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Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

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Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XXXIV. Drug and Device Distributors

Chapter 1. General Provisions

§101. Authority

A. These rules of practice and procedure are promulgated in accordance with the Louisiana Administrative Procedure Act. All rule making and hearing procedures of this board are conducted according to the Louisiana Administrative Procedure Act.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:381 (April 1992).

§103. Definition

A. As used in this regulation, unless the context otherwise requires, the following terms are defined as:

Adulterated Drug or Device—a drug or device shall be deemed adulterated if:

a. it consists, in whole or in part, of any filthy, putrid, or decomposed substance; or

b.i. it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

ii. the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets with the requirements of this part as to safety and has the identity and strength, and meets with the quality and purity characteristics which it purports or is represented to possess; or

c. its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

d. it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of federal or Louisiana law or rule; or

e. it purports to be or is represented as a drug or device the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under the authority of federal or state law or rule. No drug or device defined in an official compendium shall be deemed to be

adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from the standard is plainly stated on its label;

f. it is not subject to Subparagraph e above and its strength differs from, or its quality or purity falls below that which it purports or is represented to possess; or

g. it is a drug or any substance has been:

i. mixed or packed therewith so as to reduce its quality or strength; or

ii. substituted wholly or in part thereof.

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

Blood Components—that part of blood separated by physical or mechanical means.

Consumer or Patient—a person who is the end user of a drug or device.

Contraband Drug or Device—a drug or device which is counterfeit, stolen, misbranded, obtained by fraud, purchased and placed in commerce in violation of its own use agreement for that drug or device, or for which the documentation in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented information.

Controlled Substance—those substances, drugs, or immediate precursors listed in schedules I through VI of the Uniform Controlled Substances Act.

Counterfeit Drug or Device—a drug or device which, or the container, shipping container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a manufacturer, processor, packer, or distributor, other than the person who in fact manufactured, processed, packed, or distributed such drug or device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other manufacturer, processor, packer, or distributor.

Delivery—actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration.

Dispense or Dispenser or Dispensing—the interpretation, evaluation, and implementation of a drug order, including the preparation and delivery or transfer of possession of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

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Distribute—to sell, offer to sell, broker, give away, or transfer, drugs or devices whether by passage of title, physical movement, or both.

Drug or Device—any legend drug or legend device.

Drug Sample—a unit of a prescription drug that is labeled "sample," "not to be sold," or "complimentary," or other words to that effect, which is provided as a courtesy and not intended to be sold but is intended to promote the sale of the drug.

Facility or Physical Location—structure, warehouse, or building used by a person for the reception, storage, handling, repackaging, and/or offering for sale of a drug or device.

Label or Labeling—a display of written, printed, or graphic matter located immediately upon, or accompanying, a drug or device.

Medical Gas—any pure gas or gas mixture packaged as any liquefied (cryogenic) or compressed gas (vaporized) that is designated as a drug product.

Misbranded—a drug or device shall be deemed misbranded if the label is false or misleading in any particular, or the label does not bear the name and address of the manufacturer, packer, or distributor and does not have an accurate statement of the quantities of the active ingredients in case of a drug, or does not show an accurate monograph for legend drug, or other considerations as required in the federal Food, Drug, and Cosmetic Act.

Off-Site Storage Facility—a structure, warehouse, or building used by a licensed wholesale drug or device distributor strictly for storage of legend drugs or devices.

Standard Distributors—distributors of legend drugs and legend devices not to include third-party logistics providers and wholesale distributors.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:381 (April 1992), amended LR 29:1479 (August 2003), LR 32:394 (March 2006), LR 34:874 (May 2008), LR 35:1537 (August 2009), amended by the Department of Health, Board of Drug and Device Distributors, LR 42:2182 (December 2016).

§105. Exemptions

A. Distribution does not include:

1. intra-company distribution to licensed drug or device distributors physically located in Louisiana;
2. the distribution of a drug or device or an offer to distribute a drug or device 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;
3. the distribution of a drug or device or an offer to distribute a drug or device among hospitals or other health care entities that are under common ownership;

4. the distribution of a drug or device or an offer to distribute a drug or device for emergency medical reasons including transfers of drugs or devices by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage that arises from delays in or interruptions of regular distribution schedules or a public health emergency declaration;

5. the dispensing of a drug or device pursuant to a prescription;

6. the distribution of drug or device samples by manufacturers' representatives or distributors' representatives;

7. the distribution of blood and blood components intended for transfusion; or

8. the distribution of legend drugs by retail pharmacies to licensed practitioners for office use where the annual dollar volume of legend drugs sold to licensed practitioners does not exceed five percent of the dollar volume of that retail pharmacy's annual legend drug sales.

9. the distribution of devices by manufacturers' sales representatives during transportation to customers;

10. the distribution of a software utilized in a non-emergency, delayed patient monitoring system to be used in remote monitoring not intended to provide real time integrated data from a continuous or long-time, non-invasive patient monitoring device, and that has been previously approved by the appropriate federal agency; this exemption shall not be deemed to prohibit regulation in accordance with quarantine statutes.

B. Wholesale distribution does not include:

1. intra-company distribution between members of an affiliate or within a manufacturer;

2. the distribution of or offer to distribute among hospitals or other health care entities which are under common control;

3. the distribution or offer to distribute for emergency medical reasons including a public health emergency declaration, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

4. the dispensing pursuant to a prescription;

5. the distribution of minimal quantities by a licensed retail pharmacy to a licensed practitioner for office use;

6. the distribution or offer to distribute by charitable organizations to nonprofit affiliates of the organization;

7. the purchase or other acquisition by a retail dispenser, hospital, or other health care entity for use by such retail dispenser, hospital, or other health care entity;

8. the distribution by the manufacturer;

9. the receipt or transfer by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership;

10. a common carrier that transports a drug product, provided that the common carrier does not take ownership;

11. the distribution or offer to distribute by an authorized repackager that has taken ownership or possession and repacks;

12. salable drug product returns when conducted by a retail dispenser;

13. the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user, if:

a. the kit is assembled in an establishment registered with FDA as a device manufacturer;

b. the kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970 and any amendments to;

c. the kit includes a product, the person that manufactures the kit:

i. purchased directly from the manufacturer or from a wholesale distributor that purchased directly from the manufacturer, and

ii. does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

d. kits that include a product and the product is:

i. an intravenous solution intended for replenishment of fluids and electrolytes;

ii. intended to maintain the equilibrium of water and minerals in the body;

iii. intended for irrigation or reconstitution;

iv. an anesthetic;

v. an anticoagulant;

vi. a vasopressor, or

vii. a sympathomimetic;

14. the distribution of an intravenous drug that by its formulation is intended for the replenishment of fluids and electrolytes or calories;

15. the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body;

16. the distribution of a drug intended for irrigation, or sterile water, whether intended for such purposes or for injection;

17. the distribution of medical gas;

18. facilitating the distribution by providing solely administrative services including processing orders and payments; or

19. the transfer by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital, or other healthcare entity, to a repackager who is registered for the purpose of repackaging for use by the hospital, or other health care entity, and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 35:1537 (August 2009), amended LR 36:321 (February 2010), LR 36:2560 (November 2010), LR 37:899 (March 2011), amended by the Department of Health, Board of Drug and Device Distributors LR 42:2182 (December 2016).

Chapter 3. Drug and Device Distributors

§301. Licensing, Renewal and Reinstatement Requirements

A. The board shall issue sub-types for distributors of legend drug and legend device licenses as follows:

1. standard distributors;
2. wholesale distributors; and
3. third-party logistics provider distributors.

B. Every drug or device distributor shall submit an initial application for a new license on a form furnished by the board and accompanied by the initial license fee.

1. The board shall require a separate license for each facility or physical location directly or indirectly owned or operated by the same business entity or for a parent entity with divisions, subdivisions, subsidiaries, and/or affiliate companies when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

2. Parent entity must license all divisions, subdivisions, subsidiaries, and/or affiliate companies owned by the parent company that sell and/or ship legend drugs or devices in or into Louisiana.

C. All new licenses issued by the board shall expire on December 31 of the calendar year issued.

D. A license shall be renewed annually by timely submitting an application and the license renewal fee.

E. Each application for the renewal of the license must be made between October 1 and December 31 of each year on a paper or electronic form provided by the board.

1. If a license is not renewed on or before the expiration date, a person may apply for reinstatement of the expired license within one year by submitting an application, the license renewal fee, and the license reinstatement fee.

2. If a license is expired beyond one year, a person may apply for reinstatement of the expired license by

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submitting an application, the initial license fee, the license reinstatement fee, and if applicable, the initial inspection fee.

3. A person may not lawfully operate as a drug or device distributor in Louisiana until the expired license has been reinstated.

F. Licenses renewed annually between October 1 and December 31 shall expire on December 31 of the following calendar year.

G. Each license issued hereunder shall be displayed by the licensee in a conspicuous place at the licensed facility or physical location.

H. Out-of-state drug or device distributors licensed by the board must have on file at all times with the board a current copy of a valid certificate of registration or license for drug or device distribution as issued by the appropriate regulatory board or agency of the state in which the facility or physical location licensed with the board is located or registration or license as issued by the appropriate federal agency when applicable.

1. If the state in which the facility licensed with the board is located does not require the facility to be registered or licensed as a drug or device distributor and the facility or physical location is registered or licensed in the state in which it is located as a manufacturer of drugs or devices, a current copy of the valid manufacturer registration or license must be submitted to and maintained with the board.

2. If the state in which the facility or physical location licensed with the board is located does not require the facility or physical location to be registered or licensed as a drug or device distributor and/or the facility or physical location is not a registered/licensed manufacturing facility and the state in which the facility or physical location is located does not require any registration or licensure of the facility or physical location, a letter from the appropriate state regulatory board or agency must be submitted to the board confirming such fact.

a. If the state in which the facility or physical location is located does not require any registration or licensure for distribution or manufacturing but a federal agency does require and issues registration or licensure to the facility or physical location licensed by this board, a copy of the federal registration or license must be submitted.

3. If the facility or physical location licensed with the board does not physically distribute and/or manufacture the drugs or devices that it owns or holds title to and/or the facility or physical location licensed with the board contracts with a third-party logistics provider for distribution of the drugs or devices and the state in which the facility or physical location licensed by the board is located does not require any registration or licensure of the facility or physical location, a letter from the appropriate state regulatory board or agency confirming this fact and a current copy of the valid registration or license from the state in which the third-party logistics provider facility is located must be submitted to the board.

a. if the state in which the third-party logistics provider facility or physical location is located does not require any registration or licensure for third-party logistics providers but a federal agency does require and issues registration or licensure to the third-party logistics provider facility or physical location licensed by this board, a copy of the federal registration or license must be submitted.

I. An initial application for a new license is valid for 180 days after receipt by the board and must be completed within this time frame.

1. If the application is not completed, the application becomes void and any application fee(s) paid is forfeited by the applicant and is non-refundable.

2. After the 180 days have expired, a new application for a license will be required to be submitted by the applicant to include payment of another license application fee.

J. Requests for voluntary cancellation of a license made by a licensee must be made in writing and must include information such as, but not limited to, the date the request is effective and the reason for the voluntary cancellation of the license.

1. If the request for voluntary cancellation is made before the license has expired, the original unexpired license certificate must be returned to the board and no refund of any portion of the license fee(s) paid will be made by the board.

K. If a licensed in-state drug or device distributor has an additional off-site storage facility, the off-site storage facility may operate under the current drug or device distribution license held by the licensee as long as the off-site storage facility is in compliance with §309.A.1 of this Part and has temperature monitoring and an alarm system and the off-site storage facility does not physically receive or distribute legend drugs or devices from its location.

L. A license shall not be issued by the board for any drug or device distributor to operate from or out of a dwelling, building, or property zoned as residential.

M. A license issued to a drug or device distributor will be revoked after 180 days from the date of issuance if an inspection and disciplinary hearing reveal a lack of legitimate business activity as per recordkeeping requirements of §311.B of this Part or a violation of any provisions of this Title.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992), amended LR 29:1480 (August 2003), LR 32:396 (March 2006), LR 34:875 (May 2008), LR 35:1538 (August 2009), LR 36:322 (February 2010), LR 39:2758 (October 2013), amended by the Department of Health, Board of Drug and Device Distributors LR 42:2183 (December 2016), repromulgated LR 43:49 (January 2017).

§303. Required Information

A. The board requires the following from each applicant as part of the initial licensing procedure and as part of any renewal or reinstatement of such license:

1. the company name, physical distribution address, business address, and the name and contact information of the person for the facility or physical location of the applicant;
2. all trade or business names used by the applicant;
3. the mailing address, and the name and contact information of the person for regulatory compliance used by the applicant;
4. the type of ownership or form of business operation used by the applicant (i.e., partnership, corporation, or sole proprietorship); if other than a natural person, the type of entity and the name of the state where formed;
5. the names of the owners of the applicant including the percentage of interest owned;
6. the name and contact information of the person appointed as the designated responsible party;
7. the names and titles of the directors and officers of the applicant;
8. a list of every state or territory, other than Louisiana, where the applicant holds a current license for wholesale drug or device distribution;
9. any other information which the board may require to determine qualification for obtaining, renewing, or reinstating a license.

B. Changes in any information with regard to, but not limited to, contact persons for the facility or physical location, the owners of the licensee including the percentage of interest owned, the person appointed as the designated responsible party, the directors and officers of the licensee, or the regulatory contact person shall be submitted in writing to the board within 60 days after such changes become effective. Failure to do so may result in disciplinary action being taken against the licensee.

1. Any licensee changing their physical location is required to submit an application for location change at least 30 days prior to such change of location. Failure to do so may result in disciplinary action being taken against the licensee.

C. A license shall be valid only for the person or the facility or physical location for which it is issued. Licenses are not transferable for change of location or change of ownership of the facility or physical location licensed by the board. Any such change shall require the submission of an application and fee for, and the issuance of, a new license by the board and the termination of the existing license.

D. Drug or device distributors with a place of business physically located in Louisiana must notify the board, in writing, within three business days of discovery of, or being

in a position to have acquired such knowledge of, any theft or diversion of drugs or devices.

E. Drug or device distributors with a place of business physically located in Louisiana must notify the board, in writing, within 24 hours of discovery of, or being in a position to have acquired such knowledge of, any contraband, counterfeit, or misbranded drugs or devices in their possession whether actual or constructive.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992), amended LR 29:1480 (August 2003), LR 30:1481 (July 2004), LR 32:397 (March 2006), LR 35:1539 (August 2009), LR 36:1246 (June 2010), amended by the Department of Health, Board of Drug and Device Distributors, LR 42:2184 (December 2016).

§305. Qualifications

A. The board shall consider the following factors in issuing an initial license, the renewal of an existing license, or reinstatement of a license to a person to engage in the distribution of drugs and devices:

1. any convictions of the applicant or designated responsible party under any federal, state, or local laws relating to drug samples, drug or device distribution, retail drug dispensing, or distribution of controlled substances;
2. any felony convictions of the applicant or designated responsible party under federal, state, or local laws;
3. the applicant's past experience in the manufacture or distribution of drugs or devices, including controlled substances;
4. the furnishing by the applicant of false or fraudulent information to the board;
5. suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant, including a license to distribute or manufacture any drug or device, including controlled substances;
6. compliance with the licensing requirements under any previously granted licenses;
7. compliance with the requirements to maintain and/or make available to the state licensing authorities or to federal, state, or local law enforcement officials those records required to be maintained by drug or device distributors;
8. any other factors that the board considers relevant to and consistent with its function to protect public health and safety;

9. failure to timely comply with a request made by the board shall result in the termination of an application for license or renewal. The applicant may apply for reinstatement if timely done and in accordance with the

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requirements for reinstatement, as well as timely complying with the request made by the board.

B. The board shall request all criminal history records information necessary to discover any information relating to the above factors for all new license applicants physically located in Louisiana. Criminal history records information shall only be requested for those licensees of previously issued licenses if they have appointed a new designated responsible party or if they have transferred an ownership interest of more than 10 percent to another owner.

C. The board shall deny a license to an applicant if it determines that the issuing of such a license would not be in the interest of public health, safety or welfare.

D. The designated responsible party must have knowledge of the policies and procedures pertaining to operations of the applicant or licensed drug or device distribution facility.

1. A designated responsible party must meet the following requirements:

- a. be at least 21 years of age;
- b. have at least two years of full-time employment history with either a pharmacy, legend drug or device distributor, or medical gas distributor in a capacity related to the retail drug dispensing, distribution, and recordkeeping of legend drugs or devices; or other similar qualifications as deemed acceptable by the board;
- c. be employed by the applicant or drug or device distributor in a full-time position;
- d. be actively involved in and aware of the actual daily operation of the wholesale drug or device distributor;
- e. be physically present at the facility of the applicant or drug or device distributor during regular business hours, except when absence of the designated responsible party is authorized, including, but not limited to, sick leave and vacation leave;
- f. serve in the capacity of a designated responsible party for only one applicant or drug or device distributor at a time, except where more than one licensed drug or device distributor is co-located in the same facility;
- g. not have any felony convictions under federal, state, or local law relating to drug or device distribution, retail drug dispensing, or distribution of controlled substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992), amended LR 32:398 (March 2006), LR 35:1539 (August 2009), LR 39:2758 (October 2013), amended by the Department of Health, Board of Drug and Device Distributors, LR 42:2185 (December 2016).

§307. Personnel

A. Personnel employed in drug or device distribution shall have appropriate education and/or experience to

assume responsibility for positions related to compliance with state licensing requirements.

B. A drug or device distributor licensed by the board shall be responsible for the acts and/or omissions of such personnel which are deemed in violation of the Louisiana statutes for drug or device distributors and board promulgated regulations. The board shall have the authority to proceed with disciplinary action and sanction its licensee for such acts and/or omissions of his personnel in violation of the statutes and/or regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992), amended LR 32:398 (March 2006), amended by the Department of Health, Board of Drug and Device Distributors, LR 42:2185 (December 2016).

§309. Storage and Handling Requirements

A. The following are required for the storage and handling of drugs or devices, and for the establishment and maintenance of drug or device distribution records by drug or device distributors and their officers, agents, representatives, and employees.

1. Facility. A facility at which drugs or devices are stored, warehoused, handled, held, offered, marketed or displayed shall:

- a. be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- b. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
- c. have a designed and clearly identified quarantine area for storage of drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
- d. be maintained in a clean and orderly condition; and
- e. be free from infestation by insects, rodents, birds, or vermin of any kind.

2. Security

a. A facility used for drug or device 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 drugs or devices are held shall be limited to authorized personnel.

b. A facility, with the exception of a facility distributing medical gases only, shall be equipped with a monitored alarm system to detect entry after hours.

c. A distributor that distributes medical gases only shall store a medical gas under lock and key if the medical gas is stored inside a board-approved storage facility that is not equipped with a monitored alarm system to detect entry after hours.

d. A distributor that distributes medical gases only who stores the medical gas on an open dock shall be equipped with a monitored alarm system to detect entry after hours.

e. A facility shall be equipped with a security system that will provide suitable protection against theft or diversion and provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

3. Storage. Drugs or devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or devices or in compliance with applicable requirements in the current edition of an official compendium.

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

b. Appropriate electromechanical or electronic temperature recording equipment, devices, and logs approved by the board shall be utilized to document proper storage of drugs or devices. Spring-loaded or mercury driven temperature monitoring devices are not approved by the board for use in monitoring and recording product temperature.

c. The recordkeeping requirement in §311 shall be followed for all stored drugs or devices.

4. Examination of Materials

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

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

c. The recordkeeping requirements in §311 shall be followed for all incoming and/or outgoing drugs or devices.

d. Brokers, freight forwarders, agents, or representatives of a principal that receives at their place of business licensed by the board shipments of drugs or devices that are to be forwarded to their clients may not open the

shipment packages. These packages are to be unopened and free of tampering when forwarded by carrier to the client.

5. Returned, Damaged, and Outdated Drugs or Devices

a. Drugs or devices that are outdated, damaged, deteriorated, misbranded, contaminated, adulterated, misbranded, counterfeit, or contraband shall be quarantined and physically separated in a clearly identified area from other drugs or devices until they are destroyed or returned to their supplier.

b. Any drugs or devices 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 in a clearly identified area from other drugs or devices until they are either destroyed or returned to the supplier.

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

d. The recordkeeping requirements in §311 shall be followed for all outdated, damaged, deteriorate, misbranded, contaminated, adulterated, counterfeit, or contraband drugs or devices.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:382 (April 1992), amended LR 29:1480 (August 2003), LR 32:398 (March 2006), LR 34:875 (May 2008), amended by the Department of Health, Board of Drug and Device Distributors, LR 42:2185 (December 2016).

§311. Drug or Device Distribution Recordkeeping

A. Drug or device distributors shall establish and maintain perpetual inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs or devices. These records shall include the following information:

1. source of the drugs or devices, the name and principal address of the seller or transferor, and the address of the facility or physical location from which the drugs or devices were shipped;

2. the identity and quantity of the drugs or devices received and distributed or disposed of; and

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3. the dates of receipt and distribution of the drugs or devices.

B. Drug or device distributors shall establish and maintain financial records, including all financial and banking receipts as they relate to drug, device, or medical gas sales, distribution, inventories, receipts or deliveries and monthly banking statements and deposit receipts for all banking accounts containing funds with which drugs or devices have been purchased and/or sold for a minimum of three years from the date each record was created.

C. Inventories and records shall be made available for inspection and photocopying by any official authorized by the board for a period of three years following disposition of the drugs or devices at issue.

D. Records described in this regulation that are kept at the inspection site facility or licensed physical location 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 facility or licensed physical location and not electronically retrievable shall be made available for inspection within two working days of a request by any official authorized by the board.

E. Copies of current licenses for customers who are authorized by law or regulation to procure or possess drugs or devices shall be maintained for all customers that are shipped or sold drugs or devices. If customer licenses are maintained off site, a list of customer names, addresses, license numbers, and license expiration dates shall be maintained at the licensed distribution location for all customers that are shipped or sold drugs or devices.

F. Distributors that distribute medical gas are not required to maintain a perpetual inventory on oxygen, but are required to maintain perpetual inventories on all other medical gases.

G. Drug or device distributors physically located and conducting operations in Louisiana:

1. shall not purchase or receive drugs or devices from other than drug or device distributors licensed by the board to distribute in or into Louisiana; and

2. shall notify the board of any distributors not licensed by this board distributing or offering to distribute drugs or devices in or into Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:383 (April 1992), amended LR 29:1480 (August 2003), LR 32:399 (March 2006), LR 34:875 (May 2008), LR 36:322 (February 2010), LR 39:2758 (October 2013), amended by the Department of Health, Board of Drug and Device Distributors, LR 42:2186 (December 2016).

§313. Policy and Procedures

A. Drug or device distributors shall establish, maintain, and adhere to written policies and procedures, which shall be

followed for the receipt, security, storage, inventory, and distribution of drugs or devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories including contraband or counterfeit drug or device information. Drug or device distributors shall include in their written policies and procedures the following:

1. a procedure whereby the oldest approved stock of a drug or device 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 drugs or devices. Such procedure shall be adequate to deal with recalls and withdrawals due to:

a. an 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;

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

c. 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 drug or device 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 drugs or devices shall be segregated from other drugs or devices and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs or devices. This documentation shall be maintained for three years after disposition of the outdated drugs;

5. a procedure to validate customer licenses, to review excessive or suspicious purchases, to inspect all incoming and outgoing shipments, and to monitor and record the temperature of product storage;

6. a procedure to notify the board, in writing, within three business days of discovering, or being in a position to have acquired such knowledge, of any theft or diversion of a drug or device;

7. a procedure to notify the board, in writing, within 24 hours of discovery, or being in a position to have acquired such knowledge, of any contraband, counterfeit, or misbranded drug or device in his possession, whether actual or constructive.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992), amended LR 29:1480 (August 2003), LR 32:400 (March 2006), LR 39:91 (January 2013), amended by the

Department of Health, Board of Drug and Device Distributors, LR 42:2186 (December 2016).

§315. Organizational On-Site List

A. Drug or device distributors shall establish and maintain an on-site list of owners, officers, directors, managers, and other persons in charge of drug or device distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992), amended LR 32:400 (March 2006), LR 35:1539 (August 2009), amended by the Department of Health, Board of Drug and Device Distributors, LR 42:2186 (December 2016).

§321. Inspection Alternatives

A. The board, in its discretion, may accept a satisfactory inspection by the United States Food and Drug Administration (USFDA) or a state agency which the board determines to be comparable to that made by USFDA or the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992), amended LR 32:401 (March 2006), LR 35:1539 (August 2009).

Chapter 5. Powers and Functions of the Board

§505. Rules of Order

A. All meetings of the board shall be conducted in accordance with *Robert's Rules of Order* (Latest official edition).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992), amended LR 32:401 (March 2006).

§509. Inspection Contracts

A. The board may contract with any person or agency it deems qualified to conduct any inspections or reinspections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992), amended LR 30:1481 (July 2004), LR 32:401 (March 2006), LR 35:1540 (August 2009).

Chapter 7. Disciplinary Procedures

§701. Complaint Initiations

A. Complaints may be initiated by any person, including the state of Louisiana acting through any of its departments, or by the board on its own initiative.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992), amended LR 32:401 (March 2006).

§703. Complaint Investigations

A. Upon receipt of complaints or inquiries, the board shall take the following action.

1. The complaint or inquiry shall be received by the board office and assigned for investigation.

2. If the information in the complaint is insufficient, the board may request further information by either written correspondence or the board may cause an investigation to be made.

B. All complaints received shall be assigned a docket code number which shall be utilized in all official references.

C. The board, through its appointed representative(s), shall act upon all complaints and inquiries received.

D. The identity of all parties to a complaint, and other sensitive information, shall not be revealed during an investigation if to do so would potentially jeopardize the ongoing investigation. If formal charges are filed, then the process of discovery will apply to parties involved in the action.

E. The board shall inform the complainant of the action taken and any final results.

F. If the person against whom a complaint is filed with the board refuses or fails to cooperate with the board in the investigation, he shall be sent a notice, by certified mail to the address on file with the board, that if he continues to refuse to cooperate, such action or inaction on his part shall be considered a separate violation for which he may be denied a license, or his license may be suspended or revoked, or otherwise sanctioned, and/or he may be assessed a monetary penalty as provided by law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992), amended LR 32:402 (March 2006).

§705. Complaint Withdrawals

A. If the complainant wishes to withdraw the complaint, the investigation and/or proceedings are not automatically terminated. The board may complete the investigation and/or proceedings in its own right and in the interest of public health, safety and welfare.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992), amended LR 32:402 (March 2006).

§707. Hearings

A. Notice of Hearings. The board shall formally charge the party against whom a complaint has been made when said complaint appears to be sufficient cause for suspension

or revocation of a license, or other disciplinary sanction. At least 30 days prior to the date set for a public hearing, the formal charges and notice shall be sent by certified mail to the party against whom the complaint is made at his last known address on file with the board. The formal charges and notice shall conform to the requirements of the Administrative Procedure Act.

B. Disposition of Complaint. The board shall conduct such investigations, order such hearings, and take such other action as it finds necessary to make an intelligent decision on the complaint submitted for review.

C. Appearance. The party against whom the complaint has been made and upon notice being served, must appear at the date, time and place fixed for the hearing.

D. Default in Appearing. In the event the party against whom the complaint has been made fails to appear at the hearing provided for and also that notice has been given as to the hearing date, time and place, the party so failing to appear or otherwise obtain approval of the board for its absence shall be deemed to be in default and the evidence as received by the board at that time may be entered into the record and may be taken as true and the order of the board entered accordingly.

E. The procedure for notice, hearing and appeals, there from, shall be that of the Louisiana Administrative Procedure Act.

F. Hearing Procedure. The hearings called according to these rules and regulations shall be conducted by the board in accordance with the Administrative Procedure Act.

1. The chairman of the board or the vice-chairman in the absence of the chairman shall announce the title and docket number of the proceeding before the board. Attorneys and/or other representative of the accused party shall be recognized along with the representatives of the board and other proper parties.

2. The board's attorney and/or representative shall then present its evidence.

3. The accused or his attorney shall then be entitled to present its evidence subject to cross examination by the board's attorney and/or representative.

4. The board, after deliberation in executive session, may render a decision in the case by order, consent order, or default order.

G. Board's Decision. The decision of the board shall be submitted, in writing, to the accused and/or his attorney, if any, by certified mail within a reasonable period after it is rendered by the board.

H. Rehearings. A decision or order of the board shall be subject to rehearing or reconsideration by the board within 10 days from the date of receipt of the decision by the accused and/or his attorney, if any. Rehearings or reconsiderations shall be conducted in accordance with the Administrative Procedure Act.

I. Recording of Hearings. The board shall make a full recording of all proceedings before it and shall at the request of any party have prepared and furnished to him a copy of the transcript or any part thereof upon payment of the actual cost thereof.

J. Judicial Review of Decision. A person who is aggrieved by a final decision or order of the board is entitled to Judicial Review in accordance with the Louisiana Administrative Procedure Act. Proceedings for Judicial Review may be instituted in the district court of the parish in which the board is located within 30 days after receipt of the notice of the final decision by the board or if a rehearing or reconsideration occurs within 30 days after the decision thereon.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992), amended LR 32:402 (March 2006).

§709. Emergency Action

A. If at any point the board finds that public health, safety, or welfare requires emergency action, and incorporates a finding to that effect in its order, the board is hereby given authority to obtain a restraining order from a judge of the appropriate court to suspend the license pending investigation or proceedings for disciplinary action. The order may be issued without bond. If the board seeks and obtains such a restraining order, the investigation and disciplinary action shall be commenced and completed as rapidly as possible.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:386 (April 1992).

§711. Grounds for Disciplinary Action

A. After notice and hearing, the board may deny, revoke or suspend a license or otherwise sanction a licensee, for any of the grounds set forth in R.S. 37:3474.1 or R.S. 37:3474.2 and any of the following:

1. violation of any federal, state, or local law or regulation relating to drugs;
2. violation of any provision of this regulation;
3. commission of any act or engaging in a course of conduct which constitutes a clear and present danger to the public health and safety.

B. The authority of the board to impose a monetary penalty in a case is not to be affected by any other civil or criminal proceeding concerning the same violation, nor shall the imposition of a monetary penalty preclude the board from imposing other sanctions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR

18:384 (April 1992), amended LR 32:403 (March 2006), LR 35:1540 (August 2009).

§713. Declaratory Statements

A. The board may issue a declaratory statement in response to any written request for clarification of the effect of the provisions of the state statutes for wholesale drug distribution, the regulations of the board, and/or other applicable legal authority regarding wholesale drug distribution industry, on a stated set of circumstances.

B. The declaratory statement shall be in writing and be issued by the board within a reasonable period of time taking into consideration the nature of the matter and circumstances involved.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 32:403 (March 2006).

Chapter 8. Fees

§801. Fees

A. The board may collect the following fees:

1. initial license fee:
 - a. one license sub-type—\$400;
 - b. two license sub-types—\$425;
 - c. three license sub-types—\$450;
2. license renewal fee:
 - a. one license sub-type—\$300;
 - b. two license sub-types—\$325;
 - c. three license sub-types—\$350;
3. initial inspection fee—\$100;
4. duplicate license fee—\$10;
5. license reinstatement fee for licenses suspended, revoked, or expired—\$300;
6. license verification fee—\$15.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 32:403 (March 2006), amended LR 35:1540 (August 2009), LR 38:1961 (August 2012), amended by the Department of Health, Board of Drug and Device Distributors, LR 42:2186 (December 2016).

Chapter 9. Proceedings for Enforcement Action

§901. Proceedings

A. The board, through its compliance officer, may investigate, mediate, or initiate enforcement action or legal proceedings on behalf of the board with respect to charges initiated or information received by the board alleging that a

non-licensee committed or engaged in any of the acts or offenses listed in R.S. 37:3474.2.

B. Enforcement action is instituted by the board, acting through its compliance officer, filing charges against any non-licensee who commits or engages in any of the acts of offenses listed in R.S. 37:3474.2.

C. Within 20 days of the board's filing of charges, the board shall mail a copy of said charges to the last known address of the non-licensee so charged.

D. All charges shall be heard by the board within 12 months after the date on which filed. This 12-month period may be extended for good cause shown.

E. The date, time and place for said hearing shall be fixed by the board and a copy of the charges, together with a notice of the date, time and place of the hearing, shall be personally served on or mailed to the last known address of the charged party, at least 30 days before the date fixed for hearing. At any hearing, the charged party shall have the right to appear in person, or by counsel, or both, to cross-examine witnesses in his defense, and to produce evidence and witnesses in his defense. If the charged party fails or refuses to appear at the hearing, the board may proceed to hear and determine the validity of the charges.

F. If, after such hearing, a majority of the board participating in the proceeding vote in favor of sustaining the charges, the board may take enforcement action against the charged party.

G. A charged party aggrieved by any enforcement action taken by the board may appeal therefrom, pursuant to the provisions of the Administrative Procedure Act.

H. All enforcement actions taken shall be published in the official journal of the board and may be released to other boards, agencies, or professional organizations relating to wholesale drug distribution, or to the news media.

I. The board, through its compliance officer, may make informal disposition by consent order, agreement, settlement, or default of any enforcement proceeding pending before it. Each such informal disposition shall have no force of effect until ratified by the board. Consent orders are considered enforcement actions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 36:321 (February 2010).

Chapter 11. Quarantine of Legend Drugs or Legend Devices

§1101. Order of Quarantine

A. The board's inspector or executive director may issue an order of quarantine on site.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 39:91 (January 2013).

Chapter 13. Wholesale Distributors

§1301. License Requirements

A. No person may engage in wholesale distribution of drug products in the state unless such person:

1.a. is licensed by the state from which the drug product is distributed; or

b. if the state from which the drug product is distributed has not established a licensure requirement, is licensed by the appropriate federal official in accordance with federal regulation; and

2. if the drug product is distributed interstate is licensed by the state into which the drug product is distributed if the state into which the drug product is distributed requires the licensure of a person that distributes drug products into the state.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Drug and Device Distributors, LR 42:2186 (December 2016).

§1303. Definitions

A. As used in this chapter, the following terms are defined herein.

Exclusive Distributor—the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer’s product to a subsequent repackager, wholesale distributor, or retail dispenser.

Illegitimate Product—a product in which credible evidence shows that it:

a. is counterfeit, diverted or stolen;

b. is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

c. is the subject of a fraudulent transaction; or

d. appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

Suspect Product—a product for which there is reason to believe it may be illegitimate.

Trading Partners—a manufacturer, repackager, wholesale distributor, or retail dispenser from whom a manufacturer, repackager, wholesale distributor, or retail dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or retail dispenser transfers direct ownership of a product; or a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or retail dispenser accepts direct possession of a product or to whom a manufacturer,

repackager, wholesale distributor, or retail dispenser transfers direct possession of a product.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Drug and Device Distributors, LR 42:2187 (December 2016).

§1305. General Requirements

A. A wholesale distributor shall not accept ownership of a product unless the previous owner provides the transaction history, transaction information, and a transaction statement for the product at the time of the transaction.

B. When a wholesale distributor purchases product, whether or not directly from a manufacturer, an exclusive distributor, or a repackager that purchased directly from a manufacturer, the wholesale distributor shall provide a transaction statement, transaction history, and/or transaction information in accordance with federal regulations at the time of each transaction in which the wholesale distributor transfers ownership of product to subsequent purchasers.

C. A wholesale distributor shall:

1. capture the transaction information, transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than six years after the date of the transaction; and

2. maintain the confidentiality of the transaction information, transaction history, and transaction statement for a product in a manner that prohibits disclosure to any person other than the appropriate federal or state official except where required among trading partners.

D. Wholesale distributors physically located and conducting operation in Louisiana:

1. shall not purchase or receive product from other than trading partners licensed by the board to distribute in or into Louisiana; and

2. shall notify the board of any trading partners not licensed by this board distributing or offering to distribute product in or into Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Drug and Device Distributors, LR 42:2187 (December 2016).

§1307. Returns

A. A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom the product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the transaction history, transaction information, and transaction statement for the product.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Drug and Device Distributors, LR 42:2187 (December 2016).

§1309. Requests for Information

A. In the event of a recall or for the purpose of investigating a suspect or an illegitimate product and upon a request by the appropriate federal or state official, a wholesale distributor shall, not later than one business day and not exceeding 48 hours after receiving the request for information, provide the applicable transaction information, transaction history, and transaction statement for the product.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Drug and Device Distributors, LR 42:2187 (December 2016).

§1311. Verification Requirements

A. A wholesale distributor shall have systems in place to enable the wholesale distributor to comply with the following requirements.

1. Upon making a determination that a product in possession or control of a wholesale distributor is a suspect product, or upon receiving a request for verification from the appropriate federal official that has made a determination that a product within the possession of a wholesale distributor is a suspect product, a wholesale distributor shall:

a. quarantine the suspect product from product intended for distribution until the suspect product is cleared or dispositioned; and

b. promptly conduct an investigation to determine whether the suspect product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the wholesale distributor and otherwise investigating to determine whether the product is an illegitimate product.

2. If the wholesale distributor determines that a suspect product is not an illegitimate product, the wholesale distributor shall promptly notify the appropriate federal or state official of such determination and such product may be further distributed.

3. A wholesale distributor shall keep records of the investigation of a suspect product for not less than six years after the conclusion of the investigation.

B. In a manner consistent with the systems and processes of the wholesale distributor, the wholesale distributor shall:

1. upon determining that a product in the possession or control of a wholesale distributor is an illegitimate product:

a. quarantine the illegitimate product from product intended for distribution until the illegitimate product is dispositioned;

b. disposition the illegitimate product that is in the possession or control of the wholesale distributor;

c. take reasonable and appropriate steps to assist trading partners in the disposition of the illegitimate product that is not in the possession or control of the wholesale distributor; and

d. retain a sample of the illegitimate product for further physical examination or laboratory analysis of the product as necessary and appropriate;

2. upon determining that a product is an illegitimate product, the wholesale distributor shall notify the appropriate federal or state officials and all immediate trading partners that there is reason to believe the wholesale distributor may have received an illegitimate product no later than 24 hours after making such determination;

3. upon the receipt of a notification from the appropriate federal or state official or a trading partner that a determination has been made that a product is an illegitimate product, a wholesale distributor shall identify all illegitimate product subject to the notification that is in the possession or control of the wholesale distributor, including any product that is subsequently received, and shall perform the activities described in Subsection A of this Section;

4. upon making a determination, in consultation with the appropriate federal official, that a notification is no longer necessary, a wholesale distributor shall promptly notify immediate trading partners that such notification has been terminated;

5. a wholesale distributor shall keep records of the disposition of an illegitimate product for not less than six years after the conclusion of the disposition.

C. A wholesale distributor may satisfy the requirements of this Section by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Drug and Device Distributors, LR 42:2187 (December 2016).

§1313. Federal Reporting

A. Any person who owns or operates an establishment that engages in wholesale distribution shall:

1. report to the appropriate federal official, on an annual basis on a schedule determined by the appropriate federal official:

a. each state by which the wholesale distributor is licensed and the appropriate state license number issued by the state to the wholesale distributor; and

b. the name, address, and contact information of each wholesale distributor facility at which, and all trade names under which, the wholesale distributor conducts business; and

2. report to the appropriate federal official within a reasonable period as determined by the appropriate federal official, any significant disciplinary actions, such as the

revocation or suspension of a wholesale distributor license, as taken by any state or federal agency against the wholesale distributor during the reporting period.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Drug and Device Distributors, LR 42:2188 (December 2016).

Chapter 15. Third-party Logistics Providers

§1501. General Requirements

A. No third-party logistics provider may conduct distribution activities in the state unless each facility of the third-party logistics provider:

1.a. is licensed by the state from which the drug or device is distributed by the third-party logistics provider; or

b. is licensed by the appropriate federal official in accordance with federal regulation, if the state from which the drug or device is distributed by the third-party logistics provider does not require licensure for third-party logistics providers;

2. is licensed by each state into which the drug or device is distributed by the third-party logistics provider, if the drug or device is distributed interstate; unless the third-party logistics provider is licensed by the appropriate federal official in accordance with federal regulations.

B. If the third-party logistics provider is licensed by the appropriate federal official in accordance with federal regulations and will be conducting distribution activities into the state, the third-party logistics provider must notify the board in writing on a form provided by the board to include a copy of the federal license as issued by the appropriate federal official in accordance with federal regulations and with no state fee required for the notification.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Drug and Device Distributors, LR 42:2188 (December 2016).

§1503. Federal Reporting

A. Third-party logistics provider shall report to the appropriate federal official on an annual basis on a schedule determined by the appropriate federal official:

1. the state in which the third-party logistics provider facility is licensed and the appropriate state license number issued by the state to the third-party logistics provider; and

2. the name and address of the third-party logistics provider facility and all trade names under which the third-party logistics provider facility conducts business.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3461-3482.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Drug and Device Distributors, LR 42:2188 (December 2016).