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CHAPTER 8

MANUFACTURER, DISTRIBUTOR, WHOLESALER PRESCRIPTION DRUG REGULATIONS

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Section 1. Authority.

These regulations are promulgated as authorized by the Act.

Section 2. Purpose.

The purpose of this regulation is to provide for the minimum licensing standards necessary to ensure the safety and efficacy of prescription drugs offered for sale by manufacturers and wholesale distributors.

Section 3. Scope.

This Chapter applies to any person, partnership, corporation or business engaging in the wholesale distribution of human prescription drugs either into, out of, or within this State.

Section 4. Definitions.

(a) "Adulterated" means a drug shall be deemed adulterated if:

(i) It consists in whole or in part of any filthy, putrid, or decomposed substance; or

(ii) It 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; or if the methods used in, or the facilities or 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 practices to assure that the drug meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess; or

(iii) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(iv) It bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of the Federal Food, Drug and Cosmetic Act (Federal Act); or it is a color additive, the intended use of which is for purposes of coloring only, and is unsafe with the meaning of the Federal Act.

(b) "Authenticate" means to affirmatively verify before any wholesale distribution of a prescription drug takes place that each transaction listed on the Pedigree

has occurred, in accordance with this Chapter.

(c) "Authorized Distributor of Record" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. 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:

(i) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and

(ii) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which must be updated by the manufacturer on no less than a monthly basis.

(d) "Chain Pharmacy Warehouse" means a permanent physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs to chain pharmacies under common ownership and control. Chain pharmacy warehouses must be licensed as wholesale distributors.

(e) "Co-licensee" means an instance where two or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with the FDA's implementation of the Prescription Drug Marketing Act.

(f) "Counterfeit Drug" means a drug, the container, shipping container, seal, or product labeling which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, distributed, or wholesale distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed, distributed, or wholesale distributed by such other manufacturer, processor, packer, or distributor.

(g) "Drop Shipment" means the sale, by a manufacturer, that manufacturer's co-licensee, that manufacturer's third-party logistics provider, that manufacturer's exclusive distributor, or an authorized distributor of record that purchased the product directly from the manufacturer to a wholesale distributor whereby the wholesale distributor takes title but not possession of such prescription drug. That wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer a drug to a patient. The pharmacy, chain pharmacy warehouse, or other authorized person may receive delivery of the prescription drug directly from the manufacturer, that manufacturer's co-licensee, that manufacturer's third-party logistics provider, that manufacturer's exclusive distributor, or an authorized distributor of record. Drop shipments shall be part of the "Normal Distribution Channel".

(h) "Drug sample" means a unit of a prescription drug that is not intended to be sold but is intended to promote the sale of the drug.

(i) "Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of prescription drugs consistent with the FDA definition of "manufacturer" under the FDA's regulations and interpretive guidances implementing the Prescription Drug Marketing Act, including any amendments thereto.

(j) "Manufacturer's Exclusive Distributor" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have a general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor must be licensed as a wholesale distributor under this Chapter, and to be considered part of the "normal distribution channel" must also be an "authorized distributor of record".

(k) "Normal Distribution Channel" means a chain of custody for a prescription drug that goes, directly or by drop shipment, from a manufacturer, the manufacturer's co-licensee, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

(i) an authorized distributor of record and, subsequently, to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(ii) an authorized distributor of record, then to a chain pharmacy warehouse and, subsequently, to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(iii) a chain pharmacy warehouse and, subsequently, to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient; or

(iv) an authorized distributor of record and, subsequently, to other authorized distributors of record who subsequently distribute to an office-based healthcare practitioner authorized by law to dispense or administer such drug to a patient; or

(v) a pharmacy to a patient or other designated persons authorized by law to dispense or administer such prescription drug to a patient.

(l) "Prescription drug" means any drug required to be dispensed only by a prescription, by State law or regulations or by Federal law or regulations, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act.

(m) "Third Party Logistics Provider" means an entity that:

(i) Provides or coordinates 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; and

(ii) Is licensed as a wholesale distributor under this Chapter.

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

(n) "Wholesale Distribution" means the distribution of prescription drugs by wholesale distributors to persons other than consumers or patients, and includes the transfer of prescription drugs by a pharmacy to another pharmacy if the value of the goods transferred exceeds five percent (5%) of total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve (12) month period. Wholesale distribution does not include:

(i) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug pursuant to a prescription;

(ii) The sale, purchase, or trade of a prescription drug or the offer to sell, purchase, or trade a prescription drug by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(iii) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(iv) The sale, purchase, or trade of blood and blood components intended for transfusion;

(v) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between co-licensees of a co-licensed product;

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

(vii) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals, chain pharmacy warehouses, pharmacies, or other health care entities that are under common control;

(viii) 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, in accordance with board regulations;

(ix) The return of recalled, expired, damaged, or otherwise non-salable prescription drugs, when conducted by a hospital, health care entity, pharmacy, chain pharmacy warehouses or charitable institution in accordance with board regulations;

(x) The transfer of prescription drugs between pharmacies pursuant to a centralized prescription processing agreement;

(xi) Sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons, as defined under 21 CFR 203.3(m), including any amendment thereto. For purposes of this section "emergency medical reasons" includes transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;

(xii) Sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record during a time period for which there is documentation from the manufacturer that the manufacturer is unable to supply a prescription drug;

(xiii) Delivery of a prescription drug by a common carrier; or

(xiv) The sale or transfer from a pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, original wholesale distributor, or to a third party returns processor or reverse distributor.

(o) "Wholesale Distributor" means anyone engaged in wholesale distribution of prescription drugs in or into the State, including but not limited to, manufacturers, repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, co-licensees, exclusive distributors, third party logistics providers, chain pharmacy warehouses and wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distributions.

Section 5. Wholesale Distributor Licensing Requirement.

Every wholesale distributor, wherever located, who engages in wholesale distribution into or within this State shall be licensed by the board in accordance with the laws and regulations of this State before engaging in wholesale distribution of prescription drugs.

(a) The board shall require the following minimum information from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license:

(i) All trade or business names used by the licensee (includes "is doing business as" and "formerly known as"), which cannot be identical to the name used by another unrelated wholesale distributor licensed to purchase/distribute prescription drugs in the State;

(ii) Name(s) of the owner and operator of the licensee (if not the same person), including:

(A) If a person: the name, business address, social security number, and date of birth;

(B) If a partnership: the name, business address, and social security number and 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, social security number, date of birth, and title of each corporate officer and director; the corporate names, state of incorporation, federal employer identification number, and name of the parent company, if any; the name, business address, and social security number 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;

(D) If a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity; and

(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, and the name of the state in which the limited liability company was organized.

(iii) Name(s), business address(es), and 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 wholesale distribution of prescription drugs. The board shall be notified of each change in designated representative within 30 days of the change. Effective January 1, 2009 fingerprints and a fifty dollar ($50.00) fee must be submitted for each designated representative for a criminal background history and with each change in designated representative;

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

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

(vi) A full description of each facility and warehouse, including all locations utilized for prescription drug storage and/or wholesale distribution. The description shall include the following:

(A) Square footage;

(B) A general description of security and alarm systems;

(C) Terms of lease or ownership;

(D) Address; and

(E) Temperature and humidity controls in accordance with Section 11 below.

(vii) 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 which has an original term of not less than one (1) calendar year (if the establishment is not owned by the wholesale distributor);

(viii) Information regarding general and product liability insurance, including copies of relevant policies;

(ix) A description of the wholesale distributor's drug import and export activities;

(x) An electronic copy of the wholesale distributor's written policies and procedures as required by this Chapter. (See Section 15(a) through (h).)

(xi) 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 prescription drugs or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

(xii) The information collected pursuant to Section 5(a)(vi) and (x) 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 shall make provisions for protecting the confidentiality of the information collected under this section.

(b) Effective January 1, 2009 all current wholesale distributor licensees and all applicants for licensure as a wholesale distributor must submit security in the amount of $100,000 to the board. Acceptable forms of security include:

(i) "Surety" bond naming the board as the payee; or

(ii) Irrevocable letter of credit naming the board as the payee; or

(iii) Funds deposited in a trust account or financial institution naming the board as the payee.

The purpose of these funds will be to secure payment for any administrative penalty assessed by the board, which remains unpaid thirty days after the liability for the payment is final. A separate bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their wholesale distributor license with the board. The board will waive the security requirement, if the wholesale distributor:

(i) has previously obtained a comparable bond or other comparable security for the purpose of licensure in another state provided the board is named as a payee; or

(ii) is a publicly held company.

(c) Effective January 1, 2010, all wholesale distributors licensed by the board

and all applicants for licensure must provide evidence of VAWD® accreditation from the National Association of Boards of Pharmacy or from another third party recognized by the board to inspect and accredit wholesalers and must undergo the re-accreditation process no less than every three (3) years after initial accreditation. Manufacturing facilities are exempt from this requirement provided the manufacturing facilities are currently registered with the FDA in accordance with Section 510 of the Federal Act.

(i) Any applicant that is denied accreditation described under this section shall have the right of review of the accreditation body's decision, by:

(A) The accreditation body; and

(B) The board.

(ii) The recognized accreditation body shall ensure that the proprietary information obtained during the accreditation process remains confidential and privileged.

(iii) Individual or third party inspectors must demonstrate to the board that they have received training or demonstrate familiarity with the inspection standards. A letter of certification from a training program, a notice from the inspector's employing third party organization, or other means recognized by the board shall be accepted as meeting the requirement.

(d) The board may license by reciprocity a wholesale distributor that is licensed under laws of another state, if:

(i) The requirements of that state are deemed by the board to be substantially equivalent; or

(ii) The applicant is accredited by a third party recognized by the board. An applicant that is accredited by a third party recognized and approved by the board shall not be subject to duplicative requirements set by the board.

(e) Where operations are conducted at more than one location by a single wholesale distributor, each location shall be licensed by the board.

(f) Changes in any information required by this Section shall be submitted to the board within thirty (30) days after the change.

(g) Any applicant denied licensure by the board shall have the right of timely review and appeal as authorized by the Wyoming Administrative Procedure Act.

Section 6. Minimum Qualifications.

(a) The board shall consider the following factors in determining eligibility for licensure of persons or firms who engage in the wholesale distribution of prescription drugs:

(i) Any criminal convictions, except minor traffic violations, or civil

penalties of the applicant under any federal, state or local laws;

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

(iii) The applicant's past experience in the manufacture or distribution of prescription drugs;

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

(v) Suspension, sanction, or revocation by federal, state or local government against any license currently or previously held by the applicant or any of its owners for violations of state or federal laws regarding prescription drugs;

(vi) Compliance with previously granted licenses related to wholesale distribution of prescription drugs;

(vii) Compliance with the requirements to maintain or make available to the board or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors; and

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

Section 7. Personnel.

(a) Each person that is issued an initial or renewal license as a wholesale distributor, whether in state or out of state, must designate in writing on a form required by the board, a person for each facility to serve as the designated representative.

(b) To be certified as a designated representative, a person must:

(i) Submit an application on a form furnished by the board and provide information that includes:

(A) Fingerprint cards and fee for a criminal background history;

(B) Date and place of birth;

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

(D) Principal business and address of any business corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;

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

(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, wholesale distributed, or stored prescription drugs in which such businesses were named as a party in a lawsuit;

(G) Description of any felony criminal offense, or any offense (misdemeanor or felony) involving moral turpitude, or any offense related to the qualifications, functions or duties of that person in connection with the operation of the wholesaler, of which the person, as an adult, was found guilty, regardless of whether adjudication of guilty 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 30 days after the disposition of the appeal, submit a copy of the final written order of disposition to the board;

(H) Passport type and size of photograph of the person taken within the previous year;

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

(iii) 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 facility and such wholesale distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code;

(iv) Be actively involved in and aware of the actual daily operations of the wholesale distributor:

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

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

(C) Aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor.

Section 8. General Minimum Requirements for Facilities Storing and Handling of Prescription Drugs.

The following are required for the storage, handling, transport, and shipment of prescription drugs.

(a) All facilities at which prescription drugs are received, stored, warehoused,

handled, held, offered, marketed, transported from or displayed shall:

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

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

(iii) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution or wholesale distribution, or that are in immediate or sealed secondary containers that have been opened prior to receipt by the wholesale distributor in accordance with Section 12 below;

(iv) Be maintained in a clean and orderly condition;

(v) Be free from infestation of any kind;

(vi) Be a commercial location and not a personal dwelling or residence;

(vii) Provide for the secure storage of information with restricted access and policies and procedures to protect the integrity of the information;

(viii) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs; and

(ix) Provide to another wholesale distributor or pharmacy, written or electronic pedigrees for prescription drugs that leave the normal distribution channel in accordance with Section 10 below.

Section 9. Security and Anti-Counterfeiting.

(a) Facility Security. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be adequately controlled;

(ii) The outside perimeter of the premises shall be adequately lighted;

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel;

(iv) All facilities shall be equipped with an alarm system to detect unauthorized entry after hours; and

(v) 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.

(b) All facilities shall be equipped with inventory management and control

systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting.

(c) Wholesale distributors engaged in wholesale distribution shall be equipped with security measures to protect the integrity of data and documents and make such data and documents readily available to the board and other state and federal law enforcement officials.

Section 10. Pedigrees.

(a) Pedigrees shall be required for wholesale distribution of prescription drugs that leave or have ever left the normal distribution channel. Each person who is engaged in wholesale distribution of prescription drugs that leave, or have ever left, the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug. A retail pharmacy or pharmacy intracompany warehouse shall comply with the requirements of this section only if the pharmacy engages in wholesale distribution of prescription drugs.

(b) The contents of each pedigree shall:

(i) Include all necessary identifying information concerning each sale in the chain of ownership of product from the manufacturer (or the manufacturer's third-party logistics provider/co-licensed product partner/manufacturer's exclusive distributor) through acquisition and sale by any wholesale distributor or repackager until final sale to a pharmacy or other person furnishing, dispensing, or administering drug. At a minimum, the necessary chain of ownership information shall include:

(A) Name, address, telephone number, and, if available, the email address of each owner of the prescription drug, and each wholesale distributor of the prescription drug;

(B) Name and address of each location from which the product was shipped, if different from the owner's;

(C) Transaction dates; and

(D) Certification from the designated representative that each recipient has authenticated the pedigree.

(E) A certification from the designated representative of the wholesale distributor that the information contained therein is true and accurate (under penalty of perjury).

(ii) At a minimum, the pedigree shall also include the

(A) Name of the prescription drug;

(B) Dosage form and strength of the prescription drug;

(C) Size of the container;

(D) Number of containers;

(E) Lot number and the National Drug Code of the prescription drug; and

(F) Name of the manufacturer of the finished dosage form.

(iii) Each pedigree or electronic file shall be maintained consistent with 21 CFR 203.60, including any amendments thereto.

(c) Wholesale distributors engaged in wholesale distribution and manufacturers from whom wholesale distributors have acquired prescription drugs shall cooperate with pedigree authentication efforts and provide the requested information in a timely manner.

(d) Each wholesale distributor engaged in wholesale distribution that has distributed a prescription drug for which an acquiring wholesale distributor is conducting a pedigree authentication, shall provide to the acquiring wholesale distributor, upon request, detailed information regarding its acquisition of the prescription drug.

(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, as defined by the board, with the board within three (3) business days after completing the attempted prescription drug pedigree authentication;

(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 two (2) years, and shall produce them to the board upon request.

(g) Wholesale distributors and manufacturers shall maintain an ongoing list of persons with whom they purchase or sell prescription drug products.

Section 11. Storage of Prescription Drugs.

(a) All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the product labeling of such prescription drugs, or with requirements in the current edition of an official compendium such as the USP-NF.

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

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

Section 12. Examination of Materials.

(a) Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit or contraband, or damaged prescription drugs or prescription drugs that are otherwise unfit for wholesale distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, contraband, suspected of being counterfeit or contraband, or other damage to the contents.

(b) The prescription drugs found to be unacceptable under paragraph (a) shall be quarantined from the rest of the stock until examination and determination that the prescription drugs are not outdated, damaged, deteriorated, misbranded, counterfeit, contraband, or adulterated.

(c) 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.

Section 13. Returned, Damaged, and Outdated Prescription Drugs.

(a) 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 to either the original manufacturer 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. Both licensees under this Chapter and pharmacies for other persons authorized by law to administer or dispense drugs shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit products into the marketplace.

(b) Appropriate documentation shall be made to the pedigree if any prescription drug that was ordered in excess of need by the wholesale distributor from a source outside the normal distribution channel, if identified as such, and which the integrity has been maintained, that is returned to the manufacturer or wholesale distributor from which it was acquired after which the wholesale distributor shall abide by the provisions of these regulations that govern returned, damaged and outdated prescription drugs.

(c) Any prescription drug that is damaged, deteriorated, misbranded, counterfeit, contraband, suspected of being counterfeit or contraband, adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically

separated from other prescription drugs until it is destroyed or returned to either the manufacturer or wholesale distributor from which it was acquired or to a third party returns processor. Notice of prescription drugs identified under this paragraph shall be given to the board and manufacturer or wholesale distributor from which they were acquired within three (3) business days of identification.

(d) 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 either the manufacturer or wholesale distributor from which it was acquired. Notice of prescription drugs identified under this paragraph shall be given to the board and manufacturer or wholesale distributor from which they were acquired or to a third party returns processor within three (3) business days of identification.

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

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

(g) 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 the FDA.

(h) The recordkeeping requirements of this Chapter shall be followed for all outdated, damaged, deteriorated, counterfeit, contraband, misbranded, or adulterated prescription drugs.

Section 14. Electronic Track and Trace Requirements.

(a) Electronic track and trace requirements shall not be considered as a requirement until such time as the FDA implements a uniform electronic track and trace system utilizing widely accepted standard technology that is universally available to manufacturers, wholesalers, and pharmacies and is technically and operationally feasible and reliable for manufacturers, wholesale distributors and pharmacies.

(b) After the FDA has implemented a uniform and universally available standard for an electronic track and trace system to initiate, provide, receive, or maintain pedigrees, the board shall consult with manufacturers, wholesales distributors, and pharmacies and prepare a report before adopting any rules to implement such electronic track and trace system and imposing such requirements on all manufacturers, wholesaled distributors and pharmacies. Implementation of the FDA's standards shall satisfy the requirements under section 10 of this Chapter.

Section 15. Policies and Procedures.

Wholesale distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, shipping, and wholesale 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 distributors shall include in their written policies and procedures the following:

(a) 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:

(i) Any action initiated at the request of the FDA or any other federal, state, or local law enforcement or other governmental agency, including the board of pharmacy; or

(ii) Any volunteer action by the manufacturer to remove defective or potentially defective prescription drugs from the market.

(b) 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 a strike, fire, flood, natural disaster, or other situations of local, state, or national emergency.

(c) A procedure to ensure that any outdated prescription drugs shall be segregated from other prescription drugs and either returned to the manufacturer or third party return processor or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs.

(d) A procedure for the destruction of outdated prescription drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of two (2) years, and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements.

(e) 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 two (2) 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.

(f) 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/or appropriate federal or state agency upon discovery of such discrepancies.

(g) A procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drugs to the board, FDA, and, if applicable, DEA, within three (3) business days.

(h) A procedure for conducting authentication of pedigrees in accordance with this Chapter.