NOTICE OF INTENT

Department of Health
Board of Drug and Device Distributors

General Provisions, Requirements, Qualifications, Recordkeeping, Fees, Wholesale Distributors, and Third-Party Logistics Providers
(LAC 46:XCI.103, 105, Chapter 3, 801, Chapter 13 and Chapter 15)

The Louisiana Board of Drug and Device Distributors proposes to amend LAC 46:XCI.103, 105, 301, 303, 305, 307, 311, 315, and 801, and to adopt Chapter 13 and Chapter 15 in accordance with the provisions of the Administrative Procedures Act, R.S. 49:950 et seq., and R.S. 37:3467 et seq. of the Louisiana Drug and Device Distributors Act. This proposed Rule will support the board's ability to license entities and regulate the distribution of legend drugs and legend devices into and within the state of Louisiana in its effort to safeguard the life and health of its citizens and promote the public welfare. The proposed Rule is set forth below.

Title 46
PROFESSIONAL AND OCCUPATION STANDARDS
Part XCI. Drug and Device Distributors
Chapter 1. General Provisions
§103. Definition

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

* * *

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.

* * *

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:

§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. …

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 manufacturers 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;

ii. 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 heath 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:

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. - 2. …

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. - 2. …

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. - 2. ...

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. ...

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:

§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. ...

3. the mailing address, and the name and contact information of the person for regulatory compliance used by the applicant;

4. - 5. ...

6. the name and contact information of the person appointed as the designated responsible party;

7. - 9. ...

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.

B.1. - C. ...

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:

§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. ...

3. the applicant's past experience in the manufacture or distribution of drugs or devices, including controlled substances;

4. - 6. ...

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;

A.8. - C. ...

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. ...

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. ...

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:

§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:

§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. - 1.e. …

2. Security

a. A facility used for drug or device distribution shall be secure from unauthorized entry.

a.i. - b. …

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.

2.e. - 3. …

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.

3.b. - 5.b. …

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. …

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:

§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. - 3. …

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. - E. …

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:

§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. - 2.c. ...

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. - 7. ...

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:

§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:

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. - 6. ...

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:

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:

§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:

§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:

§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:

§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:

§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 distribution 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 includes 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 identity 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:

§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:

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:

§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:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature and in accordance with R.S. 49:972, it is anticipated that the proposed rules and amendments will have no impact on family stability, functioning, and autonomy.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature and in accordance with R.S. 49:973, it is anticipated that the proposed rules and amendments will have no impact on household income, assets, and financial security; early childhood and educational development; employment and workforce development; taxes and tax credits; or child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature and in compliance with R.S. 49:965, it is anticipated that the proposed rules and amendments should have no significant adverse impact on small businesses.

Provider Impact Statement

In compliance with House Concurrent Resolution 170 of the 2014 Regular Session of the Louisiana Legislature, it is anticipated that the proposed rules and amendments will have no impact on providers of services to individuals with developmental disabilities.

Public Comments

Interested parties may submit written comments to Kimberly Barbier, Executive Assistant, Louisiana Board of Drug and Device Distributors, 12091 Bricksome Avenue, Suite B, Baton Rouge, LA 70816. Comments will be accepted through the close of business on September 20, 2016.

Public Hearing

If it becomes necessary to convene a public hearing to receive comments in accordance with the Administrative Procedures Act, the hearing would be held on September 27, 2016, at 11 am at the office of the Louisiana Board of Drug and Device Distributors, 12091 Bricksome Avenue, Suite B, Baton Rouge, LA.

George Lovecchio
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: General Provisions, Requirements, Qualifications, Recordkeeping, Fees, Wholesale Distributors, and Third-Party Logistics Providers

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The estimated implementation cost to the state for the proposed rule changes is approximately $1,400 in FY17 associated with publishing the proposed rule changes. Licensees will be informed of the rule changes via the Board's

regular newsletter or other direct mailings, which will result in minimal costs to the Board. Local governmental units will not incur any costs as a result of this rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule changes are anticipated to increase annual revenues for the Board by approximately $18,100 beginning in FY17. Proposed rule changes include the addition of license sub-types to the distributor license issued by the Board and re-structuring of the Board's current initial and renewal fees in association with the new distributor license sub-types. The proposed distributor license sub-types include standard distributor, wholesale distributor, and third-party logistics provider distributor. The delineation of license sub-types increases the initial license fee and annual license renewal fee by $25 per additional sub-type delineated on the distributor license.

There are approximately 2,170 licenses in the current fiscal year. It is anticipated if twenty percent (20%) of these current licenses (434 licenses) will add one additional license sub-type ($10,850) and 5% of these current licensees (108 licenses) will add two additional license sub-types ($5,400) for a total projected increase in annual revenues of $16,250. In addition, it is estimated there will be 250 new applicants and licensees in FY17. Using the same percentage projection for new applicants (250: 20%=50; 5%=12), there would be an annual estimated increase of $1,850 in initial license fees.

The total estimated annual revenue increase is approximately $18,100 beginning in FY17.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

Current drug and device distributor licensees and applicants for licensure will pay $25 per additional license sub-type based on the proposed rule changes.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

No impact on competition and employment is anticipated as a result of the proposed rule change.

George Lovecchio
Executive Director
1608#011

Evan Brasseaux
Staff Director
Legislative Fiscal Office