AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2180 et seq., and in particular, 2186(A)(2).

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Hazardous Waste Division, LR 10:200 (March 1984), amended LR 10:496 (July 1984), LR 11:1139 (December 1985), LR 12:319 (May 1986), LR 13:84 (February 1987), LR 13:433 (August 1987), LR 13:651 (November 1987), LR 14:790 (November 1988), LR 15:181 (March 1989), LR 16:47 (January 1990), LR 16:217, LR 16:220 (March 1990), LR 16:398 (May 1990), LR 16:614 (July 1990), LR 17:362, 368 (April 1991), LR 17:478 (May 1991), LR 17:883 (September 1991), LR 18:723 (July 1992), LR 18:1256 (November 1992), LR 18:1375 (December 1992), amended by the Office of the Secretary, LR 19:1022 (August 1993), amended by the Office of Solid and Hazardous Waste, Hazardous Waste Division, LR 20:1000 (September 1994), LR 21:266 (March 1995), LR 21:944 (September 1995), LR 22:813, 831 (September 1996), amended by the Office of the Secretary, LR 23:298 (March 1997), amended by the Office of Solid and Hazardous Waste, Hazardous Waste Division, LR 23:564, 567 (May 1997), LR 23:721 (June 1997), amended by the Office of Waste Services, Hazardous Waste Division, LR 23:952 (August 1997), LR 23:1511 (November 1997), LR 24:298 (February 1998), LR 24:655 (April 1998), LR 24:1093 (June 1998), LR 24:1687, 1759 (September 1998), LR 25:431 (March 1999), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:268 (February 2000), LR 26:2464 (November 2000), LR 27:291 (March 2001), LR 27:706 (May 2001), LR 29:317 (March 2003), LR 30:1680 (August 2004), amended by the Office of Environmental Assessment, LR 30:2463 (November 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2451 (October 2005), LR 32:605 (April 2006), LR 32:821 (May 2006), LR 33:450 (March 2007), LR 33:2097 (October 2007), LR 34:614 (April 2008), LR 34:1008 (June 2008), LR 34:1893 (September 2008), LR 34:2395 (November 2008), LR 35:1878 (September 2009), LR 36:2553 (November 2010), LR 38:791 (March 2012), amended by the Office of the Secretary, Legal Division, LR 40:1336 (July 2014), LR 42:2181 (December 2016).

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RULE

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 has amended LAC 46:XCI.103, 105, 301, 303, 305, 307, 311, 315, and 801, and adopted 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 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 Rule is herein set forth.

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 42:2182 (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. …

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 42:2182 (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. - 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 42:2183 (December 2016).

§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 42:2184 (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. …

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 42:2185 (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. - 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 42:2185 (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. - 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 42:2186 (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. - 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 42:2186 (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).

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 42:2186 (December 2016).

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 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 42:2187 (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).

George Lovecchio
Executive Director

1612#025

Title 43
NATURAL RESOURCES
Part XXVII. State Lands
Subpart 2. Use and Management of State Lands
Chapter 27. Rights-of-Way
§2701. Granting Rights-of-Way to Corporations or Individuals

A. - L. …

M. Fees for permits shall be as follows:

1. class 1: pipe 2 inches up to 19 inches outside diameter with a minimum of 75 feet right-of-way during construction to revert to 35 after construction is completed with the additional right of ingress and egress for the purpose of maintenance, repairs, removal or modification—$50 per rod;

2. class 2: pipe 19 inches up to 36 inches outside diameter with a maximum of 100 feet right-of-way during construction to revert to 50 feet after construction is completed with the additional right of ingress and egress for the purpose of maintenance, repairs, removal or modification—$70 per rod;

3. class 3: pipe over 36 inches outside diameter with a maximum of 200 feet right-of-way during construction to revert to 60 feet after construction is completed with the additional rights of ingress and egress for the purpose of maintenance, repairs, removal or modification—$90 per rod;

M.4. - R. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 41:1173.

HISTORICAL NOTE: Adopted by the State Land Office, LR 1:147 (February 1975), amended by the Department of Natural Resources, Office of the Secretary, LR 3:314 (July 1977), repealed and repromulgated by the Office of the Governor, Division of Administration, State Land Office, LR 19:493 (April 1993), amended by the Office of the Governor, Division of Administration, Office of State Lands, LR 43:48 (January 2017).

Mark Gates
Assistant Director

1701#039

RULE

Department of Health
Board of Dentistry

Advertising and Soliciting by Dentists and Complaints and Investigation (LAC 46:XXXIII.701 and 1509)

In accordance with the applicable provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the Dental Practice Act, R.S. 37:751 et seq., and particularly R.S. 37:760(8), the Department of Health, Board of Dentistry has amended LAC 46:XXXIII.701 and 1509.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XXXIII. Dental Health Profession
Chapter 7. Dental Hygienists
§701. Authorized Duties

A. …

B. A person licensed to practice dentistry in the state of Louisiana may delegate to any dental hygienist any chairside dental act which said dentist deems reasonable, using sound professional judgment. Such act must be performed properly and safely on the patient. Furthermore, the act must be under the direct on-premises supervision of the treating dentist. A dentist may not delegate to a dental hygienist:

B.1. - G.2. …

3. No duly licensed and registered dentist in a private practice shall supervise a dental hygienist for more than five consecutive business days or for more than 20 total days in any calendar year. These limits do not apply to a hygienist working at a school or public institution.

4. - 6. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:760(8).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Dentistry, LR 14:791 (November 1988), amended LR 15:965 (November 1989), LR 19:206 (February 1993), LR 22:22 (January 1996), LR 22:1217 (December 1996), LR 24:1116 (June 1998), LR 27:1892 (November 2001), LR 32:2056 (November 2006), LR 37:590 (February 2011), LR 37:1406 (May 2011), amended by the Department of Health, Board of Dentistry, LR 43:48 (January 2017).

Chapter 15. Anesthesia/Analgesia Administration
§1509. Third-Party Sedation/Anesthesia

A. …

B. In order to utilize a third-party to administer sedation and/or anesthesia as described in Subsection A, a dentist must obtain an office permit for each office location at which a third-party anesthetist will be administering sedation or anesthesia, subject to the exceptions in R.S. 37:793(H). This permit will only be issued after an office inspection by the board to assure that the office meets the minimum requirements for facilities, personnel and equipment for sedation/anesthesia procedures. Additionally, the dentist who is performing the dental work but not performing the sedation/general anesthesia must have current certification in advanced cardiac life support (ACLS) as described in §1503.E and, if children are to be sedated, must also have current certification in pediatric life support (PALS) as described in §1504.A.4. If a dentist's practice is restricted to treating only children, the certification in pediatric life support (PALS) described in §1504.A.4 will suffice as a substitute for ACLS.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:760(8).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Dentistry, LR 42:54 (January 2016), amended by the Department of Health, Board of Dentistry, LR 43:48 (January 2017).

Arthur F. Hickham, Jr.
Executive Director

1701#077

RULE

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.301)

Editor's Note: This Rule is being repromulgated to correct citation error's. The original Rule can be viewed in the

December 20, 2016 edition of the *Louisiana Register* on pages 2182-2188.

The Louisiana Board of Drug and Device Distributors has amended LAC 46:XCI.103, 105, 301, 303, 305, 307, 311, 315, and 801, and adopted 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 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 Rule is herein set forth.

Title 46
PROFESSIONAL AND OCCUPATION STANDARDS
Part XCI. Drug and Device Distributors
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 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).

George Lovecchio
Executive Director

1701#019

RULE

Department of Health
Board of Pharmacy

Pharmacist-in-Charge of Nonresident Pharmacy
(LAC 46:LIII.2307)

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy has amended Chapter 23, Nonresident Pharmacy, of its rules. In particular, the board has amended §2307 relative to the requirements for the pharmacist-in-charge of a nonresident pharmacy. In addition, the board made technical changes in the Chapter title and Section headings to change "out-of-state" to "nonresident."

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists
Chapter 23. Nonresident Pharmacy
§2307. Pharmacist-in-Charge

A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege.

1. The acquisition of the PIC privilege shall require:

a. possession of an active Louisiana pharmacist license;

b. possession of an active license in the state in which the pharmacy is located, and further, said license shall not have any restrictions which prohibit the position of pharmacist-in-charge;

c. active practice as a pharmacist for a minimum of two years under the jurisdiction of any board of pharmacy in the United States; and

d. the completion of the affidavit of responsibility and duties described in Subsection J of this Section.

2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 20 hours per week, the PIC shall be present and practicing at least 50 percent of the normal business hours.

B. An initial and renewal pharmacy permit application shall designate and identify the licensed pharmacist-in-charge.

C. - J. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992), effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004, LR 33:1133 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 43:50 (January 2017).

Malcolm J. Broussard
Executive Director

1701#008

RULE

Department of Health
Bureau of Health Services Financing

Forensic Supervised Transitional Residential and Aftercare Facilities
Licensing Standards
(LAC 48:I.Chapter 72)

The Department of Health, Bureau of Health Services Financing has repealed and replaced LAC 48:I.Chapter 72 in the Medical Assistance Program as authorized by R.S.