

WEST VIRGINIA  
SECRETARY OF STATE  
KEN HECHLER  
ADMINISTRATIVE LAW DIVISION

Form #4

Do Not Mark In this Box

FILED

1992 JAN -8 PM 3:17

OFFICE OF WEST VIRGINIA  
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY 60A-8-9

AMENDMENT TO AN EXISTING RULE: YES  NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 5

TITLE OF RULE BEING AMENDED: Licensure of Wholesale Drug Distributors

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: \_\_\_\_\_

TITLE OF RULE BEING PROPOSED: \_\_\_\_\_

THE ABOVE PROPOSED LEGISLATIVE RULE, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

  
\_\_\_\_\_

TITLE 15  
LEGISLATIVE RULE  
SERIES 5

LICENSEURE OF WHOLESALE DRUG DISTRIBUTORS

15-5.1. General

- 1.1 Scope. -- To establish rules for the Prescription Drug Marketing Act.
- 1.2 Authority. West Virginia Code, 60A-8-9.
- 1.3 Filing Date.
- 1.4 Effective Date.

15-5.2. Definitions

- (a) Blood means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- (b) Blood component means that part of blood separated by physical or mechanical means.
- (c) 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.
- (d) Manufacturer means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.
- (e) 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.
- (f) Wholesale distribution means distribution of prescription drugs to persons other than a consumer or patient, but does not include:
  - (1) Intracompany sales, [defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;]
  - (2) 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];

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

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

(5) 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;

(6) 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;

(7) 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; or

(8) 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.

(g) 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, jobbers, private-label

distributors, 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, including, but not limited to, any pharmacy distributor as defined in this section. 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 Licensing Requirement.

Every wholesale distributor, wherever located, who engages in the wholesale distribution of drugs into, out of, or within the State of West Virginia must be licensed by the West Virginia Board of Pharmacy in accordance with the laws and regulations of this State before engaging in the wholesale distribution of prescription drugs.

15-5-4. Minimum Required Information For Licensure.

- (a) The West Virginia Board of Pharmacy requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of license:
- (1) The name, full business address, and telephone number of the licensee;
  - (2) All trade or business names used by the licensee;
  - (3) 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) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship) and
  - (5) The name of the owner and/or operator of the licensee, including:

- (i) If a person, the name of the person;
- (ii) If a partnership the name of each partner, and the name of the partnership;
- (iii) 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;
- (iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(b) Where operations are conducted at more than

one location by a single wholesale distributor, each location shall be licensed by the West Virginia Board of Pharmacy. However, the West Virginia Board of Pharmacy may provide for a single license 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 location and there exists joint ownership and control among all entities.

(c) A wholesale distributor shall submit changes in this section to the West Virginia Board of Pharmacy within thirty (30) days after the change.

15-5-5. Minimum qualifications.

(a) The West Virginia Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the State:

(1) Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under Federal, State, or local laws;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

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

(5) Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to The West Virginia Board of Pharmacy or to Federal, State, or local law enforcement officials those records required under this section; and

(8) Any other factors or qualifications The West Virginia Board of Pharmacy considers relevant to and consistent with the public health and safety.

(b) The West Virginia Board of Pharmacy has the right to deny a license to an 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.

As a condition for receiving and retaining a wholesale distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such 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.

(a) The West Virginia Board of Pharmacy may suspend or revoke any licenses granted under this section upon conviction of violations of Federal, State, or local drug laws or regulations. Before any license may be suspended or revoked a wholesale distributor shall have a right to prior notice and a hearing pursuant to Chapter 29A, Administrative Procedures Act of the Code of West Virginia.

(b) The West Virginia Board of Pharmacy may suspend or revoke any license granted under this section for willful

and serious violations of these regulations.

15-5-8. Minimum requirements 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 distributors and their officers, agents, representatives, and employees.

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

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

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

(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;

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

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security.

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

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

(ii) The outside perimeter of the premises shall be well-lighted.

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

(2) All facilities shall be equipped with an alarm system to detect entry after hours.

(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.

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

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

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

(3) The recordkeeping requirements in (f) of this section shall be followed for all stored drugs.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined by the appropriate state agency 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.

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

(3) The recordkeeping requirements in (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) Returned, damaged, and outdated prescription drugs.

(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.

(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.

(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 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.

(4) The recordkeeping requirements in (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) Recordkeeping.

(1) Wholesale 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:

- (i) 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;
- (ii) The identity and quantity of the drugs received and distributed or disposed of; and
- (iii) The dates of receipt and distribution or other disposition of the drugs.

(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 2 years following disposition of the drugs.

(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 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency.

(g) Written policies and procedures. Wholesale distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, 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 distributors shall include in their written policies and procedures the following:

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

(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:

- (i) 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 West Virginia Board of Pharmacy;
- (ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
- (iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects 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.

(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 2 years after disposition of the outdated drugs.

(h) Responsible persons. Wholesale 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.

(i) Compliance with Federal, State, and local law. Wholesale distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale distributors shall permit the West Virginia Board of Pharmacy'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 distributors' premises and delivery vehicles.

(2) Wholesale distributors that deal in controlled substances shall register with the West Virginia Board of Pharmacy and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) Salvaging and reprocessing. Wholesale 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, 210D, and 211.