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|  | ***Commonwealth of Virginia*** |  |
|  | **Regulations Governing Wholesale Distributors, Manufacturers, Warehousers, and Third-Party Logistics Providers**    **Virginia Board of Pharmacy**  **Title of Regulations: 18 VAC 110-50-10 et seq.**  **Statutory Authority: § 54.1-2400 and Chapters 33 and 34**  **of Title 54.1 of the *Code of Virginia***  **Effective Date: March 18, 2021** | |
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# 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:

"Authorized collector" means a registered manufacturer, wholesale distributor, or reverse distributor that is authorized by the U.S. Drug Enforcement Administration to receive drugs from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility for the purpose of destruction.

"Authorized distributor of record" means a wholesale distributor with whom a manufacturer has entered into a written agreement under which such wholesale distributor is either authorized to distribute all of that manufacturer's prescription drug products, or only those products listed in the agreement, for such a period of time or number of shipments as specified in the agreement.

"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.

"DEA" means the U.S. Drug Enforcement Administration.

"Drop shipment" means the sale and distribution of a prescription drug in which a manufacturer or a third-party logistics provider directly ships the prescription drug to a pharmacy, chain drug warehouse, or other person authorized to dispense or administer the prescription drug, and the pharmacy, chain drug warehouse or other authorized person is invoiced by a wholesale distributor that took title to the prescription drug during the shipping, but did not take physical possession of the prescription drug.

"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 U.S. Food and Drug Administration.

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

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

## 18VAC110-50-20. Fees.

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

B. Initial application fees.

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| 1. Nonrestricted manufacturer permit | $350 |
| 2. Restricted manufacturer permit | $235 |
| 3. Wholesale distributor license | $350 |
| 4. Warehouser permit | $350 |
| 5. Nonresident wholesale distributor registration | $350 |
| 6. Controlled substances registration | $120 |
| 7. Third-party logistics provider permit | $350 |
| 8. Nonresident manufacturer registration | $350 |
| 9. Nonresident warehouser registration | $350 |
| 10. Nonresident third-party logistics provider registration | $350 |

C. Annual renewal fees shall be due on February 28 of each year.

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| --- | --- |
| 1. Nonrestricted manufacturer permit | $350 |
| 2. Restricted manufacturer permit | $235 |
| 3. Wholesale distributor license | $350 |
| 4. Warehouser permit | $350 |
| 5. Nonresident wholesale distributor registration | $350 |
| 6. Controlled substances registration | $120 |
| 7. Third-party logistics provider permit | $350 |
| 8. Nonresident manufacturer registration | $350 |
| 9. Nonresident warehouser registration | $350 |
| 10. Nonresident third-party logistics provider registration | $350 |

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.

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| --- | --- |
| 1. Nonrestricted manufacturer permit | $120 |
| 2. Restricted manufacturer permit | $80 |
| 3. Wholesale distributor license | $120 |
| 4. Warehouser permit | $120 |
| 5. Nonresident wholesale distributor registration | $120 |
| 6. Controlled substances registration | $40 |
| 7. Third-party logistics provider permit | $120 |
| 8. Nonresident manufacturer registration | $120 |
| 9. Nonresident warehouser registration | $120 |
| 10. Nonresident third-party logistics provider registration | $120 |

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:

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| --- | --- |
| a. Nonrestricted manufacturer permit | $315 |
| b. Restricted manufacturer permit | $275 |
| c. Wholesale distributor license | $315 |
| d. Warehouser permit | $315 |
| e. Nonresident wholesale distributor registration | $315 |
| f. Controlled substances registration | $235 |
| g. Third-party logistics provider permit | $315 |
| h. Nonresident manufacturer registration | $315 |
| i. Nonresident warehouser registration | $315 |
| j. Nonresident third-party logistics provider registration | $315 |

F. Application for change or inspection fees.

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| --- | --- |
| 1. Reinspection fee | $300 |
| 2. Inspection fee for change of location, structural changes, or security system changes | $300 |
| 3. Change of ownership fee | $65 |
| 4. Change of responsible party | $65 |

G. The handling fee for returned check or a dishonored credit card or debit card shall be $50.

H. The fee for verification of license, permit, or registration shall be $35.

## 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 nonresident wholesale distributor, nonresident manufacturer, nonresident warehouser, or nonresident third-party logistics provider; or permit as a manufacturer, warehouser, or third-party logistics provider 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, warehouser, nonresident wholesale distributor, nonresident manufacturer, or third-party logistics provider, nonresident warehouser, or nonresident third-party logistics provider.

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, permit, or registration shall not be issued to any wholesale distributor, manufacturer, warehouser, nonresident warehouser, nonresident wholesale distributor, nonresident manufacturer, third-party logistics provider, or third-party logistics provider 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, permit, or registration is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.

D. If a wholesale distributor, manufacturer, warehouser, or third-party logistics provider engages in receiving, possessing, storing, using, manufacturing, distributing, or otherwise disposing of any Schedules II through 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. The proposed location, structural changes, or security system changes shall be inspected by an authorized agent of the board prior to issuance of a license or permit.

1. Applications that indicate a requested inspection date, or requests that 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 that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

3. At the time of the inspection, the proposed prescription drug storage area shall comply with 18VAC110-50-40 and 18VAC110-50-50, and wholesale distributors shall meet the requirements of 18VAC110-50-90.

4. If an applicant substantially fails to meet the requirements for issuance of a permit or license 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 18VAC110-50-20 prior to a reinspection being conducted.

F. 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 as a wholesale distributor or permit as a manufacturer, warehouser, or third-party logistics provider, or registration as a nonresident wholesale distributor, nonresident warehouser, nonresident third-party logistics provider, or nonresident manufacturer shall restrict access to 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, permit, or registration, except for those distributors of only medical gases other than nitrous oxide, shall install a 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. One communication line installation shall be hardwired and both the installation and device shall be based on accepted burglar alarm industry standards to include wireless motion sensors.

3. The device shall be maintained in operating order, shall have an auxiliary source of power, and shall be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

4. The device shall fully protect all areas where prescription drugs are stored and shall be 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, permit, or registration 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, permit, or registration shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

3. Prescription 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, warehouser, third-party logistics provider, nonresident wholesale distributor, nonresident warehouser, nonresident third-party logistics provider, or nonresident manufacturer 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.

## 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.

## 18VAC110-50-51. Disposal of drugs by authorized collectors.

Any manufacturer, wholesale distributor, or reverse distributor wishing to accept for return a previously dispensed drug in Schedules II through V for the purpose of destruction from an ultimate user, or a person lawfully entitled to dispose of an ultimate user decedent’s property, shall first be authorized by the DEA as a collector. The process used to collect and destroy drugs, along with any required recordkeeping, shall comply with federal and state law.

1. Prior to collecting drugs, an authorized collector shall submit in writing to the board:

a. The name, address, and license number, if applicable, of the facility;

b. The intended method or methods of collection (i.e., collection receptacle or mail-back program); and

c. Signature of the responsible party.

2. If an authorized collector chooses to cease acting as a collector, the responsible party shall notify the board within 30 days.

## 18VAC110-50-55. Delivery of Schedule VI devices.

A. In accordance with the provisions of subsection A of § [54.1-3415.1](http://law.lis.virginia.gov/vacode/54.1-3415.1/) of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third-party logistics provider, nonresident third-party logistics provider, warehouser, or nonresident warehouser licensed, permitted, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user or consumer on behalf of a medical equipment supplier.

1. Such delivery shall only occur in accordance with an agreement between a delivering entity named in this subsection and a medical equipment supplier in compliance with law and regulation.

2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and an individual medical equipment supplier or multiple medical equipment suppliers under shared ownership. The agreement shall be applicable to all ultimate users or consumers receiving services from the medical equipment supplier who require delivery of Schedule VI prescription devices.

3. The medical equipment supplier shall represent to the delivering entity that it has complied with the provisions of § [54.1-3415.1](http://law.lis.virginia.gov/vacode/54.1-3415.1/) of the Code of Virginia regarding the existence of a valid order from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of orders of prescribers shall be the responsibility of the medical equipment supplier upon request of the board or delivering entity.

B. In accordance with the provisions of subsection B of § [54.1-3415.1](http://law.lis.virginia.gov/vacode/54.1-3415.1/) of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third-party logistics provider, nonresident third-party logistics provider, warehouser, or nonresident warehouser licensed, permitted, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence to be administered by persons authorized to administer such devices, provided that (i) such delivery is made on behalf of a medical director of a home health agency, nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI prescription device and directs the delivery of such device to the ultimate user's or consumer's residence and (ii) the medical director on whose behalf such Schedule VI prescription device is being delivered has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider for such delivery.

1. Such delivery shall only occur in accordance with an agreement between a delivering entity authorized in this subsection and a medical director of a home health agency, nursing home, assisted living facility, or hospice and in compliance with law and regulation.

2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and the medical director of an individual home health agency, nursing home, assisted living facility, or hospice, or multiple such entities under shared ownership. The agreement shall be applicable to all ultimate users or consumers of the home health agency, nursing home, assisted living facility, or hospice who require delivery of Schedule VI prescription devices.

3. The home health agency, nursing home, assisted living facility, or hospice shall represent to the delivering entity that it has complied with provisions of § [54.1-3415.1](http://law.lis.virginia.gov/vacode/54.1-3415.1/) of the Code of Virginia regarding the existence of a request from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of the request from a prescriber shall be the responsibility of the home health agency, nursing home, assisted living facility, or hospice upon request of the board or delivering entity.

C. The agreement, as required by subdivisions A 1 and B 1 of this section, shall be in written or electronic format and shall be retained in a format available upon request to the board at all times the agreement is in effect and for two years after the date the agreement is terminated or concluded.

D. An agreement shall not contain any patient specific or patient health information that would be subject to the provisions of the Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191.

# Part II. Wholesale Distributors and Third-Party Logistics Providers.

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

The board may issue a limited-use wholesale distributor license, limited-use nonresident wholesale distributor registration, limited-use manufacturer, limited-use nonresident manufacturer, limited-use third-party logistics provider permit, or limited-use nonresident third-party logistics provider registration to entities that do not engage in the wholesale distribution of prescription drugs or in the acts of a third-party logistics provider except medical gases and may waive certain requirements of regulation based on the limited nature of such distribution. The issuance of such a license shall be subject to continuing compliance with the conditions set forth by the board.

## 18VAC110-50-70. Minimum required information.

A. The application form for a new license, registration as a nonresident wholesale distributor or a nonresident third-party logistics provider, or permit as a third-party logistics provider 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, registrant, or permit holder and name and telephone number of a designated contact person;

2. All trade or business names used by the applicant or licensee, registrant, or permit holder;

3. The federal employer identification number of the applicant or licensee, registrant, or permit holder;

4. The type of ownership and name of the owner of the entity, including:

a. If an individual, the name, address, and social security number or control number;

b. If a partnership, the name, address, and social security number or control number of each partner who is specifically responsible for the operations of the facility, 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, and 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 who is specifically responsible for the operations of the facility;

(3) For nonpublicly held corporations, the name and address of each shareholder that owns 10% 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, 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, registered, or permitted to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs;

7. A list of all disciplinary actions 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 nonresident 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, owners, directors, or officers.

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

## 18VAC110-50-80. Minimum licensure and permitting qualifications and eligibility; responsible party.

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors, registration of nonresident wholesale distributors or nonresident third-party logistics providers, and permitting of third-party logistics providers:

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, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider, 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 or third-party logistics provider licensed, registered, or permitted in Virginia or another state where the person's responsibilities included 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, nonresident wholesale distributor registration, third-party logistics provider permit, or nonresident third-party logistics provider registration 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, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider 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, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider and all applicable state and federal laws related to wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider.

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. An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A federal criminal history record check; and

5. A 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 years, that manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning third-party logistics providers or wholesale distribution of prescription drugs in which such businesses were named as a party.

D. Responsibilities of the responsible party.

1. Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider;

2. Requiring any employee who has access to prescription drugs to attest that the employee has not been convicted of a violation of any federal or state drug law or any law relating to third-party logistics providers or to the manufacture, distribution, or dispensing of prescription drugs;

3. Maintaining current working knowledge of requirements for wholesale distributors or third-party logistics providers and assuring continued training for employees;

4. Maintaining proper security, storage, and shipping conditions for all prescription drugs; and

5. Maintaining all required records.

E. Each nonresident wholesale distributor or nonresident third-party logistics provider shall designate a registered agent in Virginia for service of any notice or other legal document. Any nonresident wholesale distributor or nonresident third-party logistics provider that does not designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon whom may be served all legal process in any action or proceeding against such nonresident wholesale distributor or nonresident third-party logistics provider. A copy of any such service of legal documents shall be mailed to the nonresident wholesale distributor or nonresident third-party logistics provider 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, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider must review records for accuracy, completeness, and the integrity of the drugs considering the total facts and circumstances surrounding the transactions and the wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider 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, another wholesale distributor, or a third-party logistics provider shall be kept under the proper conditions and documentation showing that proper conditions were maintained shall be provided to the manufacturer, wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider 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, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider shall:

1. Provide notice to the board and the manufacturer, wholesale distributor, or third-party logistics provider 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, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider 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, nonresident wholesale distributors, third-party logistics providers, or nonresident third-party logistics providers shall establish, maintain, and adhere to written policies and procedures for the proper receipt, security, storage, inventory, and distribution of prescription drugs. Wholesale distributors, nonresident wholesale distributors, third-party logistics providers, or nonresident third-party logistics providers 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 authorities;

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, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider;

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 violation of a drug law or any law related to wholesale distribution of prescription drugs or to third-party logistics providers; 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 upon request 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, nonresident wholesale distributor, third-party logistics provider, or nonresident third-party logistics provider. If records are not maintained onpremises at the address of record, they shall be made available within 48 hours of such request. A wholesale distributor, nonresident wholesale distributor, third-party logistics provider, or nonresident third party logistics provider shall establish and maintain the following:

1. Unless otherwise indicated in federal law, inventories and records of all transactions, including the dates of receipt and distribution or other disposition or provision, and records related to the federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed;

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, 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 or provides prescription drugs as a third-party logistics provider or nonresident third-party logistics provider; and

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

B. Records shall either (i) 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 (ii) 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 or third-party logistics provider not residing and licensed in Virginia, a wholesale distributor or third-party logistics provider shall obtain, and update annually, the following information from the selling wholesale distributor or third-party logistics provider:

1. A copy of the license to wholesale distribute or act as a third-party logistics provider from the resident state. If the resident state does not require licensure as a third-party logistics provider, documentation confirming active registration with the U.S. Food and Drug Administration is acceptable;

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

3. A list of other names under which the wholesale distributor or third-party logistics provider 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 nonpublicly 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 or for the legal acts of a third-party logistics provider; and

7. A listing of any manufacturers for whom the wholesale distributor or third-party logistics provider is an authorized distributor of record.

B. If the selling wholesale distributor's or third-party logistics provider'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 or third-party logistics provider may conduct an inspection of the wholesale distributor's or third-party logistics provider's facility prior to the first purchase of drugs or devices from another wholesale distributor or third-party logistics provider 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 or third-party logistics provider.

C. Prior to the first purchase of drugs from another wholesale distributor or third-party logistics provider not residing in and licensed in Virginia, the purchasing wholesale distributor or third-party logistics provider shall secure a national criminal background check of all of the wholesale distributor's or third-party logistics provider'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 Part 211 are adopted by reference.

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

## 18VAC110-50-160 through 18VAC110-50-190. (Repealed.)