WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Pharmacy TITLE-SERIES: 15-05

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: 15-05 Licensure of Wholesale Drug Distributors, Third Party Logistics Providers, and Manufacturers

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: 60A-8-9

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

Controlled Substances Act. Changes include the following: including "non-sterile" in definition of outsourcing facility; requiring discipline to be reported; and technical cleanup.

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 7/22/2020

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 8/21/2020

COMMENTS RECEIVED: No

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

none

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

This rule establishes rule for the federal Drug Quality and Security Act, and Prescription Drug Marketing Act, as amended, for the licensing by this state of persons who engage in wholesale distribution, provision of third-party logistics, and manufacturing, of prescriptions drugs in interstate commerce within and into this state.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Rule needed updated.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

none

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

none

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

none

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2020 Increase/Decrease (use "-")	2021 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

none

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Ryan L Hatfield -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 5
LICENSURE OF WHOLESALE DRUG DISTRIBUTORS, THIRD PARTY LOGISTICS PROVIDERS, AND MANUFACTURERS

§15-5-1. General.

1.1. Scope. -- To establish rules for the federal Drug Quality and Security Act, and Prescription Drug Marketing Act, as amended, for the licensing by this state of persons who engage in wholesale distributions, provision of third-party logistics, and manufacturing, of prescription drugs in interstate commerce within and into this state.

1.2. Authority. -- W. Va. Code §60A-8-9.

1.3. Filing Date. -- ~~June 24, 2016.~~

1.4. Effective Date. -- ~~July 1, 2016.~~

1.5. Sunset Date -- This legislative rule shall terminate ~~July 1, 2026~~ unless renewed prior to that date.

§15-5-2. Definitions.

2.1. Except as otherwise specifically stated in this rule, the definitions set forth in Title 15, Series 1, Section 2 are incorporated by reference as if set forth fully herein, and are fully applicable hereto.

2.2. "Affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly:

2.2.1.~~(a)~~ one business entity controls, or has the power to control, the other business entity; or

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

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

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

2.5. "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

2.6. "Healthcare entity" means any person or entity that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale drug distributor. Except as provided in § 203.22(h) and (i) of Chapter 21 of the Code of Federal Regulations, a person cannot simultaneously be a "healthcare entity" and a retail pharmacy or wholesale drug distributor.

2.7. "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

2.8. "Outsourcing facility" means a facility engaged in manufacturing by compounding of sterile or non-sterile drugs which has registered with the Federal Food and Drug Administration as an outsourcing facility pursuant to Section 503B of the Federal Drug Quality and Security Act.

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

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

2.11. "Wholesale distribution" means distribution of prescription drugs, including directly or through the use of a third-party logistics provider or any other situation in which title, ownership, or control over the prescription drug remains with one person or entity but the prescription drug is brought into this state by another entity on their behalf, to persons other than a consumer or patient, but does not include:

2.11.1.~~(a).~~ Intracompany sales, (which include but are not limited to a transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;)

2.11.2.~~(b).~~ The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, (except that the gross dollar amount shall not exceed five (5) percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve (12) month period);

2.11.3.~~(c).~~ The distribution of drug samples by manufacturers' representatives or distributors' representatives;

2.11.4.~~(d).~~ The sale, purchase, or trade of blood and blood components intended for transfusion;

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

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

2.11.7.~~(g).~~ The sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the United States Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

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

2.11.9.~~(i).~~ Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with § 203.23 of Title 21 of the Code of Federal Regulations; or

2.11.10.~~(j).~~ The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use (except that the gross dollar amount shall not exceed five (5) percent of the total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive twelve (12) month period).

2.12. "Wholesale drug distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; reverse distributors, jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians, dentists, veterinarians, birth control and other clinics, individuals, hospitals, nursing homes and/or their providers, health maintenance organizations and other health care providers, and retail and hospital pharmacies that conduct wholesale distributions. A wholesale drug distributor shall not include any for hire carrier or person or entity hired solely to transport prescription drugs.

§15-5-3. Wholesale Drug Distributor and Third-Party Logistics Provider Licensing and

Manufacturer Permit Requirements.

3.1. Every wholesale distributor, wherever located, who engages in the wholesale distribution of drugs into, out of, or within the state must be licensed by the West Virginia Board of Pharmacy (hereinafter, the "Board") in accordance with the laws and regulations of this state before engaging in the wholesale distribution of prescription drugs. Every wholesale distributor, wherever located, who engages in the wholesale distribution of drugs into, out of, or within the state shall report discipline from any jurisdiction within thirty days of the entry of the final order.

3.2. Any person operating as a manufacturer of prescription drugs must obtain a manufacturing permit issued by the Board in accordance with the laws and regulations of this state before engaging in manufacturing of prescription drugs in this state.

3.3 Notwithstanding any other provision to the contrary, each entity that meets the definition of a third-party logistics provider shall obtain a license as a third-party logistics provider and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.

§15-5-4. Minimum Required Information For Wholesale Drug Distributor or Third-Party Logistics Provider Licensure, and Manufacturer Permit; Applications and Renewals.

4.1. A wholesale drug distributor or third-party logistics provider, and a manufacturer, including prescription drug manufacturers and outsourcing facilities, as part of the initial licensing procedure and as part of any renewal of license, shall provide on the application form as required by the Board:

4.1.1.~~(a).~~ The name, full business address, and telephone number of the licensee;

4.1.2.~~(b).~~ All trade or business names used by the licensee;

4.1.3.~~(c).~~ Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

4.1.4.~~(d).~~ The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship) and

4.1.5.~~(e).~~ The name of the owner and/or operator of the licensee, including:

4.1.5.a.~~(1).~~ If a person, the name of the person;

4.1.5.b.~~(2).~~ If a partnership, the name of each partner, and the name of the partnership;

4.1.5.c.~~(3).~~ If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent

company, if any;

4.1.5.d.~~(4).~~ If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

4.2. Where operations are conducted at more than one (1) location by a single wholesale drug distributor, third-party logistics provider, or manufacturer, each location shall be licensed or permitted by the Board. However, the Board may provide for a single license or permit for a business entity operating more than one facility within this state, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within this state when operations are conducted at more than one (1) location and there exists joint ownership and control among all entities.

4.3. A wholesale drug distributor, third-party logistics provider, or manufacturer shall submit changes in any of the information required by this section to the Board within thirty (30) days after the change.

4.4. Applicants for an original wholesale drug distributor license or third-party logistics provider license shall pay an application fee of $750.00 which shall be submitted along with a satisfactory application for licensure. Each applicant for a wholesale drug distributor or third-party logistics provider license located in this state where prescription drugs will be handled, stored, or kept must complete an inspection satisfactory to the Board. Each applicant for a wholesale drug distributor or third-party logistics provider license located outside of this state must be properly licensed as such in that state or United States territory, of, if no such licensure is granted by that state or territory, then with the Federal Food and Drug Administration, and must supply proof of that authorization along with its application.

4.5. Applicants for an original manufacturer permit shall pay an application fee of Five Hundred Dollars ($500.00) which shall be submitted along with a satisfactory application for a permit. Each applicant for a manufacturer permit must be authorized to operate as a manufacturer with the Federal Food and Drug Administration, and must supply proof of that authorization along with its application. The manufacturer must supply proof of satisfactory inspection by the FDA within the previous 5-year period, or pay an additional fee of Four Hundred Dollars ($400.00) for inspection by the Board.

4.6. A wholesale drug distributor and third-party logistics provider license shall expire on June 30, of each calendar year. Applications for renewal of wholesale drug distributor and third-party logistics provider licenses shall be provided to each licensee at least thirty days before the first day of July of each calendar year by the Board. The notification may be sent electronically to an e-mail or be mailed to the last known address of the licensee. The fee for renewal is Seven Hundred Fifty Dollars (750.00).

4.6.1.~~(a).~~ If a completed application for renewal is not received in the Board office on or before June 30 of the year in which it expires, the license is expired. Renewal applications received after June 30 shall require the payment of a late fee in the amount of One Hundred Fifty

Dollars ($150.00) in addition to the application fee of Seven Hundred Dollars ($750.00), for a total amount of Nine Hundred Dollars ($900.00).

4.6.2.~~(b).~~ If a completed application for renewal is not received in the Board office before the first day of August each year, then, in order to renew, the licensee shall pay a reinstatement fee of two hundred fifty dollars ($250.00), and pay the required renewal fee of Seven Hundred Fifty Dollars ($750.00), for a total amount of One Thousand Dollars ($1,000.00).

4.7. A manufacturer permit shall expire on June 30, of each calendar year. An application for renewal of a manufacturer permit shall be provided to each licensee at least thirty days before the first day of July of each calendar year by the Board. The notification may be sent electronically to an e-mail or be mailed to the last known address of the licensee. The fee for the annual renewal is Five Hundred Dollars ($500.00).

4.7.1.~~(a).~~ If a completed application for renewal is not received in the Board office on or before June 30 of the year in which it expires, the permit shall expire. Renewal applications received after June 30 shall require the payment of a late fee in the amount of One Hundred Fifty Dollars ($150.00) in addition to the application fee of Five Hundred Dollars ($500.00), for a total amount of Six Hundred Fifty Dollars ($650.00).

4.7.2.~~(b).~~ If an application for renewal is not received in the Board office before the first day of August each year, then, in order to, the manufacturer must supply proof of inspection by the FDA within the previous 5-year period, and the permittee shall pay a reinstatement fee of Two Hundred Fifty dollars ($250.00), in addition to the application fee of Five Hundred Dollars ($500.00), for a total amount of Seven Hundred Fifty Dollars ($750.00).

4.8. Licenses and permits issued under this section are not transferable, and become immediately expire upon change of ownership.

§15-5-5. Minimum Qualifications.

5.1. The Board shall consider, at a minimum the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs, act as a third-party logistics provider, or manufacturer prescription drugs within or into the state:

5.1.1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, drug manufacturing, wholesale or retail drug distribution, or distribution of controlled substances;

5.1.2. Any felony convictions of the applicant under Federal, State, or local laws;

5.1.3. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

5.1.4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution or acting as a third-party logistics provider;

5.1.5. Suspension or revocation by Federal, State, or local government of any license, permit, or other authorization currently or previously held by the applicant for the manufacture or distribution of, or acting as a third-party logistics provider related to, any drugs, including controlled substances;

5.1.6. Compliance with licensing requirements under previously granted licenses, if any;

5.1.7. Compliance with requirements to maintain and/or make available to the Board or to Federal, State, or local law enforcement officials those records required under this section;

5.18. An outsourcing facility must complete an initial inspection satisfactory to the board; and

5.1.9. Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

5.2. The Board may deny a license to any applicant if it determines that the granting of a license would not be in the public interest. The Board shall base public interest considerations upon factors and qualifications that are directly related to the protection of the public health and safety.

§15-5-6. Personnel.

6.1. As a condition for receiving and retaining a wholesale drug distributor or third-party logistics provider license or manufacturer permit, the licensee or permittee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law.

§15-5-7. Violations and Penalties.

7.1. The Board may reprimand, suspend, restrict, or revoke any licenses or permits granted under this series upon conviction of violations of Federal, State, or local drug laws or regulations. Before any license or permit may be reprimanded, suspended, restricted, or revoked, a licensee or permittee under this series shall have a right to prior notice and a hearing pursuant to Chapter 29A, Administrative Procedures Act of the Code of West Virginia.

7.2. The Board may reprimand, suspend, restrict, or revoke any license or permit granted under this section for violations of these regulations.

7.3. In any case where the Board finds that any licensee or permittee under this section shall be disciplined as set forth above, the Board may also levy an administrative penalty not to exceed one thousand dollars per day per violation, and may assess administrative costs against the licensee.

§15-5-8. Minimum Requirements for Wholesale Drug Distributors for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Records.

The following constitutes the minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees.

8.1. Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

8.1.1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

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

8.1.3. Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

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

8.1.5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

8.2. Security.

8.2.1. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

8.2.1.a. Access from outside the premises shall be kept to a minimum and be well controlled.

8.2.1.b. The outside perimeter of the premises shall be well-lighted.

8.2.1.c. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

8.2.2. All facilities shall be equipped with an alarm system to detect entry after hours.

8.2.3. 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.

8.3. Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

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

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

8.3.3. The recordkeeping requirements in 8.6 of this section shall be followed for all stored drugs.

8.4. Examination of materials.

8.4.1. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

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

8.4.3. The recordkeeping requirements in 8.6 of this section shall be followed for all incoming and outgoing prescription drugs.

8.5. Returned, damaged, and outdated prescription drugs.

8.5.1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

8.5.2. Any prescription drugs whose immediate or sealed outer or sealed secondary

containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

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

8.5.4. The recordkeeping requirements in 8.6 of this section shall be followed for all outdate, damaged, deteriorated, misbranded, or adulterated prescription drugs.

8.6. Recordkeeping.

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

8.6.1.a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

8.6.1.b. The identity and quantity of the drugs received and distributed or disposed of; and

8.6.1.c. The dates of receipt and distribution or other disposition of the drugs.

8.6.2. Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

8.6.3. Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a Federal, State, or local law enforcement agency.

8.7. Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for

identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

8.7.1. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.

8.7.2. A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

8.7.2.a. Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the Board;

8.7.2.b. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

8.7.2.c. Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

8.7.3. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects the security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

8.7.4. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

8.8. Responsible persons. Wholesale drug distributors shall establish and maintain a list of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications and provide the board with such list upon licensure and renewal.

8.9. Compliance with Federal, State, and local law. Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

8.9.1. Wholesale drug distributors shall permit the Board's authorized personnel and authorized Federal, State, and local law enforcement officials, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall show appropriate identification prior to being permitted access to the wholesale drug distributors' premises and delivery vehicles.

8.9.2. Wholesale drug distributors that deal in controlled substances shall register with the Board and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local, and DEA regulations.

8.10. Salvaging and reprocessing. Wholesale drug distributors are subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including 21 CFR, 207, 210, and 211.

§ 15-5-9. Minimum Requirements for Third-Party Logistics Providers and Manufacturers for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Records

9.1. Third-party logistics providers and manufacturers shall meet the minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records as required by the Federal Food and Drug Administration.

§15-5-10. The West Virginia Board of Pharmacy inspection powers and access to licensee and permittee records.

10.1. A person authorized by the board may inspect during normal business hours any premises being used by a wholesale drug distributor, third-party logistics provider, or manufacturer in this state in the course of its business.

10.2. Licensees and permittees under this series may keep records regarding purchase and sales transactions at a central location apart from the principal office of the licensee or permittee or the location at which the drugs were manufactured, housed, or stored by the licensee or permittee, and from which they were shipped: Provided, That such records shall be made available for inspection within two working days after a request to inspect by the board is made. Such records may be kept in any form permissible under federal law applicable to prescription drugs record keeping.