FINAL REGULATIONS ON WHOLESALE DISTRIBUTORS, MANUFACTURERS AND WAREHOUSERS

VIRGINIA BOARD OF PHARMACY

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees

1. Pharmacist license $180

2. Pharmacy intern registration $15

3. Pharmacy technician registration $25

4. Pharmacy permit $270

5. Permitted physician licensed to dispense drugs $270

~~6. Nonrestricted manufacturer permit $270~~

~~7. Restricted manufacturer permit $180~~

~~8. Wholesale distributor license $270~~

~~9. Warehouser permit $270~~

~~10~~ 6. Medical equipment supplier permit $180

~~11~~ 7. Humane society permit $20

~~12~~ 8. Non-resident pharmacy $270

~~13. Non-resident wholesale distributor $270~~

~~14~~ 9. Controlled substances registrations $90

~~15~~ 10. Robotic pharmacy system approval $150

~~16~~ 11. Innovative program approval $250

If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.

17. Approval of a pharmacy technician training program $150

18. Approval of a continuing education program $100

D. Annual renewal fees:

1. Pharmacist active license $90

2. Pharmacist inactive license $45

3. Pharmacy technician registration $25

4. Pharmacy permit $270

5. Physician permit to practice pharmacy $270

~~6. Nonrestricted manufacturer permit $270~~

~~7. Restricted manufacturer permit $180~~

~~8. Wholesale distributor license $270~~

~~9. Warehouser permit $270~~

~~10~~ 6. Medical equipment supplier permit $180

~~11~~ 7. Humane society permit $20

~~12~~ 8. Non-resident pharmacy $270

~~13. Non-resident wholesale distributor $270~~

~~14~~ 9. Controlled substances registrations $90

~~15~~ 10. Innovative program continued approval based on board order not to exceed $200 per approval period

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license $30

2. Pharmacist inactive license $15

3. Pharmacy technician registration $10

4. Pharmacy permit $90

5. Physician permit to practice pharmacy $90

~~6. Nonrestricted manufacturer permit $90~~

~~7. Restricted manufacturer permit $60~~

~~8. Wholesale distributor license $90~~

~~9. Warehouser permit $90~~

~~10~~ 6. Medical equipment supplier permit $60

~~11~~ 7. Humane society permit $5

~~12~~ 8. Non-resident pharmacy $90

~~13. Non-resident wholesale distributor $90~~

~~14~~ 9. Controlled substances registrations $30

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license $210

2. Pharmacist license after revocation or suspension $500

3. Pharmacy technician registration $35

4. Pharmacy technician registration after revocation or suspension $125

5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Pharmacy permit $240

b. Physician permit to practice pharmacy $240

~~c. Nonrestricted manufacturer permit $240~~

~~d. Restricted manufacturer permit $ 210~~

~~e. Wholesale distributor license $240~~

~~f. Warehouser permit $240~~

~~g~~ c. Medical equipment supplier permit $210

~~h~~ d. Humane society permit $30

~~i~~ e. Non-resident pharmacy $115

~~j. Non-resident wholesale distributor $115~~

~~k~~ f. Controlled substances registration $180

G. Application for change or inspection fees for facilities or other entities

1. Change of pharmacist-in-charge $50

2. Change of ownership for any facility $50

3. Inspection for remodeling or change of location for any facility $150

4. Reinspection of any facility $150

5. Board-required inspection for a robotic pharmacy system $150

6. Board-required inspection of an innovative program location $150

7. Change of pharmacist responsible for an approved innovative program $25

H. Miscellaneous fees

1. Duplicate wall certificate $25

2. Returned check $25

PART XVI. ~~MANUFACTURERS, WHOLESALE DISTRIBUTORS, WAREHOUSERS, AND~~ MEDICAL EQUIPMENT SUPPLIERS

18VAC110-20-630. ~~Licenses and permits generally.~~ [~~(Repealed)~~ Issuance of a permit as a medical equipment supplier.

~~A license or permit shall not be issued to any manufacturer, wholesale distributor, warehouser, or medical equipment supplier to operate from a private dwelling, unless a separate business entrance is provided, and the place of business is open for inspection at all times during normal business hours. The applicant shall comply with all other federal, state and local laws and ordinances before any license or permit is issued.~~

A. Any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the board on a form approved by the board. An application shall be filed for a new permit, or for acquisition of an existing medical equipment supplier.

B. A permit holder proposing to change the location of an existing license or permit or make structural changes to an existing location shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.

C. A permit shall not be issued to any medical equipment supplier to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.]

18VAC110-20-640. ~~Safeguards against diversion of drugs.~~ (Repealed)

~~The following requirements shall apply to manufacturers, wholesale distributors, or warehousers of prescription drugs:~~

~~1. The holder of the permit shall restrict all areas in which prescription drugs are manufactured, stored, or kept for sale, to only designated and necessary persons.~~

~~2. The holder of the permit shall provide reasonable security measures for all drugs in the restricted area.~~

~~3. The holder of the permit, except for those manufacturers or distributors of only medical gases other than nitrous oxide, shall install a device for the detection of breaking subject to the following conditions:~~

~~a. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.~~

~~b. The installation shall be hard wired and both the installation and device shall be based on accepted burglar alarm industry standards.~~

~~c. The device shall be maintained in operating order and shall have an auxiliary source of power.~~

~~d. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.~~

~~e. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.~~

~~4. The holder of the permit shall not deliver any drug to a licensed business at which there is no one in attendance at the time of the delivery nor to any person who may not legally possess such drugs.~~

18VAC110-20-660. ~~Good manufacturing practices.~~ (Repealed)

~~A. The Good Manufacturing Practice for Finished Pharmaceuticals regulations set forth in 21 CFR 211 are adopted by reference.~~

~~B. Each manufacturer of drugs shall comply with the requirements set forth in the federal regulations referred to in subsection A of this section.~~

18VAC110-20-670. ~~Prescription drug marketing act.~~ (Repealed)

~~A. The requirements for wholesale distribution of prescription drugs set forth in the federal Prescription Drug Marketing Act of 1987 (21 USC §321; 21 CFR 205) are adopted by reference.~~

~~B. Each wholesale distributor of prescription drugs shall comply with minimum requirements for qualifications, personnel, storage, handling, and records as set forth in the federal regulations referred to in subsection A of this section.~~

18VAC110-50-10 et seq. Wholesale Distributors, Manufacturers, and Warehousers
Part I. General Provisions

18VAC110-50-10. Definitions.

In addition to words and terms defined in §§54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"DEA" means the United States Drug Enforcement Administration.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"FDA" means the United States Food and Drug Administration.

"USP-NF" means the United States Pharmacopeia-National Formulary, current edition.

"Control number" means the unique identifying customer number assigned by the Virginia Department of Motor Vehicles to an individual when issuing a driver's license, learner's permit, or official identification card. This number is displayed on the driver's license or ID card in lieu of the Social Security Number.

18VAC110-50-20. Fees

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Initial application fees

1. Nonrestricted manufacturer permit $270

2. Restricted manufacturer permit $180

3. Wholesale distributor license $270

4. Warehouser permit $270

5. Non-resident wholesale distributor $270

6. Controlled substances registration $90

C. Annual renewal fees

1. Nonrestricted manufacturer permit $270

2. Restricted manufacturer permit $180

3. Wholesale distributor license $270

4. Warehouser permit $270

5. Non-resident wholesale distributor $270

6. Controlled substances registration $90

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Nonrestricted manufacturer permit $90

2. Restricted manufacturer permit $60

3. Wholesale distributor license $90

4. Warehouser permit $90

5. Non-resident wholesale distributor $90

6. Controlled substances registration $30

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Nonrestricted manufacturer permit $240

b. Restricted manufacturer permit $210

c. Wholesale distributor license $240

d. Warehouser permit $240

e. Non-resident wholesale distributor $240

f. Controlled substances registration $180

F. Application for change or inspection fees

1. Reinspection fee $150

2. Inspection fee for change of location, structural changes, or security system changes $150

3. Change of ownership fee $50

4. Change of responsible party $50

G. The fee for a returned check shall be $25.

18VAC110-50-30. Application; location of business; inspection required.

A. Any person or entity desiring to obtain a license as a wholesale distributor, registration as a non-resident wholesale distributor, or permit as a manufacturer or warehouser shall file an application with the board on a form approved by the board. An application shall be filed for a new license, registration, or permit, or for acquisition of an existing wholesale distributor, manufacturer, or warehouser.

B. A licensee or permit holder proposing to change the location of an existing license or permit, or make structural or security system changes to an existing location, shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.

C. A license or permit shall not be issued to any wholesale distributor, manufacturer, or warehouser to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.

D. If a wholesale distributor, manufacturer, or warehouser engages in receiving, possessing, storing, using, manufacturing, distributing, or otherwise disposing of any Schedule II – V controlled substances, it shall also obtain a controlled substances registration from the board in accordance with § 54.1-3422 of the Code of Virginia, and shall also be duly registered with DEA and in compliance with all applicable laws and rules for the storage, distribution, shipping, handling, and transporting of controlled substances.
E. Prior to issuance of a license or permit by the board, a proposed location shall be inspected by an authorized agent of the board.
1. Applications which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.
2. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days prior to conducting a scheduled inspection.
3. At the time of the inspection, the proposed prescription drug storage area shall be in compliance with 18 VAC 110-50-40 and 18 VAC 110-50-50, and wholesale distributors shall meet the requirements of 18 VAC 110-50-90.
4. If an applicant substantially fails to meet the requirements for issuance of a permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18 VAC 110-50-20 prior to a reinspection being conducted.
5. Prescription drugs shall not be stocked within the proposed location or moved to a new location until approval is granted by the inspector or board staff.

18VAC110-50-40. Safeguards against diversion of drugs.

A. The holder of the license or permit shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture receipt, storage, distribution or quality control of the controlled substance inventory, and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.

B. The holder of the license or permit, except for those distributors of only medical gases other than nitrous oxide, shall install an operable device for the detection of breaking subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The installation shall be hard-wired and both the installation and device shall be based on accepted burglar alarm industry standards.

3. The device shall be operable, centrally-monitored, and have an auxiliary source of power.

4. The device shall fully protect all areas where prescription drugs are stored and shall be reasonably capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to the person named on the application as the responsible party, or to persons specifically designated in writing in a policy and procedure manual.

6. The system shall be activated whenever the drug storage areas are closed for business.

C. Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.

1. The holder of the license or permit shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs, and only at a time when someone authorized to possess such drugs is in attendance.

2. The holder of the license or permit shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

3. Prescriptions drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, or warehouser, and provided the identity and authorization of the agent is verified and such transfer is only used to meet the immediate needs of a patient or patients.

18VAC110-50-50. Storage

A. All prescription drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements of USP-NF.

B. If no specific storage requirements are established for a drug or a device, it may be held at controlled room temperature, as defined in 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, or logs shall be utilized to document proper storage of prescription drugs.

D. Packaging of the prescription drugs should be in accordance with USP-NF standards.
E. Schedule II – V controlled substances shall be separated from Schedule VI prescription drugs and stored in a secure area in accordance with DEA security requirements and standards.
F. Any facility shall be of adequate size and construction and have the proper equipment necessary for the proper storage of prescription drugs and devices as set forth in this section.

Part II. Wholesale Distributors

18VAC110-50-60. Special or limited-use licenses.

The board may issue a limited-use wholesale distributor license to entities that do not engage in the wholesale distribution of prescription drugs except medical gases and may waive certain requirements of regulation based on the limited nature of such distribution.

18VAC110-50-70. Minimum required information.

A. The application form for a new license or for registration as a non-resident wholesale distributor, or any change of ownership shall include at least the following information:
1. The name, full business address, and telephone number of the applicant or licensee and name and telephone number of a designated contact person;
2. All trade or business names used by the applicant or licensee;
3. The federal employer identification number of the applicant or licensee;
4. The type of ownership and name(s) of the owner of the entity, including:
a. If an individual: the name, address, social security number or control number;

b. If a partnership: the name, address, and social security number or control number of each partner, and the name of the partnership and federal employer identification number;
c. If a corporation:
(1) The name and address of the corporation, federal employer identification number, state of incorporation, the name and address of the resident agent of the corporation;
(2) The name, address, social security number or control number, and title of each corporate officer and director;
(3) For non-publicly held corporations, the name and address of each shareholder that owns ten (10) percent or more of the outstanding stock of the corporation.
(4) The name, federal employer identification number, and state of incorporation of the parent company.
d. If a sole proprietorship: the full name, address, and social security number or control number of the sole proprietor and the name and federal employer identification number of the business entity;
e. If a limited liability company, the name and address of each member, the name and address of each manager, the name of the limited liability company and federal employer identification number, the name and address of the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized;
5. Name, business address and telephone number, and social security number or control number, and documentation of required qualifications as stated in 18VAC110-50-80 of the person who will serve as the responsible party;
6. A list of all states in which the entity is licensed to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs;
7. A list of all disciplinary actions, to include date of action and parties to the action, imposed against the entity by state or federal regulatory bodies, including any such actions against the responsible party, principals, owners, directors, or officers over the last seven years;
8. A full description, for non-resident wholesale distributors, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or warehouse space used for prescription drug storage and distribution; and
9. An attestation 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. Such attestation shall include the responsible party, principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation.

B. An applicant or licensee shall notify the board of any changes to the information required in this section within 30 days of such change.

18VAC110-50-80. Minimum qualifications, eligibility, and responsible party.

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors:

1. The existence of grounds to deny an application as set forth in §54.1-3435.1 of the Code of Virginia;

2. The applicant's past experience in the manufacture or distribution of drugs or devices;

3. Compliance with the recordkeeping requirements;

4. Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

5. The responsible party's credentials as set forth in subsection B of this section.

B. Requirements for the person named as the responsible party:

1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, who shall be responsible for managing the wholesale distribution operations at that location;

2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor licensed in Virginia or another state, where the person's responsibilities included, but were not limited to, managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

3. A person may only serve as the responsible party for one wholesale distributor license at any one time;

4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor and all applicable state and federal laws related to wholesale distribution of prescription drugs.

C. The person named as the responsible party on the application shall submit the following with the application:

1. A passport size and quality photograph taken within 30 days of submission of the application;

2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

3. A sworn statement or affirmation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A criminal history record check through the Central Criminal Records Exchange; and

5. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning wholesale distribution of prescription drugs in which such businesses were named as a party.

D. Responsibilities of the responsible party

1. The responsible party shall ensure that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs.

2. The responsible party shall require that any employee who has access to prescription drugs attest that he has not been convicted of any federal or state drug law or any law relating to the manufacture, distribution or dispensing of prescription drugs.

3. The responsible party shall be responsible for maintaining current working knowledge of requirements for wholesale distributors and assuring continued training for employees.

4. The responsible party shall be responsible for maintaining proper security, storage and shipping conditions for all prescription drugs.

5. The responsible party shall be responsible for maintaining all required records.

E. Each non-resident wholesale distributor shall designate a registered agent in Virginia for service of any notice or other legal document. Any non-resident wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon who may be served all legal process in any action or proceeding against such non-resident wholesale distributor. A copy of any such service of legal documents shall be mailed to the non-resident wholesale distributor by the board by certified mail at the address of record.

18VAC110-50-90. Minimum requirements for the storage, handling, transport, and shipment of prescription drugs

A. All locations where prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

1. Be of suitable construction to ensure that all drugs and devices in the facilities are maintained in accordance with the labeling of such drugs and devices or with official USP-NF compendium standards;

2. Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

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

4. Have a quarantine area for storage of drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;

5. Be maintained in a clean and orderly condition; and

6. Be free from infestation of any kind.

B. The facility shall 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.

C. The facility shall provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs.

18VAC110-50-100. Examination of drug shipments and accompanying documents.

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

B. Upon receipt of drugs, a wholesale distributor must review records for accuracy, completeness, and the integrity of the drugs considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

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

18VAC110-50-110. Returned, damaged and counterfeit drugs; investigations

A. Any drug or device returned to a manufacturer or another wholesale distributor shall be kept under the proper conditions and documentation showing that proper conditions were maintained shall be provided to the manufacturer or wholesale distributor to which the drugs are returned.

B. Any drug or device that, or any drug whose immediate or sealed outer or secondary container or labeling, is outdated, damaged, deteriorated, misbranded, adulterated, counterfeited, suspected of being counterfeited or adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other drugs and devices until its appropriate disposition.

C. When a drug or device is adulterated, misbranded, counterfeited, or suspected of being counterfeit or when the immediate or sealed outer or secondary container or labeling of any drug or device is adulterated, misbranded other than misbranding identified by the manufacturer through a recall or withdrawal, counterfeited, or suspected of being counterfeit, the wholesale distributor shall:

1. Provide notice to the board and the manufacturer, and to the other wholesale distributor if applicable, from which such drug or device was acquired within three business days of that determination.

2. Maintain any such drug or device, its containers and labeling, and its accompanying documentation or any evidence of criminal activity until its disposition by the appropriate state and federal government authorities.

D. The wholesale distributor shall fully cooperate with authorities conducting any investigation of counterfeiting or suspected counterfeiting to include the provision of any records related to receipt or distribution of the suspect drug or device.

18VAC110-50-120. Policies and procedures

All wholesale distributors shall establish, maintain, and adhere to written policies and procedures for the proper receipt, security, storage, inventory, and distribution of prescription drugs. Wholesale distributors shall include in their policies and procedures at least the following:

1.A procedure for reporting thefts or losses of prescription drugs to the board and other appropriate persons;

2. A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this process provided the deviation is temporary and appropriate for the distribution;

3. A procedure for handling recalls and withdrawals of prescription drugs and devices;

4. Procedures for preparing for, protecting against, and handling emergency situations that affect the security and integrity of drugs or the operations of the wholesale distributor;

5. A procedure to ensure that outdated drugs are segregated from other drugs to include the disposition of such drugs;

6. A procedure to ensure initial and ongoing training of all employees;

7. A procedure for ensuring, both initially and on an ongoing basis, that persons with access to prescription drugs have not been convicted of a drug law or any law related to the manufacture, distribution, or dispensing of prescription drugs; and

8. A procedure for reporting counterfeit or suspected counterfeit prescription drugs or counterfeiting or suspected counterfeiting activities to the board and other appropriate law enforcement or regulatory agencies.

18VAC110-50-130. Recordkeeping

A. All records and documentation required in this subsection shall be maintained and made available for inspection and photocopying by an authorized agent of the board for a period of three years following the date the record was created or received by the wholesale distributor. A wholesale distributor shall establish and maintain the following:

1. Inventories and records of all transactions regarding the receipt and distribution, or other disposition of all prescription drugs, including the dates of receipt and distribution or other disposition;

2. Records documenting monitoring of environmental conditions to ensure compliance with the storage requirements as required in 18VAC110-50-50;

3. Documentation of visual inspection of drugs and accompanying documents required in 18VAC110-50-100, including the date of such inspection and the identity of the person conducting the inspection;

4. Documentation of quarantine of any product and steps taken for the proper reporting and disposition of the product shall be maintained, including the handling and disposition of all outdated, damaged, deteriorated, misbranded, or adulterated drugs;

5. An ongoing list of persons or entities from whom it receives prescription drugs and persons or entities to whom it distributes prescription drugs; and

6. Copies of the mandated report of thefts or unusual losses of Schedule II-V controlled substances in compliance with the requirements of §54.1-3404 of the Code of Virginia.

B. Records shall be either: a) be kept at the inspection site or immediately retrievable by computer or other electronic means and made readily available at the time of inspection; or b) if kept at a central

location and not electronically retrievable at the inspection site, be made available for inspection within 48 hours of a request by an authorized agent of the board.

C. All facilities shall have adequate backup systems to protect against the inadvertent loss or deliberate destruction of data.

18VAC110-50-140. Due diligence.

A. Prior to the initial purchase of prescription drugs from another wholesale distributor not residing and licensed in Virginia, a wholesale distributor shall obtain, and update annually, the following information from the selling wholesale distributor:

1. A copy of the license to wholesale distribute from the resident state;

2. The most recent facility inspection report, if available;

3. A list of other names under which the wholesale distributor is doing business, or was formerly known as;

4. A list of principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation;

5. A list of all disciplinary actions by state and federal agencies;

6. A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for drug storage and distribution;

7. A listing of any manufacturers for whom the wholesale distributor is an authorized distributor of record.

B. If the selling wholesale distributor's facility has not been inspected by the resident board or the board's agent within three years of the contemplated purchase, the purchasing wholesale distributor may conduct an inspection of the wholesale distributor's facility prior to the first purchase of drugs or devices from another wholesale distributor, to ensure compliance with applicable laws and regulations relating to the storage and handling of drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the purchasing wholesale distributor.

C. Prior to the first purchase of drugs from another wholesale distributor not residing in and licensed in Virginia, the purchasing wholesale distributor shall secure a national criminal background check of all of the wholesale distributor's owners, corporate officers, and the person named as the responsible party with the resident board or licensing agency.

Part III. Manufacturers

18VAC110-50-150. Good manufacturing practices.

A. The Good Manufacturing Practice for Finished Pharmaceuticals regulations set forth in 21 CFR 211 are adopted by reference.

B. Each manufacturer of drugs shall comply with the requirements set forth in the federal regulations referred to in subsection A of this section.