party logistics provider facility located in NM shall be inspected as a condition of initial licensure and periodically inspected to ensure compliance with board regulations.

G. Trading partner list: A third-party logistics provider must provide the board, upon a request by the board, a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility.

H. Compliance with federal, state, and local law: Third party logistics providers shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Third party logistics providers 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, and to confiscate prescription drugs and records to the extent authorized by law or rules. Such officials shall be required to show appropriate identification prior to being permitted access to third party logistics providers' premises and delivery vehicles.

(2) Third party logistics providers that deal in controlled substances shall register with the board as required, and with the DEA, and shall comply with all applicable state, local and DEA regulations.

(3) A third party logistics provider may distribute only to authorized trading partners. Product shall be shipped only to the address listed on the licensee's license.

(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.

[16.19.8.18 NMAC - N, XX-XX-17]

16.19.8.19 REPACKAGER LICENSING REQUIREMENTS:

A. Every repackager, wherever located, who engages in 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 repackaging or distribution of prescription drugs.

B. A repackager shall have valid registration with the FDA as a drug establishment under section 510 of the Federal Act.

C. Repackagers cannot operate from a place of residence.

D. Where repackaging operations are conducted at more than one location, each such location shall be licensed by the board.

E. The repackaging facility shall be located apart and separate from any pharmacy licensed by the board.

[16.19.8.19 NMAC - N, XX-XX-17]

16.19.8.20 MINIMUM REQUIRED INFORMATION FOR REPACKAGER LICENSURE:

A. Every repackager who engages in the distribution of product shall be licensed with the board by submitting an application and providing information required by the board on an application approved by the board, including but not limited to:

(1) applicant's full name; 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, third party logistics provider, or repackager licensed by the board; full business address and telephone number;

(2) type of ownership, e.g. individual, partnership, limited liability company or corporation;

(3) name(s) of the owner(s) of the applicant, including:

(a) if a person, the name, address, Social Security number or FEIN, and date of birth;

(b) if other than a person, the name, address, Social Security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(c) if a corporation, the State of incorporation; and

(d) if a publicly traded corporation, the information in (A)(3)(b) is not required for corporate officers and corporate directors.

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

(4) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the repackager that engages in the distribution of drugs;

(5) evidence of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;

(6) proof of valid registration as a drug establishment with the FDA;

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

(8) a list of all disciplinary actions or any other sanction by state and federal agencies against the repackager as well as any such actions against principals, owners, directors or officers;

(9) a full description of each facility and warehouse located in NM, 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;

(10) a description of the repackager's drug import and export activities;

(11) a copy of the repackager's written policies and procedures as required in Subsection D of 16.19.8.23 NMAC (written policies and procedures);

(12) a facility located outside of NM shall submit a copy of a current satisfactory inspection report issued by the FDA, or State licensing authority, or by a third-party inspection service approved by the FDA or the State authority licensing such repackager, or by the board.

(13) the information collected pursuant to Paragraphs (5), (9) and (11) of this subsection shall be made available only to 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 repackager shall submit a reasonable fee to be determined by the board.

C. Each facility located in New Mexico that engages in repackaging must undergo an inspection by the board for the purpose of inspecting the repackaging facility and operations prior to initial licensure.

D. All repackagers 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 within thirty (30) days of such change unless otherwise noted.

F. Information submitted by the repackager to 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 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 inspect repackagers.

H. The board may license by reciprocity, a repackager that is licensed under the laws of another state if:

(1) the applicant submits documentation of a current satisfactory inspection conducted by the FDA, or State licensing authority, or by a third-party inspection service approved by the FDA or the State authority licensing such repackager, or by the board; and

(2) the requirements of that state are deemed by the board to be substantially equivalent.

[16.19.8.20 NMAC - N, XX-XX-17]

16.19.8.21 MINIMUM QUALIFICATIONS:

A. The board shall prohibit a person from receiving or maintaining repackager licensure if the person:

(1) has been convicted of any felony for conduct relating to manufacturing or distribution, any felony violation of subsection (i) or (k) of section 301, or any felony violation of section 1365 of title 18, United States Code, relating to product tampering; or

(2) has engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

B. The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage as a repackager within the state:

(1) any conviction of the applicant under any federal, state or local laws relating to drug manufacture, 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;

(5) suspension, revocation or any other sanction 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 regulatory and 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 part; and

(8) any findings by the board that the applicant has violated or been disciplined or subject to administrative action by a regulatory or licensing 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.

C. The board shall consider the results of a criminal and financial background check and fingerprinting of the applicant and designated representative, to determine if an applicant or others associated with the ownership, management or operations of the repackager have committed criminal acts that would constitute grounds for denial of licensure.

D. 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.

E. 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.

[16.19.8.21 NMAC - N, XX-XX-17]

16.19.8.22 PERSONNEL: As a condition of receiving and retaining a repackager license, the licensee shall require each person employed in any repackaging or 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 repackager 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 repackager.

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) evidence of criminal background check and fingerprinting, the background check shall be sufficient to include all states residence since the person has been an adult;

(b) date of birth and Social Security number;

(c) occupations, positions of employment and offices held during the past seven (7) years;

(d) 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 manufacturing, possession, control or distribution of prescription drugs or devices, together with details of such events;

(e) 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;

(f) 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, distributed or stored prescription drugs and devices in which such businesses were names as a party in a lawsuit;

(g) 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;

(h) any other information the board deems relevant;

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

(3) be actively involved in and aware of the actual daily operations, purchasing and inventory control of the repackager;

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

(b) physically present at the repackager facility 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 repackager.

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 repackager located outside of this state that distributes prescription drugs in this state shall designate a registered agent in this state for service of process. Any licensed repackager 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 repackager growing out of or arising from such manufacture or distribution. A copy of any such service or process shall be mailed to such repackager by the board by certified mail, return receipt requested, postage prepaid, at the address such licensed repackager has designated on its application for licensure in this state. If any such repackager 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.
[16.19.8.22 NMAC - N, XX-XX-17]

16.19.8.23 REPACKAGER MINIMUM STANDARDS:

A. Compliance with federal, state, and local law. A repackager shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) A repackager shall comply with 16.19.9 NMAC, including operation in compliance with the Federal Food, Drug, and Cosmetic Act Good Manufacturing Practices, 21 U.S.C. §§ 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. §§ 216, 262, 263a, 264; and 21 C.F.R. Parts 210 and 211.

(2) A repackager shall permit board authorized personnel and authorized federal, state and local law enforcement officials, to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law, and to confiscate prescription drugs and records to the extent authorized by law or rules. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

(3) Inventories, records and written operating procedures shall be made available for inspection and photocopying by authorized inspectors employed by the board for a period of three (3) years following disposition of the drugs.

(4) Repackagers 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.

(5) A repackager may distribute only to authorized trading partners. Product shall be delivered only to the licensed address of the authorized trading partner.

(6) 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.

(7) Product tracing, product identifier, and verification: Repackagers licensed by the board shall comply with the requirements for tracing products through the distribution system as defined in sections 353 and 360eee, et seq., of the DSCSA, 21 U.S.C. 301, et seq., and successor FDA regulations, with respect to the role of such repackager including any requirements with respect to: transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

(8) Authorized trading partners: The trading partners of a repackager may be only authorized trading partners.

B. Shipment. A repackager shall ship product only to the address listed on the licensee's license.

C. Theft or loss. A repackager shall have and follow diversion detection and prevention plan that includes all prescription drugs. A repackagers shall report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and where applicable, to the DEA.

D. Written policies and procedures. Repackagers 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; repackagers 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 FDA 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 repackagers 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 that ensures all common carriers contracted with or utilized by the repackager conduct a criminal background check and drug screen of the employees whose responsibilities include the known handling of prescription drugs;

(10) a procedure for conducting periodic assessments of the security provisions of common carriers contracted with or utilized by the repackager 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;

E. Responsible persons. Repackagers shall establish and maintain lists of officers, directors, managers, and other persons in charge of operations, storage, and handling, including a description of their duties and a summary of their qualifications.

F. Salvaging and reprocessing. Repackagers 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 D of 16.19.8.23 NMAC (written policies and procedures).

[16.19.8.23 NMAC - N, XX-XX-17]

16.19.8.24 MANUFACTURER REQUIREMENTS:

A. Product tracing, product identifier, and verification: Manufacturers shall comply with the requirements for tracing products through the distribution system as defined in sections 353 and 360eee, et seq., of the DSCSA, 21 U.S.C. 301, et seq., and successor FDA regulations, with respect to the role of such manufacturer including any requirements with respect to: transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

B. Authorized trading partners: The trading partners of a manufacturer may be only authorized trading partners.

C. Compliance with federal, state, and local law: Manufacturers shall operate in compliance with applicable federal, state, and local laws and regulations. Manufacturers 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.

[16.19.8.24 NMAC - N, XX-XX-17]

HISTORY OF 16.19.8 NMAC:

Pre NMAC History: The material in this part was derived from that previously filed with the state records center and archives:

BOP 69-2, Rules and Regulations of the State Board of Pharmacy, filed 6/13/1969.

BOP 69-3, New Mexico Laws and Regulations, Pharmacy Act, Drug and Cosmetic Act, Narcotic Drug Act, Poisons Act, Board of Pharmacy Rules and Regulations, filed 8/15/1969.

BOP 72-1, New Mexico Board of Pharmacy Rules and Regulations Promulgated Pursuant to New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act, filed 7/31/1972.

Regulation No. 8, Minimum Standards For Wholesalers, filed 2/07/1980.

Regulation No. 8, Minimum Standards For Wholesalers, filed 10/23/1985.

Regulation No. 8, Minimum Standards For Wholesalers, filed 2/02/1987.

Regulation No. 8, Minimum Standards For Wholesalers, filed 7/27/1990.

Regulation No. 8, Wholesale Prescription Drug Distribution, filed 5/14/1992.

History of Repealed Material:

BOP 72-1, New Mexico Board of Pharmacy Rules and Regulations Promulgated Pursuant to New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act (filed 7/31/1972) repealed 10/29/1985.

16.19.8 NMAC, Wholesale Prescription Drug Distribution (filed 2/02/1996 and 3/1/2002) repealed 12/02/2009.

Other History:

Regulation No. 8, Wholesale Prescription Drug Distribution (filed 5/14/1992) was renumbered, reformatted, amended and replaced by 16 NMAC 19.8, Pharmacists - Wholesale Prescription Drug Distribution, effective 2/15/1996.

16 NMAC 19.8, Pharmacists - Wholesale Prescription Drug Distribution (filed 2/02/1996) was reformatted and renumbered to 16.19.8 NMAC, Wholesale Prescription Drug Distribution, effective 3/30/2002.

16.19.8 NMAC, Wholesale Prescription Drug Distribution (filed 2/02/1996 and 3/01/2002) replaced by 16.19.8 NMAC, Wholesale Prescription Drug Distribution, effective 12/02/2009.