WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

Form #2

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative Rule CITE AUTHORITY: W.Va. Code §60A-8-9

AMENDMENT TO AN EXISTING RULE: YES X 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 RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 25, 2011 AT 4:00 P.M., Eastern Time ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

West Virginia Board of Pharmacy
C/O Public Comment on Series 2
232 Capitol Street
Charleston, West Virginia 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

David E. Potters
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Phone (304) 558-0558
Fax (304) 558-0572

State of West Virginia
Board of Pharmacy

David E. Potters,
Executive Director &
General Counsel

Betty Jo Payne,
Asst. Exec. Director

Office
232 Capitol Street
Charleston, West Virginia 25301

APPROVAL OF FILING OF RULES

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the filing of the following modified rules with the Secretary of State and the Legislative Rulemaking and Review Committee, each of which were considered and approved for filing by the Board at its regular meeting held on June 17, 2011:

(1) Title 15, Series 2, "RULES OF THE BOARD OF PHARMACY FOR THE UNIFORM CONTROLLED SUBSTANCES ACT", with modification regarding electronic prescribing (per SB 1001, 2007 1st Special Session and subsequent changes in federal law), limiting early refills, and clarifying other provisions;

(2) Title 15, Series 3, "BOARD OF PHARMACY RULES FOR CONTINUING EDUCATION FOR LICENSURE OF PHARMACISTS", modernizing certain language and updating requirements to match national standards; and

(3) Title 15, Series 5, "LICENSURE OF WHOLESALE DRUG DISTRIBUTORS", to update language as required by federal law, and clarify requirements for licensing of distributors who maintain title, ownership, or control over their product which is brought into this State by another entity on their behalf.

Signed this 23th day of June, 2011,

BY: George Karos
George Karos, President

State of West Virginia
Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

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Signed this 23th day of June, 2011,

BY: David E. Potters
David E. Potters
Executive Director & General Counsel

BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED LEGISLATIVE RULE

LICENSURE OF WHOLESALE DRUG DISTRIBUTORS

15 CSR 5

Summary and Statement of Circumstances: The Board last modified this Series in 1992. Since that time, the federal law placing requirements on the state regulators of wholesale distributors of prescription drugs was amended and clarified. Therefore, the Board determined that it needed to modify the rule to update language as required by federal law. While doing so, the Board sought to clarify requirements for licensing of distributors who maintain title, ownership, or control over their product which is brought into this State by another entity on their behalf. It has fielded many questions from manufacturers whether they need to be licensed as a distributor for product they are shipping into this State through the use of third-party logistics providers or other wholesalers or distributors while the manufacturer still maintains title, ownership or control over the product. Other States, such as Ohio, do require them to be licensed as distributors to provide another link to safeguarding the supply chain of these prescription-only drugs flowing into their State. West Virginia had, in the past, not required such licensure for these distributions, although the law covered it. With these clarifications in the rule, it will permit the board to provide clear notice to all distributors of the requirements for licensure, and allow for a further protection to the public health, safety, and welfare for the supply of these drugs into the State. Finally, the Board sought to clean up and make minor clarifications throughout.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.com, or interested parties may call the Administrative Law Division of the Office of the Secretary of State at (304) 558-6000.

Further information may be obtained by contacting the West Virginia Board of Pharmacy, David E. Potters, Executive Director and General Counsel, 232 Capitol Street, Charleston, West Virginia, 25301, telephone (304) 558-0558.

Note: This is a modification of the Series, such that changes are reflected by strike-throughs and underlining in the proposed rule.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Title 15, Series 5, "LICENSURE OF WHOLESALE DRUG DISTRIBUTORS"

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street
Charleston, WV 25301

Phone Number: 304-558-0558 Email: david.e.potters@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

This will impact costs which will be exceeded by revenues. The Board currently processes approximately 35 wholesale distributor licenses of manufacturers who are acting as their own distributors. Based upon conversations with the Ohio Board of Pharmacy and a company from Ohio with a database of manufacturers with which the Ohio BOP is contracting, we will likely see the licensing of such manufacturers distributing into this State grow to 800 to 1,000 additional licenses. Currently, the cost of a wholesale distributor's license is $400.00. Ohio sees approximately 25% of their license fee go to administrative costs for these licenses, working with the company from Ohio. We are in discussions to contract with this same company. Therefore, wholesale distributor license gross revenues should grow by approximately $360,000.00 to $400,000.00 per year at current fee levels. Costs of 25% will reduce that to a net revenue of $270,000.00 to $300,000.00 per year.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	100,000.00	100,000.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	400,000.00	400,000.00

Title 15, Series 5, "LICENSURE OF WHOLESALE DRUG DISTRIBUTORS"

Rule Title:

Rule Title: _____

3. Explanation of above estimates (including long-range effect):
Please include any increase or decrease in fees in your estimated total revenues.

The national average for a wholesale distributor license is $750.00. Ohio is currently raising their fee from $150.00 to $750.00 per year, and reports no pushback from the manufacturers and wholesale distributors who will be affected. The company out of Ohio with which the Ohio BOP contracts indicates that their break-even point is approximately $500.00 per license. Therefore, we anticipate requesting authority to raise our fee to the national average of $750.00. This will generate significant additional revenue over that estimated above, with the costs fixed at 25%. All of the additional revenue is anticipated to be used by the Board of Pharmacy to fund mandates for the Controlled Substances Monitoring Program (CSMP) database and efforts to curb prescription drug diversion. This is a significant program which has been the subject of many legislative efforts to expand the program and make additional proactive uses of it, while at the same time federal grant funds have been exhausted and are not likely to continue into the future given the economic climate. These additional funds will be vital to the Board's operations to inspect pharmacies, monitor the drug supply chain, and staff and operate the CSMP database.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date: June 23, 2011

Signature of Agency Head or Authorized Representative

David E. Potters

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 5
LICENSURE OF WHOLESALE DRUG DISTRIBUTORS

§15-5-1. General.

1.1. Scope. -- To establish rules for the federal ~~p~~Prescription Drug Marketing Act, as amended, for the licensing by this State of persons who engage in wholesale distributions in interstate commerce of prescription drugs into this State.

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

1.3. Filing Date. -- ~~April 9, 1992~~_____.

1.4. Effective Date. -- ~~April 9, 1992~~_____.

§15-5-2. Definitions.

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

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

2.3. "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.

2.4. "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.

2.4~~5~~. "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

2.5~~6~~. "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.

2.6~~7~~. "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:

2.67.1. Intracompany sales, (defined as any transaction or transfer between any division, ~~subsidary~~subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity;)

2.67.2. 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~~;~~);

2.67.3. The distribution of drug samples by manufacturers' representatives or distributors' representatives;

2.67.4. The sale, purchase, or trade of blood and blood components intended for transfusion;

2.67.5. 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;

2.67.6. 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;

2.67.7. 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~~

2.67.8. 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~~.~~;

2.7.9. 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

2.7.10. 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.~~7~~8. "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;; 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~~, 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.

3.1. 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.

4.1. 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:

4.1.1. The name, full business address, and telephone number of the licensee;

4.1.2. All trade or business names used by the licensee;

4.1.3. 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;

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

4.1.5. The name of the owner and/or operator of the licensee, including:

4.1.5.a. If a person, the name of the person;

4.1.5.b. If a partnership, the name of each partner, and the name of the partnership;

4.1.5.c. 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. 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, 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 (1) location and there exists joint ownership and control among all entities.

4.3. A wholesale drug distributor shall submit changes in any of the information required by this section to the West Virginia Board of Pharmacy within thirty (30) days after the change.

§15-5-5. Minimum Qualifications.

5.1. 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:

5.1.1. 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;

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;

5.1.5. 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;

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 West Virginia Board of Pharmacy or to Federal, State, or local law enforcement officials those records required under this section; and

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

5.2. The West Virginia Board of Pharmacy has the right to 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 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.

7.1. The West Virginia Board of Pharmacy may reprimand, suspend, restrict, 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 reprimanded, suspended, restricted, or revoked, a wholesale drug distributor 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 West Virginia Board of Pharmacy may reprimand, suspend, restrict, or revoke any license granted under this section for willful and serious violations of these regulations.

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

§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 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 ~~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.

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, identify, 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 West Virginia Board of Pharmacy;

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.

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 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 drug distributors' premises and delivery vehicles.

8.9.2. Wholesale drug 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.

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, 2100, and 211.

Code of Federal Regulations

Title 21 - Food and Drugs

Volume: 4
Date: 2011-04-01
Original Date: 2011-04-01
Title: PART 205 - GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS
Context: Title 21 - Food and Drugs. CHAPTER I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED). SUBCHAPTER C - DRUGS: GENERAL.

PART 205—GUIDELINES FOR STATE LICENSING OF WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS

Sec.

205.1 Scope.
205.2 Purpose.
205.3 Definitions.
205.4 Wholesale drug distributor licensing requirement.
205.5 Minimum required information for licensure.
205.6 Minimum qualifications.
205.7 Personnel.
205.8 Violations and penalties.
205.50 Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

Authority: 21 U.S.C. 351, 352, 353, 371, 374.
Source: 55 FR 38023, Sept. 14, 1990, unless otherwise noted.

§ 205.1 Scope.

This part applies to any person, partnership, corporation, or business firm in a State engaging in the wholesale distribution of human prescription drugs in interstate commerce.

§ 205.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs.

§ 205.3 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* and *wholesale distribution* means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) 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 organizations;

(3) 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 Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) 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;

(5) 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;

(6) 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;

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

(8) The sale, purchase, or trade of blood and blood components intended for transfusion.

(9) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with § 203.23 of this chapter; or

(10) The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

(g) *Wholesale distributor* means any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

(h) *Health care entity* means any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor. Except as provided in § 203.22(h) and (i) of this chapter, a person cannot simultaneously be a "health care entity" and a retail pharmacy or wholesale distributor.

[55 FR 38023, Sept. 14, 1990, as amended at 64 FR 67762, Dec. 3, 1999, 73 FR 59501, Oct. 9, 2008]

§ 205.4 Wholesale drug distributor licensing requirement.

Every wholesale distributor in a State who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the State licensing authority in accordance with this part before engaging in wholesale distributions of prescription drugs in interstate commerce.

§ 205.5 Minimum required information for licensure.

(a) The State licensing authority shall require the following minimum information from each wholesale drug distributor as part of the license described in § 205.4 and as part of any renewal of such 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 all facilities 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(s) 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

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(b) The State licensing authority may provide for a single license for a business entity operating more than one facility within that State, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within that State when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) Changes in any information in paragraph (a) of this section shall be submitted to the State licensing authority as required by such authority.

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§ 205.6 Minimum qualifications.

(a) The State licensing authority 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 State licensing authority or to Federal, State, or local law enforcement officials those records required under this section; and

(8) Any other factors or qualifications the State licensing authority considers relevant to and consistent with the public health and safety.

(b) The State licensing authority shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

§ 205.7 Personnel.

The State licensing authority shall require that personnel employed in wholesale distribution have appropriate education and/or experience to assume responsibility for positions related to compliance with State licensing requirements.

§ 205.8 Violations and penalties.

(a) State licensing laws shall provide for the suspension or revocation of licenses upon conviction of violations of Federal, State, or local drug laws or regulations, and may provide for fines, imprisonment, or civil penalties.

(b) State licensing laws shall provide for suspension or revocation of licenses, where appropriate, for violations of its provisions.

§ 205.50 Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

The State licensing law shall include the following 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:

(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 paragraph (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 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 paragraph (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 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.

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

(f) *Recordkeeping.* (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:

(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 3 years after the date of their creation.

(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 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:

(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 such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or other government agency, including the State licensing agency;

(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 drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of 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 drug distributors shall establish and maintain lists 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 drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale drug distributors shall permit the State licensing authority 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.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) *Salvaging and reprocessing.* Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.

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